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Medications and oral restrictions

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Doctor of Philosophy

Abstract

Many patients presenting for a procedure/surgery take long-term oral medications. Many of these medications are omitted inappropriately during the fasting period, which can put patients at risk of undesirable complications. The PhD took a qualitative-quantitative approach to explore potential causes, solutions, implementation considerations and impact of strategies to improve medication management in patients with oral intake restrictions, such as when fasting before a procedure/surgery.

Four studies were conducted: The first identified barriers to managing medications appropriately, while the second investigated barriers and enablers to implementation of improvement initiatives. The third was a focus group exploring the perceptions and experiences of surgical nurses operating the initiatives. This was followed by a retrospective interrupted time series analyses of medications omitted inappropriately and overall omissions in patients fasting before a procedure/surgery, pre- and post-implementation of improvement strategies in Medical and Surgical areas of one hospital.

The barriers analysis indicated confusion about how to manage medications when patients have oral intake restrictions. This was exacerbated by lack of a standardised approach, leadership and using fasting and nil by mouth interchangeably. These findings supported development of improvement strategies that provide clarity and guidance for staff; specifically, clear definitions for fasting and nil by mouth in relation to medication administration and decision aids to highlight these instructions at the frontline. This was the basis of the Medications and Oral Restrictions Policy (the Policy).

Resource and infrastructure, staff interpretation of their roles and the perceived applicability and credibility of the Policy were common themes for both barriers and enablers to policy implementation. Challenging barriers included variability in the communication structure, differing interpretation of responsibility and staff movement and turnover. Despite a considered implementation approach, the enablers and strategies employed were insufficient to manage the barriers.

The focus group findings corroborated those from the medication management barriers analysis and barriers and enablers to policy implementation. Surgical nurses concurred about the confusion and lack of guidance pre-policy introduction; however, although the Policy offered clarity, guidance and context for managing medications for some, limitations in the Policy's reach and individual staff interpretation of its messages and inherent decision-making process meant it was unhelpful for others.

The interrupted time series study suggested a moderate but statistically significant reduction in inappropriate and overall medication omissions in patients fasting before a procedure/surgery following policy implementation, especially in Medical areas. Surgical baseline omissions were lower than Medical's, which contrasted evidence from the literature and requires exploration.

In summary, a pragmatic approach to medication management was associated with a moderate reduction in inappropriate and overall dose omissions in patients fasting before a procedure/surgery. The Policy provided clarity and guidance for some: Those who understood the context found the Policy helpful to their practice. Nonetheless, insufficient resources to provide context, ensure adequate uptake and sustainability affected wider policy impact. Existing systems that do not require ongoing staff effort to sustain, that are relatively impervious to staff movement, such as the electronic prescribing platform, should be capitalised on to improve the reach and uptake of the Policy.

Declaration

I certify that:

- the thesis comprises only original work towards this PhD, except for some overlaps with the NHMRC Translating Research Into Practice Fellowship as indicated in the preface;
- due acknowledgement has been made in the text to all other material used; and
- the thesis is fewer than 100,000 words in length, exclusive of tables, maps, bibliographies and appendices.

The-Phung To, September 2020

Preface

Except for the overlaps with the TRIP fellowship program, discussed below, no works in this PhD have been submitted towards other qualifications. Refer to the timeline for PhD activities, below.

Some of the background information presented in this thesis overlaps with those reported during my National Health and Medical Research Council Translating Research Into Practice (NHMRC TRIP) Fellowship (APP1035729, 2012 – 2014). This was a two-year part-time Fellowship that provided protected time to support future leaders to implement established evidence into practice – the Fellowship did not contribute to any qualifications. The central component of the Fellowship was the pilot of the draft Medications and Oral Restrictions Policy. Chapter 2 (Literature review), section 4.3 (Investigating the problem) and Chapter 5 (Identifying strategies) of the thesis covers some of the concepts addressed in the TRIP Fellowship. This was necessary to provide context and flow to tell a cohesive story. For the thesis, the data and information were re-examined and restructured and further findings and evidence included.

Much of the Medication and Oral Restrictions Policy development occurred prior to the PhD candidature, which commenced in April 2014; however, the process for considering medication management and implementation strategies had not been systematically reviewed or formally reported (except the pilot project for the TRIP fellowship, as discussed). Chapter 5 addresses the sequence of events that occurred and documents the thought process, explanations and the evidence-base for the choices made. The final review and update and hospital-wide ratification for the Medications and Oral Restrictions Policy occurred during the PhD candidature. None of the work conducted done prior to the PhD was done in anticipation of doing a PhD.

No third-party editorial assistance was received for preparation of the thesis.

All components of the ‘Barriers to managing medications appropriately when patients have restrictions on oral intake’ study, including concept and design, were conceived and conducted by me in consultation with both my supervisors, Professors David Story and

Jo-anne Brien. The study was published in the Journal of Evaluation in Clinical Practice in 2019.

Every element of the 'Barriers and enablers to the implementation of a policy to improve medication management in patients with oral intake restrictions' study was conceived and conducted by me and overseen by my supervisors. This is unpublished/not submitted for publication.

I was the lead researcher and was involved in every aspect of the 'Surgical nurses' perceptions and experiences of a medications and oral restrictions policy change: A focus group study'. I was responsible for the conception, development, execution, analysis and write-up. Gillian Dunnachie was involved with the development of the study and conduct of the focus groups and had a role in the analysis and write-up. My two supervisors oversaw the project and had a role in the analysis and write-up of the study. This study was published in the Journal of Clinical Nursing in 2019.

I was the primary researcher for the 'Impact of a policy to improve the management of oral medications when patients are fasting before a procedure: a retrospective interrupted time series analysis' study. I contributed 80% or greater to all aspects of the study, except conducting the sample size calculation and interrupted time series regression modelling. I worked with the hospital's data department to extract the original electronic data and received assistance from Stephen Cheung (IT Pharmacist) for presenting the electronic data in suitable format for data mining. Sabine Braat advised on the statistical methods and data analysis, wrote the statistical analysis codes and performed the interrupted time series regression modelling. Andrew Lim was the second rater for inter-rater checking and played a role in the resolving differences component and appraising the write-up of the study. Both supervisors, Jo-anne Brien and David Story, were involved with the inception and development of the study, provided input for the direction of the study and were involved in the study write-up. David Story was also involved in the resolving differences component. This is unpublished/not submitted for publication.

I completed the remaining body of work under supervision from both my supervisors.

Timeline for PhD activities

Activity/project	Date	Notes
Patient adverse incidents related to medications and oral intake restrictions	2010/2011	-
Quality assurance process commenced	2011	Verbal feedback and comments from staff written down to aid decision-making and development of strategies to manage the issues.
NHMRC TRIP Fellowship	2012 – 2013	Pilot project conducted.
Concept of potentially doing a PhD raised	2013	-
PhD commenced	20 April 2014	Part-time candidature.
Update of pilot Policy, including tools/signage	2014	-
Formal/final hospital approval of Policy	August 2014	Ratified by the hospital's Drug & Therapeutics Committee.
Policy rollout	February 2015 March 2015 June 2015	Implemented in Surgical areas. Implemented in Medical areas. Hospital-wide rollout completed except ICU (which occurred in November 2015).
Literature review, chapter 2	2015 2019 2020	Search strategy developed and literature review conducted. Search strategy repeated. Updated literature Search strategy repeated. Updated literature
Methodology, chapter 3	2015 – 2019	-
Understanding the issues, chapter 4	2015 – 2020	-
Using theory, chapter 7	2015 – 2020	-
Case studies, chapter 4	May 2015 April 2019 February 2020 April 2020 July 2020	Write-up of cases. Consulted Ethics regarding requirements for inclusion in thesis following Ethics rule changes. Followed up with Ethics as no update provided by them after they requested further information in April 2019. Followed up again after no further response. Followed up again after no further response (after providing Ethics with the clarifications they requested in April). Final version as stipulated by Ethics included in thesis.
Focus group study, chapter 6	November 2015 2016 – 2017 December 2018	Focus groups conducted. Analysis and write-up. Submitted for publication.
Extended leave from PhD	*2017*	*Six months.*
'Barriers' project commenced, chapter 4 (and 6)	November 2017	Feedback from the quality assurance process that had been logged/written down, free text section of in-house surveys, emails etc., relating to medications and oral restrictions from 2010 to 2014 abstracted and uploaded into NVIVO for coding and analysis.

Activity/project	Date	Notes
Separated into two individual projects	March 2018	While coding and analysing the data, I began to realise that the 'barriers' to medications and oral restrictions project needed to be separated into two individual studies – barriers to managing medications appropriately and barriers (and enablers) to hospital implementation. Thus, data including the implementation period (2015) would be needed for the latter, barriers and enablers to implementation, study since the original Ethics application for audit of pre-existing data/feedback and comments for the 'barriers' project was approved in 2014.
Ethics advice/approval sought to audit qualitative data obtained up to and including the implementation process	March 2018	All data, including those that occurred during the implementation process (in 2015, during PhD candidature), have been generated in the same manner because it had not been anticipated that the information/data from the implementation period would be used for research.
Barriers to managing medications appropriately, chapter 4	May 2018 November 2018	Ongoing analysis and initial report. Submitted for publication.
Barriers and enablers to hospital implementation, chapter 6	2018 – 2019 July 2020	Analysis and writeup. Report updated prior to thesis submission.
Identifying strategies, chapter 5	2018 – 2020	-
Interrupted time series study, chapter 6	January 2018	Final version of matched electronic data obtained from data department. (Data request and statistical considerations initiated in 2014.)
Fine-tuning of data	2018 – 2019	E.g., checking for anomalies, mapping against hospital admissions to ensure data is correct, randomisation processes, discussions with statistician, etc.
Manual data abstraction, analysis, writeup, etc.	2019 – 2020	Includes inter-rater reliability, resolving differences and statistical analysis.
Introduction, chapter 1	2020	-
Discussion, chapter 8	2020	-

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Thematic analysis: a reflexive approach – section 3.2.2

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Six steps for conducting interrupted time series analysis – section 3.4.3

'Interrupted time series regression for the evaluation of public health interventions: a tutorial' is an open access article by Bernal et al., 2016 distributed under the terms of the Creative Commons CC BY license, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Barriers to managing medications appropriately when patients have restrictions on oral intake – section 4.4

This study was published in the Journal of Evaluation in Clinical Practice. The peer reviewed version is included in this thesis (section 4.4). John Wiley & Sons state that this article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions. A license was also obtained for use in a Dissertation/Thesis – No. 4915060713664.

Surgical nurses' perceptions and experiences of a medications and oral restrictions policy change: A focus group study – section 6.3

This study was published in the Journal of Clinical Nursing and the peer reviewed version of the article is presented in section 6.3 of this thesis. John Wiley and Sons state that this article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions. A license was also obtained for use in a Dissertation/Thesis – No. 4915060852547.

Theoretical Domains Framework, various sections, including Chapter 7

The framework (Cane et al., 2012) and practical clarifications (Lipworth et al., 2013) presented in various sections of this thesis were derived from open access articles from BioMed Central Ltd distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution and reproduction in any medium, provided the original work is properly cited.

Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups – Appendices 1, 2 & 3

Permission has been received for use in a Thesis/Dissertation for Table 1 of the article 'Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups' by Tong & Sainsbury 2007, published in the International Journal for Quality in Health Care. License No. 4914771183670.

Methodological and reporting recommendations for interrupted time series studies – Appendix 7

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Medications and Oral Restrictions Policy and associated tools

The Medications and Oral Restrictions Policy (and its associated tools) is an Austin Health hospital-wide policy. I am permitted to use/discuss this policy and its signs as part of the PhD thesis.

Acknowledgements

To my principal supervisor, Professor David Story, my sincere thanks for your guidance, support and mentorship. Your pragmatic approach to research and the PhD was a balm for the complexities I encountered along the way. It has been a long road and I am very grateful for the patience, flexibility and kindness you have shown me throughout this journey, especially during the times that I struggled between the demands of the PhD and my children's exhausting schedule and illnesses, as well as my back injury and subsequent surgery. You never judged: you empathised and tried to find ways to help me 'lighten the load'.

To my co-supervisor, Professor Jo-anne Brien, my most grateful thanks for agreeing to be my supervisor even though you are interstate. At the start of our association, though you did not know me, you agreed to referee my work because you wanted to help me, a pharmacist colleague, out. You then found yourself inveigled into becoming my supervisor! Sincere thanks also for continuing to supervise me despite your retirement. I appreciate your thoughtful reflections on my work and your ever insightful and worldly advice, especially on the toils of real-world, practice-based research.

To the Chair of my Advisory Panel, Professor Kate Leslie, thank you very much for taking on this role and for your sage advice and encouragement. Kate, I still think about and use the Eisenhower matrix you showed me on our first meeting to help me visualise my priorities and study/work-life balance. Thanks for being an inspiration!

Sincere thanks to Professor Andrew Hardidge and Ms Melodie Heland for giving me the opportunity that started this pathway. Andrew, thank you kindly for your support, pragmatism and enthusiasm. Melodie, I am very grateful for the opportunities and linkages that you have paved for me.

To my boss, Mr Kent Garrett, Director of Pharmacy at Austin Health, my immense gratitude to you for giving me the opportunity to do this PhD. Your support and belief in me since I first landed at Austin as a naïve pharmacy student has helped me achieve what I have today and has made me the pharmacist that I am. Heartfelt thanks to Mr Stephen

Cheung, ‘computer’ pharmacist extraordinaire. Thank you so much for all your help, wizardry and patience, not only during this PhD but throughout the years. You are amazing and you now have my permission to retire… Many thanks also to my friends (and colleagues), Dr Simone Taylor and Associate Professor Rohan Elliott. I am forever indebted to you both for your advice, support and friendship.

A special mention to Ms Sabine Braat, Biostatistician at the University of Melbourne. Thank you so much for your expert advice, saintly patience and for always promptly replying to my emails no matter how busy you are. Thanks too to Dr Andrew Lim, Hospital Medical Officer at Eastern Health and Ms Gillian Dunnachie, Associate Nurse Unit Manager, Recovery, Austin Health. Andrew, I am grateful for your help with the quantitative study – your determination in getting the honorary research position at Austin and then your commitment to doing what was required of you was critical to the completion of this study. Gill, thank you for working with me on the focus group study. It was a huge undertaking and learning curve for both of us but the experience was worth it in the end.

Thank you to Mr David Moran (and Mr Peter Davey) from the Business Intelligence Unit at Austin Health for working with me to extract, match and refine the medication administration electronic data. It was a complex and extremely time-consuming task and I am grateful for what you were able to produce.

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Last, but not least, thank you to my wonderful family – my husband Daniel and children, TC and TL. Daniel, I could not have done this PhD without you. Thank you for your love, friendship, patience, understanding and unwavering support. I must be the luckiest person in the world, or as the Chinese would say, I must have done some great deeds in my previous incarnation to deserve you in this one. To my two ‘bundles of joy’, thank you for your love and support too – even if this PhD stretched longer than it should so that I could be there for you, but I would not have had it any other way. I may now finally have time to do all that I promised.

Table of contents

Abstract ii
Declaration iv
Preface v
Acknowledgements xi
Table of contents xiii
List of tables xix
List of figures xx
List of appendices xxi
List of abbreviations xxii
Chapter 1. Introduction 1
1.1. Background 1
1.2. Aims 2
1.3. Significance of study 2
1.4. Thesis overview 5
Chapter 2. Literature review 7
2.1. Chapter introduction 7
2.2. Search strategy 7
2.2.1. Databases used for literature search 8
2.2.2. Search strategy 8
2.2.3. Update of literature review 9
2.3. Medication errors 11
2.3.1. Introduction 11
2.3.2. Defining medication errors 11
2.3.3. Medication error rate 12
2.3.4. Impact of medication errors 12
2.3.5. Medication administration errors 13
2.3.6. Medication omissions 13
2.3.7. The ageing population 16
2.3.8. Perception of consequence of medication errors 16
2.3.9. Patient safety should be optimised 18

2.4. Procedures and medication omissions 19
2.4.1. Introduction 19
2.4.2. Perioperative medication omission 19
2.4.3. Examples of adverse effects of medication omission 21
2.4.4. Continuing long-term medications perioperatively 24
2.5. Fasting and nil by mouth before a procedure 25
2.5.1. Introduction 25
2.5.2. Terminologies used 25
2.5.3. Pulmonary aspiration 26
2.5.4. Fasting rules 26
2.5.5. Fasting and medications 29
2.6. Chapter discussion 30
Chapter 3. Methodology 32
3.1. Chapter introduction 32
3.2. Qualitative research techniques 32
3.2.1. Qualitative research overview 32
3.2.2. Thematic analysis 43
3.2.3. Focus group research 47
3.3. Use of theory 55
3.3.1. Introduction 55
3.3.2. Human behaviour 56
3.3.3. Theories 58
3.3.4. Limitations of theories 61
3.3.5. Theoretical domains framework 62
3.4. Quantitative research techniques 65
3.4.1. Process versus outcome measures 65
3.4.2. Retrospective record review 67
3.4.3. Quasi-experimental designs 77
3.5. Reporting guidelines 86
3.5.1. Introduction 86
3.5.2. What are reporting guidelines? 87
3.5.3. Advantages of reporting guidelines 88
3.5.4. Limitations of reporting guidelines 89

3.5.5. Qualitative and quantitative guideline differences 90
3.5.6. Qualitative reporting guidelines 90
3.5.7. Quantitative reporting guidelines 91
3.6. Ethics approvals.....93
3.7. Chapter discussion.....94
Chapter 4. Understanding the issues 99
4.1. Chapter introduction.....99
4.1.1. The setting 99
4.2. Confusion associated with medications and restrictions on oral intake 100
4.2.1. Introduction..... 100
4.2.2. Patient 1 100
4.2.3. Patient 2 101
4.2.4. Patient 3 101
4.2.5. Discussion..... 101
4.2.6. Patient safety issues 102
4.3. Investigating the problem 103
4.3.1. Introduction..... 103
4.3.2. Examining existing local data..... 104
4.3.3. Investigating local practice 106
4.4. Barriers to managing medications appropriately when patients have restrictions on oral intake 108
4.4.1. Introduction..... 110
4.4.2. Methods 111
4.4.3. Results 112
4.4.4. Discussion..... 122
4.4.5. Conclusion 127
4.5. Chapter discussion.....127
4.6. Addendum 128
Chapter 5. Identifying strategies..... 131
5.1. Chapter introduction.....131
5.2. Quality improvement.....132
5.2.1. Introduction..... 132
5.2.2. Human factors engineering..... 132
5.3. Medication management strategies 135

5.3.1. Introduction 135
5.3.2. The draft consultation paper 135
5.3.3. Justifying the recommendations 137
5.3.4. Consulting the pilot ward 146
5.3.5. Updating the draft Policy 150
5.3.6. Professional design of the Policy tools 150
5.3.7. Final consultation of the Policy 150
5.3.8. Summary of quality improvement strategies employed 151
5.4. Implementation science 154
5.4.1. Introduction 154
5.4.2. What is implementation science? 155
5.4.3. Education 156
5.4.4. Clinical decision support 157
5.4.5. Reminders 158
5.4.6. Champions 158
5.4.7. Opinion leaders 159
5.4.8. Audit and feedback 159
5.4.9. Patient mediated interventions 160
5.4.10. Involvement of stakeholders 160
5.4.11. Staff engagement 160
5.4.12. Multiple professions 160
5.4.13. Reviews of implementation 161
5.4.14. Importance of context 164
5.4.15. Further considerations 165
5.4.16. A pragmatic approach 165
5.5. Hospital implementation strategies 166
5.5.1. Summary of implementation strategies employed 167
5.5.2. Strategies not employed 168
5.6. Chapter discussion 169
Chapter 6. Assessing the impact 171
6.1. Chapter introduction 171
6.2. Barriers and enablers to the implementation of a policy to improve medication management in patients with oral intake restrictions 171
6.2.1. Aim 172

6.2.2. Methods 172
6.2.3. Results 175
6.2.4. Discussion 191
6.2.5. Conclusion 199
6.3. Surgical nurses' perceptions and experiences of a medications and oral restrictions policy change: A focus group study 200
6.3.1. Introduction 202
6.3.2. Background 202
6.3.3. Aim 203
6.3.4. Methods 203
6.3.5. Results 206
6.3.6. Discussion 213
6.3.7. Conclusion 217
6.3.8. Relevance to clinical practice 217
6.3.9. Impact statement 217
6.3.10. Addendum 218
6.4. Impact of a policy to improve the management of oral medications when patients are fasting before a procedure: a retrospective interrupted time series analysis 219
6.4.1. Aim 222
6.4.2. Methods 222
6.4.3. Results 230
6.4.4. Discussion 250
6.4.5. Conclusion 266
6.4.6. Recommendations for practice 267
6.5. Chapter discussion 267
6.5.1. Implications of findings 269
Chapter 7. Using theory 272
7.1. Chapter introduction 272
7.2. Using the theoretical domains framework 272
7.2.1. Making sense of the TDF 272
7.2.2. The TDF as a checklist 275
7.2.3. Evaluating barriers and enablers 275
7.2.4. Planning strategies 287
7.2.5. Question guide 290

7.2.6. Coding data for qualitative analysis 292
7.2.7. Overlap of TDF domains 294
7.3. Chapter discussion 295
Chapter 8. Discussion 296
8.1. Chapter introduction 296
8.2. Summary and significance of key findings 296
8.2.1. Literature review 296
8.2.2. Methodology 298
8.2.3. Understanding the issues 300
8.2.4. Identifying strategies 301
8.2.5. Assessing the impact 303
8.2.6. Using theory 307
8.3. Strengths and limitations 307
8.4. Recommendations for practice 309
8.5. Future research recommendations 311
8.6. Chapter discussion and conclusion 312
Chapter 9. Appendices 315
9.1. Barriers to managing medications appropriately 315
9.2. Barriers and enablers to policy implementation 317
9.3. Focus group study 319
9.4. Interrupted time series analysis study 322
9.5. Ethics approval documents 350
Chapter 10. References 359

List of tables

Table 1. Theoretical domains framework 63
Table 2. Benefits and limitations of process and outcome measures 68
Table 3. Strengths and weaknesses of interrupted times series 80
Table 4. Six steps for conducting interrupted time series analysis 85
Table 5. Ethics approvals and exemptions 94
Table 6. Summary of methods to be used in the PhD 97
Table 7. Documented reasons for not giving oral medications 105
Table 8. Coding tree for barriers to managing medications when orally restricted 114
Table 9. Medications to consider withholding before a procedure 144
Table 10. Groups consulted about the Policy 151
Table 11. Implementation strategies for the policy 168
Table 12. Codes for barriers and enablers to policy implementation 175
Table 13. Coding tree for barriers and enablers to policy implementation 176
Table 14. Minimum change in level detectable with at least 80% power 228
Table 15. Ward description 231
Table 16. Demographic characteristics 233
Table 17. Doses requiring manual audit 234
Table 18. Data per ward 235
Table 19. Top six Australian Medicine Handbook medication class 237
Table 20. Top six medications 238
Table 21. ITS of inappropriate omissions 243
Table 22. Post-implementation linear trend – inappropriate omissions 243
Table 23. ITS of total omissions 244
Table 24. Post-implementation linear trend - total omissions 244
Table 25. Cumulative before and after comparison of doses withheld 247
Table 26. 'With food' medications 249
Table 27. No further documentation on medication administration record 249
Table 28. Making sense of the TDF 273
Table 29. TDF mapping of barriers to managing medications appropriately 276
Table 30. TDF mapping of potential barriers and enablers to policy implementation. 280
Table 31. Focus group question guide 291

Table 32. Codes for focus group study 292

List of figures

Figure 1. Google scholar output 10
Figure 2. Surgical patient medication journey 107
Figure 3. Draft policy bedside signs 139
Figure 4. Badge card with table of medications to consider withholding 148
Figure 5. Flowchart 149
Figure 6. Policy bedside signs 152
Figure 7. Policy flowchart 153
Figure 8. Policy badge card 154
Figure 9. Example of subtheme and theme development 176
Figure 10. Data acquisition 231
Figure 11. Timeframe of dose omissions – Medical 240
Figure 12. Timeframe of dose omissions – Surgical 240
Figure 13. Time series of inappropriate omissions 245
Figure 14. Time series of total omissions 246

List of appendices

Appendix 1. Consolidated criteria for reporting qualitative studies: Barriers to managing medications appropriately when orally restricted 315

Appendix 2. Consolidated Criteria for Reporting Qualitative Studies (COREQ): Barriers and enablers to policy implementation 317

Appendix 3. Consolidated criteria for reporting qualitative studies: Focus group study 319

Appendix 4. Coding tree for focus group study 321

Appendix 5. Rollout procedure 322

Appendix 6. Coding manual 324

Appendix 7. Methodological and reporting recommendations for interrupted time series studies 345

Appendix 8. Demographics per month – Medical 348

Appendix 9. Demographics per month – Surgical 349

Appendix 10. Barriers to managing medications Ethics approval 350

Appendix 11. Focus group Ethics approval 351

Appendix 12. Focus group email to Nurse Unit Managers 353

Appendix 13. Focus group patient invitation sheet 354

Appendix 14. Quantitative study Ethics approval 355

Appendix 15. Barriers and enablers to policy implementation Ethics exemption 356

Appendix 16. Riskman Q registration 357

Appendix 17. Case studies Ethics exemption 358

List of abbreviations

Procedure	Except where used to reflect wording as found in the literature, the word 'procedure' is used in this thesis to represent both operative and non-operative procedures
CI	Confidence interval
COREQ	Consolidated criteria for reporting qualitative studies
IQR	Interquartile range
IS	Implementation science
ITS	Interrupted time series
IV	Intravenous
MAOR	Medications and oral restrictions
MAR	Medication administration record
NBM	Nil by mouth/nothing by mouth
NG	Nasogastric
NHMRC	National Health and Medical Research Council
NPO	Nil per os (nothing by mouth)
OT	Operating theatre
OR	Operating room
PR	Per rectal
QA	Quality assurance
QI	Quality improvement
SAS	Statistical analysis software platform
TDF	Theoretical domains framework
TRIP	Translating Research Into Practice (Fellowship)
WH	Withhold/held

Chapter 1. Introduction

In late 2010 and early 2011 a string of local adverse patient incidents associated with managing medications inappropriately when patients have restrictions on their oral intake raised considerable concerns at Austin Health. These incidents played a pivotal role in the sequence of events that followed. Coincidentally, around the same time, the National Patient Safety Agency in the United Kingdom (UK) published reports on adverse patient events due to delayed or missed medications and harm to patients when they are nil by mouth.[1,2] These reports underscored the wide-scale reach of issues surrounding medication management and oral intake restrictions and provided further impetus for the work at Austin Health.

1.1. Background

Medications are the most commonly used treatments in healthcare, with patients frequently prescribed multiple agents.[3-5] Medications treat symptoms and manage chronic diseases and often need to be taken regularly to maximise benefit and/or to prevent relapse or worsening of the disease. While medications can alter people's ability to live with disease and increase life expectancy, they can cause serious harm if used or managed incorrectly.[6,7]

Evidence abounds that oral medications are managed inappropriately when patients have restrictions on their oral intake.[1,8-14] These medication management issues include medications being withheld or given inappropriately in patients needing to limit oral intake before a procedure, given orally, inappropriately, to those unsafe to swallow and being manipulated inappropriately to facilitate administration in those with swallowing difficulties.[1,2,8,12,13,15-18] Errors in these contexts are likely propelled by the complexity of the medication administration process; many components are involved and interact before patients are administered medications.[19-22] The harm that it can bring patients means that it is vital to explore the root causes for medications being managed inappropriately and invest in solutions to improve medication management in these settings.

1.2. Aims

The PhD has three aims. The primary aim is to assess the impact of implementing a pragmatic approach to medication management in patients with restrictions on oral intake, such as when fasting before a procedure. Although medications may be given or withheld inappropriately pre-procedure, this PhD focuses on the latter.

Three studies will be performed to achieve this aim:

(i) An analysis of barriers and enablers to implementation of the strategies
(ii) A focus group interview to explore the perceptions and experiences of frontline surgical nurses eight months following implementation
(iii) Interrupted time series analyses of medication omitted inappropriately, and overall omissions, in patients fasting before a procedure in two key areas of the hospital up to 14 months before and after implementation

The secondary aim is to evaluate the causes of medications being managed inappropriately when patients have restrictions on their oral intake. A barriers analysis will be conducted.

The tertiary aim is to review the most appropriate strategies to:

(i) Improve the management of medications in the context of oral restrictions
(ii) Implement the identified strategies

The PhD will undertake both a qualitative and quantitative approach to accomplish these aims and employ the use of 'theory' to ensure as many aspects of influence as possible have been considered and to maximise comprehensiveness.

1.3. Significance of study

Medication errors are common[3,4,23], with global cost implications estimated at US$42 billion annually.[7] Errors are possible throughout the medication process but occur most frequently at the administration stage, as they are least likely to be intercepted.[24,25] Of

medication administration errors, Australian and international studies indicate that omissions are common[26-28], comprising up to half of all administration errors.[24,29,30] Within the medication administration errors spectrum, there is evidence that restrictions on oral intake presents a particular problem.[1,8-14] Omission errors and oral intake restrictions are often intertwined, as evidenced by case reports to the National Reporting and Learning System in the UK. A total of 27 deaths, 68 severe harms and 21,383 other patient-safety incidents associated with omitted or delayed medications were received by the organisation between 2006 and 2009.[31] Many incidents related to oral restrictions, including a case where a patient with Parkinson's disease 'failed to wake' after an operation because anti-Parkinson's medications had not been administered perioperatively.[1]

Medication omissions have the potential to cause patient harm[8,29,32-35] and reducing omissions has been associated with reducing hospital mortality by 16.2%.[32,36] In the perioperative setting, a prospective study of 1025 surgical patients found increased postoperative complication associated with omission of their long-term regular medications (relative risk 2.7, 95% CI [1.76, 4.04]) – as time without their medications increased, so did the complication rate (p=0.007).[8] When 34 patients that experienced complications were reviewed, the authors reported that the symptoms/complication resolved once the patients' regular medications were re-introduced. Abrupt withdrawal of certain medications, such as the omission of β-blockers perioperatively, have resulted in major cardiac events, including myocardial infarction and sudden death.[37,38] In a single-centre propensity-matched cohort study of 1096 elective, non-cardiac surgery patients on β-blockers, major cardiac events were 4.7% (n=962) for those whose long-term β-blocker therapy was continued compared with 9.7% (n=134) in those whose therapy was withdrawn.[38]

Oral intake restrictions also affect medication management in non-perioperative settings and adverse outcomes have similarly been reported.[12-14,39-43] Patients have been given oral medications despite being categorised as nil by mouth due to risk of choking[39,40] and consequences ranging from rapid decline to unresponsiveness and death have been reported following administration of medications that had been manipulated (e.g., crushed) inappropriately.[14,41,42] A variety of reasons exists for why some medications

should not be manipulated inappropriately; as an example, the entire dose, intended for delivery over a 24-hour period, may be released immediately upon crushing of a sustained-release formulation thus resulting in toxicity/adverse effects for the patient.

Based on these facts, the planned body of work in this doctorate is highly relevant. As medication errors are prevalent worldwide, the scale of medications consumed makes the errors and comparative proportion of medications omissions – up to 50% of all medication errors – extremely important and burdensome to the health system. Furthermore, it is likely that medication errors will continue to rise as the population is ageing: As the population ages, comorbidities will likely increase and along with it the consumption of medications to manage these comorbidities. Older people are more susceptible to morbidity and mortality from medication-related harms due to changes and pathophysiology related to age[44]; specifically, pharmacokinetic and pharmacokinetic effects of medications are altered.[45] Additionally, increased comorbidities associated with an ageing population is likely to translate into a corresponding demand for surgical services.[46,47] These factors make this group especially sensitive to medication-related issues in the perioperative period, as well as in other oral intake restriction settings such as stroke/swallowing difficulties, and highlights the urgency to improve medication management around the time of oral intake restrictions.

This PhD builds on a pilot conducted as part of my NHMRC TRIP Fellowship. The pilot results suggest that key medication management strategies were associated with a reduction in the number of medication doses withheld inappropriately in the period immediately before surgery; however, the data were limited by several factors, including focus on only one ward and Orthopaedic admissions, and two different data formats were compared because electronic prescribing was introduced during the pilot. The PhD work will examine impact across two areas of the hospital most effected by medication administration and oral intake restrictions before a procedure. Based on the prevalence and potential adverse impact of inappropriate medication omissions around the pre-operative period highlighted in the literature[8,33-35,48,49], the findings will not only be meaningful locally but of relevance to other institutions nationally and internationally.

1.4. Thesis overview

The thesis is a journey into the sequence of events instigated by a series of adverse patient incidents. The first part of the thesis, comprising the Introduction (Chapter 1) and Literature review (Chapter 2), outlines the scope of the PhD and positions the need for the body of work relative to the existent literature. Factors such as harms associated with medication errors, perioperative medication omissions and pre-procedure oral intake restrictions concerns will be highlighted.

The literature review continues with the Methodology chapter (Chapter 3). The philosophy underpinning a variety of approaches and techniques used in this PhD will be reviewed, including the practicalities of their application in real-world, practice-based research. Paradigms ranging from thematic analysis and focus group interviews to use of theory and the interrupted time series design will be addressed.

The next section of the thesis begins with the investigation of the local circumstances that provided the scope for the PhD. Chapter 4 strives to 'understand the issues'; it will open with a discussion of the three cases instrumental to the quality improvement work that resulted to improve medication management in the context of oral restrictions. This is followed by an account of the investigations of local practice undertaken to identify the causes and sources of the medication management problems. A qualitative analysis will then be conducted to explore the barriers faced by staff when managing oral medications in patients with restrictions on their oral intake. Findings from these three components will be aligned and used to inform and support the next steps.

Chapter 5 focuses on 'Identifying strategies' and will commence with a discussion on quality improvement and implementation science and draw on the issues uncovered in Chapter 4 to determine the most appropriate approach. Evidence-based arguments, as well as consideration of the practicalities of the local context, will be presented in defence of the medication management strategies and implementation strategies chosen.

In Chapter 6, the impact of the improvement strategies will be investigated from three perspectives and timeframes. A qualitative analysis of barriers and enablers to hospital implementation will explore the factors influencing the uptake of the improvement

strategies, including those encountered during the implementation process. This will provide guidance on whether the implementation measures were effective and which components may require redress. The research will employ similar methods to the barriers to managing medications appropriately study, including inductive-deductive coding and thematic analysis.

An exploration of the perceptions and experiences of surgical nurses charged with operating the medication management initiative at the frontline will be conducted eight months after implementing the strategies. The focus group format will be used since it offers the most suitable premise when considering limited clinical time and the ability to maximise group interaction to generate meaningful opinions, suggestions and feedback.

The retrospective record review and the interrupted time series design will be used to determine the impact of the improvement strategies quantitatively. This investigation will compare medications omitted inappropriately, as well as overall omissions, before and after the implementation of improvement strategies in patients fasting before a procedure. Two key areas of the hospital will be compared and medication administration data up to 14 months pre- and post-implementation will be examined.

Findings from these investigations will provide direction on the overall influence of the medication management initiatives and implementation process and guide future improvement attempts.

Chapter 7 will bring together the components of the thesis in which the use of theory – specifically, the Theoretical Domains Framework – was applied. Brief examples of each of these components will be discussed.

Finally, the overall discussion for the thesis will be presented in Chapter 8. This chapter will highlight the major findings and their significance and discuss implications for practice relative to these findings. Strengths and weaknesses of the research program will be considered and recommendations for future research will be outlined.

Chapter 2. Literature review

2.1. Chapter introduction

This chapter focuses on the background medication-related issues that fuelled the need for research and strategies to improve the management of medications in the setting of restrictions on patients' oral intake.

The first part of this chapter outlines the search strategies used for the background literature search. A précis of the literature is then presented on the significance of medication errors, especially those related to medication omissions in patients with restrictions on their oral intake before a procedure.

A small amount of the literature carried over from the TRIP project, however the vast majority (over 90%) of the literature review was new to the PhD. Further, the small amount of TRIP literature was integrated into the broader PhD review. The approach to the search strategy as outlined below was conceived specifically for and during the PhD.

2.2. Search strategy

As the following literature review will show, terminology addressing the present research field is inconsistent and disparate. Consequently, it was often difficult to use definitive 'Mesh' terms or rely on common key words and frequently searches needed to be drilled down to the level of text words. In many instances, the most pertinent articles were identified through handsearching the references of the few helpful and/or suitable papers formally identified through these official search engines.

The strategies detailed below are a representation of the scope of searches conducted at the outset of, and updated throughout, the PhD.

2.2.1. Databases used for literature search

- Ovid Medline
- Ovid Embase
- PubMed
- BMJ Best Practice
- Cochrane library
- NICE Evidence Search
- National Guideline Clearinghouse
- University of Melbourne EBSCO database

2.2.2. Search strategy

2.2.2.1. Example 1 (Ovid)

medication administration/ or medication error/ or medication safety/

(medication-related problem? or adverse medication event? or adverse medication outcome?).mp.

(medication or drug).mp. and (surgery/ or procedure/ or "swallowing difficulties"/ or "swallowing".mp.) [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

(appropriate administration or inappropriate administration).mp.

(medication? adj3 (ability or capacity or knowledge)).mp.

exp fasting/ or nil by mouth/ or nil oral*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

surgery/ or procedure/ or "swallowing".mp.

((medication or drug) adj3 admin*).mp.

or/1-7

8 and 9

limit 10 to (English language and humans)

2.2.2.2. Example 2 (Ovid)

(preoperative fasting or nil by mouth or nil oral* or npo).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

exp Patient Medication Knowledge/ or exp Medication Systems/ or exp Preanesthetic Medication/ or medication.mp. or exp Medication Reconciliation/ or exp Self Medication/ or exp Medication Systems, Hospital/ or exp Medication Errors/ or exp Medication Adherence/ or exp Medication Therapy Management/

1 and 2

from 3 keep 5-6,9,11-13,15,17-22,24-30

2.2.2.3. Example 3 (PubMed)

Search ((((((((((omit*) OR omission) OR error) OR interrupt*) OR continue)) OR withho*) OR withdra*)) AND ((drug) OR medic*)) AND (((surg*) OR periop*) OR preop*))) AND (((fast*) OR nil*) OR npo)

Monthly updates for this search are received via email.

2.2.3. Update of literature review

Example 1 – Redone 24/10/19 and 27/07/20

Medline/Ovid – 2232 entries (2019), 2320 entries (2020)

Embase 13 (2019), none relevant (2020)

Joanna Briggs and Nursing database – NA (2019), 17 (2020) mainly related to dose modifications and swallowing difficulties

Example 2 – Redone 24/10/19 and 27/07/20

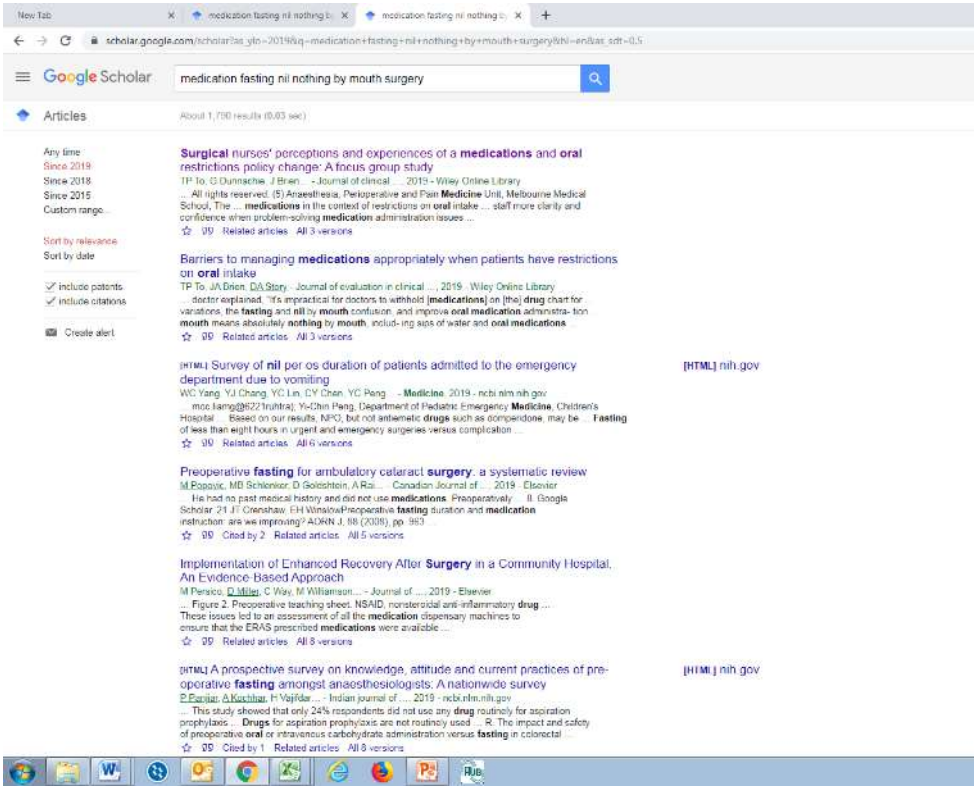
Medline/Ovid 53 studies (2019) – Seven vaguely related, including ours, 55 (2020) – similar to previous update

Embase 7 (2019) – not useful, 1 (2020) – conference proceeding

PubMed – 18 identified (2019), 2 had minor relevance. One was relevant. 112 records (2020), nothing useful.

Google scholar – 'fasting nil nothing by mouth medication'. Search repeated (07/11/19 and 27/07/20) identified previous studies found, plus a few others including our publications – see html example, Figure 1.

Figure 1. Google scholar output



2.3. Medication errors

2.3.1. Introduction

Medications are the most common healthcare treatment and it is likely that everyone will take medications to prevent or treat illness.[7] Medications play a central role in healthcare and contribute to significant improvements in health outcomes.[4] While medications can alter people's ability to live with disease and increase life expectancy, they sometimes cause patient harm if not used appropriately or due to an error, accident or communication problem.[6,7]

Medications are the most commonly used treatments in healthcare, with patients often prescribed multiple agents.[3-5] Consequently, they are associated with a higher incidence of errors and adverse events than other healthcare interventions.[3,4] This issue is a global concern and, consequently, the World Health Organization made medication safety the theme for its third Global Patient Safety Challenge in 2017.[7]

2.3.2. Defining medication errors

In healthcare, an error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.[19] For a medication error, there are various definitions of what this constitutes. One definition is 'a discrepancy between the doses ordered and the dose received'; for example, a dose administered differently than as ordered on the patient's medical record.[50] Another definition, from the 1998 United States National Coordination Council for Medication Error Reporting and Prevention is 'any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer'.[51] A further definition is 'adverse drug events', which encompasses adverse drug reactions, as well as medication errors, and are harm resulting from complications related to medication use.[3] Although it has been stated that all medication errors are typically considered avoidable[3,7], harm associated with adverse reactions to medications may not be avoidable whereas all medication errors tend to be considered preventable.

To unite all the definitions highlighted: a medication error is a discrepancy between the doses as intended or ordered, and any preventable event, including the failure of a planned action to be completed as intended or the use of a wrong plan to achieve this, which may cause or lead to inappropriate medication use and/or patient harm.

2.3.3. Medication error rate

A review of medication incidents reported to the National Reporting and Learning System in England and Wales over six years (2005-2010) found that medication incidents accounted for 9.68% (526,186) of all incidents reported and 10% (394,951/3,921,212) of the total number of incidents reported in acute/general hospitals.[52] Among hospital inpatients, errors involving medications are frequent.[53] An Australian Medication Standard stated that medication incidents are the second most frequently reported clinical incidents in public hospitals, accounting for 25% of reported incidents.[3] Individual studies have identified inpatient medication error rates of 4.8% to 5.3%.[54]

2.3.4. Impact of medication errors

Although the majority of medication errors do not result in patient harm, they can adversely affect patients, be catastrophic and increase healthcare costs.[3,24,55,56] Given the large number of medication administration that occurs, the number of people who suffer harm is likely to be considerable.[57]

Data from the United States (US) in 2015 indicate that medication error-related costs per hospital range from $600,000 to $5.6 million annually.[56] An investigation of all adverse and preventable drug events in 1997 postulated that the annual costs attributable to these events for a 700-bed teaching hospital were US$5.6 and $2.8 million, respectively[58], which is equivalent to approximately US$9 and $4.5 million today. Globally, the cost associated with medication errors, reported in 2017, was estimated at US$42 billion annually (or almost 1% of total global health expenditure).[7]

2.3.5. Medication administration errors

A medication administration error occurs when there is 'any deviation from the prescriber's medication order as written on the patient's chart, manufacturers' preparation/administration instructions, or relevant institutional policies'.[20,26] Failure to administer medications according to the prescription schedule can cause or has potential to cause patient harm and is a medication error.[36]

For prescribed medications, the medication management pathway includes the decision to treat/prescribe, the medication order, review of medication order, medication supply, administration and monitoring.[59] Although there are risks at different stages of the medication process, errors occur most frequently during administration.[24] These errors are least likely to be intercepted before they reach the patient.[25] At least half of medication incidents are medication administration errors.[24] Errors at the administration stage form the majority of patient harm and deaths.[25]

In a review of all medication incidents reported to the National Reporting and Learning System in England and Wales (2005 to 2010), 50% (263,228/526,379) of medication incidents reported occurred at the administration stage of the medication process – more than any other stage.[52] Worldwide, medication administration errors have been reported to occur in 8.0% to 19.6% of doses in hospitals.[60] A review of published literature on medication safety in the acute care setting in Australia found that the best evidence available from 2002 to 2013 indicates an error rate of appropriately one error per 10 medication administration in hospital[4], which aligns with the worldwide figure quoted.

2.3.6. Medication omissions

When a medication is prescribed there is usually the expectation that the patient will have the medication administered in accordance with the prescription instruction.[36] When a medication is omitted, this falls under the broad category of medication errors.[27] The failure to administer medications to patients when scheduled has not received as much attention compared with other medication administration errors despite evidence that up to 50% of incidents occur at the medication administration stage.[36] As with other forms

of medication errors, there are multiple definitions for medication omission errors, including:

- An event in which an appropriate medication is not provided to a patient, either because the medication has not been prescribed or has not been administered[29]
- A dose not administered before the next scheduled dose, not including delayed administrations[61]

Definitions also depended on whether the omission was preventable or 'therapeutic', for example:

- A preventable omitted dose is a dose omitted either because the medication was not available on the ward, a standard reason for not administering code was not used or it was otherwise unclear whether dose administration had occurred[61]
- A non-therapeutic medication omission is a medication dose not administered before the next due dose[27]
- A therapeutic medication omission is a medication not administered based on clinical decisions documented in the medical notes[27]

Some definitions considered medication doses that were given late ('delayed' administration) as an omission and often reported this together with medication doses that were not given (before the next scheduled dose).[32,36]

2.3.6.1. Rate of medication omission

Australian and international studies indicate that, among medication administration errors, medication omissions are common.[26-28] Studies examining medication omissions have found dose omissions rates ranging from 1% to 58%[62] and 8.1 to 50 in 100 doses.[30] Omission rates from around one third to half of all reported medication administration errors have also been quoted.[24] Medication incidents reported to the National Health Service indicated that missed or delayed medication incidents constituted approximately 15% of all incidents and were one of the most frequent causes of medication incidents reported to the National Patient Safety Agency in the UK.[28,36,52]

Omission of medications has been associated with adverse events in hospitalised patients – over a 10-year period omissions were the most commonly reported medication administration error causing mortality in acute care trusts.[24,36] They occurred more frequently on wards than any other location and especially in patients aged over 75 years.[24]

2.3.6.2. Impact of omissions

Clinically inappropriate omissions are a key concern.[36] It has been reported that approximately 80% of omitted medications placed patients at some risk of harm[27,61], and that up to 57% of missed medications could be detrimental or even life-threatening.[29] The impact of omissions varies from insignificant to severe harm, depending on the medication and the patient's medical conditions.[29] Studies have demonstrated the deleterious effects of missed medication doses on patient outcomes[32], including a study that found reducing missed doses was associated with lowered hospital mortality by 16.2%, irrespective of indication.[32,36] In the UK, reports of 27 deaths, 68 severe harms and 21,383 other patient-safety incidents relating to omitted or delayed medications were received by the National Reporting and Learning System between 2006 and 2009.[31] Some authors have called for more attention to be placed on the gravity of medication omissions, since the consequence can be serious.[24,36]

Some medications may cause clinical problems if withdrawn abruptly.[9,35,37] Due to the complexity of the body's homeostatic mechanisms, sudden withdrawal of certain medications may affect the normal homeostatic control and therefore cause adverse effects[37], including unmasking of the underlying condition in which the medication was used to manage.[63] Where abrupt withdrawal is considered, such as before surgery, the risks and benefits should be carefully deliberated as continuation of therapy may be safer than sudden discontinuation.[37] This topic is discussed further in section 2.4.3.

2.3.6.3. Oral restrictions as a reason for omissions

Many dose omissions relate to the oral route being unavailable or compromised; for example, when the patient is fasting before a procedure or is nil by mouth due to stroke/dysphagia.

A review of 1882 omitted or delayed medication incidents where the oral route was not available reported to the National Reporting and Learning System in the UK (between 2005 and 2013) identified six deaths and 581 instances of harms.[31] Most of the incidents related to patients who were categorised as nil by mouth (114, 57%). Similarly, an investigation of 271 patient medication charts/records in the UK indicated that 32% of medication omissions were associated with patients being nil by mouth.[33] The National Reporting and Learning System review specified that the omission of critical medications preoperatively frequently resulted in the patients' condition worsening; for example, developing hypertension during surgery.[31] In an Australian study of 288 randomly selected patients drawn from 5,654 patients admitted to four target wards, 5.9% (13) of those fasting before a procedure had medications omitted without a documented medical instruction.[27]

Medication omission in patients needing to fast before a procedure is discussed further in section 2.4.

2.3.7. The ageing population

The population is ageing, which will impact the uptake of healthcare resources[46], including medications and surgical interventions.[44-47] Older people are more susceptible to morbidity and mortality from medication-related harms due to changes and pathologies related to age[44]; specifically, through the altered pharmacokinetic and pharmacodynamic effects of the medications.[45] Additionally, increased comorbidities associated with an ageing population is likely to translate into a corresponding demand for surgical services.[46,47] Increased medication use, increased susceptibility to adverse effects of medications and the increase in surgical services will likely increase the risk of medication-related errors and adverse effects at this juncture.

2.3.8. Perception of consequence of medication errors

Although omissions or delay in medication administration can cause serious consequences, the problem continues to occur frequently in hospitals.[28] There are likely numerous reasons for this, although the perceived lack of harm from omission (or delay

in administration) may influence some factors; for instance, it has been reported that physicians and patients underestimate the number of deaths due to preventable errors of any type, including deaths related to medications[54] and the 'possibility of discontinuation syndromes has usually been neglected until adverse clinical events force them to be noticed'.[63]

Some authors referring to medication errors in the literature appear especially cautious to specify the low rate for harm; for example, 'although some medication errors cause harm to the patient, most do not'.[54] Viewing the risk from the perspective that most medication errors do not cause harm has the potential to reduce the vigilance towards harm from medication errors. To borrow an analogy posited by Yourstone et al., in 2002[64], if the medication error harm rate was projected to harms or people dying from jumbo jet accidents, this rate would likely be considered intolerable. Moreover, considering that medication use is the most common healthcare intervention and the usage is vast, even a less than 1% adverse event rate for medication errors[54] is significant.

In an investigation of medication errors, a panel of three physicians rated only 7% of errors as having potential for harm.[50] The authors commented that many medications have the potential for harm in some patients, but were deemed safe in their study because the patients involved were not vulnerable. An example highlighted was the administration of enteric coated aspirin 325mg to a patient without an order. Although rated as insignificant, if the patient had been on warfarin therapy, it could have been a clinically significant error.[50]

The perception of low potential for harm from medication omissions by physicians (medical staff) compared with the pharmacological properties and/or desired clinical action of the medication has been encountered locally. As an example, during discussion about the importance of continuing the agent lactulose orally for liver disease patients during the fasting period before a procedure to avoid hepatic encephalopathy one of the physicians in the audience dismissed the risk. A similar reaction was displayed by other physicians during discussions about the need to continue patients' long-term 'statins' perioperatively, despite evidence supporting its continuation in those already on this agent long-term during this period to avoid the risk of postoperative cardiac events.[65] There is likely the inclination to rate the potential for harm low when no untoward effects have

been experienced locally because patients have not been susceptible, despite pharmacological basis/evidence to the contrary; however, this may not always remain the case.

Ideally, the withholding or continuation of any medication (perioperatively) should be a considered approach; the relative risk for harm should be weighed for each patient, clinical circumstance and the specific medication. In reality, this is often challenging to achieve due to a myriad of reasons, including the dynamic clinical environment, limited resources and sometimes conflicting evidence and/or uncertainty.

2.3.8.1. Nurse perception of errors

It has been reported that some nurses do not perceive certain medication administration anomalies, such as medication omission or delay in administration, as a medication error or that it will harm patients.[66,67] In a study of nurse perception of medication errors, the investigators found that although nurses were 'usually sure what constitutes an error' (92.6% yes), there was not high agreement among them when given actual medication (error) scenarios.[66] The authors stated that 'there is a gap between the nurse's perceived knowledge and his or her actual knowledge'. In a small qualitative study of six nurses on managing medication errors, it was revealed that nurses believed that late medication administration does not always constitute an error.[67]

2.3.9. Patient safety should be optimised

Systems should be designed to maximise patient safety and consider the potential adverse clinical conditions that may be faced.[50] In the example of the enteric coated aspirin error rated as insignificant, as discussed by the authors, had the patient been on warfarin and happened to be at high risk of bleeding the administration of an unprescribed dose of aspirin could have caused an undesirable outcome. The potential for an adverse consequence is a representation of the worst-case scenario, an accumulation of delayed human errors.[23] It is an illustration of Reason's 'Swiss Cheese' model[68], whereby all the 'holes' or latent errors may feasibly align to result in a disastrous outcome. Consequently, patient safety efforts need to be based on minimising the potential for medication errors, regardless of the rating for potential of harm of the errors.

2.4. Procedures and medication omissions

2.4.1. Introduction

Patients attending surgery may be on a number of medications for the treatment of acute or chronic illnesses.[9] Studies show that up to 50% of patients undergoing surgery take regular long-term medications, unrelated to their surgical procedure.[8,9,34]

Previously, patient's long-term medications with the potential to cause haemodynamic anomalies were withheld because it was believed that it would impair the patient's ability to respond to surgical stimuli or intraoperative complications.[69] In addition, concern about the possible aspiration of stomach contents has resulted in restrictions on oral intake, including oral medications, for at least six hours before anaesthesia.[8,33-35,49,69-71] Patients having elective and non-elective surgery may be fasted for prolonged periods perioperatively. Depending on local policies, available theatre time and unexpected delays, interruption of oral medication therapy can continue for many days.

As discussed in section 2.3.6.2, medication omission can potentially adversely affect the patient: Among other issues, the patient may be predisposed to withdrawal effects, which can range from loss of therapeutic effect, to rebound syndromes and even drug resistance.[72]

2.4.2. Perioperative medication omission

Evidence demonstrates that patients' regular medications are managed inappropriately during the perioperative period and this may cause patient harm and affect length of stay.[8,33-35] Medication omission before surgery has been consistently reported in around one-third of patients on long-term medications and represents a public health issue.[48]

A prospective study of a general surgical ward over three months in the UK found that, of 1746 medications charted, 256 (15%) were not given on the day of surgery or the next day unbeknown to the medical staff. When analgesics and premedications were excluded, the omission prevalence increased to 29% of medications charted.[34]

An Australian study of 241 patients found that almost half (49%) of all medications prescribed were omitted on the day of surgery.[35] There are circumstances that make it necessary and appropriate to withhold certain medications pre-procedure, such as oral hypoglycaemic agents; however, the investigators found that fasting was interpreted as withholding all oral intake, including all oral medications, and that the reason for withholding was due to lack of appreciation by the doctor and/or nurse of the potential for drug withdrawal. It was identified that about two-thirds of medications prescribed to patients presenting for surgery had potential adverse effects if these were stopped abruptly and many of the medications could have been administered via an alternative route so there was no reason a greater proportion could not be given in the perioperative period.[35]

Another UK study investigated elective surgery patients over six weeks and found that, of 53 patients on regular medications, 23 (43%) did not receive their medications and 18 (45%) did not receive their cardiovascular medications.[49] The authors reported that the nurses did not seem to understand the importance of ensuring that patients receive regular medications perioperatively and patients were fasted longer than necessary.

A New Zealand investigation of 1025 consecutive elective or emergency surgical admissions over a seven-month period concluded that taking long-term regular medications was associated with an increased relative risk of a complication postoperatively by 2.7 (95% CI [1.76, 4.04]) compared to those who were not taking medications.[8] The rate was not adjusted for comorbidity – a logistic regression analysis was conducted, which considered confounding factors and which did not identify significant interactions terms other than the ones investigated such as age, duration of the operation and being without oral medications for more than 24 hours. The investigators found that where patients' regular medications were omitted, as time without medication increased, so did the complication rate (p=0.007). They reviewed 34 individual patient cases where a complication had occurred and reported that in every case the symptoms/complication resolved once the patients' regular medications were re-instated. The authors asserted that the symptoms/complication were reported after reasons, other than medication withdrawal, could be disregarded as underlying factors. The study found that acute withdrawal of regular medications around the time of surgery affects outcome

and the authors recommended that more focus is needed on patients' regular medications during preoperative assessment and postoperative care.[8]

A study in the US found that when medication administrations were optimised in patients undergoing planned surgeries, that is, ensuring that relevant medications were continued and others temporarily omitted, there was a statistically significant reduction in post anaesthetic care unit stays (88, IQR [55, 121] vs 94, IQR [59, 129] minutes, P=0.021).[73] An Australian study of preoperative medication adherence and early postoperative recovery reported that patients who discontinued their medications without being advised to were more likely to experience a postoperative complication, particularly those taking antihypertensives (P<0.001).[48] The authors postulated that the higher complication rate increased demands on nursing involvement and monitoring, even if the overall post anaesthetic care unit time was unaffected.[48]

As discussed in section 2.3.8, the relative risk for harm should, ideally, be weighed for each patient's clinical circumstances and the specific medication before any medication is omitted or continued perioperatively. However, as also highlighted, for various reasons this is often difficult to accomplish and/or not accomplished.

2.4.3. Examples of adverse effects of medication omission

The following highlights examples of adverse consequences of medication omission, especially in the surgical context.

2.4.3.1. Antibiotics

A study of 200 patients prescribed a course of antibiotic (intravenous or oral) in an intensive care/trauma ward found a nonlinear relationship between length of stay and frequency of early or late doses.[32] The authors reported that, for patients without an infection (but prescribed a prophylactic antibiotic course), the length of stay was three to four days longer for patients whose antibiotic dose was not given within an hour of the scheduled time compared with patients who have their dose administered within one hour of the due time. This was more significant or detrimental in patients with an infection,

with a length of stay difference of four to five days. The authors also found that a common reason cited for missing doses was 'patient in surgery' (0.42%).

2.4.3.2. β-blockers

Myocardial infarction and sudden death have been reported following withdrawal of β-blockers.[37] In a single centre study of 1096 elective, non-cardiac surgery patients on β-blockers, major cardiac events (infarct, arrest, death) was 4.7% (n=962) for those whose long-term therapy was continued, compared with 9.7% (n=134) in those whose therapy was withdrawn.[38]

The European Society of Cardiology and European Society of Anaesthesiology reported that randomised trials, cohort studies and meta-analyses offer evidence for a decrease in cardiac mortality and myocardial infarction with β-blockers in at risk patients undergoing high-risk surgery.[65] Consequently, their combined guideline recommends the perioperative continuation of β-blockers in patients on this medication long-term.

2.4.3.3. Parkinson's disease

Many hospitalised patients with Parkinson's disease do not have their medications on administered time or have doses omitted altogether.[74] Patients with Parkinson's disease need their individualised antiparkinsonian medication scheduled to be adhered to precisely.[75] When medications are not given on time patients can immediately experience an increase in symptoms, including 'worsening tremors, increased rigidity, loss of balance, confusion, agitation, and difficulty communicating'.[75] A decrease or immediate withdrawal of dopaminergic medications can be life-threatening.[76] The concern is such that 'Parkinson's UK' launched a 'Get it on time' campaign to ensure that people with Parkinson's disease admitted into hospital get their medications on time.[77]

Patients with Parkinson's disease presenting for surgery are at risk of increased mortality and longer length of stays than those without this disease.[78] One reason is that antiparkinsonian medications have been withheld inappropriately because patients were NPO (nil per os/nothing by mouth) for surgery.[75] Omission of dopaminergic agents

perioperatively can be life threatening.[76,78] These medications should be administered as close as possible to the patient's individualised schedule pre- and post-operatively.[75]

2.4.3.4. 'Statins'

Statins (3-Hydroxy-3-methylglutaryl coenzyme A reductase inhibitors) induce coronary plaque stabilisation through 'pleiotropic effects and may prevent plaque rupture and subsequent myocardial infarction in the perioperative period'.[65] A prospective cohort study of consecutive elective major vascular surgery in The Netherlands between 2000 and 2006 examined the effect of acute withdrawal of statin therapy perioperatively.[79] The 228 (73%) patients who continued statin therapy had significantly better cardiac outcomes in terms of cardiovascular death and non-fatal myocardial infarct than patients (70, 23%) who interrupted therapy (5.7% vs 31.4%).[79] Many observational studies indicated that use of perioperative statin was associated with a 'beneficial effect on the 30-day rate of death or myocardial infarction, and on long-term mortality and cardiovascular event rates'.[65] The VISION study – a prospective cohort study of matched (2845 treated with a statin and 4492 controls) non-cardiac surgery patients aged $\geq$ 45 years from eight countries – found that statin use was associated with lower risk of all-cause mortality (RR, 0.58, 95% CI [0.40, 0.83], P=0.003).[80] Results such as these have guided institutions such as the European Society of Cardiology, European Society of Anaesthesiology and the American College of Cardiology to recommend that statins be continued perioperatively.[65,81]

2.4.3.5. Other medications

Many medications have the potential to result in withdrawal syndromes if stopped abruptly[37,63], including anticonvulsant agents, corticosteroids and nitrates.[37]; as an example, intracranial hypertension may develop in some patients when corticosteroids are abruptly omitted and symptoms such as tiredness, weakness, nausea, anorexia, postural hypotension and hypoglycaemia and even death may occur.[37]

A review article reported that in some medications, such as those acting on the central nervous system, symptoms associated with withdrawal syndromes may result from removal of the medication from the system or related to a relapse of the condition in

which it was used to manage.[9] The authors indicated that 'patients at particular risk for withdrawal syndromes are those taking high dosages and have been treated for long periods'. They also reported the development of withdrawal symptoms, such as flu-like symptoms, nausea and dizziness, resulting from discontinuation of serotonin specific reuptake inhibitors perioperatively. Reinstituting these agents at the patients' previous dosage after stopping may result in the development of 'serotonin syndrome', a potentially fatal reaction adverse reaction.[9]

Another factor to consider is that some patients may require time to build tolerance to side-effects of certain medications and omission for several days can result in loss of this tolerance. As an example, galantamine (acetylcholinesterase inhibitor) is an agent with significant gastrointestinal adverse effects (nausea, vomiting, diarrhoea) to which individuals appear to develop tolerance.[82] The patient could experience these side-effects again on recommencement of the medication if doses were missed, leading the Australia Medicines Handbook (AMH) to recommend restarting the medication at initial dosage to minimise the risk of severe vomiting if treatment is interrupted for several days.[82]

2.4.4. Continuing long-term medications perioperatively

With some exceptions, it has been reported that continuing patients' long-term medications improved the management of adverse haemodynamic stimuli resulting in a reduction in frequency and severity of these episodes perioperatively.[37,69] Additionally, there is no evidence that a truncated fast from fluids increases the risk of aspiration, regurgitation or related morbidity compared with the standard 'nil by mouth from midnight' fasting rule.[83]

The safety of administering clear fluids to patients about to undergo general anaesthesia and who have normal gastrointestinal tract function has been reported and should not be a deterrent to continuing regular medications perioperatively.[69] One institution has advised that, with very few exceptions (such as anti-diabetes medications), patients' long-term medications should be maintained perioperatively, even when nil by mouth.[84] Alternative routes of administration should be considered for critical drugs such as antiarrhythmics (including β-blockers), anticonvulsants, and antiparkinsonian drugs[84],

especially if the oral route is not available. The Royal College of Nursing guidelines recommend that concurrent/regular oral medications should be continued preoperatively unless there is advice to the contrary and up to 30mL water may be given orally to help patients take their medication.[85] The Australian and New Zealand College of Anaesthetists recommend that prescribed medications may be taken with a sip of water less than two hours prior to anaesthesia unless otherwise directed.[86]

2.5. Fasting and nil by mouth before a procedure

2.5.1. Introduction

It is a long-held concept that subjecting patients to nil per os (NPO, nil/nothing by mouth) would 'prevent vomiting, aspiration and death from aspiration pneumonia'.[70] This concern originates from Mendelson's 1946 observation that aspiration of vomitus into the lungs may occur while the laryngeal reflexes are minimised during general anaesthesia and that aspiration of stomach contents may be avoided by abstaining from oral intake.[87] Consequently, 'fasting before general anaesthesia is considered essential to patient safety' to prevent regurgitation of gastric contents and complications such as pulmonary aspiration.[88,89] 'Respiratory failure secondary to aspiration pneumonitis during anaesthesia became synonymous with Mendelson's syndrome, and its prevention a cornerstone of anaesthetic practice'.[90]

2.5.2. Terminologies used

A range of terminologies are used to represent the restriction of food and/or fluids prior to a procedure. These include 'preprocedural fasting'[91], 'pre-operative'[92] or 'preoperative'[88,89,91,93] fasting, 'NPO'[70,88,94,95], 'nil by mouth'[83,88], 'nothing by mouth'[70] and just 'fasting'[88,92-94,96]; some authors use a combination of terms in their publication.[70,88,92] The American Society of Anesthesiologists defines 'preoperative fasting' as a prescribed period of time before a procedure when patients are not allowed the oral intake of liquids or solids and recommends that the term 'preoperative' should be considered synonymous with 'preprocedural' as the latter term is often used to describe

procedures that are not operations.[89] (That 'procedure' is used to describe operations and non-operations but that 'pre**procedur**al' tend only be used for procedures that are not operations and that 'pre**operative**' is recommended to be used synonymously with 'preprocedural', is confusing.)

The terminologies to represent the concept of restriction from food and/or fluids for a defined period of time, as found in the literature, are reproduced in the following report.

2.5.3. Pulmonary aspiration

The American Society of Anesthesiologists defines perioperative pulmonary aspiration as the aspiration of gastric contexts occurring after induction of anaesthesia, during a procedure, or in the immediate postoperative period.[89] The consequence of pulmonary aspiration exists on a continuum from asymptomatic to fatal aspiration pneumonitis.[91] Gastric pH and volume of stomach contents are important parameters to assess the severity of pneumonitis; however, acid secretion occurs, even during fasting.[92]

The overall incidence of pulmonary aspiration of gastric contents during anaesthesia is very low, with the risk of mortality and deaths even lower.[88,92,93,95,96] Pulmonary aspiration incidence rates such as approximately 1:900 to 1:10000 in adults and in 2:10000 children[96], and 1 in 7000[92], have been reported. Pulmonary aspiration has been reported to be more frequent during emergency procedures and death occurs predominantly in severely ill adults.[96] The risk of aspiration is considered lower in procedural sedation compared to general anaesthesia.[91]

2.5.4. Fasting rules

Prevention of perioperative pulmonary aspiration is part of preoperative evaluation and preparation of the patient[89]; however, the concern about aspiration, and the notion that the longer the patient fast the safer it is for the patient, has led to unnecessary preoperative food and fluid restriction.[92]

The incidence regurgitation and aspiration are rare and hence the size of a trial needed to definitively show a difference in the effectiveness of a fasting schedule based on such an

infrequent event would be likely be unattainable.[88] Nonetheless, numerous studies have demonstrated that free fluids may be administered safely up to two hours before surgery:[92] Studies have shown no increase in volume or pH with administration of 150mL water given between 120 minutes and 180 minutes before anaesthesia.[92] A Cochrane systematic review found that there is no evidence to suggest that a shorter fast from fluids leads to an increased risk of aspiration, regurgitation or related morbidity compared with the standard 'nil by mouth from midnight' practices[83]; no aspiration or regurgitation was reported by trials comparing the preoperative administration of less than or equal to 150mL of fluids, or more than 150mLs to the standard fasting from midnight.[88] This evidence, as well as other considerations, has stimulated organisations such as the American Society of Anesthesiologists to adopt the 6-4-2 rule; that is, six hours fasting from food, four hours from breast milk and two hours from fluids.[89]

2.5.4.1. Nothing by mouth after midnight

Nil by mouth after midnight is common amongst patients undergoing procedures with anaesthesia.[70] Nil by mouth from midnight or early light breakfast then fast is an easy policy to carry out and allows for last minute alterations to the operating list without impacting theatre time and is commonly expected by both patients and staff:[88] Clinicians and patients consider fasting from midnight to guarantee patient safety, with a further perceived benefit being this process afforded more flexibility with planning the theatre list.[88] But this practice is not without sequelae, including patient discomfort, prolonged fasting times and dehydration and medication omission.

Despite evidence and guidelines to the contrary, NPO after midnight and other excessive fasting practices remain in effect.[70,88,94] A 2017 retrospective review of 924 NPO orders (for imaging study, procedure or operation) found that the median NPO length was 12.7 hours (IQR [10.1, 15.7]).[94] The researchers discovered that a procedure was not even performed in 19.8% (183) of the NPO orders. In paediatric studies, a two-hour clear fluid fasting rule showed measured fasting durations of six to 13 hours and that patients were unlikely to be anaesthetised less than one hour from admission.[92]

2.5.4.2. One-hour fluid fast

Recently, some have argued that even the 6-4-2 rule with a drink at two hours allowed is outdated and that it would be more beneficial if a more liberal approach to fasting is considered.[92,96] This is based on several considerations, including: The fact that the half-life of water in terms of stomach content volume is about 15 minutes[92] – fluids or gastric secretions will always be present and the quantity and composition of this varies between individuals and is dependent on many variables[96]; and, recent studies in the paediatric elective anaesthesia population, which showed no increase in the aspiration rate with the introduction of the 6-4-0 rule or 'ad lib' fasting policy.[92,96] These observations suggest that a one hour fasting time for water is entirely reasonable.[92] Further, the paediatric studies found that the shortened fasting time (e.g., one hour for clear fluids) improved the perioperative experience for the children and their parents and several centres in the UK allow this practice in select low risk patients.[96] Thus, the change to a one hour clear fluid fasting time seems to be a major but overdue change in anaesthetic practice.[92] As the risk and outcomes for aspiration of fluid are very low, the advantages of a more liberal approach may outweigh the stringent observance of the 6-4-2 rule.[96]

2.5.4.3. Exceptions to the fasting rule

The 6-4-2 guidelines should be used for otherwise healthy patients undergoing elective procedures and 'may not apply or need to be modified for patients with coexisting diseases or conditions that affect gastric emptying or fluid volume (such as pregnancy, obesity, diabetes, hiatal hernia, gastroesophageal reflux disease, ileus or bowel obstruction, emergency care, or enteral tube feeding)' and in those whose airway management may be problematic.[89] These considerations would also apply for the one hour fluid rule.[92] Conversely, in emergency (non-elective) surgery patients the urgency of the condition determines the timing of surgery, particularly since additional fluid restriction does not guarantee an empty stomach in this situation[93] and surgery may proceed despite inadequate fasting times.

2.5.5. Fasting and medications

The NPO stance, particularly prior to surgery, impacts medication administration. One investigation found that medications for conditions such as infection, asthma, cardiac problems and seizures that should not be withheld were not given while the patient was NPO.[70] A study investigating preprocedural fasting for coronary interventions revealed that 'patients mostly do not take their antihypertensive medication' when NPO, 'which may lead to poorly controlled hypertension during the procedure'.[95]

In practice, many medications are taken in the morning, usually around breakfast time (before, with or after breakfast), especially 'once daily' medications. Practices such as NPO after midnight and the belief, by some, that fasting includes oral medications will likely interrupt the usual morning medication routine.

2.5.5.1. Risk of medication aspiration when fasting

A concern with the administration of oral medication preoperatively is the risk of aspiration. Opioid medications have been reported to contribute to the risk of aspiration due to its effect on gastric emptying, especially in the presence of other predisposing factors.[97] Of 5000 anaesthetic incidents reported to the Australian Anaesthetic Incident Monitoring Study there were 133 (2.7%) cases of aspiration and of these 13 (9.8%) were attributable to opioid medication given as premedication or prior to induction of anaesthesia.[97] However, other medications were not noted and the presence of medications *per se* in the aspirate or as a cause of adverse outcomes was not reported.

Paracetamol given orally is poorly absorbed by the stomach and its absorption has been demonstrated to reflect the rate of gastric emptying of liquids.[98,99] Paracetamol is thus used as a measure of gastric emptying.[98] A study of paracetamol serum concentration showed that the peak paracetamol concentration occurred at 60 minutes when paracetamol was administered orally in the fasted state.[100] Another study determining the gastric emptying time of an indigestible tablet using a metal detector found that, with an empty stomach and after ingestion of 250mL of water, the mean time for gastric emptying of a plastic tablet with a metal core was 38+/-11 minutes.[101] These studies suggest that,

in most circumstances, there is adequate gastric transit time for oral medications administered with a small sip of water to a fasting patient 1-2 hours before a procedure.

A review of fasting guidelines found that, in otherwise healthy patients with no risk factors, oral medications with up to 150mL of water was allowed 1-2 hours before surgery in Canada, the US and Norway.[102] This recommendation is also found in the Scandinavian guidelines.[90,103] A survey of the impact of the Norwegian national guidelines for preoperative fasting in elective surgery three years after its introduction found no reported increase in the incidence of pulmonary aspiration or other unwanted side-effects.[104]

A further consideration in support of the safety of administering patients' long-term oral medications during the fasting period before surgery is that anaesthetists sometimes strategically give certain medications during this time. The American Society of Anesthesiologists guidelines recommend that 'gastrointestinal stimulants (metoclopramide) and medications that block gastric acid secretion (H_2 receptor antagonists, proton pump inhibitors) may be preoperatively administered to patients at increased risk of pulmonary aspiration, and antiemetics to patients at increased risk of postoperative nausea and vomiting.[89] Many of these are likely to be administered orally and as the medications need to be given with sufficient time to ensure optimal function they will be administered prior to induction, during the preoperative fasting period.

2.6. Chapter discussion

This chapter presented evidence that medication errors, specifically omissions, are a common problem worldwide. These errors and omissions have been shown to place patients at risk of harm and may even be detrimental or life-threatening and account for a substantial proportion of worldwide health expenditure. Managing medications inappropriately when patients have oral intake restrictions is a medication error. Many of these patients are particularly susceptible to medication omissions – in those fasting before a procedure, evidence indicates that abrupt omission of long-term regular medications can result in adverse consequences.

Research has shown that oral medications may be safely administered with a sip of water, up to 1-2 hours before a procedure. Guidelines advocating these instructions have found no increase in the incidence of pulmonary aspiration or other unwanted effects. Taken together with the evidence of adverse outcomes from medication omissions and/or stopping medications abruptly, there should be no need for most patients attending a procedure to have their long-term oral medications withheld unless there is clinical reason to do so. These factors have prompted leading authorities around the world, including the Australian and New Zealand College of Anaesthetists and The Royal College of Nursing, to highlight the importance of the continuation of long-term medications perioperatively and have promulgated guidelines to that effect.

The gravity of medication omissions appears to be de-emphasised by some, including physicians and nurses, who do not believe or recognise that omission of patient's long-term medication during the perioperative period can harm patients. This is intensified by the low significance rating ascribed to certain medication omissions or errors, as well as the dogma of prevention of pulmonary aspiration and the concept of nothing by mouth before anaesthesia. The latter has spurned the widespread adoption of excessive fasting practices, of which sequelae include omission of patients' long-term medications.

Patient safety efforts need to focus on minimising medication errors and omissions, especially in the context of oral restrictions, regardless of the perception or rating of potential for harm; there is the possibility that a seemingly benign medication omission may lead to serious consequences given the right circumstances. Uniformity is needed for terminology use that relates to medication administration. The terminologies surrounding the concept of oral intake restrictions prior to a procedure is bewildering. The inconsistent use may lead to flow-on consequences, such as when nil by mouth as used in the perioperative setting where 'sips of water' and oral medications may be given is applied in the stroke/dysphagia context where oral intake presents a choking risk.

Chapter 3. Methodology

3.1. Chapter introduction

The PhD aims to undertake a comprehensive approach to examine medication management in the context of oral restrictions, especially where patients are required to restrict oral intake before a procedure. The program of works will use a range of different approaches to fulfil this aim. In this chapter, the philosophy and methods behind the approaches used in this PhD are discussed, including, where applicable, why an alternative method was not used.

Section 3.2 examines the methodologies for qualitative research, including the mixed methods approach, and techniques such as thematic analysis and focus group interviews will be discussed, while section 3.3 addresses the use of 'theory' to provide a systematic approach to understand behaviour. In section 3.4, quantitative research methodologies and techniques, particularly interrupted time series analysis and retrospective record reviews, will be appraised. Section 3.5 discusses the use of reporting guidelines to improve research reporting.

3.2. Qualitative research techniques

3.2.1. Qualitative research overview

3.2.1.1. Introduction

Research has tended to use quantitative approaches to determine the utilisation, cost and effectiveness of health care through randomised and nonrandomised experimental designs.[105] Research in healthcare, especially clinical medicine, however, is becoming more complex.[106] Quantitative methods are unable to measure the complexity of the healthcare system, including 'organisational change, clinical leadership in implementing

evidence-based guidelines and patient perceptions of quality of care, which are also critical issues in outcomes research'.[105]

Historically, the traditional perception was that quantitative results were reliable and absolute while qualitative data were 'impressionistic and vulnerable to bias'.[107] In fact, qualitative research was perceived to be 'second class' among communities such as research funding agencies, clinicians and policy makers.[108] But quantitative work is not without flaws – research fraud has been subjected to scrutiny in recent times and is reminder that the measures taken to minimise bias and improve quality are more important than the research method.[107]

There are many questions that cannot be addressed by quantitative research, such as patient safety and medication education and so there is a need and expanding role for well-designed qualitative studies to fill in some of this gap.[107] Consequently, qualitative research is appreciated and used for what it can contribute in addition to quantitative research instead of being viewed as having methodological inadequacies.[109]

3.2.1.2. What is qualitative research?

Qualitative research describes, interprets and generates 'theories about social interactions and individual experiences as they occur in natural, rather than experimental, situations'.[110] It uses 'non-quantitative methods to bring about new knowledge and to offer new perspectives'[108] and aims 'to 'dig deeper' than the numerical data generated by quantitative studies'.[107] It is usually exploratory in nature and generally directed by 'a research question or conceptual framework rather than hypotheses'.[111] Qualitative research is usually concerned with understanding social or human problems or 'phenomena and processes by considering 'why?' and 'how?''.[107,110] The conventional requirements quantitative research, such as validity, reliability and empirical generalisability are normally 'not directly applied to qualitative research because of the different frameworks, sampling approaches, size of sample and goals of qualitative research'.[106]

3.2.1.3. Aim of qualitative research

The purpose of qualitative research is to add to knowledge by providing an in-depth understanding into human behaviour, emotion, attitudes and experiences of individuals, groups or populations of interest and the context in which these perspectives or experiences exist.[110,111] As the aim of qualitative research is to 'account for multiple perspectives, the goal of analysis is to comprehensively incorporate those perspectives into discernible findings and generalisability beyond the study sample is not generally the concern'.[111] Furthermore, qualitative studies are not intended to be representative and 'sampling methods do not aim to identify a statistically representative set of respondents'.[112]

3.2.1.4. Why do qualitative research?

Qualitative methods may be used to understand complex social issues to encapsulate important facets of a phenomenon from the participants' perspective and to discover beliefs, values and motivations responsible for individual behaviours.[105] An important aspect of qualitative approaches is that multiple viewpoints surrounding a phenomenon are crucial, and that it is best to inductively obtain or explore those outlooks from those with personal experience of that phenomenon.[111] These types of research can also inform about organisational context and healthcare delivery factors that may affect organisational performance and quality of care.[105] Qualitative research should be considered in the following situations[105,113,114]:

- Investigating complex phenomena that are difficult to assess quantitatively
- Generating the data necessary for a thorough understanding of a problem
- Gaining insights into potential causes
- Developing rigorous quantitative measurements or instruments
- Studying special populations
- Generating data/understanding in exploratory studies where there is limited knowledge of the issues
- Helping researchers to address and understand complexities of a phenomena, and bring in the voices of users and providers of services to help them to do so

3.2.1.5. Limitations of qualitative research

Despite the surge in the number, the improvement in quality and increasing acceptance of qualitative research, there remains some concerns. Some of the criticisms or limitations include:

- Questions about scientific rigour remain around the potential for researcher bias, a lack of reproducibility, and limited generalisability of findings.[105]
- Incomplete reporting of key elements makes it difficult to evaluate the quality of qualitative research.[110]
- 'Truly inductive analysis is not possible and is limited by the unconscious application of prior knowledge to the analysis, either from the researcher's own experience or from their reading of the literature'.[115]
- Investigators influence the qualitative process, because of 'their personal traits, biases, prejudices and beliefs, which occurs at all stages of the research, including the interview itself, the development of codes and themes and the final coalescence of themes into a story'.[115]
- Since generalisability beyond the study sample is usually not the intention, therefore reproducibility or application to other settings is limited.[111]

3.2.1.6. Types of qualitative data collection methods and data

Focus group design is one of the most common method for data collection in qualitative research in health. Together with interviews, these two techniques are especially useful for provoking 'patient and consumer priorities and needs to improve the quality of healthcare'.[108] Other data appropriate for qualitative enquiry include field notes of participant observation, journals, documents, open-ended survey responses, drawings, artefacts, photographs and email correspondence.[116]

The noting down of feedback from the quality assurance process can be considered as 'field notes', which are acknowledged data sources for qualitative studies.[116-118] While there may be limitations with the use of field notes, in a guide to field notes for qualitative research, the authors state that 'field notes can be useful in subsequent analyses including secondary analyses'.[118] In a recent study, field notes made/collected through academic

detailing were used as the primary data source to analyse barriers to opioid prescribing.[117] Using field notes together with other data sources provide depth and context to the study.[118]

3.2.1.7. Types of qualitative methodologies

There are numerous and different qualitative methodologies or stances, each with different underlying assumptions and traditions.[110,111] One particular approach is not necessarily 'better' than another – each simply emphasises different views on how to methodologically tackle a research problem or aim.[119]

Grounded theory is considered one of the first 'methodologically systematic approaches to qualitative inquiry'.[116] It is used to develop theories that are grounded in the study data.[120] The increasing popularity of grounded theory is likely due to the pragmatic focus on problems faced by participants and how these are resolved, and also because it 'provides a structured and systematic process of analysis that allows themes to be developed from the data'.[115] Results from this type of this study would, for example, build a theoretical model describing how individual-, context- and other related factors impacted the study participants.[120]

3.2.1.8. Analytic methods

In essence, in qualitative research data collection and analysis happen concurrently and in an iterative fashion[105] and the data analysis enables exploration of the themes and how these connect[121]; nonetheless, just as there are many qualitative methodologies, there are also a number of different analytic methods. A method that has associations with grounded theory is thematic analysis.[115]

Thematic analysis is similar to a modified version of grounded theory, involving coding and generating and interpreting broader patterns in data but with different terminology (e.g., categories versus themes); however, 'although thematic analysis can produce conceptually informed interpretations of data, it does not attempt to develop a theory'.[122]

Section 3.2.2 discusses thematic analysis in more detail.

3.2.1.9. Codes and coding

In qualitative analysis, a code is often a word or short phrase that characteristically 'assigns a summative, salient, essence-capturing, and/or evocative attribute for a section of language-based or visual data'.[116] Codes 'capture a single idea associated with a segment of data, and consist of succinct labels identifying what is of interest in the data in relation to the research question'.[122] It is a construct produced by the researcher that symbolises or translates data and thus ascribes interpreted 'meaning to each individual datum for pattern detection later on, categorisation, assertion or proposition development, theory building, and other analytic processes'.[116] Codes can be seen as the building-blocks that can be assembled to create themes.[122]

Approach to coding

There are many ways to approach the coding. Two such methods are inductive and descriptive coding. Inductive coding occurs when a word or short phrase from the actual language from the qualitative data (that is, the words used by the participants) is used and descriptive coding occurs when a word or short phrase is used to describe the essence of a portion of qualitative data.[116] Coding is cyclical, as it is rarely achieved in one attempt and it also depends on the angle from which the researcher approaches the coding.[116] 'Coding is always reflective of the subjectivity of the researcher, and one person's subjectivity cannot be correct and another's incorrect'.[122] Where coding is conducted solo, coding (and analysis) should be discussed with a colleague or mentor as checking or sharing coding with another researcher will help to reflect on how the data has been coded, the assumptions made with data coding and elements that may have been missed.[116,122] An experienced researcher can help novice researchers foster the skills for coding and theme development.[122]

Coding may be conducted manually or computer-assisted, and analytic memos and field notes should be made to assist with reflections and insights when analysing the data.[116]

3.2.1.10. Themes

A theme 'can be an outcome of coding, categorisation, or analytic reflection'[116] and 'captures something important about the data in relation to the research question and represents some level of patterned response or meaning within the data set'.[123] It generally illustrates the different elements of a central concept, showing the patterning of the theme in the dataset.[122,124] It is preferable that there will be a number of occurrences of the theme within the data, but more examples do not necessarily mean the theme is more important.[123] The order in which themes are presented is important.[124] 'Themes should connect logically and meaningfully and, if relevant, build on previous themes to tell a coherent story about the data'.[124]

3.2.1.11. Rigour in qualitative studies

As with quantitative research methods, ensuring rigour in qualitative research is paramount. Techniques for enhancing rigour in qualitative research include data saturation, peer debriefing, triangulation, respondent validation/member checking, and inter-rater reliability. These strategies are time and resource intensive and should therefore be contemplated judiciously at the outset of the qualitative study.[105] An outline of each of these strategies are presented because they are important considerations when conducting qualitative research; however, for a variety of reasons, discussed in other sections of this thesis, not all strategies were applied in this PhD.

Sample size/saturation

In many forms of qualitative research, there are no conclusive rules about sample size.[111] Qualitative studies usually comprise comparatively 'small numbers of participants or settings selected or recruited because of their involvement with the topic under scrutiny and focus on building an in-depth picture of the topic or problem'.[107]

Where sample sizes are considered, the most used principle for ascertaining sufficient sample size is theoretical saturation[105]; however, sample sizes may be not be known at the beginning of a study, as the point where data collection stops is often controlled by the point at which additional data collection no longer generates new understanding.[107,125]

This could be problematic from the Research Ethics application perspective where the number of participants is expected to be identified at the outset, prior to approval of the study. Nevertheless, researchers should endeavour to 'show evidence that the data were saturated by a sample with sufficient variation to permit detailing shared and divergent perspectives, meanings, or experiences about the topic of enquiry'.[111] One strategy that some researchers use to manage the Research Ethics application dilemma is to overestimate the number of participants needed for the study. Another method is to use rules of thumb, such as the case with the number of participants and number of sessions needed for focus group interview studies – further discussion about focus groups are covered in section 3.2.3.

Peer debriefing

The aim of peer debriefing is to ascertain if another researcher, mentor or colleague concur with the codes and the direction taken to reach those codes, 'not for independent analysts to arrive at the exact same coding and thematic structure as the researchers'.[109] Qualitative research analysis is 'an individual, unique process between the researcher and the data'[109] and therefore it is unlikely that two researchers will elucidate the data in exactly the same way. As alluded to in the 'Coding' section, peer debriefing is especially relevant where coding is conducted solo, in which case coding and analysis should be discussed with a colleague or mentor; checking or sharing coding with another researcher will help to reflect on how the data has been coded, the assumptions made in coding the data, and things that may have been overlooked.[116,122] While it may be useful to 'code data with another researcher to 'bounce around ideas' this does not necessarily result in 'better' coding'.[122]

Triangulation

Triangulation occurs where a single phenomenon is studied 'with multiple investigators, theories, methods, or data sources to determine the degree of convergence across components'.[105,126] Triangulation is viewed as corroboration of results using data collected through different methods.[113] Examples of triangulation include comparing the findings from two or more different data collection methods or two or more sources of data, such as interviews with participants from different backgrounds.[127]

The internal validity of a particular research study is seen to be addressed with triangulation, as this process uses more than one method of data collection to answer the research question.[128] It is generally considered to promote a more comprehensive understanding of the phenomenon under study, determine the completeness of the data, increase the confidence in the findings and enhance the rigour of a research study.[126]

There are several limitations to triangulation. It depends on the concept of 'a fixed point, or superior explanation against which other interpretations can be measured'.[128] It is also difficult to perform properly: There is an assumption that the data from two distinct research methods are comparable but 'data collected using different methods come in different forms and defy direct comparison'.[126,128] This is the case for 'different types of qualitative data, such as interview and focus group transcripts, as well as for the more obvious differences between quantitative and qualitative data'.[128] Looking for 'patterns of convergence to develop or corroborate an overall interpretation is controversial as a test of validity because the assumption is that any weaknesses in one method will be compensated by strengths in another, and that it is always possible to arbitrate between different accounts such as from interviews with clinicians and patients'.[127] Moreover, producing 'similar findings from different methods merely provides corroboration or reassurance; the absence of similar findings does not provide grounds for refutation'.[128] Triangulation should be used to ensure breadth and promote 'a more reflexive analysis of the data than as a pure test of validity'.[127]

Respondent validation

Respondent validation or 'member checking' involves presenting the investigator's account to participants to establish if the report presents a reasonable representation of their experience.[105,127] The participants' responses to the account are then included in the study report.[127] These responses to 'emerging findings can help refine explanations' of study findings.[128] Respondent validation can be useful on research projects in which 'researchers work with participants on an ongoing basis to facilitate change'.[128] It can be viewed as part of a process to minimise error and which also produces further data that can be interpreted and used.[127]

Although some researchers perceive respondent validation as the strongest available check on the credibility of a research project, other researchers have questioned whether it is always appropriate.[127,128] A major consideration is that the version generated by the researcher is aimed at a wide audience and will likely be different from that of an individual participant simply because of where they are positioned the in the research process.[127] Other concerns include collusion (romanticising respondent accounts), time imposition of respondents and potential for topic and transcript content to be 'exploitative or distressing'.[128] Additionally, as 'most health services research involves a one-off data collection exercise respondent validation may be more trouble than it is worth'.[128]

Inter-rater reliability

A thorough method to determine reliability of data coding is to tabulate the agreement between the generation of the codes to the data by two different coders.[121] Inter-rater or coder reliability indicates the degree to which 'coders agree in their independent assignment of codes to text'.[105] If used, the recommendation is that it is applied to usually between 10-20% of the data.[121] If there was inconsistency, the relevant code would need to be more carefully described and operationalised via a discussion between the two researchers.[121] For further rigour, the degree of concordance between the coders can be reported; a concordance rate above 75% is regarded as relatively transparent and reliable.[121] Percentages of agreement are occasionally reported.[105]

Depending on the qualitative research approach, assumptions or traditions, inter-rater reliability can be a useful tool to provide a more complex and nuanced understanding of the possible interpretations; however, it does not guarantee the reliability or validity of interpretations and is therefore not universally agreed upon as the best strategy.[105,129] Those against the concept of inter-rater reliability argue that qualitative research is usually carried out from the perspective that 'acknowledges the existence of multiple views of equal validity'[128] and that the participant's, as well as the researcher's, bias or worldview is present, both intentionally and unintentionally.[130] As such, coding will unavoidably 'bear the mark' of the researcher(s) and hence one person's subjectivity cannot be correct and another's incorrect.[122] Consequently, some researchers feel that multiple coders and inter-rater reliability are irrelevant; inter-rater reliability scores can be interpreted as

'showing that two researchers have been trained to code data in the same way but not that their coding is 'accurate''.[122]

3.2.1.12. Other issues

Advocates of a qualitative research tradition known as the 'antirealist position argue that qualitative research represents a distinctive paradigm and as such it cannot and should not be judged by conventional measures of validity, generalisability and reliability'.[127] Ostensible inconsistencies or exceptions do not threated the researchers' accounts; they simply allow more opportunity for honing theories.[128] Other considerations are that 'qualitative researchers cannot guarantee the direction of data collection methods such as interviews and observation and conflict can arise for the researcher if they also have a professional interest in the study topic'.[131] Therefore, breadth may be a more pragmatic objective in qualitative research than internal validity.[128]

3.2.1.13. What should be reported in qualitative research?

There should be a balance between data representation and the researcher's elucidations in the findings and participant quotes should be used judiciously; it is not necessary to support every theme with multiple quotes.[111] Research needs to be relevant and this can be the case 'when it either adds to knowledge or increases the confidence with which existing knowledge is regarded'.[127] It is incumbent on the researchers to assemble the themes to produce overall findings, situate these results 'in the context of what is already known and describe the specific and novel contributions made by their findings'.[105,111]

Further discussions about reporting qualitative research are presented in section 3.5.6

3.2.1.14. What is mixed methods research?

More and more, researchers are combining elements of quantitative and qualitative studies to address complex questions.[107] The term 'mixed methods' is used to describe research that use both qualitative and quantitative data collection and analysing techniques.[113] Often, mixed methods research occurs when both qualitative and quantitative methods are used in the same study.[114]

The qualitative and quantitative components of a mixed method study may be performed in parallel or sequentially[105,113] and importance may be placed on either component or equal weighting provided to both.[105] It may include 'a first phase of quantitative data collection that provides results to inform a second phase of the study that includes qualitative data collection, or vice versa'.[111] Development studies are an example of this format of 'sequential designs where the data from the initial data collection informs the development of the subsequent method'.[113] The timing, priority, and stage of integration of the two approaches are multifaceted and may differ depending on the research question.[111]

The combination of qualitative and quantitative methods provides a comprehensive approach to complex research problems.[113] Some of the justifications put forward for using mixed methods include:

- Increased confidence in findings and to ensure that disempowered groups in society are heard[114]
- Combining quantitative and qualitative components of a larger study can corroborating findings and generate more complete data[105]
- The use of a mixed methods approach is pragmatic, especially in an applied field studying complex issues in complex environments[114]
- The use of mixed methods research enables looking at a research problem from a multiple angles[113]
- The need for comprehensiveness, particularly for researchers in health services research[114]

3.2.2. Thematic analysis

3.2.2.1. Introduction

Thematic analysis is a method for analysis and not an approach to conducting qualitative research.[124]

3.2.2.2. What is thematic analysis?

Thematic analysis is a method for systematically identifying, organising, and reporting patterns of meaning within a data set.[122-124,132] It is a way of identifying views that are shared in a discussion on a subject and of making sense of those commonalities.[124] It involves familiarisation of the transcript, coding, identification of possible themes and review and analysis of themes.[115,122] The nuances of the high frequency themes are explored in depth, as are group-based differences.[121,124] However, this does not mean that if the theme is common that it is necessarily meaningful or important[124] and while idiosyncratic or less common responses cannot be categorised as dominant themes, they may be important regardless.[121]

While numerous patterns may be identified across any data set the purpose of thematic 'analysis is to identify those relevant to answering a particular research question'.[124] It aims to 'reflect a balanced view of the data and its meaning within a particular context of thoughts, rather than attaching too much importance to the frequency of codes abstracted from their context'.[121]

3.2.2.3. Advantages of thematic analysis

The flexibility afforded by thematic analysis means that may be used to analyse most types of qualitative data, including focus group data.[121,122] Thematic analysis can result in trustworthy and insightful findings if conducted in a rigorous, systematic and transparent manner.[121,123,132] It is not tied to any existing theoretical framework and it can therefore be used within many different theories and epistemological approaches.[121,123] Also, it 'does not require the detailed theoretical and technological knowledge of approaches and can therefore offer a more accessible form of analysis, particularly for those early in a qualitative research career'.[124] Researchers who are relatively new to qualitative methods may find thematic analysis easy to understand and comparatively quick to learn, 'as there are few prescriptions and procedures'.[132] It also provides a valuable method for researchers 'doing more applied research, or when doing research steps outside of academia, such as into the policy or practice areas'.[133]

3.2.2.4. Limitations of thematic analysis

Limitations to thematic analysis include:

- It is generally accepted that the interpretative components of thematic analysis are influenced by the researchers' perspectives[121]
- Studies utilising thematic analysis tend not to reflect on the influence of the researcher's predetermined ideas, and presence, on the data that emerge[121]
- It may miss more nuanced data[134]
- Flexibility makes it difficult to concentrate on what aspects of the data to focus on[123]
- Limited interpretative data if analysis excludes a theoretical framework[123]

3.2.2.5. Braun & Clarke's thematic analysis

There are different variations of thematic analysis, one of which is the Braun and Clarke version.[122,124,133] Differences between the Braun and Clarke interpretation and other forms of thematic analysis revolve around the approach to coding and theme creation. Some key interpretations of this method highlighted on the University of Auckland website[122] include:

- Data analysis is a situated and interactive process, reflecting both the data, the positionality of the researcher and the context of the research itself.
- Codes are the building blocks for themes and themes are patterns of shared meaning supported by a central idea. In contrast, other forms of thematic analysis may conceptualise coding as a process of searching for evidence for themes and themes are often understood as summaries of what participants said in relation to a topic or data collection question.
- Coding is an active and reflexive process but flexible and organic, and should evolve throughout the coding process. As such, the coding unavoidably 'bears the mark' of the researcher(s) and hence there is no one 'accurate' way to code data.
- Themes do not exist within the data prior to analysis. Rather, themes are analytic output that are created from codes and through the researcher's active engagement with their data. As themes are developed from active co-productions on the part of the researcher, the data/participants and the context they therefore do not 'emerge' from the data.

- The concept of coding reliability necessitates the development of themes early in the analytic process and therefore conceives themes as analytic inputs rather than as analytic outputs, which contradicts Braun and Clarke's thematic analysis method: Coding reliability hinders the claimed theoretical flexibility of using the thematic analysis method.

3.2.2.6. How is thematic analysis conducted?

In thematic analysis patterns of meaning across a dataset are identified through a rigorous process of data familiarisation, data coding, and theme development and revision, which is summarised in the following University of Auckland six phase process[122]:

1. Familiarisation with the data: This phase involves reading and re-reading the data, to become immersed and intimately familiar with its content.
2. Coding: This phase involves generating succinct labels (codes!) that identify important features of the data that might be relevant to answering the research question. It involves coding the entire dataset, and after that, collating all the codes and all relevant data extracts, together for later stages of analysis.
3. Generating initial themes: This phase involves examining the codes and collated data to identify significant broader patterns of meaning (potential themes). It then involves collating data relevant to each candidate theme, so that you can work with the data and review the viability of each candidate theme.
4. Reviewing themes: This phase involves checking the candidate themes against the dataset, to determine that they tell a convincing story of the data, and one that answers the research question. In this phase, themes are typically refined, which sometimes involves them being split, combined, or discarded. In our TA [thematic analysis] approach, themes are defined as pattern of shared meaning underpinned by a central concept or idea.
5. Defining and naming themes: This phase involves developing a detailed analysis of each theme, working out the scope and focus of each theme, determining the 'story' of each. It also involves deciding on an informative name for each theme.
6. Writing up: This final phase involves weaving together the analytic narrative and data extracts, and contextualising the analysis in relation to existing literature.

Analysis is typically a recursive and/or iterative process, hence although these phases are sequential, each build on the previous and there is movement back and forth between different phases.

3.2.2.7. An inductive/deductive approach

An inductive/deductive approach has been used within thematic analysis. This approach 'allows the data to be analysed with particular preconceived ideas derived from theories, but also allowing for the emergence of new concepts'[121]; for example, the codes or themes can be created from the data (inductive) or they can be identified from pre-existing theories or ideas (deductive). The advantage of this approach is that it is possible to analyse the data with preconceived ideas derived from theories but also remain open to new concepts that may be found in the data.[121]

3.2.3. Focus group research

3.2.3.1. Introduction

The focus group interview is one of the most common data collection method in qualitative health research[108] to 'develop or improve research instruments such as questionnaires, explore issues and generate data and evaluate and validate findings from other research methods'.[135]

3.2.3.2. What is focus group research?

Focus group interviews are 'the most appropriate method for the purposeful use of interaction to generate meaningful opinions, suggestions and feedback'.[135] Typically, a researcher convenes a group of participants to discourse on a key subject matter, with the intent 'to draw from the complex personal experiences, beliefs, perceptions and attitudes of the participants through a moderated group interaction'.[136] The aim of the focus group 'is to illuminate, describe and explain narrow categories of inquiry within the context used by the respondents'[137]; it is generally not aimed at seeking consensus between participants.[135]

A principle of the focus group process is the effect of the group dynamic to help people 'express and clarify their views in ways that are less likely to occur in a one-to-one interview'.[135] The group setting allows the 'participants to hear and respond to diverse viewpoints, which can facilitate discussion, as a comment from one participant may trigger a chain of responses from others'.[138]

The focus group 'is sometimes seen as synonymous with interviews, especially the semi-structured 'one-to-one' and 'group interviews' and relate to the tendency to uncover people's perceptions and values'.[136] However, in the focus group method, the researcher adopts the role of a facilitator or moderator, as opposed to the investigator in the one-to-one interview, and therefore takes a peripheral rather than a centre-stage role.[136]

3.2.3.3. Advantages of focus group research

Effective data collection method

Focus group interview is seen to be a cost-effective method compared to other forms of participatory research[136] as it provides the 'benefit of interviewing several people in a short time'.[138] It is an effective data collection method for a variety of topics, especially where the researcher wishes to seek opinions, values and beliefs in a collective context.[135] Focus group interviews are often 'used to obtain knowledge, perspectives and attitudes about issues, and seek explanations for behaviours in a way that would be less easily accessible with direct questions such as with one-to-one interviews'.[139] The focus group 'may provide a stimulus for elaborating, analysing and justifying views and could thus offer insight into the reasons why people think the way they do'.[138]

Interaction among members

An important characteristic of focus groups is the interactions among members.[135,139] Since 'group interaction allows participants to respond to and build on the accounts of other group members, focus groups can generate data and ideas that might not be uncovered using alternative methods of data collection'.[138] The 'ability to observe the extent and nature of participants' agreement and disagreement is a unique strength of focus groups'.[135]

The focus group discussion enables the perspective of key stakeholders to be heard to learn from their experiences of the phenomenon.[135] It may be especially suitable for determining how clinicians reason and address a particular issue: group interaction may divulge more about participants' understanding of a difficult clinical problem and the reasoning behind clinical decisions that may not be possible with other data collection techniques, including surveys or interviews.[138]

3.2.3.4. Limitations of focus group research

Factors such as heterogeneity within a focus group, the complexity of a topic, the size of a focus group or the structure of the data collection process may impact on the saturation rate and the nature of the data produced.[140] Other key considerations include bias, the sensitivity of the discussion topic, rigidity of approach, group interaction issues and data saturation considerations.

Bias

A major disadvantage of focus groups is its vulnerability to bias[130,138,139], although the 'participant's, as well as the researcher's, bias or worldview is present in all social research, both intentionally and unintentionally'.[130] In the focus group setting, group and individual opinions can be influenced by dominant participants[139] and/or the moderator, who can, intentionally or unintentionally, endorse a particular view.[138,139]

Volunteer bias occurs with the convenience sampling of available, willing and accessible participants.[136] This is a concern with the use of local contacts for the recruitment process, which may lead to the loss of control and direction of the researcher in the recruitment process.[136]

As focus groups participants are rarely selected randomly, the data obtained may be non-representative.[137]

Topics and structure

Focus groups are best employed to examine specific or narrowly-focused topics; otherwise the resultant data may be likely to be disparate, thereby making data analysis

difficult.[139] Even within specific or narrowly-focused topics there may be limitations to optimal data extraction: A more structured approach may mean a balance between more opportunities to hear about the researchers' interest and less opportunities to ensure that what is discussed truly concerns the participants.[125] In contrast, a less structured approach may mean a greater potential to learn about the participants' view in their own words but at the expense of the inability to follow any feature of these perspectives in a consistent manner.[125]

Focus groups may be less useful for investigating sensitive topics such as behaviours that may be considered socially deviant because participants are reluctant to talk about such issues as a group.[135]

Group interaction issues

While group interaction is key to the focus group format, its mechanism may be limited by several factors, including the following[135]: the personal characteristics of participants and social factors such as class, gender and race; the interaction between participants may be limited if power differentials exist because the less powerful may indicate agreement with their more powerful colleagues to avoid reprisal; the potential domination of the group by one or a small number of participants may censor an emerging group view and interaction, and; a group setting can cause uncontrollable divergent discussions resulting in irrelevant responses and data, especially when a moderator is inexperienced.

3.2.3.5. What is involved in focus group research?

Participant recruitment

A consideration in the design of focus groups is whether participant selection is random or via convenience strategies.[137] Generally, participants are engaged based on their experience or involvement relative to the topic being researched.[139] It is also suggested that each focus group be made of ;homogenous participants in terms of the nature of their experience of the issue to circumvent the generation of power issues and promote the comfort of participants;.[135] In some situations, a convenience sample may be the only practical way of obtaining potential participants.[137]

Convenience sampling occurs with the recruitment of available, willing and accessible participants.[136] Snowballing recruitment is where 'initial contacts are asked to suggest people who would make interesting contributions to discussion'.[139] Purposeful sampling 'is the identification and selection of individuals or groups that are particularly knowledgeable about or experienced with a phenomenon of interest for the most effective use of limited resource'.[141] Purposeful sampling is generally recommended because 'focus group discussion relies on the ability and capacity of participants to provide relevant information'.[136]

Participant numbers

The 'number of participants per focus group should not be too large or too small to allow meaningful discussion as well as diversity of discussion'; that is, 'the size of each group is large enough to create discussion but not too large that it prevents some participants from sharing their insights'.[135]

In the literature, the suggested number of participants per focus group varies from four to 15.[125,135,136,139,140,142] The risk with too few participants include the breadth of data may not be achieved and group dynamics may not be maximised. Smaller groups can be effective for complex topics, particularly with expert participants enabling them to focus on the topic.[135] Conversely, 'with more than 12 participants, the group becomes difficult to manage and may separate into two or more small groups, each having their own independent discussion'.[136] It seems that the compromise is to aim for at least six participants per group.[125,139,140,142]

Group numbers

The ideal approach to determining the number of focus groups needed depends on whether new information may be obtained with each new group[143], that is, the concept of data saturation where further focus groups become unnecessary.[135,139] Despite this, many authors support a particular range in the number of focus groups to generate adequate data. As with the number of participants, there is variability in the range of number of groups suggested in the literature – from as few as three focus groups to as many as six or more.[125,135,136,140] It has been justified that with four to six groups the data become

saturated and further focus groups are unnecessary.[135] Other researchers suggest only three to four focus groups may be necessary for a simple research question[125,136,140,142], especially among a fairly homogenous group of participants. Whether three more groups will be adequate for saturation depends on many factors, including the variability of the participants both within and across groups.[125] Therefore, general recommendations include[125]:

- Projects that have less structured interviews and lower levels of moderator involvement require more groups
- Only perform the number of required to provide a trustworthy answer to the research question owing to the costs involved in conducting more groups
- Avoid using a bare minimum number of groups because this can make the project vulnerable when a single group fails
- The most prudent approach is to determine a target number of groups in the planning stage but to have a flexible alternative if more groups are needed

3.2.3.6. Data saturation considerations

As discussed previously, the most commonly used measure for determining adequate sample size is theoretical saturation[105], 'when there is enough information to replicate the study, the ability to attain additional new information has been attained and further coding is no longer feasible'.[130] It has 'become the gold standard by which sample sizes for qualitative inquiry, including focus groups, are determined'.[140] The lack of data saturation can affect the quality of the research conducted and impede content validity.[130]

Focus group sessions should, ideally, be conducted until saturation is reached for all concepts[135,136,139,142,143]; however, the constraints of the field situation must also be taken considered.[125] Depending on the depth and complexity of the topic, it has been reported that saturation may occur with anywhere from three to six focus groups.[105,125] A 2016 study investigating how many focus groups are enough[140] found that as few as two to three focus groups are likely to identify 80% of the themes and that the most prevalent themes within the data were identified with three focus groups, particularly with a relatively homogenous population using a semi-structured interview guide. More focus groups may be needed to reach saturation for topics that have greater complexity or more

abstract in nature, greater heterogeneity within the sample population, degree of instrument structure e.g., closed ended questions and those that are interpretive or quantify theme data.[140]

3.2.3.7. Moderating focus groups

Facilitators must have the skills and techniques to ensure that the issues under discussion are addressed comprehensively, including the following: ability to build rapport, active listening, speaking, observation, flexibility to adapt to the flow of the discussion and ability to remain impartial.[136] Good moderating skills are key to the reliability and validity of focus group research since, for example, 'a few highly disruptive or vocal participants can reduce the variability of responses within a focus group'.[140]

Moderator bias occurs when the moderator, intentionally or otherwise, supports a particular view so it is crucial for distance between the moderator and the topic to 'enhance the objectivity of the data collection and the impression of naivete to prompt more elaborate responses from the participants'.[138]

3.2.3.8. Setting

A convenient venue needs to be identified for the discussion. Researchers must consider participants' comfort, access to the venue and levels of distraction.[136] Participants must also have a clear view of each other and the facilitators.[136] A circular seating arrangement will enable this to occur.[138,139] The moderator and note-taker should sit opposite one another to avoid creating a power block in the circle.[138]

The rule of thumb for the duration of a focus group session is approximately 1-2 hours, depending on how complex the subject matter is, the number of questions and number of participants; Participants may be susceptible to experience fatigue with lengthy discussions.[136]

3.2.3.9. Considerations for breadth and depth of data extraction

A discussion guide should be prepared for the focus group session. This 'provides a framework for the moderator to ask and probe questions and increases the

comprehensiveness of data collection making data collection more efficient'.[139] Discussion guides generally contains five to 10 'open-ended questions designed to stimulate discussion on central topics of interest'.[105] A well-designed guide allows the flexibility to follow unexpected yet relevant issues that may develop during the discussion.[139]

A more structured approach to the focus group is helpful when there is a strong, pre-existing agenda for the research, which requires a standardised interview guide and a higher level of moderator involvement will be a factor to meeting this agenda.[125] If the research is more exploratory in nature, the basic issues are poorly understood or existing knowledge is based on researcher-imposed agendas, then a less structured approach will be more useful.[125] Minimising moderator involvement in the discussion will provide participants with more change to engage in what they find interesting; if the aim is to learn something new from participants then it is better to let participants speak for themselves.[125]

3.2.3.10. The focus group session

'Descriptive validity (factual accuracy) and interpretative validity (grounded in the language of participants) requires a recording technique that is as accurate as possible; the best way is to use audiotaping that is then transcribed verbatim'.[135]

Ideally, two people – the moderator and note-taker – should conduct each focus group; the moderator attends to the discussion and group dynamics to encourage balanced participation, while the note-taker captures elements such as what was said, the tone of the discussion and phrases or statements made by each participant.[139]

3.2.3.11. Data analysis

Writing the focus group report requires a balance between the direct connotations of participants and the scientific interpretation: The quality of the responses and their association are more relevant than their frequency.[135] In theme identification, the researcher looks for patterns, themes, concerns or responses that are presented repeatedly by the respondents.[137]

3.2.3.12. Rules of thumb

The size of the group and the number of groups is dependent on the purpose of the research and the type of participants.[135] A number of 'rules of thumb' have evolved to encapsulate the most common choice that researchers have made regarding how the data will be collected.[125] These are:

- Use homogenous participants
- Rely on a relatively structured interview with high moderator involvement
- Have six to 10 participants per group
- Have a total of three to five groups per project

In actuality, most projects have some components that require special attention and it may be relatively rare for a project to match all four of these criteria.[125]

3.3. Use of theory

3.3.1. Introduction

Within the Australian healthcare setting, and throughout the world, there are many gaps between best available evidence and current clinical practice.[144] Evidence-based practice demands for the rapid integration of best available evidence into routine practice[145] but although recommendations for evidence-based practice are frequently published, these are often not implemented effectively and best health outcomes are therefore not achieved.[146]

Research has shown that interventions to improve care can achieve moderate improvements in care, but there is substantial disparity in the observed effects within and across interventions[147]; 'those most likely to achieve desired outcomes are centred on a clear understanding of targeted health behaviours, and the environmental context in which they occur'.[148]

Due to the complexity of the medication administration process[20], the knowledge that there is a high degree of variation within the process[22] and that no single factor is responsible for adverse medication events[21], a considered approach is needed when contemplating a program to tackle any medication-related issue. To evaluate and improve medication management when patients have oral intake restrictions a systematic approach should be applied to ensure all relevant factors are considered and the most appropriate strategies may be developed to specifically address the issues identified.

3.3.2. Human behaviour

The recent Victorian response to the COVID-19 pandemic highlights the difficulty with changing human behaviour. Despite stage three sanctions that hugely impacted many Victorian lives and livelihood and daily media coverage of people dying from the disease, there continued to be those who were unwilling to modify their behaviour and/or who did not believe the restrictions and repercussions of COVID-19 applied to them. Even escalation to level four lockdown, with a 'State of Disaster' announced and bigger penalties threatened and increased law enforcement presence some remained undeterred and uncooperative. When viewed from this scale it emphasises the challenges faced by those attempting to change behaviour in clinical practice.

Other than dictionary descriptions, it was surprisingly difficult to find an exact definition for what is meant by 'human behaviour'. In their paper 'Why is changing behaviour so difficult', Kelly and Barker defined human behaviour as[149]:

'… the result of the interplay between habit, automatic responses to the immediate and wider environments, conscious choice and calculation, and is located in complex social environments and cultures. The fundamental belief about the role of information and knowledge in determining behaviour is wrong and unscientific – giving people information does not make them changes. Predicting behaviour and supporting behaviour requires careful, thoughtful science that leads to a deep understanding of the nature of what motivates people as well as other pressures that act upon them.'

Human behaviour then is highly complex and results from a culmination of numerous elements, and many factors and contexts need to be considered when trying to explain why people do what they do.

3.3.2.1. Changing behaviour

Implementation of evidence-based practice requires behaviour change, but changing behaviour is difficult[144,150,151], particularly in healthcare because of the 'complex relationships between a wide range of organisations, professionals, patients and carers'.[152] Implementation of initiatives to change healthcare practitioner behaviour may be influenced by: contextual factors e.g., time, workload, and staffing; qualities of the intervention e.g., clarity of instructions for delivery; and, psychological factors e.g., motivation, memory and attention.[153] Understanding the nature of a behaviour, the factors that contribute to variations in practice and the part played by the context in which it occurs is important to developing interventions that are more likely to prove effective in changing that behaviour and so reduce variability in the delivery of recommended practices.[151,154]

It is widely presumed that efforts to change professional practice have a lower prospect of success unless barriers are identified and considered[155] but in implementation research there are issues with attempting to understand the effect of interventions to change healthcare professional behaviour.[156] Methods to disseminate and implement change in the behaviour of healthcare professionals have been shown to have variable impact; some strategies to change the practice or behaviour of healthcare professionals have been successful whereas others have not, which is problematic since 'it limits the ability to predict with any confidence whether an intervention will work for a given issue and context'.[157,158]

Previously, behaviour change methods used for guideline dissemination and implementation strategies focused on behaviour change methods that were mainly intuitive or educational[146], such as relying on educating, persuading, or reminding people to change their behaviour.[159] Selection of methods may also be based on habit and/or disciplinary perspectives rather than an explicit rationale that takes the targeted behaviour and context into consideration.[158] There was no clear pattern of results recommending

any particular methods and no basis for understanding what behaviour change methods were responsible for the observed change and therefore no basis for selecting an intervention with confidence.[146] Most implementation studies were not informed by any theories of behavioural or organisational change and there was little evidence on whether selecting strategies informed by theory were any more or less effective than those that were not.[157] It is difficult to identify the specific components of interventions that have been used, and of those, which were effective when theories that underpin the implementation of clinical quality interventions are not explained.[159] A lack of explicit rationale for the intervention choice and use of inappropriate methods to design interventions may be partly responsible for the limited and variable effects of implementation interventions.[160]

One study reported a lack of understanding on the issues that make it more or less likely for clinicians to implement clinical quality interventions – it was incongruous that clinicians tend to focus on whether a clinical practice guidance was evidence-based but were not particularly aware of, or worried about, the degree to which general types of interventions were evidence-based.[159] Evidence should not only apply to what is being changed but also how the change is executed.[161]

3.3.3. Theories

There is an assumption that clinical practice is a form of human behaviour and can be described in terms of general theories relating to human behaviour.[147]

3.3.3.1. What are theories?

A theory is a set of a coherent and non-contradictory set of statements, concepts or ideas, definitions, and propositions that organises, explains or predict events, situations or phenomena by illustrating the relationships between variables.[147,148,162] A theory 'presents a systematic way of understanding events or situations'.[148] In the context of behaviour change, 'theories seek to explain why, when and how a behaviour does or does not occur, and the important sources of influence to be targeted in order to alter the behaviour'[151]; that is, theories describe the process by which behaviour occurs and offer insight into how best to change it.[153]

3.3.3.2. Why use theories?

Complexity abounds in the field of behaviour change and theories can provide a way of addressing this.[151] Using theory provides a foci[163] and gives users 'tools for moving beyond intuition to design and evaluate health behaviour and health promotion interventions based on understanding of behaviour'.[148] An assessment founded on theory 'allows for the systematic identification of factors that may impact interventions, can guide implementation and evaluation design and may provide the basis for a better understanding of behaviour change processe's[150] and offers a framework to support generalisability.[156] Theories are needed to develop 'testable hypotheses about when and why specific factors will lead to certain implementation' behaviour.[164,165] Health behaviour change theories provide a way in which tailored and theoretically underpinned interventions can be designed to address the barriers.[159] Use of theory as a basis for planning and developing programs is 'consistent with current emphasis on using evidence-based inventions in public health, behavioural medicine, and medicine'.[148] It is important to canvas the full range of potential levers for change; the use of theory promotes a systematic approach to this process and reflection about the causal nature of particular relationships associated with any given behaviour and therefore appropriate behaviour change techniques can be selected and/or refined and tailored.[151]

There is a growing recognition that theories of behaviour and behaviour change should be employed when designing implementation research studies to change behaviour.[151,156] The Medical Research Council in the UK proposed a framework that recognises the need to establish the theoretical basis of interventions and recommends taking a theoretical based approach to designing interventions to provide understanding of the likely process of change[147,151]; however, there is no recommendation on which theory to use.[151]

Desirable qualities of theories explaining behaviour change (at the level of individual, professional, groups or teams) include: demonstrated effectiveness in predicting and explaining behaviour change in other settings; explain behaviour in terms of factors that are changeable e.g., knowledge, beliefs, rather than e.g., personality, intelligence; consider non-volitional components i.e., individuals working in healthcare do not always have complete control over their actions due to e.g., patient preferences, organisational

barriers.[147] 'A useful theory makes assumptions about a behaviour, health problem, target population, or environment that are logical, consistent with everyday observations, similar to those used in previous successful programs and supported by past research in the same area or related ideas'.[148] Many theoretical outlooks are more comprehensive than an overall theory for guiding knowledge translation processes.[165]

3.3.3.3. A pragmatic approach

A pragmatic approach to developing implementation interventions, proposed by French et al.,[160] is to draw on theory together with consideration of evidence and practical issues, that is:

- Theory can be used to understand the factors that may influence the clinical behaviour change being targeted, understand possible techniques that could be used to change clinical behaviour and clarify how such techniques might work.
- Evidence can inform which clinical behaviours should be changed and which potential behaviour change techniques and modes of delivery are likely to be effective.
- Practical issues then determine which behaviour change techniques are feasible with available resources, and which are likely to be acceptable in the relevant setting and to the targeted health professional group.

French et al., used a four-step approach to direct the choice of the most appropriate components of an implementation intervention.[160] These were: (1) identifying the problem (who needs to do what, differently?); (2) assessing the problem (using a theoretical framework, which barriers and enablers need to be addressed?); (3) forming possible solutions (which intervention components could overcome the modifiable barriers and enhance the enablers?); (4) evaluating the selective intervention (how can behaviour change be measured and understood)?

3.3.3.4. Identifying barriers and enablers

Deciding on a theory that will enable a useful viewpoint of the research problem begins with a comprehensive assessment of the situation, 'the units of analysis or change, the

topic, and the type of behaviour to be addressed'.[148] Influences on healthcare practice are factors that might impede or enable improvements or implementation interventions to change clinical practice behaviour and improve the uptake of evidence into practice[157,160,161,166]; Such factors are sometimes referred to as barriers and enablers, barriers and facilitators, problems and incentives, moderators and mediators, or as obstacles and incentives to change.[162,166] For most changes in healthcare, 'a range of factors interact at different levels (patients, professionals, interactions among professional in teams, the organisational context, and the economic and political context) to determine whether and to what extent change is achieved'.[162] Because the 'interaction of factors at multiple levels may influence the success or failure of quality-improvement interventions, an understanding of these factors' is crucial to an effective intervention[162] and 'the success of implementation efforts depends on a careful assessment of barriers to and enablers of the behaviour to be changed'.[150] As 'interventions are more likely to be effective if factors influencing practice change are targeted'[154] there is a need to carefully select the interventions most likely to be effective to address the barrier(s) identified[157] (or to enhance existing enablers); for example, reminders may be effective only when not having the correct information at the correct time is a key cause of suboptimal performance.[167] There are a number of ways in which barriers and enablers to best clinical practice may be examined including brainstorming, case studies, key informants, direct observation, surveys and focus groups.[144]

3.3.4. Limitations of theories

A multitude theories and theoretical frameworks for both individual and organisational behaviour change are available.[146,156,160] 'Different theories may be relevant to interventions at different levels; for example, theories of individual behaviour are more relevant to interventions directed at individuals and teams, whereas theories of organisational change may be more relevant to interventions directed at hospitals'.[147] Many theories have shared or overlapping constructs and are therefore often difficult to access and understand by health professionals who do not have a background in psychology.[146,150,164] There is currently no methodical way for ascertaining which of the many available theories best anticipates behaviour or behaviour change most precisely, or which is best placed to support implementation research.[160] There have been

interventions that have purportedly been informed by theory that have not necessarily been found to be more effective than those that have not – a factor for this may be the way the theory has been used and the choice of appropriate theory.[151] The theoretical domains framework is an integrative framework that may overcome these constraints.[164]

3.3.5. Theoretical domains framework

The theoretical domains framework (TDF) is not a theory, *per se*, as it does not propose relationships between its elements but, rather, a theoretical approach.[168] It was developed to help understand clinical behaviours associated with evidence-based guidelines[169] in response to the need of implementation researchers who found a requisite for an integrative framework to manage the behaviour change issues relevant to intervention studies.[170] The TDF simplified and integrated a plethora of behaviour change theories to make theory more accessible and usable by those involved in evidence-based practice implementation who do not have a background in psychology.[146,171] It draws together key influences on behaviour from 33 theories of behaviour. The original validated version consisted of 12 domains made up of 124 components or constructs, which was later refined to 14 domains consisting of 84 constructs and further validated.[171] Table 1 lists the 14 TDF domains and their associated constructs.

3.3.5.1. Strengths of the TDF

The TDF is a feasible and acceptable framework and flexible tool that can be used across different settings, clinical quality contexts and in different ways to understand implementation issues and guide implementation activities.[150,158,159,172] It has been shown to be useful in many different types of studies for the comprehensive exploration of possible explanations for suboptimal implementation behaviour and for the identification of suitable theories to further investigate these behaviours.[164,170] It has been applied in very specific decision-making behaviours, general behaviours as well as complex behaviours[168] and has been used prospectively to facilitate implementation of healthcare interventions and retrospectively in theory-based process evaluation and using interview, observational as well as survey data.[150]

Researchers can use this integrative framework instead of having to choose between different theories.[164] Use of the TDF allows its users to not be prematurely confined to a particular psychological theory[169]; the TDF ensures a wide range of influences on behaviour are considered rather than the restricted set of influences that may be explored when research is limited to individual theories of behaviour.[168]

A qualitative study investigating use of the TDF across diverse clinical environments found the TDF was used to 'ensure that all aspects of possible influences' were considered.[150] Another study suggested that a questionnaire based on the TDF might be a quicker way than interviews to identify key domains of behaviour change among a larger sample, as interviews are resource intensive, time consuming, and often allow for a small sample size, limiting generalisability of findings.[173]

Table 1. Theoretical domains framework

From Cane et al.,[171]	
TDF domain	**TDF constructs**
Knowledge	Knowledge, procedural knowledge, knowledge of task environment
Skills	Competence, skills, skill assessment, ability, interpersonal skills, skills development, procedural knowledge
Social/professional role & identity	Professional identity, role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment. Organisational commitment, change management, champions, project management, team working, hierarchy, management commitment.
Beliefs about capabilities	Self-efficacy, perceived competence, self-confidence, perceived behavioural control, professional confidence, self-esteem
Optimism	Optimism, pessimism, unrealistic optimism, identity, mindsets
Beliefs about consequences	Beliefs, attitude, outcome expectancies, characteristics of outcome expectancies, illness representations
Reinforcement	Rewards (proximal/distal, valued/not valued, probable/improbably), incentives, punishment, sanctions contingencies
Intentions	Stability of intentions, stages of change model, transtheoretical model and stages of change, certainty of intensions, commitment, intrinsic motivation
Goals	Goals (distal/proximal), goal priority, goal/target setting, goals (autonomous/ controlled), action planning, implementation intention, representation of tasks
Memory, attention & decision process	Memory, attention, attention control, decision making, cognitive overload/ tiredness
Environmental context & resources	Environmental stressors, resources/material resources, organisational structure/climate, salient events/critical incidents, person x environment interaction, barriers & facilitators, anticipated regret, threat, past behaviour, knowledge, empowerment, negotiation
Social influences	Group norms, group conformity, group identity, social pressure, social norms, social comparisons, social support, intergroup conflict, alienation, social identity (modelling)
Emotion	Anxiety, depression, positive/negative affect, stress, fear, affect, burn-out.
Behavioural regulation	Learning, review, direct experience, self-monitoring, breaking habits, evaluation

In a review of 50 qualitative studies of clinicians' perceptions and experiences of clinical quality interventions to determine the extent to which the domains of the TDF 'played out' in the context of clinical quality the researchers found that the TDF accounts to a considerable extent for barriers and facilitators for behaviour change – all 14 domains of the TDF appeared to be relevant to clinical behaviour change in the context of promoting clinical quality.[159]

A 2012 study exploring the performance of four different (overlapping) theories and models used when designing implementation research studies involving behaviour change suggested that the TDF could be used as a screening instrument to help identify potentially relevant domains and to then target theoretical surveys addressing key domains.[156] Another study proposed that the TDF is especially useful for 'drilling down' because it begins with an exploration of the possible barriers and enablers that might be present in a specific local context and then quickly drills down to those that are most relevant for the people involved.[159]

3.3.5.2. Limitations of the TDF

A criticism of the TDF is the apparent overlap of some of the domains and the fact the interpretation or mapping of barriers into a domain may be subjective.[150,159,168] It is also not possible to distinguish clearly between clinicians' perspectives and qualitative researchers' interpretation of these perspective.[159] Another concern is it does not intuitively address interventions targeting multiple levels of the healthcare system.[168] For instance, a study using the TDF to optimise the implementation of a hand hygiene intervention found a difference between responses for the majority of the theoretical domains were noted between administrators and nurses.[174] The authors felt that these differences were significant to providing insight into how the interventions should be implemented; hence, it is necessary to consciously establish the angle of approach for different levels of the healthcare system when using the TDF.

3.4. Quantitative research techniques

3.4.1. Process versus outcome measures

3.4.1.1. Introduction

To improve patient safety and healthcare quality it is necessary to have some form of measurement or benchmarking. To measure quality, the ideas of what constitutes quality 'must be translated to more concrete representations that are capable of some degree of quantification'.[175] One of the debates for medication safety is 'how to measure the safety of the medication system reliably and how to assess the effect of interventions designed to improve the safety of medication use'.[176] Some experts assert that patient safety efforts need to be aimed at adverse events whereas others have maintained for a focus on errors as a means of assessing and improving the safety of the healthcare system.[176,177] Should the endpoint of quality improvement be measurable reduction of adverse events or the reduction or complete elimination of errors?[176]

'Errors are failures in the process of medical management and have the potential to harm the patient'.[176] Adverse events are outcomes of healthcare, related to actual harm: 'injury caused by medical management, rather than solely by the patient's underlying disease'.[176] Although medical errors and adverse events represent two different categories of events both of these are equally valid as measurements and their overlap—preventable adverse events—should ideally be the target of process and technology improvement efforts in the world of patient safety.[175,176]

3.4.1.2. Types of healthcare quality measures

There are three measures used to assess and compare the quality of healthcare. Structural measures assess the organisation's capacity, systems, and processes to provide high-quality care, while process and outcome measures reflect what is being done and the impact of the healthcare service, respectively.[178] Inclusion of elements of structure, process, and outcome in any system of assessment enable supplementation of weakness in one approach by strength in another.[175]

Structural Measures

Structural measures provide information about the environment, such the hospital infrastructure, culture, systems, policies, procedures, and activities, required to provide quality healthcare.[51] Examples of structural measures include whether the organisation uses electronic medical records or medication order entry systems, the number or proportion of board-certified physicians and the ratio of healthcare providers to number of patients.[178] Structural measures are usually monitored by an external quality assessment or self-assessment and are based on written and published standards.[51]

Process Measures

Process measures show what is being done to uphold or improve health. 'These measures reflect generally accepted recommendations for clinical practice, for example percentage of those with diabetes who had their blood sugar tested and controlled'.[178]

The process-oriented approach focuses on errors, near misses and other variations in care.[177] Process measures can provide information about medical care for a given condition or disease, and can contribute toward improving health outcomes.[178] Process measures offer quantitative data on the influence or effectiveness of systems, policies and procedures and can monitor changes over time with repeated measurements; if process measures are evidence-based, there is the assumption that the improved performance corresponds to improved health outcomes.[51] Most quality measures used for public reporting in healthcare are process measures.[178] Clinical processes are related to the behaviour of healthcare providers so measurement of these can offer 'a critical starting point in the development of methods to improve care received by patients'.[179] Process measures are often used to measure medication practice.[51]

Outcome Measures

Outcome measures manifest as the influence of the healthcare service or intervention on the health status of patients, such as the percentage of those who died as a result of surgery or the rate of surgical complications or hospital-acquired infections.[178]

Outcome measures provide quantitative data about the outcomes of health system performance, for example, morbidity, mortality, satisfaction with healthcare.[51] Outcome measures are seen to represent the 'gold standard' in measuring quality[178] as they appear to have higher reliability than process measures.[180]

Considerations for both process and outcome measures are presented in Table 2.

3.4.1.3. Which measure to use for the PhD quantitative study?

System-based failures in healthcare organisations 'can occur during any processes and are likely to be important underlying contributory factors for recurring medication errors'.[60] Moreover, since outcome measures are 'difficult to develop and implement in practice', process (and structural measures) are therefore more 'frequently used to measure medication practice'.[51] A further consideration is that medication administration information is routinely collected. Consequently, for the PhD study, the medication administration process measure is the most appropriate approach.

3.4.2. Retrospective record review

3.4.2.1. Introduction

In healthcare, it is important that programs and other initiatives implemented to improve patient care are monitored to assess their effectiveness. To do this, there needs to be easily accessible strategies to determine existing practice that impacts upon patient safety. However, measuring patient safety is complex and, although several different methods may be used, there is no single validated process for measuring overall safety of care provided in a particular healthcare setting.[181] For quality assurance and other purposes, such as studies of patterns of disease or behaviour over extended periods, it may be impractical to conduct prospective studies.[182] For some types of data, retrospective review of the patients' records may be the most feasible type of study.[183]

Table 2. Benefits and limitations of process and outcome measures

	Process measures	Outcome measures
Uses and benefits	Information about technical care is readily available in the medical record and is available in a timely manner, so that prompt action to correct deficiencies can be taken.[175]	Outcome measures are seen to represent the "gold standard" in measuring quality.[178]
	For tracking purposes, administrative database or medical records will yield far more accurate data than incident reports, which do not capture the vast majority of adverse events.[177]	Outcome measures are seen to have higher reliability than process measures.[180]
	Process-oriented reports are better for determining incidents' preventability and identifying contributing system and provider factors.[177]	Outcomes have the advantage of reflecting all contributions to care, including those of the patient.[175]
	Process measures are useful for delayed events.[184]	Outcome-oriented incident reports are better for identifying patient factors.[177]
	Process measures allow the use of opportunity for error rather than the number of patients treated as the denominator and reduce the confounding that arise when one clinician or institution cares for sicker patients than another.[184]	Medication-error-incident reporting systems provide a simple method to describe actual harm or potential harm from medication use.[51]
	Process measures are less likely to stigmatise as it encourages the improvement of care processes.[184]	Outcome measures such as those derived from voluntary medication-error reporting systems is less costly and less time intensive than evaluating case notes for process measures.[184]
	Process measures encourage action from all organisations or individuals with room for improvement, not just a small proportion of outliers.[184]	
Limitations	Process is expensive to measure as it currently requires access to patients' case notes. Evaluating case notes is time intensive and requires staff with clinical expertise.[184]	Although health outcomes can be informative, they are only likely to be a crude measure of quality because of the inherent unpredictability in patients' responses to healthcare.[179]
	The poor reliability of process assessment is strongly related to difficulties in judging preventability. Factors contributing to poorer reliability for process measures are: inability of reviewers to differentiate between cases with respect to the quality of management; bias related to the type and training of the reviewer; and bias of individual reviewers.[180]	It is not possible to say precisely what went wrong with outcome measures unless the antecedent process is scrutinised.[175]
	-	If outcomes are used to assess the quality of antecedent care there will the issue specifying which factors were responsible and weighting the importance of these factors.[175]
		Outcomes are likely to be affected by factors other than the quality of care, for example, mortality is neither a sensitive nor a specific test for quality.[184]
		As outcomes are likely the result of numerous factors, many beyond providers' control, there is the risk of reporting of misleading or even inaccurate information

		about healthcare quality remains with use of outcome measures. Risk-adjustment methods can help account for these factors but the science is still evolving.[178]
		Many outcomes, by their nature, are delayed, and if they occur after care is completed, information about them is not easy to obtain.[175]
		Opportunity for error, rather than the number of patients treated, method cannot be used when outcomes are assessed because the patient is the smallest possible unit of aggregation under these circumstances.[184]
		The quantitative use of incident report outcomes, such as medication error reports, should be used with great caution because they do not capture the vast majority of adverse events.[51,177]
		Outcome measures providing quantitative data related to the outcomes of health-system performance are the hardest to develop and use in practice Consequently, process and structural measures are frequently used to measure medication practice.[51]
		There are currently few useful and valid outcome measures that can be directly related to medication practice and hospital pharmacy services.[51]

3.4.2.2. What is a retrospective record review

Retrospective record studies use existing data that have already been collected for reasons other than research.[185] In the healthcare setting, these are often referred to as 'chart reviews', 'medical record review' or 'retrospective record (or chart) reviews' because the data source is the patient's medical record[182,185] or 'charts', such as the 'drug chart'. These types of studies use pre-recorded, patient-focused data as the primary source of information to answer a research question.[182,186]

The retrospective record review is a popular technique widely applied in many healthcare-based disciplines and important information may be gleaned from study results to direct subsequent prospective studies.[186] Studies have found that the review of medical records has validity as a method and is considered the cornerstone of quality assurance and improvement programs[180] and the 'gold standard' for safety measurement strategies as it contains rich and detailed clinical information.[181] Large population-based record reviews

have been the foundation of research into errors and adverse events.[187] Record reviews have been used to evaluate disease characteristics, treatment course outcomes, determining the appropriateness of diagnosis and assessing adherence to guidelines.[183]

3.4.2.3. Advantages of retrospective record reviews

One of the major advantages to using retrospective record review is that the data has been collected as part of routine patient care.[182,187] The record review enables assessment of a large sample at limited cost[183]; for example, a comparison between prospective assessment by clinical teams and review of medical records in France established that the cost of the prospective technique was 20% more than the retrospective method.[180] The record review enables easy collection of information which is routinely recorded, minimises recall bias for an event in the past and reduces the need for intrusion into patients' time for assessment as part of the study.[183] The data can be quickly gleaned from existing records to answer a question, leading retrospective studies to sometimes be viewed as 'quick and dirty'; however, this is not necessarily the case in a well-conducted retrospective study.[185] Also, the risk posed directly to patients when records are retrospectively reviewed is likely to be minimal.

The 'suitability of review of medical records for large scale studies in developed countries has been demonstrated'.[180] Record reviews have enabled research into an area that cannot be answered in prospective trials, such as the effects of harmful or potentially beneficial exposures to which people cannot be randomised.[182] Record reviews may also be more helpful in finding associations than prospective studies, which seem to be more appropriate to demonstrate causal relationship.[183]

3.4.2.4. Limitations of record reviews

The assumption that the documentation is a record of what occurred in the actual medical care delivered is significant to record review studies; however, this is often not well supported.[188] Data on the records are not documented for research purposes, hence comprehensiveness and quality may be lacking.[183] There may be variation in the manner in which data has been gathered and recorded in the charts, which, together with incomplete records or missing data, limits the extraction and interpretation of the

variables.[180,181,183] A major criticism of the record review is that it is not always capable of providing data that are both reproducible and valid[182]; it may not be possible to establish the reliability and validity of the data, as well as the researchers' interpretation of the data. Missing information can lead to nonresponse bias in that those with missing information may differ systematically from others, which is an unavoidable problem with retrospective studies where there may be partial to complete absence of documentation or records.[182]

The retrospective record review can be costly and labour-intensive.[181,187] Sifting through large databases may require extensive and dedicated computing time.[180,183] In a medical service of a university affiliated teaching hospital in the US, the cost of medical record review of 3146 admissions in a medical service was US$54,000 ($13 per admission and $116 per adverse event) while reporting by staff physician through an electronic mail system during the same period was $15,000 ($3 per admission and $7 per adverse event).[180]

The retrospective record review is subject to variability in judgement and bias; for instance, it requires extensive use of professional review[180] and the difference in perspectives or approaches related to inter-professional or other variances may affect coding of the data. Numerous discrepancies have been found when reviews conducted by nurses and by doctors were compared.[180] The risk of systematic bias from misinterpretation of clinical information documented[188] is also a major concern. Also, because of the retrospective nature of the record review, it is subjected to hindsight bias – the tendency to input causation when the outcome is known.[180,187]

The record review must be the appropriate method of data collection to answer the proposed research question.[183] For certain types of studies, medical record reviews of free text data and/or subjective findings cannot be depended upon to yield valid and reliable study results compared with those based on relatively objective data sources[182]; for example, review of medical records is unlikely to deliver valid analysis of root causes since the medical record does not include all relevant information.[180]

3.4.2.5. Key considerations to conducting a record review

Record review utilises data or information collected for a different purpose, such as the patient's medication administration chart/record. The data exist in many forms: paper charts, electronic databases, diagnostic test results and clinical notes from health service providers.[186]

There are several important factors to consider when conducting a retrospective record review. Many relate to maximising rigour and validity and reducing bias. Overall, a systematic approach should be undertaken.

Clarity of research direction

It is essential that there is clarity with the direction of the intended research, including what is being studied, how the data will be collected and whether the methods will be appropriate to the research.

A literature review should be conducted to discover how other relevant or similar types of research studies have been operationalised to understand all the variables that need to be considered for the study.[186] The direction of the intended research will also be facilitated with clearly defined research questions, which will serve to form the initial structure of the retrospective record review and guide the study design and data analysis.[186]

Sampling

The sample size and potential sampling issues should be considered before research commencement.[186] There are three sampling approaches for retrospective record review studies: random, convenience and systematic. Where researchers have access to a large number of records, random sampling is considered the 'gold standard'.[186] A sample size calculation can help ensure that the study outcomes have the desired precision.[188] Convenience sampling is the selection of all consecutive cases within a given timeframe[182] and is useful when dealing with a smaller number of cases available.[186] Systematic sampling occurs when the researcher selects every k-th medical record for coding but, although systematic, this method is not truly random.[186] Studies that fail to

use all or a random sample of available charts may lack internal validity[188] – convenience sampling is an acceptable method if the period is sufficient to include seasonal variations or other changes over time in relation to the research question.[182]

Inclusion and exclusion criteria

There should be well-defined inclusion and exclusion criteria for the study. This will help refine the data abstraction process, especially if it can be applied before inclusion in the retrospective record review.[186]

Data abstraction

Abstraction forms

Abstraction forms can be either paper or electronic and should be standardised to facilitate consistency among the abstractors and to help reduce error in data collection. An advantage of electronic forms is that data can be entered directly into the database, which minimises the number of omitted, illegible or mis-transcribed entries.[182] Paper-based forms can be cost effective and easier to use across multiple coding sites.[186]

Procedure manual for coding

A data abstraction procedure manual should be compiled to ensure accuracy, reliability, and consistency for all data reviewers and coders.[186] Data collection that is not systematic may lead to misclassification bias.[188]

Training of data abstractors

Coding must be performed accurately and consistently, or the validity of the data may be compromised and therefore coders must be appropriately trained prior to data abstraction.[186] Abstractor training will be facilitated with factors such as availability of a standardised data abstraction form and a priori determination of abstraction criteria and/or agreement on a systematic approach to abstraction and recording of details.[186] Thus, a coding manual is essential. Data abstractors should code several patient records for practice and any discrepancies in coding should be reviewed and discussed to clarify any issues.[186]

Blinding of abstractors

Ideally, data abstractors should remain blind to the study objectives because this will decrease reviewer bias.[186,188] Reviewer bias is particularly a concern when the study investigators are also the data abstractors; there is a risk of multiple contradictory entries in the review.[188]

Determining reliability of data abstraction

Well-designed research studies need to ensure procedures that measure agreement among various data collectors are included.[189] The 'degree to which the results obtained from data abstraction were reproduced on subsequent observations of the same record' when the abstraction was repeated should be measured and reported.[182] Intra-rater reliability assesses the differences when the same abstractor recodes the same set of variables, while inter-rater reliability determines the extent of agreement among data collectors.[186] Inter-rater reliability assessments are especially crucial when there are groups of different data collectors as the case in a multicentre study.[188,189]

Inter-rater reliability is a concern to some extent in most large studies because of multiple data collectors and the fact that each 'may experience and interpret the phenomena of interest differently'.[189] Ideally, two abstractors should independently analyse each record such that differences could be identified and resolved; however, as this is time-consuming and costly, it is rarely conducted.[188] An alternative approach is to determine the inter-rater reliability of abstractions of one observation.[182] The criteria for considering the variable, whether it is one or more observations, reliable should be justified, together with why a certain level inter-rater reliability is presumed acceptable.[188]

Several statistics are used to measure inter- and intra-rater reliability, including percentage agreement and Cohen's kappa coefficient.

Percentage agreement

The percentage agreement calculates the total number of variables agreed upon by (two) data collectors/raters divided by the total number of variables, that is[189]: a matrix listing the outcomes for each rater for each variable is used; the difference between the raters for

each variable is recorded as, for example, '0' (both agree), 1 (rater 1 disagree), -1 (rater 2 disagrees); the use of the matrix allows the researcher to discover if errors are random (distributed evenly across all raters) or whether a particular rater frequently records a different value to another rater.

This method makes several assumptions, including that all raters made a deliberate choice of a rating, as opposed to this occurring by chance and can therefore be misleading when used alone.[182,189] Many texts recommend 80% agreement as the minimum acceptable inter-rater agreement.[189]

Cohen's kappa coefficient

Cohen's kappa statistic (κ) is a measure of inter-rater reliability that considers random agreement; that is, the likelihood that there will be some level of agreement among raters even when they do not know the correct answers and are simply guessing and this should be taken into account.[189-191] (A reasonable percentage agreement may return a low to moderate kappa depending on the extent of chance agreement.[189])

Cohen's kappa is calculated using the following formula[189,191]:

$$\kappa = Pr\ (a) - Pr\ (e)/1 - Pr\ (e)$$

Where Pr (a) is the actual observed agreement and Pr (e) is chance agreement. The chance agreement is calculated as:

$$P\ (correct) = (A+B/A+B+C+D)*(A+C/A+B+C+D)$$

$$P\ (incorrect) = (C+D/A+B+C+D)*(B+D/A+B+C+D)$$

$$P\ (e) = P\ (correct) + P\ (incorrect)$$

Where:

A = total number of instances that both raters said something was correct (or positive or yes…)

B = total number of instances that Rater 1 said incorrect but Rater 2 said correct

C = total number of instances that Rater 2 said incorrect but Rater 1 said correct

D = total number of instances that both raters said something was incorrect (or negative or no…)

Kappa values of 0.0 to 0.2 are considered to show slight agreement, 0.21 to 0.40 suggest fair agreement, 0.41 to 0.60 indicate moderate agreement, 0.61 to 0.80 show substantial agreement, and 0.81 to 1.0 indicate almost perfect or perfect agreement.[189,190]

A minimum level of inter-rater agreement of 60% ($\kappa \geq 0.6$) beyond chance agreement is achieved is recommended.[182] Kappa values below 0.60 indicates inadequate agreement among the raters and little confidence should be placed in the study results.[189]

There are no published recommendations for what proportion of the abstracted data should be randomly checked for accuracy of abstraction.[182] Many studies sample 10% of charts; however, this may or may not be adequate depending on the situation.[182,188] It is preferable that a larger proportion is reviewed.[182]

Since percentage agreement does not account for agreements that may occur through chance, the kappa coefficient will be used to determine inter-rater reliability for the quantitative study.

Pilot testing

A pilot study should be performed prior to commencing the research proper. Pilot studies are small scale versions of a research investigation that are conducted to assess the study design, its feasibility, and evaluate the methodology and procedures of the investigation.[186] The pilot sample should be selected via a randomised process and should consist of approximately 10% of the targeted investigation sample.[186]

The data collection instrument should also be pilot tested.[188]

Missing data

Missing data should be specified.[182,188] Missing data can be a form of selection bias and the level to that this bias can affect the validity differs from variable to variable and

governed by the context and subject matter.[188] The proportion of missing data considered acceptable is dependent on many factors, including the study question, the type of variable, and impact on the results.[182] When deciding on the variables to study, investigators need to ascertain the proportion of data that are missing and whether this threaten validity.[188]

3.4.2.6. Electronic data

Historically, retrospective record studies involved reviews of paper-based medical records, such as the 'drug chart'. With the increase in use of electronic health records, many retrospective studies are now conducted using electronic data.[192] There is the potential to interrogate and manage the electronic data in such a way so as to improve the reliability of the data abstraction process; for example, two separate electronic systems with a common entity (e.g., patient's identification number) can be combined to target data relevant to a research question. This process will increase accuracy and reduce the potential for error compared with a data abstractor conducting this task manually. However, this function may require new or specific programming and may be beyond the functionality of the local existing electronic system.[192]

Data should be recorded electronically, directly into the computer to minimise the amount of omitted, illegible or mis-transcribed entries, although the possibility of clerical error related to transcribing the data from the chart to the database remains.[182]

3.4.3. Quasi-experimental designs

3.4.3.1. Introduction

Interventions that are implemented need to be evaluated in a robust way.[193] Rigorous techniques for 'evaluating positive, intended and negative, unintended consequences of interventions and policies are needed'.[194] Experimental designs are favoured over observational designs in most situations for evaluating the effectiveness of an intervention[195,196], including healthcare interventions.[197] Designs such as the randomised controlled trails are considered the gold standard of causal evidence because they, theoretically, reduce the potential for unmeasured confounding.[194] Randomised trials,

however, are often not the best approach for evaluating the impact of policy changes or other healthcare interventions[196-198] for many reasons, including the following[193-198]:

- There are many interventions for which it is infeasible to use randomised controlled trial design
- Answers often cannot be provided timely way to make decisions
- It is often necessary to retrospectively assess interventions that have already been implemented, either without randomisation or to a whole population
- It is often impractical and costly to utilise a randomised trial at the population level
- The number of possible options to compare and potential trial arms often makes it impractical for the required number of participants to be recruited
- Most trials also use stringent inclusion and exclusion criteria, which limit the generalisability of the results

Quasi-experimental designs involve the use of non-randomised methods to assess the impact of an intervention. A quasi-experimental design may 'allow causal interpretation of observed association when randomisation is not feasible or ethical and are a valuable option to randomised controlled trials, needing less time and resources to evaluate the effectiveness of specific interventions'.[199] The internal validity and strength of evidence of these types of studies depend on the study design and the capacity to manage factors such as confounding, correlation, seasonal or time trends.[199] Quasi-experimental designs that are informed by wide qualitative evaluation of 'decision-making, are likely the best way to move the discipline of quality improvement and implementation science forward'.[194]

3.4.3.2. Before-and-after studies

The before-and-after design is an example of a quasi-experimental design. Two group tests, such as the student's t-test or chi square test, make unadjusted comparisons of the study outcome between pre- and post-intervention periods.[199] They are easy to perform and need minimal data; however, these types of studies assume independence between individual variables and between time points, which is incorrect, and are unable to control for confounders or identify changes in temporal trends.[199] Merely comparing the means

before and after an intervention, without considering secular tends, may result in over or under estimations of the intervention effects.[200] An interrupted time series analysis can be used to overcome the limitations of the before-and-after design.[197]

3.4.3.3. Interrupted time series

The interrupted time series (ITS) analysis 'is the strongest and most commonly used quasi-experimental design to evaluate the impact of an intervention when a randomised controlled trial is not feasible'.[201] It is a 'simple but powerful tool' that has been used for assessing 'the impact of a policy change or quality improvement' imitative or the rate of an outcome in a particular population.[194] This study design is used more and more for assessment of public health interventions; it is well-suited to 'interventions implemented at a population level over a clearly defined timeframe and that target population-level health outcomes'.[196]

A time series is 'a continuous sequence of observations on a population' or values of a variable, taken repeatedly over an equally spaced time interval.[196,202] In an ITS study, 'a time series of a particular outcome of interest is used to establish an underlying trend, which is interrupted by an intervention at a known point in time'[196]; the intervention is anticipated to interrupt the level and/or trend of the outcome variable following its implementation.[203] The basic premise in an ITS is that 'observations from the baseline timeframe predict where the future data points would be in the absence of an intervention: If an intervention results in observations that deviate from the predicted observations, the difference represents the effect of the intervention'.[204] The design attempts to certain if the intervention has had a significant effect greater than any underlying trend over time.[202]

The ITS study is often conducted retrospectively using data routine that have been routinely collected and typically there is no investigator control over the allocation of the intervention; however, they can be conducted prospectively, be used to assess interventions allocated by the investigators and may include a control group.[202]

3.4.3.4. Strengths and weaknesses of the interrupted time series design

There are many strengths of the ITS analysis, particularly in quality improving research where randomisation is often infeasible, but there are also several weaknesses. A major concern with the ITS design lies in the complexity of the environment in which the intervention may be implemented. Health policy changes occur in complex systems and it is likely that parallel initiatives or events may have a direct or indirect influence on the outcome of interest.[205] It is often a challenge to obtain longitudinal data about possible influential local events for interpretation and discussion of alternative explanations.[205] **Error! Reference source not found.** lists some of the reported strengths and weaknesses of the ITS design.

Table 3. Strengths and weaknesses of interrupted times series

Strengths	Weaknesses
The ITS analysis is considered the strongest, quasi-experimental designs to assess intervention effects in non-randomised setting.[198]	ITS analysis is only valid if the policy/program of interest was the only thing that changed at the demarcated point in time.[194] The greatest threat to validity of ITS designs is that an event other than the control of the researchers occurred at the same time as the intervention, thereby making causal inferences impossible.[197] In quality improvement work, many initiatives often happen simultaneously and it can be hard to discern one from the other.[204]
It is particularly useful in quality improvement research for evaluating the effects of interventions when it is difficult to randomise or identify an appropriate control group.[206] Settings such as the inability to randomise clinicians or clinics or conduct a sequential rollout of the intervention are examples where the ITS design is useful.[194]	Segmented regression analysis of time series data does not allow control for individual-level covariates.[198] Individual-level characteristics would confound the time series results if they predicted the outcome and change in relationship to the time of the intervention.[198]
The ITS approach is conceptually simple.[204]	The strength of inference from ITS is weaker in the absence of the counter factual outcome and the nonexistence of a suitable control group.[194] Studies have demonstrated that the single group ITS (with no control group) can either fail to identify the effects of external factors on the times series, resulting in a false causal attribution, or conversely confuse the causal interpretation when a directionally correct change in the time series also occurs prior to the intervention.[203]
It is a practical research tool to evaluate the effect of complex interventions on pharmacy or related practice.[193]	ITS data have been shown to often be inappropriately analysed.[204] While the ITS approach is conceptually simple, its application is not always straightforward and often statistical expertise is needed to set up a segmented regression analysis.[204]
The ITS approach controls for the effect of secular trends in a time series of outcome measures that	Although simple regression models allow for multivariable analyses when evaluating associations

other designs, such as the before and after, may not; for example, the trend for medication error rate may have been sloping downwards for several years and a pre/post t-test may incorrectly attribute any changes to the intervention when in fact the decrease was likely due to other factors.[194]	between an intervention and an outcome, permitting statistical adjustment for measured confounders, they also assume independence between observations,[199] which may or may not be valid.
A simple ITS requires only one experiential group, with multiple observations before and after an intervention.[193]	Findings from ITS analysis can be misleading as the assumption that the baseline trend would have continued into the future in the absence of the intervention can be violated in various ways.[204] External causes other than the specific intervention in question may have influenced the outcome.
Analyses can be conducted with respect to population rates rather than at the individual level; confounding by individual level variables will not introduce serious bias unless it occurred simultaneously with the intervention.[194]	Changes in instrumentation, data collection method, or the ability to measure the outcome rate of interest.[194,204]
The ITS method readily lends itself to the analysis of unintended consequences of interventions and policy changes.[194]	Selection bias or changes in the type of patients or health professionals providing data for the study, particularly if the composition of the intervention group changes at the same time as the policy/program may impact on the outcome.[194,204] For example, the intervention may have led to increased attrition due to more intensive follow-up, meaning that patients who would have provided data in the preintervention periods dropped out from the postintervention period, which reduces the compatibility of the preintervention and postintervention populations.[194,204]
Investigators can easily conduct stratified analyses in order to evaluate the differential impact of an intervention or policy change on sub populations of individuals (e.g., age, sex, race etc).[194]	A drawback of segmented regression analysis can stem from the limitation of the data that it relies upon, especially when the sample is small.[205] Routine data may not always be very complete.[205] Missing data can affect the outcome of the ITS analysis.
ITS provides extremely clear and easy to interpret graphical results.[194]	Methods for analysing ITS data such as segmented (linear) regression may be inappropriate when the data are aggregated per time point or the data are from a skewed distribution.[207]

3.4.3.5. Data suitable for interrupted time series

Generally, time series analysis based on models such as segmented regression or autoregressive integrated moving average (ARIMA) analyses can be used for all types of numerical data.[200] Routinely maintained medication/pharmacy and medical databases are rich data sources in which the ITS methods can be applied.[201]

3.4.3.6. Sampling considerations

In ITS investigations data are collected at discrete points over time before and after an intervention to determine whether or not this had a significantly greater effect than any

underlying secular trend.[193,197,200] As observations taken over time are correlated, therefore observations that are taken closer together in time and the longer the period of observation, the more correlated or valid the data.[193,194] In designing an ITS study, the number of time points and how many observations to sample at each time point must be established to obtain stable estimates of intervention effects.[208]

Number of time points

The Cochrane Effective Practice and Organisation of Care guidelines specifies a minimum criteria of at least three data points before and after the intervention with a clearly defined time point of when the intervention occurred for all time series analysis studies.[200] This threshold is based on the argument that drawing a line through any fewer than three data points would estimate trend unreliably.[202] Other studies have suggested that a larger number of time points is needed to achieved sufficient power[194,198,202,208], especially for models based on autoregressive integrated moving average or segmented regression analysis.[202] These recommended number of time points range from a minimum of eight to 24 data points.[194,198,202,208] In studies that have multiple interventions, an adequate number of time periods between interventions is needed to estimate their impact independently.[194]

Number of observations

A sufficient number of observations at each time point of the time series is required to achieve an acceptable level of variability of the estimate at each point.[198] Depending on the minimum effect size and the amount of variation, a general recommendation is a minimum of 100 observations per data point.[198,201]

3.4.3.7. Power calculation

Methods to estimate power and sample size can be used to determine the number of time points and observations required per data point. A 2011 study found that power increased when the number of time points in the time series increase, had the tendency to decrease when the autocorrelation increased, and increased with the increase of the expected effect size.[208] However, it is not necessarily better to have more data points where historical patterns have changed considerably, as this would not provide an accurate portrayal of

the current underlying trends.[196] Another finding from the 2011 study was that, compared with designs where equal numbers of study periods were included in the analysis before and after the intervention, unbalanced designs tend to have less power.[208] This study suggested that analyses with less than 24 time points or with small expected effect sizes (<0.5) should be interpreted with caution as they may be underpowered.[196,208]

3.4.3.8. Analysing time series data

The ITS analysis involves using statistical techniques to measure changes in level and trend from before to after an intervention, and to determine if the estimated different effects are statistically significant.[204] It is based on the 'hypothetical scenario under which the intervention had not taken place and the trend continues unchanged'[196]: that is, it compares the post-intervention trend with the prediction of what would have happened had the intervention not taken place using pre-intervention trends.[202] The 'expected' trend, in the absence of the intervention, given the pre-existing trend is referred to as the 'counterfactual'.[196,202] A 'change in level is the difference between the observed level at the first intervention time point and that predicted by the pre-intervention time trend, while a change in trend is the difference between post- and pre-intervention slopes'.[200] A 'negative change in level and slope indicates a reduction in, for example, infection rates'.[200]

There are several statistical methods that can be employed to analyse time series data depending on the type of the data, the number of data points available for analysis and the presence of autocorrelation.[200,202,207] Several methodological issues such as autocorrelation (dependence/correlation between data points), non-stationarity (existing natural trend(s) in data), and seasonality (regular expected seasonal changes) need to be considered when completing an ITS analysis.[201] Failing to account for these may lead to biased results.[201,205] An appropriate statistical analysis considers adjustment for secular trend and studies should openly discuss secular trend in the report.[202]

Currently, segmented regression and autoregressive integrated moving average appear to be the two main methods used to analyse ITS data, particularly in implementation type studies.[194,200,202,205,209] The latter has been reported to require very sophisticated statistical skills to identify the best fitting model most appropriate for the outcome series before the

intervention[205], which was one of the reasons for choosing segmented regressions analysis for the PhD quantitative study.

Segmented regression

The 'goal of regression analysis is to estimate the interaction terms between implementation of an initiative and time'.[194] In segmented regression, the first segment consists of the rate of the event prior to the intervention or policy, and the second segment is the rates after the intervention[194] and separate intercepts and slopes are calculated in each segment.[209] The analysis estimates immediate (level) changes, changes in trends (slope) and rate of the outcome (intercepts) from pre- to post-intervention periods.[194,199,209] A segmented regression model is preferable to a standard regression model[199] and has been reported to be the recommended approach for analysing data from an ITS study.[209] It provides a practical approach to evaluating the impact of a health policy change.[205]

A six-step process for conducting the ITS analysis as recommended by Bernal et al.,[196] is shown in Table 4 and will be used to guide the ITS approach for the PhD.

3.4.3.9. Some further considerations

Time series analysis using the segmented regression analysis technique is based on 'the assumption of normal distributed error terms'.[200] When the time series analysis relies on data that are all near 0% (less than 5-10%) or near 100% (more than 90-95%) analysis may produce an expected value at time points of interest outside the range between 0% and 100%, in which case alternative approaches and/or the advice of an experienced statistician may be required.[200]

If it is identified beforehand that the underlying standard deviation of the data is small, segmented regression models can expect to have sufficient power to detect effects in equal data series in as little as 12 data points; however, if it is suspected that the effect sizes will be large, segmented time series studies with less than 18 data points need to be avoided.[208]

3.4.3.10. Graphical representation

ITS studies should incorporate a graphical display to enable interpretation of the results[201,202]; however, this should not be use alone as it can be misleading as a means of identifying or measuring an effect without the accompanying statistical analysis.[202]

Table 4. Six steps for conducting interrupted time series analysis

From Bernal et al.,[196]
Step 1: Determine whether an ITS design is appropriate.
ITS analysis requires a clear differentiation of the pre-intervention period and the postintervention period
Outcomes may take various forms such as counts, continuous data or binary variables.
ITS works best with short term outcomes that are expected to change either relatively quickly after an intervention is implemented or after a clearly defined lag.
Sequential measures of the outcome should be available both before and after the intervention.
Step 2: Propose the impact model if possible
Hypothesising how the intervention would impact on the outcome if it were effective may help determine the most appropriate model to use for data analysis. This process may be possible if pilot or other pre-study data is available.
Consider whether the change will: • Be a gradual change in the gradient of the trend or a change in the level or both • Will follow the intervention immediately or there will be a lag period before any effect is expected • Impact models include (a) Level change; (b) Slope change; (c) Level and slope change; (d) Slope change following a lag; (e) Temporary level change; (f) Temporary slope change leading to a level change • Selecting the most appropriate impact model can be difficult if existing knowledge of the intervention is limited and may require exploratory analysis of alternative data • It is best not to rely on the outcome data to select the best impact model as this increases the likelihood of an effect being detected due to random fluctuations or chance, and consequent artefactual conclusions on the effect of the intervention
Step 3: Perform descriptive analysis
Initial summary statistics and plots should be undertaken to familiarise researchers with the data. This should include a scatter plot of the time series, which can help to identify the underlying trend, seasonal patterns and outliers.
More traditional descriptive analyses, such as summaries and bivariate comparisons between the outcome and potential time-varying confounders, as well as simple before-and-after comparisons, are recommended.
Step 4: Conduct regression analysis
A minimum of three variables are required for an ITS analysis: • T: the time elapsed since the start of the study in with the unit representing the frequency with which observations are taken (e.g., month or year); • X_t: a dummy variable indicating the preintervention period (coded 0) or the postintervention period (coded 1);

• Y_t: the outcome at time t. In standard ITS analysis, the following segmented regression model is used: $Y_t = \beta_0 + \beta_1 T + \beta_2 X_1 + \beta_3 TX_t$ where β_0 represents the baseline level at T = 0, β_1 is interpreted as the change in outcome associated with a time unit increase (representing the underlying preintervention trend), β_2 is the level change following the intervention and β_3 indicates the slope change following the intervention (using the interaction between time and intervention: TX_t).
Step 5: Address methodological issues
A number of distinctive issues with time series data may need to be addressed in order to improve the robustness of the analysis, such as seasonality, time varying confounders, use of controls and other more complex ITS designs and autocorrelation.
Step 6: Model checking and sensitivity analyses
Model checking techniques such as plotting residuals and partial autocorrelation functions should be conducted, as well as sensitivity analyses to test the impact of varying a range of model assumptions, such as different lags, types of impact model or approaches to adjusting for seasonality.

3.4.3.11. Potential bias

Any study reporting ITS results should include a discussion of possible competing interventions (that may have occurred at the same time).[194] In quality improvement, many programmes often happen concurrently and it can be difficult to discern one from the other.[204] It is therefore important to assess the full range of possible causes of change.[194,204]

3.5. Reporting guidelines

3.5.1. Introduction

Research articles are primarily intended to communicate findings to interested parties[210], but the status of all forms of research depends on the quality of the methods used.[127] The undertaking of systematic reviews of quantitative research established the difficulty with determining how results of studies can be included in systematic reviews or whether they should be included at all if the information has not been transparently reported.[211] Among the large and growing volume of research publications, many lack clarity, transparency and completeness in terms of the methods employed and adequacy of reporting of the results.[211,212] In fact, the reporting of scientific studies in many areas of health research has been found to be unsatisfactory.[213] Widespread deficiencies, including selective or biased reporting, in research publications have been extensively documented.[210] Selective

or biased reporting of results has the potential to harmfully impact patient care as it can have far reaching consequences should, for example, the information be used to influence healthcare policy and treatment of large populations.[213,214]

Biased or selective reporting occurs when two main decisions are made based on the direction and statistical significance of the data – whether to publish the research, and if so, which analyses and results to report.[214] It involves data suppression, misrepresentation and manipulation, such as withholding publications of whole studies or prespecified outcomes, often with negative or undesired results and omissions of crucial information in the publication.[213-215] Statistically significant outcomes that were more likely to be fully reported and studies with positive or significant results were more likely to be published.[213,214]

Poor reporting practices misrepresent the available body of research evidence and compromise its use and reliability.[216] It also violates ethical responsibilities of researchers and sponsors to disseminate results accurately and comprehensively.[214]

The arrival of evidence-based healthcare and the 'development of methodologies and methods for the synthesis of both quantitative and qualitative research' have facilitated the momentum for a 'much stronger focus on improving the reporting of results of research in the literature'.[211] One important process for improving the quality of reporting is to devise and define clear reporting standards.[110]

3.5.2. What are reporting guidelines?

A reporting guideline has been defined as 'a checklist, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology'.[212] Reporting guidelines were developed to 'overcome the well-established limitations in the reporting of scientific studies in many areas of health research'.[215] They specify a minimum set of items that should be included to provide a clear and transparent account of what was done and what was found reflecting aspects that might introduce bias into the research to maximise the value of the research to others.[210,213] Many reporting guidelines have been 'carefully considered by multidisciplinary groups of relevant experts and stakeholders and there is a strong rationale for each item of requested

information'.[210] While reporting guidelines offer defined guidance on the information to be included in an article reporting a particular type of medical research[216] they do not prescribe how research should be done.[210]

When researchers submit their work for publication, the peer review process is of pivotal importance to ensure the quality of research papers being published.[211] Optimal reporting by researchers will enable editors, reviewers, other researchers, and practitioners to critically appraise the research and/or results.[110]

There is a multitude of reporting guidelines available, with many found on the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network.[217] There are generic guidelines, as well as specific guidelines that are relevant to a particular specialty or aspect of research that should be used in conjunction with the relevant generic guideline.[210]

3.5.3. Advantages of reporting guidelines

Reporting guidelines should be considered, and is useful, in many different aspects of the research process, including planning the study, writing up the research and appraising research.[210] Reporting guidelines help to improve the quality of research output. Being aware of the general principles of good reporting of a particular type of research design at the start of the research help researchers determine what type of information should be collected and recorded throughout the research process.[213] This is especially important for novice researchers – reporting guidelines may also suggest ways in which a study can be strengthened.[210] Observance of reporting guidelines will improve the completeness and transparency of publications, making writing up much easier and provides readers with adequate information to enable them to critically evaluate the quality and relevance of the study.[210,213] Improved reporting also has important benefits for systematic reviewers and those developing clinical practice guidelines and improves the efficiency of electronic literature searches.[210] Use and endorsement of reporting guidelines has been associated with more complete and transparent research reporting.[218]

There is widespread agreement that complete reporting and increase in transparency, facilitated by reporting guidelines, have the potential to increase quality, rigour and

credibility and increase the overall accountability of qualitative research.[110,119] Reporting guidelines have provided those unfamiliar with this approach a method to 'evaluate or review qualitative work (by providing guidance on crucial questions that need to be asked) and serve to remind qualitative researchers of the need for a systematic approach (by providing an aide-memoire of the various stages involved in research design and data analysis)'.[128]

3.5.4. Limitations of reporting guidelines

There are concerns that reporting guidelines, particularly those addressing qualitative studies, may be used prescriptively instead of as part of the overall approach to the research: One author has warned of the risk of the tail (the reporting guideline) wagging the dog instead of the dog (the research) wagging the tail, which is counterproductive.[128] Additionally, despite the number and range of reporting guidelines, the evidence on how particular guidelines were developed is limited.[212] Many reporting guidelines have been developed based on a consensus between international, methodological experts and are supported by a broad range of researchers[119] but only limited assessments have been conducted on the effectiveness of widely accepted and well-established guidelines for reporting research.[211]

Some qualitative researchers argue that qualitative research embodies a distinctive paradigm and therefore cannot and should not be evaluated through conventional measures of validity, generalisability, and reliability[127]: The diversity of qualitative approaches in research design pertaining to sampling, choice of methods, and approaches to analysis cannot be solved by prescriptive checklists.[106,119,128,215] Others are concerned about the 'uncritical adoption of a range of 'technical fixes' (such as purposive sampling, grounded theory, multiple coding, triangulation, and respondent validation), which does not, in itself, confer rigour'[128] – responding to the criteria in reporting guidelines does not automatically guarantee proof of quality.[119]

3.5.5. Qualitative and quantitative guideline differences

Although there are many similarities with guidelines for both qualitative and quantitative research, the criteria may have different meanings[215]; for example, the concepts of validity and reliability may have different interpretations depending on the whether the research is quantitative or qualitative.

Most quantitative research relates to 'measuring the magnitude, size or extent of a phenomenon and data collection is by formal rules of procedure and verification'.[106] Sampling approaches are structured and preferably randomised. Analysis is through 'standardised statistical formats and prediction and empirical generalisation are the desired outcomes'.[106] There are some broad-based, assumptions with quantitative research that are usually considered unnecessary to explain in journal articles, including random sampling, accuracy of diagnostic tests and sample size estimates.[215]

In contrast, 'rigour (thoroughness and appropriateness of the use of research methods), credibility (meaningful, well presented findings) and relevance (utility of findings) are used to assess the quality or 'trustworthiness' of a qualitative study'.[106] Sampling for qualitative studies can be based on a defined or developing theory and may not be random and may be 'purposive, maximum variation, as well as snowball in form'.[215] Validity and reliability may be determined through triangulation (where the same issue or single dataset is investigated from multiple perspectives) and respondent validation.[215] Authors of qualitative research are often required to provide an explicit account of their research method and methodological approach and also to rationalise it.[105,215]

3.5.6. Qualitative reporting guidelines

There has been a 'perception among research funding agencies, clinicians and policy makers, that qualitative research is 'second class' research'.[108] It has come a long way from views such as 'a soft option, lacking scientific rigour, open to possible bias or even fraud, and a form of research unsuited to evidence-based practice'.[211] Increasingly, with the evidence-based healthcare movement, qualitative synthesis is no longer considered a marginalised pursuit and qualitative evidence is viewed as an important source of information and has a place in clinical decision-making.[211]

The increased interest in qualitative research, however, has resulted in concerns by those appraising the research about the assessment of quality.[106] Poorly designed qualitative studies and insufficient reporting can result in inappropriate use of qualitative research in decision-making, healthcare, health policy and future research.[108] Analysis of the current qualitative literature in health services research showed that only half of qualitative research papers provided sufficient detail about the methods employed.[211]

3.5.6.1. Qualitative reporting guideline for this PhD

There are two well-known qualitative reporting guidelines – the Standards for Reporting Qualitative Research (SRQR)[110] and the Consolidated criteria for REporting Qualitative research (COREQ).[108] The SRQR is considered a standard, whereas the COREQ is a comprehensive 32-item checklist.[108] The comprehensiveness of the COREQ is demonstrated with items such as the researchers' credentials, occupation at the time of study and gender, the number of data coders, software used to manage data and clarity of major and minor themes.

As the COREQ offers comprehensiveness, it seemed the better choice to guide qualitative research reporting for those with limited qualitative experience, such is the case for all the researchers involved in the qualitative aspects of the PhD, including me.

3.5.7. Quantitative reporting guidelines

There are numerous reporting guidelines available and each address a type or focus of research. It is important that the most relevant reporting guideline is used for the research of interest.

3.5.7.1. Quantitative guideline for this PhD

Presently, there is no official reporting guideline for the ITS research design; however, following a systematic review of drug utilisation research using the ITS design in 2015, Jandoc et al., drafted a table of methodological and reporting recommendations for ITS studies.[201] The recommendations were based on the Strengthening the Reporting of

Observational studies in Epidemiology (STROBE) statement.[219] Some examples of the STROBE recommendations specific to the ITS design, include;

- Indicate the regression model
- Indicate how autocorrelation, non-stationarity, and seasonality were tested and handled
- Comment on data variability and appropriateness of the number of data points.

A more recent review of 'Methodology and reporting characteristics of studies using ITS design' in healthcare identified some gaps not previously addressed by the 2015 Jandoc et al., paper.[220] Recommendations and observations from this review include[220]:

- A description of a sample size calculation or a justification should be provided, as well as how missing data were handled
- For reporting of effect sizes, there needs to be consistency in what should be reported and confidence intervals should be provided
- The study design should be indicated in the main paper (in addition to the title and abstract)
- Clearer guidelines for reporting standards are needed
- There is a need to assess methodological strengths and weaknesses of current ITS analysis methods as there appears to be numerous ways of analysing these studies, which can make interpretation difficult.

3.5.7.2. A pragmatic approach for the ITS study

In the absence of a formal reporting guideline for the ITS design, the most appropriate path is to utilise Jandoc et al's.,[201] 'Methodological and reporting recommendations for ITS studies' because of its STROBE origins. Recommendations from Hudson et al.,[220] as well as those for reporting of retrospective record reviews should also considered, including the following[182,188]:

- Describe abstractor training
- Describe the original purpose of the collected data

- Include a flow diagram delineating how the study population was derived from the source population
- Provide the coding rules for each abstracted element. Where possible the coding guide should be provided as an appendix
- Include the data collection forms and coding definitions as an appendix
- Discuss the absence of blinding as a limitation
- Generally, report results with confidence intervals around the summary measure and therefore sample size should be based on the desired confidence interval width (usually 95%)
- Report the intra and/or inter-rater reliability of the data abstractors
- Report proportion of missing data, as well as how the missing data were handled in the analysis

3.6. Ethics approvals

Austin Health Ethics approvals and exemptions and University of Melbourne registration details for the works conducted in this PhD are disclosed in Table 5. Further details are in Appendices 12-19.

Table 5. Ethics approvals and exemptions

Name of project	Ethics approval number	Date of approval/comments
Improving the management of regular medications when patients are fasting or nil by mouth (audit of staff feedback – barriers to medication management).	LNR/13/Austin/306	31 March 2014 Approved as audit activity. Study published as 'Barriers to managing medications appropriately' University of Melbourne registration number: 1750930
Improving the management of medications when patients are fasting or nil by mouth (audit of medications omitted inappropriately – ITS study)	LNR/14/Austin/233	16 May 2014 University of Melbourne registration number: 1442467.1
Understanding the issues at the frontline: The Medications and Oral Restrictions Project (focus group study)	LNR/15/Austin/403	15 October 2015 University of Melbourne registration number: 1545945.1
Improving the management of medications when patients are fasting or nil by mouth (audit of staff feedback – barriers and enablers to policy implementation study)	Exempt, as considered a 'Quality improvement and innovation project'	28 March 2018 Riskman Q (Quality Activity) ID: 24744
Manuscript for 'Barriers to managing medications appropriately (description of cases)	Exempt, as information does not identify patients	14 January 2019 Email from Ethics (Priyanka Sathe)
Confusion associated with medications and restrictions on oral intake (case studies)	Exempt, as cases do not identify patients	13 July 2020 Email from Ethics (Sianna Panagiotopoulos)

3.7. Chapter discussion

This chapter addressed the diverse approaches and techniques considered in this PhD. The review offered explanations for why a technique may be the most appropriate for the investigations being undertaken and discussed the practicalities and characteristics that need to be considered when dealing with real-world quality improvement/practice-based research, such as those being planned.

The PhD program requires both a qualitative and quantitative viewpoint so that the findings of one study may inform or corroborate another and to provide breadth and depth to the findings. Use of theory will help understand human behaviour, ensure comprehensiveness and a systematic approach has been undertaken. The TDF is a theoretical approach that has been validated and shown to be relevant in diverse clinical settings exploring human behaviours and will provide theoretical underpinnings to many aspects of the PhD.

To investigate the potential causes of medications being managed inappropriately, a qualitative analysis of the barriers is needed. The domains of TDF will aid deductive categorisation of the data, and thematic analysis is a flexible data analysis method that can be used across a wide range of settings and offers a more accessible form of analysis for those relatively new to qualitative research.

Assessment of the impact of implementing the quality improvement strategies should be examined from different perspectives to secure a more comprehensive outlook that may allow for triangulation of results. A qualitative analysis of the barriers and enablers to implementation, using the same techniques described for barriers to medication management, will propose explanations for potential implementation issues that may impact uptake of the quality improvement strategies. The perceptions and experiences of staff at the frontline will provide valuable knowledge and insight into the influences of the quality improvement strategies. A focus group interview offers the most suitable premise when considering precious clinical time and facilitating group interaction to generate meaningful opinions, suggestions and feedback. The ITS design offers the best approach to quantitatively determine the effectiveness of the quality improvement strategies implemented hospital-wide since it is considered the gold standard for before and after studies where randomisation is not feasible. Retrospective record review of medication administration process measures should be employed because the administration data are collected routinely. As the kappa coefficient accounts for agreements that may occur through chance, which percentage agreement calculations do not, it will be used to determine inter-rater reliability for the retrospective record review. To conduct the ITS analyses, segmented linear regression will be used as this was the method applied for the pilot data and appears simpler to conduct (and requires less data points) than other methods such as autoregressive integrated moving average analysis.

Finally, based on the literature the Consolidated criteria for REporting Qualitative research and the Methodological and reporting recommendations for ITS studies appear to be the most appropriate reporting guidance currently available to report the qualitative and quantitative research, respectively, for the PhD program.

A summary of the methods discussed in this chapter that will be applied for each PhD research component and/or a brief reason for not using a particular technique/procedure is presented in Table 6.

Table 6. Summary of methods to be used in the PhD

	Chapter 4, section 4.4.	**Chapter 6, section 6.2.**	**Chapter 6, section 6.3.**	**Chapter 6, section 6.4.**
Study	Barriers to managing medications appropriately when patients have restrictions on oral intake	Barriers and enablers to the implementation of a policy to improve medication management in patients with oral intake restrictions	Surgical nurses' perceptions and experiences of a medications and oral restrictions policy change: A focus group study	Impact of a policy to improve the management of oral medications when patients are fasting before a procedure: a retrospective interrupted time series analysis
Study type	Qualitative review of pre-existing data, including emails and field notes (3.2.1.6.)	Qualitative review of pre-existing data, including emails and field notes (3.2.1.6.)	Focus group interviews (3.2.3.)	Interrupted time series (3.4.3.2.), considered the gold standard for before and after studies where randomisation is not feasible
Data collection method	Retrospective review of pre-existing qualitative data e.g., emails and field notes (3.2.1.6.)	Retrospective review of pre-existing qualitative data e.g., emails and field notes (3.2.1.6.)	Focus group interviews (3.2.3.)	Retrospective record review (3.4.2.) – patient medication dose administration data i.e., 'process measure' rather than 'structural or outcome measure' to measure medication practice because data is already available (3.4.1.3.). Also used clinical notes hospital, admissions records
Analysis	Thematic analysis (3.2.2.). Grounded theory is a 'methodology' and thematic analysis is a technique and is 'similar to a modified version of grounded theory'	Thematic analysis (3.2.2.). Grounded theory is a 'methodology' and thematic analysis is a technique and is 'similar to a modified version of grounded theory'	Thematic analysis (3.2.2.). Grounded theory is a 'methodology' and thematic analysis is a technique and is 'similar to a modified version of grounded theory'	Segmented regression (3.4.3.8. and 3.7., i.e., method to be used as it was applied for the pilot and appears simpler to conduct); inter-rater reliability (Cohen's kappa) (3.4.2.5. and 3.7.)
Approach to coding	Inductive/deductive (3.2.2.7)	Inductive/deductive (3.2.2.7)	Inductive/deductive (3.2.2.7)	A priori coding manual (3.4.2.5.)
Use of theory/TDF	For coding and to frame barriers (3.3.5.)	For coding and to frame barriers and enablers (3.3.5)	For question guide and coding (3.3.5.)	-
Rigour	Section 3.2.1.11.: Peer debriefing with other	Section 3.2.1.11.: Peer debriefing with other	Sections 3.2.1.11., 3.2.3.5. and 3.2.3.6.: Peer debriefing with	Sections 3.4.3.6., 3.4.3.7. and 3.4.2.5.: Power/sample size

	researchers; triangulation (multiple data sources, multiple methods, i.e., corroborate with focus group findings); breadth with multiple data sources	researchers; triangulation (multiple data sources, multiple methods, i.e., corroborate with focus group findings); breadth with multiple data sources	other researchers, triangulate with barriers/enablers findings; at least 3 focus group sessions; homogenous participants and simple research question	calculation; data abstraction form; procedure manual for coding; training of data abstractors; pilot testing; inter-rater reliability/resolving differences
Reporting guideline	COREQ (3.5.6.1.) – see Appendix 1 for critique of the study against the COREQ checklist	COREQ (3.5.6.1.) – see Appendix 2 for critique of the study against the COREQ checklist	COREQ (3.5.6.1.) – see Appendix 3 for critique of the study against the COREQ checklist	Methodological and reporting recommendations for ITS studies (3.5.7.2.) – see Appendix 7 for critique of the study against these recommendations
Techniques not to be applied for reasons briefly discussed here and in the respective sections of this chapter	Section 3.2.1.11.: Inter-rater reliability (not deemed necessary by all researchers); descriptive coding given as example but inductive/ deductive coding highlighted in Thematic analysis section; SRQR (COREQ is more comprehensive)	Section 3.2.1.11.: Inter-rater reliability (not deemed necessary by all researchers); descriptive coding given as example but inductive/ deductive coding highlighted in Thematic analysis section; SRQR (COREQ is more comprehensive)	Sections 3.2.1.11., 3.2.3.5., 3.2.3.6., and 3.5.5.1.: Inter-rater reliability (not deemed necessary by all researchers); descriptive coding given as example but inductive/ deductive coding highlighted in Thematic analysis section; SRQR (COREQ is more comprehensive)	Percentage agreement, section 3.4.2.5. (Cohen's kappa deemed more rigorous, section 3.7.); ARIMA, section 3.4.3.8. (segmented regression was felt to be the better option for the PhD study as used for pilot and easier to conduct, section 3.7.)
Techniques unable to be applied for reasons detailed in the relevant study's 'Limitations' section	*Section 3.2.1.11.: Sample size/saturation and respondent validation (due to data collection method. Respondent validation is also not universally deemed necessary/ appropriate by other qualitative researchers/the literature)*	*Section 3.2.1.11.: Sample size/saturation and respondent validation (due to data collection method. Respondent validation is also not universally deemed necessary/ appropriate by other qualitative researchers/the literature)*	*Sections 3.2.1.11., 3.2.3.5. and 3.2.3.6.: Sample size/saturation (due to only three sessions allocated to conduct focus group by nursing education; respondent validation (unable to perform as participants' details were not collected. Respondent validation is also not universally deemed necessary/appropriate by other qualitative researchers/the literature)*	*Bias/blinding of abstractors (3.4.2.5.)*

Chapter 4. Understanding the issues

4.1. Chapter introduction

This chapter describes the circumstances prompting the need to seek strategies to improve medication management in patients with oral intake restrictions. Section 4.2 reports three exemplar adverse patient incidents that highlight the cause for concern. This is followed by a documentation of the processes undertaken as part of the quality assurance response at Austin Health (section 4.3) to investigate the issues. As discussed in the preface, the broad-based concept has been broached in my NHMRC TRIP Fellowship: The information presented in this thesis has been restructured, with further data and supporting evidence added.

Section 4.4 is a formal qualitative analysis performed – as a specific component of the PhD – on staff feedback/comments obtained during the hospital's quality assurance processes. to identify barriers to managing medications appropriately when patients have oral intake restrictions.

4.1.1. The setting

The setting for the local investigations and PhD program of works was Austin Health. This is a tertiary-referral, metropolitan teaching hospital in Victoria with over 900 beds, including over 500 acute-care beds. The organisation consists of three campuses – Austin Hospital, Heidelberg Repatriation Hospital and Royal Talbot Rehabilitation Centre – and delivers a range of clinical services, including state-wide liver transplant, spinal cord injury, respiratory support and toxicology services, as well as aged care and rehabilitation.

4.2. Confusion associated with medications and restrictions on oral intake

4.2.1. Introduction

It is vital that due consideration is given to the management of medications, particularly when circumstances may bring about some form of restrictions on patients' oral intake, to avoid unintended adverse outcomes as discussed in Chapter 2. These oral intake situations include when patients have swallowing difficulties and are unsafe to swallow, require modifications to food, drink and/or medication to help swallow safely, or when patients are required to abstain from food and drink prior to a procedure to reduce the risk of aspiration while being anaesthetised.

The purpose of this section is to present three cases that occurred locally, are representative of the oral intake situations affecting medication management encountered by clinical staff and patients and thereby central to the work considered in this PhD.

Advice regarding ethics requirements for reporting these patient cases in the thesis was sought from Austin Health Ethics. Ethics advised that any information that may potentially, unnecessarily, identify the patients, such as the type of surgical procedure, need to be excluded. The presentation of the cases below are in line with Ethics specifications.

4.2.2. Patient 1

A non-elective patient was fasted for surgery. Although the patient's long-term medications were prescribed/charted, they were all withheld during this time, including pyridostigmine (acetylcholinesterase inhibitor) for a neuromuscular condition. Fasting was annotated in the dose administration boxes. Due to a protracted fasting period, as well as other circumstances, three (consecutive) days of oral medications were missed. Postoperatively, the patient went into respiratory failure. Medication omission may have contributed to this adverse outcome.

4.2.3. Patient 2

A patient with dysphagia was on several long-term oral medications including levodopa/carbidopa (dopaminergic agent/decarboxylase inhibitor) tablets. On the day concerned the patient was made nil by mouth; however, despite this categorisation medications were crushed and administered to the patient orally. This was suspected to cause the patient to aspirate.

4.2.4. Patient 3

A patient experienced a substantial drop in blood pressure and one of the patient's long-term medications, metoprolol (β blocker), was withheld. The patient then became tachycardic. The pharmacist discovered that, due to the patient's swallowing difficulties, nurses had been crushing the patient's oral medications to help the patient swallow them, including a prolonged-release formulation of tamsulosin (alpha-adrenergic blocker). Crushing a such a formulation (of tamsulosin) is likely to change its pharmacokinetics; for example, instead of the medication being delivered steadily over a 24-hour period, crushing is likely result in the immediate release of the 24-hour supply. Administration of this crushed tablet may have contributed to hypotension, which initiated a series of events including the rebound tachycardia from withholding metoprolol.

4.2.5. Discussion

The three cases represented three different medication management issues when patients have restrictions on their oral intake. The first case illustrates a scenario where medications were withheld inappropriately, the second was a situation where medications were given inappropriately and the third highlights medications should not be manipulated without prior knowledge of the potential consequence of the action.

Medication management issues in the context of restrictions on oral intake such as that highlighted through these three cases are also problematic elsewhere. A report from the UK described a case where a Parkinson's disease patient 'failed to wake' after an operation because anti-Parkinson's medications had not been administered

perioperatively.[1] Section 2.4 of this thesis addressed the adverse outcomes of medication omissions in the perioperative setting in other parts of the world.

The Medication Safety Series of the Journal of Pharmacy Practice and Research described two cases – one where a patient designated as nil by mouth had their intravenous medication withheld and another where eye drops were withheld for the same reason.[10] In the UK, a patient in a hospital 'died when he was mistakenly fed a pill' even though there was a nil by mouth sign above his head/hospital bed.[39] A patient with cerebral palsy, who had been nil by mouth for more than 10 years, was given vitamins orally by the nurse looking after her despite a warning from the carer that the patient was nil by mouth.[40]

The Institute for Safe Medication Practice in the US highlighted a case where an Alzheimer patient's rapid decline began around the time the patient's medications, which included donepezil and quetiapine, were crushed prior to administration.[41] A case report in the Canadian Medical Association Journal described a 70-year-old woman becoming unresponsive after a sustained release preparation of oxycodone was crushed and administered to her.[14] The Daily Mirror in the UK reported a coroner's case where the crushing of a slow release formulation of verapamil for angina resulted in the death of an elderly person.[42] The patient's granddaughter had crushed the slow release verapamil tablet the same way that the nurse had been.

Non-medication related cases associated with oral intake restrictions have also been described. The Herald Sun Melbourne reported on a nurse who was struck off because of a number of errors including feeding a patient who was nil by mouth because she did not hear or understand when told a stroke patient was nil by mouth.[221] In the UK, a surgical patient was to be 'strictly nil by mouth' postoperatively but, despite these instructions, the patient was given custard and pudding. He aspirated and then died from pneumonia.[11]

4.2.6. Patient safety issues

The cases suggest that there is confusion about how to manage medications when patients have oral intake restrictions, which has resulted in adverse outcomes for patients. The nil by mouth cases from the literature presented demonstrate the dangers of administering food, drink or medications to a patient who is nil by mouth due to swallowing difficulties.

The risk to patients when their long-term medications were omitted inappropriately before surgery have been outlined[8,38,76,78] in section 2.4, and the hazards of inappropriately manipulating (e.g., crushing, breaking, tablets or opening capsules) medications are well-documented in the literature.[43,222] Clarification is needed on whether to give, withhold or crush medications and oral restrictions contexts such as fasting before a procedure, being unsafe to swallow, or texture modifications to food/drink/oral medications to facilitate safe swallowing.

4.3. Investigating the problem

4.3.1. Introduction

Following a local adverse patient incident related to omission of oral medications during the perioperative period, a group of staff, representing various areas of the hospital, gathered to discuss the implications of this incident. The group consisted of key stakeholders for managing medications in the context of restrictions on oral intake and included representatives from nursing, surgery, orthopaedics, anaesthetics, medicine, pharmacy, speech pathology and Clinical Governance. Two consumer representatives were also invited to joined. The Medical Director of Orthopaedics and the Executive for the Surgical Clinical Service Unit led the group, which became known as the Perioperative Medication Committee (the Committee). I, as senior Quality Use of Medicines Pharmacist, represented the pharmacy department and volunteered to take on the role of project officer for the Committee.

The Committee served to drive the agenda and provided the executive level backing to the investigations and subsequent program of approaches to manage the medication issues identified. Importantly, the Committee's work aligned with the hospital's quality improvement processes.

I investigated the potential causes of inappropriate medication management in patients with oral intake restrictions by examining existing local data, as well as instigating a review of local practice. During the investigations, I became aware of two other oral

restriction issues – a 'nil by mouth' incident being investigated by the 'stroke' group and another related to crushing a medication inappropriately. I persuaded all groups to address the medication and oral restrictions management issues collectively.

An important consideration for the investigations was that, although the hospital had guidelines relating to surgery and medications, these did not specifically address the management of oral medications in the immediate preoperative time when patients were required to limit oral intake.

4.3.2. Examining existing local data

Existing local data relating to the management of oral medications when patients have restrictions on their oral intake were reviewed. These included the hospital incident reporting database, a snapshot audit of medication management and results from an audit of intravenous paracetamol use, which contained information about management of paracetamol when patients were nil by mouth.

4.3.2.1. Adverse patient medication incidents

In addition to the case described in section 4.2, there was an incident where oral analgesic agents were withheld when the patient was fasting before a procedure, resulting in the patient being in considerable pain. Two other cases were post-operative increase in heart rate and increase in blood pressure related to omission of 'heart' and antihypertensive medications preoperatively, respectively. There was also an anecdotal report of a patient having had his/her corticosteroid withheld during the fasting period, which was suspected to be implicated in the onset of Addisonian Crisis/withdrawal-related symptoms perioperatively. Corticosteroids, especially those that constitute long-term therapy, should not be stopped abruptly: additional cover during surgery is even recommended in certain circumstances.[223]

The two cases identified relating to medications administered inappropriately when patients were unsafe to swallow and medications manipulated inappropriately to facilitate swallowing were described in section 4.2.

It is likely that the number of incidents identified was an underestimate. It was not possible to obtain a comprehensive report of the incidents due to the non-systematic way in which staff reported them, the way in which the data were compiled and the limitations of the database platform at the time. Searching for incidents relied on the use of key text words such as fasting, 'nil orally' and 'medication' or 'drug'; however, there was no assurance that staff completing the reports would necessarily include any of the keywords in their report. Typographical errors, different spelling conventions and the use of (non-systematic) abbreviations further complicate this problem. The examples in Table 7, extracted from nursing documentation of the reason for not giving oral medications, illustrate this point (spelling is as found).

Table 7. Documented reasons for not giving oral medications

in OR	for ot	fasting
in OT	for proc	fasting for OR
In thearte	for theater	fasting for ot
in theater	fastinmg	fasting for procedure
in theatre	foir theatre	fasting for procidure
for theatre	fastimg	fasting for theatre

It is possible that some incidents may not have been reported. A weak incident reporting culture among the staff directly involved may be another reason, although those overseeing adverse medication incident reporting assert that there is a strong reporting culture at Austin Health. It is also possible that some adverse events related to withholding or incorrectly manipulating medications go undetected; staff may not have been unaware of the link or were unable to make that connection because of a lack of knowledge and/or due to the elapse of time between the adverse event occurring relative to when the medication process took place. This association would be made more challenging if the patient transitioned from one area of the hospital to another during that time. The case of the medication manipulated inappropriately (crushed) particularly highlights the former point: It was not until the ward pharmacist investigated that the association between the crushing of the modified-release medication and the patient's blood pressure drop were considered.

4.3.2.2. Snapshot audit of medication management

A snapshot audit of medication administration (conducted by a pharmacy assistant and me in 2004, unpublished) when patients were classified as nil by mouth, fasting or have a 'tube' (nasogastric, percutaneous endoscopic gastrostomy [PEG] or jejunostomy) in situ suggested inconsistencies with how medications were managed when patients had oral intake restrictions. Medications seemed to be withheld on an ad hoc basis – some medications were withheld while others were continued. In one case, a slow release formulation of verapamil (calcium channel blocker) was administered – the dose administration box was signed for – even though the patient had a PEG tube. In two cases, isosorbide mononitrate (nitrate) was not charted for patients with a history of ischaemic heart disease because they were categorised as nil by mouth and an alternative had not been prescribed. In one of these patients, the ECG became abnormal nine days after admission.

4.3.2.3. Intravenous paracetamol audit data

An audit of intravenous paracetamol use (conducted by another Quality Use of Medicines Pharmacist in 2010, unpublished, for which I was consulted about a question on 'nil by mouth') suggested that there was confusion with the interpretation of what nil by mouth meant in terms of giving oral medications. For instance, to the question, 'Which route of administration would you choose if your patient was NBM [nil by mouth]?' responses included, 'the patient can take [the oral] medication with sips', 'depends how strictly NBM patient is' and 'depends on [the] reason for fasting'. This audit suggested that nil by mouth was being used in different contexts to mean different things.

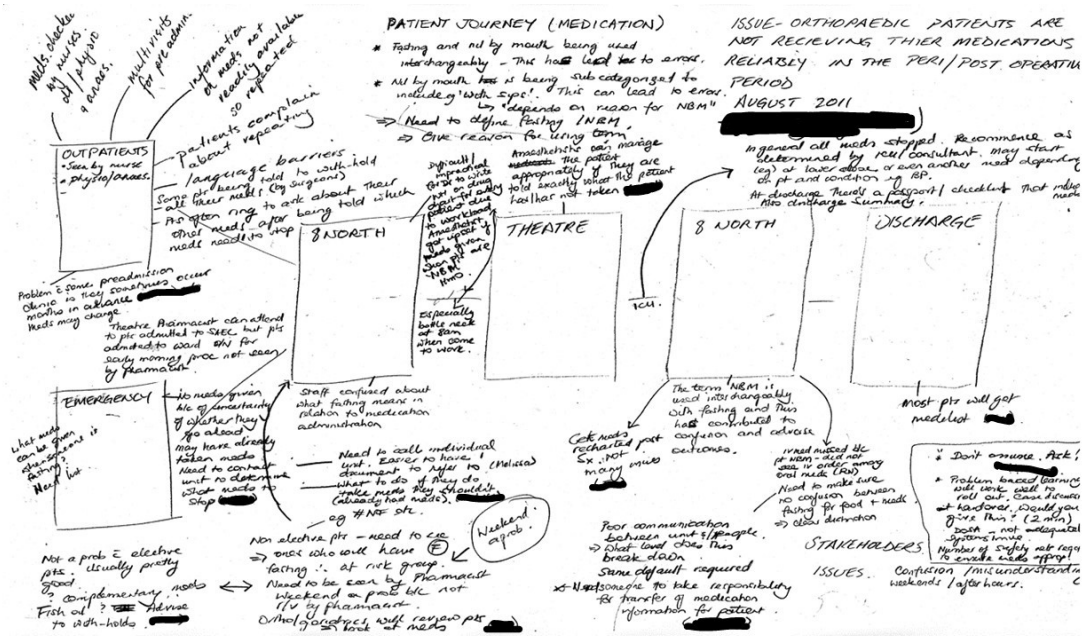
4.3.3. Investigating local practice

4.3.3.1. Patient journey mapping

A simple patient medication journey process mapping was conducted by a senior nurse and me in 2011 (unpublished) under the premise of a surgical patient's journey through the hospital system. Process mapping allows the visualisation and understanding of the patient's experience by separating the management of a specific condition or treatment

into a series of consecutive events or steps.[224] This exercise, which sought feedback from nurses, doctors, pharmacists, speech pathologists and a physiotherapist, highlighted the complexity of the patient's journey, particularly at the various hospital interfaces and with regards to communication among staff (Figure 2). As an example, it was highlighted that information about patient's oral medications was not reliably transitioned from one interface to another throughout the patient's journey; many aspects affected this process, including the 'bottleneck' of the morning rush. It also suggested practice variations between the interfaces and between and within professions; for instance, staff in the Emergency Department needed to check with individual 'units' (e.g., medical, surgical) about the management of medications for each patient – there seemed to be inconsistencies between different units and different medical staff regarding medication management when patients had restrictions on their oral intake.

Figure 2. Surgical patient medication journey



4.3.3.2. Snapshot audit

A snapshot audit of patients classified as 'fasting' or 'nil by mouth' (conducted in 2011 by a pharmacy assistant and pharmacy students and overseen by me, unpublished) found that from 82 patients (85%, n=97) on regular long-term oral medications, 60 (73%) missed at least one dose of at least one medication. Twenty-one (35%) missed at least one

dose of a β blocker and/or statin. Of those 'fasting' and on regular medications (54, 82% n=66), 40 (74%) missed their medications while 'fasting' pre-procedure/surgery. Within this latter group, 17 (43%) missed at least one dose of a β blocker &/or statin.

4.3.3.3. Staff medication survey

An online survey[225], led by me, based on a fictitious patient to gauge staff understanding suggested that there were varying interpretations and grasp about managing oral medications in patients with restrictions on oral intake. One-third of the 622 respondents indicated they would withhold all oral medications when the patient was fasting two hours before surgery, irrespective of what the medications were. Given the patient's regular long-term medications included metoprolol (β blocker), atorvastatin ('statin') and levodopa/carbidopa (dopaminergic agent/decarboxylase inhibitor), these omissions were inappropriate. Conversely, 10% of participants would give oral medications to a patient who has just had a stroke and classified as nil by mouth, which in practice would have placed the patient at risk of choking.

4.4. Barriers to managing medications appropriately when patients have restrictions on oral intake

The following study was published in the Journal of Evaluation in Clinical Practice and the version presented, commencing with the 'Summary', is the peer reviewed version of the following article: The-Phung To, Jo-Anne Brien, David A. Story. Barriers to managing medications appropriately when patients have restrictions on oral intake, which has been published in final form at https://doi.org/10.1111/jep.13139 (J Eval Clin Pract. 2020;26: 172-180). This article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions. A license was also obtained for use in a Dissertation/Thesis – No.4915060713664.

I was responsible for all components of this study, which was overseen/conducted in consultation with my supervisors.

Summary

Rationale, aims and objectives: Investigation of several serious adverse events in our organisation highlighted that medications were managed inappropriately when patients have oral intake restrictions. The aim of this work was to identify the barriers to optimal medication management when patients have restrictions on their oral intake.

Method: Data were feedback and comments obtained between 2010 and 2014 from a hospital-wide quality assurance project. Data had not been purposefully collected and were in response to a general request for feedback regarding managing oral medications when patients have oral intake restrictions. Data came from a range of clinical staff and from various forums associated with the quality assurance project including; 37 presentations, 34 group meetings and over 50 one-on-one meetings, as well as emails and other sources.

Data were analysed using the Thematic Analysis approach. Data were coded inductively, and the domains of the Theoretical Domains Framework were used to categorise the data. Subthemes and themes were then developed.

Results: Barriers could be broadly grouped into systems level issues (organisational guidance, work environment) and the individual person level issues (staff knowledge, beliefs). These barriers highlight the complexity of the medication management task. The lack of standardised guidance and consistent terminology regarding medication administration when patients have restrictions on oral intake, particularly when *fasting* or *nil by mouth*, were important systems factors, as were workflow issues and the 'culture' of the environment in which staff practiced. Lack of knowledge about medication administration, social influences and role interpretation were important individual person factors.

Conclusion: Systems and individual person level issues were significant contributors to inappropriate medication management when patients have oral intake restrictions. Many of the barriers may be addressed with systems approaches such as hospital-wide guidance that simplifies and standardise oral medication administration instructions, particularly regarding *fasting* and *nil by mouth* terminology.

4.4.1. Introduction

Patients sometimes have restrictions on what may be administered orally for several reasons. These restrictions may include the need to limit food and fluids prior to a procedure, the need to seek an alternative route for oral administration because of swallowing difficulties and gut dysfunction and the necessity of modifying the texture of what is administered orally to aid swallowing.

There are indications that oral medications may be managed inappropriately and inconsistently when patients have restrictions on their oral intake; for example, medications withheld when they ought to be given, given when they ought to have been withheld or manipulated (crushed) inappropriately. All of these actions have the potential to adversely affect the patient.[1,8-14] Some examples of reported incidents from our organisation illustrate these issues:

- All the patient's long term regular oral medications were withheld over several days because the patient was *fasting* (for surgery). Not receiving these medications may have contributed to the patient's postsurgical respiratory failure;
- Administration of oral medications to a patient designated as *nil by mouth* due to swallowing difficulties resulted in the patient aspirating;
- Crushing a controlled-release medication and administering this to a patient with swallowing difficulties may have led to a significant drop in blood pressure with subsequent sequelae.

We were unable to ascertain the total number of incidents at our organisation due to the way in which the incidents were reported. However, it seems these issues are not unique to our organisation as similar incidents have been described in the literature.[1,8-14] It is imperative there is an understanding of how and why these scenarios occur so that strategies may be instigated to minimise the risk to patients.

The purpose of this work was to identify barriers to the appropriate management of medications when patients have oral intake restrictions.

4.4.2. Methods

4.4.2.1. Design, setting and time period

This was a qualitative analysis of feedback and comments that had been provided by clinical staff between 2010 and 2014 in response to a general request for feedback and comments to an organisation-wide quality assurance project. The quality assurance project had been set up to investigate the issues and to develop strategies to improve the management of oral medications when patients have restrictions on their oral intake. The project was conducted at a tertiary-referral, metropolitan teaching hospital in Melbourne, Victoria, with more than 500 acute-care beds. The organisation provides a broad range of generalist acute, subacute and rehabilitation care, in addition to being the state-wide referral centre for liver transplantation, spinal medicine and toxicology.

The hospital's Human Research and Ethics Committee provided approval for the use of the data for this qualitative analysis (LNR/13/Austin/306).

4.4.2.2. Participants and data collection

Data had not been purposefully collected and were feedback and comments about the management of oral medications during periods of restrictions on patients' oral intake received from clinical staff by the first author as part of clinical quality assurance processes.

The feedback and comments came from clinical stakeholders such as nursing, medical, pharmacy and speech language pathology and ranged from senior management to those at the frontline. The verbal data came from various forums directly related to the quality assurance project in which discussions about the issues surrounding the management of oral medications during periods of restrictions on patients' oral intake took place and included; approximately 37 presentations, 34 group meetings and over 50 one-on-one meetings. Some of the presentations and group meetings were multidisciplinary; the number of staff present or type of professions had not been noted. Of the 50 one-on-one meetings, there were 23 with nurses, nine with medical staff, 13 with pharmacists and five with speech language pathologists.

The first author took notes during and/or immediately after the presentations or meetings to record feedback or comments that were of relevance to the quality assurance project. None of the verbal feedback and comments had been audio-recorded.

Written feedback or comments were from emails from over 100 staff, with at least 50 from nursing, 20 from medical, 30 from pharmacy and 15 from other staff including speech language pathologists. Written feedback or comments were also taken from an in-house survey (unpublished) of intravenous paracetamol use and a medication administration survey[225] because these responses related to the management of oral medications when patients had restrictions on their oral intake. Data were also drawn from an in-house snapshot audit (unpublished) of medication administration during the period of restriction on patients' oral intake before a surgical procedure.

4.4.2.3. Data analysis

Data were analysed using a Thematic Analysis approach.[121,124,133] Data were coded (NVIVO 11, QSR International, Melbourne) inductively, and the domains of the Theoretical Domains Framework[159,171] were then used to categorise the data. Subthemes and themes were then developed. The process was iterative, with data, subthemes and themes sorted and resorted before the final themes were reached. The coding was conducted by the first author in consultation with the other authors and data analysis was discussed by all authors.

4.4.2.4. Researcher experience and potential influence on findings

All authors have prior experience with qualitative research.

The first author was the project officer for the quality assurance project and therefore this involvement may have influenced the findings. The third author was also involved in the quality assurance project.

4.4.3. Results

[The 'Consolidated criteria for reporting qualitative studies: 32-item checklist' was included in the manuscript as a supplement – it is Appendix 1 in this thesis.]

The identified barriers could be broadly grouped into two overall themes – those stemming from the systems level and those arising at the individual person level; although many of the issues were co-dependent and interrelate. (See Table 8 for the coding tree.)

4.4.3.1. The systems level

Lack of standardised, organisation-wide guidelines or policy

Staff from all disciplines highlighted that there was no unified hospital-sanctioned reference that staff could use to guide their decisions about whether to give or withhold medications when patients have restrictions on oral intake. Nursing and pharmacy staff were required to check with their patient's medical or surgical unit on an individual basis to determine whether to give or withhold oral medications. Many staff, particularly junior staff, indicated this individualised approach was impractical, frustrating and time consuming.

Junior doctors were often reliant on their superiors (either registrars or consultants) or other specialist units for direction but the recommendations provided by this range of sources were inconsistent. There was often a lack of standardisation about oral medications administration between specialties. A junior doctor reported there was a "difference of opinion between surgical and anaesthetics" and, according to nursing staff from one ward, there were "different opinions from different medical teams". Other staff also indicated that anaesthetists vary with when they allow tablets and sips of water. One senior medical consultant wrote, "It is my experience that ...advice about the limit of any oral intake [including water intake for tablets] varies considerably between anaesthetists/proceduralists and we have had people cancelled from having ... [a procedure]...because medications were given with a small amount of water within four hours. This has been a recurring frustration over the years when people think they are doing what is acceptable only to encounter a different opinion".

The lack of hospital-sanctioned guidance coupled with the lack of agreement between staff created complexity and uncertainty with managing oral medications in patients with restrictions on oral intake.

Table 8. Coding tree for barriers to managing medications when orally restricted

Inductive Coding Examples	Categories Using Theoretical Domains Framework	Subtheme	Theme
Clarity; communication; confusion; environment; experience; important medications; inter-professional relationships; knowing what to do; professional role; risk to patients; understanding;	Knowledge; social professional role; beliefs about consequences; memory, attention and decision process; environmental context and resources;	Lack of standardised, organisation-wide guidelines or policy	Systems Level
Clarity; communication; environment; inter-professional relationships; knowing what to do; professional role; risk to patients;	Social professional role; beliefs about consequences; memory, attention and decision process; environmental context and resources;	Lack of clarity around roles and key decision makers	
Communication; environment; inter-professional relationships; understanding;	Social professional role; beliefs about consequences; environmental context and resources;	Workflow issues	
Environment; important medications; professional role; risk to patients; understanding;	Knowledge; social professional role; memory, attention and decision process; environmental context and resources; social influences;	Workplace 'culture' and 'rules of thumb'	
Clarity; communication; confusion; environment; important medications; knowing what to do; risk to patients; understanding;	Knowledge; beliefs about consequences; memory, attention and decision process; environmental context and resources; social influences;	*Fasting* and *nil by mouth* terminology	
Clarity; confusion; experience; important medications; knowing what to do; risk to patients; understanding;	Knowledge; social professional role; beliefs about consequences; social influences;	Lack of knowledge	Individual Person Level
Clarity; confusion; communication; environment; important medications; knowing what to do; risk to patients; understanding;	Knowledge; beliefs about consequences; memory, attention and decision process; environmental context and resources; social influences;	*Fasting* and *nil by mouth* context confusion and medication administration	
Communication; confidence; environment; experience; inter-professional relationships; professional role; understanding;	Social influences; social professional role; environmental context and resources	Social influences	
Environment; important medications; knowing what to do; professional role; risk to patients; understanding;	Knowledge; beliefs about consequences; environmental context and resources; social influences;	Beliefs	
Communication; environment; inter-professional relationships; knowing what to do; professional role; understanding;	Social professional role; environmental context and resources; social influences;	Role interpretation	

Lack of clarity around roles and key decision makers

Where an individual patient was under the care of several medical teams (e.g., general medical, surgical and anaesthetics) it was often unclear to nursing and pharmacy staff which doctor was responsible for decisions around medication administration. A common cause of frustration for nursing and pharmacy staff was that often several units needed to be contacted before a decision was made. One pharmacist lamented, "Units say call someone else".

Some units/doctors did not feel it was their responsibility to make medication-related decisions for their patients and thought these decisions should be deferred to another unit or specialty. This point was emphasised during a discussion at a surgical unit meeting where surgeons in that unit felt it was "up to medical units or anaesthetists to decide" about patients' oral medications. However, this concept was not universal.

Workflow issues

Many staff found it challenging to follow up on medications in a timely manner, especially in dynamic clinical situations and changeable surgical timeframes. This was a particular issue with doctors charting/ordering or withholding patients' oral medications perioperatively. Some doctors felt they were too busy to follow up medications; one surgical doctor stated he is "too busy, don't have the time and therefore don't write it [the medications] down or withhold the medications perioperatively". A junior surgical doctor explained, "It's impractical for doctors to withhold [medications] on [the] drug chart for every patient due to work load, especially during the bottleneck at 8am". For nursing staff much time was spent clarifying the decisions made by the various medical teams and attempting to "chase up individual doctors or units" about whether to give or withhold oral medications. For many reasons, it was often difficult to establish the exact timeframes for patients going to surgery. Therefore, as one of the pharmacists pointed out, "Medications are not given because there is uncertainty about whether the patient's procedure is going ahead".

A workflow issue impacting on oral medication administration related to patients admitted on the day of surgery. As identified by a senior pharmacist, "The problem with

some preadmission clinics is they sometimes occur months in advance and medications may change". The medication therefore needed to be verified at the time of admission and prior to surgery. A further source of uncertainty that took time and resources to clarify related to whether the patient had taken their oral medications prior to admission for surgery, which may in turn be dependent on what they had been advised by their specialist, general practitioner, and/or others (e.g., nurse liaison, pharmacist).

Other workplace considerations also affected patients having their medications managed in a timely manner when they have restrictions on oral intake: for example, the time needed for medications to be reviewed by the doctor and for a suitable route of administration to be found, and during periods of reduced staff such as on weekends and after hours.

Workplace 'culture' and 'rules of thumb'

The culture of the workplace contributed to inappropriate management of oral medications when patients had restrictions on their oral intake. There were often 'rules of thumb' – either specific to the local area (ward) or across the hospital – that were considered accepted practice and generally applied, but which were not always best practice for the patient.

Fasting and nil by mouth terminology

The terms *fasting* and *nil by mouth* were being used in a number of different contexts and there was a culture of using these terms to mean the same thing. One surgical registrar said her training was to "use *fasting* and *nil by mouth* interchangeably". When conversations or questions were posed with one of the terms, some staff would respond using the other – for example, a question specifically stating *nil by mouth* elicited the response of, "[It] depends on [the] reason for *fasting*…" The fact that official documents such as the 'National Inpatient Medication Chart' define *fasting* and *nil by mouth* as the same entity,[226] particularly in the surgical context, lent support to this culture. One of the nurses used this reference to reinforce the view that *fasting* can be used in different contexts – "*Fasting* can mean anything and may not relate to presurgery. It was taken from the National Inpatient Medication Chart". However, the culture of using *fasting* and

nil by mouth interchangeably has the potential to cause confusion in different clinical settings, particularly where oral medication administration may be involved and may lead to oral medications being managed inappropriately and adversely affect patient care.

Rules of thumb

There were a number of 'rules of thumb' in use. One such rule was that all oral medications were withheld if patients were categorised as *fasting* regardless of the setting, such as whether patients were having surgery or have difficulty swallowing, or the type of medication. A different rule was to only give oral medications that were considered 'important/urgent/critical': where this rule was used it was sometimes applied to all patients, regardless of the context. This was further complicated by the fact that there was no consensus as to which medications were considered 'important/urgent/critical'; for example, during meetings to ascertain a list of 'must give' medications an agreement could not be reached on which medications must be included. Other 'rules of thumb' examples included:

- Oral medications (tablets) were routinely crushed and given via the nasogastric tube if the patient was unable to take medications orally, regardless of whether the medication should be crushed or not;
- Some speech language pathologists provided the generic recommendation of 'crush tablets if possible' for patients with swallowing difficulties;
- If patients' long-term morning medications were charted/ordered after 8am some nurses would assign the task to the following day and there was a risk that the morning medications would be missed, especially if nurses do not check whether patients have already taken/received those medications;
- It was routine practice for some doctors not to chart/order medications for patients prior to surgery.

Consequences of these rules may include:

- Patients having their medications inappropriately withheld because;
  - All oral medications, including patients' long-term medications, were not charted/ordered by the doctor.

  - Only some medications were charted/ordered for patients by the doctor.
  - All or some medications were not given by the nurse prior to surgery.
- Medications were given orally to a patient who should not be receiving anything orally;
- Some oral medications were manipulated (e.g., crushed) inappropriately.

4.4.3.2. The individual person level

Lack of knowledge

There appeared to be a lack of knowledge about medications in the context of restrictions on oral intake. Knowledge deficits were also implicated with the face-value acceptance and ongoing practice of certain 'rules of thumb'. There was not only uncertainty about whether medications in general should be given or withheld in a particular oral restriction context but also a lack of understanding about the medications themselves and which medication should be given or withheld. The clinical context and the individual medications were not consistently considered by nurses when withholding all of their patient's medications. An incident that illustrates this issue occurred when a patient with acute appendicitis was made *nil by mouth* by the doctor and although the patient had a number of oral medications charted/ordered the nurse did not give these because of the *nil by mouth* status. However, when the pharmacist clarified the order with the doctor it was discovered that it was not the doctor's intent for the medications to be withheld. The doctor expected oral medications to be given by the nurse when a patient was categorised as *nil by mouth* (and was not aware *nil by mouth* may be interpreted differently). Other examples of lack of knowledge included; nurses crushing medications without checking whether this affects the medications' integrity, and the provision of the generic advice to 'crush tablets if possible' by some speech language pathologists as this may be misinterpreted as crush if it is manually possible for the tablets to be crushed as opposed to whether the tablet's formulation/integrity will be affected if crushed.

Fasting and nil by mouth confusion and oral medication administration

Relating to the systems level issue of using *fasting* and *nil by mouth* interchangeably is how these terms were interpreted with respect to oral medication administration. In one

example, a pharmacist recounted an incident where a surgical intern changed all the patient's medications to a different route because she was told by her registrar that the patient was *nil by mouth*. However, the registrar did not mean medications cannot be given orally. An in-house survey (unpublished) exploring use of intravenous paracetamol highlighted the breadth of interpretation of the *nil by mouth* terminology and oral medication administration by nurses. Responses to the question of 'what form of paracetamol should be given to a patient who is *nil by mouth*', included:

- "Depends on how strictly *nil by mouth* [the] patient is. If strict, [give via] NG/IV/PR"
- "The patient can take medication [orally] with sips [of water]"
- "Depends on how severe her swallowing is..."
- "Depends on [the] reason for *fasting*, if for procedure [give] oral, otherwise [give] IV"

Although the term *nil by mouth* was often used to describe patients' oral intake status around the time of surgery, many such patients could safely take medications orally; as one surgical consultant pointed out, "very few surgical patients fit the category of *nil by mouth* where this meant total restriction from giving anything orally".

There was uncertainty with the use of *fasting* too; for example, a senior nurse wrote, "Consideration also needs to be for the surgical patients who are *fasting* for theatre as they do require their medications and can swallow and should have medications administered – [but] this is sometimes not attended to as nursing staff may be reluctant to administer meds due to the *fasting* provision". Similarly, one of the consultants expressed, "My personal issues have been staff identifying if a patient is *fasting* preprocedure – able to take meds, or true nil orally need UV/IM/PC substitutes".

The *fasting* and *nil by mouth* terminology use in different clinical contexts affected how medications were managed. This has the potential to place patients at risk of harm; for example, if patients' long-term medications are unnecessarily withheld or if oral medications are given to patients who are unable to swallow.

Important/urgent/critical medications

Some staff strongly believed 'important/urgent/critical' medications such as 'cardiac' medications should be given but these and other medications that staff may deem 'important/urgent/critical' may not be the only important medications on the patient's regime. An in-house snapshot audit (unpublished) found that medications that many would consider 'important/urgent/critical' such as oral antibiotics, neuromuscular systems and central nervous systems medications were withheld (without being administered via an alternative route) when patients were categorised as *fasting* or *nil by mouth*.

Other than 'cardiac' medications there did not appear to be consistency with the interpretation of which other medications were considered 'important/urgent/critical'. Some staff were unaware stopping some medications abruptly may lead to adverse outcomes for the patient; the default for some was to withhold all oral medications without consideration of the 'importance' of the medications. As one of the ward pharmacists related, "Surgical units don't chart/order [medications] if [patient is] NBM (*nil by mouth*) including important meds…"

4.4.3.3. Social influences

Whether oral medications were given or withheld in a patient with restrictions on oral intake often depended on local influences and/or staff prior experiences. Staff working in an area specialising in patients with swallowing difficulties tended to be reluctant to give medications orally in any patients categorised as *nil by mouth* or *fasting*. Peers or mentors also influenced practice; several nurses reported they were, "taught to withhold everything" or as one nurse understood, "[I would] withhold [medications] unless otherwise instructed". Other staff were swayed towards only giving 'important' medications or had been led to interpret that 'important' medications must be given when the patient is classified as *fasting* or *nil by mouth* – sometimes without considering the clinical context.

Past experiences also impacted on medication administration practice; one senior nurse revealed, “I was told off once by a surgeon for giving meds presurgery and once was enough for me not to do it again”.

4.4.3.4. Beliefs

Staff strongly believed that they were acting in the patient’s best interest. Senior doctors needed evidence supporting the necessity of continuing certain medications perioperatively; for instance, a senior anaesthetist questioned, “What is the evidence that missing just one dose is harmful?” There was also the belief that medications considered ‘important/urgent/critical’ must be given but that others could be withheld; for example, one nurse wrote, “Give only important meds, things that can be missed [are] not needed”. Other staff held the firm belief that all oral medications should be withheld when a patient was *fasting* for a procedure to prevent the risk of aspiration; one anaesthetist remarked that some surgeons routinely advised their patients to withhold all oral medications. Adding to the complexity, anaesthetists themselves had a range of individual beliefs as highlighted by this comment, “I personally prefer my patients to have all their normal medications prior to anaesthesia, with the exception of... Anaesthetists, however, have widely ranging views on this and my view is not a universal one”.

4.4.3.5. Role interpretation

Staff interpretation of their role and the opportunity (or lack of) to carry this out sometimes impacted on the administration of oral medications when patients have restrictions on oral intake.

There was widespread expectation that it was the doctors’ role to make decisions about medications; for example, “Nurses should not be withholding any medications without discussing with the doctor” (senior consultant) and, “It is the doctors’ decision what has to be withheld, not mine” (nurse). However, for various reasons, doctors did not always initiate medication-related decisions when patients had restrictions on oral intake, particularly when patients were going for surgery. In the absence of a decision, some nurses took the initiative as shown by this feedback from a senior pharmacist, “Nurses generally withhold [certain medications as], there is no written protocol”. However, there

was some uneasiness with nurses initiating medication decisions without consultation with medical staff as shown from this question and comment from the same pharmacist, "Does the doctor need to document which meds are to be withheld? I think currently this is done by nursing staff, therefore if the doctor is unable to review the meds, could there be a risk of nurses inadvertently administering meds which are to be withheld?"

An added layer of complexity with role perception was the wide range of opinions among doctors about whose role and/or which specialty/unit it was to make decisions about the patients' oral medications.

4.4.4. Discussion

Medications were managed inappropriately when patients have restrictions on their oral intake due to a myriad of barriers. While the overarching factors were those arising at the systems level and the individual person level these were often co-dependent and interrelated. This is likely a result of the complexity of the hospital system and the medication administration process; a multitude of tasks and decisions impact on whether patients receive their medications or not.

4.4.4.1. Lack of guidance

In our setting, contributing to the complexity of the hospital system was a lack of hospital-wide unified guidance for the management of oral medications when patients have some form of restrictions on their oral intake. The process to discovering whether medications were to be administered or withheld was time consuming, frustrating and riddled with too many levels of uncertainty. Staff were uncertain as to which clinician was responsible for making the final decision. This uncertainty was compounded by differences in opinions amongst medical staff and a lack of knowledge and awareness about the medications and oral restrictions in a variety of clinical contexts. The inconsistencies affected workflow leading some staff to resort to or rely on local 'rules of thumb' and other workarounds that were not necessarily appropriate and which had potential to place patients at risk.

Our findings support a 2014 Australian qualitative study of nine surgical nurses focusing on factors influencing nurses to withhold surgical patients' oral medications pre- and

post-operatively.[227] The study found that the ward culture or environment was characterised by a lack of direction and leadership, which led to inconsistent practices and decisions surrounding the withholding of medications.[227] The authors reported that forming part of the ward culture were factors such as lack of guidelines, decisions based on 'a rule of thumb' and diversity in experience and levels of knowledge of staff.[227] Our findings also concurred with other aspects of the paper, such as issues around staff role perception and medication knowledge.[227] The similarities suggest that the barriers to managing medications appropriately in patients with restrictions on oral intake are not confined to our institution.

Fasting and nil by mouth context confusion and medication administration

The culture of using the terms *fasting* and *nil by mouth* interchangeably and employing them in an inconsistent manner seems to be a significant basis for some of the confusion with managing oral medications. *Fasting* and *nil by mouth* may be interpreted as absolutely nothing orally on a stroke ward because it is unsafe to give anything orally to those patients but on a surgical ward it may be understood that oral medications and/or sips of water are allowed. In the wrong context, a stroke/swallowing difficulty patient may be administered oral medications and a surgical patient may be withheld medications needlessly. The use of terminology that potentially confers different meanings in different contexts within the same institution is concerning for its potential to contribute to patient harm.

There is a paucity of literature addressing the *fasting* and *nil by mouth* terminology confusion; however, there is substantial literature on the mismanagement of medications when patients are *fasting* or *nil by mouth*. Publications about the inappropriate omission of oral medications and the potential for harm from this when patients were *fasting* or *nil by mouth* for surgery have existed for a number of years.[8,33,71,228-230] Two of these studies suggest that the *nil by mouth* terminology is misleading and needs defining.[71,229] There have also been a number of case reports discussing adverse patient outcomes, such as 'pill aspiration', resulting from the inappropriate administration of oral medications or other oral intake to patients who were designated *nil by mouth*.[11,13,40] Many of the studies highlighted, as well as official documents such as the Australian 'National Inpatient Medication Chart'[226] and the New South Wales Agency for Clinical Innovation's

'Preoperative fasting in NSW public hospitals'[231] use *fasting* and *nil by mouth* interchangeably. However, as discussed, the interchangeable use of these terms has the potential to adversely impact patient care. Therefore, it is imperative the meaning of these terms is clarified, particularly with regards to the clinical context and oral medication administration.

Relating to *nil by mouth* and medication administration is the issue of inappropriate manipulation of oral medications, particularly when patients are unable to swallow medications and/or require their medications administered via a feeding tube. There is numerous literature regarding inappropriate manipulation of oral medications and the potential adverse implications of this for patients.[12,14,15,232-234] Some oral medications are formulated in such a manner that its reliability, and even safety to the patient, cannot be guaranteed if the medication is manipulated, such as when certain tablets are crushed or split. This medication administration context needs to be considered, along with the *fasting* and *nil by mouth* context confusion. Generic advice such as 'crush tablets if possible' should not be given and 'rules of thumb' such as crushing tablets for administration when a patient has a swallowing difficulty should not be followed without understanding the implications and/or consulting a pharmacist or a suitable reference such as the 'Australian Don't Rush to Crush Handbook'.[235]

4.4.4.2. Systems versus individual person level barriers

Addressing both the systems and the person level considerations is important to minimising the barriers to managing medications appropriately in patients with restrictions on oral intake. The nurse who admitted, 'I was told off once by a surgeon for giving meds presurgery and once was enough for me not to do it again', may have subsequently advocated and/or perpetuated the 'withhold all oral medications when *fasting*' stance and played a part in that 'culture'. The surgeon responsible may have firmly believed he was providing optimal care and in doing so may have contributed to a chain of events that led to the culture of the hospital. So, although these situations began as 'individual person' consideration, the experience eventually contributed to the 'system' issues. In contrast, it could be argued that the system did not provide the capacity and/or means for both the nurse and the surgeon to be apprised of the most recent evidence

regarding best practice for their patients. Nevertheless, at its core, the problem appears to be a lack of standardised guidance, resulting in the observed inconsistency and uncertainty, which would appear more systemic in origin. Therefore, strategies for improvement should initially focus on the systems perspective. It may be possible that improvements to some of the individual person level barriers to managing medications appropriately, such as lack of knowledge and social influences, may follow with the introduction of systems level strategies. Once the systems approaches are imbedded, individual person level issues such as perception of role and responsibility could be further explored and addressed.

4.4.4.3. The systems approach

The medication administration process is highly complicated and has been labelled as a 'complex system' by organisations such as the Institute of Medicine in the US and the Australian Council for Safety and Quality in Healthcare.[19,21] One description of complex systems is 'any collection of a large number of technological and human parts, which are free to interact in a proportionately larger number of ways, such that determining their long-term safety is difficult.[236] The 'complexity' of such a system has been defined as the 'interrelatedness of components of a system' that increases with the number of components in a system, number of relations between them and uniqueness of those relations'.[237] These definitions are highly relevant to our findings and the interrelatedness of the key barriers to optimal medication management identified. A 'systems approach'[19,21,238] is recommended for complex systems. This approach maintains that the overall effectiveness and efficiency in achieving objectives depends on identification, understanding and management of interrelated processes as a collective system.[239] Proven systems-based medication safety practices such as simplification, standardisation and reducing reliance on memory[19,21,238] were needed to address the barriers to appropriate medication management identified in our setting.

4.4.4.4. Strategies instigated at our institution

This exploration of barriers to the appropriate management of medication when patients have restrictions on oral intake informed the design of our subsequent systems focused

quality improvement interventions. A number of systems level strategies have been developed to address the unwanted practice variations, the *fasting* and *nil by mouth* confusion and improve oral medication administration when patients have restrictions on oral intake at our organisation. We now have a hospital-wide standardised policy that specifically distinguishes *fasting* from *nil by mouth.* This policy provides oral medication administration instructions in the context of oral restriction categories. The Policy states:

- The term *fasting* is only to be used before a procedure or surgery and means that all oral medications may be administered with a small sip of water up to one hour prior to the procedure unless there is a clinical reason to withhold, such as oral hypoglycaemics/risk of hypoglycaemia;
- The term *nil by mouth* means absolutely nothing by mouth, including sips of water and oral medications. A different route of administration should be sought where possible;
- *Restricted oral intake* means there are special conditions for giving oral intake; for example, 'sips only' immediately after surgery or texture modifications are required for oral administration. Therefore, medical orders need to be checked and/or the relevant clinical staff need to be consulted before giving anything orally.

The Policy is supported by a Procedure Manual and colour-coded bedside signs that represent each oral restriction category. We are working on incorporating this Policy into our electronic medication management system.

4.4.4.5. Limitations

A limitation of this study was that data had not been collected purposefully for the study or in a controlled and standardised manner. The data were mainly derived from interrelated settings and investigations done in response to real-world, sometimes urgent clinical scenarios that required prompt attention. It was after most of the data became available and the complexity of the problem became apparent that a review of the available findings, to provide context, seemed warranted. This meant that validation of data via investigator and respondent triangulation could not be undertaken. A strength of this outcome is that the barriers identified were derived from a wide range of perspectives.

Despite data being in different formats, there was consistency with much of the findings across formats, suggesting the issues identified were highly relevant to our setting.

4.4.5. Conclusion

Medications were managed inappropriately when patients have restrictions on oral intake and this had the potential to adversely affect patient care. This qualitative study found that many factors contributed to the medication management issue, including lack of standardised guidance, workflow issues and the culture of the system or the environment in which staff practiced. Lack of awareness, confusion over context and terminology, particularly *fasting* and *nil by mouth*, social influences and role interpretation of the individuals also contributed. Our findings suggest the core issues were systemic in origin and systems level strategies were needed to address the barriers. We have subsequently instituted a number of systems approaches to manage the barriers at our organisation, including; development of a standardised, organisation-wide policy to reduce unwanted variations, simplifying and standardising medication administration instructions in the context of oral intake restrictions and clarifying the *fasting* and *nil by mouth* terminology. The Policy is in use at our institution and plans are underway to assess its impact on oral medication administration.

4.5. Chapter discussion

The case reports, investigations of local practice and the barriers analysis established that medication management in the context of oral restrictions was problematic, especially when considered together with the evidence-base from the literature review in Chapter 2. Key factors identified were the use of fasting and nil by mouth interchangeably and the inconsistent interpretation of what either term meant in regards to medication management causing confusion. The interpretation of nil by mouth from different perspectives with potentially different outcomes or actions is risky, particularly if patients are consequently given or withheld their oral medications inappropriately due to an incorrect interpretation. This confusion was amplified by a lack of guidance, leadership

and ownership of the medication administration process. Workflow issues and the culture or local environment in which staff practiced also contributed.

The findings suggested the core issues were systemic in origin and that practical, standardised, hospital-wide guidance for staff on how to manage medications when patients have some form of restrictions on their oral intake was overdue.

4.6. Addendum

- Appendix 1 displays the 'Consolidated Criteria for Reporting Qualitative Studies (COREQ) checklist critiqued against this study.
- The feedback and comments from staff written down by me during the quality assurance process can be considered as 'field notes', which are acknowledged data sources for qualitative studies.[116-118] Section 3.2.1.6. (Methodology chapter) of the thesis highlighted that field notes are appropriate for qualitative inquiry. As stated in that chapter, while there may be some limitations with the use of the feedback and comments field notes, in a guide to field notes for qualitative research the authors state that 'field notes can be useful in subsequent analyses including secondary analyses'.[118] In a recent study, field notes made/collected through academic detailing were used as the primary data source to analyse barriers to opioid prescribing.[117] Using field notes together with other data sources (such as email records and the free text/comments section of a medication survey and paracetamol survey that addressed medications and oral restrictions) provide depth and context to the study.[118] Furthermore, data collected through different methods may be viewed as corroboration or triangulation.[240]
- Although not purposefully collected with the view of research at the time, the 'field notes' for this study had been taken within the boundaries of a central theme – medications and oral restrictions.
- The 'field notes' made by me had been logged electronically onto my work computer (e.g., in a list or table of 'notes' in a word document), written in a notebook initially and then logged electronically or presented as the patient journey mapping (section 4.3.3.1.). Field notes were uploaded into NVIVO for data coding and analysis.

- Ethics approval was given to retrospectively 'audit' the feedback and comments data, including the field notes, obtained during the quality assurance process (see Ethics approval, section 9.5., appendix 10).
- 'Abstraction' of the field notes list/table sources and other data sources, such as emails, relating to medications and oral restrictions, for the study began in 2017 during the PhD candidature.
- There were 77 sources of data (and approximately 120 references), of which seven were field notes list/table sources and two were free text responses from two in-house surveys. The remainder were email correspondence. Although there were many more emails than field notes sources, approximately 25% of the data references were field notes because the field notes list/table sources contained multiple entries
- Author credentials were included in the Cover Letter to the Journal of Evaluation in Clinical Practice and the author information was on the published paper, hence was not presented in the main section of the paper. The author details were: Ms The-Phung To (BPharm, MClinPharm) was a Quality Use of Medicines Pharmacist and PhD Candidate; Professor Jo-anne Brien (BPharm, PharmD, BSc) was a pharmacist, Chair in Clinical Pharmacy (St Vincent's Hospital) and Conjoint Professor of Medicine at the St Vincent's Hospital Clinical School; Professor David A Story (MBBS, MD, BMedSci, FANZCA) was an anaesthetist, Professor and Foundation Chair of Anaesthesia and Deputy Head, Centre for Integrated Critical Care at the University of Melbourne.
- The interpretation of the data may be influenced by the fact that data saturation had not been ascertained; however, the data and findings were valuable and sufficient in providing understanding of barriers to managing medications appropriately when patients have restrictions on oral intake, particularly given the opportunities and circumstances of the project. The data helped to inform and corroborate other works in this PhD.
- The value of having the data from 2010 to 2014 was that it was more likely to reflect the thinking that was underlying the hospital changes at the time. A formal prospective data collection method during the PhD candidature may provide more robust data, but it may also be possible that the timeframe and circumstances of such

a project may not reflect the context of the 2010 to 2014 period. Hence, the data used in this study provided appropriate time related context for the analysis.

Chapter 5. Identifying strategies

5.1. Chapter introduction

This chapter attempts to identify the most prudent strategies to improve medication management in the context of restrictions on oral intake and the most pragmatic approach to implement the strategies. Chapter 4 in general, and the qualitative barriers analysis in particular, suggested that the heart of the issues for managing medications inappropriately when patients have oral intake restrictions were likely systemic in origin. Consequently, a systems approach to improving medication management appears to be required.

Section 5.2 examines quality improvement concepts, specifically systems approaches. This is followed by the layers of consideration for strategy selection, along with justification for the decisions made, for the medication management strategies in section 5.3. Implementation science will be discussed in section 5.4 and the strategies selected for hospital-wide implementation will be outlined in section 5.5.

Like chapter 4, some sections of this chapter recount the sequence of events that occurred towards the development of a policy to improve medication management in oral intake restrictions and hence some areas overlap with my NHMRC TRIP Fellowship. As with chapter 4, the work in this section has been restructured with further information included and explanations with reference to quality improvement and implementation science provided.

Although the development of the improvement strategies commenced prior to the onset of the PhD candidature, the work leading to the final update, hospital-wide ratification and rollout occurred during the candidature.

The majority (over 80%) of this Chapter was done specifically for and during the PhD. As discussed in the Preface and above, and similar to the Literature review section, the remaining portion that overlaps the TRIP Fellowship have been integrated, re-examined and/or presented with inclusion of updated information specifically for and during the PhD.

5.2. Quality improvement

5.2.1. Introduction

Both quality improvement and implementation science efforts are part of a spectrum of approaches that have the fundamental objective to improve the quality of healthcare.[241,242] Although they share some assumptions and techniques[242], they arise from different foundations and are often confused.[243]

Quality improvement efforts 'focus on a patient oriented endpoint and seek to address recognised gaps in providing optimal care'.[244] It is an ongoing process 'that uses a set of tools and methods to achieve measurable changes in processes of care and outcomes in a particular setting'.[245] Quality improvement initiatives tend to begin with a particular issue specific to a healthcare system that is recognised at the provider, clinic, or health system level, which leads to the design and testing of initiatives to improve the specific problem for that particular system.[241] It has its basis in industry[243] and often borrows methods from industry quality control systems to improve best practices and prevent sources of error.[244] As such, it involves systems-level effort to improve the quality and safety of healthcare.[243] (Implementation science is discussed in section 5.4.)

5.2.2. Human factors engineering

Application of human factors principles into the technology design is known as human factors engineering.[246] This is a discipline long used in industries such as aviation and considers 'human strengths and limitations in the design of interactive systems involving people, tools, and technology and work environments to ensure safety, effectiveness, and ease of use'.[181] Human factor engineering considers an overall or 'systems approach' to manage factors that may impact any aspect of the design process: A systems approach takes the perspective that 'the overall effectiveness and efficiency in achieving objectives depends on identification, understanding and management of interrelated processes as a collective system'.[239] Errors are understood as outcomes rather than causes, 'having their origins not so much in the perversity of human nature as in 'upstream' systemic factors'.[68] A system-oriented approach is recommended to reduce medication error.[19]

In human factors engineering, a 'complex system is any collection of a large number of technological and human parts that are free to interact in a proportionately larger number of ways, so that determining their long-term safety is difficult'.[236] The probability of error increases with complexity[246] and the behaviour of a complex system is such that the observable outcomes are more than merely the sum of the parts.[247] Across all disciplines, at all levels, and throughout the world, healthcare is becoming more complex.[247] Factors that 'contribute to system failures can become even more significant in complex, multistep systems such as the medication use process'.[21,22]

Although the essence of human factors engineering 'precludes one size fits all solutions, several tools and techniques are commonly used as human factors approaches to address safety issues'.[181] Human factors systems approaches adapted for the design of safety systems in healthcare and shown to improve medication safety include: reducing reliance on memory; simplification; standardisation; use of constraints and forcing functions; the wise use of protocols and checklists; decreasing reliance on vigilance, handoffs, and multiple data entry; and differentiating among products to eliminate look-alike and sound-alike products.[19] Some of these concepts – many of which fall under the principle of 'respect human limits' – are described below.

5.2.2.1. Reduce reliance on memory

In humans, short term memory is generally weak and the probability that an omission error is made in the absence of a reminder is 1% – relatively high considering the number of tasks and steps that a healthcare worker must perform.[246] Reminders and checklists help make important information readily available[248]: The probability that a person will forget a step in a process when all of the necessary items are embedded in that process has been reported as 0.3%.[246] Consequently, strategies aimed at reducing reliance on memory, such as the use of checklists, are increasingly being implemented as safety measures.[181]

5.2.2.2. Standardisation

Standardisation is an effective strategy for reducing error[246] and is 'an axiom of human factors engineering'; that is, equipment, techniques and processes should be standardised

whenever possible so that reliability can increase, information flow can improve and cross training needs can be minimised.[181,246] Standardisation produces 'a uniform model to adhere to when performing various functions and tends to reduce the complexity and variation of a specific process'; however, standardisation relies on human attentiveness to make certain that a procedure is being adhered to.[248]

5.2.2.3. Simplification

Simplifying key processes can minimise 'problem solving and greatly reduce the likelihood of error'.[19] As the error rate has been shown to increase with the number of steps, reducing the number of steps in a process can substantially reduce the probability of error.[246] Process simplification is regarded as a proven methodology for reducing error and increasing quality by creating greater reliability – even in the delivery of complex care processes, opportunities exist to remove unnecessary steps, procedures, and other sources of complexity.[64]

5.2.2.4. Rules and policies

Effective rules and policies are necessary in organisations as these guide staff toward an intended outcome.[248] Rules and policies are related to a number of medication safety human factors techniques, including the wise use of protocols and checklists, standardisation and simplification.

5.2.2.5. Forcing function

Forcing functions are an function of a design that provides a 'hard stop' by restricting choice or requiring some action 'during a process to help ensure that important information is provided before proceeding'.[181,248,249] An example in medication safety is removing concentrated potassium from general hospital wards, which helps prevent the accidental addition of concentrated potassium to intravenous solutions prepared by nurses on the wards.[181] It has been suggested that even 'leaky' forcing functions or those with a 'soft stop' option may be sufficient to improve compliance for certain tasks.[249]

5.2.2.6. Pilot testing

Usability testing of the design or initiative under real-world conditions should be conducted as much as possible to identify potential problems and inadvertent consequences of new technology.[181] This is vital for pinpointing workarounds – 'the consistent bypassing of policies or safety procedures by frontline workers' – which often occur because of poorly developed 'systems that actually increase the time necessary for workers to achieve a task and frontline personnel work around the system to get work done efficiently'.[181]

5.3. Medication management strategies

5.3.1. Introduction

The background investigations established the confusion surrounding managing oral medications when patients are fasting or nil by mouth. Staff were not only confused about when to give or withhold oral medications but also about what fasting or nil by mouth meant in regards to giving medications. The terms fasting and nil by mouth were being used to mean the same thing, which exacerbated the confusion. Furthermore, there was a lack of standardisation as each unit had their own approach to how medications should be managed – there were even individual variations within units. Although the hospital had Perioperative Medication Guidelines and Fasting Guidelines, these did not address medication management during the time the patient is fasting before a procedure. There was no specific guidance for oral medication management in patients with difficulties swallowing.

5.3.2. The draft consultation paper

The Committee considered the issues identified and agreed that one of the most pressing concerns was that clarity was urgently needed for the confusion resulting from the interchangeable use of the terms fasting and nil by mouth. Other compelling factors were that guidance, as well as appropriate signage or visual cues, was needed for staff at the

point of care to aid decision-making about giving, withholding or manipulating oral medications in patients with restrictions on oral intake. With these concepts in mind, I drafted a consultation paper and prepared the bedside signs – with oversight from the Committee – to highlight the issues and recommend management strategies: Specifically, there needed to be a distinction between the terms fasting and nil by mouth – these should not be used interchangeably. It was proposed that;

- Fasting means regular long-term oral medications should be given with a small sip of water, up to 1-2 hours before a procedure/surgery unless there is a clinical reason for the medications to be withheld.
- Nil by mouth means absolutely nothing by mouth including sips of water and oral medications. A different administration route should be sought.
- Restricted oral intake means check for special conditions before giving anything via the mouth. This category may be used post-surgery for sips of water or in patients who require texture modifications to enable safe swallowing.
- Each oral intake category is to be represented by a traffic light colour, with green for fasting, red for nil by mouth and amber for restricted oral intake.
- Bedside signs* (Figure 3, actual size A4) were to be used to facilitate the oral restrictions messages.

**The wording relating to texture modified diet on the restricted oral intake sign was in response to speech pathology input.*

This consultation paper became the draft Medications and Oral Restrictions Policy (the Policy).

5.3.2.1. Widespread consultation

When developing policies that require practice change, the knowledge and experience of providers must be respected – they need to appreciate and endorse changes in practice, to be 'on board' with at least the intent of the policy; they need to value, support and act on any policy entitlement.[250] I endeavoured to consult as many stakeholders for input as possible. As such, the consultation paper was discussed with key stakeholders including the heads from Stroke, Neurology, Anaesthetics and Medical Units, as well as other

important stakeholders identified by the Committee. In addition, the consultation paper was sent to all department Heads and managers for comment, including Pathology and Nutrition & Dietetics. For each consultation/area, I asked for the correspondence to be forwarded to all relevant staff for feedback and to be referred to the correct person to discuss the Policy if the Head of the unit or the person I contacted was not the correct person.

5.3.2.2. Consultation paper feedback

Much of the feedback for the consultation paper was positive. The area that raised some concerns was the recommendation to 'give all medications unless otherwise advised' to a fasting patient. Some staff worried that medications such as oral hypoglycaemic medications may be given inappropriately. A question common among medical staff was, 'Is there evidence that missing just one dose causes harm?' Some staff were sceptical about the necessity of continuing some medications perioperatively, particularly those medications that they did not consider 'critical' or 'urgent'. Other concerns included that the terminology should be different; for example, it should be 'surgical nil by mouth' and 'medical nil by mouth' rather than fasting and nil by mouth, and that orange should represent the fasting sign rather than green. Many of these concerns had already been considered (discussed below). The two potential areas of uncertainty arising from the feedback lie with the possibility that medications may be inappropriately continued/given perioperatively, such as the administration of oral hypoglycaemics to patients are fasting, and whether the fasting sign should be orange rather than green.

5.3.3. Justifying the recommendations

In formulating the draft paper, the Committee's considerations revolved around:

- Improving medication administration and reducing the risk of medication-related adverse incidents to patients with restrictions on oral intake
- Providing clarity for staff around medication administration in the oral intake restrictions contexts, and

- Providing hospital-wide consistency so that practice variations related to medication management and oral intake restrictions that are potentially harmful to patients are minimized

5.3.3.1. Clarifying the terminology

In a study from Poole Hospital in the UK exploring 'Nil by mouth: a misleading statement' the authors asserted that although 'nil by mouth from midnight' is commonly used to convey the necessity of preoperative fasting for elective surgery patients, it was an inaccurate and misleading term, particularly with regard to oral medication administration.[71] A study investigating medication 'omission after admission' suggested that while nil by mouth is highly appropriate in some patients many were placed nil by mouth for weak or temporal reasons and in most circumstances this should not prevent the giving of essential oral medication.[33] In a study titled 'Nil by mouth needs defining' it was found that nursing staff understood the concept of nil by mouth to include oral drug therapy but there was uncertainty as to who should decide which oral medication is given prior to surgery if the patient is nil by mouth.[229] All these studies emphasised the confusion with the term nil by mouth and oral medication administration.

Fasting is also subject to confusion. A study on the frequency and severity of omitted medication doses found that when a patient was fasting, the majority of oral medications were not given.[228] In Mosby's dictionary of medicine, nursing and health professions fasting is defined as 'the act of abstaining from food for a specific period, usually for therapeutic or religious purposes' and 'fast' as 'abstinence from all or certain foods'. Conversely, Nil by mouth, is 'a patient care instruction advising that the patient is prohibited from ingesting food, beverage, or medicine'.[251] Dorland's illustrated medical dictionary defines fasting as 'abstinence from all food and drink except water for a prescribed period, performed for both spiritual and therapeutic purposes' while NPO is simply 'nothing by mouth'.[252] These definitions clearly distinguish fasting from nil by mouth, with fasting indicating some exceptions to oral intake restrictions allowed while nil by mouth was absolute with nothing allowed.

Figure 3. Draft policy bedside signs

Beyond the issues with risk of medication omission is the risk that a patient who is nil by mouth for medical reasons such as stroke/dysphagia may be inadvertently administered medications (or other solids) orally. This is underscored in a 2011 UK case, where a 'strictly nil by mouth' post-surgical patient was fed pudding then aspirated and died.[11,253]

Consequently, fasting and nil by mouth became separate entities in the Policy, with the former indicating pre-procedure/operative where oral medications may be given up to 1-2 hours beforehand, while nothing is to be given orally in the latter, including medications – a different route should be sought.

5.3.3.2. Simplification and standardisation

Medication safety is a complex area and no single factor is responsible for adverse medication events.[19] There is a high degree of variation within the medication use process, including the involvement of multiple disciplines and a lack of standardisation.[238] Hence a systems approach such as simplification, standardisation and reducing reliance on memory, should be used to improve medication practices.[19,21,238,254] Separating fasting from nil by mouth also functioned to simplify the complexity of medication administration in patients with restrictions on oral intake. A third category, restricted oral intake, encompassed such patients as those needing texture modifications or allowed sips of water.

As people are conditioned to respond to what is familiar[238] a common system that is easily recognisable, such as the traffic light system, may further the message. The red was selected to represent nil by mouth, with restricted oral intake being amber and fasting, green. This traffic light colour system mirrors medication management when orally restricted, for example: nil by mouth (red) is stop, do not give anything orally, seek an alternative route; fasting, (green) is give oral medications when fasting unless there is a clinical reason to withhold them/otherwise advised; and, restricted oral intake (amber) is caution, check for special conditions before giving anything orally, including oral medications (Figure 3).

The placement of the medication administration instructions was also considered (Figure 3). As discussed, since people tend to respond to what is familiar, it was felt that placing

the medication administration instructions ahead of the oral restriction category on the bedside signs may reduce the chance of staff only reading the category and automatically associating it with their previous conception of what the terminology meant.

There was already a culture of using bedside signs for oral restrictions at the hospital so the use of the Policy signs would present minimal change and burden for most staff. Most importantly, the signs would provide staff with a reminder and/or decision aid at the point of care.

5.3.3.3. Continue long-term medications perioperatively unless...

There were two aspects to this recommendation; one addressed the presupposition that omitting a dose or so of medications is not harmful for patients while the other related to the preconception of 'important' versus 'unimportant' medications.

5.3.3.4. Missing just one dose

From local experience, some doctors do not perceive that certain medication anomalies constitute a medication error, especially the omission of medications during the fasting period before surgery. One example is the perception that missing 'just one dose' will not adversely affect the patient. Depending on the medication, as well as the medical condition for which that medication managing, missing 'just one dose' of the medication can adversely affect the patient.[38,74,79,80,223] Although evidence may be conflicting or controversial for some agents, medications where missing 'just one dose' has been associated with adverse outcomes include antiparkinsons medications, β blockers and antibiotics.[32,38,74] There is also a risk that patients may miss more than just one dose. A review of 1882 omitted or delayed medication incidents where the oral route was not available highlighted that length of time for which the patient was nil by mouth was often extended due to delayed operating lists[31], which therefore extended the delay in medication administration. The high likelihood of unexpected delays around the time of surgery and transitions from one area of the hospital to another during this time means that interruption to patients' oral medications may continue for days and more than 'just one dose' of medication will be missed, as was the case with the fasting patient discussed in section 4.2.

Omission of essential long-term regular medications predisposes patients to withdrawal effects, which may range from loss of therapeutic effect, to rebound syndromes, drug resistance and even loss of tolerance to side-effects to certain medications that patients have built a tolerance towards.[37,72,82]

A phenomenon that may further increase the risk of missing more than just one dose is the 'weekend effect', which relates to the period between midnight Friday and midnight Sunday.[255] A study found that patients undergoing nonemergent major cardiac and noncardiac surgery on the weekends have a clinically significant increased risk of death and major complications compared with patients undergoing surgery on weekdays.[256] A 2017 meta-analysis of 97 studies found that weekend admissions were associated with a 19% relative increase in mortality compared to weekday admissions across a variety of diagnosis, including selected surgical conditions.[255] A systematic review and meta-analysis in 2018 (of 39 studies in the UK) found an effect of 1.07 (odds ratio 95% CI [1.03, 1.12]) suggesting that patients admitted at the weekend had higher odds of mortality than those admitted during the week.[257] Possible explanations for this include lower levels of hospital staffing or staffing by relatively less experienced staff and reduced or delayed access to specialised diagnostics or therapeutics that could delay diagnosis or treatment of time sensitive conditions.[255] One could speculate that these mechanisms, together with other factors that extend the weekend effect, such as public holidays, will lengthen medication administration delays, particularly for inpatients preparing for a procedure.

5.3.3.5. Critical or important medications

The concept of critical or important medications is often referred to in clinical practice. Yet, it is uncertain that all staff are able to definitively identify which medications are critical or important and which are not. The Institute for Safe Medication Practice's 'Guidelines for the timely administration of scheduled medications' define time-critical scheduled medications as those where early or delayed administration within of maintenance doses of greater than 30 minutes before or after the scheduled dose may cause harm or result in substantial suboptimal therapy or pharmacological effect.[258] Even for most non-time critical scheduled medications, the institute recommends

administration within 1-2 hours before or after the scheduled time.[258] This is a useful guide and will highlight medications such as antiparkinson's and β blockers if each hospital produces and regularly maintains its list of time critical scheduled medications; however, it may not be necessarily helpful for the management of other medications that ought to be continued if the belief of 'missing just one dose' is harmless for patients persists.

Our staff survey about oral medication administration found that respondents would administer medications such as β-blockers and antiparkinson's medications (which are considered 'critical') and omit medications such as statins (HMG-CoA reductase inhibitors) in a patient fasting before surgery.[225] Studies show that statins should not be interrupted during the perioperative period due to adverse cardiac outcomes and the European Society of Cardiology, European Society of Anaesthesiology and the American College of Cardiology support this concept.[65,79,81] The clinical indication for the statin is important; depending on the indication, it may be safe to miss a dose or so of this medication for some patients but for others the missed dose(s) may predispose the patients to adverse cardiac outcomes. Other examples of medication omission being harmless in one setting but potentially risky in others include the use of the osmotic laxative lactulose for constipation versus its use in hepatic encephalopathy and the use of calcium as a supplement for osteoporosis compared to its use to prevent hypocalcaemia post thyroidectomy: A medication that is considered 'unimportant' in one setting may potentially be critical in another depending on the patient's clinical circumstances.

Patient safety agencies such as the National Patient Safety Agency in the UK and the Institute for Safe Medication Practices in the US recommend the identification of a list of critical medications where timeliness of administration is crucial.[1,258] There is a need for such a list to manage delays in the administration of key medications to patients but it would be difficult to compile an accurate and universal list of critical medications for the reasons already outlined. As the National Patient Safety Agency discovered, after wide consultation with stakeholders, a national list of critical medications could not be recommended 'because medicines considered critical in one hospital may differ significantly from another hospital'.[1]

In addition to difficulties achieving consensus, the critical list would require ongoing review as new evidence and new medications become available. A simpler approach would be to advocate that patients' long-term medications be continued perioperatively unless there is a clinical need to stop them. Consequently, for patients fasting before a procedure/surgery, the Committee recommended that oral medications should be given with a small sip of water, 1-2 hours before the procedure unless instructed otherwise/there is a clinical reason to withhold. This 'give unless advised' approach is supported by others, including The Royal College of Nursing.[84,85,259] A potential risk with this approach, however, is that medications that should be withheld preprocedure such as oral hypoglycaemics and antithrombotics are inadvertently given. In the ideal situation, the doctor/anaesthetist communicates which medications to give or withhold, the pharmacist advises on the appropriateness of giving or withholding the medication, and the nurse administering the medication checks (with the doctor, pharmacist, suitable reference) if unsure. In practice, the situation is likely complex and may not necessarily follow the expected course. Therefore, the impact of the 'give all medication unless advised' instruction need to be investigated. As guidance and to reduce the risk of inadvertent inappropriate medication administration, a 'Medications to consider withholding' list (Table 9) was developed to assist staff with identifying medications that require review prior to giving before a procedure/surgery. Table 9 displays the original list – more recently, the anti-diabetes agents, sodium-glucose cotransporter 2 inhibitors, have been added, as these are associated with increased risk of diabetes ketoacidosis, especially in the perioperative setting.[260]

Table 9. Medications to consider withholding before a procedure

Medication	Reason for withholding/comments
Angiotensin converting enzyme inhibitor (ACEI) e.g., perindopril, ramipril, enalapril	Risk of hypotension. Consult unit/anaesthetist.
Antacids in particulate form e.g., mylanta	Deleterious effects if particulate aspirated.
Anticoagulants e.g., warfarin, dabigatran, rivaroxaban	Risk of bleeding. Consult individual unit protocol.
Antidepressants MAOIs e.g., moclobemide, tranylcypromine	Interactions with many medications used in the perioperative period. Consult anaesthetist.
Antiplatelets e.g., aspirin, clopidogrel, prasugrel	Risk of bleeding. Consult individual unit protocol.
Angiotensin receptor blocker (ARB) e.g., irbesartan, candesartan	Risk of hypotension. Consult unit/anaesthetist.

Bisphosphonates e.g., alendronate	Risk of gastrointestinal burning if taken too close to surgery.
COX-2 inhibitors e.g., celecoxib	Risk of bleeding. Consult unit/anaesthetist.
Cyclophosphamide	Effect on wound healing. Consult unit.
Diuretics e.g., frusemide	Risk of hypotension. Risk of electrolyte imbalances. Consult unit/anaesthetist.
Insulin	(Do not withhold in type 1 diabetes.) Usual dose may require adjusting depending on time/type of procedure. Check with Endocrinology if unsure.
Iron	Gastric discomfort.
Methotrexate	Increased risk of perioperative infections, effect on wound healing. Consult unit.
NSAIDs e.g., ibuprofen, diclofenac	Risk of bleeding. Consult unit/anaesthetist.
Oral hypoglycaemics e.g., gliclazide, glibenclamide, glipizide	Avoid hypoglycaemia for anaesthesia. Check BSL. Give insulin as per unit protocol or consult Endocrinology if unsure.
e.g., metformin	Risk of lactic acidosis in patients who develop acute renal failure due to contrast media.
Strontium	Risk of VTE with temporary immobility.

5.3.3.6. Risk of medication aspiration when fasting

The concern about aspiration was discussed in the literature review (section 2.5.3). As established in the review, the safety of giving clear fluids to patients preparing for general anaesthesia and who do not have any gastrointestinal tract disorders has been demonstrated and this should therefore not be a deterrent for continuing regular medication therapy in the perioperative period.[69] Leading authorities, including the Australian and New Zealand College of Anaesthetists[86] and the Royal College of Nursing in the UK[85], have advocated for the administration of prescribed oral medications with a small sip of water in the pre-procedure period unless advised to the contrary.

5.3.3.7. Policy versus guideline

It was important that the key recommendations for managing oral medications in patients with oral intake restrictions were structured as hospital-wide policy rather than a guideline. Rules and policies are necessary for organisations: Effective rules and policies guide staff toward an intended outcome.[248] The Cambridge Dictionary[261] online defines policy as, 'a set of ideas or a plan of what to do in particular situations that has been agreed to officially by a group of people' whereas a guideline is 'a piece of information that suggests how something should be done. The University of Sydney Office of General Counsel[262] states that, '…a good policy is a tool which makes administration easier, and

allows people to get on with the organisation's core business more efficiently and effectively' and pinpoints some key features of all policies, that is it:

- States matters of principle
- Is focused on action, stating what is to be done and by whom
- Is an authoritative statement, made by a person or body with the power to do so

The following functions illustrate the importance of policies (and procedures) to the healthcare system and patient safety[263]:

- Facilitate adherence with recognised professional practices
- Promote compliance with regulations, statutes, and accreditation requirements.
- Reduce practice variation
- Standardise practices across multiple entities within a single a health system.
- Serve as a resource for staff, particularly new personnel
- Reduce reliance on memory, which, when overtaxed, has been shown to be a major source of human errors or oversights

Policies are therefore directives where guidelines are recommendations. This was important in our consideration of strategies to improve medication management in oral intake restrictions. Consequently, to ensure hospital-wide consistency the subsequent hospital-wide approved document needed to be a directive that all staff use the same terminology, rather than a recommendation.

5.3.4. Consulting the pilot ward

I discussed the practicalities of the draft Policy with a group of frontline nurses from the proposed pilot ward and sought their advice to refine the tools. A focus of the discussion was the layout and wording of the bedside signs. This group of staff agreed that the placement of the medication administration instruction before the oral restriction category, e.g., 'No medications, food or fluids via mouth, (patient name) is Nil by mouth' (Figure 3) was beneficial and logical. The group explicitly suggested that a badge card with Policy information was needed to provide easy access to advice about medications to consider withholding before surgery, as well as a decision flowchart especially for

junior staff and/or those working after hours. These were developed accordingly (Figure 4 and Figure 5).

Informal feedback about the Policy bedside signs was also received from patients and Patient Service Assistants staff. The feedback indicated the messages were clear and easy to understand.

5.3.4.1. Piloting the draft policy

It was essential that the draft Policy be piloted not only to determine its effectiveness but also so that any unforeseen issues arising from its operationalisation may be exposed prior to widespread use. The orthopaedic ward was chosen as the pilot site primarily because of direct links with the Medical Director of Orthopaedics and the Executive member for the Surgical Clinical Service Unit. In addition, evidence suggests that orthopaedic patients are more likely to experience medication errors.[264,265]

The pilot was implemented in May 2012 as part of a NHMRC TRIP Fellowship (APP1035729). Implementation strategies used included stakeholder buy-in, opinion leaders, clinical champions, interactive education sessions, emailed information and audit and feedback.

Data for the pilot was collected retrospectively and were of medications omitted inappropriately when patients were fasting before a surgical procedure. Data were retrieved from approximately 20 patients per month and sampled eight months pre- and post-intervention.

There was an average of about 100 medications per month, of which about 35% were inappropriately omitted at the start of the pre-intervention period. A segmented linear regression analysis showed a level change, that is, the monthly proportion of medications omitted inappropriately decreased by 21.7% (95% CI [10.0, 33.5]) post-intervention, but no change in trend. There was insufficient evidence found to suggest the presence of autocorrelation (based on the Durban-Watson statistic).

The pilot was confounded by transition from paper-based to an electronic medication management system (Cerner®, Missouri, USA) during the study, as well as the removal

of ‘fasting’ from the list of standardised reasons for omitting medications from the platform.

Feedback from staff indicated the Policy was well-received, practical and provided clarity in an area where there had previously been confusion.

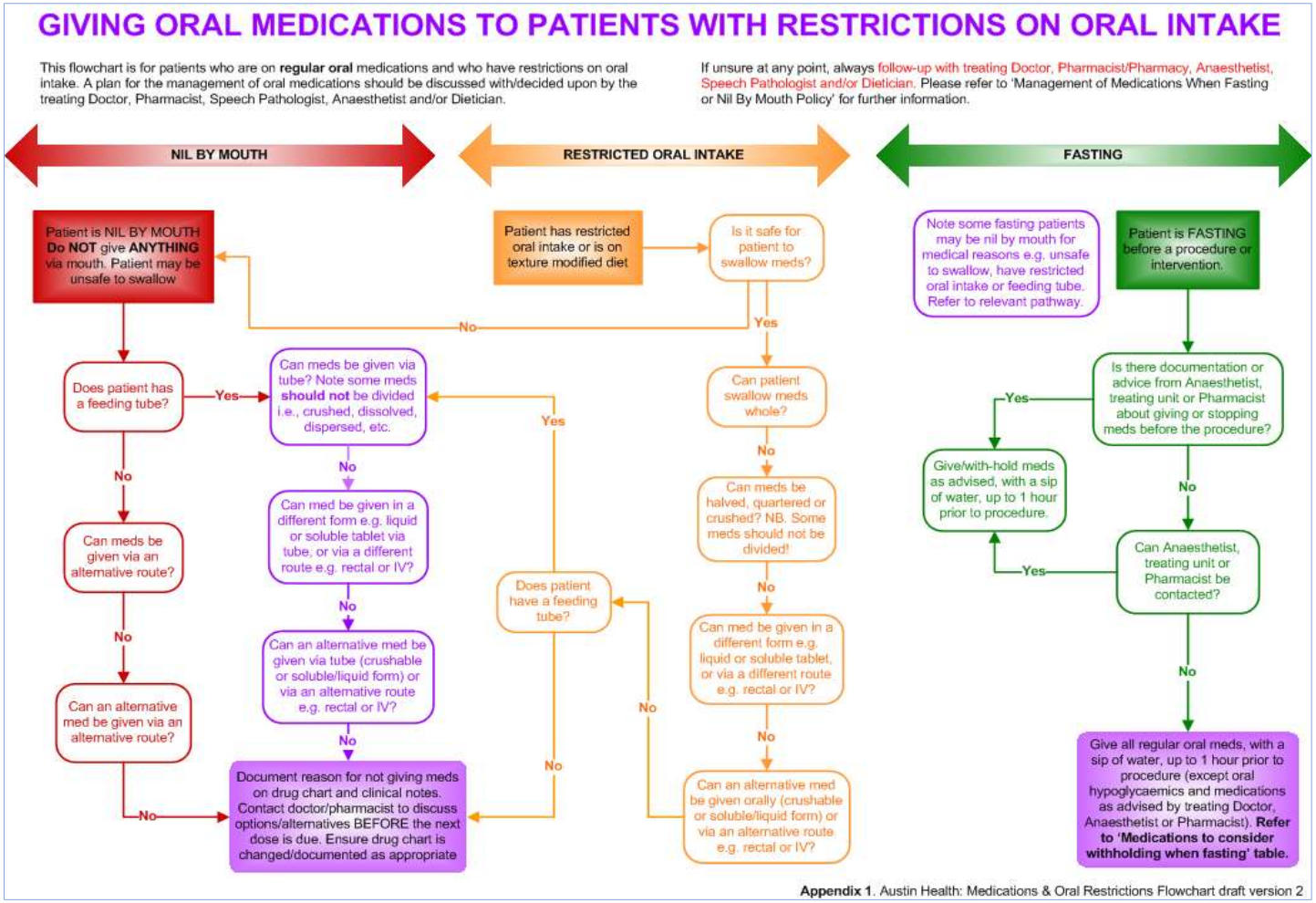
Figure 4. Badge card with table of medications to consider withholding

MEDICATIONS TO CONSIDER WITHHOLDING WHEN FASTING

Medication	Reason/comments
Angiotensin converting enzyme inhibitor (ACEI) eg perindopril	Risk of hypotension. Check with unit/anaesthetist if unsure.
Antacids e.g. mylanta	Deleterious effects if particulate aspirated.
Anticoagulants eg warfarin, rivaroxaban	Risk of bleeding. Check with unit if unsure.
Antidepressants MAOIs eg moclobemide, tranylcypromine	Interactions with many drugs in theatre. Check with unit/anaesthetist if unsure.
Antiplatelets eg aspirin, prasugrel, clopidogrel	Risk of bleeding. Check with unit if unsure.
Angiotensin receptor blocker (ARB) eg irbesartan	Risk of hypotension. Check with unit/anaesthetist if unsure.
Bisphosphonates eg alendronate	GI burning risk if taken too close to surgery.
COX-2 inhibitors eg celecoxib	Risk of bleeding. Check with unit if unsure.
Cyclophosphamide	Effect on wound healing. Check with uniy.
Diuretics eg frusemide	Risk of hypotension. Risk of electrolyte imbalances. Check with unit if unsure.
Insulin	*Do not with-hold in type 1 diabetes. Usual dose may require adjusting depending on time/type of procedure. Check with unit*
Iron	Gastric discomfort
Methotrexate	Increased risk of perioperative infections, effect on wound healing. Check with unit.
NSAIDs eg ibuprofen, diclofenac	Risk of bleeding. Check if unsure.
Oral hypoglycaemics eg gliclazide, glibenclamide	Avoid hypoglycaemia for anaesthesia. Check BSL. Give insulin per unit protocol or consult Endocrinology if unsure.
eg metformin	Lactic acidosis risk in patients who develop acute renal failure due to contrast media.
Strontium	Risk of VTE with temporary immobility.

This table is to be used where arrangements have NOT already been made to withhold certain oral medications. It does not address management of oral medications in the days/weeks before a procedure. Always check if unsure.

Figure 5. Flowchart



5.3.5. Updating the draft Policy

Following the pilot, the draft Policy was refined with further staff consultation. Hospital funding, via the Drug & Therapeutics Committee, was obtained to engage a professional graphic designer to improve the Policy's tools for hospital-wide implementation.

5.3.6. Professional design of the Policy tools

The professional design of the tools was an unexpectedly complicated and demanding process – many factors needed to be addressed. One issue was that, due to aesthetic reasons, there was a strong push from the graphic designer to have the oral restrictions categories appear first, in large font, as the major heading for the bedside signs, rather than the oral administration instructions as presented on the pilot/draft version of the signs. This would have defeated the purpose of the signs because, without the accompanying administration instructions for the categories, it would not confer anything different to what staff may have previously understood. After both formal and informal consultations with staff, a compromise was made whereby both the category and oral administration instructions appeared side by side on the bedside signs (Figure 6, actual size is A4). The flowchart and badge card were also updated (Figure 7, actual size is A3 and Figure 8, actual size is 57mm x 95mm).

5.3.7. Final consultation of the Policy

The updated Policy became a one-page document, with all the associated recommendations forming the Procedure Manual. The latter contained sections on communication processes as well as recommendations for input from each profession. The refined Policy, as well as the results from the pilot, were presented and discussed at numerous forums, including those shown in Table 10.

Table 10. Groups consulted about the Policy

Medical grand rounds	Pharmacy department
Medication Safety Committee	Speech pathology department
Clinical Outcome Review Committee	Neurology and Stroke department
Anaesthetics department meeting	Nursing Educator group
Oncology Quality meeting	Nurse Unit Managers group
Medical unit meeting	Renal department
Surgical Heads of Department meeting	Cardiology department
Intensive Care meeting	Drug & Therapeutics Committee
Other, non-clinical, departments, such as Patient Services Assistants and Food Services, were also consulted	

The Policy was subsequently officially ratified by the hospital's Drug & Therapeutics Committee and Clinical Policy & Procedures Committee in the latter part of 2014. It was made available on the hospital's intranet for hospital-wide implementation.

5.3.8. Summary of quality improvement strategies employed

The evidence-based concepts employed for the medication management strategies and implementation of the Policy were:

- Adopting a systems approach
- Standardisation
- Simplification
- Reducing reliance on memory
- Forcing function
- Rules and policies

Figure 6. Policy bedside signs

Figure 7. Policy flowchart

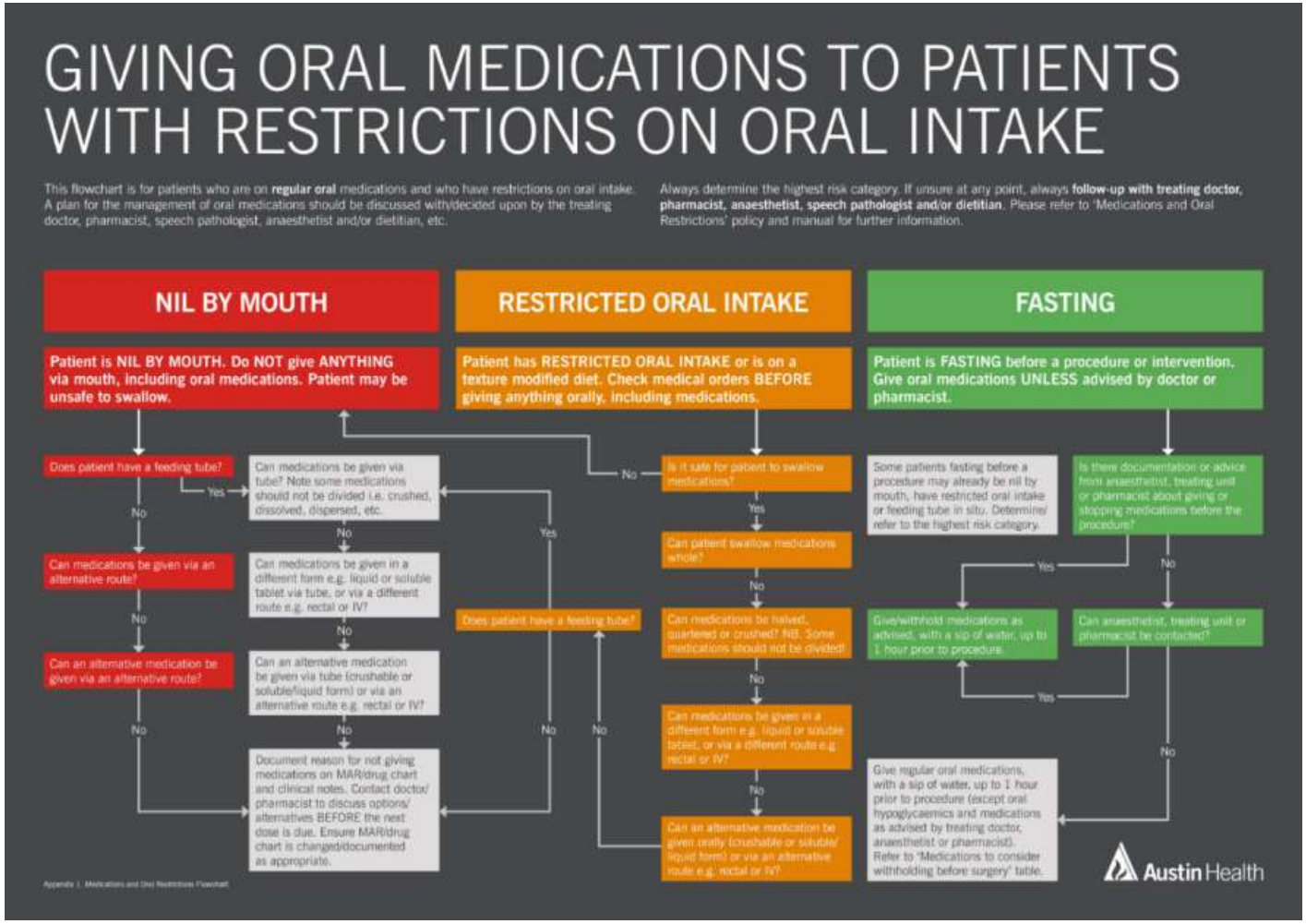


Figure 8. Policy badge card

MEDICATIONS TO CONSIDER WITHHOLDING BEFORE SURGERY

MEDICATION	REASON FOR WITHHOLDING/COMMENTS
Angiotensin converting enzyme inhibitor (ACEI) eg perindopril	Risk of hypotension. Check with unit/ anaesthetist if unsure.
Antacids eg mylanta	Deleterious effects if particulate aspirated.
Anticoagulants eg warfarin, rivaroxaban	Risk of bleeding. Check with unit if unsure.
Antidepressants MAOIs eg moclobemide, tranylcypromine	Interactions with many drugs in theatre. Check with unit/anaesthetist if unsure.
Antiplatelets eg aspirin, prasugrel, clopidogrel	Risk of bleeding. Check with unit if unsure.
Angiotensin receptor blocker (ARB) eg irbesartan	Risk of hypotension. Check with unit/ anaesthetist if unsure.
Bisphosphonates eg alendronate	GI burning risk if taken too close to surgery.
COX-2 inhibitors eg celecoxib	Risk of bleeding. Check with unit if unsure.
Cyclophosphamide	Effect on wound healing. Check with unit.
Diuretics eg frusemide	Risk of hypotension. Risk of electrolyte imbalances. Check with unit if unsure.
Insulin	Do not withhold in type 1 diabetes. Usual dose may require adjusting depending on time/type of procedure. Check with unit/Endocrinology.
Iron	Gastric discomfort.
Methotrexate	Increased risk of perioperative infections, effect on wound healing. Check with unit.
NSAIDs eg ibuprofen, diclofenac	Risk of bleeding. Check if unsure.
Oral hypoglycaemics eg gliclazide, glibenclamide	Avoid hypoglycaemia for anaesthesia. Check BSL. Give insulin per unit protocol or consult Endocrinology.
eg metformin	Lactic acidosis risk in patients who develop acute renal failure due to contrast media.
Strontium	Risk of VTE with temporary immobility.

Confirm with medical staff before withholding. This table is to be used where arrangements have NOT already been made to withhold certain medications.

5.4. Implementation science

5.4.1. Introduction

Over 250 years ago James Lind discovered that citrus fruits were effective for the treatment of scurvy but although the implication of this finding was profound the treatment was not translated into practice until almost 50 years later.[266] Nearly 300 years later, it is frequently stated that research evidence takes an average of 17 years to be incorporated into routine clinical practice.[241,267] Even this depressing approximate 'presents an unrealistically rosy projection, as only about half of evidence-based practices ever reach widespread clinical use'.[241]

Despite 'ample evidence of the efficacy of affordable, lifesaving interventions, there is little understanding of how to deliver those interventions effectively in diverse settings and wide range of existing health systems'.[268] Substantial efforts have not produced quality improvement of significant magnitude.[269] Billions are spent on health innovations, but very little is spent on how best to use them.[268]

Historically, academic clinical researchers focused on 'conducting descriptive or mechanism-oriented studies and intervention studies on highly selected, typically academic medical centre-based populations': Whether or not the findings translate into public health impact has traditionally not been of interest.[241] Recently, a field of research focusing on 'the strategic spread and uptake of evidence-based practices to target populations, known as implementation science, is gaining momentum'.[245] This research area is predicated on the concept that the understanding of how factors and experiences influence implementation of quality improvement efforts are needed to guide the planning and employment of appropriate strategies that are more likely to be effective and sustainable.[270]

5.4.2. What is implementation science?

Implementation science stems from behavioural science[243] and is 'the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice and, hence, to improve the quality and effectiveness of health services'.[244,271] Implementation science usually begins with an evidence-based practice that is underutilised, and then identifies and addresses ensuing 'quality gaps at the provider, clinic, or healthcare system level'.[241] It encompasses the study of 'influences on healthcare professional and organisational behaviour'[271] and uses theory-based models such as specific tools, methods or frameworks to promote systematic uptake of evidence-based interventions into practice and to study designs to achieve objectives within a local context.[243,245]

Implementation research investigates how evidence-based practices are integrated locally and 'explicitly considers barriers and enablers to adoption, focuses on the degree to which the intervention was accurately employed (i.e., fidelity) and the degree to which local adaptations led to more or less successful adoption'.[245] While clinical research generally focuses on the health impacts of an evidence-based initiative, implementation studies normally 'focus on rates and quality of use of the initiative rather than their effects'.[241] Implementation science takes 'an explicit goal of developing generalisable knowledge that can be widely applied beyond the individual system under study'[241] and is a rapidly emerging field of study with infinite practical implications.[244]

5.4.3. Education

Education and information are important tactics when combined with other strategies for implementation.[248]

5.4.3.1. Printed educational materials

Printed educational materials are a simple, relatively inexpensive knowledge translation intervention for the dissemination of clinical information that is aimed at improving the provision of care.[272] Many types of educational materials have been used, including printed or electronic clinical practice guidelines, email summaries, small laminated cards and posters.

Studies have established that the passive dissemination of information, such as education material, to be generally ineffective[272-274]; however, it has been shown to be effective when combined with educational sessions and workshops.[275] Furthermore, this strategy could potentially be useful for raising awareness.[273]

5.4.3.2. Education sessions

Educational meetings are any teaching and learning discussion sessions for staff that functioned to increase their knowledge about the initiative, as well as meetings that discuss process issues of dissemination and managing logistic changes to the organisation.[276] Education and information have been reported to be important strategies when combined with others that strengthen the medication use system; however, the effectiveness of education as a strategy relies on an individual's ability to remember what has been presented and therefore offer little leverage to prevent errors when used alone.[248]

5.4.3.3. Educational outreach

An outreach visit is defined as use of a trained person who meets with a health provider in their own setting or practice to provide information with the intent of changing the provider's performance.[277] Systematic reviews have found educational outreach to be effective in changing prescribing practice[275,277], especially when the visits are combined

with additional interventions[277]; however, educational outreach may be resource intensive.

5.4.4. Clinical decision support

A clinical decision support system is 'any electronic or non-electronic system designed to aid directly in clinical decision-making, in which characteristics of individual patients are used to generate patient specific assessments or recommendations that are then presented to clinicians for consideration'.[278]

The majority of studies show improved provider performance in an array of environments when decision aids have been used to improve knowledge and influence behaviour.[279] An analysis of 70 randomised controlled trials in 2005[278] found that four features independently predicted the decision support system's ability to improve clinical practice:

- provide decision support automatically as part of clinician workflow
- deliver decision support at the time and location of decision-making
- provide actionable recommendations
- use a computer to generate the decision support

The study suggested that an effective clinical decision support system need to minimise the effort required by clinicians in receiving and acting upon recommendations.[278]

5.4.4.1. Computerised decision support

In addition to the previous study, a systematic review of 52 trials found that compared with manual initiation, automatic prompting via 'computerised clinical decision support systems may improve integration into practitioner workflow as well as provide better opportunities to correct inadvertent deficiencies in care'.[280]

5.4.4.2. Decision board

The decision board is a visual aid that presents information in an efficient and standardised manner and is an instrument aimed at trying to improve communication by presenting information simply.[281] It has been studied particularly in the physician-patient

interaction for patient's treatment decisions and results indicate that use of the boards helped patient with comprehension and decision-making about their therapy options.[281] Although there appears to be a paucity of literature on the use of these boards for health professional communication and decision-making, anecdotally, boards dedicated to the presentation of key patient information are widely used in hospitals.

5.4.5. Reminders

Reminders are 'the episodes that healthcare providers receive at the point of care at the appropriate time and are targeted, active and patient specific and can be electronic pop ups that appear on the screen when a chart is opened or a paper reminder, such as a pharmacist's note advising clinicians about a medication concern'.[276] Computerised and manual reminders have been shown to impact prescribing practices and appear to be particularly effective in preventative care.[275]

5.4.6. Champions

Champions are (healthcare) professionals within an organisation who embrace a project as their own and enthusiastically promote it through the stages of its implementation; personal ownership of the innovation or project is a central feature of the champion role.[282] Clinical champions are described 'as possessing passion, enthusiasm and drive to create change, with an understanding of organisational structure and culture that allows them to leverage appropriate relationships for implementing change'.[283] Champions convince others to accept an innovation through meaningful education, advocacy using appropriate approaches, cultivating relationships with end users and navigating professional boundaries via effective communication.[284] The champion may self-identify as a champion or may be selected by peers or leadership to take on this role, which may be informal but also can be formalised.[282]

The presence of clinical champions has been endorsed for patient safety practice change and have been attributed to be the driving force behind implementation of a wide range of change initiatives in healthcare.[284] However, clinical champions appear not to achieve success isolation, with managerial and executive champions appearing to also be

important factors for success, as the three roles were complementary and supportive of one another.[284]

5.4.7. Opinion leaders

The opinions of peers or other healthcare professionals have the potential to influence behaviours among healthcare professionals, and practitioners who are particularly influential are known as opinion leaders.[285] Opinion leaders tend to be those individuals who are well integrated with their peers, are respected sources of information and are often enlisted to exert influence over others' decision-making to increase the uptake of recommendations and adoption of innovations.[285,286]

Despite their widespread use, opinion leaders are not universally effective, reliable and cost effective and identifying them is not straightforward.[285] A Cochrane review found that 'opinion leaders, alone or in combination with other interventions, may successfully promote evidence-based practice, but effectiveness varies both within and between studies'.[287] This review detected that opinion leaders were associated with a median adjusted 12% absolute increase in health professionals' compliance with recommendations but the range across studies varied from a 15% decrease to a 72% increase in compliance.[287] The review also observed that the role of opinion leaders was insufficiently defined, thereby making it difficult to determine the best approach to this intervention.[287]

5.4.8. Audit and feedback

Audit and feedback are processes where healthcare providers receive information about a measurable outcome or process related to the operationalisation of an innovation, for example a measure of the number of patients in the previous month who received appropriate care according to a particular guideline, to gauge their performance in adhering to that guideline.[276] One finding suggested that audit and feedback were most effective in an area where baseline compliance with recommendations was low[275]; however, other reviews found audit and feedback to only have modest effects.[273,288]

5.4.9. Patient mediated interventions

Patient mediated interventions occur when the 'patient provides information that was not previously available to the healthcare professional, which in turn has an effect on the intervention'.[276] A Cochrane review found two types of patient-mediated interventions to have a small to moderate effect – patient-reported health information and patient education – on improving 'professional practice by increasing healthcare professionals' adherence to recommended clinical practice'.[289]

5.4.10. Involvement of stakeholders

Stakeholders may include anyone affected by an issue and/or anyone who can provide input or influence a topic, for example guideline development and implementation.[290,291] Expected users of the innovation such as patients, caregivers and clinicians, as well as researchers, advocacy groups, policy makers or others may be stakeholders.[291] As the importance of buy-in cannot be understated[244], involving stakeholders, particularly in the development phase, has been shown to enhance the chance of successful implementation.[291,292]

5.4.11. Staff engagement

Relating to stakeholder buy-in, engaging all relevant staff is a necessary process to ensure that intended objectives are achieved at each stage of any practice from adoption, implementation and maintenance.[279] Those with 'more involvement may attach greater value to incorporating recommended practices into their behaviour, while those who were not involved may perceive the practice as burdensome or detrimental to patient care making them reluctant to adhere to the practice as it was designed'.[279]

5.4.12. Multiple professions

When compared with the uni-professional reviews, a team approach to dissemination and implementation seems to have a higher percentage of significant findings.[276] For a team, especially a interprofessional one, to work together, it makes sense for them to receive

similar dissemination and implementation strategies; however, it takes time to develop a team.[276] Also, for teamwork to be successful, 'common understandings of patient care need to be established so that patients receive consistent and evidence-based information and practice'.[276] A challenge for those developing multidisciplinary guidelines aimed at several different groups with inconsistent educational levels and backgrounds (including patients) will be to present recommendations in such a manner that are understandable and helpful for all intended groups.[276]

5.4.13. Reviews of implementation

Reviews of dissemination, implementation and impact of clinical practice guidelines in nursing revealed that certain factors may influence implementation, such as 'combinations of opinion leaders and in-service lectures, group culture or belief systems, time and resources, computerised reminders of recommendations, documentation systems, interprofessional partnerships and strategic commitment'.[270]

A qualitative study of the perceptions of staff about factors influencing implementation of best practice guidelines identified that the four most commonly reported facilitators, as perceived by nurses, for implementing nursing or multidisciplinary practice guidelines were: 'presence of change champions, local facilitators, local leaders and/or specialist nurses; staff training, education and problem solving related to guidelines; strong unit or organisational leadership; collaboration with multidisciplinary teams'.[270] The most commonly stated barriers were: staff time, workload and resource constraints; lack of access to equipment and resources; and, staff resistance to change. This study involved 22 organisations in acute, community and long-term care settings consisting of eight clinical resource nurses, 58 nurses and other healthcare providers and 59 administrators.[270]

A systematic review of 88 studies (identified from 12083 studies) focusing on healthcare teams and team-based practice revealed that local opinion leaders, audit and feedback, and reminders were strategies that resulted in significant findings.[276]

A systematic review (of 34 from 4585 identified studies) of interventions that pharmacists ought to employ to impact health practitioners' prescribing practices identified

interventions consistently effective for changing prescribing practices included; reminders (manual and computerised), audit and feedback, educational outreach visits (academic detailing), organisational strategies and patient mediated interventions.[275] Interventions that were inconsistently effective included computerised decision support systems, clinical pharmacists, and educational meetings.[275]

In a systematic review of the effectiveness of research implementation strategies for promoting evidence-informed policy and management decisions in healthcare, the authors reported that interrelating factors believed to be connected with effective research implementation strategies focused on: 'a unidirectional, hierarchal flow from establishing an imperative for practice change; building trust between implementation stakeholders; and, developing a shared vision to actioning change mechanisms'.[293] This was supported by the use of effective communication strategies and providing resources to support the change.[293]

A theory-led overview of systematic reviews on promoting professional behaviour change in healthcare found that 'interventions based on action (such as audit and feedback, and reminders) and various types of education tend to be more likely to successfully change professional behaviour than those based on persuasion, such as local consensus processes and opinion leaders'.[285] The review found that 'the most effective interventions (that is, educational outreach using academic detailing, audit and feedback, and reminders) call for coherence but also emphasise collective action and reflexive monitoring'.[285] It seems that successful behaviour change interventions tended to occur when participants respond positively to 'a clear sense of how what they were asked to do made sense, and how their responses to this measured up to the expectations of external observers'.[285]

5.4.13.1. Multifaceted versus single interventions

A multitude of systematic reviews have determined that a multifaceted approach to dissemination and implementation is more likely to be more effective than single ones.[273,275,276,292] Also, utilising multiple approaches to dissemination and implementation seems to be useful when working with teams.[276] The authors of one review suggested that it is possible that 'bundles of interventions seem more effective than single interventions

because they link together to form social systems that promote change in behaviour norms'; if this is so then it may explain the prevalence of 'negative trials of behaviour change interventions founded on models of individual intentions and behaviours'.[285]

In contrast, some reviews have found no clear evidence to support the superiority of multifaceted versus single interventions[245,294,295]; however, researchers have highlighted that the definition of a single intervention can be problematic because it can constitute a single but composite intervention in one setting as well as multifaceted interventions in another depending on the researchers' interpretation.[296] The authors of an overview of systematic reviews reported that some studies claimed to review single intervention types but actually included bundles of interventions.[285]

5.4.13.2. Passive versus active approaches

Those implementing guidelines and policy makers should consider that implementation may be hindered simply because professionals are often unaware that the initiative exists, or are not familiar with its content.[292] The so-called translation gap is partially due to ineffective dissemination.[297] The 'selection of interventions tailored to prospectively identified barriers is more likely to improve professional practice than no intervention or dissemination of guidelines or educational material alone'.[155] These latter, 'passive approaches to dissemination are largely ineffective because uptake does not happen spontaneously'.[297]

Increased awareness of the importance of applying active dissemination and implementation strategies has arisen from the recognition of the failure to translate evidence in the form of policies or guidelines into practice.[273] Active, multiple and coordinated interventions are likely to be costly; however, there is evidence that they are often more effective.[273,279]

5.4.13.3. Heterogeneity

Although implementation evidence is slowly building, there remains uncertainty and controversy about what is the most efficacious strategy. Issues such as differing contexts,

multiplicity in researcher interpretation and description of interventions and publication bias limits the usability and applicability of research results.

Many authors of reviews of implementation research report difficulties with analysing the data of the underlying studies due to issues with the quality, heterogeneity of study approaches, overlapping definitions of interventions, complexity of interventions and variability in effect sizes.[275,285,293,294] Another limitation is the (small) number of studies that may fulfil the inclusion criteria.[293]; for example, of 7783 articles identified on research implementation strategies to facilitate evidence informed decision-making by healthcare policy makers and managers, only 19 studies met all relevant inclusion criteria.[293]

5.4.13.4. Bias

Publication bias has been highlighted as an issue, particularly by authors conducting systematic reviews of implementation research[285,294] and has implications on the reliability of the results of systematic reviews.

5.4.14. Importance of context

Among factors important for successful implementation, context is central. A study determining factors affecting the use of clinical practice guidelines among physicians found that context was a key factor that either encouraged or hindered the intention to use clinical practice guidelines.[298] The authors recommended that 'guideline implementers should recognise and make better use of context and guideline factors that can have a positive effect on implementation'.[298]

A review of implementation science and quality improvement highlighted four important premises for evaluating implementation of patient safety practices – 'structural organisational characteristics such as size and financial status, external factors such as regulations or financial incentives, patient safety culture, teamwork and leadership at the level of the unit and availability of resources for implementation such as opportunities for provider education and training'.[245] The settings presented in the literature and how it

may or may not apply to the local environment should be considered when identifying and evaluating suitability of implementation strategies.

Despite the significance, context is often not appropriately described in quality improvement and implementation research in the literature.[245] A review of 19 studies found that although many implementation strategies can be used to foster evidence-informed policy and management decisions in healthcare the reasons behind 'why some implementation strategies succeed where others fail in different contexts' were not determined.[293]

5.4.15. Further considerations

The quality improvement outcome has a direct relation with individual patient care while the implementation science factors assesses the processes such as the intervention development, team education, and practical execution.[244] There are numerous quality improvement and implementation interventions or strategies that have been used either alone or in combination to facilitate or compel change.[245] However, as quality improvement focuses on creating timely local change while the aim of implementation science approaches is to create more explicitly theory-based generalisable knowledge that necessarily proceeds more slowly[242], 'challenges exist in balancing the desire to institute rapid changes with the need for vigorous evaluation of benefits versus harms and unintended consequences'.[245]

5.4.16. A pragmatic approach

Ideally, what is needed is an intervention that will do 'more good' than harm, without requiring a degree of specification that would be hard to replicate and/or that only works when implemented by a research team committed to the cause.[299] Currently, there seems to be no single or multifaceted intervention that is effective across all situations, 'nor is a single intervention necessarily the only effective method for facilitating change within a specific setting'.[245] Furthermore, strategies that are more complicated than they need to be should not be implemented[300] and although evidence-based strategies are essential,

ultimately practical issues, such as resource constraints, need to be considered when determining which strategies are feasible locally.[160]

While the strategies discussed have an evidence base, it is important to consider that evidence also suggests that an approach may be effective in one setting but not others. As an example, a study that replicated a previously successful implementation process in a different setting yielded less than optimal results.[301,302] Consequently, any strategies conceived/implemented need to realistically reflect achievability in the local context.

5.5. Hospital implementation strategies

The draft policy was piloted using key implementation strategies such as stakeholder buy-in, opinion leaders, clinical champions and audit and feedback, together with the draft bedside signs/decision aids at the point of care. A nurse clinical champion/the nurse educator and/or I discussed the draft policy with staff at shift handover times. Information about the draft policy had also been sent via email.

For the hospital-wide implementation, feedback and comments from staff relating to the Policy encountered during the policy development process was mapped to the TDF domains to explore potential barriers and facilitators to policy implementation. There were two motives for this – to ascertain whether the strategies used for the pilot was appropriate for hospital-wide rollout and to check that as many aspects of influence as possible had been considered.

The key factors identified centred on *Knowledge*, *Social professional role & identity*, *Beliefs about consequences*, *Memory, attention & decision process*, *Environmental context & resources* and *Social influences*. As an example, staff not realising that harm to patients can occur when medications are withheld inappropriately was mapped under the 'Beliefs about consequences' domain. One strategy to address this is to discuss actual adverse patient events in an interactive education setting. An enabler (*Environmental context & resources*) for this strategy was the availability of regular, shared education session times that could be accessed for that purpose, which enables a large group of staff to be targeted at the same time and allows more time for discussion compared to

handovers, as used in the pilot. The nursing education structure, including Nurse Educators, was an 'enabler'.

Section 7.2.3.2 (Using theory) provides further details on this TDF mapping process.

5.5.1. Summary of implementation strategies employed

The TDF mapping process suggested that the following strategies for the hospital-wide implementation of the Policy, based on consideration of the evidence from the literature and the practicalities of the local context, including experience from the pilot:

- Stakeholder/staff consultation, involvement, engagement, buy-in
- Decision aid/reminder at point of care (bedside signs, badge cards)
- Interactive education/information sessions detailing the case studies
- Opinion leaders
- Clinical champions
- Printed educational materials (printed badge cards, emails, posters, intranet page)

Strategies that had already been instigated during the Policy development process were involvement of stakeholders and stakeholder buy-in and extensive hospital-wide consultation and approval for the Policy. Table 11 details the overall strategies and tools for the hospital-wide implementation process.

Some of the factors that could impact the implementation of the Policy had already been factored in the development process: For example, bedside signs (Figure 6) were developed as a tool to facilitate the Policy's message at the patient's bedside. These signs contain simplified and standardised medication administration instructions in the context of oral restriction categories and will provide a clinical decision aid/and or reminder at the point of care, which also serves to reduce reliance on memory. To some extent, a forcing function is also involved as existing signs were to be replaced with the Policy's bedside signs.

Table 11. Implementation strategies for the policy

Strategies	Tool used	Description
Stakeholder buy-in	Wide consultation for Policy development	Attendance at numerous forums to seek input for the development of the Policy. Email consultation also took place.
	Wide consultation for implementation	Attendance at numerous forums to discuss the impetus for the Policy and raise awareness of the Policy. Emails sent to key staff about the Policy implementation. Meetings conducted with key stakeholders to discuss implementation.
Decision support for Policy	Bedside signs	Traffic light colour-coded with: 1. Green Fasting – give all oral medications unless advised. 2. Red Nil by mouth – do not give anything orally. Seek alternative route. 3. Amber *Restricted oral intake* – check orders/clinical notes before giving anything orally.
	Badge cards	Includes Policy message and table of medications to consider withholding.
	Flow chart	Flowchart guiding decisions for each of the three medication scenarios – fasting, nil by mouth and *restricted oral intake*.
Education	Education sessions	Three to six interactive education sessions were scheduled, during nursing education sessions, per Clinical Service Unit or area, depending on the size of that unit or area. Discussion of the Policy at each medical/surgical unit. Discussion of the Policy at the pharmacy and speech pathology departments.
Information dissemination	Posters	Posters of the Policy placed on the wards and other areas as determined by staff in the relevant area.
	Email	An email summary of the Policy sent to staff prior to the rollout
	Badge card	Badge card with Policy summary on one side and table of medications to consider withholding on the other side to guide medication decisions presurgery
	Intranet site	A site devoted to the Policy containing links to the document as well as other information relevant to the Policy, such as FAQs or 'frequently asked questions'.
Opinion leaders		Heads or Directors of departments or units or key staff member identified as being opinion Leaders were enlisted to promote the Policy. Opinion leaders provided support, especially during presentations or meeting discussions about the Policy.
Clinical champions		Champions to facilitate the Policy implementation were selected by their Nurse Unit Manager and/or Senior Nurse Educator.

5.5.2. Strategies not employed

Audit and feedback were used in the piloting of the Policy and was a strategy considered for the hospital-wide implementation. During the pilot audit and feedback was conducted by me as the project officer; however, this was not feasible for the hospital-wide implementation due to resource considerations. Although the hospital had transitioned to electronic prescribing by the time the Policy was piloted, abstracting the data to provide the relevant information from the electronic platform was still in its infancy and therefore

the process to obtaining meaningful data was extremely laborious. It was impractical for one person (me) to conduct the ongoing auditing and feedback for all areas of the hospital due to the workload required. Additionally, this process involved different parameters for different patient contexts and the ability to abstract the data for use in an efficient and useful way had not been refined around the time of policy implementation. A further point was that a long-term dedicated project officer position was not sustainable. Given the workload and lack of ongoing resources for a project officer to conduct the audit and feedback, this was excluded as a strategy for the hospital-wide implementation of the Policy.

Development of clinical decision support on the electronic medication management platform for prescribing or administering medications when patients have restrictions on their oral intake had also been considered as a strategy and was something that I had proposed at the outset. Unfortunately, this was rejected, during the Policy development phase, by those responsible for the electronic platform due to concerns about 'alert fatigue'. Moreover, as the use of the electronic medication management system was in its infancy at the hospital at that time, there was a lack of expertise as well as lack of capability within the platform itself for a practical decision support to be built for the Policy.

Educational outreach was not considered due to the resource intensive nature of this strategy. Patient mediated approaches may be considered in future.

5.6. Chapter discussion

The most appropriate strategies to improve medication management in the context of oral intake restrictions needs to be considered from an evidence-based quality improvement, as well as an implementation science, perspective. Furthermore, it is important to consider not only evidence-based strategies but also those that are relevant and feasible to the local context. Using the evidence-base from the literature and issues identified (in Chapter 4), this chapter deliberated the merits and difficulties of key quality improvement and implementation strategies with reflection of the realities of the local context. These considerations guided a pragmatic approach of a hospital-wide, unified policy that

simplified and standardised medication instructions. The terms fasting and nil by mouth were separated and clarified, with fasting meaning that oral medications may be given with a small sip of water, up to 1-2 hours before a procedure/surgery unless there is a clinical reason for the medications to be withheld. Nil by mouth meant absolutely nothing by mouth including sips of water and oral medications and a different route should be sought. A third category, restricted oral intake, meant that medical orders needed to be checked to confirm the oral intake conditions, such as 'sips or ice' only postoperatively or texture modified diets.

Policy bedside signs were to replace all existing oral intake signs and were the vehicles to convey the medication administration instructions and serve as decisions aids and reminders at the point of care.

The planned implementation approach built on the medication management strategies, particularly the stakeholder buy-in, opinion leaders, clinical championship and the decision support tools (bedside signs, badge card, flowchart). This was supported by factors such as hospital-wide consultation/approval and formal ratification of the Policy, the nursing education structure and the availability of existing education timeslots that could be accessed to conduct interactive education sessions.

Chapter 6. Assessing the impact

6.1. Chapter introduction

The Policy was implemented hospital-wide in 2015. This chapter investigates the impact of its implementation from three perspectives. Section 6.2 examines the barriers and enablers to implementation and how this may have affected Policy uptake. This qualitative analysis considers the factors encountered during the implementation process, as well as those identified during policy development.

The perspectives and experiences of frontline surgical nurses affected by the Policy eight months following implementation is explored using the focus group format in section 6.3.

In section 6.4, the impact of the Policy on medication administration is investigated with the ITS analyses of medications omitted inappropriately and overall omissions when patients are fasting before a procedure pre- and post-implementation of the Policy. Two separate studies, each investigating a key area of the hospital, will be conducted and combined to enable meaningful comparisons between the areas. Medication data up to 14 months pre- and post-policy implementation will be evaluated.

6.2. Barriers and enablers to the implementation of a policy to improve medication management in patients with oral intake restrictions

This analysis applied the same qualitative approach undertaken in the published 'Barriers to managing medications appropriately' paper presented in section 4.4 of this thesis. Where it differs is the focus on hospital implementation of the Policy, its exploration of enablers as well as barriers and inclusion of feedback and comments received up to 2015, during the implementation process itself.

Every aspect of this study was conceived and conducted by me and overseen by my supervisors. This study has not been submitted to a journal/published.

6.2.1. Aim

To explore the barriers and enablers to implementation of the Medications and Oral Restrictions Policy.

6.2.2. Methods

6.2.2.1. Design, setting and time period

This was a review of staff feedback and comments about issues relating to implementing the Policy. The data had not been purposefully collected and were obtained as part of quality assurance processes during policy development and implementation.

The quality assurance project associated with the Policy occurred at a tertiary-referral, metropolitan teaching hospital in Melbourne, Victoria, with approximately 500 acute-care beds. The hospital provides a broad range of generalist acute, subacute and rehabilitation care and is the state referral centre for liver transplantation, spinal medicine and toxicology.

This study utilised data from the reservoir of feedback and comments obtained from the early phases of the quality assurance project in 2011 through to the Policy rollout phase in 2015.

The hospital's Human Research Ethics Committee granted an exemption for the use of the data in this study because it was deemed a quality assurance activity (Riskman Q No: 24744).

6.2.2.2. Participants and data sources

The data came from staff from the Executive level through to those at the frontline.

The verbal feedback and comments occurred at forums where discussions about medications and oral restrictions issues, the Policy and/or its implementation took place. There were formal presentations as well as group and one-on-one meetings. Examples of these settings included the Patient Safety Committee, Drug & Therapeutics Committee, departmental meetings, unit meetings, Nurse Unit Managers' group, Nurse Educators' group and Quality groups. Many of the presentations and group meetings were multidisciplinary. I noted the feedback and comments (i.e., wrote field notes), either during the sessions or immediately afterwards; none of the sessions were audio or video recorded.

Over the course of the quality improvement project, I gave 113 presentations and convened 44 group and over 80 one-on-one meetings. At least 26 presentations were directed at nurses (but which other professions, such as speech pathologists, dietitians and patient services assistants, may have been present), 12 for doctors (but which other professions may have been present), eight for pharmacists and two for speech pathologists. Of the one-on-one meetings, there were approximately 30 with nurses, 10 with doctors, 10 with pharmacists and five with speech pathologists.

I received emails relating to the Policy from approximately 200 staff. Of these, at least 90 were from nurses, 40 from doctors, 30 from pharmacists and 20 from others, including speech pathologists, dietitians, food services and patient service assistants.

The field notes had been logged electronically on my computer (e.g., in a list or table of 'notes' in a word document), or hand written initially and then logged electronically. 'Abstraction' of the field notes list/table sources and other data sources, such as emails, for the study began in 2017 during the PhD candidature.

6.2.2.3. Data analysis

Thematic analysis[121,124,133] was used to examine the data. This method provides a flexible approach for identifying, analysing, organising, describing and reporting themes found within a data set and offers an accessible form of analysis, particularly for those early in their research career.[132] Data were coded inductively, and then deductively using the Theoretical Domains Framework (TDF).[159,171] The TDF was used to aid organisation of

the data because it is a comprehensive, theory-informed approach developed to identify influences on health professional behaviour and provides a theoretical lens through which to view the cognitive, affective, social and environmental influences on behaviour.[303] The data were then sorted into subthemes, and developed into themes. Data were sorted and re-sorted until a best fit was achieved. Data coding and analysis was conducted by the first author (me) in consultation with co-authors (Jo-anne Brien and David Story); coding, subthemes and themes were discussed and any differences in opinions were resolved by consensus. Coding was facilitated by the NVIVO 11 platform (QSR International, Melbourne).

6.2.2.4. Researcher experience and potential influence on findings

All authors have some experience with qualitative research.

I was the project officer for the development and implementation of the Policy. The third author, David Story, was involved in the development of the Policy. The findings may reflect this association.

At the time of analysing and reporting the study, I, Ms The-Phung To, was a Quality Use of Medicines Pharmacist (BPharm, MClinPharm) and PhD Candidate. Professor Jo-anne Brien (BPharm, PharmD, BSc) was the Chair in Clinical Pharmacy (St Vincent's Hospital) and Conjoint Professor of Medicine at the St Vincent's Hospital Clinical School. Professor David Story (MBBS, MD, BMedSci, FANZCA) was staff anaesthetist at Austin Health and was the Professor and Foundation Chair of Anaesthesia and Deputy Head at the Centre for Integrated Critical Care at the University of Melbourne.

6.2.2.5. Reporting guideline

Appendix 2 displays the 32-item Consolidated Criteria for Reporting Qualitative Studies (COREQ)[108] checklist critiqued against this study.

6.2.3. Results

6.2.3.1. Coding, subtheme and theme development

There were 137 sources of data and approximately 240 references to the data. The majority (130) of the sources were email correspondence. When the proportion of references from the sources where compared, approximately 35% of the items were from field notes (as there were multiple entries in each of the field notes list/table sources).

The codes allocated from the data is shown in Table 12. The first 14 (deductive) codes/categories are TDF domains – the remaining are inductive codes.

Table 12. Codes for barriers and enablers to policy implementation

Inductive and deductive codes	Occurrence
1: Social professional role and identity	116
2: Social influences	2
3: Skills	0
4: Reinforcement	4
5: Optimism	4
6: Memory, attention and decision process	11
7: Knowledge	57
8: Intentions	8
9: Goals	3
10: Environmental context and resources	195
11: Emotion	1
12: Beliefs about consequences	53
13: Beliefs about capabilities	1
14: Behavioural regulation	4
15: Visual prompt	4
16: Understanding	14
17: Risk to patients	21
18: Professional role	102
19: Knowing what to do	26
20: Issues with policy	7
21: Interprofessional relationships	32
22: Information delivery	55
23: Important medications	6
24: Experience	7
25: Environment	193
26: Did not change practice	1
27: Confusion	17
28: Conflict	10
29: Confidence	3

30: Communication	94
31: Clarity	16

A representation of subtheme and theme development is shown in Figure 9 Table 13.

Figure 9. Example of subtheme and theme development

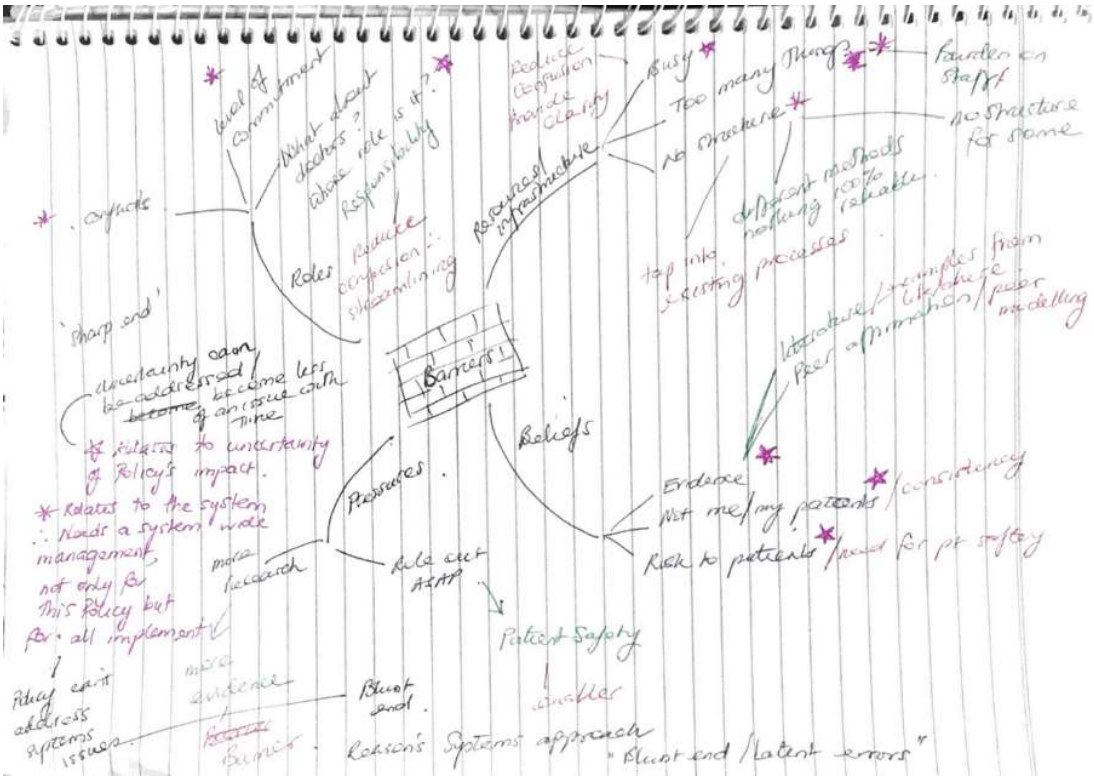


Table 13. Coding tree for barriers and enablers to policy implementation

Inductive Coding Examples	Categories Using TDF	Subtheme	
Time pressure on staff Too busy to do this Getting information to staff reliably and consistently Too many initiatives Patient privacy issues	Environmental context and resources, beliefs about consequences	Resources and Infrastructure	Barriers
Whose job is it…? Interpretation of responsibility Have the doctors been educated? Inter-professional dissonance (dissent, clash, discord, animosity)	Social professional role and identity, social influences	Roles and Responsibility	
Create more confusion Evidence Does not apply to me…	Beliefs about consequences, knowledge	Relevance of Policy	

Hospital-wide support Standardisation and simplification Visibility and tangible support for staff Using existing structure for rollout	Environmental context and resources, knowledge, memory, attention and decision process	Resources and Infrastructure	Enablers
Clarification of roles Leadership, proactive, commitment, facilitation	Social professional role and identity, social influences, goals	Roles and Responsibility	
Relevance to clinical practice Evidence	Beliefs about consequences, knowledge	Relevance of Policy	

6.2.3.2. Resources and Infrastructure

6.2.3.3. Barrier: Burden on staff

Workload

Some staff were concerned that carrying out the Policy would lead to an increase in work load. Some nurses were reluctant to use the signs because they felt it would take more time; for instance, it was considered easier to flip over a small pre-mounted placard that stated fasting on one side and 'nil orally' on the other rather than use the Policy's bedside signs. Although the Policy's signs contained medication administration instructions for each oral intake category it was substantially larger and unable to fit the mounted platform. Others were worried that the Policy would increase their work load if they had to constantly follow-up to verify what the doctors intended. One nurse queried whether medical staff had been educated about the Policy because she is "too busy to check with the doctors if they use the wrong terminology". Doctors too were concerned about potential increase in their workload, especially during busy times such as the mornings. Some believed that they were already too busy as it was and did not have the time to withhold medications on the drug chart/electronic prescribing system. One surgical resident remarked, "It will be hard for doctors to withhold medications"; he thought it was impractical due to the overall number of patients, as well as the number of those awaiting surgery on the day.

Competing priorities

There was pressure for staff to fit in too many initiatives on an already packed agenda. Some nurses lamented that there were "an overwhelming number" of initiatives and that they "move onto the next rollout almost straight away". A Nurse Educator spoke about

the "pressure on wards" and quantified it with, "There are three policies to be rolled out in addition to this one". One of the Nurse Unit Managers related that some of her nurses have "other roles already" and she did not "want to burden them further". Competing priorities also led many Medical Heads of units to only offer a short period of time for their staff to be briefed about the Policy; for example, in response to a request to attend their unit meeting to speak to their staff, one Head of unit requested, "Please make it a brief presentation, as we are always short of time". Others stipulated "five mins" only of contact time for discussing the Policy at their meetings. Access to new interns (graduate doctors) during their orientation was also precious. As a Pharmacy Educator stated, "There's barely enough time to cover the basics", let alone including a discussion about the Policy.

6.2.3.4. Barrier: Lack of reliable and consistent method for information transfer

Too many variations

Attempting to get information across to staff in a reliable and consistent manner was a key barrier. Different areas and different professions seemed to have their own variation of how this should be managed; however, there was not one method that suited staff across the board that was reliable. Some areas relied on handovers and others on their ward 'communication book'. Certain wards assigned clinical champions or key staff the task of disseminating the Policy information and/or assisting with the rollout, while others deferred this to their 'Educators'. Dedicated area/unit education sessions were the mode of information transfer for many; but there were areas where this was deemed ineffective, as attendance was unreliable and it was not possible to capture all staff. One area even had notices on staff toilet doors as a major communication method. Other areas felt that "email is the best way". In fact, for some areas and groups, such as medical staff, email was the main portal of communication despite general acknowledgement that not everyone reads their emails.

A potential issue related to variability in information transfer is the individual interpretation of the Policy by the Educator or clinical champions tasked with facilitating the Policy's implementation and the subsequent teaching of this interpretation to their

staff. An example highlighting this issue occurred when a few staff members fed back that they had been advised that medications considered 'unimportant' could be withheld. These staff had been absent during the Policy information sessions and were educated about the Policy by their clinical champion. The Policy's message was to give all oral medications unless there was a clinical reason to withhold them to improve consistency because individual staff interpretation of what was considered 'unimportant' or 'important' had been identified to be inconsistent and potentially erroneous.

Staff movement

There was perpetual staff movement with shift work, various types of leave, rotations within the hospital (or to other hospitals) and job commencement or termination all adding to the complexity and challenge of the getting the Policy information across to staff. A Nurse Unit Manager acknowledged the "work force fluctuates…it's not constant…" It was also difficult to address certain groups of staff such as bank, pool and agency staff. There were approximately 600 of these staff at the hospital and realistically, according to a senior manager, "…only about 14 would attend an information session specifically conducted for them". Given the high number of staff and the coordination of conducting information sessions to suit all, senior management for this group felt that email was the best option; it was thought this group was "good at reading their emails".

The staff movement issue also affected local championship and leadership of the Policy; for example, during the piloting of the Policy many of the staff who had been assigned champions for the Policy moved to other job/areas.

Education sessions

Many staff indicated they valued "face-to-face" encounters such as an education session (or 'in-service') where the context and relevance of the Policy to practice could be discussed and staff given the opportunity to ask questions and address their concerns. Nevertheless, face-to-face encounters were resource intensive and were not always practical. There was a limit to the number of sessions that could be conducted by one project officer, as well as the limited number of sessions that could be accessed for each area. Many sessions were scheduled during nurse education times, which occurred during

the overlap of the end of the morning shift and the beginning of the afternoon shift and there is a doubling of nursing staff. Theoretically, this frees up nurses to attend but, regardless, attendance was not guaranteed. For some staff attendance at information sessions ate into their precious clinical time and busy schedule.

In some areas, night duty staff education about the Policy was an issue. Although the strategy in the rollout plan recommended each area allocate a 'clinical champion' or a key staff member to educate their night staff, several areas requested dedicated night-time education sessions; however, the night-time sessions did not eventuate because sufficient turnout of night duty nurses could not be guaranteed.

Access to doctors

It was difficult to disseminate information to doctors. Other than 'Grand Rounds', doctors did not have regular, shared meeting/education sessions. Most medical disciplines functioned as 'units' and even within weekly unit meetings or their own educational forums there was no assurance that all relevant staff would be present. One Nurse Educator wryly commented, "…it would be beneficial to address medical staff [about this Policy] but getting them together may prove problematic". Another Nurse Educator stated, "There is room to improve medical education…"

When the Heads of medical units were consulted about the best method to access the doctors in their unit to disseminate information about the Policy most suggested email. This method seemed to be unreliable, but perhaps the effectiveness of the method depends on repetition and perseverance; for example, in response to a request for advice about a lack of response from a group of doctors about a meeting to discuss the Policy, a Nurse Educator for that area advised, "You just need to be persistent with them [the doctors]. Keep sending them emails and [eventually] you will get a reply". For a small-scale implementation initiative and with adequate resources this is a feasible strategy; however, in wider setting and with finite resources and timeline this may be difficult to achieve.

Who to consult?

An unexpectedly complex issue was who should be consulted about hospital-wide documents or concerns. Traditionally, the initial point of contact for consultation about

any policy is the Head of department or unit. For this Policy, the draft document was sent to all Heads of department and/or units (as well as key stakeholders as identified by the Committee) for comment and for consultation with their staff. Discussions and presentations about the Policy also occurred at numerous forums. Notwithstanding, there was no guarantee that staff in that department or unit were aware of the Policy's existence. When the Policy was discussed with a senior consultant in the lead up to the hospital-wide rollout he complained, "We are never consulted about anything …we just get told what we have to do". The Head of that unit had been consulted during the development phase and had responded in full support of the Policy. Although some Heads of departments/units may forward the Policy and/or discuss it with their staff and/or approve the Policy on behalf of their area this did not translate to their staff being informed or necessarily agreeing with the decision.

6.2.3.5. Barrier: Sign placement concerns (one size does not fit all)

The logistics of where to place the signs and the visibility of the signs were a concern in a small number of areas. Some wards had a common eating area and others, such as the short stay units, longer stay and mental health wards, had differing layouts to the rest of the hospital. A Nurse Coordinator for one of these wards commented, "Since most of our patients are spending their day in the lounge and medication is administered while they are in the dining room or in the lounge, displaying the card [Policy sign] in the bedroom wasn't a real choice for us". In other areas, there was the perception that displaying the signs may cause sensitivity or a loss of privacy for certain patients and their families.

6.2.3.6. Enabler: Hospital-wide endorsement

The Policy's concepts generated much interest and garnered wide support across the hospital, most likely because the impetus for the Policy came from several medication-related adverse patient incidents. Presentation about the Policy was invited and the Policy was endorsed at numerous forums within the hospital, including; The Drug and Therapeutics Committee, Clinical Policy and Procedure Committee, Medication Safety Committee, Clinical Outcomes Review Committee, Surgical Committee, Nurse Unit Managers group, Nurse Educators group, departmental and other meetings.

This wide endorsement provided the backing that staff at the frontline required to confidently carry out the Policy. At one of the information sessions, a Nurse Educator emphasised to nurses in the audience, "...the Policy is supported by the hospital. You can refer doctors to the information [if there are any concerns]".

6.2.3.7. Enabler: Hospital-wide simplification and standardisation

Many staff seemed to support the Policy because it provided much needed clarity in an area that often caused confusion. The reasons for the confusion were varied and complex but likely attributable to a lack of guidance, lack of consistency and interpretation of oral restrictions language, and a lack of understanding of oral restrictions context and how this relates to oral medication administration. Hence, simplifying and standardising medication administration instructions and oral restrictions language across the board provided "good clarification" and "made sense at the bedside" for many staff. One consultant concurred that, "…separation [of what fasting and nil by mouth means] is exactly what we need" while a junior doctor agreed that there needed to be a "standardised procedure, especially with anaesthetists who can get upset if tablets are given [to patients prior to surgery]…" During an information session for the Policy, one of the nurses in the audience admitted that although she was "ok with it [the fasting/nil by mouth confusion] now" she had "problems with this" when she first started out and indicated that the Policy provided the clarity needed. Reflecting this thought process, a senior nurse who read the Policy exclaimed, "Where was this [Policy] when I was a baby nurse?" There was also a general feeling that the Policy signs provided clarity at the point of care; it was "visible" and was a source of communication for all relevant staff.

6.2.3.8. Enabler: Access to existing resources and practices

The nurse education infrastructure, and Nurse Educators in particular, were invaluable resources. Many Nurse Educators embraced the Policy and took responsibility for its promulgation to their staff. The nurse education infrastructure also consisted of nurse education sessions, which were dedicated sessions that were pre-allocated several times per week during the morning and afternoon shift change period where there would be a doubling of nurses. These sessions served several purposes including as a forum where

new policies and guidelines may be discussed. During the rollout planning stage, one of the Nurse Unit Managers suggested, "If the [Policy information] sessions get added to the education planner we can ensure there aren't competing requirements for the staff". Having access to this pre-existing platform was advantageous to the implementation of the Policy as it minimised impact on nursing time and followed a known path or expectation for nurses on the ward. It was also beneficial in that it was open to all nursing staff working in the area. Rather than organising dedicated education sessions for certain groups of nurses such as bank, pool and agency staff (in which very few would attend), one Nurse Educator advised, "…get them to ward sessions – utilise existing ward in-service". Depending on the topic other staff/professions were also welcome to attend.

There was already a tradition of using bedside sign for several situations, including oral restriction, before the Policy. Staff, particularly nurses, were already putting up signage for their patients. Hence, for most areas the Policy bedside signs were not an extra onerous task.

Education sessions

Many staff expressed their appreciation for the content provided in the education sessions, including those who were initially doubtful about the merits of having the sessions. A Nurse Educator who was unconvinced an education session about the Policy was needed conceded, after attending one herself, "I do agree [the session was needed]…so that you can introduce the reason for doing the project…" A Nurse Unit Manager commented in support of the sessions, "…staff need to know why we are doing this" and a Night Duty nurse stated, "You can read all the information but this presentation clarified everything. It made sense". This reception also appeared to apply to medical staff as shown by the feedback from a Nurse Educator, "…medical staff present at meeting were receptive and interested in hearing about the Policy".

An alternative dissemination strategy

A dissemination strategy in some areas was the back of staff toilet doors – a few surgical doctors confessed they already knew about the Policy because of this strategy. There were

areas that routinely used this strategy, but it was not a consistent approach across the hospital due to hygiene concerns and shared facilities with the public.

Nurses as a source of dissemination

Nurses played an essential role with information dissemination and operationalising the Policy. An incident underlining this point occurred during the piloting of the Policy – one of the senior nurses was overheard clarifying with the doctor, "We are piloting new terminology on this ward. What do you mean by nil by mouth? Do you mean the patient is fasting for surgery and can have their meds or do you mean they can't have anything at all via mouth?" Reinforcing that nurses play a significant role in information dissemination, another senior nurse observed, "I think that the language change will be driven by the nurses and will take some time to convert". This was also echoed by a statement from a senior pharmacist, "I think the nurses have a grasp on this – and they're the ones educating the doctors".

6.2.3.9. Role perception

Barrier: Role and responsibility

Role perception and interpretation of responsibility regarding operating the Policy influenced its implementation. Concerns were voiced by some staff about whose role it was to carry out specific aspects of the Policy. The problems, as viewed by a variety of staff, ranged from who should be putting up the Policy signs, to whose responsibility it was to withhold medications and who had the final say in the medication administration process. Junior nursing staff were particularly anxious about whose responsibility it was to put up the signs. Other nurses were concerned about whose job it was to decide whether patients were fasting or nil by mouth.

Facilitation of the Policy implementation and rollout process fell to Nurse Educators, their delegates or local area clinical champions but there seemed to be differences in the interpretation of what this facilitation meant and/or how it was executed. To some, for example, facilitation was setting a date and booking a venue for the education sessions – no further assistance, including set-up on the day, were provided. This sometimes hindered the smooth execution of the sessions, especially when the audio-visual

equipment did not work and ate into the precious contact time. Additionally, more staff may have attended if someone familiar with the area rounded up staff to attend the session instead of relying on the presenter to do so or relying on staff attending of their own accord.

Although the Policy rollout plan specifically advocated that each area enlists local clinical champions to implement the Policy in their area, this was not always done. As an example, a Nurse Unit Manager and an assistant took on the task themselves; "We didn't have clinical champions. Just…[another person]…and I doing the rounds". This may have been a resource issue but it may also have been a role expectation concern; another Nurse Unit Manager admitted, "...and there are others that can't be relied upon," when she discussed about not wanting to further burden some of her staff who already had extra responsibilities.

Barrier: Inter-profession considerations

Professional discordance was encountered over which profession was responsible for executing certain aspects of the Policy. Many nurses believed it was the doctors' responsibility to ensure that patients' oral medications were charted appropriately, in particular whether medications should be given or withheld. Therefore, the Policy's position advising that all oral medications were to be given when patients were fasting unless advised by the doctor was "a big ask for nurses" according to some nurses. Some were worried that other professions, particularly doctors, will not fulfil their responsibilities with carrying out the Policy. During an information session about the Policy one nurse strongly asserted, "[it's the] doctor's responsibility to be identifying which ones [medications] to give and withhold," while another nurse questioned, "What are the doctors' responsibilities? … [it's] too much on nurses".

There was considerable anxiety expressed from nurses about whether doctors were aware of the Policy and the potential impact of this on nurses. A worried nurse said, "Doctors need to know the categories because if they keep writing something and not using the correct terminology then it will be a problem". Another frustrated nurse asked whether doctors were being educated about the Policy and grumbled, "I don't have the time to go and chase them [the doctors] to check what they mean when they say nil by mouth". Some

doctors were likewise exasperated with the Policy and its potential effect on their function and authority on clinical decisions. This was highlighted by an incident during the pilot of the Policy where a speech pathologist categorised a patient as nil by mouth but the doctor was resolute that oral medications be given. When the decision was challenged, the irate doctor rejected any opposition with, "Speech can advise but we (doctors) can override".

Enabler: Role and responsibility

Many areas supported the Policy implementation plan and assigned clinical champions or had de facto champions, such as their Nurse Educators, to assist with the implementation. A Nurse Unit Manager from one ward reported that her champions "were responsible for informing night staff and also changing over the signs on the day of the rollout". Many champions and/or Nurse Educators held themselves accountable for the Policy implementation process: some not only coordinated the information sessions but also ensured facilities were available and functioning, ensured relevant staff were rounded up for the session and attended a session themselves and provided input during discussions. Some even took the initiative of inviting other (non-nursing) staff, as demonstrated by this comment, "Just to let you know, I have invited all the wards, medical and allied staff to these sessions". Some Nurse Unit Managers and/or their champions continued to facilitate the Policy with the education of new staff; one Nurse Unit Manager advised, "I have added this Policy to my orientation to new staff – so I explain the process to them so they understand what is required of them to do and I also explain the difference in terminology". Similarly, a Nurse Educator informed, "I usually repeat sessions when new staff commence".

Other professions too took responsibility for their role in carrying out the Policy. As an example, during a conversation with two interns (doctors) about assessing and/or withholding patients' medications prior to surgery, one intern stated matter-of-factly, "It's what we do anyway" despite the fact her colleague had emphasised the pressures and busyness that makes it difficult to achieve this task, particularly during the morning rush. Speech Pathologists embraced the *Restricted Oral Intake* bedside sign and incorporated it into their practice.

Enabler: Inter-profession considerations

The Policy was developed with in-depth consultation with a broad spectrum of staff, professions and specialties. Inter-professional concerns were considered and where it was feasible, these were addressed during the Policy development process. Speech pathologists, for example, were initially reluctant to be involved, with many proclaiming, "It's not my role to advise about medications". However, some speech pathologists were already inadvertently giving medication related advice by providing the generic recommendation 'crush tablets if possible' for certain patients requiring texture modified diets. This advice could be interpreted as a directive as oppose to a suggestion to check if it is safe to crush the tablets. Hence, there needed to be agreed, well thought-out communication pathways and consistent language across all professions, including abolishment of the 'crush tablets if possible' advice. The collaboration with speech pathologists resulted in the agreement that they would flag that 'a medication swallowing problem was identified' and then either discuss the management with the pharmacist or recommend that the pharmacist be consulted for medication management.

6.2.3.10. Applicability and credibility

Barrier: Applicability

There was some uncertainty about the applicability of the Policy to practice. Some staff expressed concern that the Policy's terminology may cause confusion because people are "used to the old terms". One registrar (doctor) commented, "It'll require a lot of education emphasising that fasting is a completely different concept to NBM as patient can be both, either or neither and to check and clarify if in any doubt". A consultant had similar reservations, "…the implementation of the NBM/fasting policy is likely to cause great confusion for many, many months". Others, including a senior medical consultant, felt that the terminology was inappropriate, "… [it] should be medical nil by mouth and surgical nil by mouth…" Another senior consultant observed, "…fasting should be an orange sign rather than a green sign". Nursing staff also had their own interpretation of what the terminology ought to be, for example two nurses disputed, "It should be fasting pre [and/or] post [surgery] as opposed to fasting before surgery", and, "Isn't fasting and

nil by mouth the same thing?" The latter was echoed by a surgical registrar who stated, "My training was to use fasting and nil by mouth interchangeably".

A few staff were concerned about the potential consequence of the Policy; for example, a senior nurse stated, "…the doctors never review medications preop…so patients may receive medications that need to be omitted until post-surgery".

The likelihood of certain types of staff being persuaded by the Policy was a consideration. A senior nurse offered the following advice, "Interns (junior doctors) are impressionable but consultants are 'old school' so [will be] harder to convert". She suggested to "connect with interns and registrars [as it is] not a priority for consultants".

Some staff felt the Policy did not apply to them and/or their area; for example, a few intensive care unit nurses questioned the need to have the Policy signs in their ward due to 'one-on-one' nursing. Other nurses were resistant to having the Policy implemented, asserting their area was different to the rest of the hospital because they have a different patient population. A further reason, according to these nurses, was that staff in their area already knew what to do. There was also resentment with the (perceived) increase in workload for "something that was not a problem" in their area.

Barrier: Credibility

The credibility of the Policy and/or some of its concepts were challenged by a number of staff; for instance, when changes were made to the electronic prescribing platform (during the pilot period) a senior nurse remarked, "I am concerned that prior to any official data regarding the management of [the] Fasting and *Nil By Mouth* patient that we have removed…[fasting as a reason for not giving medications]...already". Some medical staff felt that stronger evidence was needed to support the necessity of continuing certain oral medications perioperatively, especially those that they consider 'unimportant' or not critical. Similarly, some were dubious about the potential for harm with patients missing 'just one dose' of their medications. Others questioned the Policy's instruction that oral medications should be given up to one hour prior to a procedure due to the belief that all oral intake should be withheld while fasting for a procedure/surgery or at least two hours prior.

Enabler: Applicability

Many staff found the Policy relevant and appropriate to their practice, with many saying the Policy "makes sense" and that "there is more clarity about the terminology". A ward pharmacist conveyed that the Policy signs were useful because it allowed her to identify the oral intake status of the patient at the bedside without having to specifically search for that information. One of the Nurse Educators related that the "negativity to change did not happen with this project", implying that the change was helpful and accepted by staff. Other indications of the Policy's applicability were multiple requests to implement the initiative in other areas when the Policy was being piloted; for instance, "I've been asked by a few nurses on my ward if we could implement the NBM traffic light systems...?" (ward pharmacist) and, "Just wondering if there are any plans to roll out the new NBM forms on level x?" (senior medical consultant).

The importance of hospital-wide consistency to address the confusion that was associated with several known adverse patient incidents gave the Policy some influence, especially for those who initially felt that they or their area were exempt from the Policy. Some of the resistance to implementing the Policy was attenuated when staff acknowledged that they have bank, pool and agency as well as other staff rotating through their area. Moreover, as the Policy was a medication safety initiative this corresponded well with the Australian Commission on Safety and Quality in Health Care's National Safety and Quality Health Service Standards.[304] The idea of the Policy being associated with medication safety and a national standard was significant for some.

Enabler: Credibility

Pilot results

Piloting the Policy gave it credence. The pilot results (unpublished) suggested that, in patients fasting before surgery, there was a reduction in the number of medications (such as 'cardiac medications' and proton pump inhibitors) omitted inappropriately following Policy implementation in the pilot ward. The pilot also helped to resolve some concerns raised by staff; for example, a senior consultant suggested that the fasting sign should be orange instead of green during the Policy development phase. When this was raised again

by the same consultant prior to hospital-wide Policy implementation, it was possible to report that the colour coding had not been an issue during the pilot. The risk of patients inadvertently given medications they should not have perioperatively had been a concern for some. This concern was allayed with the report the incidence of inappropriate administrations during the pilot was low (five of over 3000 administrations).

Case reports

The adverse patient incidents that inspired the development of the Policy were persuasive facilitators for the implementation of the Policy. Providing the background for the Policy and discussing the adverse impact of inappropriate management of oral medications in those patients helped staff understand the need for the Policy; staff were generally motivated to provide optimal care for their patients and understanding the background gave staff the context needed for their own clinical perspective. As explained by senior Nurse Educator, "Adults learn when they understand the reason why".

Peer affirmation

Peer representation and support was crucial for the implementation process. Having influential staff, including a leading surgeon, respected anaesthetist and a well-regarded nurse executive member on the Policy development committee gave credence to the project. It lent the Policy authority, especially among the team members' peers, co-workers and staff. For those who remained unconvinced or were cautious affirmation from their own peers or another specialty moderated their doubts. One consultant was unconvinced about the Policy's instructions to 'give oral medications with a small sip of water up to one hour prior to surgery' until a colleague advised, "Tablets and a sip of water are fine. In fact, it can be a problem if they don't take their morning antihypertensives and antianginals". Another senior consultant stated, "As long as you have Anaesthetics onboard, I'm happy for ALL meds to be given to fasting patients with the exception of …"

6.2.3.11. Considered approach versus unacceptable delays

It was essential to ensure that the development of the Policy and the consultation and implementation processes were sufficiently robust; it was imperative to garner as much

support as well as take into consideration as much feedback as possible. In addition, it was necessary to pilot the Policy prior to hospital-wide implementation because as one senior consultant sagely advised, "This would mean that the Policy would have some local evidence-base and problems can be sorted out rather than promulgating a policy that may have unforeseen flaws". Another senior consultant agreed it was tempting to "ride the wave of enthusiasm" and roll out the Policy but "we need to make sure everything is working on a smaller scale first. Nothing worse than rolling out something only to wish we had changed a small (or large) section". Unfortunately, this took time, which aroused criticism. A senior nurse mused, "As the policy work and decision-making tool are probably still some time away, I worry that in the meantime similar incidents with patients receiving medications when unsafe to swallow may still occur. This could be a preliminary barrier (awaiting something more permanent) to help address immediate patient safety concerns". One consultant who was very supportive of the Policy became so frustrated with the delay in its rollout that he protested, "…I was wondering what remaining hurdles there were to us rolling out this signage… I do not understand why it needs approval from by all the committees you have listed. This is a quality issue and patients continue to miss medications and remain at risk of aspiration".

6.2.4. Discussion

There were significant barriers to the implementation of the Policy but there were important enablers too. Both barriers and enablers seemed to fall within the same broad-based thematic structure, namely resource and infrastructure, role perception, and perceived applicability and credibility of the Policy. One explanation is that many barriers had been identified pre-implementation and existing avenues (enablers) were sought/capitalised on to manage the anticipated barriers; for example, use of existing resources such as Nurse Educators and nurse education sessions to reduce the burden on resource and infrastructure; a collaborative approach to Policy development and hospital-wide endorsement to minimise inter-profession concerns; and, using case studies, pilot results, peer affirmation and alignment with the National Medication Safety to buffer concerns relating to credibility and applicability of the Policy. Notwithstanding, the enablers/strategies appeared to be insufficient against some of the more challenging barriers such as such as staff movement, communication structure and role perception.

6.2.4.1. Resources and infrastructure

Some of the challenging barriers potentially compromising the uptake of the Policy were related to resource and infrastructure. It is difficult to ensure staff education and awareness of the Policy with ongoing staff movement, turnover and limited or lack of access to certain groups of staff. In addition, staff workload, competing demands and significant variability in the structure for information dissemination from area to area and group to group will likely affect the uptake of the Policy. Many of these barriers were not unique to our setting[270,305-307] and this suggests that there are issues at an organisational or systems level that are beyond the confines of this Policy's implementation. Unless these organisational elements are addressed it is likely that these barriers will remain a factor in other/future implementation initiatives.

Local context

Consideration of local needs and context – what is known to work in that area as determined by those working in the area – and relying on local leadership were important for implementation of the Policy; however, there appears to be a risk of inconsistency and suboptimal implementation with this approach. There seems to be a reliance on emails as the sole dissemination method for some areas or groups, with some believing that 'email is the best way' and that staff were 'good at reading their emails'; however, there were also acknowledgements among many staff that not everyone reads their emails. A 2015 Cochrane review of email for clinical communication between healthcare professionals found that there is currently a lack of evidence to reliably support this mode of communication.[308] There was also the potential that the individual interpretation of the Policy by the clinical champions and the subsequent teachings of this interpretation to other staff may be at odds with some of the aims of the Policy, as represented by the feedback that a champion had advised that medications considered 'unimportant' may be withheld pre-surgery. The concern is: was this advice given in context or as a standalone and which medications were classified as 'unimportant'?

Medical staff consultation

As a group, there were challenges with access to medical staff for dissemination and education about the Policy. In contrast to the nursing education infrastructure, there was not a regular shared forum that could be accessed as an avenue for medical staff education, prompting one Nurse Educator to comment, 'there is room to improve medical education'. Educational outreach, combined with other interventions, has been shown to have effects on prescribing[277] and this may be a possible strategy to address medical staff education about implementation initiatives; however, this is resource intensive and will require ongoing infrastructure support to achieve.

There also seems to be some controversy over who should be consulted about the Policy. The Head of department or unit was the initial point of consultation for this Policy, which seemed to be the most logical approach as research indicates there is a perceived hierarchy within the medical culture.[309,310] Nevertheless, the structure of medicine, though hierarchal, is modified by the independent practitioner status of each doctor.[311] This could be one explanation for why, although the unit Head was consulted, one senior doctor felt "we are never consulted about anything …we just get told what we have to do". This requires consideration in future implementation initiatives; who should be consulted, if not the Head of department/unit? Should every senior medical staff be consulted directly instead of via their unit and should this be done for every hospital initiative (and what is the best approach to ensure all relevant medical staff are consulted)?

Ongoing leadership

An important barrier for implementation of this Policy was that staff turnover also impacted on the local leadership and championship of the Policy. Studies have found that presence of leadership and ongoing championship of an initiative were instrumental to the successful implementation and sustainment of initiatives.[312,313] A 2015 study suggests that initiatives flourish because key staff drive the innovation and hold it in place for as long as a year while more permanent integrating mechanisms began to work.[314] Presence of leadership and ongoing championship relies on infrastructure support, that is, availability and presence of staff. Shortage of infrastructure support[315] is why many quality improvement initiatives fail.

Capitalise on existing infrastructure

Clinical championship relies on consistency of workload and the assumption that the relevant person remains in the same job. New initiatives will continue to emerge demanding time and attention as highlighted by a Nurse Educator's complaint that there are "too many new initiatives", and staff movement is inevitable. Therefore, strategies that are largely independent of key staff and/or staff changes are needed. An Australian study exploring the context of care in an acute care hospital setting found that some dimensions of context, such as leadership vary at the ward level, while others, such as structural and electronic resources do not.[316] Capitalisation on electronic resources had been considered for the Policy at the outset, with the concept of electronic documentation of the oral intake status and use of pathways to assist with management of oral medications. Unfortunately, this strategy has been hampered by multiple hurdles, including technology limitations, lack of staff expertise for development, lack of staff resources to develop the pathways and resistance to having yet another electronic pathway to manage. Consequently, it is still in the development phase.

6.2.4.2. Role perception

Staff interpretation of responsibility, accountability and even the perception of their workload is a minefield that requires exploration beyond this work. The present findings suggest that there was wide variance in the individual interpretation of role, although it is possible this stem from a workload issue. An example of this variance was one intern accepting the task of managing medications pre-surgery as "it's what we do anyway" whereas her colleague (in the same unit) stressed that it was difficult to achieve due to the busyness. Similarly, some Nurse Educators appeared to contribute by arranging the venue and timetabling of information sessions while others took on a more proactive role during and beyond the Policy implementation process. A further example was that some staff seemed to be able to be entrusted with certain tasks or responsibilities while others, in accordance to a Nurse Unit Manager, "can't be relied upon". Perhaps a standardised accountability framework needs to be introduced to promote consistency in this area. An element of that framework would be 'is it safe for my patient if I do (or do not do) this?'

for clinical decision-making and taking action. This framework would be useful at the outset of any undergraduate healthcare education and/or professional training.

Clearly defined expectations

Studies suggest that the level of commitment, sense of responsibility and/or accountability for those charged with leadership roles, such as clinical champions, are critical to the implementation process.[312-315] Our findings indicate that there is variability with this aspect to implementation of the Policy. The Policy's rollout plan recommended that each area assign a clinical champion to assist with the implementation; however, there was variation in how this was interpreted. To minimise this in future hospital-wide initiatives each area should have some involvement/representation in the development phase of the initiative. The representative/champion should be involved in the local implementation of the initiative and be accountable for all aspects including information dissemination, education of staff, any ongoing monitoring and/or sustainability in their area. Involvement at the outset at the ward level may encourage local ownership. There could even be, if resources allowed, a key staff member whose only role is to implement new hospital initiatives in their local area.

Foster inter-professional learning

A study of factors impacting the implementation of surgical safety checklists found that the complex reality of the process requires more than the elimination of barriers and supporting the enablers.[317] The authors suggested fostering team learning to promote mutual understanding of perspectives and motivations and the realignment of routines. Our findings indicate some inter-professional friction, particularly in the expectations of doctors as viewed by nursing staff, and professional conflict as experienced by the doctor who said, "Speech can advise but we (doctors) can override". The World Health Organization supports fostering of team learning and mutual respect and advocates undergraduate exposure to encourage this model.[318] However, it seems that this approach requires ongoing development at both the undergraduate level as well as the work environment; a New Zealand study of first year medical students found that the early introduction of inter-professional education may not be beneficial if stereotypes – the

perception of characteristics and backgrounds of nurses and doctors – have already been formed prior to entering medical school.[319]

6.2.4.3. Applicability and credibility

Research indicates that implementation initiatives gain better results when the people affected by the initiative were part of the development process[320]; staff having more involvement may attach greater value to incorporating recommended practices into their behaviour.[279] This supports our findings, which suggests that those who were consulted and/or involved in the development of the Policy were very supportive and keen to implement the Policy in their area; however, despite wide consultation and discussions with numerous groups, there were still many staff who had not been involved or may have missed the consultation process. For some of these the ownership and motivation to make the Policy work may not be a priority, particularly if they were inundated with "too many initiatives". It is possible that some who were unfamiliar with the reason for the Policy merely viewed it as a task that needed to be dealt with in amongst the many other tasks without giving the significance of the Policy much thought. There is also the risk that staff who were unaware of the context behind the Policy may use its bedside signs with their preconceived idea of what the terminology means despite the written instructions on the signs.

6.2.4.4. Limitations of the Policy

The complexity of medication management is well known[19,304] and while this Policy attempted to simplify and standardise instructions for oral medication management in patients with restrictions on oral intake there remains a multitude of circumstances that the Policy may be unable to address. Some of these include individual patient factors and medical staff interpretation of evidence. Ultimately, whether or how oral medications are given requires appropriate assessment for each patient, based on their individual circumstance, which may remain complicated and may be a hurdle for the successful uptake of the Policy. The Policy advocated that all oral medications be given to patients fasting before a procedure unless there is a clinical reason to withhold rather than dictating which medications should or should not be given because individual interpretation of this

can be controversial; however, the concept of giving all oral medications may itself be regarded as controversial by medical and other staff due to their individual views, interpretation of the evidence related to the medication, as well as other factors. Of interest is that, despite medical staff's focus on evidence, the strength of the evidence has been shown to be insufficient for them to use guidelines.[321]

6.2.4.5. Considered approach versus unacceptable delays

The issue of a considered approach for the development of strategies to reduce inappropriate medication management, which took time, against the need to institute measures to prevent further adverse incidents from occurring in a timely manner requires attention. There were those who wanted to ensure the robustness of the Policy, that it had enough evidence-base and pilot tested prior to implementation so that 'problems can be sorted out'; but, there were also some who felt the process was taking too long and were concerned that patients remained at risk in the meantime. The challenges in balancing the need to introduce rapid changes with the need for rigorous evaluation of benefits against harms and unintended consequences has been raised.[245] This concept needs exploring in future implementation initiatives: should there be an agreed time limit for development and implementation of initiatives, especially where it pertains to patient safety? Should the fact that this, being a "quality issue", as pointed out by one consultant, impact the timeline and/or how it should be developed, its consultation or hospital endorsement process?

6.2.4.6. Reflection on the evidence-based implementation strategies

Evidence-based strategies were considered for the implementation of this Policy. Opinion leaders, clinical champions, staff buy-in and ownership, simplification and standardisation and a decision aid at the point of care were some of the strategies used. The effectiveness of opinion leaders and clinical champions relies on consistency of presence and availability of staff time. With busyness, competing priorities and staff turnover, these strategies may not be as reliable. A concerted attempt was made to obtain maximal staff buy-in but access to the relevant staff, time and resource issues and staff turnover were some of the barriers that made it difficult to ensure that relevant staff were

consulted. As the context was particularly important for this policy, the significance may have been lost on those who were unaware of the impetus for the Policy and the reasons why the terminology needed to be distinguished. Simplification and standardisation of oral restrictions categories and medication administration instructions, and even the presence of a decision aid at the point of care, will likely have limited impact without this understanding. Enablers such as scheduled interactive education sessions and clinical champions will be ineffective if staff are unable to reliably access them.

6.2.4.7. Strengths and weaknesses of the study

The data mainly consisted of unsolicited feedback about the Policy from staff: it is likely that staff 'spoke their mind' rather than just reporting what they thought we wished to hear. Conversely, barriers and enablers had not been identified specifically for the study in a formal, structured manner and had been obtained from multiple sources. The major reason is that the process that eventually led to the development and implementation of the Policy took place over four years. Consultation for Policy implementation overlapped with the Policy development and hospital-wide approval/engagement process. During this time countless stakeholders and forums were consulted and numerous feedback and comments were received. Consequently, it seemed superfluous to conduct a purpose-built 'barriers and enablers' questionnaire when much of the data had already been collected. This process meant that member checking could not take place and data saturation was not guaranteed, thus reliance of this data to interpret the findings may be limited. Nevertheless, the data collection approach was considered to be the most practical given the opportunities and circumstances at the time to meet the objectives of ascertaining the barriers and enablers to Policy implementation. It could be argued that the different sources and formats for the data were a way of corroborating evidence from more than one avenue.[114,240].

The data were skewed towards a greater focus on nursing compared to other professions so the relevance of the findings may not be applicable across all areas. Nevertheless, the operationalisation of this Policy impacted nursing staff the most so the concerns affecting this group warranted attention. Although frontline staff feedback was included it was not

based on an exhaustive direct survey of this group, therefore there may have been other implementation issues that had not been uncovered.

6.2.5. Conclusion

Challenging barriers as well as important enablers existed for the implementation of the Policy. The barriers and enablers shared the principal themes of resource and infrastructure, staff interpretation of their roles and the perceived applicability and credibility of the Policy. This suggests that many barriers had been anticipated and relevant strategies were employed and enablers capitalised on to manage them; however, the implementation process may have been insufficient to overcome the more challenging barriers such as staff resource and turnover, which will likely compromise the long-term uptake of the Policy.

Our findings suggest the following:

- For this medication-related policy the context was especially important. One implementation strategy employed to convey the context to staff relied on interactive education sessions conducted by the project officer. This appeared to be important in the provision of context and should be accessible beyond the Policy's rollout phase but was resource intensive. To manage this issue and for long-term sustainability an alternative approach is warranted, such as deferring the education to local Educators or champions or development of electronic learning that can be accessed as needed.
- Sustainability will be affected by variations in the interpretation of championship or facilitation of the implementation at the local level, as well as staff movements.
- Staff adapting the Policy and implementation to their local context had the potential to create inconsistencies and unwanted practice variations.
- All aspects of the implementation process should be assigned to the local area to promote ownership and accountability.
- There needs to be an agreed and standardised approach to the stakeholder consultation process, especially amongst the medical staff hierarchy.
- Consideration needs to be given to the timeline of quality assurance processes that have been stimulated by adverse patient incidents. The potential risk to patients from

an adverse event recurring needs to be balanced with the lag time it takes to develop a suitable prevention strategy.

- Due to staff resource and turnover issues, strategies to manage the barriers may be more reliable if they seize opportunities from the existing infrastructure and preferably be largely independent of ongoing leadership and specific personnel to maintain, such as the electronic prescribing system.

6.3. Surgical nurses' perceptions and experiences of a medications and oral restrictions policy change: A focus group study

This study was published in the Journal of Clinical Nursing and the format included is the peer reviewed version of the following article (but with a different referencing style and line numbers have been removed): The-Phung To, Gillian Dunnachie, Jo-anne Brien, David A. Story. Surgical nurses' perceptions and experiences of a medications and oral restrictions policy change: A focus group study, which has been published in final form at https://doi.org/10.1111/jocn.14898 (J Clin Nurs. 2019;28:3242–3251). This article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions. A license was also obtained for use in a Dissertation/Thesis – No.4915060852547.

I was the lead researcher and was involved in all components of this study. I was responsible for the conception, development, execution/conduct of the focus groups, transcribing of the audio recording, data coding, data analysis, write-up and amendments following reviewers' feedback. Ms Gillian Dunnachie (Associate Nurse Unit Manager) was involved with the development of the study, conduct of the focus groups and had a role in review of the transcript, coding, analysis and write-up. My two supervisors oversaw the project and had a role in the analysis and write-up of the study.

Researcher credentials were added to section 6.3.4.6. in response to comments from the examiner.

ABSTRACT

Aims and objectives: To explore the perceptions and experiences of surgical nurses before and after introducing the Medications and Oral Restrictions Policy (the Policy).

Background: The Policy was developed following extensive consultation, and evidence-based strategies were considered for its implementation. However, it is possible uptake did not meet expectations.

Design: Focus group interviews.

Methods: Three focus groups were conducted in November 2015 around 'what worked, what didn't and why', before and after hospital-wide implementation of the Policy. Data were coded and analysed using an inductive-deductive Thematic Analysis approach. The COREQ checklist guided reporting (see Supplementary File).

Results: The three groups consisted of 16, 14 and six surgical nurses. Before the Policy there was confusion, lack of clarity and guidance, and lack of experience and confidence in managing medications when patients had oral restrictions. After the Policy rollout there was a sense of 'knowing what to do' because of improved clarity and decision support; but there were also problems with: not everyone knowing about the policy, particularly due to staff movement and turnover; and, individual interpretation of the policy including use of its signs outside of context, and decision-making processes.

Conclusion: Exploration of nurses' perceptions of a medication-related policy change found that while the Policy provided clarity and decision support for some it made little difference for others. Limited reach of the policy was an issue despite an effort to address this at the outset, as well as variations in interpretation of the policy and subsequent decision-making.

Relevance to clinical practice: How individuals interpret information and their understanding of the context behind the policy or guideline may affect implementation and should be considered alongside other barriers when implementing medication-related initiatives. Furthermore, implementation strategies that are independent of ongoing resources and/or key champions to sustain should be prioritised for all initiatives.

Key words: Nurse, surgical nursing, medication, medication management, focus groups, policy

6.3.1. Introduction

Guidelines, policies, procedures and other evidence-based initiatives are often implemented with the expectation they will be taken up by staff. However, research shows evidence-based guidelines are not implemented effectively and health outcomes are therefore not achieved.[146] Although evidence-based strategies were considered for the implementation of the Medications and Oral Restrictions Policy (the Policy) it is possible uptake of the Policy did not meet expectations. Previous research suggests that even theoretically informed implementation may not go according to plan.[301] An understanding of factors that contribute to variations in practice is needed to develop implementation interventions to increase the uptake of evidence into practice and so reduce variability in the delivery of recommended practices.[154] Understanding the issues from the perspective of staff who are most affected by the Policy will guide further improvement attempts and future implementation initiatives.

6.3.2. Background

The Policy was developed in response to adverse medication-related incidents occurring when patients had restrictions on oral intake and strategies such as simplification and standardisation, decision support at the point of care, Opinion Leaders and Clinical Champions[19,22,254,322] were considered in its development and implementation. The Policy aimed to simplify and standardise oral restriction terminology and medication administration instructions to reduce confusion and unwanted practice variations: *Fasting* meant give patients' regular oral medications up to one hour prior to surgery unless advised; *nil by mouth* meant absolutely nothing by mouth, including sips of water and oral medications; *restricted oral intake* meant check medical orders before giving anything by mouth, including medications. The Policy is supported by coloured-coded bedside signs, which explains each category and provides decision support at the point of care; green for *fasting*, amber for *restricted oral intake*, and red for *nil by mouth*. The

Policy was approved at numerous forums hospital-wide and had the backing of key Opinion Leaders, including those from medical, nursing, pharmacy and speech pathology.

Implementation for the surgical wards occurred in February 2015 and included: Opinion Leaders, engagement with stakeholders including consultation with key senior staff from each ward to seek support for the Policy and assignation of Clinical Champions, and six information sessions over two weeks; these sessions included case studies highlighting the need and context behind the Policy. The sessions were open to all staff in the area and were scheduled during nursing education times. The Policy was discussed at surgical unit meetings to capture doctors. Key staff representing graduate nurse education, medical education, casual (supplemental) nursing staff, speech pathology, food services and patient service assistants were consulted about the Policy. A summary of the Policy, the Policy document, and a link to the Policy's intranet site were sent to these contacts for distribution to their group. The email was also sent to pharmacy and surgical ward staff. A reminder email was sent to nursing staff on the morning of the rollout and all signs previously used for oral restrictions were removed and replaced with the Policy's bedside signs.

6.3.3. Aim

The purpose of this study was to explore the perceptions and experiences of surgical nurses to understand whether the Policy addressed the relevant issues encountered before the Policy was introduced and to understand factors that may contribute to variations in practice after Policy implementation.

6.3.4. Methods

6.3.4.1. Design

Focus group interviews.

6.3.4.2. Sample/Participants

Purposeful sampling, which is the identification and selection of individuals or groups of individuals that are especially knowledgeable about or experienced with a phenomenon of interest for the most effective use of limited resource[141], was used in this study. Surgical nurses from the Surgical Clinical Service Unit of the hospital (which covers most surgeries except oncology and paediatrics) were targeted because they were most likely to be affected by the Policy.

6.3.4.3. Data collection

The study was conducted at an acute campus of a tertiary teaching hospital in Australia and was approved by the Austin Health Research Ethics Committee (LNR/15/AUSTIN/403).

An email about the study and that sought assistance with identifying participants was sent to the four Nurse Unit Managers. The Managers were asked to forward the Participant Information Sheet – which specified demographic data will not be requested to encourage participation – to potential participants. This information sheet also detailed the researchers' personal goals and reasons for doing the research.

The number of participants per focus group should not be too large or too small to allow meaningful discussion as well as diversity of discussion; many researchers aim for at least six participants per group.[125,140,142,323] The determining factor for the number of focus groups needed depends on whether new information may be obtained with each new group[143], that is, when the data become saturated and further focus groups become unnecessary[135]; some researchers suggest only three to four focus groups may be necessary for a simple research question.[125,136,140,142] We therefore aimed for at least three focus groups, with at least six participants per group. Consent was assumed if the participant attended the focus group session.

6.3.4.4. Focus group format

Two researchers, TT and GD, conducted the sessions with TT moderating and GD observing. No other observers were present. Each session ran for approximately 45

minutes and was audio-recorded using the 'voice memo' application on two iPhones (Apple, Cupertino, California).

Two broad-based questions provided the setting for the sessions:

- What worked well, what didn't, and why, before the Policy was implemented?
- What worked well, what didn't, and why, after the Policy was implemented?

These two questions had been piloted prior to the study and were included in the Participant Information Sheet.

If further prompting was needed, the Theoretical Domains Framework[171] was used to guide discussion. Brief field notes were made during and immediately after the interview sessions. These notes were used, where required, to assist with reflection of data during analysis.

6.3.4.5. Analysis

The audio recordings were transcribed 'verbatim' by one researcher (TT). Another researcher (GD) checked the transcriptions against the audio content for accuracy. The transcriptions were read and re-read by TT and GD to allow for immersion of data. One researcher (TT) coded the data (NVivo 11 for Windows, QSR International Pty Ltd.) inductively, and deductively using the Theoretical Domains Framework[171], while another (GD) independently coded the data inductively and then discussed the coding with the first coder. Coding was also discussed with DS and JB. Data were analysed using the Thematic Analysis approach. Thematic analysis is a method for identifying, analysing and reporting patterns within data.[123,124] As thematic analysis does not require the detailed theoretical and technological knowledge of approaches, it can offer a more accessible form of analysis, particularly for those early in a qualitative research career.[124] It also offers a useful approach for those doing more applied research, or when doing research that steps outside of academia, such as into the policy or practice areas.[133] Focus group data is suitable for thematic analysis.[121] The inductive/deductive approach allows the data to be analysed with certain preconceived templates derived from theories, but also

allowing for the emergence of new concepts.[121] Subtheme and theme development were discussed by all researchers. The whole process, from coding to themes, was iterative.

6.3.4.6. Researcher experience and potential influence on results

Three researchers, TT, DS and JB, have prior experience with qualitative research.

One researcher (TT) was the project officer for the Policy and may have been known to some participants. Another researcher (GD) was the Surgical Quality Coordinator and was known to some participants. It is possible participants' responses were influenced by this. Data coding, analysis and the subsequent report may reflect the authors' involvement with the Policy.

The 32–item Consolidated Criteria for Reporting Qualitative Studies (COREQ) was used to guide reporting.[108] *[Refer to Appendix 3.]*

6.3.5. Results

Three focus groups, consisting of 16, 14 and six surgical nurses respectively, were conducted over two weeks in November 2015, approximately eight months post Policy rollout. The focus group sessions occurred during nursing education times.

Participants were female and had worked at the hospital for at least 12 months; none were recent (less than 12 months) graduates. Although demographic data were not elicited, based on discussions during the sessions all four surgical wards were represented. Two sessions contained participants from different wards. Participants in the third focus group were from the pilot ward, which had been operating the Policy since mid-2012.

Some participants from the first two groups stated they did not know about the Policy; however, once discussion occurred all indicated they had seen and/or used the Policy signs. Participants from the third session knew about the Policy and were aware of its aims.

6.3.5.1. Before Policy rollout

Prior to the Policy there was no hospital-wide guidance for giving oral medications when patients had oral intake restrictions. Discussions relating to pre Policy focused on what didn't work well. *[See Appendix 4 for coding tree.]*

Not knowing what to do

Confusion about fasting and nil by mouth

There was confusion about what *fasting* or *nil by mouth* meant. One participant said, "You would be confused about patient's *fasting* status; were they going to theatre, were they not?" Another participant said, "Or *nil by mouth* might have been used inappropriately when they are not." One nurse summed it with, "I think there was confusion with nil orally and *fasting* – there was no difference." Sometimes *fasting* meant patients were not allowed to have anything orally, while *nil by mouth*, on the other hand, may mean oral medications or sips were allowed. One participant commented, "But even sometimes with just the plain *fasting* sign you're like, 'ooh, can they have sips of water?'" and another said, "…when it said nil orally I was like, 'oh, can they swallow, can they not?'" This confusion has the potential to affect patient safety; for example, the risk of giving oral medication to a patient with swallowing difficulties or the withholding of essential medications from patients who are safe to swallow. One nurse said, "So there was no clear distinction and, you know, sometimes they would be nil orally but you could still give meds or, you know, so there was (sic) compromises being made…" Another nurse, referring to a particular incident, said, "...then they've ended up (in ICU)…so ICU are like, going well, 'it's because you've been withholding the medication'…Patients were getting compromised…"

Lack of clarity and guidance

There was a sense of lack of clarity and guidance. One participant talked about the need to get an understanding of what to do when coming onto a shift, "you'd have to, before you can do anything, just work out….are they *fasting* or not?" Another participant commented about not knowing if patients are allowed to have their medications and needing to get that clarified. The lack of clarity and guidance meant it was open to

interpretation as to whether medications were given or withheld. One nurse said, "Because they didn't have a guideline or anything to sort of follow, so they were sort of making the decisions themselves." Another stated, "So it could be quite random as to who got what medication and who didn't." A further consequence of this issue was some staff were giving or receiving inconsistent information; as one nurse stated, "...someone tell you one thing and someone else would tell you something else."

The lack of clarity and guidance also impacted on staff time and resources with nurses having to spend time trying to contact doctors to clarify what was intended – what exactly did they mean by *fasting* or *nil by mouth*, and should oral medications be given or withheld? Participants agreed there were "lots of phone calls, pages", and "paging units then units saying call someone else…."

Without structured guidance, it appears that, often decisions were made at the 'nurses' discretion'. These decisions can tend towards, from one participant's point of view, erring on the side of caution; "I think we tend to withhold rather than give something thinking that, 'oh, that's OK.' We'd rather, we'd be a little bit more reserved."

Lack of experience and confidence

An issue discussed as problematic was the lack of experience and confidence of the doctor or the nurse to make a decision about giving or withholding medications; for instance, one participant offered, "I think sometimes with the doctors they were….some were confident to tell you which ones to withhold and some were not as confident so they would, maybe, withhold everything just to be sure." In terms of nurses, one participant said, "I think it's a confidence thing too, that you don't feel confident to make a decision and sort of think outside the square a little bit."

A consequence of the lack of experience and confidence is the effect on communication; particularly when junior nurses need to communicate with doctors. As one participant said, "it came down to how long you've been on the ward and how comfortable you felt having those conversations [about whether to give or withhold oral medications]. So, the more experienced nurses were more confident….broaching that subject or that discussion with the doctors than the junior nurses." Another participant added, "Often they [junior

nurses] don't even go to the doctors first, they'll come to the nurse in charge…" There was also the issue of unwillingness to challenge a medical decision; one participant said, "…some people wouldn't necessarily felt comfortable dealing, you know, going, 'oh but the doctor said they [the patient] can have their medication', but then you're like, 'they're nil orally….!'"

6.3.5.2. Post Policy rollout

Post Policy, there was a sense of knowing what to do but also a perception of limited impact of the Policy.

Knowing what to do

Improving clarity

Many participants agreed there was better clarity, particularly with the difference between *fasting* and *nil by mouth*, what needs to be done for each category and whether or not medications should be given. One participant, who was confused pre Policy about whether a patient was able to swallow when classified as 'nil orally', said, "now, if it's a red sign I know definitely not." Another participant added, "We know if a patient is *fasting*, nil oral or restricted so we know exactly what to do. When it's right there, they [the doctors] can see it and it's simple." One participant summed it with, "[It's a] conversation that you don't need to really have."

Having a clear understanding of what to do has reduced the amount of time wasted following things up; one participant reported, "It's cut out a lot of time as well trying to contact the doctors to find out what they are happy for them [the patients] to have and what they're not happy."

Visible decision aid at point of care

Many participants felt the bedside signs provide a decision aid at the point of care. One participant remarked, "….it's there in front of you. You don't have to have your own sort of definition or double check with anyone else exactly what that means." The signs seem to also assist other professions including doctors, food monitors and patient service

assistants. For example, one participant said, "I've noticed a few times they'd [the doctors] go 'oh yep they're *fasting'* or 'oh wait what's that sign? Oh, that's OK, they're not infectious, and they're,' you know, 'restricted'." Another admitted, "…I've come back [from annual leave] and this was already being rolled out and I didn't even notice they were there but food monitor and patient service assistants are constantly been, like, 'are you sure they're *fasting*?' They're not….but I forgot it was there so yeah they're noticing it more." One nurse remarked on the merits of the A4 sized signs and the associated colour of each category, "I think, well, it's more obvious. Bright, big. Like, before the rollout it was this little, you know, magnetic strip, you know, with half-faded, crossed out orally and you put what you want sort of thing. So, this is obvious, it's right there; stop, you know, go….it's right there in your face."

Some participants felt the Policy signs have led to improved communication between professions. One participant observed, "I feel it's put a bridge between speech pathology and the doctors", while another said, "…the doctors go and see the patients they need to review; when it's right there they can see it and it's simple."

Policy providing support for clinical decisions

Some participants concurred the Policy gave them the backup needed when their decisions were challenged. Having a visual reminder and reference to backup clinical decision-making seems to provide some participants with confidence; particularly when justifying their decisions or actions to doctors. As one participant puts it, "whereas now....this is what we're doing and …if the doctors do question we're like, 'well you said that that's what this patient is'…" Similarly, "If the doctor is questioning you then you can say, 'well does it fill this criteria, then we can't use this sign, we have to use that sign then that means no oral medications'." Another participant added, "It's like a bit of leverage for a nurse to go… 'well, actually, you [the doctor] need to make it really clear' ….when it [the Policy] first came out and the doctors were still a bit wishy washy with it you would, you know, take them back to that policy and it's like, 'they're *fasting* so they can have orals or are they *nil by mouth* so nothing goes into their mouth at all?'"

6.3.5.3. Limited impact of Policy

The implementation of the Policy did not change practice across the board.

Already practicing in line with Policy

Some participants held they already distinguished between *fasting* and *nil by mouth*. Consequently, the advent of the Policy did not affect their previous conception of what *fasting* and *nil by mouth* meant nor did it change their practice. These participants reasoned it was because of the area of practice. For instance, one participant said, "I've never thought if someone was *fasting* they would be not, like, nil orally completely because of the ward, like the environment we work whereas other wards may be completely different." Another elaborated, "It's got more to do with patient care, like, you know what [procedure] your patient is going for…so if we know they going for …they can have their medications and can still have sips of water."

Individual experience and interpretation

According to some, the terminology and instructions on the Policy bedside signs are open to interpretation. One concerned participant expressed, "To me I still worry though because there are still people who read that [the bedside sign] and still go 'do I give it [the medication]?' Oh my goodness, how much more can you say…?! It tells you what to do and they're still questioning!" Another participant commented, "They've definitely highlighted the fact that stop is red sign, nothing orally but I don't know if our whole team understands why yet." One participant reasoned that, "…it comes back to the skills of that nurse whether or not they're gonna click withheld, patient going to surgery [and not give oral medications]. So that comes down to own experience."

Some participants did not feel the Policy applied to them because of the area worked or the type of patients on their ward. For example, they felt their patient type meant it was appropriate to use *nil by mouth* to include exemptions such as sips of water and oral medications because as one participant argued, "it's mostly from a surgical point of view… you know, being a gastrointestinal ward…. A sip or ice or….it's not to do with swallowing…." Another stated, "…we have more the digestive reason [for being *nil by mouth*] rather than swallowing reasons." Another added, "…they aren't *nil by mouth* because of swallowing. They [the doctors] just want their [the patients'], you know, bowel

rested or something like that….but still let them have their tablets; we just don't want them to eat." These participants acknowledged they had not attended the Policy information session.

6.3.5.4. Sign fatigue

One focus group discussed the green *fasting* sign failing to make an impact due to the similarity in size and colour to another sign on their ward. "I didn't notice it because….it's really rare for us to have *nil by mouth*. They're mostly green *fasting* but our bed cards….they're bright green as well, about the same size." This issue is currently ward specific but may become problematic if more signage of similar size and/or colour is used.

6.3.5.5. Insufficient reach of policy

Not all participants were aware of the Policy. One participant said, "I work two days a week and I haven't heard about any of that." Similarly, another commented she had not noticed the signs after coming back from annual leave. Some participants were concerned certain groups of staff had not been targeted, or insufficiently targeted – one participant asked, "Did the doctors have much education about [the Policy] ….?" Another participant declared, "I don't know if it's necessarily the nurses – the doctors, I don't think, even notice that sign even though it's right next to their head. They don't even realise that *nil by mouth* and *fasting* are different."

Participants from all focus groups suggested mandatory training is needed to improve awareness of the Policy. One participant, thought the Policy was more relevant to practice than the yearly compulsory Fire, Hand Hygiene, and Bullying, Harassment and Aggression Management training and remarked, "I just think it should be, like, a mandatory training thing….for everyone."

6.3.5.6. Inter-professional friction

Some participants were frustrated doctors did not seem to conform to practice nor take on a more proactive role with carrying out the Policy. One exasperated participant said, "Well doctors would write in the notes '*nil by mouth* for theatre'. Do they mean *fasting*

for theatre or do they mean keep *nil by mouth* until theatre? That wouldn't really change with the signs, 'cos if they are gonna write that they are gonna write that anyway. They're not gonna….look at the signs." Another participant said, "They'll [the doctors] say '*nil by mouth* except for meds'….that means *fasting* because obviously they can have water and medications. So the doctors, they don't even notice the signs on our ward." Another grievance was about doctors not being pre-emptive, "If they [the doctors] have their own restrictions on they won't write them up and let you know. You find out later after you've already done everything else." One of the participants described a situation where conflict arose when the surgeon tried to override the speech pathologist's categorisation of the patient's oral intake status. One nurse confessed that when there is disagreement between the doctor and speech pathologist, nurses would side with the latter, "…a unit [doctor] might say… [the patient] can start fluids but…we are completely guided by Speech."

6.3.6. Discussion

The perceptions and experiences of surgical nurses prior to the Medications and Oral Restrictions Policy suggest there was confusion and lack of guidance with giving oral medications to patients who have restrictions on oral intake. There was a feeling of not knowing what to do and much time wasted with lots of phone calls and 'chasing up' of doctors to clarify what needed to be done. Staff were sometimes left to their own interpretation of what is and is not appropriate, and whether or not patients were given oral medications can depend on the individual staff member's experience and interpretation and confidence. This was sometimes fraught with risk as decisions may not have been appropriate and had the potential to compromise the patient.

The advent of the Policy provided a unified structure for staff to work with when giving oral medications in the context of restrictions on oral intake. For many this was perceived to improve communication, provide a timely decision aid at the point of care, and gave some staff more clarity and confidence when problem-solving medication administration issues. The Policy also appears to provide a backup for clinical decisions; some participants use the Policy to justify their decision if challenged by doctors. For some, the Policy was 'leverage', especially when dealing with doctors.

For other participants the Policy made little impact – either for them directly or for others around them.

6.3.6.1. Limited reach of Policy

It seems the implementation process was insufficient to ensure information about the Policy reached all staff. It is possible knowledge of why the Policy was needed – the reasons behind all the bedside signs and categories – may improve the impact of the Policy; it seems those who attended the information sessions had a better understanding, were supportive of the Policy and even found it beneficial to their practice. Six face-to-face information sessions were conducted, as well as presentations at surgical unit meetings to capture doctors. Unfortunately, more sessions could not be scheduled because they were time, resource and labour intensive for all concerned.

Staff movement and turnover makes it challenging to reach all staff when rolling out a new Policy. A number of participants commented they didn't know about the Policy or did not attend the information sessions due to for example, being on leave or working part-time. We had anticipated staff movement and had instigated strategies such as consultation with numerous stakeholders, engaging Opinion Leaders and Clinical Champions, and removing/replacing all old signage with the Policy bedside signs that simplify and standardise medication instructions to provide decision support at the point of care to manage longevity beyond the implementation phase. However, these strategies appeared to be inadequate, and others have similarly reported on difficulties with providing education processes when faced with higher than expected staff turnover, the number of part-time and night shift positions among nursing staff and job share positions.[306,307,324,325] A possible solution to alleviate the time, availability of staff to attend and labour commitments of face-to-face education sessions may be the use of a Webinar and/or eLearning module, which can be accessed by staff when they choose. Future work is required to assess whether these resources are effective; anecdotal experience suggests the availability of these will be of limited use unless: individual and hospital barriers to accessing them are addressed; or, the hospital makes it mandatory – in this era of information overload, this will be a challenge.

6.3.6.2. Individual decision making process

It appears the experience, confidence and interpretation of individual staff were likely to affect whether the Policy was followed appropriately: there was the mistaken interpretation by some that, because of their patient type, the Policy did not apply to them; and, it seems some staff were still uncertain and/or still sought advice despite the instructions on the Policy bedside signs. It is possible understanding the context of the Policy may help with the experience, confidence and individual interpretation of staff when making a decision about giving medications in patients with restrictions on oral intake. However, it may also be the solution is not that simple; as summed up by one participant, "Oh my goodness, how much more can you say…?! It tells you what to do and they're still questioning!" – there may be other elements affecting each individual's clinical decision process. Nurse decision making is a complex process[326,327] and is influenced by many factors including experience and intuition, context of the situation, knowing the patient, interpretation and reflection.[327] A systematic review of the effectiveness of education interventions found that clinical decision making involves cognition, judgement, and socially located behaviour and does not always respond as expected to educational interventions or variables such as clinical experience.[328] So while the information presented on the bedside signs may seem self-explanatory and serve as a decision aid to some, others interpreted the signs differently or did not find the same instructions helpful to practice. It has been suggested theories that address judgements and decisions themselves are needed[328] to guide appropriate methods for educational interventions. For example, two decision making theories described in the literature are the 'intuitive' and 'analytic' models; research suggests experienced nurses tend to favour intuitive clinical decision making whereas inexperienced nurses tend to employ a more analytic approach.[326,327,329,330] Therefore, considering these clinical decision making perspectives during the development phase may improve the design of educational aids or interventions. Future implementation attempts need to consider clinical decision making factors in tandem with the other barriers to implementation.

6.3.6.3. Inter-professional friction

There seemed to be some inter-professional friction with operationalising the Policy. Some participants were frustrated doctors were not following the Policy; others described conflict between medical staff and speech pathologists. Doctors not following the Policy could be a consequence of lack of knowledge/limited reach of the Policy. Nonetheless, inter-professional conflict in healthcare is well recognised[331-337] and it is possible the basis of the conflicts is not exclusive to this Policy and needs to be addressed at the (hospital and professional) institution level. Strategies such as inter-professional competency framework[338], conflict resolution protocols[333] and inter-professional education[318,339] at the undergraduate level have been recommended.

6.3.6.4. Limitations

We had not collected demographic data to emphasise anonymity to encourage participation and discussions without fear of judgement; this meant we were also unable to use methods such as member checking to improve the rigour of the study. Ideally, focus group sessions should be conducted until saturation is reached for all concepts[135,136,142,143,323]; however, the constraints of the field situation must also be taken into account[125] and in our situation it was the imposition on staff time. We therefore sought to tap into the existing arrangements of a busy clinical setting and worked with what was allocated to us. Nevertheless, many of the themes highlighted were discussed by all three focus groups; exceptions were 'lack of experience and confidence' (not discussed by first group, but discussed at length by the second and third) and sign fatigue (relevant to only one ward). Additional focus group sessions may have provided more data but not necessarily more scope, and would have been an unnecessary burden on precious staff resources. One group only had participants from the pilot ward. This was beyond our control though an observation from this inadvertent outcome was all participants from this group were familiar with the Policy and appeared to be comfortable with it. In contrast, some participants from the other two focus groups did not know about the Policy and/or its context. Possible explanations include a scaling up issue (from the pilot) or perhaps more time was needed to allow the intervention to become 'culture' – this requires exploration beyond this current work. The study only examined the views of

surgical nurses from one institution in the implementation of one policy and may not be applicable to other settings.

6.3.7. Conclusion

From surgical nurses' perspectives, the Medications and Oral Restrictions Policy provided a unified structure to work with when giving oral medications when patients have restrictions on oral intake where previously there was confusion and a lack of guidance – those who understood the context of the Policy found it relevant and beneficial to their practice. However, despite a considered implementation process, which included simplification and standardisation of medication administration instructions on the Policy's bedside signs, many of the issues highlighted post Policy implementation could be attributed to inadequate reach and a lack of understanding of the context of the Policy; how medication-related information was interpreted and the resulting clinical decision-making process seemed to vary between individuals and impacted on the appropriate uptake of the Policy.

6.3.8. Relevance to clinical practice

The understanding of the context behind a policy or guideline and how individuals interpret information or instruction about medication and the subsequent decision-making process can affect the implementation of medication-related initiatives. This concept should be considered alongside other barriers in future implementation initiatives. Furthermore, continuous staff movement and turnover and resource issues seem to be the reality of any large organisation and therefore strategies that are independent of ongoing resources and/or key champions to sustain need to be prioritised for all implementation.

6.3.9. Impact statement

What does this paper contribute to the wider global clinical community?

- Staff who understood the context of the Policy found it beneficial to their practice. Hence, more innovative and time/resource effective ways to provide context for staff and/or to educate staff about the Policy need to be found.

- Strategies to minimise the variations in how staff may interpret information presented in medication-related policies or guidelines and the subsequent individual decision-making process should also be considered for all future initiatives.
- Continuous staff movement, turnover and insufficient ongoing resources are the reality of many organisations. Therefore, strategies that are largely independent of ongoing key staff/champions to drive need to be prioritised for all implementation initiatives.

6.3.10. Addendum

- The 32-item Consolidated Criteria for Reporting Qualitative Studies (COREQ)[108] checklist was critiqued against this study in Appendix 3. As discussed in the Limitations section (6.3.6.4.), data saturation was not ascertained and it was not possible to attribute the quotes provided to a participant number because of the pace of the sessions and the multiple, sometimes concurrent interactions at the time.
- The authors' credentials were included in the Cover Letter to the Journal of Clinical Nursing and the authors' details were on the published article. At the time of the study, Ms The-Phung To (BPharm, MClinPharm) was a Quality Use of Medicines Pharmacist and PhD Candidate. Ms Gillian Dunnachie (RN, GradCertCritCare) was a nurse and Surgical Quality Coordinator. Professor Jo-anne Brien (BPharm, PharmD, BSc) was a pharmacist, the Chair in Clinical Pharmacy (St Vincent's Hospital) and Conjoint Professor of Medicine at the St Vincent's Hospital Clinical School. David Story (MBBS, MD, BMedSci, FANZCA) was staff anaesthetist at Austin Health and was the Professor and Foundation Chair of Anaesthesia and Deputy Head at the Centre for Integrated Critical Care at the University of Melbourne.
- Although the three focus groups provided useful, relevant information to inform and corroborate other studies in the PhD and the PhD program as a whole, the interpretation of the data and findings may be influenced by the fact that data had not been collected until saturation was reached. As we were allocated only three timeslots to conduct the focus groups by those who managed the nursing education program, we had to utilise all the avenues and data that were available to us.

- The study only reported on the perspectives of nurses because they were the profession most likely to be affected by the Policy, as discussed in the Methods section (6.3.6.4.), and were central to the success or failure of the Policy. Consequently, one of the aims of this PhD was to explore the surgical nurses' perspective of the Policy since this group was more likely than any other to be operationalising the Policy. The findings from the present study will inform future researchers exploring other viewpoints in this context such as multidisciplinary and patient perspectives.

6.4. Impact of a policy to improve the management of oral medications when patients are fasting before a procedure: a retrospective interrupted time series analysis

The study has not been submitted for publication.

This component of the PhD is a combination of two separate investigations. Due to the established differences between ward areas such as 'medical' and 'surgical'[265,340-343], comparison between these key areas was vital. Thus, both the 'Medical' and 'Surgical' areas of the hospital were studied. To enable comparisons between the two, it was necessary to report the results together.

I conceived this study, was the primary researcher and contributed 80% or greater to all aspects of the study, except conducting the sample size calculation and interrupted time series modelling. I worked with the hospital's data department to extract the original electronic data and received assistance from Stephen Cheung (IT Pharmacist) for presenting the electronic data in suitable format for data mining. Sabine Braat (Biostatistician) advised on the majority of the statistical methods and data analysis, wrote the statistical analysis codes, performed the interrupted time series regression modelling and was primarily responsible for writing up the ITS statistical modelling methods. She also reviewed the section of statistical methods that I wrote and the tables and figures that

I compiled for accuracy. Andrew Lim (Hospital Medical Officer) was the second rater for inter-rater checking and played a role in the resolving differences component and appraising the write-up of the study. Both supervisors, Jo-anne Brien and David Story, were involved with the inception and development of the study, provided input for the direction of the study and were involved in the study write-up. David Story was also involved in the resolving differences component.

I conducted the initial inter-rater checking analysis and descriptive statistics using Excel (version 1808, Microsoft Office Professional Plus 2019). Sabine then provided me with codes to perform/confirm the statistics in Stata (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) for Windows. She also provided me with the codes for the ITS analyses and modelling.

The challenge with applying Sabine's codes to the Stata program on my computer was that I had not used Stata nor any other statistical analysis program before and Stata is not an easy/intuitive program to use, especially for someone with no coding experience (but it was the program that Sabine preferred). The coding reflected storage files on Sabine's computer and I was required to adapt the codes to my local computer; for example, I had to ensure that any codes that retrieved or stored data were changed/coded to retrieve/store in the correct location on my computer. Due to Sabine's busyness, she sometimes sent me codes separately (and sporadically) and they did not always execute as intended. Usually, this was because I had made a minor error when changing the codes to my local setting but sometimes it was because the coding was slightly different to the way Sabine had coded them previously (or a code was assumed to be present that was not). On several occasions it was because my local Stata program did not have the update or add-on installed or there was a mistake with Sabine's coding. This was usually, eventually, rectified after liaising with Sabine but often I would have had spent many hours trying to work out what the problem was to determine whether I could resolve it myself and/or so that I had an idea of what I needed to discuss with Sabine.

The other time-consuming aspect to Stata was the inability for it to produce presentable tables and graphs that can be adapted for word documents. As such, many hours were required to copy individual numbers from Stata to produce tables and graphs and to check and recheck accuracy of transcription. All these tables and graphs needed to be manually

updated and rechecked with every change/slight difference/update in coding, which occurred a number of times; for example, I discovered that one of the Stata descriptive statistics output differed slightly to my Excel results. Discussion with Sabine revealed that the difference was due to the way in which she had coded the data to extract the monthly results. Changing the coding resulted in corresponding changes for all other outputs.

This study was also besieged by other challenges. Data acquisition was especially problematic because the electronic prescribing platform was implemented at Austin Health in 2013 and was still in its infancy at the time of Policy implementation: Expertise was needed to extract the electronic medication data in a meaningful format. Moreover, the volume of data required, dictated by the anticipated ITS design, as well as the record review method meant that substantial resource was needed to interrogate the data. Consequently, it was crucial the data be fine-tuned considerably to reduce the workload. I started off discussions about the data requirements early 2014, at the start of the PhD candidature, well before Policy implementation. Data staff not having a clinical background meant there were multiple 'back and forth' attempts in obtaining the relevant data, which was tedious and time-consuming for all involved. Moreover, staff change and competing priorities for data staff and other issues meant that it took from 2014 to 2018/19 for the data to reach a usable format.

Because of the lag-time for data acquisition, planned strategies such as a clinical panel of experts to assess the medication omissions did not eventuate – two of the intended panellists moved to other roles/institutions.

There were challenges locating a second rater to conduct the inter-rater checking in place of assessment by panellists but when someone (Dr Andrew Lim) was finally found the research appointment process was delayed by the hospital's procedures, the two-month Christmas-New Year break and then COVID-19!

The advent of COVID-19 greatly impacted clinical work at the hospital, as well as research: COVID-19 related matters took precedence and all other work receded into the background. Sabine's availability to perform the ITS modelling to assess for secular trends was hugely impacted because COVID-related and funded research were

prioritised. Consequently, it was the second half of August 2020 before the ITS modelling component was conducted.

6.4.1. Aim

To evaluate the impact of a policy to improve medication management in the context of oral restrictions on medication doses omitted inappropriately and overall omissions in patients fasting before a procedure in 'Medical' and 'Surgical' areas.

6.4.2. Methods

6.4.2.1. Study design setting and period

This was a retrospective time series analyses of medication doses omitted inappropriately and overall omissions between January 2014 and May 2016 to examine the impact of implementing the Medications and Oral Restrictions Policy. The Policy was implemented at a tertiary-referral, metropolitan teaching hospital in Melbourne, Australia, with more than 500 acute-care beds. The organisation provides a broad range of generalist acute, subacute and rehabilitation care, in addition to being the state-wide referral centre for liver transplantation, spinal medicine and toxicology.

The hospital's Human Research and Ethics Committee approved the study (LNR/14/Austin/133).

6.4.2.2. The intervention

The intervention was the hospital-wide rollout of a policy that provided medication administration instructions in the context of restrictions on oral intake and distinguished the terms fasting from nil by mouth with respect to oral medication administration. Briefly:

- Fasting means oral medications may be given with a small sip of water, up to one hour prior to a procedure unless advised and/or there is a clinical reason to withhold, such as risk of bleeding, low blood glucose or low blood pressure

- Nil by mouth means nothing should be given orally, including oral medications and sips of water, and an alternative route of administration should be sought
- A third category, restricted oral intake, meant medical orders needed to be checked before giving any orally. This category could be used for patients who required texture modifications to food, fluid or medications to enable safe swallowing or those only allowed sips of water or ice post-operatively.

The Policy was implemented using several strategies, including interactive education sessions, as summarised in Table 11 (of section 5.5). Further information on the rollout can be found in Appendix 5.

The following were also carried out: Consultation/discussion with senior and education staff for the relevant area prior to implementation (in addition to any earlier consultation/discussions during Policy development); An email informing about and another reminding about the Policy and rollout was sent to all nursing staff; All other staff were informed either through departmental, unit or other meetings, email, or a combination of these.

6.4.2.3. Data sources and measurements

Study population

Patients who had a non-elective procedure on wards in the Surgical and Medical Clinical Service Units of the hospital were targeted. The Surgical Clinical Service Unit ('Surgical' areas) covered areas that primarily cared for surgical type patients. The Medical Clinical Service Unit ('Medical' areas) was associated with areas that primarily cared for non-surgical type patients (but whose patients required a non-planned procedure during their inpatient stay). These areas were selected because they were most likely to be affected by the Policy.

Electronic data extraction

Two data sources were used to compile the data: the hospital's inpatient admissions data and medication administration records from the electronic prescribing platform (Cerner®, Missouri, USA). The data were matched for admission episodes between January 2014

and June 2016 in which patients underwent non-elective procedures/surgeries and their electronic medication administration records during this time. The anaesthetic start date/time was used as the reference point for data selection and data were also refined to:

- Within three days before the anaesthetic commencement time to capture the scenario of patients being fasted for lengthy periods due to uncertainty of available theatre time for non-planned procedures and other unexpected delays
- Only capture patients who were on the ward from where they went to the procedure for at least eight hours beforehand to ensure that there was adequate time for medications to be prescribed and documented. This also minimised the chance of the data being generated in one ward but being attributed to another because of patient transfer to another ward before the procedure

The data were then limited to 'Medical' or 'Surgical' areas, and further refined to within 12 hours of anaesthetic commencement time due to the volume of data. The data were presented in a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, Washington, USA). This spreadsheet also became the data collection platform for the manual data extraction component of the study.

The Policy rollout for Medical areas occurred in March 2015 and Surgical areas in February 2015. Consequently, the data spanned January 2014 through to May 2016 for Medical areas (that is, 14 months prior and 14 months following the rollout month) and January 2014 through to March 2016 for Surgical areas (that is, 13 months pre and 13 months post rollout month).

Variables

The primary outcome is the proportion of medication doses omitted inappropriately in 'Medical' and 'Surgical' areas pre- and post-implementation of the Policy. The secondary outcome is the proportion of overall medication doses omitted.

Codebook

A codebook was developed a priori to facilitate a more systematic approach to determining whether the dose omission was appropriate. The codebook specified the

reasons and conditions that conferred appropriateness or inappropriateness to a medication omission. In general, the assumption was that all doses should be given if prescribed for the patient and that, when fasting, oral medications should be given with a small sip of water, up to one hour before a procedure unless there was an appropriate clinical reason to withhold them. Thus, all administered doses were considered 'appropriate' and all medication omissions were 'inappropriate' unless an acceptable reason was recorded. As it would have been difficult to retrospectively verify some of the justifications, valid documented reasons for omissions included: 'Medication not available' or 'patient not available'; 'duplicate task' or 'patient has IV'; low or high blood pressure, low blood sugar or other valid clinical reason; 'as instructed by doctor'; and, 'patient refused'.

No further investigation was conducted for entries in which appropriateness can be determined based on the information already available in the electronically extracted database. All entries that were unclear or had a non-valid reason for the omission required a review of the patients' medical records to check if there was any further documentation/appropriate reason for the omission – there were no inappropriate doses without a manual audit. See 'Data coding manual' (Appendix 6) for further information.

Manual data extraction

Manual data extraction was conducted by me. This involved a review of the patient's medication administration record and clinical notes. Before the commencement of the actual study manual data retrieval was piloted for 20 randomly selected patients.

The following components of the electronic medication administration record were checked: the 'comments' section for each dose, as nurses sometimes recorded the reason for dose omission here and this information was not captured in the data download; the administration instructions (e.g., 'with food' or 'empty stomach'), and; the prescribing history (e.g., date/time, start/stop). Patient's clinical notes were checked for: instructions by the prescriber to withhold the medication; nursing notes about withholding medications or any other situations that would otherwise require the medication to be withheld, such as swallowing difficulties, and/or; other clinical data, such as blood pressure, where this was relevant for the specific medication.

Categorisation of appropriateness

An omission was categorised as 'inappropriate' if there was no documentation in the medical records about withholding the medication or if the reason provided was deemed invalid, for example, 'patient for procedure' without any further clarification.

Medications requiring administration with food

As part of the interactive education sessions during the Policy rollout, I provided advice to nursing staff regarding medications that require administration with food: For these medications, the risk against the benefits of giving or withholding the medication in patients who are fasting needed to be weighed; for example, an oral antibiotic may irritate the gut if given on an empty stomach but not giving it when the patient is fasting could place the patient at risk of the infection worsening.

The agreed rule for assessing appropriateness of omission of medications that required co-administration with food was to consider whether omission/absence of the medication for up to three days could potentially negatively affect the patient's quality of life. The three days was based on the worst-case scenario of patients missing medications due to an unexpected, protracted period without food, such as occurs with a long fasting period and longer than expected theatre time and return to oral intake post-operatively. This three-day rule was also modelled on the (long) 'weekend effect,' in which a higher proportion of error and/or mortality have been implicated amongst patients presenting to the hospital on the weekend.[255-257]

Other factors

A further rule was to consider the actual due time of the doses rather than the time documented for the dose omission. Using the example of a dose normally due at 0800: Omission of this dose at 0800 would be appropriate if the anaesthetic start time was 0845 because a valid reason for omissions was less than one hour prior to the procedure. In contrast, if the procedure was at 1000, the omission would be inappropriate if omitted at 0930, despite this being less than one hour before the procedure, because it should have been given at 0800 when the dose was due. Another factor was that if a nurse then administers a dose that he/she previously annotated as withheld within one to two hours

of the omission, then it is considered appropriate; however, if a different nurse administers the dose then it would be inappropriate.

Excluded medications

Anticoagulants, antiplatelets, non-steroidal anti-inflammatory agents (including Cyclooxygenase-2 (COX-2) inhibitors) and most laxatives except lactulose in liver disease were excluded from assessment of appropriateness: continuing or withholding these agents were felt to be subject to clinical debate and/or too many factors would have needed to be known to make a sound judgment, which would be resource intensive and difficult to establish in a retrospective analysis.

Inter-rater checking

An inter-rater reliability analysis was performed to assess the degree to which the primary data collector (me) and another researcher (Andrew Lim) consistently assigned medications omitted inappropriately independently from each other.

Only medication doses that required manual review of patient records were used for inter-rater checking. A 10% random sample of unique episodes from each area pre- and post-implementation was selected. Inter-rater reliability was evaluated using Cohen's kappa coefficient and corresponding two-sided 95% confidence interval. Kappa values of 0.0 to 0.2 were considered as indicating slight agreement, 0.21 to 0.40 indicating fair agreement, 0.41 to 0.60 indicating moderate agreement, 0.61 to 0.80 indicating substantial agreement, and 0.81 to 1.0 indicating almost perfect or perfect agreement.[190] Initial analysis was performed by me using Excel (version 1808, Microsoft Office Professional Plus 2019). Sabine Braat performed the final/confirmation statistical analyses using Stata (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) for Windows.

Resolving differences

All entries that required manual checking were subject to resolving differences. The dataset with the manually abstracted information (but without my decisions on the appropriateness of the medication omissions) were reviewed by another researcher

(Andrew Lim) who independently determined the appropriateness of the omission. Andrew then discussed his results with me and where there was uncertainty or a decision could not be agreed upon, the unresolved entries were discussed with a third researcher (David Story).

6.4.2.4. Statistical methods

Power/sample size calculation

Results from the pilot study were used to conduct a sample size calculation. A segmented linear regression analysis of the pilot data showed the presence of a change in level, i.e., the monthly proportion of medications that were omitted inappropriately decreased by 21.7% (95% CI [10.0, 33.5]) post-intervention (from 35% pre-implementation), but there was no change in trend suggested. The results also indicated approximately 6% variability and insufficient evidence for the presence of autocorrelation (Durban-Watson statistic).

Assuming 6% variability pre- and post-implementation and no autocorrelation, a minimum of 12 time points (i.e., months) pre- and 12 time points post-implementation and 100 observations per time point per area (Medical and Surgical) were needed to have at least 80% power to detect a change in level of at least 12% if the pre-intervention level is 35% for the present study (F-test of change in level regression parameter in a segmented linear regression, two-sided alpha = 0.05) – refer to Table 14. *Sabine Braat performed the calculations using SAS (version 9.4, SAS Institute, Cary, NC) for Windows.* Further, a minimum of 12 time points (i.e., months) pre- and 12 time points post-intervention are needed to be able to explore potential seasonal effects.

Table 14. Minimum change in level detectable with at least 80% power

Variability Time points	3% (half the pilot study)	6% (same as pilot study)	12% (twice the pilot study)
12 pre and 12 post	-8%	-12%	-16%
18 pre and 12 post	-7%	-9%	-13%
18 pre and 18 post	-5%	-7%	-10%
100 medication records per area per month; Autocorrelation = 0 Variability: pre-intervention, assumed identical in pre- and post-intervention period Pre-intervention level = 35%, post-intervention level = 35% plus change in level Based on segmented linear regression on the aggregate data of the two types of areas			

Up to 30 patient episodes (with non-elective procedures) were randomly selected per month from each of the Surgical and Medical areas based on the estimate that each episode would generate approximately four medication records and that at least 100 medication records per month were needed. The general recommendation of a minimum of 100 observations at each time point[208] motivated the use of monthly instead of weekly aggregate data.

Statistical analysis

This section was written by Sabine: All available data were included in the analysis. Patient and medication characteristics were summarised using descriptive statistics presented for the pre- and post-implementation period separately by Medical or Surgical area. A segmented linear regression model[196] was used to assess the effect of the Policy implementation on the primary and secondary outcome. The regression was based on two periods of consecutive months each with linear segments defined as the pre-implementation time and the post-implementation time. The implementation month was excluded from the model because not enough time points were collected to model the implementation period as a separate segment. The following underlying assumptions were examined for the primary outcome: linearity assumption by exploring alternative shapes using fractional polynomials, autocorrelation including the Cumby-Huizinga test along with the Durban-Watson statistic, non-stationary using the Dickey Fuller test, cyclic patterns/seasonality, and outliers. If linearity was considered violated, an appropriate power transformation was determined and this non-linear term was added to the model. An autoregressive error term was incorporated if autocorrection was considered present. The absolute change in level and absolute change in trend after the implementation (linear model only) were obtained to estimate the implementation effect along with Newey-West standard errors. In addition, the post-implementation linear trend over time was estimated. The relative effect estimate and associated confidence interval (via the delta method) were obtained to allow comparison of the effect sizes with relevant literature. No covariates were included in the models. As a secondary analysis for the secondary outcome, all pre-implementation and post-implementation data were pooled and analysed as a before-after comparison for all available months and six months pre- and post-implementation. The absolute (relative) difference was obtained using a

generalised linear model with binomial distribution and identity (log) link, respectively. A two-sided 5% level of significance was used without adjustment for multiple testing. Statistical analyses, especially the regression modelling, were performed by Sabine, using Stata (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) for Windows.

6.4.2.5. Reporting guideline

Two papers that provided recommendations on reporting for studies employing the ITS design[201,220] were used to guide reporting this study. A checked version of the 'Methodological and reporting recommendations for interrupted time series studies' guidance[201] is presented as Appendix 7. Most of these recommendations were centred on the STROBE statement.[218]

6.4.3. Results

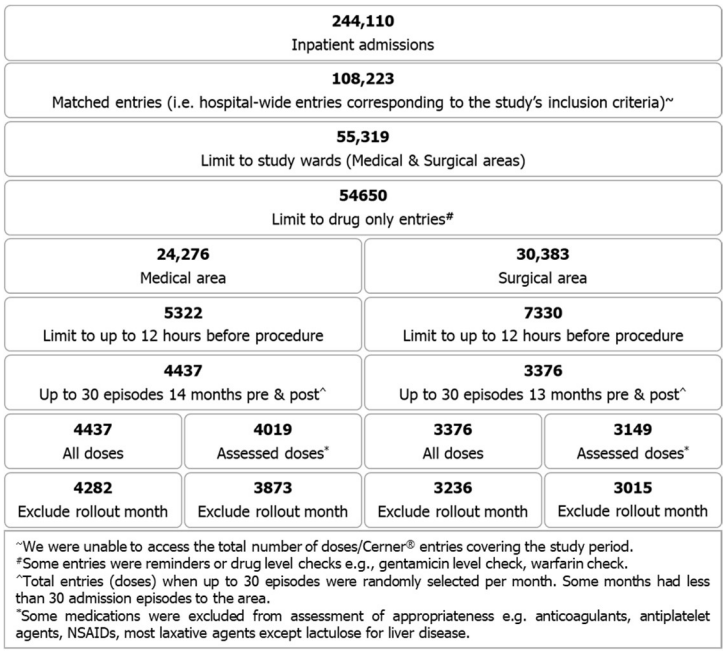
6.4.3.1. Participants

Data acquisition

Figure 10 details the data mining process. In total, there were 244,110 inpatient admissions to the hospital from January 2014 to June 2016. Due to data access issues it was not possible to determine the volume of electronic dose administration data for this period; however, based on an estimate of an average of four medications per patient, with at least one dose of each medication a day and an inpatient stay of three days, there would have been at least 2,900,000 entries.

Refinement of the data resulted in 3873 and 3015 medication records (excluding the rollout month) of doses that could be assessed for Medical and Surgical areas, respectively; that is, doses remaining after removal of excluded medications such as antiplatelets, anticoagulants, non-steroidal anti-inflammatory agents and all laxatives except lactulose for liver disease.

Figure 10. Data acquisition



6.4.3.2. Ward description

There were five wards in Medical areas and three in Surgical areas (Table 15). A fourth surgical ward was excluded because it had been the pilot ward for the Policy. Medical areas primarily consisted of acute medical wards, including specialties such as renal, respiratory and infectious diseases. Surgical areas had a more surgical focus although there were cardiology and gastroenterology patients.

Table 15. Ward description

Medical areas		Surgical areas	
Ward	Specialty	Ward	Specialty
1	Respiratory, infectious diseases	A	Cardiothoracic (surgery and cardiology)
2	General medical	B	General surgery
3	Renal	C	Gastroenterology, liver transplant
4	General medical	-	-
5	Medical acute assessment ward	-	-

6.4.3.3. Types of procedures

The non-elective procedures were diagnostic and/or therapeutic in which the patient needed to fast beforehand and ranged from endoscopies, to cystoscopies, cholecystectomies and internal fixation of fractures.

6.4.3.4. Outcome data

Medical areas

The number of unique episode and unique patients were lower post-implementation, as were the median doses per unique patient, doses per month, episode and patient per month. In contrast, the median doses per episode was higher post-implementation (Table 16). The smaller proportion of patients/episodes seen in some months in the Medical areas, particularly in the post-implementation period, was related to a smaller number of admissions to the area during that time.

Surgical areas

The majority of the Surgical area demographics were similar pre- and post-implementation. There was a higher median for doses per month post-implementation and the median age was one year younger (Table 16).

Doses requiring manual audit

In Medical areas, 22% of doses required manual audit to ascertain appropriateness of the omission pre- compared to 11.3% post-implementation. This proportion was 13.5% and 9.3% pre and post, respectively for Surgical areas (Table 17).

6.4.3.5. Individual ward data

The data breakdown for the individual wards indicated that, post-implementation, there was a decrease in the proportion of doses withheld inappropriately for four of the five Medical area wards. In Surgical areas, a more notable decrease was seen in one ward compared with the other two (Table 18).

Table 16. Demographic characteristics

	Medical wards			Surgical wards		
	Pre-implementation	Post-implementation	Total	Pre-implementation	Post-implementation	Total
Number of unique episodes, n	394	353	747	376	373	749
Sex, n (%)						
Females	189 (48.0)	162 (45.9)	351 (47.0)	167 (44.4)	172 (46.1)	341 (45.3)
Males	205 (52.0)	191 (54.1)	396 (53.0)	209 (55.6)	201 (53.9)	410 (54.7)
Age (years)	73 (57-83)	73 (59-81)	73 (58-82)	60 (46-74)	59 (41-73)	59 (43-74)
Doses per episode^	4 (2-7)	5 (2-7)	4 (2-7)	3 (2-6)	3 (2-5)	3 (2-6)
Unique medications per episode^	4 (2-6)	4 (2-7)	4 (2-7)	2 (1-5)	3 (1-5)	3 (1-5)
Number of unique patients, n	386	338	724	363	366	729
Sex, n (%)						
Females	184 (47.7)	157 (46.4)	341 (47.1)	167 (46.0)	170 (46.4)	334 (45.8)
Males	202 (52.3)	181 (53.6)	383 (52.9)	199 (54.8)	196 (53.6)	395 (54.2)
Age (years)	73 (57-83)	73 (59-81)	73 (57-82)	60 (45-74)	59 (41-74)	59 (43-74)
Doses per patient^	5 (2-7)	4 (2-7)	5 (2-7)	3 (2-6)	3 (2-5)	3 (2-6)
Unique medications per patient^	4 (2-7)	4 (2-7)	4 (2-7)	3 (1-5)	3 (1-5)	3 (1-5)
Unique episodes per patient	1 (1-1)	1 (1-1)	1 (1-1)	1 (1-1)	1 (1-1)	1 (1-1)
Number of months, n	14	14	28	13	13	26
Doses per month^	146 (132-154)	138 (121-142)	142 (123.5-148)	107 (95-131)	123 (101-131)	116 (99-131)
Unique medications per month^	63 (60-65)	63 (54-66)	63 (59-66)	53 (49-57)	53 (51-58)	53 (50-58)
Episodes per month	28 (28-29)	25 (23-28)	28 (25-29)	29 (28-29)	29 (28-29)	29 (28-29)
Patients per month	28 (28-29)	25 (23-28)	28 (25-29)	29 (28-29)	29 (28-29)	29 (28-29)

Statistics are median and IQR (25th to 75th) percentile unless stated otherwise.
Data are based on up to 30 episodes (with a non-elective procedure) randomly selected per area per month.
^Captured in the 12-hours preprocedural timeframe.

Table 17. Doses requiring manual audit

Outcome	Statistic	Medical wards		Surgical wards	
		Pre-implementation (N = 2026)	Post-implementation (N = 1847)	Pre-implementation (N = 1470)	Post-implementation (N = 1545)
Total doses withheld	Total number, n (%)	581 (28.7)	359 (19.4)	308 (21.0)	284 (18.4)
	Number per episode, median (IQR)	1 (0-2)	0 (0-1)	0 (0-1)	0 (0-1)
Withheld appropriately (per available information on data download)	Total number, n (%)	135 (6.7)	151 (8.2)	110 (7.5)	140 (9.1)
	Number per episode, median (IQR)	0 (0-0)	0 (0-1)	0 (0-0)	0 (0-1)
Doses requiring manual audit#	Total number, n (%)	446 (22.0)	208 (11.3)	198 (13.5)	144 (9.3)
	Number per episode, median (IQR)	0 (0-2)	0 (0-1)	0 (0-1)	0 (0-0)
Withheld appropriately	Total number, n (%)	88 (4.3)	103 (5.6)	46 (3.1)	50 (3.2)
	Number per episode, median (IQR)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
Withheld inappropriately*	Total number, n (%)	358 (17.7)	105 (5.7)	152 (10.3)	94 (6.1)
	Number per episode, median (IQR)	0 (0-1)	0 (0-0)	0 (0-1)	0 (0-0)

#All doses that did not have sufficient information or appeared to be omitted inappropriately based on information on the data download required a review for potential reasons for the omission in the patient's medical records to be conducted.
*Primary outcome for the ITS analysis.

Table 18. Data per ward

Medical areas					Surgical areas				
Ward	Pre-implementation (N = 2026)		Post-implementation (N = 1847)		Ward	Pre-implementation (N = 1470)		Post-implementation (N = 1545)	
	Total doses n (% pre)	Doses withheld inappropriately n (% ward total)	Total doses n (% post)	Doses withheld inappropriately n (% ward total)		Total doses n (% pre)	Doses withheld inappropriately n (% ward total)	Total doses n (% post)	Doses withheld inappropriately n (% ward total)
1	439 (21.7)	61 (13.9)	361 (19.5)	21 (5.8)	A	155 (10.5)	14 (9.0)	160 (10.4)	2 (1.3)
2	491 (24.2)	120 (24.4)	454 (24.6)	29 (6.4)	B	583 (39.7)	68 (11.7)	673 (43.6)	47 (7.0)
3	611 (30.2)	99 (16.2)	575 (31.1)	25 (4.3)	C	732 (49.8)	70 (9.6)	712 (46.1)	45 (6.3)
4	409 (20.2)	62 (15.2)	422 (22.8)	21 (5.0)	-	-	-	-	-
5	76 (3.8)	16 (21.1)	35 (1.9)	9 (25.7)	-	-	-	-	-

6.4.3.6. Medication dose types

The top six Australian Medicines Handbook[82] (AMH) medication classes prescribed and omitted inappropriately for both Medical and Surgical areas were analgesics, cardiovascular, gastrointestinal, blood and electrolyte, anti-infective and endocrine agents (Table 19). Across these top six classes, there was at least a 10% reduction in the proportion omitted post-implementation in Medical areas.

The medication most prescribed and most likely to be withheld inappropriately was paracetamol. Others included pantoprazole, cholecalciferol and furosemide (Table 20). Medications that did not make the list but that were also likely to be withheld inappropriately included thyroxine (levothyroxine sodium), 'statins' (e.g., atorvastatin) and dexamethasone.

6.4.3.7. Medications given inappropriately

A small proportion of doses were given inappropriately.

Anti-diabetes medications

A total of 14 doses of anti-diabetes medications were given pre-implementation compared with 16 doses post-implementation. When separated into Medical and Surgical areas; four (12%, n=34) anti-diabetes medication doses were administered pre- compared with seven (16%, n=43) post-, and 10 (33%, n=30) given pre- compared with nine (28%, n=32) post-implementation, respectively.

In the post-implementation period for Medical areas, there was one dose in which the nurse had documented high blood glucose levels and the anti-diabetes medication (linagliptin, dipeptidyl peptidase-4 (DPP-4) inhibitor) was given soon afterwards. For another dose, the patient was fasted after early morning breakfast and the anti-diabetes medication (gliclazide, sulfonylurea) was given at 6.14 am, presumably with breakfast. Furthermore, high blood sugar levels were recorded at midmorning (18.3) and at midday (14.9). These doses were assigned inappropriate because there was no documentation to explicitly indicate the administration of medications was deliberate. Had these entries been excluded, the rate would have been similar to pre-implementation.

Table 19. Top six Australian Medicine Handbook medication class

	Medical areas				Surgical areas			
	Pre-implementation N = 2026		Post-implementation N = 1847		Pre-implementation N = 1470		Post-implementation N = 1545	
	All doses N (% pre)	Withheld inappropriately N (% AMH class)	All doses N (% post)	Withheld inappropriately N (% AMH class)	All doses N (% pre)	Withheld inappropriately N (% AMH class)	All doses N (% post)	Withheld inappropriately N (% AMH class)
1	Cardiovascular 478 (23.6)	Analgesics 89 (23.5)	Cardiovascular 448 (24.3)	Analgesics 27 (9.0)	Analgesics 325 (22.1)	Blood & electrolytes 29 (11.9)	Analgesics 364 (23.6)	Gastrointestinal 23 (7.9)
2	Analgesics 379 (18.7)	Cardiovascular 64 (13.4)	Analgesics 301 (16.3)	Cardiovascular 16 (3.6)	Cardiovascular 291 (19.8)	Gastrointestinal 27 (10.5)	Cardiovascular 283 (18.3)	Blood & electrolytes 19 (8.6)
3	Gastrointestinal 206 (10.2)	Endocrine 54 (26.3)	Gastrointestinal 240 (13.0)	Blood & electrolytes 15 (7.0)	Gastrointestinal 216 (14.7)	Analgesics 25 (7.5)	Gastrointestinal 257 (16.6)	Analgesics 12 (3.2)
4	Endocrine 205 (10.1)	Blood & electrolytes 44 (22.2)	Blood & electrolytes 214 (11.6)	Gastrointestinal 10 (4.2)	Blood & electrolytes 178 (12.1)	Cardiovascular 24 (8.2)	Blood & electrolytes 173 (11.2)	Endocrine 8 (6.8)
5	Blood & electrolytes 198 (9.8)	Gastrointestinal 37 (18.0)	Endocrine 175 (9.5)	Anti-infectives 8 (6.0)	Anti-infectives 122 (8.3)	Anti-infectives 18 (14.8)	Endocrine 117 (7.6)	Cardiovascular 6 (2.1)
6	Anti-infectives 135 (6.7)	Anti-infectives 26 (19.3)	Anti-infectives 134 (7.3)	Endocrine 8 (4.6)	Endocrine 112 (7.6)	Endocrine 16 (14.3)	Anti-infectives 94 (6.1)	Anti-infectives 6 (6.4)

Table 20. Top six medications

	Medical areas				Surgical areas			
	Pre-implementation N = 2026		Post-implementation N = 1847		Pre-implementation N = 1470		Post-implementation N = 1545	
	All doses N (% pre)	Withheld inappropriately N (% medication)	All doses N (% post)	Withheld inappropriately N (% medication)	All doses N (% pre)	Withheld inappropriately N (% medication)	All doses N (% post)	Withheld inappropriately N (% medication)
1	Paracetamol 313 (15.5)	Paracetamol 86 (27.5)	Paracetamol 239 (12.9)	Paracetamol 22 (9.2)	Paracetamol 265 (18.0)	Paracetamol 23 (8.7)	Paracetamol 299 (19.4)	Lactulose 12 (18.2)
2	Colecalciferol 113 (5.6)	Colecalciferol 38 (33.6)	Pantoprazole 90 (4.9)	Colecalciferol 7 (8.8)	Pantoprazole 65 (4.4)	Colecalciferol 14 (23.7)	Pantoprazole 76 (4.9)	Paracetamol 12 (4.0)
3	Furosemide 95 (4.7)	Furosemide 20 (21.1)	Furosemide 89 (4.8)	Magnesium 6 (20.7)	Colecalciferol 59 (4.0)	Esomeprazole 9 (23.1)	Lactulose 66 (4.3)	Colecalciferol 7 (10.9)
4	Pantoprazole 74 (3.7)	Pantoprazole 14 (18.9)	Colecalciferol 80 (4.3)	Multivitamins 4 (23.5)	Lactulose 47 (3.2)	Pantoprazole 8 (12.5)	Colecalciferol 64 (4.1)	Magnesium 5 (11.9)
5	Metoprolol 50 (2.5)	Esomeprazole 10 (29.4)	Metoprolol 48 (2.6)	Nystatin 4 (12.1)	Magnesium 43 (2.9)	Thiamine 8 (19.5)	Magnesium 42 (2.7)	Multivitamins 4 (28.6)
6	Fluticasone-salmeterol 50 (2.5)	Thiamine 10 (27.8)	Esomeprazole 47 (2.5)	Doxycycline 3 (18.8)	Furosemide 41 (2.8)	Amoxicillin-clavulanate 5 (41.7)	Thiamine 42 (2.7)	Metronidazole 3 (33.3)

An observation that requires verification is that fasting from early morning breakfast seemed to be interpreted by some as give the morning dose of oral anti-diabetes medications. It is unclear whether this was a nursing decision or whether there were verbal, unrecorded discussions with the medical team. There are recommendations that certain oral anti-diabetes medications, such as 'glitazones' (thiazolidinediones) and 'gliptins' (dipeptidyl peptidase 4 inhibitors), may be continued on the day of the procedure because of concerns over increased risk of post-operative infection and delayed wound healing due to poor glycaemic control if omitted[344]; however, the Austin Health guidelines recommend the omission of all oral anti-diabetes medications on the morning of the proposed procedure/surgery.

Other medications

Liquid forms of antacids contain particulate matter and should therefore be avoided while fasting before an anaesthetic procedure due to the risk of aspiration; however, the exact cut-off time allowed for dosing before a procedure for these agents is unclear. As a conservative approach, six hours was used in this study. There were four Gastrogel® entries, one at three hours before anaesthetic start pre-implementation of the Policy and three at four hours before the procedure post-Policy implementation. The other two medications given inappropriately were pancreatic extract (one dose pre- and one post-implementation) and Sevelamer (phosphate binder, one dose pre). These latter agents have specific functions on the food itself and should only be given if the patient is eating and therefore inappropriate to administer during the fasting period.

6.4.3.8. Timeframe of dose omissions

In Medical areas, dose omission was most likely to occur within one to four hours before a procedure, regardless of whether the omission was appropriate or not. This was followed by another spike between seven to eight hours prior to the procedure (Figure 11). In Surgical areas, dose omissions tended to increase as it got closer to the procedure/anaesthetic start time (Figure 12).

Figure 11. Timeframe of dose omissions – Medical

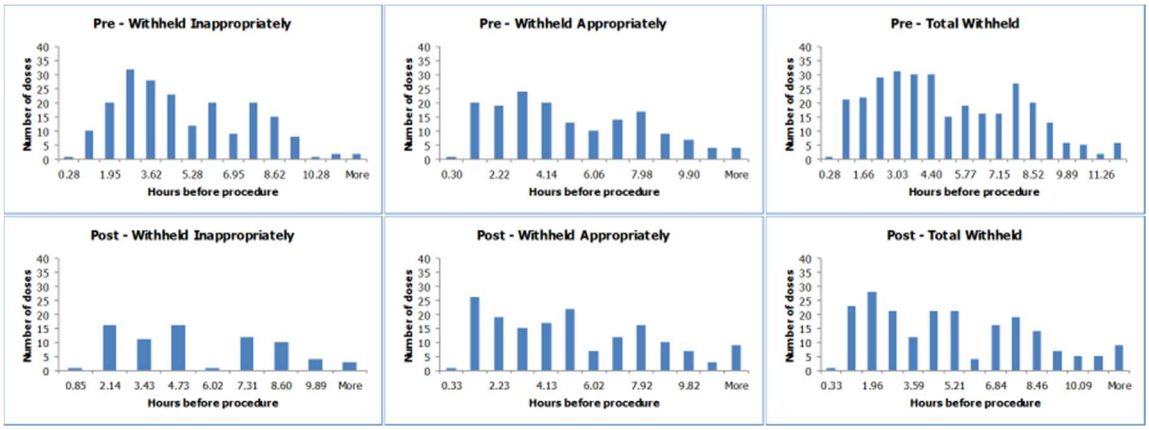
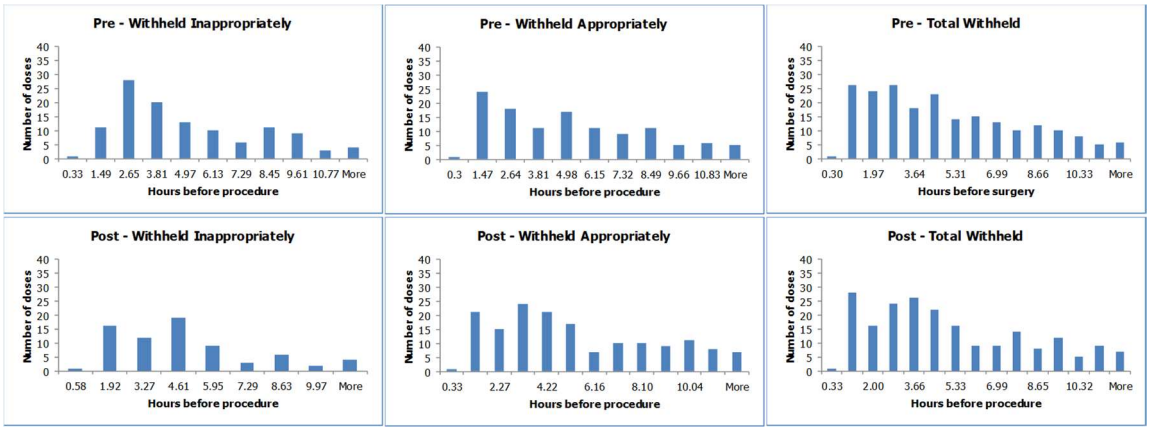


Figure 12. Timeframe of dose omissions – Surgical



6.4.3.9. Inter-rater checking

A total of 81 medication records from Medical areas and 45 from Surgical areas were randomly selected and checked by the second rater. The kappa coefficient was 0.83 (95% CI [0.71, 0.96]) and 0.85 (95% CI [0.68, 1.00]), respectively.

Inter-rater differences resulted from differences in opinion for whether an omission was inappropriate and/or differences in interpretation of the clinical notes; for example, "'meds WH due to pending theatre' in the nursing notes" recorded by one researcher compared with "'NBM' as noted by medical team" recorded by the other for the same entry.

6.4.3.10. Resolving differences

Resolving differences was conducted for 1021 entries. A large proportion of the entries were resolved in the first round, either with immediate agreement between the two researchers (628, 94%, n=666, Medical; 329, 93%, n=355, Surgical) or upon discussion (13, 2%, Medical; 4, 1%, Surgical). The remaining entries (25, 4%, Medical; 22, 6%, Surgical) required discussion and resolution with the third researcher.

6.4.3.11. ITS of doses omitted inappropriately

The ITS analysis output for doses omitted inappropriately is presented in Table 21. (Monthly data for Medical areas can be found in Appendix 8 and Surgical areas in Appendix 9).

Medical

The initial proportion of doses withheld inappropriately for the Medical areas was 18.1% per month between January 2014 and February 2015, inclusive. Prior to March 2015, there was no significant linear trend in the proportion of doses withheld inappropriately (P=0.829). In April 2015, there was a significant reduction in the proportion of doses withheld inappropriately of 13.4% (95% CI [9.0, 17.7], P<0.0001), followed by an insignificant increase (P=0.302) (Table 21). Post-implementation linear trend analysis showed that after implementation, there was a 0.3% increase in the proportion of doses withheld inappropriately per month (95% CI [0.0, 0.6], P=0.034) (Table 22).

Surgical

The estimated proportion of doses withheld inappropriately prior to implementation was 11.9% with no significant linear trend (P=0.595). Following implementation (February 2015), the linear model showed a non-significant reduction in the proportion of doses withheld inappropriately (5.5%, 95% CI [-2.9, 13.9], P=0.188). After accounting for the non-linear shape of the pre-implementation phase, there was a larger and significant reduction in the proportion of doses withheld inappropriately (8.3%, 95% CI [0.8, 15.7], P=0.031) (Table 21). The post-implementation linear trend was insignificant (Table 22).

6.4.3.12. ITS of total omissions

The ITS of overall doses withheld indicated a statistically significant reduction of 11.1% post-implementation in Medical areas (Table 23). The results for Surgical areas were insignificant (Table 23), as was the post-implementation trend for both areas (Table 24).

6.4.3.13. Visual inspection of ITS output

For Medical areas, the ITS of inappropriate omissions (Figure 13) was assessed as stationary and incorporated an autocorrelation with lag 1, hereby assuming that adjacent months are correlated. The pre-implementation period of inappropriate omissions for the Surgical area suggested a quadratic trend (parabola) violating the linearity assumption of the segmented linear regression model. The data were checked to rule out erroneous data. In addition to the primary segmented linear regression analysis, non-linearity was accounted for in the model to assess the sensitivity of the estimate for the change in level post-implementation. No autocorrelation was assumed for Surgical area. For the secondary outcome of overall doses omitted (Figure 14), an autocorrelation with lag 1 was assumed for Medical area and no autocorrelation for Surgical area while both were assumed as stationary. In addition, for Surgical areas, similar to inappropriate omissions, we allowed for a non-linear shape of the pre-implementation period.

The visual inspection of the ITS output (Figure 13 & Figure 14) indicated that the omissions became more sporadic after the first six months following implementation for both Medical and Surgical areas.

Table 21. ITS of inappropriate omissions

	Level before implementation			Monthly slope before implementation			Level change after implementation			Change in slope after implementation		
	Estimate	**95% CI**	**P-value**	**Estimate**	**95% CI**	**P-value**	**Estimate**	**95% CI**	**P-value**	**Estimate**	**95% CI**	**P-value**
Medical	18.08	12.31 – 23.85	<0.0001	-0.07	-0.69 – 0.56	0.829	-13.38	-17.73 – -9.02	<0.0001	0.37	-0.35 – 1.08	0.302
Surgical	11.92	4.47 – 19.36	0.003	-0.24	-1.18 – 0.69	0.595	-5.50	-13.89 – 2.89	0.188	0.72	-0.48 – 1.93	0.227
Surgical non-linear*							-8.28	-15.73 - -0.83	0.031			

*The level change after implementation after accounting for the non-linear shape of the pre-implementation period.
Relative effect of level change after implementation:
Medical; 0.78, 95% CI [0.64, 0.92]
Surgical linear model; 0.63, 95% CI [-0.10, 1.36]^
Surgical non-linear model; 0.72, 95% CI [0.18, 1.26]^
^The relative effect of level change was calculated to enable approximate comparisons with other studies only. The estimate of the relative effect is extracted from the model of the absolute effect and as a result is not bounded by logical boundaries such as 1, hence the confidence interval greater than 1 displayed.

Table 22. Post-implementation linear trend – inappropriate omissions

	Estimate	**95% CI**	**P-value**
Medical	0.30	0.02 – 0.58	0.034
Surgical	0.48	-0.28 – 1.24	0.203
Surgical non-linear*	0.48	-0.30 – 1.26	0.214

*The level change after implementation after accounting for the non-linear shape of the pre-implementation period

Table 23. ITS of total omissions

	Level before implementation			Monthly slope before implementation			Level change after implementation			Change in slope after implementation		
	Estimate	**95% CI**	**P-value**	**Estimate**	**95% CI**	**P-value**	**Estimate**	**95% CI**	**P-value**	**Estimate**	**95% CI**	**P-value**
Medical	28.00	21.42 – 34.60	<0.0001	0.11	-0.62 – 0.84	0.766	-11.07	-19.56 – -2.57	0.013	0.05	-0.88 – 0.98	0.911
Surgical	24.83	17.58 – 32.07	<0.0001	-0.60	-1.49 – 0.28	0.173	-2.71	-9.76 – 4.34	0.434	1.28	0.12 – 2.45	0.032
Surgical non-linear*							-5.54	-12.77 – 1.69	0.126			

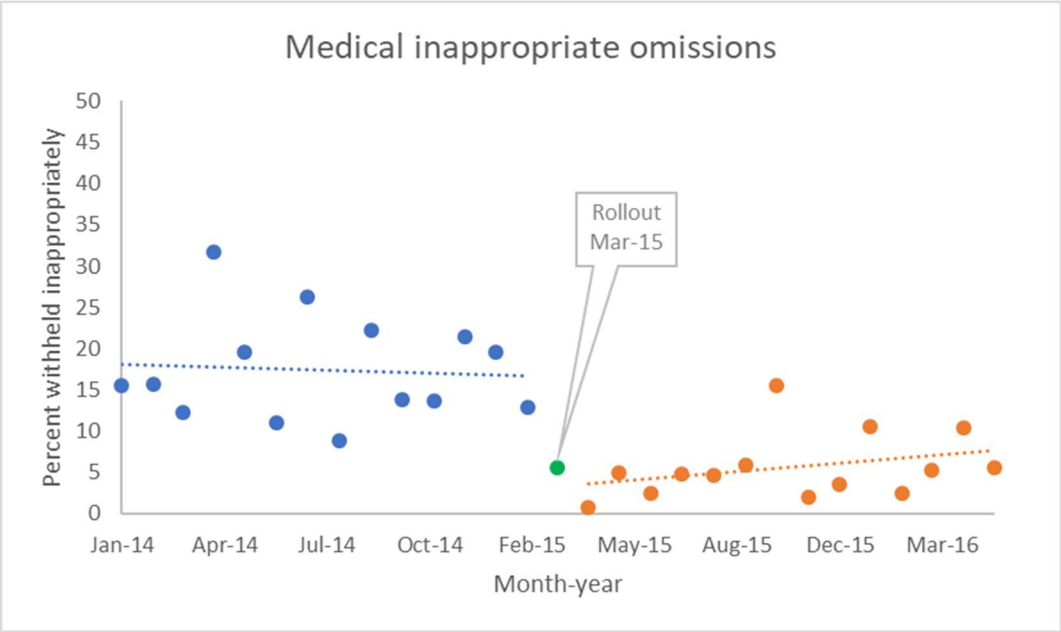
*The level change after implementation after accounting for the non-linear shape of the pre-implementation period
Relative effect of level change after implementation:
Medical; 0.38, 95% CI [0.13 – 0.62]
Surgical; 0.16, 95% CI [-0.21 – 0.53]
Surgical non-linear model; 0.28, 95% CI [-0.02 – 0.58]

Table 24. Post-implementation linear trend - total omissions

	Estimate	**95% CI**	**P-value**
Medical	0.16	-0.50 – 0.81	0.622
Surgical	0.69	-0.07 – 1.45	0.074
Surgical non-linear*	0.69	-0.09 – 1.47	0.081

*The level change after implementation after accounting for the non-linear shape of the pre-implementation period

Figure 13. Time series of inappropriate omissions



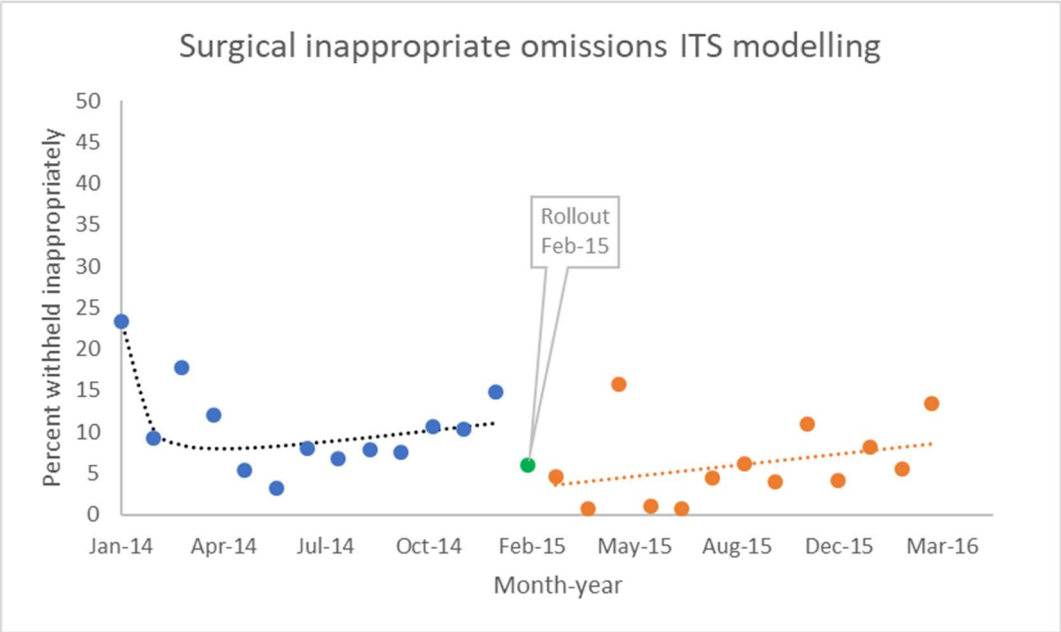
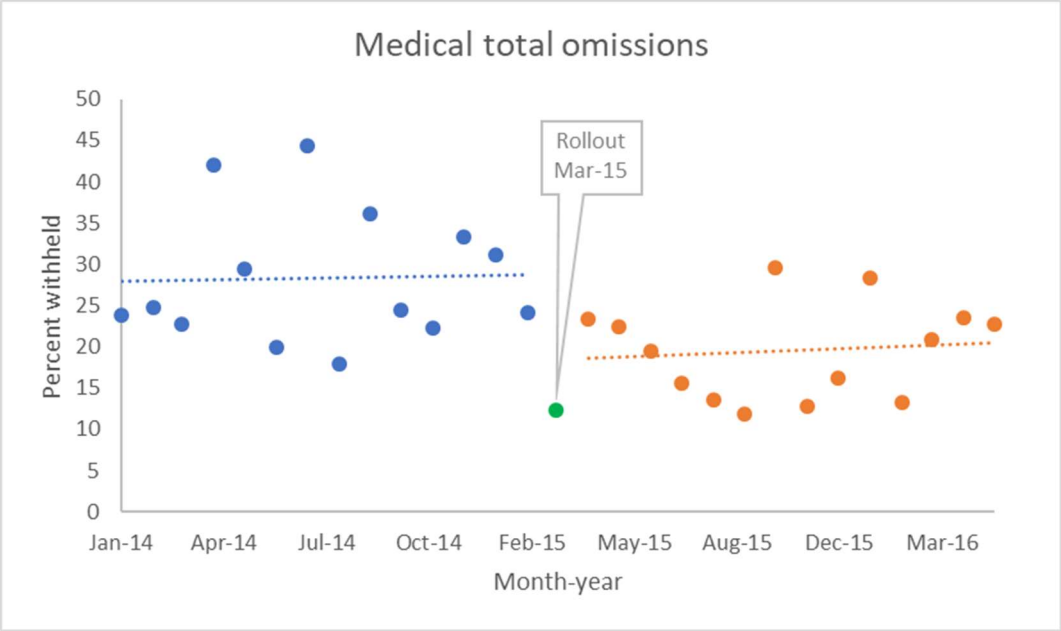
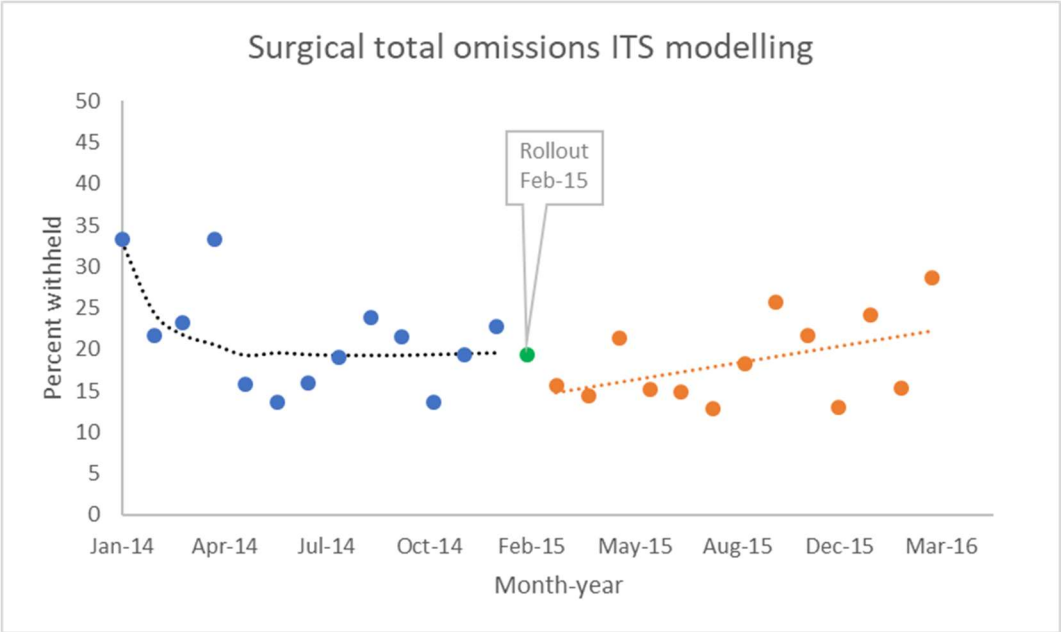


Figure 14. Time series of total omissions





6.4.3.14. Cumulative before and after comparison

The before and after comparison of overall omissions is shown in Table 25. When the six months cumulative data were compared, there was a statistically significant absolute reduction of 11.2% for Medical areas (95% CI [7.2, 15.3], P<0.0001) and 4.4% for Surgical areas (95% CI [0.5, 8.2], P=0.026). Medical area results remained statistically significant when the entire study period data were compared but at a slightly lower reduction (9.2%, P<0.0001), while Surgical results were insignificant.

Table 25. Cumulative before and after comparison of doses withheld

	Medical			Surgical		
	Effect	**95% CI**	**P-value**	**Effect**	**95% CI**	**P-value**
Six months						
Before vs after %	28.80 vs 17.57			19.87 vs 15.49		
Absolute difference %	-11.22	-15.28 – -7.18	<0.0001	-4.38	-8.24 – -0.51	0.026
Relative difference	0.39	0.28 – 0.50	-	0.22	0.05 – 0.39	-
Overall						
Before vs after %	28.68 vs 19.44			20.95 vs 18.38		
Absolute difference %	-9.24	-11.91 – -6.57	<0.0001	-2.57	-5.41 – 0.27	0.076
Relative difference	0.32	0.24 – 0.40	-	0.12	-0.004 – 0.25	-

6.4.3.15. Other observations

There were two incidental insights from the data collection process: The first related to medications that require administration with or after food and the second concerned documentation about withholding medications. As these observations had not been planned and had not been systematically retrieved, the data presented may be incomplete.

With food medications

A note involving food had been logged in the database for 166 entries requiring manual checking. These were based on food-related documentation by the doctor, nurse or pharmacist in their respective section in the medication administration record or in the patient's clinical notes. Of these entries, two thirds were deemed to have been omitted inappropriately (Table 26).

In the Medical group, the most affected AMH class agents requiring administration with food were anti-infectives (e.g., amoxicillin-clavulanate, doxycycline, and metronidazole), blood and electrolytes (e.g., potassium, magnesium) and immunomodulators (e.g., dexamethasone). For the Surgical group, the two major classes were anti-infectives and blood and electrolytes.

Documentation pre- and post-implementation

In many instances, there was a lack of documentation of a reason for dose omission. Where there was documentation, many of the reasons for the omissions, particularly in the pre-implementation period, were inappropriate; for example, 'fasting (or nil by mouth) for procedure.' There were many cases where all or some of the patients' medications were withheld, and sometimes this occurred despite earlier specification of 'meds with sips' by the doctor in the clinical notes.

Table 27 details entries that revealed no further documentation with manual audit of the medication administration record. Overall, 68% and 69% of entries that required manual checking did not have further documentation for the dose omission in Medical and Surgical areas, respectively. In the pre-implementation period, there was no further documentation for 74% of entries in both Medical and Surgical areas (328, n=446 and 147, n=198, respectively). Following policy rollout, 8% (16, n=208) of entries in Medical areas had no clear documentation compared to 63% (91, n=144) in Surgical areas.

In the patients' clinical notes, there was no documentation about withholding the medication for 304 entries (68%, n=446) in Medical areas pre-implementation compared to 107 entries (51%, n=208) post. This information had not been collected for Surgical areas.

Post-implementation, the reasons documented appeared to be more specific; for example, a notation that the patient was unable to swallow oral medications with only a small sip of water, as opposed to the generic 'fasting for theatre'.

Table 26. 'With food' medications

	Medical areas			Surgical areas			
	Pre-implementation	Post-implementation	Total	Pre-implementation	Post-implementation	Total	Grand total
Total	75	46	123	20	20	43	166
Omitted appropriately, n (% total)	25 (33.3)	23 (50.0)	48 (39.0)	5 (25.0)	2 (10.0)	8 (18.6)	56 (33.7)
Omitted inappropriately, n (% total)	50 (66.7)	23 (50.0)	75 (61.0)	15 (75.0)	18 (90.0)	35 (81.4)	110 (66.3)

Table 27. No further documentation on medication administration record

	Medical areas					Surgical areas				
	Entries with ND*	Total checked	% checked with ND*	Total for period	% for period	Entries with ND*	Total checked	% checked with ND*	Total for period	% for period
Pre-implementation	328	446	73.5	2026	16.2	147	198	74.2	1470	10.0
Post-implementation	16	208	7.7	1847	0.9	91	144	63.2	1545	5.9
Rollout	7	12	58.3	146	4.8	7	13	53.8	134	5.2
Total	451	666	67.7	4019	11.22	245	355	69.0	3149	7.8
*ND = no further documentation										

6.4.3.16. Completeness of data

It was not possible to determine potential missing data for total hospital admissions or the electronic medication administration platform. In the case of the latter, the database retains only medication doses that had been acted upon by nursing staff, whether this was to notate that the dose had been given or not. Doses not acted on after a series of reminder 'flags' eventually disappear from the electronic prescribing platform and, consequently, from the hospital's medication administration database. Data administrators consider this issue insignificant owing to the overall volume of doses/entries and the view that nurses were inclined to act on tasks such as reminders/flags. Regardless, there were no reason to expect that completeness of data differed pre-and post-Policy implementation.

6.4.3.17. Extrapolation of results

Generalising the hospital-wide proportion of doses omitted inappropriately pre- and post-implementation using Surgical area linear data (5.5%) as the minimal improvement and Medical area data (13.4%) as the maximum improvement yields a reduction of approximately 5,952 to 14,500 doses omitted inappropriately. These figures assume 108,223 doses hospital-wide (during the 12-hour timeframe before a procedure over 30 months, Figure 10). The estimate equates to a reduction of approximately 198 to 483 inappropriate omissions hospital-wide per month, which could be sufficient to prevent adverse outcomes.

6.4.4. Discussion

Policy implementation was associated with a statistically significant decrease in the proportion of doses withheld inappropriately in both Medical areas and Surgical areas. The absolute reduction was 13.4% (relative effect 78%) and 8.3% (relative effect 72%), for Medical areas and Surgical areas, respectively. A change in trend was not observed for evidence of a long-term implementation effect for both Medical and Surgical areas. In contrast, post-implementation linear trend analysis indicated a small (0.3%), statistically significant increase in the proportion of doses omitted inappropriately per month in Medical areas, which suggests issues with sustainability.

6.4.4.1. Medical versus Surgical areas

The reduction in doses withheld inappropriately and overall doses withheld was greater in Medical compared to Surgical areas post-implementation; however, Surgical areas had a lower proportion of both these parameters pre-implementation. This was unusual and contrasted with many reports in the literature, which suggest that patients in surgical wards more likely to have medication omissions than those in medical wards.[265,340-343] It is possible this stems from the impetus for the Policy being driven by key leaders in the Surgical area, as well as the Policy being piloted on one of the surgical wards (excluded from this study). Some in the Surgical cohort may have already been practising the Policy prior to hospital-wide implementation.

Alternatively, it is possible that Surgical area staff were more adept with managing medications during the fasting period as the surgical setting was their area of expertise. Also, the patient types may have meant that staff were less likely to manage patients with 'medical' issues such as swallowing difficulties, or that the focus of management and/or the decision-making process related to oral restrictions were less complicated. Wards in Medical areas were likely to be exposed to a wider variety of oral restriction conditions and the larger reduction seen post-implementation may be attributed to clinical context being provided by the separation of fasting from nil by mouth in terms managing oral medications. The trend of Medical type wards having a greater improvement was also seen in the Surgical area ward that had a cardiology load (Ward A).

It may also be possible that the comparatively lower level of improvement seen in Surgical compared Medical areas was due to the focus of attention being on the surgical intervention rather than other medical aspects. This, together with the volume of patients passing through those areas, may lead to medication management not being as prioritised. It has been reported that surgical specialties rarely initiate drug treatment outside their own therapeutic areas, and generally, knowledge about and interest in drugs may be poor.[265] This is likely heightened by the view from some that it is not the surgeon's role to manage patients' medications.[345]

6.4.4.2. Pool nurses and education structure

The hospital has a structure of 'pool' nurses, whereby nurses in a pool could be allocated to any of the wards in that pool. Consequently, it is possible that surgical pool nurses had been allocated to the pilot ward. The pilot ward is located on the same floor as two of the Surgical area wards and has continued to operate the Policy after the completion of the pilot in December 2013. This proximity may have played a role and it is conceivable that many pool nurses were already familiar with the Policy and used it in other Surgical areas before the official rollout.

Due to the cardiology focus on Ward A of the Surgical area, it may be less likely for general surgical pool nurses to be allocated to this area. This ward is also located on a different floor to the other Surgical area wards. The difference in proportion of doses omitted inappropriately in Ward A pre- and post-implementation appears to be slightly greater than other Surgical area wards (approximately 8% compared to 3%-5%, respectively) (Table 18). This observation needs verification, although it may be difficult to do so because of the low number of patients matching the selection criteria in this ward.

Medical and Surgical areas have their own education structure but within the areas there will likely be overlaps, especially with Educators and those with education support roles. It is plausible that such overlaps during and after the Policy pilot resulted in staff practising the concepts of the Policy in other wards of the Surgical areas before hospital-wide implementation.

6.4.4.3. Ceiling effect?

There is the possibility that a threshold for policy impact was reached; that is, the capacity of the Policy's message to further improve practice was saturated. The 'ceiling effect' has been described as an intervention having limited effect because the population is already at/near pinnacle point, or the limitation of an assessment to capture the extent and variance of an accomplishment because the assessment is too simplistic or a maximum achievable score given the background of the group being investigated and the available information.[346] Perhaps the study results reflect a combination of the first and third descriptions or all three if the second description was taken as the assessment being too

simplistic for the complexity of the process. Alignment with the 'ceiling effect' lies with the observation that post-implementation proportions of (inappropriate) omissions were not too dissimilar for some Medical and Surgical area wards (Table 18, around 6%) and between the two areas generally (Table 21, Table 23 & Table 25). Additionally, the cumulative overall omission results for Medical areas post-implementation were also not too dissimilar to Surgical pre-implementation proportions (Table 25). A review of guideline dissemination and implementation strategies found that in 86% of studies that observed improvements in process-of-care indicators the median absolute improvement was about 10%[347] – perhaps these studies also experienced a ceiling effect. Awareness of the distinction between the oral intake categories does not necessarily translate to the understanding of what to do next for some – focus group interviews about the Policy following implementation indicated that interpretation of the information on the signs and the resulting clinical decision-making process varied between individuals.[348] A review of how oral medications were managed in patients fasting before a procedure in Surgical areas prior to the pilot study may provide further insight into the potential 'ceiling effect'; unfortunately, this exploration would be confounded by the transition from paper-based to an electronic prescribing platform.

6.4.4.4. Ward differences

Although the numbers were small, the individual ward data (Table 18) suggest that certain wards performed better than others: As an example, there was an 18% reduction in the proportion of doses withheld inappropriately in one general medical ward post-Policy implementation, compared with around 10% in another general medical ward (and one ward seemed to have performed worse). It also appears that the Surgical area ward catering for cardiology patients (Ward A) achieved a more favourable improvement than other Surgical area wards. Incidentally, this ward attained a similar result to Ward 1 in the Medical area, which happens to be on the same floor of the hospital.

Other than potential influence of ward location, a key theme to explore from these observations is the influence of local (ward level) champions/opinion leaders for the Policy and how this differed among the wards. The enthusiasm and intensity in which senior staff in the area, such as the Nurse Unit Manager, Nurse Educator and/or assigned

clinical champions, approached the implementation and subsequent maintenance of the Policy in their area likely impacted the Policy implementation. Initiatives flourish because key staff drive the innovation and hold it in place while more permanent integrating mechanisms began to work[314] and the longevity of an adopted intervention may be a direct function of original implementation intensity.[315]

6.4.4.5. Important versus non-essential medications

The practice of weighting the decision of whether to give oral medications during the fasting period in favour of perceived 'critical or important' medications over 'non-essential' medications was suggested in the types of medications omitted. Paracetamol, due to its widespread use, easy access and often symptom management role, was the most omitted medication during the fasting period despite being prescribed as a regular dose. In some instances, other, 'stronger', oral analgesics (e.g., opioids) were given where paracetamol was omitted. Paracetamol provides important baseline analgesia; it is recommended as the agent of first choice for long-term use in a variety of mild to moderate chronic pain states.[349] A randomised, controlled study found no additional benefit with the addition of opioids or a non-steroidal anti-inflammatory agent over oral paracetamol alone[350] in acute pain situations. Consequently, paracetamol should not be omitted, especially in those patients about to undergo an invasive procedure and, even more so, in those who have been prescribed this agent to manage long-term pain.

Pantoprazole (and other proton pump inhibitors) was also more likely to be omitted, especially in Medical areas pre-Policy. Proton pump inhibitors inhibit gastric acid secretion and are used to manage conditions such as gastrointestinal ulcer disease/reflux. The American Society of Anesthesiologists has identified evidence for and supports the administration of medications that block gastric acid secretion – including proton pump inhibitors – as a preoperative preventative measure for patients at risk of pulmonary aspiration.[89] This reason makes it even more important that proton pump inhibitors not be omitted prior to a procedure, especially in patients already on these medications long-term.

Examples of other agents omitted but that should have been continued perioperatively include 'statins'[65,344] (atorvastatin, simvastatin), various anti-infective agents, dexamethasone, prednisolone, levothyroxine, potassium and magnesium.

6.4.4.6. Timeframe of dose omissions

Many doses were omitted within four hours before anaesthetic start time, which, although inappropriate in some cases, was understandable given that the standard fasting regime is six hours prior to a procedure. Of concern, was the spike within the seven to eight-hour timeframe for Medical areas across all data settings. Explanations for this spike include uncertainty about procedure times/theatre availability, patients fasted (early) as a precaution and/or that procedures were delayed leading to a longer than expected fasting period. The latter scenario corresponds to patients being fasted overnight, have their morning doses of medications withheld and having their procedure/surgery later (than intended) in the day. This in turn may be related to patients needing to abstain from breakfast thereby missing medications that require administration with food/breakfast. A 2015 Mayo Clinic study reported that one in four 'nil per os' (nothing by mouth, NPO) orders and nearly half of missed meals could have been avoided and that some patients miss up to one to two mealtimes because of the NPO status.[351] The authors followed this with a retrospective study of 924 NPO orders related to a procedure (e.g., imaging study or operation) and found that the median NPO length was 12.7 hours (IQR [10.1, 15.7]) and an intervention was not performed in 19.8% (183) of orders.[94] These considerations highlight that many patients have their oral medications withheld needlessly before a procedure and further support the importance of ensuring continuity of the patients' usual medication regime. In most instances, it should not be disrupted purely because the patient is fasting.

6.4.4.7. 'With food' medications

There appears to be an inclination for medications requiring administration with or after food to be withheld – a 'risk versus benefit assessment' did not appear to be applied for many of these medications when patients were fasting before a procedure. A number of anti-infective agents, such as amoxycillin-clavulanate, doxycycline and metronidazole,

that required administration with/after food to minimise gastrointestinal irritation were omitted. The benefit of continuing these agents and managing the infection outweighs the risk of 'gut irritation' that may be caused by these agents in the absence of food. (Further, it is possible for antiemetics to be given for nausea associated with these medications). Thus, it was inappropriate to withhold them if the absence of food was the only reason for the omission. Of 166 food-related doses, two thirds (110, 66%) were omitted inappropriately. This premise requires further deliberation, especially in regards to strategies that best guide staff for each medication/clinical/patient circumstance for these types of medications – would an interactive flow chart at the point of care be the most appropriate way for the risk versus benefit tenet to be expounded, and if so, how can this be incorporated into the electronic prescribing platform in a quick and user-friendly way?

6.4.4.8. Documentation

Incidental observations suggest better documentation or justification for medication omissions following Policy rollout in Medical areas; there seemed to be more comprehensive documentation about withholding medication, both in the medication administration records as well as the patient's clinical notes. In contrast, many of the reasons for medication/dose omission documented pre-implementation had been inappropriate, for example, 'fasting (or nil by mouth) for procedure'. The documentation also suggests a greater understanding of oral restrictions contexts. It is possible that doses may have been withheld appropriately pre-implementation but that the reasons had not been expressly or appropriately recorded – if the Policy has resulted in better documentation then this clarity can only be beneficial for patients and staff. The reduction in the proportion of overall omissions post-implementation is independent of assigning appropriateness based on what was documented and suggests an improvement, particularly for Medical areas (Table 23 & Table 25).

6.4.4.9. Comparison with other studies

The primary focus of our study was ascertaining appropriateness of medication omissions in patients fasting before a procedure, which makes it difficult to directly compare our results with published studies. Many of these studies, for example, targeted overall,

hospital-wide omissions, did not determine the appropriateness of each omission, did not target fasting before a procedure/surgery, targeted patient instigated medication omissions prior to a planned procedure or studied the impact of pharmacist involvement on the preoperative medication prescription/orders.[36,71,73,352,353]

A prospective study of a general surgical ward over three months in the UK found that, of 1746 medications charted, 256 (15%) were not given on the day of surgery or the next day unbeknown to the medical staff.[34] An Australian study also described this rate, that is, 15% of medications were not administered on the clinical ward before surgery (as reported by patients).[230] This figure is not too dissimilar to the base rate for inappropriate omissions in Medical (18.1%) and Surgical (11.9%) areas in our study (Table 21); however, it is almost half our baseline overall omission rate for both areas (Medical, 28% ITS and 29% cumulative; Surgical, 25% ITS and 20% cumulative – refer to Table 23 & Table 25). Our baseline total omission rate is within the range of a study investigating the introduction of medication guidelines (25.7%), discussed below. It is also in line with two Australian studies: One – a cross-sectional analytical study of preoperative medication adherence and early postoperative recovery at St Vincent's Hospital, Sydney – found a medication omission rate of 35% among patients with prespecified conditions such as chronic pain, epilepsy and hypertension.[48] The other study – a prospective audit at Flinders Medical Centre – found almost half (49%) of all medications prescribed were omitted on the day of surgery and the most common reason for omission was because patients were 'fasting'.[35]

A retrospective time series analysis of missed medication doses in hospitalised patients by Coleman et al., in the UK (Queen Elizabeth hospital Birmingham, ~1200-beds) spanning 239 weeks found that the rate of missed antibiotic and non-antibiotic doses decreased (10.3% to 4.4% and 16.4% to 8.2%, respectively) upon the introduction of clinical dashboards, executive-led root cause analysis meetings and publication of a rapid response alert.[36] Further, the study's visual ITS output indicated an ongoing implementation effect. Due to the volume of medications, the authors asserted the reductions in omissions significant. For both antibiotic and non-antibiotic doses, the relative reduction was approximately 50%. In our study, the absolute reduction for inappropriate omissions was 13.4% for Medical areas and 8.3% for Surgical areas

representing a relative reduction of 78% and 72%, respectively (Table 21); however, the ITS analysis of overall omissions for Medical areas showed a decrease of 11.9% post-implementation, which is a 38% relative reduction and lower than that achieved by Coleman et al.,. The results for total omissions in Surgical areas were insignificant. The volume of doses in our study was lower, the results reflected specific areas as opposed to hospital-wide, the study spanned only 116 weeks and the visual ITS output indicated an increase in inappropriate omissions, especially six months following implementation. A possible explanation for the continued effect may be the implementation strategies used in the Coleman et al., study, namely the dashboard eliciting ongoing, timely, relevant (electronic) information to staff, as well as the hospital-wide staged approach. In contrast, our strategies relied on standardised, static bedside signs and local area championship of the Policy after the rollout.

Another study from the UK (Poole Hospital, ~790-beds) investigated the impact of introducing guidelines for managing medications before surgery.[71] The guidelines stipulated the continuation of regular oral medications perioperatively unless advice to the contrary and that up to 30mLs of water may be given to help patients take medications. The guidelines were distributed to the study ward. Data were collected six months pre- and post- distribution of the guidelines. There was almost 19% decrease (25.7% pre versus 6.9% post, $p<0.001$, student's t-test, approximately 74% relative reduction) in the proportion of medications omitted post-intervention. These results fared better than our six months before and after cumulative omissions in Medical areas, which yielded an absolute reduction of 11.2% (relative reduction 39%, Table 25). Key differences exist between this study and ours, including the data collection being retrospective for the pre-intervention period but prospective post-intervention, as well as the measurements conducted in only one ward.

A prospective Australian study investigated the incidence of omitted medication doses before and after a nurse education program consisting of education sessions, ward posters and questionnaires introduced over three months in a 174-bed non-acute hospital (aged care, rehabilitation, psychiatric).[352] The education program targeted nurses' lack awareness of the significance of omitting medication doses. Data were collected over one month pre- and post-intervention after a one-month lag period. The proportion of

omissions pre- compared to post-intervention decreased by approximately one third (4.2%, n=20,154 versus 2.9%, n=24,337, p<0.001, respectively). Our study was in an acute care, procedural/surgical setting; however, the results, in terms of six months cumulative doses withheld in Medical areas, were similar (28.8% pre versus 17.6% post, 39% relative reduction, Table 25). Surgical area results were lower (Table 25).

6.4.4.10. Visual ITS output, pre/post trends and sustainability

Surgical area ITS visual output (Figure 13) suggests a three to six months pattern per calendar year in the pre-implementation period. Possible theories for this pattern include nursing staff rotations (e.g., 'graduate' nurses), commencement of new staff to the area and school holiday periods whereby regular staff may have been temporarily covered by those who may not normally work in the area. (Victorian school holidays – December/January, March/April, June/July, September/October). Doctors' rotations (three to six monthly) may play a role. It is possible that the staffing structure in Medical areas was not as susceptible to this variation.

The ITS graphs also suggest variability in the pattern observed in Surgical areas pre-implementation and all areas post-implementation. This relates to the above observation and could may be attributable to whether the staff working at the time were familiar with the Policy (through the hospital-wide implementation process or via piloting of the Policy); for example, when staff familiar with the Policy were working, the inappropriate omissions were reduced but on days where staff rostered on were unfamiliar with/unaware of the Policy then it is possible omissions increased. The proportion of inappropriate omissions appears to become more sporadic after the first six months following implementation for both Medical and Surgical areas. The post-implementation linear trend revealed a small but statistically significant increase in inappropriate omissions in Medical areas post-implementation. This is most likely attributed to staff movement and turnover and will affect the long-term sustainability of the Policy.

Many innovations that are initially successful fail to become part of the habits and routines of the host organisations and communities.[354] Studies show that presence of leadership and ongoing championship were instrumental to the successful implementation and sustainment of the initiatives.[312,313] Sustainability efforts, such as

targeting staff at orientation and eLearning modules, have been implemented (after the study) but these approaches require consistent input and resources to maintain. They require leadership and championship at the ward, as well as hospital-wide level, which is challenging with constant staff turnaround and competing priorities. Coleman et al., showed that manipulating drug administration data from electronic prescribing systems for real time reporting on 'clinical dashboards', together with approaches such as executive level endorsement, resulted in a significant decrease in the rates of missed antibiotic and non-antibiotic doses.[36] In our situation, it may be simpler and less resource intensive to harness existing systems, such as the electronic prescribing platform, and potentially dashboards, to provide staff with decision support and contextual information (and by default, education) 'on the ground' via these systems; for example, building medication pathways for the medication or medication type, patient type or medical condition. An advantage of this approach is that it may be feasible to incorporate these pathways or decision support as routine components of the electronic medication management process, which will likely not require significant ongoing resources to champion and to remind staff to use once established.

6.4.4.11. Potential unintended results

The Policy's fasting bedside sign states 'give oral medications unless advised by a doctor or pharmacist.' This instruction was the result of much consultation and consensus during the Policy development. The driving force behind it was the finding that some nurses withhold oral medications even when there was no directive from the doctor to do so – there were occasions in the current study where doses were omitted despite documentation of 'meds with sips' by the doctor. Regardless of the substantive stakeholder consultation, there is a chance that the sign may be subject to individual interpretation.

Ideally, the doctor should notify nursing staff if a medication is to be withheld, likewise, the pharmacist should advise about withholding medications where appropriate and the nurse confirms with either/both if uncertain; however, if this does not occur when the fasting sign is used then there is the risk that some nurses may follow the direction of the sign without consideration of the patient's clinical situation. That is, they may administer

all the oral medications irrespective of whether it is clinically indicated in that fasting scenario. This is potentially reflected in the slight increase in the number of medications administered inappropriately in the post-implementation period. Some nurses may use their clinical judgement to verify the order in the absence of direction from the doctor or pharmacist, but others may not. It is also possible that, without the awareness of the context behind why specific management of oral medications was needed for each of the oral intake categories, staff may interpret the signs according to their earlier conception of what fasting or nil by mouth meant.

The complexity of the medication administration process and the nuances of the various oral intake statuses, as well as patients' individual clinical situation and individual health professional factors/stance, make it difficult to prepare any simple, brief, static sign to capture all oral medication administration scenarios in these settings. Potential resolutions may rest with clinical electronic 'dashboards' that provide real time results or meaningful, patient-specific alerts, in conjunction with medication management pathways related to oral restrictions incorporated into the electronic prescribing platform. We are working on clinical pathways and 'orderables' on the electronic prescribing platform to provide more contexts to decision-making in this area, as well as looking into how clinical dashboards may best be used to provide relevant, timely information.

6.4.4.12. Limitations

It would have been much easier, less resource intensive, more rigorous and less susceptible to bias had the study focused primarily on the overall proportion of omissions pre- and post-implementation rather than those omitted inappropriately; however, this disregards that oral medications may have been omitted for valid reasons. Ascertaining the reasons for the omissions also provided insight about whether the Policy concepts were understood. It appears that the Policy offered clarity on giving or withholding oral medications before a procedure; that is, the distinction between fasting and nil by mouth with regards to medication administration was recognised and appreciated by some and they were able to demonstrate this understanding by what they documented.

It was not possible for comparative analyses with a non-treatment group to be undertaken because the Policy was implemented hospital-wide and this potentially limits the strength of the results.

Bias and judgement

There was potential for bias in this study, which may affect the estimate of the implementation effects in terms of inappropriate omissions. The major of these were that the researchers were also the data collectors/reviewers and that the study was not blinded – the date/time of dose omission relative to pre- or post-Policy introduction was known.

The retrospective nature of the record review puts it at risk of reviewer bias, systematic bias from misinterpretation of clinical information documented[188], as well as hindsight bias[180,187], the tendency to input a connection when the outcome is known.

The issue of bias was considered prior to the data being collected and a codebook was developed to provide a more systematic and thorough approach to deciding whether a medication omission was appropriate. Furthermore, inter-rater checking was conducted, as well as 'resolving differences' to increase the rigour of the study. Despite this, it was not possible to absolutely remove all potential for bias: By its nature, medical record reviews are susceptible to bias.[180,187,188]

The dose omission date/time and anaesthetic commencement date/time were necessary to ascertain whether the dose omission was appropriate. These were also needed to identify where to check for relevant information in the patient's medical records to make a judgement about appropriateness of the omission. This could have been minimised by having an external person do all the data collection and then reallocating a different or dummy date/time for medication administration and anaesthetic start; however, this option was not feasible because the study was not funded and it was conducted as part of a PhD where it was necessary for the candidate to experience all aspects of research, including the data collection. An independent panel of two physicians to review the appropriateness of the dose omissions had been arranged at the outset but did not eventuate because of the protracted study period and staff movement to a different role/ institution.

Although the manual data collection and allocation of appropriateness to the dose omissions could be subjected to researcher bias, there was a reduction in the proportion of overall doses omitted post-Policy implementation in Medical areas. This component was not subject to bias.

Documentation discrepancies

The advantage of using data from electronic prescribing is that it is more likely to include essential information that may be omitted on the paper form and wrong dose errors resulting from ambiguous handwriting are eliminated.[355] A potential risk is that a dose is signed for that had not been administered; for example, due to a nurse signing for the dose prior to administration but that, for various reasons, the administration did not take place.[355] Conversely, a dose may have been given but was not signed for. The latter was reflected in our local setting during a focus group session about the Policy following its implementation – some nurses explained "you've given it (the medication)", but it is not necessarily documented because "you're not sitting at a computer screen all the time…" A study evaluating the consistency between nursing records and observed nursing care reported that the records underrepresented what nurses actually did.[356] Interestingly, our study suggests improved documentation for dose omissions, especially in Medical areas, post-Policy implementation.

Missing data

Lack of documentation was regarded as an inappropriate reason for medication omission in this study, but lack of documentation could be attributed to 'missing data.' It may be possible that the impact of the Policy was overestimated since the reasons for some of the omissions could have been appropriate had the data been available/documented appropriately. The retrospective aspect of the study meant that the researcher's clinical judgement about appropriateness of the omissions can only be applied based on what was documented or not in the medical records. It is possible that there may have been valid reasons that had not been documented.

Missing data is often an unavoidable factor in many studies utilising retrospective record review.[181,182] If missing data was a factor there is the likelihood that this affected all

months similarly and there is no reason to expect that missing data patterns were different pre- compared to post-Policy implementation. Regardless, there was a decrease in overall proportion of doses withheld following introduction of the Policy, which was independent of the record review and tempers the potential concern about missing data.

Potential for systematic bias

There is evidence that the risk of medication/dose omission increases with the number of medications prescribed.[27,340,353] Medical area patients had a higher number of medications/doses compared to Surgical area patients. This, together with the lower of number of patients in Medical areas, particularly post-implementation, may produce systematic bias; that is, there was potentially a greater opportunity for improvement in Medical areas, or, if a particular nurse or group of nurses tended to omit all medications when a patient is fasting then this would be more problematic in Medical areas where patients were generally on more medications (especially post-implementation).

We randomly selected up to 30 episodes per area per month to achieve as close to 100 records per data point as possible: It was a balance for Surgical area patients likely to have less medications but there were generally more episodes for this area and Medical areas likely have more medications per episode but generally less episodes. Despite this, one of the 28 months in Medical areas and eight of the 26 months in Surgical areas had less than 100 records, which may influence the study results. Due to a variety of reasons, including time constraints and the fact the hospital transitioned to the electronic prescribing system late 2012/early 2013, it was not practical to randomly select more patients and/or examine data before January 2014 and beyond May 2016.

Professional perspectives

The retrospective record review requires extensive use of professional judgement[180], and it has been highlighted that clinical judgements can vary between professions.[50,180] The difference in perspectives or approaches related to inter-professional or other variances may affect the coding of the data. Numerous discrepancies have been found when reviews conducted by nurses and by doctors were compared.[180] In our study, while the manual data collection was conducted by a pharmacist, the inter-rater checking involved a

hospital medical officer and the resolving differences component was conducted by a pharmacist, hospital medical officer and anaesthetist. The involvement and combined judgements of different professions may confer some balance to the study.

Confounding factors

As conceded by Coleman et al., segmented regression analysis is susceptible to limitations, including the assumption that all other factors remain constant throughout the whole intervention period, and variability caused by factors other than the intervention may have confounded their results.[36] They argued that, given the large tertiary care hospital setting from which the data were extracted, they believed it unlikely to be the case. Our study was also based at a large tertiary care hospital setting, and other than potential flow-on effect in Surgical areas from the pilot of the study as discussed, it is unlikely that factors other than implementation of the Policy confounded our results.

Retrospective data collection

It is possible that prospective data collection may have conferred more rigour to the results. Our study was prospectively conceived, but it was felt that collecting data retrospectively was the most efficient and resource effective method for the lengthy period (29 months) in which the study spanned. Furthermore, although the process of refining the database also took some time, the definitive review of the matched data, manual data collection and assessment of appropriateness occurred within a relatively short timeframe (six months). This, together with a priori determined criteria for deciding appropriateness, is likely to minimise inadvertent coding differences over time.

6.4.4.13. Interpretation

The Policy was moderately effective in reducing medications omitted inappropriately in patients fasting before a procedure in Medical areas. This was supported by a corresponding decrease in the overall proportion of medications withheld. The improvements for Surgical areas were lower but the proportion of medications omitted inappropriately in this area pre-Policy implementation was lower too. It is possible that there may have been a flow-on effect from the piloting of the Policy on a (non-study) surgical ward. Further investigations are needed to confirm this result.

The Policy and its tools provided clarity for some staff; however there appears to be factors impeding wider uptake of the Policy. One such issue pertains to medication-related decision processes following interpretation of the Policy's bedside signs, such as around medications that require administration with food.

In Medical areas, the small trend of increasing medications omitted inappropriately post-implementation, when considered with the visual ITS output, indicated that the application of the Policy became more sporadic six month after implementation, which suggests issues with sustainability. This is likely due to staff turnover, movement and/or competing workloads of the clinical champions or others involved with the Policy implementation at the local level.

6.4.4.14. Generalisability

Our study only focused on patients with non-elective procedures/surgeries residing in the Medical and Surgical areas of the hospital; however, this group of patients likely comprise the bulk of those who require non-elective procedures and whose medication management during the fasting period would occur entirely in the hospital setting. Moreover, the difference in results for the two areas provides an indication of the spectrum of the Policy's impact, which is important for considering our next steps. It is likely a reflection of the general differences between areas in many other institutions. A further consideration is that medication management issues in the context of oral restrictions in general, and fasting before a procedure in particular, have been reported as problematic elsewhere. From these perspectives, although the study was conducted in only one hospital, the results may resonate with a wider audience beyond our setting.

6.4.5. Conclusion

The results suggest that a policy that sought to improve medication management in the context of oral restrictions was associated with a moderate but statistically significant reduction in medication dose omitted inappropriately and overall omissions in patients fasting before a procedure in Medical areas of the hospital. A small trend of increasing medications omitted inappropriately post-implementation was discernible, suggesting sustainability issues. The reductions were lower in Surgical areas and only significant for

inappropriate omissions but not total omissions, although baseline omissions in this area were lower than Medical areas'. Further investigations are needed to ascertain the reason for this discrepancy, as well as to confirm the effects of the Policy on a wider scale and which includes a comparison group unexposed to the Policy.

6.4.6. Recommendations for practice

The terms fasting and nil by mouth should be separated and clarified with respect to oral medication administration when patients have oral intake restrictions. Nil by mouth should not be used to mean different things in different settings. Additionally, more context and support for making decisions about managing medications in patients with oral intake restrictions are needed for staff at the point of care. The concept of giving only those medications considered important and withholding all others during the fasting period should be reconsidered; there should be a culture change to giving all medications unless there is a clinical need to withhold them. Clinical dashboards and pathways in the electronic medication management system should be exploited to provide prompt and relevant information and context for medication management for patients with restrictions on their oral intake. The resulting system(s) needs to be presented in a cohesive manner so that it will not be a burden for staff to use; that is, staff can easily navigate from one interface to another seamlessly

6.5. Chapter discussion

In this chapter, the impact of Policy implementation was investigated from several viewpoints and timelines. The barriers and enablers analysis considered data that included those obtained during Policy implementation while the focus group work was conducted approximately eight months following implementation. The ITS analyses used data obtained up to 14 months afterwards.

Exploration of barriers and enablers to Policy implementation indicated that, despite a considered implementation approach, there remained barriers that impeded uptake of the Policy. Many of the key barriers and enablers fell under the principal themes of resource

and infrastructure, staff interpretation of their roles and the perceived applicability and credibility of the Policy. That both barriers and enablers were represented in these major themes suggested that, although many barriers had been anticipated, the enablers and strategies employed were insufficient to manage them. Barriers such as staff movement and turnover, unpredictable communication structure, interpretation of responsibility and accountability and applicability of the Policy challenged its uptake and will likely compromise the long-term sustainability unless it can be built into a structural aspect of the system.

The focus group findings corroborated those from the medication management barriers analysis in section 4.4, as well as the exploration of barriers and enablers to Policy implementation. Surgical nurses expressed that the Policy provided a unified structure to work with when giving oral medications in patients with restrictions on oral intake where previously there was confusion and a lack of guidance – those who understood the context of the Policy found it relevant and beneficial to their practice. Nonetheless, despite clarity and guidance, many of the issues uncovered post-implementation related to limitations in the Policy's reach, a lack of understanding of the context of the Policy and individual staff interpretation of its messages and the subsequent decision-making process.

The ITS study suggested that Policy introduction produced a moderate, statistically significant reduction in the proportion of inappropriate (13.4%) and overall (11.1%) dose omissions in patients fasting before a procedure in Medical areas of the hospital. Surgical areas experienced a smaller, statistically significant reduction for inappropriate omissions (8.3%) but not overall omissions. Pre-implementation inappropriate omissions were lower for Surgical than Medical areas, which was surprising given that the evidence-base suggests the former to be more susceptible to medication errors. Another interesting factor is that the Surgical area pre-implementation inappropriate omission rate (11.9%, Table 21) is much lower than that of the pilot surgical ward (35%) and not too dissimilar to its post-Policy implementation proportion (13.3%). A flow-on effect from the pilot ward is a potential explanation for the difference. Visual inspection of the ITS graph suggests that the small trend of increasing proportion of inappropriate omissions in Medical areas post-Policy implementation became more prominent after six months, which indicates issues with sustainability.

An inadvertent discovery was that medications requiring administration with food seemed to be problematic for staff when patients needed to fast and a dedicated review of this matter is required. The trend of a greater number of omissions around seven to eight hours prior to a procedure in Medical areas also warrants further thought. It is likely related to medication omissions in the morning, due to fast from midnight practices, when many patients take many of their daily medications (many 'with breakfast') or when procedures are delayed resulting in longer fasting times. This reiterates the importance of ensuring continuation of patients' regular oral medications unless there is a clear clinical indication for these to be omitted perioperatively.

Overall, the three studies suggest that the Policy provided clarity and guidance for staff, which translated to a moderate, statistically significant improvement in medication management for the patients affected. Several factors impeded wider uptake and application of the Policy and its sustainability, including issues with staff movement and turnover, communication structure, responsibility and accountability, contextual understanding and interpretation of the Policy's messages and the subsequent decision-making process.

An evidenced-based implementation strategy used in the pilot but not hospital-wide implementation was audit and feedback. It is possible this strategy may have furthered the Policy's uptake – a review of systematic reviews found that participants (staff) were receptive to how their response to behaviour change interventions measured up to the expectations of external observers.[285] Limited resources, competing priorities and the workload associated with extracting the relevant data made infeasible project officer-led audit and feedback for the hospital-wide implementation; however, if this process could be automated, such as via the clinical dashboard, it would be a major enabler in future implementation attempts.

6.5.1. Implications of findings

- Limited staff resources, staff movement and turnover are likely to be the reality for many institutions and unlikely to change unless systems can be restructured to maximise output and reduce staff movement. Thus, improvement attempts ought to

minimise reliance on key staff to promote or sustain and be relatively impervious to staff movements. Rather, it may be best to explore existing structural systems for potential strategies, such as the electronic prescribing platform (and clinical dashboards).

- Context plays an important role for both understanding the motivation for the medication improvement initiative, as well as when applying the initiative to a setting. Both situations require consideration when introducing new initiatives. Without context, the medication initiative may become yet another Policy or 'red tape' as opposed to improving patient safety and preventing adverse patient outcomes. Furthermore, staff may continue to practice with their previous conception or knowledge of the situation despite instructions advising differently.
- An implementation strategy employed to convey the context to staff relied on interactive education sessions conducted by the project officer, which was resource intensive and unrealistic for sustainability beyond the implementation phase. (I have subsequently developed a webinar and eLearning module but it still relies on a champion to prompt staff to use – the eLearning Committee voted against have these as 'Mandatory' learning. Staff are therefore required to voluntarily search for the modules in the eLearning platform. I am still asked to do a presentation on the Policy face-to-face – because this is preferred – but a (sufficient) turnout is not guaranteed.)
- How some people interpret information and the subsequent decision-making process can impact on the initiative being rolled out: Acknowledgement of the medication management instructions does not necessarily equate to knowing/understanding what to do next. This theme needs to be addressed when developing new initiatives. One possible method to safeguard against variability in this process is to provide explicit clarification and information using (an interactive, electronic) clinical pathway. The electronic medication management system offers potential in this arena.
- Sustainability will be affected by variations in the interpretation of championship or facilitation of the implementation at the local level.
- All aspects of the implementation process should be assigned to the local area to promote ownership and accountability and sustainability.
- Staff adapting the Policy and implementation to their local context had the potential to create inconsistencies and unwanted practice variations.

- It is implicit that the doctor or medical staff take overall responsibility for the patient but in these times of multidisciplinary teams this may not necessarily be applicable in some respect. Attributing responsibility to someone else lessens accountability, especially since even within medical staff there are different specialties, roles and rank. Consequently, there needs to be a shift towards how anyone with a role in managing oral restrictions and/or medications can contribute to ensure best practice for the patient. This concept applies to all aspects of healthcare. A framework to this effect should be introduced at the undergraduate level for all health professionals, especially in settings of multidisciplinary learning.
- There needs to be an agreed and standardised approach to the stakeholder consultation process, especially amongst the medical staff hierarchy
- Consideration needs to be given to the timeline of quality assurance processes that have been stimulated by adverse patient incidents. The potential risk to patients from an adverse event recurring needs to be balanced with the lag time it takes to develop a suitable prevention strategy;

Chapter 7. Using theory

7.1. Chapter introduction

Theory, as a concept, was presented in the Methodology chapter.

Changing practice is difficult. The use of theory provides explanations into human behaviour and a considered and systematic approach when developing implementation interventions to change clinical practice. Using theory allows testable hypotheses for why things happened and provides an evidence-base that can be drawn upon when applying strategies to change practice.

Numerous theories exist that are appropriate to different settings and knowing which to use can be confusing for those new to using theory. A potential compromise is the TDF. Throughout the PhD (and quality improvement process), the TDF was applied in a variety of formats to promote a systematic approach and comprehensiveness. This chapter further details the application of the TDF, consolidating the uses alluded to in previous chapters.

7.2. Using the theoretical domains framework

7.2.1. Making sense of the TDF

Although the developers of the TDF aimed to make theory more accessible to and usable by those involved in evidence-based practice implementation who do not have a background in psychology[146,171], some of that audience have described difficulty with operationalising the TDF: a particular issue is the unfamiliarity of the language of the psychological constructs.[150]

The definitions offered by Lipworth et al.,[159] provided a practical clarification to make sense of the 14 domains and constructs of the TDF[171] (Table 28).

Table 28. Making sense of the TDF

Adapted from Cane et al.,[171] and Lipworth et al.,[159]	
TDF domain	**TDF constructs**
Knowledge (1)	Knowledge, procedural knowledge, knowledge of task environment *An awareness of the existence of something. A person's perceived awareness of the scientific rationale, procedures and task environment associated with a desired behaviour is likely to affect whether a person decides to implement it.*
Skills (2)	Competence, skills, skill assessment, ability, interpersonal skills, skills development, procedural knowledge *An ability or proficiency acquired through practice. A person's perceived sense of their own competence in performing a desired behaviour is likely to affect whether or not they are willing and able to implement it.*
Social/professional role & identity (3)	Professional identity, role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment. Organisational commitment, change management, champions, project management, team working, hierarchy, management commitment. *A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting. The extent to which someone believes that a particular behaviour aligns with their social/professional identity is likely to influence whether or not they will implement it.*
Beliefs about capabilities (4)	Self-efficacy, perceived competence, self-confidence, perceived behavioural control, professional confidence, self-esteem *Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put into constructive use. The level of confidence an individual possesses about their ability to perform a particular behaviour is likely to affect whether or not they implement it.*
Optimism (5)	Optimism, pessimism, unrealistic optimism, identity, mindsets *The confidence that things will happen for the best or that desired goals will be attained. The extent to which a person believes a goal will be achieved will affect the likelihood of them performing the behaviours that will lead to that goal.*
Beliefs about consequences (6)	Beliefs, attitude, outcome expectancies, characteristics of outcome expectancies, illness representations *An acceptance of the truth, reality, or validity about the outcomes of a behaviour in a given situation. The beliefs a person holds about the outcomes of particular behaviour will affect or not they decide to comply.*
Reinforcement (7)	Rewards (proximal/distal, valued/not valued, probable/improbably), incentives, punishment, sanctions contingencies *Increasing the probability of a response through a dependent relationship, or contingency, between the response and a given situation. The perceived rewards and punishments associated with performance or non-performance of a particular behaviour are likely to affect whether or not someone decides to implement it.*
Intentions (8)	Stability of intentions, stages of change model, transtheoretical model and stages of change, certainty of intensions, commitment, intrinsic motivation *A conscious decision to perform a behaviour or a resolve to act in a certain way. The level of motivation a person has or commitment that they make to act in a particular way is likely to affect whether or not they do so.*
Goals (9)	Goals (distal/proximal), goal priority, goal/target setting, goals (autonomous/ controlled), action planning, implementation intention, representation of tasks *Mental representations of outcomes or end states that an individual wants to achieve. The existence of a goal and the value placed on it in relation to a*

	particular behaviour is likely to influence whether or not someone decides to activate that behaviour.
Memory, attention & decision process (10)	Memory, attention, attention control, decision making, cognitive overload/ tiredness T*he ability to retain information, focus selectively on aspects of the environment, and choose between on or more alternatives. Remembering to enact a particular behaviour, or remaining focused on it, is likely to affect whether or not the behaviour is implemented.*
Environmental context & resources (11)	Environmental stressors, resources/material resources, organisational structure/climate, salient events/critical incidents, person x environment interaction, barriers & facilitators, anticipated regret, threat, past behaviour, knowledge, empowerment, negotiation *Circumstances of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour. The nature of the environment in which a person is required to perform a specific behaviour is likely to affect whether or not a person is able or willing to perform it.*
Social influences (12)	Group norms, group conformity, group identity, social pressure, social norms, social comparisons, social support, intergroup conflict, alienation, social identity (modelling) *Those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours. Factors such as pressure, encouragement, or support from others can influence the performance of a desired behaviour.*
Emotion (13)	Anxiety, depression, positive/negative affect, stress, fear, affect, burn-out. *A complex reaction pattern, involving experimental, behavioural, and physiological elements, by which an individual attempts to deal with a personally significant matter or event. Negative emotions such as fear and anxiety, and positive emotions such as joy and pride, associated with a desired behaviour, are likely to affect whether or not a person decides to perform it.*
Behavioural regulation (14)	Learning, review, direct experience, self-monitoring, breaking habits, evaluation *Anything aimed at managing or changing objectively observed or measured actions. The existence of an action plan, or monitoring progress towards a behaviour, is likely to influence whether or not a behaviour is performed or an outcome is achieved.*

As an example, the TDF constructs for the domain 'Reinforcement' were:

> '*Rewards (proximal/distal, valued/not valued, probable/improbably), incentives, punishment, sanctions, contingencies.'*

The descriptions offered by Lipworth et al.,[159] for this domain were:

> *'Increasing the probability of a response through a dependent relationship, or contingency, between the response and a given situation. The perceived rewards and punishments associated with performance or non-performance of a particular behaviour are likely to affect whether or not someone decides to implement it.'*

The explanations help to locate the constructs in more user-friendly language, thereby making it more accessible to researchers who may not have a background in psychology, such as the case in this PhD.

7.2.2. The TDF as a checklist

In the most simplistic approach, the TDF was a checklist to ensure that as many elements of potential impact on an initiative as possible were considered. Systematically working through each of the TDF domains and/or constructs any aspects, feedback or comments that may correspond to the constructs and which had the potential to affect the particular situation were reflected upon. Different 'angles' could be taken depending on the situation, for example, barriers versus enablers.

7.2.3. Evaluating barriers and enablers

The TDF was used to review whether as many barriers (and enablers) as possible that may impact on managing medications appropriately when patients have restrictions on their oral intake or policy implementation had been considered.

7.2.3.1. Barriers to managing medications appropriately

As emphasised in the previous chapters, medications were managed inappropriately when patients had restrictions on their oral intake. Consequently, as part of quality improvement processes, feedback was sought from staff about this issue. This feedback was mapped to the TDF domains to help establish that we had considered as many factors as possible as to why there were issues with giving medications in patients who have restrictions on oral intake and what was being planned (and the thought process) to address the issues identified were appropriate and relevant to the findings (Table 29).

Table 29. TDF mapping of barriers to managing medications appropriately

TDF domain	TDF constructs	Barriers	Strategy	Intervention
Knowledge (1)	Knowledge, procedural knowledge, knowledge of task environment	Confusion. Lack of knowledge, e.g., do not realise meds should be given when fasting before surgery and withheld if nil by mouth due to swallowing issues, confusion between the terms fasting and nil by mouth. Different units say different things.	Provide clarity. Provide information.	Separate fasting from NBM; Availability of a common hospital-wide policy;
Social/ professional role & identity (3)	Professional identity, role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment	Whose role is it? 'That's not my job'. Professional boundaries. Profession confidence in addressing the issue.	Emphasise common outcome/clear goals.	Working towards common goal – patient safety. Promote professional 'ownership'. Promote interdisciplinary collaboration.
Beliefs about consequences (6)	Beliefs, outcome expectancies, characteristics of outcome expectancies, anticipated regret, consequent	Lack of knowledge. Unaware that there is anything wrong/that decision can potentially harm.	Audit/ feedback. Use local case reports. Use case reports from media. Evidence from literature.	Feedback of audit results. Use case reports from sentinel events & Riskman.
Memory, attention & decision process (10)	Memory, attention, attention control, decision making, cognitive overload/ tiredness	Too many units to ask – who to ask? No clarity.	Reminders. Decision aid tools.	Use of logo/brand and identifiable message; Availability of decision aid tools e.g., flowchart, lanyards & bedside signs;
Environmental context & resources (11)	Environmental stressors, resources/material resources, organisational structure/climate, salient events/critical incidents, person x environment interaction, barriers & facilitators	Time constraints e.g., to look up pros & cons of administering each medication or to address all the issues at bottleneck times. No standardised guidance. The area worked affected medication management.	Improve workflow by providing a consistent approach hospital-wide. Decision aid tools.	Standardisation and simplification hospital-wide. Availability of decision aid tools e.g., flowchart, lanyards & bedside signs;
Social influences (12)	Social pressure, social norms, group conformity, social comparisons, group norms, social support, power, intergroup conflict,	Staff actions were determined by their peers, mentors and the culture of the area in which they worked.	Clear/hospital-wide agreed goals. Use of modelling.	Common goal of patient safety; Use modelling to influence intergroup decisions.

	alienation, group identity, modelling			
Behavioural regulation (14)	Self-monitoring, breaking habits, action planning	Habit of using fasting & NBM interchangeably	Standardise terminology hospital-wide. Reminders. Decision aid tools.	Use of logo/brand and identifiable message. Provide decision aid tools e.g., flowchart, lanyards & bedside signs.

Several TDF domains emerged as being of particular relevance, namely *Knowledge*, *Social/professional role & identity*, *Beliefs about consequences*, *Memory, attention & decision processes*, *Environmental context and resources* and *Social influences*. The analysis of this mapping was discussed in section 4.4.

Knowledge

A key TDF domain for managing medications appropriately was *'Knowledge'*. Many staff were confused about how to manage medications when patients have restrictions on oral intake. An important cause was a lack of knowledge about medications and what do with oral medications for different oral restrictions situations.

Social professional role & identity

There were differences in stances between and within professions and a lack of leadership with managing oral medications when patients have restrictions on their oral intake.

Beliefs about consequences

In the context of medication management issues and oral intake restrictions, this domain was, in many ways, related to the *Knowledge*, that is, a lack of knowledge about medications. Many staff were unaware or did not believe that managing medication in a certain way when patients have oral intake restrictions may lead to patient harm.

Memory, attention & decision process

The relevant constructs for this domain were decision-making, cognitive overload and attention control; for example, nursing staff found it difficult to identify who to seek for a decision about oral medication administration because, often, one unit (doctor) would

defer the decision to another. Some doctors found it difficult to address the multitude of expected tasks, especially at 'bottleneck' times such as 8am.

Social influences

How staff perceived oral medications ought to be managed when a patient has oral intake restrictions was determined by the actions of people – mentors, other professions, peers – around them. Two examples include some staff being 'taught to withhold everything' and nurses in the stroke ward feeling reluctant to give oral medications in any patient categorised as fasting, regardless of the context.

Environmental context & resources

Time constraints, workflow issues and lack of guidance were some of the findings under this domain. Many of these issues have overlaps with other domains, for example, difficulty with addressing the multitude of expected tasks, especially at 'bottleneck' times is linked to *Memory, attention & decision process*. This domain also addresses the issue of nurses in certain wards reluctant to give oral medications, even when fasting relates to an otherwise healthy surgical patient instead of a stroke patient with swallowing difficulties.

7.2.3.2. Barriers and enablers to policy implementation

Feedback from staff, obtained during the Policy development process, was mapped to the TDF domains to identify potential barriers and enablers to implementation of the Policy (Table 30). Similar to the medication management barriers, *'Knowledge'*, *'Social professional role & identity'*, *'Beliefs about consequences'*, *'Memory, attention & decision process'*, *'Environmental context & resources'* and *'Social influences'* were identified as being important factors for implementation.

Knowledge

Knowledge was a key domain as a barrier to a hospital-wide policy to address the medication management issues when patients have restrictions on oral intake. A significant barrier was that, because of the lack of knowledge about the potential for harm

caused by inappropriate medication administrations in patients with oral intake restrictions, there was a perception by some that a policy to address the issues were not needed or not needed/relevant in their area. In contrast, having a hospital-wide policy was an enabler as it would provide clarity and consistency.

Social professional role & identity

The central issues addressed by this domain were 'whose job it was' to operationalise various aspects of the Policy, professional confidence, professional boundaries and communication issues. An example that highlights many of these issues was the stance taken by some speech pathologists that it is not their role to advise about medications. Although this was entirely reasonable given their training does not include medication management, however, some speech pathologists were already providing medication advice with their generic recommendation of, 'crush medications if possible'. A hospital-wide policy that has been discussed with and agreed upon by all stakeholders and that clearly specifies the role of each profession/group would be an important enabler.

Beliefs about consequences

A specific example in this domain is that a lack of knowledge about the significance of managing medications inappropriately in patients with restrictions on their oral intake led some staff to be oblivious to the potential adverse implications for patients. Therefore, some felt the Policy was unnecessary. Similarly, some staff believed that medication management problems associated with oral intake restrictions did not happen in their area. Enablers for this domain included discussion of the adverse patient cases that provided the impetus for the policy, the results of the draft policy pilot and the fact that staff, in general, want to do what is best for their patients.

Table 30. TDF mapping of potential barriers and enablers to policy implementation

TDF domain	TDF constructs	Barriers	Strategy	Intervention	Enablers
Knowledge (1) Frontline	Knowledge, procedural knowledge, knowledge of task environment	Confusion; Lack of knowledge e.g., do not realise meds should be given when fasting before surgery and withheld if nil by mouth due to swallowing issues, confusion between the terms fasting and nil by mouth therefore do not feel there is a need to change.	Provide consistency throughout hospital. Provide clarity. Simplify and standardise. Provide information via policy, manual, information packs and intranet page. Opinion leaders to support Policy's message. Clinical champions.	Separate fasting from NBM. Hospital-wide policy/manual that provides clarity for giving medications in patients with restrictions on oral intake. Use bedside signs. Availability of intranet information page (ease of access of info.). Information session about background for policy.	The policy will provide clarity – will standardise and simplify medication management instructions. Cases from sentinel events and Riskman. Results from pilot project.
Skills (2)	Competence, skills, skill assessment, ability, interpersonal skills, skills development, procedural knowledge	Decision making may be inadequate in junior staff.	Simplification and standardisation hospital-wide. Bedside signs as reminder and decision aid at point of care.	Information session. Use of traffic light colours and availability of bedside signs, badge cards, flowchart, badge cards. Clinical champions (and/or Nurse Educators) available for support.	Availability of standardised hospital-wide policy. Hospital-wide support for policy.
Social/ professional role & identity (3) Frontline Management	Professional identity, role, social identity, identity, professional boundaries, professional confidence, group identity, leadership, organisational commitment. Organisational commitment, change management, champions, project management, team working, hierarchy, management commitment.	Whose role is it? 'That's not my job'. Professional boundaries. Profession confidence in addressing the issue. Poor communication between professions.	Emphasise common outcome/clear goals of patient safety. Standardise terminology and communication method (policy bedside signs). Engage opinion leaders.	Policy/manual will provide guidance regarding roles and responsibilities. Indicate wide consultation. Indicate multidisciplinary input/ interdisciplinary collaboration. Bedside signs will provide clear communication.	Hospital-wide approval and agreement for policy. Consultation of multiple groups and forums for policy development. Support for policy received from senior

					management and opinion leaders.
		Discrepancy between senior/mid-level staff & staff 'on the floor' (I didn't know about that….). Doctors should advise to give/withhold but they don't. Speech pathologists don't feel it is their role to advise about medications. 'I was told off by a surgeon once for giving meds pre-surgery and once was enough for me not to do it again '.	Multidisciplinary approach (involve stakeholders in conversations). Multi-pronged approach to disseminate information. Repetition of message. Determine what each profession willing to do. Clinical champions. Opinion leaders.	Clinical champions and opinion leaders to support message. Information transfer over time via posters, handovers, email, bedside handovers. Information sessions. Involvement of stakeholders in consultation process. Work together with groups/professions to determine what they are willing to do.	Organisational commitment. Management commitment. Common patient safety goal among staff. Availability of a hospital endorsed policy.
Beliefs about capabilities (4)	Self-efficacy, perceived competence, self-confidence, perceived behavioural control, professional confidence, self-esteem	Decision making may be inadequate in junior staff.	Simplification and standardisation hospital-wide. Bedside signs as reminder and decision aid at point of care.	Availability of a hospital approved policy. Indicate that actions in accordance with the policy will be supported by the hospital. Use of traffic light colours and availability of bedside signs, badge cards, flowchart, badge cards.	Hospital-wide agreement for policy. Availability of tools such as bedside signs, which act as decision aids and reminder at point of care. Nurse Educators/ Clinical champions for support.
Optimism (5) Organisational Frontline Management	Optimism, pessimism, unrealistic optimism, identity, mindsets	Unrealistic optimism of ease of staff acceptance/ease of uptake. Also, pessimism, 'It's a bit complicated'.	Consistency throughout hospital. Audit/feedback.	Hospital-wide rollout to provide consistency/use of same language/ Availability of audit tool for each area to access and use to assess uptake\.	Hospital-wide approval for policy; Support by senior management and opinion leaders Optimism about uptake of policy. Optimistic that it provides clarity for

					staff and is patient care focused.
Beliefs about consequences (6) Frontline	Beliefs, attitude, outcome expectancies, characteristics of outcome expectancies, illness representations	Don't feel policy is needed. Don't feel there is a need to change in their area. Previous negative experience. Unaware there's anything wrong/that decision can harm. 'This doesn't apply to us'; 'We're different to the rest'. 'We don't need the signs.'. 'I was told off once by a surgeon for giving meds and once was enough for me not to do it again.'.	Use case reports. Pilot study results. Clinical champions. Opinion leaders. Medication safety initiative in line with National Medication Safety standards. Stress that staff rotate through different areas of the hospital and consistency vital.	Use case reports from sentinel events and Riskman. Use pilot study data. Information session about need for policy.	Feedback from pilot project. Will be hospital approved policy therefore staff will be supported if they follow policy. Belief in the policy (to do what it intends to do). Genuinely wants to do the right thing for patients. If policy will help patients then staff are willing to give it a go.
Reinforcement (7)	Rewards (proximal/distal, valued/not valued, probable/improbably), incentives, punishment, sanctions contingencies	Negative reinforcement from previous experience(s) e.g., nurse who got told off by surgeon or nurses who were 'taught to withhold everything'.	Policy bedside signs provide reminder and decision aid at point of care. If this happens again nurse can refer surgeon to hospital approved policy for support'.	Availability of hospital approved policy. Indicate that actions in accordance with policy are supported by the hospital. Use of traffic light colours and availability of bedside signs, badge cards, flowchart, badge cards.	Hospital-wide consultation and approval of the policy.
Intentions (8) Management	Stability of intentions, stages of change model, transtheoretical model and stages of change, certainty of intensions, commitment, intrinsic motivation	Intentions initially strong but will wane over time; Staff will lapse back to old habits after a while; Turnover can dilute intentions;	Use policy signs as decision aid and reminder; Remove all old signs and replace with policy signs. Orientation for new staff. Clinical champions (Nurse Educators).	Use of policy tools e.g., traffic light colours bedside signs, badge cards etc. Clinical champions (Nurse Educators). Information on webpage. Development of sustainability tools such as Webinar, eLearning and Quiz for policy.	Support by senior management and opinion leaders. Senior staff support strong at outset. Hospital-wide consultation for policy; Policy signs to replace all existing oral intake

			(Also, availability of audit tool for champions to conduct audit locally.	Include policy concepts in orientation packages.	signs (forcing function).
Goals (9) Frontline Management Organisational	Goals (distal/proximal), goal priority, goal/target setting, goals (autonomous/ controlled), action planning, implementation intention, representation of tasks	Supported by senior staff but floor staff may have different opinion. Different areas may have different levels of commitment.	Clinical champions (and/or Nurse Educators) facilitate implementation. Provision of appropriate tools to make it easier;	Provide an implementation package. Ask 'how can new policy be implemented in your area?' Provide a level of flexibility for dissemination in each area.	Common goal of patient safety. High level of enthusiasm & support by senior management & opinion leaders.
Memory, attention & decision process (10) Frontline	Memory, attention, attention control, decision making, cognitive overload/ tiredness	Memory of concept will lapse over time. Decision making may be inadequate in junior staff. Cognitive overload – too many initiatives being rolled out.	Simplification and standardisation hospital-wide. Bedside signs as reminder and decision aid at point of care.	Use of traffic light colours and bedside signs, badge cards and other decision aids e.g., flowchart, poster. Nurse Educators for continuing education. Development of education tools such as Webinar, eLearning and Quiz.	Hospital-wide agreement for policy concepts. Availability of tools such as bedside signs, which act as decision aids and reminder at point of care. Nurse Educators/ Clinical champions.
Environment-al context & resources (11) Frontline Organisational	Environmental stressors, resources/material resources, organisational structure/climate, salient events/critical incidents, person x environment interaction, barriers & facilitators, anticipated regret, threat, past behaviour, knowledge, empowerment, negotiation	Time constraints e.g., to look up whether pros & cons of administering each medication. Interruptions. Effort to put up and complete signs. Easier to write on whiteboard than find sign to put up. Too busy ('bottle neck in mornings…don't have time to review meds').	Decision aid tools (bedside signs). Intranet information source. Provide sufficient, easily accessible signs. Remove old signage. Simplification/ standardisation of medication instructions. Provision of table of meds to consider withholding.	Availability of decision aid tools e.g., flowchart, badge cards and bedside signs. Bedside signs with appropriate information included will provide details about patient's oral intake needs at a glance. Intranet site with appropriate hyperlinks.	Hospital-wide approval for policy concepts. Simplified and standardised medication instructions. Feedback from pilot project. Bedside signs will reduce time for some staff as don't have to go and look in patient's notes or have to ask nurse. Many areas already putting up bedside
		High staff turnover. Bank staff, pool, agency staff.	Orientation processes. Hospital-wide standardisation.	Bedside signs. Include policy as part of orientation process.	

		Weekend and afterhours a problem due to reduced staff e.g., pharmacists, doctors.	Bedside signs serving as decision aid at point of care. Clinical champions/ Nurse Education.	Present information at nurse 'Study Days' e.g., night duty, medication safety etc.	signs so no different to previous/no extra time needed. Ability to access nurse education sessions and medical unit meetings to discuss/educate about policy. Ability to access education sessions by Clinical Service Units.
		Inconsistencies in the way that education is conducted and/or managed. 'Our staff don't do that here . . . ', 'that method won't work here'; Education structure is in place for nursing but not medical and 'allied health' (as a group) within the Clinical Service Units; Education structure occasionally results in boundaries to sharing e.g., information only shared within Clinical Service Units.	Orientation processes. Hospital-wide standardisation. Clinical champions/ Nurse Education. Consult/involve each area.	Seek championship in each area. Present information for each area/ profession.	
Social influences (12) Frontline Management	group norms, group conformity, group identity, social pressure, social norms, social comparisons, social support, intergroup conflict, alienation, social identity (modelling)	Group identities may prevent a unified approach to address issues, e.g., Speech don't feel it's their role to look at/advise about meds. They are happy to write 'crush if possible' but don't feel they should be looking to see if patients are on meds. 'The docs are the ones doing this.'; 'I don't have time to chase them up to clarify!'.	Clear/common goals. Use modelling. Multidisciplinary involvement. Policy instructions simplify and standardise medication administration instructions.	Common goal of patient safety. Use modelling, stories and cases to influence intergroup decisions. Wide inter discipline consultation.	Hospital-wide consultation and approval for policy. Support by senior management and opinion leaders. Feedback from pilot project. Use modelling to help influence e.g., 'was there a clinician in the discussion group?' (yes, and it was sent to Dr this and Dr that as well....). Were anaesthetists consulted? Yes.

					Was speech involved? Yes What did X think? X was supportive. Support by opinion leaders.
Emotion (13) Frontline	Anxiety, depression, positive/negative affect, stress, fear, affect, burn-out.	'I was told off once by a surgeon for giving meds pre surgery and once was enough for me not to do it again'.	'If this happens again nurse can refer surgeon to hospital approved policy for support'.	Availability of hospital approved policy. Indicate that actions in accordance with policy are supported by the hospital.	Hospital-wide consultation and approval of the policy.
Behavioural regulation (14)	Learning, review, direct experience, self-monitoring, breaking habits, evaluation	Habit of using fasting and NBM interchangeably.	Policy bedside signs provide reminder and decision aid at point of care.	Use of traffic light colours and availability of bedside signs, badge cards, flowchart, badge cards.	Availability of policy tools for use at implementation e.g., bedside signs, badge cards with policy information, etc.

Memory, attention & decision process

Barriers identified for this domain were that the decision-making process may be inadequate for junior staff and, if implemented, the Policy's concepts will lapse over time. A hospital-wide policy would support decision-making processes by junior staff – they will have a reference to work with. The decision support tools such as the bedside signs will facilitate decision-making at the point of care, which will also support the Policy's message with the passage of time. Clinical champions and Educators will provide education about the Policy, especially for new staff.

Social influences

There were some overlaps with other domains, particularly *Social professional role & identity*. There were intergroup conflicts, for example, between nursing and medical staff, and medical and speech pathology staff regarding various aspects of medication management and oral intake restrictions. Group identity was a barrier to the unified approach espoused by the Policy. Conversely, social influence was also an enabler because it gave some staff the confidence that the Policy was sound; for example, many were keen to learn who (e.g., which specialty, unit, health professional/department) had been consulted about the Policy. Since a concerted effort had been made to consult at numerous levels across the hospital this put many at ease about the Policy.

Environmental context & resources

This domain was represented by barriers associated with time constraints or busyness, as perceived by staff, to manage medications appropriately and/or to operationalise the Policy: An example was the perception that it would be quicker to write on a whiteboard than to put up the Policy's bedside sign. Conversely, a hospital-wide policy would provide uniformity and potentially reduce uncertainty and improve workflow. Moreover, most areas of the hospital were already using bedside signs of some form related to oral intake restrictions so the Policy's bedside signs were not new in concept, only in appearance and wording. Another barrier in this domain, which overlaps *Social professional role & identity* was the communication structure within the hospital, especially within the medical profession – the structure appeared not to necessarily be 'top down' (or 'bottom

up'). That being so, how could flow of communication/sufficient consultation be ensured, especially if some also do not read their emails?

7.2.4. Planning strategies

The TDF mapping for barriers to medication management and barriers and enablers to policy implementation also served to guide the development of targeted strategies to the barriers and enablers identified. These strategies were discussed in Chapter 5.

7.2.4.1. Medication management strategies

Refer to Table 29 for the barriers to managing medications appropriately in patients with restrictions on oral intake.

Knowledge

To improve knowledge and to minimise confusion, clarity, simplification and standardisation hospital-wide were needed; for example, there needed to distinct definitions for the terms fasting and nil by mouth and these terms must not be used interchangeably. There also needed to be a unified, hospital-wide sanctioned approach to the management of oral medications when patients have restrictions on their oral intake, such as a policy.

Beliefs about consequences

Related to *Knowledge*, there was a lack of knowledge and therefore a lack of belief that certain actions may be harmful towards patients (oral medication administration to an otherwise healthy surgical patient before surgery is different from to a dysphagic stroke patient, regardless of whether both are categorised as fasting or nil by mouth). There was also the belief that short-term omission of oral medications was harmless for the patient. Therefore, the adverse patient events associated with inappropriate management of medications when patients had oral intake restrictions needed to be highlighted to staff, together with other similar events featured in the media and the literature.

Memory, attention & decision process

Staff had difficulties knowing who to seek for a decision about medication administration, which impacted on their own decision-making process and which in turn had the potential to have adverse repercussions for the patient. Consequently, a hospital-wide, ratified stance on medication administrations and oral intake restrictions, supported by decision aids or reminders at the point of care will be beneficial for staff and patients.

Environmental context & resources

As discussed, many staff did not know who to refer to and there was no standardised guidance for staff when it came to managing oral medications in different oral restrictions contexts. In some situations, this impacted on time, affected workflow and served to increase staff workload. These issues would be minimised with standardised guidance, such as a hospital-wide policy and decision aids at the point of care.

7.2.4.2. Hospital implementation strategies

The barriers and enablers to a policy to improve medications management when patients have restrictions on oral intake encountered during the policy development phase were mapped in Table 30. The mapping process was used to assess whether suitable strategies were considered for the identified barriers and that potential facilitators were recognised and maximised.

Social professional role & identity

The barriers mapped to this domain revolved around role expectations, professional confidence, inter-professional boundaries/conflicts and communication between (and within) professions. Consequently, it was crucial to emphasise the common goal of patient safety, highlight the adverse patient events that led to the Policy and involve as many stakeholders as possible in the development and implementation processes to maximise acceptance and uptake hospital-wide. Organisational wide support of the Policy, opinion leaders and clinical champions were key strategies, together with role clarifications for the relevant professions and the use of the bedside signs as a decision aid and communication tool at the point of care.

Beliefs about consequences

Since some staff did not think there was a problem or did not feel there was a need to change practice so discussion about the impetus for this change was needed, a forum for discussion about the local adverse incident reports and cases from the media would likely accentuate the very real risks to patients. Another strategy could be audit and feedback of medication practice around oral intake restrictions for each area. Support for the Policy by key opinion leaders and clinical champions who were respected by staff would also be an important enabler.

Intentions

Staff were well-intentioned but there were always too many things to do and remember and it was easy to revert back to what is familiar; for example, many staff were familiar with using the terms fasting and nil by mouth interchangeably. Therefore, a reminder needed to be available at the point of care, such as bedside signs clarifying the terminology.

Memory, attention & decision process

For Policy implementation, the issues in this domain would likely be associated with the appropriate use of the terminology and medication administration instructions and the subsequent decision-making processes, as well as the long-term sustainability of the implementation. Strategies should therefore include use of decision aids or reminders at the point of care. and approaches that do not require additional resources, for instance, tapping into existing forums for education.

Environmental context & resources

Potential strategies to manage barriers in this domain included the provision of tools such as bedside signs to provide decision aid at the point of care, a badge card with a table to medications to consider withholding before a procedure/surgery, and access to existing platforms to educate staff about the policy, such as nurse education sessions.

French et al.,[160] advised that there is need to consider what is feasible with the available resources, which are likely to be relevant to the setting and health professional group and

what is sustainable. In most areas of our hospital setting there was already a culture of using bedside signs. Therefore, replacing existing signs with the fasting, nil by mouth, and restricted oral intake sign was feasible, achievable with a limited budget and does not require extra resources to operate. It is sustainable because the signs would replace existing ones rather than being additional to current practice and the removal of the old signs mean that staff will only be able to use the Policy signs for oral intake status.

Social influences

Group identities may influence implementation, such as when speech pathologists do not feel it their role to provide advice about medications. Social influences could also be related to inter-professional conflict with managing medications in patients with restrictions on oral intake. An example is where there may be differences in opinion between two professions about the patient's oral intake status and whether medications ought to be given orally. Overcoming this barrier would include involvement of all relevant stakeholders in the development of the Policy, particularly to establish what each profession would be willing to do; wide consultation among as many staff as possible for the proposed Policy document will be essential. The ability to identify and to refer staff to opinion leaders who support the policy will be invaluable.

7.2.5. Question guide

The TDF was used to guide further questions in the semi-structured focus group interview. The interview guide (Table 31) provided examples of questions, linked to specific domains of the TDF, to consider if needed during the focus group sessions; for instances, some questions under Social professional role & identity (or Social influence) could include, 'Did who you work with influence how you would go about managing medications?', 'Who advised you on your practice?', and 'Were there any conflicts between professions?'.

Table 31. Focus group question guide

TDF domain	Example questions
Knowledge	Did/do you know what to do? How would you have gone about it? Who taught you? Were all meds given or just selected ones and how would the selected ones be decided on?
Skills	Were/are you confident with managing meds? Is it something that should be taught?
Social/professional role & identity	Did who you work with influence how you would go about managing meds? Who advised you on your practice? Was there an element of whose role it is to do what? (Were there any conflicts between professions)
Beliefs about capabilities	How confident were you to manage meds when patients had some form of restrictions on their oral intake?
Optimism	Do you think the signs/policy will do what it is supposed to do?
Beliefs about consequences	Were there any concerns about how meds were managed e.g., would you have always had to check with the doctor or would there have been times when you give or withhold meds based on your own clinical decisions. Did you have any concerns about this?
Reinforcement	What would influence your decisions to give or withhold meds e.g., based on what you thought best for the patient, an incident that happened in the past, habit of always checking with the doctor, or knowing what a certain doctor/unit expects?
Intentions	How likely are you to follow this policy? What influences you to follow a certain action? Would you always follow a certain path or set format for following up meds administration or would this sometimes depend what else is happening, i.e., whether there is time, distraction etc.
Goals	How important would giving or not giving meds be in practice? I.e., is it something that should be followed up immediately or would you decide on the urgency of follow-up depending on which med it is or whether it's a daily dose or more regular.
Memory, attention & decision process	Do/did you have to rely on your memory? Was there anything to help with your decision process?
Environmental context & resources	What helped and what hindered? E.g., lack of time, not knowing who to ask, not knowing what to do? Does your environment or resources (time) play a role?
Social influences	Was there support previously to help if not know what to do. Is there support now? What influences your decision to give or not give meds? Did any notable past experience influence your action or the way you would approach giving medications in these patients
Emotion	Did you feel anxious, stressed, frustrated about managing meds?
Behavioural regulation	When the policy first came out did you have to do anything to check whether the policy was being followed? Was it difficult to change your practice with the new policy/signs? Did you have to do anything different?
Post policy general questions	
What are some of the issues you are facing still? What other issues we don't know about that impacts/affects giving meds on the floor.	
Any issues with communication with different professional groups e.g., doctors, patient services assistants, speech pathologists	
Are all medications given now or is it still at own discretion or ask doctor?	
If you still have to chase doctors does it mean policy made no difference?	
Has the policy affected patient safety in any way?	
Has the policy caused any issues itself (caused conflicts)?	
What would make it easier to adopt a new policy – do you have any suggestions on how it can be improved?	

7.2.6. Coding data for qualitative analysis

Together with inductive coding, the domains of the TDF were used as categories to deductively code data for qualitative analysis. Examples of the TDF domains as coding categories are in Table 12 (barriers and enablers to policy implementation) and Table 32 (focus group study).

Table 32. Codes for focus group study

TDF codes/categories	Negative	No change	Positive	Suggestions
Before policy				
1: Behavioural regulation	0	0	0	0
2: Beliefs about capabilities	4	9	1	1
3: Beliefs about consequences	18	17	4	3
4: Emotion	2	4	0	2
5: Environmental context and resources	63	31	43	14
6: Goals	1	0	0	0
7: Intentions	0	0	0	0
8: Knowledge	75	40	81	23
9: Memory, attention and decision process	11	13	36	1
10: Optimism	0	0	0	0
11: Reinforcement	6	4	40	11
12: Skills	18	20	10	5
13: Social influences	3	0	3	2
14: Social professional role and identity	34	21	30	8
After policy				
1: Behavioural regulation	0	0	0	0
2: Beliefs about capabilities	4	9	1	1
3: Beliefs about consequences	18	17	4	3
4: Emotion	2	4	0	2
5: Environmental context and resources	63	31	43	14
6: Goals	1	0	0	0
7: Intentions	0	0	0	0
8: Knowledge	75	40	81	23
9: Memory, attention and decision process	11	13	36	1
10: Optimism	0	0	0	0
11: Reinforcement	6	4	40	11
12: Skills	18	20	10	5
13: Social influences	3	0	3	2
14: Social professional role and identity	34	21	30	8

Using the codes/categories, themes were then developed for the assessment of:

- Barriers to medication management appropriately (Table 8)
- Barriers and enablers to policy implementation (Table 13)

- Surgical nurses' perceptions and experience of a policy change (Appendix 4)

7.2.6.1. Barriers to managing medications appropriately

This published study was presented in section 4.4. Deductive coding of the feedback and comments was done using the domains of TDF. The deductive coding was analysed together with codes derived from inductive coding of the data. Table 8 details the TDF domains associated with barriers to managing medications appropriately.

The systems and individual level barriers were primarily associated with the TDF domains *Knowledge*, *Environmental context & resources*, *Social professional role & identity, Social influences*. Other domains, such as *Emotion* and *Beliefs about consequences* that also played a role could be seen to represent 'person level' issues but may equally be argued to be 'systemic' in origin; for example, the senior nurse who said she never gave oral medications to patients presurgery again after being told off by a surgeon for doing so would likely have perpetuated and ingrained that practice in the system. Additionally, why did the surgeon tell the nurse off? Was it because s/he believed the practice to be inappropriate, and if so why? Was it because it was the 'accepted thinking' amongst peers at the time? If so, then the issue would have been more systemic.

7.2.6.2. Barriers and enablers to policy implementation

This study was reported in section 6.2. Table 13 highlights the TDF domains found to be most relevant during the Policy implementation process.

The main barrier themes were issues relating to resource and infrastructure, roles and responsibility and perceived relevance of the Policy. These themes were represented by many of the domains already highlighted earlier and reflected issues such as: burden on staff, reliable methods of information dissemination to all staff (*Environmental context & resources*); perception of roles, for example, interpretation of responsibility with carryout the Policy (*Social professional role & identity, Social influences*); and, applicability, such as how staff felt the Policy fit into their practice, and credibility, such as evidence-base and who championed the Policy (*Beliefs about consequences, Knowledge, Social influences*).

The main 'enabler' themes related to: standardised guidance for managing medications in the context of oral intake restrictions and hospital-wide approval for the Policy (*Environmental context & resources, Knowledge, Memory, attention & decision process*); clarity of roles and leadership (*Social professional role & identity, Social influences, Goals*); and, relevance of the Policy to clinical practice (*Beliefs about consequences, Knowledge*).

7.2.6.3. Focus group study

The full report of this focus group work was presented in section 6.3.

Major themes were knowing (or not knowing) what do, limited impact of the Policy and inter-professional friction (see Appendix 4). Not knowing what to do was prominent before the Policy rollout and encompassed issues such as confusion, lack of clarity and guidance and lack of experience and confidence. The major TDF domains were *Knowledge, Environmental context and resources, Beliefs about consequences, Social professional role & identity, Beliefs about capabilities* and *Skills*. Post Policy implementation, knowing what to do was hindered by limited impact resulting from insufficient reach of the Policy, as well as other issues. The TDF domains were similar to those found before Policy rollout.

7.2.7. Overlap of TDF domains

Some of the identified issues were mapped to more than one TDF domain; for example: speech pathologists feeling that it is not their role to advise about medications could be mapped to *'Social professional role & identity'*, *'Beliefs about capabilities'* as well as *'Skills'*; and, the actions of some staff that had been influenced by their previous experience or encounters could be assigned to *'Emotion', 'Reinforcement',* and/or *'Beliefs about capabilities'*.

All 14 TDF domains were found to have some relevance or connectedness to study questions during the data coding and analysis processes. A specific example was that, on first coding, *'Beliefs about capabilities'* and *'Skills'* were not significant domains for managing medications appropriately or the intention to implement a hospital-wide policy.

However, on subsequent reviews of coding and data analyses, these two domains were felt to be relevant, for example, to speech pathologists' perception of their role, which was initially coded to *'Social professional role & identity'*. The perception that decision-making may be inadequate in junior staff had initially been mapped and coded as *'Memory, attention & decision process'* but could also be '*Beliefs about capabilities'* and/or *'Skills'*. It depended on which angle the problem was being approached, for example, the point of view of junior staff, who had not conveyed inadequacy with their capabilities, or the view of other/senior staff, who felt that junior staff needed more support. Another example is that some junior staff highlighted issues with workflow and workload, which would be coded as *Environmental context & resources* but it may be possible that these issues reside within *Skills*, *Beliefs about capabilities* and/or *Intentions*.

The overlaps were sometimes confusing, repetitive and tedious but this was balanced with the confidence that the processes were approached systematically and comprehensively.

7.3. Chapter discussion

The TDF was used in several different ways in the goal to improve the management of medications when patients have restrictions on oral intake. These include: as a checklist to ascertain that as many aspects of influence on the process as possible have been considered, mapping of medication management issues to identify barriers and enablers and to code qualitative data for thematic analysis. Use of the TDF imparted confidence that there were theoretical foundations and a measure of thoroughness to the approach.

Chapter 8. Discussion

8.1. Chapter introduction

This chapter consolidates the program of works undertaken during this PhD, of which the primary aim was to determine the impact of a pragmatic approach to improving medication management in the setting of oral intake restrictions, particularly before a procedure, in a large tertiary referral hospital. The research was inspired by my desire to make some radical changes following several local adverse patient incidents associated with managing medications inappropriately when patients had restrictions on their oral intake. This led me to design, pilot and implement strategies to improve the management of medications in patients with restrictions on oral intake.

The chapter will revisit the situations and literature base that underscored the significance of the problem and outline the key methodologies applied to fulfil the aims of the PhD. A summary of the investigations of the causes for medications being managed inappropriately when patients have oral intake restrictions will then follow, as well as an overview of the medication management and implementation strategies considered to address the issues. The effectiveness of the strategies, assessed from three perspectives and timeframes, will be summarised. A brief synopsis of the application of mixed methods research and use of 'theory' in this PhD will also be covered.

8.2. Summary and significance of key findings

8.2.1. Literature review

Medication errors are prevalent globally[3,4,23] and evidence indicates that they cause patient harms and even death.[8,12-14,29,31-35,37-43] Managing medications inappropriately when patients have oral intake restrictions is a medication error. When oral restrictions are placed on patients for clinical reasons, they may be at risk of having medications given or omitted inappropriately or manipulated inappropriately prior to administration.

Adverse outcomes have been demonstrated under all these circumstances.[8,12-14,29,31,33-35,37-43]

My PhD particularly focused on medications omitted inappropriately when patients need to limit oral intake prior to a procedure. Medications omitted inappropriately in this setting adversely impacts patients through increasing post-surgical complications, length of stay and even causing death.[8,31,37,38,65,79]

The concern over anaesthetic induced aspiration of stomach contents has spawned and sustained the doctrine of nothing by mouth from midnight prior to anaesthetic procedures[8,33-35,49,69-71,87], including oral medications, for generations. But this mantra has been shown to be excessive, with many studies in recent years reporting that the risk of aspiration is low[88,92,93,95,96] and confirming that fluids, sips of water and oral medications can be given safely up to one hour prior to the procedure.[69,83,88,90,92,96,102-104] Thus, there is no need for patients' long-term oral medications to be omitted perioperatively on the basis of concerns over potential aspiration, unless there are other clinical reasons to withhold them.

Previously, fears of aspiration also justified the ranking of importance of medications, with only those viewed as urgent or critical, such as β-blockers, administered to minimise oral intake pre-procedure. However, for some medications the decision about importance may not only be subjective – each clinician will have their own view based on the confines of their clinical sphere and experience – it may not reflect the significance of those medications otherwise considered 'unimportant' to the patient. An example of the latter scenario is the omission of MagMin® (magnesium aspartate) tablets, prescribed/taken by the patient for cramps. Anecdotally, some clinical staff view this treatment for muscle cramps dubiously because of the inconsistent evidence in the literature. The record review during the ITS study in this PhD identified a patient complaining of cramps because medications for this condition were withheld during the fasting period. The concept of subjectivity with ascribing importance to certain medications has received some recognition: An attempt to develop a national list of critical medications in the UK was abandoned 'because medicines considered critical in one hospital may differ significantly from another hospital'.[1] Likewise, the Austin Health Perioperative Medication

Committee attempted to draw up a list of 'must give' medications but consensus about which medications to include or excluded could not be reached.

It is now understood that adverse effects resulting from abrupt omission of medications may outweigh concerns about potential haemodynamic aberrations caused by continuing those medications perioperatively.[9,35,37,69,72] All the evidence outlined signify that oral medications should not be omitted perioperatively unless there is a clear clinical indication, such as risk of bleeding, hypoglycaemia or low blood pressure or conditions that increase aspiration risk.

Finally, terminology relating to oral intake restrictions prior to a procedure is diverse.[70,83,88,89,91-95] The variety and inconsistent use may lead to undesirable flow-on consequences, such as when nil by mouth, as intended in the perioperative setting where 'sips of water' and oral medications may be given, is transposed to the dysphagia context where sips and oral medications can lead to severe, adverse consequences for the patient.

8.2.2. Methodology

To apportion breadth and confidence to research investigations, it is necessary to also look beyond quantitative inquiries to discover meanings and motivations behind certain outcomes.[114] Qualitative research uses social interactions and individual experiences to 'dig deeper' to understand phenomena and contribute to new knowledge.[107,108,110] This research approach is valuable in exploring concepts such as 'why are medications managed inappropriately?', 'what are the issues that influenced whether staff use the medication management strategies?' and 'what staff thought of the implemented strategies and how did it affect them?'. There are many permutations in which qualitative research can be used with quantitative research[105,111,113,114], including within the same study.[114] A sequential approach was applied in this PhD, to inform quantitative work and to corroborate findings.

The focus group interview is a qualitative method that employs group interaction to generate meaningful opinions, suggestions and feedback and is cost-effective as several people are interviewed at the same time, in a short time.[135,136,138] Consequently, this was

the most appropriate method for exploring the views of frontline surgical nurses, especially in the clinical setting where time away from patients should be minimised.

Numerous approaches to analysing qualitative data exists but 'thematic analysis' appeared to be the most flexible and user-friendly. The Braun and Clarke method identifies patterns of meaning across a dataset through data familiarisation, coding, theme development and revision and can be used across different settings and is relatively easy to use for those new to qualitative research.[122,124]

To ensure that all relevant factors that may impact on a process are contemplated so that the most appropriate strategies can be deliberated to address the issues identified a considered, systematic approach is needed. Theories are concepts or ideas, definitions, and propositions that organises, explains or predict events, situations or phenomena by illustrating the relationships between variables.[147,148,162] They seek to explain why, when and how a behaviour does or does not occur, and the important sources of influence to be targeted in order to alter the behaviour[151] and offer a systematic way of understanding events or situations.[148] Of the theories available, the TDF attempts to make theory more accessible and usable for those involved in evidence-based practice implementation, is validated and shown to be relevant in diverse clinical settings for exploring human behaviours.[146,150,159,171]

Randomised, controlled, experimental designs are considered the gold standard for measuring the impact of an intervention.[194-196]; however, this may not be an option in many circumstances[193-198], including hospital-wide rollout of quality improvement initiatives. The ITS analysis is the strongest before and after design to assess the effect of an intervention or initiative where randomisation is not feasible.[194,198,201,206]

Errors are failures in the process of medical management and have the potential to harm the patient.[176] System-based failures in healthcare organisations can occur in any processes and are likely to be important underlying contributory factors for recurring medication errors.[60] Process measures are easier to develop and implement in practice than outcome measures and are therefore more frequently assessed as an indication of medication practice.[51] The medication administration process is routinely documented through the electronic medication management system and is relatively easy to access.

The retrospective record review is a technique that takes advantage of routinely collected data[182,187], such as medication administration records, to answer a research question. The method enables assessment of a large sample at limited cost.[183] An ITS analysis of data from a retrospective review of medication administration records would be the most suitable approach to determine the quantitative impact of introducing medication improvement strategies.

The reporting of scientific studies in many areas of health research has been found to be unsatisfactory.[213] Issues such as selective or biased reporting of results has the potential to adversely impact patient care.[213,214] Reporting guidelines should be used to improve the quality and transparency of research outputs.[210,213] Current literature, as well as practical considerations, suggests that the 'Consolidated criteria for REporting Qualitative research'[108] and the 'Methodological and reporting recommendations for ITS studies'[201,220] will be the most appropriate guidance to report the qualitative and quantitative research, respectively, for this PhD program.

8.2.3. Understanding the issues

Chapter 4 investigated the causes for medications being managed inappropriately when patients have restrictions on oral intake. The three cases presented were those that provided the impetus for the Policy and subsequent research. Each case represented a different aspect of medications managed inappropriately when patients had oral restrictions – that is, omitted inappropriately when they should have been given, given when they should have been omitted and manipulated inappropriately (crushed) altering the properties of the medication. All these adversely affected the patients involved and were not unique to the hospital: similar incidents have occurred elsewhere.[8,12-14,29,31,33-35,37-43]

The cases described, as well as those identified in the literature, implied confusion about managing medications in the setting of oral restrictions. There appeared to be confusion about what fasting or nil by mouth meant and a lack of knowledge about which medications were safe to manipulate (crush).

Investigations of local practice found further information supporting the concept of confusion and inconsistency with medication management when patients have oral restrictions. In a snapshot of 66 patients on regular oral medications and categorised as fasting, 40 (74%) missed at least one dose of their medications while 'fasting' pre-procedure/surgery and, of these, 17 (43%) missed at least one dose of a β blocker and/or statin. I led a staff medication survey based on a fictitious patient that found one-third of respondents (n=622) would withhold all oral medications when a patient is fasting two hours before surgery, irrespective of the type of medication, and 10% would give oral medications to a patient categorised as nil by mouth from swallowing difficulties due to a stroke.[225] A patient journey process mapping revealed issues such as inconsistencies and practice variations between interfaces, medical specialities and/or 'units'. An audit of intravenous paracetamol use showed inconsistency in language and interchangeable use of fasting/nil by mouth terminology.

A qualitative analysis of barriers to managing medications appropriately when patients have restrictions on oral intake was undertaken to systematically examine the issues. The data were feedback and comments obtained between 2010 and 2014 in response to adverse patient incidents and medication management issues in the context of oral intake restrictions. The TDF was used to categorise the data, which was analysed using thematic analysis. The findings proposed a systems level as well as individual person level to the barriers. Systems level issues included lack of hospital-wide structured guidance and inconsistent terminology use while individual person level factors encompassed a lack of knowledge about medication management and social influences that defined how staff practiced. The study corroborated the concept of confusion facilitated by inconsistencies with medication practice and terminology use identified in the case studies and investigations of local practice: specifically, fasting and nil by mouth were used interchangeably and in different oral restriction contexts, which impacted patient safety. The findings confirmed that clarification and consistent guidance were needed for staff.

8.2.4. Identifying strategies

Strategies based on the systems approach[19,68,239] such as simplification, standardisation and reducing reliance on memory have been reported to be effective for improving patient

safety[19,181,246,248], including in the healthcare and medication management setting. Evidence suggests that implementation science approaches such as opinion leaders, clinical champions, interactive education sessions, clinical decision support, involvement of stakeholders, staff engagement and audit and feedback confer varying degrees of success[273,276,279,284,285,287,288,291,292]; however, the evidence is limited by inconsistencies in the reporting of the studies and heterogeneity of the approaches used.[275,285,293,294] The strategy shown to be effective in a Cochrane systematic review is educational outreach.[275,277]

An evidence-base when considering potential strategies is important but it is also incumbent to consider the realities and practicalities of implementing these strategies in a real-word setting. An approach that reflects the local context is needed; for instance, educational outreach may be an effective implementation strategy but it is also exceedingly resource intensive, as is audit and feedback to multiple areas, and not realistic where resources are finite.

The factors identified from 'Understanding the issues' (Chapter 4) were considered together with evidenced-based quality improvement strategies to determine the most appropriate course of action. Although the nil by mouth confusion has previously been raised as 'a misleading statement'[71] and 'needs defining'[229], this terminology (or close associates, such as NPO) continues to be used interchangeably with fasting[70,88,94,95], in different contexts, and to mean oral medications and sips are allowed.[226,231,357,358] Some have attempted to provide clarification with the prefix 'preoperative' before nil by mouth[358] but even with this distinction what should staff do when a patient nil by mouth because of swallowing difficulties/stroke presents for surgery? In the backdrop of numerous considerations, a pragmatic approach was proposed: A hospital-wide policy that advocates three oral intake restrictions categories, with fasting and nil by mouth designated different categories. Fasting meant oral medications may be given with a small sip of water, up to 1-2 hours before a procedure/surgery unless there is a clinical reason for the medications to be withheld. Nil by mouth meant absolutely nothing by mouth including sips of water and a different route should be sought for giving medications. Restricted oral intake meant check medical orders for special conditions before giving anything orally and included texture modifications to medications, foods and fluids to

facilitate safe swallowing and sips of water following a procedure/surgery. Bedside signs were the vehicles to convey the medication administration instructions and serve as decisions aids and reminders at the point of care and were to replace all existing oral intake signs.

These medication management strategies were centred on the evidence-based, systems approach to patient safety of standardisation, simplification, reducing reliance on memory, decision aids at the point of care, forcing function and rules and policies.[19,64,68,181,239,246,248,249]

The implementation approach built on those employed during development of medication management strategies, such as stakeholder buy-in, opinion leaders and clinical championship. This was facilitated by the hospital-wide support and formal ratification of the Policy and the availability of existing education session timeslots that could be accessed to conduct interactive education sessions about the Policy.

Despite its evidence-base and use in piloting the medication management strategies, project officer-led audit and feedback was not employed for the hospital-wide implementation due to the considerable workload involved. Also, clinical decision support via the electronic prescribing system had been considered but did not eventuate due to organisational barriers.

8.2.5. Assessing the impact

In Chapter 6, the impact of policy implementation was examined from several viewpoints and timelines. The barriers and enablers analysis considered data that included those obtained during policy implementation while the focus group was conducted approximately eight months following implementation. The ITS analyses used data obtained up to 14 months before and after implementation.

8.2.5.1. Barriers and enablers to Policy implementation

Barriers and enablers to implementation of the Policy were explored using the same techniques employed for the ‘Barriers to managing medications appropriately’ study.

Data were staff comments and feedback obtained between 2011 and 2015. Data were analysed using thematic analysis and the TDF was used to help with coding.

The principal themes identified were resource and infrastructure, staff interpretation of their roles and the perceived applicability and credibility of the Policy. That both barriers and enablers were represented in these major themes suggested that many barriers had been anticipated and relevant strategies were employed and enablers capitalised on to manage them; however, it seems these were insufficient to manage some of the challenging barriers such as staff movement and turnover. There were also unexpected barriers; for example, variations in the interpretation of championship or facilitation of the implementation at the local level and communication flow issues, especially amongst medical staff, all of which had the potential to create inconsistencies and unwanted practice variations. These barriers challenged the Policy's uptake and will likely compromise its long-term sustainability unless it can be built into an existing structural system, such as the electronic medication management platform. A finding that needs attention in future quality improvement initiatives is the concept of a considered approach, which takes time, versus unacceptable delays when developing quality improvement strategies in response to adverse patient incidents.

8.2.5.2. Focus group interview of frontline nurses

Three focus groups, consisting of 16, 14 and six surgical nurses, were conducted. The findings corroborated those from the medication management barriers analysis, as well as the exploration of barriers and enablers to policy implementation. Many nurses in the focus groups corroborated that prior to the Policy there was confusion and not knowing what to do. They felt that the advent of the Policy provided clarity, consistency and guidance when giving oral medications in the setting of oral intake restrictions. Of interest was that those who understood the context of the Policy found it relevant and helpful to their practice. This observation concurred with the barriers and enablers to implementation of the Policy, and has also been reported by others[285,327] – a 2015 overview of systemic reviews found that participants in successful behaviour change interventions may respond positively to a clear sense of how what they were asked to do made sense.[285]

Conversely, issues identified were limitations to the Policy's reach, a lack of understanding of its context and individual staff interpretation of its messages and the subsequent decision-making process. It is possible that the latter two issues related to limits in the Policy's reach since those who reported they understood the context of the Policy and found it helpful were generally those that attended the interactive education session or who knew about the Policy through the pilot ward. It is possible, however, that judgement and decision-making processes differ amongst staff; that is, the presented information may seem self-explanatory and serve as a decision aid for some may be interpreted differently by others who may not find those same instructions helpful. Theories that address judgements and decisions-making to guide appropriate methods for educational interventions have been proposed.[326-330] This concept warrants consideration when developing educational aids or interventions alongside other barriers to implementation.

8.2.5.3. Interrupted time series analyses of medication omissions

The ITS study found a moderate but statistically significant reduction in the proportion of medications omitted inappropriately, as well as overall omissions in Medical areas post-Policy implementation (13.4%, 95% CI [9.0, 17.7], P<0.0001, relative reduction 78% and 11.1%, 95% CI [2.6, 19.6], P=0.013, relative reduction 38%, respectively). Although Surgical areas experienced a reduction in inappropriate omissions, this was smaller than Medical areas in terms of absolute reduction (8.3%, 95% CI [0.8, 15.7], P=0.031) but similar in terms of relative reduction (72%). It was surprising that the baseline level of inappropriate and overall omissions for Surgical areas was lower than Medical areas; this contrasts findings from other studies, which report medical wards to manage medications better than surgical wards.[265,340-343] This discrepancy could be because Surgical area wards may have already been exposed to and practising the Policy through the pilot on a surgical ward (excluded from this study). 'Pool' nurses that work across the area and a shared education structure and educators may have contributed to this effect. Further investigations are needed to verify this speculation, although it is also feasible that the differences may have resulted from Surgical area nurses routinely managing medications in patients fasting before a procedure; that is, it was their area of expertise.

The visual ITS output suggests that the Policy's impact was more significant in the first six months post-implementation. Following this period, the proportions of medications omitted inappropriately became sporadic. Post-implementation linear trend analysis showed a 0.3% (95% CI [0.0, 0.6], P=0.034) increase in the proportion of doses withheld inappropriately per month in Medical areas. This reflects issues with sustainability, perhaps caused by a reduction in championship of the Policy after six months due to other work priorities and staff movement and turnover.

There were two incidental findings worth consideration. Medications requiring administration with food seemed to be problematic when patients needed to fast. It appears that these agents tended to be withheld instead of the risk and benefit of withholding them being weighed when patients were fasting. A dedicated review of this issue is needed. The spike in omissions at seven to eight hours before a procedure in Medical areas also merits attention. This is likely related to fast from midnight practices and the associated systematic omission of morning medications and those that need to be given 'with food', or when procedures are delayed causing longer fasting times. This reiterates the importance of continuation of patients' regular oral medications unless there is a clear clinical indication for omitting these perioperatively, including medications that would otherwise require administration with food – many should not be withheld if absence of food was the only reason.

The modest impact of the Policy and sustainability issue implicated from the results were anticipated following the barriers and enablers to Policy implementation analysis, as well as the focus group exploration of nurses' views and experiences. Factors such as lack of resources/competing demands and busyness, constant staff movement and turnover are challenging and likely impeded the uptake of the Policy. High staff turnover has been widely reported to affect improvement efforts and its sustainability.[70,306,307,324,325] The authors of one study cited greater than 50% turnover in nursing staff two years following implementation of an initiative.[70] Relying on strategies that require ongoing resources to maintain is likely unrealistic in many real-world clinical settings with limited resources. As identified in the qualitative work, future implementation attempts may be better served by considering strategies that are mostly independent of ongoing resources to sustain.

8.2.6. Using theory

Chapter 7 summarised the use of theory, which provides explanations into human behaviour and a considered and systematic approach when developing implementation interventions to change clinical practice. The use of theory enables explanations for why things occurred, thereby offering an evidence base that can be considered when applying strategies to change practice and other applications.

Theory was used in this PhD to ensure that a systematic approach was taken and to provide theoretical underpinnings to findings and confidence that as many elements of influences as possible have been considered. The TDF, a theoretical framework, was used in many aspects of the PhD, such as: mapping barriers to medication management and policy implementation to identify improvement strategies (and enablers); categorising data in the data coding and analysing process for all three qualitative studies; and, as a question guide for the focus group interviews.

8.3. Strengths and limitations

The strength of the body of work in this PhD lies with the multi-pronged and wide-ranging approach to answering the research aims. Qualitative methods were used in concert with the quantitative analyses to explore motivations and provide depth and understanding to the findings. Added to this depth was the comprehensiveness offered with using theory in many components of the studies to promote the systematic identification of as many sources of influences as possible, as well as theoretical underpinnings to understand why the results may be the way they were. Furthermore, a solid evidence-base underpinned all aspects of the research, ranging from quality improvement strategies, implementation science, focus groups and thematic analysis to interrupted time series analyses, retrospective record reviews and use of reporting guidelines.

The major limitation emanates from the single centre, non-randomised, non-blinded aspect of the quantitative study. Unfortunately, it was not feasible to apply the experimental design principle of randomisation to a hospital-wide implementation of a quality improvement initiative, hence the ITS design was used. The dates and times of

the data (medication dose omissions, anaesthetic start date/time) were needed to assess appropriateness so blinding of the researcher/PhD candidate was impractical. The potential for bias was anticipated and several steps were undertaken to increase rigour. These include development of the coding manual/rules for coding a priori, randomly selecting up to 30 patients per area per month, inter-rater checking, as well as a resolving differences component. The reduction in the overall proportion of medications omitted post-implementation in Medical areas was independent of researcher input/bias and lend support to the results. Although the work in this PhD reflects findings from only one hospital, the literature review in this thesis established that medication administration issues in the context of oral restrictions are prevalent and problematic worldwide. Thus, the results will be of interest beyond the confines of this one hospital. The dual medical-surgical perspective and qualitative exploration from different outlooks and timeframes will likely further its applicability.

Some researchers may view the absence of member checking for the qualitative studies as a limitation; however, others have questioned whether member checking is always appropriate[127,128] since the account produced by the researcher is aimed at a wide audience and will, inevitably, be different from that of an individual participant simply because of their different roles in the research process.[127] Moreover, in many instances, the aim of qualitative research is to account for multiple perspectives and the goal of analysis is to comprehensively incorporate those perspectives into discernible findings[111], which may not necessarily reflect or may differ from the individual participant's worldview. The absence of member checking is balanced by the corroboration or triangulation of the qualitative study findings: The focus group findings corroborated both the barriers to managing medications appropriately and the barriers and enablers to policy implementation studies. Together, the qualitative findings informed and provided understanding and depth for the quantitative work. Triangulation promotes a more comprehensive understanding of the investigations undertaken, increases confidence in the findings and enhances the rigour of a research study.[126] It is seen to confer internal validity to a research study as it uses more than one method of data collection to answer the research question.[128]

The interpretation of the qualitative data may be influenced by the fact that data had not been collected until saturation was reached and limitations with the use of the feedback and comments field notes; however, the data available, given the opportunities and circumstances at the time for each of the qualitative studies, offered adequate and useful information to inform and corroborate the other studies in the PhD and the PhD program as a whole.

8.4. Recommendations for practice

The following practices are needed to improve patient safety in the setting of medication administration and oral intake restrictions:

- Define and standardise terminology and instructions around giving medications (and/or food and fluids) and oral intake restrictions.
- Separate fasting and nil by mouth with respect to oral medication administration when patients have oral intake restrictions Nil by mouth should not be used to mean different things in different contexts. This concept should be introduced universally.
- Provide context and support for making decisions around managing medications in patients with oral intake restrictions for staff at the point of care.
- The ethos of giving only those medications considered important and withholding all others during the fasting period should be reconsidered; there needs to be a culture change to giving all medications unless there is a clinical need to withhold them.
- Most of the above should be introduced at the nursing, medical and pharmacy undergraduate level.

Limited staff resources, movement and turnover are likely to be the reality for many institutions and unlikely to change unless systems can be restructured to maximise output and minimise movement. Until this time, reliance on key staff to continuously maintain an initiative should be minimised unless ongoing resources can be assured. Instead, it may be best to explore existing structural systems for potential strategies.

Clinical dashboards and clinical pathways in the electronic medication management system should be exploited to provide timely and relevant information and context for

medication management for patients with restrictions on their oral intake. The resulting system(s) needs to be presented in a cohesive manner so that it will not be a burden for staff to use; that is, staff can easily navigate from one interface to another seamlessly.

Context plays an important role for understanding the motivation of the medication improvement initiative, as well as when applying the initiative to a setting, and needs due consideration when introducing new initiatives.

How some people interpret information and the subsequent decision-making process can impact the initiative being implemented: Reading the instructions does not necessarily equate to knowing what to do next. This needs to be addressed when developing new initiatives.

- A potential method to safeguard against variability is to provide explicit clarification and information using (interactive, electronic) clinical pathways. The electronic medication management system offers potential in this arena.
- A framework for decision-making to promote consistency, especially during the development phase of new initiatives, may need to be considered in future initiatives.

It is implicit that the doctor or medical staff have overall responsibility for the patient but in these times of multidisciplinary teams this may not necessarily be applicable in some respects.

- Attributing responsibility to someone else lessens accountability, especially since even within medical staff there are different specialties, roles and rank.
- There needs to be a shift towards how any clinical staff with a role in managing oral restrictions and/or medications may contribute to ensure best practice for the patient, as well as other aspects of healthcare. It can be as simple as ensuring the correct person is aware of the potential issues.
- One strategy is to promote an accountability/responsibility framework at the undergraduate level (but this concept can only be successful if staff feel they can advocate for patients without fear of disdain or reprisal from others).

General considerations when planning improvement strategies:

- There needs to be an agreed and standardised approach to the stakeholder consultation process, especially amongst the medical staff hierarchy.
- Attention is needed for the timeline of quality assurance processes that have been stimulated by adverse patient incidents. The potential risk to patients from an adverse event recurring needs to be balanced with the lag time it takes to develop a well-considered prevention strategy.
- A representative for each frontline area in which an initiative will be implemented needs to be appointed. This person needs to be involved in all aspects of the implementation process to promote local area ownership and accountability.

8.5. Future research recommendations

The findings from this PhD have stimulated several questions and further research needs, such as:

- Implementation and assessment of the Policy in other institutions is needed to ascertain its effect in environments untainted by the development phase and piloting of the draft Policy. A group unexposed to the Policy should be included for comparative ITS analysis.
- What was the baseline for medications omitted inappropriately in Surgical areas before the Policy was piloted – was it greater than that for Medical areas?
- Is saturation or a ceiling effect a phenomenon in the world of quality improvement? (If so, is it dependent on available resources and staff turnaround and, from this, can this be explicitly calculated or anticipated?)
- Management of oral medications that require administration with food should be investigated. Incidental findings suggested that these were withheld when patients needed to fast before a procedure, which disregards the importance of assessing the risk and benefit of withholding the medication.
- The focus group work revealed that staff may read the bedside signs but their interpretation and/or subsequent decision-making process for the course of action required deviated from what was expected. It would be interesting to seek the opinion

of staff from other institutions to determine how they would interpret the bedside signs and their proposed course of action.

- When the 'orderables' (decision pathways) for the Policy on the electronic platform is finalised and/or the clinical dashboard is employed to support the Policy, the ITS analyses should be repeated to determine the impact of these initiatives on the proportion of medications omitted inappropriately. A less resource intensive approach could be to measure the overall proportion of medications withheld rather than those considered inappropriate, though this will not be as informative.
- Further review is needed for the most appropriate approach to managing anti-diabetes medications when patients are fasting before a procedure. Currently, Austin Health guidelines recommend the omission of all oral anti-diabetes agents on the day of the procedure. Other organisations have raised concerns about increased risk of infection and delayed wound healing from poor glycaemic control and have recommended the continuation of some anti-diabetes agents on the day of the procedure.[344]
- Multidisciplinary focus groups should be considered to provide perspectives from stakeholders other than nursing, especially around the conflicts between professional groups and how this impacts the operationalisation of the Policy.
- The patients' role and perspective in relation to medications and oral restrictions should also be considered.

8.6. Chapter discussion and conclusion

The research undertaken in this doctorate indicated that the interchangeable use of fasting and nil by mouth and use of the latter to mean different entities in different contexts, lack of knowledge and guidance and paucity of staff resources contributed to the confusion surrounding medication management and oral intake restrictions. This affected workflow and impacted on patient safety. A pragmatic approach to medication management that simplified and standardised medication administration instructions and separated fasting from nil by mouth in terms of oral intake restrictions was developed to manage the issues identified. Bedside signs were employed to carry the message and to serve as a decision aid and reminder at the point of care. Hospital-wide engagement was undertaken and stakeholder buy-in was sought, including formal hospital-wide ratification as the

Medications and Oral Restrictions Policy. The Policy was implemented using a range of evidence-based implementation techniques, including opinion leaders, clinical champions and interactive educations session.

The impact of the Policy from three perspectives and timelines suggests that its implementation provided clarity and guidance for staff managing medications, especially when patients have restrictions on oral intake before a procedure; those who understood the context found the Policy helpful to their practice. This translated into a moderate, statistically significant reduction in inappropriate medication omissions in patients affected for both Medical and Surgical areas, as well as overall medication omissions in Medical areas. Several factors impeded wider uptake and application of the Policy – it was unable to reach all staff due to issues with staff movement and turnover and communication flow, and unable to adequately address the contextual understanding at the point of care. There appears to be elements of individual interpretation of the Policy's messages and/or the subsequent decision-making process, which limited the Policy's impact.

The program of research suggests that clarification of terminology around oral intake restrictions and its relation to giving medication is urgently needed to improve patient safety. The term fasting should be separated from nil by mouth with respect to oral medication administration and there should be no exceptions to giving anything orally when nil by mouth. Context and support for decision-making on medication management in patients with oral intake restrictions need to be provided for staff at the point of care. There also needs to be a culture shift from only giving medications considered important or critical to giving all medications unless there is a clinical need to withhold them.

Barriers to implementation such as limited staff resources, movement and turnover are unlikely to change unless systems can be restructured to maximise output and minimise movement. Until then, existing structural systems and/or those that are relatively independent of key staff to continuously maintain should be explored for potential strategies. Systems such as clinical dashboards and clinical pathways in the electronic medication management platform should be exploited to provide timely and relevant information and context for medication management for patients with restrictions on their oral intake at the point of care. Use of these systems will allow a number of

implementation science and human factors engineering principles, including (computerised) clinical decision support, reminders, reducing reliance on memory and a 'forcing function', to be built in to maximise the uptake of the Policy. Furthermore, the possibility of instantaneous feedback from these platforms will greatly aid 'audit and feedback' and staff education strategies.

Chapter 9. Appendices

9.1. Barriers to managing medications appropriately

Appendix 1. Consolidated criteria for reporting qualitative studies: Barriers to managing medications appropriately when orally restricted

Item	Guide questions/description	Reported
Domain 1: Research team and reflexivity		
Personal Characteristics		
Interviewer/facilitator	Which author/s conducted the interview or focus group?	Not applicable/done as not interview/focus group. First author obtained data. Discussed in section 4.4.2.2.
Credentials	What were the researcher's credentials? E.g. PhD	Was in Cover Letter. NA for thesis.
Occupation	What was their occupation at the time of the study?	Was in Cover Letter. NA for thesis
Gender	Was the researcher male or female	Was in Cover Letter. NA for thesis
Experience and training	What experience or training did the researcher have?	Section 4.4.2.4.
Relationship with participants		
Relationship established	Was a relationship established prior to study commencement?	Not applicable
Participant knowledge of the interviewer	What did the participants know about the researcher? E.g. personal goals, reasons for doing the research	Not applicable
Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? E.g. bias, assumptions, reasons and interests in the research topic	Section 4.4.2.4.
Domain 2: Study design		
Theoretical framework		
Methodological orientation and theory	What methodological orientation was stated to underpin the study? E.g. grounded theory, discourse analysis	Section 4.4.2.3.
Participant selection		
Sampling	How were participants selected? E.g. purposive, convenience, consecutive, snowball	Section 4.4.2.2.
Method of approach	How were participants approached? E.g. face to face, telephone, mail, email	Not applicable as data not purposefully collected – see section 4.4.2.2.
Sample size	How many participants were in the study?	Section 4.4.2.2.
Non-participation	How many people refused to participate or dropped out? Reasons?	Not applicable
Setting		

Setting of data collection	Where was the data collected? E.g. home, clinic, workplace?	Workplace. Section 4.4.2.1.
Presence of non-participants	Was anyone else present besides the participants and researchers?	Not applicable
Description of sample	What are the important characteristics of the sample? E.g. demographic data, date	Section 4.4.2.2.
Data collection		
Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	No. See section 4.4.2.2.
Repeat interviews	Were repeat interviews carried out? If yes, how many?	Not applicable
Audio/visual recording	Did the research use audio or visual recording to collect the data?	No. See section 4.4.2.2.
Field notes	Were field notes made during and/or after the interview or focus group?	Notes made during &/or after interaction with staff. Section 4.4.2.2.
Duration	What was the duration of the interviews or focus group?	Not applicable
Data saturation	Was data saturation discussed?	See 'Limitations' section 4.4.4.5.
Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Not applicable
Domain 3: Analysis and findings		
Data analysis		
Number of data coders	How many data coders coded the data?	Section 4.4.2.3.
Description of the coding tree	Did authors provide a description of the coding tree?	See Table 8
Deviation of themes	Were themes identified in advance or derived from the data?	Inductive and deductive coding. Section 4.4.2.3.
Software	What software, if applicable, was used to manage the data?	NVIVO, section 4.4.2.3.
Participant checking	Did participants provide feedback on the findings?	Not applicable/done. See 'Limitations' section 4.4.4.5.
Reporting		
Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? E.g. participant number	See examples page 120 and 121
Data and findings consistent	Was there consistency between the data presented and the findings?	See examples section 4.4.3.1 and 4.4.4.3
Clarity of major themes	Were major themes clearly presented in the findings?	See examples section 4.4.3.1 and 4.4.4.3
Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	No.

9.2. Barriers and enablers to policy implementation

Appendix 2. Consolidated Criteria for Reporting Qualitative Studies (COREQ): Barriers and enablers to policy implementation

Item	Guide questions/description	Reported in
Domain 1: Research team and reflexivity		
Personal Characteristics		
Interviewer/facilitator	Which author/s conducted the interview or focus group?	Not interview or focus group. See section 6.2.2.2. page 172. Data analysis, 6.2.2.3. page 173
Credentials	What were the researcher's credentials? E.g. PhD	Section 6.2.2.4. page 174
Occupation	What was their occupation at the time of the study?	Section 6.2.2.4. page 174
Gender	Was the researcher male or female	Section 6.2.2.4. page 174
Experience and training	What experience or training did the researcher have?	Section 6.2.2.4. page 174
Relationship with participants		
Relationship established	Was a relationship established prior to study commencement?	Not applicable. Data were collected as part of quality assurance activity. See 6.2.2.2.
Participant knowledge of the interviewer	What did the participants know about the researcher? E.g. personal goals, reasons for doing the research	Not applicable, see 6.2.2.1. See section 6.2.2.4. for researcher details page 174
Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? E.g. bias, assumptions, reasons and interests in the research topic	Researcher experience and potential influence on findings, section 6.2.2.4. page 174
Domain 2: Study design		
Theoretical framework		
Methodological orientation and theory	What methodological orientation was stated to underpin the study? E.g. grounded theory, discourse analysis	Data analysis, section 6.2.2.3. page 173
Participant selection		
Sampling	How were participants selected? E.g. purposive, convenience, consecutive, snowball	Section 6.2.2.2, page 172 Participants and data sources. Retrospective data collection
Method of approach	How were participants approached? E.g. face to face, telephone, mail, email	Not applicable as not data not purposefully collected – see also Participants and data sources, page 172, section 6.2.2.2.
Sample size	How many participants were in the study?	Section 6.2.2.2.,172 Participants and data sources and section 6.2.3.1 (Results) page 175
Non-participation	How many people refused to participate or dropped out? Reasons?	Not applicable. Retrospective data collection. Quality assurance data.
Setting		
Setting of data collection	Where was the data collected? E.g. home, clinic, workplace?	Workplace. See section 6.2.2.1., Design, setting and time period
Presence of non-participants	Was anyone else present besides the participants and researchers?	Not applicable. Quality assurance data used. Retrospective collection

Description of sample	What are the important characteristics of the sample? E.g. demographic data, date	Section 6.2.2.1, 6.2.2.2. page 172, Methods and 6.2.3.1.,page 175 Results.
Data collection		
Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Not applicable. Retrospective data collection from quality assurance process.
Repeat interviews	Were repeat interviews carried out? If yes, how many?	Not applicable, as above.
Audio/visual recording	Did the research use audio or visual recording to collect the data?	No. Section 6.2.2.2., Participants and data sources page 173
Field notes	Were field notes made during and/or after the interview or focus group?	Notes made during &/or after interaction with staff. Section 6.2.2.1. Participants and data sources page 172
Duration	What was the duration of the interviews or focus group?	Not applicable. Retrospective data collection from quality assurance process
Data saturation	Was data saturation discussed?	No. See section 6.2.4.7. page 198, Strengths and weaknesses of the study
Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Not applicable. Retrospective data collection from quality assurance process
Domain 3: Analysis and findings		
Data analysis		
Number of data coders	How many data coders coded the data?	Section 6.2.2.3., Data analysis page 173
Description of the coding tree	Did authors provide a description of the coding tree?	Section 6.2.3.1. page 175, Coding, subtheme and theme development, Table 13 page 176
Deviation of themes	Were themes identified in advance or derived from the data?	Inductive and deductive coding. Section 6.2.2.3., Data analysis
Software	What software, if applicable, was used to manage the data?	Section 6.2.2.3., NVivo 11. Data analysis, page 173
Participant checking	Did participants provide feedback on the findings?	Not applicable. See Strengths and weaknesses of the study, Section 6.2.4.7., page 198
Reporting		
Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? E.g. participant number	See examples in section 6.2.3.10., page 187 under Applicability (barriers) & page 188, Credibility. Participant number not used.
Data and findings consistent	Was there consistency between the data presented and the findings?	Themes discussed in section 6.2.4.1., page 191. Discussion correlate to subheadings in section 6.2.3.3., Results page 177
Clarity of major themes	Were major themes clearly presented in the findings?	Major themes were Resources & infrastructure, role perception and applicability & credibility. Presented in Discussion section. Subthemes discussed in Results
Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes. Section 6.2.3.11., Considered approach versus unacceptable delays page 190

9.3. Focus group study

Appendix 3. Consolidated criteria for reporting qualitative studies: Focus group study

Item	Guide questions/description	Reported
Domain 1: Research team and reflexivity		
Personal Characteristics		
Interviewer/facilitator	Which author/s conducted the interview or focus group?	Methods section, Focus group format, section 6.3.4.4
Credentials	What were the researcher's credentials? E.g. PhD	Title page. NA for thesis
Occupation	What was their occupation at the time of the study?	Title page. NA for thesis
Gender	Was the researcher male or female	Title page. NA for thesis
Experience and training	What experience or training did the researcher have?	Methods section, Researcher experience and potential influence…, 6.3.4.6
Relationship with participants		
Relationship established	Was a relationship established prior to study commencement?	Methods section, Researcher experience and potential influence…, 6.3.4.6
Participant knowledge of the interviewer	What did the participants know about the researcher? E.g. personal goals, reasons for doing the research	Methods section, Researcher experience and potential influence…, 6.3.4.6 Data collection, 6.3.4.3
Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? E.g. bias, assumptions, reasons and interests in the research topic	Methods section, Researcher experience and potential influence…, 6.3.4.6
Domain 2: Study design		
Theoretical framework		
Methodological orientation and theory	What methodological orientation was stated to underpin the study? E.g. grounded theory, discourse analysis	Thematic analysis – Methods section, Analysis, 6.3.4.5
Participant selection		
Sampling	How were participants selected? E.g. purposive, convenience, consecutive, snowball	Purposeful sampling – Methods section, Sample/Participants, 6.3.4.2
Method of approach	How were participants approached? E.g. face to face, telephone, mail, email	Email – Methods section, Data Collection, 6.3.4.3
Sample size	How many participants were in the study?	Results section, 6.3.5
Non-participation	How many people refused to participate or dropped out? Reasons?	Not applicable
Setting		
Setting of data collection	Where was the data collected? E.g. home, clinic, workplace?	Methods section, Data collection, 6.3.4.3
Presence of non-participants	Was anyone else present besides the participants and researchers?	Methods section, Focus group format, 6.3.4.4
Description of sample	What are the important characteristics of the sample? E.g. demographic data, date	Results, section 6.3.5

Data collection		
Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Methods section, Focus group format, 6.3.4.4
Repeat interviews	Were repeat interviews carried out? If yes, how many?	Methods section, Data collection, 6.3.4.3 Results section, 6.3.5
Audio/visual recording	Did the research use audio or visual recording to collect the data?	Methods section, Focus group format, 6.3.4.4
Field notes	Were field notes made during and/or after the interview or focus group?	Methods section, Focus group format, 6.3.4.4
Duration	What was the duration of the interviews or focus group?	Methods section, Focus group format, 6.3.4.4
Data saturation	Was data saturation discussed?	Discussion section, Limitations, 6.3.6.4
Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Unable to do as participant names not collected
Domain 3: Analysis and findings		
Data analysis		
Number of data coders	How many data coders coded the data?	Methods section, Analysis, 6.3.4.5
Description of the coding tree	Did authors provide a description of the coding tree?	See Appendix 4
Deviation of themes	Were themes identified in advance or derived from the data?	Inductive and deductive coding – Methods section, Analysis, 6.3.4.5
Software	What software, if applicable, was used to manage the data?	Methods section, Analysis, 6.3.4.5
Participant checking	Did participants provide feedback on the findings?	Unable to do as participant names not collected
Reporting		
Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? E.g. participant number	See examples in Results section, 6.3.5.1 Participant number was not used
Data and findings consistent	Was there consistency between the data presented and the findings?	See coding tree – Appendix 4
Clarity of major themes	Were major themes clearly presented in the findings?	Discussion section, Limited reach of policy, 6.3.6.1 Individual decision making process, 6.3.6.2 Inter-professional friction, 6.3.6.3
Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Results section, Sign fatigue, 6.3.5.4 Discussion section, 6.3.6.4

Appendix 4. Coding tree for focus group study

Inductive Coding	Theoretical Domains Framework/Categories	Subtheme	Theme
Clarity; communication; confusion; environment; understanding; risk to patients	Knowledge; beliefs about consequences; environmental context and resources	Confusion	Not knowing what to do
Clarity; communication; confusion; environment; understanding; important medications; risk to patients	Knowledge; environmental context and resources; belief about consequences	Lack of clarity and guidance	
Confidence; experience; inter-professional relationships; professional role; understanding	Environmental context and resources; social professional role; belief about capabilities; skills; belief about consequences	Lack of experience and confidence	
Clarity; knowing what to do; understanding	Knowledge; reinforcement; memory, attention and decision process; environmental context and resources; social professional role	Improved clarity	Knowing what to do
Clarity; communication; environment; knowing what to do; understanding; visual prompt	Memory, attention & decision processes; environmental context and resources; knowledge; reinforcement; beliefs about capabilities; social professional role and identity	Visible decision aid at point of care	
Clarity; communication; confidence; inter-professional relationships; knowing what to do	Knowledge; beliefs about capabilities; reinforcement; social professional role and identity	Policy providing support for clinical decisions	
Confidence; did not change practice; environment; experience, knowing what to do; understanding	Environment context and resources; beliefs about capabilities; knowledge; skills	Already practicing in line with Policy	Limited impact of Policy
Clarity; confidence; did not change practice; environment; experience; issues with policy	Knowledge; beliefs about consequences; environmental context and resources; beliefs about capabilities	Individual experience and interpretation	
Communication; did not change practice; environment; information delivery; issues with policy	Environmental context and resources	Sign fatigue	
Communication; did not change practice; environment; information delivery; issues with policy	Knowledge; environmental context and resources	Insufficient reach of policy	
Communication; conflict; environment; experience; inter-professional relationships; professional role	Behavioural regulation; environmental context and resources; memory, attention and decision processes; intentions; knowledge; social professional role and identity		Inter-professional friction

9.4. Interrupted time series analysis study

Appendix 5. Rollout procedure

1. The project officer met with Nurse Education Coordinators for the relevant Clinical Service Unit. In the case of the Medical and Surgical units, the meeting took place approximately two months prior to rollout in those areas.
2. The Policy, its background and aims were discussed as well as factors that need to be considered for rollout.
3. The Nurse Education Coordinators supplied the dates for rollout for their area.
4. The project officer met with the unit Nurse Educators and Nurse Unit Managers for the area a month or so prior to rollout to discuss the Policy, the steps required for rollout, including the need to allocate clinical champions who will support the rollout.
5. Six education sessions per area (three sessions per week during nurse education times held during the overlap of the morning and the afternoon shift) were conducted two to three weeks prior to rollout in that area. The 45-minute education sessions consisted of a presentation about why the Policy was needed, three patient cases, explanation of the bedside signs and other Policy tools, frequently asked questions and questions/general discussion about the Policy.
6. One week before rollout, an email containing a brief overview of the Policy were sent to all staff in the area. This email also had links to electronic copy of the Policy and its associated Manual, and an intranet page about the Policy, including frequently asked questions.
7. On the day of rollout (Monday), a reminder email was sent to all staff in the relevant area to advise about the Policy going live.
8. Also, on the day of rollout, all signs previously used for oral intake status were replaced with the Policy bedside signs by Nurse Unit Manager, Nurse Educator, Clinical Champion or an appointed delegate.
9. The Nurse Unit Manager, Nurse Educator, Clinical Champion or an appointed delegate also checked the signs regularly during the rollout week to ensure the correct signs were being used.

10. Speech pathologists and pharmacists were educated about the Policy at departmental meetings.
11. Individual pharmacists were contacted in the week or so prior to their area going live to ensure they were aware of the Policy and the impending rollout date.
12. Medical staff were informed about the Policy via various channels, including unit meetings, grand rounds, ward meetings and intern meetings. Emails about the Policy were also sent to group email distribution lists and via their departmental heads.
13. Other areas such as Food Services and Patient Service Assistants were notified through their respective departments, as well as directly by the Nurse Unit Manager or delegate on the relevant ward close to rollout time.

Appendix 6. Coding manual

Medications and Oral Restrictions

Data Coding Manual

Contents

Inclusion criteria for database extraction/download 326
Further refinement of inclusion criteria post electronic database download 326
Deciding on appropriateness 327
Stage 1: Documentation on the medication administration record 327
Stage 2: Documentation in patient's notes 327
Stage 3: Resolving differences 327
Considerations for deciding on appropriateness 328
Medications excluded from assessment 328
With food medications 328
Pilot data abstraction 329
Inter-rater reliability checking 329
Notes for resolving differences 329
Abbreviations and codes 332
Medication administration record reasons considered appropriate 332
Downloaded data dose omission reasons requiring further investigation 336
A priori discussion notes (panel) 339
Discussions with Pharmacists regarding reasons for not giving 342
Medications to consider withholding before surgery 343
Definitions 344

Inclusion criteria for database extraction/download

- Non-elective surgery
- Only pre and day one post-surgery/procedure data included
- Only oral medication administration events included, other forms excluded
- Only regular medications included, 'prn' or as needed medications excluded
- Selection of patient is based on the date of surgery
- Patient needs to be on the selected ward, and therefore having their medications managed by staff on that ward, before the surgery
- Where the patient has multiple episodes/surgeries, only the first episode per month is captured
- Medication administration event range of 72 hours from time of surgery, to capture patients who are fasted multiple times within a small period of time (and therefore have the potential to miss multiple days of medications)
- Timeframes: pre = Jan 2014 to Jan 2015, during = Feb 2015 to June 2015, post = July 2015 to June 2016
- Only acute patients are included, 'Day' ward patients are excluded
- All critical care type patients and emergency patients are excluded
- Randomly select 100 patients per month to review, with possibility of sub analysing 50 medical ward and 50 surgical ward patients

Further refinement of inclusion criteria post electronic database download

- Medication administration events refined to within 12 hours of commencing surgery
- Only patients on 'medical' and 'surgical' wards are included. Any wards involved with the pilot are excluded. Medical wards included – 1, 2, 3, 4, 5, Surgical wards included – A, B, C. Ward excluded – pilot ward.
- Timeframes: Medical areas, pre = Jan 2014 to Feb 2015, rollout = Mar 2015, post = April 2015 to May 2016 (14 months pre, 1 months during and 14 months post). Surgical areas, pre = Jan 2014 to Jan 2015, rollout = Feb 2015, post = Mar 2015 to Mar 2016 (13 months pre, 1 months during and 13 months post)
- Randomly selected up to 30 patients per month per area with the knowledge that there were some months, especially in Medical areas with low patient numbers.

Deciding on appropriateness

The Institute for Safe Medication Practice's 'Guidelines for timely administration of scheduled medications' recommend that all scheduled medications should be given within 1-2 hours before or after the scheduled time.[258] Therefore, omission of scheduled oral medications during the fasting period prior to surgery will be considered inappropriate, unless there is an appropriate reason documented.

See Abbreviations and codes for data coding.

Stage 1: Documentation on the medication administration record

Was the reason documented on the medication administration record appropriate? Check all relevant sections, including the prescribing instruction, pharmacist notation and the comments:

1. For patients who are in hospital for more than eight days, only review notes seven days prior to procedure/surgery and 1-day post.
2. Report on only documentations related to medication administration.
3. Check relevant clinical notes.
    a. If there is documentation that indirectly relates to medication administration, this can be included in the comments section.

Stage 2: Documentation in patient's notes

Was there documentation in the patient's notes and does it conform to the Hospital's Policy (Medication and Oral Restriction Policy) or a priori decisions?

Stage 3: Resolving differences

Two researchers, including the data abstractor, will review all entries that required examination of the patient's records. Each entry is to be discussed using the details recorded by the data abstractor. If there is a disagreement about the appropriateness then a dialogue will take place in an attempt to resolve the disagreement. If it remains unresolved, then the entry will be discussed with a third researcher.

Considerations for deciding on appropriateness

The Policy recommends that all regular oral medications be given with a small sip of water, up to one hour prior to surgery, unless advised by the doctor. Therefore the assumption is that all omissions are inappropriate except, for example:

- Anti-diabetes medications
- Mylanta, bisphosphonates, strontium etc. SHOULD be withheld

Although the omission of most vitamins/supplements will not impact on patient's short term quality of life, omission of some will in some circumstances. An example is the need of calcium supplementation after parathyroidectomy. Furthermore, in patients with an acute deficiency, for example low potassium or low magnesium, supplementation is important and should not be not interrupted.

Medications excluded from assessment

- Complementary medicines will be excluded from the analysis as there is inconsistent data on their merits (it will be considered appropriate if withheld as some complementary medicines may increase surgical risk, such as bleeding)
- All aperients except lactulose for 'liver' patients
- Antiplatelets, anticoagulants
- Non-steroidal anti-inflammatory agents and COX-II inhibitors

With food medications

If the reason for medication omission is related to administration with food, then appropriateness will depend on the risk versus the benefit of giving or not giving the medication. The risk will depend on:

- Why the medication needs to be given with food.
  - If the medication is for a local effect on food, for example binding phosphates, then the omission is appropriate
  - If the medication causes nausea and/or gastrointestinal irritation then a risk versus benefit assessment needs to be made

- Whether absence of the medication for up to three* days has the potential to impact on the patient's short-term quality of life. If there is a risk, then the medication should be given even in the absence of food.
  - If the reason is nausea then there needs to be an attempt to manage the nausea, for example whether an antinauseant has been administered.

*The three-day rule of thumb was based on the potential for patients to miss up to three days of oral medications because of longer than anticipated oral restrictions resulting from transitions of care, surgery/theatre delays, reduced staff on (long) weekends[33,255,257] and circumstances delaying return to oral intake post procedure.

Pilot data abstraction

A pilot of 20 randomly selected patients will be conducted prior to the commencement of the actual study data abstraction.

Inter-rater reliability checking

A (10%) random sample of the data will be subject to inter-rater reliability checking.

- Check to see if there is documentation up to seven days prior and up to one day post procedure relating to withholding medications.

Notes for resolving differences

Things to consider when deciding on appropriateness – inter-rater checking

Austin Policy definition

Fasting means to restrict food/fluid prior to a procedure, surgery or clinical intervention such as blood test. For clarity 'fasting before a procedure' should be specified.

Oral medications

In otherwise healthy patients with no risk factors for aspiration (such as obesity or diseases affecting gastrointestinal emptying) regular oral medications should be

continued/given when a patient is fasting unless there are clinical reasons to withhold them, e.g., risk of low blood sugar, bleeding, low blood pressure etc.

All oral medications should be given with a small sip of water, up to one hour prior to the procedure, if there are no clinical reasons to withhold them.

The audit aims to check whether the reasons for withholding oral medications are appropriate. If there is a clear documentation of (reasonable) reason or an identifiable explanation found in the clinical notes then the action is appropriate. If not, then assign as inappropriate. The premise is that all oral medications should be given unless there is an obvious explanation that it needed to be omitted.

Check the medication administration record summary (check before clinical notes)**:**

- Go to given/not given entry. There will be a flag (triangle) if the nurse has inputted comments. If so, click on it and go to comments section.
- Check the order itself. There may be specific instructions e.g., with or after food.
- Check the time the dose is due (based on the prescription or previous day's doses) as doses are sometimes documented later/retrospectively and not necessarily at the time the meds were actually due. It should be assessed based on when the dose should have been given.
- Check time relative to anaesthetic start time. The recommendation is oral doses may be given up to 1 hour before surgery/procedure, i.e., anaesthetic start time.
- Check for IV administration of the same drug.
- Check for duplicated orders and concurrent prn orders of the drug.
- If there were two entries/nurses' documentation for the same drug e.g., one is withheld and the other given slightly later on – check names of the person making the entries. If the same, then the order is appropriate if the same nurse gives/updates within a small time frame. If different nurse gives dose later on then not appropriate. If dose given after procedure then considered inappropriate because there was no need to withhold the dose.
- If order states 'with food', then base the risk assessment on whether there may be consequences/an effect on quality of life if the medication is missed for up to 3 days, e.g., to cover long weekends and late Friday night onset of missed medications. E.g.

antibiotics, potassium, sulfasalazine may have quality of life impact whereas magnesium and zinc may not. (Thus, it is inappropriate to withhold any anti-infective, unless it is within one hour of anaesthetic start.)

- If order does not state 'with food' and no other apparent risk/reason to withhold then the dose should be given, even if perceived as 'unimportant' e.g., colecalciferol, calcium, paracetamol.
- Up to 30mLs or so of liquid may be given so meds /liquids such as lactulose can be given, especially for hepatic encephalopathy.
- It is appropriate to omit alternative medicines such as Krill oil etc.

Check the scanned medical records (clinical notes) if the decision appears inappropriate following the medication administration record summary checking**:**

- Check admission notes for idea of patient's regular oral medications and oral intake status and doctor's plans, especially regarding medications.
- Check notes around time of the procedure in question, especially 1-2 days immediately before and immediately after the procedure (especially for nursing notes) for documentation about medication management.
- Look out for oral intake status e.g., difficulty swallowing, nasogastric tube, i.e., whether patient able to take/tolerate oral medications/have normal oral diet since this affects whether they should be getting medications orally when they are fasting.

Exceptions

- We are not assessing antiplatelets and anticoagulants because whether to give or withhold these is controversial and dependent on the patient's individual circumstances and the considerations of the care team. Similarly, NSAIDs etc. are not assessed as there are arguments for and against giving them.
- Assume that all laxatives (given or) withheld is appropriate, except for lactulose for encephalopathy.
- Strontium, bisphosphonates, and antacids such as Gastrogel should be withheld, but the latter depends on how close it is given relative to anaesthetic start time e.g., within 6 hours may be inappropriate but greater than this should be appropriate.

- It is appropriate to withhold medications that have a local action e.g., phosphate binders, pancrease lipase etc., unless they were given at the time of a patient's meal (as many were fasted after early morning breakfast).
- I assigned meds such as methylphenidate as appropriate if they were omitted close to anaesthetic start but not if omitted hours before because patients will need to still be 'awake' in the hours before the surgery.

Actions

- Assign HA = appropriate or HI = inappropriate to each entry in the clin_notes column.

Abbreviations and codes

Code	Meaning
Stage 1: Checking for reason(s) stated on medication administration record	
GA	Given, appropriate
GC	Given, need to check for further information.
WA	Withheld, appropriate per a priori criteria
WC	Withheld, need to check notes to ascertain appropriateness
Stage 2: Checking for documentation in scanned medical records (clinical notes)	
• Considered appropriate	
HA	Appropriate per Hospital Policy, or as agreed a priori (see 'Considerations for deciding on appropriateness', 'MAR documented reasons' and a priori discussion notes). Other appropriate reason, e.g., reschedule, documented 'patient refused' in notes
• Considered inappropriate	
HI	Inappropriate per Hospital Policy, or as agreed a priori (see 'Considerations for deciding on appropriateness', 'MAR documented reasons' and a priori discussion notes).
Stage 3: Resolving differences	
NR	Not rated (resolving differences not done)
AS	Agreed, first round
RF	Resolved, first round
RS	Resolved, second round
Miscellaneous	
MAR	Medication administration record
Comments	Any information of relevance found
ND	Nothing documented
DN	Doctor's notes
NN	Nursing notes

Medication administration record reasons considered appropriate

Oral medication omission is considered appropriate if the reasons documented are clinically appropriate and is not simply because the patient is fasting before a procedure.

Examples include: patient refused, patient or medication unavailable, patient usually takes at another time. The following is a list of all the omission reasons, as documented by nursing staff, allocated as appropriate.

Reasons for NOT GIVEN, NOT DONE doses	Count	Appropriate
/in theatre	3	Yes
/ordered	3	Yes
/ordered from pharmacy	2	Yes
? Given in other ward and not signed	1	Yes
2 x panadol ordered.	1	Yes
Absent	486	Yes
already given	1	Yes
approval expired, awaiting ID	1	Yes
as per dr. ceased	1	Yes
as per p.m. staff as meds not available	1	Yes
As per RMO orders	2	Yes
attended procedure	1	Yes
awaiting ID approval	1	Yes
BP 117/50	1	Yes
BP low	1	Yes
BP only 113	1	Yes
BP only 113 systolic	1	Yes
BP was 95/60 and HR was 48	1	Yes
BSL's 4.3mmol/l	1	Yes
cancelled by medical staff	1	Yes
ceased	4	Yes
Ceased by RMO	1	Yes
Charted at 0915	1	Yes
Charted at Incorrect Time	62	Yes
Charted on Incorrect Order	7	Yes
Charted on Incorrect Patient	5	Yes
CHARTED TWICE	1	Yes
Clinically Inappropriate, double charted	1	Yes
Clinically Inappropriate/absent/ordered	1	Yes
coloxyl and senna/lactulose given	1	Yes
DAUGHTER THAT MEDS TAKEN AT ORE-ADMISSION	1	Yes
dc	1	Yes
deranged LFT's	1	Yes
discontinue	1	Yes
Doctor's order is daily, which has been given today.	1	Yes
double order	1	Yes
Double order of paracetamol, Dr notified	1	Yes
dr request to with hold	3	Yes
duplicate order	10	Yes
duplicated	1	Yes
duplicated med order.	1	Yes
duplicated medicatiion	1	Yes
Duplictae order	1	Yes

eorror statdose ordered twice	1	Yes
Equipment/Supplies Unavailable	187	Yes
gave 8mg STAT at 0400	1	Yes
given @ 0400 hrs	1	Yes
given 0730 in ED	2	Yes
given 2 prn	1	Yes
given already	2	Yes
given as nurse initiated, prior to order being made	1	Yes
given at 0100hrs	1	Yes
given at 0400	1	Yes
given at 0830	1	Yes
given at 1119	1	Yes
given at 1209	1	Yes
given clexane 70mg	1	Yes
given in ED	5	Yes
given in theatre	1	Yes
given intra-op	1	Yes
given iv instead	1	Yes
had panadol at 1200hrs	1	Yes
in OR	1	Yes
in OT	1	Yes
in recovery	1	Yes
In thearte	1	Yes
in theater	5	Yes
in theatre	10	Yes
inhaler unavailable	1	Yes
low BP	1	Yes
med not avail await pharm	1	Yes
med not available	4	Yes
med not avaliable	1	Yes
Med unavailable	1	Yes
Medication Discontinued	174	Yes
Medication Not Available	643	Yes
Medication Not Available await restock from pharm	1	Yes
medication not available, pharmacy paged	1	Yes
medication ordered from pharmacy but dose not available, dose not administered due to drug not avai	1	Yes
medication unavailable	1	Yes
medicine now iv	1	Yes
mijnimal pain. refused.	1	Yes
nebulazer given	1	Yes
Nil by Mouth for OT. GIVEN EARLIER IN AM.	1	Yes
not avail	1	Yes
not avail on 8th floor. ordered	1	Yes
Not Available	10	Yes
not available - ordered from pharmacy	1	Yes
not available and needs new id approval	1	Yes
not available orderd from pharmacy	1	Yes
not available ordered from pharmacy	1	Yes
not given as per pharmacy once daily dose recommended	1	Yes

not given as per unit	1	Yes
not given in ED	2	Yes
On Leave	72	Yes
On Leave pt for procedure	1	Yes
On Leave-pt self administered	1	Yes
on pantoprazole infusion	1	Yes
on pca opiod	1	Yes
on pca opiod therapy	1	Yes
order ceased	2	Yes
order expired	1	Yes
order out of date	2	Yes
ordered from pharmacy	1	Yes
ordered twice	1	Yes
Other double charted	1	Yes
Other duplicate order	2	Yes
Other- not avaiable.	1	Yes
Other, ? allergy as pt now has an area of redness on th	1	Yes
Other: duplicate order	1	Yes
Patient is in surgical theatre having LP and NGT insertion	3	Yes
Patient Not Available	85	Yes
Patient Unavailable	106	Yes
Patient usually takes at night-time	1	Yes
previous dose given late	1	Yes
pt altered conscious state	1	Yes
Pt apparently refused, according to am staff	1	Yes
Pt at theatre.	1	Yes
Pt has already had 2 doses	1	Yes
pt hasnt been takig it for last few wks bp 120\80	1	Yes
pt having hdx today. does not take on dialysis days	1	Yes
Pt in ICU	1	Yes
Pt in OR	1	Yes
Pt in OT	7	Yes
Pt in other ward at time	1	Yes
pt in scope	1	Yes
pt in theatre	5	Yes
Pt normally takes this dose at 2200hrs	1	Yes
pt not taking	1	Yes
pt off ward at mri	1	Yes
pt on day leave	1	Yes
pt on iv panadol	1	Yes
pt refused	8	Yes
Pt refused as feels can not swallow. RMO aware NFO	3	Yes
PT STATED NOT ON FENOFIBRATE PRIOR TO ADMISSION - SPOKE WITH UNIT	1	Yes
pt states had in AM on other ward	1	Yes
Pt states he does not use seretide puffer???	1	Yes
pt states she had this medication on Monday	1	Yes
pt took own mediation - not available from ward	1	Yes
PT was in theature	1	Yes
pt was not on the ward	2	Yes
ref	1	Yes

Refused	4453	Yes
Refused ,pt wants the tablet w jam but shes fasting	1	Yes
Refused. denied pain	1	Yes
Reported Allergy Interaction	3	Yes
rescehduled	1	Yes
second daily	1	Yes
See PRN order	2	Yes
Site Compromised	7	Yes
Taken this morning	1	Yes
takes PRN	1	Yes
Task Duplication	147	Yes
Task Rescheduled	12	Yes
time changed to earlier	1	Yes
todays date 20/05/2016. old task remains	1	Yes
was given at 0601	1	Yes
wh bp 90\70 manually ,as per unit	1	Yes
witheld as per unit	1	Yes
Withheld after D/W renal reg	1	Yes
withheld as per unit	1	Yes
Withheld, medication being ceased as per NSURG	1	Yes
written twice	1	Yes

Downloaded data dose omission reasons requiring further investigation

The following lists all entries (by nursing staff) considered inappropriate and/or requiring further elucidation in the patient's medication records/clinical notes to determine appropriateness. Spelling in the list is as per electronic data download.

Reasons for NOT GIVEN, NOT DONE doses	Count	Appropriate
.	7	No
/fasting since midnight for theatre	1	No
/witheld for surgeryu today	1	No
? given by am staff??	1	Check
? previous nurses shift	2	Check
?causes nausea	1	Check
agitated as per PM shift	1	Check
already given on 24/02/2016	1	Check
AM nurse did not give meds due to pt fasting	8	No
Am shift not given	1	No
As per doctors order due to surgery	2	Check
asleep	2	Check
asleep and had oxynorm prior	1	Check
cerner mistake	1	Check
chart not done on 21	1	Check
clear fluid	3	No
clear fluid only	1	No
Clinically Inappropriate	1997	No
Clinically Inappropriate nil by mouth	1	No

Clinically Inappropriate pt too drowsy	1	Check
Clinically Inappropriate/fasting for theatre.	1	No
dose given 11:50	1	Check
dose not given	1	No
dose not given by night staff - reason unknown	1	No
error	1	Check
extra dose	1	Check
fastimg	1	No
fasting	71	No
fasting 9needs to have with food	1	Check
fasting for abdo u/s	2	No
fasting for colonoscopy	1	No
fasting for OR	2	No
fasting for ot	3	No
fasting for procedure	2	No
fasting for procidure	1	No
fasting for theatre	4	No
fasting needs to have with food.	1	Check
fasting OT	2	No
Fasting, BSL 4 - 5.6.	1	Check
fasting, nil pain	1	Check
Fasting.	1	No
fastinmg	1	No
foir theatre	1	No
for ot	1	No
for proc	1	No
for theater	1	No
for theatre	1	No
From Ed	1	Check
given late	1	Check
left from previous shift	1	No
missed	2	No
nbm	4	No
needs to be given w food ,pt fasting	1	Check
nil	1	No
Nil by Mouth	2650	No
Nil by Mouth for theatre	1	No
Nil by Mouth/fasting pre op	1	No
no completed by previous nurse	1	No
Not Appropriate at this Time	190	No
not appropriate now	1	No
not attended by previous staff	1	No
not avaialbel, (and fasting)	1	No
not charted	1	Check
not charted as complete by nurse on shift	6	Check
Not charted by rostered Nurse.	1	Check
not charted on thi8s day	1	Check
not comlpeted when due reason unknown	2	Check
not completed by am staff	1	No
not due	1	Check

not eating	2	Check
not eating now	1	Check
Not eating...usually taken with food	1	Check
not given	2	No
not given by am nurse	2	No
not given by evening staff	2	No
not given forthetre	1	No
Not given in morning due to patient fastin	1	No
not previously charted	1	Check
Not quick charted at appropriate time	1	Check
not quick charted ny AM staff	1	Check
not signed off	1	Check
not signed off by night staff ? dose was given	1	Check
not sure if given- old order	1	Check
notgiven fortheatre	1	No
notgiven ptis fasting	1	No
OT	1	No
ot going to theatre	1	No
Other	1788	No
Other as per order	2	No
Other-fasting for theatre	1	No
OVER DUE MEDS	2	Check
overdue	4	No
overdue drug,unknown it was done or not	1	No
paracetamol only	1	No
patient fasting. (empty stomach)	1	Check
patient sleeping	1	Check
previous order	2	Check
procedure	1	No
Pt already drinking picoprep and colonlytely	1	Check
pt asleep	2	Check
pt bp has been on the lower side	1	Check
Pt currently FASTING	1	No
pt fasted all day, and fasting again EMB	1	No
pt fasting	17	No
pt fasting ,needs tobe given w or after food	1	Check
pt fasting for o/r	2	No
pt fasting for OT	2	No
pt fasting for procedure	2	No
pt fasting for theatre	4	No
pt fasting from food	1	Check
pt fasting needs to be given w or after food	1	Check
Pt fasting. Pt nil wanting medication before OT	1	No
Pt for OT	1	No
pt for OT- not apropriate to give	1	No
pt for theatre	1	No
pt for theatre today	1	No
pt had bwoels well opened	1	Check
pt has to have it w meal	1	Check
pt in theatre. NBM	1	Check

Pt needs before fasting for OT after	1	No
pt not eating	2	Check
Pt OT	1	Check
pt ref for procedure	1	Check
pt ref going to theatre	1	Check
pt refused for procedure	1	Check
Pt refused to have the tablet while fasting	2	Check
Pt sleeping	1	Check
pt sleeping, has been denying any pain	1	Check
Pt to drowsey	2	Check
pt too drowsy/asleep	1	Check
pt. fasting	1	No
Pt. Nil by mouth	1	No
refused by patient ,as what instructed by pts own spec	1	Check
theatre	1	Check
to colse	1	Check
unable	1	No
Unknown	1	No
Vomiting	93	Check
w	1	No
w/h - feeling symptomatic	1	No
wh for theatre	1	No
with held fasting	1	No
Withheld	2563	No
withheld going to OT	1	No
Withheld OT	1	No
Withheld pre op	1	No
Withheld pt fasting	2	No
Withheld pt is for stres test tomorrow	1	Check
Withheld, BSL 5.0 and on CF's.	1	Check
Withheld. for theatre, as per DR	1	Check
Withheld. pt for OT	1	No
Withheld/not eating	1	Check
Withheld-fasting. as per dr	1	Check
Withheld-for theater. fasting	1	No
Withheld-for theatre	1	No
(blank)		No

A priori discussion notes regarding appropriateness

Panel: Phung To, A/Prof Pat Charles, A/Prof Douglas Johnson (Senior General Medical Physicians)

Criteria	issues to resolve	Resolution
Identify patients with non (elective) planned surgery only	Are there any surgical procedures that should be excluded e.g., transplants?	Transplants but only small numbers. ?Gastrectomies. Check admission dx for e.g., bowel obstruction.

Admitted to key ward for at least 8 hours prior to surgery	Is 8 hours appropriate? Is it sufficient time for medication chart to be done?	Yes. (Charts should be done in around 4 hours.) Not enough meds within 4 hours. Use 12-hour data for (overnight) fasting procedures that may have been delayed.
General rule for appropriateness of medication administration	If medication prescribed regularly it should be given unless there is a documented reason to stop/withhold. If no documentation assume against inappropriate. However, should some meds/groups of meds be excluded?	Yes, there should be exceptions e.g., antiplatelets, anticoagulants. Check Endo and gen med periop guidelines. For those with no documentation, compare with hospital guidelines in the analysis. (Therefore need to code these to extract/ analyse data later on. Code might be that no was documentation made). Use UK (pharmacy) perioperative guidelines if required.
Commence data extraction from when the patient starts fasting for surgery	What happens if meds already being withheld prior to commencing fasting?	Still active decision - compare to hospital guidelines in analysis.
Number of missed doses	Record the total number of consecutive doses of meds omitted from time patient starts fasting.	Agree. Assume fasting start at least 6 hours prior to surgery.
Meds with more than 1 dose omitted	For meds that have more than 1 dose omitted, what happens if there are different annotations/reasons for the omitted doses? How should this be handled? Should each dose and reason for not giving should be recorded but all counted as inappropriate.	Agree
Surgery delays/multiple fasting status	What about when patients are fasted multiple times due to delays or other reasons?	Only collect data for one episode per patient per month.
Regular oral medications only	Medications in the regular administration section only	
PRNs medications	PRN or as needed medications not included	
Antibiotic prophylaxis	Include oral only? Should short term e.g., 3 doses be excluded?	Should include all regular medications.
Oral hypoglycaemics	Assume withholding appropriate? What about metformin?	See Endo guidelines.
Classification of medication groups	Use AMH classification - Note has recently changed	
Aspirin	What assumptions should be made?	Consider appropriate if not given.
Antiplatelets	What assumptions should be made?	Consider appropriate if not given.
Opiates	What happens if they are withheld - need to check if IV given	Appropriate if given in a different form. Need to check IV or PCA chart.
NSAIDs	Should they be given or withheld - what to assign? Renal/bleeding implications but need pain control for surgery?	Should be withheld because of risk of bleeding, renal impairment and/or fluid retention. BUT some patients Rx non steroidals for pain perioperatively, therefore consider

		appropriate if given or withheld. Exclude
Vitamins - other		Exclude
Vitamin D/cholecalciferol	include	Include
Calcium	include unless phosphate binding/renal pt?	Include
Iron	Exclude	Include
Bisphosphonates	exclude	Appropriate to omit
Aperients	Exclude. What about lactulose in liver patient? What about if patient is constipated.	Exclude all except lactulose in liver patient.
Complementary medicines	Exclude in analysis but collect for record	Exclude
Antacids e.g., mylanta	exclude	Exclude
Oral hypoglycaemics e.g., glibenclamide, gliclazide	Consider appropriate if omit?	Use Endo guidelines.
Metformin	consider appropriate if omit prior to Radiological procedures	Yes. Use Endo guidelines.
Strontium	Appropriate to omit	Agree
Chemotherapy	Do not include?	Most usually stopped pre anyway. Assume appropriate if continue.
Pain control	Unless prescribed as prn, pain control should be given around time of surgery. Either as oral or other forms.	Agree
Other medications	Should there be any other exceptions, ie, that should not be included or that should be appropriate to omit?	Use UK (pharmacy) Perioperative Guidelines to check if unsure.
Patient with 2 surgical procedures within 1 admission	Need to count/analyse both	Agree but only collect one episode per month
Analysis	Number of missed doses, number of missed medications as well as number of patients will be analysed	Agree
Events recorded according to predetermined rules.	Meds assessed by whether or not doctor has agreed/stipulate to stop/withhold. If events unclear then send to panel. Need response from at least 2 members. If disagree, get third opinion or reach consensus?	Consensus should be reached (between Doug, Pat and Phung) as long as there are 3 points of view (odd number).
Assessment of rigour	For rigour, obtain 10% random sample for panel (or another researcher) to assess to see if agree with assessment of appropriateness.	Agree
For the policy we are saying that there is no need to withhold meds pre-surgery unless there is a reason (usually other than fasting) for withholding the meds. Exceptions include appropriate documented reason for not giving e.g., doctor's orders, as per doctor, low BP. Other	Patient not available, for purpose of this study, will be considered appropriate. Meds not available, for this study, will be considered appropriate. What about if meds not given before or at the time but given after the procedure before next dose is due?	Consider as inappropriate but code so that can be identified for analysis/comparison later on. Too difficult/too much work to identify meds given after the procedure, therefore assume 'inappropriate' if not given

acceptable reasons include patient refused, patient absent.		
Transition delays	What about when patient moves from one are to another and meds not given due to transition delays?	Consider as inappropriate but code so that can be identified for analysis/comparison later on. Only collecting data from patients who are in a specific ward at least 8 hours prior to surgery.
Medications with no proven benefits or that are 'critical' to their acute care are to be excluded e.g., complementary meds and vitamins.	Areas to exclude: subacute areas, ICU, ED, psyche, short stay units etc	Agreed that blanks and any other unrecognisable documentation will be considered inappropriate.

Discussions with pharmacists regarding appropriateness of reasons for not giving

Reason	Y/N (appropriate?). Comments?	My comments
Charted at incorrect time	If the RN then went on and got it charted at the correct time, I would be happy. Also depends on the medicine – if it is Vit D, I'm not fussed about the time and it probably should have just been given. If it was gent/vanc, I'm pleased if the nurse got it given at the right time.	Could there be something sinister with this reason? Is there something I need to know?
Vomiting	Depends on the medicine – e.g., if antiepileptic, antibiotic, warfarin – discussion needs to be had with prescriber. If alendronate or a vitamin, I wouldn't be so fussed.	Depending on medicine, should alternative be sought/given?
Patient sleeping	Depends on medicine and the time it is due – I wouldn't wake a patient at 2am for a paracetamol, but I would for an antibiotic.	DS thinks this is no excuse! What do you think?
Time changed to earlier	Depends how much earlier and what medicine – if it is the vancomycin for surgical prophylaxis it shouldn't be given earlier. If it is the β-blocker and they gave it early because the patient would be in surgery when it was scheduled, I would be pleased they did this.	Theoretically shouldn't need to change to earlier time under the Policy (if 1 – 2 hours prior to surgery)
All doses rescheduled	If it still meant the medicines were given at an appropriate time, then I wouldn't be fussed.	As above, shouldn't need to specifically reschedule? Is it inappropriate if they did?
Task duplication	If there are two orders for the same medicine, I would be pleased they only gave one of the orders and hope they got the duplicated one ceased.	Could there be something sinister with this reason? Is there something I need to know?
Patient takes medicine with food	This is fine as long as the dose ultimately got given at an appropriate time and it was a medicine not impacted by being taken with food.	During rollout, I advised it needs to be risk vs benefit but I know that some meds are very unpleasant on empty stomach. Thoughts?
Awaiting ID approval	Did the RN let the Dr know they needed to get ID approval? If they just skipped the task and didn't do anything about it because the Dr hadn't done their bit, then that is not ok.	Could there be something sinister with this reason? Is there something I need to know?
Patient declined, fasting for OR	Depends on the medicine. RN should document that they explained the importance of the dose and patient still declined.	If patient misinformed, should nurses correct this misinformation and give meds?

Too drowsy	Depends on the medicine – if it is an opioid and patient is excessively sedated according to the sedation scale, then this would be appropriate and the RN should inform the Dr. If patient is at risk for aspiration, then not giving the dose is fine, but prescriber should be informed to reassess.	Depending on medicine, should alternative be sought/given?
Patient refused	See 'Patient declined'	If patient not want meds because fasting, should nurses correct this misinformation and give meds?
Altered conscious state	See 'Too drowsy'	Depending on medicine, should alternative be sought/given?
Patient unavailable/on leave	If patient was in CT/Xray/physio, did the dose get given when they returned? If on w/e leave, were doses given for patient to take over the w/e?	For the purpose of this study I've indicated this is an appropriate reason but is there anything I need to be aware of?
Meds unavailable	We have ward pharmacists to assist in getting doses during hours, a Master imprest list to locate medicines on other wards after hours, an afterhours cupboard and access to an on-call pharmacist. I would say this is not appropriate, except in the case of CAMs or patient's own clinical trial meds where you are waiting for these to come in from home.	For the purpose of this study I've indicated this is an appropriate reason but is there anything I need to be aware of?
Low BP (or e.g., BSL 3)	For antihypertensives and anti-diabetic meds, I would take these as appropriate, esp a BSL of 3.	If there's been a clinical reason documented I am assuming it's appropriate. Thoughts?
As per doctor	It is tough to challenge a nurse for not giving a dose when the Dr said not to. Generally I would accept this, unless it was a medicine that definitely should have been given preop.	I would like to accept this as appropriate but the issue is that some doctors aren't aware of the Policy, which means it may be an inappropriate decision???
No documentation	If nothing is documented in the patient's notes about decisions to withhold the medication then it needs to be considered inappropriate, unless it follows Hospital Policy. A reasonable attempt needs to be taken to check IV charts, BP records etc. to establish potential explanations.	Lack of documentation does not mean discussion has not taken place. However, as this is a retrospective review this cannot be verified.

Medications to consider withholding before a procedure list

Medication	Reason for withholding/comments
Angiotensin converting enzyme inhibitor (ACEI) e.g., perindopril, ramipril, enalapril	Risk of hypotension. Consult unit/anaesthetist.
Antacids in particulate form e.g., mylanta	Deleterious effects if particulate aspirated.
Anticoagulants e.g., warfarin, dabigatran, rivaroxaban	Risk of bleeding. Consult individual unit protocol.
Antidepressants MAOIs e.g., moclobemide, tranylcypromine	Interactions with many medications used in the perioperative period. Consult anaesthetist.
Antiplatelets e.g., aspirin, clopidogrel, prasugrel	Risk of bleeding. Consult individual unit protocol.

Angiotensin receptor blocker (ARB) e.g., irbesartan, candesartan	Risk of hypotension. Consult unit/anaesthetist.
Bisphosphonates e.g., alendronate	Risk of gastrointestinal burning if taken too close to surgery.
COX-2 inhibitors e.g., celecoxib	Risk of bleeding. Consult unit/anaesthetist.
Cyclophosphamide	Effect on wound healing. Consult unit.
Diuretics e.g., frusemide	Risk of hypotension. Risk of electrolyte imbalances. Consult unit/anaesthetist.
Insulin	(Do not withhold in type 1 diabetes.) Usual dose may require adjusting depending on time/type of procedure. Check with Endocrinology if unsure.
Iron	Gastric discomfort.
Methotrexate	Increased risk of perioperative infections, effect on wound healing. Consult unit.
NSAIDs e.g., ibuprofen, diclofenac	Risk of bleeding. Consult unit/anaesthetist.
Oral hypoglycaemics e.g., gliclazide, glibenclamide, glipizide e.g., metformin	Avoid hypoglycaemia for anaesthesia. Check BSL. Give insulin as per unit protocol or consult Endocrinology if unsure. Risk of lactic acidosis in patients who develop acute renal failure due to contrast media.
Strontium	Risk of VTE with temporary immobility.

References used for this list:

- Austin Health Perioperative Medication Guidelines, 2005.
- Halaszynski TM, Juda R, Silverman DG. Optimizing postoperative outcomes with efficient preoperative assessment and management. Crit Care Med 2004; 32[Suppl]: S76-S86.
- Nagelhout J, Elisha S, Waters E. Should I continue or discontinue that medication? AANA Journal 2009; 77: 59-73.
- Castanheira L, Fresco P, Macedo AF. Guidelines for the management of chronic medication in the perioperative period: systemic review and formal consensus. Journal of Clinical Pharmacy and Therapeutics 2010. Doi:10.1111/j.1365-2710.2010.01202.x
- Smith I, Jackson I. Beta-blockers, calcium channel blockers, angiotensin converting enzyme inhibitors and angiotensin receptor blockers: should they be stopped or not before ambulatory anaesthesia? Curr Opin Anesthesiol 2010; 23: 687-690.
- Hyse FJ, Touw DJ, Strack van Schijndel et al, Psychotropic drugs and the perioperative period: A proposal for a guideline in elective surgery. Psychosomatics 2006; 47: 8-22.
- Drug Safety Advice – Strontium. http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON152727

Appendix 7. Methodological and reporting recommendations for interrupted time series studies

From Jandoc et al.,[201]			
No	**Item**	**Recommendation**	**Reported in**
1	Title and abstract	Indicate the study design (ITS) in the title or abstract	Title, section 6.4. page 219
Introduction			
2	Background/ rationale	Provide background regarding the intervention and setting under investigation to support the study rationale and methods.	Literature review, Chapter 2 Methodology retrospective record review section 3.4.2, interrupted time series section 3.4.3 Study design setting and time period, section 6.4.2.1. page 222
3	Objectives	State specific objectives and any prespecified hypotheses Distinguish between primary and secondary objectives	Section 6.4.1, page 222, 6.4.2.3., 'variables' page 224
Methods			
4	Intervention	Define the intervention time point(s) used in the analysis	Design, setting and time period, section 6.4.2.1. Data sources and measurements page 222, section 6.4.2.3. (electronic data extraction) page 223
5	Participants	List eligibility criteria and methods of selection Define subgroups Consider including a comparison group not exposed to the intervention as a secondary group of participants	Data sources and measurements, 6.4.2.3., page 223, Limitations 6.4.4.12, page 262
6	Data sources and measurement	List data source(s) Comment on data completeness, validity, and changes in data coverage over time	Data sources and measurements, section 6.4.2.3. page 223
7	Variables	Define all variables a) Outcome variable(s) b) Descriptive and stratifying variable(s) Comment on change in variable coding over time Consider including details of variable coding in supplemental material, for example, appendix or research Website	Variables, page 224 Appendices, including coding manual, page 324. Comment on change in coding – see section 6.4.4.12, page 265 (under retrospective data collection)
8	Statistical methods	a) Report all statistical methods 1. Study time intervals, for example, monthly, quarterly 2. Regression model, for example, ARIMA, linear, segmented (i) For ARIMA models, indicate the intervention function, for example, point, ramp, or step (ii) Indicate the appropriateness of linear model(s) when applied 3. Number of preintervention, post intervention, and between intervention data points	Statistical methods, section 6.4.2.4, page 228 Data sources and measurements, section 6.4.2.3, page 223

		b) Define the study period and number of preintervention data points used in forecasting c) Indicate how autocorrelation, non-stationarity, and seasonality were tested and handled d) Consider a lag period if intervention effects are gradual or delayed e) Define and distinguish between primary and secondary or sensitivity analyses f) Consider use of comparison outcome(s) and/or population(s) not exposed to the intervention(s) as secondary analyses g) Report statistical software used for analysis	
Results			
9	Participants	a) Report the number of individuals and/or observations in each group analysed b) Consider use of a flow diagram c) Describe characteristics and indicate missing data	Participants, 6.4.3.1., page 230, Figure 10 page 231 Ward description, 6.4.3.2., page 231, Table 15, Table 16 page 233 Missing data, 6.4.4.12., page 263
10	Outcome data	a) Report the number of outcomes examined over the study period b) Report the average, minimum, and maximum number of outcomes across time intervals c) Report on data variability d) Comment on outliers and ceiling or floor effects where relevant	Outcome data, 6.4.3.4., page 232, Table 15, Table 16, Table 17, Table 18, Table 19 Ceiling effect?, 6.4.4.3., page 252
11	Main results	a) Present results using a graphical display with intervention time point(s) clearly defined b) Consider including forecasted results graphically c) Report absolute and/or relative change(s) and their significance, for example, clinical or policy and statistical	ITS inappropriate omissions output, 6.4.3.11., page 241, Table 21, page 243 ITS total omissions output, 6.4.3.12., page 242, Table 23, page 244 Visual output, section 6.4.3.13. page 242, Figure 13 & Figure 14 Table 21. ITS of inappropriate omissions
12	Other analyses	Report additional results (secondary and sensitivity analyses) in the article, appendix, or research Web site	ITS of total omissions, 6.4.3.12., page 242 Cumulative before and after comparison, 6.4.3.14., page 247
Discussion			
13	Key results	Summarise key results with reference to study objectives	Discussion, 6.4.4., page 250
14	Context	a) Provide context related to possible confounding 1. Discuss relevant co-interventions that occurred during the study period 2. Comment on the stability of participant characteristics over time 3. Comment on the stability of outcome coding over time b) Discuss results of comparison analyses or provide a rationale if no comparison group was considered	Limitations, section 6.4.4.12., page 261 Confounding factors, page 265 Retrospective data collection, page 265
15	Limitations	a) Discuss limitations of the study	Limitations, section 6.4.4.12., page 261

		b) Comment on data variability and appropriateness of the number of data points c) Comment on ceiling or floor effects and outliers where relevant d) Discuss direction and magnitude of any potential bias	Ceiling effect? 6.4.4.3., page 252 Confounding factors, page 265 Bias and judgement, page 262 Documentation discrepancies, page 263 Missing data, page 263 Potential for systematic bias, page 264 Retrospective data collection, page 265
16	Interpretation	Provide overall interpretation of results considering objectives, limitations, results from similar studies, and other relevant evidence	Limitations, section 6.4.4.12., page 261 Interpretation, 6.4.4.13., page 265 Conclusion, 6.4.5., page 266
Other information			
17	Funding	List funding source(s) and role of funders	NA
18	References	Reference methodological articles that support statistical methods used	Statistical analysis, section 6.4.2.4 page 229

Appendix 8. Demographics per month – Medical

	Pre-implementation N = 2026						Post-implementation N = 1847					
Month	Total episodes	Total doses	Withheld inappropriately n (%)	95% Confidence Interval	Total withheld n (%)	95% Confidence Interval	Total episodes	Total doses	Withheld inappropriately n (%)	95% Confidence Interval	Total withheld n (%)	95% Confidence Interval
1	29	142	22 (15.5)	10.0-22.5	34 (23.9)	17.2-31.8	25	124	1 (0.8)	0.0-4.4	29 (23.4)	16.3-31.8
2	28	153	24 (15.7)	10.3-22.4	38 (24.8)	18.2-32.5	30	142	7 (4.9)	2.0-9.9	32 (22.5)	16.0-30.3
3	29	181	22 (12.2)	7.8-17.8	41 (22.7)	16.8-29.4	22	118	3 (2.5)	0.5-7.3	23 (19.5)	12.8-27.8
4	30	145	46 (31.7)	24.3-40.0	61 (42.1)	33.9-50.5	29	147	7 (4.8)	1.9-9.6	23 (15.6)	10.2-22.5
5	28	153	30 (19.6)	13.6-26.8	45 (29.4)	22.3-37.3	26	148	7 (4.7)	1.9-9.5	20 (13.5)	8.5-20.1
6	29	146	16 (11.0)	6.4-17.2	29 (19.9)	13.7-27.3	25	135	8 (5.9)	2.6-11.3	16 (11.9)	6.9-18.5
7	28	171	45 (26.3)	19.9-33.6	76 (44.4)	36.9-52.2	25	142	22 (15.5)	10.0-22.5	42 (29.6)	22.2-37.8
8	23	112	10 (8.9)	4.4-15.8	20 (17.9)	11.3-26.2	29	148	3 (2.0)	0.4-5.8	19 (12.8)	7.9-19.3
9	29	158	35 (22.2)	15.9-29.4	57 (36.1)	28.6-44.1	28	142	5 (3.5)	1.2-8.0	23 (16.2)	10.6-23.3
10	28	123	17 (13.8)	8.3-21.2	30 (24.4)	17.1-33.0	23	141	15 (10.6)	6.1-16.9	40 (28.4)	21.1-36.6
11	29	139	19 (13.7)	8.4-20.5	31 (22.3)	15.7-30.1	28	121	3 (2.5)	0.5-7.1	16 (13.2)	7.8-20.6
12	28	117	25 (21.4)	14.3-29.9	39 (33.3)	24.9-42.6	17	96	5 (5.2)	1.7-11.7	20 (20.8)	13.2-30.3
13	28	154	30 (19.5)	13.5-26.6	48 (31.2)	24.0-39.1	21	115	12 (10.4)	5.5-17.5	27 (23.5)	16.1-32.3
14	28	132	17 (12.9)	7.7-19.8	32 (24.2)	17.2-32.5	25	128	7 (5.5)	2.2-10.9	29 (22.7)	15.7-30.9

Appendix 9. Demographics per month – Surgical

	Pre-implementation N = 1470						Post-implementation N = 1545					
Month	Total episodes	Total doses	Withheld inappropriately n (%)	95% Confidence Interval	Total withheld n (%)	95% Confidence Interval	Total episodes	Total doses	Withheld inappropriately n (%)	95% Confidence Interval	Total withheld n (%)	95% Confidence Interval
1	29	90	21 (23.3)	15.1-33.4	30 (33.3)	23.7-44.1	28	108	5 (4.6)	1.5-10.5	17 (15.7)	9.4-24.0
2	30	129	12 (9.2)	4.9-15.7	28 (21.7)	14.9-29.8	30	125	1 (0.8)	0.0-4.4	18 (14.4)	8.8-21.8
3	29	82	14 (17.1)	9.7-27.0	19 (23.2)	14.6-33.8	28	108	17 (15.7)	9.4-24.0	23 (21.3)	14.0-30.2
4	30	99	12 (12.1)	6.4-20.0	33 (33.3)	24.2-43.5	29	99	1 (1.0)	0.0-5.5	15 (15.2)	8.7-23.8
5	28	95	5 (5.3)	1.7-12.0	15 (15.8)	9.1-24.7	29	141	1 (0.7)	0.0-3.9	21 (14.9)	9.5-21.9
6	29	95	3 (3.2)	0.7-9.0	13 (13.7)	7.5-22.3	29	155	7 (4.5)	1.8-9.1	20 (12.9)	8.1-19.2
7	29	125	10 (8.0)	3.9-14.2	20 (16.0)	10.1-23.6	29	131	8 (6.1)	2.7-11.7	24 (18.3)	12.1-26.0
8	28	131	9 (6.8)	3.1-12.5	25 (19.1)	12.7-26.9	29	101	4 (4.0)	1.1-9.8	26 (25.7)	17.6-35.4
9	30	101	8 (7.9)	3.6-5.3	24 (23.8)	15.9-33.3	27	138	15 (10.9)	6.2-17.3	30 (21.7)	15.2-29.6
10	28	107	8 (7.5)	3.3-14.2	23 (21.5)	14.1-30.5	29	123	5 (4.1)	1.3-9.2	16 (13.0)	7.6-20.3
11	28	132	14 (10.6)	5.9-17.2	18 (13.6)	8.3-20.7	29	99	8 (8.1)	3.6-15.3	24 (24.2)	16.2-33.9
12	29	135	14 (10.4)	5.8-16.8	26 (19.3)	13.0-26.9	28	91	5 (5.5)	1.8-12.4	14 (15.4)	8.7-24.5
13	29	149	22 (14.8)	9.5 (21.5)	34 (22.8)	16.3-30.4	29	126	17 (13.5)	8.1-20.7	36 (28.6)	20.9-37.3

9.5. Ethics approval documents

Appendix 10. Barriers to managing medications Ethics approval

Austin Health

Austin Hospital
145 Studley Road
PO Box 5555 Heidelberg
Victoria Australia 3084
Telephone 03 9496 5000
Facsimile 03 9458 4779
www.austin.org.au

Date: 31 March 2014

To: Phung To
Pharmacy Department, Austin Health

Project: **Improving the management of regular medications when patients are fasting or nil by mouth**

Project No: **LNR/13/Austin/306**
Approval Period: 1 year

Approval of Audit Activity

Document	*Version*	*Date*
Audit Activity Application	1	07 November 2013
Response to Request for Further Information- Email		25 March 2014

I wish to inform you that the audit application named above has been reviewed and approved by the Austin Health Office for Research on behalf of the Austin Health Human Research Ethics Committee.

An audit is defined as an activity instigated by an Austin Health Principal Investigator with the relevant expertise and experience, involving a research hypothesis which includes the analysis of data from previous collected patient information with an intention to publish or otherwise present the data beyond the staff of the hospital. Audits are generally retrospective reviews however prospective audits can be conducted in certain circumstances.

An audit does not involve the collection of new raw data (other than information that would ordinarily be collected as part of patient management) from a patient either in person, through a survey/questionnaire.

Should your audit not commence twelve (12) months from the date of this letter this approval will lapse. A resubmission to the Office for Research would then be necessary before you could commence.

Should you plan for your audit to go beyond the ethics approval period, please request in writing an extension of ethics approval prior to it lapsing.

Please note a final report must be submitted for all audits once completed.

Yours sincerely,

[redacted]

Victoria McMorran
Ethics Officer
Office for Research
Level 8, Harold Stokes Building, Austin Hospital
Phone: (03) 9496 3613 E-mail: ethics@austin.org.au

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMR/ICH Note for Guidance on Good Clinical Practice annotated with TGA comments (July 2006) and the applicable laws and regulations, and the Health Privacy Principles in The Health Record Act 2001. The process this HREC uses to review multi-centre research proposals has been certified by the NHMRC.

Document name: Audit Activity approval Author: VM
Version Date: March 2014

Appendix 11. Focus group Ethics approval

Austin Health

AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL FOR NEW STUDY

Professor David Story
Anaesthetics Department
Austin Health

15.10.2015

Dear David Story

AU RED HREC Reference Number: LNR/15/Austin/403

Project Title: Understanding the issues at the frontline: The Medications and Oral Restrictions Project

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I am pleased to advise that the above project has **received ethical approval** from the Austin Health Clinical Research Review Committee

HREC Approval Date: 15.10.2015

Participating Sites:

Ethical approval for this project applies at the following sites:

Site
Austin Health

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
MAOR Focus Group Protocol	1	17.09.2015
Participant Invitation Sheet MAOR focus group	2	16.10.2015

Site Specific Assessment:

SSA Authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval must be submitted to the Research Governance Office in order to obtain authorisation to commence your project. It is recommended that you check details of governance application submission requirements with each participating site.

Conditions of Ethics Approval:

- You are required to submit to the HREC:
  - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval

Austin Health New Study Ethics Approval Letter Version 1, dated 03 Sept 2015 based on REx Ethics Approval letter template Version 1, dated 6 Aug 2015 *Page 1 of 2*

is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.

- A comprehensive Final Report upon completion of the project.

- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

The HREC may conduct an audit of the project at any time.

Yours sincerely

Appendix 12. Focus group email to Nurse Unit Managers

Subject: Medications and Oral Restrictions Focus Groups

Dear Nurse Unit Manager,

Nurses are very good at delivering really rich information which is relevant to every day practice, they are forthcoming with opinions and are the drivers of successful change. To this end, we wish to hold focus groups of approximately 6 staff each to glean information about their opinions and experiences regarding giving medications to patients who are fasting or nil by mouth.

We envisage the focus groups to commence at the beginning of November; there will be one focus group per ward and each focus group session will be for about 45 minutes (max), during double staffing and at a day which suits you, the Managers.

We are cognisant of the busyness of the wards and the demands on all of the staff, therefore we will be happy to chat with you on the morning of the predetermined day(s) to ascertain who you nominate and/or who would be available to attend the focus group. We will be asking a question relating to before the rollout of the Medications and Oral Restrictions Policy therefore would prefer to interview nurses who have been at Austin Health for more than 12 months.

Attendance at the focus group is voluntary and all responses/conversations will be reported anonymously.

Attached is the Participant Invitation Sheet, which explains the aims and processes of the focus groups. We would be grateful if you could forward this to the staff who you think are suitable/available to attend the focus group for your ward.

If you have any questions please do not hesitate to contact us.

Many thanks for your time and support with this project.

Gillian Dunnachie and Phung To

Appendix 13. Focus group patient invitation sheet

Austin Health

Title *Understanding the issues at the frontline: The Medications and Oral Restrictions Project*

Principal Investigator *Professor David Story*

You are invited to be part of this study. Your participation in this study is voluntary. Your decision whether to take part or not to take part, will not affect your work, your relationship with other staff or your relationship with Austin Health. By attending the focus group you will be giving your consent to participate.

What does my participation involve?
We are conducting focus groups as part of a study called 'Understanding the issues at the frontline: The Medications and Oral Restrictions Project.

You have been invited to participate in this study because we wish to learn about the issues that are faced by staff working at the frontline when giving medications to patients who are fasting or nil by mouth. You have been identified as a nurse working at the frontline by your Nurse Unit Manager.

We wish to learn about your experiences and the issues you face or need to consider whenever you have to administer medications to patients who are fasting or nil by mouth.

The focus group will take aproximately 45 minutes and during this time we will discuss 2 questions around the theme 'medications are not always managed appropriately when patients are fasting or nil by mouth'. The 2 questions we will ask are:

1. What worked well, what didn't, and why, BEFORE the 'Medications and Oral Restrictions Policy' was implemented at Austin Health?
2. What worked well, what didn't, and why, AFTER the 'Medications and Oral Restrictions Policy' was implemented at Austin Health?

Two investigators will be present at the focus group. One person will moderate the group while the other will take notes. An audio recording of the focus group session will also be done using 2 iPhones. Once the audio recording has been transferred onto a password protected computer, the original iPhone recording will be deleted.

We will not use your name in our data and in any reports or publications arising from this study. However, for data analysis we will be assigning each participant a number e.g. N1, N2, N3 etc. and this number may be used where needed so that we can specify that comments were made by different participants.

In a focus group setting 'whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.'

What is the purpose of this research?
The aim of this project is to explore the issues faced by staff at the frontline when giving medications to patient who are fasting or nil by mouth. This project is significant and fills a current gap in knowledge because often guidelines, policies, procedures and other evidence based initiatives are rolled out with the expectation that they will be taken up by staff. However, research shows that evidence based guidelines are not implemented effectively and health outcomes are therefore not achieved. Strategies used in

Austin Health

policy/guideline rollouts are often based on assumptions about why people behave in certain ways e.g. 'lack of knowledge'. However, it is possible these assumptions are incorrect. An understanding of the factors that affect practice is needed to develop strategies to increase the use of evidence based practice and to reduce variability in the delivery of recommended practices.

Understanding the issues around giving oral medications to patients who are fasting or nil by mouth will guide further improvement attempts, if needed, and will also guide future hospital wide implementation initiatives by looking at the issues that most affects staff on the floor and which may not be recognised at other levels of the organisation.

This research will be conducted as part of Phung To's PhD studies. David Story is Phung's PhD Supervisor. Phung has an NHMRC PhD scholarship. This project is not sponsored.

Who to contact
Research contact person

Name	Phung To
Position	Quality Use of Medicines Pharmacist
Telephone	9496 5868
Email	Phung.to@austin.org.au

Complaints contact person

Name	Sianna Panagiotopoulos
Position	Manager Office for Research
Telephone	9496 5088
Email	ethics@austin.org.au

Appendix 14. Quantitative study Ethics approval

Austin Health

Austin Hospital
145 Studley Road
PO Box 5555 Heidelberg
Victoria Australia 3084
Telephone 03 9496 5000
Facsimile 03 9458 4779
www.austin.org.au

Date: 16 May 2014

To: Prof David Story
Anaesthetics, Austin Health

Project: **Improving the management of medications when patients are fasting or nil by mouth**

Project No: **LNR/14/Austin/233**

Approval Period: 1 year

Approval of Audit Activity

Document	Version	Date
Audit Activity Application incorporating the Protocol	1	07 May 2014

I wish to inform you that the audit application named above has been reviewed and approved by the Austin Health Office for Research on behalf of the Austin Health Human Research Ethics Committee.

An audit is defined as an activity instigated by an Austin Health Principal Investigator with the relevant expertise and experience, involving a research hypothesis which includes the analysis of data from previous collected patient information with an intention to publish or otherwise present the data beyond the staff of the hospital. Audits are generally retrospective reviews, however prospective audits can be conducted in certain circumstances.

An audit does not involve the collection of new raw data (other than information that would ordinarily be collected as part of patient management) from a patient either in person, through a survey/questionnaire.

Should your audit not commence twelve (12) months from the date of this letter this approval will lapse. A resubmission to the Office for Research would then be necessary before you could commence.

Should you plan for your audit to go beyond the ethics approval period, please request in writing an extension of ethics approval prior to it lapsing.

Please note a final report must be submitted for all audits once completed.

Yours sincerely,

[redacted]

Victoria McMorran
Ethics Officer
Office for Research
Level 8, Harold Stokes Building, Austin Hospital
Phone: (03) 9496 3613 E-mail: ethics@austin.org.au

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CIPMR/ICH Note for Guidance on Good Clinical Practice annotated with TGA comments (July 2005), and the applicable laws and regulations, and the Health Privacy Principles in The Health Record Act 2001. The process this HREC uses to review multi-centre research proposals has been certified by the NHMRC.

Document name: Audit Activity approval
Version Date: March 2014

Author: VM

Appendix 15. Barriers and enablers to policy implementation Ethics exemption

Austin Health

Austin Hospital

145 Studley Road
PO Box 5555 Heidelberg
Victoria Australia 3084
Telephone 03 9496 5000
Facsimile 03 9458 4779
www.austin.org.au

Date: 28 March 2018 (updated 29 March 2018)

To: David Story
Anaesthetics Department
Austin Health

Project Title: Improving the management of medications when patients are fasting or nil by mouth (short title: Medications and Oral Restrictions).

Dear Professor Story,

Riskman Q No: 24744

Thank you for your application and email dated 26 March 2018. It is our understanding that this application is a Quality Improvement & Innovation project involving collection, use and disclosure of data in a de-identified format to be conducted at Austin Health. Such data is to be accessed by an Austin Health employee only. As such, we advise that it does not raise any ethical concerns and does not fall within the category of a 'research' project within the National Statement on Ethical Conduct in Human Research (NHMRC, 2007). This project does not require submission to the Austin Health Human Research Ethics Committee. In addition, this Quality Improvement & Innovation project can be described as an activity to monitor, improve and evaluate the quality of health services provided by Austin Health.

Please note this letter only pertains to the Quality & Service Improvement project being conducted at Austin Health. If it is intended the Quality & Service Improvement project will be conducted at another institution, the appropriate review and authorisation will be required prior to commencement at another institution.

Document/s Approved:

Document	Version	Date
Audit activity hospital implementation FNBM project	2.0	19 March 2018

Yours sincerely,

[redacted] Digitally signed by Chelsea Webster Date: 2018.03.29 10:01:24 +11'00'

Ms Chelsea Webster
Ethics and Research Governance Manager
Office for Research, Austin Health
Level 8 HSB,
Phone: +61 3 9496 3248
E-mail: chelsea.webster@austin.org.au

Appendix 16. Riskman Q registration

Comprehensive Report — **Austin Health**

Quality Activity ID: 24744

Activity Involved

Activity Involved: Quality Improvement Project
Other Relevant Topic:
Is this a Redesign Activity?: Yes
Reporter's Name: To, Phung
Contact Phone: 9496 5046
Site of Activity: Austin Hospital
Is this an Organisation Wide Activity?: Yes
Directorate: Chief Medical Officer
Division / Aggregate Area: Other
Location: Pharmacy Department

Key Dates

Activity Status: In Progress
Activity Commencement Date: 1 January 2014
Activity Completion Date: 1 January 2020

Activity Details

Activity Title: Improving the management of medications when patients are fasting or nil by mouth
Activity Aim / Objective: To improve the management of oral medications when patients have restrictions on their oral intake, such as when fasting or nil by mouth
Are Consumers / Community Involved in this activity?: Yes
Please Provide Details: Consumers were involved as part of the project team for the development of the Medications and Oral Restrictions Policy, which was implemented hospital wide in 2013. Consumers were also involved as part of the research team related to this project/policy.
Methodology:
Baseline Results: Evaluation of the impact of the policy implementation is in progress.
Follow-up: No

Classification

Classification	
National Safety and Quality Health Service Standards	4. Medication Safety

Journals

Documents

No Attached Documents.

- End of Record -

Quality Activity ID: **24744** Printed On: 22 Mar 2018 9:30:50 AM Page 1 of 1

Appendix 17. Case studies Ethics exemption

TO, Phung

From: PANAGIOTOPOULOS, Sianna
Sent: Monday, 13 July 2020 6:10 PM
To: TO, Phung
Cc: STORY, David
Subject: RE: Case Report Form? Phung TO, "Confusion associated with medications and restrictions on oral intake"

Sorry Phung to

looks fine - except for case 1 – could you please delete the word [redacted] (is that necessary for the case study?)

sorry about the delay – COVID got in the way again!

Case 1

A non-elective [redacted] patient was fasted for surgery.

good luck with your thesis – I would like to read some of the papers that you publish

when COVID is over, I will chat to you about crushing of tabs on a stroke word that I witnessed (not at our hospital!)

kind regards
Sianna

From: TO, Phung <Phung.TO@austin.org.au>

Manager, Office for Research

research@austin.org.au

Chapter 10. References

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