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**Factors Influencing the Outcome of
Nurse Delivered Procedural Sedation
and Analgesia During Atrial
Fibrillation Ablation: A Mixed Methods
Study**

S J Barker

PhD

2021

**Factors Influencing the Outcome of
Nurse Delivered Procedural Sedation
and Analgesia During Atrial
Fibrillation Ablation: A Mixed Methods
Study**

Stuart John Barker

A thesis submitted in partial fulfilment of
the requirements of the University of
Northumbria at Newcastle for the degree
of Doctor of Philosophy.

Research undertaken in the Faculty of
Health and Life Sciences

April 2021

Abstract

Despite continual rising demand for atrial fibrillation ablation, numbers of cases performed have plateaued. One reason for this is a shortage of appropriately skilled sedationists. Administration of sedation by nurses using a protocol is a potential solution, but virtually no research exists on the impact of this on the quality of patient care.

This project aimed to evaluate the use of such a protocol in a single NHS Trust in terms of safety and patient experience. By doing so, it was intended that it should ascertain the feasibility of protocol-based sedation by nurses, and identify areas in the practice studied requiring alteration in order to optimise patient outcomes.

A two-stage mixed methods project was undertaken. An initial survey phase provided statistical data that allowed comparison between the safety of protocolised nurse-led sedation and other sedation practices. Fuzzy set Qualitative Comparative Analysis (QCA) of the survey data allowed for exploration of patterns of complexity between components determining patient experience, a possibility identified within existing theories of pain such as the 'Gate Control Theory'. Subsequently pathways leading to positive experiences were modelled. These pathways were then tested using a series of case studies to ascertain the existence of causal links between the identified factors and positive outcomes as well as the extent to which protocol-adherence facilitated positive outcomes.

This thesis presents findings from both stages. These include the conclusion that nurse-delivered sedation is at least as safe as other methods. It establishes more than one pathway to positive patient experiences may exist, but finds strongest evidence that effective management of patient anxiety leads to a positive outcome. However, it also concludes that creating this outcome depends on the clinical judgement of the individual nurse, and identifies alterations in the status of the protocol and its content to facilitate optimal outcomes.

Contents:

Front Sheet.....	II
Abstract	III
List of Contents.....	IV
List of Abbreviations	VIII
List of Logical Notation.....	IX
List of Tables and Figures.....	X
List of Appendices.....	XI
Acknowledgements	XII
Declaration.....	XIII
Chapter 1: Introduction	1
Chapter 2: Context	3
2.1 Introduction	3
2.2 Cardiac Ablation	3
2.2.1 Demand.....	4
2.3 Standards for Sedation	4
2.4 Procedural Sedation and Analgesia During Ablation	5
2.5 The Expansion of the Nursing Role	7
2.5.1 The Expanded Role and Quality of Care	8
2.5.2 The Nurse as Sedationist in Cardiology.....	8
2.6 Implications for Research	9
2.7 The Nurse-Delivered Sedation and Analgesia Protocol	10
Chapter 3: Literature Review	14
3.1. Introduction	14
3.2. Literature Search Strategy	14
3.3. Providers of Procedural Sedation and Analgesia	17
3.3.1 Responsibility for Titration.....	17
3.3.2 Training and Transferability	20
3.4. Priorities of Procedural Sedation and Analgesia	21
3.4.1 Safety	21
3.4.2 Patient Experience.....	22
3.4.3 Reoccurrence.....	23
3.4.4 Economic Factors.....	25
3.5. Safety	26
3.5.1 Procedural Complications.....	26
3.5.2 Sedation-Related Complications.....	28
3.5.3 Approach to Ascertaining Safety	30
3.6. Measuring Patient Experience	32
3.6.1 Pain, Anxiety and Amnesia.....	32
3.6.2 Questionnaires to Assess Patient Experience.....	34
3.6.3 Observation to Assess Patient Experience.....	35
3.6.4 Use of Interviews.....	36

3.7. Determinants of Patient Experience	37
3.7.1 Drugs Used	37
3.7.2 Energy Source	38
3.7.3 Patient Age	39
3.7.4 Procedural Duration	39
3.7.5 Patient Expectation	40
3.8. Summary	41
Chapter 4: Theoretical Background	42
4.1 Introduction	42
4.2 Defining Pain	42
4.2.1 Theories of Pain	43
4.2.2 Analgesia	44
4.3 Defining Anxiety	45
4.3.1 Anxiolysis and Pain	45
4.4 Protocol-Based Care	46
4.4.1 Standardisation	47
4.4.2 Other Benefits	48
4.5 Alternative Models of Decision Making	49
4.5.1 Benner's Model	50
4.5.2 Competence, Proficiency and Expertise	51
4.5.3 Criticisms	52
4.5.4 Intuition	53
4.6 Implications for Study	54
Chapter 5: Methodology	56
5.1 Introduction	56
5.2 Critical Realism	57
5.2.1 Implications for Empirical Inquiry	57
5.3. Types of Evaluation	58
5.3.1 Realist Evaluation or Mixed-Methods Study	60
5.4 Case Orientation	61
5.4.1 Advantages of case-orientated research	62
5.5 Research Methods	62
5.5.1 Case Study: Advantages	63
5.5.2 Case study: Disadvantages	64
5.5.3 Survey Phase	66
5.5.4 Qualitative Comparative Analysis (QCA)	67
5.6 Survey Details	68
5.6.1 Sample Size	72
5.6.2 Sampling Strategy	73
5.6.3 Procedure	73
5.7 Case Study Phase	74
5.8 Ethics	74
5.8.1 Informed Consent	75
5.8.2 Confidentiality	75
5.8.3 Data Protection	75
Chapter 6: Survey Analysis	77
6.1 Survey Results	77
6.1.1 Demographics	79
6.1.2 Case Types	79

6.1.3	Patient Knowledge	79
6.1.4	Drug Use.....	80
6.1.5	Patient Experience	80
6.1.6	Safety.....	82
6.2	Analysis of Safety	83
6.2.1	Sedation-Related Complications.....	83
6.2.2	Non-Sedation-Related Complications.....	89
6.2.3	Conclusion.....	91
6.3.	Hierarchical Cluster Analysis	91
6.3.1	Decisions in the Clustering Process.....	92
6.3.2	The Number and Meaning of Clusters	93
6.4	Non-Parametric Testing	105
6.4.1	Distribution of Continuous Independent Variables Across Clusters... 105	
6.4.2	Distribution of Dichotomous Variables across Clusters.....	110
6.5	Qualitative Comparative Analysis	112
6.5.1	Calibration of Fuzzy Sets	112
6.5.2	Tests of Sufficiency for Positive Experience.....	119
6.5.3	Robustness of Procedure	133
6.5.4	Tests of Sufficiency for Negative Experience	134
6.6	Dimensions to investigate during case studies	136
6.6.1	The Contribution of the Sedationist.....	137
6.6.2	The Contribution of Prior Anxiety.	140
6.6.3	The Use of Fentanyl.....	140
Chapter 7: Case Study Development.....		143
7.1	Introduction	143
7.2	Issues Outstanding from Survey Analysis	143
7.2.1	Limitations of method.....	144
7.2.2	Philosophical Considerations	144
7.2.3	Missing Factors.....	145
7.2.4	Optimisation	146
7.3	The Suitability of Case Study	146
7.3.1	Process Tracing.	147
7.4	Theoretical Explanations	150
7.4.1	The Role of Age.....	151
7.4.2	The Role of Midazolam.....	153
7.4.3	The Role of Obesity	153
7.4.4	The Role of Anxiety.....	154
7.5	Case Expectations	156
7.5.1	Pathway 2	157
7.5.2	Pathway 3	159
7.6	Thematic Analysis	161
7.7	Case Study Design	162
7.7.1	Data Collection Methods.....	163
7.7.2	Case Selection.....	166
7.7.3	Number of Cases.....	168
Chapter 8: Case Study Analysis.....		169
8.1	Introduction	169
8.2	Process Tracing Within Cases	169
8.2.1	Case A	170
8.2.2	Case B	173

8.2.3	Case C	176
8.2.4	Case D	178
8.2.5	Case E	181
8.2.6	Case F	185
8.3	Cross-Case Analysis	188
8.3.1	Pathway 2	188
8.3.2	Pathway 3	190
8.3.3	Optimisation of Sedation	193
8.4	Thematic Analysis	193
8.4.1	Proactivity	196
8.4.2	Situational Awareness, Communication and Experience	198
8.4.3	Concern for Safety	201
8.4.4	Deviation from Protocol	203
Chapter 9:	Findings	208
9.1	Introduction	208
9.2	The Safety of NDPSA	208
9.3	Patient Satisfaction with NDPSA	209
9.4	Optimisation of NDPSA	211
9.5	The Contribution of the Sedationist	216
Chapter 10:	Discussion	220
10.1	Introduction	220
10.2	An Alternative to Established Models of Sedation	220
10.2.1	A Safe Alternative	220
10.2.2	Experience Compared to Other Studies	222
10.2.3	Unaddressed Questions	225
10.3	Optimisation of NDPSA	226
10.3.1	Unification of the Pathways	226
10.3.2	The Need for Different Approaches	227
10.3.3	Age, Stoicism and Anxiety	230
10.3.4	Additional Means of Reducing Anxiety	233
10.4	The Relationship Between Protocol and Practice	235
10.4.1	Protocol Adherence	235
10.4.2	Experience, Competence and Expertise	236
10.4.3	Implications	239
Chapter 11:	Conclusions	244
11.1	Introduction	244
11.2	Conclusions	244
11.3	Unique Contribution to Knowledge	251
11.4	Limitations	253
11.5	Recommendations for Further Research	256
Appendices	259
Reference List	305

List of Abbreviations

ACS: Acute Coronary Syndrome
AF: Atrial Fibrillation
ALS: Advanced Life Support
AoMRC: Academy of Medical Royal Colleges.
APN: Advanced Practice Nurse
BMI: Body Mass Index
BPS: Behavioural Pain Scale
CCL: Cardiac Catheter Laboratory.
CMO: Context-Mechanism-Outcome
CPOT: Critical Care Pain Observation Tool
CS: Conscious Sedation
CsQCA: crisp-set Qualitative Comparative Analysis
DoH: Department of Health
FET: Fisher's Exact Test
FsQCA: fuzzy-set Qualitative Comparative Analysis.
GA: General Anaesthetic
GCT: Gate Control Theory
HCA: Hierarchical cluster analysis.
HRA: Health Research Authority
I: Interviewer.
IASP: International Association for the Study of Pain.
JFC: Joint Formulary Committee.
NCAP: National Cardiac Audit Programme.
NDPSA: Nurse-Delivered Procedural Sedation and Analgesia.
NHS: National Health Service.
NI: Nurse Interview.
NICE: National Institute for Health and Care Excellence.
NICOR: National Institute for Cardiovascular Outcomes Research.
NMC: Nursing and Midwifery Council.
O: Observations.
P: Patient.
PI: Patient Interview.
PLP: Phantom Limb Pain.
PSA: Procedural Sedation and Analgesia.
QCA: Qualitative Comparative Analysis.
RFA: Radiofrequency Ablation.
TA: Thematic Analysis.
UK: United Kingdom.
WHO: World Health Organisation.

Logical Notation.

Software used in this study provides outputs using the following logical notation. Output using this notation is included in this thesis.

“*” AND (Conjunction)

“+” OR (Union)

“~” NOT (Negation)

List of Tables and Figures.

Figure 2.1: Sedation Flowchart.....	12
Figure 3.1: Summary of Literature Search.....	16
Figure 6.1 Summary of Survey Data	78
Figure 6.2: Adjustment of Pain Relative to Acceptability.....	81
Figure 6.3: Comparisons of Sedation-Related Complications.....	86
Figure 6.4: Comparisons of Rates of Ventilatory Support.....	88
Figure 6.5: Comparisons of Rates of Tamponade.....	90
Figure 6.6: Icicle Plot.....	94
Figure 6.7: Dendrogram.....	95
Figure 6.8: Agglomeration Schedule.....	96
Figure 6.9: Kruskal-Wallis Testing Summary.....	99
Figure 6.10: Pairwise Comparison of Clusters.....	100
Figure 6.11: Distribution of Variables Across Clusters.....	102
Figure 6.12 Cluster Changes When Including “frequency of worst pain”.....	104
Figure 6.13 Kruskal-Wallis Testing of Independent Variables	106
Figure 6.14: Individual Independent Variables Across Clusters	107
Figure 6.15: Further Individual Independent Variables Across Clusters	109
Figure 6.16: Chi-Squared Tests of Dichotomous Variables Across Clusters	111
Figure 6.17 Set Calibration Summary.....	113
Figure 6.18: Simple Count of Response Regarding Anxiety On Ward.....	118
Figure 6.19: Truth Table and Algorithm Using Drugs as Causal Conditions	121
Figure 6.20: XY Plot Demonstrating Consistency of Drugs-Only Solution.....	123
Figure 6.21: FsQCA Analysis of Drugs Administered and “Obese Patient”.....	125
Figure 6.22: FsQCA Analysis of Drugs Administered, “Obese Patient” and “Young Patient”.....	128
Figure 6.23: Logical Remainders in Truth Table Algorithm.....	130
Figure 6.24: Quine-McCluskey Algorithm Including Counterfactual Assumptions.....	131
Figure 6.25: FsQCA of Sufficient Conditions for Negative Experience	135
Figure 6.26 Table of Case Outcomes and Solution Set Membership by Sedationist	139
Figure 6.27: XY Plots of “Moderate Analgesia with Fentanyl” against “Short Case” and “Not Obese Patient”.....	141
Figure 7.1: Matrix 2.....	158
Figure 7.2: Matrix 3.....	160
Figure 8.1: Identity and Experience of Sedationists Participating in Case Studies	195
Figure 9.1 Flowchart Diagram Describing Optimal NDPSA via Anxiolysis	214

List of Appendices.

Appendix A: Nurse Delivered Cardiac Sedation Protocol.....	259
Appendix B: NDPSA Documentation.....	270
Appendix C: Survey Questionnaire.....	273
Appendix D: Ethics Approvals.....	277
Appendix E: Participant Information and Sample Consent Forms.....	287
Appendix F: The Critical-Care Pain Observation Tool.....	302
Appendix G: Interview Schedule (patient).....	303
Appendix H: Interview Schedule (sedationist).....	304

Acknowledgements

When submitting this, I wish to acknowledge the support, both academic and emotional, of my supervisor, Dr. Michael Hill throughout the project. I would also like to thank Stephen Lord, Julie Rutherford, Byrony Makari, and Camilla Hodgson and her team for facillitating this project. Without their support and patience, this project could never have been completed.

Declaration

I declare that the work contained in this thesis has not been submitted for any other award and that it is all my own work. I also confirm that this work fully acknowledges opinions, ideas and contributions from the work of others.

Any ethical clearance for the research presented in this thesis has been approved. Approval has been sought and granted by the Faculty Ethics Committee on 30/11/2016. This approval is included in Appendix D.

I declare that the Word Count of this Thesis is 84999 words

Name: Stuart John Barker

Signature:

Date: 24/04/2021

Chapter 1: Introduction

This thesis is the final report of a research project which aimed to critically evaluate the use of an innovative protocol for Nurse-Delivered Procedural Sedation and Analgesia (NDPSA) for patients undergoing ablation of atrial fibrillation (AF). This protocol is currently in use in a National Health Service (NHS) Trust. The need for innovation in procedural sedation for this type of procedure is extensively discussed in Chapter 2, but it can be summarised here as the product of two main issues: the growing demand for AF ablation, and the unsuitability of existing models of procedural sedation and analgesia (PSA), both in terms of resource management and professional requirements. However, the need for this research derives from the professional need to maintain quality of care. Chapter 3 critically reviews current research regarding sedation practices used in the cardiac catheter laboratory (CCL). In doing so, it establishes the scope for this project to make a unique and original contribution to the body of knowledge relating to PSA in the CCL. This review also serves to justify some of the project's aims and objectives. For the benefit of the reader, these are listed in this introduction; in practice, they were refined following an initial literature review. This review also identifies factors of potential importance in determining the outcomes of sedation, thus providing focus for further investigation. It also appraises the strengths and weaknesses of the research methods used in previous studies which, in turn, influenced the research approach used in this study. Finally, both the project's aims and objectives, and its methodology, have been shaped by existing theoretical knowledge regarding the nature of both pain and anxiety, and the concept of protocol-based care and other models of clinical decision-making. An exploration of this theoretical knowledge, and its implications for this project, is undertaken in Chapter 4.

The following aims and objectives were formulated for this project following the review of context, existing research, and theoretical knowledge:

Aims:

1. To critically evaluate the practice of protocol-based NDPSA within this Trust.
2. To identify the conditions under which NDPSA is most effective.
3. To appraise the contribution made by the individual sedationist to effective NDPSA.

4. To identify aspects of NDPSA practice requiring development in order to optimise outcomes.

Objectives:

1. To ascertain the safety of NDPSA
2. To measure patients' satisfaction with the service they receive.
3. To determine which intrinsic and extrinsic factors (or combination of factors) contribute to high satisfaction with the patient's experience of NDPSA.
4. To ascertain how individual sedationists use the protocol in practice.
5. To discuss any differences identified between individual sedationists in the context of clinical decision-making theory.

Once these aims and objectives have been justified, Chapter 5 details this project's methodology. It establishes an orientation to research that is required by the aims and objectives, that is justified in terms of existing theoretical knowledge, and avoids the criticisms of existing research that are made in the literature review. It establishes the need for a mixed-methods approach and proceeds to provide justification for, and details of, the first phase of data collection. The analysis of this first stage of data collection is contained in Chapter 6. Chapter 7 consists of an assessment of the extent to which this first stage of analysis has met the aims and objectives of the research. As some aims are not yet achieved, this chapter identifies further issues needing to be addressed in the second stage of data collection, and justifies the design for this second stage. The analysis method selected requires further exploration of theoretical explanations of issues identified during first phase analysis, and this is also done here. It ends by specifying the data that will be collected in the second phase, and the details of how it will be collected. Chapter 8 details the analysis of data from this second phase, and Chapter 9 provides a summary of key findings, with specific reference to the project's objectives. Chapter 10 then returns to many of the themes identified in the early chapters, and discusses the findings of the project in relation to the contexts which gave rise to this research, existing theories of decision-making, and previous research into PSA in the CCL. The thesis concludes by stating its unique contribution to knowledge regarding PSA in the CCL, and by making recommendations for development of practice, and for ongoing research in this field.

Chapter 2: Context

2.1 Introduction.

NDPSA is a potentially valuable innovation as it addresses two contextual needs: the growing demand for cardiac ablation, and the need to formalise the sedation practices of non-anaesthetists. However, a third requirement necessitates the need for this research: this is the professional need to maintain and improve standards of care. This chapter examines the first two drivers, explaining how they have created the need for NDPSA. The third driver is then introduced, which explains the need for this research and supports the aims stated in the introduction. In doing this, it defines some key terms used throughout the thesis. It ends by introducing the NDPSA protocol, and establishing it as a legitimate method of PSA as defined by national guidelines.

2.2 Cardiac Ablation

The National Institute for Cardiovascular Outcomes Research (NICOR) gives the following definition of cardiac catheter ablation:

“Catheter ablation is a technique for treating (and usually curing) heart rhythm disturbances (arrhythmias), using fine, flexible electrodes threaded into the heart via veins. These are used to make small burns that eliminate the abnormal tissue responsible for the arrhythmias.” (NICOR, 2015, p.5)

The National Cardiac Audit Programme (NCAP) (2019) add that instead of burning, known as radiofrequency ablation (RFA), freezing, or ‘cryoablation’ can be used to eliminate abnormal tissue. Both methods are included in the compass of this study. Cardiac ablation may be used to treat many arrhythmias: NICOR (2015) categorise ablations by type, distinguishing between ablations of AF, atrial flutter, atrioventricular node re-entry tachycardia, atrial tachycardia, ventricular tachycardia, and ablations of accessory pathways or the atrioventricular node itself. Of these, AF ablations are recognised as taking longer (NICOR, 2015), and being more painful than other types (Kottkamp *et al.*, 2011). This study therefore decided to focus exclusively on AF ablations as they were considered to represent the greatest challenge to the sedationist.

2.2.1 Demand.

Numbers of cardiac ablations performed in the UK rose from 8,152 in 2007, to 19,517 in 2016 (NCAP, 2019). Of these, the proportion of AF ablations has increased from 27% in 2007 (NICOR, 2015), to 41% in 2016 (NCAP, 2019), now making it the most common ablation target. This provided a second reason to focus exclusively on AF ablation. Ablation figures rose sharply in the first half of this timeframe, reaching 17,657 by 2012 and increasing little since (NCAP, 2019). The plateauing of case numbers does not result from demand being met. In 2013, the United Kingdom (UK) lagged behind many other European nations in terms of ablations performed per million of population (NICOR, 2015). Germany performed 44% more AF ablations, and Denmark 189% more; it is implausible to believe demand in the UK is lower by such a margin. Furniss and Sneyd (2015) confirm this, stating that demand for AF ablation continues to rise in the UK. A more convincing explanation for plateauing numbers is that resources, either CCL capacity or skilled staff, have reached the point of maximum capacity, thus preventing further increase. Furthermore, the growing proportion of more time-consuming cases such as AF ablation (NCAP, 2019) may absorb any increased capacity. Reed, Tushman and Kapadia (2018) identify that operational inefficiency remains common in CCLs, and Furniss and Sneyd (2015) state that effective service delivery depends upon rapid turnovers between cases. This growing demand requires consideration of causes of inefficiency in the CCL, and how these inefficiencies can be reduced.

2.3 Standards for Sedation.

The Academy of Medical Royal Colleges (AoMRC) (2013) state that:

“By relieving anxiety, reducing pain and providing amnesia, sedation techniques have the potential to render uncomfortable diagnostic and therapeutic procedures more acceptable for patients.” (AoMRC, 2013, p.5)

They then identify that these techniques have the potential to cause life-threatening complications, stating that these complications mainly result from poor training and practice. To address this, the AoMRC require formal competency-based training for those whose roles required them to administer sedation, and set fundamental standards with which practice must comply. They also advocate the development of additional standards for areas of specialist practice as additions to their own guidance. For cardiological practices, this was done on behalf of the

British Cardiovascular Society and the British Heart Rhythm Society by Furniss and Sneyd (2015). The development of NDPSA, and competencies for this, is therefore part of a wider movement towards patient safety when sedation is administered by non-anaesthetists.

Neither the AoMRC (2013) nor Furniss and Sneyd (2015) specify a particular model of sedation; instead, they establish standards which can be encompassed by several models. Of greatest importance, the AoMRC (2013, p.2) state that optimisation of safety requires “defined methods” of sedation, for which formal training has been received. The term “defined method” is taken to mean a framework or protocol, such as the one being studied here. Also important is the principle that, regardless of education or professional background, the skills required for safe sedation remain the same: in their exemplar core curriculum, the AoMRC (2013) include a demonstration of an understanding of the pharmacology of used drugs, recognition of the limitations of conscious sedation techniques, and the ability to recognise and manage complications arising from sedation. Furniss and Sneyd (2015) add that nurses must have a minimum of intermediate life support training. Finally, Furniss and Sneyd (2015) recognise that the CCL is routinely equipped with electrocardiogram monitoring, oximetry, intubation equipment, piped oxygen and defibrillators, but also states that the presence of this equipment is mandatory for safe sedation.

2.4 Procedural Sedation and Analgesia During Cardiac Ablation.

Cardiac ablation can cause the patient pain and anxiety (Lü *et al.*, 2013; Furniss and Sneyd 2015). Kottkamp *et al.* (2011) state that this is particularly true of AF ablations, meaning some form of PSA is necessary. Piot (2015) identifies four models of PSA used in CCLs; the first of these is the classic model, in which an anaesthetist delivers sedation. Historically, this model has been utilised during ablation (Kezerashvili *et al.*, 2008), though Piot (2015) notes that availability of anaesthetists may restrict numbers of procedures performed. This is supported by an American survey (Gaitan *et al.*, 2011): amongst electrophysiologist who believed the presence of an anaesthetist was warranted during their cases, 60% identified the unavailability of anaesthetists as a reason for not using them, while 60% also identified scheduling difficulties. A further 20% noted that use of anaesthetists increased turnover times in CCL. All three figures increased amongst electrophysiologist who did not believe an anaesthetist’s presence was

warranted. Nurses in Australia and New Zealand also identified that responsibility fell to them to administer sedation *because* of a lack of anaesthetists, and that insistence on the use of anaesthetists would hinder the efficiency of the CCL (Conway *et al.*, 2014a). Due to increased turnaround times and paucity of anaesthetists, adherence to the classic model reduces, rather than increase, the utilisation of CCLs. Despite this, AF ablation remains one of the CCL procedures where the classic model is most utilised; in 60% of cases in the USA (Gaitan *et al.*, 2011) and in 51% in Australia and New Zealand (Conway *et al.*, 2014b); UK figures were not found. This may be an acknowledgement that AF ablations are particularly painful (Kottkamp *et al.*, 2011). However, given the growing proportion of AF ablations (NCAP, 2019), an alternative to the anaesthetist model can improve CCL utilisation.

Piot's (2015) second and third models are also problematic in the CCL. The operator model requires the electrophysiologist to manage the sedation as well as perform the procedure. UK guidelines specific to cardiology (Furniss and Sneyd, 2015, p.1528), dismiss this as "not relevant or appropriate". Reasons for this include that responsibility for sedation may distract the operator from the case itself (Lù *et al.*, 2013) or, conversely, focus on the procedure may prevent necessary attention to the patient's condition (AoMRC, 2013). The presence of a second electrophysiologist can navigate this problem, but is likely to encounter the same issues of resourcing and scheduling noted by Gaitan *et al.* (2011). Meanwhile Piot's (2015) third model, in which nurses are in charge of both procedure and sedation, can be given equally short shrift. Piot (2015) mentions it in relation to procedures such as cardioversion, rather than ablation. This model is not relevant until nurses begin performing cardiac ablation. This prospect seems unlikely, and would be subject to the earlier criticisms as the operator model.

The final model, the doctor/nurse model, is defined as:

"a nurse sedationist under (or not) the direct supervision of the anaesthetist and the doctor performing the procedure." (Piot, 2015 p.1525)

However, this definition does not distinguish between the nurse acting on the operator's direct instruction, and the nurse acting with autonomy. This is problematical; the former option is open to the criticisms levelled at the operator model (AoMRC, 2013; Lù *et al.*, 2013) as it only delegates responsibility to the nurse for injecting drugs, rather than for assessment of the patient's condition and

titration of medication. These criticisms can be avoided by the nurse taking responsibility for patient monitoring and for titration of medication. Furthermore, this also avoids the resourcing and scheduling issues identified by Gaitan et al. (2011) as a barrier to the classical model. However, while NDPSA may address both of these issues, it can only be considered a solution if the practice of NDPSA is effective. The meaning of “effective PSA” will be explored in more detail in the next chapter.

2.5 The Expansion of the Nursing Role

Barton, Bevan and Mooney (2012a) track the expansion of the nurse’s role from the recognition of the specialist nurse in 19th Century America, through the development of the practice nurse in the 1960s, whose practice then began to overlap with that of the doctor, to the development of the advanced practice nurse (APN). Hill (2017) identifies confusion in terminology used in relation to expanded nursing practice due to the plethora of titles used (APN, clinical nurse specialist, nurse consultant, physician’s associate), and a failure to distinguish between advanced nursing practice and the more formalised advanced practice nursing. Those practicing NDPSA are not afforded any additional title; however, Kezerashvili *et al.* (2008) note that PSA in the CCL was traditionally the role of the anaesthetists. The assumption of this role by the nurse is part of the movement towards advanced nursing practice. It is therefore important that the drivers behind this movement are considered.

Delamaire and Lafortune (2010) identify a number of drivers: a shortage of doctors; the need to improve access to service and raise quality of care; changing patient needs; cost-containment and career progression of nurses. They observe that advanced nursing roles were largely pioneered in nations in which a shortage of doctors left gaps in services. Barton, Bevan and Mooney (2012a, p.18) express some cynicism, arguing that in the UK, the Department of Health (DoH) has regarded advanced nursing as a “cost-effective redesign” used to overcome the shortage of medical staff. They state that this position contrasts rather than contradicts their own view of advanced practitioner as cutting-edge innovators in healthcare. This is taken to mean that advanced practice should be primarily regarded as a means of improving services, but that economic benefits may occur alongside this. However, they imply that expanded nursing roles might occur for resource reasons alone, potentially to the detriment of other aspects of service.

2.5.1 The Expanded Role and Quality of Care

In the UK, The Nursing and Midwifery Council (NMC) states that the nurse must:

“identify priorities, manage time, staff and resources effectively and deal with risk to make sure that the quality of care or service you deliver is maintained and improved, putting the needs of those receiving care or services first” (NMC, 2018, p.22)

An expansion of nursing practice, therefore, is only professionally acceptable if it at least maintains quality of service to the patient; economic or resourcing benefits would not justify a decline in the quality of the service. This can happen:

Delamaire and Lafortune (2010) identify Australia as a nation where shortage of doctors was the principal driver behind expanded nurse role, and an Australian study indicates some truth in Barton, Bevan and Mooney’s (2012a) concern:

“Participants described, though, when anaesthetists were not available, the responsibility for administering PSA fell to the nurse, regardless of patient or procedure complexity.” (Conway *et al.*, 2014a, p. 378)

The disregard for patient and case complexity indicate that this is not an expansion of practice intended to improve quality, but a stopgap solution when anaesthetist numbers are insufficient to maintain services. It may therefore be to the detriment of service quality, and would therefore not meet the NMC’s standard. Previously in this chapter, it has been indicated that NDPSA may have benefits in terms of increasing CCL use; from a professional perspective, this is insufficient to justify its use if the practice does not provide a high-quality service to the patient. While Barton, Bevan and Mooney (2012b) regard issues of motivation behind expanded role as crucial, Hill (2017) argues that benefits or, by implication consequences, of an expanded role are more important than the rationale behind them. Sharing the latter view, as a piece of nursing research, this study must question the impact of NDPSA on quality of care, if potential resourcing benefits are to be realised. Again, the meaning of “quality” will be discussed in the next chapter.

2.5.2 The Nurse as Sedationist in Cardiology.

The expanded role of the nurse has included the development of nurse-led sedation practices being implemented and evaluated in areas including paediatric magnetic resonance imaging (Sury *et al.*, 1999), and burns dressing (O’Hara *et al.*, 2013). Similar developments in cardiology have been slower, with only a single example of Piot’s (2015) nurse model (Boodhoo *et al.*, 2004) being found in an

initial search; this practice was limited to cardioversions, a very brief procedure, which cannot be compared to cardiac ablation. This slow expansion in cardiology may be due to safety concerns: cardiac disease itself has been identified as an additional risk in guidelines for non-anaesthetists (British Society of Gastroenterology, 2003, p.4), and the presence of cardiac disease requires caution in the use of some sedatives, including midazolam (Joint Formulary Committee (JFC), 2021). Little research has focused on nurse-led sedation in the CCL:

“no research has focused on identifying factors that impact nurses' ability to facilitate optimal PSA titration. Such research is needed because it could lead to the development of strategies to improve the care of patients who receive nurse-administered PSA in the CCL.” (Conway *et al.*, 2014a, p.375)

This is somewhat confusing as, in an earlier article, the same authors maintained that nurse-administered sedation was becoming increasingly common in the CCL (Conway *et al.* 2011). However, in their 2011 article, these authors stress that the word administered means prescribed by the operator and administered by the nurse; as discussed earlier, this can be seen as a subset of Piot's (2015) operator model as the operator maintains responsibility for titration of drugs. It is this optimal PSA titration by nurses that concerns this thesis. Since 2014, one other study (Sawhney *et al.*, 2017) has been published addressing NDPSA in the CCL. However, as this study focuses exclusively on the safety of NDPSA, it is doubtful whether this study delves deeply enough to identify the quality required by the NMC (2018) or the optimal sedation identified by Conway *et al.* (2014a).

2.6 Implications for Research

This discussion has established the need for research into the utility of NDPSA during cardiac ablation. The operator model described by Piot (2015) is considered neither relevant nor appropriate by Furniss and Sneyd (2015). While the use of anaesthetists meets such standards, their level of skill is regarded as unnecessary, and their use causes scheduling issues and increased turnaround time between cases (Gaitan *et al.*, 2011). Though ablation numbers have plateaued (NCAP, 2019), Furniss and Sneyd (2015) identify that demand continues to rise, and that a need exists to improve CCL efficiency. NDPSA represents a potential third option; that it meets the standards required by the AoMRC (2013) and Furniss and Sneyd (2015) is established in Section 2.7. It also avoids the scheduling issues and extended turnaround times associated with the

use of anaesthetists (Gaitan *et al.*, 2011), and therefore can improve efficiency in the CCL. However, professional requirements (NMC, 2018) mean that any possible efficiency must not come at the expense of quality of care. This gave rise to the first two of the project's stated aims: to critically evaluate the practice of NDPSA within this Trust, and to identify the conditions under which NDPSA is most effective. Should the evaluation prove positive, it can establish NDPSA as an alternative to other used models which both meets professional requirements and improves efficiency. Should the evaluation show mixed or inconsistent results, it may be able to inform the improvement of NDPSA practice and thus contribute to it becoming a viable alternative. The need for such research is supported by Conway *et al.* (2014a), whose observation regarding the lack of research in this area represents an opportunity for this thesis to make a unique contribution to knowledge.

2.7 The Nurse-Delivered Sedation and Analgesia Protocol.

Some detail of the NDPSA protocol should be given to introduce the reader to scope of the nurse's responsibility, and to establish that this practice meets the professional guidelines (AoMRC, 2013; Furniss and Sneyd, 2015), and thus represent a legitimate alternative. A copy of the sedation protocol is included as Appendix A.

It should be noted that this protocol represents a distinct model from the operator model deemed inappropriate by Furniss and Sneyd (2015). Although Appendix A notes the presence and overall responsibility of the operator, O'Hara *et al.* (2013) argue that terms such as "nurse-led" do not require a complete absence or lack of input from medical staff. There is no need to become embroiled in this semantic debate, because the protocol makes a key distinction between itself and the practice described, for example, by Conway *et al.* (2011). This is a categorical statement of the responsibilities of the nurse-sedationist:

"This nurse is responsible for the vigilant observation of the patient, titration of the medication and the completion sedation documentation." (Appendix A, p.262)

It also states that its aims include the minimisation of operator input regarding the management of sedation. Conway *et al.* (2011) described practice in which nurses administered doses of medication specified by the operator; here the responsibility for clinical decision-making clearly belongs to the nurse.

The AoMRC's (2013) requirement for a defined method of sedation can be considered as met through 3 aspects of the protocol. First is the flowchart of the sedation process (Figure 2.1). Within this flow chart, specific criteria are set for raising concerns:

- A drop in the mean arterial pressure of more than 10% or more than 20mm Hg
- A respiratory rate of less than 8 per minute
- Oxygen saturation of less than 90%
- Any other cause for concern, including apnoea, hypoxaemia, poor respiratory effort, increased respiratory effort, irregular breathing patterns, such as suprasternal or intercostal retractions, or paradoxical abdominal movement. (Appendix A, p.267)

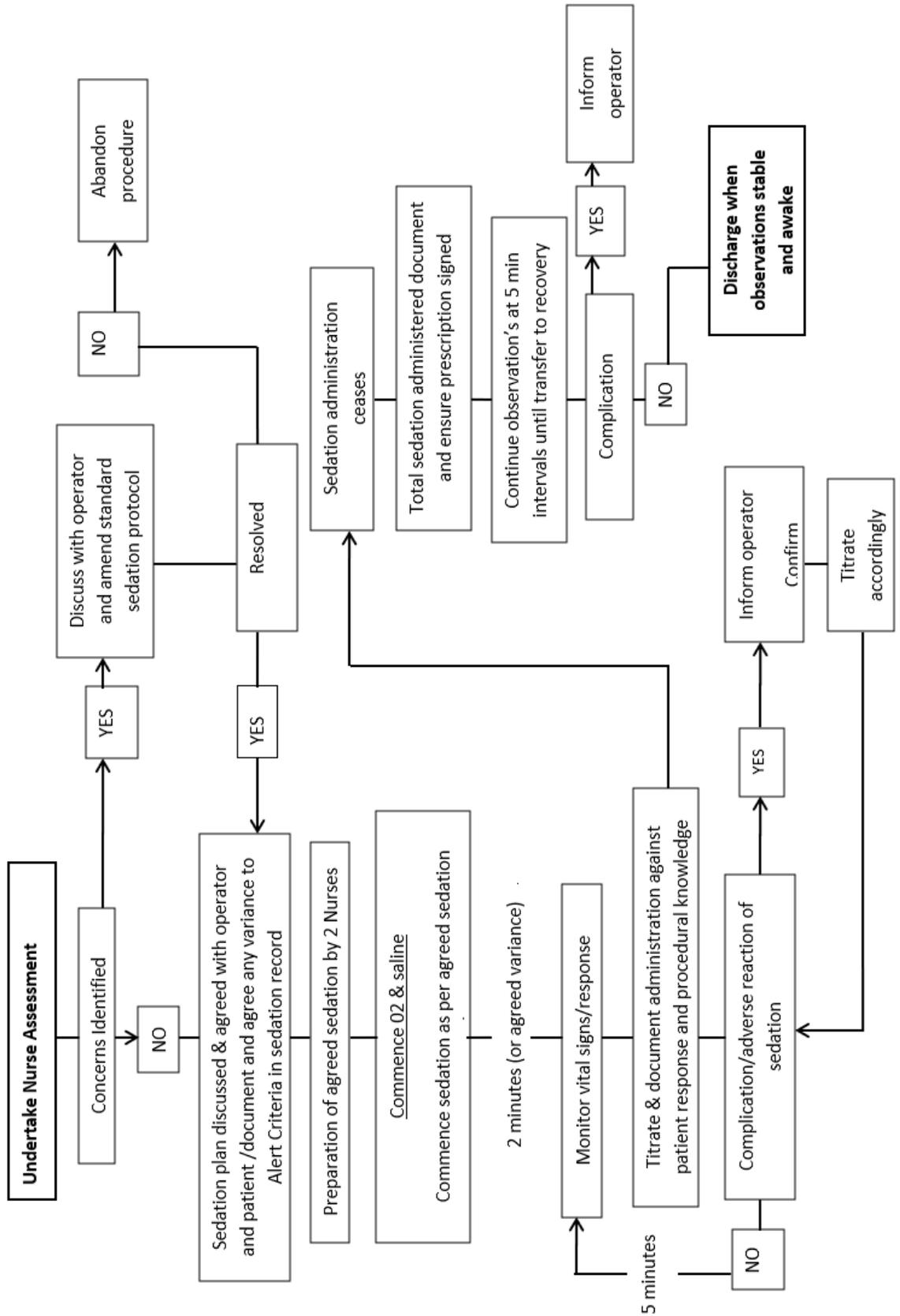
Furthermore, aliquots are specified for the titration of drugs:

- Provided baseline observations are satisfactory administer 10mcg of Fentanyl observing patient for immediate effects/response.
- Record one full set of observations following first dose and wait 2 minutes before administering any other medication.
- Commence Midazolam.
- Titrate as required further doses of Fentanyl 10-20 mcg. There should be one full set of observations and two minutes between each dose.
- Titrate as required further doses of Midazolam 1mg. There should be one full set of observations and two minutes between each dose. (Appendix A, p.265)

Both sets of specifications, alert criteria and drug aliquots, set parameters within which the nurse operates. Combined with the flowchart which outlines the sedation process, this constitutes a well-defined method of sedation. However, the scope for the utilisation of professional judgement within this protocol should also be noted. While the first three alert criteria are highly specific, the fourth empowers the nurse to act if anything else causes them concern. Likewise, with the specification of drug aliquots, the use of the repeated phrase "titrate as required" allows scope for the use of professional judgement. The use of such a protocol cannot, therefore, guarantee uniformity of practice, a point to which is returned to later.

Figure 2.1: Sedation Flowchart

(Appendix A, p.261)



As well as complying with the need for a defined method, this protocol meets the other requirements of the AoMRC (2013) and Furniss and Sneyd (2015). Chief amongst these was the demand for competency-based educational standards, regardless of professional background (AoMRC, 2013); the need to complete such competencies is stated in specification for performing NDPSA (Appendix A, p.262). Though not stated in the protocol, all nurses using it had undertaken a study day combining theory sessions on pharmacology, airway assessment and management, and also simulation-based practical sessions in which titration was practiced, along with response to emergency situations. All were subsequently supervised until they met the required competencies for independent practice, with one exception who had been involved in PSA prior to the formalisation of the NDPSA protocol and was deemed “competent by experience” (Appendix A, p.262). Also met by the protocol document are Furniss and Sneyd’s (2015) requirement for a minimum of intermediate life support. Elsewhere, compliance with Furniss and Sneyd’s (2015) equipment requirements are demonstrated (Appendix A, p.263). It is therefore concluded that this protocol is in accordance with national standards, and those specific to cardiology. To this extent, it represents an acceptable alternative to other models of PSA. However, the need to explore the quality of care that the NDPSA protocol provides remains.

Chapter 3: Literature Review.

3.1 Introduction.

This chapter reviews existing literature regarding the efficacy of PSA in the CCL. The paucity of literature on the ability of the nurse to optimise titration of PSA was asserted by Conway et al. (2014a); a first question for this review was to ascertain that the veracity of this assertion has endured in the intervening years. Secondly, it identifies which of Piot's (2015) models have been evaluated by existing research, the extent to which demarcation of responsibility for titration has been established by these studies, and the limit on transferability of findings imposed by this demarcation. The implications of this for the current study are also considered. Another issue identified in the previous chapter is also addressed: if this study seeks to identify factors optimising NDPSA, it must ascertain the criteria by which "quality of care" has been defined. Some of these criteria are unsuitable for the constraints of doctoral study; therefore, the criteria used to define optimal sedation and quality of care in this study are identified, along with reasons for excluding other criteria. The review continues with a critique of the research methods used to evaluate PSA in previous studies. Strengths and weaknesses of these methods are identified which, subsequently, inform the methodology and research design of this study in Chapter 5. This chapter then identifies factors recognised as contributing to quality of care by previous studies, before summarising the implications of the review for this study.

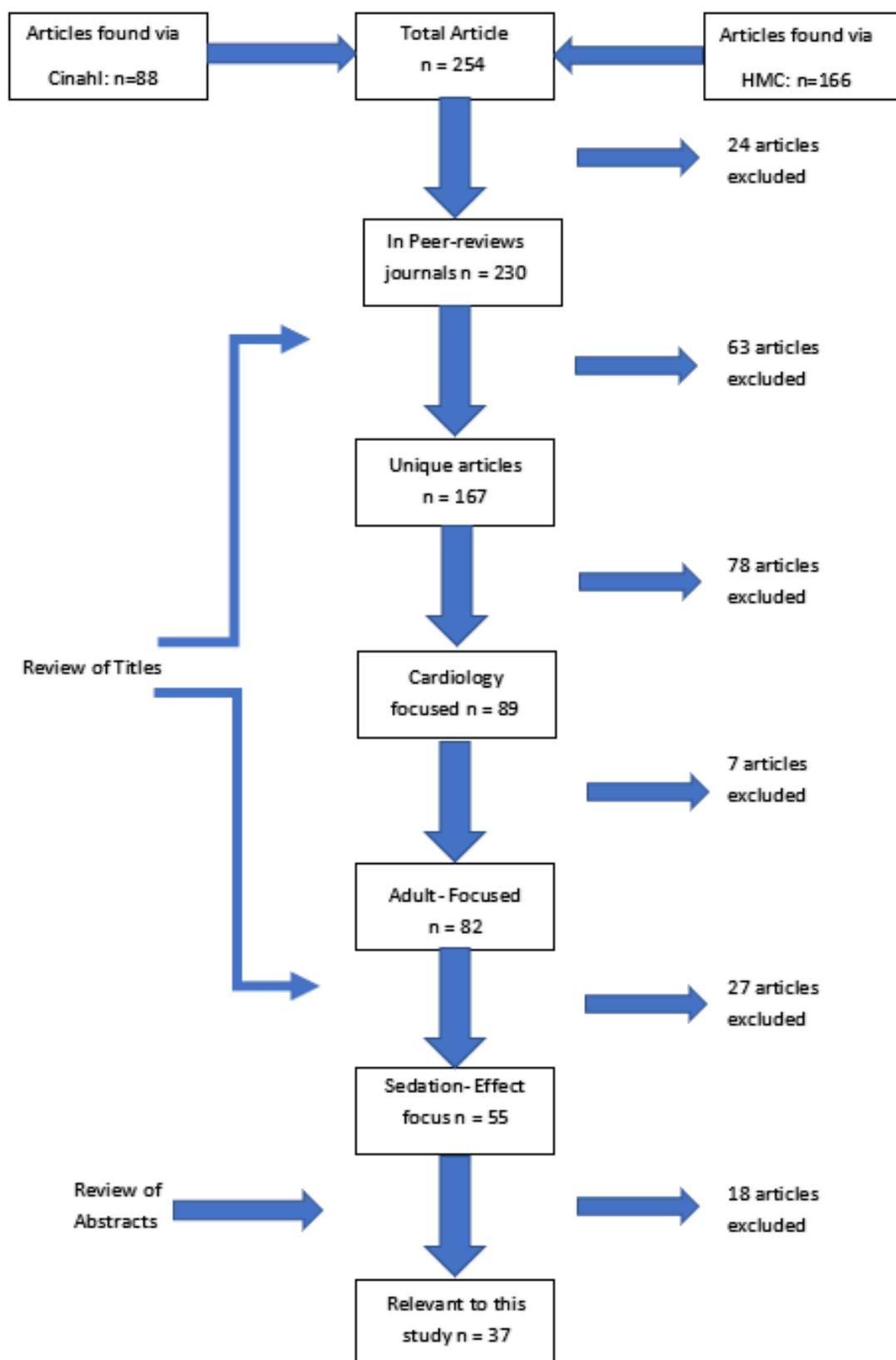
3.2 Literature Search Strategy

This project began with an initial focus on PSA during all CCL procedures, rather than AF ablation in particular. Initial reading reflected this, and it was through this reading that the preferability of a refined focus on AF ablation alone became apparent. Some articles reviewed do not, therefore, focus on AF ablation, but still contained important insight into the priorities of PSA in the CCL, methods used to evaluate PSA in the CCL, and factors influencing outcome of PSA. They are therefore included in this review. Literature was sought using *The Health and Medical Collection* and *CINAHL* databases. Search terms used were "sedation" or "analgesia" in a Boolean AND conjunction with each of the terms "cath* lab*", "electrophysiology", "ablation", "atrial fibrillation" and "pulmonary vein". In total, this search was conducted 3 times: during the formative stages of the project in 2015,

during drafting of the review in 2017, and nearing completion in 2020. Due to the paucity of research focused on PSA during ablation within the UK, it was decided to include literature from all nations. This decision has implications for the relevance of some research at specific stages of the review that will be acknowledged as they arise.

The search yielded a total of 254 articles. After 63 duplicates and 24 articles in non-peer reviewed journals were excluded, abstracts were reviewed. 78 were then excluded for having non-cardiological focus; many of these focused on analgesia in labour, while others considered ablation to other parts of the body. 7 were excluded due to a focus on paediatric patients. Finally, 27 articles were excluded as they did not focus on the effects of sedation on the case. This left a total of 55 articles which were read in full; 18 were found not to be relevant, leaving a total of 37 articles to be included in the review. This process is summarised in the diagram on the next page. Although all 37 articles were read, not all have contributed material to the subsequent review; in particular, prolific authors in the field such as Conway and Wutzler made repeated points in different articles, and duplicate references have been excluded. A further 10 articles were identified via repeated citation by those identified via the literature search, and were included in the review. This process is summarised in Figure 3.1.

Figure 3.1: Summary of Literature Search



3.3 Providers of Procedural Sedation and Analgesia

The assertion that no research has examined the nurse's ability to titrate optimal PSA during ablation (Conway *et al.*, 2014a) remains largely undisputed by the reviewed literature. A single exception was identified (Sawhney *et al.*, 2017) but, as shall be shown, this article only partially addresses the need identified by Conway. Many articles have focused on practices in which sedation is administered by nurses but fail to answer any questions regarding the ability of the nurse to titrate sedation.

3.3.1 Responsibility for Titration.

Many studies (Natale *et al.*, 1996; Geiger *et al.*, 1997; Kovoov *et al.*, 1997; Kezerashvili *et al.*, 2008; Defaye *et al.*, 2010; Ezzat *et al.*, 2012; Wasserlauf *et al.*, 2016; Múnkler *et al.*, 2017; Miśkowiec *et al.*, 2018) have focused on PSA when administered by nurses. However, in these studies, the demarcation of responsibility for titration of sedation, and for monitoring of the patient's condition, is unclear. Though they would all be classified as using the doctor/nurse model (Piot, 2015), they fail to discern that this model covers two distinct models, one of which is acceptable under UK standards, and one which is not (Furniss and Sneyd, 2015). The above articles were all published in medical, rather than nursing, journals, and concerned themselves with the distinction between Piot's (2015) classic model and his doctor/nurse model. This is immediately apparent in the titles and abstracts of some articles such as "in the absence of an anesthetist" (Geiger *et al.*, 1997, p.1808), "by non-anesthesia personnel" (Kezerashvili *et al.*, 2008, p.43), and "without the presence of a specialist anaesthetist" (Kovoov *et al.*, 1997, p.2765). Some studies make the demarcation of responsibility for titration difficult to discern; Kezerashvili *et al.* (2008, p.45) write of nurses administering under the "general direction" of the electrophysiologist. Múnkler *et al.* (2017, p.586) describe sedation being administered "under supervision of the operating physician", while Pachulski, Adkins and Mirza (2001) indicate that PSA might be adjusted on the judgement of the doctor or the nurse. With such lack of clarity, no judgement can be made regarding whether such practice meets the professional standards of Furniss and Sneyd (2015), or the contribution of the nurse to the optimisation of that case. It is intended that the identification of the nurse as the individual responsible for titration in Section 2.7 guards against similar criticism. However, in studies where clarity exists, most identify the cardiologist as the

individual responsible for titration; in Kottkamp *et al.* (2011, p.1340) “the electrophysiologist had the responsibility for the whole procedure, including the sedation and analgesia”; Defaye *et al.* (2010, p.390) state that “doses were titrated by the physician”; Wutzler *et al.* (2013, p.116) write of propofol being administered “under direct supervision of the operating electrophysiologist”, and Miśkowiec *et al.* (2018, p.145) describe the nurse administering PSA “under instructions and the supervision of the electrophysiologist”. While this detail is valuable in discerning the extent to which practices studied meet professional standards (Furniss and Sneyd, 2015), and whether they address the research need identified by Conway *et al.* (2014a), the answer to both questions from these studies is negative.

The failure of international practices to comply with UK standards does not make these studies irrelevant to the study of NDPSA, or this review. If for no other reason, they were considered worthy of inclusion for their support in identifying the priorities of NDPSA, and all PSA practices. As with domestic research, safety of practice is a common theme within them. More importantly though, they allowed for comment on the value of UK guidelines; these exist specifically to maintain the safety of PSA by non-anaesthetists. However, should the evaluation of NDPSA identify inferior safety and experience compared to practices that these guidelines would consider inappropriate, the appropriacy of the guidelines themselves must be questioned as they would fail to serve their purpose, despite NDPSA complying with them. Alternatively, should NDPSA be shown to provide superior safety and comparable patient experience to practices outside of UK guidelines, this evaluation can provide some endorsement of the UK guidelines which could contribute to their adoption in other countries.

Conway *et al.* (2014a) themselves provide evidence that nurses can contribute to the titration of PSA dose; in interviews, their respondents disclosed that they are able to recognise patient discomfort, recommend adjusting PSA dosage, and that their judgement is valued by operating physicians. However, this evidence is based on the opinions of the nurses themselves: they believe that they contribute to what they perceive as being the optimisation of PSA. No meaning is ascribed to “optimal” that is independent of their own perception; as the study does not relate to specific cases, there is no external means by why the optimisation of PSA could be measured. Furthermore, Conway *et al.* (2014c) establish that their understanding of facilitating optimal PSA means vigilance in assessing the patient

and their needs, and fastidiousness in communicating these to the cardiologist to support titration, rather than making decisions regarding titration themselves. While it is recognised that nurses have a role to play in supporting optimal titration in a doctor/nurse model, it does not answer the question regarding factors allowing nurse to facilitate optimal titration of PSA.

Two articles study practices which identify nurses as the professionals responsible for the titration of medication (Boodhoo *et al.*, 2004; Sawhney *et al.*, 2017). Of these, Boodhoo *et al.* (2004) write in the context of a nurse-led cardioversion service, in the absence of medical staff. Although this study offers some general support to the feasibility of nurses titrating PSA for cardiac procedures, cardioversion is a much shorter procedure than AF ablation, lasting a matter of minutes rather than hours. It cannot therefore be assumed that efficacy of nurse-led sedation in this context can be transferred to the context of AF ablation. The nurse's responsibility for the titration of PSA is less definitively stated by Sawhney *et al.* (2017, p.1211); the practice in their study is described as "nurse-led" but also states that the operator "guides the nurses with regard to the level of sedation". However, the included protocol and details of competencies required of these nurses infer that nurses were responsible for titration of PSA. As such, it is comparable to NDPSA protocol studied in this project, and complies with UK professional standards. The scope of this study extends beyond AF, and all ablation-types, to include device implants and cardioversions, although 1969 of 7117 patients (27.6%) did receive atrial ablation. However, it cannot be claimed that Sawhney *et al.* (2017) have identified factors impacting on nurse's ability to optimise sedation. Possibly because this was a retrospective study, Sawhney *et al.* (2017) sought to appraise only the safety of their version of nurse-delivered PSA. As will be discussed, safety is an important aspect of PSA, but by itself is insufficient to identify optimal sedation. Furthermore, though it provides statistics on case types and patient demographics, no variance in outcome is recorded within their sample. Even the argument that the safety of their practice is established could be undermined if the small number of complications were concentrated within a particularly challenging type of case, such as AF ablation. To ascertain optimisation, it is necessary to look at variation within a cohort, rather than the results of the cohort in general.

3.3.2 Training and Transferability.

While Boodhoo *et al.* (2004) and Sawhney *et al.* (2017) emphasise the responsibility of the nurse for the titration of PSA, they further qualify this by providing details on the training and competency-assessment of the nurses administering such sedation. Boodhoo *et al.* (2004) specify a year of coronary care experience, advanced life support (ALS) certification, attendance on specialist training and a minimum of 20 supervised sedation-cardioversion procedures. Sawhney *et al.* (2017) stipulate formal competency-based training, ALS, and 3 assessments by different assessors, leading to certification. They go on to identify the importance of providing such detail:

“The results of this study reflect the practice of highly trained nurses taking on the role of sedationists while following a strict protocol in a well-structured EP laboratory. Hence, these findings may not be generalised to other centres.”
(Sawhney *et al.*, 2017, p.1214)

This acknowledges that the protocol under study could not be transferred to another CCL in which nurses had not been trained to the same level of proficiency, and similar levels of safety guaranteed. This point is not limited to studies focusing on nurse-titration; Geiger *et al.* (1997), Kottkamp *et al.* (2011) and Münkler *et al.*, (2017) also emphasise the importance of well-trained nurses to their results. It was therefore imperative that this thesis included similar detail regarding training; this has been done in the previous chapter (p.13). This does not guarantee the transferability of findings, but delineates an important limit on any transferability. This also prompts further consideration regarding the transferability of the findings of international studies and, potentially, the transferability of findings from this study to other countries. These studies stress the importance of specialist training but, of them, only Sawhney’s study was conducted in the UK. It would be wrong to assume that all entry-level international nursing qualifications are equivalent. The NMC (2021) does not recognise all nursing qualifications as equal and, therefore, while also recognising the relevance of specialist training, it should be stressed that both the findings of this study, and those of previous studies, may be contingent on the level of training required to qualify in the country in which the study took place. While qualification standards are likely to be equivalent in Germany (Kottkamp; Münkler), the NMC (2021) does not assume this, and therefore neither does this study.

However, uniformity of training does not guarantee uniform practice; the protocol described by Sawhney *et al.* (2017) offers scope for discretionary action by the nurse. If sedation is inadequate, it allows the nurse to administer 2.5mg of diamorphine with, or without, a further 1mg of midazolam. Smaller aliquots of these drugs may also be used, although the protocol provides no guidance on making these decisions. It is conceivable, therefore, that different nurses who fulfil training requirements, will apply this protocol differently. The NDPSA protocol being evaluated in this study allows similar scope for discretion and, therefore, variation. In terms of supporting transferability, evidence demonstrating that it is applied consistently by different nurses is desirable, but cannot be assumed at this point. Alternatively, variations in practice within the scope of the protocol may be identified which, in turn, may be relevant to optimised practice. Should this be the case, their identification may be used to refine the protocol itself, both enhancing practice in the area in which it is currently used, and making the protocol more transferable. Therefore, while this thesis has identified the training completed by nurse-sedationists, it will not regard them as a homogenous unit, but as individuals between whose practice variation may occur.

3.4 Priorities of Procedural Sedation and Analgesia.

To identify factors leading to the optimisation on NDPSA, it is necessary to recognise the different means by which the success of PSA has been measured. The literature review identified four main themes; each will be examined in turn, and those used to define optimal sedation in this study will be identified.

3.4.1 Safety.

When appraising PSA in the CCL, safety has been the primary outcome assessed by the largest number of studies (Natale *et al.*, 1996; Geiger *et al.*, 1997; Kovoor *et al.*, 1997; Pachulski, Adkins and Mirza, 2001; Boodhoo *et al.* 2004; Kezerashvili *et al.*, 2008; Kottkamp *et al.* 2011; Salukhe *et al.*, 2012; Dupanovic *et al.*, 2013; Looi *et al.*, 2013; Wutzler *et al.*, 2012; Wutzler *et al.*, 2013; Yamamoto *et al.*, 2013; Sawhney *et al.*, 2017; Miśkowiec *et al.*, 2018), and as a secondary outcome by more. By weight of numbers, the primacy of safety is established; it is therefore of fundamental importance that any evaluation of a PSA innovation explores the safety of that innovation: if it is unsafe, any other findings are meaningless. Some variation in measuring safety exists within the literature, along with distinctions

between inherent procedural risks and risks attributable to sedation; these will be explored in detail in Section 3.5. However, safety is not the primary purpose of PSA: it is not given in order to keep the patient safe, but to render the painful acceptable (AoMRC, 2013). As a result, studies which appraise only the safety of a particular PSA technique (Natale *et al.* 1996; Pachulski, Adkins and Mirza, 2001; Kezerashvili *et al.*, 2008; Yamamoto *et al.*, 2013; Sawhney *et al.*, 2017) invite critical speculation: did PSA techniques employed succeed in rendering the noxious acceptable to the patient? Therefore, without denying the importance of safety, it is important that this project evaluates NDPSA in greater depth, rather than simply in terms of safety.

3.4.2 Patient Experience.

Münkler *et al.* (2017) argue that establishment of the optimal sedation protocol requires assessment of the patient's experience of pain as well as any adverse pharmaceutical effects. In doing so, they are in agreement with UK health policy; political drivers have placed greater emphasis on patient experience in recent years (DoH., 2012; National Institute for Health and Care Excellence (NICE), 2012), with the *NHS Patient Experience Framework* (DoH. 2012) specifically including pain management within its definition of patient experience. In accordance with this, patient experience in the CCL has also been an important focus of research, frequently studied in conjunction with the safety of PSA (Kovoor *et al.*, 1997; Geiger *et al.*, 1997; Boodhoo *et al.*, 2004; Tang *et al.*, 2007; Looi *et al.*, 2013; Münkler *et al.*, 2017). Ironically, given their previous assertion, Münkler *et al.* (2017) make no attempt to appraise the safety of the deep sedation practice that they evaluate, and acknowledge this as a limitation of their study.

Other studies likewise appraise patient experience in isolation from safety (Lowe *et al.*, 2003; Ezzat *et al.*, 2012; Laish-Farkash *et al.*, 2016), but these three studies appraise patient experience of established PSA practices, rather than innovations. Although a few projects have studied patient experience of innovations in isolation from safety, these innovations have been non-pharmaceutical interventions, such as hypnosis (Barbero *et al.* 2018; Scaglione *et al.*, 2019) or visualisation techniques (Nørgaard, Pedersen and Bjerrum, 2015). The scope for safety issues such as narcosis does not exist in these innovations. Laurent *et al.* (2006) stand alone in trialling an innovative sedation regime without reference to safety, though they focused on a new anaesthetic agent, rather than level of sedation, or the

person delivering sedation. This current project conceives of NDPSA as an innovation, which uses pharmaceutical means to manage the patient's pain and anxiety; it cannot therefore dissociate patient experience from safety in the way others have done, and both will be appraised in this study. Factors which may contribute to determination of patient experience, both positive and negative, will be considered in Section 3.6, alongside the challenge of measuring patient experience.

3.4.3 Reoccurrence

Several studies have considered reoccurrence of AF as an indicator of the efficacy of the PSA method used (Tang *et al.*, 2007; Di Biase *et al.*, 2011; Firme *et al.*, 2012; Wasserlauf *et al.*, 2016; Narui *et al.*, 2017; Chikata *et al.*, 2017; Martin *et al.*, 2018). This is because patient immobility is required for accurate function of electronic mapping systems (Tang *et al.*, 2007; Narui *et al.*, 2017) and to maintain stability of catheters in the heart (Firme *et al.* 2012). However, evidence is equivocal as to whether the form of sedation makes a difference to the reoccurrence rate: Tang *et al.* (2007), Firme *et al.* (2012) and Wasserlauf *et al.* (2016) record no significant difference in reoccurrence rates when comparing different means of PSA. Chikata *et al.* (2017) and Narui *et al.* (2017) occupy the centre ground of this debate. Chikata *et al.* (2017) found that general anaesthetic (GA) improved catheter contact force, and reduced formation of gaps in the line of tissue created by the ablation when compared to conscious sedation (CS), while Narui *et al.* (2017) observe greater initial freedom from AF in the months following ablation when using deep sedation rather than moderate sedation. Despite this, neither study observed significant difference in long-term rates of reoccurrence. However, Di Biase *et al.* (2011) identify rates of freedom from atrial arrhythmias of 69% in the CS group, compared to 88% in the patients receiving GA approximately 18 months post-procedure. Martin *et al.* (2018) report a similarly significant difference of 42.3% to 63.9% comparing CS against GA.

Neither side of this debate is beyond criticism. The hypothesised link between PSA method and reoccurrence is, as described above, the immobility of the patient. Tang *et al.* (2007 p.2036) describe patients as “fixed on the bed by two restraint straps”, practice not reported in any other study. This is likely to impact on patient mobility and could, therefore, bring reoccurrence rates of sedated patients closer in line with those of patients receiving GA. This limits the generalisability of

their findings, and may account for the difference between their results and those of Di Biase *et al.*, (2011) and Martin *et al.*, (2018). Meanwhile, the conclusions drawn by Firme *et al.* (2012) rest on a relatively small sample size of 32, randomised to 2 groups of 16. As a basis on which to judge statistical significance, this limits the credibility of their conclusions when compared to the larger samples of 292 (Martin *et al.*, 2018) and 257 (Di Biase *et al.*, 2011).

Conversely, the studies of Di Biase *et al.* (2011) and Martin *et al.* (2018) are limited to the use of RFA only; some studies argue that cryoablation causes less pain (Section 3.7.2). The conclusions of these two studies are not incompatible with that of Wasserlauf *et al.* (2016), which focused exclusively on cryoablation; it may be that, between them they identify that moderate sedation is more appropriate for AF ablation using cryoablation, and GA preferable for RFA. Distinguishing between cases using RFA and those using cryoablation may form an important aspect of this study. However, both Di Biase *et al.* (2011) and Martin *et al.* (2018) provide limited detail of the sedation regimes to which they compare GA. Di Biase *et al.* (2011, p.369) state only that “intravenous doses of fentanyl or midazolam were administered to achieve moderate sedation”; no details on how this was assessed or adjusted, and no detail of doses given, are included. Martin *et al.* (2018, p.936) state medication was administered as “directed by the physician to achieve moderate sedation”. Not only can the titration by the physician be seen as contravention of professional standards (Furniss and Sneyd, 2015), the mean dose of analgesia administered to patients, 75 ± 35 mcg fentanyl, appears very low when compared to possible dose ranges of 150mcg-300mcg per hour discussed in the NDPSA protocol (Appendix A, p.265). As such, the practice of moderate sedation to which GA is compared appears to be something of a straw man: it is possible that GA shows improvements in reoccurrence rates, only when compared to poorly implemented CS. It is conceivable that CS can be equally effective as GA when a structured protocol is used, or a specific staff member is designated to monitor the patient and titrate PSA, to which Martin *et al.* (2018) would doubtlessly reply that it is the prerogative of future research to show that such CS practice is the equal of GA.

Inconclusive though evidence may be, the link between PSA and reoccurrence cannot be dismissed, and was considered as an outcome when assessing the efficacy of the NDPSA protocol. However, for reasons of practicality, it did not form

one of the main outcomes in this study. First, studies reaching either conclusion recognise the need to continue monitoring reoccurrence for a matter of years, up to 3 in the study of Narui *et al.* (2017). This timescale does not fit within the constraints of doctoral study. Second, the researcher for this project has no control over the sedation received by patients in the Trust in question; doing a comparison between NDPSA and GA within this department was not possible. Were results obtained regarding the reoccurrence of AF under NDPSA in this Trust, the question would arise of to which rates of reoccurrence under GA could they be usefully compared? These vary dramatically within existing studies, with rates of freedom from AF following GA ranging from 61.8% (Wasserlauf *et al.*, 2016) to 88% (Di Biase *et al.*, 2011). Evidently factors other than the type of anaesthetic used influence reoccurrence rates, therefore any comparison of reoccurrence rates would lack meaning. Therefore, reoccurrence rates were not considered a measure of quality in this study, and this represents a limitation of the study.

3.4.4 Economic Factors

In Section 2.4, Gaitan *et al.* (2011) identified that sedation was often used for reasons of economy, in terms of finance, lab space and time. One study has sought to appraise the financial benefit of non-anaesthetist sedation; Kezerashvili *et al.* (2008) quote a precise saving of \$5,365,691 over a decade, but go on to concede that this is only a conservative estimate as it considers only anaesthetists' fees, not the cost of all anaesthetic personnel. This study was undertaken in the USA, whose healthcare system may make the additional cost of GA easier to discern than under the UK's healthcare system. However, in a British study, Martin *et al.*, (2018) concede that a procedure under GA costs slightly more than the procedure under sedation. They proceed to argue that the lower reoccurrence rate they observe in their GA group ultimately makes GA more cost-effective, but previously expressed reservations regarding this study apply to this conclusion too. The salient point is that the cost-efficiency of a procedure under CS rather than GA is not disputed. What dispute exists relates to the reoccurrence rate, rather than to the sedation method itself. As reoccurrence rates will not be measured in this study, it will also not engage in speculation regarding this.

However, Gaitan *et al.* (2011) also identify reduced theatre turnaround times as reason why sedation is preferred to GA. A number of studies make the point of

recording the duration of procedures under investigation, either of a single study cohort (Kottkamp *et al.*, 2011), or as part of a comparison between equipment types (Lowe *et al.*, 2003; Attanasio *et al.*, 2016), or sedation methods (Kovoor *et al.*, 1997; Yamamoto *et al.*, 2013). While none consider this an outcome measure of greater importance than safety or patient experience, it is relevant given the point in the previous chapter regarding utilisation of CCL space. Again, the researcher had no immediate alternative to which the duration of NDPSA can be directly compared. However, as in the work of Kottkamp *et al.* (2011) this information will be recorded for the single study cohort, and included in reports to allow comparisons.

3.5 Safety

Many studies have primarily investigated the safety of sedation practices. Except for Dupanovic *et al.* (2013), they all conclude that the practices under study were safe, yet variations in the rate of complications exist within their results. In order to evaluate the safety of NDPSA during AF ablation, it is necessary to consider the standards of safety against which it can be measured.

3.5.1 Procedural Complications.

Procedures performed in the CCL contain some risk of complication regardless of the PSA method used, and many studies distinguish between risks inherent in the procedure, and those attributable to PSA. This study will do the same and, to identify risks inherent in ablation, studies concerned with cardioversion (Boodhoo *et al.*, 2004), device implant (Natale *et al.*, 1996; Looi *et al.*, 2013) and trans-aortic valve insertion (Yamamoto *et al.*, 2013) may be discarded, although they retain value in identifying PSA-related complications. Most important are the studies focusing on AF ablation such as Kottkamp *et al.* (2011) and Salukhe *et al.* (2012), though others whose study-population includes patients undergoing AF ablation, such as Sawnhey *et al.*, (2017) remain relevant.

Occurrences of cardiac tamponade were recorded in many AF-focused studies, with rates of 1.2% (Wutzler *et al.*, 2013), 0.9% (Kottkamp *et al.*, 2011) 0.66% (Ichihara *et al.* 2015) and 0.5% (Salukhe *et al.* 2012). Wasserlauf *et al.* (2016) report no such incidents, but their study used a markedly smaller sample of patients (174) compared to the other 4 (650, 401, 819 and 1000 respectively). Salukhe *et al.* (2012) state that tamponade is a recognized complication of AF

ablation, unrelated to the sedation regimen. They do not elaborate on this position, but Narui *et al.* (2017) implicitly concur, identifying two cases of tamponade in their study before immediately stating no complications were related to anaesthetic agents. Servatius *et al.* (2016) present a dissenting view when discussing ablation of ventricular tachycardia, suggesting that patient agitation may lead to cardiac perforation. In this way, such procedural complications may derive, not from the use of specific anaesthetic agents, but from inadequate sedation. Given this possibility, this study must identify occurrences of cardiac tamponade, but its occurrence will not necessarily be interpreted as an indication of unsafe practice or inadequate sedation. Were the rate of occurrence significantly higher than that observed in previous studies, this possibility may need to be considered. Likewise, patient agitation may also impact on the rate of vascular complications (bleed, haematoma or aneurysm). Wutzler *et al.* (2013) report a 1.5% occurrence rate of these, Miśkowiec *et al.*, (2018) 4.2%, and Wasserlauf *et al.* (2016) 0.6%. In a study focusing on vascular complications, Sharma *et al.* (2016) report a rate of 1.1% when puncture is guided by ultrasound, 5.6% when it is not. Again, vascular complications would not be regarded as remarkable in this study if they were consistent with, or less, than the results of these previous studies.

Several other complications are possible during AF ablation; Kottkamp *et al.* (2011) report 2 cases of allergic reaction to contrast medium, 1 of transient ischemic attack, and 1 of air embolus in their cohort of 650 patients while Wasserlauf *et al.* (2016) and Miśkowiec *et al.*, (2018) identify one case each of phrenic nerve palsy amongst their respective samples of 174 and 71 patients. Narui *et al.* (2017) also identify atrio-oesophageal fistula as a major complication, but none of the studies reviewed record any instances of this. None of the studies suggest that these complications are related to the PSA used.

A number of deaths were reported in studies focusing on electrophysiological procedures. Servatius *et al.* (2016) identify one death several days after ablation, though they relate this to the underlying diagnosis of ventricular tachycardia, rather than the procedure. Meanwhile, Kezerashvili *et al.* (2008, p.49) report 5 deaths amongst their 9558 patients; they note all 5 were undergoing electrophysiological procedures, before stating “It is uncertain whether any of the five deaths (0.05%) were sedation-related”, finally noting that, in all 5 cases, these patients were “very elderly and sick”. These studies have made a principle of

reporting all complications that occur during procedures, or in the aftermath, without suggesting that they are related to the PSA. It is unlikely that a fatality will occur in this study; Sawhney *et al.* (2017) record state no sedation-related fatalities occurred in 7117 cases. However, to maintain this approach of transparency and rigour, this study will also report any adverse events, along with the known details of the case, and ascertain whether the event could be considered PSA-related in any way.

3.5.2 Sedation-Related Complications.

Some complications are unequivocally attributed to the PSA, specifically those resulting from over-sedation. One frequently employed means of measuring over-sedation is through recording instances in which reversal agents, naloxone and flumazenil, are administered (Natale *et al.*, 1996; Geiger *et al.*, 1997; Pachulski, Adkins and Mirza, 2001; Looi *et al.*, 2013; Sawhney *et al.*, 2017). These studies record reversal rates of 5.6%, 2.6%, 2.5%, 0.9% and 1.2% respectively. However, it should be noted that Pachulski, Adkins and Mirza. (2001) do not distinguish between those requiring flumazenil, and those requiring crystalloids to increase blood pressure: they record 10 instances where either were given during PSA. While Pachulski, Adkins and Mirza (2001) do not state how many patients required flumazenil, they do identify patients triggering concern and requiring intervention: the important issue. A possible criticism of using reversal rates as measures of safety is that flumazenil may also be given to reverse effects of midazolam due to patient agitation (Sawhney *et al.*, 2017); agitation is not necessarily a safety issue, despite Servatius *et al.* (2016) suggesting a link. Although reversal of PSA does not always equate to safety issues, agitation is still of interest to this study as immobility has been identified as important for case-competition (Tang *et al.*, 2007; Firme *et al.*, 2012; Narui *et al.*, 2017). Recording instances of PSA reversal can therefore be regarded as a useful starting point in ascertaining the safety of NDPSA, but it is also important to identify the reasons for it.

Another means of measuring sedation-related complication has been the frequency with which predefined thresholds in the patient's clinical observations are crossed (Geiger *et al.*, 1997; Pachulski, Adkins and Mirza; Kezerashvili *et al.*, 2008; Kottkamp *et al.*, 2011; Salukhe *et al.*, 2012; Dupanovic *et al.*, 2013; Wutzler *et al.*, 2013; Sevatius *et al.*, 2016; Sawhney *et al.*, 2017). Observations commonly used are oxygen saturation and blood pressure. However, thresholds used for

these parameters are inconsistent between studies. Hypotension is taken as meaning a systolic blood pressure of less than 90mmHg by Salukhe *et al.* (2012) and Geiger *et al.*, (1997). By contrast, Kottkamp *et al.* (2011) record the cases whose blood pressure fall below 70mmHg, and Pachulski, Adkins and Mirza, (2001, p.144) record episodes of “reversible hypotension”, meaning a systolic pressure of between 60 and 90mmHg. Unsurprisingly, the threshold of Salukhe *et al.* (2012) is crossed more frequently than that of Kottkamp *et al.* (2011): 13.6% of cases compared to 2.3%. Other more complex measures of blood pressure are also used: Wutzler *et al.* (2013) use a 40% reduction in systolic blood pressure, or a systolic pressure of less than 80mmHg. They also add the caveat “without any presence of pericardial tamponade or myocardial infarction” (p.116); this acknowledges that reasons other than PSA may account for changes in blood pressure, and indicates the importance of case-detail in interpreting results. Meanwhile, Dupanovic *et al.* (2013) use a reduction of 30% in blood pressure as their threshold. Dupanovic *et al.* (2013) stand alone in acknowledging safety issues forced the adjustment of the trialled dexmedetomidine regime to sub-optimal levels; in 8 of 11 cases, this was due to hypotension.

Thresholds used for oxygen saturation also vary; Pachulski, Adkins and Mirza (2001) and Salukhe *et al.*, (2012) use the figure 90%, while Kottkamp *et al.* (2011) use 85%. The rates of these thresholds being crossed are 3.6%, 1.9% and 1.5% respectively. Dupanovic *et al.* (2013) alone use bradycardia as a measure (heart rate less than 40), and record an incidence of 18%; this idiosyncrasy is an acknowledgement of the properties of the regimen under study, and will not be repeated here. Meanwhile, Wutzer *et al.* (2012) identify that propofol infusion resulted in mild acidosis in some patients. Again, the hypothesis studied in this article is that this effect is unique to deep sedation, and the effects of propofol in particular. No need exists therefore to include such a measure in this study.

It can be concluded that no definitive observational thresholds exist for the measurement of safety. It can also be concluded that rates of complication will differ depending on the stringency of the thresholds selected. This is not a criticism of Kottkamp *et al.* (2011) who selected the lowest thresholds for both blood pressure and oxygen saturation and, subsequently, found some of the lowest incidence of complication. They also record a mortality rate of 0 from 650 cases, which provides some endorsement of their position that 70mmHg and 85%

oxygen saturations are sufficiently stringent thresholds. It may be that “safe” thresholds vary depending on the context in which they are recorded. Kottkamp *et al.* (2011) describe a second physician being present in all cases; they might be expected to safely manage the care of a patient with a systolic blood pressure of 70mmHg, whereas a nurse might feel the need for expert help if the pressure fell below 90mmHg. In accordance with this reasoning, it is evident that the alert criteria stipulated by the NDPSA protocol under investigation (Appendix A) represent relatively stringent thresholds in terms of safety: a 10% fall in mean arterial pressure, oxygen saturations below 90% or a respiratory rate below 8. Accepting the crossing of these thresholds as markers of complications would bias this study against NDPSA: complications would be identified that would not have registered in other studies study. That said, if few crossings were recorded, it would support the conclusion that this practice is safe. Furthermore, recording the frequency with which these thresholds are crossed remains useful; this may indicate the extent to which nurses rely on advice and support from the physician and thus comment on the practicality of the protocol. It was therefore decided to record the frequency with which the protocol’s own thresholds are triggered, with the awareness that this is more stringent than in other studies. It is intended that combining this information with other data (use of reversal, use of anaesthetic support) will then be used to distinguish between cases with genuine complications, rather than those with relatively minor changes in observations.

3.5.3 Approach to Ascertaining Safety.

To ascertain safety of PSA, most studies have made use of a large-n sample, with Kezerashvili *et al.* (2008) and Sawhney *et al.* (2017) using the largest samples of 9558 and 7117 respondents respectively. Given the infrequency of complications noted earlier, this approach appears justified. Exceptions to this approach are Natale *et al.* (1996) and Dupanovic *et al.* (2013), with samples of 57 and 22 respectively. These exceptions appear to have been through necessity rather than design; Natale *et al.* (1996) studied sedation during the implantation of cardiac defibrillators at a time when this treatment was new; the population from which their sample was drawn was therefore small. Dupanovic *et al.* (2013), trialled an experimental protocol which resulted in frequent haemodynamic instability, possibly leading to the curtailment of this study. They therefore do not challenge the consensus that matters of safety are best ascertained using large-n samples

and statistical power to support the generalisability of findings. Many of these studies also make use of consecutive sampling, by which all patients undergoing a particular procedure are invited to participate in the study (Kovoor *et al.*, 1997; Pachulski, Adkins and Mirza, 2001; Boodhoo *et al.*, 2004; Kottkamp *et al.*, 2011; Looi *et al.*, 2013). This can provide a representative sample in health research (Bowers, House and Owens, 2011), but risks invalidating findings if the timeframe of the sample covers a variable for which the study makes no allowance (Sapsford, 1999). For example, Yamamoto *et al.* (2013) and Chikata *et al.* (2017) compare the effects of different sedation methods on safety and catheter contact force respectively. Different sedation methods are trialled sequentially, rather than simultaneously, thus neither sample takes the learning curve of the operator into account during, what each admits, was a new procedure. This biases results in favour of the intervention trialled second. However, studies such as (Kottkamp *et al.*, 2011) and (Boodhoo *et al.*, 2004) avoid such criticism as their participants represent a single group receiving the same treatment, rather than a comparison of two groups receiving different treatment. As this study represents a single group study, rather than a comparison, this sampling method is appropriate.

Using a large-n, variable-based approach has some weakness in reporting the safety of PSA. Kovoor *et al.* (1997) provide the mean and standard deviation in change for the vital observations that they record, all of which appear reasonable. Kottkamp *et al.* (2011) do the same, but demonstrate a problem with this while simultaneously trying to address it: they report the mean lowest oxygen saturation for all patients in the cohort was 94.5% +/- 3.1%, before adding that saturations fell below 85% in 10 cases. The sample of 650 patients and acceptable average disguise 10 cases in which, for this parameter alone, there was considerable concern for patient safety. It might be asked if this is important given that, ultimately, no fatalities occurred. The answer is yes; it is imperative that any CCL looking to implement the practice evaluated by Kottkamp *et al.* (2011) is aware of the potential for harm that it contains, and can therefore recognise the need for contingencies to manage these occurrences. Maintaining awareness of individual cases, as Kottkamp *et al.* (2011) do, identifies the potential for harm, and prompts one to wonder if similar episodes requiring attention went unreported in Kovoor *et al.*'s (1997) larger sample of 1344 patients. Others have demonstrated the importance of maintaining some case-focused context when analysing such data: for example, Wutzler *et al.* (2013) contextualised the triggering of their

observational thresholds as significant only if they occurred in the absence of tamponade or myocardial infarction. This study will therefore make use of statistical means of analysing data regarding safety, but will also maintain focus on individual cases, so as not to obscure significant detail in processed metadata.

3.6 Measuring Patient Experience.

This section will further refine the understanding of the term “patient experience” before considering the strengths and weaknesses of methods previously used to measure these. It will end by identifying factors that may be of importance in determining patient experience.

3.6.1 Pain, Anxiety and Amnesia.

The AoMRC (2013) state that PSA renders procedures acceptable to the patient by reducing pain, anxiety, and providing amnesia. When researching patient experience, most studies have focused on only the first of these (Lowe *et al.*, 2003; Tang *et al.*, 2007; Beddoes, Botti and Duke, 2008; Looi *et al.*, 2013; Attanasio *et al.*, 2016; Münkler *et al.*, 2017). Ezzat *et al.* (2012) record anxiety prior to ablation, but only pain during it. This project did not dispute the importance of adequate pain relief during AF ablation, and therefore included this in this study. However, it also included intra-procedural anxiety; Laurent *et al.* (2006) demonstrate that scores for anxiety varied even more than pain scores when comparing two sedation regimens, while Nørgaard, Pedersen and Bjerrum (2015) provide evidence suggesting anxiety alone is of great importance to the patient, and varies independently of pain. The relationship between pain and anxiety is discussed in the next chapter, while the advantage of Nørgaard, Pedersen and Bjerrum’s (2015) research methods in ascertaining the importance of anxiety is discussed later in this chapter. Meanwhile, Sawhney *et al.* (2017) state that amnesia is desirable, but do not seek to measure it. Carbonell (2014) makes a philosophical objection that amnesia should not be considered a desirable PSA outcome, an argument that does not withstand her acknowledgement that some patients do desire it. Studies which have sought to measure the extent of amnesia (Kovoor *et al.*, 1997; Geiger *et al.*, 1997; Boodhoo *et al.*, 2004; Beddoes, Botti and Duke, 2008; Münkler *et al.*, 2017) have done so in an observational manner, rather than ascribing positive value to it. Whether it is considered desirable or not, nurses have an ethical duty to prevent pain (Carr and Thomas, 1997, p.60), and

Davidson (2014) convincingly argues that amnesia cannot be considered an ethical substitute for adequate analgesia. This study did not consider amnesia an inherently positive aspect of NDPSA; however, it was necessary to identify its occurrence as a means of distinguishing between positive experiences, and those where amnesia masked suffering.

Some comment should be made at this point on the different national contexts in which these studies took place, with specific regard to report of pain. The phenomenon of pain is discussed in greater detail in the next chapter (Section 4.2), when the neurological processes by which it is transmitted from the site of ablation to the brain will be explored. However, even assuming that these neurological processes remain constant between all ethnic groups participating in these different studies, neither the experience nor the report of pain would necessarily remain constant, even if all other variables were accounted for. This is because the expression of suffering due to pain may vary depending on the value and meaning attributed to pain by specific cultures (Peacock and Patel, 2008). According to these authors, experience of pain may vary depending on whether pain is regarded as normal or abnormal in a specific culture, while the expression of pain depends on whether a specific culture values or disapproves of displays of emotion or pain behaviours. Following a systematic review of 26 studies, Rahim-Williams *et al.* (2012) support this position, but also allow the possibility that biological factors, as well as psychological and cultural factors, may contribute to differences in pain perception by different ethnic groups. This means that the results of any evaluation of NDPSA in terms of pain should only be compared to other studies with caution; practices studied in China (Tang *et al.*, 2007) and France (Laurent *et al.*, 2006) may result in different outcomes in terms of reported pain if implemented in the UK. Likewise, reported experiences of pain from those undergoing ablation using NDPSA may not necessarily be replicated if NDPSA were to be implemented in another culture. A UK study such as that of Ezzat *et al.* (2012) potentially provides greater confidence in comparison, though even this makes a dubious assumption of cultural uniformity between London and Northeast England where the current study was conducted. Any comparison of results must therefore remain acutely aware of the cultural contexts in which studies were conducted.

3.6.2 Questionnaires to Assess Patient Experience.

Retrospective questionnaires have frequently been used to ascertain patient experience of procedures in the CCL (Kovoor *et al.*, 1997; Boodhoo *et al.*, 2004; Beddoes, Botti and Duke, 2008; Ezzat *et al.*, 2012; Looi *et al.*, 2013; Pison *et al.*, 2015; Múnkler *et al.* 2017; Scaglione *et al.*, 2019). A potential weakness to the use of these is that some anxiolytic drugs also possess amnesic properties: Beddoes, Botti and Duke (2008) and Kovoor *et al.* (1997) seek to evaluate this and measure rates of 3.3% and 87% respectively. The disparity in results reflects the different drug, dose and route administered in each study. However, the greater the degree of amnesia recorded, the less value can be ascribed to the patient's retrospective report of pain and amnesia during the case. Confusingly, Kovoor *et al.* (1997) report that, of sedated patients who retrospectively reported extreme distress during the procedure, 67% had been evaluated as having complete amnesia of the procedure. This leads to the conclusion that at least one of the tools for assessing amnesia and distress in this study was flawed. Múnkler *et al.*'s (2017) results of high satisfaction and high amnesia are more consistent. However, as with issues of safety, these results are potentially undermined by the use of metadata, rather than a case focus. Satisfaction and amnesia figures are given in isolation from each other. If the relatively few dissatisfied patients were also those with greater recall of events, Múnkler *et al.*'s (2017) high satisfaction rate can be suspected of masking unsatisfactory procedures. One study (Laurent *et al.*, 2006) navigates the challenge of amnesia through verbal questioning of patients during cases. While such an approach does indeed avoid such criticism, it is also resource-intensive, and is unlikely to be suitable for a lone research conducting a large-n study.

Within retrospective and intraoperative questionnaires, numeric rating scales have been used to measure pain (Lowe *et al.*, 2003; Tang *et al.*, 2007; Beddoes, Botti and Duke, 2008; Looi *et al.*, 2013; Pison *et al.*, 2015), and anxiety (Laurent *et al.*, 2006; Ezzat *et al.*, 2012). These scales, while insufficient to capture the complexity of chronic pain, are valuable in recording acute pain (Thomas, 1997a), making them appropriate to experience in the CCL. Davey *et al.* (2007) also found them a valid means of measuring state anxiety. However, inconstancy in their use may cause confusion; Beddoes, Botti and Duke (2008, p.197) are vulnerable to criticism as they measure pain before and after the procedure on an 11-point

scale, with 0 representing no pain, but measure comfort during the procedure on a 6-point scale ranging from “very uncomfortable” to “very comfortable”. Positive experiences are therefore represented by opposite ends of the scales, which may confuse patients and compromise accuracy of results. Furthermore, McCaffrey and Beebe (1994) recognise that different patients may attach different meanings to the same score; Beddoes, Botti and Duke’s (2008, p.197) decision to categorise scores of 1-3.9 as “mild pain”, and 4-6.9 as “moderate pain” may not be inaccurate for all patients. McCaffrey and Bebee’s (1994) solution is to calibrate pain scales by asking each patient which score represents an acceptable level of pain to them. None of the cited studies do this. If such scales are used, participants should be asked to state what pain score is acceptable to them in order to give meaning to the numbers. Accepting the need for this modification, numeric scales to measure pain appear preferable to the other approach used. Ezzat *et al.*, (2012, p.294) give answer-options such as “less than expected” or “more than expected” in response to their question “How bad was the pain during the procedure?” Such questions lack validity (de Vaus, 2014) as answers may reflect variation in expectation, rather than variation in experience of pain. The patient’s experience of pain cannot be known due to its entanglement with their expectation.

3.6.3 Observation to Assess Patient Experience.

Observational approaches have been used as an alternative to directly asking patients about their experience (Defaye *et al.*, 2010; Attanasio *et al.*, 2016; Laish-Farkash *et al.*, 2016). As self-report is considered the gold standard in pain recognition (Herr *et al.*, 2011), these approaches are less desirable. However, they may be of value when the patient is semi-conscious during PSA, or as a means of addressing the issue of amnesia. Of these studies, Attanasio *et al.* (2016) stand alone in using a recognised tool to record numbers of pain reactions. They select the FLACC Behavioural Pain Assessment Scale, which was developed for use in infants and requires adaption for adult use (Li, Puntillo, and Miaskowski, 2008); validated tools exist for use in adult patients (Payen *et al.*, 2001; Gelinis *et al.*, 2006). Such a tool may be an effective way of measuring pain; however, this would require an individual familiar with its use to be present during a large number of cases, given the sample size required by the safety dimension of this study. Laish-Farkash *et al.* (2016) do not use a tool, but infer the presence, or absence of pain, from pain reactions such as moaning, movement of

legs and shoulders or a sudden rise in blood pressure. The extent to which any of these reactions must be present is not specified: a degree of subjectivity may therefore influence pain identification. Defaye *et al.* (2010) attempt to compare the pain experience of patients undergoing cryoablation and RFA by comparing morphine dose received by patients in each group. They describe dosage being titrated “to achieve an adequate comfort level” (*ibid*, p.390) but do not indicate who judges comfort. They do state that drugs are administered on the direction of the physician, and also cite evidence in their rationale for the study that cryoablation is less painful than RFA. It is possible, therefore, that the lower doses of morphine administer to those undergoing cryoablation reflect the physicians’ belief that such patients experience less pain, rather than a response to fewer pain reactions amongst such patients. This means of measuring patient experience was not repeated in this study.

3.6.4 Use of Interviews

Interviews have rarely been employed to gather information regarding patient experience in the CCL. This may be because much research had focused on safety of PSA in the CCL which, as discussed earlier, favours large-n studies, making interviews an impractical means of data collection. Two studies have utilised them, both of which used non-pharmaceutical interventions: hypnosis (Barbero *et al.*, 2018) and visualisation (Nørgaard, Pedersen and Bjerrum, 2015). As the risk of over-sedation did not exist in these studies, the need to demonstrate safety was reduced, thus freeing them from the need for a quantitative approach. The same cannot be said of NDPSA, but the benefits of interviews should be acknowledged. It can be questioned whether interviews have any greater utility than retrospective questionnaires in assessing patients’ awareness during the procedure and navigating the issue of amnesia. Their use by Barbero *et al.* (2018, p.18) suggest that they do; some respondents reported being in different places during the procedure with one, most vividly, having a “lively perception of being home with his own sons”. By comparison, the ridged approach of Kovoor *et al.* (1997) of asking if the patient recalled specific events resulted in confusion: of patients reporting extreme distress during the procedure, 67% had been assessed as having complete amnesia. Herein lies the advantage of the interview: it allows the patient to express what they experienced, rather than infer this from arbitrary checkpoints. Furthermore, interviews allow the identification of more subtle

relationships between mental state and pain than the numeric scales used in other studies; for example:

“Some patients experienced that even though they perceived pain, they did not have to deal with it – to go into the pain because they had something else to think of, something more comfortable. ‘I felt pain in the chest, but somehow I did not have to go into the pain.’” (Nørgaard, Pedersen and Bjerrum, 2015, p.555)

Despite acknowledging the presence of pain, the visualisation techniques appear to have rendered this experience acceptable to the patient, a fact which the authors support, stating that all participants stated preference for visualisation if repeat ablation were required. Thus, the use of interviews can be seen to prevent erroneous assumptions that numeric scales alone cannot. This recognition prompted further consideration of the relationship between mental state and pain tolerance, which is explored in the next chapter.

3.7 Determinants of Patient Experience.

Existing literature indicates several factors that impact on patient experience. Each which will each be reviewed in turn.

3.7.1 Drugs Used.

First amongst these is the medication regimen used. Laurent *et al.* (2006) and Tang *et al.* (2007), set out to compare different sedation regimens and patient experience. Tang *et al.* (2007) report that patients receiving propofol gave significantly lower pain scores during procedures than those receiving midazolam and fentanyl. However, since they stress that patients receiving propofol were unconscious, these pain scores must have been ascertained retrospectively, thus leaving them vulnerable to the possibility that amnesia due to propofol prevented report of pain. Laurent *et al.* (2006) are not vulnerable to the same accusation as, in their study, pain and anxiety scores were recorded during the case when comparing sedation with nitrous oxide and nalbuphine. Scores for both pain and anxiety were lower in the group receiving nitrous oxide. Finally, Kovoov *et al.* (1997) report lower distress levels amongst patients receiving an infusion of Midazolam and Fentanyl than amongst those receiving only oral Diazepam during electrophysiological procedures. This study does not identify what is meant by “distress” and has been criticised several times during this chapter; on its own, it carries little weight. However, in conjunction with other studies, particularly the robust work of Laurent *et al.* (2006), it contributes to a coherent pattern indicating

that drugs used do impact patient experience. Unlike these previous studies, the current project does not seek to compare different regimens. However, the NDPSA protocol allows scope for the nurse to utilise clinical judgement to titrate dose (p11). Therefore, it is necessary to determine the extent to which variation in dosage influences the patient experience within this practice.

3.7.2 Energy Source.

Some consensus exists that cryoablation is less painful than RFA. Lowe *et al.* (2003) note significantly lower pain scores reported by patients receiving cryoablation than those undergoing RFA. However, this study focuses on patients undergoing ablation for supraventricular tachycardia rather than AF, so the conclusion may not extend to other case types. However, Attanasio *et al.* (2016) focused exclusively on patients undergoing AF ablation and, within these, found 92% of patients undergoing RFA under deep sedation displayed pain reactions, while only 13% of those undergoing cryoablation did likewise. Amongst patients displaying pain, those undergoing RFA did so with greater frequency. Though their choice of tool was criticised in section 3.6.2, the significance of their results makes their conclusion relevant. Finally, Defaye *et al.* (2010) note a statistically significant difference in the amount of morphine required by RFA and cryo- patients (3.0 vs 2.09 mg/m² of body area). Measuring pain in this way is highly suspect and this study alone adds little weight to the belief that RFA causes more pain than cryoablation. While all three of these studies contain weaknesses, they are sufficient to convince that energy source used should be considered a factor that may impact upon the nurse's ability to optimally titrate PSA. Meanwhile, it should be noted that energy source may affect more than pain intensity. Pison *et al.* (2015) report 80% of patients receiving cryoablation experienced headaches, and compares this to previous studies of RFA, in which up to 87.5% of patients experienced chest pain. Pains in these sites are not mutually exclusive, and the simultaneous existence of both is not considered, but some variation in pain site may be related to the energy source. Pison *et al.* (2015) also do not comment if patients considered pain in one site more acceptable than the other: their findings therefore note a difference in experience, but not in quality of experience.

3.7.3 Patient Age.

Patient age may play some role in determining their experience of PSA. Ichihara *et al.* (2015) note a significant difference in the ages of those patients requiring escalation from minimal to moderate sedation for pain when compared to the rest of the cohort: 53.6+/-2.3 years compared to 62.6+/-10.4 (p.347). Laish-Farkash *et al.* (2016) also note a tendency for patients experiencing pain to be younger, but note that this finding is statistically insignificant. Disputing the importance of age, Looi *et al.* (2013) note no difference in the pain reported by different age groups; this study appraised PSA during device implantation rather than ablation, and patients were divided into groups of under and over 75. This may reflect a different demographic undergoing device implant compared to ablation: many of the younger patients in this study would have been part of the older age range in that of Ichihara *et al.* (2015), meaning that no real contradiction exists. Furthermore, while Looi *et al.* (2013) note no difference in pain scores, they do note that patients in the younger group received greater doses of sedation. Patients were also asked if they had felt able to ask for more pain relief; Looi *et al.* (2013) state that an unspecified but significant proportion of older patients replied that they felt unable to do so. It may therefore be the case that the extra pain relief received by the younger patients alleviated the higher levels of pain in younger patients noted in the other studies. This study therefore needed to consider both the age of patients, and their willingness to ask for further medication as a potentially important factors in determining their experience.

3.7.4 Procedural Duration.

Some correlation may exist between procedure length and patient discomfort. Looi *et al.* (2013, p.562) state that “only duration of the procedure predicted intra-operative pain” during device insertion. “Predicted” may be an inappropriate selection of word, as procedure duration may not be known in advance. However, the link between the two is supported by Beddoes, Botti and Duke (2008) who report a significant correlation between procedural duration and severity of pain during coronary investigations and interventions. It should be noted that both sets of procedures require considerably less time than AF ablations; Beddoes, Botti and Duke (2008) report a mean procedure duration of 38.7+/-28.3 minutes, while Looi *et al.* (2013) report mean duration of 76+/-32 minutes. Even relatively long procedures of these types would be considered short by the standards of AF

ablation which last in the region of 148.7+/-57.7 minutes (Salukhe *et al.* 2012). It is possible that any variation in experience based on duration occurs during the earlier stages of a procedure, with little variation thereafter. It may therefore not be an important factor in determining patient experience of AF ablation, but this cannot be assumed. Further doubt regarding the significance of duration is prompted by Lowe *et al.* (2003), who note that cryoablations not only caused less pain than RFA, but lasted significantly longer too; this they attribute to operators gaining familiarity with new technology, cryocatheters, at the time of study. Familiarity appears to have progressed to the extent that, in later studies, procedures using them have been shorter than those using RFA (Attanasio *et al.*, 2016). Both studies concluded that cryoablation was less painful than RFA; this suggests that if duration exercises any influence, it is of lesser importance than energy source. However, it is possible that the extended duration of cryoablation (Lowe *et al.*, 2003) masked the true extent of the difference between pain experienced during cryoablation and RFA. In conclusion, procedural duration cannot be discounted as a determining factor, but the possibility of a complexity of related factors determining the patient experience is raised. It was therefore important that the research methods used in this study were able to accommodate causal complexity.

3.7.5 Patient Expectations.

A final factor to consider is the role of patient expectations. In Section 3.6.2, Ezzat *et al.* (2012) were criticised for asking questions which included double variables: pain and expectations. This was considered an inadequate means of appraising pain during the procedure. However, it is taken from a larger piece of work which considers patient's preparation prior to the procedure, during it, and afterwards. These authors state:

“while patients were not unduly anxious nor felt inadequately prepared at the time of consent, they subsequently found the procedure to be more unpleasant and more uncomfortable than expected.” (Ezzat *et al.*, 2012, p.295)

Once again, the metadata included in this report does not allow the reader to ascertain the veracity of this claim: data relating to individual cases is not presented, leaving the reader to take the authors' conclusion on trust. Their use of the phrase “unduly anxious” is an interesting one, which implies that a level of appropriate anxiety in advance is beneficial. However, they phrase this as “realistic expectations” (ibid, p.279) rather than “due anxiety”, arguing that these

improve patient satisfaction with the procedure. The data they present is insufficient to support this, and no other study evaluates patients' experiences prior to and during the case. However, Ezzat *et al.* (2012) find some support from Conway *et al.* (2014a), who identify a recurrent theme that patients' unrealistic expectations of PSA make sedation a greater challenge. These results are drawn from interviews with CCL nurses, so reflect their perception rather than patient account. While neither study is conclusive, the argument presented by Ezzat *et al.* (2012) appears plausible, and the paucity of literature on this relationship mean that further exploration is necessary.

3.8 Summary

This chapter has explored the concept of optimal sedation and limited this concept to patient safety and patient experience for the purposes of this study. This, in turn, identified the first two study objectives stated in the introduction (p.1). Within the term "patient experience" it has identified control of pain and anxiety to a level acceptable to the patient. It has not accepted amnesia as fundamental good of PSA, but has noted that it confounds attempts to appraise patient experience in some studies. Existing research has identified a range of factors thought to be significant in determining patient experience. The methods of these studies have, on occasions, been vulnerable to criticism, and therefore left their conclusions open to doubt. However, their conclusions have not been refuted, and rarely have they been challenged. Therefore, as precursors to this project, they were regarded as useful indicators of factors that may be of relevance to optimisation of NDPSA. The range of these factors led to the development of the third stated project objectives. A final consideration running through this chapter was the research methods used. The relatively rarity of adverse incidents in the CCL meant that large-n studies are commonly used to appraise safety. However, the reduction of data from these studies to metadata (Kovoor *et al.*, 1997; Kottkamp *et al.*, 2011), can be seen as obscuring important case detail. Kottkamp *et al.* (2011) recognise this, and include a degree of focus on individual cases as a solution. To avoid mistakes of other studies, the current study selected research methods that do not obscure the individual case behind processed data.

Chapter 4: Theoretical Background

4.1 Introduction.

The literature review ended with the intention of evaluating the NDPSA protocol in terms of patient experience. Pain and anxiety were identified as the dimensions of the experience against which NDPSA would be appraised. To evaluate the protocol in these terms, this thesis must engage with wider theoretical issues. The first of these is regarding the nature of pain and its relationship with the emotional and mental state of the patient. The second of these is the concept of protocol-based care, and its utility as a means of optimising patient experience. This chapter gives an overview of existing theoretical knowledge regarding these topics, both as a means of shaping the research objectives and methods used in this study, and as a basis for discussions of findings later in the thesis.

4.2 Defining Pain.

The International Association for the Study of Pain (IASP) define pain as:

“An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.” (IASP, 2020)

This definition will be used in this thesis. Due to its unpleasantness, Carr and Thomas (1997) argue that ethical principles of non-maleficence and beneficence are violated should the patient be allowed to endure pain. Alleviation of pain is, therefore, considered to be a fundamental good of nursing.

Consensus also exists that pain is a subjective phenomenon (McCaffrey and Bebee, 1994 p.15; Thomas, 1997b; Herr *et al.*, 2011, IASP, 2020). The truth of McCaffery’s enduring assertion that “pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does” (McCaffrey, 1968, cited in McCaffery and Bebee, 1994) will not be disputed. However, McCaffery is not taken as meaning that an absence of a report of pain necessarily means an absence of pain. The IASP (2020) definition of pain was an update of a previous definition that was specifically discarded as it was felt that it failed to include those unable to self-report. A range of reasons for this exist why this is particularly applicable in this study. This study focuses on sedation; the sedated state may prevent the report of pain, but not the experience of it as it occurs (Herr *et al.*, 2011). Furthermore, drugs used to induce anxiolysis such as benzodiazepines in NDPSA have amnesic properties (Rang *et al.*, 2012), meaning

that retrospective reports of pain absence allow scope for experienced pain to go unreported. McCaffrey and Bebee (1994) also acknowledge reasons why patients may choose to deny the existence of pain; one such reason is stoicism (Gammon and Caswell, 2014, Mah *et al.*, 2018). While patient report may not always be forthcoming, other evidence of pain may exist in the form of non-verbal behaviour such as facial expression or muscle tension (Payen *et al.*, 2001; Gelinias *et al.*, 2006). Therefore, a patient's report of pain will be regarded as conclusive proof of pain; however, in the presence of other evidence suggestive of pain, the absence of report of pain will not be assumed to equate to an absence of pain.

4.2.1 Theories of Pain.

Many attempts have been made to explain the unpleasant experience of pain. Of these, *Specificity Theory* is the oldest, and proposes that each sensation has a different receptor and a specific pathway along pain is transmitted to the brain (Moayedi and Davis, 2013). While the identification of specific nociceptors supported this theory, observed evidence disproved *Specificity Theory's* implicit assumption that stimulation of nociceptors must always produce the same experience of pain (Melzack and Wall, 1965). In contrast to the *Specificity Theory*, *Pattern Theory* denied the existence of a specific pathway for each sensation, and instead postulate that each sensation creates a specific pattern or sequence of signals, which are then interpreted by the brain as either painful, or non-painful (Trachsel and Cascella, 2020). While *Pattern Theory* may explain differing responses to sensory input in a way that *Specificity Theory* cannot, Melzack and Wall (1965) note that physiological evidence refuted it, as the identification of specialist receptor fibres undermined its key assumption.

Melzack and Wall's (1965) attempt to reconcile the physiological strengths of the *Specificity Theory* and the psychological strengths of the *Pattern Theory* produced the *Gate Control Theory* (GCT). This theory hypothesises that nociceptive afferent fibres carry impulses from the site of injury to the substantia gelatinosa, in the dorsal horn of the spinal cord. Here, the afferent fibre synapses with a second order neuron which carries the signal towards the brain (*ibid*). This synapse they identify as *the gate* (*ibid*, p.975). However, they hypothesise that, in divergence from the *Specificity Theory*, this gate must be open to allow the passage of the signal; intensity of nociceptor stimulation may force *the gate* open (*ibid*). Other factors may close *the gate*, specifically the stimulation of other, larger diameter

fibres originating from mechanoreceptors, that respond to pressure. Subsequently, the transmission of noxious stimulation in the substantia gelatinosa can be blocked by stimulation of these fibres. Of greater importance for this study is the assertion that signals descending from the brain modulate the opening of *the gate*;

“some central activities, such as anxiety or excitement, may open or close the gate for all inputs at any site on the body”. (Melzack and Wall, 1965, p.976)

They do not specify whether they believe anxiety to open or close *the gate*; other authors have expanded on this, which will be discussed later. However, the GCT recognises that pain and anxiety are not discrete aspects of the patient experience: they may directly affect one another. Finally, it should be noted that, since publication, it has been recognised that the GCT does not entirely explain all aspects of pain; one of its creators noted its inability to explain the phenomenon of phantom limb pain, subsequently leading to their expanded Neuromatrix Theory of pain (Melzack, 2004). However, as this study focuses on acute pain, the GCT was thought to provide a sound theoretical basis on which to build further discussion.

4.2.2 Analgesia

Analgesia is defined as:

“Absence of pain in response to stimulation which would normally be painful.”
(IASP, 2017)

Analgesics used in the practice of NDPSA are fentanyl and paracetamol. Levobupivacaine is also administered as a local anaesthetic by the operator; however, this is not at the discretion of the nurse and is a constant between cases. It is therefore not considered a determinant of the success or failure of each case. Opioids, such as fentanyl, act by inhibiting transmission of impulse between neurons; they do this by inhibiting the ingress of calcium ions to presynaptic neurons, thus inhibiting the release of neurotransmitters, and by promoting the egress of potassium ions from post-synaptic neurons, hence preventing the action potential needed to transmit the sensation of pain onwards (Rang *et al.*, 2012). The action of paracetamol remains under investigation (Rang *et al.*, 2012, p.325), but it is not in the remit of this study to investigate the action of these drugs on a cellular level. However, the fentanyl mechanism described is compatible with the GCT: by inhibiting the release of neurotransmitters at the

substantia gelatinosa, it closes *the gate*, thus explaining why a state of analgesia is created.

4.3 Defining Anxiety.

An enduring definition of state anxiety is:

“a transitory emotional state consisting of feelings of apprehension, nervousness, and physiological sequelae such as an increased heart rate or respiration.”
(Spielberger, 1979 cited in Wiedemann, 2001, p.565)

This contrasts to trait anxiety, which refers to the stable tendency to experience and report negative emotions including worries and fears. As this study is concerned with the manifestation of anxiety in the specific context of cardiac ablation, state anxiety is of greater relevance. Some literature makes a subtle but significant distinction between anxiety and fear in relation to pain. Ploghaus *et al.* (2003) explain this distinction as the response to the possibility of pain (anxiety) and the response to certainty of pain (fear). The distinction is important, they demonstrate, by citing works in which the fear of certain pain reduced perception of pain due to the fight or flight response and the activation of opioidergic and non-opioidergic analgesic systems. By contrast, their own results, in which participants were subjected to the uncertain prospect of pain (anxiety), showed that anxiety led to increased pain sensitivity. They also identify a physiological basis for this: anxiety-induced hyperalgesia was associated with activation of the entorhinal cortex of the hippocampal formation of the brain (Ploghaus *et al.*, 2001). This, in turn, is consistent with the GCT which identifies descending brain signals resulting from anxiety may open *the gate* to allow the sensation of pain to reach the brain (Melzack and Wall, 1965).

4.3.1 Anxiolysis and Pain

Ploghaus *et al.* (2001) found that both moderate and intense pains were rated as significantly more painful when the subject was in a state of high anxiety than compared to low anxiety. Anxiolytics are medicines that work on the central nervous system to reduce anxiety; benzodiazepines, including midazolam used in NDPSA, fall into this category of drug (Rang *et al.*, 2012). Using magnetic resonance imaging, Wise *et al.* (2007) observed a consistent reduction in the brain activity associated with anticipation between a group receiving midazolam and a control group. While they admit the differences between brain activity in these groups were not statistically significant, they note that pain intensity scores

following a noxious stimulus were significantly lower in the group receiving midazolam. The relevance of these finding for the current study is that a single factor, dose of midazolam, may potentially have more than one effect on the patient's perception of the case. Not only may it reduce their anxiety, but it may also reduce their perception of pain, and their emotional response to it. In conjunction with the GCT (Melzack and Wall, 1965), it hints at a complexity of processes by which pain may be prevented during NDPSA. While analgesics such as fentanyl work directly at *the gate*, binding to receptors to close *the gate*, midazolam can exert its influence by modulating descending signals from the brain, also closing *the gate*.

4.4 Protocol-Based Care.

Rycroft-Malone *et al.* (2009) and Ilott *et al.* (2010) cite *The NHS Plan* (DoH., 2000) as first introducing the concept of protocol-based care to the UK. This section will begin by considering the benefits of protocols as perceived by the DoH., and other proponents of this approach to healthcare, before considering criticisms of it. First it is necessary to clarify the scope of this discussion. Rycroft-Malone, Morrell and Bick (2004) recognise that a glut of terms such as care pathway, algorithm, local guideline, protocol, procedures, patient group directive and more, are often used interchangeably to refer to the same concept. They reconcile these concepts under the umbrella term "protocol-based care" (*ibid*, p.34), and use this in later work (Rycroft-Malone *et al.*, 2009). However, while agreeing that guidelines and protocols share many similar aims, others recognise "protocol" as a more exacting term. Based on dictionary definition, Hewitt-Taylor (2004) argues that protocols require adherence; Flynn and Sinclair (2005) state that protocols add greater specificity as to when action should be taken, and by whom, and Ilott *et al.* (2006) identify protocols as setting boundaries, while guidelines make recommendations. The DoH. (2000, p.133), recognise the need for protocols to be "flexible enough to take account of patients' individual needs"; this suggests that variation should be within the boundaries of the protocol, rather than deviation from it. Both the umbrella term protocol-based care, and the more rigid demands of a protocol are relevant to future discussion. The former is relevant as protocols share many of the benefits with systems covered by the umbrella. The latter is relevant as the rigidity of protocols makes them particularly vulnerable to criticisms of protocol-based care.

4.4.1 Standardisation.

The NHS Plan (DoH., 2000) aimed to redress unacceptable variation in practice. It introduced protocol-based care to reduce variation through standardisation of practice (Ilott *et al.*, 2006; Rycroft-Malone *et al.*, 2009). As previously identified, the DoH did not conceive of this standardisation as being absolute, but allowed scope for flexibility within protocols. It should also be noted that the DoH (2000) conceived of protocols being instituted at a national level, standardising practice between hospitals and regions, rather than at a local level, standardising the practice of individual practitioners, as is the case with the NDPSA protocol. It should also be recognised that more recent political documents have placed less emphasis on protocol-based care than *The NHS Plan* (DoH, 2000), and the introduction of relatively broad national standards such as those of Furniss and Sneyd (2015) can be considered an alternative to it. Despite this, the concept of protocol-based care, and its purpose of standardising the practice of those working within it, remain the same.

The desirability of standardisation itself has been questioned, with Delamothe (1993) labelling guidelines intellectually suspect, and arguing they may standardise practice around average, rather than best, practice if they are the product of expert consensus. Protocol-based care, as envisaged by *The NHS Plan* seeks to avoid this by not only standardising practice using protocols, but by basing protocols on best evidence rather than expert opinion:

“best, modern clinical practice is identified, and decisions are made about which professional should best carry out which functions. The result is a standard guideline or protocol for each condition.” (DoH, 2000, p.103)

This makes the assumption that best practice is already identifiable from research; this may be correct for some areas of practice, but cannot be guaranteed. Even when this is so, NICE (2014) state that guidelines must be audited and revised to ensure that they remain in line with best evidence. Yet there is risk that the use of protocols can fossilise practice: Delamothe (1993) argues that innovation can be stifled by the standardised practice resulting from protocol-based care. This is a convincing argument, as to produce evidence to challenge the parameters of a protocol, some alternative must be trialled and studied. *The Plan* (DoH, 2000), also acknowledges the need for ongoing research, but does not directly address the tension between innovative practice and protocol-based care. *The Plan's* vision of top-down introduction of protocol based on best-evidence also appears a

naïve account of how protocols are actually developed: of the 33 protocols studied by Ilott *et al.* (2006), 28 were developed via a bottom-up approach in response to local need. Possibly those envisaging protocols as a nationwide, top-down, movement might criticise some of these local protocols as unacceptable variations. However, although Ilott *et al.* (2006) do not specify what the local needs were in these examples, they cannot be dismissed as unimportant. Herein lies a key question regarding protocol-based care: can the flexibility described by *The Plan* ever be sufficient to accommodate local or individual need?

4.4.2 Other Benefits.

Other benefits have also been attributed to protocol-based care; *The NHS Plan* (DoH, 2000) identify it as a means of supporting the expansion of the nurse's role. Specifically, it identifies Patient Group Directions as enablers of nurse prescribing. In turn, *The Plan* envisages this expanded nursing role as having economic benefits, and preventing career stagnation amongst nurses. These benefits are not disputed *per se*, but their citation returns the discussion to a point identified in Chapter 2 (p.8): expansion of the nursing role must not be at the expense of the quality of the service. This issue of quality, in turn, leads back to the issue identified in Section 4.4.1: whether protocol-based care can maintain the quality of service will depend on it being sufficiently flexible to respond to the needs of the individual case.

Another perceived benefit of protocol-based care is legal protection. Rycroft-Malone *et al.* (2008) identify a recurrent view amongst nurses that following standardised care paths protects the individual against litigation in the event of adverse incident. Hewitt-Taylor (2004) challenges this, citing the 2002 edition of *The NMC Code*, which states that nurses remain accountable for their practice regardless of advice from other health professionals. The distance between the belief of Rycroft-Malone *et al.*'s (2008) respondents and the position of Hewitt-Taylor (2004) is the assumption that protocols are based on best evidence: were this assumption erroneous, following such a protocol would afford little protection. The standard cited by Hewitt-Taylor (2004) is omitted from the most recent edition of *The Code* (NMC, 2018). This edition introduced the need for indemnity arrangement, normally supplied via the employing Trust. Following Trust protocol may, therefore, provide greater legal protection than in 2004. However, *The Code* (NMC, 2018, p.9) retains the professional requirement for nurses to "always

practice in line with the best available evidence”. This returns the discussion to the need to base protocols on best-evidence discussed in the previous section, and the need for protocols to be reviewed to ensure they continue to reflect best evidence, if they are to provide professional protection.

Finally, Illott *et al.*'s (2006) concept analysis identified protocol-based care as providing training, a basis for assessment, and verification of competence when an individual takes on new responsibility. This perception of protocol-based care as a means of supporting skill acquisition is shared by nurses participating in studies by Flynn and Sinclair (2005) and Rycroft-Malone *et al.* (2008; 2009). Senior nurses perceived that junior nurses and doctors benefitted most from the availability of protocols (Rycroft-Malone *et al.*, 2008). While the experienced nurses in Rycroft-Malone *et al.*'s (2009) study concurred with this perception, they reported combining protocols with experience in their own practice and, when observed, did not overtly use protocols, or interpreted them flexibly. Flynn and Sinclair (2005) go beyond flexible interpretation, stating that senior nurses were perceived as actually deviating from protocol more frequently than the less experienced. The argument that protocols support skill acquisition by junior staff goes unchallenged but the relegation of protocols to the status of learning aids which, once mastered, are interpreted through the filter of experience sits in stark contrast to *The NHS Plan's* vision of standardised care (DoH, 2000), which is not limited to junior staff.

4.5 Alternative Models of Decision Making.

Standing (2010, p.8) identifies frameworks, guidelines and algorithms as “prescriptive models” of decision-making. Protocol-based care also fits into this category as it is not entirely abstract: the NDPSA protocol integrates real world situations by specifying definitive alert thresholds. However, these are context-free, detached from any given case, and thus retain a large degree of abstraction. The observations of Flynn and Sinclair (2005), and Rycroft-Malone *et al.* (2009) dispute that this is how nurses actually make decisions in practice. An alternative is the hypothetico-deductive or information-processing model (Banning, 2008), under which decisions are conscious, analytic and rational; Standing (2010, p.8) would classify this as a “normative model”. This differs from the prescriptive model as it does not integrate real world situations, but depends on the identification of cues in individual situations. Such a model can explain the observed variations as

it allows for nurses to utilise their experience via situation recognition (Banning, 2008). However, Benner's application of the Dreyfus and Dreyfus Model of Skill Acquisition to nursing (Benner, 2001) asserts that an expert level of practice is characterised by moving beyond the constraints of protocols and conscious thought, and instead depends on intuition. This is a descriptive, rather than a prescriptive or normative model of decision-making as it begins with observations and asks, not how decisions should be made, but how they are actually made (Standing, 2010). As such, it gains support from the limited use of protocols noted by Rycroft-Malone *et al.* (2009) and Flynn and Sinclair (2005). If, as Benner suggests, nursing expertise depends on intuitive judgement rather than protocol-based rules, the premise that optimal PSA can be facilitated for all patients when using a protocol is dubious. As an alternative model of decision-making to protocol-based care, this theory requires further exploration.

4.5.1 Benner's Model.

Benner's Novice to Expert Model of skill acquisition states that nurses may move through five stages of practice with increasing experience; between the titular stages stand Advanced Beginner, Competent and Proficient (Benner, 2001). Experience does not automatically result from career longevity (*ibid*, p.36), nor guarantee that every nurse will progress past the competent phase. Benner states that advancing practice is characterised by progression in three dimensions of performance, the first of which is

“a movement from a reliance on abstract principles to the use of past concrete experience as paradigms”
(Benner, 2001, p.13)

Benner therefore indicates that an increasing reliance on experience, rather than protocols, is part of a natural progression in nursing. She goes on to warn against the “excessive formalization of hospital nursing” (*ibid*, p.175). Later, Benner, Chelsa and Tanner (2009) argue that, while protocols are helpful to the advanced beginner and competent nurse, they should be regarded as guidelines for the proficient and expert practitioner because no protocol can ever capture the complexity of practice, and that the expert judgement is better able to respond to the nuances of practice situations. This theory therefore has the power to explain the behaviour observed by Rycroft-Malone *et al.* (2009) and Flynn and Sinclair (2005), though this does not necessarily mean that the explanation is correct. The two other dimensions noted by Benner (2001) in this progression are a change in

perception of a situation as compilation of equally important parts, to seeing a whole, of which only certain aspects are significant, and a progression from being a detached observer to an invested performer. However, as this dissertation focuses on the utility of a protocol to facilitate optimal outcomes, it is the relationship between the protocol and the action of the nurse that is of greatest interest. It should be noted that, thus far, the extreme ends of Benner's progression have been compared, as appears often to be the case with works citing this theory. However, intermediate stages exist, and some attention must be paid to the described relationship between protocols and decision-making at these stages, and the differences between them.

4.5.2 Competence, Proficiency and Expertise.

Little will be said here of the advance beginner stage of Benner's model as little changes between the novice and the advanced beginner in terms of their use of abstract principles. Benner (2001) describes the planning of competent nurses as conscious and analytic, by which it is understood that hypothetico-deductive reasoning as described by Banning (2008) can fit within Benner's model. However, the distinctions between the intermediate stages of Benner's model are more sharply defined in later work (Benner, Chelsa and Tanner, 2009) than the original text. Of the relationship between protocols and competence they write:

“the competent nurse is for the first time in a position to alter protocols and standardized care according to the patient's particular course of illness and individual and familial needs.” (Benner, Chelsa and Tanner, 2009, p.71)

Rather than describe this flexibility as being fluid or natural, they portray this stage as a time when the competent nurse will feel indecision and conflict (ibid, p.76). This, they argue, is because the nurse at the competent stage perceives a need to deviate from protocol based on their assessment of the patient, but is not yet fully trusting of their own judgement. They may therefore be unsure as to which is the ethical course of action. In addition to this changing relationship with protocols, Benner, Chelsa and Tanner (2009) note that the competent nurse develops a temporal perspective compared to the advanced beginner. Actions may be based now, not on the assessment of the patient's current condition, but on the projected progression of their condition. This is a result of the competent nurse having has experience of caring for many patients in a similar situation.

When contrasting the practice of the competent and proficient nurse, Benner (2001) states that the proficient nurse now has sufficient experience to recognise a situation as part of an overall picture, and to hone in on the relevant features. Benner, Chelsa and Tanner (2009) add that “the crucial shift is the perceptual ability to read the situation and respond appropriately”. Judgement, therefore, becomes a matter of situation recognition, and is less dependent on analytic assessment. This contrasts with the analytic approach ascribed to the competent nurse. This is also reflected in a reduction in anxiety regarding decision-making (Benner, Chelsa and Tanner, 2009).

At the expert stage, Benner (2001, p.31) states that the nurse no longer relies on analytic principle, and has an “intuitive grasp of each situation”. It is therefore understood that documents such as protocols do not determine the expert nurse’s practice. Benner, Chelsa and Tanner (2009) expand on the understanding of intuition, and the contrast between the proficient nurse by distinguishing between assessment and response. The major change between competent and proficient was in assessment of situation; this does not change between proficient and expert. However, the assessment of the expert nurse is automatically linked to a response, whereas the proficient nurse still needs to think what to do. Furthermore, they note the minimal language used by the expert nurse to describe their decision, arguing that this is evidence that the assessment is so intrinsically linked to the response that, to the expert nurse, the link is self-evident.

4.5.3 Criticisms.

While Benner’s model (2001) might account for certain variations in practice between those with different levels of experience, it is vulnerable to a number of criticisms. First is the means by which Benner identifies expertise; experts were identified by their managers and subsequently invited to participate; whether they truly represent expert nurses is dependent upon the judgement of their managers, leading to Gobet and Chassy (2008) calling the method unreliable. Benner (2001) also notes that expertise is not years of experience, making length of practice an unsuitable identifier. Yet another approach would be to infer expertise based on the outcomes of cases in which practitioners had been involved. However, Christensen and Hewitt-Taylor (2006) object to this, arguing that, due to the complexity of nursing, and the close collaboration of the nurse with other professionals, outcome is not determined by the performance of the nurse alone.

In the absence of a better method, Benner's method of identification is defensible, but her findings are contingent on the judgement of those identifying experts.

A second criticism is that Benner's research methods contain a bias towards intuitive practice (Standing, 2010); specifically, Lamond and Thompson (2000) note that participants in Benner's study are asked only to identify instances when their intuition has led them to make the correct decision. Episodes of inaccurate intuition, or the frequency with which they occur, are not considered. Benner can therefore be seen as identifying that experienced nurses do rely on intuition, and that it can lead to appropriate intervention. However, Christensen and Hewitt-Taylor (2006, p.1533) argue that any definition of nursing expertise must include "the ability to provide a high standard of care". It is not immediately clear how Benner's vision of nursing expertise tangibly benefits the patient. The authors of the model on which Benner built her theory state:

"Being an expert, or being at any particular stage in our skill-acquisition model, does not necessarily mean performing as well as everyone else."
(Dreyfus and Dreyfus, 2009, p.9)

Although Benner (2001) has, as detailed above, indicated that the proficient and expert nurse will make decisions more efficiently, little indication of the superiority of expert decision-making other than speed is given. If expertise, as understood by Benner, is merely a qualitative feature of the decision-making process, the questions must be asked of why employers and nurse managers should value expertise, and why should it not be replaced by protocol-based care (Christensen and Hewitt-Taylor, 2006)?

4.5.4 Intuition.

The concept of intuition is central to Benner's theory, and is a contentious issue. First, it is challenging to define, with Hamm (1988) stating that it has only been defined as a lack of analysis. It should be noted that Benner does not mean that nurses become so familiar with protocols that they memorise and follow them without overt or conscious reference to them. Rather, Dreyfuss and Dreyfuss (1979, cited in Benner, 2001, p.37) state that pilot instructors found visual display errors faster than trainees, and did so by breaking the rules they taught. Many attempts at definition have been made since, and most include "rapid perception", "lack of awareness of the process engaged", "holistic understanding of the problem situation" and "concomitant presence of emotions" (Gobet and Chassy,

2008, p.130). While acknowledging some cynicism as to intuition's existence, Gobet and Chassy (2008) argue that there is strong evidence indicating that the phenomenon is real, including evidence from fields as diverse as games, science, business and the military, in addition to nursing.

The implications of accepting intuition for the nursing profession must also be considered. Traynor, Boland and Buus (2010) argue the professional status and autonomy of nursing is enhanced by the employment of tacit judgement and, conversely, reduced by limiting the professional role to explicit rules, which also allows for bureaucratic interference. Yet current healthcare culture leaves little room for the embrace of intuitive decision-making: Thompson and Dowding (2002) emphasise the growing need for transparent rationales underpinning decisions, while Standing (2010) note the difficulty of defending decisions based on intuition. By contrast, following a protocol provides an auditable trail of decision-making, and a perceived benefit of protocol-adherence was the legal and professional protection that it afforded the nurse (Rycroft-Malone *et al.* 2008). Although the limits of this protection were discussed in Section 4.4.2, Benner's assertion (2001, p.172) that "There is no higher court than the expert's reading of a particular situation" may not provide equivalent protection.

4.6 Implications for Study.

This chapter has identified a fundamental challenge to the concept of a protocol for the management of pain and anxiety. Pain is accepted as being subjective to the individual experiencing it. Although acute pain, including that from cardiac ablation, is relatively simple compared to chronic pain, the discussion of the GCT (Melzack and Wall, 1965) revealed that it too is complex, and that different contexts may mediate the unpleasant sensory and emotional experience of acute pain. As anxiety may open *the gate*, the psychological state of each patient arriving in the CCL may mean that differing approaches to sedation optimise the experience of it for different patients. Against this complexity stands the concept of protocol-based care, which aims at standardisation, and is therefore reductionist. The DoH (2000) conceived of protocols as being flexible and, as noted (p.11), the NDPSA protocol allows some opportunity to exercise professional judgement. However, Benner (2001) argues that expert nursing practice requires a move away from tools such as guidelines and protocols, and towards intuition, to

respond to the subtleties and complexity of clinical situations. As such it disputes whether a protocol can ever be sufficiently flexible to optimise PSA in all cases.

These arguments prompted some important considerations for this project: can the success of an individual case of sedation be ascribed to the protocol, or does it depend on the clinical judgement of the nurse using it? This question gave rise to the third of the stated aims for the project: to appraise the contribution that the individual sedationist makes to effective NDPSA, and fulfilling this aim has important implications for the transferability of this study's findings. Noting the allowance for flexibility within the protocol, it may be that nursing practice varies within the parameters of the protocol, either in terms of drug dosage, or other aspects of practice. Alternatively, as Benner (2001) suggests, it may be that optimal practice depends upon the breaking of the protocol. In either occurrence, if a particular variation in practice is shown to contribute to the optimisation of patient experience, it may mean that the protocol needs updating, as suggested by NICE (2014), to reflect the evidence provided by this study. These possibilities gave rise to the fourth of the stated project aims: to identify aspects of NDPSA practice requiring development in order to optimise outcomes. Alternatively, if optimisation depends on intuition, it may be concluded that the concept of a protocol for this aspect of practice is flawed. However, to draw such conclusions, it is necessary to identify any variations in practice between individual sedationists, which gives rise to the fourth of the project objectives, and to recognise the possibility that intuition may inform practice, which gives rise to the fifth.

Chapter 5: Methodology

5.1 Introduction.

The previous three chapters have explained the need for this study, and justified the stated research aims and objectives. These aims and objectives were taken as the starting point for the project methodology. The tension between the concepts of protocols as a means of standardising care, and pain as a subjective, individual experience, has implications for the approach this research should take. Aim 1 seeks to evaluate NDPSA specifically when using the identified protocol; as identified in Section 4.4.1, protocols aim to provide standardised care and, if this protocol is to be of value, the standard of care it provides must be acceptable to many patients. This directed the researcher towards a positivist approach to evaluate the net effect of the protocol. However, Aim 2 seeks to identify the conditions under which NDPSA is most effective, and Section 3.4.2 has defined effectiveness in terms of the patient's subjective experience. This makes the perception of the individual patient, both of their experience and the determinants of it, of paramount importance. This guides the researcher towards the constructivist paradigm, and qualitative methods. It was necessary therefore to focus on both the particular and the general: the protocol's general applicability is of interest, but this can only be gauged in terms of the experience of individuals. This prompted the reflection that the concept of a protocol to manage the subjective experience stands on a philosophical fault line. However, Creswell and Plano Clarke (2011) identify that the inadequacy of one data source to meet research aims, and the need to explain initial results, can be used to justify the use of a mixed methods approach; both apply to this study. However, Robson and McCartan, (2016) identify that such an approach has been criticised for the mixing of philosophical positions. They reject this criticism, but recognise the need to adopt a philosophical position that could reconcile the mixing of methods.

While the NDPSA protocol might be a dubious philosophical concept, it was not designed by philosophers, but by pragmatic practitioners. Pragmatism was considered as a philosophical basis for the mixing of methods (Biesta 2010; Creswell and Plano-Clarke, 2011). This approach can be criticised as "anything goes" (Robson and McCartan, 2016, p.183) and "pick-n-mix" (Lipscomb 2008, p.36), which the latter state has the potential to harm the credibility of research. This may be due to confusion between philosophical pragmatism and the everyday use of the word (Biesta 2010). However, alternatives were sought and,

while reading the works of Pawson and Tilley (1997) and Clarke and Dawson (1999), the researcher recognised a theoretical explanation of a previously identified concern. This regarded the non-transferability of results from a study in which the NDPSA protocol was used by nurses experienced in its use. As such, the researcher realised that he had conceived of evaluation in realist, rather than experimental terms (Pawson and Tilley, 1997). This led to an exploration of the critical realist philosophy underpinning such a conception of evaluation. This was eventually adopted as the philosophical basis for this project. The position requires further explanation as it provides the basis for the mixing of methods in this study.

5.2 Critical Realism.

The central tenet of critical realism is that reality is stratified in to three domains: the real, the actual and the empirical (Bhaskar 2008). The real domain contains mechanisms and constructs that exist independently of human consciousness, including intransitive mechanisms, such as gravity (Schiller, 2016). It also includes social constructs: while the existence of culture is dependent on the existence of humans, humans need not be aware of it for it to exert an influence over, for example, decision-making (Harwood and Clark, 2012). Critical realism, therefore, conceives of culture as independent of individuals (Oladele *et al.*, 2013). These mechanisms and structures are viewed as exerting generative causality (Schiller, 2016): they activate, or fail to activate, resulting in the phenomena that humans experience. The actual domain consists of all events and phenomena that occur, regardless of whether or not any individual experiences them (Schiller, 2016). These phenomena are the results of mechanisms activating, or not activating; they are not the mechanisms themselves. The empirical domain consists of human perspective of the world, including the perceptions of an individual, and scientific theories of the mechanisms of the real domain (Oladele *et al.*, 2013). All knowledge in this domain is considered socially produced and therefore, mind-dependent (Schiller 2016).

5.2.1 Implications for Empirical Inquiry.

Bhaskar's (2008) understanding of the purpose of empirical inquiry is to gain knowledge of the mechanisms that exist in the real domain. These mechanisms may not be directly observable (Harwood and Clark 2012). Gravity itself cannot be observed, but the outcome of its action can be observed in, for example, an apple

falling in the actual domain. The role of the realist researcher, therefore, is to produce knowledge in the empirical domain, of mechanisms in the real domain, through study of the actual domain. As it may not be possible to directly observe mechanisms (Harwood and Clark 2012), and because mechanisms may remain latent until the correct contexts cause them to become active (Lipscomb 2008; Oladele *et al.*, 2013) it is impossible to know how many mechanisms relevant to a specific outcome exist in the real domain. For this reason, all knowledge in the empirical domain is considered fallible (Harwood and Clark 2012; Oladele *et al.*, 2013; Schiller, 2016). Even if a scientific theory accurately accounted for the interaction of all mechanisms and contexts in the real domain, it cannot be known that it is complete. Lipscomb (2008) notes that the products of scientific inquiry are, therefore, not knowledge of reality, but descriptions of it.

Critical realism distances the researcher from the philosophies underpinning both quantitative and qualitative purism, with the consequence that:

“critical realists can employ empirical methods and methodologies to identify those aspects of reality that are amenable to quantification without accepting Hume’s limiting assertion that the only things that can be known are those things that can be demonstrated.... Similarly, qualitative methods and tools that explore the meanings and values that people invest in their world can be utilized without accepting associate idealist notions that limit knowledge to the identification of such constructs”.
Lipscomb (2008 p.42)

Critical realism therefore has been recognised as a philosophical basis for mixed methods research (Creswell and Plano Clarke 2011; Oladele *et al.* 2013; Schiller 2016). No research method is incoherent with its combined ontological and epistemological assumptions. Adopting a critical realist position will allow the researcher to address all the identified aims for this project. However, accepting this philosophical approach does commit the researcher to accepting the fallibility of all knowledge.

5.3 Types of Evaluation

As previously stated, critical realism was adopted as basis for mixed-methods research, but first became of interest as a basis for realist evaluation, which explained a doubt that had already occurred to the researcher. This doubt was that an evaluation of the use of this NDPSA protocol, in terms of patients’ satisfaction with their experience compared to an alternative practice, would have little value if it failed to account for existing experience of the nurses using the protocol. As a result, the NDPSA protocol could not be utilised in another CCL with

novice sedationists, with the same results necessarily expected. To study the efficacy of NDPSA in this way would have constituted “experimental evaluation” (Pawson and Tilley, 1997, pp.30-54), of which they are highly critical. By contrast, they write of realists:

“Realists do not conceive that programs ‘work’, rather it is the action of stakeholders that makes them work... The evaluator needs to understand the conditions required for the programs’ causal potential to be released and whether this has been released in practice.” Pawson and Tilley (1997, p.215)

The extent to which the success of any case is attributable to the NDPSA protocol itself, or the skill of the practitioner using it, is therefore of great interest to the realist evaluator, but not to the experimentalist.

Experimental evaluation concerns itself with the “effect of an intervention on an outcome” (Farrington, 2003, p.65). It is successionist (Harré, 1972) in its understanding of causation, and follows the Humean view that causation can only be inferred on observational data (Pawson and Tilley, 1997). It recognises causation through comparison between groups, which are thought to be identical in all ways, except that only one is subject to a particular intervention. While it transfers the experimental logic of the laboratory on to society, it does not make the mistake of assuming that social causation is simple, but seeks to address this by having measures of internal validity (Farrington 2003; Pawson and Tilley 1997). However, the critical realist notices that strength of such inference depends on the evaluator being aware of all relevant factors at work to ensure the two groups are identical. The possibility of the unknown mechanism makes this questionable. The rigid adherence to positivist logic, and the rejection of interventions due to one failure, is criticised for leading to the derided conclusion that “nothing works” because nothing works universally (Martinson, 1974, cited in Pawson and Tilley, 1997, p.9).

Realist evaluation derives from the philosophy of critical realism (Pawson and Tilley, 1997), and anticipates the same causal complexity as this philosophy. Unlike experimental evaluation, it considers causation to be generative rather than successionist (Harré, 1972). Generative theory

“stresses the need to observe regular patterns between inputs and outputs, between causes and their effects, but seeks to establish the connection in quite a different way. Generative theory holds that there is a real connection between events which we understand to be connected causally.” (Pawson and Tilley, 1997, p.33)

It is important to note that observation of regular patterns remains of interest in generative theory. However, while successionist only concern themselves with establishing that cause and effect are connected, the realist seeks to identify the connection between them, explain how it links cause and effect, and understand why the circumstances in which a connection may or may not activate.

Experimental evaluators have been critical of the realist emphasis on explanation of why it works, dismissing realist evaluation as practically unrealistic (Farrington, 2003). Realists dispute this by citing the successionists' fallibility that led to Martinson's erroneous conclusion that nothing works. In deciding between the two approaches, it proved useful to consider the example with which this discussion started. The contribution made by the nurse in NDPSA could be evaluated using an experimental approach; the performance of an experienced team could be compared to that of a team of novices. Such an approach is beset by practical problems: the researcher does not have the authority to exert experimental control in such a way, a common problem for the social scientist (Clarke and Dawson, 1999). It could also be ethically questionable to loose a group of inexperienced sedationists on patients on the supposition that their performance would be inferior to that of the control group currently using the protocol. A more academic objection would be that existing theories regarding experience, and its influence on clinical decision-making, indicate that the concept of experience cannot be accurately quantified in terms of how long an individual has been practicing (Benner, 2001). Thus, experimental evaluation is of limited use: while some difference between the novice and experienced groups would be discernible, there may also be differences within the experienced group that escape identification. Therefore, rather than have existing theories used to criticise the results of experimental evaluation, the decision was made to approach evaluation in a way that could utilise such theories to explain data.

5.3.1 Realist Evaluation or Mixed-Methods Study.

Although this discussion has identified an alternative to experimental evaluation that is better suited to the project aims, this study does not consider itself to be a piece of realist evaluation. Specifically, this was due to the formality of the Context-Mechanism-Outcome (CMO) configuration around which realist evaluators construct their explanations (Pawson and Tilley, 1997). Specifically, given that patient experience, and pain in particular, has been identified as an

outcome, further elaborations on the neurological mechanisms of pain perception are beyond the scope of this study. Indeed, Section 4.2.1 has already accepted the GTC as a model of the mechanism of pain perception. However, in evaluating the practice of NDPSA, this thesis will share the realist aim of identifying “*why* a program works for *whom* and in *what* circumstances” (Pawson and Tilley, 1997, xvi).

Instead, it conceives of itself as a mixed-methods study which accepts critical realism as its philosophical basis. Specifically, it takes the form of what Creswell and Plano Clarke (2011, p.81) name an “explanatory sequential design”. Both they, and Robson and McCartan (2016) agree that such a design allows the second, qualitative phase, to add understanding of *why* the pattern of results established by the initial exploratory quantitative phase occurred. The need for initial exploration is well-justified in this study; Section 3.7 identified a list of factors that might be relevant to determining the success of any case, and this list may not be exhaustive. Furthermore, the recognition of the GTC allows that even the experience of acute pain may be complex (p.53); therefore, it is conceivable that more than one pathway to an optimal patient experience exists. Explanation of why NPDSA works for some individuals in some circumstances first requires that each pathway be identified. The initial quantitative phase will also provide some indication of the general experience of patients receiving NDPSA, and of consistency of application of the protocol. As this chapter has already accepted causation as generative, rather than successionist, it is necessary to explain *why* these pathways lead to optimal results. As the precise quantitative results requiring explanation cannot be known before the analysis of exploratory data (Creswell and Plano Clarke, 2011), and because multiple theoretical explanations of their casual links may be possible, it is not possible to specify the details of the explanatory phase in this methodology chapter. Instead, the thesis will consider theories which may explain the causal links in action, and their implications for the design of the explanatory phase, once exploratory analysis has been completed.

5.4 Case Orientation.

Case study can be considered a research methodology (Jones and Lyons, 2004; Luck, Jackson and Usher, 2005; Lalor *et al.* 2013) within which research methods are selected. Alternatively, it can be considered a research method (Jones and Lyons, 2004). It was considered as a methodology for this project, but was

rejected because case studies alone would be insufficient to produce any kind of generalisation, which the evaluation of a protocol required. For case studies to do this, it is necessary to have some form of theory to support, challenge or refine (Stake, 1995; Yin, 2014). The multiplicity of potential causal factors identified in Section 3.7 meant that relevant theories could not be identified prior to the case studies, thus reinforcing the need for the exploratory phase. This exploration, therefore, needed to stand outside of the case studies themselves. However, there was much about case-orientated research that remained valuable to this project and rejecting the case study as a methodological approach did not mean abandoning the advantages of a case-orientation (Byrne, 2013).

5.4.1 Advantages of case-orientated research.

Research may be orientated towards cases, or towards variables. Variables are conceived as underlying causal agents, with events understood as the product of these variables (Byrne, 2013). As such, cases are viewed as sites in which variables are observed (ibid), or, somewhat pejoratively described, cases are “decomposed” into variables (della Porta, 2008, p.209). This reduction of cases to a product of variables has some advantage in producing generalizable results (ibid). However, Byrne (2013) argues that this approach makes the assumption that there exists some nomothetic model that underlies the variables, and denies the possibility of causal pluralism. By this, he means that the activation of different causal mechanisms might produce the same outcome, a concept that Schneider and Wagemann (2012, p.5) name “equifinality”. The acceptance of a theoretical construct such as the GCT (Melzack and Wall, 1965) requires the acknowledgement of the possibility of equifinal means via which pain might be controlled. Furthermore, Section 3.7 identified a substantial range of potentially relevant contexts in the determination of the patient experience which, in turn, gives rise to the possibility that equifinal combinations of contexts may produce a positive outcomes. Accepting variable-orientated methods would be to assume causal simplicity, and neither previous research nor theoretical models of pain supported such an assumption. By treating each case as a complete, indivisible unity, this study prepared itself to recognise causal complexity

5.5 Research Methods

A sequential mixed methods design consisting of a survey followed by a series of case studies was developed. However, the survey phase was developed in

response to certain challenges for the case study phase. To explain the rationale for the selection of these methods, it is therefore necessary to reverse the sequence in which they will occur in practice.

5.5.1 Case Study: Advantages

Woodside (2010, p.1) offers a broad definition of case study research, describing its “an inquiry that focuses on describing, understanding, predicting, and/or controlling the individual”. “Individual” in this context means the particular, not necessarily a person. It may include a process such as NLP. Yin (2014 pp.16-17) offers a more complex, two-fold definition that stresses the in-depth study of a phenomenon in its real-world context, relies on triangulation of data, and benefits from the prior development of theoretical propositions to guide data collection. Yin (2014) presents a guide to selecting case method based on three criteria: the form of the research question; the control the researcher holds over events, and whether the research focuses on contemporary events. Case studies, and indeed surveys, are considered suitable if contemporary events over which the researcher has no control are being investigated (ibid). However, it is the form of question which, made the case study the preferred method here:

““how” and “why” questions are more explanatory and likely to lead to the use of a case study, history or experiment as the preferred research method. This is because such questions deal with operational links needing to be traced over time, rather than mere frequencies or incidence” (Yin, 2014, p.10)

By adopting critical realism as the philosophical basis for this research, the researcher attached great importance to the “operational links” in action: it sought to answer the question of *why* the practice NLP is effective in particular cases. As the researcher had no control over the unfolding of events in the CCL, and as it was concerned with the evaluation of a current innovation, experiments and histories were not options. Thus, case study was the only suitable method according to Yin’s classification of this project’s starting position.

A further advantage of case study lies in its ability to triangulate data (Woodside, 2010; Yin, 2014). This was of particular value when, as was anticipated, the decision-making processes of the individuals studied was of interest. Woodside (2010, p.3), argues that the individual is not always aware of the decision-making process that determine their actions, and their account of their actions may disagree with that of an observer. This is consistent with the critical realist view of unknown social mechanisms shaping behaviour (p.56); it can also be considered

applicable to Benner's (2001) concept of expert intuition, if the practitioner is unable to articulate their rationale for their action. Woodside (2010) argues that multiple sources of data are a means by which case study research can address this: a sedationist may account for their actions in hypothetico-deductive terms; however, if researcher-observation suggests the patient was not in pain at the time, and clinical records concur that vital signs did not indicate any distress, expert intuition may be a possible explanation of the sedationist's decision to increase analgesia. Alternatively, if concordance exists between sedationist's account, observation and clinical records, the hypothetico-deductive model (Banning, 2008) better accounts for the decision-making process. This triangulation process was considered useful for drawing out the causal mechanisms in action.

5.5.2 Case Study: Disadvantages.

The use of the case study method presented some difficulties, first of which was the acknowledged criticism of how conclusions drawn from case study data can be generalised (della Porta, 2008; Yin, 2014). As the concept of a protocol includes some form of standardisation of practice (DoH., 2000; Ilott *et al.*, 2006; Rycroft-Malone *et al.*, 2009), this was a major concern for any such evaluation. One solution is to regard case studies as the basis of further research (della Porta, 2008); this was considered during the initial development of this project. However, Yin (2014, p.40) presents a solution that is more coherent with the philosophy of critical realism, by distinguishing between "statistical generalisation" and "analytic generalisation". He accepts that even in a multiple-case study, the number of cases will be too small to allow statistical generalisation. By contrast, analytic generalisation requires the introduction of theory:

"The theory or theoretical propositions that went into the initial design of your case study, as empirically enhanced by your case study's findings, will have formed the groundwork for an analytic generalisation" (Yin, 2014, p.41)

By this, it was understood that a case study should begin with some tentative theory as to how the features of a specific case interact to produce the outcome. This theory is then supported, elaborated upon or, possibly, overturned by the analysis of the case study data. In elaborating upon theory, in strengthening the understanding of the causal links within the case, the theory itself is strengthened; thus, by using theory, case study results may be generalised. This analytic generalisation requires pre-existing theory which has previously been noted as

lacking regarding NDPSA. However, given the accepted possibility of causal complexity in NDPSA it was conceivable that more than one theoretical proposition may need to be explored, which would require the use of multiple case studies. Yin (2014) argues that analytic conclusions drawn from multiple case studies are stronger than those from single studies, though he insists that this strengthening comes from replication, rather than statistical, logic (Yin, 2014).

Another noted challenge for case study research is the definition of the case (Byrne 2013). For this project, this is relatively straightforward: the case was the patient's experience in the CCL, bounded by clearly defined time and place, although the influence of factors beyond these boundaries, such as the nurse's experience, or the patient's predisposition, must be acknowledged. More problematic is the selection of cases to study. NDPSA is common in the Trust in which it is practiced; which of the 300 or more AF cases per year should be selected? Clarke and Dawson (1999, p.54) suggest that the researcher "endeavours to create a context which the theory identifies as being favourable to the drawing out of the causal mechanism". However, it has already been asserted that the researcher had no control over clinical events, thus the researcher cannot "create" these contexts. Yin (2014, p.57, p.95) indicates that, for the multiple-case study researcher, what "control" the researcher has is exerted through careful case selection that either predict an expected outcome, a literal replication, or a different outcome for anticipated reasons, a theoretical replication. For this study, however, it was only ethical to select cases in which the outcome of high patient satisfaction was anticipated. Although Yin (2014) compares this process to an experiment, it should not be confused with experimental evaluation as earlier discussed: he stresses that, although the case may be selected on the basis of known features, the replication tests a theoretical proposition, rather than confirms a correlation. Theory is therefore required for analytic generalisation, and for identification of cases suitable for study. While the literature review has identified a range of possible relevant factors, and discussions of protocols and intuitive practice have identified more, this has only been done speculatively. To meet the aim of evaluating the practice of NDPSA, it was therefore necessary for broader theoretical propositions to be developed prior to the case study.

5.5.3 Survey Phase

It was planned to achieve the necessary theoretical development through the conduct and analysis of a survey. Sommer Harrits (2011, p.159) introduces the concept of “nested analysis” in which a tentative model is developed in a large-n study, followed by a small-n study used to address issues of ordering and causation: the case studies would be “nested” within the large-n study. It was, therefore, decided that the case studies would be preceded by a survey phase, which would be used to develop theory regarding causation in NDPSA. Like case studies, surveys are suitable for study of contemporary situations over which the researcher has no experimental control (Yin, 2014). A definition of survey research is:

“Surveys are characterised by a structural or systematic set of data which I will call a variable by case data grid. All this means is that we collect information about the same variables or characteristics from at least two (normally far more) cases and end up with a data grid”
(de Vaus, 2014, p.3)

This identified the survey method as suitable for garnering large numbers of responses. However, de Vaus twice uses the word “variable” in his definition, which requires some clarification given this project’s orientation towards cases. His “variable by case data grid” is consistent with a case-orientation as, while in this formalised grid, no analysis has taken place; data has not been processed, or decomposed into, for example, averages. Furthermore, de Vaus (2014, p.5) indicates that survey analysis does not inherently involve the processing of the data grid into statistical variables, going so far to state that “the survey analyst tries to locate causes by comparing cases”. Accepting this, survey research can be considered coherent with the case orientation of this project.

Mixing survey methods with case study does not present a philosophical problem to the critical realist; indeed, the triangulation of data is regarded as enhancing the quality of the project (Clarke and Dawson, 1999). It should be noted that, while de Vaus (2014) states that survey research aims at causal inference, he acknowledges that correlations identified by surveys do not prove a causal link. However, the identification of generative causation does not dismiss the relevance of correlation; it merely regards it as an incomplete explanation (Pawson and Tilley, 1997). By recognising correlation, this project does not make the mistake described by de Vaus; the use of a survey simply identifies potentially relevant factors and regular patterns, thus guiding the researcher where to look for causal

links. The purpose of the survey was therefore the identification of case characteristics thought to contribute to a high level of patient experience. These characteristics were subsequently compared to existing literature to form tentative explanations of how these characteristics contributed. The identification of these characteristics was then used to select cases for the case study phase in which high satisfaction might be predicted; these cases were then studied to confirm, elaborate or reject the theories of causation that were developed.

5.5.4 Qualitative Comparative Analysis (QCA)

While de Vaus's (2014) definition of survey research does not necessitate the reduction of data to variables, many examples of analysis which he discusses do (ibid). These methods are incoherent with the case-orientation of this project. Furthermore, Byrne (2013) argues that traditional statistical modelling fails to recognise the possibility of causal complexity. Schneider and Wagemann (2012, p.5) introduce "equifinality", by which it is understood that different combinations of factors may ultimately lead to the same outcome; Byrne's position is that traditional statistical modelling is ill-equipped to recognise this equifinality. Given this project's embrace of critical realism, which assumes causal complexity, traditional statistical modelling appeared inadequate (by itself) for the analysis of the survey data. Rhieux and Lobe (2013) concur with Byrne's position, stating that hard sciences neutralise complexity; they advocate QCA as an alternative means of data analysis by which causal complexity might be explored. Schneider and Wagemann (2012) take this further still, stating QCA initially assumes a maximum level of causal complexity, before seeking to simplify the results into the most parsimonious form. This emphasis on complexity was consistent with the philosophical position of this project; QCA was therefore adopted as the principle means of survey data analysis.

A further advantage of QCA is that it aims at "casual interpretation" (Schneider and Wagemann 2012, p.8), again consistent with the aims of this project; however, they also describe this causation as "conjunctural". By this it is understood that the combination of two or more factors may result in the outcome; this strays close to the successionist understanding of causation previously rejected by this project. This concern can be dismissed for two reasons: first is the use of the word "interpretation", which invites the researcher to utilise theory to explore causation, rather than accept conjunction as causation. Furthermore, the

identification of conjunctions, in this study, does not mark the end of project. Rather, it provides the opportunity for hypothesising as to causal mechanisms at work, and identification of appropriate cases in which to observe their manifestation. Thus, the use of QCA was consistent with the realist stance of this project.

Other concerns regarding the use of QCA includes the forced dichotomisation of data into group membership or non-membership, which Schneider and Wagemann (2012) circumnavigate by introducing the concept of fuzzy-set QCA (fsQCA) which allows for partial group membership. This was potentially important: the amount of sedation administered may best be understood as a continuum, rather than a dichotomy between “lightly” and “heavily” sedated. Furthermore, Schneider and Wagemann (2012) demonstrate that use of fuzzy sets does not exclude the use of crisp set data (where a case has either complete membership or non-membership of a group); rather these crisp sets can be regarded as a subset of fuzzy-sets. This was valuable as dichotomous data such as (male/not male; RFA/Cryoablation) may also be relevant and could subsequently be included in fsQCA. Finally, the value of QCA is somewhat contingent on the assumption of causal complexity; Schneider and Wagemann (2012) acknowledge that statistical analysis techniques may be preferable if a single factor applies a linear additive effect. This project anticipated causal complexity, therefore QCA was appropriate; however, the project was prepared to identify any simple linear relationships if they existed. It therefore complimented QCA with some bivariate analysis (Field 2013). It was also necessary to utilise these analytic techniques to assess the safety of NDPSA.

5.6. Survey Details.

Of questionnaire design de Vaus writes:

“There are a number of ways of working out which questions to ask. First, the research problem will affect which concepts need to be measured. Second, the indicators we devise for these concepts are crucial in determining which questions to ask. Third, our hunches about the mechanisms by which variables are linked will require that certain questions be included. Fourth, the way data are to be analysed affects what information is needed: it is pointless collecting information which cannot be analysed and frustrating to discover that you do not have the necessary data for certain analysis.” (de Vaus, 2014, p.93)

These factors were all taken into consideration in designing this project’s questionnaire (Appendix C). This section works through them, and explains how each contributed to the final document. Broadly they split into 2 categories:

concepts and hunches, that determined question focus, while existing indicators and planned analysis determined *how* the questions were asked and recorded.

In terms of concepts, Section 3.4 identified pain and anxiety as key indicators of the patient's quality of experience, yet both required further specification of what was to be measured. Anxiety had the most complex position, as it could be considered a causal condition for pain (Melzack and Wall, 1965; Ezzat *et al.*, 2012) and an outcome condition in its own right (Laurent *et al.*, 2006). Therefore the survey needed to distinguish between anxiety prior to the procedure and outcome anxiety, experienced during the procedure. It also needed to consider which indicators of pain would be measured. Intensity was, of course, of interest. However, this project needed to study pain over the whole procedure as it could transpire that a brief, intense pain was more acceptable to the patient than a moderate pain over a prolonged period. Therefore, duration or frequency of pain also needed to be recorded alongside intensity. Relatedly, the site of pain may indicate a different cause of pain: back pain may be the product of a lengthy procedure, while chest pain may be more intrinsic to the case itself. If a specific type of pain is poorly controlled, this could indicate an aspect of the NDPSA practice requiring modification. Description of pain quality was considered, but omitted; the wooliness of language would have made these responses unsuitable for QCA. Furthermore, while such data could be useful in diagnosing causes of pain, it was considered that, in this controlled environment, identification of pain site would be easier to interpret.

As an exploratory questionnaire, some of the clinical data included in section B (Appendix C) is admittedly speculative. However, the hunch that it may be relevant meant that it was preferable to dismiss it at the analysis stage than risk omitting a significant detail. Smoker status is an example of this; it was hypothesised that compromised respiratory status might make sedation more challenging as the NDPSA sets alert criteria in terms of respiratory function (Appendix A, p.267) as fentanyl and midazolam may also reduce respiratory function and compromise the airway (Rang *et al.* 2012). Other clinical information, such as the patient's alcohol intake, was included as alcohol binds to the same receptors as midazolam (Rang *et al.* 2012, pp.602), and long-term alcohol use leads to a reduction in density of these receptors (Rang *et al.* 2012), thus potentially making sedation more challenging. However, many of the measured concepts were identified from the review of previous literature (Section 3.7). These include drugs used (Laurent *et*

al., 2006; Tang *et al.*, 2007); energy source (Lowe *et al.*, 2003; Attanasio *et al.*, 2016); patient age (Ichihara *et al.*, 2015; Laish-Farkash *et al.*, 2016) and procedure duration (Beddoes, Botti and Duke, 2008; Looi *et al.*, 2013). This clinical data could easily be obtained from clinical records and was measured in well-established objective terms, unlike the complex social concepts that de Vaus (2014) describes. As patients were unlikely to be aware of many of these details, it was decided that this was best added by the researcher following the return of the questionnaire by the patient. Consent therefore included permission for the researcher to access the patient's medical records.

In developing indicators for pain and anxiety, the researcher utilised his knowledge of the practice of NDPSA. Prior to the procedure, patients are instructed in the use of a 0-10 verbal pain scale as a means of expressing their pain during the procedure. While this is considered insufficient for the appraisal of chronic pain, it is regarded as a valid and reliable tool in the measurement of acute pain (Thomas, 1997a), valuable for assessing change over time (McCaffery and Bebee, 1994) and is used in some of the studies previously reviewed (e.g. Beddoes, Botti and Duke, 2008; Looi *et al.*, 2013). However, these studies neglect to ask what level of pain is acceptable to the individual; this is necessary to give meaning to the pain scale (McCaffery and Bebee, 1994) and was therefore included alongside measures of pain experienced (Q.6 & 9) as a separated item (Q.11). De Vaus (2014) notes that an 11-point scale may offer too many options, risking confusion without guaranteeing any greater accuracy. However, given the patients' existing familiarity with an 11-point scale, using anything else could have been confusing and, potentially, contaminated results.

The use of the same type of scale to measure anxiety has been shown to strongly correlate to a validated, reliable tool, the State Trait Anxiety Inventory, when used to measure acute (state) anxiety (Davey *et al.*, 2007). 11-point scales were, therefore, used to measure acute feelings of anxiety prior to, and during, the procedure (Q 4 & 5). Measuring overall satisfaction with NLPISA was somewhat more challenging than measuring acute pain or anxiety. Given the convention of the questionnaire, it was considered reasonable to employ an 11-point scale once more as a measure of this (Q.14). One variation was made: in measuring pain and anxiety intensity 10 was considered the worst score. In measuring satisfaction, it was thought confusing to offer 0/10 as the mark of complete satisfaction, so the scale was reversed. Neither approach appeared beyond criticism, but the clarity of

this reversal was confirmed during piloting. However, overall satisfaction was the ultimate outcome condition in this study: the measure of the efficacy of NDPSA. While numeric scales are a practical and efficient means of communicating an experience between two individuals, the numbers remain abstract. Does 6/10, for example, indicate an acceptable experience? The decision was therefore made to compliment this question with something less abstract. A useful measure of satisfaction lay in the willingness to undergo a repeat procedure under the same means of PSA (Nørgaard, Pedersen and Bjerrum, 2015): would the patient be willing to have a repeat procedure done under NDPSA? The wording of this question (Q.15) established that alternative means of PSA were possible, to avoid the misunderstanding that accepting NDPSA was the only way such a procedure could go ahead.

Developing indicators to ascertain the mental preparation of patients for procedures was also challenging. Ezzat *et al.* (2012) cite this as a key means of improving patient satisfaction with their experience of their procedure; however, their means of measuring expectation is irrevocably linked to the patient's actual experience. In linking experience and expectation in such a way, they cannot accurately measure either. The approach of asking "did you receive enough" or "too little" information avoided this confusion (Q.3). As with pain and overall satisfaction, this project took the position that the patient was the authority on what constitutes too little; some patients may have chosen not to know many details of the case in advance. Therefore, the approach taken was not to measure the patient's mental preparation by their knowledge of case, but their satisfaction with the information received. However, it was still considered useful to have some understanding of what the patients knew of sedation procedures, regardless of whether or not they felt well-informed. By asking what they knew of PSA prior to the procedure (Q.1, 2) it was intended to ascertain what information patients had received beforehand. By asking these questions alongside the question of "did you receive enough information", it was intended to distinguish between patients who were relatively well informed, but wanted more, and patients who received little information because they preferred not to do so.

The questionnaire was piloted prior to use, with 10 members of the public providing feedback on the clarity of questions and instructions for responses (de Vaus, 2014). All found the questions easy to understand, and the instructions simple to follow.

5.6.1 Sample size.

Factors taken into account when determining the sample size were the purpose of the survey phase, the types of analysis to be used, and the number of variables specified by the questionnaire. QCA can be effectively undertaken using a small to medium-sized sample (Schneider and Wagemann, 2012). Furthermore, generative causation is not established by the number of times a conjunction is seen (Pawson & Tilly 1997) and the study did not expect to produce much in terms of statistical generalisation (Yin 2014). Against this, the exploratory nature of the survey, the possible large number of independent variables included on the questionnaire, and the possible complexity and number of causal configurations, suggested that a larger sample was required. Furthermore, a stated objective of the study is to ascertain the safety of NDPSA during cardiac ablation. This objective alone, meant that it is desirable that sample size is sufficiently large to be considered representative of the cases performed under NDPSA. It was therefore decided that a power calculation (McCrum-Gardner, 2010) would be used. The population to be surveyed consisted of everyone undergoing a cardiac ablation while receiving NDPSA, a never-ending number. It was therefore decided to use the number of AF ablations performed in one year as the size of population: 315 (NICOR, 2015). A 95% confidence level and 5% margin of error were used, which Bowers, House and Owens (2011) state is standard in clinical research. The response distribution was set at 95%, assuming that NDPSA is safe in 95% of cases. This may appear a generous assumption, but one which represented a rate of complication well in excess of that recorded in other studies: Looi *et al.* (2013) and Sawhney *et al.* (2017) recorded reversal rates of 0.9 and 1.2% respectively, while Salukhe *et al.* (2012) and Kottkamp *et al.* (2011) note their oxygen saturation threshold were triggered in 1.9% and 1.5% of cases respectively. Should complication rates be higher in NDPSA, the assumption of 95% safety would allow a sample size sufficiently large to identify this. Using these figures, a sample size of 60 cases was calculated. It should be noted that such a sample size was insufficient to prove that NDPSA is safer than other methods used. Given the rarity of complications, this would require an extremely large sample. However, this sample was sufficient to test the hypothesis that NDPSA is less safe than other methods.

5.6.2 Sampling Strategy

A continuous sample was considered appropriate for this study. This can provide a representative sample in health research (Bowers, House and Owens, 2011) and was used in previous evaluations (e.g. Sury *et al.*, 1999; Beddoes, Botti and Duke, 2008). No reason existed to believe any seasonal or time-related changes could compromise the validity of the study in the manner suggested by Sapsford (1999). Thus, all patients meeting the inclusion criteria were invited to participate.

Inclusion criteria for this study were:

1. Undergoing elective radiofrequency ablation or cryoablation for atrial fibrillation.
2. Receiving nurse-delivered conscious sedation and analgesia using the Trust's protocol.
3. Adult, i.e. 18 years of age or older.

Exclusion criteria were:

1. Patients undergoing combined procedures, for example an ablation and a pacemaker implant. This was because any anxiety or pain recorded may not be attributable to the ablation aspect of the case.
2. Patients undergoing ablation when admitted with an acute presentation. It was considered unreasonable to expect these patients to make an informed decision to participate.
3. Patients with barriers to communication such as limited English or learning disabilities. Such cases were unlikely to meet inclusion criteria 1 as the Trust routinely conducts procedures for such patients under general anaesthetic.

5.6.3 Procedure

Potential patient-participants were asked if they would be willing to speak to a researcher by the nurse at the pre-admission clinic, approximately one week prior to their procedure. If willing, their name and planned admission date were communicated to the researcher via secure Email. They were also provided with written information (Appendix E) regarding the project at the clinic. The researcher then approached them on the ward on the morning of their procedure, gave them opportunity to ask questions, and showed them a list of the data to be collected from their clinical records (Appendix C, part B). If willing, they were asked to sign a consent form which included giving the researcher permission to access their medical records to collect this data (Appendix E).

Once consented, the participant was issued with a questionnaire document inside an envelope. They were instructed not to open the envelope until after

their procedure. This is because reading questions 1-3 in advance could change the patient's response to them. Having undergone their procedure, they were asked to complete section A of the questionnaire prior to their discharge, before sealing the questionnaire in the envelope and depositing it in a locked post box on the ward. This marked the end of the patient's participation in the survey phase. The researcher then collected the questionnaire, and completed section B of the questionnaire from data in the patient's clinical records. The survey document did not contain any identifying data, but it was paired to the patient's consent form using a survey reference number. The consent form included the patient's name, date of birth and hospital number so that the correct medical records could be obtained.

Meanwhile, as it was intended that the identity of each sedationist would be recorded on the survey document, the researcher gave a presentation to the nursing team in advance of the project, asking for permission to include their identities when collecting data. A written information sheet was provided (Appendix E). Nurses were asked to either give their written permission to have their identities collected, or to state that they do not want them to be collected. The researcher, when collecting data, recorded the identity of any nurse who has provided sedation as "anonymous" if that individual had withheld permission. No active participation was required from staff at this stage of the study.

5.7 Case Study Phase

The operational details of the case study phase will be discussed in Chapter 7 because these details were not confirmed until after analysis of the survey data. It was anticipated that methods of data collection would include direct observation by the researcher, review of clinical records, and interviews with both patient and nurse-sedationist. However, for ethical reasons, the data from the survey phase was used to exclude patients who could be predicted to have a negative experience of NDPSA.

5.8 Ethics.

Ethical approval was obtained from The Faculty of Health and Lifesciences of Northumbria University and the Health Research Authority (HRA) using the Integrated Research Application System (Appendix D). In addition, a research

passport was obtained for the researcher from the NHS Trust in which the study took place.

5.8.1 Informed consent.

No individual was required to take part in this study. Informed consent was taken from all patients and nurses participating in the study. Patient consent included permission to access their medical records. All participants received written information regarding the aims of the study, and what participation would involve, and were given the opportunity to ask questions. The information sheets stressed that declining to take part would not result in their receiving a different standard of care. They also informed participants of the right to withdraw and the action to be taken should they wish to do this. No inducements to take part were offered, other than the offer of feedback of results to the nurse participants, and that this would count towards the requirements of their professional revalidation. All information sheets and types of consent forms are included as Appendix E.

5.8.2 Confidentiality.

No details from which a participant could be identified are included in this thesis, or will be included in any other report deriving from this study. Participants were guaranteed this on the participant information sheets. It was also stated that direct quotes from interviews may be used, but attributed to a pseudonym. It was also guaranteed that any information disclosed throughout the study would be treated as confidential. The exception to this is required by the NMC Code (2018) which requires the breach of confidentiality if failure to do so might result in harm to individuals. As this may apply to staff-participants, this was specifically stated in the staff participation information (Appendix E, p.294).

5.8.3 Data protection.

Caldicott Approval was obtained from the Trust for this study. It would have been a breach of confidentiality for the researcher to screen medical records for potential participants. It was therefore necessary for preadmission nurses, during the normal execution of their duties, to ask all patients undergoing elective ablation under NDPSA if they would be willing to speak to a researcher. If they agreed, details were then forwarded to the researcher via secure Email.

Consent forms contained identifiable data and were stored in a locked cupboard in a locked university office. Documents containing research data (e.g.

questionnaires) were stored in another locked cupboard in the same office; these documents contained no identifying data, but could be matched to the consent forms by use of a common reference number. This was considered necessary to allow any participants who wished to withdraw their data. Only the researcher held keys to these cupboards.

Electronic forms of data (audio recordings and transcripts of interviews) were stored on a password protected computer drive, to which only the researcher had access. It was agreed as part of the HRA approval process that hard and electronic copies of data would be stored for 5 years, in line with university policy.

Chapter 6: Survey Results and Analysis.

6.1 Survey Results.

Collection of survey data began on 09/10/2017 and lasted until 19/04/2018. This coincided with a staff shortage in the CCL in which these AF ablations took place, and a harsh winter during which some patients encountered travel problems; many cases were cancelled, which hindered progress. No patients declined to take part in the study once approached. 68 patients were consented, and 64 questionnaires were returned, which exceeded the intended sample size. 4 of these took place on the last intended day of data collection; given the number of cancellations, the researcher considered it prudent to consent all 4 patients. On that day, all cases went ahead, and all questionnaires were returned. A patient whose procedure had previously been postponed subsequently returned his completed questionnaire: no reason existed to exclude these extra surveys from the analysis. 4 patients initially consented to take part but did not do so. 3 of these were due to cancelled lists. A fourth patient's response was not included as their unusual venous anatomy meant the medical team was unable to access the patient's heart via the usual femoral venous approach, leading to abandonment of the procedure before ablation took place. As the patient was not exposed to this noxious stimulus, their responses were discarded. Of the 64 returned documents, 62 provided complete and unambiguous answers. One was only partially completed, and another contained answers with more than one number, for example, 4 and 7, both circled on some numeric scales. These provided sufficient information for inclusion in the analysis of patient safety, but insufficient data for inclusion in the analysis of patient experience. A summary of the survey data is shown in Figure 6.1. All results in section 6.1 were processed using SPSS software (IBM Corp., 2019).

Figure 6.1 Summary of Survey Data

Sex (Male/Female)	62.5%	37.5%		
Age	62.6 ± 10.3			
Body Mass Index	29 ± 6			
Smoker (yes/no)	10.9%	89.1%		
Alcohol use (0, low, medium, high)	9.4%	51.6%	29.7%	9.4%
Equipment (Cryo/RFA)	54.7%	45.3%		
Case Duration	136 ± 69			
Aware they would be awake (Yes/No)	95.3%	5.7%		
Aware that a nurse would administer (Yes/No)	90.6%	9.4%		
Received Enough Information (Yes/No)	84.4%	15.6%		
Received Paracetamol 1G (Yes/No)	64.1%	35.9%		
Fentanyl dose (mcg) (Mean/skew)	224±113	0.824		
Fentanyl dose (mcg/Kg/hr) (Mean/skew)	1.41± 0.64	1.419		
Midazolam dose (mg) (Mean/skew)	4.97 ± 2.26	0.478		
Midazolam dose (mg/hr) (Mean/skew)	2.48 ± 1.31	1.189		
Worst Pain Score	4.47± 2.83			
Duration of Worst Pain (%)	15.5± 18.13			
Typical Pain Score	2.22± 2.26			
Acceptable Pain Score	4.83± 2.04			
Episodes of Pain Recorded Per Case	2.20± 3.72			
Anxiety During Procedure Score	3.90± 2.73			
Overall Satisfaction Score	8.89± 1.81			

6.1.1 Demographics

This survey's respondents comprised 40 men and 24 women (62.5% male), had a mean age of 62.6 ± 10.3 years, and a mean body mass index (BMI) of 29 ± 6 . The population was therefore conspicuously similar to the populations in other studies focusing on AF ablation, such as Kottkamp *et al.* (2011), in which 68% of 650 patients were male, with a mean age of 60 ± 10 and mean BMI of 28 ± 4 . This consistency provided assurance that the sample was representative of the population undergoing this treatment. Of the 64 patients, 57 (89.1%) were non-smokers; 9.4% consumed no alcohol, 51.6% had low intake, 29.7% moderate, and 9.4% high intake.

6.1.2 Case Types

35 cases (54.7%) were performed using cryoablation, while the remaining 29 cases (45.3%) used RFA. Cases had a mean duration of 136 ± 69 minutes, which is noticeably shorter than the 170 ± 51 mean in Kottkamp *et al.*'s (2011) study. This is due technological advancement since 2011. Kottkamp's participants only underwent RFA as cryoablation is a relatively new treatment. Within this study, cryoablation cases lasted considerably less time than RFA: 101 ± 45 minutes compared to 179 ± 69 minutes. A Mann-Whitney Test demonstrates significant difference ($P= 0.000$) between the rankings of duration of different types of procedure within this study. The mean of 179 ± 69 minutes in this study for cases using RFA is also more in line with the 170 ± 51 recorded by Kottkamp.

6.1.3 Patient Knowledge

Participants appeared well-informed regarding the sedation they would receive during their ablation; 95.3% were aware they would be awake during the procedure and 90.6% were aware in advance that a nurse would be administering their sedation. It is possible, however, that the research process itself played a part in raising awareness of sedation procedures. Preadmission nurses were responsible for identifying potential study participants, and for providing prior information about the ablation itself. The process of identifying patients willing to participate in a study regarding sedation may have inadvertently led to more information than normal being sought and given. Furthermore, 15.6% of patients stated that they did not receive enough information regarding sedation prior to the

case; the nature of the information they wished will be explored in the case study phase.

6.1.4 Drug Use

41 patients (64.1%) received a 1G dose of intravenous paracetamol during the procedure. Some processing of drug dosages was needed for other drugs: fentanyl is often prescribed in terms of micrograms/Kilogram/hour (JFC, 2021). This measurement may, therefore, prove a more relevant contributor to the patient's experience of a case than the cumulative dose itself. Midazolam was also calculated in terms of milligrams/hour to reflect the varying lengths of cases, but bodyweight was not included as the drug is not prescribed according to this (JFC, 2021). Figure 6.1 displays means and standard deviations of drugs given. A noticeable positive skew in drug doses becomes even more pronounced once case duration and weight, in the case of fentanyl, were included.

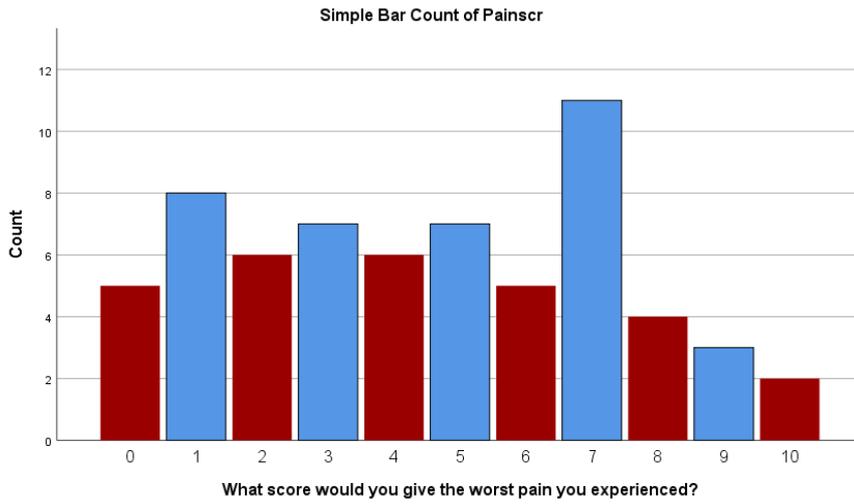
6.1.5 Patient Experience

The scores attributed to the worst pain experienced in the procedure ranged from 0-10, with a mean of 4.47 ± 2.83 and median of 4.5. The most typical pain ranged from 0-9, with a mean value of 2.22 ± 2.26 and median of 2. However, this thesis (p.35) has already criticised previous research for failing to calibrate pain scales in order to make responses meaningful. Item 8, acceptable pain, was specifically included, as recommended by Benner (1994), to avoid repeating the same mistake in this study. The importance of this was demonstrated by the range of answers, for 0 to 8, to this question, with a mean of 4.83 ± 2.04 and median of 5. The importance of this is demonstrated by the distribution of answers to this item: it is apparent that a pain score of 5 from two different patients might describe two very different experiences (Figure 6.2b). The answers to questions about pain experienced were then adjusted to account for this by subtracting the acceptability scores from the answers regarding the worst pain experienced and most commonly experienced pain. The means of these new variables were -0.30 ± 3.04 , and -2.59 ± 2.64 respectively, with a negative number indicating that the score given was below the level of acceptability to that patient (Figure 6.2c). These were labelled "sharp pain" and "long pain" in future analysis.

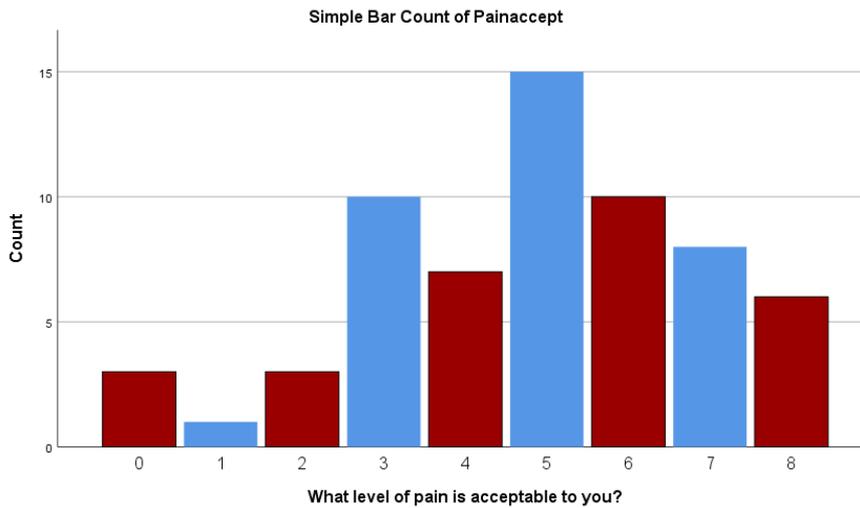
23 patients reported a worst pain that exceeded the level of pain acceptable to them, while 6 patients reported a frequent level of pain that exceeded the acceptable level.

Figures 6.2: Adjustment of Pain Relative to Acceptability.

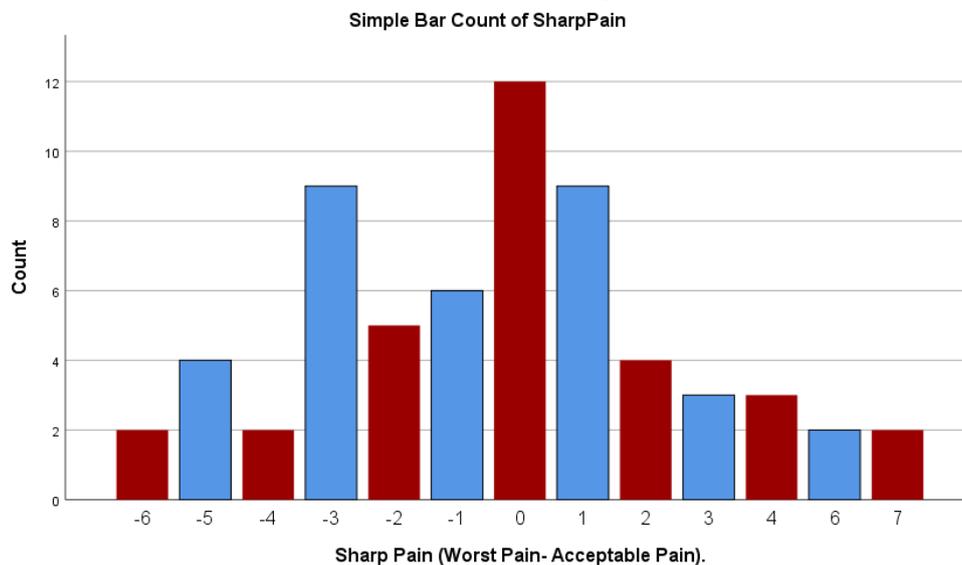
6.2a: Simple Count of Worst Pain Experienced



6.2b: Simple Count of Acceptable Pain Level



6.2c: Simple Count of Worst Pain - Acceptable Pain



The number of pain episodes recorded by the nurse in each case ranged from 0 to 16. However, the distribution of these was heavily skewed; the median value was 0, and the mean 2.20 ± 3.72 . Including this statistic may have biased further analysis against longer cases, as the prolonged procedure would offer greater opportunity for pain to be observed. Therefore, the occurrence of episodes of pain per hour were also calculated for each case.

Scores for anxiety during the procedure ranged from 0 to 10 with a median value of 3 and a mean of 3.90 ± 2.73 .

Only 4 patients answered that they would be unwilling to have such a procedure performed under NDPSA again (Q 16). This question was intended to ascertain practical attitudes towards NDPSA and, in some cases (57 and 60), the negative response was perceptibly the result of a negative experience. However, in others (42 and 59), the data itself revealed no obvious reason for their response, but patient 42 chose to write on their questionnaire that their response was due to the procedure itself being ineffective. This, in turn, forced the researcher to reconsider the validity of this question, and speculate whether other patients might answer positively based on procedural success rather than the experience of NDPSA. It was subsequently excluded from further analysis. However, the scores given for overall satisfaction were high, ranging from 3 to 10, but heavily skewed towards the higher scores. The median score given was 10, with a total of 37 patients giving this score. The mean was 8.89 ± 1.81

6.1.6 Safety

No fatalities were recorded during the 64 cases of this study. Nor did any case require reversal of sedation using naloxone or flumazenil. The protocol alert criteria were triggered on 45 occasions distributed over 28 of the cases; in 36 cases these criteria were never triggered. There were no cases of alert criteria being triggered due to oxygen desaturation; all alert criteria were due to hypotension. Of these 45 alerts, 9 occurred in a single case in which it was noted that the patient suffered a vasovagal episode leading to a prolonged period of hypotension. A second patient also suffered a vasovagal response, treated with atropine, which accounted for the 2 alert episodes recorded on their chart. Vagal reactions are now recognised as a specific side effect of the use of cryo-balloons (Chang, Lin and Cheng, 2018) which were used in both cases. As such, the triggering of alert criteria in these cases cannot be considered sedation-related

complications, rather a consequence of the procedure itself. Of the other 27 cases in which alerts occurred, 21 triggered for single incidents of hypotension and required no medical intervention to resolve.

In terms of procedure-related complications, 2 of the 64 cases (3.12%) suffered vascular complications. Of these, one patient suffered from a haematoma at the femoral site, and the second suffered a bleed requiring a prolonged period of pressure to control. 2 episodes of cardiac tamponade (3.12%) were recorded during these cases; one of these 2 cases suffered damage to their heart's conduction system and subsequently required a pacemaker. One patient's procedure was interrupted due to an episode of nausea and vomiting; the reason for this episode is unclear, though it may be related to the NDPSA medication. No other medical complications were recorded during these cases.

6.2 Analysis of Safety.

This section analyses safety by comparing results obtained in this study to those of previous studies, and will also provide discussion of these findings. The rationale for this is that the main focus of analysis and discussion is patient experience. It was therefore considered preferable to conclude discussion of the issue of safety before proceeding to this main issue. As identified during the literature review, complications during AF ablation, and electrophysiological procedures are generally low. Fisher's Exact Test (FET) was considered more appropriate than the Chi-square test to compare the rate of complications in this study to those in others as expected frequencies of complications in this study were lower than 5 (Field 2013); a specialist programme was used for this (Stangroom, 2021a).

6.2.1 Sedation-Related Complications.

Evaluation of the safety of sedation regimens have used the frequency with which predetermined thresholds in oxygen saturation and blood pressure are crossed as indicators of safety (Kottkamp *et al.*, 2011; Salukhe *et al.* 2012; Sawhney *et al.*, 2017). The potential difficulty of using these triggers as measures of safety was discussed in the literature review (pp.28-9) and is confirmed here: comparing the triggering of Kottkamp *et al.*'s (2011) thresholds (25 in 650 cases) to the 28 cases out of 64 in the NDPSA study would lead one to conclude that NDPSA is significantly less safe than Kottkamp's infusion of propofol (FET statistic value <

0.00001). Such a conclusion is undermined by the fact that changes in clinical observations required either additional medication (with ephedrine) or ventilation (with bag, valve and mask) in 105 of Kottkamp's 650 cases, while only 2 of the NDPSA patients required intervention on this basis (both received atropine). Atropine is not included in the NDPSA protocol; while its requirement was unlikely to be due to the action of sedation, its use represented occasion on which the nurse was unable to manage the patient's condition without support from the operator, so they were included here. It was therefore considered appropriate to compare the frequencies with which NDPSA patients required additional medication to other studies, as well as frequencies with which patients required changes in sedation regime, and frequencies with which ventilatory support (either use of bag, valve and mask, or intubation) was required.

Kottkamp *et al.* (2011) and Wutzler *et al.* (2013) record instances in which additional medication was required to manage the patient's changing condition. The sum total of these were 98 in 1051 cases. This was compared to the 2 cases of the 64 in this study using FET (Figure 6.3a). This shows the difference to be insignificant ($P=0.113$) though it should be noted that, were this comparison significant, it would be in favour of NDPSA. However, although Wutzler and Kottkamp both compare regimes for deep sedation using propofol, they each record significantly different rates in administration of additional medication to maintain the patient's safety when compared to each other (FET statistic < 0.00001), with Wutzler's patients requiring less frequent intervention. NDPSA patients too also required significantly less frequent intervention than those of Kottkamp (Figure 6.3b, $P=0.0069$). This is not to suggest Kottkamp's propofol regime is unsafe, only to show that maintenance of safety when using this regime would require greater medical input than the NDPSA protocol, unless a propofol protocol allowed for the nurse independently to administer ephedrine. No cases in the NDPSA study required a change in sedation strategy. Sawhney *et al.* (2017) record 85 cases requiring reversal of sedation amongst their 7117 cases (1.2%). Meanwhile, Salukhe *et al.* (2012) report a change from a propofol-based regimen to midazolam was required in 156 of their 1000 cases (15.6%). 136 of these were due to persistent hypotension, 19 to respiratory depression and 1 due to hypersalivation; this last complication is included here as it could progress to compromise the patient's airway (Lynch and Crawley, 2018), and required a

change to sedation strategy. These results were not combined into a larger sample, as they covered two very different sedation protocols: Sawhney studied combinations of midazolam with diamorphine, or diazepam with pethidine, while Salukhe appraised the use of propofol. The difference in rate of sedation protocol change between these two other studies was significant (FET statistic < 0.00001), so were therefore independently compared to NDPSA. No discernible difference can be noted between the rates of reversal in the NDPSA study and the results of Sawhney *et al.* (2017) (Figure 6.3c). However, the rate with which protocol-change was required in Salukhe *et al.*'s study (2012) is significantly higher (Figure 6.3d). As with the earlier discussion of Kottkamp *et al.*'s (2011) results, it is demonstrated that a propofol-based regime will require more frequent medical intervention to maintain safety.

Figure 6.3: Comparisons of Sedation-Related Complications

6.3a Additional medication compared to all other studies.

Results			
	NLPSA	Comparison	<i>Marginal Row Totals</i>
No additional medication	62	953	1015
Additional medication	2	98	100
<i>Marginal Column Totals</i>	64	1051	1115 (Grand Total)

The Fisher exact test statistic value is 0.113. The result is *not* significant at $p < .05$.

6.3b Additional medication compared to Kottkamp.

Results			
	NLPSA	Kottkamp	<i>Marginal Row Totals</i>
No additional medication	62	553	615
Additional medication	2	97	99
<i>Marginal Column Totals</i>	64	650	714 (Grand Total)

The Fisher exact test statistic value is 0.0069. The result is significant at $p < .05$.

6.3c Change in strategy compared to Sawhney

Results			
	NLPSA	Sawhney	<i>Marginal Row Totals</i>
No Change	64	7032	7096
Change	0	85	85
<i>Marginal Column Totals</i>	64	7117	7181 (Grand Total)

The Fisher exact test statistic value is 1. The result is *not* significant at $p < .05$.

6.3d Change in strategy compared to Salukhe

Results			
	NLPSA	Salukhe	<i>Marginal Row Totals</i>
No Change	64	844	908
Change	0	156	156
<i>Marginal Column Totals</i>	64	1000	1064 (Grand Total)

The Fisher exact test statistic value is 0.0001. The result is significant at $p < .05$.

Finally, the need for ventilatory support was considered. 2 patients in Sawhney *et al.*'s (2017) study required intubation. However, this is insignificant compared to the 0 in 64 cases recorded by the NDPSA study; furthermore, one of these two cases was the result of tamponade, and therefore cannot be cited as evidence of over-sedation. In the 3 studies using propofol (Kottkamp *et al.*, 2011; Salukhe *et al.*, 2012; Wutzler *et al.*, 2013), a total of 10 patients required ventilation via bag, valve and mask. The highest occurrence of this was in Kottkamp's study (8 in 650 patients). However, no significant difference was discernible comparing these rates to NDPSA, either as an aggregate (Figure 6.4a), or individually (Figure 6.4b). No differences in safety were distinguished on this measure.

Figures 6.4: Comparisons of Rates of Ventilatory Support

6.4a Ventilatory support compared to all other studies.

Results			
	NLPSA	Comparison	<i>Marginal Row Totals</i>
No intervention	64	2041	2105
BVM	0	10	10
<i>Marginal Column Totals</i>	64	2051	2115 (Grand Total)

The Fisher exact test statistic value is 1. The result is *not* significant at $p < .05$.

6.4b Ventilatory support compared to Kottkamp.

Results			
	NLPSA	Kottkamp	<i>Marginal Row Totals</i>
No intervention	64	642	706
BVM	0	8	8
<i>Marginal Column Totals</i>	64	650	714 (Grand Total)

The Fisher exact test statistic value is 1. The result is *not* significant at $p < .05$.

6.2.2 Non-Sedation-Related Complications.

Deaths during AF ablations are extremely rare; 5 studies focusing exclusively on AF cases (Kottkamp *et al.*, 2011; Salukhe *et al.* 2012; Wutzler *et al.*, 2013; Ichihara *et al.* 2015 and Wasserlauf *et al.*, 2016) report no fatalities from a combined sample of 3044. As such, the zero fatalities among the 64 patients in this study was as expected. However, a single fatality amongst this study's 64 patients would have been sufficient to support the hypothesis that NDPSA as practiced in this study is not as safe as methods used in other studies (FET statistic value 0.0206, significant at $p < .05$). It should be recalled from the methodology (p.72) that the focus of safety in this study was to identify evidence that NDPSA was not as safe as sedation practices elsewhere; on this measure, it rejects this hypothesis.

The 5 AF-focused studies listed above have recorded rates of tamponade during cases ranging from 0 (Wasserlauf *et al.*, 2016) to 1.2% (Wutzler *et al.*, 2013). By comparison, the rate of 3.12% recorded in this study appeared high. Although tamponade is commonly regarded as a procedural complication, one author (Servatius *et al.*, 2016) suggests a possible relationship between tamponade and patient agitation. Due to this possibility, it was considered necessary to ascertain whether the rate observed in this study was significantly higher than those observed in previous studies. FET was again used to compare these figures with the 2 tamponades in 64 cases observed in this study (Figure 6.5a). The test statistic value was 0.0925, which meant an insignificant difference between the rate of occurrence in the studies. However, as this was approaching the significance threshold of 0.05, the results of the NDPSA study were also compared against those of Wasserlauf *et al.* (2016), which had the lowest rate (0%) of tamponades (Figure 6.5b). The FET statistic value was 0.0715: again, insignificant. As these test values approach significant levels, a larger-scale study of the rate of complications during NDPSA would be beneficial to confirm this finding.

Figure 6.5: Comparisons of Rates of Tamponade

6.5a Compared to all other studies.

Results			
	NDPSA	All Other Studies	Marginal Row Totals
No Tamponade	62	3021	3083
Tamponade	2	23	25
Marginal Column Totals	64	3044	3108 (Grand Total)

The Fisher exact test statistic value is 0.0925. The result is *not* significant at $p < .05$.

6.5b Compared to Wasserlauf.

Results			
	NDPSA	Wasserlauf	Marginal Row Totals
No Tamponade	62	174	236
Tamponade	2	0	2
Marginal Column Totals	64	174	238 (Grand Total)

The Fisher exact test statistic value is 0.0715. The result is *not* significant at $p < .05$.

The rate of vascular complications was also compared to other studies which recorded these, specifically Wutzler *et al.* (2013), Wasserlauf *et al.* (2016) and Sharma *et al.* (2016). Once again, their samples and total of complications was aggregated. Sharma *et al.* (2016) distinguished between complication rates depending on whether or not ultrasound was used while obtaining vascular access. It is unknown if any cases in the NDPSA study used ultrasound, therefore both halves of Sharma's sample were used here. In this comparison, the difference in the rates of vascular complications does not approach a significant level (FET statistic value= 0.6662).

6.2.3 Conclusion

No evidence was found that NDPSA exposes patients to any greater risk than other sedation regimens used for AF ablation and other electrophysiological procedures. The comparison to the studies of Kottkamp *et al.* (2011) and Salukhe *et al.* (2012) led to the conclusion that the NDPSA protocol requires less adaption, and fewer changes, of sedation method during cases in order to maintain safety, than regimens that make use of propofol. Such adaption may be beyond the nursing role and, given the need to reduce anaesthetist input identified in Section 2.4, NDPSA can be seen as advantageous regarding efficiency. It was noted that the alert thresholds set by Kottkamp *et al.* (2011) were triggered in only 25 cases, but 97 cases required ephedrine, which suggests that operators developed concern regarding the patients' falling blood pressure at an earlier juncture than the researchers did. By comparison, the NDPSA study recorded 28 cases in which its own thresholds were triggered, yet only 2 cases in which restorative intervention was needed as a result. This poses the question whether the NDPSA thresholds are overly sensitive in detecting changes in the patient's condition? Against this, it should be considered whether lowering these thresholds would have any functional benefit in terms of managing cases, or whether it would simply be an academic point? This question can be addressed during the case study phase of this study.

6.3 Hierarchical Cluster Analysis

Hierarchical cluster analysis (HCA) was used to classify cases in terms of positive and negative patient experience. 6 remaining variables could be considered measures of patient experience: overall satisfaction, anxiety during the case,

duration of worst pain, and the calculated variables “sharp pain”, “long pain” and “episodes of pain per hour” (pp.80-1). HCA is used to categorise cases into clusters that are both useful (Uprichard 2013; Everitt *et al.*, 2011) and meaningful (Bartholomew, 2008). Uprichard (2013) understands clusters to be meaningful if they reflect an already present structure amongst cases, an acknowledgement that clustering procedures impose structure on all data, regardless of whether a structure exists (Everitt *et al.*, 2011). It was therefore necessary to establish that resulting clusters represented similarities between their constituent cases, and differences between each other. HCA was considered a preferable alternative to multivariate analysis as it is consistent with the case-orientation of this project; rather than focusing on relationships between variables, it focuses on relationships between cases (Uprichard 2013).

6.3.1 Decisions in the Clustering Process.

SPSS software (IBM Corp., 2019) offers 7 different methods of clustering cases. Choosing the most appropriate method is challenging as the researcher cannot know the structure of the data in advance (Everitt *et al.*, 2011), which may lead to some algorithms imposing artificial structures on the data. Ultimately, Ward’s Method was utilised as it was designed for interval-scale measurements such as those recorded the measures of patient experience (Kaufman and Rousseeuw, 2005) and because it receives some support as providing the clearest image of any existing clustering (Bartholomew, 2008). Ward himself (1963) states that his method was designed to identify clusters amongst many variables while minimising loss of information. However, prior to the adoption of Ward’s Method, the advice of Kaufman and Rousseau (2005), to run the clustering programme using different methods, was also heeded. Other methods, such as the nearest neighbour method resulted in all but two cases being assigned to the same cluster. This phenomenon is an acknowledged weakness of this method, known as “chaining” (Everett *et al.*, 2011, p.80); as a result, it failed Uprichard’s (2013) requirement that clusters produced should be useful.

Clustering was intended to identify groups of patients having positive and negative experiences. Therefore all 6 outcome measures listed previously were included in the clustering process. However, this did not produce useful clusters; rather, it grouped cases together solely on the basis of the variable “duration of worst pain” regardless of all other variables. This variable was measured on a scale of 0-100,

rather than the 0-10 scales used elsewhere, leading to greater Euclidean distances relating to this variable, hence its domination of the final clustering. Furthermore, 5 patients had not responded to this question; this resulted in their cases not being allocated to any cluster. Two solutions to this problem were considered: exclusion of the “duration of worst pain” variable from the analysis, or the rescaling of the variable to a range of 0-10 to prevent it distorting the final clusters. This issue will be reconsidered later in the analysis. However, analysis initially took part using the remaining 5 variables, with cases labelled by case number.

6.3.2 The Number and Meaning of Clusters.

HCA produced the following icicle plot, dendrogram and agglomeration schedule. The dendrogram in particular (Figure 6.7) reveals the structure of the case clusters, but does not establish the number of clusters that exist. Ascertaining this is an acknowledged challenge for the cluster analyst (Everitt *et al.*, 2011; Yim and Ramdeen, 2015). Everitt describes that an informal method of doing this is to examine the dendrogram, though he acknowledges that this approach is vulnerable to influence by a priori expectations. Use of such an approach to the below dendrogram is useful to some extent: distinct clusters are conspicuous at either end. However, this approach does not establish whether a three- or four-cluster solution would be best: the bifurcation between 5 and 10 on the x-axis (rescaled distance) could be considered to represent the division between two clusters, or it could be considered an umbrella under which similar cases are gathered. Yim and Ramdeen (2015) advocate combining the dendrogram with the agglomeration schedule to inform this decision. Again, this proved inconclusive: the increase in coefficients between the 58th and 59th stage is substantial (169.568), but little more than half the size of the increase between the 59th and 60th stage (332.406). These increased are highlighted on Figure 6.8, but they could be used to justify a three- or four-cluster solution.

Figure 6.6: Icicle Plot

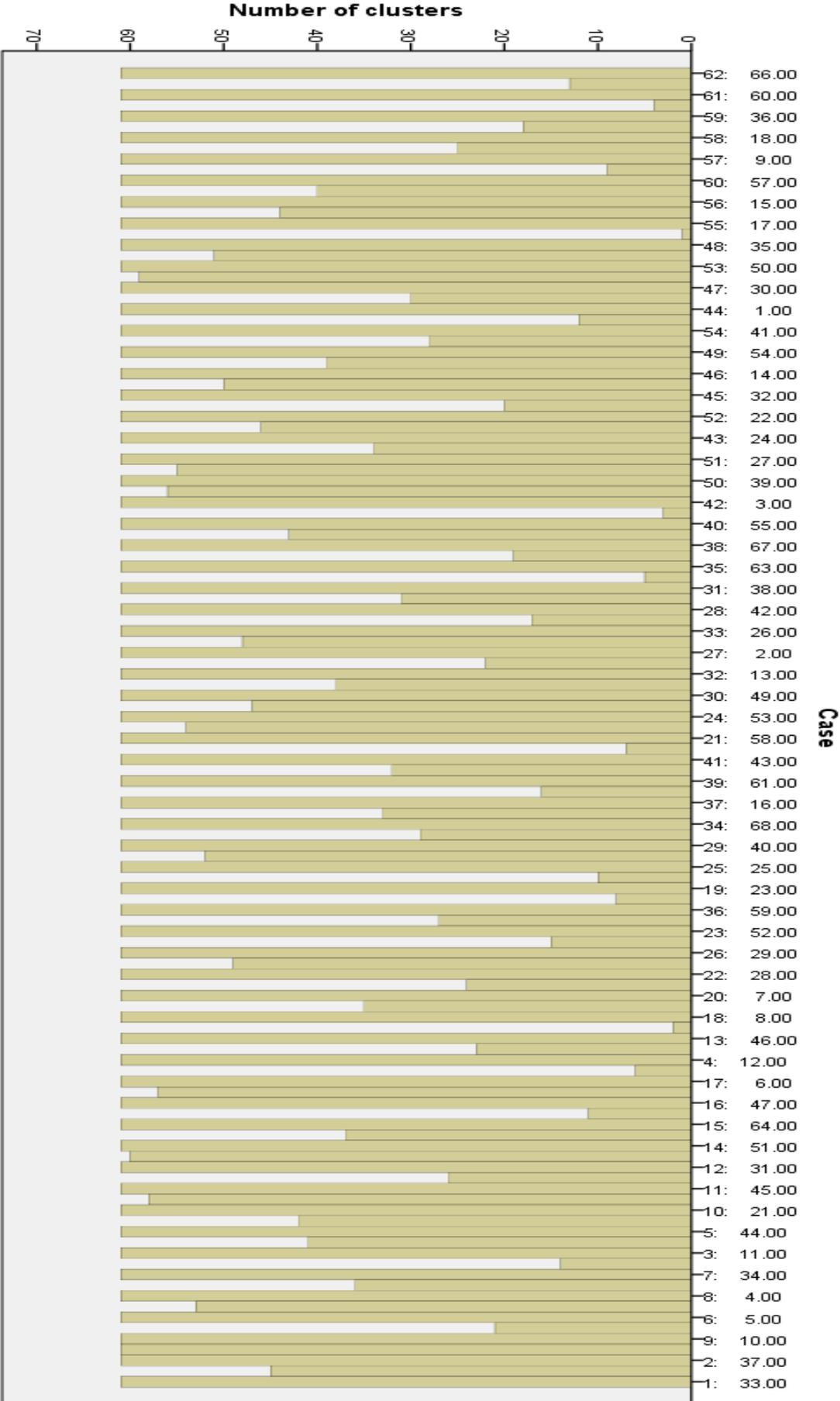


Figure 6.7: Dendrogram

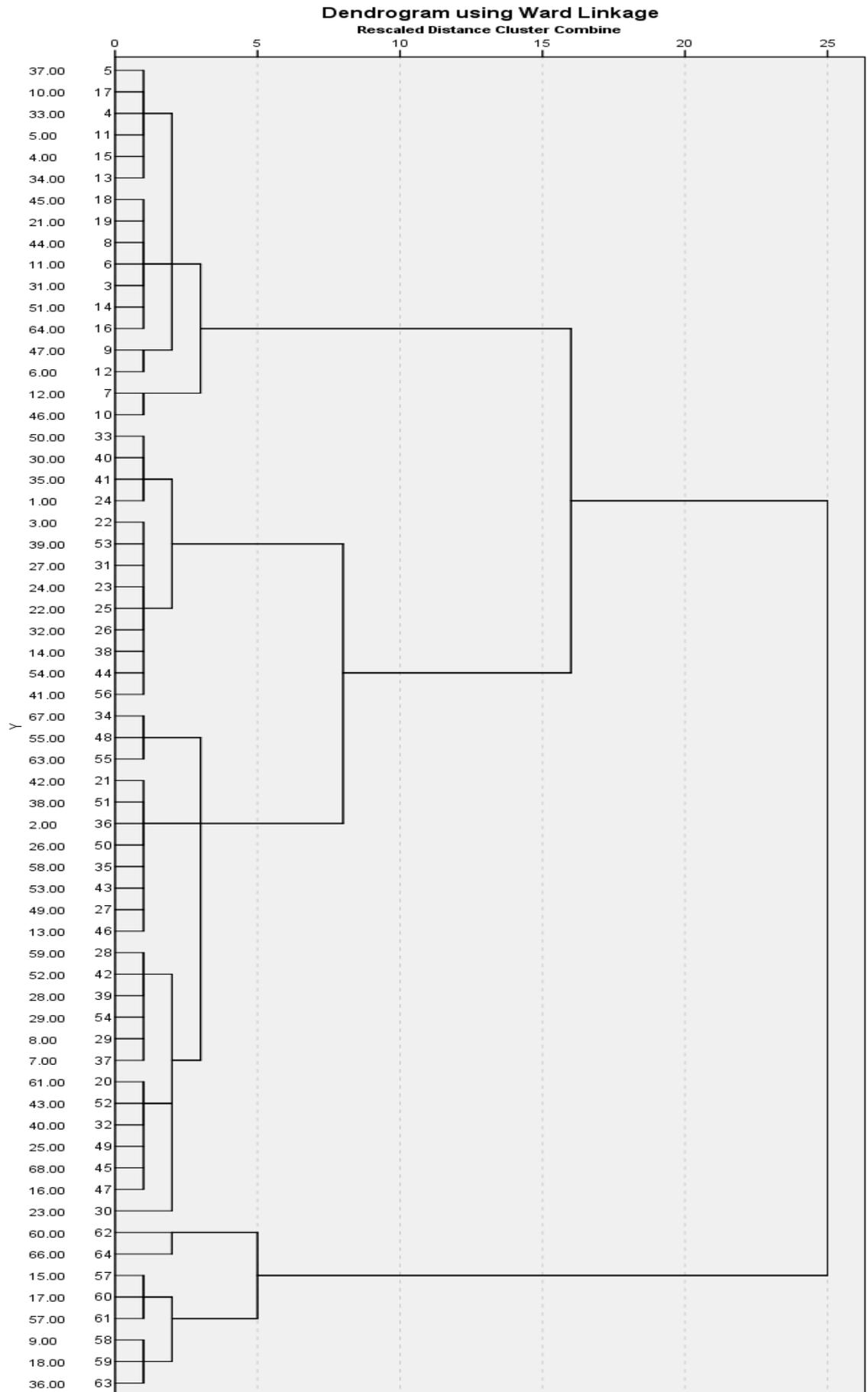


Figure 6.8: Agglomeration Schedule

Stage	Cluster Combined		Coefficients	Stage Cluster First Appears		Next Stage
	Cluster 1	Cluster 2		Cluster 1	Cluster 2	
1	7	12	.000	0	0	17
2	4	8	.293	0	0	25
3	26	31	.793	0	0	12
4	2	15	1.345	0	0	20
5	11	16	2.028	0	0	51
6	18	23	2.721	0	0	7
7	18	50	3.695	6	0	28
8	33	36	4.695	0	0	15
9	3	10	5.695	0	0	26
10	48	51	6.938	0	0	33
11	27	43	8.438	0	0	23
12	26	28	9.938	3	0	32
13	24	25	11.438	0	0	38
14	49	54	13.044	0	0	40
15	30	33	14.915	0	8	24
16	45	47	16.815	0	0	28
17	5	7	18.815	0	1	41
18	59	60	21.315	0	0	22
19	35	38	23.854	0	0	43
20	2	13	26.705	4	0	21
21	1	2	29.630	0	20	36
22	55	59	32.587	0	18	53
23	27	34	35.754	11	0	34
24	30	42	39.118	15	0	40
25	4	9	42.702	2	0	36
26	3	6	47.036	9	0	41
27	40	41	51.661	0	0	38
28	18	45	56.428	7	16	42
29	39	44	61.379	0	0	33
30	21	53	66.479	0	0	46
31	29	52	71.829	0	0	45
32	22	26	79.079	0	12	50

33	39	48	86.475	29	10	46
34	19	27	94.298	0	23	42
35	20	32	102.243	0	0	47
36	1	4	110.442	21	25	48
37	58	61	118.942	0	0	44
38	24	40	128.254	13	27	47
39	14	17	137.574	0	0	56
40	30	49	146.925	24	14	45
41	3	5	157.758	26	17	48
42	18	19	169.394	28	34	50
43	35	37	182.275	19	0	57
44	57	58	199.775	0	37	53
45	29	30	219.119	31	40	55
46	21	39	240.548	30	33	52
47	20	24	262.116	35	38	54
48	1	3	285.251	36	41	51
49	56	62	308.946	0	0	58
50	18	22	335.754	42	32	59
51	1	11	368.817	48	5	56
52	21	46	408.364	46	0	54
53	55	57	450.061	22	44	58
54	20	21	493.580	47	52	55
55	20	29	550.480	54	45	57
56	1	14	607.825	51	39	60
57	20	35	672.615	55	43	59
58	55	56	777.242	53	49	61
59	18	20	946.810	50	57	60
60	1	18	1279.216	56	59	61
61	1	55	1823.317	60	58	0

No formal method of resolving this issue was forthcoming; it was recalled that clusters should be useful in aiding understanding, as well as meaningful (Uprichard 2013). The decision on whether a 4th cluster would be useful was therefore postponed until the stage of cluster validation. This validation process was performed on 3 and 4 cluster solutions, with the eventual decision that the 4th cluster was not useful. The subsequent clusters were labelled Clusters A, B and C.

To address the concern that HCA might impose a meaningless structure on the data (Everitt *et al.*, 2011), Kruskal-Wallis testing was used to ascertain that the algorithm had indeed found differences between different clusters. This revealed significant difference in the ranking between clusters on all measures except the number of pain episodes observed per hour. Although the variable “rescaled pain frequency” had not been included in the clustering process, it was included in this analysis and significant difference in the ranking between clusters was found on this measure also (Figure 6.9). Pairwise comparisons between these clusters showed significant difference between all three clusters on the measures “Sharp Pain” and “Long Pain” (Figure 6.10a and 6.10b). For overall satisfaction (Figure 6.10c) and pain frequency, significant differences were only found between Clusters A and C. Peri-procedural anxiety revealed significant differences between Clusters A and B, and A and C (Figure 6.10d).

The lack of significance in terms of episodes per hour can be considered unsurprising: 32 of the 62 cases included in the clustering algorithm contained no episodes: as such they receive identical ranking in a Kruskal-Wallis test, making discernment of differences unlikely. Despite this lack of significance, the parameter was retained in the clustering process for two reasons: first running the clustering algorithm without it made only one difference to the clusters produced. On inspection, this one case (case 17) was allocated to Cluster C when using this parameter, and Cluster B when it was not included. Inspection of this case supported its inclusion in Cluster C. Furthermore, observations of pain were considered an important detail to include as they represented the only measure of discomfort that did not rely on the retrospective report of the patient. Given the amnesic action of midazolam (p.42) it was important to include a measure independent of the patient’s recollection.

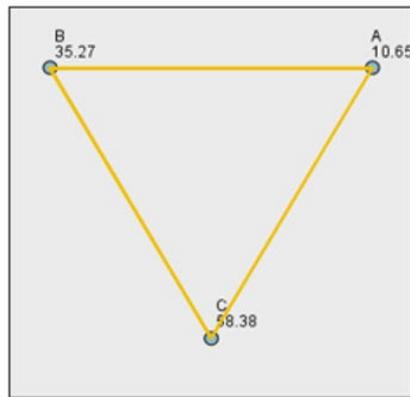
Figure 6.9: Kruskal-Wallis Testing Summary

Hypothesis Test Summary				
	Null Hypothesis	Test	Sig.	Decision
1	The distribution of OverallSat is the same across categories of Cluster.	Independent-Samples Kruskal-Wallis Test	.018	Reject the null hypothesis.
2	The distribution of SharpPain is the same across categories of Cluster.	Independent-Samples Kruskal-Wallis Test	.000	Reject the null hypothesis.
3	The distribution of LongPain is the same across categories of Cluster.	Independent-Samples Kruskal-Wallis Test	.000	Reject the null hypothesis.
4	The distribution of AnxietyProc is the same across categories of Cluster.	Independent-Samples Kruskal-Wallis Test	.000	Reject the null hypothesis.
5	The distribution of EppHours is the same across categories of Cluster.	Independent-Samples Kruskal-Wallis Test	.593	Retain the null hypothesis.
6	The distribution of Painfreq is the same across categories of Cluster.	Independent-Samples Kruskal-Wallis Test	.010	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .050.

Figure 6.10: Pairwise Comparison of Clusters

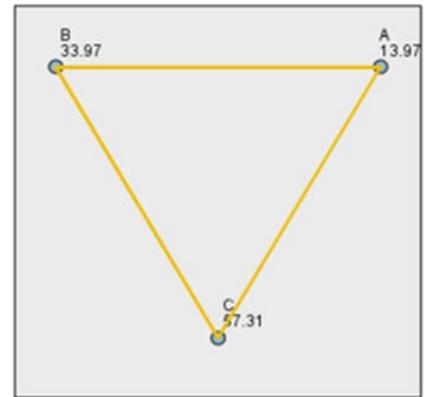
6.10a: Pairwise Comparison of SharpPain



Each node shows the sample average rank of three split.

Sample 1-Sam...	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj.Sig.
A-B	-24.623	5.248	-4.692	.000	.000
A-C	-47.728	7.679	-6.215	.000	.000
B-C	-23.105	6.983	-3.309	.001	.003

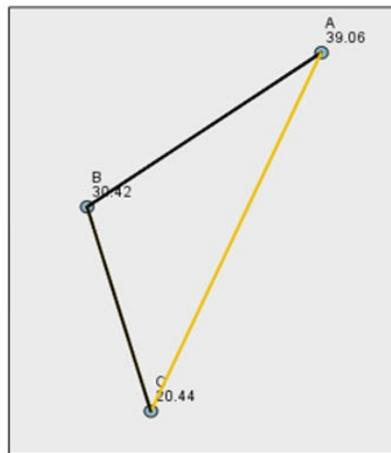
6.10b: Pairwise Comparison of LongPain



Each node shows the sample average rank of three split.

Sample 1-Sam...	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj.Sig.
A-B	-20.002	5.239	-3.818	.000	.000
A-C	-43.342	7.667	-5.653	.000	.000
B-C	-23.340	6.972	-3.348	.001	.002

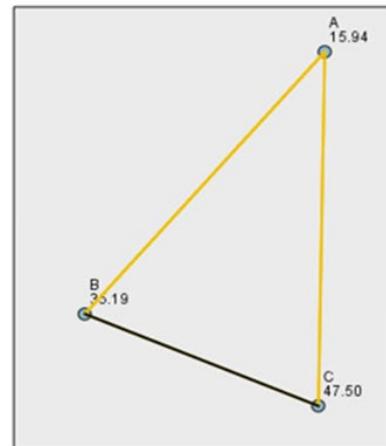
6.10c: Pairwise Comparison of OverallSat



Each node shows the sample average rank of three split.

Sample 1-Sam...	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj.Sig.
C-B	9.981	6.161	1.620	.105	.316
C-A	18.621	6.775	2.749	.006	.018
B-A	8.640	4.630	1.866	.062	.186

6.10d: Pairwise Comparison of AnxietyProc



Each node shows the sample average rank of three split.

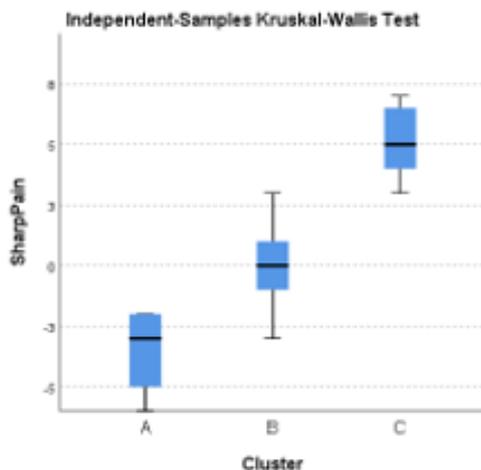
Sample 1-Sam...	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj.Sig.
A-B	-19.248	5.243	-3.671	.000	.001
A-C	-31.559	7.672	-4.114	.000	.000
B-C	-12.311	6.977	-1.765	.078	.233

Not only did the Kruskal-Wallis test demonstrate difference between clusters, it also proved useful in assigning meaning to clusters: both patient-reports of pain increased across the clusters from A to C (Figures 6.11a, 6.11b). The same pattern was noted for in-case anxiety (Figure 6.11d). Meanwhile, overall satisfaction decreased from A to C (Figure 6.11f). The number of observed episodes of pain was earlier identified as an insignificant difference between clusters, but what trend exists show that these too were more frequent in Cluster C cases (Figure 6.11e). It can therefore be concluded that Cluster A cases represent optimal cases; Cluster C were the least satisfactory. Cases in Cluster B represent an intermediate category, although the structure of the dendrogram (Figure 6.7) indicates that Type B cases are more closely related to Type A cases than to Type C: Type C cases do not join the overall structure until the final agglomeration. Type B cases were, therefore, considered to represent a mostly positive experience.

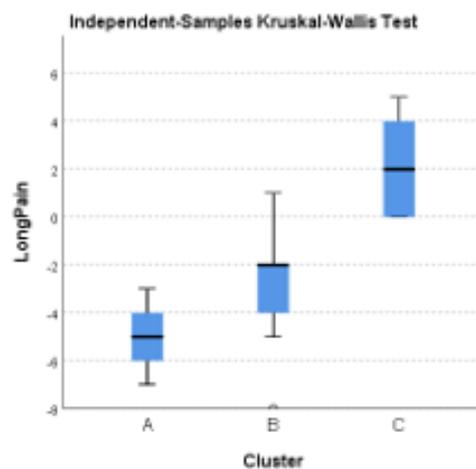
It was during this process that the decision to work with a three-, rather than a four-cluster solution was made. Testing the clusters of a four-cluster solution (A to D) in the same manner still demonstrated significant differences between the clusters: the optimal (A) and least satisfactory (D) clusters remained unchanged. However, it did not prove useful in ascribing value to the two middle clusters. On some parameters, sharp pain and long pain, Type B clusters appeared to represent slightly, though not significantly, better experiences than Type C cases. However, the only significant difference between Type B and C cases during pairwise comparison came on the parameter of anxiety during this case, which suggested Type C cases were preferable. Consequentially, it could not be confidently asserted whether Type B or C cases were superior to the other when using a four-cluster solution. The four-cluster solution was therefore abandoned as it was neither meaningful nor useful compared to the clarity of the three-cluster solution.

Figure 6.11: Distribution of Variables Across Clusters

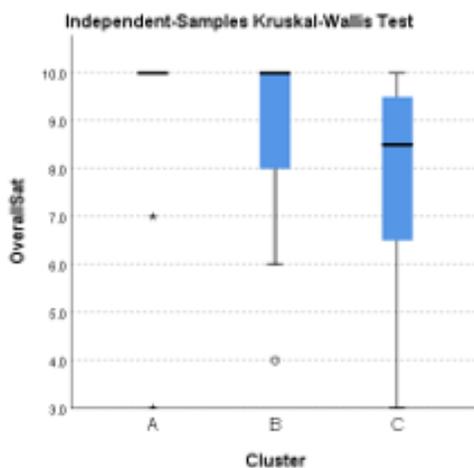
a: Sharp Pain



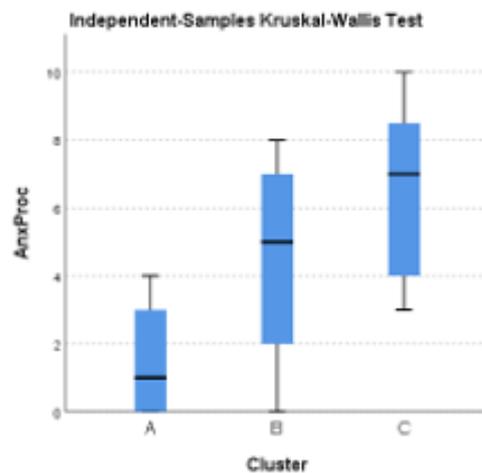
b: Long Pain



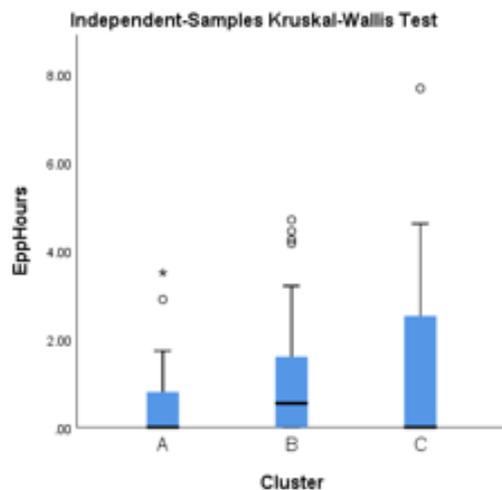
c: Overall Satisfaction



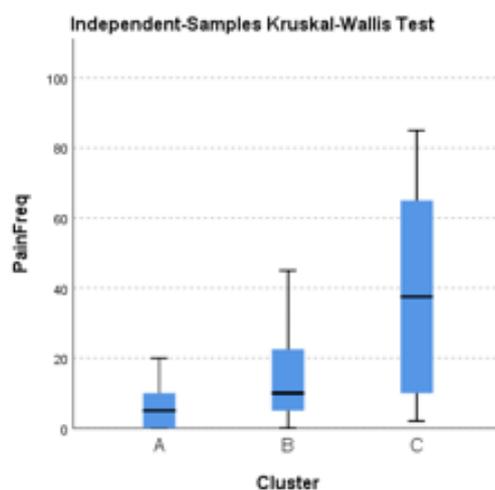
d: Anxiety During Procedure



e: Episodes of Pain per Hour



f: Frequency of Worst Pain



Finally, a solution to the problem of the parameter “frequency of worst pain” distorting results when included in the clustering process was found. It was rescaled by dividing it by 10 to make it comparable (0-10) to the other parameters, then the clustering process to ascertain what difference, if any, it produced. It meant that 4 further cases were excluded from the clustering as some respondents did not answer this question. De Vaus (2014) suggests the inclusion of a mean value for this score for missing data to allow such cases to be included, but this would be contradictory to the case-focused approach taken by this research. Of the remaining 58 cases, 54 remained in the same cluster. The other 4 cases (case numbers 15, 17, 46 and 57) are detailed in Figure 6.12. A subjective review of these 4 cases suggests that cases 17 and 57 were allocated to the correct cluster by the initial process which excluded the rescaled pain frequency score. Case 15 appears more accurately classified by the inclusion of this pain frequency. Case 46 appeared more ambiguous as the low overall satisfaction appears incongruous with all other scores, which posed the question of why their satisfaction was so low? A check of the survey reveals that the procedure in this case was incomplete, which suggests the low satisfaction did not relate to the control of pain or anxiety. However, what is evident from this review is that neither approach to clustering is infallible. Clustering procedures aim at objectivity (Kaufman and Rousseeuw, 2005), making reallocation of cases on subjective grounds inappropriate. This forced a decision. It was decided to continue analysis with the clusters formed without the inclusion of the rescaled pain frequency as it allowed for a total of 62 cases rather than 58 to proceed in the analysis. However, this decision was made with the intention of returning to cases 15, 17, 46 and 57 later in the analysis to ensure that they did not distort any conclusions.

Figure 6.12 Cluster Changes When Including “frequency of worst pain.”

CaseNo	OverallSat	SharpPain	longpain	Anxproc	EppHours	Painfreq	Rescaledpainfreq	threesplit	Alternative
15.00	10	4.00	.00	3	.00	2	.20	C	B
17.00	8	3.00	.00	3	.00	35	3.50	C	B
46.00	3	-5.00	-6.00	3	.80	2	.20	A	B
57.00	9	4.00	.00	5	.43	40	4.00	C	B

6.4 Non-Parametric Testing.

This study adopted a case-orientation on the expectation that outcome will be a complex structure of causal factors (p.62). However, it did not ignore the possibility of more simple causal processes. It was therefore considered necessary to perform more non-parametric testing to ascertain if any single causal factor could account for the structure of clusters identified by the HCA process. Again, non-parametric testing, specifically the Kruskal-Wallis test was utilised as it makes no assumptions regarding the distribution of the independent variables (Field, 2013). However, this test was not suitable for every independent variable that was analysed: some, such as the selection of equipment and administration of intravenous paracetamol were recorded in binary format which, in turn, makes ranking procedures such as Kruskal-Wallis tests ineffective. Instead, a Chi-squared Test (Field, 2013) was utilised, using specific software (Stangroom, 2021b).

6.4.1 Distribution of Continuous Independent Variables Across Clusters.

Many independent variables were considered potentially significant in determining the clusters to which a case belonged. These were anxiety prior to the procedure, age, weight, BMI, procedure duration, fentanyl dose (in mcg and mcg/Kg/hr), Midazolam dose, sex, alcohol intake, Paracetamol dose and equipment used. The Kruskal-Wallis test failed to detect any significant difference in independent variables containing interval level or continuous data across the three clusters (Figure 6.13). Despite this, the process still yielded some useful insights. The first of these is that patient's body weight and BMI approached levels of significance ($p=.094$ and $p=.078$ respectively). The box and whisker plots of these independent variables across the clusters associates lower weights (Figure 6.14a) and BMI (6.15b), with Type A cases, with both variables rising across Clusters B and C. However, 6.15a also displays an outlying case in Cluster A, indicating that factors other than body mass are relevant.

Figure 6.13 Kruskal-Wallis Testing of Independent Variables

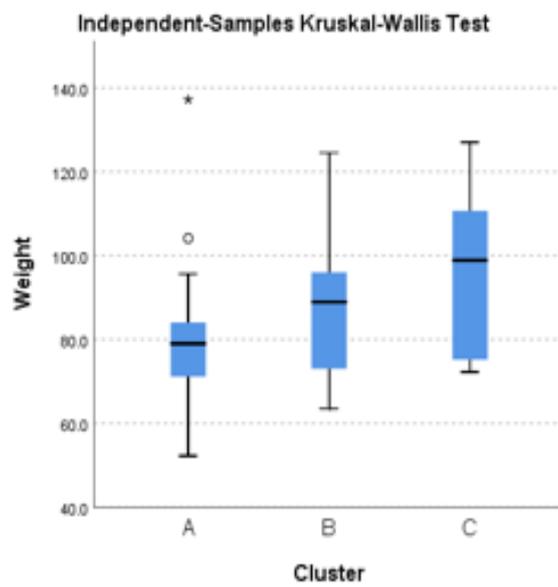
Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of AnxietyOnWard is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.269	Retain the null hypothesis.
2	The distribution of Age is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.592	Retain the null hypothesis.
3	The distribution of Weight is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.094	Retain the null hypothesis.
4	The distribution of BMI is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.078	Retain the null hypothesis.
5	The distribution of Duration is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.730	Retain the null hypothesis.
6	The distribution of FentanylDose is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.910	Retain the null hypothesis.
7	The distribution of MidazolamDose is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.234	Retain the null hypothesis.
8	The distribution of FentanylFKgHr is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.601	Retain the null hypothesis.
9	The distribution of MidazolamPerHour is the same across categories of Clusters.	Independent-Samples Kruskal-Wallis Test	.613	Retain the null hypothesis.

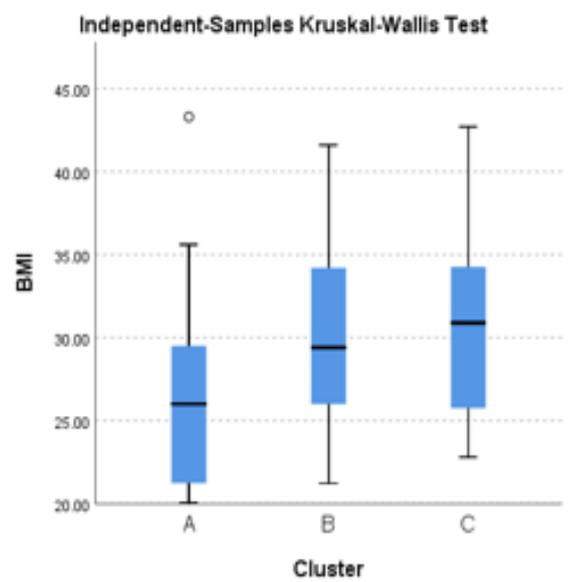
Asymptotic significances are displayed. The significance level is .050.

Figure 6.14: Individual Independent Variables Across Clusters

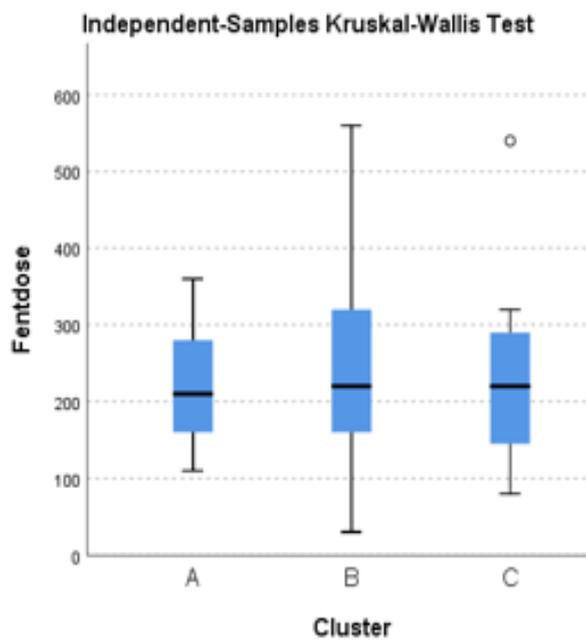
a: Weight



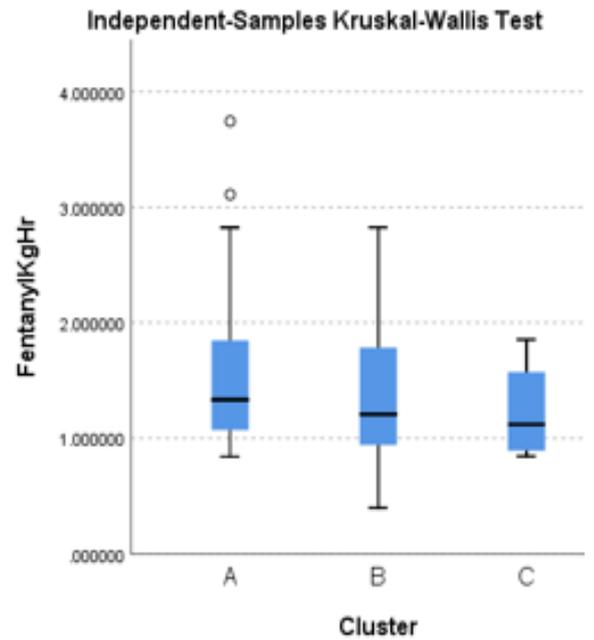
b: Body Mass Index



c: Fentanyl Dose in Micrograms



d: Fentanyl Dose in Micrograms/Kilogram/Hour



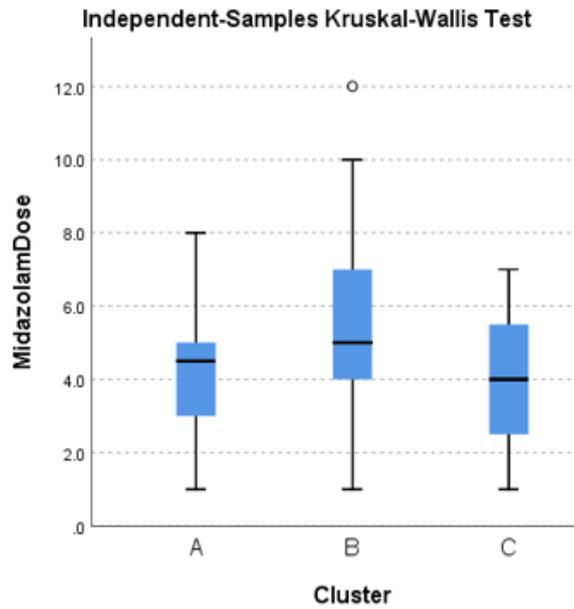
No significant difference was found in the distribution of fentanyl doses across cases, either in terms of micrograms or micrograms/kilogram/hour. This was somewhat surprising, given the significant differences in pain scores across the clusters, and the analgesic action of fentanyl. However, the box and whisker plots of these afford some useful insights. The first point of interest is the confirmation that dosage of fentanyl is best used in terms of mcg/Kg/hr rather than just cumulative dose. Figure 6.14c (Fentanyl dose in milligrams) reveals no pattern but, once adjusted for case duration and patient weight (6.15d), a pattern is discernible. Although median values and quartile ranges remain similar, the outliers indicate that dose of fentanyl may exert some influence on the clustering. Cluster C contains no patient receiving more than 2 mcg/Kg/hr of fentanyl. Clusters A and B, however, contain cases receiving between 2 and 3 mcg/Kg/hr, with Cluster A containing both cases receiving in excess of 3 mcg/Kg/hr. The extent to which these cases differ from the median value does not affect the median itself and, as such cases are relatively rare, they do not impact on the quartile range. However, they do prompt the hypothesis that dose of fentanyl in excess of 2 mcg/Kg/hr resulted in a satisfactory patient outcome; the presence of lower doses amongst Cluster A also indicates that it is not the only route leading to this outcome. However, no such pattern could be observed in the pattern of midazolam doses below, with the midrange Cluster B cases receiving the highest doses (Figure 6.15a)

Some pattern of interest could also be discerned on the box and whisker plot of ages across clusters. Patients below the age of 50 were relatively few (n=9), but 3 of these cases appeared in the 8 cases of Cluster C, hence the lower quartile limit is conspicuously lower for Cluster C than for A and B (Figure 6.15b). Conversely, only one of the nine patients below the age of 50 appeared in Cluster A; this patient was 49.

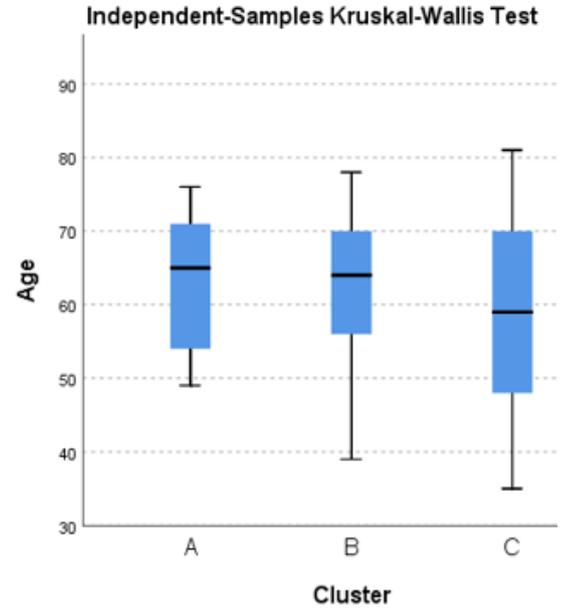
The final independent variables considered were the duration of the case in minutes (Figure 6.15c) and anxiety levels prior to the procedure (6.16d). The plot of case duration did not identify any patterns of interest. It was noted that the median anxiety score of patients in Cluster A was considerably lower than in the other groups.

Figure 6.15: Further Individual Independent Variables Across Clusters

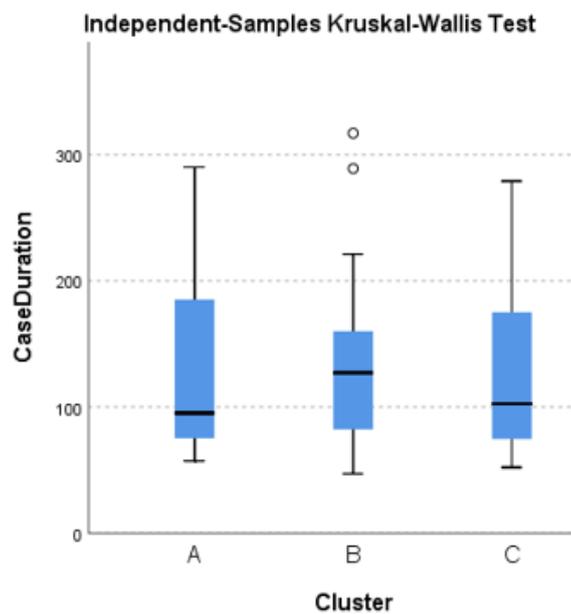
a: Midazolam Dose in Milligrams



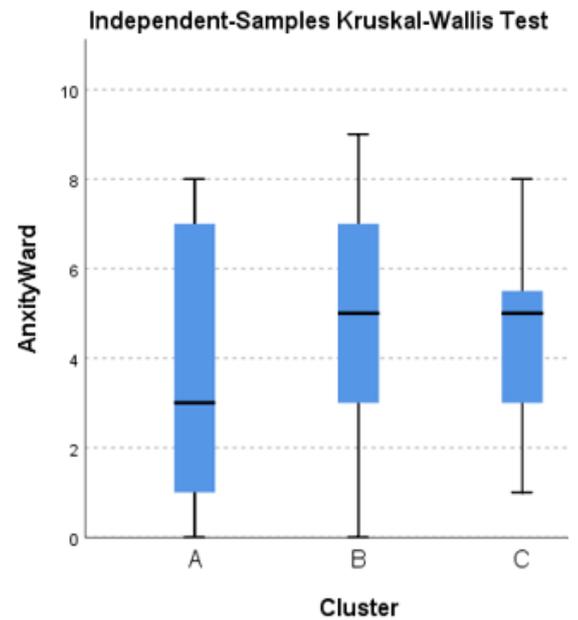
b: Patient Age in Years



c: Duration of Procedure in Minutes



d: Anxiety Score on Ward



6.4.2 Distribution of Dichotomous Variables Across Clusters.

The Chi-Squared Test was used to analyse the distribution of dichotomous independent variables across clusters. Only one significant difference was noted: this difference came in the distribution of the administration of 1 gram of intravenous paracetamol during the case ($P=0.038$) (Figure 6.16a). However, on closer inspection, this figure resulted from a much higher use of paracetamol in Type B cases than in Type A or C. Given that Type B cases represented a middling experience, little conclusion can be drawn from this in terms of paracetamol determining a positive or negative experience .

However, the lack of significance for one variable is particularly worthy of comments. This test relates to the energy source used, as several previous studies had identified RFA as more painful than cryoablation (Lowe *et al.*, 2003; Defaye *et al.* 2010; Attanasio *et al.* 2016). However, the Chi-Squared Test noted no significant differences between the clusters based on this (Figure 6.16d). This was investigated further out of interest; absolutely no difference was noted between individual pain, anxiety or satisfaction scores between groups dependent on their receiving RFA or cryoablation. Significant differences were found between doses of fentanyl and midazolam given dependent on energy source (Kruskal-Wallis $P=0.00$ for each), which superficially supports the findings of Defaye *et al.*(2010). However, RFA cases were also significantly longer ($P=0.00$), and the difference in drugs dosage vanished once adjusted for time.

Figure 6.16: Chi-Squared Tests of Dichotomous Variables Across Clusters

a: Administration of Paracetamol

Results						
	Paracetamol	No Paracetamol				Row Totals
A	8 (10.69) [0.68]	9 (6.31) [1.15]				17
B	28 (23.27) [0.96]	9 (13.73) [1.63]				37
C	3 (5.03) [0.82]	5 (2.97) [1.39]				8
Column Totals	39	23				62 (Grand Total)

The chi-square statistic is 6.628. The p -value is .036371. The result is significant at $p < .05$.

b: Patient Sex

Results						
	Male	Female				Row Totals
A	12 (9.60) [0.60]	5 (7.40) [0.78]				17
B	21 (20.89) [0.00]	16 (16.11) [0.00]				37
C	2 (4.52) [1.40]	6 (3.48) [1.82]				8
Column Totals	35	27				62 (Grand Total)

The chi-square statistic is 4.6024. The p -value is .100139. The result is *not* significant at $p < .05$.

c: Smoking Status

Results						
	Smoker	Non-Smoker				Row Totals
A	3 (1.92) [0.61]	14 (15.08) [0.08]				17
B	2 (4.18) [1.13]	35 (32.82) [0.14]				37
C	2 (0.90) [1.33]	6 (7.10) [0.17]				8
Column Totals	7	55				62 (Grand Total)

The chi-square statistic is 3.4666. The p -value is .176704. The result is *not* significant at $p < .05$.

d: Energy Source Used

Results						
	Radio Frequency	Cryo				Row Totals
A	8 (7.40) [0.05]	9 (9.60) [0.04]				17
B	15 (16.11) [0.08]	22 (20.89) [0.06]				37
C	4 (3.48) [0.08]	4 (4.52) [0.06]				8
Column Totals	27	35				62 (Grand Total)

The chi-square statistic is 0.3568. The p -value is .836595. The result is *not* significant at $p < .05$.

6.5 Qualitative Comparative Analysis.

Non-parametric testing failed to identify any independent conditions that account for the clusters identified during the HCA process. This therefore supported the need for an analytic method which allowed for the possibility of both causal complexity and equifinality, as discussed in the methodology (p.62). QCA allows for both (Schneider and Wagemann, 2012; Rhioux and Lobe 2013). This case was further strengthened by the distribution across clusters of cases outside quartile limits: little difference existed between clusters' median values and quartile ranges for independent conditions such as fentanyl dose, but variance occurred beyond these. There were few cases receiving more than 3 mcg/Kg/hr of fentanyl, yet all of them occurred in Cluster A (Figure 6.14d). Meanwhile the youngest patients were to be found in Cluster C, and Cluster A contained no patient younger than 49 (Figure 6.15b). Such variance might be irrelevant, or harmful to a linear solution, but may be greatly significant in an equifinal solution. For example, the use of high dose fentanyl could represent one context by which an optimal patient experience could be achieved, without it needing to account for all optimal outcomes recorded in the study. Analysis was performed using specialist fsQCA software (Ragin and Davey, 2016).

6.5.1 Calibration of Fuzzy Sets

To perform fsQCA, it was necessary to allocate set memberships to each case on every relevant condition. Ragin (2008) states that the first step in this process is clear specification of the target set; by this, it was understood that it is necessary to specify what each set is intended to mean. For this study, it was intended to calibrate the recorded variables so that they reflected membership of the sets in Figure 6.17. Some sets used shorter titles in the fsQCA process as the software made full titles difficult to read. For data calibrated into fuzzy sets, the thresholds for set non-membership and full set membership, along with the point of ambiguity, are included. Sets without this information are dichotomous crisp sets, which can be analysed in the same process as fuzzy scores (Schneider and Wagemann, 2012). Due to the dichotomous nature of this data, it was not considered necessary to include sets for "Female Patient" or "Cryoablation": non-membership of sets "Male Patient" or "Radiofrequency Ablation" inferred membership of the omitted sets.

Figure 6.17 Set Calibration Summary

Variable	Meaning of Full Set Membership	Short Set Title	Non-membership	Point of Ambiguity	Full membership
Sex	Male Patient				
Patient Age	Young Patient		55	50	45
Body Mass Index	Obese Patient		24.95	29.95	34.95
Smoking Status	Smoker				
Alcohol Intake	Patient Regularly Exceeds Recommended Alcohol Intake	HighAlcohol			
Anxiety on Ward	Anxious Prior to Procedure	AnxiousPatient	0	4	7
Procedure Duration	Long Procedure		120	170	220
Paracetamol	Patient Received 1G Intravenous Paracetamol	FzParacetamol			
Fentanyl (mcg/Kg/Hr)	Patient Received Heavy Analgesia Using Fentanyl*	FzFentanyl	1	2	3
Midazolam (mg)	Patient Received Heavy Sedation Using Midazolam	FzMidazolam	3.5	5	7.5
Equipment Used	Radiofrequency ablation performed.	RFA			
Cluster	Positive Patient Experience.	PositiveExp			

* The meaning of this set was ultimately “Patient Received Moderate Analgesia Using Fentanyl”

Schneider and Wagemann (2012) state that a researcher's priorities in calibrating fuzzy sets are for the process to be transparent, and for the set to have high content validity. The first requirement is achieved by detailing the process used. Most of the non-dichotomous data was allocated set membership scores using the direct method of calibration (Ragin, 2008), performed by the fsQCA software (Ragin and Davey, 2016). Direct calibration of a set requires the researcher to identify 3 thresholds: those for full membership and full non-membership of a set, and the point of maximum ambiguity, either side of which a case is considered mostly in, or mostly out of a set (Ragin, 2008). To meet the second requirement, both Ragin (2008) and Schneider and Wagemann (2012) advocate the use of thresholds external to the data itself, while acknowledging that data regarding the distribution of raw data may also be considered. It is therefore necessary to explain which external data was used to calibrate these sets, why this selection was made, and any consequences the use of this data has for the meaning of the sets.

The set "Obese Patient" proved the least challenging of these sets to calibrate as pre-existent thresholds for obesity exist on the BMI (World Health Organisation (WHO), 2021). The WHO classifies BMIs exceeding 25 as pre-obesity, 30 as obesity class 1, and 35 as obesity class 2. However, 24.95, 29.95 and 34.95 were selected as respective thresholds due to a concern about the point of maximum ambiguity: a patient with a BMI of 35 is objectively classified as obese by this system, not in some ambiguous state between overweight and obese. It was therefore necessary to calibrate this set in such a way that this was reflected. It was decided at this point not to calibrate the variable "patient weight" for use in fsQCA. First, it was considered to add little new information not contained in the "Obese Patient" set and, second, objective standards such as the BMI scale did not exist for weight alone. Conclusions drawn from the set "Heavy Patient" would therefore be contingent on the arbitrary classification of it.

For calibration of drug doses, the JFC (2021) was used as the primary source of objective measures. Of midazolam used for conscious sedation, this stated that usual total dose is 3.5–5 mg, with a maximum of 7.5 mg per course. This provided objective thresholds for non-membership, the point of ambiguity and full membership of the set "Heavy Sedation Using Midazolam".

The set “Heavy Analgesia Using Fentanyl” proved more challenging to calibrate. The benefit of calibrating this set from the dose of fentanyl in mcg/Kg/hr had previously been noted as it uncovered a pattern of interest in the data and, unlike midazolam, some guidelines for administration of fentanyl using these units exist. Furthermore, the JFC’s (2021) guidance on fentanyl during operations with spontaneous breathing in terms of cumulative dose (mcg) gives no indication of upper limits of dose. However, their guidance states a range of 3–4.8 micrograms/kg/hour, adjusted according to response. 3 mcg/Kg/hr and 4.8 mcg/Kg/hr were considered as points of ambiguity and full set membership. However, this would have meant that only 2 patients’ doses were above the point of ambiguity, and such thresholds would not be useful for discerning differences between the cases in this study. 3 mcg/Kg/hr was therefore taken as the point of full membership of this set, but this necessitated a change in the meaning of the set: instead of “Heavy Analgesia Using Fentanyl”, it was understood as “Moderate Analgesia Using Fentanyl”. The question of why fentanyl use was relatively low was noted for further investigation. It also remained to identify thresholds for non-membership and ambiguity for this set and the JFC offered no further guidance. However, the off-label use of 1-2mcg/Kg/hr infusions in adult patients is recognised (Medscape, 2020); 1 and 2 were therefore taken as the respective thresholds for non-membership and the point of maximum ambiguity.

The set “Long Procedure” was calibrated using research data external to the study (Schneider and Wagemann, 2012). Kottkamp *et al.* (2011) recorded mean case duration of 170 ± 51 minutes during radiofrequency ablation, while Wasserlauf *et al.* (2016) recorded case duration of 174.5 ± 50.2 minutes for cryoablation with moderate sedation. These figures give a consistent measure of AF ablation duration. It was therefore decided to use 170 minutes as the point of maximum ambiguity for the set “Long Procedure”, with a standard deviation of 50 above and below this as the two thresholds.

The sets “Young Patient” and “Anxious Prior to the Procedure” proved the most challenging to calibrate. “Young Patient” is a relative term: the youngest patient was 35, with the majority over the age of 60; however, this patient sample appears to be typical of patients undergoing AF ablation (p.79). Initially, this set was conceived of as “Older Adult”, using pensionable ages as thresholds. However, these vary between men and women, so were not used. Furthermore,

as noted during the Kruskal-Wallis analysis (Figure 6.15b), variation between clusters based on age appeared to be among patients under the age of 50. Calibrating the set with the intention of identifying variation in this age range was therefore preferable. Thresholds of 55, 50 and 45 were respectively chosen for non-membership, ambiguity, and full-membership thresholds. This was not with reference to external criteria as no suitable measure was found; instead it reflected the distribution of the data itself (Schneider and Wagemann, 2012).

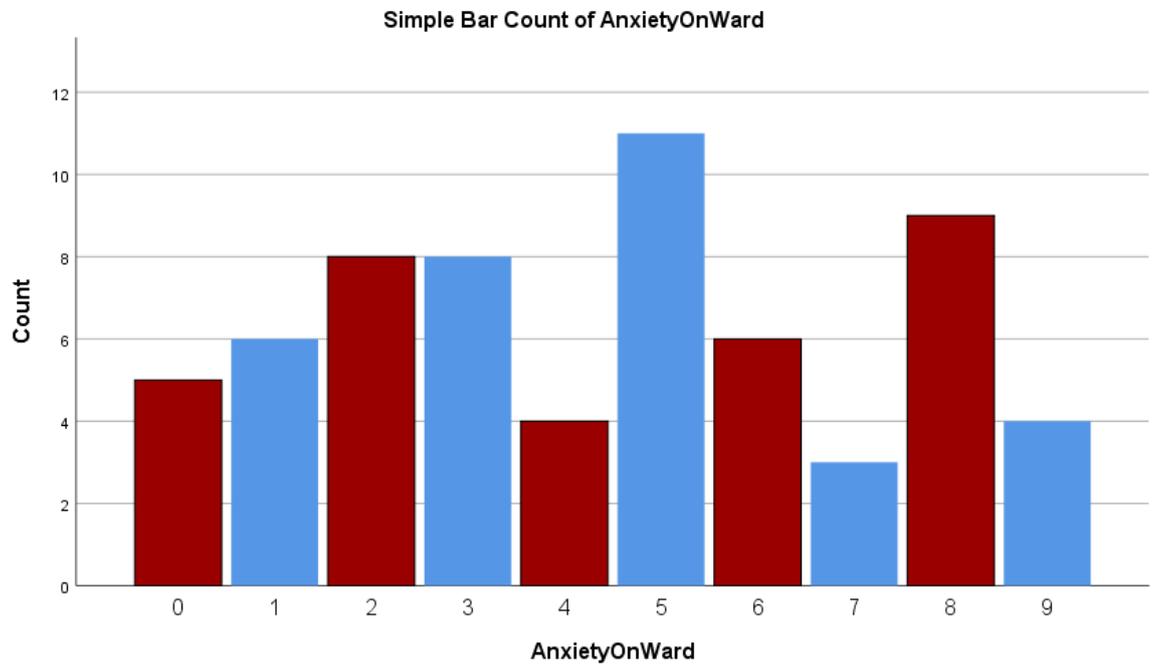
Calibrating the set “Anxious Prior to the Procedure” was the least satisfactory aspect of this process. No objective measures against which this could be calibrated were found. As a result, the data was calibrated using only its distribution as a guide. Schneider and Wagemann (2012) indicate that gaps in the data can mark suitable points for thresholds. Troughs in the response regarding prior anxiety are conspicuous at scores of 4 and 7 (Figure 6.18); these were selected as the point of maximum ambiguity and full membership respectively. 0 was taken as the point of non-membership. As a point of reflection this problem could have been anticipated in the design of the questionnaire; however, it was included in further analysis with awareness that this step in the process could make result dubious.

The set “Patient Regularly Exceeds Recommended Alcohol Intake” was ultimately a crisp set. While a definitive threshold for full membership was identified in the form of the Chief Medical Officer’s advice (DoH., 2016) regarding alcohol intake, suitable thresholds were not identified below this. By including this set, the effects of regularly consuming more than the recommended 14 units of alcohol on sedation could be appraised.

The remaining variable, the division of cases into Clusters A, B and C was intended to form the outcome condition for the fsQCA process. This study aimed to identify differences between cases within the study; therefore it was considered appropriate to calibrate this set without reference to data outside of it. Type A cases were identified during the validation process (p.101) as being the optimal cases in this study; as this study intends to identify factors that optimise the patients’ experiences, Type A cases were allocated the fuzzy score 1 in the set “Positive Patient Experience”. Likewise, Type C cases were least satisfactory; they were allocated the score of 0. Allocating a score to Type B cases was more challenging. This outcome set could have been calibrated to represent “optimal”

outcomes, with Type B cases allocated the score of 0. Alternatively, Type B cases could have been recognised as successful cases, and allocated a score of 1 in such a set. Effectively, either solution would turn the fuzzy outcome set into a crisp set. Ragin (2008a, cited in Schneider and Wagemann, 2012, pp.191-192) argues that “when fuzzy sets are available, there is never a good reason for turning them into crisp sets”, while Schneider and Wagemann themselves point out that the finer grade of information represented in fuzzy sets is never lost, but is reflected in the consistency and coverage values of any solution. It was therefore necessary to allocate a fuzzy value to Type B cases. It could be confidently asserted that they were more closely aligned to Type A cases than Type C (Figure 6.7), and therefore should have a score that placed them above the point of ambiguity. Scores of 0.67 and 0.75 were considered. 0.67 was chosen as the dendrogram identifies Type B case positions in relation to other case types, not to the point of ambiguity. However, acknowledging the somewhat arbitrary nature of this score, subsequent analysis was run using both values. Both resulted in the same outcome formulae, though coverage and consistency varied slightly.

Figure 6.18: Simple Count of Response Regarding Anxiety on Ward



6.5.2 Tests of Sufficiency for Positive Experience.

The truth table algorithm (Ragin and Davey, 2016) was utilised to identify sufficient causal conditions for membership of the set “Positive Patient Experience”. The decision to focus on the determinants of a positive experience was determined by the project aims, the logic of QCA, and the purpose of QCA within the larger context of the study. A stated aim of this project was to identify the conditions under which NDPSA is most effective (p.1). The logic of QCA, specifically the allowance for causal asymmetry, means that the determinants of a positive outcome are *not* simply the inversion of the determinants of a negative solution (Schneider and Wagemann, 2012). Furthermore, within the study, the QCA analysis was intended to provide a theoretical model of causal factors into which individual cases in the case study phase could fit, and act as explanations of *why* this combination of factors led to a positive outcome. By providing a theoretical structure of similar case-types, this would aid the analytic generalisation described by Yin (2014). To do this ethically, it was necessary for the QCA model to focus on positive outcomes; university ethics regulations required case study participants to be informed of *why* they were being asked to participate; giving the reason that it was anticipated that they would have a negative experience was considered inappropriate. It should be noted that ethical approval for the project was necessarily obtained before the distribution of positive and negative cases could be known. To work within this ethical approval, it was necessary for QCA to focus on the determinants of a positive experience. This had some notable implications for the subsequent QCA as there were many more positive (Type A and B) cases than negative cases. First, Schneider and Wagemann (2012) explain that there is frequently a trade-off between consistency and coverage in QCA: with such a large proportion of positive cases, achieving a high consistency score could be relatively easy. However, it simultaneously becomes more challenging to achieve a high coverage value, as so many cases would need to be explained by the solution term in order to achieve this. Furthermore, the high proportion on positive cases means that even high consistency values of truth table rows could mask a true logical contradiction. With so few negative cases, the existence of such a contradiction would create considerable doubt over the validity of such a solution. It was therefore necessary to examine solution terms to ensure that no true logical contradictions were included.

The first potential causal conditions to be included in this algorithm were those relating to drug administration as these were conditions over which the nurse had direct control. The truth table produced an interesting pattern of drug combinations consistent with a positive experience. These combinations were ranked by this order of consistency with the outcome condition (Figure 6.19a). A logical remainder existed: no patient receiving moderate analgesia and heavy sedation but not paracetamol. The combination of none of these drugs was least consistent with a positive patient experience. Above that, use of midazolam and then paracetamol in isolation have lowest consistency values, followed by the two in combination. The introduction of fentanyl led to a further rise in the level of consistency; ultimately the combination of all 3 drugs resulted in the highest consistency with a positive patient experience.

Application of the Quine-McCluskey algorithm (Ragin and Davey, 2016) to this truth table (using a consistency cut off point of 0.8) led to the conclusion that two pathways led to the membership of the set Positive Patient Experience: patients who received moderate analgesia using fentanyl, or patients who received both paracetamol and heavy sedation using midazolam (Figure 6.19b)

Figure 6.19: Truth Table and Algorithm Using Drugs as Causal Conditions

a: Truth Table

FzFentanyl	FzMidazolam	Paracetamol	number	PositiveExp	raw consist.	PRI consist.	SYM consist
1	1	1	1		0.937901	0.837989	0.837989
1	0	0	4		0.914286	0.892583	0.899485
1	0	1	2		0.862654	0.711974	0.763889
0	1	1	12		0.852805	0.758397	0.918635
0	0	1	15		0.79276	0.683747	0.811016
0	1	0	10		0.712025	0.622928	0.711357
0	0	0	8		0.615746	0.525399	0.546828
1	1	0	0				

b: Quine-McCluskey Algorithm

```
--- PARSIMONIOUS SOLUTION ---
frequency cutoff: 1
consistency cutoff: 0.852805
```

	raw coverage	unique coverage	consistency
FzFentanyl	0.300312	0.195502	0.895789
FzMidazolam*Paracetamol	0.328069	0.22326	0.823918

solution coverage: 0.523571
solution consistency: 0.842186

```
*****
*TRUTH TABLE ANALYSIS*
*****
```

```
File: FinalData.csv
Model: PositiveExp = f(FzMidazolam, FzFentanyl, Paracetamol)
Algorithm: Quine-McCluskey
```

```
--- INTERMEDIATE SOLUTION ---
frequency cutoff: 1
consistency cutoff: 0.852805
Assumptions:
```

	raw coverage	unique coverage	consistency
~FzMidazolam*FzFentanyl	0.240967	0.164154	0.884886
FzMidazolam*Paracetamol	0.328069	0.251257	0.823918

solution coverage: 0.492224
solution consistency: 0.838907

This conclusion derives from the parsimonious solution, rather than the intermediate solution. fsQCA software gives 3 solutions: complex, intermediate, and parsimonious. None of these solutions contradict the empirical data (Schneider and Wagemann, 2012), but differ in assumptions made about logical remainders. The complex solution makes no assumptions regarding logical remainders; the parsimonious solution assumes that any remainders that would contribute to a logically simpler solution are true; the intermediate solution requires the researcher to supply information on “easy counterfactuals” to decide which remainders to use (Ragin, 2018, p.45). However, at this stage the researcher supplied no information on easy counterfactuals, so the intermediate and complex solutions were identical. Here, the difference between the two solutions rests on a single logical remainder:

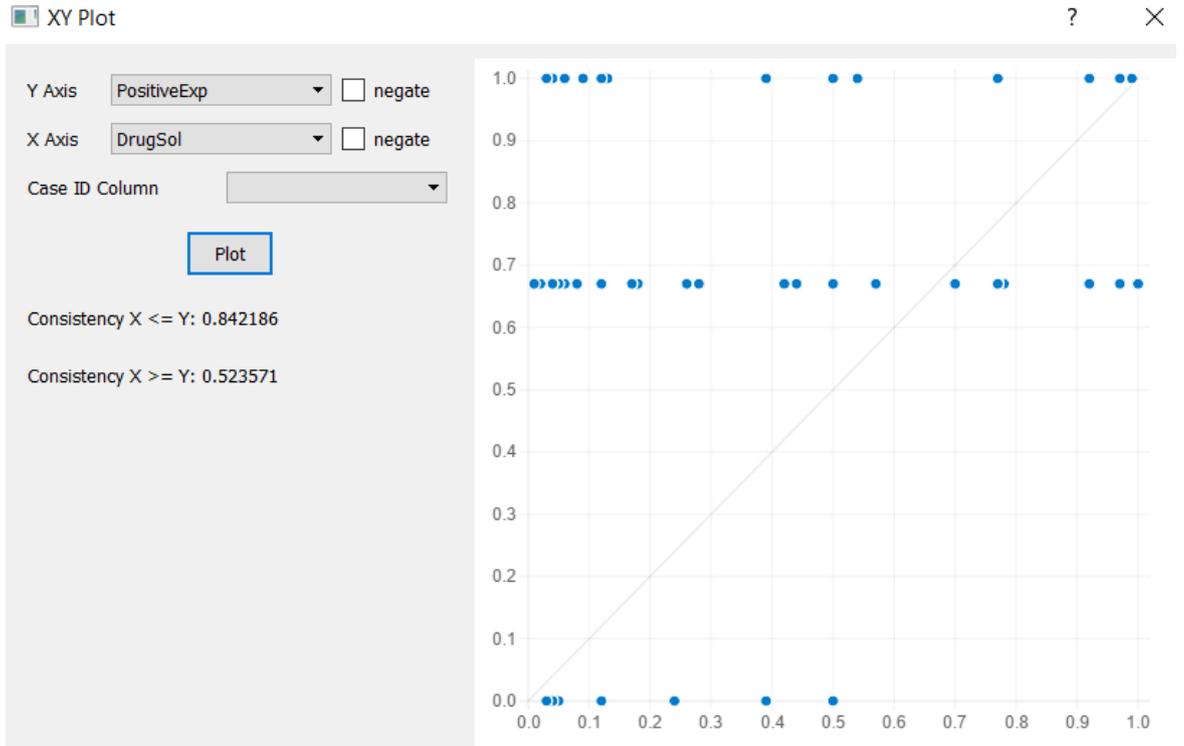
“FzFentanyl*FzMidazolam*~FzParacetamol”. No patient received this combination of medications. An “easy counterfactual” is defined as

“those simplifying assumptions that are in line with both the empirical evidence at hand and existing theoretical knowledge on the effect of the single conditions that compose the logical remainder”. Schneider and Wagemann (2012, p.168)

This definition allows the easiest of easy counterfactual claims regarding the logical remainder in this analysis: it should be included, and the parsimonious solution should be accepted over the complex. Empirically, Figure 6.19a shows that fentanyl alone had consistency with the outcome of over 0.9. Theoretical knowledge indicates that Midazolam should reduce anxiety (JFC, 2021), improving experience, and consistency as it does. Furthermore, the truth table shows very high consistency when fentanyl is combined with midazolam and paracetamol. It is therefore in line with the “principle of expectation” (Schneider and Wagemann, 2012, p.168) that cases with the configuration FzFentanyl*FzMidazolam*~FzParacetamol would be members of the outcome set “Positive Patient Experience”.

The solution term FzFentanyl+(FzMidazolam*Paracetamol) was computed as a single condition: DrugSol (drug solution). When plotted against membership of “Positive Patient Experience” (Y-axis), the scatter plot shows no cases that are both above 0.5 on the X-axis and below 0.5 on the Y-axis, demonstrating its consistency (Figure 6.20).

Figure 6.20: XY Plot Demonstrating Consistency of Drugs-Only Solution



However, the moderate coverage of this solution (0.523571) is also apparent: many cases are clustered close to the Y-axis regardless of their position on the X-axis. This acknowledges that, while the two pathways identified are sufficient for a positive patient experience, they are not the only determining factors. Further analysis of data was therefore needed to identify other combinations resulting in a positive experience.

It was noted in Section 6.4.1 that patient BMI came closest to being a significant independent variable. The set derived from this, "Obese Patient", was therefore added to the truth table algorithm. This uncovered a significant problem for the fsQCA process. Solutions were ascertained as on the next page, but when these solutions were plotted against "Positive Patient Experience", they revealed a true contradictory case: Case number 35 can be seen at the coordinates 0.83,0 (Figure 6.21b). While the solution seemed to increase coverage to 0.758316 for the parsimonious solution (Figure 6.21a), the presence of a true contradiction amongst only 8 cases prevented the conclusion that this solution was sufficient for membership of "Positive Patient Experience" (Schneider and Wagemann, 2012). The relatively large proportion of Type A and B cases could allow certain combinations of casual conditions to appear consistent with the outcome condition while including a contradictory case. To prevent this, it was necessary to adjust the consistency cut off point upwards from 0.8. This is the default setting on the fsQCA software (Ragin and Davey, 2016), and is commonly used as a starting point in analysis (Elliott, 2013). However, Schneider and Wagemann (2012) argue that no universally accepted cut off point should exist, and that consistency levels should be set higher for relatively small samples or in the presence of true logical contradictions. Therefore, the process was repeated using a cut-off point of 0.85. This succeeded in removing the contradictory case from the solution. However, coverage (0.501795) and consistency (0.845906) values solutions were near-identical to those obtained when using drugs only (Figure 6.19b). The inclusion of the set "Obese Patient" had therefore done little to increase insight into sufficient combinations of casual conditions.

Figure 6.21: FsQCA Analysis of Drugs Administered and “Obese Patient”

a: Quine-McCluskey Algorithm

```

--- PARSIMONIOUS SOLUTION ---
frequency cutoff: 1
consistency cutoff: 0.82058

```

	raw coverage	unique coverage	consistency
FzFentanyl	0.300311	0.108639	0.895789
~ObesePatient*FzMidazolam	0.356306	0.0813592	0.876914
~ObesePatient*Paracetamol	0.426658	0.153386	0.823176
FzMidazolam*Paracetamol	0.328069	0.0926061	0.823918

solution coverage: 0.758316
 solution consistency: 0.806977

 TRUTH TABLE ANALYSIS

File: FinalData.csv
 Model: PositiveExp = f(ObesePatient, FzMidazolam, FzFentanyl, Paracetamol)
 Algorithm: Quine-McCluskey

```

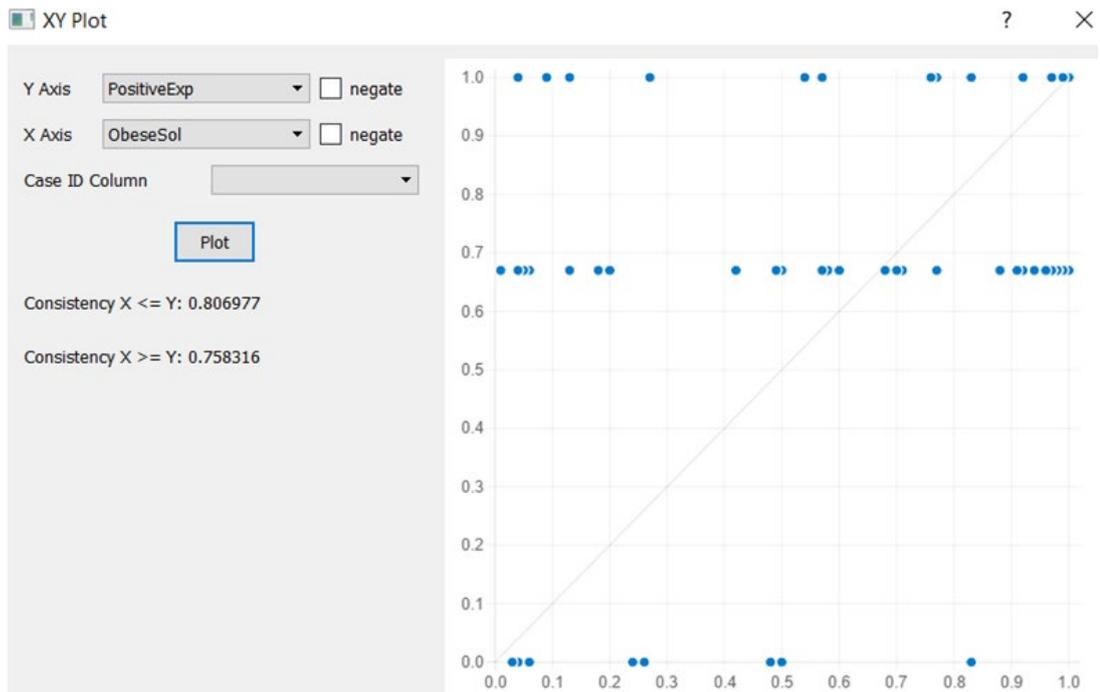
--- INTERMEDIATE SOLUTION ---
frequency cutoff: 1
consistency cutoff: 0.82058
Assumptions:

```

	raw coverage	unique coverage	consistency
~ObesePatient*Paracetamol	0.426658	0.164872	0.823176
~ObesePatient*FzMidazolam*~FzFentanyl	0.324719	0.0921273	0.89571
~ObesePatient*~FzMidazolam*FzFentanyl	0.217995	0.086863	0.905567
FzMidazolam*~FzFentanyl*Paracetamol	0.309165	0.0923666	0.852805
~FzMidazolam*FzFentanyl*Paracetamol	0.133764	0.0184255	0.862654

solution coverage: 0.734626
 solution consistency: 0.823498

b: XY Plot Demonstrating Inconsistency of Solution



Each of the remaining potentially causal conditions was individually added to the conditions already in the truth table algorithm to investigate which, if any, led to a rise in the coverage and consistency of the solution terms. Again, the inclusion of energy source made very little difference: no change in coverage and marginal change in consistency. The inclusion of “Anxious Prior to the Procedure” led to a dramatic increase in coverage (0.713568), but a reduction in consistency which also masked true logical contradictions. It was therefore discarded. Only one casual condition, “Young Patient” led to a rise in both coverage and consistency (Figure 6.22a). The rise in consistency was small, increasing from 0.845906 to 0.865169; however, the increase in coverage was substantial, from 0.501795 to 0.625748, indicating that the solution pathways from the 3 solution terms found via this process accounted for considerably more of the positive experiences than previous analysis. It was immediately ascertained that these solution terms contained no true logical contradictions. The parsimonious solution configurations were computed as a single condition:

$$\text{“FzFenanyl+(FzParacetamol*~YoungPatient*~ObesePatient)+FzMidazolam*FzParacetamol*~YoungPatient)”}$$

This new condition was named “Parsimonious Sol” and was then plotted against “Positive Patient Experience” (Figure 6.22b). This demonstrated the absence of true logical contradictions as all cases with complete non-membership of “Positive Patient Experience” are below 0.5 on the X-axis. A single case, Case 60, approached the point of ambiguity (plotted at 0.48, 0). In the interests of rigour, this case was reviewed to ensure that selection of calibration thresholds, for example, did not disguise a true logical contradiction. The membership of 0.48 case came from the pathway “~YoungPatient*~ObesePatient*FzParacetamol”. This patient had a BMI of 30.06 which led to his being slightly more in the set “Obese Patient” than out of it and, subsequently, his membership score of the solution term was less than 0.5. The use of the objective BMI to calibrate this set prompted confidence in the solution term. Furthermore, the review identified that this patient was particularly large: (1.93 meters tall, weighing 112Kg). BMI was selected as the basis of the fuzzy set “Obese Patient” because objective standards existed against which to calibrate it, whereas they did not exist for body weight alone. A consequence of this decision would be that such a patient would receive a relatively low membership score of the set “Obese Patient”, but

their weight could still present a considerable sedation challenge. As such, this review not only confirmed that Case 60 presents no contradiction to the solution, but also supported the hypothesis that body mass presents a challenge to the sedationist.

Figure 6.22: FsQCA Analysis of Drugs Administered, “Obese Patient” and “Young Patient”

a: Quine-McCluskey Algorithm

File: C:/Users/stuar/Desktop/FinalData.csv
 Model: PositiveExp = f(FzFentanyl, FzMidazolam, FzParacetamol, YoungPatient, ObesePatient)
 Algorithm: Quine-McCluskey

--- PARSIMONIOUS SOLUTION ---
 frequency cutoff: 1
 consistency cutoff: 0.865169

	raw coverage	unique coverage	consistency
FzFentanyl	0.300311	0.177076	0.895789
FzParacetamol*~YoungPatient*~ObesePatient	0.357023	0.116057	0.872005
FzMidazolam*FzParacetamol*~YoungPatient	0.295047	0.0892559	0.866479
solution coverage: 0.625748			
solution consistency: 0.853738			

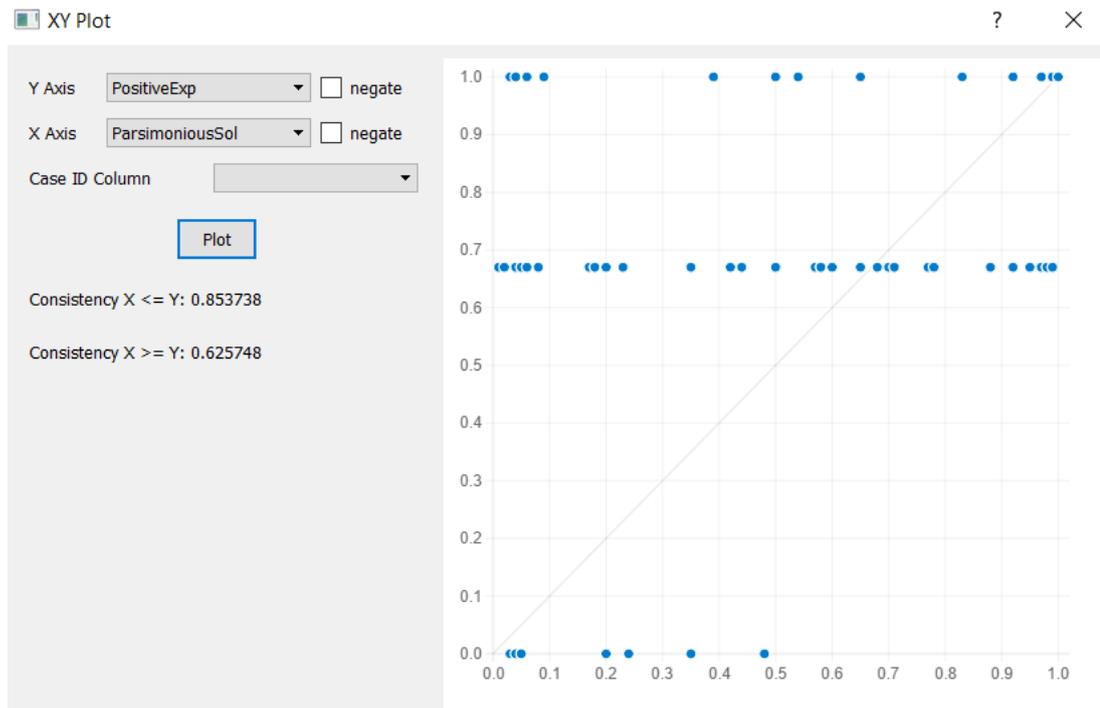
 TRUTH TABLE ANALYSIS

File: C:/Users/stuar/Desktop/FinalData.csv
 Model: PositiveExp = f(FzFentanyl, FzMidazolam, FzParacetamol, YoungPatient, ObesePatient)
 Algorithm: Quine-McCluskey

--- INTERMEDIATE SOLUTION ---
 frequency cutoff: 1
 consistency cutoff: 0.865169
 Assumptions:

	raw coverage	unique coverage	consistency
FzFentanyl*~FzMidazolam*~YoungPatient*~ObesePatient	0.203637	0.102417	0.907249
FzFentanyl*~FzMidazolam*FzParacetamol*~YoungPatient	0.120842	0.0184255	0.879791
~FzFentanyl*FzMidazolam*FzParacetamol*~YoungPatient	0.2905	0.161522	0.891991
FzFentanyl*FzMidazolam*FzParacetamol*YoungPatient*~ObesePatient	0.0337401	0.0167505	0.892405
~FzMidazolam*FzParacetamol*~YoungPatient*~ObesePatient	0.242163	0.0815986	0.881533
solution coverage: 0.548218			
solution consistency: 0.871103			

b: XY Plot Demonstrating Consistency of Solution



While the still-limited coverage of this solution is evident from the scatter plot, this plot does not do full justice to the coverage of the solution. This is because several cases above the point of ambiguity share identical scores on both axes and are subsequently represented by a single dot; for example, (0.97, 1) represents 3 cases; (0.77,0.67) represents 4. It should also be noted at this point that no assumptions have been made about logical remainders; consequentially, the intermediate solution is the same as the complex solution. In this analysis, there were 17 possible causal configurations containing no cases (Figure 6.23): this makes handling of them considerably more complex than the single logical remainder configuration when using drugs alone.

FsQCA software allows the research to include assumptions regarding the influence of each casual condition in line with the principle of directional expectation (Schneider and Wagemann, 2012). Both theoretical knowledge (JFC, 2021) and empirical evidence thus far (Figures 6.22, 6.29) suggested that all 3 drugs contribute to a positive experience. Conversely, both the Kruskal-Wallis, and the existing solution terms (Figure 6.20) indicated that high body mass index was an obstacle to positive experience. It was harder to make assumptions about the action of relative youth; some empirical evidence suggested it was another obstacle (Figure 6.23); however, membership of the set “Young Patient” was also included in an intermediate solution pathway (Figure 6.22a). Furthermore, no theory was found at this point that suggested why relative youth should be an obstacle. Considering the first row in Figure 6.23, it could be confidently asserted that this combination would result in a positive experience: all factors contributing to a positive experience (drugs) are present while neither of the potential obstacles are. However, a conclusion is harder to reach regarding the third row: again, all drugs are used, but both obstacles are present. The truth table algorithm was therefore repeated (Figure 6.24), this time including directional expectations regarding all drugs and obesity. No assumptions were included regarding the influence of age; though it was suspected youth was an obstacle, insufficient evidence existed to support this counterfactual claim.

Figure 6.23: Logical Remainders in Truth Table Algorithm

FzFentanyl	FzMidazolam	FzParacetamol	YoungPatient	ObesePatient	number	PositiveExp	raw consist.	PRI consist.	SYM consist
1	1	1	0	0	0				
1	1	1	0	1	0				
1	1	1	1	1	0				
1	1	0	0	0	0				
1	1	0	1	0	0				
1	1	0	0	1	0				
1	1	0	1	1	0				
1	0	1	1	0	0				
1	0	1	1	1	0				
1	0	0	1	0	0				
1	0	0	0	1	0				
1	0	0	1	1	0				
0	1	1	1	1	0				
0	1	0	1	0	0				
0	0	1	1	1	0				
0	0	0	1	0	0				
0	0	0	1	1	0				

Figure 6.24: Quine-McCluskey Algorithm Including Counterfactual Assumptions

```

--- PARSIMONIOUS SOLUTION ---
frequency cutoff: 1
consistency cutoff: 0.865169

                                raw      unique
                                coverage  coverage  consistency
                                -----  -----  -----
FzFentanyl                      0.300311   0.177076   0.895789
~YoungPatient*~ObesePatient*FzParacetamol  0.357023   0.116057   0.872005
FzMidazolam*~YoungPatient*FzParacetamol    0.295047   0.0892559  0.866479
solution coverage: 0.625748
solution consistency: 0.853738

*****
*TRUTH TABLE ANALYSIS*
*****

File: C:/Users/stuar/Desktop/FinalDataBackUp.csv
Model: PositiveExp = f(FzFentanyl, FzMidazolam, YoungPatient, ObesePatient, FzParacetamol)
Algorithm: Quine-McCluskey

--- INTERMEDIATE SOLUTION ---
frequency cutoff: 1
consistency cutoff: 0.865169
Assumptions:
FzFentanyl (present)
FzMidazolam (present)
~ObesePatient (absent)
FzParacetamol (present)

                                raw      unique
                                coverage  coverage  consistency
                                -----  -----  -----
FzFentanyl*~YoungPatient*~ObesePatient    0.250539   0.129696   0.92328
~YoungPatient*~ObesePatient*FzParacetamol  0.357023   0.116056   0.872005
FzFentanyl*~YoungPatient*FzParacetamol    0.141661   0.0184255  0.890226
FzMidazolam*~YoungPatient*FzParacetamol    0.295047   0.0892559  0.866479
FzFentanyl*FzMidazolam*~ObesePatient*FzParacetamol  0.100024   0.0167504  0.96092
solution coverage: 0.613544
solution consistency: 0.858674

```

This intermediate solution maintained near identical coverage and consistency values as the parsimonious solution. Were fsQCA to form the final stage of analysis in this project, the 5 pathways of the intermediate solution would be the endpoint: 5 different combinations of factors that always resulted in a positive or mostly positive outcomes. As it was being used here as an exploratory phase prior to the case study phase, the simpler parsimonious solution could be used in further analysis.

Next it was considered how many causal conditions could be added to the process while maintaining confidence in the derived solutions, given the total number of 62 cases. Responding to the criticism that QCA can identify patterns in random data, Marx (2010) found that this did indeed happen if the number of causal conditions was high in relation to the number of cases. Marx demonstrates that crisp set QCA (csQCA) was capable of identifying logical contradictions in random data for 50 when using up to 8 causal conditions on 50 cases. Marx argues that identification of these contradictions indicates that csQCA can distinguish between random data and pre-existing patterns, but that such lessons are not necessarily transferable to fsQCA. However, his findings give some assurance that the use of 5 causal condition is not excessive in a study with 62 cases. A sixth condition might also be possible, but some consideration was given to the implication of doing so.

Marx, Rihoux and Ragin (2014) restate the fact that the number of truth table rows, or possible combinations of causal conditions, will always be 2^K with K being the number of causal conditions. With 5 causal conditions, this means 32 combinations; for 6 it would be 64: more than the number of cases. As this number of combinations increase, they argue that solution terms become increasingly descriptive of individual cases as analytic reduction becomes impossible. This in turn defeats the intention of using fsQCA to develop theoretical propositions for exploring during the case study phase. Furthermore, it has long been acknowledged in social sciences that a trade-off exists between generality, simplicity and accuracy, with Thorngate (1976) arguing that any theory will compromise one dimension in favour of the other two. Including a sixth causal condition was trialled; however, minimal increases in consistency and coverage were achieved by doing so, meaning only a small increase in accuracy. However, the solution terms became considerably more complex, with up to 8

pathways to a satisfactory experience being described. Some of these included all 6 casual conditions and described only a single case. As such, including a 6th condition was considered to cross the limit of the value of fsQCA as an analytic tool with this data.

6.5.3 Robustness of Procedure.

Some limitations on the combination of HCA and fsQCA in this study should be acknowledged which, in turn, impact on the consistency and coverage values obtained. First is the grouping of midrange cases (Type B) into a single cluster rather than 2. Some variation between cases in this cluster did exist, yet during fsQCA they were all allocated the same score, 0.67, for membership of the group "Positive Patient Experience". Though this was justified, it did consequently accept some loss of fuzziness. Higher coverage and consistency could have been obtained if the HCA process were able to identify more clusters with meaningful differences between them. Second, it has been acknowledged that the fuzzy value allocated to these Type B cases, 0.67, was itself somewhat arbitrary, though based on the justifiable conclusion that Type B were more closely related to Type A than Type C cases. However, 0.75 was also considered. Selection of 0.75 resulted in increased coverage but reduced consistency; Schneider and Wagemann (2012) note that fsQCA should not be an exercise in maximising these values, rather it should focus on understanding the cases under study. As the actual solution terms generated by using the 0.75 value were identical to those when using 0.67, seeking the fuzzy value that maximised coverage and consistency did not appear a profitable exercise in aiding understanding of these cases.

Finally, it should be recalled that some uncertainty existed regarding to which cluster certain 4 cases should be allocated by the HCA algorithm (Figure 6.12). These were cases 15, 17, 46 and 57. The alternative classification process, using rescaled pain frequency, classified each of these cases to Cluster B, which would have resulted in a membership score of 0.67 of the set "Positive Patient Experience". Importantly, reallocating any case to a fuzzy value of 0.67 cannot lead to the formation of a true logical contradiction of the solution terms in this study. It should be noted that reallocating the most controversial case, 15, to Cluster B would result in a slight reduction in solution coverage, and that reducing case 46 to Cluster B would marginally reduce the consistency of the

solution terms. However, the solutions themselves would not be challenged and, as has previously been argued, minor differences in figures are of less importance than an understanding of cases.

6.5.4 Tests of Sufficiency for Negative Experience.

Although the priority of this study was to identify factors leading to the success of NDP_{PSA}, consideration was also given to whether a specific case-type consistently resulted in negative experiences, for which NDP_{PSA} should not be considered. Because fsQCA allows for causal asymmetry, the answer to this question was not simply the logical inversion of the solutions for positive experience. Furthermore, to have practical utility, only factors that could be known in advance of the case could be considered in identification of unsuitable patients: drug doses could not be included as these were determined during the case, rather than in advance. Though smoking status, alcohol use and patient sex were considered in this process, their inclusion led to no remarkable pattern; indeed, the small number of cases with non-membership of “Positive Patient Experience” made it challenging to discern any combination with consistency values greater than 0.75, the minimum possible limit (Schneider and Wagemann, 2012). Despite this, one combination provided much higher consistency, and is therefore worthy of comment. A truth table analysis of three sets, “RFA”, “Obese Patient” and “Anxious Prior to the Procedure” revealed a combination of RFA*ObesePatient*AnxiousPatient which consistently result in a negative outcome (Figure 6.25a). On the scatter plot (Figure 6.25b), the set “Positive Patient Experience” has been negated. 3 of 8 negative experiences were described by this combination of factors (2 cases are represented by the dot at 0.72, 1). One true logical contradiction exists (0.51, 0.33); however, given that, unlike before, the vast majority of cases now have a fuzzy value of less than 0.5 in the set “~(Positive Patient Experience)”, this solution cannot be dismissed so confidently. For ethical reasons, this study could not pursue the determinants of a negative experience during the case study phase. However, some inferences will later be made that support the conclusion that the combination of obesity and anxiety makes PSA particularly challenging for the sedationist.

Figure 6.25: FsQCA of Sufficient Conditions for Negative Experience.

a: Quine-McCluskey Algorithm

--- PARSIMONIOUS SOLUTION ---
 frequency cutoff: 4
 consistency cutoff: 0.863711

	raw coverage	unique coverage	consistency
RFA*ObesePatient*AnxiousPatient	0.260267	0.260267	0.863711
solution coverage:	0.260267		
solution consistency:		0.863711	

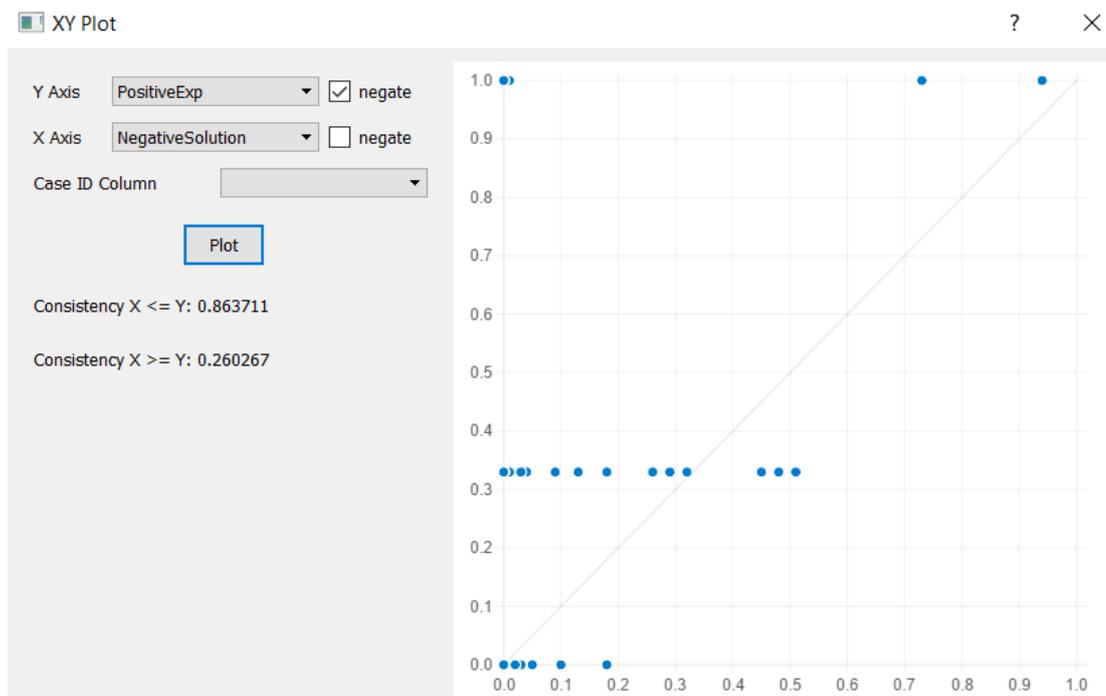
 TRUTH TABLE ANALYSIS

File: C:/Users/stuar/Desktop/FinalDataBackUp.csv
 Model: ~PositiveExp = f(RFA, ObesePatient, AnxiousPatient)
 Algorithm: Quine-McCluskey

--- INTERMEDIATE SOLUTION ---
 frequency cutoff: 4
 consistency cutoff: 0.863711
 Assumptions:

	raw coverage	unique coverage	consistency
RFA*ObesePatient*AnxiousPatient	0.260267	0.260267	0.863711
solution coverage:	0.260267		
solution consistency:		0.863711	

b: XY Plot of Consistency of Solution



A final point of interest is this configuration's relationship with the pathways to a positive experience (Section 6.5.2), as potential exists for a case to be a member of both the solution for a negative experience, and at least one pathway for a positive experience. $\text{Paracetamol} * \sim \text{ObesePatient} * \sim \text{YoungPatient}$ is a contradiction of the solution: no case could be described by both this, and the formula for a negative solution. A second pathway, membership of FzFentanyl alone, is not a contradiction, although a relationship exists between obesity and membership of this set which makes this combination unlikely (pp.140-142). However, members of the set $\text{RFA} * \text{ObesePatient} * \text{AnxiousPatient}$ could also be members of $\sim \text{YoungPatient} * \text{FzMidazolam} * \text{FzParacetamol}$. Whether such a case would result in a positive or negative experience is a matter of speculation; this study contained no such case. As such, the limited diversity of the cases studied marks a limitation of this study.

This analysis has one important implication for the case study phase; while gaining ethical approval it was agreed that this study would not target patients who were anticipated to have a bad experience. Ethical approval required the researcher to inform potential participants *why* they were being asked to participate. The researcher conceded that asking an obese, anxious patient awaiting RFA to participate because of the expectation of their having a bad experience would exacerbate their anxiety and fulfil the prediction. Therefore, it was not considered ethically appropriate to include patients matching this description in the case study phase.

6.6 Dimensions to Investigate During Case Studies.

Parsimonious and intermediate solutions were identified as leading to a positive experience. Were this the only cycle of data collection in the study, only the intermediate solutions could be asserted with any confidence as the parsimonious solution made unsubstantiated counterfactual claims. However, as the survey analysis was always intended as an initial phase of data collection, the parsimonious solution did not need to be discarded. It could be used as a hypothetical model of contributing factors to a positive experience. As such, the counterfactual assumptions that it made could be tested by the case study, with new data used either to discredit or substantiate those assumptions.

6.6.1 The Contribution of the Sedationist.

Early in this study (p.20), it was identified that the efficacy of the NDPSA may depend on the practice of the individual practitioner applying it, with results not necessarily transferable to other CCLs. This has not been assumed; other factors have first been analysed to ascertain whether they explain variation in outcome. However, the best coverage value recorded was little more than 0.62, suggesting that at least one significant causal condition has been neglected. At this point, the identity of sedationist for each case was compared to set membership of “Positive Patient Experience” and the parsimonious and intermediate solution terms. Only nurses who had sedated 4 or more patients in this study were included; the patients of those who had sedated fewer, or of nurses who had not consented to be in the study, were allocated the code 999. The remaining 8 sedationist were allocated numbers 1 to 8 (Figure 6.25)

For each sedationist, the proportion of patients having a negative (Type C) experience was a minority. However, it was conspicuous that the patients of sedationists 1, 2, 4 and 8 contained no Type C cases at all. Statistically, the numbers of these cases were too small to prove any significant difference between practice. Furthermore, an element of chance must be acknowledged in the success of these sedationists: BMI and age have been identified as relevant factors, and the nurse has no control over these. However, all solution terms recognise the importance of medication, over which the sedationist did have control. These 4 individuals therefore represented suitable starting points to investigate the sedationist’s contribution to the success of NDPSA. Sedationists 1 and 2 were of particular interest: 8 of their 13 cases showed membership values of the solution terms of less than 0.5. While previously identified solution terms accounted for some of the success of these sedationists, they did not explain why these 8 cases produced positive experience. Their success also appeared to be despite uncontrollable factors such as BMI or age, rather than because of it. By contrast, the success of sedationists 4 and 8 came as little surprise: all their cases displayed membership of the solution terms greater than 0.5. While their decisions regarding administration of fentanyl, for example, were still of interest, some explanation of why these cases resulted in positive experience already existed. The same was not true for sedationists 1 and 2: to identify the

contribution made by individual sedationist, observing the practice of these two individuals seemed particularly important.

Figure 6.26 Table of Case Outcomes and Solution Set Membership by Sedationist.

SedID	PositiveExp	IntermediateSol	ParsimoniousSol
1	0.67	0.99	0.99
1	1	0.35	0.39
1	0.67	0.18	0.18
1	0.67	0.77	0.77
1	1	0.09	0.09
1	0.67	0.6	0.6
1	0.67	0.68	0.68
2	0.67	0.55	0.65
2	0.67	0.44	0.44
2	1	0.06	0.06
2	0.67	0	0.05
2	1	0.03	0.03
2	0.67	0.02	0.02
3	1	0.99	0.99
3	0.67	0.17	0.17
3	0	0.05	0.05
3	0.67	0.04	0.04
4	0.67	0.7	0.7
4	1	0.65	0.65
4	0.67	0.71	0.71
4	0.67	0.58	0.58
4	1	0.97	0.97

SedID	PositiveExp	IntermediateSol	ParsimoniousSol
5	1	0.97	0.97
5	0.67	0.42	0.42
5	0.67	0.92	0.92
5	0	0.08	0.2
5	0	0.35	0.35
5	1	0.97	0.97
5	0.67	0.04	0.04
6	1	1	1
6	0.67	0.08	0.08
6	0.67	0.97	0.97
6	1	0	0.04
7	1	0.86	0.92
7	0	0.24	0.24
7	0.67	0.23	0.23
7	1	0.03	0.03
7	0	0	0.03
8	0.67	0.92	0.92
8	0.67	0.5	0.78
8	1	0.54	0.54
8	0.67	0.97	0.97
8	0.67	0.95	0.95
8	0.67	0.77	0.77

6.6.2 The Contribution of Prior Anxiety.

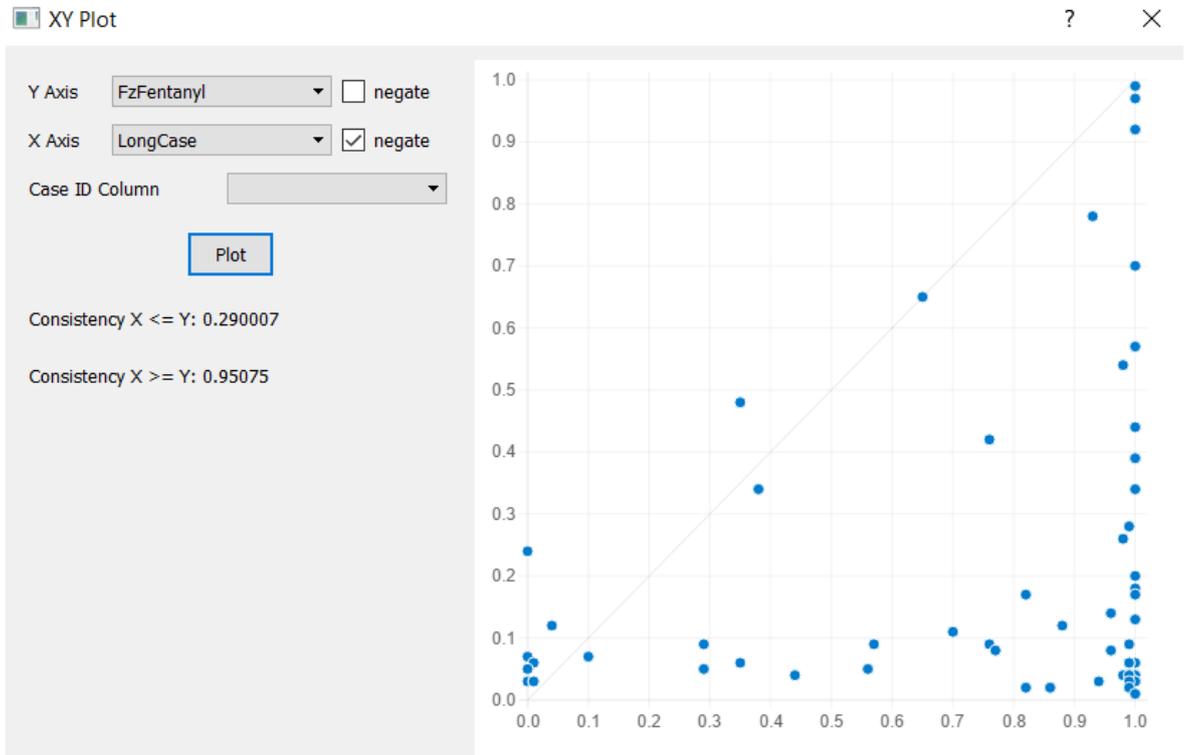
Pre-existing anxiety was not included in the solution terms for a positive experience. However, the median score of Type A cases was noticeably lower than other cases (Figure 6.15d). Including this parameter in fsQCA (p.126) also appeared to lead to increased coverage, although this inclusion also resulted in a logical contradiction. Ultimately fsQCA did not persist with using this causal condition because of concerns regarding the calibration of the set “Anxious Prior to the Procedure” (p.116), and it was considered that the significance of pre-existing anxiety could be better assessed during the case study phase. The incomplete coverage of both parsimonious and intermediate solutions indicated that at least one contributing factor was not captured by the solution terms, and pre-existing anxiety could partly account for this.

6.6.3 The Use of Fentanyl.

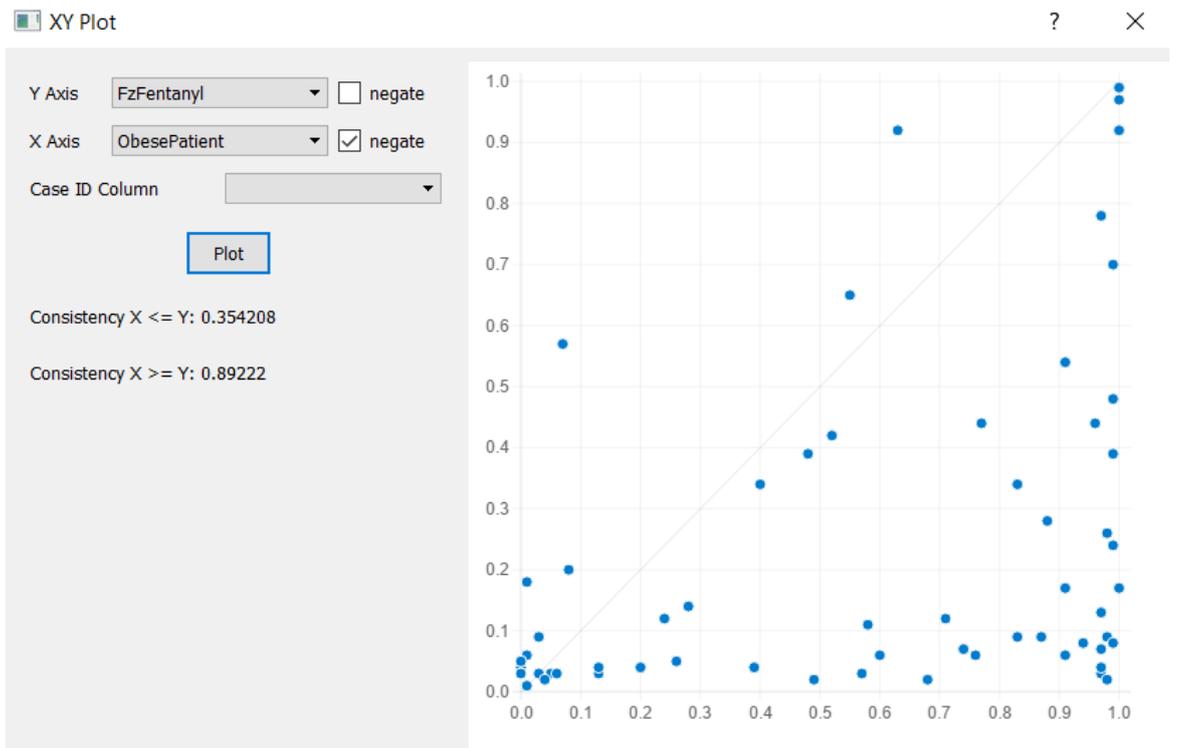
The parsimonious solution in this study identified that moderate analgesia with fentanyl, defined as more than 2 mcg/Kg/hr, was sufficient for a positive experience during AF ablation. The intermediate solution qualifies this in view of the large number of logical remainders relating to this condition. However, no patient receiving more than 2mcg/Kg/hr had a negative experience. The number of logical remainders was itself indicative that few patients received more than this threshold: 9 out of 62 patients. Indeed, the set “Moderate Analgesia with Fentanyl” was only used because the set “Heavy Analgesia with Fentanyl” would have excluded a further 7 of these. The analgesic property of fentanyl is widely known (JFC, 2021), and its efficacy in practice is supported by this study. It was therefore queried why so few patients received even moderate doses? The data itself suggested one explanation. Plotting membership of the set “Moderate Analgesia with Fentanyl” against inverted membership of “Long Procedure” (i.e. a short procedure) reveals that only short cases received more than 2mcg/Kg/hr (Figure 6.27a).

Figure 6.27 XY Plots of “Moderate Analgesia with Fentanyl” against “Short Procedure” and “Not Obese Patient”

a: XY Plot against “Short Procedure”



b: XY Plot against “Not Obese Patient”



As such, a short case can be considered a necessary condition for moderate analgesia with fentanyl (consistency 0.95). This study discussed whether fentanyl dose is best analysed in terms of cumulative dose (i.e. micrograms) or in terms of micrograms/Kilogram/hour. While the latter was used in this study, it was possible that the nurses utilising the NDPSA protocol consider only the cumulative dose. If true, a similar relationship would be expected when replacing “not Long Case” with “not Obese” (Figure 6.27b). The same pattern was roughly discernible: 8 of the 9 cases receiving moderate analgesia are in the top right quadrant. An exception did occur (0.07, 0.57); however, this was insufficient to disprove the supposition that nurses administered fentanyl in terms of micrograms rather than mcg/Kg/hr: a single nurse who conceives of fentanyl dosage in terms of mcg/Kg/hr could account for this. Such a conclusion cannot be drawn from this data alone. Moderate analgesia with fentanyl may be sufficient for membership of “Positive Patient Experience”, but it is not necessary: 13 Type A cases did not receive more than the 2mcg/Kg/hr threshold. It may be that sedationists understand the need to adjust fentanyl dose according to duration and body weight, yet favour alternative strategies to managing intra-procedural pain. It was there necessary to identify how sedationists utilise fentanyl, alongside other strategies for managing the patient’s experience.

Chapter 7: Case Study Development

7.1 Introduction

The previous chapter provided parsimonious and intermediate models of factors leading to the positive experience of patients undergoing AF ablation using NDPSA. The parsimonious solution included some counterfactual assumptions which the researcher would be reluctant make if this were the endpoint of the evaluation. However, the researcher does not commit to these assumptions when using the parsimonious solution for further investigation, and the relative simplicity of the 3-pathway parsimonious solution over the 5-pathway intermediate solution made it a more practical alternative for ongoing study. Thus, the parsimonious solution was used as the basis of the case study phase:

1. Patient Received Moderate Analgesia Using Fentanyl

OR

2. Patient Received 1G Intravenous Paracetamol AND (not a young patient) AND (not an obese patient).

OR

3. Patient Received Heavy Sedation Using Midazolam AND Patient Received 1G Intravenous Paracetamol AND (not a young patient).

Solution Coverage 0.625748

Solution Consistency: 0.853738

This chapter starts by considering the extent to which this model meets the aims of this project. This examines the model in relation to the philosophical position taken in the methodology, and the extent to which this model predicts an optimal patient experience. By doing this, it will confirm the need for the case study phase, and also specify questions for it. In turn, these questions identify process tracing as the form of case study best suited to answering many of these questions. This identification requires some discussion of existing explanatory theories as both a guide to data collection, and to analyse the data collected. This is therefore be done before details of the case study protocol are explained.

7.2 Issues outstanding from survey analysis.

This project aimed to critically evaluate the practice of NDPSA within this Trust, to identify the conditions under which NDPSA is most effective and to appraise

the contribution that the individual sedationist makes to effective NDPSA. In terms of meeting these outcomes, the model created thus far was insufficient for the following reasons.

7.2.1 Limitations of method.

Regarding identification of conditions under which NDPSA is effective, some success can be claimed. However, the classification of patient experience was largely determined by retrospective report by the patient. The model can therefore be criticised as identifying the determinants of a positive report, rather than a positive experience. The difference significant ethically (Davidson, 2014), but practically too, as an agitated patient may complicate a case (Servatius *et al.*, 2016). When considering theoretical mechanisms by which identified causal conditions may lead to a positive outcome, some supported the suggestion that this model predicts positive report rather than experience. These mechanisms will be detailed in Section 7.4. The model therefore requires validation to substantiate its claim to represent the determinants of a positive experience, rather than just a positive report.

7.2.2 Philosophical considerations.

This thesis embraced critical realism as a philosophical basis for mixed methods research. As such, it conceives of causation as generative (Schiller, 2016), and the purpose of empirical research as the identification of causal links in the real domain (Bhaskar, 2008). Answering such questions is more than philosophical dogmatism: by identifying “*why* a program works for *whom* and in *what* circumstances” (Pawson and Tilley, 1997, xvi), recommendations for improving practice can be made. Beach (2016) states that, like regression analysis, QCA relies on cross-case association to infer causation. Inference from association does not explain the causal mechanisms in action: the fsQCA model was therefore insufficient to meet this aim. It was not, however, necessary to explore every possible causal mechanism at work in the fsQCA model. For example, the first pathway identified “Patient Received Moderate Analgesia Using Fentanyl” as sufficient for a positive experience. The context of a higher dose of fentanyl led to the closure of *the gate*, preventing transmission of pain signals. It was not within the scope of this research to challenge or reaffirm the understanding that opiates acted by binding to opiate receptors and inhibiting the passage of

neurotransmitters (Rang *et al.*, 2012). However, the GCT (Melzack and Wall 1965) postulates that other contexts may also close *the gate* to noxious stimuli, and the contributions of contexts such as midazolam dose, age and low BMI were not yet explained.

The parsimonious solution included “not a Young Patient” in 2 of its 3 pathways. A configuration such as “Patient Received Heavy Sedation Using Midazolam AND Patient Received 1G Intravenous Paracetamol AND not a Young Patient” was logically challenging. Recalling the principle of causal asymmetry (Schneider and Wagemann, 2012) this did not mean that there was some aspect of youth that prevented younger patients having positive experiences. A young patient receiving heavy sedation using midazolam and 1G paracetamol *could* have a positive experience without falsifying this pathway. Rather, the calibration of the set “Young Patient” (pp.115-6) meant that non-members are necessarily older patients. This led to the subtlety different question of how aging contributed to a positive experience. However, it was also possible that aging encompassed more than one relevant context or mechanism. It was also necessary to identify these to meet the aims of this project. It was also necessary to explain the mechanism by which “not an Obese Patient” and “Received Heavy Sedation Using Midazolam” contribute to case outcome. The reason why the pharmacodynamic effect of midazolam could not be assumed in the same way the analgesic mechanisms of paracetamol and fentanyl could is discussed in section 7.4.2.

7.2.3 Missing Factors

The parsimonious solution had a modest coverage of 0.625748, indicating that a substantial number of positive reports of experience were not described by it. This coverage did not increase with the inclusion of more potential causal conditions. It was concluded that an important causal factor was not covered by the fsQCA. As such, the model could only be seen as partially meeting the aim of identifying conditions under which NDPSA is effective. Identification of missing factors, and their contribution to effective NDPSA was therefore a priority for the case study phase. Possible missing factors were previously identified in Section 6.6, and need not be listed again here. However, the critical realist must acknowledge the possibility of a previously unsuspected mechanism at work, whose existence might be inferred through empirical data, or may remain beyond the scope of identification (Section 5.2.1). The case study phase therefore

needed to allow for the emergence of other contexts or mechanisms which contributed to the successful outcome of individual cases.

7.2.4 Optimisation

Aim 2 was to identify the conditions under which NDPSA is most effective. During the classification process, Type B cases were considered to represent “mostly positive” experiences due to their relative similarity to optimal Type A cases (pp.116-117). However, important differences between Type A and B cases did exist, specifically in terms of reported pain (Figure 6.10). The fsQCA model can therefore be criticised as identifying conditions under which NDPSA is effective, but not *most* effective. Furthermore, no individual path led exclusively to Type A outcomes. In exploring cases described by the fsQCA terms, it was therefore important to explain why some cases result in optimal reports, while others led to only to mostly positive outcomes. It was possible that the exploration of missing factors discussed above would identify this determining condition. However, it was imperative that the case study phase distinguished between mostly positive outcomes and optimal outcomes.

7.3 The Suitability of Case Study.

The suitability of case studies for further investigation, anticipated in the methodology (pp.63-65), could now be confirmed. Their use was justified by the form of question (Yin, 2014, p.10), with “how” and “why” questions regarded as particularly suitable. Many of the questions identified in the previous section fit this form: specifically, how did identified conditions contribute to a successful outcome and, how, in conjunction did they cause outcomes to occur? How individual nurses utilise the NDPSA protocol was also of interest, although how this contributes to success has not yet been established. George and Bennett (2005, p.19) express the suitability of this type of question in realist terms when they assert that case studies are “a useful means to closely examine the hypothesized role of causal mechanisms in the context of individual cases”. Though this study does not consider itself a piece of realist evaluation, the suitability for identifying generative causation is clear. George and Bennett (2005, p.6) name the method of case data analysis they describe “process tracing”.

7.3.1 Process Tracing.

Process tracing was identified as the most suitable primary means of data analysis for the case study phase as it conceives of causation in critical realist terms (Mahoney, 2012), and explanation in terms of contexts and mechanisms (George and Bennett, 2005; Reilly, 2010; Beach, 2016; Trampusch and Palier, 2016). Schneider and Rohlfing (2013) identify it as being a particularly useful complement to QCA as it can identify mechanisms underpinning set-relational patterns. Further advantages were that it emphasises the importance of pre-existing theory: Punton and Welle (2015) conceive of mechanisms as theories of why cause leads to effect. George and Bennett's above understanding therefore tests these theories, thus allowing for what Yin (2014, p.40) names "analytic generalization". This was essential; as previously noted (Section 5.5.2), what worked in a single isolated case was of little use in evaluating a protocol which aims at generalization of practice to many cases. Furthermore, process tracing is a relatively formalised approach to case data analysis, which proved useful in terms of guidance. However, this means that some explanation of the analysis method is needed prior to the design of the case study.

The number of steps involved in process tracing varies between authors; however, all agree that it begins with the definition of theoretical expectations (Reilly, 2010; Punton and Welle, 2015; Ricks and Liu, 2018): it is necessary to hypothesise how the casual condition identified by fsQCA model might lead to the outcome of a positive report of experience. Furthermore, Reilly (2010) and Ricks and Liu (2018) advocate explication of plausible rival theories connecting causal conditions to outcomes; theory will determine the type of evidence collected (Ricks and Liu, 2018). Failure to consider plausible rival explanations could lead to the researcher only seeking data to confirm a hypothesis, and to justifiable accusations of bias (Yin, 2014). Reilly (2010) then instructs the researcher to set criteria for causal and outcome conditions: however, as it is being used as a complimentary method to QCA, this has already been done during the calibration process.

Reilly (2010), Punton and Welle (2015), and Ricks and Liu (2018) concur that the next step is to detail what the researcher would expect to observe or measure if each of the specified theories were true. At this point some divergence is conspicuous in the literature: Beach's (2016) understanding of mechanisms

requires the researcher to describe them in the smallest possible observable parts, in order to most rigorously test for their occurrence. He contrasts this approach to those stressing the importance of the sequence of events, arguing that this approach fails to open the “black box” (ibid, p.464) of causation. Philosophically, this researcher concurs with Beach; however, in this study, explication of causal mechanisms will demonstrate that significant variations in sequences of events will occur, depending upon which causal mechanism is in action. Furthermore, this thesis has previously accepted some links in the casual chain, such as the cellular effect of fentanyl and the mechanism on *the gate* (pp.44); it is not necessary or possible for this study to further explore these on pharmacodynamic or neurological level. Therefore, process tracing in this study “takes time seriously” (Trampusch and Palier, 2016, p.439) and infers the causal mechanisms in action from the sequence of events.

The next step is for researcher to identify the types of data that could be collected, and would be useful to distinguish between rival theories; Punton and Welle (2015) includes this in the previous step, while Ricks and Liu (2018) conceive of it as a separate stage. For reasons of validity, reliability, and rigour that will become apparent (pp.163-164), this study took the latter approach. The identified datatypes then formed the basis of the case study protocol. Data is then collected in accordance with this design (Punton and Welle, 2015). Analysis then takes the form of comparing the actual unfolding of events compared to theories of how each mechanism might connect cause to outcome (Reilly, 2010; Beach, 2016).

Following analysis, the significance of the outcome is determined via means of one of 4 possible logical tests: the “straw-in-the-wind test”, “smoking gun test”, “hoop test” or the “doubly decisive test” (Collier, 2017, p.825). The last two include the process of falsifying a hypothesis should the theorised mechanism fail to activate. However, based on the previously made allowance for causal complexity and equifinality (p.62), failure of the mechanism to activate cannot disprove a theory. Critical realism allows for the possibility that unknown mechanisms or contexts might confound a mechanism which, in other circumstances, would activate. Neither can the observation of a hypothesised mechanism in action, a “smoking gun test” (Collier, 2017, p.825), lead to the conclusion that the same mechanism activates in every case with the same

configuration of causal conditions: it merely confirms its relevance. Instead, the researcher must rely upon the “straw in the wind test”: a theoretical explanation of how a cause leads to an outcome is strengthened if the hypothesised mechanism is observed, and weakened if it is not (Collier 2017, p.825). Collier (2017) considers this the weakest of the 4 tests; while Mahoney (2012) concurs with this, he adds that multiple straw in the wind tests can generate a high level of confidence in their inferential validity. By confirming a theory via multiple episodes of corroboration, this approach allows the analytic generalisation described by Yin (2014). For this reason, and because causal processes linking more than one casual conditions to outcomes needed to be observed, multiple case studies were required.

Although process tracing appeared a good fit for the aims of the case study phase, it presented some problems too. The first related to case selection; George and Bennett (2005) conceive of process tracing as an historical method, further exploring cases in which causal conditions and outcome are already known. Schneider and Rohlfing (2013) also conceive of process tracing as a retrospective study of cases already included in a QCA model. Additionally, Beach (2018) argues that cases should be selected that isolate a specific causal configuration, by which it is understood only one pathway of the fsQCA model is described. Selection of specific cases to explore specific causal mechanisms was not possible in this study; the depth of data required for retrospective processing tracing was not collected during the QCA phase, and the configuration of causal conditions in individual cases regarding drug doses could not be known in advance. Nor could a predetermined configuration of conditions be contrived: this would require a specific set of instructions to be given to the sedationist which, in turn, would compromise any explanation of their contribution. Instead, this study anticipated cases which were likely to allow the exploration of the hypothesised causal mechanisms. Further detail will be given in the case study design.

A second problem is highlighted by Beach (2018); he argues that process tracing following QCA should focus on the mechanics of how conjunctions of causal conditions combine to produce an outcome if it is to share the ontological assumption of QCA. This begs the question of whether identified causal conditions act as independent factors pushing in the same direction, or that some are “scope conditions” (Beach 2018, p.65) which allow the triggering of a causal

mechanism. However, Beach also adds that it is extremely difficult to avoid theorising about causal conditions as isolated influences that contribute to the outcome.

Theorising how identified casual conditions might contribute individually was the necessary starting point for this exploration. However, by using multiple cases, it was intended to observe individual causal conditions in conjunction with other conditions which result in sufficiency for a positive outcome, and also in isolation from these conditions. By doing so, it was intended to identify whether these factors did indeed act in conjunction, or independently of each other to contribute to sufficiency.

A final problem for process tracing is its dependence on theory, which has already been identified as its starting point (Reilly, 2010; Punton and Welle, 2015; Ricks and Liu, 2018). For some questions of interest, such as the contribution of the individual sedationist, there were a multitude of ways in which practice might vary: case knowledge, confidence with drugs, timing of administration, safety concerns, rapport with patient, communication with multidisciplinary team and distractions during cases might all be relevant. However, to plot what would be observed if each, or each combination, were true was unrealistic. Furthermore, with a small number of cases, it would lead to a weak process tracing conclusion: with so many possible theoretical explanations, it was unlikely that the result of one “straw in the wind” test would be corroborated by another case in the way described by Mahoney (2012). While the plotting of case timelines could offer some insight into how individuals use the NDSAP, for example in terms of timing of medication, any contribution they made to effective sedation could be better explored via thematic analysis, thus allowing for themes to emerge, rather than identifying what these themes might be in advance, as process tracing requires.

7.4 Theoretical Explanations

Process tracing begins with identification of how casual conditions might lead to the outcome. The pharmacodynamic actions of paracetamol and fentanyl were not explored as these are already understood (Rang *et al.*, 2012). However, the same was not true of midazolam, and age, anxiety and obesity could contribute

in different ways to the positive report of experience. The theoretical explanations for these contributions will now be explored.

7.4.1 The Role of Age.

Reported pain was a major factor in determining which to which outcome cluster each patient's case belonged. Rival theories exist as to how age exerts its influence over reported pain. While patient self-report has been accepted as proof of pain, this assumed that a patient will always report pain when it is present (p.42). However, it is possible that, in the language of fsQCA, an asymmetrical relationship exists between pain and its report: a report of pain always indicates an experience of pain, but an experience of pain does not necessarily cause a report of pain. This is important, not only because critical realism seeks to identify causal processes, but because reducing the experience of pain is ethically and practically more desirable than reducing the report of pain.

A body of literature maintains that older patients are less likely to report pain than their younger counterparts. An overarching reason for this was the prevalence of stoic attitudes towards pain in older age groups (Ross *et al.*, 2001; Yong, 2005; Schofield, 2006; Gammon and Caswell, 2014, Mah *et al.*, 2018). Several reasons for stoic attitudes were recognised by these studies, including maintaining a sense of control over pain (Gammon and Caswell, 2014) and, conversely, a sense of increasing dependence by admitting pain (Schofield, 2006). Also recognised were beliefs that nothing could be done about pain (Schofield, 2006), an acceptance that pain was an inevitable aspect of aging (Ross *et al.*, 2001; Gammon and Caswell, 2014), the desire to be a good patient (Chatwin, Closs and Bennett, 2009) and reluctance to use pharmacological interventions (Ross *et al.*, 2001; Schofield, 2006).

Despite these reasons, both Mah *et al.* (2018) and Gammon and Caswell (2014) noted that older patients demonstrated no greater stoicism in the face of cancer-related pain than their younger counterparts. This may be because cancer pain has an organic root, and admission of pain is therefore socially acceptable (Cornally and McCarthy, 2011, cited in Gammon and Caswell, 2014). As all these studies deal with chronic pain, the barrier of stoicism may not necessarily transfer to acute pain. Specific reasons, the belief that nothing can be done, or the social acceptability of admitting pain, may not apply to an acute environment such as

the CCL. However, articles focusing on acute pain make specific reference to stoicism as a barrier to pain reporting in that context (Hallingby et. al, 2011; Fitzgerald, Tripp and Halksworth-Smith, 2017), but present no data to support this. Furthermore, some sources have cited low expectations of staff as reasons for underreporting of pain, noting both a belief that staff will not be able to help (Schofield, 2006), or that negative staff attitudes lead to the ignoring of reports of pain (Gammon and Caswell, 2014). The latter is particularly concerning and behoves the researcher not to dismiss the possibility of unreported pain without due consideration.

An alternative explanation is that older patients report less pain because they experience less pain. While Yong (2006) reports that correlation between age and pain report is accounted for by varying attitudes of stoicism, this is using a single pain measure questionnaire. When using a second (the McGill Pain Questionnaire) stoic attitudes did not mitigate the reports of pain, and age remained an independent factor. It is possible that physiological changes account for differing experience of pain in older age groups (Somes *et al.*, 2011; Daoust *et al.*, 2016; Lautenbacher *et al.*, 2017) and, subsequently, lower report of pain. In a meta-analysis of 31 studies, Lautenbacher *et al.* (2017) noted that older patients, defined as over the age of 60, displayed higher pain thresholds than their younger counterparts, and the authors hypothesise that this may be the result of pain senses dulling in old age in a similar manner to sight and hearing. With such a large number of studies, they do not detail the methods used to collect data regarding pain experience in each one. This is significant because it makes it impossible to determine whether these studies distinguished between pain experienced and pain reported. Should these studies rely on self-report, the argument can be made that stoical attitudes could account for these differences as convincingly as physiological change. However, in a study not included in the meta-analysis, Daoust *et al.* (2016) note that reported pain differed between age groups when experiencing visceral pain, with older groups reporting less, while no such difference existed between age groups when patients experienced extremity fracture or dislocation. This is particularly relevant as the pain of ablation has a visceral cause. Lautenbacher *et al.* (2017) cite 2 further studies that replicate a particularly pronounced gap in recorded pain between age groups when pain has a visceral source. The reduced functioning of the nervous system

will therefore be considered as a rival mechanism to stoicism in explaining the role of age in the fsQCA model.

7.4.2 The Role of Midazolam

Pathway 3 included the term “Heavy Sedation with Midazolam”. Belonging to the family of benzodiazepines, midazolam shares this family’s ability to cause anxiolysis (Rang *et al.*, 2012). Significant differences between clusters based on peri-operative anxiety were seen during cluster testing (Figure 6.10d). Direct reduction of anxiety via anxiolysis can be seen as one explanation of how midazolam contributes to a positive outcome. However, another effect of these drugs is anterograde amnesia (Rang *et al.*, 2012). Therefore, the contribution of heavy sedation with midazolam was vulnerable to the same concerns as the contribution of aging: both could mask a poor experience behind a positive report. Amnesia should not substitute for analgesia (Davidson, 2014); furthermore, a patient who is relaxed during a case is clearly preferable from a practical perspective than patient who is agitated. It was therefore necessary to identify by which of these mechanisms a high dose of midazolam contributed to a positive report. It should be noted that midazolam could cause anxiolysis and amnesia simultaneously, and that some evidence suggests that some patients may see amnesia as desirable in its own right (Carbonell, 2014). Reports of memory loss would therefore be insufficient to infer that the patient actually had a negative experience. Amnesia in the presence of evidence of pain or agitation during the case would support the theory that midazolam contributed by the mechanism of amnesia.

7.4.3 The Role of Obesity.

Pathway 2 included the term “not an Obese Patient”. Of all causal factors, obesity came closest to being a statistically significant as a determinant of experience type (Figure 6.13), where it was associated with more negative experiences. This is contrary to theoretical explanations, as previous studies have linked obesity to higher pain tolerance (Price *et al.*, 2013; Torensma, 2017). Price *et al.* (2013) noted that this was only true of noxious stimuli applied to areas with excess fat, and that such differences did not exist when the stimuli were applied to non-fatty areas. Thus, they hypothesised that reduced sensitivity was due to decreased nerve fibre density due to the stretching of the skin. Such an explanation is

unlikely to have implications for this study as the ablation stimulus bypasses nerves in the skin.

As external theory proved unfruitful in providing explanations of the mechanism in action, attention returned to existing data: only one patient above the threshold of ambiguity for the set “Patient Received Moderate Analgesia Using Fentanyl” was also a member of the set “Obese Patient” (Figure 6.27a). The other 8 cases mostly in the set “moderate fentanyl”, were below the threshold for membership of “Obese Patient”, or full non-members of it. This suggested that patient’s BMI played some role in preventing therapeutic doses of fentanyl. Reasons could include sedationists’ knowledge of drugs: they might conceive of doses in terms of micrograms, rather than micrograms/Kilogram/hour, which meant they did not adjust the dose according to body mass. Alternatively, obesity might promote caution in the administration of sedatives and opioids that may, for example, compromise a patients’ airway (Adams and Murphy, 2000). Exploring these possible explanations may provide a basis for improving nurse performance and improving the experience of the obese patient.

Such exploration, however, would not provide insight into the contribution of non-obesity in Pathway 2. This pathway makes no reference to fentanyl or midazolam, yet all patients received some of both. It was therefore conceivable that effective sedation and analgesia was achievable for lighter patients while using lower doses of drugs that did not make these cases members of the fuzzy midazolam set. This was a plausible theory as the set “Heavy Sedation using Midazolam” was calibrated without reference to patient mass (as fentanyl was), because the JFC (2021) quantified doses in these terms (p.115). It could therefore be that members of this solution set achieved adequate sedation using less than 5mg of midazolam, which was the point of maximum ambiguity in the calibration of the midazolam set, a dose that would be insufficient for an obese patient.

7.4.4 The Role of Anxiety.

A link between preoperative anxiety and case outcome had not yet been established; however, some theorising regarding its possible contribution helped shape the case study. It was easy to suppose that greater preprocedural anxiety would lead to higher levels of anxiety during that procedure if unmanaged.

Heightened state anxiety has already been seen to increase experience of pain (Ploghaus *et al.*, 2001; Wise *et al.*, 2007). However, no clinical studies measuring the effects on preprocedural anxiety on perioperative pain were found. Sjöling *et al.* (2003) and Raichle *et al.* (2015) both studied the effects of preoperative state anxiety on postoperative pain following total knee arthroplasty and limb amputation respectively. Sjöling *et al.* (2003) conducted a trial in which some patients were given additional information prior to the procedure which resulted in reduced preoperative anxiety, and correlated with lower reports of pain on days following surgery. However, it could not be concluded that reduced preoperative anxiety directly reduced postoperative pain: information given included emphasising the patient's responsibility for asking for analgesia when required. Therefore, patients receiving this information may also have received more analgesia. Raichle *et al.* (2015) did not trial an intervention, relying instead on anxiety scores prior to limb amputation and pain scores for phantom limb pain (PLP) and residual limb pain after the operation. The correlation between preoperative anxiety and PLP remained even after adjustments for factors such as preoperative pain. Given this link between anxiety and pain, it was possible that higher preoperative anxiety could cause worse pain experience during the procedure.

A rival to this explanation, specific to AF ablation, does exist:

“while patients were not unduly anxious nor felt inadequately prepared at the time of consent, they subsequently found the procedure to be more unpleasant and more uncomfortable than expected” (Ezzat *et al.*, 2012, p.295)

They use this observation as an argument for promoting realistic expectations amongst patients, suggesting that naïve expectations regarding the comfort of ablation may lead to lower preoperative anxiety but, subsequently, a negative experience. This theory resonates with the researcher, as one survey-phase patient (Case 60), when submitting his survey, volunteered that his previous positive experience of AF ablation had led to his being unprepared for the painful (Type C) experience he had undergone that day. This patient had rated his anxiety as 1/10 prior to the procedure. There is, of course, some difference between fostering realistic expectations amongst patients and deliberately making them anxious. McCaffrey and Bebee (1994) suggest that anxiety does not make the experience of pain more intense, but does impact the individual's ability to cope with it. Evidence to support this assertion was cited in the literature

review in the work of Nørgaard, Pedersen and Bjerrum (2015) regarding visualisation techniques, which did not eliminate experience of pain but allowed patients to tolerate it. Also, Moore, Eccleston and Keogh (2013) suggest that interpreting manifestation of pain as evidence of catastrophe has a significant detrimental impact on individuals' abilities to cope with pain.

These arguments left four theories regarding the relationship between anxiety and patient experience. The first was that high preoperative anxiety would directly lead to a worse experience if not effectively managed, through both higher levels of in-case anxiety, and increased sensation of pain. The second was that heightened levels of anxiety would be recognised and treated by the sedationist, for example, via increased doses of midazolam. Third, naïve expectations of an entirely pain free procedure could lead to the patient catastrophizing when any pain occurs, leading to increased intra-case anxiety and worsening experience of pain. Finally, while realistic expectations of pain during a case might prompt moderate anxiety prior to the case, they might contribute to any experience of pain being interpreted as non-threatening, therefore increasing the patient's ability to cope and reduce their emotional response. If the theory that a moderate degree of anxiety prior to a procedure is beneficial, this could explain the contradictory results when including preoperative anxiety in the fsQCA analysis (p.126). FsQCA could not accommodate a condition which exerted greatest influence around its point of ambiguity, but little at the points of full membership and non-membership.

7.5 Case Expectations.

Next it was necessary to describe the expected observations if each explanation were true (Reilly, 2010; Punton and Welle, 2015; Ricks and Liu, 2018). This was challenging as it would be impossible to observe each causal condition in isolation from all others. However, when building on fsQCA, it is not desirable to do so: Beach (2018) has already argued that further analysis should focus on conjunctions of conditions. FsQCA identified conjunctions of interest; it was necessary to state what would be observed if the theories explored above were true or false in these conjunctions. Pathway 1, "Patient Received Moderate Analgesia Using Fentanyl" is not described below, as the mechanisms in this pathway were not under scrutiny here, "Matrix 1" does therefore not exist. As this study committed to taking time seriously (p.148), it was necessary to describe the

sequence of events that would be anticipated for Pathways 2 and 3 if each theory were true. For example, were the hypothesis that midazolam contributes to a positive report via the mechanism of amnesia true, it would be anticipated that the administration of a large dose of midazolam would be followed by observation of pain, but still followed by a positive report of the experience. All combinations would anticipate a positive report from the patient following the procedure; were this not so, the fsQCA model would be overturned.

7.5.1 Pathway 2

The analgesic mechanism of paracetamol was not scrutinised in the analysis of this pathway. This effectively left a 2x2 matrix of theories regarding how the other factors in this conjunction could function. As an alternative theory to adequate sedation using lower dose midazolam was not found, row 2 represents an unknown mechanism which may emerge. Anticipated timelines of events, were each combination of hypotheses to prove true, are given in Figure 7.1.

The range 3.5-5 mg of midazolam was selected as it covered doses between the lowest usual dose (p.114), and the point of ambiguity. This matrix could be an over-simplification of how cases would present, and some flexibility in analysis would be required. In this description, it was anticipated that a patient would receive 3.5mg or more midazolam at an early juncture because they were conspicuously anxious. This may not necessarily be true; an individual nurse might routinely give a large early dose of midazolam regardless of presentation; this would lead to the same hypothesised mechanisms being active. However, to explicate every single possible variation within this typology was impossible, so analysis must recognise slight variations within these types. Furthermore, it was unlikely that case features, such as pain and memory loss, would be as absolute and constant as this matrix suggests. A single, brief indication of pain in a case that goes unreported would be insufficient to argue that the patterns in Column A were being followed. However, multiple occasions of pain going unreported, or a single prolonged episode, would make stoicism a convincing explanation, particularly in the absence of other explanations, and if stoic attitudes were demonstrated. The patient's clarity of recollection could also vary within a single case; it was therefore important that any variation was recorded relative to any dose of midazolam received at that point.

Figure 7.1: Matrix 2

	A. Stoicism leads to older patients reporting pain	B. Reduced sensitivity leads to older patients experiencing less pain.
<p>1.</p> <p>Non-obese patients achieve adequate sedation using less than 5mg midazolam</p>	<p>Patient displaying or expressing anxiety prior to procedure</p> <p>Receives 3.5-5 mg midazolam prior to ablation.</p> <p>Evidence of pain (verbal or observed) during ablation.</p> <p>Positive report of experience.</p> <p>Expressions of stoic attitudes.</p> <p>Possible limited recollection of ablation following conclusion.</p>	<p>Patient displaying or expressing anxiety prior to procedure</p> <p>Receives 3.5-5 mg midazolam prior to ablation.</p> <p>Little evidence of pain during ablation.</p> <p>Positive report of experience.</p> <p>No indication of stoic attitudes.</p> <p>Possible limited recollection of ablation following conclusion.</p>
<p>2.</p> <p>Non-obesity contributes via another mechanism.</p>	<p>No evidence of anxiety prior to the case.</p> <p>Receives less than 3.5mg midazolam prior to ablation.</p> <p>Evidence of pain (verbal or observed) during ablation.</p> <p>Positive report of experience.</p> <p>Expressions of stoic attitudes</p> <p>Clear recollection of ablation following conclusion.</p>	<p>No evidence of anxiety prior to the case.</p> <p>Receives less than 3.5mg midazolam prior to ablation.</p> <p>Little evidence of pain during ablation.</p> <p>Positive report of experience.</p> <p>No indication of stoic attitudes.</p> <p>Clear recollection of ablation following conclusion.</p>

7.5.2 Pathway 3

Again, the role of paracetamol was not under investigation and, again, this allowed for a 2x2 matrix of how events would be expected to unfold depending on which theories were true (Figure 7.2). Many qualifications regarding Matrix 2, regarding anxiety, frequency of pain and of recollection, also applied to Matrix 3. More specifically, in this matrix, cases in the Cell 2B would be severely limited in their explanatory power of the role of midazolam; for it to be argued that amnesia masked the report of pain, it would be necessary for the patient to experience some pain, which this cell denies. However, the combination of factors is possible, so was included here.

A further problem could exist in drawing conclusions from cases in Cell 2A; it would be challenging to discern whether stoicism or amnesia accounted for a positive report despite the experience of pain during the case. However, as such a case features under-reported pain, it cannot be considered optimal. Therefore, identifying the exact mechanism in action in them was of lesser importance to addressing project aims. That said, cross-case comparison could also yield some insight into the mechanisms in action in Cell 2A. It could be possible to draw comparisons with cases in Cell 2A of Matrix 2: patients indicating stoic attitudes but who do not receive effective doses of midazolam. Differences in patients' reports of experience between cases from these different cells could be attributed to the role of midazolam. The intention was to partake in cross case analysis following individual analysis of each case, to ascertain whether the same mechanisms were always in action. Ultimately, this could allow the analytic generation of findings described by Yin (2014).

Figure 7.2: Matrix 3

	A. Stoicism leads to older patients reporting less pain.	B. Reduced sensitivity leads to older patients experiencing less pain.
<p>1.</p> <p>Midazolam contributes via anxiolysis</p>	<p>Patient displaying or expressing anxiety prior to procedure</p> <p>Receives midazolam</p> <p>Changes in patient behaviour indicate relaxation.</p> <p>Ablation performed; patient exhibit some evidence of pain, but appear to tolerate it well.</p> <p>Positive report of experience</p> <p>May express stoic attitudes.</p> <p>Patient may or may not recall the ablation.</p>	<p>Patient displaying or expressing anxiety prior to procedure</p> <p>Receives midazolam</p> <p>Changes in patient behaviour indicate relaxation.</p> <p>Ablation performed; little or no evidence of pain.</p> <p>Positive report of experience</p> <p>No expression of stoic attitudes</p> <p>Patient may or may not recall the procedure.</p>
<p>2.</p> <p>Midazolam contributes only through amnesia</p>	<p>Patient displaying or expressing anxiety prior to procedure</p> <p>Receives midazolam</p> <p>Little noticeable change in patient's anxiety or behaviour.</p> <p>Indications of pain during ablation, causing distress and agitation.</p> <p>Positive report of experience.</p> <p>May express stoic attitudes.</p> <p>No detailed recollection of ablation.</p>	<p>Patient displaying or expressing anxiety prior to procedure</p> <p>Receives midazolam</p> <p>Little noticeable change in patient's anxiety or behaviour.</p> <p>Ablation performed; little or no evidence of pain.</p> <p>Positive report of experience.</p> <p>No stoic attitudes expressed.</p> <p>No detailed recollection of ablation.</p>

7.6 Thematic Analysis

Well-developed theory was needed to allow process tracing to take place. When this was absent, alternative means of analysis were required. This became necessary when considering the contribution of the individual sedationist to the success of the case. At this point, this contribution remained speculative, despite the observation that certain sedationists consistently received positive reports from patients, whether each case was described by the solution term or not (Figure 6.26). A further question was posed by the thus-far neglected third pathway of the parsimonious solution: Patient Received Moderate Analgesia Using Fentanyl. That this should lead to a positive outcome was little surprise, given that pain was a crucial factor in determining the outcome clusters (Figure 6.10a, 6.10b). However, very few patients ($n=9$) received a dose of fentanyl that put them above the point of maximum ambiguity. Why, given this predictable link, did so few patients receive even a moderate dose? Speculative responses are that nurses were inhibited in doing so, either by caution regarding the use of such drugs, or by safety concerns caused by clinical observations recorded during the procedure. It should be noted that patient safety and experience had been treated as two detached aspects of NDPSA by this project thus far, but a link is possible, if maintenance of safety were to be at the expense of patient experience. Alternatively, moderate dose of fentanyl, in the language of fsQCA, was sufficient but not necessary to result in a positive outcome. It was therefore possible that nurses regard aggressive treatment with drugs as less important than, for example, establishing a therapeutic relationship with the patient.

These explanations are speculative, and not exhaustive; with so many possibilities, explication of how cases might unfold was impossible. Rather than relying on theoretical propositions, Yin (2014) suggests an alternative strategy of working data from the ground up. This, he states, can be particularly useful when combining quantitative data with qualitative data, as this section of the study may aim to do in combining data regarding doses and times, with accounts of the case. Thematic Analysis (TA) was identified as a suitable means of analysis due to its accessibility and flexibility (Braun and Clarke, 2012), and its utility in allowing cross-case synthesis to identify consistent, or disparate themes. It also had the advantage of not requiring detailed theoretical knowledge as do other qualitative approaches (Nowell *et al.*, 2017). By using TA, it was intended that

consistent patterns in use of the NDPSA protocol would be identified, along with any discrepancies that may distinguish between optimal and negative experiences of sedation.

The steps of TA are well-defined, consisting of familiarising oneself with the data, code generation, searching for, and reviewing potential themes, before naming and identifying themes (Braun and Clarke, 2012; Nowell *et al.*, 2017). Despite its apparent simplicity, Braun and Clarke (2006) advise the thematic analyst to clarify some key points before continuing. First, they state that it can be coherent with an essentialist or constructivist methods, but also with a contextualist method, which is coherent with the critical realist stance of this study.

Furthermore, they state that TA can be either inductive or deductive; here it is being used because it allows the inductive, rather than the theory-driven deductive approach. Finally, Braun and Clarke (2006) distinguish between TA that identifies themes at an explicit level, or a latent level. At this point, the former position was assumed: the study would interest itself with how sedationist account for their actions, as observed in each specific case.

7.7 Case Study Design

Having explicated how rival explanations would manifest themselves in cases, it was possible to specify specific data collection methods that would allow the differences between these unfolding explanations to be captured (Punton and Welle, 2015; Ricks and Liu, 2018). Yin (2014) stresses than use of multiple sources of evidence enhances the validity and reliability of a study. This was of particular importance here, not only for the reasons described by Yin, but also because of the possibility of disagreement: for example, observation of pain during ablation that subsequently goes unreported would support the theory of stoicism. Likewise, given Woodside's assertion (2010) that participants have limited access to their own mental processes, triangulation between observation and sedationist-report could reveal agreement or disagreement that could indicate the use of hypothetico-deductive or intuitive reasoning respectively.

7.7.1 Data Collection Methods.

It was possible to distinguish between some of the theoretical expectations of events through the occurrence or non-occurrence of features, such as pain, in the case, but also through the ordering of events: for example, a conspicuous change in a patient's level of anxiety shortly after a dose of midazolam would support the theory that midazolam was contributing through anxiolysis. Yin (2014) states that a strength of direct observation is that it allows capture of events in real time. This was imperative for process tracing to be effective. Therefore, the researcher needed to observe each case, and record the occurrence of case events, and the times at which they occurred. Furthermore, to explore nurses' rationales for specific actions, it was necessary to have a record of the patient's condition at close intervals throughout the case, in terms of pain and anxiety, but also in terms of safety as reflected by their clinical observations. Observations are recorded at least every 5 minutes during NDPSA; by documenting these recordings, along with an assessment of pain, and any observation regarding patient behaviour, the researcher could produce a record of the patient's changing condition over the course of the procedure.

Yin (2014) highlights potential problems with direct observation, specifically those of reflexivity and of selectivity. It was possible that the process of observing cases would change behaviours in the case; although the researcher sought to limit their obtrusiveness, their presence was necessary to collect data, and this was an unavoidable risk. In terms of selectivity, Yin (2014) identifies that broad coverage of events may be challenging for the lone researcher; by identifying specific aspects of cases of interest it was intended that process tracing could help avoid this problem. This meant that events of particular interest were the patient's behaviour on arrival in the CCL and during the case, timing of doses of medication, response to medication, timing of any noxious stimuli, evidence of pain, and interactions between the nurse and patient during the case, and clinical observations.

Identifying pain presented the greatest challenge; the gold standard for recognising pain is patient-report (p.34). However, the case study explored the hypothesis that stoicism may lead to underreporting of pain. To pit the observer's opinion that the patient was in pain against the patient's assertion that they were not risked the validity of the study. Therefore, to make this aspect of data

collection robust, an objective means of measuring pain based on behaviour was identified. Several observational pain assessment tools were considered. Scales using parameters such as blood pressure and heart rate as part of their assessment criteria, such as the Nonverbal Adult Pain Assessment Scale (Odhner *et al.*, 2003) were excluded because, during a cardiac ablation procedure, the heart may be paced, artificially altering such parameters. As such, no inference of pain could be drawn from them. Moreover, research by Pereira-Morales *et al.*, (2018) suggests that changes in such parameters are a less reliable indicator of pain than others, such as vocalization of pain. Of the remaining tools, the Behavioural Pain Scale (BPS) (Payen *et al.*, 2001) and the Critical Care Pain Observation Tool (CPOT) (Gelinas *et al.*, 2006) were most widely validated, by their designers in these articles, and by independent researchers such as Pudas-Tähkä *et al.* (2009) who identified them as the most reliable and valid tools, excluding those using physiological parameters. Although Pudas-Tähkä *et al.*'s (2009) study marginally favoured the BPS over COPT, the CPOT tool was chosen as, unlike the BPS, it was designed for use on both intubated and extubated patients, whereas the BPS focused exclusively on intubated patients. Neither tool was specifically validated for patients undergoing cardiac ablation under sedation, but the CPOT had been validated for sedated patients experiencing pain during recovery, with vocalization (moans and sighs, rather than articulated pain) being the most significant indicator (Pereira-Morales *et al.*, 2018). The CPOT alone includes this indicator, making it the most suitable tool available. The CPOT (Appendix F) assesses pain on 4 indicators, scoring each on a scale of 0-2, with a maximum score of 8. A score of 3 is the accepted threshold indicating the presence of pain (Gelinas *et al.*, 2009; Pereira-Morales *et al.*, 2018). The CPOT is intended to recognise the presence of pain, not as a measure of pain intensity (Tousignant-Laflamme *et al.*, 2010).

Though direct observation was essential, it was insufficient for the triangulation of evidence as suggested by Yin (2014), or the divergence of evidence that would help support theories such as stoicism. In particular, the patient's report of proceedings, their evaluation of the experience, and their recollection of it could not be recorded by observation. Two options were considered: patient surveys or interviews. Yin (2014, p.16) considers surveys "extremely limited" in their ability to explore the context in which an event takes place, but allows for the use of

structured questions within an interview (ibid, p.112). De Vaus (2014) concurs that surveying is not limited to questionnaires of the type used in the first phase of data collection. Thus, by using semi-structured interviews, it was possible to ensure attention was given to relevant theoretical propositions while allowing sufficient licence to explore contextual issues significant to each individual (George and Bennett, 2005). Semi-structured interviews were therefore considered the superior means of data collection for the case studies. Yin (2014) acknowledges that the process of being interviewed may potentially alter the response if, for example, patients say what they believe the interviewer wants to hear. However, in a small number of case studies, it was unlikely that even an anonymous questionnaire would enhance the honesty of answers received.

A schedule of questions was devised for patient interviews (Appendix G); the design of these questions was based on Manzano's (2016) argument that interviews should be designed to validate or falsify theories under investigation. In addition to exploring the patient's evaluation of the experience, they also focused on the patient's attitude towards pain and the detail with which they recalled the experience of ablation. At this point, some divergence in the literature exists; Yin (2014) argues that poorly articulated questions can lead to bias, leading patients towards a particular response. Manzano (2016) contrasts this traditional approach to realist interviews, stating that the realist abandons a neutral stance and steers the interview towards the topic of focus. While wishing to keep the interview focused on theoretic propositions under investigation, it was important that questions did not lead interviewees to specific answers. To prevent this, it was intended that the exploration of rival theories would avoid accusations of bias (Yin, 2014). The schedule was therefore designed to allow patients to give equal consideration to each theory. Furthermore, given the realist assumption that a hitherto unconsidered factor could become apparent in any case (p.58), the schedule included some scope for flexibility, allowing the researcher to ask questions about any specific aspect of the case they noted as relevant during observation, and offering patients opportunity to comment on any features of the case that they considered particularly important to them.

Many of the above arguments regarding the advantages of interviews over questionnaires also applied to exploring the decision-making of sedationists using the NDPSA protocol. The researcher had a choice between trying to

capture rationales at the time when sedationists made decisions, or following the conclusion of the case. Asking sedationists to explain their reasoning as the case was in progress was not considered appropriate, due to the problem of reflexivity identified by Yin (2014): asking nurses to justify actions during the case might change their actions. Such distraction from the case would also be ethically dubious. Retrospective interviews were considered more suitable, though this was also imperfect, as sedationists might not accurately recall their thoughts at any given time. A schedule of general questions was produced for sedationist interviews (Appendix H), aimed at exploring the individual sedationist's approach to NDPSA. However, the decisions made in each case would be unknown to the researcher until the case was observed. It was therefore necessary to allow for a period of "progressive focusing" (Simons, 2009, p.122) between observation and interview to identify specific decisions and actions for discussion. Of particular interest to the research would be aliquots of medication used, both initially, and any change to this during the case, along with the timing of such doses. Furthermore, action in response to patient distress, or any course of action taken following change in the patient's vital signs would be of interest. While these may be noted during the case, a review of the case record took place prior to the interview to identify episodes for investigation. However, if the researcher only focused on aspects of the case that appear important to them, an accusation of bias can be levelled against the results (Yin, 2014). As well as exploring specific episodes identified by the researcher, the question schedule was intended to allow the sedationist to identify any aspects of the case that appeared important to them, and to explain how it influenced their actions.

7.7.2 Case Selection.

Ideally, cases should be selected to allow the exploration of a single pathway from the parsimonious solution (Beach, 2018). However, which pathway a case followed, if any, was unknown until drugs have been given and the case concluded. It was therefore impossible to identify cases meeting Beach's criteria in advance. Cases could have been selected by age and weight, in order to maximise the opportunity to observe the casual combinations of the parsimonious solution in action. However, it was unnecessary for every potential patient to be non-members of both the sets "Obese Patient" and "Young Patient": two of the 3 pathways do not require this. Furthermore, the limited coverage of

the parsimonious solution did not mean that cases outside of these 3 pathways would have negative experiences; were such a case included, it could provide useful insight into the missing factors of the solution models.

A model of factors leading to a negative experience was formulated (Section 6.5.4). This was “Radiofrequency Ablation AND Obese Patient AND Anxious Patient”. University ethical standards required that potential participants be told the reasons why they were being invited to participate. Telling an anxious patient that they were being asked to participate *because* they were expected to have an unpleasant experience would likely have been a self-fulfilling prophecy and leave the research project without ethical approval. As these factors could all be noted in advance of the case, it was decided that patients described by this combination would be excluded from the study. All other patients would be eligible to take part.

For a case to be included in the study, it was necessary for a willing patient to be paired with a willing sedationist. As no sedationist performed poorly or prompted concern regarding their practice, all were considered eligible to take part in the case study phase. However, the cases of some sedationists, specifically 1, 2 and 4, received exclusively positive feedback during the survey phase. When aiming to identify factors that optimise the patient experience of NDPSA, their practice appeared a suitable place to begin. They were therefore individually approached, made aware of their positive performance in the previous stage, and invited to take part in the case study phase. All three agreed to this. Pairing consenting patients with consenting sedationists presented logistical problems, and required support from CCL managers. Managers were willing to co-operate, but were understandably clear that service delivery took priority over the study if, for example, staffing levels and skill-mix made this pairing impossible. It was considered preferable for each sedationist to be observed during one case only. This was because of Yin’s (2014) point regarding reflexivity; the process of being interviewed might cause the sedationist to reflect upon their practice, and adapt practice as a result of participation. However, it was accepted that, due to the above logistical issues, the study of a particular case would not be cancelled if a new sedationist was unavailable.

7.7.3 Number of Cases.

The number of cases was not specified in advance, though a range of 6 to 8 was anticipated. It was intended at least 2 of the cases, and ideally 3, should fit within the descriptions of each of Pathways 2 and 3. This would allow testing for the replicated observation of hypothesised mechanisms contained within them. However, a case's solution set membership could not be known until after it ended. Therefore, the numbers of cases remained unspecified at this point.

Chapter 8: Case Study Analysis.

8.1 Introduction.

6 cases were studied between 25/09/2018 and 30/01/2019. Participants were 5 male and 1 female patients, whose ages ranged from 52 to 72. A seventh patient met with the researcher but was extremely anxious and declined to participate. 5 sedationists consented to take part in the case study phase; these included 3 of those identified as performing particularly well in the survey phase (pp.136-138). Another sedationist participated in 2 case studies; this was not ideal due to the possibility of reflexivity, but became necessary as the sedationist originally allocated to the case, who had previously expressed an interest in participating, declined to participate on the day of the case. This sedationist was recently assessed as competent. At this point, the patient had been consented for the study, and no new sedationists were willing to participate. It was therefore decided to include this case, and acknowledge that this sedationist had participated twice. The reluctance of new sedationists to participate was one reason why no more than 6 studies were undertaken. A second was that, on reviewing responses throughout the case study phase, it was felt that sufficient material had been gathered to meet the case study phases' other aims.

8.2 Process Tracing Within Cases.

Cases were initially analysed individually. This began by identifying the causal conditions identified in the parsimonious solution that described each case, thus determining which solution set, if any, that case belonged. This established which set of hypothesised processes should be compared to the case. The patient's interview was then analysed to ascertain the patient's response to the experience. It was anticipated that patients whose cases match the parsimonious solution terms would give positive or mostly positive reports. A negative report for such a case would challenge the solution's validity and reliability, though this was a possibility. However, once the type of case, and a positive report, was established, it was possible to compare the case to the sequences of events hypothesised in the matrices to determine *how* the causal conditions contributed to the outcome (Reilly, 2010; Beach, 2016). Individual cases were not immediately subjected to the logical testing described by Collier (2017, p.825) as this study was limited to the use of the "straw in the wind" test (p.148-9). This

required the comparison of multiple cases to allow strong conclusions to be drawn (Mahoney, 2012). This was therefore done following the analysis of each individual case.

8.2.1 Case A

Patient A was a 67-year-old gentleman undergoing cryoablation. His BMI was 27.5; he received fentanyl at a mean rate of 1.57 mcg/Kg/hr, 5mg of midazolam and 1g of paracetamol during the case. This gave him a membership score of 0.81 of the set “Patient Received 1G Intravenous Paracetamol AND (not a Young Patient) AND (not an Obese Patient)” in the parsimonious solution. Therefore, a positive or mostly positive report of the case was expected. This case was also on the threshold of ambiguity for the set “Patient Received Heavy Sedation Using Midazolam AND Patient Received 1G Intravenous Paracetamol AND (not a Young Patient)”, but a set membership score of 0.5 made no prediction regarding case report.

The patient’s report was generally positive, but contained some reports of discomfort. In particular, the insertion of venous sheaths at the start of the procedure, and the sensation of the heart being paced were negatively reported:

“I say there was one bit uncomfortable where he was putting it in, you know, pushing it in, but it was bearable. You know, I kept thinking he was shoving something too big up, and it felt as if it was going to expand at the time.”
(Patient Interview (PI)A 94-96)

The patient returned to this in his final remarks on the experience, describing it as “the only bit I felt real discomfort” but “only for a short time” (PIA 124-5). The sensation of pacing, therefore, was not considered “real discomfort”, but it appeared to cause alarm. The patient distinctly recalled the sensation, but immediately indicated that information helped mitigate any alarm from this:

“You started getting a sensation of BANG, BANG, BANG. But I was pre-warned about that.”
(PIA 34-35)

However, he twice returns to this point, indicating that further information could have improved his experience:

“He didn’t tell us how many like (chuckle), because it seemed to go on for a wee while.”
(PIA 78-79)

“he did mention I was going to get it. I didn’t realise it was going to be quite like that!”
(PIA 114-115)

Though the patient attempted to make light of this sensation, his repetition indicated it was important to him. By contrast, the ablation itself appeared to cause very minor discomfort, stating early that “The freezing wasn’t a problem” (PIA 32). Elaborating, he stated:

“Patient (P): Yeah, the freezing on that wasn’t so bad. I did get the sensations of, you know, the ice cream effect kind of thing.

Interviewer (I): the ice cream headache?

P: No, no: cold behind the eyes, and slight feeling of cold somewhere in the brain.

I: Ok, so did you consider that acceptable?

P: Yep”

(PIA 53-58)

In summary of his experience, the patient described himself as “fairly satisfied” (PIA 94); when asked if he would be willing to have such a procedure done under NDPSA in future, he answered positively, albeit with a slight hesitation (PIA 106). To conclude, this patient’s experience can be considered a generally positive, but not an optimal report of NDPSA. It does not, therefore, dispute the model of the parsimonious solution.

The positive outcome of this case was anticipated because it was a member of the solution set “Patient Received 1G Intravenous Paracetamol AND (not a Young Patient) AND (not an Obese Patient)”; the unfolding of events were therefore compared to Matrix 2. The patient was calm and relaxed on his arrival in theatre, according to both his own report (PIA 24-5), and in the opinion of the nurse sedating him (Nurse Interview (NI)A 115-6). Neither did the patient receive a substantial dose of midazolam prior to ablation; 2.5mg was administered prior to the first ablation, and 3mg by the end of the final ablation (OA 7-22). This positioned the case in row 2 of Matrix 2.

While the patient reported pain during sheath insertion, and an unpleasant sensation while the heart was paced, he reported that “The freezing wasn’t a problem” (PIA 32). However, CPOT scores greater than 2 indicated that pain was experienced, and these were recorded during ablations (Observations (O)A15, 17, 22). A score of 2 was also obtained during the first ablation (OA14); while this was insufficient to confirm the presence of pain, its conjunction with a stimulus that later caused pain gave a convincing indication of its presence. It should also

be noted that no pacing took place before OA18; evidence of pain prior to this point cannot therefore be attributed to this. Given that only 30 minutes elapsed from first to last ablation, the frequency with which pain was recorded appeared high. The sedationist also noted the patient showing evidence of pain:

“Even with some sedation and painkillers on board, I noticed that the gentleman was grimacing quite a lot, so that led to continued fentanyl administration.”
(NIA 82-83)

It was therefore concluded that the patient experienced more pain during ablation than his own report suggested.

Underreported pain guides the researcher towards Cell 2A of Matrix 2. This cell includes the expression of stoical views by the patient. Superficially, these appeared absent in this case:

“P: Oh, I can whinge. I hate throbbing pains and things like that. If I get something with a throb, toothache or owt like that, I’m a wimp.” (PIA 143-4)

While the patient did not identify himself as stoical, his description of his own behaviours led to a different conclusion:

“P: It was broke for 5 years that bugger, so they knocked us out again. Even though it was plated, and I was in the building industry at the time.

I: That sounds quite a painful type of procedure?

P: I got used to the slight pain, but when it come to the winter, my family had to work my arm, this that and the other, so after 5 years I went back to the doctor’s.”
(PIA 135-9)

His preparedness to endure pain over an extended period of time, and the reticence to seek help suggested a highly stoical attitude towards the pain from his broken arm. Stoicism is arguably best judged on behaviour rather than self-report: the stoic might simply consider themselves to be normal while actually displaying greater stoicism than the population in general. Further evidence of stoicism came from observation of the case; at no point did the patient ask for any extra analgesia or sedative. However, when the nurse offered more midazolam (OA14) or fentanyl (OA16), he accepted on both occasions. Such episodes both confirm the presence of pain, and a willingness to say nothing about it, unless raised by another individual.

In summary, the pattern described in Cell 2A of Matrix 2 is followed by this case. It therefore supports the hypothesis that stoicism leads to the underreport of pain,

thus creating the impression that NDPSA was more successful than it actually was.

8.2.2 Case B

Patient B was a 52-year-old gentleman undergoing RFA following a previous cryoablation. He had a BMI of 22.8 and received 1G paracetamol and 4mg midazolam during his procedure. He received 300mcg fentanyl over the 131 minutes of the case, which produces a mean rate of 1.9mcg/Kg/hr. Thus, he had a membership score of 0.77 of the set described by Pathway 2. A positive, or mostly positive report was therefore anticipated. The patient's report of his experience was unequivocally positive indicating a complete lack of pain (PIB 38; PIB 45), feeling at ease during the case (PIB 42-3) and willingness to undergo a similar procedure using the same system of NDPSA (PIB 70-1). No evidence contradicted this conclusion; it could be confidently asserted that this was an optimal Cluster A report.

As this case was described by Pathway 2, Matrix 2 was again used to explore the unfolding of events. The patient appeared very anxious prior to the procedure, as noted by the sedationist on the patient's arrival in the CCL, and documented by the preadmission nurse in the patient's notes (NIB 9-11), and the ward nurse on the theatre checklist (NIB 58). The patient was candid about his anxiety, both during interview (PIB 23-28), and in dialogue with the consultant (OB5). Reasons for his anxiety were twofold; the patient's previous experience of cryo-ablation had been painful (OB2; PIB 34-6), leading to understandable anxiety. However, he identified a particularly interesting and, in the researcher's experience, unique reason for his anxiety:

“The other slight anxiousness if you like was what I mentioned to you once before, is that I know the sedation is going to be done by a nurse and that's no disrespect to any nurses, but when you read about a lot of things it's done by an anaesthetist, so I was a little bit anxious as to how well trained or how well versed in sedation the nurses are.” (PIB 24-28)

No other patient during either phase of data collection indicated previous awareness of, or interest in, the issues explored by this study. However, it was evident that awareness of questions regarding the competency of nurses as sedationists, in conjunction with his previous negative experience, provoked considerable anxiety in this patient. Such a pertinent perspective merited further exploration. The patient informed that he had read various articles, using the

internet as his source (PIB 90); this preparedness to search for information indicated a strong desire for more information than received at preadmission. In particular, the patient cited one article that he found:

“And on the flip side of that there was an article from anaesthetists that I’ve read, along the lines that they were more specialist, in what they do and, if there was an emergency and something out of the ordinary happened, that they would be obviously better to deal with it than nurse-led.” (PIB 97-100)

The patient’s anxiety stemmed not only from doubting the nurse’s ability to manage pain, but also from doubts regarding the safety of NDPSA and the nurse’s ability to manage any complications arising from sedation. This prior lack of confidence in the nurse became highly relevant when considering what made this particular case so successful.

Conspicuously, the sedationist began sedation with two 1mg doses of midazolam in quick succession (OB8-9), with a single set of observations in between. Indeed, the total dose of midazolam (4mg) used during the case was administered prior to the first ablation performed (OB34). The patient’s overt anxiety, the aggressive early treatment of it with midazolam, and the patient’s subsequent reports of feeling calm (OB10,14) firmly positions the case in the top row of the matrix. It therefore supported the theory that it is possible to achieve adequate anxiolysis in lighter patients using less than the 5mg threshold dose of midazolam used during fsQCA.

The early use of midazolam was in direct response to the patient’s presentation. The sedationist described his reasoning thus:

I knew that I was going to have time to build up a therapeutic dose of the fentanyl. So, his major concern at that stage was anxiety, and so I wanted to treat that primarily with midazolam, and then give myself time. (NIB 61-64)

However, it was not the only means by which the patient’s anxiety was addressed. Earlier it was noted that this patient lacked confidence in the nurse’s ability to safely perform sedation. Later, this patient introduced the importance of the nurse’s explanation of what was to happen as a calming influence (PIB 42-3), noting that this hadn’t happened in his previous experience (PIB 49-51) and ultimately stating that:

“He put my mind at rest a little bit and me preconception about a nurse doing it as opposed to an anaesthetist, just by his interaction.” (PIB 64-5)

This confirmed the researcher's perception of a particularly detailed initial conversation regarding the patient's previous experience when they first met (OB2), followed by detailed explanations of even minor details, such as frequency of blood pressure cuff inflation during the case (OB6). This case demonstrated the importance of such interventions. This case was delayed by approximately 15 minutes due to the lab physiologist having set up equipment for a cryoablation rather than the intended RFA (OB5). The patient was aware of this (PIB 78-81), and recognised the situation's potential to increase his anxiety. That it did not, he ascribed to the interaction between himself, the sedationist, and the consultant in the CCL:

"if I hadn't had the previous interactions with other people, I might have been a bit more nervous (sic) that what I was, and saying "what's going on now" kind of thing with the equipment, because I was sitting there for a little while it was sorted out."
(PIB 86-88)

The importance of this interaction was also corroborated by the observation that this delay was ongoing for 12 minutes prior to the first dose of midazolam being given (OB5-8). That the episode did not cause the patient to panic can therefore only be ascribed to interpersonal communication rather than pharmacological intervention.

No evidence contradicted the patient's assertion that this experience was "a breeze" (PIB 38) during the procedure. 2 insignificant CPOT scores of 1 were recorded during the case, one during the insertion of a venous sheath (OB15). However, all CPOT assessments during ablation itself scored 0 (OB34-38), with the patient being easily roused to confirm that it was "fine" (OB34). The sedationist shared the view that the patient had been pain-free and relaxed throughout (NIB 91-3). This eliminated the explanation that stoicism led to experiences of pain being unreported by the patient, positioning this case in square 1B of Matrix 2. This corner supposes that, for patients with a lower BMI, effective anxiolysis is achieved with a dose of midazolam that would not include it the fuzzy set "Heavy Sedation with Midazolam". While evidence reviewed in this paragraph demonstrates that midazolam did not simply cause the patient to forget sensations of pain, evidence of amnesia also existed. He perceived that less time had passed than was true (PIB 55-9); it was also conspicuous that his description of events prior to the procedure starting were more vivid than any description of the case itself. However, evidence of amnesia does not weaken

the conclusion that midazolam contributed to the very positive report via anxiolysis.

8.2.3 Case C

Patient C was a 63-year-old man with a BMI of 37.1. He received 1G intravenous paracetamol, 6mg of midazolam and a total dose of 140mcg of fentanyl over 144 minutes, giving a mean rate of 0.49mcg/Kg/hr. His case was therefore described by Pathway 3 only, having a score of 0.77 in this set, which prompted expectations of a positive or mostly positive report. The patient's report of the case was indeed very positive, identifying feeling very relaxed (PIC 40), and complete satisfaction with his experience of sedation when asked if willing to have a similar experience again (PIC 126; PIC 132). He reported "mild discomfort" rather than pain during sheath insertion (PIC 50), before adding that this was only "felt momentarily" (PIC 58). When asked about chest pain, the patient described experiencing some palpitations but no awareness of burning during ablation (PIC 60-63). The patient later confirmed that an itchy nose was his biggest problem during the procedure (PIC 88-90). It was safely concluded that this was an optimal, Type A report.

The membership of the set described by Pathway 3 directed the researcher to examine Matrix 3 (p.160), which immediately presented a problem. All hypothesised case descriptions begin with the expectation that the patient was anxious. This did not appear to be the case here. This patient reported that this was his 6th ablation, with some of the previous ablations performed under local anaesthetic with sedation (PIC 9-12). Initially, he agreed when asked if he was feeling confident and relaxed (PIC 23), but also agreed that his outward jocularity in ordering "a nice cocktail" (OC6) disguised some anxiety (PIC 27-31). His preference for being unconscious during the procedure was confirmed by his explanation of his joke:

"The encouragement was, if she wanted to knock me out, that would be great."

(PIC 26)

The sedationist did not identify the patient as particularly anxious (NIC 10), but also began PSA with a 2mg bolus of midazolam (OC11). Reasoning behind this decision is discussed later; however, the change in patient behaviour following this dose was conspicuous. From being talkative, within 15 minutes of the

administration of midazolam, the patient was lying with his eyes closed, but easily rousable (OC14), indicating that the sedative had taken effect. The behaviour change following the first dose of midazolam positions the case in the top row of the matrix.

Given this patient's substantial body mass, and the fact that no further midazolam was administered until late in the procedure (OC30), it might be questioned the extent to which midazolam influenced the outcome of this case. The observed response to the initial dose suggests that it did but, as in the previous case, the patient recognised other factors as important in managing his anxiety.

Specifically, he compared his arrival in the CCL to his previous visit which he stated left him "feeling a little bit shocked" (PIC 34-5), describing a busy scene:

"the cath lab was kind of already up, set and running, and there were probably 6 or 7 people floating around in there, different nationalities, all seemed to have their job, and seemed to be... a little more like a car wash actually." (PIC 35-8)

He compared his experience during the studied admission, describing his arrival as "very relaxed" by comparison, and noting that the presence of the consultant on his arrival reassured him that the case was going ahead (PIC 40-1). However, he also volunteered that the conversation and "banter" with the sedationist played an important role in keeping him calm (PIC 94-5).

The patient's assertion that he experienced no pain during the ablation concurred with the researcher's observations. Of all the ablation burns delivered, only the first met with any indication of pain at all; this took the form of a slow turning of the head which scored only 1 on the CPOT (OC23). An internal cardioversion was performed late in the procedure causing convulsion and a brief, violent exclamation (OC35), before the patient again closed his eyes. Otherwise, there was no indicator of pain throughout the procedure. The sedationist emphatically confirmed this view:

"those burns were long, they weren't even short burns, they were long burns and there were quite a lot of them. So, to watch a patient and for them to be completely comfortable and not be irritated, and not move a muscle, then I think I've done as good a job as I can" (NIC 185-8)

With the exception of the cardioversion, there was no evidence to suggest that the patient underreported any pain. This discounted the hypotheses that stoicism prevented the report of pain. This patient did not express particularly stoical views; while he acknowledged the expectation of some pain with any procedure

(PIC 107), he stated that he would have no hesitation in reporting all but momentary pain (PIC 115-9). Furthermore, this patient expressed some criticism of previous experiences (PIC 34-8); it was therefore likely that this patient would have reported pain, both during the case and in the interview, had it occurred.

Evidence of amnesia did exist; when specifically asked, the patient had no recollection of the cardioversion at all (PIC 68-70). However, other than sheath insertion, the patient provided other descriptions of case events, including asking the sedationist to scratch his nose (PIC 88) and of palpitations in the chest (PIC 61-7). These events took place after the initial 2mg dose of midazolam had been given (OC11-18), causing drowsiness, but before a further 4mg were administered in preparation for cardioversion (OC30-5). A window therefore existed between the first 2mg of midazolam (OC11) and the increase in dose (OC30), where anxiolysis was achieved, but recollection was retained. All ablations took place within this window.

8.2.4 Case D

Patient D was a 72-year-old man with a BMI of 18.2. This was his first ablation, which was being performed using radiofrequency. He received 1G of intravenous paracetamol and 3.5mg of midazolam. The cumulative dose of fentanyl was 475mcg which, over the 274 minutes of the case, gave a mean rate of 1.64mcg/Kg/hr. The fsQCA model therefore predicted a positive report of experience, as the patient's case was a full member of the set set described by Pathway 2. This directed the researcher to compare the events to Matrix 2. The patient's report was coloured by his disappointment that his consultant wanted him to remain an inpatient that night (PID 155; 196-9). Though important to him, the researcher distinguished between this disappointment and the patient's experience of NDPSA. The patient's appraisal of his experience in the CCL was vaguely positive, simply answering "yes" when asked if he was happy with the pain control (PID 158), but also mentioned the pain reaching a severity up to 8 out of 10 at one point (PID 69-70). This was the point at which the patient voiced discomfort (PID 55-6); it appears the patient tolerated a considerable degree of pain until then, but considered it acceptable. Other answers were faint in their praise; when asked if he would be willing to have further ablation using the same system, he answered

“I don’t see why not, unless there was a better way that I don’t know about”

(PID 161)

His use of the phrase “better way” can be seen as an expression of reservation, though the difficulty of appraising the experience with nothing to which to compare it was a legitimate point. He expanded on this later, querying the possibility of patients “running it better for themselves” (PID 177), and describing the patient-controlled analgesia used by his daughter (PID 181-5). No literature reviewed in Chapter 3 mentioned the use of this for ablations. However, he concluded his description by confirming the acceptability of his experience:

“it seems to have been ok, so if it ain’t broke.”

(PID 185)

It was therefore concluded that this report, while evidently not unequivocally positive, was a generally positive, Cluster B, report.

Despite his low BMI, this patient’s case did not appear to be described by the top row of Matrix 2. The sedationist did not consider him particularly anxious (NID 19-29). The patient gave unexpansive answers when asked how he felt at this point, saying only that he felt “okay” prior to the case (PID 22). The researcher noted the patient making jokes on his arrival (OD2, 5; PID 25-6). The confirmed that this was his usual disposition, but admitted it may have been heightened by a degree of tension (NID 34-41). Overall, the patient was generally relaxed on arrival. Neither did he receive much midazolam prior to the ablation, with only 1 milligram administered beforehand (OD21). It should be noted that the consultant issued a specific instruction that he needed the patient to be awake (OD8). This said, as the sedationist noted, midazolam appeared to have a profound effect upon this patient (NID 122-4); 1mg provided sufficient sedation to allow a cardioversion at an early juncture (OD24), and cause the CCL team some concern regarding sleep apnoea (OD25). Despite this, the patient was conscious and conversing with the sedationist 4 minutes after the cardioversion was performed (OD26). From then until a final cardioversion, the patient appears to have been very lightly sedated, frequently complaining of an itching nose (e.g. OD43, 47, 67), and requesting sips of water (OD33,35, 63). The patient also appeared restless on the table, moving in the absence of the ablation stimulus, though sometimes this was attributable to his tickling nose (OD26, 43, 67, 71). Due to the lack of pre-existing anxiety, and his alert state during the case, anxiolysis via midazolam does not appear to have been a major determinant for

the generally positive report to this case. This directs the researcher's attention to the lower row of the matrix.

The patient experienced a number of pain episodes during this case; on 3 occasions a CPOT score of 4 was recorded (OD48, 41, 68), on each occasion corresponding with an ablation. On one other occasion, the patient described the experience as "very painful there" (OD51). In addition, there was some evidence of pain concurrent with 6 other ablations; though the CPOT score remained less than 3 on each, one episode included the patient opening his eyes and saying "That's painful" (OD85). As with Case A, a CPOT score of 2 in conjunction with a stimulus that, at other times was confirmed as causing pain, suggested that pain was occurring then too. Five confirmed episodes of pain, with a further four likely episodes, appeared a considerable burden. In mitigation, this was an extremely long case; ablations were recorded on 28 occasions during this case, of which 19 passed with no evidence of pain. However, this should not disguise the fact that the patient experienced multiple episodes of pain. In addition to causing the patient distress, these episodes occasionally complicated the case through movement in response to pain (OD54). This contrasted to the patient's general satisfaction with pain management in his case (PID 158) and his satisfaction with the experience (PID 185). This suggested that stoicism was a significant factor in determining the patient's moderately positive report.

The supposition of stoicism in action was supported by further analysis of the patient interview. Previously noted was the patient's willingness to accept pain until an intensity of 8 out of 10 was reached (PID 69-70); on questioning, he confirmed that he recalled pain prior to this crescendo:

I: Do you remember any times when you had pain but didn't speak up?

P: Today?

I: Yes

P: Well, I felt the pain was sort of escalating, I thought "say something about it" rather than just "it will pass".

I: Absolutely. So there was a little bit of pain there before you said something? But then it started mounting up, and you raised your concerns at that point?

P: yes, yes, yes." (PID 52-9)

This suggested an expectation of pain during such procedures, and a willingness to endure moderate pain intensity before seeking help. In his past medical history, the patient disclosed that he had undergone extensive dental surgery in

the past (PID 9-10); his stoicism was evinced through his dismissive attitude to local anaesthetic during dental work though he added that this attitude did not extend to extractions (PID 44-48). Again, a preparedness to endure some degree of pain was demonstrated. This directed the researcher to square 2A of Matrix 2, suggesting that stoicism was responsible for the patient giving a more favourable report of the case than observation would suggest.

8.2.5 Case E

Patient E was a 52-year-old woman with a BMI of 25.5. In addition to 1G paracetamol and 7mg of midazolam, she received 200mcg of fentanyl over the 81 minutes of the procedure, giving an average rate of 2.08 mcg/Kg/hr. The procedure was performed using cryoablation. This case had a set membership score of 0.77 for the solution sets described by both Pathway 2 and Pathway 3, and a 0.56 membership of the set "Patient Received Moderate Analgesia Using Fentanyl". This meant that a positive or mostly positive report of the case was anticipated, but also that it needed to be compared to all hypothesised ways in which the case could unfold to identify how a positive outcome was brought about.

The patient's report of the experience was superficially ambivalent; when asked if she was satisfied with her overall experience, she replied with a somewhat grudging "Just, yes" (PIE 179). However, when asked would she be willing to undergo a repeat procedure under the same system, she interrupted with an emphatic "Oh, yes" (PIE 182). On further exploration, it was recognised that the patient, in describing her overall experience, was referring to her whole journey, rather than just the experience in the CCL. She was critical of the amount of information received in advance, citing a lack of written information (PIE 41-44), the brevity of interaction with the pre-admission nurse (PIE 59), a lack of communication on the ward prior the procedure (PIE 144-6) and insufficient communication from the consultant prior to the case (PIE 127-133). By contrast, she had little recollection of pain beyond the administration of local anaesthetic (PIE 160-1) and some surprise at the sensation of pacing (PIE 96-7). She reported no recollection of pain during ablation (PIE 66), despite "dreading" (PIE 117) the freezing headache about which she had been warned. From this, and the patient's willingness to have ablation under NDPSA again, it was concluded

that her experience in the CCL was positive, and that evidence of dissatisfaction related to information and psychological support prior to the case.

It was necessary to compare this patient's case to both matrices as her case is described by both pathways. However, the most conspicuous features of this case were the anxiety of the patient as she entered the theatre suite, and the heavy use of midazolam during the early stages of the case. Matrix 3 was therefore considered first. The patient openly admitted her anxiety (PIE 18), and the patient's nerves were immediately recognised by the sedationist (NIE 13-14). The researcher also noted the patient's tearfulness on arrival (OE1). Reasons for this anxiety were fear of pain (PIE 16, 117) and risks associated with the procedure (PIE 59-62). She had also sought information via the internet (PIE 43-49), and an online patient support group (PIE 24). This latter source had prompted more anxiety regarding long-term benefits and risks of the procedure:

“Well, when it goes wrong, they say symptoms get worse afterwards. Fluid was pooling around somebody's heart. What else did they say? That it just didn't work. And then I put up a post saying I'm going in in three days, please tell me some people that it has worked.” (PIE 28-30)

She reported some had then done this, but awareness of these non-beneficial procedures contributed to her anxiety. It was interesting to note that previous patients with negative experiences were more forthcoming than those with positive experiences.

Two 2mg doses of midazolam were given (OE11,15) with 10 minutes elapsing between them. Response to the first dose was limited; the patient began to sound less anxious and was aware of a “weird” sensation (OE12), but continued asking questions. The lack of major response to the first 2mg seemed to prompt focus on the lower row of the matrix. However, amnesia was not achieved at this stage. The patient's most vivid recollection was her description of local anaesthetic, which took place 5 minutes after the first 2mg (OE13):

“I was very aware that he was going in, cos there was a massive sting. It went not just there, but right round the entire leg, you know and I thought “oh my God, it's burning!”” (PIE 160-1)

This demonstrated clear recollection, but the exclamatory response to the injection (which was not mentioned by any other patient), suggested that considerable anxiety persisted. It was therefore concluded that 2mg midazolam caused no amnesia, and only moderate anxiolysis. The patient continued asking

questions for several minutes after the second dose (OE15-17) but became quite 7 minutes after (OE19). She then appeared settled following a further 1mg (OE20-1), but remained easily rousable (OE22), directing the researcher's attention to the top row of Matrix 3.

The patient did not report experiencing any pain during ablation itself. Neither did the researcher observe evidence of pain during ablation, recording CPOT scores of 0 during each ablation (OE28-32). The sedationist supported the view, noting that the patient "seemed okay" during the ablation (NIE 83-4). However, one clear moment of pain during the case was entirely omitted from the patient's report; this occurred when the consultant was upgrading the femoral sheath to a larger size (CPOT 3 (OE23)); the patient confirming pain in her groin with "yes" when asked (OE24), which was again corroborated by the sedationist (NIE 80-1). However, when asked if she recalled this episode, the patient stated that she was "totally unaware" of it (PIE 115). The sheath upgrade was brief, and the pain associated with it may also have been very brief; however, it does represent an occasion when amnesia led to the under-reporting of an episode of pain following the case. While the patient's behaviour (CPOT 3) indicated pain, it was also noticeable that the patient's verbal response suggested a reduction in emotional suffering at this time. Her "yes" to this pain was a measured response when contrasted to her alarm on the administration of local anaesthetic (PIE 160-1). It therefore appeared that midazolam was exerting an anxiolytic influence at this point, reducing emotional response to the pain, while also exerting an amnesic effect. Indeed, the patient reported having little recall of anything between the consultant showing her an x-ray of the catheter inside her (PIE 99-102), recorded at OE17, and the sensation of pacing (PIE 96-7), recorded at OE31. In the 45 minutes between these recollections, all but one ablation was performed.

This case did not match the neat dichotomisation of the process tracing matrix. The matrix makes no allowance for the gradual onset of midazolam, an effect which could be observed to be increasing over 22 minutes (OE11-21). That an episode of pain went unreported in the interview due to amnesia cannot be denied. However, as a single, brief incident should not disguise the fact that the noxious stimulation of ablation was tolerated on multiple occasions without any physical or verbal indication of distress (OE28-32). In conclusion, observation of the case did not support the hypothesis that amnesia alone accounted for the

patient's satisfaction with her experience inside the CCL; for the large majority of the case, she was in a state in which a noxious stimulus caused her no distress. While acknowledging the single episode of pain as an exception, it is argued that this case is better matched to the top row of the matrix than the bottom.

The importance of midazolam in this case was enhanced because, unlike previous cases, the patient assigned little credit to CCL staff for controlling her anxiety.

"P: Was S my person? She was sat very far away from me. She wasn't there beside me.

I: She was sat within a couple of meters the whole time, but you weren't aware of that?

P: I was aware that she wasn't beside me." (PIE 68-70)

This exchange was notable for several reasons; the first was the negative tone of her assertion. Second was the difference in perception of distance; the researcher had considered the sedationist close to the patient. The patient later observed that the sedationist was behind "the machine" (PIE 93), which was a shield to protect the sedationist from x-rays. Safety prevented the sedationist sitting closer, but this did not appear close enough to meet the patient's expectations. Finally, the patient did not recall the sedationist's name; the sedationist clearly introduced herself to the patient when they first met (OE1), suggesting that in her distressed state, she was unable to retain this information. If the patient were unable to retain simple information at this point, it is doubtful that further information at this point would have any benefit.

The patient also reacted with an exclamation of "Oh my God!" (OE2) upon entering the CCL, stating that this made her realise that "It was serious" (PIE 82). The patient later suggested more information on what to expect in the CCL would have been beneficial, contrasting the benefits of a "pre-talk" to being "just suddenly walked into this room" (PIE 164). It was the researcher's perception that the sedationist spent considerable time discussing the procedure with the patient in the reception area prior to entering the CCL; the patient stated that she was "not really sure what I'm here for" when the sedationist checked the consent form. The sedationist then invited her to explain what she did know; the researcher recorded that the patient responded with a detailed description (OE1). Some of this was repeated in the patient interview (PIE 48-9). This knowledge was clearly ineffectual in assuaging the patient's anxiety. The sedationist, in turn,

recognised a limit to the use of communication as a means of controlling anxiety; while she engaged the patient in conversation regarding her hometown and television, she recognised that this had limited effect, and the patient's anxiety resurfaced as soon as she stepped away (NIE 113-123). It was noted that the patient was in the CCL for 20 minutes before the consultant arrived (OE2-9); when asked if she thought this negatively impacted on the patient's anxiety, her answer included "I think she was going to be quite anxious regardless" (NIE 139-40). The patient later agreed that conversations with the sedationist had been of some benefit (PIE 74-9), but this admission would have been more convincing had the patient initiated it, rather than in response to the researcher's question. In conclusion, control of this patient's anxiety was achieved via heavy use of midazolam rather than through communication.

Returning to the matrices, no evidence of stoical attitudes was found in this patient's interview: the description of the prospect of pain as "daunting" (PIE 16), her admission of "dreading" the freezing headache (PIE 117), and her willingness to admit to pain, such as the "massive sting" of local anaesthetic (PIE 160) all suggested that this patient would not hesitate to identify any painful episodes. This, therefore, prompted the researcher to focus on Cell 1B in Matrix 3 as the most accurate description of events in the CCL for this case. The lack of stoicism is also relevant to the analysis of Matrix 2. The patient's overt anxiety places the case on the top row, with the absence of stoical attitudes again positions the case in Cell 1B. However, this square hypothesises that a successful outcome is reached through exactly the same processes as the corresponding cell in Matrix 3. As such, it does not present an alternative hypothesis as to why this case resulted in a successful report.

8.2.6 Case F

Patient F was a 68-year-old man with a BMI of 30.4. He received 1G of intravenous paracetamol and 1.5mg of midazolam. The total dose of fentanyl was 220 mcg over 107 minutes, giving an average rate of 1.25 mcg/Kg/hr. Uniquely in the 6 cases studies, this case was not a member of any solution set. His BMI gave him a membership score of 0.52 of the set "Obese Patient" which excluded him from any solution using the component "not Obese", while the relatively low drug doses meant the case did not fit any solution including fentanyl or

midazolam. His case had a membership score of 0.48 of the set described by Pathway 2, but this was insufficient to make prediction regarding case report.

Superficially, the patient's report was positive, emphatically confirming his satisfaction (PIF 175), and his willingness to undergo a similar experience (PIF 178, 184). However, the patient also reported several episodes of pain during the procedure. The worst occasion (OF30) prompted him to ask for more analgesia:

“just when it started with the bump, bump, bump, my whole ribcage just got really tight, and that's when I asked R for if she could give us some.” (PIF 97-99)

This pain eased following the administration of more fentanyl, but remained present while pacing continued (PIF 103-4). Like Patient A, Patient F identified that this pacing sensation was the worst part of the procedure (PIF 112), and that he was unprepared for it, compared to the sensation of ablation itself (PIF 60-1). By contrast, he acknowledged that the sensation of the ablation had been well-described to him before (PIF 58-9), and the subsequent experience of this was “bearable” (PIF 106), and “wasn't too bad” (PIF 94). The patient also reported an aching shoulder towards the end of the procedure, which he attributed to lying flat for so long (PIF 194-6). Another possible episode of pain (OF11) was dismissed by the patient as simply his reaction to the application of cold antiseptic (PIF 82); this explanation was unconvincing as it was noted during the administration of local anaesthetic which was after the use of antiseptic. The patient recalled a sensation of pushing, but regarded it as less important than the cold (PIF 82-5). However, discomfort from the sheath insertion appeared minor.

The patient also provided evidence of ongoing anxiety throughout the procedure.

“Apart from you get a bit daunted when you see all the machines and wires and things like that. I don't think you can change anything, but it just threw me. Would they ever, ever knock people asleep for it?” (PIF 188-90)

Entry into the CCL preceded the administration of any sedation, but this echoed Patient E, who also noted that first-time exposure to an unfamiliar, complex clinical environment provoked anxiety. The additional query regarding GA indicated that, despite his statement of overall satisfaction, he would have liked to have been more heavily sedated during the case. The patient also raised a unique point about the use of music in the CCL:

“I know there was music in the background, but could you not have music, your own music if you wanted to put it in, I know the doctor got to say something to you, but just to take your mind off it a little bit?” (PIF 130-2)

The awareness of background music indicated an alertness not demonstrated in other cases, and the patient acknowledged a need for more distraction than took place, later confirming that his own music would have been beneficial to him (PIF 141). He also acknowledged that interaction with both consultant and sedationist was beneficial in helping him relax (PIF 155-8).

This case was not a member of any of the solution sets, so neither challenges nor supports the fsQCA model however this report is interpreted. Of greater interest was the question why, despite episodes of pain, and ongoing anxiety, the patient ultimately gave a positive report of the case? It transpired that this patient had a familial link to the department in which this procedure was performed. Unknown to the researcher prior to the interview, this patient's wife was a Sister on the hospital's coronary care unit. This connection may have been a factor in the patient's positive attitude towards the hospital in general (PIF 202), and inclined him towards a positive report. Any influence from this idiosyncrasy is not transferable to other cases. However, the patient also reported that the preadmission nurse had provided him with more detailed information about the procedure than his wife (PIF 70-72), eliminating the possibility that this patient had access to much more information about the case than other patients.

The amnesic properties of midazolam were dismissed as an influence on the patient's report. Not only did he receive a small dose of 1.5mg, he appeared to have clear recollection of the experience, including pain and music. However, the patient was a full member of the set "not a Young Patient", so the hypothesis that stoic attitudes led to older patients accepting pain was considered. The patient previously introduced the word "bearable" into his description of pain during ablation (PIF 97), indicating a preparedness to tolerate some pain during the procedure. This willingness also extended beyond the hospital setting; the patient described living with "a lot of pain" from an arthritic knee (PIF 26), which ultimately led to a total knee replacement. However, the patient lived with pain for a prolonged period:

"About two year I think. It was deteriorating: I ended up getting injections in my knee, you know to help, so I could stay at work." (PIF 31-32)

Demonstrated by this was a determination not to allow pain to impact on his life, and to continue working despite it. His anxiety at the prospect of orthopaedic surgery (PIF 20-22) suggested pain, for a period of time, was considered more

acceptable than surgery. He also stated that “the pain wasn’t what I expected it was going to be really” (PIF 74-76); by this, he explained it differed in type (PIF 77), indicating an expectation of some pain. Finally, the patient expressed approbation for stoical attitudes:

“I think I’ve got quite a high threshold of pain me but, you know, my wife says I’m a wimp. But, I think I’m quite alright, I don’t ask for the stuff.” (PIF 45-6)

The word “alright” suggested pride in his willingness to tolerate pain, and approval for not seeking analgesia. This contrasted to the negative connotations of the word “wimp”. It was therefore concluded that the pains which the patient openly acknowledged in his interview might not have been acceptable to a patient who did not share his stoic attitude towards pain. Although this case was not a member of the set described by Pathway 2, it shared many features of Cell A2, specifically the evidence of pain, the positive report despite pain, clear recollection, and stoic attitudes. The slight deviation from the described pattern was that this patient did exhibit anxiety. However, this was accounted for by a stoical attitude towards anxiety as well as pain: this patient also considered this to be something endured when in hospital (PIF 149-150).

8.3 Cross-Case Analysis.

Next, it was necessary to consider which of the identified theories were supported by the cases observed. Each case constitutes a relatively weak “straw in the wind” test (Collier, 2017, p.825). However, when cases repeatedly support theories, the contribution of that factor via the hypothesised mechanism can be inferred with confidence (Mahoney, 2012).

8.3.1 Pathway 2

Four cases were members of the set described by this solution. Cases A, B, and D were described only by this solution, while Case E was also a member of the other 2 pathways. During process tracing, both Cases A and D were shown to fit Cell 2A of Matrix 2. Both appeared to experience more pain than they reported, and each provided evidence of their stoic disposition during their interview. Furthermore, no strong argument could be made that their mostly positive reports were the result of lower doses of midazolam providing effective anxiolysis to patients with lower BMIs: neither appeared to be, nor admitted to being, particularly anxious prior to the case, and neither received a sufficiently large

dose of midazolam prior to ablation to match the patterns described by the top rows of the matrix. These cases sharing the same square therefore support the theory that age was a significant causal condition in determining positive report *because* stoicism amongst older patients made them more willing to tolerate pain, and less likely to report it (Section 7.4.1), while weakening the theory that reduced sensitivity with aging accounts for such differences. These cases do not support the hypothesis that lower BMIs allow the beneficial effects of midazolam to be attained using doses of less than 5mg, but this does not deny that this may be possible in other cases. At this point, Case F could also be considered: Patient F was a full member of the set “not a Young Patient” and received 1G paracetamol. His case was excluded from Pathway 2 due to his higher BMI. He too expressed approval for stoic attitudes in his interview; while he acknowledged more pain than Patients A and D, he confirmed pain was expected, that it was acceptable to him, and a willingness to undergo a similar experience in future. Finally, both Patients A and F provided indications that the anticipated sensation of ablation was more tolerable than the unexpected sensation of pacing; this suggested a willingness to tolerate noxious stimuli, so long as they were understood, and not considered threatening. The repeated demonstration of stoicism leading to mostly positive reports made a persuasive case that this is how age contributed in the fsQCA model.

However, stoicism did not account for Cases B and E, also described by this solution term; neither did it explain why “not an Obese Patient” is included in this pathway. Both of these cases were positioned in square 1B of Matrix 2. Both admitted to being highly anxious prior to the ablation, and openly displayed this when arriving in the CCL. Both received substantial doses of midazolam prior to ablation; Patient B went on to have a procedure which, by his own report and by observation, was pain free. Patient E had a single, conspicuous episode of pain but otherwise, there was no report, or observation, of pain during the ablation. Neither patient displayed stoic attitudes; Patient B had no hesitation in admitting to pain during his previous ablation, and Patient E stated she was “dreading” pain (PIE 117). However, cases in this square were expected to support the hypothesis that adequate anxiolysis could be achieved using 5mg or less of midazolam in non-obese patients. Case E provided no inferential weight to support this hypothesis as the patient went on to receive more than 5mg. Whether a positive report of the experience would have been recorded had the

patient not received midazolam beyond 5mg is a matter for speculation, but it should also be noted that Case E was in no way contrary to this theory. This lack of inferential weight is consequence of Case E being a member or both solution sets. Case B was not limited in this way and therefore supported both the hypothesis that effective sedation can be achieved in lighter patients at lower doses, and that older patients are less sensitive to the noxious stimulus of ablation.

Case B was markedly different from Cases A and D, despite the fact they are all described exclusively by the same solution pathway. From a critical realist perspective, this was not a problem; it simply suggested that two different sets of mechanisms were encompassed by the description of the solution term. The main difference between the two pathways studied here was that one substitutes the term “Patient Received Heavy Sedation Using Midazolam” for “not an Obese Patient”. Any case, such as B, that supported the hypothesis that adequate sedation could be achieved in non-obese patients using lower doses of midazolam, could have more in common with cases in the set described by Pathway 3 than it did with cases such as A and D. Case B was, therefore, included in the cross-case analysis of this second solution set.

8.3.2 Pathway 3

Only two cases, C and E, were described by this set, but Case B was also considered as supporting evidence regarding the roles of age and midazolam. Cases C and E did not fit as neatly into Matrix 3 as A, B and D fitted into Matrix 2. Case C was only moderately anxious on his arrival in CCL, and received most of his 6mg midazolam after the ablation. Case E did display a single noticeable episode of pain which went unreported. However, for reasons discussed in individual case analysis, both fit best into Cell 1B of Matrix 3. Although Case B was not strictly described by this solution set, the unfolding of this case matched the anticipated pattern in Cell 1B almost perfectly. Although Patient B had little recall of events, this is evidence of amnesia did not contradict Cell 1B. With all three cases most closely resembling the pattern in this square, the theories underpinning the described pattern are supported as explanations as to why these cases resulted in a positive report. In particular, the theory that midazolam contributes to a positive report via the mechanism of anxiolysis, rather through the mechanism of amnesia, was strongly supported.

Although this square was intended to support the theory that older patients report less pain because they are less sensitive to pain, this theory looked dubious when the analysis of both matrices was considered. Patients A, D and F were aged 67, 72 and 68 respectively. They all demonstrated evidence of stoical behaviour, either by reporting less pain than observed using the CPOT tool, or demonstrating a willingness to tolerate pain. However, Patients B, C and F were aged 52, 63 and 52 respectively. The theory that older patients experience less pain was based on the deterioration of the nervous system during the aging process (Section 7.4.1). It therefore made an unconvincing argument to suggest that Patients B, C and F experienced so little pain due to the aging process, when considerably older patients could, and did, experience it. This comparison prompted the rejection of the theory that age acted as a context that made *the gate* mechanism less responsive to pain. It also forced reconsideration of why the term “not a Young Patient” should appear in Pathway 3 in conjunction with paracetamol and heavy use of midazolam.

Analysis of these cases provided another explanation of why age could be relevant in this conjunction. It had thus far been considered whether there was an aspect of aging that makes this combination of midazolam and paracetamol effective. However, analysis suggested why this combination may be insufficient for younger patients. Establishing that heavy use of midazolam contributed to positive outcomes via anxiolysis drew attention to the high level of anxiety displayed by Patients B and E on their arrival in CCL, which they both openly acknowledged. Furthermore, both had demonstrated a strong desire for information; for Patient B, this was despite his having had the procedure done previously. Both had sought information from the internet and found information that concerned them; Patient B was aware of debate concerning the safety of nurses administering sedation, and Patient E was aware of reports from patients who considered their condition worsened by their ablation procedure.

Patients B and E were both 52, making them the youngest patients in the case studies by over a decade. They described similar patterns of behaviour: a pre-operative desire for information, seeking information online, and heightened anxiety resulting from the information they found. It was therefore hypothesised that such patients may present a greater challenge to the sedationist as a result, and that not all such patients may receive the aggressive treatment with

midazolam that they did. As such, relative youth may represent a context, heightened anxiety, that makes anxiolysis harder to achieve, and have an influence beyond the absence of stoic attitudes displayed by Patients A, D and F. 63-year-old Patient C was further evidence of this: his lack of stoic attitudes was not marked by heightened anxiety. This hypothesis means, therefore, that age can contribute to reports in more than one way.

For ethical reasons, the case study phase did not seek to explore cases where unsatisfactory sedation would be expected, therefore this hypothesis cannot be supported further. It is subject to some criticisms, but can also be defended. The first of these is that Patients B and E were mostly in the set “not a Young Patient”, not mostly out of it and, furthermore, Patient B had an optimal experience, while E’s lab experience was positive. It should be recalled that the sets regarding age were arbitrarily calibrated, with no external scale found for this purpose (pp.115-116). It was therefore possible that the calibration of this set has failed to capture all relevant variation in attitudes of different age groups. This is supported by the sharp contrast between the information-seeking behaviour of Patient’s B and E, and the fatalistic or indifferent attitudes of the older patients in the case study:

“whatever’s going to be is going to be.” (PIA 24-5)

“As long as it works, I don’t bloody care.” (PID 145)

Recalibration of this set was considered, but dismissed because it was thought unlikely that age itself would present definitive thresholds where desire for information would end, and stoic attitudes start. At this point, patient attitudes had replaced age as the focus of interest. The objection that both Patient B and E had positive experiences is also non-detrimental to the hypothesis: both patients received large doses of midazolam prior to the actual ablation, 4mg and 6mg respectively. As will be shown, this was due to deliberate action by the sedationists. It is therefore possible that not all patients displaying such anxiety receive such purposeful midazolam doses prior to ablation, even if ongoing use throughout the case leaves them in the set “Heavy Sedation with Midazolam”. As a result, their anxiety, and therefore pain, is less effectively managed.

8.3.3 Optimisation of Sedation.

The two unequivocally positive reports in the case study phase, B and C, were described by different pathways. However, process tracing revealed that the same context led to an optimal outcome in both cases: effective management of anxiety, principally through early use of midazolam. The report of Patient E was less positive, despite also receiving highly purposive treatment with midazolam. However, the negativity in this report related to communication prior to the case; report of the case is positive, and a single observed episode of pain during sheath upgrade provided the only evidence contrary to the conclusion that this was also an optimal case. After B and C, this case appears to have been the next most successful, and was achieved again through effective management of anxiety using midazolam. This is the most reliable path to an optimal experience found in the study.

Patients A, D and F provided more ambiguous reports and, though all three were generally positive, they were not as emphatic as those of B and C. For this reason alone, they were not considered optimal cases. Furthermore, A and D appeared to underreport pain, while F admitted to a considerable amount of pain, but found this acceptable. This suggests a different mechanism led to their mostly-positive reports. Process tracing revealed this mechanism to be stoicism: and expectation of some pain, a willingness to endure it, and a reluctance to admit to it. This stoicism was associated with older patients. While this may lead to a report of general satisfaction, this makes such cases unsatisfactory from the perspective of the professionals involved. First, it can mean the patient remains agitated during the case, thus hindering the procedure (OD 54, 60, 71). Second, there is “a better way that I don’t know about” (PID 161): Cases B and C demonstrated that pain is not an inevitable aspect of ablation, as these stoics assumed. It was therefore concluded that, while aging may contribute to a positive report, it did so as a predictor of stoic attitudes and did not, therefore, contribute to the optimisation of NDPSA.

8.4 Thematic Analysis

TA was identified as a suitable means of analysing any differences in approaches used by sedationists when utilising the NDPSA protocol (Section 7.6). A specific area of interest was the use of fentanyl, which had previously

been identified as low in most cases. All sedationists participating in the case study phase had participated in the survey phase. However, Sedationist DF was relatively new to NDPSA during the survey, and had participated in only 2 survey cases, insufficient to draw any conclusions regarding their practice. The cases in which each sedationist participated, their survey reference number, and their experience of administering NDPSA are given in Figure 8.1. At interview, sedationists were asked to give rationales for specific decisions taken during the case. Explanations were then compared to the researcher's observations of the case, and the patient's clinical observations to confirm the extent to which the sedationist was aware of their own decision-making process. Woodside (2010) identifies that people have limited access to their own thought process, and it was intended that any disparity between observation and rationale would help distinguish between intuitive decision-making, and hypothetico-deductive and prescriptive models (Section 4.5).

Figure 8.1: Identity and Experience of Sedationists Participating in Case Studies

Case	Sedationist code during survey	Experience of NDPSA
A	1	6.5 years
B	4	2.5 years
C	3	10+ years
D and F	N/A	18 months at time of Case D, 21 months at the time of Case F
E	2	4-5 years

8.4.1 Proactivity

A common theme amongst sedationists B, C and E was a proactive approach to the administration of drugs, most overtly fentanyl, but midazolam too on occasions, as opposed to a reactive approach once distress occurred.

Sedationist B gave the most eloquent expression of this:

“So what I like to do, is have a relatively therapeutic dose in their system so that when they do start, they don’t get caught off hand, start flailing about the bed, and experience any discomfort throughout.” (NIB 87-89)

This rationale matched the observed action: 240mcg of fentanyl were administered prior to the first ablation (OB10-34), with only 60mcg being administered once ablation began (OB34-40). Sedationist C echoed this:

“I think my personal practice is 10mcg every 10 minutes, certainly because I know it take 10 to 15 minutes to titrate in to the tissues, so you know that 50mcg that I’ve already given is working quite a long time, and then keep him topped up until the point they start ablating” (NIC 73-6)

Again, this describes what the sedationist did up to the point of ablation (OC13-23). Again, this resulted in more analgesia being given prior to ablation than during it: 90mcg were administered prior to the first burn, with only 50mcg administered thereafter (OC24-40). Furthermore, Sedationist C provided an explanation why they considered pro-action superior to reaction, recognising that response to any dose they give will not be instantaneous. Sedationist E concurred, stating that their aim was “to prevent any pain” (NIE 72), and also stated a target of administering 100mcg of fentanyl prior to ablation to achieve this (NIE 73-75). They surpassed this target, with a total of 160mcg administered prior to the ablation starting (OE12-27), with only 40mcg given during ablation itself. The target of 100mcg was surpassed because of the conspicuous episode of pain during sheath upgrade, which was immediately met with 20mcg fentanyl, and 20mcg 5 minutes later (OE23-4).

Sedationist DF also expressed a preference for proactive use: “I quite like to build it up a little bit in the system before they start ablating” (NIF 85-6). However, Patient F received 65mcg prior to ablation, with a larger dose of 155mcg after, including 35mcg when the patient was exhibiting signs of pain (OF30). Despite the intention to be proactive, the timing of fentanyl doses was more reactive than proactive in this case. While the above comment related specifically to Case F, a similar pattern was seen in Case D, with 50mcg administered prior to ablation

(OD17-36), and 425mcg during ablation (OD37-85), though the long duration of Case D exaggerated this difference. However, even when adjusted for time, the same pattern is noticeable: 0.89 mcg/Kg/hr prior to ablation, 2.44 mcg/Kg/hr during ablation. Regardless of intention, both of these patients received lower doses of fentanyl prior to ablation than Patients B, C and E. The more favourable evaluations of their experiences by Patients B, C and E, along with the consensus on the importance of proactivity by these 4 sedationists, indicated that proactive use of drugs was an important factor in optimising patient experience. Yet this begged the question of why, despite this knowledge, did this not happen in Cases D and F? This will be answered later.

Sedationist A had thus far not been considered; their patient received 100mcg of fentanyl prior to ablation (OA6-13), with only 75mcg administered thereafter (OA14-29). However, the sedationist identified that this was not due to their intention, stating that they administered more than they usually would as a reaction to the considerable pain the patient experienced during venous sheath insertion (NIA 31-33). It was also noted that this sedationist used a particularly large bolus, 50mcg, in response to pain (OA13), something this sedationist stated was not uncommon in their practice (NIA 41). This indicated a more reactive use of fentanyl. This case provided some support for the argument that a proactive approach is superior to a reactive approach. The patient had received 100mcg prior to ablation and subsequently noted little pain during ablation itself (PIA 32); this represented proactive management, even if this was not done intentionally. The sheath insertion was identified as the worst pain in the procedure (PIA 124-5) and this was managed reactively (OA12-13). However, a further item of interest was that Sedationist A received no negative reports of experience from the patients they sedated during the survey phase. However, 5 of these 7 cases were mostly positive, Type B, cases. It is therefore possible that large, reactive boluses of fentanyl used by this sedationist were effective in preventing mostly positive cases deteriorating into negative experiences, but did not lead to optimal experience.

The superiority of proactive fentanyl use provided an explanation as to why so few cases in the survey phase received a dose of fentanyl above the 2 mcg/Kg/hr threshold for inclusion in the set "Patient Received Moderate Analgesia Using Fentanyl", despite the unsurprising finding that this invariably led to a positive or

mostly positive report. In every case, time prior to first ablation represented a substantial proportion of total case time, ranging from 24% (Case C) to 61% (Case B). Some cases (D and F) did see an increase in the mean rate of fentanyl administration after the start of ablation; D saw the highest rate (2.44mcg/Kg/hr). However, even with this accelerated rate, the mean rate for the whole case remained below the 2mcg/Kg/hr threshold for membership of the fentanyl set (1.64 mcg/Kg/hr), as so little was given during the time prior to ablation. It was calculated that a total of 530 mcg fentanyl would need to be given during the ablation phase for the total case average to cross the 2 mcg/Kg/hr threshold. This is possible, but would represent a reactive use of fentanyl far exceeding anything observed in the case study phase. It is therefore hypothesised that each of the 9 survey cases which exceeded the 2 mcg/Kg/hr threshold must have received substantial, proactive doses of fentanyl prior to the ablation in order to exceed this threshold over the entire case. As such, these 9 cases can be regarded as a subset of a greater set: patients receiving proactive use of fentanyl. In the language of fsQCA, “Patient Received Moderate Analgesia Using Fentanyl” is indeed sufficient, but unnecessary, even for a case to be recognised as an effective use of fentanyl.

While this analysis has focused on the use of fentanyl, one case indicated that a proactive approach using midazolam can also be effective. Cases B and E cannot be considered to have used midazolam proactively: though its use was prioritised, both patients were already highly anxious on arrival. This was not true of Patient C, whom the sedationist described as “quite laid back and chilled” (NIC 10). Despite this, NDPSA began with a 2mg bolus of midazolam (OC11). Though Patient C was heavy (BMI 37.1), no further midazolam was administered until the point of cardioversion, and the patient maintained a relaxed demeanour throughout. Section 8.3.3 argued that optimisation of NDPSA is most reliably achieved via control of anxiety; Case C indicates that such control can be achieved with relatively low doses of midazolam if it is used proactively. Larger doses were required when the patient was highly anxious on arrival, as were Patients B and E.

8.4.2 Situational Awareness, Communication and Experience

The previous section asked why a sedationist might favour a proactive approach, yet fail to implement it? Sedationist DF was the least experienced of those

participating in the case study phase (Figure 8.1). Despite this, during both cases they were the most experienced nurse in the CCL and found themselves dealing with issues other than NDPSA. Case D was performed in a room not usually used for ablation; this led to the sedationist instructing the junior nurse as to what pieces of equipment they needed to collect (NID 36-41, OD14). The sedationist admitted being distracted while directing colleagues and, subsequently, being surprised that the consultant was about to ablate (NID 103-9), stating that this prevented them from preloading (NID 111). In Case F, the consultant asked the second nurse in the room to scrub and assist him with the procedure (OF7, 14). The sedationist stated this was the first occasion that circumstances had left them as the lone nurse on the CCL floor (NIF 169-71); this meant they answered several phone calls from the theatre co-ordinator during the case in addition to managing sedation. They were ambiguous as to whether these calls distracted from sedation, stating first that they were able to maintain focus (NIF 154) but also that “they definitely did make a difference” (NIF 157). However, they acknowledged distractions certainly could impact on their performance during more challenging sedation (NIF 162-5), and that ablation began “sooner than I thought” (NIF 82). It is therefore argued that minimising distraction of the sedationist, particularly those new to the role, would contribute to improved case awareness and, therefore, enable adequate preloading with drugs prior to ablation.

Distraction appeared to play some part in preventing preloading of Patients D and F with fentanyl prior to ablation. However, Sedationist DF also expressed an expectation that distinguished them from other sedationist: that they would receive notice from the consultant in advance of ablation (NID 109; NIF 83). The more experienced Sedationists B, C and E viewed this expectation as naïve. Sedationist B asked for 10 minutes notice before ablation began, but acknowledged that it was not forthcoming (NIB 84-7), and that it was normal not to receive any notice (NIB 141). They articulated a strategy to accommodate this:

“I tend to give the medication anticipating that I’m going to be caught off foot”
(NIB 89-90)

Sedationist B had been practicing NDPSA considerably longer than Sedationist DF. Sedationists C and E had more experience still; C expressed that verbal warning of imminent ablation is useful, but rarely forthcoming, and that this would

prove problematic for sedationists who depend upon it. When asked if consultants usually communicate clearly, they replied:

“No, they don’t always, and I have seen people get caught out by that. They give a bit at the beginning, and then there’s a long gap, and nothing is given, and then they start ablating.” (NIC 92-94)

This could be a description of events in cases D and F. It also suggested some inconsistency in communication which may be more challenging to the novice sedationist than routine lack of communication, as it may create expectation. However, this sedationist identified their own trigger point for checking medication doses, and increasing them if necessary: the opening of the ablation catheter by the consultant (NIC 87-9). Sedationist E also acknowledged that they did not receive notice prior to ablation (NIE 177), but appeared least concerned by it:

“I think because I recognise it, you know I’ve been working in the labs for years now; I recognise when they’re giving the BRK, when they’re asking for the heparin, when they’re getting all the equipment in and everything, then obviously I can recognise when they’ve gone across, but for somebody new it might be different.” (NIE 179-182)

They therefore acknowledged that their experience led to an awareness of case events. As with Sedationist C, they identified case events as cues for their proactive use of medication, substituting awareness of these events for clear verbal instruction.

Three different approaches to the administration of drugs were discernible; the first of these was to expect explicit notification of imminent ablation, as demonstrated by Sedationist DF, which subsequently led to lower doses of fentanyl being administered than in other cases. Sedationists B, C and E regarded this expectation as naïve and developed their practice to avoid such dependence. Sedationist B had been practicing sedation for a year longer than Sedationist DF and did not expect notification; nor did they make reference to case events in the way Sedationists C and E did, instead only emphasising the importance of administering a therapeutic dose early (NIB 87-88). This resulted in a larger dose of fentanyl being administered in advance of ablation. The more experienced sedationists, C and E, showed greatest awareness of case events occurring around them, and cited these as triggers for administration; Sedationist E linked this directly to their experience. It was therefore possible to hypothesise

a progression of awareness through experience that facilitated the proactive use of drugs.

8.4.3 Concern for Safety

Safety and patient experience have been key outcomes in this study, but they have not been considered as related thus far. Analysis indicated that, in some cases, safety is preserved at the expense of patient experience. This may be particularly true when a reactive, rather than proactive approach is taken to the administration of drugs. In 5 of the 6 cases, sedationists adjusted their approach to NDPSA due to safety concerns. Case C was the exception, as safety concerns did not arise. In Cases A, B and E, administration of medication was curbed by a reduction in the patient's blood pressure: single instances in A (OA15) and E (OE26), and twice in B (OB16, 25). When noting the falling blood pressure, both Sedationist A (NIA 78-9) and B (NIB 123) stated that they ceased administration of sedation, resuming only when they were satisfied that the blood pressure had recovered. Sedationist E continued administration, but with a reduced dose (NIE 93-99). Interestingly, only one of these four incidents triggered the protocol's alert criteria of a 10% fall in mean arterial pressure (OB16). The other 3 episodes were sufficient to prompt questioning by the researcher, and be noted by each of the sedationist but, according to the protocol, did not require a change in practice. That both highly experienced sedationists A and E, as well as relatively inexperienced Sedationist B reduced their rate of administration when not required to do so by protocol suggested an acute awareness of safety issues, and a prioritisation of safety over patient experience. This was not to the detriment of Patients B or E; neither patient reported or displayed signs of pain or agitation thereafter. However, Patient A was exhibiting evidence of pain immediately before (OA14) and after (OA16) the fall in blood pressure. Thus, the concern for safety, and the subsequent need to pause sedation, could be seen as hindering the sedationist's ability to manage pain when it arose.

Safety concerns in Cases D and F related to the patient's airway and respiratory rate respectively. The sedationist expressed concerns regarding Patient D snoring, to which they responded by reducing the fentanyl dose (NID 126-9). The point at which the sedationist described reducing the fentanyl dose in Case D occurs at OD42. This immediately precedes a period in which patient D exhibited the most evidence of pain during the procedure (OD 44-54). Safety concerns

therefore can be seen as causing the sedationist to use smaller aliquots of analgesia at a time when the patient needed it most. This sedationist also noted that Patient F's respiratory rate fell on the administration of midazolam (OF13-5) leading to their decision to rely almost exclusively on fentanyl thereafter (NIF 104-7). Only a further 0.5mg midazolam was given, near the end of the procedure (OF31). Again, the patient's respiratory rate did not fall below 8, which under the protocol, would have mandated an alert of the medical team, but was sufficient for the sedationist to adapt their practice. This appeared to have had some impact on the experience, as Patient F indicated ongoing anxiety during the case, for which he would have appreciated more distraction (PIF 130-2).

The safety of NDPSA was established in Section 6.2. No reversal or change of strategy was required in any case. Alert thresholds were crossed in less than half of the survey cases, on a single occasion in most cases (pp.82-83). This appears to be because nurses were acutely aware of deteriorating observations and adapted practice to maintain safety. This is not to suggest that sedation was needlessly tentative; some of the observations that prompted modification of drug dose sat immediately above the alert threshold, and were deteriorating (OE26; OF31); the modifications made to prevent observations crossing alert thresholds appeared justified. It cannot be known what would have happened had these not been made, but the recovery of observations in all cases lent credence to the sedationists' decisions. The need for these modifications, however, further strengthen the argument that a proactive approach to sedation is superior to reactive one; in both Cases A and D, the sedationist found themselves forced to prioritise safety over patient experience as their patients' deteriorating observations coincided with the manifestation of their pain. Due to the proactive approach in Case B, any deterioration in observations due to drugs used (OB16, 25) occurred in advance of the first ablation (OB34). In the intervening time, the sedationist was able to reassess (NIB 119-21), and resume administration (OB18, 26), thus ensuring adequate analgesia in advance of the first ablation. Sedationist B summarised this flexibility that a proactive approach provides. Of the early stages of the procedure they stated:

“I could have given less, but I don't feel there was any need for me to give less, if that makes sense. His observations weren't clinically significantly significant to me.”
(NIB 107- 8)

They therefore allowed the following course of action when a change in blood pressure was observed:

“So, it’s easier, he was in a nice comfortable state, I didn’t worry about him having pain; it was easier for me to stop giving medication and observe closely, before proceeding again.” (NIB 129-131)

Thus, by continuing to give medication when the patient displayed no immediate need, this sedationist was able to adjust their plan, confident that the patient was adequately prepared for noxious stimuli. Likewise, Sedationist E had already administered what they considered to be an effective dose of medication (NIE 72-5), thus allowing them to reduce medication due to concern regarding observation (NIE 97-9), without the patient exhibiting evidence of pain thereafter (OE26-37). Despite stating that they had reached a level of analgesia they considered effective, and evidence of lack of pain during ablation, Sedationist E continued to administer 10mg doses of fentanyl which echoes Sedationist B’s view of no “need for me to give less” (NIB 107), which allowed flexibility when changes in observations occurred.

8.4.4 Deviation from Protocol.

All sedationists exceeded drug aliquots specified by the NDPSA protocol (Appendix A, p.265). These stated that an initial fentanyl dose of 10mcg should be given, normally followed by midazolam. Maximum aliquots of up to 20mcg fentanyl and 1mg midazolam were specified. All sedationists were observed administering fentanyl aliquots of 25mcg or greater, with Sedationists A and C using the largest doses of 50mcg on one occasion each (OA13; OC13). Both disclosed that this was not unique to this case (NIA 41; NIC 52-7). Sedationists C and E were also observed administering midazolam in 2mg aliquots (OC20; OE11). A further variation was noted in Cases B and E, as both sedationists elected to begin NPLSA with the use of midazolam rather than fentanyl (OB8, OE11); the protocol allows this, but does not specify when to do it.

The sedationists made surprisingly little reference to protocol in explaining their actions. Indeed, the only reference to protocol training came from Nurse A:

“My practice is usually to give fentanyl, which is what both courses teach, first.” (NIA 63-4)

Rationales for actions split into two groups: the first were direct reactions to assessment of the patient's individual needs at that time. Examples of the first were given by Sedationists B and E: both identified their use of midazolam as a specific response to their assessment of the patient's anxiety (NIB 58-64; NIE 32-34); Nurse B in particular noted anxiety as the patient's most immediate issue, while potential for pain was not imminent, thus accounting for prioritisation of midazolam. The second theme was the development of new, personal approaches to NDPSA based on experience. Nurse D explained their use of initial aliquots of 25mcg fentanyl thus:

“yes that's kind of what I go with. I find 25 works quite well for patients. I think I did used to give 20 to start with, and then 30 to see how well people reacted to it, but recently I've changed as I've though 25 works better in my experience.” (NID 78-81)

Sedationists C also implied past experience informed their practice:

“I've found that the bolus at the beginning A, gets them comfortable and B, gets them, you know, quietly sedated and that they can do their mapping and still the sedation is taking effect; even though you're not ablating at the beginning necessarily, it's a good way of getting them comfortable” (NIC 53-57)

Sedationist A's comment can be seen as combining these two themes, as it was based on the patient's current condition, but also informed by previous experience:

“I think 10mcg and 20mcg of Fentanyl is quite a good dose to give to somebody when you've got them comfortable, it's a good maintenance dose, but until I was on top of somebody's pain, I'd probably be giving 25s to 50s to control pain.” (NIA 39-41)

It was noted that the sedationists using the largest aliquots, A, C and E, were those with the most experience of NDPSA. Sedationist B perceived experience as a determining factor in the practice of others, and their own relatively conservative approach:

“Other nurses, perhaps who have more experience with sedation than me, are more happy (sic) to give larger doses all at once. To me, that's rushing to a cliff edge, and I don't enjoy that, I don't enjoy that experience.” (NIB 141-143)

Sedationist C concurred that past experience provided confidence in doing so again (NIC 62), and Sedationist DF described an evolution of their practice based on growing experience (NID 78-81).

It should be recalled at this point that no evidence found in this study had indicated that the practice of NDPSA in this Trust was unsafe. The safe

resolution of these 6 cases also supported this conclusion, as did the very conscious limiting of drug by sedationist to maintain safety, seen in Section 8.4.3. Some sedationists articulated explanations as to why they considered their larger doses to be safe. Sedationist A emphasised the importance of administering a smaller test dose in advance of any larger aliquots and gauging reaction prior to an increased dose (NIA 63-6). This practice was observed, with initial doses of 25mcg being given, and its impact assessed (OA6-9), in advance of the dose of 50mcg (OA13). However, Sedationist A also considered 25mcg to be a test dose when, alone, it exceeded the largest aliquot specified by the protocol. Sedationist B also used test dose within the protocol which gave confidence to deviate slightly (NIB 102-3). Sedationist C did not administer a test dose, beginning instead with the largest aliquots used (OC11, 13). They explained they had purposefully reviewed the sedation chart from the patient's previous procedure and identified that a large amount of sedation had been required (OC22-40), implying that the possibility of a sensitive reaction to these drugs was discounted. Sedationist E only justified their deviation in terms of the patient's presentation:

“Because she was quite nervous.” (NIE 32)

The patient's anxiety alone was considered and, though Sedationist E emphasised that they assessed response to this (NIE 37-40), they offered no indication that an initial 2mg midazolam bolus represented a safety concern. When the interviewer returned to this subject, they replied:

“A little bit, it did worry me. But I recognised how anxious she was, and that she needed that to be comfortable, and to be settled.” (NIE 160-1)

This sedationist therefore recognised a slight risk but trusted their judgement that this action was necessary.

The question remained whether these deviations were necessary to facilitate an optimal experience? The preferability of proactive fentanyl administration was established in Section 8.4.1. However, in all cases, there was sufficient time between first doses of fentanyl and the first ablation for doses equal to, or exceeding, those actually given, to be administered without deviating from guidelines. Routine deviation, such as that described above (NID 78-81) was therefore unnecessary to achieve the doses of fentanyl administered prior to ablation. Admittedly, sedationists did not know how much time they had prior to the first ablation, and may have felt pressured to give larger doses to achieve

therapeutic levels prior to ablation. However, in every case observed, the timeframe did not require this. Evidence that the deviation from protocol in response to pain made a significant difference to patient experience is insubstantial. The largest deviation occurred during Case A, with 50mcg of fentanyl given immediately after the patient's expression of pain during sheath insertion (OA13). Despite this, and a further 25mcg five minutes after (OA15), the patient displayed evidence of pain during ablation (OA16, 21). Even this aggressive deviation from guidelines did not appear to have been a substitute for proactive use of fentanyl. It cannot therefore be argued that this is important to the optimisation of NDPSA; Case A was identified as mostly positive. However, it is possible that such a deviation could prevent a negative experience, an argument that was supported by the view of the sedationist NIA (39-41).

The decisions to prioritise anxiolysis over analgesia in Cases B and E did appear important to the patients' positive experience. Given that Section 8.3.3 has identified control of anxiety as key to an optimal experience, and Sedationist B's identification that anxiety, not pain, was the immediate problem (NIB 58-64), it can be argued experiences would have been less positive had analgesia been prioritised. However, this variation is allowed by protocol. Case E provided reason to believe that patient experience would have been inferior had the sedationist not deviated from the protocol. The sedationist's communication with this patient proved ineffective in reducing anxiety (PIE 68-70; NIE 113-123), leaving them more reliant on midazolam to control anxiety. The sedationist used 2mg midazolam aliquots in the initial stages of the case (OE11, 15). By deviating, the sedationist was able to administer double the dose of midazolam allowed by the protocol prior to anaesthetic injection (OE13). Some response to this dose was noted (OE12), but the injection still caused some emotional distress (PIE 161). Given the established link between anxiety and the experience of pain (Section 4.3.1), the patient's ability to cope with this noxious stimulus could have been lower had Sedationist E had not exceeded the aliquots specified by the protocol. Furthermore, Section 3.6.1 identified intraprocedural anxiety as a determinant of patient experience *in its own right*, and not simply as a modifier of pain-experience. The deviation from protocol did result in the patient receiving higher doses of midazolam at earlier points in the procedure that would have been possible via strict adherence to the protocol. Ultimately these were effective in controlling her anxiety. It is therefore argued that Patient E would have had an

inferior experience had Sedationist E not used midazolam in a way unspecified by the protocol. That these deviations and variations impacted upon patient experience has important implications for the status and utility of the NDPSA protocol, which will be explored in Chapter 10.

Chapter 9: Findings

9.1 Introduction

This chapter identifies the main findings of the study, which draw on analysis from both phases. Specifically, as this study follows an explanatory mixed-methods design, it will detail how and why the patterns and configurations identified during survey analysis occurred, as identified by the case study phase. When stating these findings, this chapter will also return to the study's objectives and ascertain whether these objectives have been achieved.

9.2 The Safety of NDPSA

Section 6.2.3 concluded that the survey phase found no evidence that NDPSA exposed patients to any greater risk than other methods of PSA used during AF ablation. It was also noted that the sedation strategy was changed significantly less frequently to preserve safety in cases in which the patient received NDPSA, than in the propofol-based regime of Salukhe *et al.* (2012). Following the case studies, this required some qualification. It was noted that aliquots of medication were adjusted in 5 of the 6 case studies. However, these represented changes within the strategy of NDPSA, rather than a change of strategy itself.

Furthermore, these adjustments were independent of medical intervention; Section 6.2.3 also concluded that NDPSA required less medical intervention to maintain safety than the regimen of Kottkamp *et al.* (2011). The case study phase provided an explanation as to why the practice is safe, which from a realist position, is more valuable than statistical power (Pawson and Tilley, 1997). In only one Case, B, was the alert threshold actually crossed; though the alert was raised, normality was resumed with nothing more than a pause in sedation. In other cases, sedationists were acutely aware of changing observations and titrated medication to maintain observations within safe limits (Section 8.4.3). Thus, safety is maintained through the agency of the sedationist who is vigilant, able to project possible deterioration, and empowered to adjust medication independently.

Some qualification of this finding is required. First, the actions of these sedationists in maintaining safety were *independent* of the NDPSA protocol. Although NDPSA dedicates a nurse to monitoring and titration of sedation, it

cannot be assumed its use inherently includes the ability to anticipate further deterioration if drug doses are not reduced. While the replications of this action in five cases was valuable in establishing analytic generalisation of it (Yin 2014), all participants had a minimum of 18 months NDPSA experience. It cannot be concluded that a novice strictly applying the protocol would anticipate impending thresholds, or would adjust medication in the same way. This study has placed a strong emphasis on training (p.13) which may have facilitated these actions, or they may be the result of experience in practicing PSA. However, they cannot be attributed to the use of the protocol. Second, it should be noted that adjustments to maintain safety were sometimes made at the expense of patient experience. Both Sedationists A and D prioritised safety over management of pain as it occurred. This lends support to the argument for proactive, rather than reactive pain management: when the majority of analgesia was administered before the patient was exposed to noxious stimuli, the dose could be titrated to maintain safety without compromising the patient's experience

9.3 Patient Satisfaction with NDPSA

The survey phase indicated that a substantial majority of patients had experiences of NDPSA which were positive or mostly positive. 8 of 62 patients (13%) had negative experiences. This said, only 27.4% were identified as having optimal experiences, with the majority having mostly positive experiences. There is, therefore, considerable scope for patient experience of NDPSA to be improved. Furthermore, investigation of the pathways identified by fsQCA using process tracing led to the conclusion that experience of NDPSA is worse than the self-report of the survey phase indicated. Pathway 2 was responsible for this concern as the evidence found indicated that in cases of this type, stoical attitudes can mask unsatisfactory experiences. A substantial body of evidence (Section 7.4.1) identified stoicism as a potential explanation as to why older patients gave consistently positive evaluations of their experience despite experiencing pain. Case study analysis of Pathway 2 supported this; three cases in the second phase were described by this pathway: A, B and D. Of these, B was by far the most positive report, but process tracing revealed that this case was successful due to effective anxiolysis, and therefore closely resembled cases following Pathway 3. By contrast, Patients A and D reported some pain, but noticeably less than was observed during the cases. This, coupled with

attitudes expressed by both patients in their subsequent interviews, indicates that stoicism accounted for their reports reaching moderately favourable levels. Case F displayed a similar pattern, with experienced pain being considered acceptable, and approbation for stoic attitudes.

This study acknowledges the role of stoicism amongst older patients in generating more positive reports of NDPSA despite pain, but this does not commit the findings to the conclusion that all older patients are necessarily stoic, or that they will endure pain in all circumstances. Patients 9 and 57 endured negative experiences despite being amongst the eldest in the survey phase, though it should be noted neither of them received paracetamol, nor doses of fentanyl or midazolam above the point of ambiguity.

That three out of six case studies relied on stoicism for mostly positive reports prompted some alarm regarding the claim resulting from analysis of survey data that NDPSA is generally effective. Specifically, Pathway 2, which described Cases A, B and D, appeared dubious as two of these three cases relied on stoicism. However, the fsQCA analysis reveals that only 4 of the survey cases (1, 3, 31 and 49) were, like A, B and D, described by this pathway alone. Of these, only Case 31 was an optimal case, and shared key features with Case B: a body mass index below the threshold for full non-membership of the set “Obese Patient”, and a 4mg dose of midazolam. This was not true of Cases 1, 3 and 49, and these patients returned Cluster B reports. In the absence of an alternative explanation, and with the evidence provided by Cases A, D and F, it is likely that stoicism played a role in the mostly positive reports from these cases. The number of cases relying on stoicism for positive report may therefore be lower than feared. However, although these stoic patients expressed general satisfaction with the experience of NDPSA, it would be unethical to rely on the patient’s expectation and willingness to endure some pain as a substitute for effective analgesia. Patient D made the valid point that he had no similar experience to which to compare it (PID 161) but cases such as B and C demonstrated that enduring pain is not necessary. Cases relying on stoicism cannot be considered optimal PSA and, though the number of cases that relied on this in the survey analysis were smaller than feared, the existence of such cases requires improvement in the practice of NDPSA.

9.4 Optimisation of NDPSA

Patients B and C gave the most positive reports of experience, followed by Patient E, once dissatisfaction with communication prior to the procedure had been excluded. Patients B and C appeared entirely calm after the early stages of their cases; neither reported any pain and, equally importantly, neither demonstrated any sign of being in pain. Patient E, after some initial agitation, behaved similarly once sedation took effect. C and E were described by Pathway 3. Case B was described by Pathway 2; however, process tracing showed it to be different from other cases described by Pathway 2, with evidence of anxiolysis following early, purposeful intervention with midazolam, evidence of reduced anxiety, and a painless procedure. Although this midazolam dose was insufficient to reach the threshold for membership of the “Heavy Sedation with Midazolam” set, the patient’s low body mass meant anxiolysis was achieved regardless. The importance of effective anxiolysis to these cases was particularly conspicuous in Cases B and E due to these patients’ extreme anxiety. More will be said of this anxiety shortly, but Patient E’s distressed response to the injection of local anaesthetic (PIE 161) indicated that a positive outcome could not be achieved without controlling her anxiety.

Early use of midazolam was a feature of all three cases; in Cases B and E, sedationists stated this was in direct response to their assessment of their patients’ anxiety. However, patient interviews revealed that use of sedatives was not the only intervention that proved effective in management of anxiety. Patient B had some very specific concerns regarding the competency of nurses to provide PSA (PIB 24-28) but stated that the professionalism demeanour of Sedationist B played a role in dispelling anxiety prior to the administration of any medication. This was echoed by Patient C, who found the orderly lab environment into which he arrived a reassuring contrast to his previous experience (PIC 34-40). Despite this, Sedationist E felt that there was a limit to what could be achieved through communication, noting that Patient E remained extremely anxious despite their attempts at distraction (NIE 120-123), and opined that aggressive use of midazolam was necessary to guarantee anxiolysis (NIE 32-34). The different causes of anxiety should also be noted at this point; previously cited studies (Ploghaus *et al.*, 2001; Wise *et al.*, 2007) consider only the relationship between pain, and pain-related anxiety. This was present (PIB

23-33; PIE 117), but patient anxieties extend beyond this, to the competence of the sedationist in Case B, to the long-term effect of the procedure in Case E (PIE 28-30). This may explain why Sedationist B was able to relieve some anxiety through professional communication (PIB 46-61): this appears to have prompted the patient's confidence in the sedationist, whereas nursing professionalism was largely irrelevant to Patient E's concerns regarding long-term effect of the procedure.

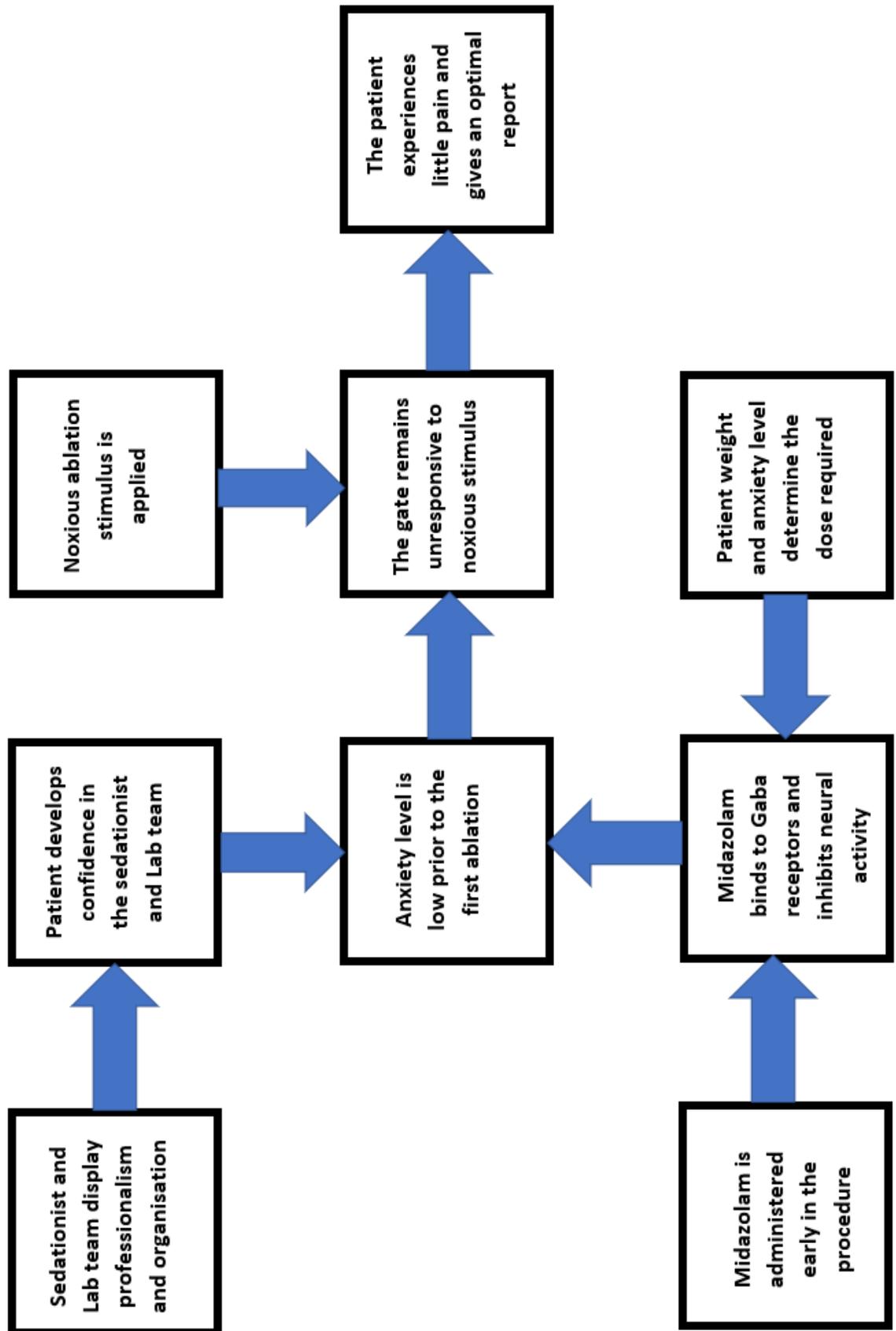
Process tracing established that, in cases described by Pathway 3 and cases such as Case B, midazolam acted by creating a state of low anxiety which, in turn, acted as a context in which the patients experienced little or no pain. The mechanism by which midazolam brings about anxiolysis is well-understood (Rang *et al.*, 2012), and not challenged in this study, but this finding is opposed to the theory that midazolam triggered an amnesic mechanism, which could lead to a positive report despite pain. That anxiolysis proved effective in controlling the patient's pain becomes a more convincing argument when Melzack and Wall's (1965) GCT is considered. This theory postulates that anxiety and emotional distress open *the gate*, enabling impulses from the nervous system to reach the brain. By contrast, if *the gate* remains closed, the experience of pain can be reduced. The single most important finding of this study is that well-controlled anxiety is the context that proved most reliable in making *the gate* unresponsive to the impulse of pain. This relationship is summarised in Figure 9.1.

This diagram details the events and processes found to lead to an optimal outcome. Central to it is a low level of anxiety prior to the first ablation. This can result from a combination of the sedationist's use of midazolam, and their interaction with the patient. However, accepting the GCT, it also serves to make the gate unresponsive to the noxious stimulus of the ablation, ultimately leading to little experience of pain, and an optimal report. In Cases B and C, the communication between the sedationist and the patient, and the growing confidence that it generated served to reduce the anxiety of each patient. This was not a feature of Case E, but it is not required that these processes are universal. It is hypothesised that this was important in Case B specifically because this patient's anxiety stemmed from doubting the competence of the nurse, while Patient E's anxiety related to the outcome of the procedure. Whether both processes were necessary to control the anxiety of Patient B is unanswered,

though in practical terms, there is no conceivable reason why the nurse would need to choose.

Also included in Figure 9.1 are patient characteristics which made anxiolysis harder to achieve. These are obesity and prior anxiety. Case B demonstrated that cases described by Pathway 2 could have an optimal outcome *because* anxiolysis could be achieved using midazolam below the 5mg threshold required for membership of Pathway 3. The logical difference between Pathways 2 and 3 is that the former substituted “not an Obese Patient” for “Heavy Sedation using Midazolam” (p.190). This meant that anxiolysis was achieved in obese patients, but this required higher doses of midazolam on some occasions. This is not logically challenged by the fact that not every obese patient required this: anxiolysis was achieved in the mildly anxious but obese Patient C, with only 2mg prior to ablation. This returns attention to *how* the sedationist used midazolam in this case. The high levels of anxiety in Cases B and E, were also controlled effectively, but required deliberate and aggressive use of midazolam early in the procedure. It is argued here that an anxious and obese patient would present the most challenging sedation case; this is also supported by Section 6.5.4, in which a solution term including the conjunction of “Obese Patient” and “Anxious Patient” was the only consistent path to a negative experience found by fsQCA. Such a challenge is surmountable, as the optimal report of Survey Case 10 demonstrated; however, this study has found that this requires deliberate, early use of relatively large doses of midazolam. Given that this required initiative beyond the protocol and, in Case E, breaking it, it cannot be guaranteed that every such patient receives such treatment.

Figure 9.1 Flowchart Describing Optimal NDPSA via Anxiolysis



It should be noted that, while Figure 9.1 emphasises the management of anxiety as central to the optimal experience, it does not deny that some analgesia is necessary too. Both Pathway 2 and 3 included 1G of intravenous paracetamol, which appeared to become standard practice in the time between the survey and case study phases. All patients also received some fentanyl: Case B (1.9 mcg/Kg/hr) approached the point of ambiguity in the set “Moderate Analgesia using Fentanyl”, and Case E (2.08) just crossed it. However, Case C received minimal fentanyl (0.49 mcg/Kg/hr); this was the lowest rate of fentanyl administration in the case study phase, and lower than all but one case in the survey phase too. Nor was this an isolated example of a case described by Pathway 3 having an optimal experience despite low dose of fentanyl; Survey Cases 5 and 44 fitted a similar pattern. It is argued that an optimal experience can be facilitated using a minimal dose of analgesia if, firstly, anxiety is well-controlled as described above, and fentanyl is used proactively. It is questionable whether Cases B and E required as much fentanyl as they received. However, as Sedationist B explicitly stated “I could have given less, but I don’t feel there was any need for me to give less” (NIB 107). It should be noted that the sedationist does not know how the patient will react to the first ablation until it actually occurs; Sedationist B’s perspective therefore becomes entirely understandable.

FsQCA indicated a third pathway to a successful outcome which was largely unconsidered by the case study analysis. This related to the use of fentanyl alone. FsQCA showed that no patient receiving more than the 2 mcg/Kg/hour point of maximum ambiguity had a negative experience. More importantly, both patients, Cases 12 and 33, who received over 3 mcg/Kg/hr of fentanyl had optimal experiences. Both these patients had membership scores of zero in Pathways 2 and 3. Unfortunately, the case study phase did not include a case in which fentanyl dose passed the upper threshold; given the rarity of such cases, it was considered unlikely to do so without compromising the sedationist’s independence. No evidence contradicted the hypothesis that a high dose of fentanyl alone was sufficient for an optimal procedure, and such a conclusion is coherent with existing theoretical understanding of fentanyl’s action (Rang *et al.*, 2012) in closing *the gate*. However, a question remains regarding the utility of this pathway in the case of highly anxious patients. Having stressed the importance of anxiolysis in such cases, and that anxiety does not derive from fear of pain alone, it is a dubious that fentanyl itself would be sufficient for an anxious

patient. Case 12 gave confidence to the assertion that fentanyl can produce an optimal outcome in patients who are not anxious; this patient rated her preoperative anxiety as 1/10. Case 33 was anxious (7/10); however, they were also amongst the lightest patient in the entire study (54.1 Kg). Given the conclusion that anxiolysis was achieved in Case B with lower dose midazolam due to their low body mass, the possibility that the same occurred in this case cannot be dismissed. Identifying whether fentanyl alone can result in an optimal experience for a highly anxious patient would require further research, though withholding the anxiolytic in such a patient could be regarded as unethical.

Finally, the case study phase did provide an explanation as to why so few patients in the survey phase received doses of fentanyl above the 2 and 3 mcg/Kg/hour threshold. In Cases B, C and E fentanyl was used proactively, with the drug given at considerably higher rates prior to ablation than after it. These sedationists identified this as a deliberate strategy to prevent pain, rather than attempting to remedy pain when it arose. Sedationist DF expressed support for this proactive approach, but their practice did not demonstrate this, with fentanyl given at a slow rate prior to the ablation, then increased as the patients evinced evidence of pain. There is strong reason to believe that the 9 cases that exceeded the 2mg/Kg/hr threshold also received large doses of fentanyl prior to ablation (pp.197-198). It is therefore theorised that more cases did not pass the 2 and 3 mcg/Kg/hr thresholds as, once they had received pre-emptive fentanyl, the need for further administration did not arise, beyond the need for maintenance doses. Thus, cases such as 51 and 64 can be considered to closely resemble Case 12, with all featuring low initial levels of anxiety, low use of midazolam, relatively high use of fentanyl, and an optimal report.

9.5 The Contribution of the Sedationist

Sedationists made virtually no reference to the protocol; the only acknowledgement was made by Sedationist A (NIA 63-4). All sedationists performed actions that were not specified by the protocol; some of these were allowed by it, while others transgressed parameters set by it. Of the first, the early adjustment of medication in response to changing observations was discussed in Section 9.2. It could be argued that these adjustments demonstrate greater respect for the boundaries of the protocol than repeatedly crossing these boundaries and alerting medical staff each time. However, the lack of reference

to protocol parameters made it possible that nurses were simply exercising clinical judgement. Either way, this contribution to patient safety represented action independent of the NDPSA protocol, albeit within its boundaries. All sedationists adjusted medication in this way, except for Sedationist C, in whose case observations did not deteriorate. This included Sedationist DF, who was the least experienced of the participants. This suggested that such adjustments are not highly dependent on experience, though it should be noted that even Sedationist DF had 18 months experience at the time of Case D. It cannot be assumed that novice sedationists would respond in such a manner. However, such responsiveness may be an inherent benefit of NDPSA, as it dedicates a member of staff to the monitoring of observations and titration of medication (Appendix A, p.262).

The prioritisation of midazolam in Cases B and E was considered of great importance to their positive outcomes, as demonstrated by the primacy given to effective control of anxiety in Section 9.4. The NDPSA protocol allows this (Appendix A, p.264), but offers no guidance on when to do it. That it was prioritised in these cases was a direct result of assessment by the sedationists (NIB 58-64; NIE 32-4). Both sedationists and the researcher noted extreme anxiety in these patients, and it appeared unremarkable that they should decide to prioritise midazolam in such cases. Nevertheless, as with the adjustments to maintain observations, such initiative cannot be assumed in the novice sedationist.

Further evidence of initiative within the protocol came in the form of proactive use of fentanyl in Cases B, C and E. This was the result of a deliberate strategy in all 3 cases: in Section 8.4.1, each of these sedationists confirmed that this was their routine approach. This approach was identified as being of significance to the optimisation of experience in Section 9.4. The protocol does not specify it, stating instead “titrate as required further doses of fentanyl” (Appendix A, p.265), which suggests a reactive, rather than proactive approach as “need” can only be identified retrospectively. The protocol does state “for patients within the normal body mass index generally are according to weight i.e. 70mcg for a 70Kg patients” (ibid, p.265), but gives no indication that 1mcg/Kg is intended as a target dose prior to ablation. Furthermore, Sedationist B identified the approach as “what I like to do” (NIB 87), and Sedationist C as their “personal practice” (NIC

73). It is implied, rather than stated, by three sedationists that their personal approach was informed by experience: Sedationist B describes unsatisfactory cases when this approach had not been used (NIB 87-8), while C and E both imply the finding of personal rules via experience (NIC 53-4; NIE 73-4).

Further evidence of experience facilitating a proactive strategy was found. While Sedationist DF indicated a preference for proactive use of fentanyl, it was not used in either case. Section 8.4.2 identified the naïve expectation of the junior sedationist that notice would be given prior to ablation, thus facilitating proactive use of fentanyl. Sedationists B, C and E were under no such illusions, and identified strategies that they had developed to ensure proactive use despite this lack of communication from the medical team. Sedationist DF was also subjected to distractions in both cases which appear to limit their situational awareness. Such distractions occurred in Cases B and C, but did not lead to any loss of awareness. There is therefore a strong argument to be made that junior sedationists must be allowed to focus on the patient in order to optimise sedation.

All sedationists exceeded protocol parameters by using aliquots of greater than 20mcg of fentanyl, and two exceeded the specified 1mg aliquots of midazolam. The most experienced sedationists, A, C and E gave the largest aliquots. Sedationists directly (NIC 52-58; NID 79-81), or indirectly (NIA 39-41), referred to experience as guiding their actions. Sedationist B used a larger aliquot of fentanyl than DF (OB32), but also cited their own relative lack of experience as why they were not willing to give larger increments (NIB 141-143). However, assessment of the individual patient also informed sedationists actions: Patients B and C had previously undergone ablation using NDPSA, and their sedationist made use of previous sedation records to ascertain previously doses (NIB 21-2; NIC 21-6). Sedationist A did not have this luxury, but cited the importance of testing the effects of medication before increasing the aliquot (NIA 63-7), as did Sedationist B (NIB 101-3). By contrast, Sedationist E offered the least support for their action, citing only the patient's level of anxiety in explanation of their action (NIE 34-5). However, the sedationist expressed little concern regarding this administration beyond stressing the need to monitor the reaction (NIE 37-40). More will be said of this action in Section 10.4.2.

Despite the lack of explanation, Case E was the case in which exceeding protocol parameters appeared most important to the patient's experience of the case. Patient E required the administration of large doses of midazolam to achieve anxiolysis. Even with this, midazolam had not reached its full effect at the time of local anaesthetic injection, which resulted in a distressed reaction (PIE 161). The dose of midazolam given at this point could not have been reached within the parameters of the protocol, and controlling anxiety was itself an important end, as well as a means of controlling pain. It is therefore concluded that the patient's positive experience did depend on the sedationist's willingness to trust their own judgement. Beyond this, little evidence to support the increased fentanyl aliquots used by all sedationists was found. Accepting the proactive administration of fentanyl as superior, all cases included an adequate length of time in which the cumulative dose at the start of ablation to be reached without exceeding the 20mcg aliquot. This may be because nurses were unaware how long they would have to administer fentanyl, but this study has revealed adequate time in all cases. Finally, it should be acknowledged that larger aliquots of fentanyl may be needed to control pain once it occurs, as argued by Sedationist A (PIA 39-41). This is not a factor in the discussion of optimal sedation as it is only needed in sub-optimal cases. However, it may be necessary to prevent an adequate experience becoming unacceptable; it was a unique event amongst these case studies, and this study draws no conclusions about the importance of such action.

This section does conclude that reference to the protocol was not the process by which decisions, specifically regarding drug use, were made. To explore these processes, these findings will be further discussed through the introduction of decision-making theory in the next chapter.

Chapter 10: Discussion

10.1 Introduction.

This chapter will discuss the project's findings in relation to the contexts, both practical and theoretical, that produced the need for NDPSA and shaped the aims of this study. This requires some comparison to other studies focusing on PSA, both in terms of results, and of methods. It also integrates the findings of Section 9.5 with decision-making theory, both to comment on the utility of the NDPSA protocol, and to make recommendations for its development. It identifies some limitations of the current study, and the need for future research to address these. It will also discuss some emergent themes which, though beyond the scope of NDPSA and practice in the CCL, appear to have an important impact upon it.

10.2 An Alternative to Established PSA Models.

This project began with the intention of ascertain the feasibility of NDPSA as an alternative to other models of PSA used during ablation, specifically Piot's (2015) anaesthetist model, and the operator model. The former was criticised as an inefficient use of resources (Gaitan *et al.*, 2011), while the latter failed to adhere to UK standards (Furniss and Sneyd, 2015). To represent a suitable alternative, literature determined that NDPSA must be safe, and it must facilitate an acceptable patient experience. This section will consider the extent to which this has been done.

10.2.1 A Safe Alternative.

The safety of NDPSA was compared to that of other methods in Section 6.2. The six case studies contained no complications, so the conclusion that NDPSA does not expose patients to any greater risk than other sedation methods remained unchallenged, and marginally strengthened. Some limitations to this conclusion should be acknowledged; the decision to base the sample size on the number of AF ablations performed within a single year was due to the time constraints of PhD study. The sample was representative of the cases within that year, but may not represent the ever-growing population undergoing AF ablation. Furthermore, it was too small to always ascertain that NDPSA was safer than alternatives; the sample was not calculated to test this hypothesis, though some analysis

indicated that this may be the case. By comparison, Sawhney *et al.*'s (2017) study into the safety of nurse-administered sedation in the CCL included a sample of 7117 cases, which took 12 years to amass. They do not justify such a large sample in terms of the statistical power that this provides; however, the sample used in this study cannot have the same claim to statistical representation. Furthermore, Hanley (1983), introduces a note of caution regarding conclusions drawn from zero numerators, explaining that they do not mean zero possibility of the event occurring. His solution, *The Rule of Three*, states that, in the event of numerators, it can be assumed with 95% confidence that the chance of an event occurring is, at most, 3 in n . The FETs detailed in Figures 6.3c, 6.3d and 6.4b were repeated, using an assumed occurrence of 3 in 70 cases, including the case studies. The hypothesis that NDPSA required more intervention than the practice of Sawhney *et al.* (2017) and Kottkamp *et al.* (2011) was still rejected; the hypothesis that NDPSA required less strategy change than cases in Salukhe *et al.* (2011) was still supported. The conclusions regarding safety remained unchallenged.

Thus far, this study has regarded the practice studied by Sawhney *et al.* (2017) as an alternative means of PSA to NDPSA as it used a different protocol. However, it should be acknowledged that this study also focused on the titration of PSA, including benzodiazepines and opiates, by nurses. As such, the safe practice recorded in that study can be regarded as supporting the conclusion that the concept of nurses managing PSA in the CCL is safe. Differences exist between the protocols: Sawhney *et al.* (2017) require observations to be recorded at maximum intervals of 15 minutes, compared to the 5 minutes required by NDPSA. Insignificant differences in reversal rates (0% vs 1.2%) were found between the protocols, which might be explained by this, but a larger NDPSA sample would be needed to identify any superiority. However, both studies support the safety of the doctor/nurse model (Piot, 2015) when responsibility for titration belongs to the nurse.

The low rates of complications in both studies suggest a benefit in a dedicated individual having responsibility for both monitoring and titration of PSA. Section 9.2 identified nursing vigilance, and authority to titrate sedation in response to changing observations, as important contexts in making NDPSA safe. Furthermore, the observations of sedationists B and C that communication

between sedationist and nurse is unreliable in the CCL (Section 8.4.2) support this: when the nurse is empowered to adjust titration without communicating with the operator, rapid adjustment of medication in response to the patient's condition could be made. Such adjustments were observed in sedationists with a range of experience, including the least experienced. While such titration represented a decision independent of the protocol, it could be argued that such adjustments by qualified professionals are common sense, and unremarkable. If true, this represents an inherent safety benefit of the NDPSA system as it dedicates an individual to the monitoring of the patient. In Section 2.4, reasons identified for the unsuitability of the operator model included that focus on the procedure distracting from the patient's condition (AoMRC, 2013). Furniss and Sneyd (2015) do not mandate a person dedicated to patient monitoring unless propofol is being used as the sedation agent. However, the value of such a dedicated person during NDPSA was apparent in maintaining observations in a safe range, and this is a fundamental aspect of NDPSA, as it is specified in the protocol document (Appendix A, p.262). The findings of this study provide some support for UK standards (Furniss and Sneyd, 2015), specifically the assertion that the operator model is inappropriate in the CCL. While full endorsement of this standard would require stronger evidence demonstrating that UK practice is safer than other practices, this study has found no evidence that UK standards are excessively stringent. Furthermore, the recorded benefits of an individual dedicated to monitoring and titration support the argument that the operator model could compromise care, and provide reason to believe NDPSA may ultimately be safer than practices using the operator model. The one limitation on the conclusion that this titration to maintain safety is an intrinsic benefit of NDPSA is that no sedationist taking part in the case studies had less than 18 months of experience; no such sedationists were willing to take part in the study. That their practice may be dependent on the protocol (Benner, 2001) cannot be denied. To confirm this mechanism is an inherent benefit of NDPSA would require the study of the practice of new sedationists.

10.2.2 Experience Compared to Other Studies.

This study did not set out to directly compare patient experience of NDPSA to other studies. However, the experience needs to be acceptable to the patient if NDPSA is to be more than a "cost-effective redesign" (Barton, Bevan and

Mooney; 2012a, p.18). As it proposes NDPSA as an alternative means of PSA during ablation, some comment on relative patient experience should be made to ascertain that this practice meets the NMC's (2018) requirement to maintain quality of care. Furthermore, as no study has delivered exclusively optimal experiences, the ability of a PSA method to enhance patient experience is a relative term, although the diversity of measurements used to ascertain experience in different studies makes statistical comparison of little value. Of particular interest were the studies of Tang *et al.* (2007) and Ezzat *et al.* (2012), as both focused on patient experience during AF ablation. The study of Laurent *et al.*'s (2006), which focusses on Atrial Flutter ablation, is also of interest.

Ezzat *et al.* (2012) measured patient experience from preoperative clinic to discharge when undergoing AF ablation. This included their experience of physician-directed, nurse-administered PSA. In summary, 79% of their respondents reported overall experience to be good or excellent, with 8% rating it as fair or poor (the remaining 13% is not explained). By comparison, 87% of participants in the NDPSA study's survey phase gave positive or mostly positive reports. Though these figures offer some support for NDPSA, Ezzat *et al.*'s respondents explicitly stated their satisfaction; by contrast, the positive reports in this study were interpretations of data using HCA. However, raw data from the survey phase also provided an argument that NDPSA is at least the equal of the practice in Ezzat *et al.*'s study. 37% of their patients reported the procedure as more painful than expected. The double variable, pain and expectation, meant there was no means of ascertaining whether the pain experienced was acceptable to them, but more pain than expected suggests some degree of dissatisfaction. By comparison, 23 of 62 patients receiving NDPSA recalled a worst pain score exceeding what they were prepared to accept, also 37%. Yet this figure included short-lived pains such as anaesthetic injection; only 6 patients (9.6%) reported that the most typical pain during ablation under NDPSA was worse than they were prepared to tolerate. Some basis therefore exists to believe that NDPSA provides a comparable, and possibly superior, patient experience to the practice described by Ezzat *et al.* (2012).

Tang *et al.* (2007) studied patients undergoing AF ablation while sedated by infusions of midazolam and fentanyl. This report gives relatively little detail regarding the patient experience, but does record that 56 of 60 (93.3%) of

patients receiving this infusion found pain during the procedure to be tolerable. It is therefore implied that the remaining 6.7% suffered intolerable pain. This is comparable to the 9.6% experiencing prolonged, unacceptable pain in the NDPSA study. Laurent *et al.* (2006) asked patients to rate their pain on a 101-point scale at intervals during the procedure when comparing PSA using nitrous oxide and their infusion of nalbuphine. The mean pain score of the group receiving nalbuphine was 45, while the mean score of the nitrous oxide group was 18. The mean worst pain experienced during NDPSA was 4.5 (on an 11-point scale), whereas the mean typical pain experienced was 2.25. Even a hostile interpretation of these figures would suggest that NDPSA is equal to the standard practice of nalbuphine infusion. If mean typical pain is used, NDPSA becomes more comparable with pain experienced when using nitrous oxide. Making this comparison, it should be recalled that Laurent *et al.* (2006) appraised pain during atrial flutter ablation. Without dismissing the pain this can cause, AF ablation is recognised as being more painful (Kottkamp *et al.*, 2011), which potentially biases this comparison against NDPSA.

Some objections to these comparisons should be acknowledged. The first is that the case study phase demonstrated that the survey phase evaluated NDPSA generously. While 54 of 62 surveys were interpreted as positive reports, the case study phase demonstrated that a proportion of those reports would be influenced by a culture of stoicism, with some patients retrospectively reporting less pain than they experienced, making comparison unreliable. Here, the NDPSA study can be seen as a victim of its own rigor: this thesis was critical of studies relying on retrospective reports alone because retrospective self-report might not give an accurate reflection of patient experience (Section 3.6.2). The case study phase guarded against this. These comparisons are therefore not discredited: Ezzat *et al.* (2012) also appraised pain via retrospective survey; this study was also undertaken in the UK and, though they do not consider it, their results may also have benefitted from a culture of stoicism. Tang *et al.* (2007) do not specify when reports of pain were elicited; furthermore, as their study was conducted in a different culture, the assumption that stoic attitudes coloured retrospective reports is less secure (Peacock and Patel, 2008) although, without evidence to the contrary, this possibility cannot be denied. The objection is more sustainable in relation to Laurent *et al.* (2006) who ascertained pain scores during the procedure: this does mean pain was reported as it happened, rather than in the

context of a safely completed operation. The stoical attitudes identified in the NDPSA study did not prevent expressions of pain during cases; therefore, comparing retrospective reports of pain obtained in a stoic culture, to scores ascertained at the time of ablation in any culture, is open to sustainable criticism. The weakness of retrospective report alone to appraise patient experience has been demonstrated by this thesis, and should be considered a valuable insight for future research into all PSA.

The second objection is that these comparisons between practices are speculative: no two evaluated patient experience using the same instrumentation. This is an entirely sustainable objection; these comparisons *are* speculative and intended only to show that NDPSA is not conspicuously inferior to other forms of sedation and, as such, represents a feasible alternative. A valid comparison would require the work of another study, with either the clinical control necessary to perform such a study in one trust, or access to a second centre in which the experiences of patients using alternative systems could be measured. Such a study, using the same data collection methods for each, would be valuable in the future. However, while the findings of this study have alleviated the concern that NDPSA is a “cost-effective redesign” (Barton, Bevan and Mooney, 2012a, p.18) that compromises the nurse’s professional responsibility to maintain the quality of care (NMC, 2018), this discussion also makes some recommendations for improvement in the current practice of NDPSA (Section 10.4.3). While the practice of NDPSA in its current form may be acceptable in terms of quality of patient experience, any direct comparison to other practices should be undertaken after recommended improvements are made. This thesis was previously critical of Martin *et al.* (2018) for comparing GA to what appeared an inadequate form of conscious sedation (p.23). To make the most useful comparison, NDPSA must first be optimised.

10.2.3 Unaddressed Questions.

Section 3.4.3 identified AF recurrence rate as an indicator of the efficacy of PSA. While evidence that sedation-type contributed to recurrence rates was mixed, some studies (Di Biase *et al.* 2011; Martin *et al.*, 2018) found significantly higher rates of recurrence in groups receiving conscious sedation when compared to GA. The substantial body of research on this topic indicates that it is of interest to those selecting PSA method. Information regarding recurrence

rates was sought from the Trust in which this study took place; these would have not related to the cases studied, but given some indication of the reoccurrence rate for patients undergoing AF ablation under NDPSA. Unfortunately, these results were not forthcoming. Further research will therefore be needed to answer the effect of this practice on reoccurrence rates. Likewise, Section 3.4.4 discussed the economic dimension of PSA selection. The economic superiority of NDPSA over GA was assumed, but has not been demonstrated by this study. While this assumption appeared safe, and is conceded by proponents of GA (Martin *et al.*, 2018), such an economy could be false if NDPSA resulted in an increased reoccurrence rate, and an increase in repeat procedures. This reiterates the need to study reoccurrence rates when using NDPSA.

10.3 Optimisation of NDPSA.

The methodology of this study allowed for causal complexity, and the possibility of equifinal paths to an optimal experience (Schneider and Wagemann, 2012). This was justified by the GCT's recognition that factors leading to the closure of *the gate* could be multiple and complex (Section 5.3.2), and the number of potentially relevant causal conditions in the literature review (Section 3.7). Complexity was not assumed and, subsequently, the mechanisms of optimal NDPSA, as described in Section 9.4 were simpler than anticipated. Although only one pathway, focused on effective control of anxiety, was firmly established, other cases identified in the survey phase indicate that at least one other pathway to an optimal experience existed. This focused on control of pain using fentanyl. The implication of these two pathways for the practice of NDPSA and for further research will be discussed in this section.

10.3.1 Unification of the Pathways.

The two routes to an optimal experience can be reconciled through the application of Melzack and Wall's (1965) GCT. This indicates that, not only can the experience of pain be inhibited by blocking ascending signals of pain at *the gate*, such as through the action of fentanyl, but can also be modulated by descending signals from the brain, with anxiety opening *the gate*, and increasing experience of pain. Demonstrations of heightened anxiety exacerbating pain were given by Ploghaus *et al.* (2001) and Wise *et al.* (2007) in Section 4.3.1. The findings of this study are consistent with these. The effective management of

anxiety in Cases B, C and E led to little experience of pain, even in Case C, in which minimal analgesia was used. Moreover, though both Ploghaus and Wise conclude that anxiety exacerbates pain, an underemphasised detail of both of these studies, was that pain also caused anxiety. Both used conditioning techniques in which particular projected shapes in the work of Ploghaus, and coloured lights in that of Wise, heralded a more intense pain than other signals. Neither set of patients was informed of the signal code, but were asked to work it out themselves; Wise *et al.* (2007) asked their respondents to explain the code afterwards, which all did correctly. In short, levels of anxiety were manipulated by using the prospect pain: pain and anxiety have a cyclical, symbiotic relationship. This begs questions of how the cycle is most effectively broken and, ultimately, if more than one approach is needed?

10.3.2 The Need for Different Approaches.

Two patients, B and E, were observed in the case study phase arriving in the lab in high states of anxiety: in such cases the cycle of anxiety and pain can be thought of as being in motion. In both cases, their sedationists prioritised the administration of midazolam over fentanyl, with Sedationist B stating that they saw anxiety, rather than pain, as the immediate issue (NIB 60-64). This led to an optimal experience in Case B, and a close to optimal experience in Case E. While the cycle described in the previous section was effectively broken using anxiolysis, evidence suggested that this would not have been possible had analgesia been prioritised over anxiolysis. The first reason is the recognition that, in a heightened state of anxiety, even relatively minor stimulation can cause distress, as demonstrated by Patient E's emotional recollection of the local anaesthetic injection (PIE 160-161); this is supported by the findings of Ploghaus *et al.* (2001) and Wise *et al.* (2007). More important though was the recognition that patient anxiety extends beyond the prospect of pain. Pain-related anxiety was the only type of anxiety to which participants were exposed in the studies of Ploghaus *et al.* (2001) and Wise *et al.* (2007), and prior to this study, it was expected that pain would be patients' main anxiety. However, Patient B specified concerned about the safety of NDPSA, while Patient E was anxious regarding the long-term effects of ablation on their health. While analgesia may help to break the pain-anxiety cycle with regards to pain-related anxiety, it is unlikely to address other anxieties. Cimpean and David (2019) found that perception of a

stimulus as threatening reduced participants' ability to tolerate pain, confirming the earlier argument of Moore, Eccleston and Keogh (2013). Safety-related anxiety, as well as pain-related anxiety impact upon individuals' perception of pain. It is therefore argued that prioritising fentanyl over midazolam would not result in an optimal outcome when the patient is in a high state of anxiety regarding their safety.

That the prioritisation of anxiolysis should be most effective in cases in which the patient is extremely anxious is unsurprising. However, it also proved effective in a case when the patient was not anxious. This was Case C and, although the patient admitted to being slightly more anxious than their demeanour suggested, their anxiety was not comparable to that of Patient B or E. In such cases, the pain-anxiety cycle is not in motion, and the sedationist's role is one of preventing this cycle becoming active, rather than stopping it. It is easy to hypothesise that, if the anxious patient is best managed through prioritisation of anxiolysis, the relaxed patient is best managed through prioritisation of analgesia. No case in this study denies that this can work, but cases receiving high doses of fentanyl and low doses of midazolam were rare: cases 12, 64 and, with a slightly lower dose of fentanyl, 51 fitted a pattern of low anxiety, low midazolam dose, relatively high fentanyl dose, and optimal experience. No such case was observed in the case study phase. However, Case C disputed that this is the best approach in low-anxiety cases; the optimal outcome demonstrated that the prioritisation of midazolam can also be effective in preventing this cycle from starting to turn. Over the course of the case, the use of fentanyl, in terms of micrograms/kilogram/hour was the second lowest in either phase. Even accepting that the fentanyl used was given proactively, the rate remained a modest of 1.1 mcg/Kg/hr prior to ablation. That this case proved optimal prompted further questions: is there any need for heavy use of analgesia during NDPSA, and given that the prioritisation of midazolam appears effective for both anxious and non-anxious patients, should the protocol not focus exclusively on this approach?

Pathway 3 includes some analgesia in the form of intravenous paracetamol. It also makes no reference to fentanyl, though every case in the study received some. Despite the very low dose of fentanyl used in Case C, it cannot be claimed with any certainty that the use of fentanyl had no bearing on the outcome of the

case. This said, the study of Barbero *et al.* (2018), which trialled hypnosis as an alternative to pharmaceutical PSA during ablation, recorded pain-free AF ablation in the absence of any analgesia except local anaesthetic. Four of the five patients in this study underwent AF ablation, some of whom were described as highly anxious due to painful past experiences when using conventional PSA. Participants received “continuous suggestions of peace, analgesia and wellness” (ibid, p.19) throughout their procedures. All 4 participants returned a numerical rating of 0 for pain throughout their procedures, and received no analgesia other than local anaesthetic.

This study was small scale, and the participants were screened and identified as susceptible to hypnosis prior to participation, indicating that such a method was not suitable for everyone. However, such findings lend credence to the control that mental state exerts over the perception of pain. In turn, this supports the hypothesis that Pathway 3 may be able to facilitate an optimal experience with minimal analgesia. How little is a purely academic question as, in the words of Sedationist B (NIB 107) “I don’t feel there was any need for me to give less”. However, the question remains whether the NDPSA protocol, both to support sedationists and optimise patient experience, should specify the prioritisation of anxiolysis over analgesia?

Some circumstances were noted during the case studies which made the aggressive use of midazolam an unsuitable approach. The first occurred in Case D, in which the operating consultant specified that he needed the patient to be awake, but advising the sedationist to go “heavy on the analgesia” (OD8). The second circumstance was the sedationist’s observation in Case F that midazolam resulted in respiratory depression in Patient F after a single initial milligram (NIF 104-5), which led to their subsequent cautious administration. For the protocol to be useful in such circumstances, it must be sufficiently flexible to allow the sedationist a range of strategies. It cannot therefore be concluded that the protocol should specify the prioritisation of anxiolysis over analgesia. This said, the protocol currently states that NDPSA should “usually and ideally” begin with administration of fentanyl (Appendix A p.264), the one aspect of the protocol specifically referenced by any sedationist during interview (NIA 63-4). Given the efficacy of the prioritisation of midazolam in both anxious and non-anxious cases identified in this study, this thesis argues that this piece of direction should be

removed from future versions of the protocol. However, it stops short of recommending the specification a midazolam-first approach, as it is evident that this is not applicable to all cases, and that the strategy should depend on the sedationist's assessment of each case.

10.3.3 Age, Stoicism and Anxiety

When considering the contribution of age to a positive report, two potential explanations were found (Section 7.1.4). Cases A, D and F supported the theory that stoicism prevented negative report. However, this did not explain why the term “not a Young Patient” was included in Pathway 3, and the alternative explanation, that pain perception reduces with age due to decline of the nervous system (Lautenbacher *et al.* 2017), was dismissed because Patients B, C and E were considerably younger than the stoic patients. It was therefore implausible to argue that the nervous systems of patients in their early 50s had declined to an extent that they experienced less pain than patients in their late 60s. However, interview data provided evidence that age, or rather relative youth, may encompass another mechanism which makes younger patients more challenging to sedate, thus excluding them from Pathway 3.

Patients B and E were extremely anxious, and both were only partial members of the set “not a Young Patient”. This alone made an unconvincing argument that younger patients are more anxious, and more challenging to sedate. Survey phase data added some weight to this supposition: a small but significant inverse correlation existed between age and anxiety on the ward (Spearman's Rho Coefficient -0.233). However, these patients' interviews revealed a common, unanticipated theme which could explain *why* younger patients may be more anxious. This was the seeking of information on the internet. Patient B described reading articles online (PIB 90), in which they became aware of the debate regarding providers of PSA during ablation, and the possible risk of NDPSA (PIB 96-100). Patient E was referred to a patient-led support group on *Facebook* (PIE 20-24) and found that responses to queries about the experiences of others were initially negative. Both patients seeking information online found causes of anxiety. Possibly these patients were anxious before receiving this information, thus explaining their information-seeking behaviour. However, even if this was true, the information found amplified anxiety. By contrast, no other patients mentioned seeking information beyond that provided in clinic. Survey data

showed that patients dissatisfied with preprocedural information received were, on average, 5 years younger than those who were satisfied, though this difference was insignificant.

The hypotheses that younger patients are more likely to seek health-related information online, and that online information exacerbates anxiety found some support in existing research. Most was conducted in the USA; however, as another developed country sharing common language, the findings are likely to be transferable to the UK. Kontos *et al.* (2014) found that age was the lone predictor of the likelihood that an individual had used the internet for health-related information in the past 12 months. In this study, patients in the age band 35-49 years were 2.5 times more likely as those over the age of 65 to have used the internet to research health issues. Meanwhile, Laurent *et al.* (2012) dispensed with age bands, instead finding that haematology patients who sought online health information were significantly (CI 95%, $P < 0.001$) younger than those who never did, with mean ages of 53.5 and 68.1 years respectively. This finding was not universally shared: within cardiology, Waring *et al.* (2018) found no significant differences between age bands in health-seeking online amongst patients diagnosed with acute coronary syndrome (ACS). This may be the result of the age bands used in this study: patients under 55, patients 55 to 64, and those over 65. Although the lower band of Waring's study could theoretically include patients as young as 21, the epidemiology of ACS means that its diagnosis will be heavily skewed towards the upper end of the 21 to 55 age range. Therefore Waring *et al.* (2018) may not have captured the same variation in population age as Kontos *et al.* (2014), thus missing variance in online information-seeking behaviour.

While Sjöling *et al.* (2003) found that written information reduced preoperative anxiety, and ultimately post-operative pain, the impact of internet use as a source of information is more ambiguous. Kim *et al.* (2019) found that an online video regarding colorectal surgery was an effective means of reducing anxiety in their subjects. Meanwhile Laurent *et al.* (2012) found mixed results; for 38% of patients, it increased anxiety, and for 32% it facilitated coping. Singh and Brown (2016) found that both anxious and non-anxious participants recorded significantly higher levels of anxiety regarding symptoms after researching them online. A possible explanation for this divergence is the quality of the material

accessed; the online video shown to patients (Kim *et al.*, 2019) was prepared by medical professionals, as was the written material of Sjöling *et al.* (2003). They therefore contained reliable information. Furthermore, it was given to the patients, rather than found via internet search, so cannot be compared to the results of studies such as Singh and Brown (2016) and Laurent *et al.* (2012) in which participants found their own information. Kirthi and Modi (2012) sought to evaluate the quality of online material regarding coronary angioplasty. Using the LIDA instrument, they evaluated 64 websites which constituted the first 50 sites identified by 3 commonly used search engines. 3 of these 64 websites met the LIDA gold standard of 90%, with reliability being the area of greatest weakness, with a mean reliability score of 61.8% (*ibid*). If the success of Kim *et al.*'s video (2019) is attributable to its reliability, it should be noted that this is regularly lacking from accessible websites. However, the fact that use of the internet can exacerbate anxiety in some cases means that it presents a credible reason why Pathways 3 excludes younger patients.

Patients B and E sat outside the set "Young Patient". This set was arbitrarily calibrated due to the lack of available external criteria (pp.115-116); it is therefore plausible that the point of ambiguity, set at 50, was too low to perfectly capture this variation. Laurent *et al.*'s (2012) mean ages of 53.5 and 68.1 for internet users and non-users support this. However, it is not argued that the age of 50, 52 or 53, was somehow significant in itself; rather that somewhere in this age range there was a frontier between a generation familiar with searching for health information online, and a generation who was not. This frontier was unlikely to be sharply defined, or static: as digital natives age, it would advance, and increase the need for reliable online material as it did. While the stories of both patients fitted a broader picture of younger patients using the internet as a source of information and becoming increasingly anxious as a result, it was noted that both had positive experience of NDPSA. However, as previously discussed, in each case their anxiety required decisive action by their sedationist to facilitate their experience; should the response be more tentative, the pain-anxiety cycle may become active and harder to control, even if larger doses of midazolam are subsequently given.

This hypothesis as to why younger patients might prove more challenging to sedate is speculative; this study focused on the optimisation of NDPSA, and it

was not in the ethical remit to actively pursue factors that caused it to fail. Furthermore, it focused on events bounded by the time patients spent in the CCL (p.65); Byrne's observation (2013, p.6) that the demarcation of "the case" is challenging to identify is borne out by this hypothesis, as searching for information stands outside the boundaries of the case in this study. However, the evidence produced by these interviews is coherent with a larger picture; as the impact of online material on the anxiety of ablation patients has not specifically been studied before, this is an area of potential future research whose importance is likely to increase as the digitally literate age. How the internet is best used to manage patient anxiety is also open to future research; Ezzat *et al.* (2012) recommended the direction of pre-ablation patients to useful websites, but do not consider what is useful. While material produced by health professionals (Kim *et al.*, 2019) allows for a high level of quality control and appears beneficial, Patient E stated that she was referred to the *Facebook* support group when diagnosed (PIE 20-1), suggesting some degree of endorsement by the NHS. This resulted in their being initially told exclusively negative experiences of ablation. Possibly the NHS has assumed that such groups will be reflective of all patient experiences, but this account suggests that negative experiences were overrepresented which, in turn, increased anxiety. It is therefore recommended that further research into the effects of peer-support forums on anxiety is undertaken, as such platforms may be misleading and potentially counterproductive.

10.3.4 Additional Means of Reducing Anxiety

Midazolam was the most obvious means by which anxiety was controlled, and the previous section has identified means by which anxiety may be controlled prior to admission. Given the primacy of anxiety-control in facilitating an optimal experience, some other contributing factors should be acknowledged. Patient C emphasised that the orderly environment (PIC 34-42) was an important factor in helping him to stay relaxed. Patient B added that his sedationist's explanation of procedures also helped relax him (PIB 42-43). While a calm environment and an explanation of procedure may appear obvious means of reducing anxiety, both patients observed these were absent in their previous experience of ablation. It was therefore considered worthwhile emphasising these here. Both Patient C and F made mention that the presence of the consultant when they arrived in the

CCL contributed to their confidence (PIC 40-1; PIF 155-6). Patient C specified that this reassured them that the procedure was going ahead, while Patient F appeared pleased to see a familiar face. This led to the conclusion that non-pharmacological anxiety management extends beyond role of the nurse, to the whole CCL team. Patients E (PIE 80-84) and F (PIF 49-52) commented on the alarm that walking into the CCL, and seeing the equipment used in ablation, had caused them. Patient F explained this:

“It goes through your head “what are they going to use this for”, and what they’re going to do?” (PIF 54-55)

This suggested a sense of vulnerability caused by an unfamiliar environment. For this reaction to occur twice in 6 cases was surprising; it should be noted Patients B and C were undergoing repeat procedures and had familiarity with the environment. It therefore occurred twice in 4 first-time patients. The impact of the alien environment on a patient’s anxiety is not reflected in literature elsewhere. Mitchell (2008) does not mention it; however, the method used limited patients to items on the questionnaire, and the theatre itself was not included. By contrast, the NPDSA study allowed the theme to emerge. It was included on a survey by Caddick *et al.* (2012), with only 1 of their 70 respondents identifying that the general theatre environment increased their anxiety. This study included a range of day surgery for which the patient remained conscious; possibly the amount of X-ray, monitoring and ablation technology required in the CCL is more daunting than other theatre environments. The impact of the CCL could merit further research, but including an introduction to the CCL environment as part of reliable online resources, as recommend in the previous section, could increase familiarity with the environment and lessen this impact.

A final means of reducing anxiety is the fostering of realistic expectations, as described by Ezzat *et al.* (2012). Patient F considered themselves less well prepared for the experience of pacing than ablation (PIF 60-16) and found pacing to be the worst aspect of the procedure (PIF 112). Patient A supported this, indicating minor discomfort during ablation (PIA 32), for which he was prepared, but returned to the issue of pacing on several occasions. He indicated more information in advance could have improved his experience (PIA 78-79; PIA 114-115). Prior information appeared to aid tolerance of ablation, and its absence worsened experience of pacing. Any reliable resource, therefore, should include information about sensations the patient may experience, and what they are.

10.4 The Relationship Between Protocol and Practice.

The aims of this study included the identification of the contribution of the individual sedationist to the optimisation of NDPSA, beyond strict adherence to the NDPSA protocol. Such a distinction is important: protocol-based care aims at the standardisation of care (DoH., 2000); should adherence to the protocol result in the high proportion of positive and mostly positive cases, the protocol could be introduced in other hospitals, with similar results expected. However, descriptive theories of clinical decision-making such as Benner's *Novice to Expert Theory* (2001) dispute that prescriptive approaches such as protocols are an accurate reflection of how clinical decisions, particularly at the expert level, are made. Indeed, this theory identifies that expert practice depends on abandoning such abstract principles. Evidence supporting this theory would reduce the transferability of the protocol to a new CCL. However, such findings may not mean the concept of a NDPSA protocol is flawed: instead, it might require modification of the protocol to share best practice, or reconsideration of the protocol's status.

10.4.1 Protocol Adherence

The sedationists interviewed made almost no reference to the protocol or its parameters. Only once was it touched upon, by Sedationist A (NIA 63-64). This lack of specific reference does not mean the protocol did not inform practice; even Benner (2001, p.37) acknowledges the possibility that "rules just become unconscious". This may be true regarding at least one aspect of the protocol: in 5 of 6 cases nurses were observed adjusting medication doses when observations approached the protocol's alert thresholds. Sedationists did account for these adjustments by citing deteriorating observations. Possibly the observance of these parameters was the result of the alert criteria being the only aspect of the protocol printed on the sedation document used (Appendix B).

Some actions leading to optimal PSA were identified which, though not violations of protocol boundaries, were not specified by it either. As identified by Sedationist A, the protocol does indeed state that fentanyl is ideally administered first, but does accept that in some cases, the anxiolytic can be prioritised (Appendix A, p.264). However, it makes no recommendation as to when to do this. In cases B and E this was done, and contributed to the optimisation of the patients

experiences (pp.206-207). The decision to prioritise analgesia can therefore be considered an enhancement of the protocol by the sedationist. The importance of pre-emptive fentanyl-use has also been identified as a factor contributing to optimal experience. The protocol states that 1 mcg/Kg of fentanyl is generally effective dose, but does not advocate this as a target. Furthermore, the protocol lists 10 indicators of the patient being in pain as triggers for administering analgesia (Appendix A, pp.266-267). The protocol then notes the taking of an ablation catheter as a trigger for analgesia, with which Sedationist C concurred (NIC 88-89); however, in the cases in which fentanyl was used proactively, sizable doses had been given prior to this moment. In Cases B, C and E, therefore, fentanyl was used in a manner unspecified, though not prohibited, by the protocol, which appears to regard analgesia as a more reactive process.

Finally, all sedationists were observed using aliquots of fentanyl or midazolam that exceeded the respective 20mcg and 1mg aliquots specified in the protocol. The impact of deviation has been extensively discussed in Section 8.4.4, and reached 3 main conclusions. These were that deviation from protocol-specified fentanyl aliquots was not necessary to achieve cumulative doses given prior to ablation, that deviation may be necessary to manage breakthrough pain when it occurs, and that deviation in use of midazolam was needed to facilitate a positive experience in Case E.

10.4.2 Experience, Competence and Expertise.

The NDPSA protocol was not the mechanism by which sedationists made decisions. While Flynn and Sinclair (2005) noted that senior nurses deviated from protocols most frequently, in this study, the most experienced sedationists were observed to deviate from the protocol by the greatest margins, with Sedationists A and C administering boluses of 50mcg of fentanyl, and C and E using 2mg boluses of midazolam. Benner's model (2001) indicates that this is because expert nurses use their past experience, rather than protocols, to guide their practice in familiar situations. Sedationist C confirmed that past experience gave them confidence to administer sedation in larger aliquots (PIC 64), while Sedationist B also perceived that experience allowed other sedationists to administer PSA more rapidly than they themselves would:

“Other nurses, perhaps who have more experience with sedation than me, are more happy (sic) to give larger doses all at once. To me, that’s rushing to a cliff edge, and I don’t enjoy that, I don’t enjoy that experience.” (NIB 141-3).

While Sedationists B and DF also exceeded the aliquots specified in the protocol, they did so to a lesser degree compared to their more experienced colleagues, using doses of 30 and 25mcg of fentanyl respectively. However, neither was new to NDPSA, with Sedationist B having 2.5 years’ experience, and Sedationist DF 18 months at the time of Case D. Perhaps understandably, no recently assessed-as-competent sedationist was willing to have their practice scrutinised. This was unfortunate as their practice would have been valuable in exploring the hypothesised progression from strict adherence to the protocol, to a reliance on experience as it is acquired by sedationists.

Sedationist B’s comment is also interesting due to sense of personal anxiety that it reveals. Benner describes the competent nurse as able to adapt protocol according to patient need (Benner, 2001), but also experiencing conflict (Benner, Chelsa and Tanner) between meeting the needs of the patient adhering to rules. That Sedationist B adapted protocol is a matter of record (OB 32); the thought of doing it to the extent of their colleagues caused alarm. Sedationist DF did not comment on the matter; however, their deviation was the smallest, with 25mcg aliquots of fentanyl used at times, suggesting tentative deviation. By contrast, Sedationist C reported no concern at using much larger aliquots (NIC 24). Sedationist E expressed awareness that they were using large doses, but also confirmed that they would have been prepared to give more if necessary (NIE 160-165).

Other decision-making models were identified as alternative mechanisms to prescriptive protocols in Section 4.5. In addition to a differing relationship with abstract principles such as protocols, different decision-making processes exist between the competent and proficient stages, and the expert stage in Benner’s model. Benner, Chelsa and Tanner (2009) explain that, for the latter, the assessment of the situation immediately informs them of their course of action, while the former consider and plan their course of action. The contrast in account for midazolam use between the relatively inexperienced Sedationist B, and the experienced Sedationist E is stark:

“He identified as being nervous and it said in the upper left-hand corner of his preoperative checklist “patient is extremely nervous”. I knew they weren’t going to

be starting off with anything apart from a perc, which going to be controlled under local anaesthetic, I didn't think he was going to be experiencing anything which was going to be painful, and I knew that I was going to have time to build up a therapeutic dose of the fentanyl. So, his major concern at that stage was anxiety, and so I wanted to treat that primarily with midazolam, and then give myself time. I wanted to see how he was going to respond to the first dose."
(NIB 58-65)

"Because she was quite nervous. It was the way she wanted the constant reassurance, and she, you know, I just wanted to make sure she'd be settled and comfortable."
(NIE 32-34)

Interviews force respondents to attempt to articulate their thoughts: without the researcher's silence, Sedationist E might not have extended their answer beyond 5 words. The researcher would have liked to have asked more pointed questions at this stage; they refrained from doing so as it was thought any response to such questions could be a distortion of the truth. The need for auditable decision-making in nursing is well-recognised (Thompson and Dowding, 2002; Standing, 2010). Asking a nurse to articulate their decision-making may therefore lead to a misrepresentation of a decision as a cognitive process, even if intuition was used. However, the bluntness of Sedationist E's answer is explained by the understanding that, for the expert practitioner, the assessment of the patient as being nervous automatically leads to the action without the need for conscious cogitation (Benner, Chelsa and Tanner, 2009).

By contrast, Sedationist B's account of their decision is meticulous, systematic and rational. It resembled hypothetico-deductive reasoning as described by Banning (2008), as it followed the process of cue acquisition, consideration of alternative options, a rejection of one option, and a plan to evaluate the plan of action. While this is not the intuitive practice described by Benner, hypothetico-deductive reasoning is compatible with her model: it is characteristic of the competent phase (Benner 2001). Sedationist B's reasoning also relied on knowledge of AF cases, in terms of temporal progression of the case, as part of the decision-making process; Benner, Chelsa and Tanner (2009) state this temporal perspective is acquired at the competent stage of development. This knowledge of the context in which NDPSA takes place is independent of the protocol and is taken to be the result of experience. Sedationist B was by far the most eloquent and garrulous of the sedationists, and their explanation reflected this. However, this was not the only example of hypothetico-deduction in action. Focused cue acquisition was demonstrated through testing reaction to smaller aliquots (NIA 31; NIB 102-3) and seeking previous records (NIC 24-6) to confirm

safety prior to administration of larger aliquots. Evaluation of hypotheses took the form of recognition that smaller aliquots used in previous cases could be ineffective (NIA 39-41; NID 78-81), and that expecting notification of imminent ablation from operators was naïve (NIB 84-88; NIC 92); thus the practice of sedationists could be seen as the product of evaluating past experiences. However, Sedationist E provided no explanation of their use of midazolam beyond their initial assessment of the patient.

Sedationist E's decision-making was of such interest because the deviation resulting from it was the most important in facilitating a positive outcome. It closely resembled the intuitive decision-making that typifies the expert phase of Benner's Theory. While Benner (2001) does not argue that experience always produces expertise, she infers that the former is a prerequisite for the latter. Sedationist E had this in abundance, but the more deductive approaches used by the equally-experienced Sedationists A and C do not threaten this explanation. The observed action, beginning sedation with a 2mg bolus of midazolam, was without hesitation, and the above description was conspicuously lacking in analysis. While Benner (2001) noted that expert nurses worked more efficiently when using experience rather than rules, Dreyfus and Dreyfus (2009), on whose model Benner's theory is based, argue that expertise does not necessarily enhance the quality of decisions made. Christensen and Hewitt-Taylor (2006) argue that, for use of expert nurse decision-making to be justified, it must exhibit some tangible advantage over protocol-based care. Analysis indicated that it did indeed contribute to the positive experience of Patient E (pp.205-7). A possible objection is that, as an isolated incident in an extreme case, it is of little importance in the wider discussion of NDPSA. However, that such an "extreme case" occurred amongst only six case studies does not support this argument. While this possibility cannot be discounted, it should also be recalled that Sedationist E was one of the few sedationists not to have received any negative reports in the survey phase (Figure 6.26). While Patient E may have represented a particular challenge, Sedationist E's practice resulted in a consistently positive patient experience, meaning credence should be given to it.

10.4.3 Implications.

Acknowledging that independent decision-making by the sedationist contributed to positive case outcomes has important implications for NDPSA, while the

evidence of intuitive decision-making has further still. The first is a limit on the transferability of findings. If independent decision-making contributed to positive experience in the case studies, it is implausible to suggest it played no part in the survey phase. Because positive experience does not depend on strict adherence to protocol, this protocol could not be used by a team of novice sedationists, with the same generally positive results obtained during the survey phase guaranteed. The insight from experience needed to achieve these results would not be present. Furthermore, the experience needed to adapt the protocol evidently took considerable time to develop. Sedationist B had been practicing NDPSA for 2.5 years, and was confident enough to adapt practice within the protocol and prioritise anxiolysis. However, they admitted reluctance to adapt practice further, as Sedationist E did by administering 2mg of midazolam. Also, having stated that the cumulative doses of fentanyl administered prior to ablation could have been reached in all cases while adhering to the maximum 20mcg aliquot, some limit on transferability to other ablation-types should be noted. This study focused on AF ablations because they were identified as particularly painful (Kottkamp *et al.*, 2011) and lengthy (NICOR, 2015), so were assumed to present the greatest challenge to sedationists. However, all cases contained a minimum of 26 minutes (Case A) between the start of sedation and the first ablation. This is an advantage to the sedationist when using fentanyl proactively, which allows adherence to protocol aliquots. This pre-ablation period is shorter in some ablation types, meaning that it cannot be guaranteed that a therapeutic dose of fentanyl could be administered prior to ablation while adhering to protocol limits. Further research would be needed to confirm the transferability of these findings to other ablation types, even within this centre.

Next, the conclusions that nurses do not adhere to boundaries of this protocols, and that deviation using midazolam is occasionally necessary, do not mean that the concept of a protocol is necessarily flawed. While the DoH's (2000) concept of protocol-based care was noted to present a barrier to innovative practice, Hewitt-Taylor (2004) argues that protocols should be adjusted in accordance with best evidence once that becomes available, and Delamothe (1993) argues protocols have the greatest chance of adherence if they are developed by those who use them. By examining the approaches used by nurses practicing NDPSA, the protocol could be refined so that it becomes a more reliable tool for facilitating optimal experiences. The hypothetico-deductive reasoning demonstrated by most

sedationists lends itself to this as the decisions are, by definition, logical and methodical. Some recommendation can therefore be made for refining details within the protocol.

First, the protocol should recognise the prioritisation of midazolam as an equally legitimate approach as prioritising fentanyl. At present, the protocol states only that fentanyl is usually and ideally administered first, but that there may be situations in which anxiolysis should be prioritised (Appendix A, p.264). This study has emphasised the importance of controlling anxiety. While it may appear obvious that this should be done when the patient is particularly anxious, and Sedationists B and E correctly identified such patients, if a protocol is to aim at standardisation and transferability, such criteria should be explicitly stated. Therefore, it is recommended that the protocol includes an initial assessment regarding initial anxiety; should the patient appear anxious, this would direct them to prioritise the anxiolytic. It should also direct them to confirm this plan with the operator, as there may be situations in which it is important that the patient remains alert, as was the case in Case D (OD8). Second, the vague points regarding 1mcg/Kg as an effective dose (Appendix A, p.265) could be made more prescriptive. For example: “aim to have administered 1mcg/Kg fentanyl prior to the first ablation” could support proactive use of fentanyl. Key to this, however, is situational awareness: sedationist evaluated the strategy of expecting notification ahead of ablation as flawed (NIB 84-88; NIC 92). Though the protocol already identifies taking the ablation catheter as a prompt to check drug doses (Appendix A., p.267), no sedationist referenced the protocol in relation to this, and the less experienced sedationists, B and DF did not mention it at all. An emphasis in training, rather than protocol-change, may therefore better address this issue. Proactive fentanyl use should not, however, come at the expense of safety; it should also be included that this target should not come at the expense of breaking the protocol’s specified aliquots, regular recording of observations, or any concerns regarding observations. It cannot be recommended that fentanyl targets are prioritised over these.

A more contentious issue is whether the aliquots of drugs specified in the protocol should be increased. It has been established that NDPSA as practiced in this Trust is safe despite the aliquots of drugs used. Furthermore, Sedationist A noted that an alternative protocol used in London allowed for larger aliquots

(NIA 43-5). Should the protocol therefore be updated? With regards to increasing the fentanyl aliquot above 20mcg, this study found little evidence to support it: no evidence indicated that this was necessary. The importance of the 50mcg fentanyl bolus given to control pain once it occurred (OA13) is uncertain, though allowing sedationists to control pain once it occurs is the only reason for considering the increase of the 20mcg aliquot. However, the use of proactive fentanyl is a more important recommendation as it prevents such episodes of breakthrough pain, making the recommendation in the previous paragraph of greater importance.

A stronger case exists for increasing the 1mg aliquot of midazolam. 2mg boluses were used in Cases C and E and was seen as important for the outcome of the latter case. While NDPSA was evaluated as safe, including in these cases, it is uncertain that increasing the maximum midazolam aliquot to 2mg would maintain safety. In both cases, 2mg of midazolam were administered by highly experienced sedationists. It is not the case, therefore, that this study has shown that 2mg doses are *always* safe, and a danger exists that new sedationists might use them inappropriately if this were allowed by the protocol. The decision in Case E appeared to be the production of intuitive decision-making; this does not lend itself to the refinement of a prescriptive protocol as suggested by Delamothe (1993), in the way hypothetico-deductive decisions did: it is harder to specify when and why this would be appropriate. Furthermore, this study has found evidence coherent with a larger picture regarding adherence to protocols: Flynn and Sinclair (2005) and Rycroft-Malone (2009) recorded that senior nurses interpret protocols flexibly or even break them. This, along with the lack of reference to protocol by senior sedationists raises the possibility that a 2mg aliquot limit would also be broken if 2mg became normalised. This discussion is therefore reluctant to recommend such a change. However, it also maintains that such doses are occasionally necessary, as in Case E. An alternative solution is to reconsider the status of the protocol itself.

In Section 4.4, the comparative status of protocols and guidelines were discussed: consensus was that protocols were rigid, while guidelines offered flexibility (Hewitt-Taylor, 2004; Flynn and Sinclair, 2005; Ilott *et al.*, 2006). Recognising this NDPSA document as a guideline to support decision-making, rather than a protocol, would allow the senior sedationist to act with discretion,

without enabling junior sedationist to administer drugs recklessly. It should be added that senior sedationists, like those in Flynn and Sinclair's (2005) study, already considered the protocol as a guideline. Such a solution has its own problems, specifically, the discretion to deviate is fundamentally at odds with the concept of protocol-based care, which aims at standardisation (DoH., 2000). Accepting this solution defeats the ultimate aim of protocol-based care, prompting a question of the concept's value. However, standardisation was not the only benefit ascribed to protocol-based care: they were also widely perceived as useful scaffolding for skill acquisition amongst nurses (Flynn and Sinclair, 2005; Ilott *et al.*, 2006; Rycroft-Malone *et al.* 2008; 2009). Therefore, it is recommended that the NDPSA document is regarded as a guideline, rather than a protocol, which supports the safe practice of those acquiring sedation skills, but also allows for senior sedationists to make use of their experience and judgment based on their assessments of individual patients. This marks an acceptance that such guidelines could not automatically be transferred to a new environment and optimal results anticipated. Optimisation would require time for staff to develop the necessary experience, as described by Benner (2001), and the confidence to adapt appropriately. Finally, as a consequence of this and in the interests of in the individual patient, it is recommended that extremely anxious patients such as Patient E, and those who are both obese and anxious, are recognised as challenging sedation cases on arrival in the CCL, and paired with a sedationist sufficiently experienced to use the guidelines flexibly.

Chapter 11: Conclusion.

11.1 Introduction

This chapter draws conclusions regarding each of the aims stated in the introduction for this project before stating the unique contribution it has made to knowledge regarding PSA in the CCL. It continues by identifying limitations to these conclusions, before stating recommendations for future research.

11.2. Conclusions

The principle aim of this project was to critically evaluate the innovative practice of protocol-based NDPSA for AF ablation. The need for this innovation stemmed from the need to improve efficiency to meet growing demand, and to comply with standards for sedation by non-anaesthetists (Section 2.4). However, the justification for this research, and this principal aim, stemmed from the professional requirement for the nurse to maintain and improve quality of care in this expanded role (Section 2.5.1). Having defined “quality of care” for PSA in terms of safety and patient experience (Section 3.4), the project evaluated the practice of NDPSA in these terms. Regarding safety, this project found no evidence indicating that NDPSA presents greater risk than PSA methods examined in other studies (Section 6.2). Some evidence suggested that NDPSA might be safer than other methods, but ultimately, the sample size used was too small to support such a conclusion statistically. However, given the realist orientation of this project, evaluation extended beyond statistical comparison, and the case study phase provided evidence of a mechanism that served to maintain safety (Section 8.4.3): this came in the form of the vigilance of the nurse, and the authority to titrate sedation that is afforded to them by the NDPSA protocol. As this mechanism was observed in 5 cases, and was not needed in the sixth, Section 10.2.1 argued that this can be regarded as an inherent benefit of NDPSA as it dedicates an individual to monitoring observations, while also making this individual responsible for titration. This contrasts with the operator model, which the AoMRC. (2013) state can cause inattention to the patient’s condition, and Furniss and Sneyd (2015, p.1528) dismiss as “not relevant or appropriate”.

In terms of patient experience, the HCA process identified 3 clusters, which represented positive, mostly positive, and negative experiences (Section 6.3.2).

Although this study did not specifically set out to compare NDPSA to other sedation methods in terms of patient experience, some comment on this was made in Section 10.2.2., and no comparison suggested NDPSA resulted in a compromise in patient experience. The 87% of survey patients providing positive or mostly positive reports was comparable to the findings of Ezzat *et al.* (2012), Tang *et al.*, (2007) and Laurent *et al.* (2006). The objection that case study analysis revealed that stoicism accounted for some of the mostly positive reports following NDPSA (Section 8.3.1) does not refute this conclusion as it is the result of a more robust research method than those used by the other studies: as argued in the discussion (p.224), these other practices may also have benefitted from stoicism in patient reports. This is considered an argument in favour of the research methods used in this study, not a criticism of NDPSA. However, any comparison is speculative due to the different instruments used to gather and analyse data; to directly compare patient experiences of different sedation practices would be the work of another study.

HCA did reveal scope for the improvement of NDPSA. Of the 62 cases included in the clustering process, only 17 (27.4%) gave optimal reports. Given the NMC's (2018) requirement that nurses should seek to improve quality, it was necessary to consider the determinants of these optimal experiences to make recommendations to improve future practice. This is regardless of any comparison to other practices, though if implemented, such improvements may lead to any future comparison identifying NDPSA as a facilitator of superior, rather than comparable, patient experience. These determinants are identified below. However, it is concluded that NDPSA can provide a feasible alternative to other models of PSA currently used, avoiding criticism of inefficiency (Gaitan *et al.*, 2011) and inappropriacy (Furniss and Sneyd, 2015) levelled at other models, without compromising quality of care in terms of safety and patient experience. With potential to improve further, it is more than the "cost-effective redesign" feared by Barton, Bevan and Mooney (2012a, p.18).

The second aim was to identify the conditions under which NDPSA is most effective. This project allowed for the possibility of causal complexity, based on the recognition that the perception of pain itself is complex (Melzack and Wall, 1965) and the number of factors that have previously been identified as having an influence on patient experience (Section 3.7). Despite this, this thesis

concludes that the optimisation of patient experience is relatively simple, and that the most reliable pathway to an optimal experience, including minimisation of pain, depends on the effective control of the patient's anxiety (Section 9.4). Central to the effective control of anxiety is the purposeful use of midazolam at an early juncture in the procedure prior to ablation; cross-case comparison following process tracing (Section 8.3.2) led to the conclusion that this contributed to a positive experience via anxiolysis, rather than simply causing amnesia regarding pain. This conclusion has theoretical and empirical support: the GCT (Melzack and Wall, 1965) explains how mental state can influence *the gate* to alter experience of pain, and Barbero et al. (2018, p.19) provide empirical evidence of this, with previously-anxious patients receiving only "continuous suggestions of peace, analgesia and wellness" consistently reporting zero pain following AF ablation, without the use of pharmaceutical analgesia.

FsQCA produced a model of moderate complexity detailing paths to positive experience (p.128). In addition to drugs used, this included the patient's age and body mass. Though energy source and procedure duration were considered of potential importance during the literature review, inclusion of these criteria had virtually no effect on refining the model (p.126). However, the case study analysis served to refine this model, Patient age was found to be more complex; Cases A, D and F provided consistent evidence indicating underreporting of pain and stoic attitudes amongst older patients (pp.188-190). Old age was therefore dismissed as a factor contributing to optimal patient experience. However, both relative youth and obesity were noted as conditions, or contexts, which made achieving anxiolysis more challenging for the sedationist. Cases B and E led to the development of a theory that relative youth presented a challenge to achieving anxiolysis due to heightened anxiety in such patients. These patients anxiety stemmed from information-seeking on the internet, a pattern which agreed with existing theory that younger patients were more likely to seek health-related information online, and that this served to heighten anxiety (Section 10.3.3). Subsequently, management of their anxiety required decisive, independent decision-making by the sedationists. Case B (Section 8.2.2) provided evidence that non-obesity allows effective anxiolysis using lower doses of midazolam; the exclusion of obese patients from Pathway 2 indicates that 5mg or more are sometimes needed for heavier patients. That obese patients (Case C), and highly anxious patients (Cases B and E), had positive experiences can be attributed to

decisive actions taken by the sedationists in each case. However, it cannot be assumed that less experienced sedationists would have taken such decisive action. The action taken in all 3 cases required initiative independent of the protocol and, in Case E, depended on breaking the protocol regarding midazolam dose. Conclusions regarding sedationists' decision-making are identified later.

Despite emphasising the primacy of anxiety-control in facilitating and optimal experience, this thesis cannot conclude that analgesia played no role in these positive experiences. Patients B, C and E all received paracetamol and some fentanyl; although Patient C received one of the lowest cumulative doses of fentanyl in the entire study, that which he received was given proactively. While the findings of Barbero *et al.* (2018) support such a conclusion, the GCT (Melzack and Wall, 1965) argues that sufficient noxious stimulation can force *the gate* open. This thesis cannot support Barbero's finding that intravenous analgesia was not needed, but nor does it refute it. However, this thesis does conclude that an optimal experience can be facilitated using minimal analgesia if anxiety is well-controlled, citing Case C as evidence of this. Whether optimal PSA can be achieved using anxiolytic agents alone is a question for purely academic speculation only. Answering it has little practical value; as Sedationist B observed (NIB 107), no reason to withhold analgesia exists.

Finally, evidence was found that an optimal patient experience can be facilitated without the prioritisation of anxiolysis. Both survey cases with a mean fentanyl rate exceeding 3mcg/Kg/hr returned optimal reports. Case 12 in particular achieved this while reporting low pre-case anxiety, and using little midazolam. No such examples were observed during the case study but, in interview, four of the five sedationists expressed a preference for proactive, rather than reactive use, of fentanyl (Section 8.4.1). This did not always translate into action, as in Cases D and F, but it was calculated that, for a patient to receive a mean rate exceeding 3mcg/Kg/hr, it would be necessary for them to have received a substantial dose of fentanyl prior to the first ablation (pp.140-142). Cases 51 and 64 resemble Case 12: all patients were relaxed before; all received low dose midazolam and relatively high fentanyl dose; all gave optimal reports. It is therefore believed that Cases 51 and 64 likewise received substantial doses of fentanyl prior to ablation. This controlled pain and made further administration unnecessary. However, the

longer duration of these cases meant the mean rate fell well below the 3mcg/Kg/hr rate. Though this conclusion is more speculative than that regarding anxiety-control, it is believed that proactive fentanyl use can facilitate an optimal experience in patients who are not excessively anxious. The size of this dose is uncertain, though the 50-65mcg doses given in advance by Sedationist DF were ineffective. The case studies provided evidence that the NDPSA protocol must allow the sedationist flexibility in strategies; in Case D the consultant specified that the patient must remain awake, and in Case F, the use of midazolam prompted concern regarding the patient's airway. Thus, a single optimal strategy prioritising the use of midazolam cannot be considered appropriate to all cases. However, the recognition of the importance of proactive use of fentanyl returns consideration to the relationship between nurse and protocol.

The third aim was to appraise the contribution of individual sedationist to NDPSA. During the thesis, appraisal has focused on distinguishing between the contribution of the sedationist and the contribution of the protocol. Individual sedationists contributed to the success of cases through their titration of drugs in ways not specified by the protocol. Specifically, these came in the form of prioritising the use of midazolam over fentanyl (Cases B, C and E) and the proactive use of all medication in these three cases when compared to Cases D and F. The protocol allows for both actions, despite not specifying them. However, the protocol does state that fentanyl should normally be administered first (Appendix A, p.264). Given the paramount importance of anxiety control, particularly in Cases B and E, the sedationists' abilities to assess their patient and to make the decision to prioritise midazolam use were key to the success of these cases. Although the protocol also makes a vague statement that fentanyl 1mcg/Kg provides effective analgesia, it does not present this as a target. The proactive use of fentanyl prior to the first ablation can therefore also be seen a contribution by the individual sedationist. Though Sedationist DF stated a preference for this proactive use, they did not implement this plan. In both cases, the sedationist was subjected to distractions, and worked under the assumption that they would receive notification from the operator that ablation was imminent. More experienced sedationists, B and C, regarded this expectation as naïve, and detailed their own strategies for ensuring that adequate medication was administered prior to the first ablation without relying on communication from the operator (Section 8.4.2). This is one way in which the practice of experienced

sedationists differed from that of the least experienced. This will lead to recommended updates of the protocol, but also to the recommendation that junior sedationists be allowed to practice their skill in an environment free from distractions that allows them awareness of case progression.

Every case study included examples of the sedationist exceeding the drug aliquots specified by the protocol. It was conspicuous that the most experienced sedationists did this to the greatest extent. In this, findings fitted a pattern also recorded by Flynn and Sinclair (2005) and Rycroft-Malone *et al.* (2009) that deviation from protocol is greatest amongst senior nurses. It has been debated whether these deviations were necessary (Section 8.4.4). Few were; However, it was necessary to use increased aliquots of midazolam in Case E to alleviate anxiety rapidly, and minimise the distress caused by noxious stimuli. Given the importance of anxiolysis, it is concluded that the successful outcome of this case did depend upon Sedationist E's action.

Sedationists did not reference the protocol when accounting for their actions: adherence to this prescriptive model was not the means by which decisions were made during NDPSA. All sedationists referenced their experience in accounting for their actions; in this it was conspicuous that the more experienced sedationists exceeded the protocol-specified aliquots by the greatest margin. Most sedationists accounted for their actions in hypothetico-deductive terms (Section 10.4.2), specifically identifying focused cue acquisition regarding appropriate aliquots, and evaluation of experience in which they had considered specified aliquots to be inadequate. Sedationist E's decision-making regarding their deviation did not follow a hypothetico-deductive approach; instead it closely expert, intuitive, decision-making as described by Benner (2001) in that immediate situation recognition simultaneously led to a plan of action with little recourse to the analysis shown by other sedationists. Both observed decision-making processes are considered alternative mechanisms to the prescriptive protocol model, and the identification of both have important implications for the development of the NDPSA protocol, especially as the result of Sedationist E's intuitive action was judged as significant in managing the patient's experience.

Finally, having previously noted the primary importance of controlling anxiety, the contribution to this made by the interpersonal skill of the individual sedationist can play an important role in promoting patient trust (Case B). Likewise, an

orderly and organised environment contributed to low anxiety in Case C. While it would be hoped that a trusting relationship and an orderly environment were standard features of NDPSA, Patients B and C noted that their experiences on this occasion were superior to previous experience in these respective aspects, demonstrating that this is not always so. The rapport between patient and sedationist in Case B appeared particularly important, as Patient B had identified concerns regarding the competence of the nurse in administering PSA. The confidence this fostered directly addressed this concern. The protocol limits itself to purely technical aspects of NDPSA; these interpersonal and organisational aspects therefore stand outside of its scope, yet evidently contributed to the control of anxiety in these cases, which should be emphasised as contributions of the individual sedationist.

Given Hewitt-Taylor's (2004) assertion that protocols should be updated in accordance with best evidence, and that they have greatest chance of adherence when shaped by those who use them (Delamothe, 1993), recognising how sedationists contributed to the success of particular cases has implications for the development of NDPSA to optimise outcomes. As hypothetico-deduction is analytic and rational (Banning, 2008), decisions using this process allow some recommendations for refinement of the protocol (Section 10.4.3). Given the primacy of anxiety control, this thesis must recommend that the protocol should abandon the line that fentanyl should usually be prioritised over midazolam (Appendix A p.264). This stops short of recommending that this order of priority is reversed, even though it recognises anxiety control as the most reliable route to an optimal experience. This is because circumstances (Cases D and F) existed where this would not be practical. Instead, it is argued that the protocol should stress the need for patient assessment, and recommend prioritisation of midazolam, if the patient expresses or displays a high level of anxiety. Second, to ensure the proactive use of medication, the currently vague "1mcg/Kg" statement regarding fentanyl could usefully be rephrased as a target, providing that safety issues allowed this. The setting of this particular target somewhat arbitrary. However, it builds on the existing protocol, and the observation that the patients displaying pain received less than this prior to exposure to noxious stimulus.

However, the main recommendation made for the future of NDPSA is a revision of the document's status as a protocol. Section 4.4 identifies that protocols

require adherence, while guidelines make recommendations. Strict adherence to protocol could not have facilitated as positive result in Case E as non-adherence did. The inability of the current protocol to accommodate this challenging case recalls Delamothe's (1993) concern that practice can be consolidated around standard, not optimal, practice. Instead, the deviation by Sedationist E facilitated a positive outcome in a challenging case. Two recommendations are possible: that the aliquots of midazolam allowed by the protocol are increased to 2mg, or that the protocol is reclassified as a guideline, making recommendations, but not requiring adherence. This thesis concludes that the latter is preferable. Because this decision appeared intuitive, an updated protocol could not specify when such a dose would be appropriate, or inappropriate: though 2mg aliquots may have been safe in Cases C and E, such an adjustment to the protocol could imply that they are always safe, leading to new sedationists using them inappropriately. However, reclassifying this document as a guideline, rather than a protocol, would still allow it to offer practical guidance to those developing skills in PSA (Flynn and Sinclair, 2005; Ilott *et al.*, 2006; Rycroft-Malone *et al.* 2008; 2009) without inhibiting the ability of the expert practitioner to manage a particularly challenging case such as Case E. Allowing such variation ultimately defeats the concept of protocol-based care as a standardiser of practice (DoH, 2000) which, subsequently means that the guidelines could not be transferable to a new CCL with the same outcomes expected. However, given that this study has demonstrated that variation within practice exists, and that optimisation can depend on the discretionary action of the sedationist, this transferability cannot be claimed even while NDPSA is regarded as a protocol. It could be that the concept of a protocol that allows optimal outcomes in all cases, and can easily be transferred to other CCLs, is impossible to achieve. This thesis therefore concludes that the practice within this Trust should be optimised by reclassifying NDPSA as a guideline rather than as a protocol.

11.3 Unique Contribution to Knowledge.

The assertion that "no research has focused on identifying factors that impact nurses' ability to facilitate optimal PSA titration" in the CCL (Conway *et al.*, 2014a, p.375) was identified early in this thesis. The literature review (Section 3.3.1) demonstrated that this remained true; since the start of this project, only the work of Sawhney *et al.* (2017) can be seen as addressing this issue.

However, this study defines quality in terms of safety only; other studies (Section 3.4.2) and UK health policy (DoH.,2012; NICE, 2012) regard this definition as too narrow, and include patient experience. This has been done in this study. However, while Sawhney *et al.* (2017) establish the general safety of nurse-titrated PSA, this study adds some valuable details. First, this study was limited to AF ablation, whereas Sawhney included all electrophysiology cases. AF ablation is recognised as the most painful of these (Kottkamp *et al.*, 2011), and can therefore be considered the most challenging to sedate. Were the small number of complications observed by Sawhney concentrated amongst the AF ablations, it could question the safety of their nurse-titrated PSA for this procedure. However, the finding of this thesis is that NDPSA was safe for AF ablation. It also adds the realist explanation as to why it is safe: the dedication of an individual to monitoring the patient and titration of drugs allowed rapid response to any change in condition (Section 9.2) and appeared to be an intrinsic feature of NDPSA. This thesis has established that NDPSA is safe when a nurse is dedicated to monitoring the patient and titrating drugs; this safety could not be guaranteed if the nurse were required to perform additional duties in addition to sedation.

The main finding of this thesis, that control of anxiety is the most reliable route to an optimal patient experience (Section 9.4) does not directly address the need identified by Conway *et al.* (2014a). However, many of its findings regarding how this control is achieved do. It has found that the nurse's interpersonal skills can be a significant factor in the control of the patient's anxiety as they can increase the patient's confidence in the nurse (Case B). Patient B was able to compare experiences, and emphasised the superiority of Sedationist B's interaction in allaying his anxiety compared to his previous sedationist. It is hypothesised that this was effective *because* this patient's anxiety related to the competency of nurse-sedationists. It has also found evidence that certain types of patients, those who are obese or highly anxious, present a greater challenge to the nurse in facilitating an optimal experience (p.213). These challenges are surmountable, but require direct action by the sedationist to achieve an optimal outcome. The different ways in which sedationists utilised the NDPSA protocol therefore become relevant to meeting Conway's research need.

Section 9.5 identified that optimal titration of PSA did not depend on strict adherence to this NDPSA protocol. Instead, it was identified that the optimal PSA resulted from sedationists' utilisation of their clinical judgement, based on their previous experience, to inform their decisions (pp.217-219). Examples of this were the decisions to prioritise the use of midazolam, and to use fentanyl proactively rather than reactively. As these decisions were often rational and analytic, this does not mean that the concept of a protocol to titrate optimal PSA is fundamentally flawed; rather it means that the experience of these sedationists can be combined with the findings of this thesis to refine the protocol to make it a more effective tool in facilitating optimal practice. Such recommendations are made in Section 10.4.3. However, this thesis has also found a limit on the value of a protocol to facilitate optimal titration. This came in the form of Sedationist E's intuitive decision to begin sedation using 2mg aliquots of midazolam, which proved important to the positive outcome of the case (pp.237-239) but did not depend on analytic thinking; it therefore cannot be accommodated in a refined protocol. As such, this marks a limit on a protocol's utility in facilitating optimal titration. It was argued that the optimisation of PSA for such a challenging case depended upon the expert sedationist having the freedom to utilise their clinical judgement and deviate from the protocol. This, in turn, led to the recommendation that the protocol be reclassified as a guideline to allow for this (pp.250-251).

11.4 Limitations.

This study accepted critical realism as a philosophical basis for inquiry (Section 5.2.1) and therefore accepted that all knowledge in the empirical domain is fallible, including the findings of this thesis. Specifically, critical realism always allows for the possibility of an unknown mechanism. When preparing for process tracing, this thesis reviewed existing theories regarding the mechanisms by which contexts identified by fsQCA might cause positive report (Section 7.4). Case studies were subsequently designed to distinguish between these theorised mechanisms. Should this review have excluded a relevant theory, or if existing literature did not identify it, it is possible that the subsequent analysis failed to recognise it in action. Thematic analysis was employed to reduce this risk as it allowed the emergence and identification of relevant mechanisms that may have been previously unidentified by literature (Section 7.6). Nevertheless, accepting

critical realism means accepting the possibility of another relevant mechanism that has remained latent in all cases observed, but may become active in other cases. This does not discredit the findings of this thesis, but means that it cannot be known if the findings represent a complete picture of factors relevant to the success of NDPSA.

Some less philosophical limitations should also be acknowledged. This project was conducted within the time constraints of doctoral study. This limited the scope of the project; firstly, with regard to safety. The sample was large enough to be considered representative, and to prove the hypothesis that NDPSA was less safe than other methods, if that was the case. Analysis rejected that hypothesis and, furthermore, case study revealed a reason *why* safety was maintained, nursing actions that served to keep patient observations within the ranges specified by the protocol. This gave rise to the possibility that NDPSA may be safer than other methods used. However, the sample size did not allow the statistical power to prove this. Given the nursing mandate to improve quality (NMC, 2018) this is a valuable question that it is beyond the scope of this research to answer.

Likewise, this study did not appraise the rate of AF reoccurrence following ablation; while debate remains as to whether this can be considered a consequence of sedation method (Section 3.4.3), it is evidently of concern to those making decisions regarding PSA. It could not be included in this study as it would have required prolonged monitoring of survey patients for up to 3 years (Nauri *et al.*, 2017) to identify successful cases. While the economic advantage of NDPSA is conceded by proponents of general anaesthesia (Martin *et al.*, 2018), they add that this may be false economy if a higher reoccurrence rate requires repeat procedures amongst NDPSA patients. This thesis cannot claim to have addressed these issues, which limits the claim of this thesis that NDPSA represents a viable alternative to other means of PSA to matters of safety and patient experience.

It might be argued that this thesis has not utilised process tracing to its full potential as it does not divide mechanisms down into the smallest observable parts to open the “black box” of causation (Beach, 2016, p.464). Rather, mechanisms in action were inferred from the sequence of events (Trampusch and Palier, 2016), and observation, including the CPOT tool (Gelinias *et al.*, 2006)

to gauge this. Other studies have revealed how process tracing inside this “black box” may function: Ploghaus *et al.* (2001) and Wise *et al.* (2007) use magnetic resonance imaging to identify changes in neurological function of the brain when the subject was anxious or in pain. Such monitoring was beyond the resources of this study and may be incompatible with equipment required to perform the ablation. However, this objection is challenged here as it is believed that observation of patient behaviour during this case provided a sufficiently robust means to distinguish between hypothesised mechanism such as amnesia and anxiolysis. Smaller links in the chain of causation can be observed, but such links did not need to be observed in order to accurately identify the mechanism in action. Thus, recording neurological activity would have done little to strengthen the conclusion of this study.

Finally, some of the conclusions of this study are limited by ethical considerations. It has been acknowledged that some arguments (Section 10.4.2) regarding the progress of a sedationist from use of abstract principles to a reliance on prior experience are limited by the absence of any true novices in the study. This also limits the conclusion that nursing vigilance and response to changing patient condition are inherent benefits in NDPSA. Such junior sedationists existed, but were unwilling to have their practice observed, and the researcher could not ethically compel them to participate. Thus, the identification of this progression depended on matching observed practice to the theoretical expectations of progression based on Benner’s model (2001). The tentative deviation from protocol by those with 18-30 months experience, and Sedationist B’s analytic account of decision-making, contrasted with the more confident deviations made by those with five or more years of experience, matched this theorised pattern, as did Sedationist E’s immediate, intuitive decision-making. This theory identifies that new sedationist will depend on the scaffolding such as protocols. However, the observation of such sedationists would be useful in confirming this progression, and the value of NDPSA guidelines to support their practice.

Due to a similar lack of control, this study cannot confirm the second pathway, prioritising use of fentanyl over midazolam. Cases 12, 51 and 64 indicate that this alone can be effective in facilitating an optimal experience, and Section 8.4.1 provides strong evidence that these cases must have included proactive use of

fentanyl to achieve their mean rates of administration. However, without tracing the processes of such cases, some doubt remains, particularly given the previously identified possibility of the unknown mechanism. However, such cases were rare, and the researcher could not compel the sedationist to administer PSA in such a way that the case would only be described by this single pathway. Such control could be regarded as unethical, given the noted reliability of the anxiolysis pathway, and would not have allowed the exploration of the sedationist's decision-making process. Therefore, while the evidence of this thesis supports the existence of such a pathway, it cannot conclude its existence or efficacy with the same conviction as the pathway prioritising the control of anxiety.

11.5 Recommendations for Further Research.

The above limitations automatically identify some issues that future research should aim to address. This study has not tested the hypothesis that NDPSA is safer than other forms of PSA. It has identified an aspect of NDPSA that makes it safe, the sample size was too small to recognise superior safety, given that the rates of complications in existing practices was low. Given the paramount importance attached to safety when appraising PSA (Section 3.4.1), and the professional mandate to improve quality (NMC, 2018), it is argued that such research would be valuable. Likewise, the study of AF recurrence rates in cases using NDPSA could confirm its value as a viable method of PSA. Neither piece of research need be as detailed or as rigorous as the methods used in this study; freed from the need to identify the mechanisms by which a positive experience is delivered, such research could take the form of an ongoing audit of either adverse incidents, or rates of recurrence.

Although this thesis has discussed its findings regarding patient experience in comparison to studies of other sedation methods (Section 10.2.2), it has not claimed these comparisons are analytic or reliable. These comparisons were made to demonstrate that there was no conspicuous sacrifice of quality in terms of patient experience when NDPSA was used. It was conceded that any direct comparison of practices would require the study of them using the same data collection instruments and analysis methods. Ultimately, such a comparison is needed if the NMC's (2018) mandate to aim to improve quality of care is to be met, particularly when patient experience, and specifically pain control, are recognised as indicators of quality (DoH., 2012). This thesis can be seen as a

precursor to such a study: it was necessary to identify the conditions under which NDPSA is most effective, and to make recommendations for the optimisation of NDPSA, so that the concept was not prematurely dismissed by any comparison before it was fully developed. This thesis was critical of Martin *et al.* (2018) for making such a comparison (p.23). After the implementation of recommendations, a useful comparison between NDPSA guidelines and other practices would be possible. The recognition that optimisation of NDPSA can depend of the judgement of the individual sedationist indicates that the NDPSA guidelines could not be transferred to a new department with the same results expected immediately. A level of expertise would need to develop to allow the management of challenging cases. The current study would therefore act as a valuable qualifier of any future comparison.

This project has identified that skill in NDPSA advances with experience, there is scope to investigate the development of these skills. Recommendations have included making guidelines more prescriptive, specifically in terms of identifying situations in which midazolam should be prioritised, and in setting targets for analgesia prior to ablation. It has also identified these written guidelines as being primarily of value to those acquiring skill in NDPSA. However, the possibility that the acquisition of sedation skills might be enhanced by other methods, such as formal training, could also be usefully explored. In addition to establishing that sedationist skill plays a key role in the management of challenging cases, it has also demonstrated that this skill presently takes in excess of three years to fully develop. While the benefits of NDPSA may be recognised by any future comparison, it may not be an attractive model if the slow acquisition of experience is the only means by which optimal practice is ultimately reached. While refined guidelines are intended to support the development of practice, exploration of training to accelerate this development would be valuable.

A final area for further investigation is the effect of digital resources in both exacerbating and allaying anxiety. This was explored in Section 10.3.3 following an inquiry into why relatively young patients were excluded from one solution pathway. Patients B and E were relatively young and suffered from heightened anxiety, for which they cited online information as a cause. Both cases required the sedationist to utilise clinical judgement and adapt protocol to gain positive outcomes. Thus, it was theorised that it was not relative youth itself that led to

greater anxiety, but the inclination of the young to seek information on the internet, and that the control of anxiety that leads to optimal experience is more challenging in such cases. This is a tentative theory; first, it results from emergent themes and, second, it was not in the ethical remit of this project to pursue factors that caused NDPSA to fail. However, Section 10.3.3 found several existing studies that supported this theory, along with that of Kim *et al.* (2019) which suggested that high quality, reliable online resources can reduce anxiety. As use of the internet as a source of health information is likely to increase as the digitally literate age, this appears a particularly important area for future research. Two potential projects can be recommended: first, a survey to identify and confirm any correlation between age, internet use and anxiety in patients undergoing ablation and, second, an exploration of the impact of an introductory film, similar to that of Kim *et al.* (2019) on the anxiety and experience of those undergoing ablation. This marks a recognition that factors influencing the outcome of NDPSA include those outside of the CCL itself. As such, the outcome of NDPSA, and indeed other PSA methods, may be enhanced by considering the preparation of patients before their arrival in theatres.

The growing number of AF ablations and the need to optimise utilisation of CCLs were identified as drivers behind the development of NDPSA. These drivers remain, as does the need to maintain and improve quality of care, mandated by the NMC (2018). This thesis has demonstrated that NDPSA can provide an optimal patient experience that also addresses the issues of demand. However, it does so inconsistently. While it is already a viable alternative to other models of PSA, it is believed that the recommendations in this thesis can further enhance the experience of patients undergoing AF ablation. The recommended research regarding management of anxiety prior to hospitalisation can both enhance patient experience, and establish NDPSA as consistent facilitator of optimal patient experiences, as well as a practical, economic and professionally acceptable alternative to established models.

Appendix A: Nurse Delivered Cardiac Sedation Protocol

Within the Cardio Catheter Labs intravenous conscious sedation is delivered by a RGN nurse in the presence and under the supervision of the Cardiologist responsible for the procedure, usually this is the operator who is performing the procedure. This is working primarily within the Trusts Guidelines for the practice of intravenous sedation in Adults. Nurse delivered cardiac sedation is a technique within the Cardio Catheter Labs that is specific to administering sedation to adults during Cardiology procedures.

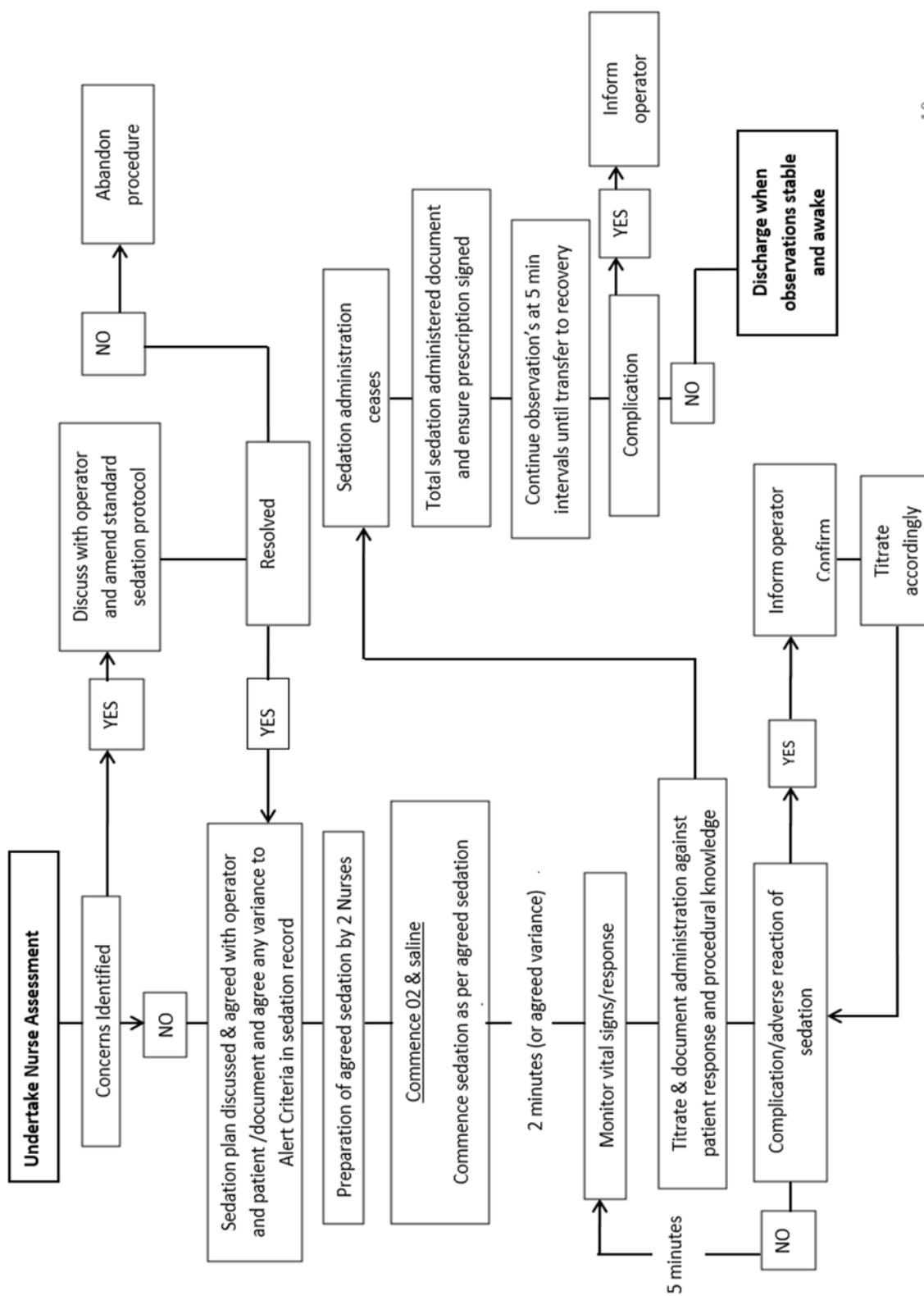
The procedures include:

- Electrophysiology studies of the heart,
- Combined electrophysiology studies and ablation procedures,
- DFT testing/cardioversion,
- Implantation of permanent pacemakers, implantation of permanent internal Cardiac defibrillators.
- Loop recorder implant.

Cardiothoracic Sedation Flowchart

Expected Standards to be in place

- Room for GA/Sedation
- Minimum 1 sedation competent nurse
- Appropriate Consent
- IV Access
- Appropriate Starvation
- Premedication as prescribed
- Medical Assessment for Sedation Completed
- Two way communication between operator and nurse seditionist, throughout.



Context.

Whilst most instances of conscious sedation are electively planned there are instances when conscious sedation is commenced intra procedurally to help the patient remain comfortable when they have become unexpectedly agitated or unable to tolerate the pain. This is a technique of sedation that has evolved under the supervision of consultant Cardiologists and Guidance from Consultant Cardiac Anaesthetists. The technique requires careful titration of Fentanyl 10mcg/ml and Midazolam 1mg/ml administered by the registered nurse within the presence of the doctor performing the procedure. The operator continues to carry the ultimate responsibility for the overall safety of the sedation for each patient and must have assessed the patient and documented the patient as suitable to undergo the procedure with nurse delivered conscious sedation. This is usually identified on the operating list under anaesthetic type. The nurse in collaboration with the operator is responsible for the safe titration and dosage of the sedation medication that will keep the patient pain free and comfortable, while safely minimising the supervision required by the operator. This includes monitoring of vital signs and the response of the patient to the analgesic, anxiolytic and amnesic effects of the medication. This minimises the direct supervision and instruction required from the operator during the procedure but identifies through the alert criteria when the operator must be informed of changes to the patient's condition.

The Physician responsible for the overall conduct of the sedation is generally required to have performed a history and physical examination within 30 days of procedural sedation. From this the physician formulates the sedation plan and confirms the suitability for nurse delivered conscious sedation.

Nursing Staff Preparation

Minimum two qualified nurses and operating physician.

- Sedation is to be administered by a nurse competent in sedation by either experience and or completion of competencies. This nurse is responsible to provide dedicated monitoring and care of the sedated patient until discharge from the department or handover to another competent professional. This nurse must be competent and successfully assessed to give IV drugs according to the Trusts Intravenous sedation policy, competent to administration infusions via relevant devices and trained in intermediate life support. As this is an intravenously administered sedation with an almost immediate resultant blood plasma levels, the side effects and complication can be immediate. This nurse is responsible for the vigilant observation of the patient, titration of the medication and the completion sedation documentation. It is recommended that the sedation nurse completes the entire procedure and only in rare and necessary circumstances is relieved from this duty, i.e. case continuing into out of hours, an exceptionally long procedure or an unplanned event that requires handover to an anaesthetist.
- A second registered nurse competent to check intravenous drugs and controlled drugs is required. This nurse primarily acts as a support/circulating nurse and should be familiar with the procedural requirements of the case.

PRE PROCEDURAL PREPARATION

Equipment and Catheter Labs area.

Whenever nurse delivered conscious sedation is administered in a Catheter Laboratory a fully functioning anaesthetic machine that is appropriately checked and ready to use should be present. In addition the nurse administering the sedation is responsible to ensure that appropriate resuscitation or supplementary equipment is available in the room before the patient's arrival. This equipment includes:

- oro-pharyngeal airway,
- provision to provide positive pressure ventilation e.g. an ambubag
- High pressure suction, ready for use which nurse is familiar with operating in an emergency.
- O2 mask connected to oxygen supply (CO2 monitoring optional but must be through a dedicated mask)
- Re breathe mask.
- Stethoscope.
- Vital sign monitoring equipment is available and ready for pulse oxymetry, BP monitoring, with an appropriate size blood pressure cuff (too small a cuff can give an erroneous reading), respirations, and ECG monitoring if required in addition to technicians cardiac monitoring. Preferably monitoring with automatic repeat set at 5 minutes.
- Correct documentation available including the nurse delivered sedation chart, WHO checklist, catheter labs drug chart and intraoperative record.
- The correct skill mix of staff is available.

Ensure appropriate medication to be available for use in the room.

Although there is a wide range of medication kept in the drug cupboard for a number of various other procedures, the nurse giving sedation should check drugs listed below, before giving any sedation. They should be present, in sufficient quantities, in date and with labels available.

Fentanyl
 Midazolam
 Oxygen via face mask.
 Naxolone, out but unopened on bench.
 Flumazenil out but unopened on bench.
 Adult resuscitation box (blue)
 Hydrocortisone
 Adrenaline
 Atropine
 Chlorphenamine

Pre administration of any medication.

The present departmental checking in list should be completed when the patient is admitted onto the department. This should ensure the patient is:

- Fasted 6 hours for light meal 2 hours for clear fluids only, no milky drinks or fruit juices. Sips of water are permitted to take the pre med.

- A valid consented for the procedure. Current practice is that the patient is not specifically consented specifically for sedation but it consented for the procedure to be undertaken.
- Where possible the procedural drugs should be prescribed pre procedure.
- **The operator must be present from the start of sedation to the end of the administration of medications.**
- Verify and document from Erecord the time and type of any premedication, particularly premed analgesia and sedative. Premeds are dependent upon the patient's requirements and the type of procedure. In some instances pre meds or commencing sedation too early can interfere with the aims of the procedure. Discuss with the operator if there is regular relevant medications the patient may have taken in the last 24hrs. Patients routinely taking narcotics, alcohol or benzodiazepines routinely may require significantly increased doses of sedation.

The nurse delivered cardiac sedation document must be commenced before any medication is administered to the patient. Document all relevant information in the pre-operative assessment of the form.

Identifying the

- Allergies
- Smoking status
- Respiratory disease
- Sleep apnoea
- Opioid naïve
- Body mass index calculated using height and weight.
- Any significant information passed on from the ward or operator.

Emergency contact details of available anaesthetist or consultant in charge must identified, to facilitate a speedy response to any procedural complications. The WHO checklist and patient involvement at this point should re-confirm consent for the procedure.

- Discuss with the operator the sedation plan.
- The patency of indwelling venous cannula should be checked.
- One full set of base line sedation vital signs to be recorded once patient is settled onto the x-ray table, including the AVPU and pain score before any medication or oxygen are administered.**

The physician in charge of the case should confirm the ASA grading of the patient immediately pre procedure. Any instruction, sedation strategies for the individualised care of the patient should be agreed between the operator, patient and the nurse delivering the sedation and documented in the significant comments. For example ICD not being tested, patient has a history of back pain etc.

The sedation start time is recorded as when the first dose of sedation medication is administered, usually and ideally the Fentanyl when commencing planned sedation. The sedation end time is the time the last dose of sedation medication either Midazolam or Fentanyl is administered. However, there may be occasions due to the individual requirements of the patient where the anxiolytic is used first. Discuss with the operator prior to administering sedation,

- Any patients whose BMI is outside the normal range.
- Patients with other relevant underlying conditions.
- High risk or new procedures or equipment.

ADMINISTERING SEDATION

To allow medications to be administered at any time, a safe distance from the radiation field **500mls of 0.9% saline** should be connected to a giving set with a three way tap or with an additional extension if necessary and documented. This also allows free movement of the x-ray table and reduces the need to disturb the drapes or operator during the procedure,

Commence administration of oxygen 2 litres per minute via a facemask. This may need to be continued during the recovery period.

Initial dose of Fentanyl

Dilution: 100 mcgs/2 mls diluted with 8 mls of saline=10 mls (10 mcg/ml)

Effective doses for patients within the normal body mass index generally are according to weight i.e. 70mcg for a 70Kg patients. Guidelines suggest a maximum of 500mcg in 4 hours but this is dependent upon BMI and the response of each patient. The dose range can be 150-300 mcg over 60 minutes in divided doses in fit and otherwise healthy patients. Particular care should be given to patients who are opioid naive in case of a sudden reaction and/or airway issue.

- Provided baseline observations are satisfactory administer 10mcg of Fentanyl observing patient for immediate effects/response. The onset of Fentanyl is 1 to 2 minutes, and duration of action 30 - 60 minutes.
- Record one full set of observations following first dose and wait 2 minutes before administering any other medication. Inform the operator if the alert criteria is met.
- Commence Midazolam.
- Titrate as required further doses of Fentanyl 10-20 mcg. There should be one full set of observations and two minutes between each dose.

Initial dose of Midazolam

5mg in 5ml drawn into 5ml syringe = 1mg/ml

The onset of Midazolam is 1- 2 minutes reaching maximum effect in 5 to 10 minutes with duration of 60 -90 minutes.

- Provided observations are satisfactory administer 1mg of Midazolam and observing patient for immediate response. The usual onset of Midazolam is 1 to 2 minutes. Particular care should be given to patients who may have been prescribed a sedative pre med consider reducing dose to 0.5mg.
- Record one full set of observations following first dose and wait 2 minutes before administering any other medication. Inform the operator if the alert criteria are met.
- Titrate as required further doses of Midazolam 1mg. There should be one full set of observations and two minutes between each dose.

Monitoring the Patient and Titration of Sedation

The combined effect of Fentanyl and Midazolam together is greater than the sum of both drugs. Titration and the doses required can vary significantly dependent upon the requirements of the individual patient and the type of procedure. Stimulation either through direct verbal communication, pain or environmental factors can suddenly affect the sedated patient. The most important monitor is the vigilant, well trained and skilled person who has immediate access to anaesthetic assistance. The nurse administering the sedation must be vigilant in monitoring physical changes and assessing their significance. This will require initiating consultation with the physician when necessary and evaluating any intervention. With uneventful sedation observations should be recorded throughout the procedure at 5 minutely intervals. These include

- Respiratory rate for frequency and adequacy
- Oxygen saturation and oxygen administration
- Observation of patients colour
- Non-invasive blood pressure and mean arterial pressure from non-invasive BP. MAP can be obtained in some procedures from the electro physiologist's equipment or an in situ arterial line, it must be clearly documented where the MAP has been read from.
- Heart rate
- Conscious level using the AVPU scale.
- Patient's temperature should be monitored ½hrly to prevent significant Hypothermia (less than 35C).
- End tidal CO₂ monitoring to be considered.

Observations may be recorded more frequently if:

- Alert criteria is met
- Suspected tamponade
- Requested by the operator

The aim of sedation is ideally to keep the patient within the V of the AVPU score throughout the procedure, however this is susceptible to fluctuation, as the response of the patient can fluctuate between under sedation and slight over sedation depending upon the stimulation or any withdrawal of stimulation. Vigilant monitoring of the patient for the effects of the medication and relevant stimulation throughout the procedure are paramount. Knowledge of the procedure is important in the appropriate administration of sedation. The operator must be informed whenever the alert criteria are met.

Indication to administer further pain relief and/or anxiolytic can vary according to the patient. The patient should be aware that they can inform the sedationist at any time of any aspect of their care for example if they are experiencing pain or anxiety. In addition, agree with patient any nonverbal sign or signals they may want to use during the procedure for example, a thumbs up or down.

Patient triggers to administer medication

- Patient states they are in pain or anxious
- Facial Grimacing
- Looks anxious
- Restlessness
- Rigidity
- Rises in blood pressure
- Heart rate
- Holding breath

Tense appearance,
Tensing of muscles

Procedural triggers to administer sedation

Change from mapping procedure to ablation catheter.
Pre pectoral pocket about to be made.
DC shock about to be administered.

Any other medication required during the procedure.

These need to be kept separate, preferable on the bench. All other medication administered should be checked at administration by two nurses, as per the Trust's intravenous drugs policy and recorded on the conscious sedation documentation.

Alert criteria and procedural complications.

When the alert criteria are triggered the physician should immediately be informed and their response recorded. The nurse may need to be assertive in ensuring the operator's attention and supervision of the situation.

The agreed alert criteria is

- A drop in the mean arterial pressure of more than 10% or more than 20mm Hg
- Any respiratory rate of less than 8 per minute
- Any SaO₂ is less than 90%
- Any other cause for concern. These include,
 - Apnoea, hypoxaemia can be a late symptom in patients receiving supplementary oxygen.
 - Poor respiratory effort,
 - Increased respiratory effort,
 - Irregular breathing patterns, such as suprasternal or intercostal retractions, paradoxical abdominal movement.
 - Noisy breathing is obstructive breathing but not all obstructive breathing is noisy.

The operator may respond by

Not giving further sedation
Increasing the observations to every 2 minutes
Consider further airway support and increasing oxygen,
Giving further IV fluids for volume
Consider giving reversal
Calling an anaesthetist.

If the operator makes a request you are concerned about i.e. give more medication or different medication, respond in accordance with your own accountable clinical judgement but if you have concerns, act without delay and escalate your concerns to senior nursing staff.

ENDING OF SEDATION

Within the cardiac catheter laboratory the sedation is recorded as ended at the time when the last conscious sedation medication was administered. The recovery period is recorded as beginning when the sheaths are removed, for ICD when the last cardioversion test has been administered and for pacemakers when the dressing is put on. This is because further sedation is not usually required after these points and it is usually 10-15 minutes pressing on puncture sites or doing further pacing test before the patient can be transferred from the x ray table to the bed and to the transit area. Observations should be continued throughout this time at 5 minutely intervals, this is important if any painful stimuli has ceased as the patient may then fall into a deeper level of sedation.

All drugs totals should be checked by both registered nurses and then documented in the theatre register. The physician/operator should review the observation chart, identify any relevant post-operative care and sign it.

The total volume of all fluids given to the patient including an estimate of the volume administered through any coolflow or irrigation through ablation equipment.

If any untoward incidents have occurred during the case the Datix number and relevant information must be recorded on the sedation chart. Care should be taken when giving the patient any verbal information, as it might be difficult for them to retain it due to the sedation medication.

PATIENT RECOVERY AND TRANSFER TO WARD

Recovery from conscious sedation differs from recovery from a general anaesthetic because although they both depress the patient's level of consciousness, the aim of conscious sedation is that throughout the patient should be able to

Retain protective airway reflexes.

Independently and continuously maintain a patent airway.

Respond appropriately to physical and verbal stimuli.

The patient should continue to be monitored every 5 minutes until handover to the ward staff. This will require ECG monitoring to be commenced again, once the specialist ECG equipment has been disconnected and upon transfer to the transits area.

Patients who have received reversal agents should be recovered for at least 30 minutes before discharge to the ward.

Discharge to the ward

Patients who have received conscious sedation should be handed over to an appropriately trained member of staff this is usually a qualified ward nurse.

Discharge criteria:

Awake, responsive and maintaining own airway, without excessive stimulus.

Adequate analgesia

Patient maintaining own airway and has intact cough reflex.

Awake, alert and aware of surroundings.

Wound site(s) dry, intact and no unusual swellings.

Skin warm, dry and an acceptable temperature

Haemodynamically stable and possibly returned to pre procedure baseline BP and

Pulse or better depending upon the procedure.

P02 saturation normally above 95% seek advice from the operator if less than this.

Instructions to ward to include procedure, drugs administered, wound sites oxygen levels and details of any untoward incidents.

Post-operative ward observation should commence at a minimum of every ½ hr.

References

British Anaesthetic and Recovery Nurses Association, (2005, Revised 2012) Standards of Practice, London, UK.

Hatfield, A. and Tronson, M. (2009) The Complete Recovery Room Book. Oxford University Press, Oxford.

Kost, M. (1998) Manual of Conscious Sedation, W. B Saunders Company, Philadelphia, Pennsylvania.

Kovoor, R. Porter, R. Uther, J. B. and Ross, D. (1997) Efficacy and Safety of a New Protocol for Continuous Infusion of Midazolam and Fentanyl and its Effects on Patient Distress during Electrophysiological Studies. PACE, Vol 20, 2765 – 2774.

Malviya, S. Naughton, N. N. and Tremper, (editors) (2010) Sedation and Analgesia and Therapeutic Procedures. Humana Press Inc. New Jersey, USA.

Medicines and Healthcare products Regulatory Agency, (2006) Fentanyl 50mcg/ml Injection, UK licence No PL01502/0062, Medicines and Healthcare products Regulatory Agency, London.

Medicines and Healthcare products Regulatory Agency, (2010) Midazolam 5mg/ml solution for Injection or Infusion, UK licence No PL00156/0123, Medicines and Healthcare products Regulatory Agency, London.

Nursing and Midwifery Council, (2007) Standards for Medicines Management, Nursing and Midwifery Council, London.

Nursing and Midwifery Council, (2008) The Code, Standards of Conduct, Performance and Ethics for Nurses and Midwives, Nursing and Midwifery Council, London.

Royal College of Nursing (2004) Managing Patients Undergoing Sedation, Sheet 5, Day Surgery Information, Royal College of Nursing, London, UK.

Skelly, M. and Palmer, D. (2003) Conscious Sedation. Whurr, Publishers. London.

The Royal College of Radiologists (2003) Safe Sedation, Analgesia and Anaesthesia within the Radiology Department. The Royal College of Radiologists, London.

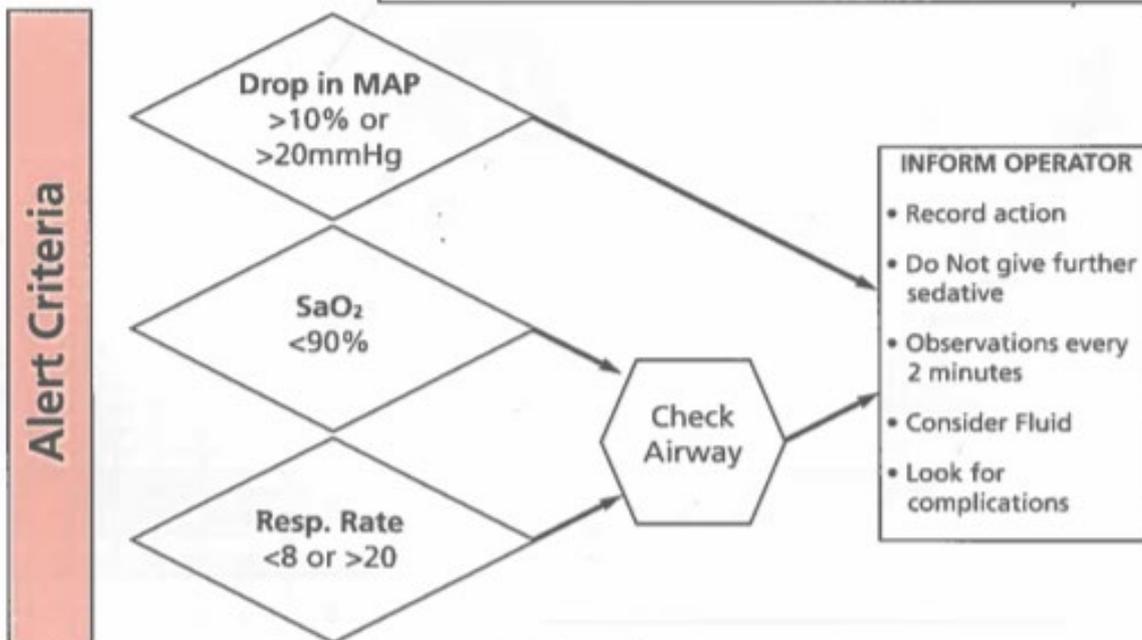
U.K. Academy of Medical Royal Colleges and Their Faculties. (2001) Implementing and Ensuring Safe Sedation Practice for Healthcare Procedures in Adults, Report of an Intercollegiate Working Party chaired by the Royal College of Anaesthetists. UK

Appendix B: NDPSA Documentation.

Nurse Delivered Cardiac Sedation

Date	Theatre	Affix patient identification label in box below or complete details	
Cardiologist	Sedationist	Surname	Patient i.d.No.
Procedure		Forename	D.O.B. DDMMYYYY
		Address	NHS No.
			Sex: Male / Female
		Postcode	

Pre Operative assessment							
Allergies	ASA	BMI	Height				
			Alcohol (units weekly)	Weight			
					Low	Moderate	High
					Smoker		
Yes	No						
Sleep apnoea							
Yes	No						
Respiratory disease		Significant comments					
Yes	No						
Opioid naive							
Yes	No						
Signed		Name					



Contact numbers			
Cardiologist	Anaesthetist	Anaesthetic nurse	On call cardiac surgeon

Appendix C: Survey Questionnaire



IRAS Project Number: 215901

Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Chief Investigator: Stuart Barker

Survey Reference Number:

Section A: to be completed by the patient.

1. Before going to theatre, did you understand that you would be awake as your procedure was carried out?

Yes: No:

2. Before going to theatre, did you understand that a nurse would be administering the medication to keep you comfortable?

Yes: No:

3. Before going to theatre, do you think you received enough information about the medication you would receive to keep you comfortable?

Yes: No:

4. Before this procedure, did you consider yourself to have an existing neck or back problem that made lying flat uncomfortable?

Yes: No:

5. On a scale of 1-10, how anxious do you remember feeling as you waited on the ward for your procedure? (Circle the number).

Least 0 (none) 1 2 3 4 5 6 7 8 9 10 Worst

6. On a scale of 1-10, how anxious do you remember feeling DURING this procedure? (Circle the number)

Least 0 (none) 1 2 3 4 5 6 7 8 9 10 Most

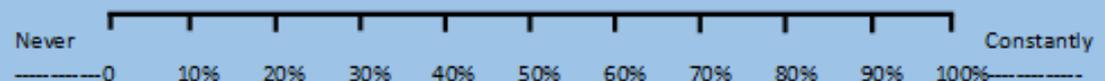
7. During the procedure, on a scale of 0-10, what was the worst pain that you remember experiencing? (Circle the number)

Least 0 (none) 1 2 3 4 5 6 7 8 9 10 Most

8. When answering question 7, you have indicated a level of pain. For what percentage of the procedure time did you experience this pain?

Put a cross on the line. You may mark between the numbers if you wish.

If you have answered 0 to question 7, please leave this blank.



9. Where in your body did you feel this worst pain? Leave this blank if you have answered 0 to question 7.

.....

10. For most of the time, what level of pain do you remember experiencing during the procedure? (Circle the number)

Least 0 (none) 1 2 3 4 5 6 7 8 9 10 Most

11. Where in your body did you feel this most typical pain?

Leave this blank if you answered 0 to question 10.

.....

12. On a scale of 0-10, what level of pain is acceptable to you? (Circle the number)

Least 0 (none) 1 2 3 4 5 6 7 8 9 10 Most

13. Did the nurse providing the medicine provide you with enough information during the procedure?

Yes: No: Can't remember:

14. Did you feel able to ask for more medicine for anxiety or pain?

Yes: No: Can't remember:

15. Over all, how satisfied are you with your experience of nurse-led pain relief and sedation? (Circle the number)

Dissatisfied 0 1 2 3 4 5 6 7 8 9 10 Very Satisfied.

16. If it were necessary, would you be willing to have a repeat procedure done under the same process of nurse-led procedural pain relief and sedation?

Yes: No:

Thank you for taking the time to complete this questionnaire.

Section B: to be completed by the RESEARCHER

Patient age:

Male / Female

Height:

Weight:

Patient body mass index:

Smoker: Yes / No

Alcohol Intake per week:

Opioid naive: Yes / No

Atrial Fibrillation / Atrial Flutter

RFA / Cryo-ablation

Duration of procedure (mins):

Paracetamol Yes/ No

Total dose of fentanyl (mcgs):

Total dose of midazolam (mgs):

Total episodes of pain recorded on sedation chart:

Occasions of alert criteria being triggered:

Sedationist ID number:

Reversal of PSA medication administered: Yes / No

Procedure completed under NLPSA: Yes / No

Recorded complication (specify):

Number of days post-procedure of patient's discharge:



Professor [REDACTED]

Executive Dean

Stuart Barker
Graduate Tutor
Department of Nursing, Midwifery and Health

This matter is being dealt with by:

Professor [REDACTED]

Ethics Lead

Department of Healthcare

Faculty of Health and Life Sciences

Coach Lane Campus

Newcastle upon Tyne

NE7 7XA

Tel: [REDACTED]

Email [REDACTED]

30 November 2016

Dear Stuart

Faculty of Health and Life Sciences Research Ethics Review DHC Barker130916

Title: What factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Thank you for your resubmission, and for clearly indicating areas altered. Following independent peer review of the above proposal, I am pleased to inform you that University approval has been granted on the basis of this proposal and subject to compliance with the University policies on ethics and consent and any other policies applicable to your individual research. You should also have recent Disclosure & Barring Service (DBS) and occupational health clearance if your research involves working with children and/or vulnerable adults.

The University's Policies and Procedures are available from the following web link:
<http://www.northumbria.ac.uk/researchandconsultancy/sa/ethgov/policies/?view=Standard>

You may now also proceed with your application (if applicable) to:

- NHS R&D organisations for approval. Please check with the NHS Trust whether you require a Research Passport, Letter(s) of Access or Honorary contract(s).

- IRAS (please see guidance attached). A 'favourable opinion' must be obtained prior to commencing your research. You must notify the University of the date of that favourable opinion.

You must not commence your research until you have obtained all necessary external approvals.

All researchers must also notify this office of the following:

- Commencement of the study;
- Actual completion date of the study;
- Any significant changes to the study design;
- Any incidents which have an adverse effect on participants, researchers or study outcomes;
- Any suspension or abandonment of the study;
- All funding, awards and grants pertaining to this study, whether commercial or non-commercial;
- All publications and/or conference presentations of the findings of the study.

We wish you well in your research endeavours.

Yours sincerely



On behalf of Faculty Research Ethics Review Panel

Mr Stuart Barker
Graduate Tutor
Northumbria University
H214
Coach Lane Campus
Newcastle upon Tyne
NE7 7XA
stuart.j.barker@northumbria.ac.uk

Email:
hra.approval@nhs.net

5 June 2017

Dear Mr Barker

Letter of HRA Approval

Study title:	Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?
IRAS project ID:	215901
Protocol number:	N/A
REC reference:	17/SW/0122
Sponsor	University of Northumbria at Newcastle

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document “*After Ethical Review – guidance for sponsors and investigators*”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **215901**. Please quote this on all correspondence.

Yours sincerely

[Redacted]

[Redacted]

Assessor

Email: hra.approval@nhs.net

Copy to: [Redacted] [sponsor contact] samantha.king@northumbria.ac.uk

[Redacted]

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
IRAS Application Form [IRAS_Form_05052017]		05 May 2017
Non-validated questionnaire [Questionnaire Document]	4.0	10 April 2017
Other [Caldicott correspondence]	1	01 July 2015
Other [Caldicott approval]	1	30 December 2016
Other [SoA-amended]	2	05 June 2017
Other [SoE-amended]	2	05 June 2017

Participant consent form [patient survey_amended_DPA]	4	02 June 2017
Participant consent form [staff ID_amended_DPA]	4	02 June 2017
Participant consent form [staff survey-amended-DPA]	4	02 June 2017
Participant consent form [staff case study-amended-DPA]	4	02 June 2017
Participant consent form [patient case study-amended-DPA]	4	02 June 2017
Participant consent form [consultant consent to observe-amended DPA]	4	02 June 2017
Participant information sheet (PIS) [Patient survey_amended DPA]	4	02 June 2017
Participant information sheet (PIS) [staff_amended_DPA]	3	02 June 2017
Participant information sheet (PIS) [patient case study-amendedDPA]	3	02 June 2017
Research protocol or project proposal [Protocol]	2.0	10 April 2017
Summary CV for Chief Investigator (CI) [CV Stuart Barker]	1.0	01 February 2017
Summary CV for student [Student-researcher CV]	1	01 February 2017
Summary CV for supervisor (student research) [TMH]	1	13 September 2016

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) sections in this appendix.*

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Sponsor name: [REDACTED]

Email: [REDACTED]

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	This is a qualitative study involving patients and NHS staff.

2.1	Participant information/consent documents and consent process	Yes	<p>There are three participant information sheets (PIS): staff, patient survey, patient case study.</p> <p>There are six informed consent forms (ICF): patient case study, patient survey, staff case study, staff survey, Staff ID, and consultant permission consent.</p> <p>All PIS and ICF study documents have been updated in line with HRA standards.</p> <p>Refer to section 5.1.</p>
3.1	Protocol assessment	Yes	No comments

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	<p>The statement of activities will act as agreement of an NHS organisation to participate.</p> <p>A Schedule of Events has also been provided detailing research activities required of the local NHS research team.</p> <p>Caldicott approval has been issued by the NHS organisation for the sharing of patient data.</p>
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	There has been no application for external funding and no funding will be available to the NHS site.

5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	All PIS and ICF documents have been updated in accordance with the Data Protection Act as a non-substantial amendment.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC favourable opinion on further information was issued by Oxford B REC on 30 May 2017.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no	Not Applicable	No comments
Section	HRA Assessment Criteria	Compliant with Standards	Comments
	objection received		
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is one NHS site type acting as a full research site; performing the study activities described in the study protocol/schedule of events.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research.**

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capability will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The [Assessing, Arranging, and Confirming](#) document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A local collaborator is required for the NHS site to oversee the patient identification and facilitate access to the NHS premises of the external research team based at Northumbria University.

The applicant has confirmed that as most of the research activities are being conducted by the external research team, there will be no training delivered to the local research team at the NHS site nor any training expected of them.

GCP training is not a generic training expectation, in line with the [HRA statement on training expectations](#).

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

As a non-commercial single site study taking place in the NHS where that single NHS organisation's partner University is the study sponsor, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix E : Participant Information and Sample Consent Forms.

Participant Information Sheet (patient Survey)

Dear patient,

My name is Stuart Barker; I am a research student at Northumbria University. Before this, I worked for over 12 years as a staff nurse at the [REDACTED]

During my time working here, I became interested in the system of medication used to keep patients relaxed and comfortable during ablations, and helped develop training for team members looking to develop skills in this area. I now wish to gather evidence about the process of using this medication

I would like to speak to you about the possibility of you taking part in my study. Taking part would mean you completing a short questionnaire (taking less than 10 minutes) after your procedure, and giving me permission to see the information about the procedure stored in your medical records. I have attached more detailed information.

You may or may not wish to talk to me. You may also agree to talk to me, and then decide not to take part. This is entirely your choice, and deciding either way will not change the care you receive. Thank you for taking the time to read this.

Kind regards,

Stuart Barker

Stuart Barker

**Graduate Tutor,
Northumbria University.**

Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

You are being invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part.

What is the Purpose of the Study?

This study has two stages which, together, will explore the protocol used during cardiac ablation to keep patients relaxed and comfortable. It aims to identify in what circumstances it works best.

In this stage, I will measure patient satisfaction with their experience, and identify details that may have influenced their experience.

Why have I been invited?

All patients having cardiac ablation procedures using this protocol are being invited to take part in this survey.

I aim to recruit 135 patients for this stage of the study and it is important that this number of responses is obtained.

What will happen if I take part?

I will meet you on the ward on the morning of your procedure. I will answer any questions that you have, and invite you to sign a consent form. This form will say that you are willing to complete section A of my questionnaire, and that you give me permission to access your medical records to collect certain data. This information (section B) will include procedure type, the length of time it took, and the amount of medicine you were given. I will offer to show you a full list of the information I need before you sign the form.

Following your procedure, you will be asked to complete a brief questionnaire about your experience and deposit it in the post box on the ward. This will take, at most, 10 minutes.

Once I have collected the questionnaire, I will then access your medical records and complete section B of the questionnaire.

Do I have to take part?

No. It is up to you whether you would like to take part in the study. I am giving you this information sheet to help you make that choice. Not taking part will not change the treatment you receive in any way.

If you agree to take part, you can also choose to withdraw without having to give a reason why. This will not change the treatment you receive in any way. Should you wish to withdraw, please contact the researcher via the Email address at the end of this sheet and state this fact.

If you do not return the questionnaire and do not contact the research team, the research team will still access your notes to see if there was a medical reason for you not returning the questionnaire. If there was, this fact will be recorded and included in the study. No further information will be taken.

What are the possible disadvantages of taking part?

I do not think there are any disadvantages in taking part in this stage of the study apart from the short period of time required to complete the questionnaire.

What are the possible benefits of taking part?

Unless you were to require a repeat procedure, it is unlikely that you would experience the benefits of any results of this study. However, repeat procedures are sometimes required. Otherwise, the benefits of this study are more likely to be felt by future patients.

Will my taking part in this study be kept confidential and anonymous?

Yes. Your name and date of birth is needed to match your questionnaire your medical records. Beyond this, it is not important to the study. On transfer of the data from paper questionnaire to computer, your name and date of birth will be removed.

Your name and date of birth will not appear in any reports or documents resulting from this study.

The only exception to this confidentiality is if the researcher feels that you or others may be harmed if information is not shared.

How will my data be stored?

Your consent form, which includes your name, date of birth and hospital number, will be stored in a locked cupboard to which only the researcher will have access.

Your questionnaire, which will not include your name, date of birth or hospital number, will be stored in a different locked cabinet, to which only the researcher will have access.

Data will be transcribed to a document on a password protected computer. Only the researcher will have access to this. No data that might identify you will be transferred to the computer.

Patients will be allocated a case number, which allows an individual's responses to be identified in case that individual wishes to withdraw. This number will appear on both consent forms and questionnaire forms.

What will happen to the results of the study?

The findings might be reported in a scientific journal or presented at a research conference. However, no personal data, or data that could be used to identify any individual will be included in these reports. We can provide you with a summary of the findings from the study if you email the researcher at the address listed below.

Who is Organizing and Funding the Study?

This research has been organised by Northumbria University

This research is funded by Northumbria University as part of my PhD programme.

Who has reviewed this study?

Before this study could begin, permissions were obtained from [redacted] NHS Foundation Trust and Northumbria University.

The Faculty of Health and Life Sciences Research Ethics Committee at Northumbria University, and the Research and Development department of [redacted] NHS Foundation Trust have reviewed the study in order to safeguard your interests, and have granted approval to conduct the study.

Contact for further information:

Researcher email: [redacted] (principal supervisor)

Patient survey consent form

Faculty of Health & Life Sciences

Survey Reference number:

Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Principal Investigator: Stuart Barker

*please tick or initial
where applicable*

I have carefully read and understood the Participant Information Sheet.

Yes No

I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers.

Yes No

I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice.

Yes No

I agree to complete the questionnaire

Yes No

I give the researcher permission to access my medical records to collect the information required by this study.

Yes No

Signature of participant..... Date.....

(NAME IN BLOCK LETTERS).....

Date of Birth:

Hospital Number:

Signature of researcher..... Date.....

(NAME IN BLOCK LETTERS).....

What factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Participant Information Sheet (staff)

You are being invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part.

What is the Purpose of the Study?

This is a two-stage study that aims to evaluate the practice of Nurse-led sedation in [REDACTED] NHS Foundation Trust, and identify factors which contribute to its success. It will consist of a survey of patients followed by a second phase during which I will observe some cases and interview patients and sedationists.

One aspect on which I am keen to focus is the role of the individual nurse-sedationist. I aim to investigate questions such as *do all nurses utilise the protocol in the same way in all circumstances?* If differences exist, how can we account for differences in decision-making, and what role does experience play in informing this decision?

Ultimately, this study may be used to support the spread of this practice into other Trusts, or to improve practice within this Trust.

Why have I been invited?

I am asking all staff who practice procedural sedation and analgesia in the Freeman Hospital catheter labs to allow their data to be collected during the survey.

I will, at a later point, be asking for volunteers to participate in the case study phase of this project. If you are invited to participate in this phase, it is because evidence from the first phase suggests that you will provide sedation and analgesia that the patient will find satisfactory.

Do I have to take part?

No.

For the survey phase, you will be asked to sign a form either granting or denying permission for me to record your identity. Should you not wish me to record your identity as part of my study, you will be assigned the same an anonymous code: this will be shared by all those who wish not to participate. This code will then be recorded on the questionnaire form should it transpire that a patient who has completed a questionnaire was sedated by you. Having recorded the 'anonymous' code on the questionnaire, I will have no means of identifying you.

Your decision to withhold permission will not be communicated to anyone else in the hospital team.

Should you be invited to participate in the case study phase, your participation would also be voluntary. You will be asked to sign a consent form stating that you are happy to be observed in practice and interviewed afterwards.

Should you wish to withdraw having given consent, you may do so. To do this, please Email the address at the end of this information sheet.

What will happen if I take part?

During the survey phase, once you have signed the form giving permission for me to collect your identity as part of the survey, you will be aware of nothing.

Patients will complete a questionnaire following their ablation procedure, and then return the survey to me. I will then take certain information from the patient's notes with their permission. Amongst this will be the identity of their sedationist.

Should you sign the form consenting to participation in the case study phase, I will note this agreement in my records. I shall then identify patients willing to participate in my study. In advance of their admission, I would contact a senior member of the nursing team and request that a member of the nursing team who has agreed to take part in the study be allocated to this patient's case.

I would then briefly meet with you on the morning of the case to confirm that you were happy to proceed.

I would observe the procedure from the control room and record my own case notes.

After the procedure you would participate in one-to-one interview with me focusing on the events of that case. This will take place on the same day as the case itself to ensure that the events are still fresh in your memory. It will last between 30 and 60 minutes. The interview will be recorded on audio equipment before being transferred to a password protected computer and transcribed.

What are the possible disadvantages of taking part?

During the survey phase, should patient satisfaction with your performance as a sedationist significantly below that of your colleagues, I would be professionally obliged under the NMC code in the interests of patients to inform both yourself and your manager. This would be handled discretely and supportively.

Otherwise I do not envisage any disadvantage to participation in the survey phase.

Participation in the case study phase will require a time commitment of 30-60 minutes to conduct the interview.

What are the possible benefits of taking part?

Once the study is complete, I am prepared to offer individual feedback of the data from the survey phase if you request it. This may be useful to your professional development and confidence. I will be unable to offer individual feedback on case study phase data as this would break confidentiality agreements with the patients involved.

I intend that this study will either identify aspects of practice that might be improved, or support the dissemination of good practice to other trusts. Either way, participation will contribute to the enhancement of standards of patientcare.

Will my taking part in this study be kept confidential and anonymous?

Neither your name, nor any other data that makes you identifiable will appear in any reports or documents resulting from this study. If you participate in the case study phase, you will be referred to by a pseudonym.

Any data that you disclose to the researcher will be treated as confidential. The only exceptions to this would be if you were to disclose information regarding activity that could be considered criminal or contrary to the NMC Code. In this situation I would be required to escalate concerns through your manager.

Should survey data show that patient satisfaction with sedation that you personally provided was significantly lower than that of the team as a whole, I would be required to inform both you and your manager in the interests of patients, as per the NMC Code.

Should you participate in the case study phase, I will be interviewing both yourself and the patient for whom you provided sedation. Anything you say about the patient will be treated as confidential, and therefore not repeated to them. Reciprocally, anything they say about you and the care you provided will not be repeated to you.

How will my data be stored?

Your name will never feature on any of the survey forms. You will be allocated a reference number which will appear on these forms. The forms will be locked in a cupboard inside a locked office. Another document will contain your name and reference number in case later identification is required. This will be stored in a different locked cupboard to the survey forms.

Likewise, survey data transferred to computer will include your reference number, not your name. The data will be stored on a password protected U-drive.

Recorded interview data will be transferred from the audio-recording device to a password protected computer U drive. The recording device will then be wiped. The recordings on computer will then be transcribed; the transcriptions will then be stored on the same U-drive and the audio recordings deleted.

What will happen to the results of the study?

The general findings might be reported in a scientific journal or presented at a research conference, however the data will be anonymized and you or the data you have provided will not be personally identifiable. We can provide you with a summary of the findings from the study if you email the researcher at the address listed below.

They will also form the basis for my PhD thesis.

Who is Organizing and Funding the Study?

This research has been organised by Northumbria University

This research is unfunded.

Who has reviewed this study?

Before this study could begin, permissions were obtained from [REDACTED] NHS Foundation Trust and Northumbria University.

The Faculty of Health and Life Sciences Research Ethics Committee at Northumbria University, and the Research and Development department of [REDACTED] NHS Foundation Trust have reviewed the study in order to safeguard your interests, and have granted approval to conduct the study.

Researcher email: [REDACTED] (principal supervisor)

Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Survey Phase: staff consent.

Principal Investigator: ___Stuart Barker___

please tick or initial where applicable

I have carefully read and understood the information sheet and:

I DO give consent for my identity to be recorded during collection of data from patient's notes:

OR:

I DO NOT give consent for my identity to be recorded during the collection of data from patients' notes:

Signature of participant..... Date.....

(NAME IN BLOCK LETTERS).....

Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Case Study Phase: staff consent.

Principal Investigator: Stuart Barker

*please tick or initial
where applicable*

I have carefully read and understood the Participant Information Sheet.

Yes No

I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers.

Yes No

I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice.

Yes No

I understand that I will be observed while performing my normal practice.

Yes No

I understand that interviews will be recorded on audio equipment.

Yes No

I agree to take part in this study.

Signature of participant..... Date.....

(NAME IN BLOCK LETTERS).....

Signature of researcher..... Date.....

(NAME IN BLOCK LETTERS).....

Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Participant Information Sheet (case study: patient)

You are being invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part.

What is the Purpose of the Study?

This study has two stages which, together, will explore the process used to keep patients relaxed and comfortable during cardiac ablation in [REDACTED] NHS Foundation Trust, and identify when this works best.

In this stage, I aim to focus on the details of individual cases from the point of view of both the patient and the person giving the sedation.

Why have I been invited?

This is not the first stage of this study. Results from the previous stage suggest that the practices used are likely to be effective in your case. The specific features of your case that identify your case as this are:

(To be completed after analysis of survey data)

I aim to recruit 6-8 patients for this phase of my study.

Do I have to take part?

No. It is up to you whether you would like to take part in the study. I am giving you this information sheet to help you make that decision. If you do decide to take part, you can still stop being involved in the study whenever you choose, without telling me why. Deciding not to take part will not change the treatment that you receive in any way. Should you wish to withdraw having given consent, please Email the address at the end of this information sheet.

What will happen if I take part?

I will meet you to answer any questions that you might have. If you are willing to take part, I will ask you to sign a consent form agreeing to take part.

I will visit you on the ward on the morning prior to your procedure and confirm that you wish to proceed with the study.

I will observe your procedure from an adjacent room. I will use an objective observation tool to monitor your level of sedation and comfort.

I will take a photocopy of your sedation record, from which your name, date of birth and hospital number will be removed.

I will conduct an interview of 30-60 minutes with your sedationist.

I will conduct an interview of not more than 30 minutes with you prior to discharge. This interview will be recorded on audio equipment and later transcribed

What are the possible disadvantages of taking part?

It is possible that being watched might make your sedationist slightly anxious. However, I will be observing them with their agreement, and I will be watching from a different room in order to minimise this pressure.

There is also a small time commitment on your part prior to discharge so that the interview can take place.

What are the possible benefits of taking part?

During your procedure, I would have to alert your nurse if I believed that they had failed to notice you were in distress, though I do not think this is likely to happen.

Unless you were to require a repeat procedure, it is unlikely that you would experience the benefits of any results of this study. However, repeat procedures are sometimes required. Otherwise, the benefits of this study are more likely to be felt by future patients.

Will my taking part in this study be kept confidential and anonymous?

Yes. Your name will not be written on any of the data I collect. The written information I collect will have an ID number, not your name. While your first name may feature in the recorded interview, it will be replaced with a pseudonym during transcription. This pseudonym will appear on any written reports of documents resulting from this study.

My thesis and any reports may include direct quotes from your interview. These will be attributed to your pseudonym, not your real name. While you would recognise your own words, no one else will be able to do so.

The data collected from you in this study will be confidential. The only exception to this confidentiality is if the researcher feels that you or others may be harmed if information is not shared.

I will be interviewing the nurse who provided you with sedation during your procedure. However, I will not share anything you say about them or their practice with them. In return, I will not discuss the contents of my interview with them with you.

How will my data be stored?

The recording of your interview will be immediately transferred to a file on the university computer system that will be protected by a password. The data will then be wiped from the recording device. The recordings will then be copied in to writing, with pseudonyms substituted for real names. These copies will also be stored on the password protected computer file. The audio-recordings will then be deleted. Only the researcher will know the password to this file.

A written key allowing individual respondents to be identified from their pseudonym will exist; this is so the researcher can identify the data of anyone wishing to leave the study. This will be kept in a locked cupboard to which only the researcher will have access.

Copies of documents, such as the sedation documents and consent forms will be kept separately in a different locked cupboard to which only the researcher has access.

What will happen to the results of the study?

The findings might be reported in a scientific journal or presented at a research conferences. They will also form the base for my PhD thesis. We can provide you with a summary of the findings from the study if you email the researcher at the address listed below.

Who is Organizing and Funding the Study?

This research has been organised by Northumbria University.

This research is unfunded.

Contact for further information:

Researcher email: [REDACTED] (principal supervisor)

Case Study Phase: patient consent.

Which factors contribute to the success of nurse led procedural sedation and analgesia during cardiac ablation?

Principal Investigator: Stuart Barker

*please tick or initial
where applicable*

I have carefully read and understood the Participant Information Sheet.

Yes No

I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers.

Yes No

I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice.

Yes No

I understand that interviews will be recorded on audio equipment.

Yes No

I agree to take part in this study.

Yes No

Signature of participant..... Date.....

(NAME IN BLOCK LETTERS).....

Signature of researcher..... Date.....

(NAME IN BLOCK LETTERS).....

Appendix F: The Critical-Care Pain Observation Tool (CPOT)

Gelinas *et al.* (2006)

Table 1 Description of the Critical-Care Pain Observation Tool			
Indicator	Description	Score	
Facial expression	No muscular tension observed	Relaxed, neutral	0
	Presence of frowning, brow lowering, orbit tightening, and levator contraction	Tense	1
	All of the above facial movements plus eyelid tightly closed	Grimacing	2
Body movements	Does not move at all (does not necessarily mean absence of pain)	Absence of movements	0
	Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements	Protection	1
	Pulling tube, attempting to sit up, moving limbs/ thrashing, not following commands, striking at staff, trying to climb out of bed	Restlessness	2
Muscle tension	No resistance to passive movements	Relaxed	0
Evaluation by passive flexion and extension of upper extremities	Resistance to passive movements	Tense, rigid	1
	Strong resistance to passive movements, inability to complete them	Very tense or rigid	2
Compliance with the ventilator (intubated patients)	Alarms not activated, easy ventilation	Tolerating ventilator or movement	0
	Alarms stop spontaneously	Coughing but tolerating	1
	Asynchrony: blocking ventilation, alarms frequently activated	Fighting ventilator	2
OR			
Vocalization (extubated patients)	Talking in normal tone or no sound	Talking in normal tone or no sound	0
	Sighing, moaning	Sighing, moaning	1
	Crying out, sobbing	Crying out, sobbing	2
Total, range			0-8

Appendix G: Interview Schedule (patient)**Introduction:**

Good morning/afternoon; thank you for taking part.

Repeat confidentiality rules; make patient aware of recording.

Invite questions about process.

Standard questions:

Was this the first time you have had this procedure performed?

Have you had any other operations or procedures in the past?

Do you consider yourself to have a high pain threshold/ cope well with pain?

How were you feeling about the procedure beforehand? What made you feel like this?

Can you talk me through what you remember happening during the case?

Can you describe the worst part of the experience?

X was your sedationist today; how did they make you feel during this case?

Dependent on Observations (identify incidents in advance of each interview)

I noticed that:

- You appeared to be uncomfortable at (time Y). Do you remember that?
- Can you describe to me what you were feeling at the time?
- Was that pain relieved?
- Did you feel able to ask for more pain relief?

- You appeared anxious at (time Z). Do you recall that?
- What helped you cope at that time?
- What else would have helped you feel less anxious?
- I noticed you talking to X at (time Q). Did this help you to relax?

Concluding Questions:

Overall, were you satisfied with your experience today? Would you have this done again under the same system of nurse-delivered sedation if it was needed?

What else could have been done today to improve your experience?

Invite further comments or questions.

Thank patient for their time

Appendix H: Interview Schedule (sedationist)**Introduction:**

Good morning/afternoon; thank you for taking part.

Repeat confidentiality rules; make nurse aware of recording.

Invite questions about process.

Standard questions:

How long have you worked in the catheter labs?

For how long have you been sedating?

When you first met this patient, did you have any specific concerns about their case, or did this case seem fairly typical?

Was this case itself routine, by which I mean were the circumstances at all unusual (e.g. time pressures, staffing levels, location, skill mix)?

Did you feel able to give as much medication as the patient needed? Invite expansion if answer is negative.

Dependent on Observations (identify incidents in advance of each interview)

I noticed that:

- You gave medication/dose at (time X). Why did you choose to do this?
- Did you have any concerns about giving it?
- Did you take any action as a result of having given it?

- The patient's observations at (time Y) were?/?. Did this concern you?
- Did you respond to that change in any way?

- You talked to the patient about (Z) at (time X). Was this important?
- Do you think it helped the patient?

Concluding Questions:

Overall, do you think this was a successful case of sedation?

In hindsight, would you have done anything differently?

Invite any further comments on the case.

Thank nurse for their time

Reference List

- Academy of Medical Royal Colleges. (2013) *Safe Sedation Practice for Healthcare Procedures Standards and Guidance*, London: Academy of Medical Royal Colleges. Available at: https://www.aomrc.org.uk/wp-content/uploads/2016/05/Safe_Sedation_Practice_1213.pdf (Accessed 7 March 2021).
- Adams, J.P. and Murphy, P.G. (2000) 'Obesity in anaesthesia and intensive care', *British Journal of Anaesthesia*, 85(1), pp.91–108. doi:10.1093/bja/85.1.91
- Attanasio, P., Huemer, M, Parwani, A.S, Boldt, L.-H., Mügge, A., Haverkamp, W. and Wutzler, A. (2016) 'Pain Reactions during Pulmonary Vein Isolation under Deep Sedation: Cryothermal versus Radiofrequency Ablation', *Pacing and Clinical Electrophysiology* 39(5), pp.452-57. doi:10.1111/pace.12840
- Banning, M. (2008) 'A review of clinical decision making: models and current research'. *Journal of Clinical Nursing*, 17(2), pp.187–195. doi:10.1111/j.1365-2702.2006.01791.x
- Barbero, U, Ferraris, F., Muro, M., Budano, C., Anselmino, M. and Gaita, F. (2018) 'Hypnosis as an Effective and Inexpensive Option to Control Pain in Transcatheter Ablation of Cardiac Arrhythmias', *Journal of Cardiovascular Medicine*, 19(1), pp.18-21, doi:10.2459/JCM.0000000000000605
- Bartholomew, D. J., (2008) *Analysis of multivariate social science data* 2nd edn., Boca Raton: CRC Press.
- Barton, T.D., Bevan, L. and Mooney, G. (2012a) 'Advanced nursing. Part 1: The development of advanced nursing roles', *Nursing Times*, 108(24), pp.18–20.
- Barton, T.D., Bevan, L. and Mooney, G. (2012b) 'What does the future hold for advanced nursing?', *Nursing Times*, 108(26), pp.19–21.
- Beach, D. (2016) 'It's all about mechanisms - what process-tracing case studies should be tracing', *New Political Economy*, 21(5), pp.463–472. doi:10.1080/13563467.2015.1134466
- Beach, D. (2018) 'Achieving Methodological Alignment When Combining QCA and Process tracing in Practice'. *Sociological Methods & Research*, 47(1), pp.64–99. doi:10.1177/0049124117701475
- Beddoes, L., Botti, M. and Duke, M.M. (2008) 'Patients' Experiences of Cardiology Procedures Using Minimal Conscious Sedation', *Heart & Lung* 37(3) pp.196-204. doi:10.1016/j.hrtlng.2007.05.012
- Benner, P.E. (2001) *From Novice to Expert. Excellence and Power in Clinical Nursing Practice*, Commemorative Edition. New Jersey: Prentice Hall Health.
- Benner, P.E., Tanner, C.A. and Chesla, C.A. (2009) *Expertise in Nursing Practice: Caring, Clinical Judgment & Ethics*. 2nd edn., New York: Springer Publishing.
- Bhaskar, R. (2008) *A Realist Theory of Science*, London: Routledge

- Biesta, G. (2010) 'Pragmatism and the philosophical foundations of mixed methods research' in Tashakkori, A. and Teddlie, C. (eds.) *Sage Handbook of Mixed Methods in Social & Behavioral Research*. 2nd edn. Los Angeles: SAGE, pp. 95-118.
- Boodhoo, L., Bordoli, G., Mitchell, A.R., Lloyd, G., Sulke, N., and Patel, N. (2004) 'The Safety and Effectiveness of a Nurse Led Cardioversion Service under Sedation', *Heart (British Cardiac Society)*, 90(2), pp.1443-446. doi:10.1136/hrt.2004.034900
- Bowers, D, House, A. and Owens, D. (2011) *Getting started in health research*, Hoboken, New Jersey: John Wiley & Sons.
- Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology'. *Qualitative Research in Psychology*, 3(2), pp.77–101. doi:10.1191/1478088706qp063oa
- Braun, V. and Clarke, V. (2012) 'Thematic analysis'. in Cooper, H., Camic, P.M., Long, D.L., Panter, A.T., Rindskopf, D. and Sher, K.J. (eds.), *APA Handbook of Research Methods in Psychology, Vol. 2: Research designs: Quantitative, qualitative, neuropsychological, and biological*, Washington, DC: American Psychological Association. pp.57-71
- British Society of Gastroenterology. (2003) *Guidelines on safety and sedation during endoscopic procedures*. British Society of Gastroenterology: London.
- Byrne, D.S. (2013) 'Case-Based Methods: Why We Need Them; What They are', in Byrne, D. S., and Ragin, C.C. (eds.) *The SAGE Handbook of Case-Based Methods*, London: SAGE, pp.1-10.
- Caddick, J., Jawad, S., Southern, S., and Majumder, S. (2012) 'The Power of Words: Sources of Anxiety in Patients Undergoing Local Anaesthetic Plastic Surgery', *Annals of the Royal College of Surgeons of England*, 94(2), pp.94-98. Web. doi:10.1308/003588412X13171221501267
- Carbonell, V. (2014) 'Amnesia, Anesthesia, and Warranted Fear', *Bioethics*, 28(5), pp.245–254. doi:10.1111/j.1467-8519.2012.01995.x
- Carr, E. and Thomas, V.J. (1997) 'Ethical Issues in Pain Management' in Thomas, V.J. (ed.), *Pain: its nature and management*, London: Baillière Tindall. pp.54-69.
- Chang, T-Y., Lin, C-Y. & Chen, S.-A. (2018) 'Vagal impact of cryoballoon ablation during pulmonary vein isolation', *International Journal of Cardiology*, 265, pp.132–133. doi:10.1016/j.ijcard.2018.04.132
- Chatwin, J., Closs, J. & Bennett, M. (2009) 'Pain in older people with cancer: attitudes and self-management strategies', *European Journal of Cancer Care*, 18(2), pp.124–130.
- Chikata, A., Kato, T., Yaegashi, T., Sakagami, S., Kato, C., Saeki, T., Kawai, K., Takashima, S., Murai, H., Usui, S., Furusho., H., Kaneko, S., and Takamura, M. (2017) 'General Anesthesia Improves Contact Force and Reduces Gap Formation in Pulmonary Vein Isolation: A Comparison with Conscious Sedation', *Heart and Vessels*, 32(8), pp.1997-1005. doi:10.1007/s00380-017-0961-z

- Christensen, M. and Hewitt-Taylor, J. (2006) 'From expert to tasks, expert nursing practice redefined?' *Journal of Clinical Nursing*, 15(12), pp.1531–1539. doi:10.1111/j.1365-2702.2006.01601.x
- Cimpean, A. and David, D. (2019) 'The mechanisms of pain tolerance and pain-related anxiety in acute pain', *Health Psychology Open*, 6(2), doi:10.1177/2055102919865161
- Clarke, A. and Dawson, R. (1999) *Evaluation Research : an introduction to principles, methods and practice*, London: SAGE.
- Collier, D. (2011) 'Understanding Process Tracing', *PS- Political Science & Politics*, 44(4), pp.823–830. doi:10.1017/S1049096511001429
- Conway, A., Page, K., Rolley, J.X., and Worrall-Carter, L. (2011) 'Nurse-administered Procedural Sedation and Analgesia in the Cardiac Catheter Laboratory: An Integrative Review'. *International Journal of Nursing Studies*, 48(8), pp.1012-023. doi:10.1016/j.ijnurstu.2011.04.013
- Conway, A., Rolley, J., Page, K., and Fulbrook, P. (2014a) 'Issues and Challenges Associated with Nurse-administered Procedural Sedation and Analgesia in the Cardiac Catheterisation Laboratory: A Qualitative Study', *Journal of Clinical Nursing*, 23(3), pp.374-84. doi:0.1111/jocn.12147
- Conway, A., Rolley, J., Page, K., and Fulbrook, P. (2014b) 'Trends in Nurse-administered Procedural Sedation and Analgesia across Cardiac Catheterisation Laboratories in Australia and New Zealand: Results of an Electronic Survey', *Australian Critical Care*, 27(1), pp.4-10. doi:10.1016/j.aucc.2013.05.003
- Conway, A., Page, K., Rolley, J.X., and Worrall-Carter, L. (2014c) 'A Review of Sedation Scales for the Cardiac Catheterization Laboratory', *Journal of Perianesthesia Nursing*, 29(3), pp.191-212. doi:10.1016/j.jopan.2013.05.017
- Creswell, J.W. and Plano Clark, V.L. (2011) *Designing and conducting mixed methods research*. 2nd edn., Thousand Oaks: SAGE Publications.
- Daoust, R., Paquet, J., Piette, É., Sanogo, K., Bailey, B., and Chauny, J.-M. (2016) 'Impact of Age on Pain Perception for Typical Painful Diagnoses in the Emergency Department', *The Journal of Emergency Medicine*, 50(1), pp.14-20. doi:10.1016/j.jemermed.2015.06.074
- Davey, H.M., Barratt, A.L., Butow, P.N., and Deeks, J.J. (2007) 'A One-item Question with a Likert or Visual Analog Scale Adequately Measured Current Anxiety', *Journal of Clinical Epidemiology*, 60(4), pp.356-60. doi:10.1016/j.jclinepi.2006.07.015
- Davidson, A. (2014) 'Fiddling with memory', *Journal of Medical Ethics*, 40(10), pp.659–660. doi:10.1136/medethics-2013-101970
- De Vaus, D.A. (2014) *Surveys in Social Research* 6th ed., Sydney: Allen & Unwin.

- Defaye, P., Kane, A., Jacon, P., and Mondesert, B. (2010) 'Cryoballoon for Pulmonary Vein Isolation: Is It Better Tolerated than Radiofrequency? Retrospective Study Comparing the Use of Analgesia and Sedation in Both Ablation Techniques', *Archives of Cardiovascular Diseases*, 103(6), pp.388-93. doi:10.1016/j.acvd.2010.06.004
- Delamaire, M. and G. Lafortune (2010) 'Nurses in Advanced Roles: A Description and Evaluation of Experiences in 12 Developed Countries', *OECD Health Working Papers*, 54. Available at: <https://doi.org/10.1787/5kmbrcfms5g7-en>. (Accessed 7 March 2021)
- Delamothe, T. (1993) 'Wanted: guidelines that doctors will follow', *British Medical Journal*, 307(6898), p.218. doi:10.1136/bmj.307.6898.218
- Della Porta, D. (2008) 'Comparative analysis: case-oriented versus variable-oriented research' in Della Porta, D. and Keating, M. (eds), *Approaches and Methodologies in the Social Sciences*. Cambridge University Press, pp. 198–222.
- Department of Health. (2000) *The NHS Plan: a plan for investment: a plan for reform*. London: Stationery Office. Available at: https://webarchive.nationalarchives.gov.uk/20130124064356/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digit_118522.pdf (Accessed 6 March 2021).
- Department of Health. (2012) *NHS Patient Experience Framework*. Available at: <https://www.gov.uk/government/publications/nhs-patient-experience-framework> (Accessed 9 March 2021).
- Department of Health. (2016) *UK Chief Medical Officers' Low Risk Drinking Guidelines*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/545937/UK_CMOs__report.pdf (Accessed 9 March 2021).
- Di Biase, L., Conti, S., Mohanty, P., Bai, R., Sanchez, J., Walton, D., John, A., Santangeli, P., Elayi, C.S., Beheiry, S., Gallinghouse, G.J., Mohanty, S., Horton, R., Bailey, S., Burkhardt, J.D., Natale, A. (2011) 'General Anesthesia Reduces the Prevalence of Pulmonary Vein Reconnection during Repeat Ablation When Compared with Conscious Sedation: Results from a Randomized Study', *Heart Rhythm*, 8(3), pp.368-72. doi: 10.1016/j.hrthm.2010.10.043
- Dreyfus, H.L. and Dreyfus, S.E. (2009) 'The Relationship of Theory and Practice in the Acquisition of Skill' in Benner, P.E., Tanner, C.A. and Chesla, C.A., *Expertise in Nursing Practice: Caring, Clinical Judgment & Ethics*. 2nd edn., New York: Springer Publishing. pp.1-24
- Dupanović, M., Lakkireddy, D., Emert, M.P., and Krebill, R. (2013) 'Utility of Dexmedetomidine in Sedation for Radiofrequency Ablation of Atrial Fibrillation'. *Journal of Perianesthesia Nursing*, 28(3), pp. 144-50. doi:10.1016/j.jopan.2012.10.005

- Elliott, T. (2013) *Fuzzy Set Qualitative Comparative Analysis: An introduction*. Research Notes, Statistics Group, University of California, Irving. Available at: https://www.socsci.uci.edu/~sgsa/docs/fsQCA_thomas_elliott.pdf (Accessed 13 March 2021).
- Everitt, B. (2011) *Cluster Analysis* 5th ed., Chichester: Wiley.
- Ezzat, V.A., Chew, A., McCready, J.W., Lambiase, P. D., Chow, A.W., Lowe, M.D., Rowland, E., and Segal, O.R. (2013) 'Catheter Ablation of Atrial Fibrillation—patient Satisfaction from a Single-Center UK Experience'. *Journal of Interventional Cardiac Electrophysiology*, 37(3), pp.291-303. doi: 10.1007/s10840-012-9763-5
- Farrington D.P. (2003) 'Methodological Quality Standards for Evaluation Research'. *The Annals of the American Academy of Political and Social Science*, 587(1), pp.49–68.
- Field, A.P. (2013) *Discovering statistics using IBM SPSS : and sex and drugs and rock 'n' roll* 4th edn., London: SAGE.
- Firme, E.B.P., Cavalcanti, I.L., Barrucand, L.A.A.R., and Figueiredo, N.V. (2012) 'Curative Ablation of Atrial Fibrillation: Comparison between Deep Sedation and General Anesthesia'. *Revista Do Colegio Brasileiro De Cirurgioes*, 39(6), pp.462-468.
- Fitzgerald, S., Tripp, H. and Halksworth-Smith, G. (2017) 'Assessment and management of acute pain in older people: Barriers and facilitators to nursing practice', *Australian Journal of Advanced Nursing*, 35(1), pp.48–57.
- Flynn, A. and Sinclair, M. (2005) 'Exploring the relationship between nursing protocols and nursing practice in an Irish intensive care unit', *International Journal of Nursing Practice*, 11(4), pp.142-149. doi:10.1111/j.1440-172X.2005.00517.x
- Furniss, S.S. and Sneyd, J.R. (2015) 'Safe sedation in modern cardiological practice', *Heart (British Cardiac Society)*, 101(19), pp.1526–1530. doi:10.1136/heartjnl-2015-307656
- Gaitan, B.D., Trentman, T.L., Fassett, S.L., Mueller, J.T., MD, and Altemose, G.T. (2011) 'Sedation and Analgesia in the Cardiac Electrophysiology Laboratory: A National Survey of Electrophysiologists Investigating the Who, How, and Why?', *Journal of Cardiothoracic and Vascular Anesthesia*, 25(4), pp.647-59. doi:10.1053/j.jvca.2010.11.006
- Gammons, V. and Caswell, G. (2014) 'Older people and barriers to self-reporting of chronic pain', *British Journal of Nursing*, 23(5), pp.274–278. doi:10.12968/bjon.2014.23.5.274
- Geiger, M.J., Wase, A., Kearney, M.M., Brandon, M.J., Kent, V., Newby, K.H., and Natale, A. (1997) 'Evaluation of the Safety and Efficacy of Deep Sedation for Electrophysiology Procedures Administered in the Absence of an Anesthetist', *Pacing and Clinical Electrophysiology*, 20(7), pp.1808-814. doi: 10.1111/j.1540-8159.1997.tb03571.x

- Gélinas, C., Fillion, L., Puntillo, K.A., Viens, C., and Fortier, M. (2006) 'Validation of the Critical-Care Pain Observation Tool in Adult Patients' *American Journal of Critical Care*, 15(4), pp.420-27. doi:10.4037/ajcc2006.15.4.420
- Gélinas, C., Harel, F., Fillion, L., Puntillo, K.A., & Johnston, C.C. (2009) 'Sensitivity and Specificity of the Critical-Care Pain Observation Tool for the Detection of Pain in Intubated Adults After Cardiac Surgery', *Journal of Pain and Symptom Management*, 37(1), pp.58-67. doi: 10.1016/j.jpainsymman.2007.12.022
- George, A.L. and Bennett, A. (2004) *Case Studies and Theory Development in the Social Sciences*, London: MIT Press.
- Gobet, F. and Chassy, P. (2008) 'Towards an alternative to Benner's theory of expert intuition in nursing: A discussion paper', *International Journal of Nursing Studies*, 45(1), pp.129–139. doi:10.1016/j.ijnurstu.2007.01.005
- Hallingbye, T., Martin, J. and Viscomi, C. (2011) 'Acute postoperative pain management in the older patient', *Aging Health*, 7(6), pp.813–828. doi:10.2217/ahe.11.73
- Hamm, R.M. (1988) 'Clinical intuition and clinical analysis: expertise and the cognitive continuum.' in Dowie, J. and Elstein, A. (eds.) *Professional Judgment: A Reader in Clinical Decision Making*. Cambridge: Cambridge University Press. pp.78-105
- Hanley, J.A. and Lippman-Hand, A. (1983) 'If Nothing Goes Wrong, Is Everything All Right?: Interpreting Zero Numerators'. *The Journal of the American Medical Association*, 249(13), pp.1743–1745. doi:0.1001/jama.1983.03330370053031
- Harré, R. (1972). *The Philosophies Of Science : An Introductory Survey*. Oxford University Press.
- Harwood, L. and Clark, A. M. (2012) 'Understanding health decisions using critical realism: home-dialysis decision-making during chronic kidney disease', *Nursing inquiry*, 19(1), pp.29–38.
- Herr, K., Coyne, P.J., McCaffery, M., Manworren, R., and Merkel, S. (2011) 'Pain Assessment in the Patient Unable to Self-Report: Position Statement with Clinical Practice Recommendations', *Pain Management Nursing*, 12(4), pp.230-50. doi:10.1016/j.pmn.2011.10.002
- Hewitt-Taylor, J. (2004) 'Clinical guidelines and care protocols', *Intensive & Critical Care Nursing*, 20(1), pp.45–52. doi:10.1016/j.iccn.2003.08.002
- Hill, B. (2017) 'Exploring the development and identity of advanced practice nursing in the UK', *Nursing Management*, 24(5), pp.36–40. doi:10.7748/nm.2017.e1607
- IBM Corp. (2019) *IBM SPSS Statistics for Windows*, (Version 26.0) [Computer Program] Armonk, NY: IBM Corp.
- Ichihara, N., Miyazaki, S., Taniguchi, H., Usui, Eisuke, T., Takamitsu, I., Jin, K., Akio, N., Hiroaki, Hachiya, H., and Iesaka, Y. (2015) 'Simple Minimal Sedation for Catheter Ablation of Atrial Fibrillation', *Circulation Journal: Official Journal of the Japanese Circulation Society*, 79(2), pp.346-50. doi:10.1253/circj.CJ-14-1106

- Ilott, I., Booth, A., Rick, J. and Patterson, M. (2010) 'How do nurses, midwives and health visitors contribute to protocol-based care? A synthesis of the UK literature', *International Journal of Nursing Studies*, 47(6), pp.770-780. doi:10.1016/j.ijnurstu.2009.12.023
- Ilott, I., Rick, J., Patterson, M., Turgoose, C., and Lacey, A. (2006) 'What Is Protocol-based Care? A Concept Analysis', *Journal of Nursing Management*, 14(7), pp.544-52. doi:10.1111/j.1365-2934.2006.00703.x
- International Association for the Study of Pain. (2017) *IASP Terminology*. Available at: <https://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698> (accessed: 05/03/2021)
- International Association for the Study of Pain. (2020) *IASP Announces Revised Definition of Pain*. Available at: <https://www.iasp-pain.org/PublicationsNews/NewsDetail.aspx?ItemNumber=10475> (Accessed 5 March 2021)
- Joint Formulary Committee. (2021) *British National Formulary (online)* London: BMJ Group and Pharmaceutical Press. Available at: <https://bnf.nice.org.uk/> (Accessed 12 March 2021).
- Jones, C. and Lyons, C. (2004) 'Case study: design? Method? Or comprehensive strategy?' *Nurse Researcher*, 11(3), pp.70–76. doi: 10.7748/nr2004.04.11.3.70.c6206
- Kaufman, L. and Rousseeuw, P.J. (2005) *Finding Groups in Data: An Introduction to Cluster Analysis*, Chichester: Wiley.
- Kezerashvili, A., Fisher, J.D, DeLaney, J., Mushiyevev, S., Monahan, E., Taylor, V., Kim, S.G., Ferrick, K.J., Gross, J.N., Palma, E.C. and Krumerman, A.K. (2008) 'Intravenous Sedation for Cardiac Procedures Can Be Administered Safely and Cost-effectively by Non-Anesthesia Personnel', *Journal of Interventional Cardiac Electrophysiology*, 21(1), pp. 43-51. doi:10.1007/s10840-007-9191-0
- Kim, M.J., Oh H-K., Lee, K.C., Yang, H.H. Koo, B-W., Lee, J., Kim M-H., Kang, S.I., Kim, D-W. and Kang, S-B. (2019) 'Effects of an Internet-based Informational Video on Preoperative Anxiety in Patients with Colorectal Cancer' *Annals of Surgical Treatment and Research*, 96(6), pp.290-95 doi:10.4174/astr.2019.96.6.290
- Kirthi, V. and Modi, B. (2012) 'Coronary Angioplasty and the Internet: What Can Patients Searching Online Expect to Find?' *Journal of Interventional Cardiology*, 25(5), pp.476-481. doi:10.1111/j.1540-8183.2012.00748.x
- Kontos, E., Blake, K., Chou, W. and Prestin, A. (2014) 'Predictors of eHealth usage: Insights on the digital divide from the Health Information National Trends Survey 2012', *Journal of Medical Internet Research*, 16(7), E172. doi:10.2196/jmir.3117

- Kottkamp, H., Hindricks, G., Eitel, C., Müller, K., Siedziako, A., Koch, J., Anastasiou-Nana, M., Varounis, C., Arya, A., Sommer, P., Gaspar, T., Piorkowski, C., and Dagues, N. (2011) 'Deep Sedation for Catheter Ablation of Atrial Fibrillation: A Prospective Study in 650 Consecutive Patients', *Journal of Cardiovascular Electrophysiology*, 22(12), pp.1339-343. doi:10.1111/j.1540-8167.2011.02120.x
- Kovoor, P., Porter, R., Uther, J.B., and Ross, D.L. (1997) 'Efficacy and Safety of a New Protocol for Continuous Infusion of Midazolam and Fentanyl and Its Effects on Patient Distress During Electrophysiological Studies', *Pacing and Clinical Electrophysiology*, 20(11), pp.2765-774. doi:10.1111/j.1540-8159.1997.tb05434.x
- Laish-Farkash, A., Katz, A., Cohen, O., Osherov, A., Bruocha, S. and Khalameizer, V. (2016) 'Site Localization of Painful Lesions during Radiofrequency Ablation of Pulmonary Veins Using Circular Multi-electrode Catheters', *Journal of Interventional Cardiac Electrophysiology*, 45(1), pp.63-69. doi:10.1007/s10840-015-0065-6
- Lalor, J.G., Casey, D., Elliott, N., Coyne, I., Comiskey, C., Higgins, A., Murphy, K., Devane, D., and Begley, C. (2013) 'Using Case Study within a Sequential Explanatory Design to Evaluate the Impact of Specialist and Advanced Practice Roles on Clinical Outcomes: The SCAPE Study', *BMC Medical Research Methodology*, 13(1). doi:10.1186/1471-2288-13-55
- Lamond, D. and Thompson, C. (2000) 'Intuition and Analysis in Decision Making and Choice', *Journal of Nursing Scholarship*, 32(4), pp.411–414. doi:10.1111/j.1547-5069.2000.00411.x
- Laurent M.R. (2012) 'Internet use for health information among haematology outpatients: A cross-sectional survey', *Informatics for Health & Social Care*, 37(2), pp.62-73. doi:10.3109/17538157.2011.606481
- Laurent, G., Bertaux, G., Martel, A., Fraison, M., Fromentin, S., Gonzalez, S., Pierre, F.S., and Wolf, J. E. (2006) 'A Randomized Clinical Trial of Continuous Flow Nitrous Oxide and Nalbuphine Infusion for Sedation of Patients During Radiofrequency Atrial Flutter Ablation', *Pacing and Clinical Electrophysiology*, 29(4), pp.351-57. doi:10.1111/j.1540-8159.2006.00352.x
- Lautenbacher, S., Peters, J.H., Heesen, M., Scheel, J., and Kunz, M. (2017) 'Age Changes in Pain Perception: A Systematic-review and Meta-analysis of Age Effects on Pain and Tolerance Thresholds', *Neuroscience and Biobehavioral Reviews*, 75, pp.104-13. doi:10.1016/j.neubiorev.2017.01.039
- Li, D., Puntillo, K. and Miaskowski, C. (2008) 'A Review of Objective Pain Measures for Use With Critical Care Adult Patients Unable to Self-Report', *The Journal of Pain*, 9(1), pp.2–10. doi:10.1016/j.jpain.2007.08.009
- Lipscomb, M. (2008) 'Mixed method nursing studies: a critical realist critique', *Nursing Philosophy*, 9(1), pp.32–45.

- Looi, K., Lee, A.S.Y, Cole, K., Agarwal, S., Heck, P.M., Begley, D.A., Grace, A.A., Virdee, M., and Fynn, S.P. (2013) 'Conscious Sedation and Analgesia Use in Cardiac Device Implantation', *International Journal of Cardiology*, 168(1), pp.561-63. doi:0.1016/j.ijcard.2013.01.167
- Lowe, M.D., Meara, M., Mason, J., Grace, A.A., and Murgatroyd, F.D. (2003) 'Catheter Cryoablation of Supraventricular Arrhythmias: A Painless Alternative to Radiofrequency Energy', *Pacing and Clinical Electrophysiology*, 26(1), pp.500-03. doi:10.1046/j.1460-9592.2003.00081.x
- Lü, F., Lin, J., and Benditt, D.G. (2013) 'Conscious Sedation and Anesthesia in the Cardiac Electrophysiology Laboratory', *Journal of Cardiovascular Electrophysiology*, 24(2), pp.237-45. doi:10.1111/jce.12001
- Luck, L., Jackson, D. and Usher, K. (2006) 'Case study: a bridge across the paradigms', *Nursing Inquiry*, 13(2), pp.103–109. doi:10.1111/j.1440-1800.2006.00309.x
- Lynch, J. and Crawley, S.M. (2017) 'Management of airway obstruction'. *BJA Education*, 18(2), pp.46–51. doi:10.1016/j.bjae.2017.11.006
- Mah, K., Tran, K.T., Gauthier, L.R., Rodin, G., Zimmermann, C., Warr, D., Librach, S.L., Moore, M., Shepherd, F.A., and Gagliese, L. (2018) 'Do Correlates of Pain-Related Stoicism and Cautiousness Differ in Younger and Older People With Advanced Cancer?', *The Journal of Pain*, 19(3), pp.301-16. doi:10.1016/j.jpain.2017.11.002
- Mahoney, J. (2012) 'The Logic of Process Tracing Tests in the Social Sciences', *Sociological Methods & Research*, 41(4), pp.570–597. doi:10.1177/0049124112437709
- Manzano, A. (2016) 'The craft of interviewing in realist evaluation', *Evaluation (London, England. 1995)*, 22(3), pp.342–360. doi:10.1177/1356389016638615
- Martin, C.A., Curtain, J.P., Gajendragadkar, P.R., Begley, D.A., Fynn, S.P., Grace, A.A., Heck, P.M., Salaunkey, K., Virdee, M.S., and Agarwal, S. (2018) 'Improved Outcome and Cost Effectiveness in Ablation of Persistent Atrial Fibrillation under General Anaesthetic', *Europace*, 20(6), pp.935-42. doi:10.1093/europace/eux057
- Marx, A. (2010) 'Crisp-set qualitative comparative analysis (csQCA) and model specification: Benchmarks for future csQCA applications', *International Journal of Multiple Research Approaches*, 4(2), pp.138–158. doi:10.5172/mra.2010.4.2.138
- Marx, A., Rihoux, B. and Ragin, C. (2014) 'The origins, development, and application of Qualitative Comparative Analysis: the first 25 years', *European Political Science Review*, 6(1), pp.115–142. doi:10.1017/S1755773912000318
- McCaffery, M. and Bebee, A. (1994) *Pain: Clinical Manual for Nursing Practice*. UK Edition. Edited by J.Latham. London: Mosby.
- McCrum-Gardner, E. (2010) 'Sample size and power calculations made simple', *International Journal of Therapy and Rehabilitation*, 17(1), pp.10–14. doi:10.12968/ijtr.2010.17.1.45988

- Medscape. (2020) *Fentanyl*. Available at: <https://reference.medscape.com/drug/sublimaze-fentanyl-343311#0> (Accessed 17 March 2021).
- Melzack, R. (2005) 'Evolution of the Neuromatrix Theory of Pain. The Prithvi Raj Lecture: Presented at the Third World Congress of World Institute of Pain, Barcelona 2004', *Pain Practice*, 5(2), pp.85–94. doi:10.1111/j.1533-2500.2005.05203.x
- Melzack, R. and Wall, P.D. (1965) 'Pain Mechanisms: A New Theory', *Science (American Association for the Advancement of Science)*, 150(3699), pp.971–979. doi:10.1126/science.150.3699.971
- Miśkowiec, D., Kasprzak, J.D., Wejner-Mik, P., Szymczyk, E., Qawoq, H.D., Życiński, P., Wcisło, T., Pagórek, P., Kupczyńska, K., and Lipiec, P. (2018) 'Conscious Sedation during Cryoballoon Ablation of Atrial Fibrillation: A Feasibility and Safety Study', *Minerva Cardioangiologica*, 66(2), pp.143-151. doi:10.23736/S0026-4725.17.04505-4.
- Mitchell, M. (2008) 'Conscious surgery: Influence of the environment on patient anxiety', *Journal of Advanced Nursing*, 64(3), pp.261-271 doi:10.1111/j.1365-2648.2008.04769.x
- Moayed, M. and Davis, K.D. (2013) 'Theories of pain: from specificity to gate control', *Journal of Neurophysiology*, 109(1), pp.5–12. doi:10.1152/jn.00457.2012
- Moore, D.J., Eccleston, C., and Keogh, E. (2013) 'Does Sex Moderate the Relationship between Anxiety and Pain?' *Psychology & Health*, 28(7), pp.746-64. doi:10.1080/08870446.2012.759222
- Münkler, P., Attanasio, P., Parwani, A.S., Huemer, M., Boldt, L-H., Haverkamp, W., and Wutzler, A. (2017) 'High Patient Satisfaction with Deep Sedation for Catheter Ablation of Cardiac Arrhythmia', *Pacing and Clinical Electrophysiology*, 40(5), pp.585-90. doi:10.1111/pace.13063
- Narui, R., Matsuo, Seiich, I., Ryota, Tokutake, K., Yokoyama, K., Kato, M., Ito, K., Tanigawa, S., Yamashita, S., Tokuda, M., Inada, K., Shibayama, K., Miyanaga, S., Sugimoto, K., Yoshimura, M., and Yamane, T. (2017) 'Impact of Deep Sedation on the Electrophysiological Behavior of Pulmonary Vein and non-PV Firing during Catheter Ablation for Atrial Fibrillation', *Journal of Interventional Cardiac Electrophysiology*, 49(1), pp.51-57.
- Natale, A., Kearney, M.M., Brandon, M., Kent, V., Wase, A., Newby, K.H., Pisano, E., and Geiger, M.J. (1996) 'Safety of Nurse-Administered Deep Sedation for Defibrillator Implantation in the Electrophysiology Laboratory', *Journal of Cardiovascular Electrophysiology*, 7(4), pp.301-06. doi:10.1111/j.1540-8167.1996.tb00531.x
- National Cardiac Audit Programme. (2019) *National Audit of Cardiac Rhythm Management Devices and Ablation. 2016/17 Summary Report*. London: National Cardiac Audit Programme. Available at: <https://bhrc.com/wp-content/uploads/2019/07/CRM-Report-2016-2017.pdf> (Accessed 7 March 2021)

- National Institute for Cardiovascular Outcomes Research. (2015) *National Audit of Cardiac Ablation 2013-14* London: National Institute for Cardiovascular Outcomes Research. Available at: <https://bhros.com/wp-content/uploads/2019/03/Ablation-Report-2013-14-version-9-Final1.pdf> (Accessed 7 March 2021).
- National Institute for Health and Care Excellence. (2012) *Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. Clinical guideline [CG138]*. Available at: <https://www.nice.org.uk/guidance/cg138> (Accessed 9 March 2021).
- National Institute for Health and Care Excellence. (2014) *Developing NICE guidelines: the manual*. Available at: <https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf> (Accessed 9 March 2021).
- Nørgaard, M.W, Pedersen, P.U., and Bjerrum, M. (2015) 'Visualisation during Ablation of Atrial Fibrillation – Stimulating the Patient's Own Resources: Patients' Experiences in Relation to Pain and Anxiety during an Intervention of Visualisation', *European Journal of Cardiovascular Nursing*, 4(6), pp.552-59. doi:10.1177/1474515114548643
- Nowell, L.S., Norris, J.M., White, D.E., and Moules, N.J. (2017) 'Thematic Analysis: Striving to Meet the Trustworthiness Criteria', *International Journal of Qualitative Methods* 16(1), doi:10.1177/1609406917733847
- Nursing & Midwifery Council. (2018) *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates*. London: Nursing & Midwifery Council.
- Nursing & Midwifery Council. (2021) *Register as a nurse or midwife if you trained outside the UK: step by step*. Available at: <https://www.nmc.org.uk/registration/joining-the-register/register-nurse-midwife/trained-outside-the-eueea/new-application/how-to-guide/> (Accessed 21/09/21)
- O'Hara, D., Ganeshalingam, K., Gerrish, H., and Richardson, P. (2013) 'A 2 Year Experience of Nurse Led Conscious Sedation in Paediatric Burns', *Burns* 40(1), pp.48-53. doi:10.1016/j.burns.2013.08.021
- Odhner, M., Wegman, D., Freeland, N., Steinmetz, A., and Ingersoll, G.L. (2003) 'Assessing Pain Control in Nonverbal Critically Ill Adults', *Dimensions of Critical Care Nursing* 22(6), pp.260-67. doi:10.1097/00003465-200311000-00010
- Oladele, D., Clark, A.M., Richter, S., and Laing, L. (2013) 'Critical realism: A practical ontology to explain the complexities of smoking and tobacco control in different resource settings', *Global Health Action*, 6(1), doi:0.3402/gha.v6i0.19303
- Pachulski, R.T., Adkins, D.C. and Mirza, H. (2001) 'Conscious Sedation with Intermittent Midazolam and Fentanyl in Electrophysiology Procedures', *Journal of Interventional Cardiology*, 14(2), pp.143–146. doi:10.1111/j.1540-8183.2001.tb00725.x
- Pawson, R. and Tilley, N. (1997) *Realistic Evaluation*. London: SAGE.

- Payen, J-F., Bru, O., Bosson, J-L., Lagrasta, A., Novel, E., Deschaux, I., Lavagne, P., and Jacquot, C. (2001) 'Assessing Pain in Critically Ill Sedated Patients by Using a Behavioral Pain Scale', *Critical Care Medicine*, 29(12), pp.2258-263. doi:10.1097/00003246-200112000-00004
- Peacock, S. and Patel, S (2008) 'Cultural Influences on Pain.' *British Journal of Pain*, 1(2), pp.6-9. doi: 10.1177/204946370800100203
- Pereira-Morales, S., Arroyo-Novoa, C., Wysocki, A. and Sanzero Eller, L. (2018) 'Acute Pain Assessment in Sedated Patients in the Postanesthesia Care Unit.' *The Clinical Journal of Pain* 34(8) pp.700-06. doi:10.1097/AJP.0000000000000593
- Piot, O. (2015) 'Safe sedation in cardiology: guidance in a moving field', *Heart (British Cardiac Society)*, 101(19), pp.1525. doi:10.1136/heartjnl-2015-308210
- Pison, L., Peeters, P., Blaauw, Y., Vernooy, K., Kumar, N., Philippens, S., Crijns, H.J., Vlaeyen, J., Schoenen, J., and Timmermans, C. (2015) 'Headache during Cryoballoon Ablation for Atrial Fibrillation', *Europace*, 17(6), pp.898-901. doi:10.1093/europace/euu321
- Ploghaus, A., Narain, C., Beckmann, C.F., Clare, S., Bantick, S., Wise, R., Matthews, P.M., Rawlins, J. Nicholas P., and Tracey, I. (2001) 'Exacerbation of Pain by Anxiety Is Associated with Activity in a Hippocampal Network', *The Journal of Neuroscience*, 21(24), pp.9896-903. doi:10.1523/JNEUROSCI.21-24-09896.2001
- Ploghaus, A., Becerra, L, Borrás, C. and Borsook, D. (2003) 'Neural Circuitry Underlying Pain Modulation: Expectation, Hypnosis, Placebo', *Trends in Cognitive Sciences*, 7(5), pp.197-200. doi:10.1016/S1364-6613(03)00061-5
- Price, R.C, Asenjo, J.F, Christou, N.V, Backman, S.B, and Schweinhardt, P. (2013) 'The Role of Excess Subcutaneous Fat in Pain and Sensory Sensitivity in Obesity', *European Journal of Pain*, 17(9), pp.1316-326. doi:10.1002/j.1532-2149.2013.00315.x
- Pudas-Tähkä, S-M., Axelin, A., Aantaa, R., Lund, V., and Salanterä, S. (2009) 'Pain Assessment Tools for Unconscious or Sedated Intensive Care Patients: A Systematic Review', *Journal of Advanced Nursing*, 65(5), pp.946-56. doi:10.1111/j.1365-2648.2008.04947.x
- Punton, M. and Welle, K. (2015) *Applying process tracing in five steps*. Brighton: Institute of Development Studies. Available at: https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/5997/CDI_PracticePaper_10_Annex.pdf?sequence=2&isAllowed=y (Accessed 13 March 2021)
- Ragin, C.C. (2008) 'Fuzzy Sets: Calibration Versus Measurement'. In Box-Steffensmeier, J.M., Brady, H.E. and Collier, D. (eds.) *The Oxford Handbook of Political Methodology* Oxford: Oxford University Press. pp.87-121.

- Ragin, C.C. (2018) *User's Guide to Fuzzy-Set/Qualitative Comparative Analysis*. Irvine, California: Department of Sociology, University of California. Available at: <http://www.socsci.uci.edu/~cragin/fsQCA/software.shtml> (Accessed 18 March 2021).
- Ragin, C.C. and Davey, S. (2016) *Fuzzy-Set/Qualitative Comparative Analysis* (Version 3.0) [Computer Programme]. Available at: <http://www.socsci.uci.edu/~cragin/fsQCA/software.shtml> (Accessed 18 March 2021).
- Rahim-Williams, B., Riley III, J., Williams, A., and Fillingim, R. (2012) 'A Quantitative Review of Ethnic Group Differences in Experimental Pain Response: Do Biology, Psychology, and Culture Matter?' *Pain Medicine* 13(4), 522-540. doi: <https://doi.org/10.1111/j.1526-4637.2012.01336.x>
- Raichle, K.A., Osborne, T.L., Jensen, M.P., Ehde, D.M., Smith, D.G., and Robinson, L.R. (2015), 'Preoperative State Anxiety, Acute Postoperative Pain, and Analgesic Use in Persons Undergoing Lower Limb Amputation', *The Clinical Journal of Pain* 31(8), pp.699-706. doi:10.1097/AJP.000000000000150
- Rang, H.P., Dale, M.M., Ritter, J.M., Flower, R. and Henderson, G. (2012), *Rang & Dale's Pharmacology* 7th. ed., London: Elsevier.
- Reed, G.W., Tushman, M.L., and Kapadia, S.R. (2018), 'Operational Efficiency and Effective Management in the Catheterization Laboratory: JACC Review Topic of the Week', *Journal of the American College of Cardiology*, 72(20), pp.2507-517. doi:10.1016/j.jacc.2018.08.2179
- Reilly, R.C. (2010) 'Process Tracing', in Mills, A.J., Durepos, G. and Wiebe, E. (eds.) *Encyclopedia of Case Study Research*. Thousand Oaks: Sage. pp. 735-736
- Rhioux, B. and Lobe, B. (2013) 'The Case for Qualitative Comparative Analysis (QCA): Adding Leverage for Thick Cross-Case Comparison', in Byrne, D. S., and Ragin, CC. (eds.) *The SAGE Handbook of Case-Based Methods*, London: SAGE, pp.222-242.
- Ricks, J.I. and Liu, A.H. (2018) 'Process-Tracing Research Designs: A Practical Guide', *PS-Political Science & Politics*, 51(4), pp.842–846. doi:10.1017/S1049096518000975
- Robson, C. and McCartan, K. (2016) *Real World Research: A Resource for Users of Social Research Methods in Applied Settings*. 4th edn. Chichester: Wiley
- Ross, M.M, Carswell, A., Hing, M., Hollingworth, G. and Dalziel, W.B. (2001) 'Seniors' Decision Making about Pain Management', *Journal of Advanced Nursing*, 35(3), pp.442-51. doi:10.1046/j.1365-2648.2001.01859.x
- Rycroft-Malone, J., Morrell, C. and Bick, D. (2004) 'The research agenda for protocol-based care', *Nursing Standard*, 19(6), pp.33-36. doi:10.7748/ns2004.10.19.6.33.c3730
- Rycroft-Malone, J., Fontenla, M., Bick, D. and Seers, K. (2008) 'Protocol-based care: Impact on roles and service delivery', *Journal of Evaluation in Clinical Practice*, 14(5), pp.867-873. doi:10.1111/j.1365-2753.2008.01015.x

- Rycroft-Malone, J., Fontenla, M., Seers, K. and Bick, D. (2009) 'Protocol-based Care: The Standardisation of Decision-making?', *Journal of Clinical Nursing*, 18(10), pp.1490-500. doi:10.1111/j.1365-2702.2008.02605.x
- Salukhe, T.V., Willems, S., Drewitz, I., Steven, D., Hoffmann, B.A., Heitmann, K., and Rostock, T. (2012) 'Propofol Sedation Administered by Cardiologists without Assisted Ventilation for Long Cardiac Interventions: An Assessment of 1000 Consecutive Patients Undergoing Atrial Fibrillation Ablation', *Europace*, 14(3), pp.325-30. doi:10.1093/europace/eur328
- Sapsford, R. (1999) *Survey Research*, London: SAGE.
- Sawhney, V., Bacuetes, E., Wray, M., Dhinoja, M., Earley, M.J., Schilling, R. J., & Sporton, S. (2017) 'Moderate sedation in cardiac electrophysiology laboratory: A retrospective safety analysis', *Heart (British Cardiac Society)*, 103(15), pp.1210-1215. doi:10.1136/heartjnl-2016-310676
- Scaglione, M., Battaglia, A., Di Donna, P., Peyracchia, M., Bolzan, B., Mazzucchi, P., Muro, M., and Caponi, D. (2019) 'Hypnotic Communication for Periprocedural Analgesia during Transcatheter Ablation of Atrial Fibrillation'. *International Journal of Cardiology. Heart & Vasculature*, 24(100408). doi:0.1016/j.ijcha.2019.100405
- Schiller, C. J. (2016) 'Critical realism in nursing: an emerging approach', *Nursing Philosophy*, 17(2), pp.88–102. doi:10.1111/nup.12107
- Schneider, C.Q. and Rohlfing, I. (2013) 'Combining QCA and Process Tracing in Set-Theoretic Multi-Method Research', *Sociological Methods & Research*, 42(4), pp.559–597. doi:10.1177/0049124113481341
- Schneider, C.Q. and Wagemann, C. (2012) *Set-theoretic Methods for the Social Sciences : A Guide to Qualitative Comparative Analysis*, Cambridge: Cambridge University Press.
- Schofield, P. (2006) 'Pain management of older people in care homes: a pilot study', *British Journal of Nursing*, 15(9), pp.509–514. doi:10.12968/bjon.2006.15.9.21092
- Servatius, H., Höfeler, T., Hoffmann, B.A, Sultan, A., Lüker, J., Schäffer, B., Willems, S. and Steven, D. (2016) 'Propofol Sedation Administered by Cardiologists for Patients Undergoing Catheter Ablation for Ventricular Tachycardia', *Europace*, 18(8), pp.1245-51. doi:10.1093/europace/euv303
- Sharma, P.S., Padala, S. K., Gunda, S., Koneru, J.N. and Ellenbogen, K.A. (2016) 'Vascular Complications During Catheter Ablation of Cardiac Arrhythmias: A Comparison Between Vascular Ultrasound Guided Access and Conventional Vascular Access', *Journal of Cardiovascular Electrophysiology* 27(10) pp.1160-166. doi:10.1111/jce.13042
- Simons, H. (2009) *Case study Research in Practice*, London: SAGE.
- Singh, K. and Brown, R. (2016) 'From headache to tumour: An examination of health anxiety, health-related Internet use and 'query escalation'', *Journal of Health Psychology*, 21(9), pp.2008-2020 doi:10.1177/1359105315569620

- Sjöling, M., Nordahl, G., Olofsson, N., and Asplund, K. (2003) 'The Impact of Preoperative Information on State Anxiety, Postoperative Pain and Satisfaction with Pain Management', *Patient Education and Counselling*, 51(2), pp.169-76. doi:10.1016/S0738-3991(02)00191-X
- Somes, J., Donatelli, N.S., and Barrett, J. (2011) 'Sedation and Pain Medications in the Older Adult', *Journal of Emergency Nursing*, 37(1) pp.77-78. doi:10.1016/j.jen.2010.08.002
- Sommer Harrits, G. (2011) 'More Than Method?: A Discussion of Paradigm Differences Within Mixed Methods Research', *Journal of Mixed Methods Research*, 5(2), pp.150–166.
- Stake, R.E. (1995) *The Art of Case Study Research*, London: Sage.
- Standing, M. (2010) 'Perceptions of clinical decision-making: a matrix model', in Standing, M. (ed.) *Clinical Judgement and Decision-Making in Nursing and Interprofessional Healthcare*. Maidenhead: Open University Press. pp.1-27.
- Stangroom, J. (2021a) *Easy Fisher Exact Test Calculator*. [Computer Program]. Available at: <https://www.socscistatistics.com/tests/fisher/default2.aspx> (Accessed 18 March 2021).
- Stangroom, J. (2021b) *Chi-Square Test Calculator*. [Computer Program]. Available at: <https://www.socscistatistics.com/tests/chisquare2/default2.aspx> (Accessed 18 March 2021).
- Sury, M.R.J., Hatch, D.J., Deeley, T., Dicks-Mireaux, C, and Chong, W.K. (1999), 'Development of a Nurse-led Sedation Service for Paediatric Magnetic Resonance Imaging', *The Lancet (British Edition)*, 9165(353) pp.1667-671. doi: 10.1016/S0140-6736(98)08383-4
- Tang Ri., Dong J., Zhao W., Liu X., Kang J., Long D., Yu R., Hu F., Liu X. and Ma C. (2007) 'Unconscious Sedation/analgesia with Propofol versus Conscious Sedation with Fentanyl/midazolam for Catheter Ablation of Atrial Fibrillation: A Prospective, Randomized Study', *Chinese Medical Journal*, 120(22), pp.2036-038. doi: 10.1097/00029330-200711020-00018
- Thomas, V.J. (1997a) 'The Assessment of Pain' in Thomas, V.J. (ed.), *Pain: Its Nature and Management*, London: Baillière Tindall. pp.70-92
- Thomas, V.J. (1997b) 'Psychological and social factors influencing pain: individual differences in the experience of pain' in Thomas, V.J. (ed.), *Pain: Its Nature and Management*, London: Baillière Tindall. pp.20-34
- Thompson, C. and Dowding, D. (2002) 'Decision making and judgement in nursing- an introduction' In Thompson, C. and Dowding D. (eds.) *Clinical Decision Making and Judgement in Nursing*. Edinburgh: Churchill Livingstone. pp.1-20.
- Thorngate, W. (1976) "'In General" vs. "It Depends": Some Comments of the Gergen-Schlenker Debate', *Personality & Social Psychology Bulletin*, 2(4), pp.404–410. doi: 10.1177/014616727600200413

- Torensma, B., Oudejans, L., Velzen, M., van Swank, D., Niesters, M., and Dahan, A. (2017) 'Pain sensitivity and pain scoring in patients with morbid obesity', *Surgery for Obesity and Related Diseases*, 13(5) pp. 788-795. doi: 10.1016/j.soard.2017.01.015
- Tousignant-Laflamme, Y, Bourgault, P., G elinas, C., and Marchand, S. (2010) 'Assessing Pain Behaviors in Healthy Subjects Using the Critical-Care Pain Observation Tool (CPOT): A Pilot Study.' *The Journal of Pain* 11(10) pp.983-87. doi:10.1016/j.jpain.2010.01.266
- Trachsel, L.A. and Cascella, M. (2020) *Pain Theory*. StatPearls: Web. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK545194/> (Accessed 12 March 2021).
- Trampusch, C. and Palier, B. (2016) 'Between X and Y: how process tracing contributes to opening the black box of causality', *New Political Economy*, 21(5), pp.437–454. doi:10.1080/13563467.2015.1134465
- Traynor, M., Boland, M., and Buus, N. (2010) 'Professional Autonomy in 21st Century Healthcare: Nurses' Accounts of Clinical Decision-making', *Social Science & Medicine*, 71(8), pp.1506-512. doi:10.1016/j.socscimed.2010.07.029
- Uprichard, E. (2013) 'Introducing Cluster Analysis: What Can It Teach Us about the Case?', in Byrne, D. S., and Ragin, C.C. (eds.) *The SAGE Handbook of Case-Based Methods*. London: SAGE, pp.132-147.
- Ward, J.H. (1963) 'Hierarchical Grouping to Optimize an Objective Function', *Journal of the American Statistical Association*, 58(301), pp.236–244.
- Waring, M., McManus, D., Amante, D., Darling, C. and Kiefe, C. (2018) 'Online health information seeking by adults hospitalized for acute coronary syndromes: Who looks for information, and who discusses it with healthcare providers?', *Patient Education and Counseling*, 101(11), pp.1973-1981. doi:10.1016/j.pec.2018.06.016
- Wasserlauf, J., Knight, B.P., Li, Z., Andrei, A., Arora, R., Chicos, A.B., Goldberger, J.J., Kim, S.S., Lin, A.C., Verma, N., Bohn, M.M, and Passman, R.S. (2016) 'Moderate Sedation Reduces Lab Time Compared to General Anesthesia during Cryoballoon Ablation for AF Without Compromising Safety or Long-Term Efficacy', *Pacing and Clinical Electrophysiology*, 39(12), pp.1359-365. doi: 10.1111/pace.12961
- Wiedemann, K. (2001) 'Anxiety and Anxiety Disorders' in Smelser, N.J. and Baltes, P.B. (eds.) *International Encyclopedia of the Social & Behavioral Sciences*. Vol.1. Oxford: Elsevier. pp.560-567.
- Wise, R.G., Lujan, B.J., Schweinhardt, P., Peskett, G.D., Rogers, R., and Tracey, I. (2007) 'The Anxiolytic Effects of Midazolam during Anticipation to Pain Revealed Using fMRI'. *Magnetic Resonance Imaging*, 25(6), pp.801-10. doi:10.1016/j.mri.2007.03.016
- Woodside, A.G. (2010) *Case Study Research: Theory, Methods and Practice*, Bingley: Emerald.

- World Health Organization. (2021) *Body mass index – BMI*. Available at: <https://www.euro.who.int/en/health-topics/disease-prevention/nutrition/a-healthy-lifestyle/body-mass-index-bmi> (Accessed 17 March 2021)
- Wutzler, A., Rolf, S., Huemer, M., Parwani, A. S., Boldt, L-H., Herberger, E., Hohenbichler, K., Dietz, R., and Haverkamp, W. (2012) 'Safety Aspects of Deep Sedation during Catheter Ablation of Atrial Fibrillation', *Pacing and Clinical Electrophysiology*, 35(1), pp.38-43. doi:10.1111/j.1540-8159.2011.03260.x:
- Wutzler, A., Loehr, L., Huemer, M., Parwani, A.S., Steinhagen-Thiessen, E., Boldt, L.-H., and Haverkamp, W. (2013) 'Deep Sedation during Catheter Ablation for Atrial Fibrillation in Elderly Patients'. *Journal of Interventional Cardiac Electrophysiology*, 38(2), pp.115-21. doi: 10.1007/s10840-013-9817-3
- Yamamoto, M., Meguro, K., MD, Mouillet, G., Bergoend, E., Monin, J., Lim P., Dubois-Rande, J., and Teiger, E. (2013) 'Effect of Local Anesthetic Management With Conscious Sedation in Patients Undergoing Transcatheter Aortic Valve Implantation', *The American Journal of Cardiology*, 111(1), pp.94-99
- Yim, O. and Ramdeen, K.T. (2015) 'Hierarchical Cluster Analysis: Comparison of Three Linkage Measures and Application to Psychological Data', *Tutorials in Quantitative Methods for Psychology*, 11(1), pp.8–21.
- Yin, R.K. (2014) *Case study research: design and methods* 5th edn. Thousand Oakes: SAGE.
- Yong, H-H. (2006) 'Can attitudes of stoicism and cautiousness explain observed age-related variation in levels of self-rated pain, mood disturbance and functional interference in chronic pain patients?', *European Journal of Pain*, 10(5), pp.399–407. doi: 10.1016/j.ejpain.2005.05.004

