



THE UNIVERSITY OF QUEENSLAND  
AUSTRALIA

# Advanced Practice in Paediatric Pharmacy: What is it, how do you get there, and what does it mean for children?

---

Sonya Rae Stacey

BPharm, PGDipHlthSt, PGCertHlthMgt

*A thesis submitted for the degree of Doctor of Philosophy at*

*The University of Queensland in 2014*

School of Pharmacy

## **Abstract**

The quality and safety of medicines use is as important in paediatrics as in adult medicine, and closely linked to the skills, knowledge, attitudes and behaviours of health professionals responsible for patient care. The aim of this research was to investigate advanced paediatric pharmacy practice; how to develop and assess advanced skills; and how these skills improve outcomes for children.

Prevention of adverse medication events (AMEs) is the most researched pharmacy impact on patient outcomes. However, there is limited evidence in paediatrics. The first phase of this research investigated AMEs in children, with the hypothesis that:

*Voluntary reports of AMEs can be used to identify trends over time in response to safety improvement initiatives, and identify associated skills required of health practitioners.*

The first component of this phase reviewed six months of potential and actual AMEs identified from three databases: clinical incident reports, pharmacist intervention reports and administrative coding using the International Classification of Diseases 10<sup>th</sup> Revision (ICD-10). Analysis identified 447 individual AMEs. Little duplication between data sources was found. ICD-10 coding identified the most cases of harm, and intervention and incident reports identified the most cases of error. ICD-10 events rarely involved error and were time-consuming to retrieve, hence this method was not used in subsequent research.

The next component reviewed eight years of voluntary reports of medication related events (MREs). 10,865 MREs were investigated. Two categories were reviewed in detail: chemotherapy prescribing and potassium errors. Potassium errors reduced from 6.3 to 2.2 per 10,000 occupied bed days from 2008 to 2012. Chemotherapy prescribing errors decreased from 4.2 to 1.1 per 100 oncology separations from 2005 to 2012, particularly errors in chemotherapy protocols. Education alone did not produce sustained change. System changes including forcing functions, executive endorsement and strong multidisciplinary engagement resulted in most improvement. Health practitioners required advanced skills in education, change and risk management, communication, teamwork, leadership, and research methodology.

The second phase of research tested the hypothesis that:

*Paediatric hospital pharmacists value formal recognition of advanced pharmacy practice, can describe the characteristics of advanced practitioners and identify preferred methods of assessment of advanced practice.*

Four focus groups, involving 31 Australian paediatric pharmacists, concluded that advanced practice should be formally recognised, and include a foundation in clinical practice, together with education, research and service improvement outside the institution. Multiple methods of assessment were recommended; most preferred were direct observation of practice, peer review and portfolio review. Knowledge of paediatric diseases and drug handling, and skills in communication with children and families, were important.

The third phase of the project reviewed two existing datasets to test two hypotheses, the first of which was:

*Pharmacist interventions can document progression to advanced practice.*

Six hundred interventions recorded by four pharmacists from one paediatric hospital were retrospectively reviewed over three separate periods from 2005 to 2012. Skills demonstrated in these interventions were rated using a pilot scale from 1 to 5, representing skills typical of intern pharmacists through to advanced practice. Skills increased over time, with more Level 3-5 interventions recorded in the later time periods, and mean skill level increasing from 1.9 to 2.6 ( $p < 0.01$ ).

The second hypothesis in this phase was:

*Training and development priorities in paediatric pharmacy can be identified by direct observation of pharmacists working in clinical practice.*

This study retrospectively reviewed six years of paediatric pharmacist competency assessments using the General Level Framework (GLF). Fifty assessments were retrieved from ten Queensland hospitals, including specialist and general hospitals. Ethics, confidentiality, legal compliance and appropriate dosages were performed consistently well. However, assessment of patients' understanding of illness and treatment, and assessment of adherence, were not performed well. This study demonstrated that the GLF could be used to evaluate competency and identify training needs in the paediatric setting.

The final phase of the research tested the hypothesis that:

*Advanced level paediatric pharmacy practice is most reliably evaluated using multiple assessment methods*

Thirty-six pharmacists were recruited from four Australian paediatric hospitals. Six assessment methods (direct observation of practice, peer review, portfolio review, viva voce, knowledge assessments and self-assessment) were tested over 12 months. Each method was scored against the Paediatric Advanced Level Framework. Qualitative and quantitative analysis of scores, ranking, and participant and evaluator feedback found the most reliable methods were portfolio review, peer review and oral viva. Postgraduate qualifications, CPD records, and direct observation of practice using the GLF or shpaclinCAT, provided less reliable scores and were not preferred by participants or evaluators.

This research project demonstrates the value of advanced practice to Australian paediatric pharmacists as a career pathway; the importance of advanced skills to safe medication use in paediatrics; and the importance of using a combination of assessment methods to evaluate advanced practice. Future work includes development of an electronic portfolio, a paediatric curriculum linked to accessible training, and formal credentialing of advanced pharmacy practitioners.

## **Declaration by author**

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

I have clearly stated the contribution of others to my thesis as a whole, including statistical assistance, survey design, data analysis, significant technical procedures, professional editorial advice, and any other original research work used or reported in my thesis. The content of my thesis is the result of work I have carried out since the commencement of my research higher degree candidature and does not include a substantial part of work that has been submitted to qualify for the award of any other degree or diploma in any university or other tertiary institution. I have clearly stated which parts of my thesis, if any, have been submitted to qualify for another award.

I acknowledge that an electronic copy of my thesis must be lodged with the University Library and, subject to the General Award Rules of The University of Queensland, immediately made available for research and study in accordance with the *Copyright Act 1968*.

I acknowledge that copyright of all material contained in my thesis resides with the copyright holder(s) of that material. Where appropriate I have obtained copyright permission from the copyright holder to reproduce material in this thesis.

## **Publications during candidature**

### **Peer-Reviewed Papers Included in Thesis:**

Stacey S, Coombes I, Wainwright C, Klee B, Miller H, Whitfield K. Characteristics of Adverse Medication Events in a Children's Hospital. *J Paediatr Child Health*. 2014. DOI:10.1111/jpc.12684

- Comprises Chapter 4

Stacey S, Coombes I, Wainwright C, Cardiff L, Whitfield K. What does advanced practice mean to Australian paediatric pharmacists? A focus group study. *Int J Pharm Pract*. 2014. DOI: 10.1111/ijpp.12113.

- Comprises Chapter 6

### **Peer-Reviewed Papers related to, but not included in Thesis:**

Stacey SR, Turner SC, Coulthard KP, Miller H. Paediatric pharmacy in Australia: Where have we come from and where do we need to go? *J Pharm Pract Res* 2013; 43: 45-8

- Incorporated into Chapter 1

### **Peer-Reviewed Papers during candidature not included in Thesis:**

Hennig S, McKay K, Vidmar S, O'Brien K, Stacey S, Cheney J, et al. Safety of inhaled (Tobi®) and intravenous tobramycin in young children with cystic fibrosis. *J Cyst Fibros* 2014;13:428-34.

### **Conference abstracts:**

Stacey S, Avent M, Coombes I, Coombes J. Four years' experience with the advanced level framework - what have we learned and has it made a difference? Paper presented at: Medicines Management 2011, The 37th SHPA National Conference; 2011 Nov 10-13; Hobart, Australia, p. 33.

- Incorporated into Chapter 1

Stacey S, Whitfield K. Advanced Practice in Pediatric Pharmacy – the Australian Experience. *J Pediatr Pharmacol Ther* 2012; 17(1): 133-34

- Published conference abstract from the Pediatric Pharmacy Advocacy Group Conference, Houston TX. Incorporated into Chapter 1

Stacey S, Whitfield K, Wainwright C. Adverse drug events in children: Using voluntary reports to measure the impact of medication safety initiatives in an Australian pediatric hospital. *J Pediatr Pharmacol Ther* 2012; 17(1): 133

- Published conference abstract from the Pediatric Pharmacy Advocacy Group Conference, Houston TX. Incorporated into Chapter 5

Stacey S. Becoming an advanced practitioner, a model for development? Paper presented at: Medicines Management 2013, The 39th SHPA National Conference; 2013 September 19-22; Cairns, Australia. p. 4.

- Invited speaker presentation. Incorporating Chapters 1, 6 and 9.

Klee B, Stacey S, Whitfield K, Coombes I, Wainwright C. ICD-10 coded adverse drug events and children's experience of medicines in hospital. Paper presented at: Medicines Management 2013, The 39th SHPA National Conference; 2013 September 19-22; Cairns, Australia. p. 142.

- Incorporated into Chapter 4

Stacey S, Coombes I, Wainwright C, Whitfield K. Using the "General Level Framework" to identify gaps in knowledge and skills to prioritise professional development activities for paediatric pharmacists. Paper presented at: Neonatal and Paediatric Pharmacists Group 19th Annual Conference; 2013 Nov 9-11; London, England. (Poster presentation)

- Incorporated into Chapter 8

## **Publications included in this thesis**

Stacey S, Coombes I, Wainwright C, Cardiff L, Whitfield K. What does advanced practice mean to Australian paediatric pharmacists? A focus group study. Int J Pharm Pract 2014 DOI: 10.1111/ijpp.12113) – Incorporated as Chapter 6.

<b>Contributor</b>	<b>Statement of contribution</b>
Sonya Stacey (Candidate)	Concept and design of study (50%) Analysis and interpretation of results (60%) Drafted the paper (100%) Edited the paper (60%)
Ian Coombes	Concept and design of study (10%) Analysis and interpretation of results (5%) Edited the paper (10%)
Claire Wainwright	Concept and design of study (10%) Edited the paper (10%)
Lynda Cardiff	Analysis and interpretation of results (25%) Edited the paper (10%)
Karen Whitfield	Analysis and interpretation of results (10%) Concept and design of study (30%) Edited the paper (10%)

Stacey S, Coombes I, Wainwright C, Klee B, Miller H, Whitfield K. Characteristics of Adverse Medication Events in a Children’s Hospital. J Paediatr Child Health. 2014. DOI:10.1111/jpc.12684 – Incorporated as Chapter 4

<b>Contributor</b>	<b>Statement of contribution</b>
Sonya Stacey (Candidate)	Concept and design of study (70%) Analysis and interpretation of results (60%) Drafted the paper (100%)



	Edited the paper (60%)
Ian Coombes	Concept and design of study (10%) Analysis and interpretation of results (10%) Edited the paper (10%)
Claire Wainwright	Concept and design of study (10%) Edited the paper (10%)
Karen Whitfield	Analysis and interpretation of results (10%) Concept and design of study (10%) Edited the paper (10%)
Hugh Miller	Analysis and interpretation of results (10%) Edited the paper (10%)

### **Contributions by others to the thesis**

Rob Ware and Michael David – statistical advice

Alexandra Clavarino – advice on qualitative analysis

Lynda Cardiff – advice on analysis and interpretation of evaluation data

Zachary Sheldrick – assistance with coding of medication related events.

### **Statement of parts of the thesis submitted to qualify for the award of another degree**

None

## **Acknowledgements**

I have been extremely fortunate to have this amazing opportunity to spend three years working in an area of research that I find fascinating. The first thankyou needs to be to my PhD Advisory Team: Dr Karen Whitfield, A/Prof Ian Coombes and Prof Claire Wainwright, for shepherding me through my sometimes-rocky PhD journey. Claire's extensive research experience ensured practical and meaningful advice at all times; Ian's passion, knowledge and international networks in the professional development and safety arenas were invaluable, and Karen's attention to detail and careful supervision were all greatly appreciated.

Thank you to the many people who encouraged me to embark on this journey during an eventful few weeks in early 2011. Thank you to Professor John Pearn for his absolute confidence in my ability and writing a 5-minute research plan on post-it notes. Thank you to Professors Claire Wainwright, Keith Grimwood and Peter Sly for their advice, encouragement, for supporting my application for a clinical scholarship, and reassurance that my ideas were, in fact, "real" research. Thankyou to Ian Coombes, Rebekah Moles, Lynda Cardiff and Krissy Carrington for their suggestions, encouragement and inspirational ideas during a memorable Melbourne taxi ride. And thank you to Karen Whitfield who had a timely visit to the hospital to discuss collaborative research and ended up my primary advisor.

Thank you to UQ and the School of Pharmacy for accepting my enrolment, and for financial support via the UQRS scholarship. An enormous thank-you to QCMRI and Children's Hospitals Foundation for the financial support via the Clinical PhD Scholarship and ongoing administrative, practical and emotional support whenever I needed it. Thankyou to Marcus Engeman for the invaluable support and advice; and Dr's Helen Petsky, Nadia Brown and Jeanne Marshall for sharing this journey with me and understanding as only other current PhD students can.

Thank you to Dr Rob Ware and Dr Michael David for their statistical support. Thank you to A/Prof Alexandra Clavarino for advice and guidance on qualitative analysis. Thankyou to Stuart Bowhay and Wendy Baker for assistance with interpretation of coding and patient occupancy data. Thank you to Emily D'Arcy and Nicola Harper for assistance with chart review and data retrieval. Thank-you to Zachary Sheldrick for his assistance with coding of medication related events. A special thankyou to my new friend Jillian Oldfield, who proofread the thesis for me, with patience, enthusiasm, and attention to detail.

Thank you to CoDEG and the Royal Pharmaceutical Society, particularly Professor Ian Bates and Dr Catherine Duggan for the permission to adapt and use the General Level Framework, the

Advanced and Consultant Level Framework, and their ongoing advice on advanced practice. Also thank you to Steve Tomlin from Evelina Children's Hospital in London, who gave invaluable advice and reassurance that we were heading in the same direction in paediatric pharmacy despite being in different parts of the world.

I am very grateful to the Royal Children's Hospital for allowing me to take three years away from my 'real job' and welcoming me back with open arms. In particular, thank you to my unwaveringly patient, loyal and supportive boss, Hugh Miller, who supported the project itself and for me to undertake it. Thank you also to the SHPA Paediatric COSP members, and in particular Sean Turner for advice and support throughout the process.

Thank you to the participants of focus groups and assessment project group for their time and ongoing commitment to improving pharmacy practice for children.

Thank you to my wonderful friends Lynda Cardiff, Annemaree Carroll, Helen Crook, Cathy Wilks and Mandy Taylor for their unwavering support; wise and practical advice; willing ears; and perfectly timed suggestions for coffee.

Finally, thank you to my wonderful family, who were not quite sure why I wanted to embark upon this journey, but never doubted my ability to achieve it. In particular, thank you to my husband Ward and my daughters Emma and Lauren, for their faith, patience and tolerance. There will be no more need to ask the question: "When you finish your PhD, can we...?".

I am enormously grateful to have people in my life who believe in me more than I believe in myself, and for the opportunity to prove them right.

## **Keywords**

Pharmacist, competency, advanced practice, evaluation, paediatrics, adverse drug events, development, education

## **Australian and New Zealand Standard Research Classifications (ANZSRC)**

ANZSRC code: 111503 Clinical Pharmacy and Pharmacy Practice (60%)

ANZSRC code: 111403 Paediatrics (20%)

ANZSRC code: 130303 Education Assessment and Evaluation (20%)

## **Fields of Research (FoR) Classification**

FoR code: 1114 Paediatrics and Reproductive Medicine (20%)

FoR code: 1115 Pharmacology and Pharmaceutical Sciences (60%)

FoR code: 1303 Specialist Studies in Education (20%)

# Table of Contents

<b>Table of Figures.....</b>	<b>xix</b>
<b>Table of Tables .....</b>	<b>xx</b>
<b>List of Abbreviations used in the thesis.....</b>	<b>xxi</b>
<b>1 Chapter One: Introduction.....</b>	<b>23</b>
<b>1.1 Introduction.....</b>	<b>23</b>
<b>1.2 Background to Research.....</b>	<b>23</b>
1.2.1 What are the issues with children and medications? .....	23
1.2.2 Defining Errors and Adverse Events.....	24
1.2.3 Medication Harm and Errors.....	28
1.2.4 What do we know about adverse medication events in children? .....	28
1.2.5 Why are children at increased risk of harm from medications?.....	29
1.2.6 What do paediatric pharmacists do, and how are they different? .....	34
1.2.7 What does Advanced Practice in Pharmacy mean? .....	36
1.2.8 How do other health professions develop and assess advanced practice? .....	39
1.2.9 How do we currently develop advanced practice in paediatric pharmacists? .....	41
<b>1.3 Rationale and Significance.....</b>	<b>44</b>
<b>1.4 Author Background.....</b>	<b>44</b>
<b>1.5 Conclusion .....</b>	<b>45</b>
<b>2 Chapter Two: Literature Review – Adverse Drug Events.....</b>	<b>46</b>
<b>2.1 Introduction.....</b>	<b>46</b>
<b>2.2 How do we identify and measure adverse medication events and medication errors?.....</b>	<b>46</b>
2.2.1 Spontaneous or Voluntary Reporting (Incident Reports) .....	46
2.2.2 Interventions (Pharmacist or Nursing) .....	47
2.2.3 Chart Review .....	48
2.2.4 Observation.....	48

2.2.5	Trigger Tools .....	48
2.2.6	Administrative or Coding Data .....	50
2.2.7	Comparison of Methods.....	50
<b>2.3</b>	<b>How can health practitioners most effectively improve safety and the quality use of medicines?.....</b>	<b>51</b>
2.3.1	Education .....	52
2.3.2	Clinical Pharmacists .....	54
2.3.3	Communication .....	54
2.3.4	Incident Management and Medication Safety Teams.....	55
2.3.5	Computerised Physician Order Entry (CPOE) .....	56
2.3.6	Centralised Intravenous Admixture Services (CIVAS) or Unit Dose Dispensing Systems .....	57
2.3.7	Other Technology – Smart Pumps and Bar Coding.....	58
2.3.8	Combinations of strategies.....	58
<b>2.4</b>	<b>How can we measure the value of a pharmacist in paediatric health care? .....</b>	<b>59</b>
2.4.1	Measuring value using interventions and errors .....	59
2.4.2	Measuring economic value.....	61
2.4.3	Measuring value using patient outcomes .....	62
<b>2.5</b>	<b>Conclusion .....</b>	<b>63</b>
<b>3</b>	<b>Chapter Three: Literature Review – Development and Assessment of Health Practitioners .....</b>	<b>65</b>
<b>3.1</b>	<b>Introduction.....</b>	<b>65</b>
<b>3.2</b>	<b>Professional development without assessment.....</b>	<b>67</b>
<b>3.3</b>	<b>Portfolios .....</b>	<b>69</b>
<b>3.4</b>	<b>Work Based Assessments.....</b>	<b>71</b>
<b>3.5</b>	<b>Supervisor Reports and Peer Review.....</b>	<b>75</b>
3.5.1	Progress Reports by Supervisors .....	75
3.5.2	Peer Review and Multi-Source Feedback (MSF).....	75
<b>3.6</b>	<b>Objective Structured Clinical Examinations (OSCEs).....</b>	<b>77</b>
<b>3.7</b>	<b>Knowledge Based Examinations (oral and multiple-choice) .....</b>	<b>78</b>
<b>3.8</b>	<b>Reflection and Learning Plans .....</b>	<b>79</b>

3.9	Viva Voce (Oral Interview).....	79
3.10	Combinations of Methods .....	80
3.11	Revalidation .....	81
3.12	Conclusion.....	82
<b>4</b>	<b>Chapter Four: Characteristics of Adverse Medication Events in a Children’s Hospital</b>	<b>83</b>
4.1	Introduction.....	83
4.2	Manuscript Abstract.....	84
4.3	Manuscript Introduction .....	85
4.4	Aim .....	86
4.5	Method .....	86
4.6	Results .....	89
4.7	Discussion.....	92
4.8	Manuscript Conclusion.....	94
4.9	Chapter Conclusion: .....	94
<b>5</b>	<b>Chapter Five: Adverse Medication Events – are we making a difference with high-risk medications in hospitalised children?</b>	<b>95</b>
5.1	Introduction to Chapter Five.....	95
5.2	Manuscript Introduction .....	96
5.3	Method .....	97
5.4	Results .....	102
5.5	Discussion.....	107
5.6	Manuscript Conclusion.....	111
5.7	Chapter Conclusion: .....	112
<b>6</b>	<b>Chapter Six: What does advanced practice mean to Australian paediatric pharmacists? A focus group study</b>	<b>113</b>
6.1	Introduction to Chapter Six .....	113
6.2	Manuscript Abstract.....	115
6.3	Manuscript Introduction .....	116
6.4	Method .....	117
6.5	Results .....	119
6.6	Discussion.....	125
6.7	Manuscript Conclusion.....	128
6.8	Chapter Conclusion: .....	128

<b>7 Chapter Seven: Can pharmacist interventions demonstrate the journey towards advanced pharmacy practice?.....</b>	<b>129</b>
<b>7.1 Introduction to Chapter Seven .....</b>	<b>129</b>
<b>7.2 Abstract .....</b>	<b>130</b>
<b>7.3 Background.....</b>	<b>131</b>
<b>7.4 Method.....</b>	<b>132</b>
<b>7.5 Results .....</b>	<b>135</b>
<b>7.6 Discussion.....</b>	<b>138</b>
<b>7.7 Conclusion .....</b>	<b>140</b>
<b>8 Chapter Eight: Use of the General Level Framework to guide development and training needs of pharmacists working in paediatrics.....</b>	<b>141</b>
<b>8.1 Introduction to Chapter Eight.....</b>	<b>141</b>
<b>8.2 Manuscript Abstract.....</b>	<b>142</b>
<b>8.3 Manuscript Introduction .....</b>	<b>143</b>
<b>8.4 Method.....</b>	<b>144</b>
<b>8.5 Results .....</b>	<b>145</b>
<b>8.6 Discussion.....</b>	<b>150</b>
<b>8.7 Manuscript Conclusion.....</b>	<b>154</b>
<b>8.8 Chapter Conclusion: .....</b>	<b>154</b>
<b>9 Chapter Nine: Assessment of Advanced Paediatric Pharmacy Practice: A Pilot Study</b>	<b>155</b>
<b>9.1 Introduction.....</b>	<b>155</b>
<b>9.2 Background.....</b>	<b>156</b>
<b>9.3 Aim .....</b>	<b>157</b>
<b>9.4 Method .....</b>	<b>157</b>
9.4.1 Recruitment.....	157
9.4.2 Paediatric Advanced Level Framework.....	158
9.4.3 Self-Assessment .....	158
9.4.4 Direct Observation.....	159
9.4.5 Peer Review .....	159
9.4.6 Knowledge Assessment – Postgraduate Qualifications and CPD Records .....	160
9.4.7 Portfolio Review .....	160



9.4.8	Oral Interview (viva voce).....	161
9.4.9	Methods for Analysis .....	162
<b>9.5</b>	<b>Results .....</b>	<b>163</b>
9.5.1	Participant Demographics.....	163
9.5.2	Individual Assessment Methods.....	164
9.5.3	Comparison of Assessment Scores .....	167
9.5.4	Feedback .....	170
9.5.5	Mapping Advanced Practitioners against the Framework.....	176
<b>9.6</b>	<b>Discussion.....</b>	<b>179</b>
9.6.1	Self-assessment.....	179
9.6.2	Direct observation.....	179
9.6.3	Multi Source Peer Review.....	180
9.6.4	Knowledge Assessment .....	180
9.6.5	Portfolio .....	181
9.6.6	Viva voce: .....	182
9.6.7	Combinations of methods.....	183
9.6.8	How well does the existing framework match current advanced practitioners?	183
9.6.9	Limitations .....	184
9.6.10	Future Work.....	185
<b>9.7</b>	<b>Conclusion .....</b>	<b>186</b>
<b>10</b>	<b>Chapter Ten: Thesis Discussion and Conclusion .....</b>	<b>187</b>
10.1	Introduction to Chapter Ten.....	187
10.2	Summary of the key findings .....	187
10.3	Recommendations for future research.....	191
10.4	Conclusion.....	193
<b>11</b>	<b>References .....</b>	<b>194</b>
<b>Appendix A: Paediatric ALF (Section 1.1 Professional Practice – Expert Knowledge) .</b>		<b>220</b>

**Appendix B: shpaclinCAT.....237**

**Appendix C: Feedback Questions for Advanced Practice Assessment Participants .....241**

**Appendix D: Multi Source Peer Review Survey (Mini-PAT) .....245**

## Table of Figures

Figure 3.1 Miller's Framework for clinical assessment (left) mapped against methods for assessment (right).....	66
Figure 4.1 Case Identification Chart.....	89
Figure 4.2 Harm Related Events by Medication Group.....	91
Figure 5.1 Medication Event Types.....	103
Figure 5.2 - Chemotherapy Prescribing Errors.....	104
Figure 5.3 - Potassium Errors.....	105
Figure 5.4 Oxycodone/OxyContin/MSContin errors.....	106
Figure 7.1 Intervention Scores by Skill Level by Study Period.....	136
Figure 7.2 Mean Intervention Scores by Pharmacist per Study Period.....	138
Figure 9.1 Change in self-assessment scores from beginning to the end of the research project .....	165
Figure 9.2 Change in average scores after viva (per cluster).....	167

## Table of Tables

Table 4.1 Definition for Severity of Harm.....	88
Table 5.1 - Safety Initiatives Implemented 2005-2012 .....	100
Table 5.2 - Chemotherapy Prescribing Errors as a proportion of reported oncology events and separations .....	104
Table 6.1 Participant Demographics.....	119
Table 7.1 – Pharmacist Intervention Skill Levels .....	133
Table 7.2 Examples of Pharmacist Interventions per Skill Level .....	135
Table 7.3 Mean Scores per pharmacist, with ANOVA.....	137
Table 8.1 Part 1 - Delivery of Patient Care Competencies .....	145
Table 8.2 Part 2 - Problem solving competencies .....	148
Table 8.3 Part 3 - Professional Competencies .....	149
Table 9.1 Site and Participant Demographics.....	164
Table 9.2 Scores for each assessment method against each cluster .....	167
Table 9.3 Comparison of pairs of assessment methods per cluster (p-values) .....	168
Table 9.4 Intra-Class Correlation for Combinations of Methods.....	170
Table 9.5 Quantitative Survey Feedback on Assessment Methods.....	171
Table 9.6 Advanced practitioners' competency levels mapped against ALF competencies...	177

## List of Abbreviations used in the thesis

<b>ACLF</b>	Advanced and Consultant Level Framework (from United Kingdom)
<b>ADE/AME</b>	Adverse Drug Event/Adverse Medication Event
<b>ADR</b>	Adverse Drug Reaction
<b>ALF</b>	Advanced Level Framework
<b>APC</b>	Australian Pharmacy Council
<b>APPE</b>	Advanced Pharmacy Practice Experiences (USA undergraduate teaching component of the PharmD)
<b>APPF</b>	Advanced Pharmacy Practice Framework
<b>ASHP</b>	American Society of Hospital Pharmacists
<b>BPS</b>	Board of Pharmacy Specialties (USA)
<b>CoDEG</b>	Competency Development and Evaluation Group
<b>COSP</b>	Committee of Specialty Practice (a group belonging to the Society of Hospital Pharmacists of Australia)
<b>CPD</b>	Continuing Professional Development
<b>GLF</b>	General Level Framework (tool for direction observation of pharmacists)
<b>IHI</b>	Institute of Healthcare Improvement
<b>ISMP</b>	Institute for Safe Medication Practices
<b>Mini-PAT</b>	Mini-Peer Assessment Tool (tool for multi-source peer review feedback)
<b>MRE</b>	Medication Related Event
<b>MSF</b>	Multi-Source Feedback
<b>NPPG</b>	Neonatal and Paediatric Pharmacists Group (United Kingdom)
<b>PGY1</b>	Postgraduate Year 1 Residency Program (usually generic)
<b>PGY2</b>	Postgraduate Year 2 Residency Program (can be specialised)
<b>PPAG</b>	Pediatric Pharmacy Advocacy Group (United States of America)
<b>PSA</b>	Pharmaceutical Society of Australia
<b>RACP</b>	Royal Australasian College of Physicians
<b>RPS</b>	Royal Pharmaceutical Society (UK)

<b>SHPA</b>	Society of Hospital Pharmacists of Australia
<b>UK</b>	United Kingdom
<b>USA</b>	United States of America
<b>WBA</b>	Work Based Assessments

# 1 Chapter One: Introduction

## 1.1 Introduction

Recognition of advanced pharmacy practice has developed rapidly over the past 5-10 years, both in Australia and internationally.<sup>1,2</sup> The concept of advanced pharmacy practice links professional development and formal recognition of practice for pharmacists, analogously to the journey to consultant practice for medical officers. Despite the apparent interest in the published arena, it is unknown whether this is something desired by the general pharmacy workforce, and what are the most suitable methods of assessment for the Australian environment.

There has also been an increasing focus on improving child health worldwide, including the safe, effective and appropriate use of medicines.<sup>3,4</sup> In Australia this has coincided with major changes in funding of public health systems; integration of children's health services at a state levels; new guidelines on the care of children in hospitals; and building of three substantial new paediatric hospitals in Australian capital cities.<sup>5</sup> These changes in paediatric health care have forced providers to re-consider models of care, and professional development of health practitioners to meet these evolving needs.<sup>6</sup>

This research project aims to investigate paediatric pharmacists' understanding of advanced pharmacy practice; how to develop and assess advanced skills; and how these skills contribute to improved medication outcomes for children, with particular reference to adverse medication events.

## 1.2 Background to Research

### 1.2.1 What are the issues with children and medications?

In 1911, the 'father of paediatrics' in the United States, Dr Abraham Jacobi, made the statement that *'paediatrics does not deal with miniature men and women, with reduced doses and the same class of diseases in smaller bodies, but has its own independent range and horizon'*.<sup>7</sup> This concept that 'children are not just small adults' has been a common refrain ever since, and has coincided with many health practitioner groups, including pharmacy, recognising the need for specialised training and expertise in paediatrics. Children grow at different rates, handle medications in different ways,

have different diseases than adults and are psychologically and physically different to adults, which impact on how medications should be used.

Despite the incredible advances in paediatric medical care, it is known that children experience harm from medicines. Parents report that 17% of children have experienced an adverse event from medications in their lifetime.<sup>8</sup> Investigations of adverse medication events across five countries including Australia found that 16.5% of hospitalised children experience harm from medications.<sup>9</sup> A study in the UK found 29 children were reported in the media to have died due to medication errors over an eight year period.<sup>10</sup> Some of these adverse medication events relate to differences in medication handling in children, and some due to increased risks of error, and reinforce the need to prevent unnecessary harm to children from medications. Improvement in the safety and the quality of medication use is highly dependent upon the skills of the health practitioners involved, as well as the systems in which they work. Pharmacists have a key role in this area, whether providing care to individual patients or influencing practice at a system level.

## 1.2.2 Defining Errors and Adverse Events

There are many different definitions used in patient safety literature, which make comparisons between different studies difficult. A discussion of the terms, and the definitions used for this paper are described below:

### *Medication, Medicine and Drugs*

There has been a move towards using the word “medication” or “medicine” rather than “drug” for chemical substances used therapeutically. However some phrases have traditionally used the word drug, for example “adverse drug reaction”, “drug interaction” or “therapeutic drug monitoring” and some have used the word medication such as “medication error” and “medication chart”. Although they are largely considered interchangeable, the word “medication” has become more preferred in recent years. For the purposes of this thesis, the term medication is used in preference, except when included in a direct quote, or in commonly understood terms as above.

The more commonly used terms as described below.

### *Medication Error*

An **error** has been defined as *‘the failure to complete an action as intended, or the wrong use of or the wrong plan to achieve an aim’*.<sup>11</sup> *‘Errors may occur by doing the wrong thing (commission) or*



*failing to do the right things (omission)*'.<sup>11</sup> According to the Institute of Safe Medication Practice, a simple definition of **medication error** is '*any error occurring in the medication use process*'.<sup>12</sup>

A more detailed definition by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) is the most commonly used in the North American literature:

*A medication error 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 health care professional or patient. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.*<sup>13</sup>

Importantly, these definitions for error do not require injury or harm to have occurred.

### ***Prescribing Error***

Dean et al developed a definition for a **prescribing error** in 2000:<sup>14</sup>

*A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice.*<sup>14</sup>

This is a more restrictive definition than by NCC MERP, but was developed to ensure no artificial inflation of the error rate by including trivial incidents or deviations from guidelines.<sup>14,15</sup> This definition was determined as applicable for the paediatric setting by a second Delphi process by Ghaleb et al in 2005, and used in subsequent studies in paediatrics.<sup>15,16</sup>

### ***Incident***

A **clinical incident** has been defined as: '*any event or circumstance which has actually or could potentially lead to unintended and/or unnecessary mental or physical harm to a patient*'.<sup>11,17,18</sup>

**Medication related incidents** can occur at any point in the medication use process (ordering, transcribing, dispensing, administering, and monitoring).<sup>19</sup>

## ***Harm***

Research into medication safety has often not defined harm, or used varied definitions. A simple definition used in Australia is *'Death, disease, injury and/or disability experienced by a patient.'*<sup>17</sup> A more detailed definition from the Institute for Healthcare Improvement (IHI) is used in the North American research: *'Unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death.'*<sup>20</sup> In this study we also explicitly included temporary harm, emotional or psychological harm, pain requiring intervention and abnormal laboratory values, as used in other recent research.<sup>21,22</sup>

## ***Adverse Medication (Drug) Event***

An **adverse medication event** (AME), previously referred to as an **adverse drug event** (ADE), was initially described as *'An injury resulting from medical interventions related to a drug.'*<sup>23-25</sup> Later studies clarified that the injury could be from the lack of an intended medication, and can include the lack of expected disease improvement.<sup>26-28</sup> This was clarified further by IHI as events which are *'unintended consequences of medical care, whether preventable or not.'*<sup>20</sup>

Adverse medication events can be separated into two types – those caused by errors and those that occur despite proper usage.

- A preventable AME is injury or harm caused by an error.<sup>19,21,29,30</sup>
- Non-preventable AMEs (i.e. injury but no error) are also called adverse drug reactions (ADRs).<sup>19,29</sup>

Preventability is often difficult to determine, and IHI makes the important point that *'today's unpreventable events are only an innovation away from being preventable.'*<sup>20</sup> Hence in this study all events are investigated, although preventability is considered.

The phrase “Adverse Drug Event” has been most commonly used in past research, however for consistency “Adverse Medication Event” (or AME) is used in this study.

## ***Potential ADE/AME***

**Potential AMEs** are defined as errors that have the potential to harm or injure a patient.<sup>26,29-32</sup> These may also be called ‘near-misses’.<sup>30</sup> This could be because the error was intercepted and

corrected before reaching the patient, or reached the patient but did not harm them because of specific circumstances or chance.<sup>19,29</sup>

### ***Adverse Drug Reaction (ADR)***

In 1972, the World Health Organisation defined an adverse drug reaction as one that is '*noxious, is unintended, and occurs at doses normally used in man for prophylaxis, diagnosis, therapy, or modification of physiological function*'.<sup>33</sup> This was assumed to be unrelated to error, and therefore similar to a "side effect" or a non-preventable Adverse Medication Event, as discussed above.<sup>34,35</sup>

The WHO definition was recently updated to '*A response to a medicinal product which is noxious and unintended*', which now therefore includes error as a cause of harm.<sup>36</sup> Hence an ADR as defined by WHO and used in European research is now equivalent to an AME as used in North American and most Australian research.<sup>37</sup>

### ***Clinical Pharmacist Intervention***

A number of different organisations have proposed definitions for a clinical **pharmacist intervention**. In this study we will be using the definition by the Society of Hospital Pharmacists of Australia (SHPA): '*any action by a pharmacist that directly resulted in a change to patient management or drug therapy*'.<sup>38</sup>

In many instances pharmacist interventions are 'near-miss' events, usually related to prescribing error, where the intervention prevents the error getting to the patient. In other instances pharmacist interventions need not be associated with errors: they include interventions where medication use is improved or optimised.

### ***Challenges of Classification***

The varied definitions used by different researchers described above, highlight the challenges in comparing results from different studies. The difficulty with these classifications is that, although relatively simple to understand, they imply a single error or problem resulting in a single event or harm. In contrast, as described recently by Burkle et al, many errors and events result from a complex interaction of multiple medications and processes.<sup>39</sup>

### 1.2.3 Medication Harm and Errors

Research into the area of medication safety escalated after the report by The Institute of Medicine *To Err is Human* was released in 2000, which concluded that as many as 98,000 Americans die each year as a result of medical errors.<sup>40</sup> Medication errors alone were estimated to account for over 7,000 deaths annually, and the cost of preventable adverse medication events are around US\$2 billion for the United States in hospital costs alone.<sup>40</sup> This report demonstrated the importance of patient safety to improvements in medical care, and paved the way for focused research on patient safety particularly related to medications. Similar work undertaken in Australia found that 2-4% of all hospital admissions are medication related, accounting for more than AUS\$400 million per year, and 1% of hospitalised patients experiencing harm from medications.<sup>27</sup> A recent review of the literature on medication safety in Australia estimated that medication related admissions have remained unchanged over recent years and still account for 2-3% of all admissions to Australian hospitals.<sup>41</sup> Injuries or harm caused by medications, referred to as adverse drug events (ADEs) or adverse medication events (AMEs), are common in hospitals in both adults and children.<sup>25,42,43</sup>

### 1.2.4 What do we know about adverse medication events in children?

Although children usually take fewer medications than adults, they can be subject to the same risks of error and adverse medication events as adults, with additional risks related to age, development, and availability of suitable formulations. Safety strategies may be implemented in paediatrics without sufficient evaluation, and thus result in harm. In contrast, new initiatives can be excluded from paediatrics unnecessarily due to lack of evidence. An example of this is medication reconciliation. This was widely implemented in adult medicine, but not initially recommended for use in paediatrics due to lack of evidence of efficacy. Since then it has been inconsistently implemented in paediatrics.<sup>44,45</sup> More recent research has identified that discrepancies at transfer of care are indeed a significant source of error in children, with routine medication reconciliation now recommended.<sup>46</sup>

Subsequent to the *To Err is Human* Report, Kaushal et al in 2001 published research from two US paediatric hospitals which found medication errors in 5.7% of paediatric medication orders, and adverse medication events associated with 0.24% of orders.<sup>43</sup> Importantly, this study also found that the rate of potential adverse medication events was three times higher than in adults.<sup>43</sup> Kaushal's findings correlated with the earlier report by Barber et al in the UK where the number of

prescriptions changed in response to pharmacist interventions in the paediatric wards was second only to those in the intensive care units and higher than in geriatric, medical or surgical wards.<sup>47</sup>

Since 2001, there has been increasing interest in research on medication safety in paediatrics, with particular interest in the incidence and impact of error and harm. In 2002, Cousins et al described a review of press reports of medication errors in children in the UK over an eight year period, which identified 29 children who had died due to medication errors.<sup>10</sup> Of these reports, 13 were related to dosing errors, including five involving a decimal point or ten-fold error.<sup>10</sup> A systematic review by Wong et al in 2004 on dosing errors in children found that dosing error was probably the most common medication error in children.<sup>48</sup> In 2010, a prospective study in five hospitals in the UK found that there was a prescribing error rate of 13.2% of medication orders and an administration error rate of 19.1%.<sup>15</sup> More recent studies in Spain have shown that paediatric patients had a four-fold higher risk of serious errors than the maternity population.<sup>49</sup>

When considering harm from medicines (with or without error), research undertaken using parental reporting in over 4,000 Finnish children found that the lifetime prevalence of adverse medication events in children was 17%.<sup>8</sup> The ADVISE trial across five countries found that 16.5% of hospitalised children experienced an adverse drug reaction, and 16.6% of these were considered to be preventable.<sup>9</sup> A contrasting result from Canada, using a much more stringent definition for harm (death, disability at discharge, or prolonged stay in hospital), found that 9.2% of hospitalised children experienced an adverse event, but only 13.5% of these events were related to medicines.<sup>50</sup>

Despite the varied rates of error and harm reported in the literature, and the resilience of children to recover from harm, it is clear that many children are exposed to unacceptable rates of error and harm from medication, and efforts need to be made to improve the quality and safety of medication use in children.

### **1.2.5 Why are children at increased risk of harm from medications?**

As described above, the risk of adverse medication events in children is significant, and may require a range of different strategies to prevent harm. A number of contributing factors to increased or differing risks in children have been identified:

#### ***Dosing, Calculations and Ten-Fold Errors***

Doses for children are usually calculated on an individual patient basis using actual or gestational age, weight (mg/kg) or surface area (mg/m<sup>2</sup>), and clinical condition. The dose in weight then needs

to be converted to a quantity of the formulation chosen (e.g. tablet portion or volume of a liquid).<sup>48,51-54</sup> These calculations are required to ensure doses are individualised for the patient. However the requirement for multiple calculations increases the opportunities for error.

These calculations require only basic arithmetic skills, which are generally assumed of health practitioners, however a significant proportion fail in these calculations.<sup>48,52,55</sup> Rowe et al tested the calculation skills of paediatric medical residents over two years and found that 30-60% of the residents committed at least one error in a standardized test with 10 scenarios.<sup>56</sup> A study by Lesar in 1998 found that errors involving children accounted for 69.5% of the calculation-related prescribing errors despite children only comprising 20% of the beds in the hospital studied.<sup>53</sup> Confusing dosage regimens or equations and using incorrect units can contribute to calculation and dosing errors.<sup>48</sup> A small mistake, which might be tolerated in adults, can have more significant consequences in a young child.<sup>57</sup>

The risk of ten-fold or decimal point errors (10-, 100-, or 1000-fold errors) are linked to the calculation errors described above and are a well-recognised risk in children.<sup>10,48,58,59</sup> One injection vial manufactured for adults will often contain more than ten times the dose required for an infant or young child; accounting for nearly one-third of all intravenous drugs prescribed in a neonatal unit.<sup>60,61</sup> For medications with a narrow therapeutic index, a ten-fold dosage increase may lead to serious morbidity or death. This can go undiagnosed when signs of overdose are assumed to be related to the underlying disease.<sup>62,63</sup> In contrast a ten-fold under-dose may not be identified but the patient may not respond appropriately to therapy.<sup>63</sup> This has been found to be a significant problem in the community as well as the hospital setting.<sup>10,64</sup>

### ***Medication Administration***

There is an increased need for dilutions and manipulations of paediatric medicines to make them suitable to administer to children. They require precise dose measurement and appropriate medication delivery systems.<sup>52,54,65</sup> Nurses and parents are often required to subdivide tablets, open capsules or dilute injections in order to administer the correct dosage due to a lack of available dosage forms and concentrations appropriate for administration to neonates, infants and children<sup>54</sup>. Dosage formulations are frequently extemporaneously compounded and lack stability, compatibility, or bioavailability data.<sup>54</sup> Such practices can potentially lead to a reduction in medication effect and/or increase toxicity.<sup>61</sup>

## ***Off-label, unlicensed use***

Most adults would expect to only receive medicines which have been demonstrated to be well tolerated, effective and of a high quality. However in children there is an ongoing lack of published information and government-approved labelling regarding dosing, pharmacokinetics, safety, efficacy, and clinical use of medications in the paediatric population.<sup>54</sup> As long ago as 1968, Dr Harry Shirkey coined the term ‘therapeutic orphans’ referring to the absence of evidence and appropriate licensing for the use of medicines in infants and children.<sup>66</sup> Although significant improvements have been made in the United States and Europe, this remains the case in Australia.<sup>67,68</sup>

Off-label use of medicines refers to use outside the conditions of the product license. This may be non-validated age range or indication, an alternative route of administration, altered regimen (e.g. dose, frequency), or disregard of contraindications.<sup>69-71</sup> Unlicensed medicines are used when no appropriate formulation of a particular medication is commercially available. This may include modifying currently licensed medicines in some way, preparing medicines under a special manufacturing license, use of chemicals as medicines, use of medicines before a license has been granted, or medicines licensed in another country.<sup>70,71</sup> Off-label and unlicensed use of medications is common in children, accounting for 30-65% of all prescriptions written for children and neonates, and off-label or unlicensed medicines are used in two-thirds of hospitalised children and 90% of premature infants.<sup>70,72</sup>

Many researchers have found that medicines used in an off-label or unlicensed fashion are more likely to be associated with medication errors and more often associated with harm or adverse drug reactions to patients than licensed medications, particularly in children less than 2 years old.<sup>41,71,73</sup> In contrast, more recent research from Phan et al found that there was a lower incidence of adverse drug reactions associated with off-label or unlicensed use of medicines in patients admitted to a paediatric emergency department.<sup>74</sup>

Communication of these potential risks to children and families is a challenge for health practitioners. A focus group study from Ireland in children aged 10-14 concluded that children felt off-label use of medicines in children was unethical and unsafe, and felt that parents and children from the age of 13 should be informed and provide consent for use.<sup>75</sup>

These results reflect the ethical dilemma for medicines management in children. In most circumstances these are not obscure or rarely used medicines, but medicines that are used routinely

and often the mainstay of paediatric therapeutics.<sup>69</sup> A recent policy statement from the American Academy of Pediatrics stated that off-label use does not imply improper or unethical use if it is based on sound scientific evidence or expert medical judgement.<sup>76</sup> Nonetheless, clinicians are left with the ethical dilemma of whether to deny an unwell child treatment with potentially beneficial medicines, or treat with medicines on the basis of studies in adults or anecdotal empirical experience in children.<sup>77</sup>

### ***Research and Equity of Access***

There has been significant work undertaken at an international level to improve access to better paediatric medicines (and reduce the off-label/unlicensed use described above), in particular to stimulate research and licensing of appropriate medicines and formulations for children. Legislative changes in the European Union and the United States have contributed to improved research and access to medicines for children, particularly over the past 10 years. However despite many years of advocacy, Australia still lacks any legislative and regulatory reforms addressing paediatric medicines.<sup>67</sup>

There have been some small gains since the introduction of the Paediatric Medicines Advisory Group in 2007 by the Australian Department of Health and Aging to provide advice on paediatric medicines issues. By September 2011, seven new medicines had been listed on the Pharmaceutical Benefits Scheme for children, with ten amended listings and a further twenty-five medicines that are under consideration.<sup>78</sup>

In Australia, decision-making for access to medicines in hospitals at an individual patient or institution level is often delegated to the hospital's drug and therapeutics committee. A review of the Australian medication approval process in 2010 found that most committees had poor infrastructural support for approval processes, did not formally include a pharmacoeconomic evaluation, and significantly duplicated effort across sites.<sup>79</sup>

### ***Medication Handling***

Human growth itself is not a linear process. Age associated changes in body composition and organ function are dynamic, and can be discordant during the first decade of life. Thus, simplified dose administration approaches are not adequate for individualizing medication doses across the span of childhood.<sup>62,80</sup>



The ongoing developmental changes in children, including organ system maturity and variations in body weight, body surface area, and changes in pharmacokinetic parameters such as absorption and excretion of medicines increase the risk of medication error in children.<sup>54,81</sup> Diseases in neonates, infants and children are often different to those observed in adult patients, which will affect the benefits and risks of medicines use.<sup>82</sup> Developmental changes may alter both the action of a medication and the body's response to it. Increasing information is also being discovered about the genotype-phenotype relationship that can effect a medication's pharmacokinetics and pharmacodynamics and the complicated inter-relationship with developmental changes.<sup>82</sup>

### ***High Risk Medications***

Kunac et al in 2009 and 2010 reviewed 520 paediatric admissions to a general hospital in New Zealand over a 12 week period and found that the medications most commonly involved in adverse medication events and potential adverse medication events were antibacterials (in particular aminoglycosides) and narcotic analgesics (in particular morphine).<sup>35,83,84</sup> This is comparable to the results of Kaushal et al in the US which found anti-infectives, followed by analgesics and sedatives and electrolytes and fluids to have the highest rates of potential adverse medication events.<sup>43</sup> Rashed et al also found similar results, with antibacterials then analgesics reported as the medication groups most frequently involved in ADRs.<sup>9</sup> Clavenna et al also found antibiotics as the medication most frequently associated with adverse medication events in children.<sup>85</sup> Likewise, a review of eleven years of paediatric outpatient and emergency presentations related to adverse medication events, antimicrobials, central nervous system agents and hormones were the most frequently implicated, with the frequency of presentations related hormone therapy increasing with age.<sup>86</sup>

The findings above are consistent with the frequent use of these medications in the paediatric population. In contrast, when considering fatalities in UK children, Clarkson and Choonara found that anticonvulsants, cytotoxics, anaesthetic agents and antibiotics were the most frequently mentioned medicines.<sup>87</sup> A different pattern is seen in younger children where a study from the USA in children under 2 years of age found palivizumab, cisapride, indomethacin, nitric oxide, azithromycin and acetaminophen as the medications most frequently involved in serious or fatal outcomes.<sup>88</sup>

The categories of medications most often involved in harm in children are in contrast to those in the adult population where antiplatelet agents, anticoagulants, diuretics, cardiovascular medications and cytotoxic agents are more frequently implicated in harm.<sup>84,89</sup>

These differences in risks and contributing factors mean that separate research needs to be undertaken in paediatrics to more clearly define and target areas of risk, and to identify the most successful initiatives to improve quality and safety of medication use in children. The role of the pharmacist in these areas is explored further in following sections.

## **1.2.6 What do paediatric pharmacists do, and how are they different?**

### ***History of paediatric pharmacy***

Despite the medical specialty of paediatrics emerging more than a century ago, the profession of pharmacy has taken significantly longer to appreciate that health-care needs of children are different from those of adults.<sup>90</sup> The first reports of a specific role in paediatrics for pharmacists appeared in the published literature in 1969, where George Provost encouraged hospital pharmacists to take up the challenge of improving paediatric medication therapy, and pointed out that this was the responsibility of every pharmacist, not only of those in specialist paediatric positions.<sup>91</sup>

In the same year, Michael Ellis said there was *'a need for the hospital pharmacist to come out of his basement and become interested and responsibly involved in the clinical life of the hospital.'*<sup>92</sup> Also, that the pharmacists *'were so busy counting inanimate objects that the whole purpose of being in the healthcare field seemed to escape them.'*<sup>92</sup> The focus of the role at that time was preparation of unit doses of medicines to aid nursing staff time, but it evolved to a much more clinical role at the bedside which included making daily medical rounds with the paediatricians, with enthusiasm and support from nursing and medical staff.<sup>92</sup>

More research describing the roles and benefits of paediatric pharmacy was reported in the 1970s, predominantly from the United States of America.<sup>93,94</sup> Responsibilities such as monitoring of patient charts, medication information to medical and nursing personnel, therapeutic drug monitoring, providing medication histories on admission, consultations on discharge, and an evolving role in teaching and research are similar to the responsibilities of current day paediatric pharmacists.<sup>93,95</sup>

By 2003, the American Academy of Pediatrics had recommended that pharmacists be available to prescribers and nurses to participate in medication therapy development and monitoring, and that prescribers utilize pharmacist consultation.<sup>96</sup> In 2011 the Academy recommended that clinical pharmacists trained in paediatrics should be integrated into inpatient rounds and providing education of staff and families in all settings as often as possible.<sup>81</sup>

The important role of the paediatric clinical pharmacist in monitoring medication treatment, preventing medication errors and adding value and quality to paediatric medication use is now well understood and established in the United Kingdom and the USA, where many neonatal and paediatric units have instituted ward-based clinical pharmacy services; in particular participation in physician rounds.<sup>97</sup> Unfortunately, this service is not universal across all sites, or in other countries around the world.<sup>25,65,98</sup> There is little published on the Australian paediatric pharmacy experience; anecdotally the comprehensive clinical pharmacy services instituted in some Australian paediatric hospitals (and described above) are far from consistent across the spectrum of Australian paediatric health care.<sup>99</sup>

### ***Differences in roles, knowledge and skills of a paediatric pharmacist***

Recently the Board of Pharmacy Specialties from the USA has recognised paediatrics as a specialty, with the following definition:<sup>100</sup>

*Pediatric pharmacy practice specializes in the delivery of patient care services by pharmacists that ensures the safe and effective use of medications for all children from neonates through adolescents. The practice includes direct patient care for children, often provided through interprofessional healthcare teams, as well as advocacy and education for children and their families, wellness and health promotion, and activities that advance knowledge and skills in pediatric pharmacy.*<sup>100</sup>

At a global level, the International Pharmaceutical Federation (FIP) has defined specific roles for pharmacists in improving newborn and child health, as part of the *United Nations Global Strategy for Women's and Children's Health*.<sup>3</sup> This report listed specific pharmacist strategies to improve child health such as use of child-resistant packaging to reduce risk of poisoning; provision of appropriate formulations suitable for children when not available on the market; advice on effective medication administration; and participation in research and development on new formulations for children. Other roles were similar to those seen in adult practice, such as prevention of medication misadventure by involvement in the selection of medicines, assistance during ward rounds, review of medication orders, input into prescribing decisions, development of protocols and guidelines, medication formulation and administration advice, and education of other health practitioners.<sup>101</sup>

Individual authors and professional bodies from UK and USA have described quite consistently the expertise required of paediatric pharmacists, which include

- Understanding developmental pharmacokinetics and pharmacodynamics;

- Determining and calculating doses;
- Administering medications to children effectively and safely;
- Modifying available preparations to make them suitable for children;
- Appropriately using unlicensed and off-label medicines.<sup>102-104</sup>

Specific challenges included lack of information sources; lack of suitable formulations; medication errors; monitoring of safety and effectiveness; and effective communication with children and families.<sup>102-105</sup>

Evolving roles for paediatric pharmacists include the application of pharmacogenomics in children. This presents technical, ethical and interpretive challenges that require the expertise of pharmacists with specialized training in paediatrics.<sup>106</sup> Other developing roles for paediatric pharmacists include improving the transition between hospital and the home, and enabling children to have care at home where possible. Examples described in Australia include involvement in complex care outpatient clinics (e.g. Cystic Fibrosis), Home Medicines Reviews, and Hospital in the Home.<sup>107</sup>

These current and evolving roles, and the knowledge and skills required, are largely at a general or foundation level of practice rather than at an advanced level. A definition of the requirements of an advanced paediatric pharmacist is still in its infancy, and is described further in the following sections.

### **1.2.7 What does Advanced Practice in Pharmacy mean?**

The concept of advanced practice in pharmacy has been debated for some time, whether in fact this role can be defined, whether it is good for the profession, whether it makes a difference to patients, and whether it can be justified as comparable to advanced roles in other professions.<sup>2</sup> The definition of advanced practice has been uncertain, although Brook and Rushforth made the observation in 2011 that '*advanced practice is a set of attributes which may be ascribed to any professional, practising at what might be defined at a senior or expert level*'.<sup>108</sup> In contrast to the poorly defined experience in pharmacy, other professions have had a more defined pathway to advanced practice, such as the longstanding pathway to consultant for the medical profession, and more recently the option for nursing colleagues to gain endorsement as a nurse practitioner.<sup>109,110</sup>

After some years of discussion and debate amongst the profession, there now appears to be consensus internationally among the pharmacy profession that recognition of advanced roles in pharmacy, and their contribution to patient care, is warranted: for the individual, for the profession, and for our patients.<sup>1,2,111-113</sup> The impact on specialist practice areas such as paediatrics, implementation in a smaller country such as Australia, and patient outcomes is still to be determined.

### ***United Kingdom***

The first work in this area was described by Meadows et al in 2004 with the development and validation of an advanced and consultant level competency framework (ACLF) by the Competency and Development Evaluation Group (CoDEG) in the UK.<sup>114</sup> A total of 34 separate competencies were identified that were grouped into three levels (foundation, excellent and mastery) and six separate clusters of “expert professional practice”; “building working relationships”; “leadership”; “management”; “education, training and development”, and “research and evaluation”.

Subsequent to this work, a finalised Advanced Level Competency Framework was introduced in 2005,<sup>115</sup> which has been used for professional recognition and recruitment purposes for positions in the UK designated at advanced or consultant level. This format has been further adapted in the UK by individual pharmacy specialty groups such as critical care,<sup>116</sup> education and training<sup>117</sup> and oncology,<sup>118</sup> and in some cases endorsed by the corresponding medical colleges. The framework is now incorporated into the RPS Advanced Pharmacy Framework (APF) as a pathway for membership of the RPS Faculty as an advanced practice pharmacist.<sup>119</sup>

Pharmacists in the UK also have the opportunity to become independent or supplementary prescribers as an expansion to the traditional scope of practice of a pharmacist.<sup>120,121</sup> This has been implemented in some paediatric settings in the UK.<sup>122</sup> Pharmacist prescribing is however, considered separate to advanced practice.

### ***United States of America***

“Advanced practice” is not a term used with the same meaning in the USA as in the UK and Australia. For pharmacists working in academia in the United States, “advanced practice” is synonymous with the Advanced Pharmacy Practice Experiences (APPE) offered as a component of the final year of the Doctor of Pharmacy (PharmD) program, now the entry level degree for pharmacy in the United States.<sup>123</sup> For other USA pharmacists, “advanced practice” is synonymous with an expanded scope of practice requiring an advanced set of skills or practice, rather than

advanced practice itself. In this context, individual state pharmacy laws permit pharmacists to initiate, modify and/or discontinue medication therapy as part of a Collaborative Practice Agreement with a supervising physician, in a similar fashion to the collaborative prescribing model in the UK.<sup>124</sup> Eligibility for these agreements is based on education (e.g. degrees), training (e.g. residencies), and credentials (e.g. certification by the Board of Pharmacy Specialties).<sup>124</sup>

In the USA, the additional training and formal certification as a specialist pharmacist that many pharmacists undertake after registration is analogous to “advanced practice pharmacist” as understood in the UK and Australia. Most pharmacists, particularly those who work in clinical roles in hospital, undertake a one to two year residency program after obtaining their PharmD.<sup>101</sup> These residency programs are administered by individual hospitals, which are accredited by the American Society of Health-System Pharmacists (ASHP).<sup>125</sup> The postgraduate year one residency program (PGY1) covers generic clinical and interpersonal skills, with educational outcomes and competencies similar to the Australian system for competency-based intern training programs, with the addition of a mandatory research project.<sup>125,126</sup> The second year program (PGY2) is where specialties such as paediatrics are addressed in more detail.<sup>127</sup>

Some US pharmacists then undertake Board Certification, available in a range of specialities, administered by the Board of Pharmacy Specialties (BPS), and required for many clinical positions in the USA.<sup>128-130</sup> Board certification is a means by which health practitioners can demonstrate clinical competence to the public, employers, third-party payers, and other health practitioners.<sup>131</sup> Certification requires passing an exam consisting of 200 multiple-choice questions developed by content experts.<sup>128</sup> Recertification is required every seven years which is achieved via a recertification exam or approved continuing education.<sup>129</sup> BPS is currently developing a specialty certification in paediatrics, due to be available in 2015.<sup>100</sup>

## ***Australia***

The definition for advanced practice used by the Pharmaceutical Society of Australia and others in *The National Competency Standards Framework for Pharmacists in Australia* 2010 is:

*Advanced Practice is practice that is so significantly different from that achieved at initial registration that it warrants recognition by professional peers and the public of the expertise of the practitioner and education, training and experience from which that capability was derived.*<sup>132</sup>

A number of groups within Australia adapted the ACLF from the UK for use in particular specialties in recent years. The first of these was paediatrics, when in 2008 the SHPA Paediatric COSP (with funding from Queensland Health) first developed an Advanced Level Framework (ALF) in Paediatric Pharmacy based on the 2005 version of the UK ACLF.<sup>115,133</sup> By 2011, the Paediatric ALF was being used through Queensland public hospitals, there was a commitment from other states to implement in their local jurisdictions, and the content was integrated into formal and informal postgraduate training.<sup>134,135</sup> Similar work was undertaken for cancer care,<sup>136</sup> emergency medicine,<sup>137</sup> cardiology,<sup>138</sup> infectious diseases,<sup>139</sup> and across the range of specialties of one health service network.<sup>140</sup>

Following on from the work by individual specialty groups, a profession-wide collaboration of pharmacy organisations formed the “Advanced Pharmacy Practice Framework Steering Committee” in 2011. This group developed the Advanced Pharmacy Practice Framework, based on the UK ACLF and mapped to the existing Australian National Competency Standards Framework.<sup>141</sup> The Pharmacy Board of Australia endorsed this framework in 2012.<sup>142</sup>

Although this work is progressing rapidly, there are still aspects to be defined regarding how these frameworks will be used in practice for Australian pharmacists (particularly in specialist areas such as paediatrics) and how pharmacists will be evaluated against the frameworks. It is also as yet unproven what benefit an advanced pharmacy practitioner brings to patient care, safety and outcomes, in comparison to a general level pharmacist.

## **1.2.8 How do other health professions develop and assess advanced practice?**

### ***Medical Profession***

For medical officers in Australia, development as a specialist is via vocational training, coordinated by a specialist medical college approved by the Australian Medical Council. After an initial 2-3 years of postgraduate experience, the medical official enters an accredited specialist or subspecialist training program, commonly taking 7 years to complete.<sup>110,113</sup> Slightly different processes for vocational training and assessment are used by the different medical colleges, such as the Royal Australasian College of Physicians, Royal Australian College of General Practitioners and Royal Australasian College of Surgeons. However, each involves supervised practice in the workplace coordinated by medical educators, and a requirement to pass a suite of examinations and work based assessments via direct observation of practice.<sup>113</sup>

Specialist paediatric training follows the same pathway to that of general physicians and coordinated by the Royal Australasian College of Physicians (RACP). After medical qualification and initial postgraduate workplace experience, the paediatrician enters basic training which lasts a minimum of three years, and then undertakes an advanced training program, also a minimum of three years in duration.<sup>143</sup> Completion of this training allows the paediatrician to become a Fellow of the Royal Australasian College of Physicians and be employed as a “consultant”.

Similar processes exist in other countries: with a requirement for high stakes assessment at various points along the journey, the ongoing use of viva voce and examinations, with an increasing use of work based assessments.

In addition to formalised training via the professional colleges, most teaching hospitals offer specific training in child health, with some resulting in formal qualifications. The Women’s and Children’s Hospital in Adelaide offers a Diploma in Child Health for medical officers<sup>144</sup> and the Children’s Hospital at Westmead offers a Diploma in Child Health for doctors and nurses in conjunction with the University of Sydney.<sup>145</sup>

### ***Nursing Profession***

Similar to pharmacy, there have been many different terms used internationally for nurses who have developed additional skills over time and those who have taken on roles with an extended scope of practice. Terms such as nurse practitioner, nurse consultant, advanced nurse practitioner have quite different meanings dependant on the institution and country of work.<sup>146</sup> Although clarification of titles is important, the requirement for standardised assessment formal recognition or endorsement has been acknowledged in many settings.<sup>108</sup>

In Australia, a set of competencies for an Advanced Practice Nurse has been described by professional groups with a system of credentialing being currently investigated, although this title is not currently linked to specific positions or qualifications.<sup>147</sup> In contrast, the defined endorsed title of Nurse Practitioner can be obtained currently by registered nurses in Australia via a process of postgraduate qualifications at a Masters level, experience and portfolio submission.<sup>109</sup> However, the positions of Nurse Practitioner involve extended and defined scope of practice and are specific positions within each institution.

Registered nurses and nurse practitioners work in paediatric healthcare settings, however there is no specific additional paediatric qualification as a nurse practitioner in Australia. Paediatric and child health training is available for nurses from a variety of universities across Australia at a



Postgraduate Certificate, Diploma and Masters Level. In addition, the Princess Margaret Hospital itself offers a Postgraduate Certificate of Paediatric Nursing. The Australian College of Children and Young People's Nurses offer online learning for paediatric nurses and have produced *Competencies for the Specialist Paediatric and Child Health Nurse*.<sup>148</sup>

### ***Physiotherapists***

Physiotherapists have a path to acknowledgement of advanced practice in Australia via a training program and assessments administered by the Australian College of Physiotherapists. Attainment of "Titled APA Physiotherapist" can be via completion of a Masters by coursework and two years experience or an experiential pathway including five years experience and assessment of a portfolio and examination.<sup>149</sup> Further progression to the title of "Specialist Physiotherapist" and "Fellow of the Australian College of Physiotherapists" requires completion of a two-year training program in a speciality area, submission of a portfolio (including participation in education of others, case presentations and at least one significant research project), and demonstration of specialist-level skills via final examination.<sup>149</sup>

Medical, nursing and physiotherapy professions have all developed formal recognition methods for practitioners operating at an advanced level. The evaluation programs have in common a combination of assessment methods. They all include a requirement for completion of a formal training program (although experiential learning is recognised in nursing) and comprehensive portfolio review in combination with a variety of formative and summative assessments.

## **1.2.9 How do we currently develop advanced practice in paediatric pharmacists?**

### ***International paediatric pharmacy networks***

There are a number of paediatric pharmacist organisations in different countries, which have focused on networking opportunities and the training of pharmacists new to paediatrics.<sup>150</sup> The Pediatric Pharmacy Advocacy Group (PPAG) based in the United States is an *'international non-profit professional association representing the interests of pediatric pharmacists and their patients'*.<sup>150</sup> This group began informally in 1979, officially formed the Pharmacy Directors of Pediatric Hospitals in 1985 and was later renamed as the Pediatric Pharmacy Advocacy Group (PPAG).<sup>151</sup> PPAG has been working closely with the Board of Pharmacy Specialties to develop the Certification in Paediatric Pharmacy Specialty due to be available in 2015.<sup>100</sup>

The Neonatal and Paediatric Pharmacists Group (NPPG) was established in the UK in 1994 with *'the aim of improving the care of neonates, infants and children by advancing the personal development of pharmacists and the provision of quality pharmacy services in relation to practice, research and audit, education and training, communication and advice'*.<sup>152</sup> NPPG has worked closely with the Royal Pharmaceutical Society to develop the Professional Curriculum for Neonatal and Paediatric Care, linked to membership of the RPS Faculty as an advanced practitioner.<sup>153</sup>

### ***Australian paediatric pharmacy networks***

Paediatric pharmacy has been slow to develop in Australia as a recognized speciality and little has been published on the role of Australian paediatric pharmacists. The first networking group was the Australian Paediatric Hospital Pharmacists Group, officially formed in 1993, and now renamed as the Australasian Paediatric Hospital Pharmacists Forum. This group has representatives from paediatric specific and mixed adult and paediatric sites in Australia and New Zealand. It is active in networking and strategic planning at a high level but is not specifically involved in professional development.<sup>99</sup>

In 1999 an email network for Australasian paediatric pharmacists ("Paedpharm") was launched, hosted by the University of Otago, to support hospital pharmacists working in paediatrics. This network provides a valuable avenue for queries, formulates therapeutic guidelines and shares information. However, it again has no specific responsibilities for professional development.<sup>154,155</sup>

In 2002, The Society of Hospital Pharmacists of Australia (SHPA) introduced a new Committee of Specialty Practice (COSP) in Paediatrics with representatives from paediatric hospitals from each state. The COSP's role has been coordination of educational activities (e.g. seminars and workshops) on behalf of the society, and to comment on statements and guidelines produced by the society with respect to paediatric content and applicability.<sup>99</sup>

### ***Paediatric Pharmacy training***

Pesaturo et al in 2008 reported that *'each year, many pharmacy students and new practitioners embark into one of the more feared rotations of the advanced pharmacy practice curriculum: pediatrics'*.<sup>103</sup> This fear was thought to stem from unfamiliarity due to the limited paediatric content in undergraduate teaching. This opinion was reinforced in research from New Jersey, which reported that many pharmacists had described being uncomfortable with medication orders for the paediatric population, however confidence and competency increased significantly after a series of targeted educational lectures.<sup>156</sup> A survey in 2003 of 948 practicing pharmacists in Indiana

found that, although 94% of them dispensed prescriptions for adolescents, 57% felt inadequately trained in adolescent-specific healthcare issues.<sup>157</sup> Another study from Michigan found that less than half of the pharmacists surveyed had received any formal training in paediatrics, although 55% of the respondents estimated that children comprised at least 20% of their patients.<sup>158</sup> In this study, respondents with formal training in paediatrics were more likely to believe that they have the knowledge and expertise to make recommendations in paediatric health issues.<sup>158</sup> Likewise in a study from the UK, the majority of community pharmacists had been asked to sell off-label products for children; underestimated the level of off-label prescribing in paediatrics; and had developed their awareness via work experience rather than by undergraduate or postgraduate training or professional development.<sup>159</sup>

Most pharmacists will be caring for children of all ages regularly during their career. However, a number of researchers have expressed concern regarding the lack of paediatric training for pharmacists. Research beginning over a decade ago in North America found that only 67% of pharmacy colleges in the USA included paediatrics in their curriculum, accounting for an average of 16.7 hours.<sup>160</sup> Similar results were found in Canada with only 14.7 hours of paediatric content in undergraduate pharmacy programs.<sup>160,161</sup> Subsequent to these studies, North American researchers and professional groups recommended an increase in volume and quality of didactic training and postgraduate placements in paediatrics at an undergraduate level, and increase in opportunities for postgraduate training.<sup>105,158</sup> This has had some success: follow-up research in 2014 found that 94% of USA pharmacy schools now include paediatric content, with an average of 21.9 contact hours.<sup>162</sup> Similar analysis of paediatric pharmacy training in Australia has not been undertaken. Nevertheless it is expected to face similar challenges, since there are no formal recommendations to guide paediatric content.

There is limited availability of formal training in paediatric pharmacy, in Australia and internationally. Informal seminars, workshops, conferences, and some online educational opportunities are available; however, these vary in content and quality. Paediatric residency training, as available in North America, is not available in Australia. The BPS Certification in Paediatric Pharmacy will be available to pharmacists outside of the United States (including Australia), but the certification does not itself involve professional development.

The limited paediatric pharmacy training opportunities are limited to graduate or general level rather than aiming to develop advanced practice in paediatric pharmacy. The next step of assessment of advanced practice is an additional topic addressed in the next chapter.

### **1.3 Rationale and Significance**

Despite a large amount of work in recent years to improve knowledge of medication safety issues in children and the skills and knowledge required of health practitioners to improve safety and quality, there are significant gaps remaining. It is not yet fully understood what the most effective strategies are to improve medication safety, or what differences may be required for the paediatric environment. The skills and knowledge required of pharmacists at different stages of their career in paediatrics have not been defined, particularly those required to achieve the improvements in medication safety. How to best assess these skills is also not clear. These issues will be investigated further in this research project.

### **1.4 Author Background**

At the time of commencing this research project, the author had 20 years experience in pharmacy, predominantly in a tertiary paediatric hospital. The author had completed formal postgraduate training in child health (Postgraduate Diploma in Health Studies, Community Child and Adolescent Health), and had been involved in teaching paediatric pharmacy and medication safety at workshops, seminars, and at a formal undergraduate and postgraduate level. This experience led to the project to develop and then implement the Paediatric Advanced Level Framework (ALF) in Australia in 2008.<sup>133-135</sup> Thus, the author brought to the research project the practical experience associated with working and teaching in a paediatric hospital pharmacy setting, and familiarity with the advanced practice concept.

These experiences, whilst providing valuable understanding and insight into the topics, may have introduced an element of bias into the research design and findings. Hence, an early step in the project was to undertake a series of focus groups within the profession to determine existing perceptions and beliefs regarding advanced practice. This informed the design of subsequent projects. In addition, quality assurance of all coding and analysis was undertaken with a second independent researcher rating or coding each of the data sets. A statistician ensured that valid analytical techniques were used.

## **1.5 Conclusion**

The areas of increased risk described above indicate the need for paediatric health practitioners to improve the safety and effectiveness of medication use at an individual and population level. It is also becoming apparent that additional skills are required for health practitioners to effectively contribute to the targeted and system-wide interventions required. These interventions may include assessment of clinical competencies such as medication calculations, advocacy for research in children's medications, change in practice to improve safety, and effective education strategies that truly change practice. These types of interventions require different and more advanced skills to those of a general level pharmacist.

There is currently little support for pharmacists at an undergraduate or postgraduate level to develop the knowledge and skills required to provide pharmaceutical care for children, at a general or advanced level. This is despite children making up a large proportion of the population in all countries. An increase in networking across professional organisations and international boundaries may enable sharing of specialised resources in the future. The option of a residency model for training in the USA may not be immediately suitable for use in Australia; however, sharing electronic learning resources, access to the BPS certification in paediatrics from 2015, and sharing the practice evaluation techniques being piloted in the UK and Australia may offer a way forward.

This research project investigates some of these options, related to adverse medication event identification and prevention, and development and assessment of advanced pharmacy practitioners. The next two chapters review the literature regarding these topics.

## **2 Chapter Two: Literature Review – Adverse Drug Events**

### **2.1 Introduction**

In Chapter 1, the background to: medication risks in paediatrics; advanced pharmacy practice; and the existing opportunities for development of paediatric pharmacists was described. In this chapter the current literature regarding adverse medication event measurement and analysis; interventions to improve safety; and methods for assessment of advanced practice in health practitioners is investigated more deeply.

### **2.2 How do we identify and measure adverse medication events and medication errors?**

The case identification methods used to identify medication related incidents, adverse medication events and medication errors vary widely, and have a significant effect on the rate obtained. Similarly, the denominator used also varies widely, from per medication order, or per hospital admission. This variation in case identification and denominator makes it difficult to compare rates between different research studies. The research is also very focused on the hospital environment with very limited research on medication errors or events in the community setting.

#### **2.2.1 Spontaneous or Voluntary Reporting (Incident Reports)**

Spontaneous reporting requires the person who witnessed, committed or discovered an error to document the event in a report, commonly referred to as an ‘incident report’. It is generally accepted that spontaneous reporting systems grossly underestimate the overall rate of medication errors (estimated from 0.1 to 10% of all adverse events or errors), particularly medication administration errors.<sup>48,57,163,164</sup>

Low levels of reporting may be due to multiple factors including a range of personal, practical and cultural barriers, many of which are possible to overcome at a system level. A systematic review undertaken in 2014, found that an atmosphere of shame and blame, a fear of punishment, complex policies and procedures, and a lack of support to learn from errors were significant barriers to physician reporting.<sup>165</sup> An Australian study investigating behavioural intent in health practitioners found that the strongest factors influencing safety behaviours were practitioners’ beliefs that the behaviour will lead to improved patient safety, and the patient safety related behaviours of their professional peers.<sup>166</sup>

Other limitations of voluntary reports are that the data collected are thought to be subject to the inferences drawn by the reporter and therefore may be less objective than other methods such as direct observation.<sup>163</sup>

The advantages of using incident reports to review causes of incidents are the relatively low cost and the fact that the data relative to a particular medication error has already been gathered. As described above, this method works best if the organisation has a non-punitive culture of review of incidents gathered.<sup>57,163,167</sup> More recently, research is moving towards use of voluntary reports in combination with other collection strategies such as trigger tools, as discussed further below.<sup>20,168</sup>

### **2.2.2 Interventions (Pharmacist or Nursing)**

Nurses and pharmacists frequently make interventions to correct medication orders before they reach the patient (near-misses). They also identify and correct errors that may have already occurred.<sup>169,170</sup> These may be recorded as part of standard incident reports (ie voluntary reporting as above) or recorded in a separate database. These reports have limitations similar to those of incident reports. Like incident reports, intervention reports tend to underestimate the rate of errors, as pharmacists (and nurses) will often correct errors without informing the doctor and without noting the error in the patient file or a formal report.<sup>171</sup> Research using surveys of pharmacists by Williams et al identified the barriers to reporting incidents or interventions to include the cumbersome and time consuming nature of the reporting system, the severity of patient harm, concerns about harming inter-professional relationships, and whether they had previously witnessed positive feedback and system change following an error.<sup>172</sup> A similar survey by Patterson et al found that communication openness of the individual pharmacist and their environment increased the likelihood of error reporting, indicating the need for hospitals to institute non-punitive environments and cultures that maximize trust and open communication.<sup>173</sup> These results correspond closely to the findings listed above with incident reporting and other health practitioners.<sup>166</sup>

Despite these barriers, and the limitations of pharmacist intervention reporting, the combination of incident reports with health practitioner interventions into a single reporting system is considered a valuable method to identify faulty processes.<sup>170</sup>

### 2.2.3 Chart Review

Chart review involves researchers reviewing charts, prescriptions and computer records to identify medication errors. The data collectors look for specific signals or triggers, such as a sudden change in patient condition, transfer to a critical care unit, changes or clarifications in physician orders, and orders for antidotes.<sup>30</sup> Chart review is commonly performed retrospectively, but can be done prospectively with daily review of charts.

Chart review has been shown to be a valuable method for detection of errors in medication ordering and adverse medication events, although it relies heavily on the clinical skills of the researchers to detect the error.<sup>30,163</sup> Chart review has been found to be only marginally effective in detecting errors in medication administration and monitoring.<sup>30,48</sup> It was a less expensive method of case identification than direct observation, but its lower rate of accuracy made it undesirable for measuring the frequency of errors.<sup>163</sup>

Overall, chart review has a proven track record as a method for detecting errors in medication ordering, and actual AMEs, but less effective to identify administration errors, and is time intensive and costly.<sup>24,25,30</sup>

### 2.2.4 Observation

This involves researchers observing health practitioners undertaking their duties. It has been used successfully since the early 1960's, with validity reported to be superior to other methods.<sup>163</sup> Observation will identify some errors in medication ordering, but it is particularly valuable in detecting errors in preparation and administration of medicines, and is considered more efficient and accurate than reviewing charts and incident reports.<sup>30,163,174</sup>

A major concern with the observation method is the potential effect of the researcher on the individuals under observation, although most studies involve some method of disguise of the observer to minimize the impact of the observational effect.<sup>48,175,176</sup> It is also expensive, and requires specific training for data collectors.<sup>163</sup>

### 2.2.5 Trigger Tools

Various “trigger tools” have been used, particularly in recent years, to identify adverse medication events, with a comprehensive guideline on methodology published by the Institute of Healthcare Improvement (IHI).<sup>20</sup> Specific “rules” or “triggers” to identify an AME can be determined, and



charts, laboratory, prescription, and administrative data can all be reviewed to identify adverse medication events.<sup>19</sup> Two main systems are used: manual review of a sample of charts on a regular basis, such as recommended by IHI, or analysis of all admissions using an automated or electronic trigger identification. The overall number of identified cases can be used to identify trends over time, or individual issues can be investigated in more detail as required.

Automatic detection of events requires an electronic medical record to scan for triggers using a predetermined algorithm or set of rules.<sup>20,177-179</sup> Early research found these tools to be very effective at detecting renal failure, diarrhoea and hypoglycaemia, but not as good as manual chart review at detecting symptom-related adverse medication events such as altered mental status.<sup>180</sup>

There have been varied results more recently on the efficiency of trigger tools to identify adverse medication events. Franklin et al found that, of the total prescribing errors identified using a range of methods (including prospective chart review by a pharmacist, retrospective chart review by a researcher, spontaneous reporting and the trigger tool), the trigger tool identified less than one percent of the total errors in the study.<sup>181</sup> The Franklin study was limited in that the trigger tool was used after the retrospective chart review, and counted only additional events identified, only identified errors not harm, and was associated with many false positives.<sup>181</sup> It was also in the adult hospital setting and did not include paediatric patients.<sup>181</sup>

Forster et al in 2011 undertook a systematic review to evaluate the accuracy of electronic tools in identifying AMEs, and found that detection rules were variable, definitions were variable, rules were often not validated against a “gold standard” and few of the detection algorithms considered clinical priorities.<sup>179</sup> Importantly, the review by Forster et al excluded research in the paediatric setting, however these limitations are also likely to exist with information systems used for ADE detection in paediatrics.<sup>179</sup> In contrast, automated adverse event detection was found to have positive effects on quality of care and cost-effectiveness by Lemon et al in the paediatric setting.<sup>178</sup>

Manual chart review using the IHI sampling method has had more positive success. Takata et al successfully customized the existing IHI set of adult ADE trigger tools (described above) for use in the paediatric population, which was later successfully used by Tham et al in 13 paediatric hospitals in the United States.<sup>182,183</sup> Two recent papers from Cincinnati reviewed adverse event identification using the IHI Global Trigger Tool successfully in paediatrics, although there was a need for additional triggers in paediatrics for areas such as phlebitis from medication administration.<sup>168,184</sup>

These results indicate that trigger tools have potential for use in identification of adverse medication events in children. The most cost-effective on an ongoing basis may be automated tools, however sophisticated health information systems are required for these to work effectively, and detection rules appropriate for paediatrics need to be carefully defined. Manual chart review using a sampling approach as suggested by IHI, using the paediatric tool developed by Takata et al, may be the best strategy for long term quality improvement measures; however, it is time intensive and as a sampling strategy is unlikely to identify uncommon events.<sup>20,182</sup>

## 2.2.6 Administrative or Coding Data

The International Classification of Diseases 10<sup>th</sup> revision (ICD-10) is used to code admission data for administrative purposes, primarily for reimbursement and legal purposes. These codes have been used increasingly in recent years to identify large scale (e.g. population level) rates of adverse medication events.<sup>185,186</sup> Their use for clinical purposes has limitations, due to variable accuracy, timeliness and a tendency to “code creep” to higher paid diagnostic groups.<sup>187</sup> ICD-10 coding also does not identify near miss events, or errors that have not caused harm.<sup>185</sup>

A systematic review by Hohl et al in 2013 found substantial variability in the methods and codes used to identify AMEs using administrative coding data with the majority of researchers using the external injury codes Y40.0-59.9 (“drugs, medicaments and biological substances causing adverse effects in therapeutic use”).<sup>188</sup>

Honigman et al found the positive predictive value of ICD codes for AMEs in outpatients to be very low (about 2%) and is even lower for medication errors.<sup>19,189</sup> An adult study in Slovenia also found that although adverse drug reactions were recorded in the medical record, few were coded via ICD-10, and none via voluntary reporting.<sup>190</sup> Despite these limitations, administrative (ICD) coding may be a cost effective method of high-level or population based case identification, although chart review of the identified cases is likely to be required for deeper analysis of event characteristics.

## 2.2.7 Comparison of Methods

An early study by Jha et al, comparing voluntary reporting, computer based AME identification and chart review found that chart review identified 65% of all AMEs, computer based monitoring 45%, and voluntary reports only 4%.<sup>191</sup> The overlap between chart reviewing, computer based triggers and self-reports was only 1%, hence a combination of methods is valuable.<sup>19,191</sup> Flynn et al found direct observation was superior to chart review or incident reports in identifying administration

errors.<sup>163</sup> Similar results were reported by Franklin et al, who found that prospective and retrospective chart review, trigger tool and spontaneous reporting identified different prescribing errors, with prospective review by a pharmacist and retrospective chart review by a researcher the most effective.<sup>181</sup> Hence a combination of methods may be required to identify the true effectiveness of different interventions. Nwulu et al investigated two specific electronic triggers (high INR and the use of naloxone) in the UK adult setting and found a high positive predictive value for naloxone but not for elevated INR.<sup>192</sup> This method identified many more adverse events than reported via the voluntary reporting system; however, it required a secondary manual review of the chart to avoid false positives.<sup>192</sup> Christiaans-Dingelhoff et al from the Netherlands compared patient reports and incident reports with manual chart review to identify adverse events (not just medication related) and found that only 3.6% of the events identified via chart review were also reported via one of the reporting systems. However, many events reported by health professionals were not identified via chart review.<sup>193</sup> Snyder et al reviewed eight different methods of voluntary and non-voluntary case identification methods and found that a 5% sample of charts identified the largest number of medication safety events, (34%) followed by pharmacist surveillance (27%), automated alerts (24%, via drug use or laboratory values) and then incident reports 11%.<sup>164</sup>

Mangino<sup>170</sup> and Davis<sup>57</sup> recommended that for ongoing quality assurance for institutions (rather than for research purposes), incident reports should be combined with practitioner interventions to provide a valuable database for analyzing faulty processes.<sup>57,170</sup> Likewise Olsen et al found little overlap between adverse events identified via retrospective chart review, pharmacist surveillance or incident reports and therefore recommended that hospitals use a combination of methods to identify adverse events and potential adverse events.<sup>194</sup> As discussed above, it is important to overcome the practical and cultural barriers to spontaneous reporting. In the future, these information rich ‘human’ reports should be able to be combined with increasingly sophisticated automated electronic detection systems, to enable real time monitoring of adverse medication events, with high sensitivity and specificity.

### **2.3 How can health practitioners most effectively improve safety and the quality use of medicines?**

Many interventions to reduce the risk of adverse medication events have been proposed and investigated over the past decade, with varying success. In 2003, the American Academy of Pediatrics produced the comprehensive policy statement *Prevention of Medication Errors in the Pediatric Inpatient Setting*.<sup>96</sup> The Institute for Healthcare Improvement, Institute for Safe

Medication Practices and Australian Commission on Safety and Quality in Health Care have also recommended many strategies to improve safety, ranging from hospital-wide to health-practitioner-specific.<sup>41</sup> These strategies vary in their complexity, efficacy and cost, and not all have been demonstrated to be effective in paediatrics. Some of these are summarised below.

### 2.3.1 Education

Knowledge and training have been found to be relevant factors in causation of errors, and implementation of educational solutions to reduce medication errors has proven to be effective and is considered essential for all health care providers.<sup>55,96,97,195</sup> Education can include many different methods, such as formal lectures, self-learning programs, sharing learning from clinical incidents at meetings, one-on-one review of medication errors and educational posters.<sup>97</sup>

The importance of specific paediatric training in prescribing was highlighted by the study by Isa et al which found that one-third of GP trainees from the UK did not undertake any paediatric specific training prior to starting work as a GP, and the majority of GP trainees believed that their undergraduate and postgraduate training in paediatric therapeutics was insufficient.<sup>196</sup> This reinforces the need for support for paediatric health practitioners in the community as well as hospital environments.

Many researchers have shown the benefit of education on performance, especially in the area of prescribing.<sup>197</sup> However, only a small number of studies have been undertaken in paediatrics. Davey et al found a reduction in paediatric prescribing errors from junior doctors after a prescribing tutorial, particularly if common incidents and interventions are included.<sup>198</sup> Simpson et al found a reduction in prescribing errors in the neonatal intensive care unit after introduction of a dose calculation competency assessment and a pharmacist-led daily review of medications.<sup>65</sup> Conroy and Carroll used these two studies and their own experiences to recommend a practical educational program for paediatric prescribers, using a combination of interactive lectures and practical sessions; in small groups or as part of a teaching ward round or workshop; using real cases where possible; and using a structured approach covering key paediatric points.<sup>199</sup>

A more recent study from Philadelphia found that personalised performance feedback of prescribing errors to prescribers reduced narcotic prescribing errors in the neonatal intensive care unit, but not antibiotic prescribing errors.<sup>200</sup>

A focused effort on education can show long-term improvements. A longitudinal study by Kidd et al from the UK found an improvement in paediatric prescribing competency over time, thought to be due to a combination of local and national measures to raise awareness of the importance of accurate prescribing.<sup>201</sup> Gazarian and Graudins recently reported long term reduction in adverse medication events of greater than 50% in an Australian tertiary paediatric hospital via use of multifaceted interventions including guideline development and dissemination, intensive interactive education, broad clinician involvement and continuous feedback of results to stakeholders.<sup>37</sup>

However, not all research has shown positive effects. Kozer et al in a small study from Canada found no improvement in paediatric prescribing errors after attendance at a tutorial and completion of a written test.<sup>202</sup>

A systematic review undertaken in 2013 of educational interventions to improve prescribing competency (across all settings) found that tutorials and educational programmes improved prescribing competency, and personalised feedback letters could be used effectively with limited cost.<sup>203</sup> The most effective education strategies were incorporated into multifaceted interventions including teamwork, a strong safety culture and a systems based approach.<sup>203</sup> Another systematic review into educational interventions to change behaviour of new prescribers found that although 72% of educational interventions were considered effective, results from the same type of intervention varied depending on the setting.<sup>204</sup>

Conroy and Koren both made the recommendation that all personnel involved with medicines should undergo a written test to prove their computational skills and knowledge of appropriate doses for age groups, and if the test is failed they should be retrained before being permitted to prescribe or administer medications.<sup>63,199</sup> This would be an effective method of ensuring knowledge and computational ability, however would be a significant culture change for many organisations and could be difficult to operationalize at an institutional level.

There is also significant potential for the use of e-learning programs to develop medication related competencies, particularly prescribing.<sup>205</sup> Improvement in dose calculation skills has been seen in medical students with the use of an online tool to develop and assess dose calculation skills.<sup>206</sup> This type of program could have potential uses for other health practitioners required to calculate doses, such as pharmacists and nurses. E-learning programs tend to be very costly to produce initially, but do show promise for the future, and are increasingly used in postgraduate pharmacy teaching as well as for prescribing.

The research discussed above largely deals with education to improve doctors' prescribing competency, with little evidence of educational strategies focused on improving pharmacists' competencies in safe and optimal medication use, other than the use of the General Level Framework to develop and evaluate clinical pharmacy skills, as discussed further below.<sup>207-211</sup> It is also important to recognise that skills in providing effective education and training may in fact be advanced level skills, particularly when designing courses of study.

There needs to be some caution with evaluation of effectiveness of education strategies, as demonstrating competence indicates that the practitioner "knows how" to do the task, which may not always correlate with actual performance. True change in behaviour may require significantly more than merely increasing knowledge and skills.

### **2.3.2 Clinical Pharmacists**

Directly involving pharmacists in patient care – particularly via their incorporation into multidisciplinary teams – is a highly effective strategy to reduce errors and optimise medication use in both adult and paediatric care.<sup>96,98,212</sup> The earliest studies of paediatric prescribing errors highlighted the positive impacts of a paediatric pharmacist:

*Pharmacists trained in pediatric pharmacotherapy have a significant impact on the provision of safe and effective drug therapy for pediatric patients...The greatest potential value of such services appears to be in preventing harm, minimizing unnecessary costs arising from extended hospital stay and from additional laboratory studies or therapy, and minimizing potential liability that may result from drug errors.*<sup>42</sup>

The American Academy of Paediatrics recommended 'review of the original drug order by appropriate pharmacy and nursing staff before dispensing and before administration' as an important safety strategy.<sup>96</sup>

The published research on the impact of paediatric pharmacists on error reduction, quality use of medicines and economics is discussed further below.

### **2.3.3 Communication**

Many researchers and professional groups have recommended improved communication between physicians, nurses and pharmacists as a strategy to improve all aspects of patient safety, including medication safety.<sup>55,96</sup> Fortescue et al found that improved communication among physicians,

nurses and pharmacists could prevent 86% of harmful medication errors.<sup>212</sup> Kaushal et al found that improved communication between providers and parents and between pharmacists and parents were the most potentially effective error preventive strategies in the paediatric ambulatory setting.<sup>213</sup> Associated research in recent years has been undertaken to improve clinical handover and identification of the deteriorating patient, including in the paediatric setting.<sup>18</sup>

### **2.3.4 Incident Management and Medication Safety Teams**

Incident reports (also called spontaneous or voluntary reports) were discussed above under case identification methods. As a method of improving safety, the use of continuous incident monitoring using a non-punitive approach, and quality improvement through system change has been shown to be effective in prevention of errors and is recommended by many groups and researchers.<sup>65,96,214,215</sup> A number of studies have demonstrated the increase in incident reporting that occurs once health practitioners are engaged in the process, and can see the benefits and system improvements occurring.<sup>171,214,216-218</sup> Consequently, trends in incident reporting need to be interpreted carefully as increased rates can imply improved safety culture, rather than a true increased rate of error.

It is also acknowledged that incident reporting systems capture only a small proportion of adverse events, with a recent analysis showing that only 14% of adverse events in US hospitals are reported.<sup>219</sup> There are a number of barriers to incident reporting: knowledge of what and when to report; the effort required to complete a report; the personal fears about the consequences of reporting; and the perceived lack of feedback or positive change following an error report, are consistently reported as barriers.<sup>172</sup>

Medication safety teams or committees have been integral to the success of incident reporting systems, and recommended by most safety and quality groups internationally. The American Academy of Paediatrics recommended creation of a paediatric multidisciplinary safety committee that reports to the hospital as a productive strategy to ensure cross-communication on safety issues for children.<sup>81</sup> This was used successfully in an Australian paediatric hospital where a >50% reduction in total ADEs was achieved using a combination of strategies including a motivated multidisciplinary medication safety team to produce guidelines, early clinician engagement, education of health staff, and intermittent in-depth monitoring of adverse events with continual feedback to stakeholders.<sup>37</sup> Similarly, recent paediatric work from Cincinnati showed a significant reduction in serious safety events after introduction of a range of system-wide initiatives; including

improving safety governance and culture, investigating events in detail and sharing lessons learned.<sup>168</sup>

It is clear that medication safety teams need to do more than merely discuss incident reports. Identification of underlying risk factors, effective change management, incorporation of lessons learned into education at all levels, sharing results, and staff engagement, are all required. These activities require skills in leadership, education, risk management, communication, and teamwork, as well as knowledge of medications and how they work. Hence, being an effective member of a medication safety team requires significant advanced skills.

### **2.3.5 Computerised Physician Order Entry (CPOE)**

Computerised Physician Order Entry (or CPOE) has been shown to reduce errors and harm in hospitalized patients, particularly in the medication ordering process, and is now recommended by many professional groups.<sup>96,220</sup> In paediatric patients where calculations are often more complex, electronic prescribing can potentially reduce the number of prescribing errors by ensuring that results are legible and in a standard format. More complex CPOE systems with clinical decision support (CDDS) can prevent some prescribing errors by directing doctors to the correct route and age-specific dose, warning them if current laboratory values indicate that the medication or regimen would be inappropriate, and alerting them to allergies and interactions.<sup>31,51</sup> However, even with clinical decision support CPOE will not eliminate all prescribing errors. In fact many studies have shown that CPOE can generate new problems, such as the omission of new tasks required by the system, typographical or editing mistakes, or selection errors from drop-down menus.<sup>57</sup>

A recent study from two adult hospitals in Australia, found that electronic prescribing (without a full CDDS) introduced new errors, but did prevent more errors than were generated.<sup>221</sup> In contrast to the generally successful introduction in adult settings, the overall safety improvements seen with CPOE in paediatric populations remains controversial.<sup>37</sup> Significant reduction in paediatric prescribing errors has been demonstrated in some studies, such as by Jani et al in the UK where prescribing errors reduced from 2.2% to 1.2% of prescriptions.<sup>222</sup> However other studies have shown a more modest reduction of 7% in non-intercepted serious medication errors and no change in the rate of injury.<sup>223</sup> Differences in definitions of error and adverse event make interpretation of some studies difficult, and some results have been quite conflicting. For example, the study by Potts et al from the USA shows a reduction in potential AMEs (defined as errors which could result in injury) from 2.2% to 1.3% of orders, but medication-prescribing errors (where inadequate



information was provided or further interpretation was required) reduced from 30.1 to 0.2 per 100 medication orders (a reduction of 99.4%).<sup>31</sup>

Not all studies have demonstrated a reduction in actual AMEs and mortality. King et al found a reduction in medication errors but not AMEs in a Canadian paediatric hospital.<sup>32</sup> Han et al found an increase in mortality after CPOE introduction into an intensive care unit in a USA paediatric hospital, whereas another USA hospital using the same CPOE system found a non-significant reduction in mortality.<sup>224,225</sup> A meta-analysis undertaken in 2009 found that CPOE in the paediatric setting was associated with a significant decrease in medication prescription errors, but no reduction in AMEs or mortality.<sup>226</sup>

Although CPOE systems still provide great hope in paediatrics, it is clear that they require high quality implementation processes to be successful. In addition, versions suitable for paediatrics are not widely available; the cost is not feasible for many hospitals, particularly those in developing countries; and there is a likelihood of introduction of new errors with potential for harm.<sup>226,227</sup>

### **2.3.6 Centralised Intravenous Admixture Services (CIVAS) or Unit Dose Dispensing Systems**

In 1985, Buehler et al recommended a '*centralized preparation and distribution of individual doses of medicine by hospital pharmacies*' as an effective method to decrease medication errors.<sup>228</sup> These services remove the need for bedside drug calculations and often-complex preparation of intravenous products by nursing staff, which is particularly useful in the neonatal and paediatric setting. Preparation undertaken in a clean room environment under controlled conditions with careful documentation and processes should also result in safer, cleaner, more accurate and consistent therapy in comparison to when these are prepared in a ward based environment. A systematic review by Conroy et al in 2007 found four published reports of introduction of a unit dose dispensing system with great reduction in medication errors.<sup>51</sup> A follow-up study identified CIVAS as one of the three most promising interventions to reduce the risk of calculation errors in the paediatric setting, alongside double-checking and smart-pump technology.<sup>229</sup> It is a commonly used approach in the United States of America but is not a strategy widely used in the UK or Australia due to the high set-up and recurrent costs, and different funding models.

### 2.3.7 Other Technology – Smart Pumps and Bar Coding

“Smart” infusion pumps have been recommended to decrease the incidence of infusion errors.<sup>81</sup> These pumps provide an alarm and halt the infusion if a programmed dose exceeds the pre-set limits set up specifically for the patient population.<sup>97</sup> Use of these pumps has resulted in improved documentation of medication errors and decreases in calculation and administration errors.<sup>51,81</sup> However, as with the introduction of CPOE described above, new systems such as smart pumps can introduce new potential errors and must be appropriate for paediatrics.<sup>230,231</sup>

Bar-coding is a point-of-care system where identification bands are compared to medications before administration.<sup>81</sup> It is designed to validate patient identity, verify actual medications administered, assure the correct time of administration and provide safety alerts to prevent medication errors from reaching the patient.<sup>97</sup> One study found that the use of bar-coding reduced wrong medication errors by 76% and missed dose errors by 70%.<sup>232</sup> Bar-coding is recommended by the American Academy of Pediatrics.<sup>96</sup> However Merry and Anderson commented in 2011 that in the paediatric anaesthetic area, bar-coding and the use of technology may enhance carefulness, but cannot replace it.<sup>215</sup>

### 2.3.8 Combinations of strategies

Koren described in 2002 the steady decline in reported medication errors across one paediatric hospital after introduction of a computerised prescribing system, removal of hazardous medications from clinical areas, and training of paediatric residents.<sup>195</sup> This study used voluntary reporting as the reporting measure, which is known to be an underrepresentation of the total number of events, as discussed above. Research by Muething et al in a Cincinnati paediatric hospital, described above, found that overall serious safety events (not just medication events) decreased from 0.9 to 0.3 per 10,000 bed days as a result of improvements to patient safety culture, better communication of what was learnt from safety events, and governance changes.<sup>168</sup> The Cincinnati study used trigger tool sampling (the IHI method) with spontaneous and patient reporting.<sup>168</sup> Gazarian and Graudins reported on a long term decrease of 50% in adverse medication events in a paediatric hospital in Sydney, after implementation of guidelines for safe prescribing, standardised medication chart, clinician engagement, improved communication, interactive education and data feedback.<sup>37</sup> The Sydney study used chart review and spontaneous reporting as case identification methods.<sup>37</sup> Similar results were found from a group of paediatric hospitals in California after a change package of interventions including standardisation of medication ordering, automated dispensing cabinets, safe pump use, improvement in safety culture and clinical decision support, with a 42% decrease in

total adverse medication events.<sup>183</sup> The California study also used the IHI sampling chart review trigger tool method.<sup>20,183</sup>

These studies all demonstrated the importance of implementing a variety of different safety initiatives in paediatric hospital environments. Case identification methods differed, but all included the importance of a strong safety culture. Most were only recently published, and pre-date the commencement of this research project.

## **2.4 How can we measure the value of a pharmacist in paediatric health care?**

There has been much research undertaken over recent decades to describe the impact of a clinical pharmacist on health outcomes for patients; however, much of this has been in adult patients. There has been much less research undertaken to demonstrate similar impact in paediatrics, and none on the impact of an advanced practice pharmacist. Paediatric clinical pharmacy services are now well established in many countries, which presents challenges to undertaking research to quantify the impact on patient care. This is particularly the case if comparing the presence of a clinical pharmacy service to the absence of such a service, as it would be unethical to withdraw an established service for research purposes. Determining an appropriate method to measure impact on patient outcomes remains a challenge; however, some of the methods evaluated are discussed below.

### **2.4.1 Measuring value using interventions and errors**

Pharmacist interventions and the impact on adverse medication events and errors have been discussed above. Interventions have been the most commonly used method of documenting and measuring the impact of clinical pharmacists on patient care in the adult and paediatric environment, particularly to measure error reduction.<sup>25,55,62,65,212,233</sup> There are varied definitions of interventions used by organisations and researchers, which makes comparison of results difficult. Some broadly define an intervention as any pharmacist action which results in improved quality use of medicines; some require a change in therapy to have been made; some only include errors and others include all patient-related activities of pharmacists. The most common definition presently used in Australian hospital pharmacy is by the Society of Hospital Pharmacists of Australia (SHPA): *'any action by a pharmacist that directly resulted in a change to patient management or drug therapy'*.<sup>38</sup> Importantly, this definition does not require an error to have occurred.

Many studies have investigated reduction in medication errors in paediatrics. Fortescue et al in 2003 reviewed 10,778 medication orders from two US paediatric hospitals. In this study, physicians assessed that 81% of the errors were preventable by ward-based clinical pharmacists.<sup>212</sup> Simpson et al in 2004 found that a pharmacist led clinical review of medications was an effective way of reducing medication errors in the neonatal intensive care unit.<sup>65</sup> A study by Wang et al of 16,938 medication orders in 678 children admitted to one large academic hospital in the US found that medication errors occurred at a rate of 5.2 per 100 medication orders, and pharmacists intercepted 78% of the potentially harmful prescribing errors although none of the administration errors.<sup>234</sup>

The differences between paediatric and adult safety has been investigated by a number of researchers. Higher rates of pharmacist interventions in paediatric wards have been identified in comparison to adult wards. In 1997, Barber et al found that there were more pharmacist interventions in UK paediatric wards than there were in any other ward except intensive care.<sup>47</sup> Likewise, a recent study from Spain found that paediatrics had a four fold higher risk of serious errors in comparison to the maternity population, and pharmacists made 19 interventions per 1000 patient days in the paediatric population, versus 16 per 1000 patient days in the maternity population.<sup>49</sup> Although these two studies were more than a decade apart, and from very different health care environments, they both found a significantly increased role for a pharmacist in the paediatric setting. An interesting finding from the study by Barber et al, was that higher grade pharmacists have 1.4 times as many interventions as a base grade pharmacist, which implies pharmacist with more advanced skills make more interventions to improve patient care.<sup>47</sup>

A number of different models of paediatric clinical pharmacy service have been investigated, as these can influence the impact on errors. A study from the USA in 2008 by Kaushal et al found that there was a 79% decrease in the rate of serious medication errors in the paediatric ICU after introduction of a full-time unit-based clinical pharmacist.<sup>233</sup> The same study found that a part-time clinical pharmacist in general wards (where attendance at ward rounds was more difficult to organise) was less effective at decreasing errors.<sup>233</sup> Isaac et al found similar results in a recent small study from the UK, where pharmacists frequently used their knowledge of altered medication handling (e.g. prematurity or renal impairment) to recommend changes to medication therapy in the paediatric intensive care unit. As expected, the more time the pharmacists spent on the ward, the more interventions were made.<sup>235</sup> Kaline et al found that including a pharmacist in a new multidisciplinary trauma team reduced medication prescribing and administration errors in paediatric trauma patients.<sup>236</sup>

The impact of introducing new clinical paediatric pharmacy services was investigated in two recent studies from Spain and China. Fernandez-Llamazares et al from Spain found there were 2.4 interventions in every 100 medical orders, with potentially fatal errors accounting for just over 2% of the prescribing errors.<sup>237</sup> They found that interventions by a clinical pharmacist had a major impact on reducing prescribing errors, thus improving the quality and safety of care provided.<sup>237</sup> A follow up study by the same authors in eight hospitals in Spain found an average intervention rate of 1.4 per 100 bed days.<sup>238</sup> The second study, from Zhang et al, compared 160 paediatric patients randomized to either a clinical pharmacy service or a control group in a paediatric hospital in China over a four month period.<sup>239</sup> In the experimental group the clinical pharmacists attended ward rounds, answered questions of physicians and nurses, gave advice on treating patients, checked prescriptions and counselled patients at discharge.<sup>239</sup> The control group had no clinical pharmacy service. A total of 107 clinical pharmacist interventions were made in the intervention group, and of these 31 (29%) were related to error.<sup>239</sup> Importantly, interventions by a clinical pharmacist were associated with a shorter patient stay and increased patient compliance with medication therapy after hospital discharge.<sup>239</sup>

The published research into clinical paediatric pharmacist services in Australia is limited. One small single centre study described 3.4 pharmacist interventions per 100 patient bed days with 39% of interventions rated as high or very high risk.<sup>213</sup>

The risk of relying merely on “interventions” and indeed “errors”, to determine the impact of a pharmacist on patient outcomes is that they usually refer only to a single direct patient interaction rather than the contribution by pharmacists to population based care by introduction of system improvements, including policies, guidelines and protocols, practice change and education. Pharmacists may instigate significant changes to the system in response to a single patient intervention; however, this unlikely to be recorded in the report written soon after the event.

## **2.4.2 Measuring economic value**

Studies in the adult population have measured the potential economic benefit of pharmacist interventions, with respect to cost savings and cost avoidance. A systematic review of the economic effect of US hospital pharmacists reported that positive economic benefits were found in the majority of studies (reduced medication expenditures, hospital admissions, lengths of hospital stay and emergency department visits). However, the studies were difficult to compare as many used multimodal approaches, some focused on specific medications or treatments and some on

specific disease groups.<sup>240</sup> In addition, the difference in health care environments and funding models makes it difficult to extrapolate results from the USA to Australia. Comparisons in the paediatric settings are further impeded by the scarcity of research to date.

The most significant Australian research into the economic impact of clinical pharmacy was undertaken in the adult setting, where Dooley et al reviewed the pharmacist interventions recorded from eight large tertiary hospitals. A total of 1,399 interventions were documented, and it was found that for every AU\$1 spent on a clinical pharmacist, AU\$23 was saved.<sup>241</sup> Graham et al using the same methodology as the Dooley study, followed a group of paediatric pharmacists in one Australian paediatric teaching hospital and found that for every AU\$1 spent on a clinical pharmacist wage, there was AU\$34 saved.<sup>242,243</sup>

In paediatrics, the most significant study was from America, where Krupicka et al described the effect of a paediatric clinical pharmacist in an American paediatric intensive care unit.<sup>244</sup> This study demonstrated a saving of US\$9,135/year in direct cost savings for a relatively small expenditure of less than one hour per day of clinical pharmacist time. In other words, 7.5 times the cost of the pharmacist wage was saved in direct medication costs.<sup>244</sup> A similar but longer study from New Orleans in a paediatric intensive care unit found annual cost savings of US\$119,700 for a part-time paediatric clinical pharmacist.<sup>245</sup>

### **2.4.3 Measuring value using patient outcomes**

There has been little research investigating the value of pharmacists on paediatric patient care apart from reduction in error or economic impact. Researchers in the adult setting have identified improvements in quality areas such as adherence, quality of life, and readmission rates. Kaboli et al undertook a systematic review in 2006 of the impact of clinical pharmacy services.<sup>246</sup> Adverse medication events, adverse drug reactions and medication errors were reduced; medication adherence, knowledge and appropriateness of therapy was improved; and hospital length of stay was shortened by introduction of a clinical pharmacy service.<sup>246</sup> Other outcomes in the adult setting have included improvement in severity of illness in the psychiatric setting; improved INR control with a pharmacist-managed anticoagulation program; and improved quality of life and reduced hospitalisation in a renal disease clinic.<sup>247-249</sup>

Sanghera et al in 2006 undertook a systematic review of interventions by hospital pharmacists that improved medication therapy in children. They found a small number of heterogeneous studies that were difficult to compare. However all the studies highlighted the importance of hospital

pharmacists to medicines management in paediatric patients, with the most evidence related to pharmacist reviewing of medication charts.<sup>62</sup>

The last three years have seen a small but an encouraging number of published paediatric studies investigating other impacts on patient care. However, these have tended to be small, single centre and in many cases related to a single clinical unit. In the recent study from China mentioned above, interventions by clinical pharmacist were associated with a shorter patient stay and increased patient compliance with medication therapy after hospital discharge.<sup>239</sup> A study from Chile in children with asthma found pharmacist care improved quality of life, including emotions, activity and symptoms although not spirometry.<sup>250</sup> Another study in paediatric asthma from the Netherlands found that closer interaction between pharmacists and general practitioners targeting adherence to paediatric asthma guidelines significantly improved the use of short-acting betamimetics and the use of inhaled corticosteroids while on long-acting betamimetics in children with asthma.<sup>251</sup> A study in Singapore demonstrated that a pharmacist counselling session increased parent's knowledge about epilepsy and medication adherence.<sup>252</sup>

A small study from the USA on paediatric cystic fibrosis patients found that a clinical pharmacy service (focusing on therapeutic drug monitoring) reduced length of stay, blood tests and overall costs of care when compared to no service.<sup>253</sup> A study from Egypt in a paediatric dialysis unit found a significant improvement in blood pressure, biochemical markers and patient satisfaction in a group of patients provided with a clinical pharmacy service in comparison to the control group.<sup>254</sup> A 2012 study by Marconi and Claudius found that the introduction of a full-time pharmacist based in the paediatric emergency department significantly reduced medication omissions and delays.<sup>255</sup>

The above research on paediatric pharmacy has demonstrated important improvements in patient care, particularly in error prevention. In recent years, research has begun to move towards analysis of direct patient outcomes, although these are still limited by small sample sizes.

## **2.5 Conclusion**

Adverse medication events have been intensively investigated over the past two decades, although the majority of research has been in the adult setting. The most effective methods of case identification for adverse medication events, and harm prevention initiatives, are still not confirmed particularly in the paediatric setting.

It is clear from published research that multifactorial changes are required to make sustained improvements in medication safety. Technology such as CPOE and smart pumps can be effective

but need to be planned and implemented carefully so that new errors are minimised. Education is essential and can be very effective, but it needs to be sustained, and should be measured against performance in practice, rather than as mere knowledge. Significant cultural change at an organisational level is possibly the most important strategy, including a non-punitive approach to incident management and implementation of multidisciplinary safety teams.

The impact of a clinical pharmacist on error prevention in paediatric patient care has been demonstrated in a number of studies and clinical pharmacy is now well integrated into health-care systems in most developed countries. However the studies to date have been limited by relatively small numbers, with an emphasis on prevention of error rather than broader measures of quality use of medicines, sustained system improvements and direct patient outcomes. The tasks or roles required of a clinical pharmacist service have been described in some cases, but not the knowledge and skills required of a paediatric pharmacist undertaking these roles. Gaps in research include analysis of different models of pharmaceutical care, comparison of outcomes with different pharmacist skill sets, and measurement of meaningful direct patient outcomes in children rather than just prevention of error. Assessment of skill is discussed further in the next chapter.



## 3 Chapter Three: Literature Review – Development and Assessment of Health Practitioners

### 3.1 Introduction

In Chapter 2, the current literature regarding adverse medication event measurement and analysis and interventions to improve safety were described, with some evidence emerging on the impact of clinical pharmacists in prevention of adverse medication events and improvement in quality of paediatric care. In this chapter methods for development and assessment of advanced practice in health practitioners are investigated more deeply.

Health practitioners develop from undergraduate to postgraduate to advanced practice, via formal education, experiential learning in and outside of the workplace, and formative and summative assessments used in formal and informal training. The capacity of health practitioners to deliver improvements in therapeutic outcomes, quality of life for patients, and improvements in care at a system level is dependent on a foundation of competence and capability, enhanced by specialist knowledge and skills developed over time.<sup>112</sup>

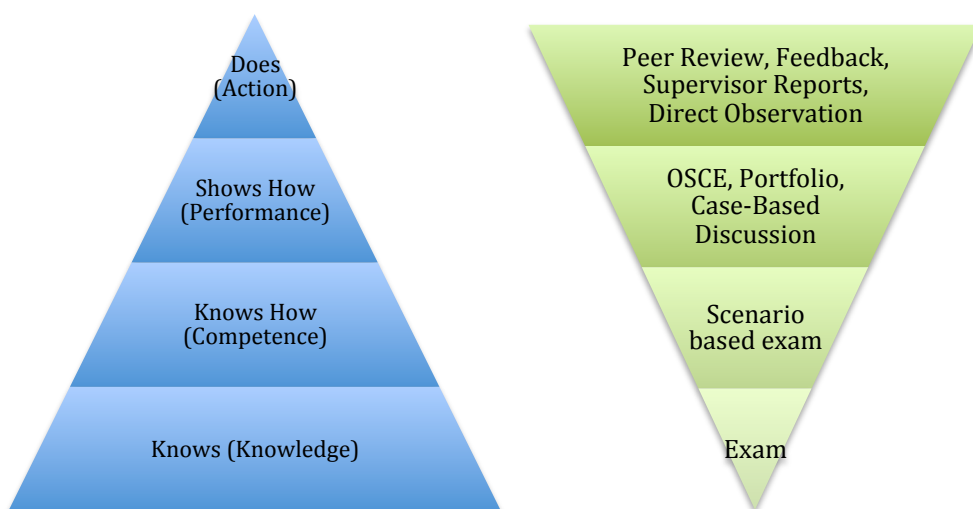
The concept of professional competency is well established in healthcare, and articulated clearly in the Kennedy Report into the Bristol Hospital Inquiry where it was stated that *'A healthcare professional's competence from the patient's point of view is not negotiable'*.<sup>256</sup> The National Competency Standards Framework for Pharmacists in Australia state that *'Competence is generally taken to mean that an individual possesses the required knowledge, skills and attributes sufficient to successfully and consistently perform a specific function or task to a desired standard'*.<sup>132</sup> The current challenge for pharmacy is to clearly define where skills, knowledge, attitudes and behaviours move from standard professional competence to advanced practice.

The journey from competence to proficiency to expert practice has been described by some authors as moving from knowledge of standardized procedures and handling pressured situations (competency, 2-3 years experience); to the ability to perceive situations holistically, detect deviations and identify what is important (proficiency, additional 3-5 years); to someone who no longer relies on rules or guidelines and has an intuitive grasp of situations (expert, 10,000 hours).<sup>257-</sup>  
<sup>259</sup> This explanation of competence versus proficiency and expertise correlates well with the

concept of development from newly qualified to advanced practice and has implications for how this is assessed or evaluated.

Assessment and evaluation are terms often used interchangeably. Cantillon et al described a continuum of assessment where *'at one end of the continuum, formative assessment is essentially about providing feedback to students in order to support and enhance learning; at the other end, summative assessment is about measuring students' achievement with the purpose of grading or informing decisions about progression'*.<sup>260</sup> Formative assessment then has the intent of sharing information about performance (or giving feedback), in contrast to summative assessment which involved conferring judgment.<sup>260</sup> Hill et al made similar points that assessment should not only determine whether the student has acquitted the set competencies deemed important, but also provide feedback on their performance and allow the student to picture the desired level of performance.<sup>257</sup>

When considering assessment of clinical practice, many researchers have referred to Miller's knows/shows/does triangle from 1990, as shown below in Figure 3.1.<sup>261</sup> The "knows" level of Miller's triangle refers to the recall of facts, principles, and theories. The "knows how" level involves the ability to solve problems and describe procedures. The "shows how" level usually involves human (standardized patient), mechanical, or computer simulations that involve demonstration of skills in a controlled setting. The "does" level refers to observations of real practice.<sup>261,262</sup>



261

**Figure 3.1 Miller's Framework for clinical assessment (left) mapped against methods for assessment (right)**

When considering assessment instruments, educators and evaluators must consider not only factors that make the instrument desirable and appropriate (reliability and validity), but also factors that make the instrument practical and achievable, including the cost to the individual, institution and society, ease of administration and acceptability to candidates and examiners.<sup>263</sup> Distinctions need to be made between assessment methods that are suitable only for formative use, and those that have sufficient psychometric rigor for summative assessment, particularly for high-stakes assessment.<sup>264</sup>

The challenge is to effectively assess competency at different levels of practice, using reliable and sustainable methods. This is a newer area of research, particularly in pharmacy practice. Two reports from Australia and the UK in the past year have comprehensively reviewed current assessment methods for health practitioners and the relevance for pharmacists practicing at an advanced level. The Australian Pharmacy Council recently released a comprehensive report on Advanced and Extended Pharmacy Practice in the Australian context.<sup>113</sup> The Royal Pharmaceutical Society in the UK also recently prepared a report on credentialing of advanced practitioners.<sup>112</sup> The recommendations from both of these important reports are combined with findings from other researchers and summarised below.

### **3.2 Professional development without assessment**

#### ***Lectures, Workshops and Seminars***

The traditional method of improving health practitioners' knowledge was to attend a lecture, workshop or seminar in the hope that the information provided will be retained and applied to improve practice. A well-designed workshop will require a learner to participate in some kind of interactive task to apply the knowledge gained. More recently, however, the traditional didactic style of teaching has been questioned by many, who see it as less effective than other teaching methods for promoting thinking skills or changing attitudes, and, at best, improving only the "knows" or "knows how" part of Miller's Triangle.<sup>261,265</sup>

Lectures, workshops and seminars do have their role, if well structured, interactive and linked to practice, and ideally in combination with other teaching methods such as case discussions.<sup>265</sup> They can be a cost-effective and valuable method to transmit knowledge, which then needs to be contextualised by the learner with activities using higher order thinking.<sup>265</sup>

## ***Online or web-based teaching***

Online or web-based learning is being used increasingly in both undergraduate teaching and professional development. It is an attractive proposition as it offers flexibility for the learner in terms of where and when learning occurs, while accommodating large numbers of learners. It can be used for professional development for individual learners, or as a component of formal education.

Blended methods including online lectures followed by face-to-face case-based discussions, have been positively evaluated by a number of researchers, particularly when such teaching is based on observed gaps in practice and undertaken in a timely fashion before experiential placements.<sup>266-270</sup> Assessment (using before and after quizzes) can be built into online learning to feed back any knowledge gaps to the learner, in association with face-to-face learning with a mentor or tutor as part of formative or summative assessment. This has been demonstrated in clinical practice where an electronic learning package for paediatric prescribing found a small but significant improvement in prescribing skills when doctors were followed up at 1 and 3 months post intervention.<sup>271</sup>

## ***Mentoring and Feedback***

Mentoring and feedback are closely linked in professional development, and are also linked to many of the assessment methods and tools described below, in particular direct observation and peer review. Cantillon et al defines feedback as providing information to students with the intention of narrowing the gap between actual and desired performance.<sup>260</sup> Without feedback, good performance is not reinforced and poor performance may be repeated at the expense of patients or colleagues.<sup>260</sup> Govaerts et al concluded that narrative feedback provided in a constructive way is the only way to help trainees to accurately identify strengths and weaknesses in their performance, and to effectively guide development of competence.<sup>272</sup>

Antoniou et al found that the use of effective feedback in conjunction with a structured clinical competency assessment tool with hospital pharmacists in the UK improved the patient-related competencies significantly more than for hospital pharmacists who were not provided feedback.<sup>207</sup> Epstein and Hundert stated that a strong mentoring system should accompany any comprehensive assessment program. '*An inadequate system for feedback, mentoring and remediation will subvert even the most well-conceived and validated examination*'.<sup>262</sup> The ability to effectively mentor and provide feedback to others, particularly outside the team and professional group, is an important skill for an advanced practitioner.

## ***Ward-based teaching***

Ward based teaching is commonly used for all hospital based health practitioners, although the challenges of ward based teaching in settings such as paediatrics have rarely been described. Reece and Kabler recently described the challenges and opportunities for teaching paediatrics to medical officers during ward rounds.<sup>273</sup> Although the article primarily describes medical teaching, it is relevant for pharmacists. Reece and Kabler describe the particular challenges in paediatrics where examination of (or discussion with) a child can be difficult in the presence of a large group, consent can be difficult to obtain, and short stays and rapid turnover result in most of the patients being new to the incoming team on the next shift.<sup>273</sup> However, they also point out that ward rounds are an excellent opportunity to model behaviours, communication and clinical skills, in addition to real-time learning.<sup>273</sup> Furthermore, for those learners less familiar with the nuances of interacting with children and young people of various ages, it is a valuable opportunity to observe how it can be done by senior members of the team.<sup>273</sup>

## **3.3 Portfolios**

Challis et al described a portfolio as '*a collection of material, made by a professional, that records, and reflects on, key events and processes in that professional's career*'.<sup>274</sup> In the health practitioner arena they tend to comprise a dossier or collection of evidence acquired over time that demonstrates the practitioner's education, assessment results, practice achievements and the fulfilment of personal learning needs.<sup>275-277</sup> They can be used for professional development and for formative and summative assessment.

Portfolios can range from a loose collection of personal reflections and individualized goals and objectives through to a structured compilation of evidence as defined by a professional program for summative assessment or credentialing purposes.<sup>277</sup> Some portfolios may be developed to create a long-term journey of personal development, to demonstrate the breadth of learning and the process of progression in learning. These may be essentially private documents, for personal review only. Or they may be used for formative assessment (as a focus for feedback), where participants document and reflect on areas where they could improve and plan with a mentor how they may rectify deficiencies.<sup>274</sup> Other portfolios will be used for summative assessment against specific targets of achievement required by other authorities and open to public scrutiny.<sup>274,275</sup>

As they involve the actual experience of the learner, portfolios enable consolidation of the connection between theory and practice.<sup>274</sup> Portfolios have been shown to improve student's self-

awareness, improve self-confidence, identify individual learning needs and achievements, improve the ability to learn independently and to integrate theory with practice.<sup>113</sup>

### ***Medical use of portfolios***

Portfolios began to be trialled in the medical field in a number of UK settings in the 1990s. Early research with GPs compared a portfolio based learning program (incorporating mentoring groups and structured reflection) with a traditional development program based on recording education attended.<sup>278</sup> They found that the portfolio-based learning scheme gave learners control over how, what and when they learned, and encouraged active and peer-supported learning.<sup>278</sup> The breadth of topics covered by the portfolios was wider than those seen with the traditional process, and the learning showed more depth.<sup>278</sup> Similar experiences have been observed in the USA, with increasing use of portfolios in graduate medical education, to record learning, reflect on experiences, and receive feedback on achievements.<sup>277</sup>

In contrast, Nagler et al and Roberts et al have recommended caution with the use of portfolios for high stakes use, particularly in the medical field.<sup>277,279</sup> Concerns regarding patient privacy and potential litigation have resulted in suggestions to leave documented reflection out of assessment rather than risk the learner's documentation of insecurities, suboptimal performance and/or bad outcomes becoming a source of a malpractice lawsuit.<sup>277</sup> The importance of different formats of portfolios for formative assessment rather than high stakes summative assessment has also been emphasised.<sup>279</sup>

### ***Nursing use of portfolios***

Portfolio use in nursing is less commonly described, but it has now been integrated into undergraduate training in some settings.<sup>280</sup> Endorsement as a nurse practitioner by the Australian Health Practitioner Regulation Agency now includes submission of a structured portfolio of evidence including description of compliance with the National Competency Standards for the Nurse Practitioner.<sup>281</sup>

### ***Pharmacy use of portfolios***

Portfolios, increasingly web-based, have been used widely in undergraduate pharmacy teaching, with a students tending to favour portfolio assessment over traditional testing.<sup>113,282,283</sup> Portfolios in a very simple form can be used to record Continuous Professional Development and personal

learning plans, which have been a part of the registration process for all pharmacists in the UK, Canada, and (since 2010) for all health practitioners in Australia.<sup>284,285</sup>

McKenzie and Borthwick described the successful use of portfolios in the UK as part of a multi-faceted tool for assessment of advanced practice critical care pharmacists.<sup>286</sup> The portfolio was used in conjunction with peer review using 360 degree appraisal, together with “assessment in practice” (observed practice), and was prepared separately for the specific purpose of summative assessment.<sup>286</sup>

The recent Royal Pharmaceutical Society report on credentialing found that portfolios were strongly supported as a principal strategy for credentialing of advanced practitioners. The format recommended mapping of evidence against the Advanced and Consultant Level Framework, and including as evidence multiple source feedback (peer review), intervention reports, case based examinations or discussions and evidence of directly observed practice.<sup>112</sup>

In summary, portfolios can be used to provide evidence of skills that would be difficult to assess otherwise, such as behaviour, quality improvement activities, and experience.<sup>113</sup> However, portfolios are time-consuming to develop and keep up to date, and health practitioners may feel uncertain about how to use them without clear guidance.<sup>287</sup> User-friendly web-based portfolios will hopefully make portfolios easier to maintain in the future. There is a key difference between portfolios maintained for individual development, for formative assessment, and for summative high stakes assessment, and the format needs to be flexible enough to accommodate these differences.<sup>279</sup> The benefits of self-reflection for meaningful learning is important. However the person undertaking it is highly unlikely to willingly present a portfolio identifying their weaknesses for high stakes assessment. Therefore a personal portfolio that can be customised for different purposes is essential.<sup>277,279</sup>

### **3.4 Work Based Assessments**

Work Based Assessments (WBAs) are assessments of practice or competency based on what a health practitioner actually does in their workplace (usually a clinical setting), using direct observation of practice by the assessor/evaluator. Provision of effective feedback is intrinsic to their use as educational as well as assessment tools. As described in the Millers Triangle, direct observation is the best method of assessing the “does” component of professional performance.<sup>261</sup> Direct observation can be undertaken in a number of ways, using a number of different tools, some of which are described below.<sup>288</sup>

Work-based assessment using direct observation allows evaluation of a health practitioner's strengths and weaknesses in areas such as interpersonal skills (e.g. interaction with patients, families and other health practitioners), professionalism, ethics, self-appraisal and the ability to improve, which are difficult to assess using traditional knowledge-based examinations.<sup>113,288,289</sup>

Work-based assessments routinely use some kind of checklist evaluation, if the competency can be broken down into specific behaviours or actions.<sup>290</sup> In addition, training of assessors in providing developmental feedback is important for successful use of work-based assessments, and requires advanced communication skills.<sup>289</sup>

Direct Observation of Practice was highly recommended by the Royal Pharmaceutical Society Credentialing paper, including by the Neonatal and Paediatric Pharmacists Group.<sup>112</sup> A sample of WBA tools with potential relevance for advanced pharmacy practice is discussed below:

### ***Direct Observation of Procedural Skills (DOPS)***

Direct Observation of Procedural Skills (DOPS) is commonly used as a component of workplace assessment in medical training, usually requiring multiple assessments for each procedural skill.<sup>288,291,292</sup> Comparable assessments in pharmacy practice at a junior level could be procedural skills in aseptic compounding of medicines. However, these types assessments may be less relevant for advanced pharmacy practice. In this context, the acronym DOPS could also be phrased Direct Observation of *Practice* Skills, and therefore comparable to the General Level Framework described below.

### ***General Level Framework***

The competency based performance evaluation and feedback tool called the General Level Framework (GLF) was developed in the United Kingdom by the Competency Development and Evaluation Group (CoDEG) in the early 2000s, then adapted in Australia by Queensland Health pharmacists.<sup>207,209,293-295</sup> This framework is a tool for evaluating pharmacists' performance, providing tailored feedback, and training and guiding professional development. It uses a competency-based checklist and descriptive feedback after a period of direct observation of practice.<sup>209</sup> In this framework the checklist gives a description of the 'correct' behaviours and a rating of 'rarely', 'sometimes', 'usually' or 'consistently'.<sup>209</sup> After the feedback session, the pharmacist prepares a professional development plan in conjunction with the evaluator.

Use of this tool has expedited improvements in pharmacist competencies in Australia, Croatia, Singapore and the UK.<sup>207,209-211,294,296</sup> This tool has been replaced in Australia in recent years by the



shpaclinCAT, based on the same original content and format as the GLF, with customisation for the Australian healthcare setting and additional examples of behaviours for each criterion.<sup>297,298</sup> These tools were designed for professional development and training rather than as a summative assessment method, and were not designed for assessment of advanced practice (although the competencies described would of course be expected of advanced practitioners).<sup>113,295</sup>

### ***Mini-CEX***

The “Mini-CEX” (or Mini Clinical Evaluation Exercise) has been widely used in the medical field as a short direct observation of a physician and a single patient in real clinical practice, with the aim for multiple encounters to be used during a training period.<sup>113,299</sup> It is another tool that uses direct observation of practice. Criteria such as interviewing, physical examination, professionalism, clinical judgment, counselling, organization and efficiency and overall competency are scored, and feedback is provided to the learner at the end of the encounter.<sup>299,300</sup> It has been found to have a high level of internal consistency and reliability among internal medicine trainees.<sup>301</sup> In comparison to other formats such as standardized patients, the mini-CEX in the medical environment was found to have a higher fidelity, to permit evaluation based on a much broader set of clinical settings and patient problems, to be more easily administered on site, and to cost less.<sup>299</sup> Subsequent research has endorsed the superior psychometric properties of the mini-CEX over the traditional CEX.<sup>300</sup>

The Mini-CEX is used as formative assessment for Australian hospital pharmacists; for advanced medical trainees in specialties such as general paediatrics and paediatric emergency medicine;<sup>110,302</sup> and for workplace based assessment of international medical graduates in Australia.<sup>301</sup> A Mini-CEX has also been used by pharmacists in the UK, including as part of summative assessment for advanced practice in critical care.<sup>286</sup>

### ***Case-Based Discussion***

Case-based Discussion involves a comprehensive review and presentation of a clinical case where the health practitioner has been significantly involved.<sup>113</sup> Case-based discussions have been used in health workplaces for many years, in various levels of formality, however most commonly for formative assessment. In medicine, they are used regularly throughout the year as formative assessments for advanced medical trainees in specialties such as general paediatrics and emergency medicine.<sup>110,302</sup> Case-based discussions are used for formative assessment in some postgraduate training in Australia and have been used as part of “assessment in practice” for advanced practice critical care pharmacists in the UK.<sup>286</sup> They are relatively inexpensive to administer and provide

the health practitioner with an opportunity to demonstrate and explain their involvement in a real case, allowing the assessment of judgement, decision-making and professionalism.<sup>113</sup>

Case based discussions have been highly recommended by the Royal Pharmaceutical Society credentialing report, including by the Neonatal and Paediatric Pharmacists Group.<sup>112</sup>

### ***Procedure or case logs***

The use of procedure or case logs where learners prepare summaries of clinical experiences including clinical data is common in the medical field. Logs are useful to document educational experiences and deficiencies<sup>290</sup>, and can be linked to self-reflection activities in a portfolio.

An analogous strategy for pharmacists may include recording activities such as therapeutic drug monitoring, items manufactured, or interventions in patient care on a regular basis, to aid in self-reflection and as a demonstration of increasing skill. Similarly, a study by Barber et al in 1997 found that pharmacists of a higher pay grade (with the assumption of higher skill) were more likely to make interventions than those in a lower grade.<sup>47</sup> These logs are easy to maintain on a regular basis. However, they should not be used alone as the number of cases and interventions do not necessarily correlate with competence.<sup>290</sup>

### ***Summary of Work Based Assessments***

Direct observation assessments generally require the assessor to complete the observation in the practitioner's usual workplace, which may provide difficult to organise.<sup>113</sup> An alternative would be to have a group of candidates all performing in a environment which is unfamiliar to them but which allows them to access appropriate assessors. This approach was used by the UK critical care group. However, such situations are likely to misrepresent the practitioner's competency and make it difficult to assess how the practitioner interacts in their usual healthcare team.<sup>113</sup>

The risk of these types of direct observation assessments is that the assessor makes use of their own personal constructs and theories about performance that develop through prolonged task experience, which can significantly effect rating outcomes.<sup>272</sup> Hawkins et al found that the manner in which examiners are trained and selected affects rating outcomes for a mini-CEX, and recommended that each trainee should be assessed by as many different examiners as is feasible.<sup>300</sup> Concerns were also raised by Basu et al regarding the reliability of feedback provided online for work based assessments of doctors in the UK.<sup>303</sup> This study found that feedback was generally delayed, and users felt there was a little positive impact on learning or performance. This related to the lack of

training and engagement of consultants providing the assessment.<sup>303</sup> These findings again reflect the importance of well trained assessors and timely and effective feedback.

### **3.5 Supervisor Reports and Peer Review**

#### **3.5.1 Progress Reports by Supervisors**

Evaluation by supervisors is commonly used to assess clinical practice in medicine. It is closely related to the workplace assessments described above, however supervisor reports tend to reflect performance over a period of supervision time rather than a single encounter. Progress reports can be presented in many different formats, and are commonly used at regular periods in postgraduate medical training for formative assessment, with the final report at the end of the training period used for summative assessment.<sup>110,143,302</sup>

Progress or supervisor reports have the benefit of including the tacit elements of professional competence otherwise overlooked by objective assessment instruments.<sup>262</sup> Tools which describe behaviours at different levels of practice have been shown in some settings, such as paediatric psychiatry, to have good reliability to demonstrate competency and skill progression when multiple evaluations are used.<sup>304</sup> However there are limitations: evaluators may have different standards and be subject to halo effects and racial and sex bias. Such reports are therefore found to have low inter-rater reliability.<sup>262</sup> To compensate for this, multiple assessments should be undertaken using standardized rating forms, preferably from multiple supervisors.

#### **3.5.2 Peer Review and Multi-Source Feedback (MSF)**

Peer assessment, multi-source assessment, multi-source feedback, 360 degree feedback, 360 degree appraisal, peer review, and peer rating are different names given to essentially the same process whereby the individual receives formal feedback on his/her performance at work from peers, subordinates and superior managers, often using a rating scale and free text statements.<sup>305</sup> These tools have been used for many years in leadership roles, and more recently in healthcare.<sup>113</sup>

Peer reviews can be done by true “peers”, or can be in the form of “multi-source feedback” (also called “360 degree feedback”). In the latter method, multiple peers are used and include staff working “above”, “below” and “around” the health practitioner and not necessarily in the same profession (e.g. senior and junior medical staff, nursing staff, administrative staff, technical staff, and other health practitioners).<sup>290</sup> The feedback is usually anonymous and compiled by an

independent facilitator. It has been commonly used in the medical profession, where a review from 2002 found that peer ratings are accurate and reliable measures of physician performance and that peers may be in the best position to evaluate professionalism.<sup>262</sup>

A number of different tools have been developed in the UK for doctors. One of the early tools used was the Sheffield Peer Review Assessment Tool (SPRAT).<sup>306</sup> This tool contained 24 questions with ratings on a six-point scale, with space for observations and examples, and was sent to 8-10 reviewers nominated by the doctors themselves.<sup>306</sup> Feedback was independently collated, summarized numerically, and sent back to the trainee together with comments. The SPRAT was then modified with nine questions removed to form the “Mini-PAT”, retaining the six point rating scale and space for comments.<sup>307</sup> The SPRAT and Mini-PAT were found to be valid methods to assess large numbers of doctors, particularly to assess behaviours, which are difficult to evaluate with other methods. The feedback can then be used to inform personal development planning and focus quality improvements.<sup>306,307</sup>

Another similar form of multi-source feedback called “Team Assessment of Behaviours” (TAB) was developed to specifically identify interpersonal attitude and behaviour problems in trainee doctors.<sup>308</sup> The tool had four domains: maintaining trust/professional relations with patients; verbal communication skills; team-working and working with colleagues; and accessibility. Each domain was rated on a three-point scale as “no concern”, “some concern” or “major concern”. Assessors and trainees found the process practical, valuable and fair, although only 23% of supervisors learned something new about their trainees.<sup>308</sup>

In 2010, review of UK doctors who used multi-source feedback (MSF) found that attitudes towards MSF in principle were positive and the tools were felt to be usable although the perceived effectiveness of the tools was low.<sup>309</sup> When evaluated as potential tools for high-stakes assessment, a study of 119 GPs found that multi-source feedback from clinical and non-clinical colleagues was a reliable and feasible assessment suitable for high stakes assessment.<sup>310</sup> In this study, six colleagues providing feedback on two separate occasions were found to provide adequate reliability.<sup>310</sup>

Multi-source feedback (in the form of “mini-PAT”) has been used successfully by junior hospital pharmacists in the UK as part of formative assessment, as described by Patel et al. It was subsequently implemented as a tool for hospital pharmacists in Queensland.<sup>311,312</sup> McKenzie et al also used multi-source feedback successfully as a component of a suite of tools used for summative assessment of advanced practice in critical care pharmacists.<sup>286</sup>

Some of the important concerns raised by researchers include inter-rater variability, particularly if used in high stakes summative assessment versus formative assessment.<sup>309</sup> Research by Archer and McAvoy found that the ratings by practitioner nominated assessors were higher than that of employer nominated assessors.<sup>313</sup> The importance of effective feedback of results by the educator has been stressed, together with the lack of evidence that the use of peer rating improves or predicts patient outcome.<sup>305,309</sup> The real impact on performance improvement has also been questioned, with recent research finding that the majority of free text comments in multi-source feedback included little to facilitate improvement of the assessee's personal development and performance.<sup>314</sup>

On the whole MSF is a reliable and feasible tool to assess practice for health practitioners including pharmacists. Successful use of MSF depends on factors such as number and choice of assessors. The format of the tool is also important. It must be simple to use – preferably electronically – and not too time consuming for assessors to complete.<sup>286,312</sup>

Peer review was one of the highest favoured evaluation methods in the Royal Pharmaceutical Society advanced practice credentialing report.<sup>112</sup>

### **3.6 Objective Structured Clinical Examinations (OSCEs)**

Objective Structured Clinical Examinations (OSCE) were defined by Epstein and Hundert as '*timed multi-station examination often using standardized patients to simulate clinical scenarios*'.<sup>262</sup> This process has been used widely in medical education and has also taken up by nursing and allied health professions. OSCE is included as a component of pre-registration training and assessment for pharmacists in the UK and Australia.<sup>113,315,316</sup> The use of a standardised patient means that OSCEs contain less variation but are closer to a "real world" environment than an examination can be. Another advantage of OSCEs is their ability to assess a range of tasks and skills within the same session.<sup>113</sup> As long as there is a sufficiently large number of patients/cases, OSCEs allow reliable rating of communication, physical examination, counselling and technical skills.<sup>262</sup>

However, OSCEs have a number of limitations. They are time intensive and costly to prepare and administer, particularly if paid rather than volunteer patients are used, and if experienced practitioners are used as evaluators.<sup>113</sup> Epstein and Hundert stated that the OSCE has low test reliability for measuring clinical ethics in medical officers.<sup>262</sup> Some researchers have found that the OSCE's process, using a set of required steps undertaken in order may not be appropriate for evaluation in the postgraduate context where most experienced physicians approach clinical decision making in a non-linear fashion.<sup>113,290,317</sup> OSCEs were not a favoured technique in the

Royal Pharmaceutical Society credentialing report, and not favoured by the Neonatal and Paediatric Pharmacists Group.<sup>112</sup>

### **3.7 Knowledge Based Examinations (oral and multiple-choice)**

Standardised multiple-choice question (MCQ) examinations are commonly used for assessment across health practitioner fields, particularly for large numbers of undergraduate students. They are economical, easy to use and administer and can test a range of knowledge in a short period of time.<sup>113</sup> They are thought to offer excellent reliability in evaluation of factual knowledge and problem solving skills, and can assess some aspects of context and clinical reasoning.<sup>262</sup> However even designed well, MCQ examinations only reliably test the “knows” level of the Millers Pyramid.<sup>261</sup> They do not test the ability of the practitioner to put theory into practice, and standardized test scores have been inversely correlated with empathy, responsibility and tolerance.<sup>113,262</sup>

Despite these reservations, MCQ examinations are used for high stakes evaluation of advanced practice in some health practitioner fields. They are one of the two mandatory summative assessments for medical officers in Australia to move from basic to advanced training<sup>110</sup> and used as the assessment for credentialing purposes by the Board of Pharmacy Specialties in the USA.<sup>128</sup>

There has been debate about the validity of an exam as the sole evaluation criteria. The American College of Clinical Pharmacy supports board certification, although it acknowledges that the board examination is a ‘*valid assessment of a pharmacist’s level of specialized knowledge in a designated area of practice*’, not necessarily assessment of skills, attitudes or behaviours.<sup>318</sup> Nevertheless, the process of preparing for the examination may in itself improve skills of the pharmacist. This was found by Westanmo et al where pharmacists who had undertaken the Board-Certified Pharmacotherapy Specialist examination participated in a nine-month curriculum and email study group to assist in preparation for the exam.<sup>319</sup> They found that 74% of respondents made interventions that they would not have previously undertaken, and 91% agreed or strongly agreed that studying for the BCPS examination helped them gain knowledge that improved the care they give as pharmacists.<sup>319</sup>

MCQs were not a favoured method of evaluation in the Royal Pharmaceutical Society credentialing report.<sup>112</sup>

### **3.8 Reflection and Learning Plans**

Reflection is a key component of education, training and continuing professional development for most health professions. It is used in undergraduate training, for registration and revalidation purposes, and is an important component of effective portfolio-based learning. There is a great deal of evidence to support reflection as being an important step in transforming superficial learning into deeper learning, with a change in thinking that then changes practice.<sup>320</sup> Insight may be developed through reflecting on and writing about professional and personal experiences, resulting in greater self-knowledge.<sup>321</sup> However, for transformation in practice to occur as part of reflective practice, it is important to have a trained facilitator or mentor, and a supportive organisation.<sup>320</sup> The use of such tools has now become so ubiquitous that there are some opinions appearing in the literature suggesting that reflection activities have now become “ritualistic” and have lost their potential impact.<sup>320</sup>

Learning plans are closely related to reflection. The trainee records their learning needs, the means of achieving them, expected time of completion and means of verification.<sup>262</sup> This is a required learning activity twice yearly for Australian advanced medical trainees and is recommended by many professional organisations.<sup>102,261</sup> Reflection activities and learning plans can also be included in a professional portfolio.

### **3.9 Viva Voce (Oral Interview)**

A viva voce, also called an oral interview or examination, is an ‘*oral examination characterised by face-to-face interaction between an examinee and one or more examiners*’.<sup>113</sup> Interviews in a variety of forms have been used for many decades as a preferred tool for recruitment and selection in the workplace, but have declined in use for assessment purposes in undergraduate and postgraduate education. The traditional viva, as used in assessment of research higher degrees and medical education, was usually an unstructured oral examination within a particular subject area away from direct patient care, with the theoretical advantage of being able to assess clinical reasoning.<sup>322</sup>

Format of the interview is important for success. A review of recent studies on interview reliability in the employment context found that “structured” interviews show greater predictive validity of job performance compared to “unstructured interviews, minimising the impact of self-presentation tactics, and without the adverse impact typically found with cognitive ability tests.”<sup>323,324</sup> Past behaviour interview questions (where applicants were asked to recall what they actually did in

situations) predicted supervisors' performance ratings while situational interviews did not.<sup>323</sup> Although both situational and past behaviour description interviews that assessed team playing behaviour correlated with typical performance.<sup>323</sup> Likewise, research on multiple mini-interviews in health practitioner selection found similar results, whereby behavioural interview questions more reliably differentiated between candidates than situational judgement questions or free-form questions.<sup>325</sup>

Oral interviews are relatively easy to administer and not particularly costly, however they can be subjective in nature and disadvantage extremely nervous practitioners. They can be useful tools for assessment of clinical reasoning, problem solving and decision making, and were one of the highest ranked evaluation methods in the Royal Pharmaceutical Society credentialing report.<sup>112,113</sup> Careful selection of interview panel, and the use of structured questions is likely to enhance the reliability of an oral interview.

### **3.10 Combinations of Methods**

It is clear that each assessment method has its own advantages and disadvantages, with no single method suitable to assess all components of professional practice. The use of multiple assessment methods can overcome many of the limitations of individual assessment methods. The use of longitudinal assessments avoids the need for excessive testing at one point in time and serves as the foundation for monitoring ongoing professional development.<sup>264</sup> Many professional bodies now use a combination of methods for high stakes assessment, reflecting the substantial research in recent years to ascertain the reliability of different combinations.

Combinations of methods are used by the Royal Australasian College of Physicians (RACP) to assess advanced trainees as suitable fellows of the college (and thus grant them consultant status). A written multiple choice examination and an oral examination using direct observation of multiple standardised patients are used as mandatory summative assessments for trainees to move from basic to advanced training. Advanced training then uses a series of formative assessments (case based discussions, mini-CEX, learning needs analysis) and summative assessments using mid and final year supervisors reports and completion of a research project.<sup>110</sup>

The RACP process is supported by recent research that tested the reliability of a toolbox of workplace assessments and found that a combination of five Mini-CEXs, six observations of practice (procedural skills), and one peer review (multisource feedback) combined in a portfolio provided feasible and reliable method of high stakes assessment.<sup>292</sup> A more complex assessment



toolkit was recently reviewed to assess the ward skills of surgeons undergoing resident training. This toolkit involved assessment of physician and patient, teamwork, and clinical skills with a deteriorating patient.<sup>326</sup> This combined toolkit showed excellent reliability and consistency in the research environment. However, because it uses direct observation of the surgeon by trained assessors, it would be time intensive to implement as part of routine practice.<sup>326</sup>

In contrast to these studies, a wide variation was found in the reliability of workplace assessments in a naturalistic (rather than experimental) obstetric and gynaecology setting.<sup>327</sup> This study found that significantly more individual assessments (Case Based Discussions, Mini-CEX and observation of procedural skills) than currently recommended by the accreditation body would be required to achieve a reliable result.<sup>327</sup>

The United Kingdom Clinical Pharmacy Association critical care group used a combination of methods for credentialing in advanced practice, including a Mini-CEX, case based discussion, peer review, portfolio review and oral viva.<sup>286</sup> This was found to be time-consuming and resource-intensive but considered to be a robust future method of credentialing for other specialties.<sup>286</sup> Feedback from three years of credentialing was reported in 2012 with participants reporting that the assessment process was valid and robust.<sup>328</sup>

Credentialing of pharmacists to undertake Medication Management Reviews in Australia requires a combination of assessment methods including portfolio review, clinical MCQs, completed case studies, OSCEs and direct observation of practice using a standardised tool.<sup>113</sup>

### **3.11 Revalidation**

The other challenge is the consideration of revalidation. Once practitioners are validated or certified for the first time, revalidation at a certain period of time is generally considered appropriate. Membership of the Faculty of the Royal Pharmaceutical Society as an advanced practitioner will require revalidation every five years.<sup>119</sup> Medical revalidation (or recertification) is undertaken in the UK, the USA and NZ with varied reports of success. Often revalidation can be onerous, expensive to administer and there are doubts on whether it actually identifies those practitioners who are not competent to practice.<sup>329</sup> Revalidation is currently proposed for introduction to medical registration in Australia.

### **3.12 Conclusion**

A significant amount of research has been undertaken in recent years regarding medication safety and practitioner development, particularly in advanced pharmacy practice. However, the skills and knowledge required to improve safety and quality of medication use, and improve patient outcomes for children, is still to be determined. These changes and improvements in practice appear to require advanced skills, such as leadership, communication, research and change management.

To determine whether advanced practice pharmacists make a difference to patient outcomes in paediatrics, it is necessary to first define what advanced practice is, and determine how to assess it. Assessment of advanced practitioners will likely require a range of methods, to be sufficiently reliable to encompass the breadth of qualities and competencies expected of an advanced practitioner. The challenge for advanced practice assessment will be to determine what combination of different assessments will form a robust, reliable, valid and feasible evaluation of practice across a variety of pharmacy practice settings.

The issues discussed in these last chapters regarding case identification, measurement of patient outcomes, definition of advanced skills, development and assessment of advanced pharmacy practice will be investigated in the following chapters.

## 4 Chapter Four: Characteristics of Adverse Medication Events in a Children's Hospital

### 4.1 Introduction

The first step in investigation of adverse medication events in children is to determine how best to identify events. This chapter investigates three potential data sources for adverse medication events in children: clinical incident reports, pharmacist intervention reports, and administrative coding using the International Classification of Diseases 10<sup>th</sup> Revision Australian Modification (ICD-10). As discussed in Chapter 2, incident and intervention reports (forms of voluntary reports) are valuable sources of information on adverse medication events in hospitals, particularly those with a strong safety culture. However these are known to underestimate the true incidence of error. ICD-10 coding is used for administrative purposes, however with specific codes for adverse events related to medicines, it is a potential source of additional information on harm in hospitalised patients. This study investigated six months of reports from each of the three data sources to investigate the level of cross-over of reporting and identify which data sources were feasible for further use in a larger longitudinal study to investigate trends in adverse medication events over time.

The hypothesis for this project is:

*ICD-10 coding identifies different adverse medication events in hospitalised children than incident or intervention reports, and is a feasible case identification method for ongoing research and quality assurance purposes.*

This chapter has been accepted for publication by the Journal of Paediatrics and Child Health.<sup>330</sup>  
The definitive version is available at [www.wileyonlinelibrary.com](http://www.wileyonlinelibrary.com).

## **4.2 Manuscript Abstract**

### ***Aim:***

To compare adverse medication events (AMEs) reported in children, via the International Classification of Diseases 10th Revision Australian Modification (ICD-10-AM) coding with events reported via other data sources.

### ***Method:***

AME reports were retrieved using codes Y40-Y59 and X40-X44 over 6 months. Patients' charts were manually reviewed to identify events associated with error and/or harm with medicines, during a hospital admission. Medication name, group, error, harm, and alert documentation were recorded. Clinical incidents and pharmacist interventions were reviewed for the same period. .

### ***Results:***

263 events from January to June 2011 were recorded by ICD-10 coding in 180 patients. After duplicated, missing or unrelated events were excluded, 146 AMEs remained. In the same period, 117 AMEs were reported as incidents and 190 as pharmacist interventions. In total 276 children with 447 events were reported via all sources. Little duplication between data sources was evident.

In total 158 events involved harm, with 135 of these from ICD-10 coding, 16 from incident reports and 2 pharmacist interventions (including 6 events from multiple sources). Error was involved in 3% of ICD10 reports, 97% of incidents and 100% of interventions. Only 14% of harm related events from ICD-10 were documented on the medical record clinical alert. Chemotherapy accounted for 31% of harm-related events, antimicrobials 18%, corticosteroids 14% and narcotics 12%.

### ***Conclusion:***

Of the harm related events 85% were documented via ICD-10 coding with few documented in other databases. Review of ICD-10 coded AMEs can provide valuable information to improve patient safety and quality.

### **What is already known on this topic:**

1. Harm from medications is common in children.
2. Chemotherapy, corticosteroids, narcotics and antimicrobials are common causes of harm from medications in children.
3. Voluntary reports from health professionals are an incomplete record of adverse medication events in hospital.

### **What this paper adds:**

1. Use of ICD-10 coding to identify adverse medication events provides valuable additional information to highlight areas to improve quality use of medicines in children.
2. Administrative coding using ICD-10 identifies many instances of harm from medications not identified elsewhere but few events associated with error.
3. Improvement is required in permanent recording of adverse medication events (including to the Therapeutic Goods Administration).

## **4.3 Manuscript Introduction**

It is well known that children are at risk of Adverse Medication Events (AMEs) and are approximately three times more likely to experience a potential adverse medication event than the adult population.<sup>43</sup> Although there has been substantial research on AME's across the world, the research in paediatrics is limited. A large all-ages study conducted in Australia in 2003, using routine national data sets, found that 2-4% of all hospital admissions are medication-related with up to three-quarters potentially preventable.<sup>27</sup> A recent Australian paediatric study using intensive chart review and voluntary reporting found that harm-related AMEs occurred in 7 per 100 patients.<sup>37</sup>

Comparison between studies is difficult as there are significant differences between existing published research in case identification methods and definitions used for error and harm. Voluntary or spontaneous reporting of AME's is known to significantly underestimate the incidence of error, however other methods using chart review or direct observation are extremely time intensive.<sup>187,331</sup> Adverse events identified via clinical coding using the International Classification

of Diseases have been studied, however rarely compared to other data sources of adverse medication event data.<sup>188,332</sup>

Most healthcare institutions have systems in place for reporting adverse medication events at an institutional level, to the regulatory body (Therapeutic Goods Administration in Australia)<sup>333</sup>, and recorded for the individual patient to minimise the risk of inadvertent re-exposure. However, despite this being a routine expectation, this documentation is often poorly completed.<sup>334,335</sup>

#### **4.4 Aim**

The aim of this study was to review adverse medication events (AMEs) reported in hospitalised children using coding from the International Classification of Diseases and Related Health Problems, 10<sup>th</sup> Revision, Australian Modification (ICD-10-AM), and compare with:

- 1) Events reported via other databases,
- 2) Patient's permanent (hard copy) clinical alert record, and
- 3) Specialised electronic health records

#### **4.5 Method**

##### ***ICD-10 reported events***

The study retrieved AME reports for patients coded as having an adverse event related to a medication using codes Y40-Y59 (“drugs, medicaments and biological substances causing adverse effects in therapeutic use”) and X40-X44 (“accidental poisoning by and exposure to noxious substances”) over a 6 month period (1<sup>st</sup> January 2011 to 30<sup>th</sup> June 2011) in one Australian tertiary paediatric hospital. ICD-10 coding was recorded as part of routine practice for all admitted patients by Clinical Coders using the International Classification of Diseases 10<sup>th</sup> Revision - Australian Modification and 3M Codefinder Software™ (3M Australia). Patients' medical notes (including progress notes, medication charts, discharge and clinical handover notes) were reviewed manually to identify date of reaction, medication name and group, and assessment of error and harm.

##### ***Other data bases recording events***

Voluntary reports of clinical incidents recorded in the hospital-wide incident reporting system (PRIME®) and clinical pharmacist interventions documented in the hospital dispensing system (iPharmacy®) were retrieved for the same time period.

### ***Documentation of event in other records:***

Documentation of the ICD-10 coded events in the permanent (hard copy) clinical alert record was manually reviewed. Electronic patient profiles in the pharmacy information system (iPharmacy®) and the oncology information management system (Pharmacy Oncology Information Management System or POIMS®) were reviewed to determine if the event was documented.

All Adverse Drug Reaction reports to the Therapeutic Goods Administration were reviewed.

### ***Exclusion criteria***

Patients and events were excluded if charts were unable to be identified after a minimum of two requests to medical records department. Events were excluded if the report did not relate to medicines, occur during admission, or involved neither error nor harm.

### ***Definitions***

Adverse medication events are referred to as injuries resulting from medical interventions related to a medication.<sup>23</sup> Potential adverse medication events are defined as medication errors with potential for injury but in which no injury occurred.<sup>23</sup> Adverse medication events can therefore encompass both harm that results from the intrinsic nature of a medication (an adverse drug reaction) and harm that results from medication errors.<sup>27</sup> This study included potential and actual adverse medication events, but excluded error prone conditions where there was neither error nor harm. (For example, pharmacist interventions where a proactive change in therapy was made but was not associated with harm or error at that time, or incident reports describing deficiencies in documentation or rule violations without risk of harm to the patient.)

Assessment of severity of harm used in this study was an adaptation of that used by Gazarian et al<sup>37</sup> with additional clarification from the National Coordinating Council for Medication Error Reporting and Prevention<sup>336</sup> and Kale et al 2012<sup>337</sup> (see Table 4.1).

Assessment of error used the definition by Ghaleb et al '*A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice*'.<sup>16</sup> This definition was expanded to include other non-prescribing errors.

Events from incident and pharmacist intervention reports were coded using the same definitions.

**Table 4.1 Definition for Severity of Harm**

	<b>Definition for Severity of Harm</b>
Nil	
Minor	Increased level of care e.g. medical review and/or referral, additional investigations or medical therapy; This involved little or no threat to life or function, and could include elevated or depressed laboratory tests, dizziness, insomnia or headaches.
Moderate	Permanent reduction in bodily function; or temporary harm increased length of hospital stay; or surgical intervention required. This could include excess sedation, allergic reactions (more than a rash but not anaphylaxis e.g. shaking, chills or fever). An increased length of stay was assumed if admitted to the intensive care unit.
Major	Major permanent loss of bodily function or disfigurement. An intervention may have been required to sustain life. Includes life-threatening adverse medication events such as anaphylaxis.
Serious	Death

### ***High Risk Medications***

Medications were categorised to groups of known high-risk medications to determine which medication groups were most associated with harm in children in this setting. Categories of high-risk medications used the commonly used acronym of “PINCH” for Potassium, Insulin, Narcotics, Chemotherapy and Heparin and anticoagulants commonly used in adult medicine.<sup>338</sup> Additional categories included intravenous fluids, antimicrobial, antiepileptic, and anaesthetic agents, and corticosteroids and immunosuppressants were added as a significant cause of harm and mortality in paediatrics.<sup>10,85,87,339</sup>

### ***Quality Assurance***

One research pharmacist retrieved the information regarding the event from the patient notes and recorded a description of the event. A second, more senior pharmacist independently reviewed the notes of each event and coded for error and harm. Differences in coding were identified and consensus reached via discussion. Time spent retrieving the data was also recorded.

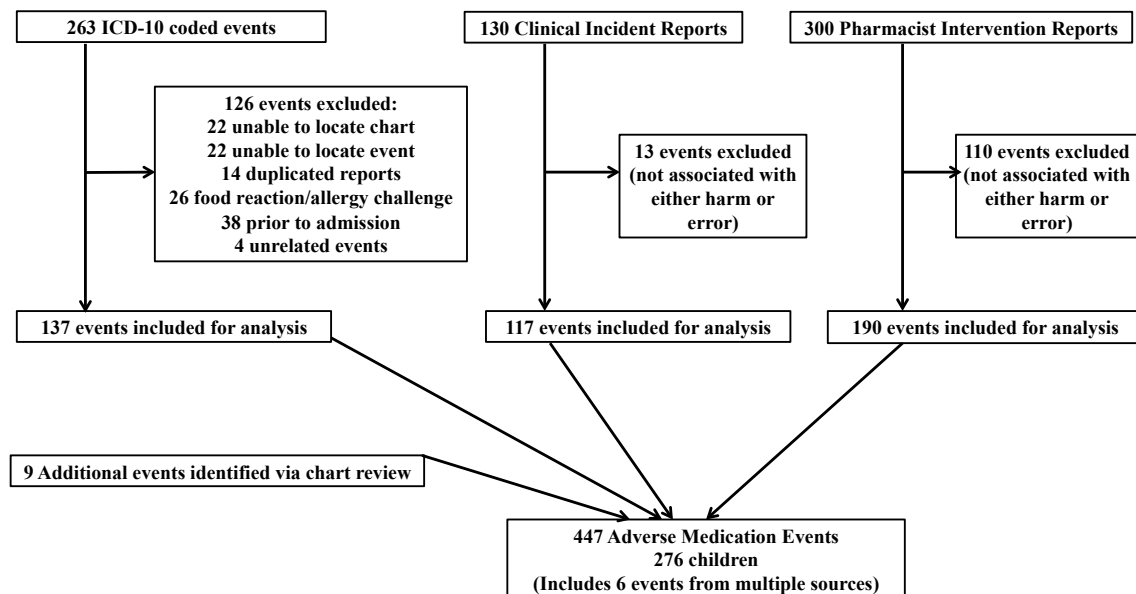
The study was reviewed and approved by the institution’s Human Research Ethics Committee (HREC/12/QRCH/22).



## 4.6 Results

### Case Identification

A total of 263 individual events from January 2011 to June 2011 were recorded by ICD-10 coding in 180 patients. Charts were unable to be accessed for 22 events (15 patients), and 22 events were unable to be identified in the medical record. Events were excluded due to duplication of reports (14), admission for management of allergic reaction or allergic challenge (26), adverse event occurring prior to admission (38) and event not related to an adverse medication event (4). After missing or unrelated events were excluded, 137 AMEs remained for analysis. (See Figure 4.1) An additional nine events were identified during review of patient notes that had not been coded as adverse events.



**Figure 4.1 Case Identification Chart**

In the same period 130 adverse medication events were reported as clinical incidents, with 13 events excluded as not associated with harm or error (e.g. system or documentation issues not involving error), with 117 events remaining. Pharmacist interventions contributed 300 initial

reports, with 110 events excluded as not involving harm or error (e.g. optimisation of therapy by a pharmacist) leaving 190 events.

In total 276 children with 447 adverse medication events were reported via ICD-10 codes, clinical incident, clinical intervention databases and chart review. The maximum number of events per child was nine, with 32% of the children experiencing two or more adverse medication events during the six-month study period.

### ***Comparison between data sources***

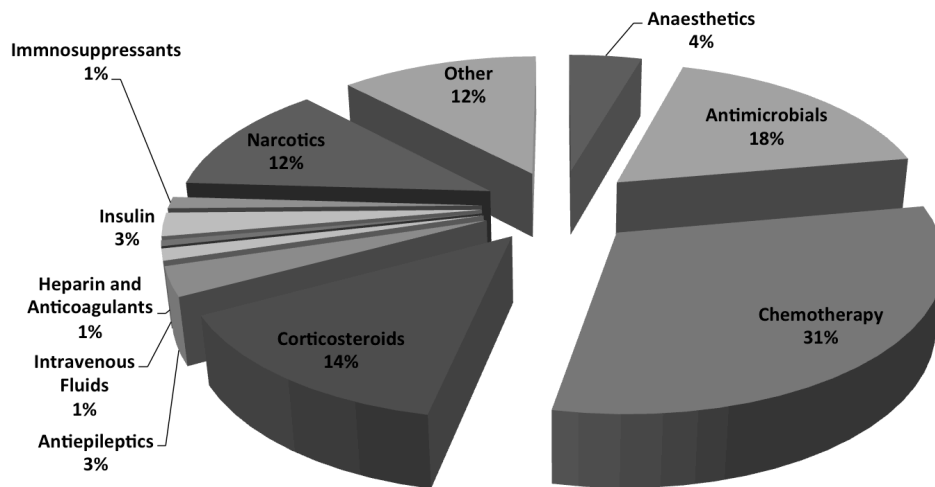
There was little duplication between the data sources, with only six events recorded in two sources: four recorded via incident and coding reports, one as an incident and pharmacist intervention and one as an intervention and ICD-10 coded report. No events were recorded in all three sources.

The datasets reported different rates of medication groups, harm and error. From the total of 447 reported events, 158 events (35%) were associated with harm. Of these 135 (85%) were from ICD-10 coding, 16 from incident reports, nine from chart review and two pharmacist interventions. The proportion of harm in the reports also differed: 99% of the ICD-10 coded events were associated with harm, 14% of the incident reported events and only 1% of the pharmacist intervention reports. In contrast, only 3% of the ICD-10 coded events were associated with error, in comparison to 97% and 100% of the incident and intervention reports.

### ***Assessment of harm***

Of the 158 events involving harm, 80% were considered minor, 18% moderate and 2% major. All of the major harm events involved anaphylaxis, unrelated to error. Of the 28 moderate harm events, only three involved error (including incorrect dosing of amphotericin or inadequate monitoring). Most of these events involved allergies or known adverse drug reactions such as diabetes from high dose steroids, excess sedation or respiratory depression from narcotics and nephro or ototoxicity from chemotherapy or aminoglycosides.

## *Comparison between medication groups*



**Figure 4.2 Harm Related Events by Medication Group**

When considering the medication groups most associated with harm, 31% of the harm-related events were from chemotherapy, 18% from antimicrobials, 14% from corticosteroids and 12% from narcotics. The individual medications most frequently associated with harm were dexamethasone (11), morphine (9), methotrexate (8), vincristine (8) and oxycodone (7). Almost all dexamethasone harm events were when high doses were used as part of chemotherapy protocols, and involved either elevated blood glucose levels or avascular necrosis. There were seven reports of harm associated with general anaesthetics, including hypotension, bradycardia, respiratory distress and nausea and vomiting.

### ***Documentation in other sources***

Of the ICD10 coded events, 14% were recorded on the permanent hard copy patient alert record, 8% were recorded electronically in the dispensing system (iPharmacy), and 11% of the events in oncology were recorded in POIMS®.

No adverse medication events involving medicines were reported to the Therapeutic Goods Administration.

There were 128 labour hours required to retrieve data on the ICD-10 coded events (excluding analysis). This equates to approximately 29 minutes per event identified, and 56 minutes per event meeting inclusion criteria.

## **4.7 Discussion**

ICD-10 coded events represent a different set of adverse events related to medicines in children that are not reported via other mechanisms in this institution. This is similar to the findings of Cox et al in a general hospital in the UK where no overlap was found between adverse drug reactions identified via ICD-10 coding and spontaneous reports.<sup>332</sup>

The coded events represent events more associated with harm from medicines than other sources researched, however few instances of error. The high proportion of harm in ICD-10 coded events is to be expected, as coding is only undertaken where an indication of harm is documented in patient notes. However, the low incidence of error in the ICD-10 coded events was unexpected.

Incident reports largely involved events involving error that did not result in harm. Almost all pharmacist intervention reports were “near-miss” events where the intervention prevented either the error reaching the patient or harm occurring. In many respects, these incident and intervention reports represent quality and safety systems working to prevent harm. Voluntary reporting is known to underrepresent the total number of safety events, with medical officer reporting particularly poor.<sup>331</sup> Research in Australia and internationally has found that the organisational safety culture (e.g. communication openness, routine feedback, non-punitive culture) has a large influence on reporting by health practitioners.<sup>165,166,173</sup> Australian research found that the observed behaviour of professional peers and a belief that safety behaviours will make a difference, were the two factors most influential on the safety behaviours of health care workers.<sup>166</sup>

ICD-10 coding is designed as an administrative rather than clinical tool, therefore unlikely to be a complete record of all AMEs. There were 12 harm events during this period reported as incident reports that were not identified via ICD-10 coding. The question of why clinicians do not document these events in an easily identifiable way in the medical notes deserves further investigation. Nine additional events were identified during chart review of a specific admission that were also not coded as adverse events via ICD-10. There were 26 ICD-10 coded events excluded from analysis as they involved allergy or anaphylaxis to food rather than medicines. Another 22 events were excluded where the details of the event were unable to be identified in the notes. These examples

indicate that the ICD-10 coded events alone do not represent a complete record of all harm events related to medicines, consistent with the findings of Bates et al.<sup>187</sup>

Incomplete recording on permanent alert records (via hard copy in the medical record, electronically in iPharmacy® or POIMS®) increases the risk of harm from unintentional re-exposure to the medication. Parents and carers may recall (and relay to the next health care provider) significant adverse effects they have observed, however those that occur when they are not with the child (such as with anaesthetics during surgery) are a particular risk if not documented carefully. Inadequate documentation of ADR alerts in patient records has been observed by many other researchers, with one study finding only 10% of ADRs recorded in the institution's electronic patient record.<sup>334</sup> An electronic health record with integrated clinical alerts supported by a well designed paediatric clinical decision support system should assist with documentation and prevention of AMEs in the future.

No reactions were reported to the TGA during the study period, including two reported reactions of extrapyramidal side effects from metoclopramide at standard doses and one case of extrapyramidal effects attributed to ondansetron. Post-marketing surveillance is an important strategy to identify rare adverse drug reactions, particularly in patient populations not well studied during the initial research phase (such as in paediatrics).<sup>82</sup> In Australia reporting of ADRs to the TGA is included in the National Safety and Quality Health Service Standards.<sup>333</sup> These standards, now linked to hospital accreditation from 2013, may have a positive impact on institutional reporting into the future.

An average of 56 minutes to retrieve data per event is resource-intensive and not suitable for routine quality assurance. This is significantly higher than 19 minutes per event described by Hodgkinson in 2009.<sup>340</sup> This study did however include multiple researchers reviewing each chart for quality assurance purposes, and many of the patients required manual review of multiple chart volumes. Future access to electronic patient notes may make this process more efficient and feasible as an ongoing safety and quality process.

Reliance on reports via voluntary reporting is known to be incomplete, and chart review combined with direct observation is thought to be the most robust method of identifying adverse medication events.<sup>187</sup> Use of chart review in conjunction with interventions and incident reports in an interrupted time series study provided valuable information on the long term reduction of adverse medication events in the study by Gazarian and Gaudins.<sup>37</sup> Computerised trigger tools as evaluated by Bates et al<sup>187</sup> are more accurate and cost-effective than voluntary reporting, and other

researchers have successfully studied periodic random samples of patients using trigger tools validated in paediatrics in conjunction with chart review.<sup>182,183</sup> Unfortunately many errors are not identified or documented in the patient record by the practitioner involved, and harm (particularly in children) may not be identified as associated with the use of medicine. Subtle signs such as lack of improvement, or worsening or new symptoms may be not identified as related to inappropriate medication therapy, and therefore would not be reported in any of these data sources.

This study has found that ICD-10 coding identifies events of harm from medicines that are not reported via other databases. This method could be used for this purpose in other hospital settings, however manual data retrieval of ICD-10 coded events is time consuming, and the dataset is not sufficiently sensitive or specific for routine use without a computerised medical record. Organisational efforts to demonstrate positive change leading from reporting, and senior clinical leaders modelling patient safety behaviours may be the most effective strategies to engage clinicians in reporting incidents and documenting events in the medical notes.<sup>166</sup> With the introduction of electronic patient health records, a combination of methods such as computerised trigger tools, ICD-10 coding and voluntary reporting may be a feasible long-term strategy to identify AMEs for ongoing quality assurance and research purposes.

#### **4.8 Manuscript Conclusion**

ICD-10 coded AMEs represented 85% of the harm related events documented, and few were recorded in other databases. However, few ICD-10 coded events were associated with error and therefore may have limited preventability. Recording on the clinical alert page in the patient medical record, and other permanent electronic records was poor. Review of ICD-10 coded AMEs resulted in valuable information on harm from medicines experienced by children in hospital that is not recorded in other databases, however is time-consuming and not a viable ongoing process until electronic patient records are available.

#### **4.9 Chapter Conclusion:**

When considering the original hypothesis, ICD-10 coding does identify different adverse medication events in hospitalised children than incident or intervention reports, however it is not currently a feasible case identification method for ongoing research or quality assurance purposes while reliant upon hard copy patient records.

## **5 Chapter Five: Adverse Medication Events – are we making a difference with high-risk medications in hospitalised children?**

### **5.1 Introduction to Chapter Five**

This chapter investigates eight years of adverse medication (drug) events in a children's hospital to identify the skills required of pharmacists to effect sustained improvements in patient care, particularly with respect to medication safety. It is important to identify how high-risk medications cause harm in children to ensure appropriate safety initiatives are implemented.

This chapter builds on the results from the adverse medication event research described in Chapter 4, where adverse medication events identified via ICD-10 coding were compared to those reported as clinical incidents and pharmacist interventions. That study found that ICD-10 coding identified the largest proportion of harm events however these events were not associated with error (therefore not preventable) and were time intensive to retrieve. This was in contrast to pharmacist intervention and clinical incident reports, which were the most effective at identifying events involving error and were more feasible as case identification strategies for a longitudinal retrospective study.

Safe medication systems and appropriately skilled and competent health practitioners (including pharmacists) are essential to ensure effective change in practice and improvement in safety. It is important to identify the most successful safety improvement strategies, and the skills required of health practitioners to enact these changes. The hypothesis of this project is:

*Voluntary reports of medication related events can be used to identify trends in response to safety improvement initiatives, and identify associated skills required of health practitioners.*

## 5.2 Manuscript Introduction

Adverse medication events (AME) have been defined as ‘*an injury, large or small, caused by the use (including non-use) of a medication*’<sup>341</sup> and AMEs are known to be a significant cause of morbidity and mortality for hospitalized children.<sup>26,43,342</sup> Although children commonly take fewer medications than adults, they are at an increased risk of adverse medication events due to changing pharmacokinetic parameters, the need to calculate individualized doses, lack of suitable dosage forms, precise dose measurement and medication delivery systems, and lack of published information and licensed products for use in children.<sup>54</sup>

Research into medication safety in children has increased over recent years, from identifying incidence of error and harm, particularly in comparison to the adult population, to more recent research investigating the effectiveness of safety prevention strategies. Early research from the United States found that potential adverse medication events were three times more common in children than in adults, and this has been reinforced by recent research from Spain identifying a fourfold higher risk of serious errors in children, in comparison to the maternity population.<sup>43,49</sup> A recent study across five paediatric hospitals in the UK found a prescribing error rate of 13.2% of medication orders and an administration error rate of 19.1% of doses.<sup>15</sup>

Contributing factors for adverse medication events have been investigated, with research from the 1990’s and early 2000’s demonstrating that system related problems including inadequate education and training, physical infrastructure, work processes, and interruptions, contributed to many adverse medication events.<sup>25,54,96,212,232,343,344</sup> A range of strategies have been suggested, with varied evidence for their effectiveness in improving safety.<sup>41,96</sup>

Recent studies in Australia and the USA involving children, have demonstrated significant reductions in adverse medication events (42% and >50%) after introduction of a combination of system level error prevention strategies, including targeted multimodal multidisciplinary education, audit and feedback and use of a standardized paediatric national inpatient medication chart.<sup>37,183</sup> Likewise, a study in Argentina found a reduction in paediatric medication errors after introduction of a non-punitive safety culture and prescribing and administration recommendations.<sup>345</sup> Similar results have been seen when reviewing all hospital safety events in paediatric institutions after introduction of a number of cultural changes.<sup>167,168</sup> One of the challenges when comparing results from medication safety research is the differing definitions and case identification methods used. Consequently studies investigating long-term trends in paediatric medication safety have been lacking.



The aims of this study were to review trends in medication related events in one tertiary paediatric hospital and to determine the impact of the initiatives and identify success factors implemented progressively over an eight-year period. .

### **5.3 Method**

#### ***Setting***

This retrospective study reviewed medication related events (MREs) in one 170 bed tertiary paediatric hospital over an eight year period. The hospital used paper-based medication charts in most clinical settings, used a ward-stock system for most medication supply, and had a limited clinical pharmacy service (weekdays only, for overnight patients). Electronic voluntary reporting systems, which were anonymous and non-punitive, were introduced in 2005,

#### ***Inclusion and Exclusion Criteria***

Inclusion criteria were voluntary reports of MREs from January 2005 to December 2012 from two electronic databases:

- Medication related incidents from a clinical incident database called “PRIME™”. Clinical incidents were defined as *‘any event or circumstance which has actually, or could potentially, lead to unintended and/or unnecessary mental or physical harm to a patient’*.<sup>346</sup>
- Pharmacist interventions from electronic records documented in the pharmacy dispensing system called “iPharmacy™”. Clinical pharmacist interventions were defined as *‘any action by a pharmacist that directly results in a change in patient management or therapy’*.<sup>38</sup>

Reports required a minimum of: date of event, clinical area and a narrative description of the event. Most reports also included the patient medical record number, medication name, and the reporter’s assessment of severity and harm. Both electronic databases were significantly upgraded during the study period, which modified some additional data recorded, however the core dataset remained unchanged.

Exclusion criteria were:

- Reports with missing narratives describing the event
- Reports unrelated to medicines (e.g. blood products)

- Event did not occur during the hospital admission.

Datasets from PRIME and iPharmacy were combined and reviewed to identify multiple reports for the same event (different staff reporting the same event, and/or the same event reported in both datasets). Multiple reports were identified using matched date of event, patient medical record number and narrative. Data from each original record were combined to create a single unique event record.

### ***Assessment of Medication Related Events***

Each Medication Related Event (MRE) was then classified as:

- Harm or no harm
- Error or no error
- Stage of the medication cycle during which the MRE occurred was identified (prescribing, dispensing and supply, administration or monitoring)
- Medication group

Definitions for harm used the trigger tool harm definitions by Tham et al, which included significantly abnormal laboratory values such as raised creatinine, hypo/hyperkalaemia, hyper/hypoglycaemia and anticoagulation lab values out of range. Unrelieved pain or vomiting were also considered harm.<sup>183</sup>

The definition for prescribing error as defined by Dean et al and validated by Ghaleb et al in paediatrics was used for events related to prescribing; this included a list of examples of events considered to be errors.<sup>14,16</sup> The authors chose to extrapolate the prescribing error definition to non-prescribing errors, using a broader definition of '*unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice*'<sup>14</sup> for other areas such as administration and dispensing. Errors related to documentation or variation from local policy, if unlikely to be associated with increased risk for the patient, were not classed as errors. Additional clarification of errors in administration included '*a medication given in a dose different by at least 20% from the recommended dose*'<sup>347,348</sup> or '*deviation by 2 hours or more from recommended*'<sup>348</sup> as used by other researchers.

One researcher coded each of the events, based on the agreed definitions, using the narratives and the reporter's assessment of outcome if available. Specific scenarios were discussed with the research team and definitions refined as required. An electronic number randomisation generator was used to select 10% of the high-risk medication events, which were independently coded by a second researcher. Differences in coding were discussed and consensus reached, with clarification of definitions as required.

All events related to medicines during admission were included, regardless of whether they were associated with harm or error. The total dataset therefore included:

- Actual Adverse Medication Events – where harm was involved, with or without error (therefore including Preventable Adverse Medication Events, and those without error, commonly referred to as Adverse Drug Reactions or ADRs)
- Potential Adverse Medication Events – where error was involved but no harm. The error may have been identified before reaching the patient or did not harm the patient.
- Error Prone Conditions – where no harm or error was involved, however the event did involve circumstances or events that have the capacity to cause error. Many pharmacist interventions occurred proactively before an error occurred and belonged to this category. These events were included in the initial analysis but removed for the detailed analysis.

### ***High Risk Medications Investigated***

Events were classified into the following high risk medication groups: Potassium, Insulin, Narcotics, Chemotherapy, Heparin and Anticoagulants, Antimicrobials, Intravenous Fluids, Anticonvulsants, Anaesthetics and Other. These groups were derived from the acronym “PINCH” (Potassium, Insulin, Narcotics, Chemotherapy, Heparin and Anticoagulants) commonly used to classify high risk drugs.<sup>338</sup> Antimicrobials, Intravenous Fluids, Anticonvulsants and Anaesthetics were added as categories as these groups have also been found to be involved in adverse drug events and fatalities in children.<sup>9,35,43,83,87</sup>

Three high-risk medication groups (chemotherapy, potassium and narcotics) were reviewed in detail over the eight years to identify trends over time after introduction of a range of safety initiatives.

Inclusion criteria for chemotherapy analysis were events involving chemotherapy, prescribing and error (with or without harm). Chemotherapy included medicines listed in the chemotherapy

protocol (including non-cytotoxic agents), but did not include routine supportive therapy such as mouth-care and antiemetics. Events were categorised with a proximal cause related to calculation errors, protocol errors, inadequate patient history or related to new technology (which included events associated with the information management system and use of pre-printed charts). To minimise reporting bias, categories were described as a proportion of the total events reported for the oncology team.

Inclusion criteria for potassium analysis were events including errors with the use of potassium, with or without harm, and included all routes of administration. Potassium related events were categorised as prescribing, dispensing, administration and monitoring related events.

Inclusion criteria for initial narcotic analysis were events involving errors with narcotic drugs, including products containing codeine. Narratives from narcotic related events were reviewed to identify events involving confusion related to oxycodone, OxyContin® and MSContin®. The oxycodone/OxyContin® events underwent further analysis and were categorised as prescribing, administration or dispensing errors.

### *Safety Initiatives*

**Table 5.1 - Safety Initiatives Implemented 2005-2012**

	<b>Institution Wide</b>	<b>Chemotherapy</b>	<b>Potassium</b>	<b>Narcotics</b>
In place prior to study period	Medication safety concepts included in medical and nursing orientation. Manual incident reporting system, reviewed by Drug and Therapeutics Committee. Electronic documentation of pharmacist interventions (iPharmacy) from 2004.	Chemotherapy prescribed by oncology registrars. All chemotherapy orders reviewed by an oncology pharmacist before preparation.	Didactic education on risks of IV potassium in medical and nursing orientation. National Medication Alert on the risks of IV potassium. Policy on the safe use of potassium.	General risks of narcotic use included in orientation.
2005	Web based incident reporting system (PRIME). Root Cause Analysis of significant incidents. Standardised national inpatient medication chart for paediatrics implemented, and	Review of incident and interventions related to chemotherapy by oncology team. Chemotherapy prescribing limited to consultants. Pre-printed chemotherapy charts progressively	Pre-mixed intravenous fluid bags containing 20mmol/L potassium were introduced. Restricted access to concentrated potassium ampoules although still available	Codeine routinely used to treat post-operative pain, alone or in combination with paracetamol.

	audited annually	implemented from 2005.	in most clinical areas.	
2006-2007	Incident reports reviewed by Drug and Therapeutics Committee. Intervention reports reviewed separately by Pharmacy Department.	Chemotherapy prescribing training and competency assessment for oncology registrars in 2007.	Smart-pumps introduced to the Paediatric Intensive Care Unit in late 2006.	Oxycodone use increased dramatically, particularly for post-operative pain, replacing codeine.
2008	Medication Safety Sub-Committee introduced, with responsibility to review incident and intervention reports. Drug Use Guidelines produced for high risk drugs including some antimicrobial and antiepileptic medications	An electronic information management system for oncology patients (POIMS®) progressively introduced from 2008 to 2011 (protocol by protocol). (Two paediatric oncology units merged into one at the study site)	Severe harm event involving intravenous potassium in PICU (Root Cause Analysis). Introduction of potassium mini-bags (10mmol/100mL and 40mmol/100mL) to allow for higher concentration infusions.	Education for nursing staff provided (inservices and specific examples in orientation). Cognitive aid (alert chart) on drug safe. Pharmacist annotations on medication chart alerting to sustained or prompt release product.
2009	“Good Catch” and “Safe Prescriber” Awards implemented. Medication Safety Champions identified for each clinical area.		Strong executive support for review of potassium use. Development of hypokalaemia management guidelines with broad multidisciplinary input.	Letter of concern sent to manufacturer. Targeted education to medical staff in orientation.
2010	Review of pharmacist interventions included in performance appraisal. Medication chart audits coordinated nationally (annual).		Hypokalaemia guideline published on state-wide intranet site.	
2011	Annual Grand Rounds presentations on Medication Safety (2011-12).		Medical orientation changed to a case based tutorial, including a potassium supplementation case (2011-12).	Specific OxyContin® confusion example removed from medical and nursing orientation (2011).
2012		Rapid audit and feedback medication chart audits in oncology.		

Table 5.1 describes the various institution-wide and drug specific safety initiatives implemented during the study period for the three drug groups under review. Pharmacists were involved in each of these initiatives: as primary providers in direct patient care initiatives (such as with annotation of prompt or controlled release on narcotic orders); primary providers of institution wide initiatives (such as medical and nursing medication safety orientation); or as members or leaders of

multidisciplinary working groups (such as with hypokalaemia guidelines). These pharmacists, in collaboration with medical and nursing staff, led many of these system redesign activities. Skills were required in critical evaluation of the literature, written and oral communication, collaboration, conflict resolution, negotiation and analysis of clinical incidents.

The electronic information management system for cancer care patients (POIMS®) included information on the patient history, incorporated cancer care pathways with some decision support, and enabled electronic prescribing to generate a hard-copy medication chart. The system was used for patients enrolled in specific cancer protocols, for day and overnight patients, but was not used to generate outpatient prescriptions for therapy at home. Pharmacists were intimately involved in the development and implementation of this system, which required skills in risk, project and change management.

### ***Data Analysis and Ethics***

Information on patient separations (number of patients discharged from hospital) and occupied bed days were obtained from the institutional health information management service to determine incident rates. A trend test for comparison of proportions was used to examine error rates over time from 2005 to 2012 with a two-sided  $p < 0.05$  considered significant. Statistical analysis was undertaken using Stata 12.0 (StataCorp, College Station, TX, USA).

Ethics approval for the study was obtained from the Queensland Children's Health Services Human Research Ethics Committee in February 2012 and institutional approval obtained from the Children's Health Services Executive in March 2012 (HREC Reference Number: HREC/12/QRCH/22, SSA Reference Number: SSA/12/QRCH/31).

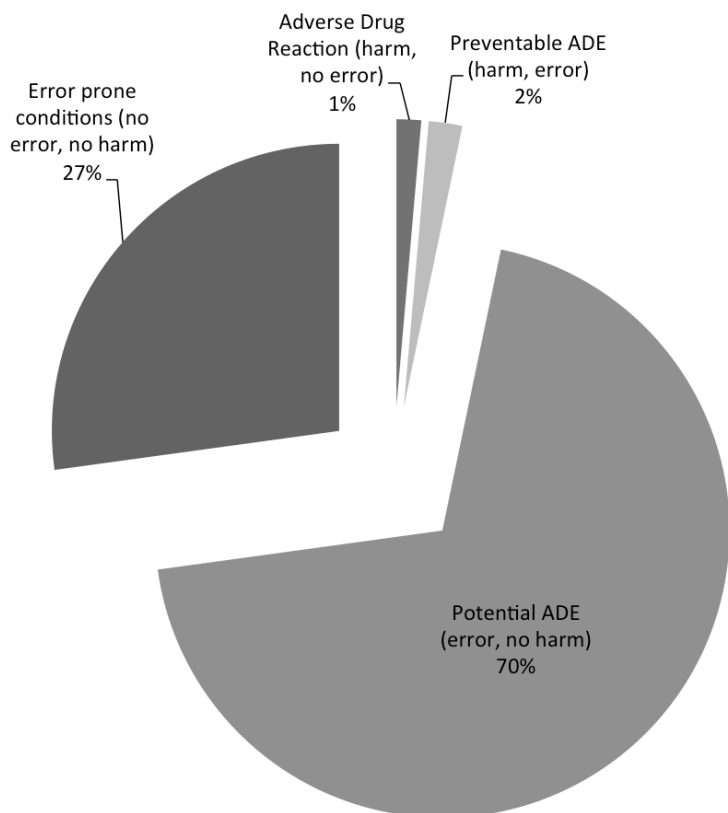
## **5.4 Results**

### ***Harm and Error***

A total of 2,743 incident reports and 8,336 pharmacist interventions involving all types of MRE were retrieved making a total of 11,079 individual reports. Once duplications and unrelated reports were removed, 10,693 separate MREs remained. There was little duplication overall, with only 0.4% of events recorded as both pharmacist interventions and incident reports.

Overall only 3.3% of the events were associated with harm (actual Adverse Medication Events) and 71% of all events were associated with error. Further analysis found that 27% of events were

associated with neither error nor harm, and therefore “error prone conditions”. Events associated with harm but not error (“Adverse Drug Reactions” or ADRs) accounted for 1.4% of events. Events associated with error but not harm (“Potential AMEs”) accounted for 70% of events. There were 202 reported events (1.9% of the total) associated with error and harm, therefore a preventable AME. (See Figure 5.1)



### **Figure 5.1 Medication Event Types**

There was an average of 7.0 Medication Related Events reported per 100 patient separations or 28.3 per 1000 occupied bed days. Medication Errors occurred at a rate of 5.0 per 100 separations, and 0.23 actual AMEs per 100 separations.

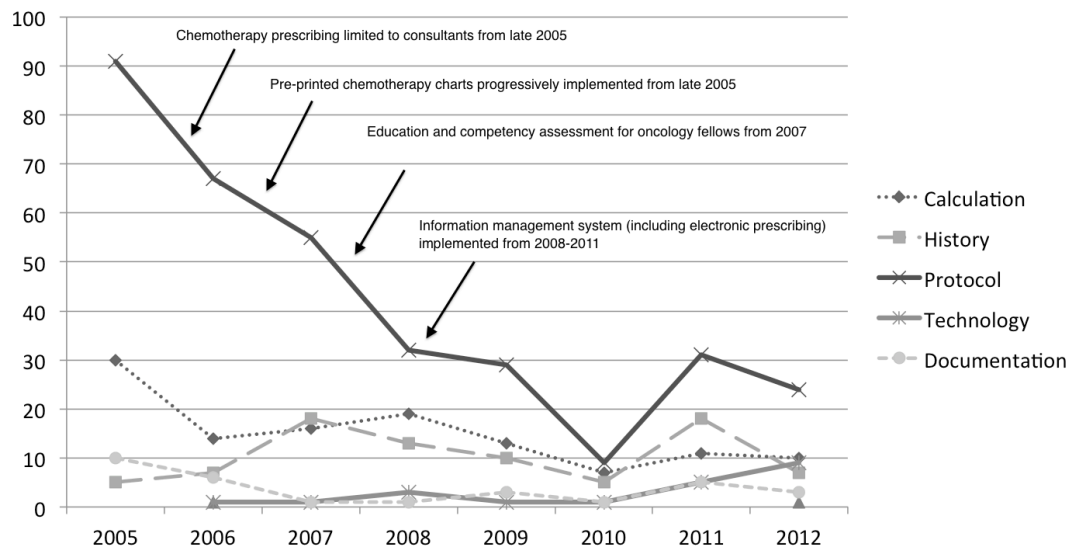
The rate of harm (actual AMEs) reduced slightly from 0.27 to 0.22 AMEs per 100 separations from 2005 to 2012 (or 1.07 to 0.87 per 1000 bed days.) The rate of reported potential AMEs reduced from 6.4 to 3.0 per 100 separations.

## Chemotherapy

There were 925 MRE's involving chemotherapy over the eight years. Total chemotherapy prescribing errors reduced from 4.2 to 1.1 per 100 oncology separations from 2005 to 2012, despite a 54% increase in activity.

Figure 5.2 shows the change in chemotherapy prescribing errors over the eight year period, demonstrating a significant reduction in protocol related errors from 91 to 24 per year, but an increase in errors related to technology (from zero to 9), in particular after the introduction of the information management system.

**Figure 5.2 - Chemotherapy Prescribing Errors**



To reduce the influence of reporting bias, chemotherapy prescribing errors were also analysed as a proportion of the total reported events from oncology and per 1000 oncology separations (See Table 5.2). Protocol related errors reduced from 17% to 12% of all oncology reported events over the eight years ( $p < 0.01$ ).

**Table 5.2 - Chemotherapy Prescribing Errors as a proportion of reported oncology events and separations**

	Number of Prescribing errors	Per 100 oncology events		P value (2005 to 2012)	Per 1000 oncology separations		P value (2005 to 2012)
		2005	2012		2005	2012	
<b>Calculation</b>	120	5.7	4.9	0.84	9	2	<0.01



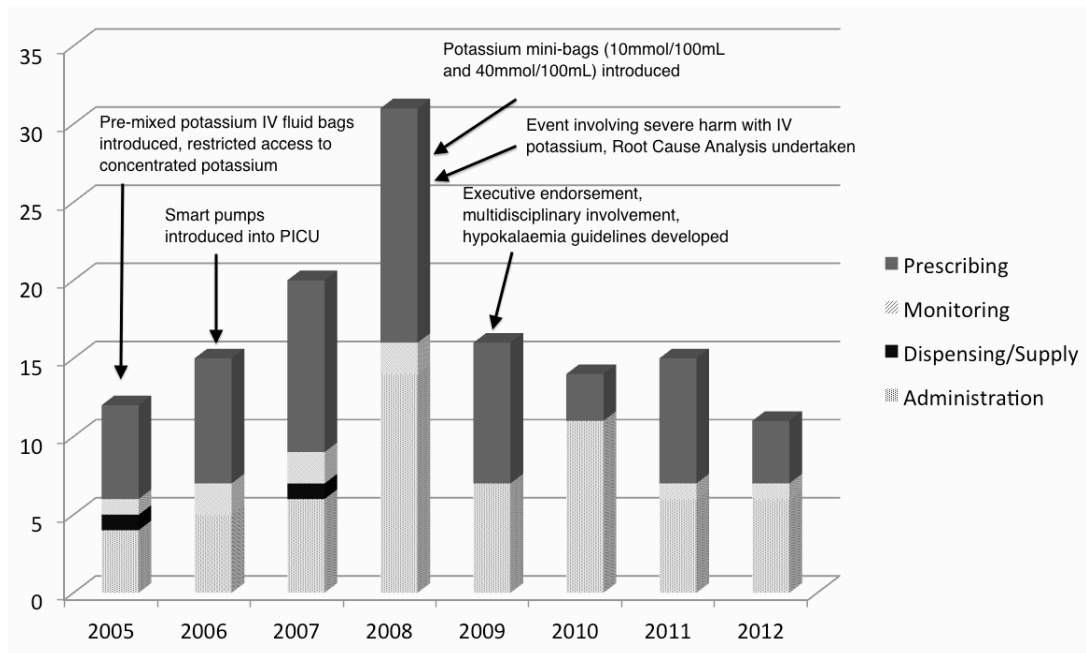
<b>Documentation</b>	30	1.9	1.5	0.91	3	1	<0.01
<b>History</b>	83	0.9	3.4	<0.01	2	1	0.51
<b>Protocol</b>	338	17	12	<0.01	28	5	<0.01
<b>Technology</b>	21	0	4.4	<0.01	1	2	<0.01
<b>Other</b>	2	0	0.5	0.39	0	0	0.91

## Potassium

There were 196 MRE's involving potassium over the eight years, with reported events (and errors) peaking in 2008. Potassium related errors increased from 2.9 per 10,000 bed days in 2005 to 6.3 in 2008 and down to 2.2 in 2012. Prescribing, monitoring and administration related errors all peaked in 2008.

Descriptors of events changed over time, from relatively simple slip/lapse type errors in the early years (such as product selection errors and incorrect addition to IV fluid bags) to more complex errors in the later years involving monitoring and the safest dose, rate and concentration for administration via different routes.

**Figure 5.3 - Potassium Errors**



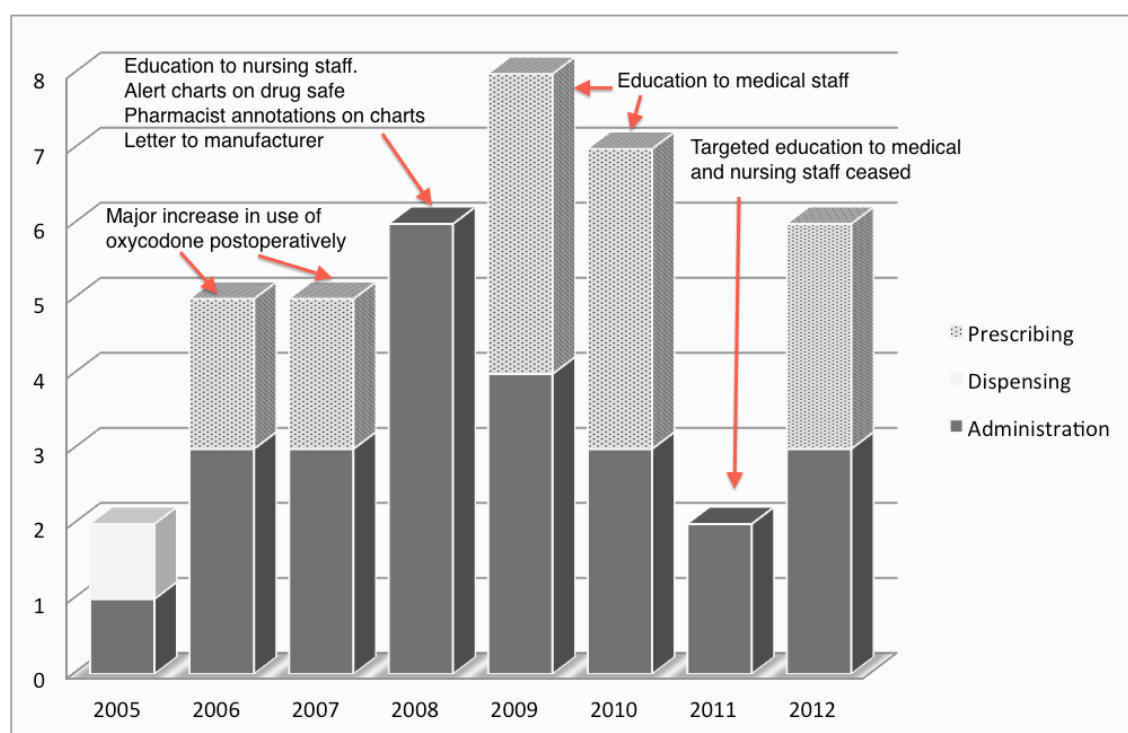
There were five potassium events associated with harm over the eight years, including one event involving severe harm in 2008 where a smart pump was incorrectly programmed resulting in a rapid

infusion of potassium and cardiac arrest. The child was resuscitated and survived, and the incident resulted in a comprehensive multidisciplinary root cause analysis and a strong institutional drive to improve potassium safety. Manufacturer pump settings were modified nationally, potassium mini-bags were introduced and clinical guidelines introduced (see Table 5.3). There were no reports of harm events with potassium after 2008.

### *Narcotics*

ADEs related to confusion between OxyContin®/oxycodone/MSContin® increased from 2 reported events in 2005 to a peak of 8 in 2009 then down to 2 in 2011 after the safety initiatives were introduced, as shown in Figure 5.4. Errors related to administration decreased after introduction of targeted education to nursing staff, alert charts and pharmacist annotation on charts. Prescribing errors reduced after targeted education was introduced to medical staff. Administration and prescribing errors both increased in 2012 after removal of the targeted education regarding this type of error from the medical and nursing education program.

**Figure 5.4 Oxycodone/OxyContin/MSContin errors**



There were only three reports of harm from this type of error, one in 2008 and two in 2009. There were a total of 43 events associated with harm involving all narcotics over the eight years.

## ***Other high risk drugs***

In comparison to the reduction in chemotherapy and potassium errors over the eight years, errors related to antimicrobials and antiepileptics also halved, intravenous fluids increased marginally, and errors related to heparin and anticoagulants increased by a factor of eight. Reporting of therapeutic drug monitoring of antimicrobial and antiepileptics reduced over this period (contributing to an decreased number of reported events in the latter years), although no specific safety initiatives. There were no safety initiatives implemented addressing heparin and anticoagulants events during the study period.

## **5.5 Discussion**

This study describes eight years of voluntary reports of medication related events in a paediatric hospital, and changes over time in adverse medication events associated with introduction of a range of implemented safety initiatives.

The total AME (ie actual harm) rate of 0.23 per 100 patients is lower than that found with some other paediatric research, which is to be expected with the differing case identification methods used. Research using chart review in addition to voluntary reports identified a rate of 3.99 AMEs per 100 patients (Australia), 7.6 AMEs per 100 patients (USA) and 12.9 AMEs per 100 patients (New Zealand).<sup>35,37,234</sup> A more detailed review from the USA using trigger tools in addition to voluntary reports and chart review identified 11.1 per 100 patients.<sup>182</sup>

The medication error rate of 5 per 100 patients is significantly higher than the 0.15 per 100 patients reported in a UK paediatric hospital, also using voluntary reporting alone.<sup>349</sup> The potential AME (error but no harm) rate of 4.9 per 100 patients is comparable to the Gazarian and Graudins result of 4.6 at the end of their study in 2007 using chart review and voluntary reports.<sup>37</sup> The varied results from our study compared to other research reflect not only differences between the case identification methods, but also that simple harm events unrelated to error (also called Adverse Medication Reactions) were unlikely to be reported via the incident or intervention reporting methods, as identified in earlier research.<sup>330</sup> However, when considering the impact of safety initiatives ADR's are also less likely to be preventable than events associated with error.

Voluntary reporting (as used in our study) has been found to significantly underestimate the extent of adverse medication events (those causing harm) in comparison to chart review or direct observation.<sup>84,191,331</sup> However, voluntary reports are relatively inexpensive to maintain on a routine

basis and effective at identifying potential adverse medication events (ie errors that are identified and resolved before reaching the patient), particularly when including pharmacist intervention reports.<sup>191</sup> Rates of voluntary reporting in this study were higher than in many other published research.<sup>15,331</sup> In comparison to voluntary reporting, chart review identifies most harm events (actual AMEs), particularly those related to prescribing, whereas direct observation is the most effective to identify administration errors that may otherwise go undetected.<sup>19</sup> Other case identification strategies have included random samples of charts using interrupted time series, which has been useful for intensive and longitudinal research.<sup>37,177</sup> Trigger tools are also increasingly being utilized for ongoing AME surveillance, predominantly in sites with an electronic medical record, and have been adapted for paediatrics.<sup>182,350</sup> Similarly, ICD coding has been used to identify AMEs, however the recorded events are predominantly not related to error.<sup>330</sup> None of these more intensive case identification methods were suitable in this study due to retrospective collection of eight years of data in a setting with reliance on a paper based medical record.

There were limitations in determining error and harm as it relied upon the written event narrative, however standard definitions by previous researchers in paediatrics, were used to determine error and harm.<sup>14,16,183</sup> In contrast to some published research, this study initially included potential adverse medication events and error prone conditions as well as actual adverse medication events, which allowed for a large number of events to initially investigate. However, only those events classified as error were included when considering trends for individual medication groups.

### ***Institution wide initiatives***

The safety initiatives implemented in this institution have been widely recommended to improve safety and quality of medication use.<sup>41,81,96</sup> True cause and effect are difficult to ascertain due to the sequential and progressive nature of the initiatives implemented, in addition to the limitations of voluntary reporting. However, the safety reporting systems themselves appear to be widely accepted and utilised by hospital staff, in particular nursing and pharmacy staff. The introduction of the multidisciplinary Medication Safety Committee enabled a more focused analysis of reports and implementation of strategies to continue to improve safety. “Good Catch” and “Safe Prescriber” Awards have been a valued acknowledgement of contribution of individuals. Introduction of a standardised medication chart was well accepted with ongoing audits indicating steadily improving documentation, as found by other researchers.<sup>37,351,352</sup>

All of these initiatives have served to raise clinicians’ awareness of risks, the need for reporting, and demonstrating a positive, change orientated approach to medication safety, rather than a traditional

punitive process with a culture of blaming individuals involved in errors. The results from our study were similar to that found in similar research in the USA and Australia, where a combination of strategies embedded in a strong safety culture is key to reduction in preventable harm.<sup>37,167,353</sup>

Is it uncertain what affect the generic educational strategies had on the rate of actual or potential AMEs. The majority of education provided in the earlier years of the project was didactic in nature as part of mandatory orientation days, where limited information retention was likely. It was too early to identify whether the case based prescribing tutorials implemented in this site in 2011 had a more positive impact on prescribing competency, as suggested by other researchers, particularly if combined with audit results and personalised feedback.<sup>203</sup>

### ***Chemotherapy***

There was a significant reduction in chemotherapy prescribing errors from 17% of oncology related events in 2005 to 12% in 2012, with the main reduction in the first few years after restriction of chemotherapy prescribing to consultants, and progressive introduction of pre-printed oncology medication charts. This reduction was maintained from 2008 onwards, despite an increase in activity of 40% after merging of two paediatric oncology units into the same institution. The introduction of new technology (electronic prescribing in a new information management system) introduced new errors into the system, with 4% of events by 2012 related to the new technology. This is consistent with the findings of a recent systematic review which found that computerised physician order entry (CPOE) and pre-printed order sheets had the greatest reduction in paediatric medication errors.<sup>354</sup>

A confounding factor in this analysis is the increasing complexity of chemotherapy treatment protocols during the eight years of analysis.

### ***Potassium***

Reported events involving potassium increased to a peak in 2008 then decreased progressively through the following years. The apparent increase in reports may have merely been due to increased awareness of the risks of potassium use, however demonstrated that restriction of access to concentrated potassium, and availability of premixed IV fluids had little positive impact on error rates initially. Characteristics of the events changed through the years, indicating improved knowledge of appropriate use of potassium over time. Introduction of “smart pump” technology appeared to contribute to a number of new types of errors immediately after introduction. The serious potassium harm event that occurred in 2008 provided significant impetus for change in

practice, including strong executive support. The findings from the root cause analysis were used to push for change in the programming by the manufacturer of the smart pumps at a national level, and in the development of Hypokalaemia Management Guidelines at a local level. These guidelines were produced in an easy to use, practical format with strong multidisciplinary input, in contrast to the poorly utilised policy on safe use of potassium previously in place. The introduction of potassium mini-bags also facilitated higher doses for administration than in the original 20mmol/L bags, and meant that concentrated potassium ampoules were rarely required outside of critical care. The increased awareness, practical guidelines and potassium mini-bags may have contributed to the reduction in reported events since 2008, including the absence of any harm events.

### ***Narcotics***

Events related to confusion between oxycodone, OxyContin® and MSContin® increased rapidly alongside increased use of oxycodone for postoperative pain. Strategies to improve knowledge and awareness via education campaigns and alert posters had an initial positive impact to reduce errors. This improvement was not maintained, with an increase in events (particularly administration errors) in 2012, possibly related to removal of the targeted content from mandatory education programs in 2011. It is also possible that cognitive aids such as alert posters become “invisible” over time and may lose their preventative effect. The absence of harm related event reports since 2010 is encouraging. However, the recurrence of events in 2012 reinforces that education alone is not sufficiently effective, and requires continuous effort.

It is important to note that the majority of efforts to reduce narcotic related events were focused on these errors involving confusion with OxyContin®. This analysis demonstrates that these errors contributed only a small proportion of the narcotic events involving harm.

### ***Skills required to improve safety***

Health practitioners require knowledge of medication uses and administration systems to identify, resolve and report medication related problems and errors on an individual patient basis. However, to make more sustained improvements at an institutional level, the changes described above required skills in communication and teamwork, including skills in persuasion, negotiation and collaboration. Management skills were required, such as change management, project management and risk management. Educators required skills to prepare and deliver an effective learning activity that actually changed practice. Skills in leadership were required to develop effective improvement initiatives and motivate others to participate effectively. Skills in research methodology are

required to design appropriate methods of analysis. Unfortunately, these skills are often underappreciated when building an effective health workforce. There is a need for a more formalised process to develop practitioners with this wider set of skills, which others have called advanced practitioners.<sup>1,114,141</sup>

### ***Summary***

The large number of events reported, including potential AMEs and error prone conditions, reflects a well functioning safety culture within the organisation. These “near-miss” events are important to identify system failures that require action to prevent future events that could harm patients.

The safety initiatives implemented show some effect in reducing the incidence of errors, and adverse medication events. The most effective strategies involved strong executive support and broad system changes supported by significant multidisciplinary input into design and implementation. Education was important but required ongoing commitment to be effective. The use of voluntary reports is a valuable and efficient method to review trends in adverse medication events over time, although detailed analysis is required to limit the effect of reporting bias. Ongoing quality assurance processes using a combination of voluntary reports with computerised trigger tools and ICD-10 reporting would be useful where electronic medical records are in place, with the addition of random samples of patients to investigate specific research questions. Future risk reduction efforts should focus on areas of greatest reported harm (and risk of harm), not only the area with the greatest number of reported events.

### ***5.6 Manuscript Conclusion***

This study confirmed the use of voluntary reports of medication related events to demonstrate a reduction in reported adverse medication events in a single paediatric hospital over eight years after a series of successive safety initiatives. Multidisciplinary input and executive endorsement was essential and broad system changes are the most effective strategy to influence safety, whereas education had only a limited effect. Health practitioners need to develop safe medication behaviours at an individual level, but also knowledge and skills on how to effect behaviour change at a profession and institutional level, to ensure positive and long-lasting improvement in the safety and quality of medication use.

## **5.7 Chapter Conclusion:**

This research confirmed the hypothesis that voluntary reports of medication related events can be used to identify trends in response to safety improvement initiatives, and identify associated skills required of health practitioners.



## 6 Chapter Six: What does advanced practice mean to Australian paediatric pharmacists? A focus group study

### 6.1 Introduction to Chapter Six

This chapter describes the opinions and perceptions of Australian pharmacists who work with children regarding advanced pharmacy practice. This project was undertaken to ensure that advanced practice was a concept accepted and desired by the workforce, and to determine the preferred methods of assessment of advanced practice. The findings in this project informed the research described in Chapter Nine where different methods of assessment of advanced practice were piloted. Three of the six major Australian tertiary paediatric hospitals were chosen to participate in the study, with input from an additional three general hospitals during the fourth focus group session.

Individual authors and professional bodies from UK and USA have described quite consistently the specific knowledge and skills required of paediatric pharmacists. These include the knowledge of developmental pharmacokinetics and pharmacodynamics; how to determine and calculate doses; how to administer medications to children effectively and safely; how to modify available preparations to make suitable for administration for children; and appropriate use of unlicensed and off-label medicines.<sup>102-104</sup> Specific challenges included lack of information sources; lack of suitable formulations; medication errors; monitoring of safety and effectiveness; and effective communication with children and families.<sup>102-105</sup> These concepts have been assumed but not confirmed in the Australian paediatric setting. Further investigation is also required to determine the difference between the expectations of a general level paediatric pharmacist, versus a paediatric pharmacist practicing at an advanced level.

The hypothesis for this research project was:

*Paediatric hospital pharmacists valued formal recognition of advanced pharmacy practice, can describe the skills, knowledge, attitudes, and behaviours of advanced practitioners and identify preferred methods of assessment of advanced practice.*

This chapter has been published by the International Journal of Pharmacy Practice.<sup>355</sup> This is the accepted version of the following article: Stacey SR, Coombes I, Wainwright C, Cardiff L, Whitfield K. What does advanced practice mean to Australian paediatric pharmacists? A focus

group study. *Int J Pharm Pract* Forthcoming 2014. doi: 10.1111/ijpp.12113, which has been published in final form at <http://onlinelibrary.wiley.com/doi/10.1111/ijpp.12113/abstract>

## **6.2 Manuscript Abstract**

### ***Objectives***

The aim of this study was to explore perceptions and attitudes of Australian paediatric pharmacists about advanced pharmacy practice and to identify suitable methods of assessment for this level of practice.

### ***Methods***

Four focus groups (with 31 participants) were held in 2012 with Australian hospital pharmacists who work with children. Written notes and audio recordings were used to produce verbatim transcriptions and extract themes.

### ***Key Findings***

There was consensus across groups that formal recognition of advanced pharmacy practice was valuable to the profession and to individuals. Elements should include a strong grounding in clinical practice, commitment to education, research and service improvement outside the department and institution. A framework for career development should be used to describe the levels of practice leading to advanced practice. Assessment should involve multiple separate criteria, and incorporate direct observation, peer review and a professional portfolio. Postgraduate qualifications are desirable but not considered essential. Different knowledge and skills are required in paediatrics however the definition of advanced practice remains the same.

### ***Conclusions***

Recognition of advanced practice is valuable for the profession and for individuals. Multiple methods of assessment should be used. Specialty areas such as paediatrics can be defined and assessed similar to other specialties, with acknowledgement of the specific paediatric knowledge and skills required.

### 6.3 Manuscript Introduction

The pharmacy profession is evolving in response to changing healthcare requirements, with recognition of advanced pharmacy practice increasingly common in many countries.<sup>1,356</sup> However, definitions and processes for assessment and recognition of advanced pharmacy practice differ between countries.

The most extensive work in this area has been undertaken in the United Kingdom, where the Competency and Development Evaluation Group (CoDEG) developed an Advanced and Consultant Level Framework (ACLF) in 2005.<sup>115</sup> This framework defines knowledge, skills and attributes expected of an advanced practitioner, in professional practice, working relationships, management, leadership, education and research. The ACLF has been endorsed by the Department of Health, used as an evaluation tool for pharmacists seeking consultant pharmacist positions in the UK and as the basis for professional recognition of advanced practice by the recently established Royal Pharmaceutical Society Faculty.<sup>357</sup> In contrast, in the USA formal certification as an advanced practitioner in a designated speciality is achieved by successfully passing a Board of Pharmacy Specialties professional practice knowledge based examination.<sup>128</sup>

In Australia, formal recognition of advanced practice is not yet available, although a definition has been endorsed:

*Advanced Practice is practice that is so significantly different from that achieved at initial registration that it warrants recognition by professional peers and the public of the expertise of the practitioner and the education, training and experience from which that capability was derived.*<sup>132</sup>

A number of specialty pharmacy groups in Australia including cancer care,<sup>136</sup> infectious diseases,<sup>139]</sup> cardiology,<sup>138</sup> emergency medicine,<sup>137</sup> palliative care and paediatrics<sup>133,134</sup> have adapted the CoDEG frameworks to their own specialties. Their use to date has focused on individual professional development rather than assessment. In 2011, a collaborative of Australian pharmacy stakeholder groups (Australian Advanced Pharmacy Practice Framework Steering Committee) commenced work on a profession-wide framework for advanced practice, based on the CoDEG (ACLF) work,<sup>115</sup> and cross-referenced to the existing Australian national competency framework.<sup>132</sup> The completed Advanced Pharmacy Practice Framework (APPF) was released in 2012 and endorsed by the Pharmacy Board of Australia.<sup>141</sup> This was an important step forward in Australian pharmacy practice, although not yet linked to a process to formally recognise advanced practice.

In paediatrics, advanced pharmacy practice has progressed in a similar form. The Neonatal and Paediatric Pharmacists Group (NPPG) in the UK developed a set of competencies specifically for paediatric and neonatal pharmacists, aligned to the ACLF.<sup>358</sup> In Australia, the Paediatric Advanced Level Framework was developed in 2008 by the Committee of Specialty Practice in Paediatrics, a subgroup of the Society of Hospital Pharmacists of Australia (SHPA).<sup>133,134</sup> In the USA, comprehensive foundation level paediatric training is provided via residency programs that have been accredited by the American Society of Health-System Pharmacists. Formal recognition of paediatric advanced practice is not currently available, however the Pediatric Pharmacy Advocacy Group (PPAG) is currently working with the Board of Pharmacy Specialties to include paediatrics as a recognised specialty in pharmacy practice.<sup>359</sup>

The aim of this study was to explore the perceptions of hospital-based pharmacists working in paediatrics regarding advanced pharmacy practice and suitable assessment methods.

## **6.4 Method**

### ***Participants***

Focus groups were held in Brisbane, Sydney, Adelaide and Auckland from January to June 2012, facilitated by a researcher (SS). Three groups were held at large tertiary paediatric hospitals and the fourth was held in conjunction with a meeting of Australasian paediatric pharmacists in Auckland. An open invitation was given to all pharmacists working in those hospitals or attending the Auckland meeting to attend a session to discuss advanced pharmacy practice. Pharmacists at each of the hospitals were invited via email from the Director or Assistant Director of Pharmacy. Pharmacists attending the Auckland meeting were invited verbally. Meeting rooms were used for the hospital sessions, and a section of a hotel lobby for the Auckland meeting. This format was designed to provide an informal environment to facilitate open discussion. Open invitations were used to obtain a purposive sample of pharmacists with a broad range of experience within paediatrics.

### ***Ethical approval and Permissions***

Permission was sought by Directors of Pharmacy at the individual hospitals to undertake the focus groups. Ethical approval was obtained from the Ethics Committee of the School of Pharmacy, The University of Queensland. Participation in the focus groups was voluntary, with attendance at the

session representing consent to participate. Additional explicit consent was obtained verbally at the commencement of the meeting.

### ***Data collection***

Demographic information was collected verbally from participants at the commencement of the session (see Table 6.1). A topic guide was used to ensure a common core of data was collected for each group. Topics were developed by the researcher (SS) based on a literature review, discussion points raised by current users of the Paediatric ALF,<sup>133</sup> and questions posed by the Australian Advanced Pharmacy Practice Framework Steering Committee.<sup>360</sup> These included: description of the characteristics of advanced practitioners; differences between specialist and advanced practice; value of formal recognition of advanced practice; appropriate assessment criteria for advanced practice; suitability of the current Australian definition of advanced practice;<sup>132</sup> and the differences between paediatric and general advanced pharmacy practice. Comments from the earlier groups were repeated in the latter group sessions to promote further exploration of the topic.

Written notes were taken and digital audio recordings of the sessions were transcribed verbatim. Data saturation was achieved at the conclusion of the fourth focus group, where no new ideas were being added and the group highlighted similar themes to the preceding groups.

### ***Data Analysis***

A summary of each group session was manually extracted from the written notes and audio recording (by SS), including general themes and illustrative quotes. Quotes were identified by Group number (e.g. G1) and Participant number (e.g. P2).

The summary was sent to all participants to provide opportunity for participants to clarify or add comments as required. One session was independently transcribed and themes extracted by a separate researcher (LC) to ensure consistency of interpretation and quality assurance. Minor discrepancies were identified, which were discussed and consensus reached. Thematic analysis was undertaken using NVivo qualitative analysis software (QSR International Pty Ltd. Version 10, 2012).

## 6.5 Results

Focus group sessions were held for an average of 59 minutes (45-73 minutes) with an average of 8 participants per group. Each session included open discussion and debate between the participants, and each participant was provided with opportunities to contribute.

### *Participant demographics*

Approximately half of the invited pharmacists attended the hospital-based sessions, and all of the Australian invited pharmacists attended the Auckland session. A total of 31 pharmacists were involved. Two pharmacists attended two separate focus groups.

Most participants worked in tertiary paediatric facilities, with three from general hospitals. Six hospitals and five Australian states and territories were represented. Two participants were Directors of Pharmacy, the remainder held a range of different roles providing direct and indirect patient care.

Table 6.1 outlines the demographic characteristics and experience for participants in each group.

**Table 6.1 Participant Demographics**

Session	City	Participants (female)	Average pharmacy experience/participant in years (range)	Average paediatric experience/participant in years (range)
1	Brisbane	8 (7)	8.8 (3-25)	7.6 (3-24)
2	Sydney	6 (6)	9.3 (3-17)	4 (3-5)
3	Adelaide	12 (6)	11.3 (3-29)	7.3 (1-24)
4	Auckland	7 (5)	21.4 (5-30)	10.1 (4-23)
	<b>Total</b>	<b>31 (23)</b>	<b>12.4 (3-30)</b>	<b>7.0 (1-24)</b>

### *Thematic analysis*

General themes extracted from the meetings included definition of advanced practice, elements of advanced practice and assessment of practice.

A system of credentialing or formal recognition of advanced practice was thought to be valuable to individuals and the profession.

*It is around rewarding and recognizing people... Gives some credence, some credibility, and some recognition of people's practice... it gives you something to aspire to and work towards. (G4/P6)*

### **Definition and description of Advanced Practice**

The current Australian definition of Advanced Practice (listed above) was acceptable to some participants, although most described it as too long and difficult to understand.

Two groups expressed concern regarding the inclusion of “*warrants recognition... by the public*”. The participants felt that the public may be unable to recognise or differentiate an advanced practice pharmacist from a general level or newly graduated pharmacist, and were unsure whether the demonstration of recognition required a formal public award such as an Order of Australia.

All groups described professional knowledge and skills as the most important components of advanced practice. More experienced participants described additional factors including research, education, and influence outside the institution. Participants from all practice areas and experience levels described personal characteristics such as motivation, commitment to improvement and being a professional leader and role model.

All groups described advanced practice as being more than providing a basic service, using phrases such as “*above the norm*” (G1/P8), “*a step ahead*” (G2/P2) or “*the next level*” (G2/P5). There was a range of expectations of advanced practice, from being an exceptional clinical pharmacist making a difference at an institutional level, up to practice and influence at a much higher level or “*someone who really stands out from their whole profession at a national level*” (G4/P5).

Some groups described a journey towards advanced practice, incorporating a series of levels, steps or gradient of increasing skills and influence. A framework describing these levels was recommended by participants to provide a career pathway for pharmacists, where each level was recognised and each new level was seen as an achievable goal.

It was acknowledged (particularly by participants from general hospitals) that being a “state or national expert” might be easier to achieve in tertiary hospitals, and in some specialties than others. The groups agreed that although paediatric pharmacists require different knowledge and skills to other pharmacists, the definition of advanced pharmacy practice would apply to all specialities.



Advanced practice was considered different to specialisation. Specialisation was thought to exist without advanced practice, and that pharmacists could be practicing at an advanced level in a generalist area without specialisation.

*You're not necessarily an advanced practitioner just because you come and work in a children's hospital. But you are specialising. (G2/P4)*

## ***Elements of advanced practice***

### **Knowledge and Skills**

All groups described knowledge and skills as the most important element of advanced practice. Some groups discussed the need for advanced practitioners to have a broad base or foundation level knowledge and develop a deeper knowledge and skills in specialist areas.

*It is like a pyramid. Your pyramid is going to look different to other people's pyramid (G1/P1)*

Specific knowledge required by paediatric pharmacists included knowledge of childhood diseases, developmental changes and medication handling in children. All groups stressed the importance of effective age-appropriate and family-centred communication skills in paediatrics.

### **Working Relationships**

Advanced practitioners were described as having a network of colleagues within and external to the profession and the institution, at a state, national and sometimes international level. Examples included being consulted for advice, and acting as a representative for the discipline, department or institution on committees or working groups.

*You have come to a level where you have expertise and knowledge that you are approached by not only your colleagues, but other people. (G3/P10)*

All groups described the requirement for good teamwork, the ability to communicate effectively and build effective working relationships.

### **Leadership and Management**

Advanced practitioners were expected to have vision and a strong commitment to quality and system improvement at an organisational level or in a specific clinical area. Advanced practitioners

were described as initiating change at least locally, and at higher levels the ability to lead the profession or specialty area forward at a state, national and international level.

Only one group explicitly mentioned management, although other groups described elements of management (e.g. providing feedback, project management and quality improvement).

### **Education (self and others)**

All groups discussed the need for education and professional development. Advanced practitioners were expected to have completed considerable professional development and learning activities to enhance their skills. Formal postgraduate qualifications were desirable, although not essential. Participants were influenced by their own experiences with postgraduate training and by the availability of quality educational opportunities locally, in particular the lack of paediatric specific training. Participants described current practitioners who work at an advanced level that do not have postgraduate training.

*It probably reflects people who are willing to do more. You often find that advanced practitioners have gone out to get further qualifications. (G3/P11)*

*Its just a piece of paper, unless it affects your behavior and how you interact when you get back to the role. The fact that you have a diploma in clinical pharmacy doesn't mean that you are advanced in your practice. (G4/P6)*

All groups mentioned education of others as a significant component of advanced practice. An advanced practitioner was expected to be involved in education of others in and outside the workplace and discipline, and act as a role model and an expert or leader in the specialised area

*When you start off, you are at foundation, learning for yourself, build up your own knowledge. You get to a point where you start disseminating that... further and wider. (G3/P11)*

### **Research, Evaluation and Publication**

Involvement in research by advanced practitioners was considered important. Critical evaluation of evidence, production of protocols and guidelines and the undertaking of research-driven service improvement projects were mentioned as relevant examples. Publication of research was highly desirable but not considered essential, and most relevant to the higher levels of practice.

## **Direct and Indirect Patient Care**

Participants did not consider direct patient care as essential to the advanced practitioner. It was noted that pharmacists in technical and management roles could also have advanced skills. There was, however, an expectation of a strong foundation in clinical practice and to remain “in touch” or “integrated” with patient care.

*I am thinking about my managers, they don't see patients all the time, but to me they are advanced practitioners... (G2/P6)*

## **Personal Characteristics**

Advanced practitioners were described as having an internal motivation or desire to learn and advance their skills, to be confident and inspire confidence in others, and to have a commitment to improvement.

*With advanced practitioner... its not just about knowledge and skills, also about character, because you are going to be a role model... professionalism, integrity, character, how you talk to your peers and people in general. (G2/P6)*

## **Assessment of Advanced Practice**

Participants agreed that there should be a range of methods for assessment and evaluation of the advanced practitioner.

*There needs to be many different criteria, and not everyone will be able to meet everything because every specialty is different. Every advanced practitioner will work in slightly different ways. (G2/P5)*

The options discussed for assessment were as follows:

## **Portfolio**

Professional portfolios were strongly supported as a method of assessment. Suggested evidence for a portfolio included contribution to quality improvement activities, production of clinical protocols and guidelines, education (e.g. lectures and presentations), research (e.g. reports and publications) and examples of leadership. A portfolio could also include evidence of peer review or recognition

(e.g. emails, references, multi-source feedback) or reports on direct observation of practice (e.g. General Level Framework<sup>209</sup> or shpaclinCAT<sup>209</sup>).

### **Years of Experience as Assessment:**

Experience was considered essential for an advanced practitioner, however there were varied opinions of how long it would take to develop advanced practice. This was linked to the years of experience of the participant themselves, and the perceived “level” of an advanced practitioner, which varied from approximately 3 years to become proficient as a clinical pharmacist in a particular area, to 5-10 years to develop the relationships and influence required for the higher end of the scale of advanced practice.

*But there might still be a time frame that it takes fit in those conversations, and those relationships, and that learning...Someone can do that quicker than another person. Someone might do it in two years and someone might do it in four years. Someone might never get to that spot because of their personal characteristics (G1/P2)*

*It took 3-4 rotations to actually see those variety of cases, to been exposed to it, and actually get confident enough that I would try new things, and do things differently, learning from previous experiences which if I had had only one rotation in there I wouldn't have done. Even though I could have read all the books or gone through all the courses or had all the mentoring that still would not have been enough to get me to that point. (G1/P4)*

### **Peer Review and Feedback**

Most groups discussed peer review as being valuable in assessment although there were different perceptions as to what peer review involved. Suggested tools included structured feedback using direct observation of clinical practice in your own site (e.g. General Level Framework or shpaclinCAT),<sup>209,297</sup> or formalised feedback from multidisciplinary peers (such as 360 degree reviews or multisource feedback).<sup>312</sup>

### **Objective Structured Clinical Examinations (OSCEs)**

There was significant doubt expressed regarding OSCE type evaluations to assess advanced practice. Concerns included relevancy of OSCEs only for those providing direct patient care, and that OSCEs assess the ability to role-play, not necessarily the ability to provide high level clinical care.

*That is again just a clinical scenario, and at advanced level you are thinking about more than the clinical scenario. (G3/P7)*

*People fail based on the role-play. You are being judged on how good you are at role-play. (G3/P11)*

### **Interview/viva**

Some groups discussed an interview or “viva” as being a valuable method to assess and confirm level of practice, particularly by an external panel. This could include discussion and evaluation of involvement in research, education, and influencing the profession.

*Someone might pass an OSCE quite comfortably but when you probe more deeply in an interview or viva you actually work out that they don't have that knowledge or skill base. (G3/P1)*

### **Knowledge Assessment**

Knowledge was felt to be an essential component of advanced practice, however formal knowledge assessment (e.g. via examination) was not specifically discussed.

## **6.6 Discussion**

This study sought to identify pharmacists' perceptions of advanced practice and processes for recognition. The participants agreed that recognition of advanced practice was valuable for individuals and for the pharmacy profession, with a combination of multiple assessment methods used to evaluate level of practice. Expert knowledge and skills, leadership and management, working relationships, education and research were all considered important components of advanced practice.

### ***Strengths and Limitations:***

Pharmacists who chose to attend the session were self-selecting and therefore more interested in advanced practice than those who did not attend. However, this method of recruitment ensured that the pharmacists who attended were prepared to participate and contribute to the discussion. The open invitation resulted in two pharmacists attending two sessions each. During analysis, care was taken to avoid duplication of comments provided by these pharmacists.

Six participants had some previous knowledge or experience of the Paediatric ALF. These participants could have subtly influenced the discussion, however participants without previous experience with any of the existing frameworks independently articulated similar concepts of advanced practice, and varied opinions on topics were freely expressed during the sessions.

The groups included only pharmacists who worked with children, however one third of the participants had three years or less specific paediatric experience, and most of the discussion was not specifically related to paediatrics. Hence much of the findings from this study could be transferrable to other pharmacy settings.

### ***Definition and description of advanced practice***

Despite previous concerns that a title of advanced practice for pharmacists was encouraging elitism within the profession,<sup>2</sup> this cohort felt that formal recognition of advanced practice had value for the profession and individuals. The participants recommended rewording of the current definition of advanced pharmacy practice to improve clarity.

Professional practice based knowledge and skills were described as core components of advanced practice. Broader attributes such as teamwork, communication, research, education, influence outside the institution, and a commitment to service improvement were also considered important.

The need to describe a series of levels leading towards advanced practice was identified. Each level would require broader skills outside of professional practice, influence extending past the discipline and institution, and a contribution toward original research. This fits well with the three levels of advanced practice in the UK ACLF,<sup>115</sup> Paediatric ALF<sup>134</sup> and the APPF.<sup>141</sup>

Peer recognition of skills and abilities was described as an important element of advanced practice, in line with a recent environmental snapshot of advanced practice.<sup>113</sup> The ability to critically evaluate the literature and prepare guidelines and protocols were considered important, although formal research was considered more relevant to the higher levels of practice. Differences in local opportunities for research impacted on the participants' opinion in this area.

All groups valued professional development as a component of advanced practice, however formal postgraduate qualifications were not considered essential. In contrast, education of others was considered a core requirement of advanced practice. This is consistent with other work describing the expectation of education growing with increased level of practice.<sup>1</sup>

## *Assessment*

The participants felt that multiple assessment methods should be used, with direct observation of practice, peer review and portfolio review the most strongly supported. These three methods are consistent with the Millers Triangle of Competency Assessment,<sup>261</sup> the methodology used by the UK advanced practice critical care group,<sup>286</sup> and the Australian medical and nursing profession as assessment of advanced practice.

Portfolios<sup>275,276</sup> were strongly supported by the participants as an assessment method. Portfolios have been shown across disciplines to be a valuable tool for formative assessment and have provided a reliable method for high-stakes summative assessment when multiple work based assessment tools are included.<sup>292</sup>

Direct observation of practice was also strongly supported. Evaluation tools currently in use in Australia (such as the General Level Framework, Mini-CEX or SHPA clinCAT) have successfully facilitated professional development for pharmacists in general clinical practice.<sup>207,209</sup> These tools, however, were not designed to differentiate advanced practice from general practice, and only the Mini-CEX (mini clinical examination) has been used as a summative assessment tool.<sup>286,292,301</sup> Other forms of peer review using multi-source feedback such as “360 degree feedback” (e.g. “Mini-PAT”) used in some institutions may require adaptation for use as an assessment as well as a development tool.<sup>312</sup>

Two other methods discussed with varied opinions were an oral viva and Objective Structured Clinical Examinations (OSCEs). An oral viva (or interview) was suggested by more experienced participants familiar with their use for recruitment purposes. An interview was found to be an effective assessment method in medical education,<sup>361</sup> and this approach has been used successfully with UK advanced practice critical care pharmacists.<sup>286,328</sup>

There were differences of opinion related to OSCEs, although these have been successfully used in formative and summative assessments in medicine and pharmacy for undergraduate and postgraduate students.<sup>315,362</sup> Pharmacists who had personal experience with OSCEs were comfortable with their use in assessment, whereas more experienced pharmacists believed that OSCEs would only assess clinical pharmacy skills rather than the broader components of advanced practice. Similar views have been expressed in medicine, where more experienced physicians approach patient care in a “non-linear fashion” unsuitable for evaluation via OSCE.<sup>290</sup>

Formal assessment of knowledge (e.g. via examination) was not discussed by any group. This may have been due to the absence of formal paediatric pharmacy postgraduate training and assessment in Australia, and the participants' reservations regarding the use of postgraduate qualifications as a mandatory assessment criterion. Availability of paediatric assessments such as with the Board of Pharmacy Specialties,<sup>363</sup> and formal recognition of advanced practice in Australia may change these views in the future.

Paediatric specific knowledge and skills such as medication and disease knowledge in children, and communication with children and families were considered important in paediatrics. The definition and other components of advanced practice remain the same as for other areas of practice.

Further work is required at a national and international level to clarify terminology of levels of practice across the various frameworks currently in use.<sup>113,134,141,364</sup> Further validation of tools for use in evaluation of advanced pharmacy practice is required, particularly if intended for high stakes assessment.

## **6.7 Manuscript Conclusion**

The current descriptions of advanced practice by Australian pharmacy groups and the Paediatric Advanced Level Framework are consistent with the expectations of Australian paediatric pharmacists. The broad components of knowledge, skills and experience; working relationships; leadership; education and research are all expectations of an advanced pharmacy practitioner. Advanced practice is not restricted to those in direct patient care, and is acknowledged as different to specialist practice. A system of assessment that includes multiple methods is preferred. Portfolio review, direct observation of practice and peer review are the most strongly supported strategies. Formal recognition of advanced pharmacy practice is beneficial to the profession, and for individuals seeking to develop their practice.

## **6.8 Chapter Conclusion:**

This research confirmed the hypothesis that paediatric hospital pharmacists valued formal recognition of advanced pharmacy practice, can describe the skills, knowledge, attitudes, and behaviours of advanced practitioners and identify preferred methods of assessment of advanced practice.



## **7 Chapter Seven: Can pharmacist interventions demonstrate the journey towards advanced pharmacy practice?**

### ***7.1 Introduction to Chapter Seven***

This chapter follows on from the research described in Chapters 4 and 5 where adverse medication events were investigated using pharmacist interventions as a method of case identification. The interventions reviewed during those projects demonstrated the value that pharmacists provide during their direct patient care work. This included optimisation of use where error is not involved, in addition to the identification and resolution of errors with significant potential for harm. During the analysis process of those projects it became clear that there was a trend toward increased complexity and sophistication of clinical skill described in intervention records by individual pharmacists as they increased in years of practice. These skills in the latter years appeared to include not only knowledge of drugs and diseases in childhood, but also the ability to enact significant organisational change to improve the safety and quality of medication use. This role in quality improvement as a component of advanced practice was also reinforced in the focus group project described in Chapter 6. These findings identified in earlier research led to the research question in this project regarding the usefulness of pharmacist interventions as evidence of advanced practice skills.

The hypothesis for this research project was that:

*Pharmacist interventions can document progression to advanced practice.*

## **7.2 Abstract**

### ***Aim***

To identify whether documented pharmacist interventions can be used to demonstrate increasing pharmacist skills towards advanced practice.

### ***Method***

Intervention records were randomly selected and retrospectively reviewed from three separate years during 2005 to 2012, for four pharmacists from one Australian paediatric hospital. Skills demonstrated in the intervention record were rated on a five-point scale, from skills expected of an intern pharmacist through to those expected of an advanced pharmacist practitioner.

### ***Results***

One hundred and fifty records were reviewed for each of the four pharmacists, with fifty interventions from each of the three periods. The level of skill demonstrated in the interventions increased over time for each of the pharmacists and corresponded to their level of advancing practice. Advanced level clinical skills were rarely recorded as an intervention.

### ***Conclusion***

Review of pharmacists' interventions can be used to demonstrate increasing skills and advances in clinical practice. Records of interventions should be documented and form part of a professional portfolio.

### 7.3 Background

Pharmacist interventions have been documented for many years: as a measure of pharmacy workload, to document errors, and identify medication risks at an individual or system wide level. Interventions also document pharmacist initiated changes in therapy where the patient has not been harmed, to identify and resolve ‘near-miss’ events where an error did not reach or harm a patient, and value-adding or optimisation of therapy where no error was involved.

Pharmacist interventions have been defined in a number of ways, from different professional organisations and published research. The definition used by many Australian hospital pharmacists is ‘*any action by a pharmacist that directly results in a change in patient management or therapy*’ which is included in the 2005 Society of Hospital Pharmacists of Australia (SHPA) Clinical Pharmacy Standards of Practice.<sup>38</sup> With the recent 2013 update to the Clinical Pharmacy Standards of Practice, SHPA has used a broader definition of ‘*any professional activity by the pharmacist directed towards improving the quality use of medicines and resulting in a recommendation for a change in the patient’s medication therapy, means of administration or medication-taking behaviour*’.<sup>365-367</sup>

Different systems for intervention recording exist in different institutions. They may be recorded routinely or as part of a workload snapshot, and may be documented in the institution’s clinical incident reporting system or within a separate pharmacy database. Interventions may be classified or categorised in a number of different ways, for example they may be based on the type of error leading to the intervention, or the risk to the patient.

The use of pharmacist interventions in education and training of pharmacy staff has been encouraged.<sup>367</sup> However, classification of the skills required of the pharmacist to make the interventions is not routinely undertaken, and the skills demonstrated via interventions have not been investigated. There have been a number of specialist advanced level competency frameworks developed and implemented in Australia in recent years, including a Paediatric Advanced Level Framework (Paediatric ALF).<sup>99,133,136</sup> These have led to the development of an Australian Advanced Pharmacy Practice Framework (APPF), endorsed in 2013 by the Pharmacy Board of Australia.<sup>141</sup> It is not yet confirmed what evidence pharmacists will use to demonstrate advanced practice, however there may be potential to use pharmacist intervention reports to demonstrate advanced skills.<sup>113</sup>

We hypothesised that as pharmacists developed their specialist clinical practice, the increasing skills documented in the intervention report would be identifiable and measurable. The aim of the project was to investigate whether intervention records could be used to demonstrate increasing pharmacists' skills over time towards advanced pharmacy practice.

## **7.4 Method**

This study investigated interventions recorded by four pharmacists participating in a larger multi-site study investigating suitable assessment methods of advanced pharmacy practice. The setting was a 170 bed tertiary paediatric hospital in Brisbane, Australia, with an established system of routine, continuous documentation of pharmacist interventions. Interventions were retrospectively reviewed over an eight-year period from 2005 to 2012. A random selection of interventions from three separate years of practice was coded on a five-point scale of increasing skill from intern to advanced practice (see Table 7.1).

The scale was developed using the descriptors in the Paediatric Advanced Level Framework (ALF).<sup>133,134</sup> Expectations for pharmacists in their intern year and early years post registration were used to define the first two levels, and descriptors of skill from the three levels of practice from the ALF itself used for the remaining three levels. These draft levels were sent to Directors of Pharmacy from Australian paediatric hospitals, and members of the SHPA Paediatric COSP for comment. Feedback was received and incorporated into the descriptors. The five levels are listed in Table 7.1 below.

Inclusion criteria were pharmacists enrolled in an advanced pharmacy practice research project at the site hospital, who had at least six years of interventions recorded in the institution database from 2005 to 2012. This project specifically investigated the pharmacist interventions documented as part of the pharmacist portfolios. Exclusion criteria were less than 150 interventions recorded in total, and less than six years of recorded interventions.

**Table 7.1 – Pharmacist Intervention Skill Levels**

Skill Level	Description and examples
<p><b>LEVEL 1:</b>  <b>Simple intervention, general.</b>  <i>Student or Intern</i></p>	<p>Identification of ‘obvious’ errors (omission and commission) e.g.</p> <ul style="list-style-type: none"> <li>• Incorrect doses based on calculation errors (e.g. easily identifiable 10-fold errors),</li> <li>• Errors from dosing slip/lapses or using non-standard texts.</li> <li>• Rounding doses to make it easier to measure</li> <li>• Not capping at adult dose</li> <li>• Identification of omissions or incorrect doses from medication history</li> </ul>
<p><b>LEVEL 2:</b>  <b>Simple intervention, patient specific.</b>  <i>General or Foundation. Expected of a newly registered pharmacist in first 1-2 years of practice</i></p>	<p>Issues requiring some knowledge of the patient:</p> <ul style="list-style-type: none"> <li>• Identification of new adverse drug reactions (ADR)</li> <li>• Identification of well-known drug interactions and contraindications</li> <li>• Ensuring appropriate dose for age of the child</li> <li>• Appropriate antimicrobial for diagnosis</li> </ul> <p>Responding to requests from other health practitioners using standard reference sources:</p> <ul style="list-style-type: none"> <li>• Dosing enquiry or compatibility of intravenous (IV) medications</li> <li>• Annotation or clarification of orders with the aim of reducing the risk of error, especially for well-known causes of error</li> <li>• Complicated ten-fold errors</li> </ul>
<p><b>LEVEL 3:</b>  <b>Paediatric specific or other clinical intervention</b>  <i>Advanced Pharmacy Practice Framework (APPF) “Transition” Expected of all registered pharmacists after 1-2 years of practice.</i></p>	<p>Identification of missing or incorrect therapy based on routine paediatric therapeutics, local protocols and guidelines.</p> <ul style="list-style-type: none"> <li>• Identification of paediatric specific contraindications</li> <li>• Identification of chemotherapy discrepancies from standard protocol (demonstrating ability to interpret a chemotherapy protocol).</li> <li>• Recommendation of change in therapy required due to ADR.</li> <li>• Therapeutic drug management (TDM) for standard care patients. This may include use of laboratory report and blood cultures for antimicrobial therapy.</li> <li>• Proactively identifying problems with IV compatibility and recommending a complex administration procedure</li> </ul>
<p><b>LEVEL 4:</b>  <b>Complex individualised intervention.</b>  <i>APPF “Consolidation”</i></p>	<p>Identification of medication related problems in patients with complex disease states, high acuity patients, multiple co-morbidities, and/or unusual medicines.</p> <ul style="list-style-type: none"> <li>• Identification of missing medications (symptoms not being treated, as opposed to medications missing compared to patient medication history)</li> <li>• Identification of medication that should be ceased</li> <li>• Therapeutic drug management and application of laboratory data in complex cases.</li> <li>• Recommendations for dose adjustment for patients with renal or hepatic impairment.</li> </ul> <p>Solving patient related problems requiring search of the literature outside of standard references and applying to individual patient circumstances.</p>
<p><b>LEVEL 5:</b>  <b>Complex individualised intervention resulting in system changes.</b>  <i>APPF “Advanced”</i></p>	<p>Identification of changes in therapy based on knowledge of paediatrics where information is lacking, using abstract knowledge, ability to search information and making efforts to implement changes in the system to prevent future problems or improve care in the future.</p> <p>These may be interventions at an earlier level where the information gained is used for education, policy change, guideline development and procedures at a broader than institutional level.</p> <p>This level also maps to Paediatric ALF Level 3</p>

Interventions were randomly selected (using an electronic random number generator) from the first and last years of intervention recording, and one year in the middle. Where less than 50 interventions were recorded per year, interventions from adjoining years were randomly selected and added to make 50 from each time period of early, middle and late. In total, 150 interventions were reviewed for each pharmacist. Each intervention was assigned a unique study number, and identifying information was removed. Only the medication name, clinical area and intervention narrative remained during the coding process, hence the independent raters were blinded to the pharmacist and period. Interventions were sorted by medication and independently rated as level 1 to 5 by two senior paediatric pharmacists with greater than 20 years clinical experience (SS and ST). The ratings from the first 20 interventions were discussed between the raters with minor modifications made to the definitions to aid clarity. For the remainder of the interventions, where disagreement on rating occurred, researchers discussed and agreed on a final rating. The study protocol included an option to ask a third researcher for a final opinion if consensus was not met; however this was not required.

Results were analysed to determine whether the skill level increased with increasing years of experience. The interventions documented in the final years were compared to the level of practice established in the larger advanced practice study, to determine whether the skill level demonstrated in the interventions matched the observed level of practice and therefore could be used as reliable evidence of practice.

Descriptive statistics for final score (means and standard deviations) were calculated for each pharmacist over each of the three periods. Levene's test was used initially to test for homogeneity of variance. A two-way ANOVA was then used to determine the effects of pharmacist, period and their possible interaction. In instances of significant interaction, data were further analysed via one-way ANOVA with Bonferroni multiple comparisons and interaction plots. All statistical analyses were performed with Stata 12.0 (StataCorp, College Station, TX). All tests were undertaken with a significance threshold for null hypothesis rejection set to  $p < 0.05$ . Ethics and institutional approval was obtained from the hospital Health Research Ethics Committee (HREC/12/QRCH/216) and the University Ethics committee.

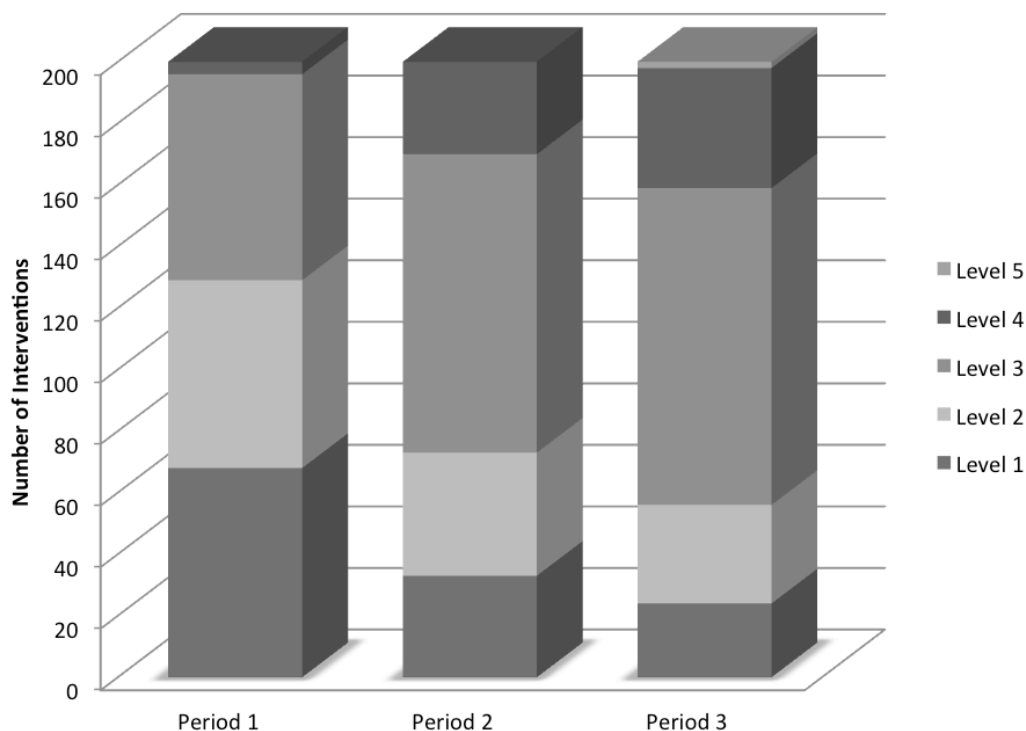
## 7.5 Results

Four pharmacists met the inclusion criteria with a minimum of 150 interventions recorded over at least six years of the study period. Two participants had two years experience before the commencement of study period, and two participants commenced their internship during the first 2-3 years of the study period. All of the four pharmacists were evaluated during 2012/13 as practicing between the equivalent of “Consolidation” and “Advanced” level in the APPF. Each had reported between 1 and 453 interventions per calendar year, with a total of 3479 interventions reported for these four pharmacists over the eight year study period, of which 600 were reviewed as part of this study. Table 7.2 below lists examples of some of the documented interventions at each skill level.

**Table 7.2 Examples of Pharmacist Interventions per Skill Level**

Skill Level	Examples of documented interventions.
<b>Level 1</b>	<p>Patient weight 5.58kg. Charted for 280mg cefotaxime once daily. Notified doctor who changed to q8h. Doctor had mistaken cefotaxime for ceftriaxone, hence 24 hourly dose.</p> <p>20mo patient admitted with ?URTI. Hx of epilepsy- on sodium valproate, oxcarbazepine and levetiracetam (100mg bd charted). Med Hx interview with Mum revealed Keppra dose increase in last week to 150mg bd - d/w treating team - order corrected.</p>
<b>Level 2</b>	<p>Patient prescribed Cotrimoxazole for Tx of UTI but is not recommended for use under the age of 6 weeks and patient was also jaundiced which the reference texts recommend not to be used. Recommended to the doctors to change to Cephalexin.</p> <p>Patient's weight recorded incorrectly on the chart by 40%. Doses of gentamicin, tazocin &amp; paracetamol all incorrectly written based on wrong weight. Contacted doctor and doses adjusted.</p>
<b>Level 3</b>	<p>Patient with gut obstruction due to Hirschsprung's disease. On long-term TPN showing symptoms of hypercholesterolemia. Suggested fish oil (Omegaven) emulsion - organised approval, SAS form and make sure stock is available. Team agreed with plan.</p> <p>Patient admitted for endoscopy etc. ? GVHD of GIT, vomiting etc. Admitted on maxolon 10mg qid and domperidone 20mg tds. Had some mouth movements- suggested ceasing maxolon.</p>
<b>Level 4</b>	<p>Oncology patient (medulloblastoma) status epilepticus. On phenytoin, phenobarb, Keppra and Midazolam. Low albumin (20g/L). Phenytoin (bound) levels low (reported levels does not report free phenytoin levels). D/w fellow - suggest correcting albumin and retest phenytoin level</p> <p>16mo patient with meningococcal sepsis requiring inotropic support and CVVHDF. On Morphine infusion, risk of accumulation of toxic metabolite in renal failure. D/W Dr- suggest change to fentanyl. Intensivist agreed. Changed to fentanyl.</p>
<b>Level 5</b>	<p>5yo treated for Ewings Sarcoma receiving HD Methotrexate (AEWS1031). Charted for Sodium bicarb as 60mmol bolus post MTX infusion (instead of NaHCO<sub>3</sub> 60mmol/L in hydration) on Charm (electronic prescribing system). D/W Charm ITS – Program Error – program corrected to prevent future errors - Dr contacted to reprint order.</p>

Figure 7.1 below shows the skill level of the combined interventions from all pharmacists for each study period. This shows the increase in higher level (levels 3-5) interventions as the years progressed. This correlates to their level of practice where clinical skills at level 4-5 would be expected to be demonstrated in the final study period when the pharmacists were evaluated as practicing between APPF Consolidation and Advanced.



**Figure 7.1 Intervention Scores by Skill Level by Study Period**

A two-way ANOVA performed after Levene's test indicated no evidence to suggest that the variance homogeneity assumption had been violated [ $F(11,588)=1.34, p=0.20$ ]. While pharmacist effect was found to be statistically non-significant [ $F(3,588)=2.45, p=0.06$ ], both period [ $F(2, 588)=39.93, p<0.01$ ] and the interaction of pharmacist by period [ $F(6,588)=5.43, p<0.01$ ] were found to be statistically significant. The mean skill level for all interventions increased from 1.92 to 2.52 to 2.64 across the three periods ( $p<0.01$ ). Mean scores per pharmacist and period are listed below in Table 7.3, showing the statistically significant increase in skill level from Period 1 to Period 2 or 3 for three out of the four pharmacists.

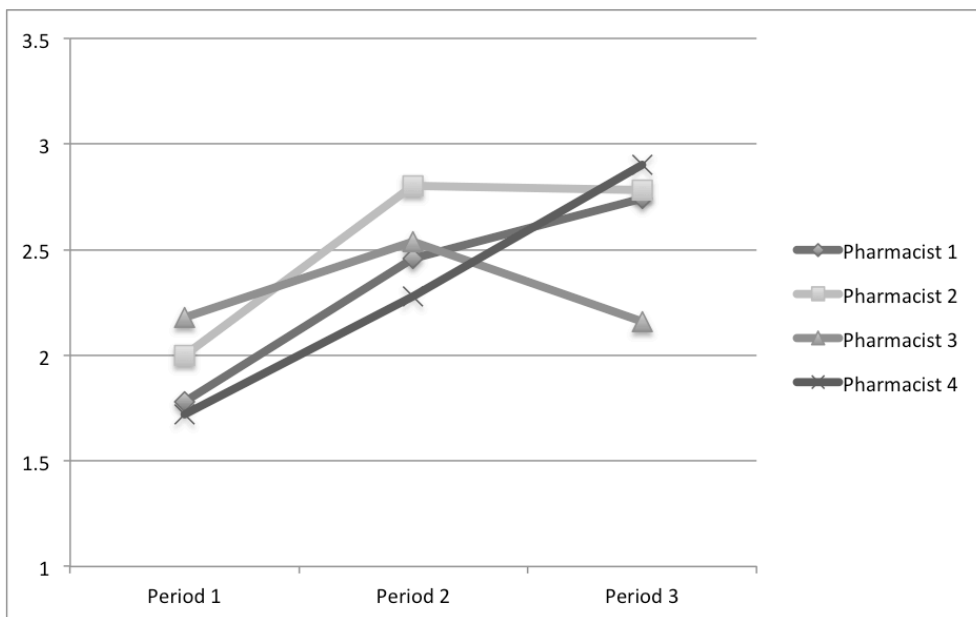


**Table 7.3 Mean Scores per pharmacist, with ANOVA**

	Period 1 (P1)			Period 2 (P2)			Period 3 (P3)			P values (ANOVA)	
	N	Mean	SD	N	Mean	SD	N	Mean	SD	P1-P2	P1-P3
<b>Pharmacist 1</b>	50	1.78	.93	50	2.46	.86	50	2.74	.88	<0.01	<0.01
<b>Pharmacist 2</b>	50	2	.86	50	2.8	1.01	50	2.78	1.02	<0.01	<0.01
<b>Pharmacist 3</b>	50	2.18	.72	50	2.54	.81	50	2.16	.82	0.07	1.00
<b>Pharmacist 4</b>	50	1.72	.76	50	2.28	.90	50	2.9	.79	<0.01	<0.01
<b>Total</b>	200	1.92	.83	200	2.52	.91	200	2.64	.92	<0.01	<0.01

The presence of a significant interaction effect was further described graphically by interaction plot (Figure 7.2). It shows mean intervention scores increased for all pharmacists over the study period, bar one, those being for Pharmacist 3. For this particular pharmacist, the mean intervention score increased from Period 1 to Period 2 then dropped in Period 3. This pharmacist was not working in a routine clinical role during Period 3, with direct patient care limited to relieving for staff leave and two years of interventions were combined for the final dataset of 50 interventions. The significant interaction effect of pharmacist and period can also be seen by the absence of parallel curves, with Pharmacist 4 having the lowest mean intervention score at period one (i.e. 1.72), but the highest at period three (i.e. 2.90).

When analysis was stratified by period, each one-way ANOVA with Bonferroni multiple comparisons showed significant pharmacist effect. For each period, the effect of pharmacist four was seen to differ significantly from one co-pharmacist. In the first period statistical significance was reached when pharmacist four was compared to pharmacist three (mean difference: -0.46, p-value=0.03). However in period 2, a significant difference was only detected between pharmacists two and four (mean difference: -0.52; p-value=0.03). Finally in period 3, significant difference was seen between pharmacists three and four (mean difference: 0.74; p-value<0.01). In addition, significant differences were also seen between pharmacists three and the two other pharmacists during this period.



**Figure 7.2 Mean Intervention Scores by Pharmacist per Study Period**

## 7.6 Discussion

This study demonstrated the increase in skill level over time using a novel skill assessment matrix. Interventions reported by pharmacists were largely changes in therapy for individual patients where the knowledge and skills required (such as knowledge of appropriate drug doses, and identification and resolution of drug related problems) are expected of pharmacists early in their career. In contrast, the more complex and broader changes at a system or institutional level required more advanced skills such as teamwork, change management, education, persuasion and negotiation.

Documentation of interventions at a lower skill level reduced over time, which may be a selective process as pharmacists may prioritise the time to record more complex interventions rather than straightforward interventions as their skills increase. The intent of the study was not to evaluate whether advanced practitioners were undertaking simple interventions, but to determine whether the interventions involving more advanced skill were only reported once those skills and practice had developed.

This recording of interventions and assessment of skill is analogous to the medical model where procedure or case logs are maintained for specialists in particular fields where complex procedures are required, such as emergency medicine, anaesthetics and obstetrics.<sup>264,290</sup>

As pharmacists develop in experience, many move away from direct patient care, which was also observed in this study with one of the pharmacists not in a regular clinical role during the later study

period. When not working in a routine clinical role there may be less opportunity for intervening at an individual patient level. However, there may be more opportunities for improving practices at a system level for those who move into more managerial or leadership roles. These interventions or improvements made at a system level may take weeks, months or even years to achieve, and therefore unlikely to be recorded in a routine intervention database. The results in this study contrast to those found by Barber et al from the UK, where more interventions were recorded by pharmacists at a higher pay scale than basic grade pharmacists.<sup>47</sup> However, practice has changed significantly since the Barber study was published almost 20 years ago.<sup>47</sup>

A more effective or feasible method of capturing and demonstrating advanced or Level 5 skills such as “advancing the knowledge base” or “advancing pharmaceutical services” may be via case based discussions of individual patients. This would allow more detail and the follow-up skills and contribution to be more clearly described.

There were a number of limitations in this exploratory study. It was undertaken in only one hospital, with an established intervention recording system, which is not the case in all hospitals. It was undertaken in a paediatric environment, however the skills described were largely general clinical skills therefore relevant across all age groups. It included a small sample size of four pharmacists, and only a randomised sample of interventions was rated; however some conclusions can still be made.

There was significant reliance on what and how the pharmacist documented the intervention in the narrative. Some were described in detail, which allowed the complexity of the intervention to be described. Others were described very briefly where nuances of complexity may have been lost. However, one expectation of pharmacy practice (particularly those at an advanced level) is to be able to clearly and concisely describe patient events in written form.

The interventions were recorded from 2005 to 2012, with the earliest interventions from almost 10 years ago. Practice has changed for many medications in that time, however the panel rated on skill demonstrated in the intervention, not whether the intervention was appropriate in today’s healthcare environment.

Standard practice in this hospital was to have pharmacists initially work in general medical and surgical areas, then rotate through higher acuity areas once assessed as competent in general clinical skills. This may skew towards a higher demonstrated skill level, as the pharmacists were caring for more complex patients in the later periods. However the fact that the pharmacists were deemed

competent to work in the high acuity areas is in itself indicative of increasing knowledge and skills over time.

There are barriers to comprehensive intervention recording, particularly related to the time required to complete the documentation and availability of an easy to use database or application at the time required. However, this documentation provides valuable information for the individual pharmacist and for the institution to improve safety and quality of patient care.

### ***Recommendation***

Interventions should be recorded routinely for both individual and institutional learning. All pharmacists should keep a record of all or a selection of their interventions in their professional portfolio on at least an annual basis, as a method of demonstrating advancing clinical practice and review. Pharmacists early in practice should regularly discuss interventions with an onsite mentor. Interesting cases should be presented to the department as a case based discussion to further gain skills in case presentation and these presentations can be used as portfolio evidence. These cases can also be used in teaching of pharmacists and other health professionals. As skills increase, cases should be shared via conference presentation and publication in peer reviewed journals. This is particularly important where the intervention and case review has led to quality improvement activities that may benefit others.

The skill level table (Table 7.1 above) could be used as a guide for appropriate examples of interventions to use as evidence at each level of practice.

## **7.7 Conclusion**

This study demonstrates that the progression in clinical pharmacist skills over time towards advanced practice can be demonstrated using recorded pharmacist interventions. The increase in patient complexity and acuity, knowledge of paediatric diseases and appropriate drug use, identify problems and resolve them, ability to negotiate change in therapy with other health care professionals, and enact changes at an increasingly broad system level, were all observed in these pharmacists. Records of interventions should be documented and form part of a professional portfolio. In addition, pharmacists practicing at an advanced level should document interventions and quality improvement achievements via methods such as case based demonstration, conference presentations and sharing via publication. Further research is required to confirm these findings via a larger sample and a broader representation of practice environments.

## **8 Chapter Eight: Use of the General Level Framework to guide development and training needs of pharmacists working in paediatrics**

### **8.1 Introduction to Chapter Eight**

This chapter investigates the strengths and priority areas for training of pharmacists working in paediatrics in Queensland Hospitals. It describes the use of the General Level Framework, a competency assessment tool, used for pharmacists using direct observation of practice. This tool was developed for formative assessment in the adult setting, however this research project investigates its use in paediatrics.

This project follows on from the findings in the focus group study in Chapter 6, where direct observation of practice was identified as one of the preferred methods of assessment for advanced practice. This topic is explored further as a tool for summative assessment of advanced practice in Chapter Nine.

The hypothesis for this study was:

*Training and development priorities of paediatric pharmacists can be identified by reviewing the strengths and weaknesses, recorded by direct observation of pharmacists working in clinical practice.*

This chapter has been submitted for publication to the Journal of Pharmacy Practice and Research.

## **8.2 Manuscript Abstract**

### ***Background***

The “General Level Framework” (GLF) has been used for many years as a tool for competency evaluation and feedback using direct observation of clinical practice, however its use in the paediatric environment has not been investigated.

### ***Aim***

To identify strengths and training and development needs for paediatric pharmacists using the General Level Framework.

### ***Methods***

Retrospective analysis of evaluations of paediatric pharmacists in Queensland hospitals using the GLF. Pharmacists from specialist paediatric hospitals were compared to those from general hospitals.

### ***Results***

Fifty GLF evaluations undertaken between 2006 -2011 were identified from 10 hospitals. Competencies related to ethical practice, confidentiality, and ensuring prescriptions are legal with appropriate doses were performed well. Assessment of patients understanding of illness and treatment, and adherence, or documentation of pharmacist interventions and medication action plans were not performed consistently well. Knowledge of pathophysiology, assessment of the patient’s experience and management of medicines were demonstrated more consistently in paediatric hospitals than general hospitals.

### ***Conclusion***

A generic tool such as the GLF can be used in specialist areas such as paediatrics to identify priority training areas for pharmacists working in clinical practice.

### **8.3 Manuscript Introduction**

The public and healthcare organisations alike expect and rely on a competent health workforce. The need to ensure the competence of healthcare workers has been highlighted in recent years after investigations into tragic events arising from failings in safety and quality in hospitals across the world, from Bristol in the United Kingdom to Bundaberg in Australia.<sup>256,368,369</sup>

The General Level Framework (GLF) has been used for many years in the United Kingdom (UK), Australia and elsewhere as a tool to support structured feedback and assist in the formation of individualised development plans after self-assessment and direct observation of pharmacist practice. The tool is commonly used in the hospital setting, although equally applicable in the community pharmacy.<sup>210,211</sup> The strength of the tool lies in its ability to guide professional development as a result of observing individual pharmacists during the daily activities and providing tailored feedback.<sup>207,209</sup> The GLF has been shown to accelerate individual improvements in clinical practice and at a population level to guide content of generic postgraduate pharmacy training.<sup>207,209-211,295,296</sup> In addition, direct observation tools (similar to the GLF) are currently being trialled to evaluate pharmacists working at an advanced level within specialist pharmacy practice areas such as critical care.<sup>286</sup>

The tool was originally developed by the Competency Development and Evaluation Group in the UK and adapted for Australian use by Queensland Health in 2006.<sup>207,209</sup> This version was mapped against the Australian standards of practice and included newer practice changes such as the use of a medication action plan to record medication history, reconciliation, and medication related problems and actions during an admission and transfer.<sup>132</sup> It has since been adapted further, and is known as the “shpaclinCAT” and used throughout Australia.<sup>297,370</sup> All versions of the GLF describe the competency in detail then the evaluator rating is based on how frequently the pharmacist undertakes the task to the quality described in each competency. The aim is for all pharmacists to be “consistently” undertaking all competencies to the described standard of practice.

A modified version of the GLF was developed and piloted for paediatrics in late 2009.<sup>133,135</sup> The paediatric version of the GLF included additional descriptors highlighting expectations for pharmacists working in paediatrics, under a selection of the original competency elements. The GLF has been used previously in specialist areas such as cancer care, however its use as a professional development tool in the paediatric setting has not been previously reviewed.<sup>136</sup>

The aim of this project was to identify strengths and weaknesses in the knowledge, skills and behaviours of pharmacists working with children in Queensland hospitals. This information has been used to prioritise training and development opportunities for paediatric pharmacists at a population level.

## **8.4 Method**

This study was a retrospective analysis of observations made using the GLF with pharmacists working with children in Queensland Health hospitals.

The GLF included 102 individual competency elements detailing performance expectations against national standards of practice.<sup>132</sup> These elements were grouped under three main domains of “Delivery of Patient Care”, “Problem Solving” and “Professional Competencies”. The evaluator observed the pharmacist in practice for approximately 2-3 hours, then completed the tool using the ratings of “Rarely”, “Sometimes”, “Usually” or “Consistently” for each competency element. An additional rating of “Unable to Comment” was available for use if that particular process or task was not observed during the evaluation. The pharmacist initially self-assessed against each of the competencies, and there was space for comments from the pharmacist and the evaluator, however the comments and self-assessment scores were not included in this study. Feedback was provided, taking approximately one hour. A personalised training plan was then prepared jointly between the pharmacist and evaluator.

Multiple evaluators were involved in the observations, all of whom had received standardised formal training in clinical education, use of the GLF tool, training plan development and provision of structured feedback. The evaluators were revalidated every 2-3 years to maximise inter-rater reliability.

Existing GLF records for pharmacists working in paediatric wards in Queensland Health hospitals undertaken from 2006 to 2011 were retrieved. Records using the paediatric version of the GLF were included in the analysis as the overarching competency elements were the same as the standard GLF. Pharmacist identifiers were removed and individual comments were excluded. Competency elements with 20 or less observations were excluded from analysis as valid conclusions and comparisons could not be made due to the small sample size.

Competency elements where all of the pharmacists rated “Usually” or “Consistently” were used to identify strengths. Elements where less than 80% of the pharmacists rated “Consistently” or “Usually” were identified as training priorities for the study population.



Results were compared for two main comparison sub-groups: Specialist paediatric hospitals versus paediatric wards in regional general hospitals, and the Paediatric GLF versus the standard GLF. An additional comparison of evaluations from 2006-8 versus 2009-11 was used to identify changes over time, and in multivariate analysis with the Paediatric GLF results to ensure validity of the comparison, as the Paediatric GLF results were limited to those used after implementation in 2009. Comparisons were made between sub-groups when greater than 50% of the results for that element were available (i.e. not coded as “unable to comment”). Stata version 12.0 (Stata Corporation) was used to perform all statistical analyses. Due to the small sample size, Fisher’s Exact Test was used to assess the strength of association between the variables.

This study was approved by the hospital Health Research Ethics Committee (HREC/13/QRCH/104) and the University Ethics Committee (2013/13).

## 8.5 Results

Records were identified for 50 observations, including 35 from pharmacists working in two different specialist paediatric hospitals and 15 from paediatric wards in eight different regional general hospitals. Six of the assessments utilised the Paediatric GLF and 44 the Standard GLF. Once elements with less than 20 observations were excluded, 83 competencies remained. Results for three domains are included in Tables 8.1 to 8.3.

**Table 8.1 Part 1 - Delivery of Patient Care Competencies**

	Number of responses	Median Rating (Range)*	% usually or consistent	General**	Specialist#	Fisher’s Exact Test
<b>1.1 Patient History</b>						
Opening the consultation – introduction	40	4 (1-4)	90%	73%	97%	0.06
Opening the consultation – setting an agenda	39	3 (1-4)	87%	70%	93%	0.10
Uses appropriate questioning	38	3 (1-4)	95%	80%	100%	0.06
Allergy / Adverse Drug Reaction Review	44	4 (1-4)	93%	85%	97%	0.20
Medication history taking	41	3 (1-4)	83%	64%	90%	0.07
Confirmation of medication history	28	3 (1-4)	75%	43%	86%	0.04
Relevant patient background retrieved	45	3 (2-4)	87%	67%	94%	0.04
Patient’s understanding of illness	29	2 (1-4)	45%	14%	55%	0.09

	Number of responses	Median Rating (Range)*	% usually or consistent	General**	Specialist#	Fisher's Exact Test
elicited						
Patient's experience of medicines use explored	34	3 (1-4)	68%	33%	80%	0.03
Patient's understanding of treatment explored	33	2 (1-4)	45%	13%	56%	0.05
Adherence assessment	23	2 (1-3)	39%	17%	47%	0.34
Patient's medication management assessed	32	3 (1-4)	63%	17%	73%	0.02
Reconciles medication history on admission	40	3 (1-4)	90%	67%	97%	0.03
<b>1.2 Assessment of Current Medication Management</b>						
Identifies drug-drug interactions	31	3 (2-4)	90%	80%	92%	0.42
Prioritises drug-drug interactions	30	3.5 (2-4)	93%	80%	96%	0.31
Appropriate action is taken regarding drug interactions	29	4 (3-4)	100%	100%	100%	.
Identifies drug-patient interactions	34	3 (2-4)	85%	75%	91%	0.32
Prioritises drug-patient interactions	30	3 (2-4)	87%	88%	86%	1.00
Appropriate action is taken regarding drug-patient interactions	28	3.5 (2-4)	96%	100%	95%	1.00
Identifies drug-disease interactions	35	3 (2-4)	86%	86%	86%	1.00
Prioritises drug-disease interactions	34	3 (2-4)	91%	83%	93%	0.45
Appropriate action is taken regarding drug-disease interactions	35	3 (2-4)	91%	83%	93%	0.44
Ensures prescription is clear and unambiguous	50	4 (3-4)	100%	100%	100%	.
Ensures prescription is legal	48	4 (3-4)	100%	100%	100%	.
Checking of appropriate dose	50	4 (3-4)	100%	100%	100%	.
Checking of route and timing of dose	47	4 (2-4)	91%	92%	91%	1.00
Selection of formulation, concentration or rate	43	3 (2-4)	91%	73%	97%	0.05
<b>1.3 Monitoring of Current Drug Therapy</b>						
Identification of drug related problems	50	3 (2-4)	98%	100%	97%	1.00
Documentation of drug related problems	43	3 (1-4)	65%	50%	71%	0.29
Prioritisation of drug related problems	47	3 (2-4)	96%	100%	94%	1.00
Appropriate use of guidelines or references	48	3.5 (2-4)	96%	100%	94%	1.00
Documents medication action plan	38	2 (1-4)	37%	33%	38%	1.00
Signs for clinical pharmacist review	42	3.5 (1-4)	67%	69%	65%	1.00

	Number of responses	Median Rating (Range)*	% usually or consistent	General**	Specialist#	Fisher's Exact Test
Documents interventions	20	2 (1-4)	45%	44%	45%	1.00
Appropriate consultation or referral	43	4 (2-4)	98%	100%	97%	1.00
Resolution of drug related problems	42	3 (2-4)	98%	100%	97%	1.00
Outcomes of contributions appropriately assessed	25	3 (2-4)	88%	88%	88%	1.00
<b>1.4 Provision of Drug Product</b>						
Ensures prescribed drugs are administered correctly	45	3 (2-4)	93%	92%	94%	1.00
Ensures availability of medication	41	4 (3-4)	100%	100%	100%	.
Provides prescribed medication for the patient in timely manner	23	4 (3-4)	100%	100%	100%	.
Documents supply on medication chart	30	4 (2-4)	87%	78%	90%	0.56
<b>1.6 Medicines Information, Patient Education and Liaison</b>						
Need for information identified	36	3 (2-4)	89%	63%	96%	0.03
Sensitive to Cultural / Social Background	31	4 (2-4)	97%	100%	96%	1.00
Provision of oral / written information	26	3 (3-4)	100%	100%	100%	.
Assessed patient comprehension of information	22	3 (2-4)	68%	67%	69%	1.00

\* Ranking: 1 = Rarely, 2 = Sometimes, 3 = Usually, 4 = Consistently

\*\* General = Regional General Hospitals

# Specialist = Specialist Paediatric Hospitals

Table 8.1 shows the results for patient care competencies, or the routine tasks expected of a pharmacist providing direct patient care.

Areas that were not undertaken consistently well included communication with children and their families, particularly during the patient history taking process. These elements included assessment of patient's understanding of illness and understanding of treatment (both 45% usually/consistently), and assessment of adherence (39% usually/consistently).

Other areas that were not undertaken consistently well included documentation issues such as recording of pharmacist interventions (45% usually/consistently), medication action plans (37% usually/consistently), and signing for clinical pharmaceutical review (67% usually/consistently). There was some improvement in documentation from the earlier to latter years of the study, with medication action plan documentation increasing from the 19% to 50% ( $p = 0.09$ ), signing for

clinical review increasing from 47% to 80% (p=0.05), although documentation of interventions did not change significantly over time (42% to 50%, p=1.00).

**Table 8.2 Part 2 - Problem solving competencies**

	Number of responses	Median Rating (Range)*	% usually or consistent <sup>IV</sup>	General	Specialist	Fisher's Exact Test
<b>2.1 Knowledge</b>						
Knowledge of pathophysiology 2.1.1	47	3 (1-4)	74%	45%	83%	0.02
Knowledge of pharmacology	49	3 (2-4)	80%	62%	86%	0.10
Knowledge of side effects	47	3 (2-4)	89%	77%	94%	0.12
Knowledge of interactions	29	3 (1-4)	66%	43%	73%	0.19
<b>2.2 Gathering Information</b>						
Accesses information from appropriate information sources	47	3 (2-4)	98%	92%	100%	0.26
Abstracts key points from information gathered	43	3 (2-4)	98%	100%	97%	1.00
<b>2.3 Analysing information</b>						
Evaluates information	44	3 (2-4)	95%	100%	94%	1.00
Appraises therapeutic options	43	3 (2-4)	77%	70%	79%	0.67
Clear decision making	47	3 (2-4)	89%	82%	92%	0.58
<b>2.4 Providing Information to other Health Care Professionals</b>						
Provides accurate information	40	4 (3-4)	100%	100%	100%	.
Provides relevant information	39	3 (2-4)	97%	100%	97%	1.00
Provides timely information	37	4 (2-4)	95%	88%	97%	0.39
<b>2.5 Follow-up</b>						
Ensures resolution of problem	33	3 (2-4)	97%	100%	96%	1.00

\* Ranking: 1 = Rarely, 2 = Sometimes, 3 = Usually, 4 = Consistently

\*\* General = Regional General Hospitals

# Specialist = Specialist Paediatric Hospitals

Table 8.2 lists the problem solving competencies, which were generally performed well, apart from knowledge of interactions.

**Table 8.3 Part 3 - Professional Competencies**

	Number of responses	Median Rating (Range)*	% usually or consistentl	General	Specialist	Fisher's Exact Test
<b>3.1 Organisation</b>						
Prioritisation	50	3 (2-4)	94%	100%	92%	0.55
Punctuality	40	4 (2-4)	98%	92%	100%	0.30
Initiative	47	3 (2-4)	96%	86%	100%	0.08
Time Management	45	3 (2-4)	91%	100%	88%	0.31
Delivers work within agreed deadlines	38	3 (2-4)	89%	100%	86%	0.56
Works efficiently	49	3 (2-4)	86%	100%	80%	0.17
<b>3.2 Communication</b>						
Communication clear precise and appropriate with patients	44	4 (2-4)	98%	100%	97%	1.00
Involves patient in medication management	38	3 (1-4)	89%	63%	97%	0.02
Communication is clear, precise and appropriate with prescribers	44	3.5 (2-4)	98%	100%	97%	1.00
Communication is clear, precise and appropriate with nursing staff	45	3 (2-4)	98%	100%	97%	1.00
<b>3.3 Team Work</b>						
Recognises value of other pharmacy team members	44	4 (3-4)	100%	100%	100%	.
Works effectively as part of pharmacy team	43	4 (3-4)	100%	100%	100%	.
Passes on relevant information to pharmacy team	39	4 (3-4)	100%	100%	100%	.
Recognises value of other multidisciplinary team members	47	4 (3-4)	100%	100%	100%	.
Works effectively as part of multidisciplinary team	44	4 (3-4)	100%	100%	100%	.
Recognises the roles of non-clinical staff	34	4 (2-4)	97%	100%	96%	1.00
Shares learning experiences with colleagues	36	3 (2-4)	92%	78%	96%	0.15
<b>3.4 Professional Qualities</b>						
Practices within professional code of ethics	46	4 (3-4)	100%	100%	100%	.
Maintains confidentiality	48	4 (3-4)	100%	100%	100%	.
Demonstrates logic	50	3 (2-4)	98%	93%	100%	0.28
Inspires confidence in others	46	3 (2-4)	96%	93%	97%	0.52

	Number of responses	Median Rating (Range)*	% usually or consistently	General	Specialist	Fisher's Exact Test
Demonstrates confidence	47	3 (2-4)	77%	65%	82%	0.26
Recognises own limitations	49	4 (2-4)	98%	100%	97%	1.00
Responsibility for own action	50	4 (3-4)	100%	100%	100%	.
Takes responsibility for patient care	50	4 (2-4)	98%	100%	97%	1.00

\* Ranking: 1 = Rarely, 2 = Sometimes, 3 = Usually, 4 = Consistently

\*\* General = Regional General Hospitals

# Specialist = Specialist Paediatric Hospitals

Table 8.3 lists the professional competencies, which were generally performed very well.

Overall, most areas were performed well, with 68 of the 83 competency elements achieving at least 80% of the evaluations “usually” or “consistently” undertaking that competency, and only five elements had a median score of less than “usually”. There were 16 elements with a 100% result, including complying with code of ethics and patient confidentiality, communication and effective teamwork within pharmacy and multidisciplinary teams, and ensuring prescriptions were legible, legal and an appropriate dose prescribed.

When comparing regional hospitals with paediatric hospitals, ten of the competency elements were undertaken more frequently in specialist paediatric hospitals. Many of these related to communication with children and families, including assessment of the patient’s experience of medicines use (80% versus 33% usually/consistently,  $p=0.03$ ), assessment of the patient’s ability to manage their medicines (73% versus 17%,  $p=0.02$ ) and reconciliation of medication history (97% versus 67%,  $p=0.03$ ). Identifying the need to provide information to patients (96% versus 63%,  $p=0.03$ ) and involving the patient in medication management (97% versus 63%,  $p=0.02$ ) were also communication tasks more frequently undertaken in paediatric hospitals than regional hospitals. Knowledge of pathophysiology (83% versus 45%,  $p=0.02$ ) and selection of appropriate formulation, concentrate or rate (97% versus 73%,  $p=0.05$ ) were also higher in paediatric hospitals.

No significant difference was found when comparing the Paediatric GLF to the Standard GLF.

## 8.6 Discussion

This study evaluated results from 50 direct observations of practice from pharmacists working with hospitalised children, which had not been previously investigated. It included data spanning six years, from regional and tertiary hospitals.

### ***Identified strengths and training needs***

Pharmacists working with children were found to undertake the routine legal and safety requirements for medication management of hospitalised patients, consistently well. However, assessment of the patient's understanding of their illness and treatment and assessment of adherence were poorly completed tasks. Identified training priorities were related to the more complex areas involving clinical reasoning and required a deeper understanding of the medication consultation process. This is similar to the results found from the initial implementation of the tool in Queensland.<sup>209</sup> These competencies also require effective age-appropriate communication skills with children and families, which are commonly acknowledged gaps by new pharmacy graduates.<sup>99,103,355</sup>

There were identified training needs related to documentation of medication related problems, medication action plans, recording interventions and clinical review activities. Most of these improved across the population from the early to the last years of the study, associated with increasing use of standardised forms for documentation, such as the medication action plan. It may be that these improve further with increased awareness of their importance, and the inclusion of these factors in the National Safety and Quality Health Service Standards, which are now linked to accreditation.<sup>333</sup>

### ***Specialist paediatric versus regional general hospitals***

There were significant differences between specialist paediatric hospitals in comparison to general or regional hospitals. Pharmacists working in specialist paediatric hospitals had greater knowledge of pathophysiology and understanding of medication administration in the paediatric environment compared to those working in general hospitals. Training priorities for general hospitals were also identified associated with communication with children and families, particularly in elements of patient history taking.

The reasons for these results are unclear as it was not possible to consider factors such as experience and postgraduate education due to de-identification of the GLF evaluations. A workforce snapshot of Australian hospital pharmacists from 2007 found that the proportion of pharmacists with postgraduate qualifications and those with greater than ten years experience was greater in regional hospitals (medium and large) than specialist paediatric hospitals.<sup>371</sup> It is unknown whether this is the case for this cohort. It is possible that professional isolation is a factor,

as most pharmacists working in the general or regional hospitals are the only paediatric pharmacist in that site and may not have easy access to a professional mentor in the specialty.

Despite the uncertainty of conclusions for these results, it is clear that training and development opportunities to improve the paediatric specific knowledge and skills of pharmacists need to be provided in a suitable format for pharmacists in regional areas to access, not only for those in tertiary paediatric sites.

### ***Paediatric GLF versus Standard GLF***

The results from the Paediatric GLF were not significantly different to the Standard GLF. This provides some reassurance that the additional descriptors included in the Paediatric GLF did not make the competency more difficult to achieve, however the very small numbers in this sub-group make any further conclusions difficult.

### ***Comparison to other research***

Our findings were similar to those from studies undertaken in the UK and Australia. The original work from the UK also found that ensuring the legality of prescriptions was a competency which is consistently performed well, which should be considered a ubiquitous competence of registered pharmacists.<sup>207</sup> A recent study reviewing recommendations on professional development for 220 GLF evaluations, found a similar set of recommendations to our study related to improvement in knowledge of pharmacology, pathophysiology, interactions and side effects.<sup>295</sup> This study also found recommendations for improvement in documentation of clinical pharmacy review activities and some recommendations to improve patient history assessment. Therefore these areas are not unique to the paediatric field, although communication with children and families offer specific challenges.

### ***Limitations***

There are limitations with using retrospective de-identified data. Years of experience and qualifications of the practitioners were not known, and it was not possible to pair two or more sequential assessments performed for the one practitioner to identify any change in practice over time. The self-assessment and comments made by the pharmacists themselves and the evaluators were not included, which may have added depth to the analysis and may be useful to include in future studies in the area.



The results also do not take into account local practices or systems. If the local expectation of service does not include recording of pharmacist interventions, or the use of a medication action plan, then a rating of “rarely” for that competency element does not necessarily indicate inadequate competency of the individual pharmacists.

There were 15 different pharmacists as evaluators, which despite regular revalidation of evaluators, may have added variation in the evaluations undertaken. The same training was completed for all assessors, including training workshops and hands on training with experience of three GLFs completed to satisfaction before being accredited as an evaluator, and re-evaluation occurred every 2-3 years. In the early stages of the GLF implementation project inter-rater reliability was tested, however this has not been undertaken in more recent years.<sup>209</sup> Despite this standardised training, there may have been variation in approach and assessment between evaluators.

### ***Future of the GLF***

The GLF itself has now been largely replaced for use in Australia by a similar tool called the shpa clinical competency assessment tool (or “shpaclinCAT”), which was developed by the Society of Hospital Pharmacists of Australia and based on the same content as the GLF.<sup>370,372</sup> The primary role of the shpaclinCAT remains for formative assessment of individual pharmacists to provide structured feedback and to develop personalised development plans.

The GLF has been expanded for use in other specialty areas such as cancer care, where the original (generic) competency elements were used, with expanded descriptors and some additional competency elements.<sup>136</sup> This study supports the use of these competency evaluation tools in specialised environments, with ongoing work required to develop supplementary documents to describe additional or differing requirements in specialty areas.

The other important area in pharmacy internationally at present is the evaluation of advanced pharmacy practice. The GLF (and shpaclinCAT) could be used to provide evidence of high-level clinical practice in some domains such as “Expert Professional Practice”. It has been used as a method of assessment in formal postgraduate training in clinical pharmacy and a related tool was successfully used in evaluation of advanced practice with critical care pharmacists.<sup>208,286,328</sup>

## **8.7 Manuscript Conclusion**

This study successfully used the GLF to identify strengths and priority training areas in knowledge and skills of pharmacists working in paediatrics. Areas that were not consistently undertaken well included detailed assessment of patient history, and recording a medication action plan. In addition, challenging areas such as knowledge of paediatric pathophysiology and effective communication with children and families were identified as training needs. These findings can be used to prioritise training opportunities for pharmacists working in paediatrics, particularly in a format accessible for pharmacists working in regional areas.

## **8.8 Chapter Conclusion:**

This study has confirmed the hypothesis that training and development priorities of paediatric pharmacists can be identified by reviewing the strengths and weaknesses, recorded by direct observation of pharmacists working in clinical practice.

## 9 Chapter Nine: Assessment of Advanced Paediatric Pharmacy Practice: A Pilot Study

### 9.1 Introduction

This research investigates the following assessment methods for the evaluation of paediatric pharmacists against an advanced practice competency framework:

- Direct observation of practice
- Peer review
- Portfolio review
- Oral interview (viva voce)
- Knowledge assessments (using postgraduate qualifications and CPD records)
- Self assessment

This chapter follows on from the advanced practice focus group study (described in Chapter 6), where components of advanced practice of paediatric knowledge and skills, communication, leadership, education, and research skills were defined. In that chapter portfolio review, peer review and direct observation of practice were recommended as methods of assessment for advanced practice. Direct observation of practice using the General Level Framework was investigated in Chapter 8, demonstrating its usefulness as a generic formative assessment tool in the paediatric setting. In this project it was tested as a tool for summative assessment. This project further investigates the use of pharmacist interventions as evidence for advanced practice, as described in Chapter 7.

The hypothesis of this project was:

*Advanced level paediatric pharmacy practice is most reliably evaluated using multiple assessment methods.*

## 9.2 Background

The efforts towards definition and recognition of advanced pharmacy practice in recent years have been positive steps in a maturing profession.<sup>1</sup> Internationally, frameworks that articulate expected competencies for pharmacists at a general level have been used to support practice for some decades. More recently, frameworks applicable for advanced practice have also been introduced.

The first advanced practice framework was the Advanced and Consultant Level Framework (ACLF), developed in the UK in 2005.<sup>115</sup> This framework was recently adopted by the Royal Pharmaceutical Society (RPS) as the basis of practice evaluation for admission to the faculty of the Royal Pharmaceutical Society.<sup>119</sup>

In Australia, the ACLF was adapted in a number of areas of specialty practice, including cancer care, emergency medicine, infectious diseases, cardiology and palliative care.<sup>136-138</sup> One of the earliest of these adaptations was in paediatrics, when the Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Paediatrics developed a paediatric version of the ACLF in 2008, with funding from Queensland Health, called the Paediatric ALF.<sup>133-135</sup> This work led to the development of an Australian Advanced Pharmacy Practice Framework (APPF) in 2012, which was established after extensive consultation and collaboration between a number of Australian pharmacy groups.<sup>141</sup> This was a generic tool, designed for all pharmacy work environments, and therefore does not contain the paediatric specific information included in the Paediatric ALF. The APPF was endorsed by the Pharmacy Board of Australia in 2013, followed by endorsement of the Australian Pharmacy Council (APC) to be the entity responsible for credentialing of advanced pharmacy practitioners.<sup>141</sup> Work in advanced pharmacy practice has continued to progress, and in May 2014 the APC released the first consultation paper regarding evaluation and credentialing of advanced practice pharmacists.<sup>373</sup>

Health practitioner groups have used a variety of methods to assess competency over recent decades. Portfolio reviews, direct observation of practice, peer review, clinical examinations, supervisor feedback, case based discussions, interviews (or viva voce) and knowledge based examinations have all been used in varied forms to assess practice in medical, nursing and allied health fields. Each of these methods contributes to the evaluation of different aspects of practice: expert knowledge and skills, teamwork and communication, managerial and leadership skills, education and research achievements. Combinations of assessment methods have been tested for reliability in postgraduate medical education.<sup>292,326,327</sup>

Assessment of experienced practitioners, including those practicing at an advanced level, has different requirements to assessment of new graduates. In the USA, advanced practice is recognised by the Board of Pharmacy Specialties (BPS), which certifies pharmacists in specialty areas using a case based multiple-choice examination.<sup>124</sup> A BPS certification in paediatric pharmacy is due to be available from 2015.<sup>100,128</sup> In the UK, a combination of assessment methods has been successfully used in advanced critical care pharmacy practice for some time.<sup>286</sup> In late 2013 a combination of portfolio review and testimonials was introduced to the first round of assessments for membership of the RPS Faculty as advanced practice pharmacists.<sup>374</sup> However none of these assessment models have been used or evaluated in Australia for advanced pharmacy practice assessment, and none specifically in the paediatric setting.

### **9.3 Aim**

The aim of this study was to investigate the reliability, acceptability and relevance of six different assessment methods in evaluating advanced pharmacy practice by Australian paediatric pharmacists.

### **9.4 Method**

#### **9.4.1 Recruitment**

Four Australian tertiary paediatric hospitals (the Royal Children's Hospital in Brisbane, Royal Children's Hospital in Melbourne, Children's Hospital at Westmead in Sydney, and the Women's and Children's Hospital in Adelaide) took part in the research, with a minimum of five pharmacists to be recruited from each site. An information session was provided at each site by the researcher (SS), with an open invitation to attend sent via email from the Director of Pharmacy and/or the site investigator to all pharmacists at the site. Pharmacists from the study sites who had participated in a previous focus group study on the same topic were individually invited via email to attend.<sup>355</sup>

- Inclusion criteria: registered pharmacists with three or more years of pharmacy experience.
- Exclusion criteria: pharmacists who did not anticipate being able to complete the assessment tasks in 12 months, and those with less than three years experience.

Pharmacists identified by the site investigators as possible advanced practitioners were specifically encouraged to participate, however all pharmacists with 3 or more years experience were eligible to participate.

Participants were recruited between January and March 2013, and assessments completed over the subsequent 12 months. Evaluators included four pharmacists and one consultant paediatrician, each experienced in practitioner development.

Verbal and written information on the project was provided to participants, and written consent was obtained from each participant. Principal ethics approval was obtained from the Royal Children's Hospital Health Research Ethics Committees (HREC/12/QRCH/216) and the University of Queensland Ethics Committee. Subsequent ethics and institutional approval was obtained from the remaining study sites.

### **9.4.2 Paediatric Advanced Level Framework**

The competency standard used was the Australian Paediatric Advanced Level Framework (ALF), which contained the same six competency clusters relating to advanced practice as the original ACLF from the UK: Professional Practice; Building Working Relationships; Leadership; Management; Education, Training and Development; and Research and Evaluation.<sup>115,133</sup> The paediatric-specific knowledge and skills overlaid the generic content in the Professional Practice cluster, whereas the other clusters remained applicable to any area of advanced practice. A sample of the Paediatric ALF is provided in Appendix A.

Each of the assessments were scored against the specific competencies within each of the six clusters on a rating scale of 1 to 3 where a level 3 was equivalent to advanced practice. An overall score for the cluster was determined. "Half" scores were permitted per cluster, where participants fully met the competency standards at the lower level, but only partially at the higher level (e.g. 2.5).

### **9.4.3 Self-Assessment**

Each participant undertook a self-assessment three times during the project. This was to identify any change in perception of practice over time, and to review the correlation with other assessment methods. A global self-assessment of advanced practice (on a scale of 1-3, with 'half' scores permitted) was recorded at the time of recruitment to the project, a more detailed self-assessment against each cluster was undertaken part way through the project in conjunction with the peer review assessment, and a final global self-assessment was carried out at the completion of the project. The detailed mid-project self-assessment was used in comparison with other assessment methods.

#### **9.4.4 Direct Observation**

Direct observation evaluations were used for pharmacists working in direct patient care roles. A minimum of one evaluation, completed within the past two years, was required for assessment. Standardised tools were used, either the General Level Framework or the shpaclinCAT, which had been successfully used as formative assessment tools in a range of practice settings.<sup>207,209-211,296-298,375</sup> The process of using the GLF (and shpaclinCAT) for practice evaluation was described in Chapter 8, and required approximately half a day to complete. A sample of the shpaclinCAT is provided in Appendix B.

Evaluators were trained in clinical education and feedback and in the use of the specific tool, with standardised training provided by educators from Queensland Health and/or the Society of Hospital Pharmacists of Australia, as described by Coombes et al in 2010.<sup>209</sup> At the time of the study, two sites were routinely using the shpaclinCAT as a professional development tool for staff engaged in direct patient care; one site was implementing its use; and one site had not yet begun to implement its use. Researchers provided support to evaluators undertaking the assessments in sites where the shpaclinCAT was not routinely in use. Direct observation assessments were scored from 1-3 against the competencies in the Professional Practice and the Building Working Relationships clusters of the ALF based on the assessor rating for the competencies, written comments by assessors, and patient complexity.

#### **9.4.5 Peer Review**

Peer review was undertaken using an adaptation of a tool used by the UK critical care group.<sup>286</sup> The participant and each peer evaluator were asked to rate the participant on a scale of 1-3 for each of the six clusters in the ALF, guided by a summarised paragraph that described each level of practice for the clusters included in the ALF. Evaluators were also asked to provide general comments and suggestions for further activities to progress professional development. The text of the survey questions is included in Appendix D.

Participants were asked to nominate six to eight peers from a range of backgrounds, including pharmacy, medical, nursing and allied health peers; administrative and technical staff; students or more junior staff reporting to the pharmacist; and direct supervisors or line managers. A matrix of escalating seniority of evaluators was recommended depending on the experience of the pharmacist. It was recommended that participants choose colleagues who would provide honest feedback and advice on professional development.

Evaluation comments were collated with the self-assessment and mean competency scores into a report for the participant. The feedback was discussed either face-to-face or over the telephone with a researcher (SS). The pharmacist was asked to write a short summary of important points and a development plan based on the feedback provided.

Reviews were undertaken using SurveyMonkey® (SurveyMonkey Inc, Palo Alto, CA, USA). Its suitability for this purpose was tested in a pilot survey. Review surveys were facilitated by a researcher (SS).

#### **9.4.6 Knowledge Assessment – Postgraduate Qualifications and CPD Records**

Continued Professional Development (CPD) records and formal qualifications were reviewed to evaluate whether existing methods of knowledge assessment could be used in Australia, as an alternative to the examination used for Board of Pharmacy Specialties certification currently used in the United States.<sup>128</sup> A record of CPD is required for registration as a pharmacist in Australia. Development activities that include assessment are encouraged. They are classed as “Group 2” activities and thus earn twice as many CPD points per hour of activity compared to activities that do not include assessment. Participants were asked to provide their CPD record for the previous two years, including their total CPD credit points and, specifically, their Group 2 (i.e. assessed) credit points.

To assess formal qualifications, participants were asked to provide the total number of qualifications, to specify the level achieved (i.e. Postgraduate Certificate, Postgraduate Diploma, Masters or PhD), and to describe any paediatric components in the training and assessment. This information was analysed in relation to the relevant clusters in the Paediatric ALF (Professional Practice, and Education, Training and Development).

#### **9.4.7 Portfolio Review**

All participants were asked to compile a professional portfolio addressing the competencies in the Paediatric ALF soon after recruitment to the study. Participants were given guidance on preparation of the portfolio. Electronic format using the ALF document was preferred; however, any format was permitted. Examples of alternatives included a matrix format in a spread sheet, or a simple summary as part of curriculum vitae. One of the researchers (SS) reviewed each portfolio,



discussed the results with the participant, and developed a learning plan in collaboration with the participant.

At the end of the study, the participants were asked to update the portfolio and submit it for review to an evaluation panel. Key pieces of supporting evidence were suggested for inclusion, including: curriculum vitae, current position description, Mini-PAT (as described below), publications, presentations (provided and attended), and direct observations of practice. Participants were permitted to include any files they felt provided evidence in support of their level of practice. A cloud-based file-sharing platform (Dropbox®, Dropbox Inc, San Francisco, CA, USA) was used to share the documents electronically between each participant and the panel members. A minimum of two panel experts evaluated the portfolio and scored it from 1-3 against each cluster, with feedback provided to each participant on achievements and suggested development activities.

Participants and evaluation panel members were asked their opinion on the most and least useful pieces of evidence to include in a portfolio to demonstrate advanced practice, using the following examples:

- Advanced Level Framework (adding evidence against the different competencies);
- ClinCAT or GLF (direct observation of practice);
- CPD records (continued professional development);
- Intervention reports or case based demonstrations;
- Mini-PAT (the summarised peer review from colleagues);
- Presentations or lectures given;
- Project Reports;
- Research - published articles;
- Research - conference or seminar abstracts, posters or presentations;
- Student or learner feedback (as an educator);
- Thank-you or other acknowledgements (e.g. emails from colleagues);
- Written references.

#### **9.4.8 Oral Interview (viva voce)**

A panel of 2-4 experts was convened for each viva panel. Panel members included a medical consultant and senior pharmacists with at least 20 years experience, each experienced in practitioner development and evaluation. A researcher (SS) was present as an observer at each of the vivas,

recording written notes for each session. Vivas were undertaken face to face, via videoconference and telephone. Video conferencing used two freely available internet based tools: WebEx® (Cisco Systems Inc, San Jose, CA, USA) and FaceTime® (Apple Inc, Cupertino, CA, USA).

The viva was semi-structured, with each participant asked to define an advanced practice pharmacist and to describe what they regarded as their own strengths and weaknesses. Questions were asked regarding specific components of their submitted portfolio in order to confirm or clarify points, explore certain aspects of their experience and add detail where required. At the conclusion of the interview, participants were asked to articulate what level they considered most applicable to their current practice.

Panel members independently reviewed the electronic portfolios prior to the viva and scored against each ALF cluster (from 1-3) based on the portfolio alone. Panel members scored against each cluster again after the viva allowing researchers to determine whether the viva changed rating scores.

## **9.4.9 Methods for Analysis**

### ***Participant Feedback***

A feedback survey was sent to all participants at the end of the study, using SurveyMonkey® (SurveyMonkey Inc, Palo Alto, CA, USA). Both quantitative and qualitative data was obtained. Survey questions were designed to determine participants' views on the value of each method for professional development and for practice evaluation. Quantitative data was obtained using multiple choice question which were based on those used in previous competency evaluation research and which asked participants to rate their extent of agreement with the following statements about each of the assessment methods:<sup>209</sup>

- *a positive experience that allowed me to reflect honestly on my practice and plan my future development;*
- *an extremely taxing process that provided little benefit to me;*
- *an inspiring experience that has given me renewed enthusiasm for pharmacy practice;*
- *a fair method of evaluation of advanced practice.*

A combination of the questions above using a five point Likert matrix scale from “Strongly Disagree” to “Strongly Agree” was used.

For each method, participants were asked open-ended questions to obtain general feedback. Participants were also specifically asked what was their preferred evidence for inclusion in a professional portfolio. In addition, viva participants were asked questions about viva format and about their personal experience of the viva. A condensed feedback survey was used in evaluators and participants who had withdrawn from the study.

Each of the surveys were piloted before use. Survey questions are included in Appendix C. Qualitative thematic analysis of feedback was undertaken using nVivo for Mac Beta® (QSR International Pty Ltd, Doncaster, Vic, AUS).

### ***Assessment Scores***

The scores for each assessment method for each individual cluster were compared for pharmacists who had completed three or more assessment methods. No gold standard was used. Assessment method scores were compared using the Skillings-Mack test, which is the non-parametric equivalent of ANOVA, and which is used where there are more than two measures and missing observations (i.e. not all methods were able to assess against each advanced practice cluster). Where differences amongst the group of assessment methods were identified, the Wilcoxon Signed Rank test was used to test paired data, with Bonferroni adjustment for multiple comparisons. All tests were two-sided and P-values <0.05 were considered statistically significant.

Intraclass Correlation Coefficients (ICC) were used to determine the reliability of scores across the assessment methods using different combinations of methods.

Scores for each of the participants were ranked, with the top scoring participants for each evaluator identified. The top ranked participants were discussed between the evaluators to identify those participants who were considered by the panel to be advanced practitioners. The characteristics of these participants were then compared against the existing framework.

Stata 12.0 (StataCorp, College Station, TX, USA) was used for statistical analysis.

## **9.5 Results**

### **9.5.1 Participant Demographics**

A total of 36 pharmacists consented to be part of the project, between 7 to 11 per site. During the study period 12 participants withdrew from the study, leaving 24 pharmacists to complete the study.

At completion of the project, 21 pharmacists had submitted three or more assessments required for comparison of score reliability. A total of 103 individual assessments were submitted for evaluation.

Participant demographics for each site are included in 9.1.

**Table 9.1 Site and Participant Demographics**

	<b>Initial recruitment (Male/Female)</b>	<b>Remained in study</b>	<b>Completed minimum 3 assessments</b>
<b>Site 1</b>	10 (2/8)	9	8
<b>Site 2</b>	11 (2/9)	3	2
<b>Site 3</b>	8 (2/6)	7	6
<b>Site 4</b>	7 (1/6)	5	5
<b>Total</b>	36 (7/29)	24	21

### ***Reasons for Withdrawal***

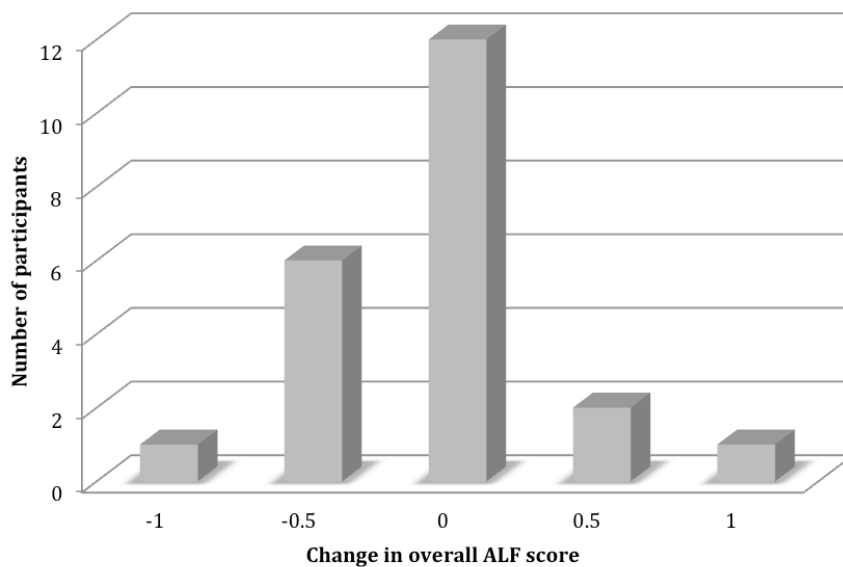
Eight participants who had withdrawn from the study provided feedback at the completion of the study. “Work commitments” was the most common reason for withdrawal, accounting for 60% of the withdrawals. Illness, and resignation or a change of role were also contributing factors.

## **9.5.2 Individual Assessment Methods**

### ***Self Assessment***

All participants completed a self-assessment of practice at the commencement of the project. At that time half of the participants (18) considered their practice to be at or approaching an advanced level (Level 3 in the Paediatric ALF). All but one of the remainder considered their practice approaching or at Level 2. Three of the four pharmacists who identified themselves as level 3 at the beginning of the project, were confirmed as level 3 by the panel at the end of the project, with the remaining pharmacist assessed at between 2 and 3. Self assessment provided evidence against each of the six clusters.

Self-assessment scores remained reasonably consistent over the time of the project, as shown in Figure 9.1 below. Half the participants did not change their self-assessment score. Only three participants increased their self-assessed level of practice, and seven participants decreased their self-assessed level.



**Figure 9.1 Change in self-assessment scores from beginning to the end of the research project**

### ***Direct Observation***

Eleven of the pharmacists in the study were evaluated using direct observation. Of those eleven, ten provided feedback on the process and its findings.

The direct observation tools used (the GLF or shpaclinCAT) provided evidence for the Professional Practice and Working Relationships clusters; however the current descriptors did not provide evidence at Level 3.

### ***Multi Source Peer Review***

A total of 23 pharmacists participated in peer review (Mini-PAT). Feedback was received from 20 study participants. An average of eight peers were invited to provide reviews, with an average of seven responses per pharmacist. Each participant received peer review feedback from (on average) one doctor, one nurse, three pharmacists and two other staff, usually pharmacy administration or technical staff.

Peer review provided evidence against each of the six clusters.

## ***Knowledge Assessment***

A total of 24 pharmacists provided information on postgraduate qualifications and CPD records. 15 (38%) had undertaken postgraduate training, with nearly half of those at Masters level. Of the qualifications undertaken, nine (60%) had some paediatric content and assessment, although no paediatric specific qualifications were undertaken.

Of the 18 pharmacists who submitted knowledge assessment information, six (33%) did not routinely record CPD points. The average total CPD points per participant per year was 126, with an average of 31 Group 2 points. There was no correlation between the level of practice and number of recorded CPD points. Pharmacists with the highest recorded CPD were those who were currently undertaking postgraduate training.

Knowledge assessment provided evidence against the Professional Practice and Education clusters.

## ***Portfolio Review***

All 24 of the pharmacists prepared a portfolio at the commencement of the project, of whom 17 pharmacists submitted a portfolio for review as summative assessment. Feedback was received from 19. Most of the participants used the Paediatric ALF itself as a tool to document their evidence of competency, however some chose to use a simple matrix format, or simply addressed the competencies in their curriculum vitae.

The portfolio (regardless of format) provided evidence against each of the six clusters.

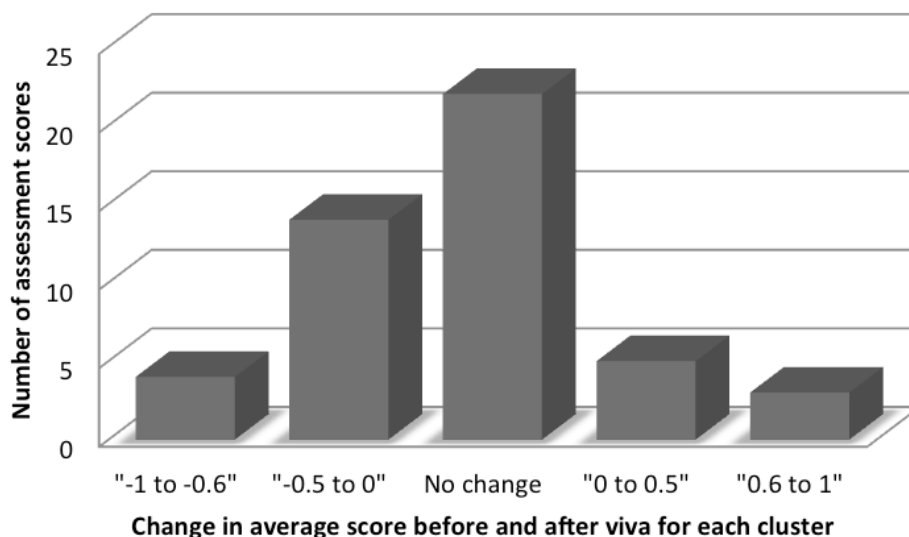
## ***Viva voce***

Eight pharmacists participated in the viva voce. Panels ranged from two to four members. Viva voce were undertaken face-to-face (3), via videoconference (2), and by telephone (3), with an average duration of 45 minutes. Panel size varied, from two (5), three (1) to four (2) members. The quality of the videoconferencing was not satisfactory; hence the final three vivas were conducted via teleconference.

The viva provided evidence against each of the six clusters.

For each participant, the evaluator scores before the viva (based on portfolio alone) changed after the viva by at least half a level in at least one cluster. Figure 9.2 shows the change in mean assessment score for each participant and cluster (i.e eight participants and six clusters = 48 mean

changes in score). The cluster with the most change in scores after the viva was leadership. Overall mean scores increased after the viva for four of the eight participants, and decreased for the other four.



**Figure 9.2 Change in average scores after viva (per cluster)**

### 9.5.3 Comparison of Assessment Scores

#### *Mean Scores for each assessment method*

**Table 9.2 Scores for each assessment method against each cluster**

Cluster		Self Assessment	Portfolio	Viva	Peer Review	Knowledge	Direct Observation
Professional Practice	N	21	17	8	21	18	11
	Mean	<b>2.29</b>	<b>2.31</b>	<b>2.59</b>	<b>2.51</b>	<b>1.72</b>	<b>1.77</b>
	Sd	.64	.40	.39	.38	.60	.26
Working Relationships	N	21	17	8	21	0	11
	Mean	<b>2.14</b>	<b>2.32</b>	<b>2.48</b>	<b>2.43</b>	.	<b>1.82</b>
	Sd	.57	.41	.48	.26	.	.25
Leadership	N	20	17	8	21	0	0
	Mean	<b>1.95</b>	<b>2.01</b>	<b>2.26</b>	<b>2.12</b>	.	.
	Sd	.51	.59	.43	.30	.	.
Management	N	20	17	8	21	2	0
	Mean	<b>2.4</b>	<b>2.13</b>	<b>2.15</b>	<b>2.30</b>	<b>1</b>	.
	Sd	.50	.53	.36	.34	0	.

Cluster		Self Assessment	Portfolio	Viva	Peer Review	Knowledge	Direct Observation
Education	N	20	17	8	21	18	0
	Mean	2.2	2.2	2.39	2.27	2.06	.
	Sd	.70	.41	.56	.42	.80	.
Research	N	20	17	8	21	0	0
	Mean	1.95	1.74	1.85	2.01	.	.
	Sd	.69	.56	.66	.46	.	.

Table 9.2 shows that direct observation and knowledge assessment did not provide evidence for every cluster. Where evidence was available, both direct observation and knowledge assessment scored lower than any of the other assessment methods.

### *Comparison of Methods*

The Skillings-Mack test was used to identify whether there was a significant difference between the scores for methods for each cluster. This analysis found a statistically significant difference in assessment scores for Professional Practice ( $p < 0.001$ ), Working Relationships ( $p = 0.026$ ), Management ( $p = 0.007$ ) and Research ( $p = 0.036$ ). The Leadership and Education clusters were not significantly different ( $p = 0.334$  and  $p = 0.294$  respectively). The statistical analysis of scores in the remaining clusters are listed below in Table 9.3, with the Wilcoxon Signed Rank test used to test each pair of methods to identify which combinations are different. The Bonferroni correction was applied to the results from the Wilcoxon Signed-Rank tests, resulting in a significance level of  $p < 0.003$  where six assessments were used (15 pairs: Professional practice),  $p < 0.005$  where five assessments were used (10 pairs: Working Relationships and Management), and  $p < 0.008$  where four assessments were used (6 pairs: Research).

**Table 9.3 Comparison of pairs of assessment methods per cluster (p-values)**

		Portfolio	Viva	Peer Review	Knowledge	Direct Observation
Professional Practice Skillings-Mack Test $p < 0.001$	Self	0.286	0.569	0.192	<b>0.001*</b>	0.006
	Portfolio		0.771	0.003	<b>0.002*</b>	0.041
	Viva			0.228	0.079	0.094
	Peer Review				<b>&lt;0.001*</b>	0.006
	Knowledge					0.800
Working Relationships	Self	0.234	0.716	0.033		0.154
	Portfolio		0.325	0.046		0.136



		Portfolio	Viva	Peer Review	Knowledge	Direct Observation
Skillings-Mack Test p=0.026	<b>Viva</b>			0.233		0.842
	<b>Peer Review</b>					<b>0.004*</b>
<b>Management</b> Skillings Mack Test p=0.007	<b>Self</b>	0.007	0.062	0.257	0.180	
	<b>Portfolio</b>		0.019	0.023	0.180	
	<b>Viva</b>			0.049	Unable	
	<b>Peer Review</b>				0.180	
<b>Research</b> Skillings Mack Test p=0.036	<b>Self</b>	0.013	0.203	0.866		
	<b>Portfolio</b>		0.725	0.010		
	<b>Viva</b>			0.036		

When pairs of assessment methods were compared, the scores for knowledge and direct observation assessments were the two methods that were statistically different to other assessment methods. The combinations of methods determined to be statistically significantly different (using the Bonferroni correction) are highlighted in bold in Table 9.3. It is noted that the use of the Bonferroni correction to avoid the risk of Type 1 error is considered to be quite conservative, and the small number of scores for some of the methods contribute to the lack of significance and in some cases inability to calculate a difference as there were no paired comparisons (such as viva versus knowledge for the management cluster).

### ***Correlation of Scores using Combinations of Methods***

The agreement between combinations of assessment methods was evaluated using the intra-class correlation coefficient (ICC). This is the correlation between the scores from any two or more randomly chosen assessments of the same individual. The closer the ICC towards 1, the more similar the scores are for each method for each individual pharmacist, with an ICC of 0.8 considered ideal for competency assessment.<sup>376,377</sup> The ICC for all assessment methods was tested initially, then for the three methods most strongly supported by the participants (peer review, portfolio review and viva voce).

Table 9.4 shows that the level of agreement between scores was low when all methods were included. However, there was closer agreement when only portfolio, peer review and viva voce were included.

**Table 9.4 Intra-Class Correlation for Combinations of Methods**

Cluster	All Six Methods			Viva, Portfolio & Peer Review		
	ICC	95% CI	P-value	ICC	95% CI	P-value
<b>Prof Practice</b>	<b>0.246</b>	0.097 – 0.466	<0.001	<b>0.476</b>	0.207 – 0.715	0.004
<b>Working Relationships</b>	<b>0.256</b>	0.092 – 0.490	0.003	<b>0.427</b>	0.169 – 0.677	NS
<b>Leadership</b>	<b>0.426</b>	0.210 – 0.660	NS	<b>0.443</b>	0.182 – 0.690	NS
<b>Management</b>	<b>0.372</b>	0.161 – 0.613	<0.001	<b>0.568</b>	0.302 – 0.777	0.005
<b>Education</b>	<b>0.467</b>	0.273 – 0.682	NS	<b>0.667</b>	0.441 – 0.834	0.034
<b>Research</b>	<b>0.506</b>	0.288 – 0.720	0.004	<b>0.419</b>	0.156 – 0.672	0.001

NS = Non statistically significant. ICC = Intra-class Correlation Coefficient, CI = Confidence Interval

### 9.5.4 Feedback

Feedback was received from 34 people in total, comprising 22 participants who had completed the project, 8 participants who withdrew from the project without completing it, 4 evaluators. Of the 12 participants in total who withdrew from the study, 8 provided feedback and four did not. Two participants who completed the study were unable to be contacted for feedback. Qualitative feedback was gathered via open-ended questions contained in the survey, as well as personal communications recorded during portfolio review and viva voce assessments in the course of the research project itself. Results below show the quantitative feedback from survey respondents regarding the assessment methods, and extracted themes from the qualitative feedback.

#### *Quantitative feedback about individual assessment methods*

Survey results comparing the individual assessment methods are included in Table 9.5 with feedback results separated according to the three categories of respondent: those participants who completed the project, participants who withdrew from the project, and evaluators.

These results show that the portfolio review, peer review and direct observation had the strongest support from participants as tools for professional development (positive experience allowing developing planning, and inspiring experience with renewed enthusiasm for practice). Whereas portfolio review, viva voce and peer review had the strongest support from participants as fair evaluation tools for advanced practice.

Panel members considered peer review and viva voce to be the fairest evaluation methods. They found the portfolio review process to be particularly taxing.

**Table 9.5 Quantitative Survey Feedback on Assessment Methods**

Assessment Method	# Respondents	Positive (Ranking)	Taxing* (Ranking)	Inspiring* (Ranking)	Fair Evaluation* (Ranking)
% of respondents "Somewhat Agree" or "Strongly Agree"					
<b>Portfolio</b>					
Participants	19	100% (1)	5% (3)	68% (4)	95% (1)
Withdrawn	6				86% (1)
Evaluators	4	50%			50% (4)
<b>Viva</b>					
Participants	8	88% (4)	13% (6)	75% (3)	88% (2)
Withdrawn	5				60% (4)
Evaluators	4	0%			100% (1)
<b>Peer Review</b>					
Participants	20	95% (2)	0% (1)	85% (1)	85% (3)
Withdrawn	5				60% (4)
Evaluators	4	0%			100% (1)
<b>Postgrad</b>					
Participants	15	60% (6)	7% (3)	60% (5)	73% (4)
Withdrawn	5				60% (4)
Evaluators	4	0%			50% (4)
<b>CPD</b>					
Participants	17	76% (5)	12% (5)	41% (6)	64% (6)
Withdrawn	5				80% (2)
Evaluators	4	0%			50% (4)
<b>Direct Observation</b>					
Participants	10	90% (3)	0% (4)	80% (2)	70% (5)
Withdrawn	5				80% (2)
Evaluators	3	0%			67% (3)

\* Positive refers to the percentage of respondents who agreed or strongly agreed that 'the assessment was a positive experience that allowed me to reflect honestly on my practice and plan my future development'. Taxing refers to the percentage of respondents who agreed or strongly agreed that 'the assessment was an extremely taxing process that provided little benefit to me'. Inspiring refers the percentage of respondents who agreed or strongly agreed that 'the assessment was an inspiring experience that has given me renewed enthusiasm for pharmacy practice'. Finally "fair evaluation" refers to the percentage of respondents who agreed or strongly agreed that 'the assessment was a fair evaluation of advanced practice'.

### ***Direct Observation of Practice***

The participants felt that direct observation of practice using tools such as the GLF or shpaclinCAT was valuable for professional development but not suitable as a summative assessment tool for advanced practice. The criteria within these tools were not designed to evaluate advanced practice

and did not match the descriptors in the ALF for advanced practice. A number of participants also commented on the need for multiple evaluations, whether for formative or summative assessment purposes.

*ClinCAT is a good tool but not for this particular thing, it's more process orientated. (Participant 28)*

*Refreshing for advanced practitioners to have new eyes on their clinical work, and works both ways - assessor also learns and can incorporate great ideas into general clinical practice. (Participant 13)*

*I think direct observation is extremely valuable to assess a practitioner who is working at an advanced level (Evaluator 3)*

### **Peer Review**

The participants were very positive regarding the use of the Mini-PAT as a development tool. However, there were some concerns from participants regarding its use as an advanced practice evaluation method because of the potential for bias when the peers are chosen by the pharmacist themselves. They also noted that it was difficult for some peers (particularly those from other disciplines) to be aware of all the different aspects of practice and experience.

*It was valuable to know my peers' perceptions of my practice. It was also surprising in that I was rated higher by my peers than I perceived myself. (Participant 26)*

*I think the opinion of people you work with every day are more valuable than how you can answer questions for one hour. (Participant 3)*

*Not completely convinced this is an adequate assessment as it relies on choosing peers who both have seen evidence of your level of expertise but also that they adequately note that in the assessment. (Participant 10)*

*I found the feedback provided in the Mini-PAT to be very honest and constructive. In the normal business of day to day work it is uncommon to receive frank comments and positive feedback and it was a pleasant reminder to me that in general I was on the "right track". Unfortunately not all supervisors feel comfortable to provide this type of feedback either in the work environment or in formal performance appraisals, so for me it was a pleasant experience to receive encouraging and constructive feedback. (Participant 9)*

## ***Postgraduate Qualifications***

There were a number of comments related to the importance of currency if training was undertaken some years ago, relevance to current scope of practice, and the absence of paediatric specific training in Australia. Both participants and evaluators felt that postgraduate qualifications were not a discriminatory evaluation method for advanced practice.

*I believe that undertaking my post graduate studies was extremely beneficial and stimulating for me at the time it occurred, however the relevance for my current field of work is less significant, so as a tool in assessing advanced level practice for me, it is not particularly useful. It should depend specifically on the subjects involved in the post graduate studies and the recency of the study, not just the fact that it had been completed. (Participant 9)*

*Current Postgraduate Qualifications available in Australia I feel does not provide relevant assessments of paediatric pharmacists practicing levels. (Participant 30)*

## ***CPD Records***

One third of the participants did not routinely maintain a CPD record, although all were clearly undertaking ongoing professional development. Comments from participants indicated that many recorded enough “CPD points” for registration purposes. However the recorded CPD was not linked to a professional development plan.

*Not completely convinced that CPD is an adequate assessment as it may provide information about areas that the person being assessed is interested in. May not provide adequate information of their overall performance or level of experience. (Participant 10)*

## ***Portfolio***

The participants considered the portfolio review process to be helpful and worthwhile, providing professional direction. Nevertheless, there were numerous negative comments regarding the time required to prepare a portfolio in the current format. Participants estimated that it took between 2-4 hours to prepare the portfolio, and the discussion with the evaluator took 1-3 hours. Participants who had previously maintained a professional portfolio found the process quicker than those for whom this was a new process, and those who prepared well before the discussion session gained more from the process than those who had spent minimal time in preparation. Panel members also

found the portfolio evaluation process time-consuming because of the large numbers of evidence examples.

*I found the portfolio review to be an excellent experience, as it gave me direct feedback on where all my current and past activities 'fit' in terms of my level of practice, and also provided ideas of how I could extend certain activities for personal development. (Participant 13)*

*It was a time consuming process, however I found it to be a positive experience. It helped give direction to my future professional development plans. (Participant 30)*

*I think it is a very valuable piece of work. However the time required to put the portfolio together and other commitments for the participants were very extensive to be completed with a busy workload. (Participant 24)*

Suggestions were made to improve the process with the use of clearer guidelines for evidence, electronic tools including hyperlinks to evidence, and a two-page summary such as used for funding grant proposals. The items of evidence with the highest preference from participants and evaluators for inclusion in an advanced practice portfolio were the ALF, peer review (Mini-PAT), research (published or conference presentations), and direct observation (using the clinCAT or GLF). Least preferred evidence were CPD records, thankyou notes or other acknowledgements, written references and student feedback.

An internet based electronic format for portfolio maintenance and submission was preferred by a majority of participants (69%), although an electronic format on a personal device, such as a USB stick, was preferred by the evaluators. There was significant difficulty for participants in accessing Dropbox in the workplace, and there were some concerns expressed regarding the security of cloud-based platforms.

### ***Viva Voce***

Participants were generally quite anxious before the viva (5 out of 8 were apprehensive or anxious) with half of the participants feeling 'a little better' or 'much better' after the viva. Most participants found the opportunity to discuss their career progress and to receive feedback and direction for the future to be very helpful and 7 out of 8 participants found the viva to be a positive experience. Two participants initially felt 'a little worse' after the viva, and found the process challenging as it identified gaps in their practice they were not previously aware of. On reflection, though they

found the process beneficial overall. One participant felt ‘much worse’ after the viva (see comment below). Some participants would have liked to know more detail about the format and likely questions prior to the viva. Other participants expressed the view that the ability to “think on your feet” in response to unforeseen questions demonstrated oral communication skills.

Most participants (86%) felt that the viva gave the opportunity to provide additional information to support their level of practice. All of the evaluators felt that the viva was valuable and should be a component of future credentialing processes. They felt that the format of the viva should be more structured, with defined questions. Evaluators preferred three members on the panel. Participants felt that four panel members were too many, and that one panel member should be a subject expert.

*The discussion and feedback was tremendous - again providing validation of current level 3 activities and guidance on how to move level 2 to 3. This should be part of all advanced level practice reviews, as it demonstrates oral communication skills described in evidence and ability to think on your feet. (Participant 13)*

*I found the oral viva process very satisfying, a bit like a good performance appraisal should be, but with external perspective and fresh ideas, which, can sometimes only come from outside your direct place of work. (Participant 9)*

*I certainly think this is important part of any assessment of advanced practice as it is a way of confirming and evaluating the material submitted. (Participant 11)*

*I felt 100% worse about my skills and experience after doing the oral viva. I also felt attacked and interrogated. Not a positive experience at all. (Participant 32)*

*Mostly very revealing – great opportunity to expand on points identified in the portfolio (Evaluator 4)*

### **Professional Development Opportunities**

Some pharmacists made comments informally and via the final survey regarding their perceptions of insufficient support and encouragement for professional development within their organisation. Despite differing perceptions of inadequate development culture between the sites, there was no difference in the amount of time provided in working hours to undertake assessment tasks, which was minimal at all sites.

*From my institutions perspective, it needs to have a mandatory component, or be incorporated into performance or annual review. Many practitioners here were keen to participate but withdrew due to time pressures at work. If all roles came with the expectation of annual review of practice and evidence, and time and resources were allocated to allow this, there would have been more uptake. (Participant 13)*

## **Research**

Many participants described a desire to be more involved in research, but they were uncertain how to begin. All were involved in quality improvement activities; however, only the more experienced staff routinely shared these experiences via conference presentation. Few participants had published. The participants described a number of barriers to undertaking research including: lack of research culture within individual departments and organisations; lack of financial or administrative support; uncertainty about where to start; and lack of mentors to ask for advice. Those who had undertaken research activities had commonly undertaken the work in their own time (often as a component of postgraduate education assessment), identified funding opportunities themselves, or had left the organisation to enable development of research skills.

### **9.5.5 Mapping Advanced Practitioners against the Framework**

The expert panel identified five participants they considered advanced pharmacy practitioners (i.e. predominantly Level 3). Table 9.6 summarises the levels of practice (from 1 to 3) of the five participants (identified as practitioners A-E) against the condensed Paediatric ALF competencies. This table shows that not all of the advanced practitioners achieved Level 3 in all individual competencies of overall clusters, although almost all of the remaining competencies were at Level 2.



**Table 9.6 Advanced practitioners' competency levels mapped against ALF competencies**

Condensed competency descriptor at Level 3		Advanced Practitioners				
		A	B	C	D	E
<i>Years of practice</i>		>25	>30	>25	>25	>20
Professional Practice	Advances knowledge base in defined areas	3	3	3	3	3
	Advances pharmaceutical care programs	3	3	3	3	3
	Responsible for patient service	3	3	3	3	3
	Ability in difficult and dynamic situations, makes decisions in absence or conflicting data	3	3	3	3	3
	Interprets health policy and establishes standards for others	3	3	3	3	3
Building Working Relationships	Communication of complex topics with large groups, snr managers, hostile environments	3	3	3	3	3
	Works across boundaries, provides expert advice and is opinion leader external to organisation	3	3	3	3	3
Leadership	Long term, sector wide planning, participates in creating national policy, shapes agenda	3	3	3	3	3
	Shares vision at higher level, innovation to improve service delivery, linked to organisational goals	3	3	3	3	3
	Motivates others at a higher level	3	2	3	3	3
Management	Accountable for delivery of national priorities at a higher level	3	3	3	3	3
	Reconfigures the use of available resources	3	3	2	3	2
	Accountable for setting and monitoring of standards at a higher level	3	3	3	3	3
	Accountable for risk management at higher level	3	3	2	3	3
	Accountable for performance management at a higher level	3	3	2	3	2
	Managed a project or change at higher level	3	3	2	3	2
Education, Training and Development	Develops role model behaviour in others, mentors outside of team.	3	3	3	3	3
	Designs course of study, shapes higher education qualifications, and national education policy, contributes to multidisciplinary and external CPD.	3	2	2	3	3
	Higher postgraduate qualifications (Masters/PhD).	3	1	3	2	3
Research and Evaluation	Peer review activities within specialty	3	3	3	3	2
	Designs specialist research strategy, critical review of protocols, peer reviewed publication	3	3	2	2	2
	Applies research evidence to shape organisational procedures/policies	3	3	3	3	3
	Supervises postgraduate students	3	2	2	2	2
	Leadership in specialist research.	3	2	2	2	2

### ***How well do the ALF clusters match the identified advanced practitioners?***

**Professional Practice:** All identified advanced practitioners had significant experience in paediatrics, two with broad experience and three with specialist experience. All had greater than 20 years experience. Only one was in a clinical team based role, although all but one had some responsibility for a patient service. All had advanced the knowledge base via contribution to published guidelines, references texts and research literature. All had evidence at Level 3 across each competency within this cluster.

**Working Relationships:** All were sought out as opinion leaders, involved in complex, high level committees and clinical groups making difficult decisions in potentially hostile environments. All had evidence at Level 3 across each competency within this cluster.

**Leadership:** All were involved at a state or national level with decision-making bodies, influencing policy and agenda. Appropriate evidence for motivation of others at a higher level was difficult to produce for some participants. All but one of the advanced practitioners had evidence at Level 3 across each competency in this cluster.

**Management:** Three had roles with direct supervision, managing a team or department. Two managed a complex service without direct supervision responsibility. All were involved in development and implementation of standards of practice, performance management and risk management at an organisational level, though few were directly accountable for these tasks. Three of the advanced practitioners had evidence at Level 3 across each of the competencies in the management cluster.

**Education, Training and Development:** None had impact on national education policy, however all contributed to the education of pharmacists and other health professionals outside of their institution and discipline. All except one had ongoing education roles with tertiary institutions and professional organisations, as regular contributors to seminars, lectures and tutorials. All except one had postgraduate qualifications, three at Masters level. For many participants, their role modelling and mentoring activities at a high level were undocumented and evidence was difficult to produce. Two of the advanced practitioners had evidence at Level 3 for every competency in the Education cluster.

**Research and Evaluation:** All had participated in specialist research, and shared research widely via conference presentations. Three had published in peer reviewed journals, and one as a first author. Those who had not published were uncertain of how to move from quality improvement

activities shared via conference to published research: for example, how to start writing a manuscript, and where to find suitable mentors or co-investigators. Only one of the advanced practitioners had evidence at Level 3 for every competency within the research cluster.

### ***How do the advanced practitioners differ from the other practitioners?***

The Level 3 advanced practitioners had an average of 26 years experience in comparison to 9 years experience for those at Level 2. They were more likely to be involved in state, national and international level groups as recognised experts in their field, and involved in significant national projects to improve quality of care. All had contributed to research to improve knowledge and practice, with the advanced group sharing research widely including in some cases by publication, in comparison to the non-advanced group who were more likely to share only via conference presentations.

## **9.6 Discussion**

This study has piloted a series of six assessment methods to evaluate advanced pharmacy practice. This is an important step towards formal recognition of advanced pharmacy practitioners in Australia.

### **9.6.1 Self-assessment**

There was close correlation between those participants who considered themselves to be advanced practitioners at the beginning of the project with those who were assessed as advanced practitioners by the expert panel. Scores from self-assessment were not significantly different to those from the other assessment methods, except knowledge assessment and direct observation. The process of working through the framework improved familiarity with the expectations of an advanced practitioner. This indicates that the process of working through an advanced practice framework in preparation for an application for formal recognition should provide sufficient guidance to current level of practice to avoid a large number of unsuitable applications.

### **9.6.2 Direct observation**

The General Level Framework and shpaclinCAT tools used in this study have been used successfully as formative assessment tools in a variety of general clinical practice settings.<sup>209,210,296</sup> However, in this study the shpaclinCAT was not found to be a reliable evaluation tool to differentiate advanced practice, primarily as it does not articulate advanced level competencies. A

customised tool such as the Mini-CEX used by the Critical Care group in the UK may be a suitable alternative for advanced practice assessment for those working in direct patient care roles.<sup>286</sup> It is still unlikely that key advanced competencies such as ‘advancing the knowledge base’ would be demonstrated in a single period of observation. The use of external experts for the evaluations would likely improve consistency and robustness of the process, however would add significantly to the cost. Nevertheless, direct observation assessments would be valuable evidence as a component of a portfolio to demonstrate ongoing commitment to (and improvement in) clinical practice, particularly if undertaken regularly.

### **9.6.3 Multi Source Peer Review**

Multi source peer review was a reliable advanced practice assessment method that provided comparable scores to the other methods. Feedback from the peer review process as a development tool and evaluation tool was overwhelmingly positive, confirming the experiences from the UK.<sup>286,311,312,328</sup> However, there were some concerns raised by participants regarding its future use for high stakes assessment, because of the possibility that the choice of evaluators by the pharmacists themselves could introduce bias, as found by Archer and McAvoy<sup>313</sup> In our study the reviewers focused on providing feedback to the pharmacist for their own professional development, although the reviewers were also informed that it was part of a research project for assessment. It is possible that the reviewers would have scored differently if the feedback were used for high stakes summative assessment, as found by Burford et al.<sup>309</sup>

### **9.6.4 Knowledge Assessment**

The knowledge assessments included in this study did not provide reliable scores when compared to the other assessment methods. The scores were statistically significantly different from those for other assessment methods. Just over one-third of the pharmacists had undertaken formal postgraduate training, which is slightly higher than the general hospital pharmacy population, according to a workforce survey from 2007 where 29% of the population and 30% of pharmacists working in specialist women’s and children’s hospitals had postgraduate qualifications.<sup>371</sup> Most pharmacists considered that undertaking formal postgraduate qualifications was a positive experience. However there were doubts regarding their use for assessment of advanced practice as set out in the APPF.<sup>141</sup> These results are similar to those from the previous focus group study where formal postgraduate training was not thought to be a mandatory component of advanced practice.<sup>355</sup>

When considering qualifications specific to the practice area, none of the pharmacists in this study group had undertaken specific paediatric training. This was due to the lack of available training in paediatric pharmacy in Australia. For some pharmacists this formed a barrier which prevented any further postgraduate training. It also makes it unfeasible for postgraduate training to be used as a mandatory component of assessment of advanced pharmacy practice. The BPS Certification in Paediatrics (available from 2015) may change this perception in the future, although this will not be a local qualification, and will only provide assessment of knowledge rather than specific training in itself.<sup>100</sup>

CPD records were not considered by the participants or evaluators to be either useful or reliable as an assessment method for advanced practice. Although all participants undertook significant professional development activities, one third of the participants did not routinely record their CPD. It was apparent that many pharmacists did not see the value of recording CPD except as a registration requirement.

### **9.6.5 Portfolio**

A portfolio provided reliable scores when compared to the other assessment methods for advanced practice, and was strongly supported by participants and evaluators as a development and evaluation tool. Feedback from the portfolio review was very positive as a development tool, despite the significant time required preparing the portfolio using the Paediatric ALF as a framework. The process of collating evidence was considered a positive experience, in identifying where the practitioner was on the journey to advanced practice. This was enhanced when the portfolio was discussed with a mentor.

There was also strong support for portfolio review as an evaluation method for advanced practice as it allowed the opportunity to present evidence across a wide range of competency areas, and this is consistent with experiences in nursing and allied health where portfolios are a significant component of advanced practice evaluation.<sup>149</sup> However a portfolio for evaluation must be shorter and more targeted than one used for professional development over a lifetime, and should be more selective than a portfolio used for formative assessment or appraisal, as described by other commentators.<sup>277,279</sup> Use of a structured template, and careful structured selection of portfolio evidence, such as used for the RPS Faculty membership, is required to avoid excessively large portfolios, and ensure the evaluation process for panel members is sustainable.

### 9.6.6 Viva voce:

The interview (or viva voce) provided comparable scores to the other methods, and was considered to be a fair evaluation method of advanced practice by all evaluators and all but one participant. It provided a valuable opportunity for evaluators to investigate evidence in the professional portfolio, and participants to explain their contribution to practice. Face-to-face format was preferred, however this may have been influenced by the poor video quality of the videoconferencing technique used during the study. This may be less of a barrier with more reliable videoconferencing technology in the future, with potential to reduce costs. A panel comprising 2-3 members (including a subject expert) was recommended by participants and evaluators, although the skills of the panel members may be more important than the number of members. Appropriate training for panel members, and consistency of approach between different panels and interviews will be essential for the use of this approach in the future.

The results of this study correlate with published research into the use of interviews as a reliable selection tool. Interviews, involving face-to-face contact with a single or multiple interviewers with varying degrees of structure, have been widely used for workplace recruitment for over 100 years.<sup>378</sup> However, the reliability and validity of interviews as a selection tool for assessment of health practitioners and admission to training programs has been questioned.<sup>322,378-380</sup> Standard interviews are no longer required for competitive grant selection and have become less commonly used for medical school entry.<sup>380</sup> More recent research has introduced a modified format of interviews called “Multiple Mini Interviews” which have been found to be a more reliable, acceptable and feasible method for assessment in medical officers but would add to the cost.<sup>380,381</sup>

The format of the interview or viva had an impact in this study. Some participants preferred a more structured format with defined questions. This recommendation is consistent with recent research that recommended structured interviews offer more reliability than a free-form interview format. Behavioural interview questions (where applicants were asked to recall what they had actually done in particular situations) more reliably differentiated candidates than a descriptive or scenario question (where applicants are asked what they thought they would do in a particular situation) to predict future performance.<sup>323-325,382</sup>

### 9.6.7 Combinations of methods

This study investigates combinations of assessment methods, as is increasingly used in high-stakes assessments in health fields. This includes the recent work by the RPS Faculty where a portfolio, curriculum vitae and testimonials are used for assessment of advanced practice and membership of the Faculty.<sup>119,374</sup>

In the medical field, admission to an advanced training program (including general paediatrics) with the Royal Australasian College of Physicians (RACP) requires completion of an accredited basic training program and passing of the RACP written and oral examinations.<sup>143</sup> Completion of advanced training requires multiple formative assessments each year, including case based discussions and Mini-CEX's, combined with summative assessments of supervisors reports at the end of each training rotation and a significant research project.<sup>143</sup> This approach is supported by recent research in the medical field which found that a portfolio which combines seven Mini-Clinical Examinations (Mini-CEX), eight direct observation of procedural skills and one multi source peer review was a feasible and reliable method of high stakes assessment.<sup>292</sup> A similar study found a minimum of four case based discussions, four Mini-CEX and 6-14 observations of procedural skills were required to achieve a reliable result in obstetrics and gynaecology setting.<sup>327</sup>

In our study, the combination of the three assessment methods (viva voce, multi source peer review and portfolio review) provided a higher Intra-class Correlation Coefficient than all six methods combined. These were also the tools most strongly supported by participants and panel members for evaluation of advanced practice, and had reliably consistent scores across each cluster.

### 9.6.8 How well does the existing framework match current advanced practitioners?

In this study, the participants identified as advanced practitioners met every Level 3 requirement for the clusters of Professional Practice, Working Relationships and Leadership. The three remaining clusters were not all met at level 3 for all practitioners, however almost all individual competencies met the requirements of Level 2. This is consistent with the original work from the UK, where the majority of “leading-edge practitioners” also did not meet the highest level for the Education and Research clusters.<sup>114</sup> There are some additional limitations with the current terminology in the framework such as ‘accountable’, which may reflect the practitioner’s defined role within an organisation, rather than the pharmacist’s actual practice or impact which may be broader than their official role.

### 9.6.9 Limitations

There were a number of limitations to this pilot study. Recruitment was a convenience sample of pharmacists from four tertiary paediatric hospitals. Therefore participants cannot be assumed to represent the beliefs, opinions or experiences of all Australian pharmacists. Only 20% of the participants were male, which was lower than the proportion of males in the registered pharmacist population, however may be more representative of the hospital pharmacist population.<sup>383</sup>

Methods were chosen based on those that were currently in common use, in order to maximise future sustainability. This imposed limitations, as tools developed for specific purposes (particularly for formative assessment such as the GLF or shpaclinCAT) may not be appropriate for use in high stakes summative assessment. The expert panels were not the same for each of the participants, and there was small degree of difference in scoring between evaluators (maximum half a point). However, the use of ranking for each panel member assisted in identifying the highest-ranking participants. This is also a ‘real world’ scenario where varied composition of panels is likely.

Feedback from participants may have been influenced by the positive relationship developed with the researcher over the course of the study. The high proportion of “somewhat agree” or “strongly agree” feedback for each of the multiple choice questions about methods was in contrast to the sometimes negative or ambivalent qualitative feedback from the participants for some of the methods. Hence the quantitative data was analysed to identify the methods with the strongest support, and this data was combined with the qualitative feedback to reach conclusions.

One third of the participants withdrew from the study. Withdrawal by participants was predominantly attributed to work commitments, as work time was not generally provided to undertake the assessment tasks. Despite the differences in withdrawal rates across the different sites, there was no difference between study sites as to the work time provided to participate in the assessments for this study. This is also a ‘real-world’ situation where most workplaces have limited allocation of time within the workday to complete professional development activities.

The commencement of this study pre-dated the release of the Australian Advanced Pharmacy Practice Framework (APPF), and therefore used the Paediatric ALF, which was the framework in use at the time. The broad competency statements within each of the documents are very similar; therefore the results should be transferrable to the APPF.



## 9.6.10 Future Work

### *Development of Advanced Practice*

It was clear that there is a need for research support for pharmacists across all levels of practice. Most pharmacists in the study expressed a desire to be more involved in research and to share their quality improvement activities via publication, but were ‘uncertain of where to start’, and could not identify suitable colleagues to approach for advice. This was consistent with recently published research by Grzeskowiak et al that found that only 10% of abstracts on paediatric topics presented at an Australian national pharmacy conference were subsequently published.<sup>384</sup> These gaps provide opportunities for professional organisations, tertiary institutions, employers and research institutes to become more involved with providing focused training in this area, including linking early career researchers with more experienced research mentors and supporting opportunities for research funding.

The current detailed format of the paediatric practice component in the Paediatric ALF makes it time intensive to use as a portfolio for assessment, although it has been valuable as a development tool. Following the recent introduction of the generic Advanced Pharmacy Practice Framework (APPF), there is a need for an aligned restructure of the paediatric component of the Advanced Level Framework (ALF). This would form a separate curriculum for professional practice learning in paediatrics – and thus facilitate progress to advanced practice.

A user-friendly electronic portfolio will need to be developed, that supports professional development through the linking of evidence across different competencies. Ideally this would link development planning, and recording of self-reflection and CPD activities to improve the current disconnection between professional development and CPD recorded for registration purposes. The same portfolio will need to have the functionality to extract a portion of the content for advanced practice assessment purposes.

### *Assessment of Advanced Practice*

The endorsement of the APPF by the Pharmacy Board of Australia, the nomination of the APC as the credentialing body, and the release of the first consultation paper on evaluation of advanced practice were all important steps in formal recognition of advanced practice pharmacists in Australia.<sup>141,373</sup> The next step will be the design of advanced practice evaluation of Australian pharmacists. The results from this study support the use of portfolio review, multi source peer

review and a viva voce as suitable evaluation methods for advanced practice. It also confirmed the approach of the Royal Pharmaceutical Society and the experience from the first phase of RPS Faculty members.<sup>112,374</sup> Further work will be needed to develop an electronic portfolio for assessment purposes (as discussed above), to provide guidance on appropriate evaluators for peer review, to identify and train suitable members for viva panels.

Additional assessment methods for professional practice may be valuable for pharmacists working in direct patient care roles, such as Case Based Discussion and customised Mini-CEX. However the feasibility of identifying appropriately trained assessors for individual specialties may influence the practicality of these for routine use.

### ***Advanced Practice and Patient Outcomes***

The cohort of pharmacists in this study had contributed significantly to improving the care of individual patients and contributing to significant improvements in safety and quality at an institutional and national level. The challenge for future research will be to measure and quantify the value of this contribution in patient outcomes.

## **9.7 Conclusion**

This study has demonstrated the reliability of multiple assessment methods to evaluate advanced paediatric pharmacy practice, with portfolio review, peer review and viva voce the most effective. These three tools provided consistent scores in combination, and were supported by the participants and panel members as preferred evaluation tools for advanced practice. Postgraduate qualifications and CPD records can be included as evidence in a portfolio but not as stand-alone assessment methods. Direct observation tools such as the General Level Framework or shpaclinCAT are valuable tools for development, but are not suitable for assessment of advanced practice. Future work is required to develop a suitable electronic portfolio that can be used for both professional development and summative assessment. Practical aspects regarding resourcing, appropriately trained expert panels and format for a viva voce, and facilitation of multi source peer review will need to be determined by the credentialing body. Significant gaps remain in support for pharmacists to develop research skills and more effectively undertake and translate important quality improvement activities at a local and national level.

# 10 Chapter Ten: Thesis Discussion and Conclusion

## 10.1 Introduction to Chapter Ten

This thesis describes a series of projects investigating the characteristics and assessment methods for advanced paediatric pharmacist practitioners and their contribution to improved safety and quality of medication use in children. Case identification methods and evidence for quality improvement activities has expanded rapidly over the past few years, alongside inclusion of medication safety as a separate standard for accreditation in Australia and rapid uptake of safety initiatives at a national level. The successful strategies in one institution as described in this thesis reflect these changes and improvements in safety and quality. At the commencement of this project, advanced pharmacy practice was still a concept being grappled with by the general pharmacy population. However, with the sharing of early results from this research, and the ongoing efforts by many at a national and international level, formal recognition of advanced pharmacy practice in Australia is now on the horizon.

## 10.2 Summary of the key findings

### *What is advanced paediatric pharmacy practice?*

The journey towards advanced practice was first described in detail by the Advanced and Consultant Level Framework in 2005.<sup>115</sup> In the absence of general or advanced level specialty training in paediatric pharmacy in Australia, a paediatric version of the ACLF, called the Paediatric Advanced Level Framework (ALF), was developed in 2008.<sup>133</sup> At the commencement of this research, the paediatric ALF had been in use in Australian paediatric hospitals as a development tool but not for formal assessment of practice.

The research described in this thesis investigated the definition, significance and potential assessment of advanced paediatric pharmacy practice to Australian paediatric pharmacists via a series of focus groups with 31 paediatric pharmacists (described in Chapter 6). These pharmacists described sound clinical skills, excellent communication and interpersonal skills, skills in education, leadership and a commitment to quality improvement as key components of an advanced practice pharmacist. The pharmacists considered that advanced pharmacy practice was essentially the same for paediatrics as for other areas of practice, with the addition of knowledge of paediatric diseases, drug handling in children as well as developmentally appropriate communication skills with children and families. The focus groups also recommended the use of portfolio review, peer review

and direct observation as assessment methods for advanced pharmacy practice. These were further investigated in Chapter 9.

The feedback from these focus groups confirmed the concepts articulated in the Paediatric ALF, including knowledge, skills, attitudes and behaviours, to be appropriate for the Australian paediatric pharmacy environment.

### ***How does a paediatric pharmacist develop advanced practice?***

The Paediatric ALF provided a practitioner-driven development pathway for paediatric pharmacists, including suggestions for strategies to develop and demonstrate competency across six clusters and three levels of practice. Two of the professional development strategies described in the Paediatric ALF were investigated in this research project as potential methods to develop and assess advanced practice within paediatrics.

The first of these was the General Level Framework (GLF), a generic competency assessment tool using direct observation of practice, in use at the time in many Australian hospitals. The research in Chapter 8 described a retrospective analysis of 50 GLFs undertaken in pharmacists working with children in Queensland public hospitals. This analysis found that pharmacists were consistently undertaking the routine legal and safety requirements including dose checking and ensuring prescriptions were legal and legible. Gaps were identified in clinical documentation and the more detailed clinical tasks of patient history assessment and recording of a medication action plan. Identified training needs included knowledge of paediatric pathophysiology and effective communication with children and families. Regional areas were particularly in need of assistance. This study confirmed the role of the GLF as a valuable tool for development and formative assessment of general clinical pharmacy skills, and appropriate for the paediatric environment. However, it did not include specific paediatric content or advanced level competencies.

The second set of tools investigated was documentation of pharmacist interventions, as described in Chapter 7. This study involved retrospective review of 600 pharmacist interventions recorded by paediatric pharmacists over eight years, matched to the skills described in the Paediatric ALF. The findings of this study were that the recorded interventions demonstrated increasing skill over time towards advanced practice, including identification of drug related problems, appropriate resolution of problems, communication and negotiation skills with patients and other health practitioners. Intervention recording, and reflective review of interventions, is a valuable strategy for professional development and can be used as evidence for developing practice. The skill level described in the

interventions matched the global level of practice assessed via an expert panel in the advanced practice assessment project described in Chapter 9.

Examples of advanced practice often include practice changes to improve safety but are commonly achieved weeks or months after the initial intervention was recorded. Therefore these interventions would not be documented in a routine intervention record. In addition, some advanced level practice improvement activities involve populations of patients rather than a single patient and therefore also not recorded as part of routine intervention documentation. The use of more complex case based demonstrations and reports or publication of quality improvement activities may be more useful as evidence of skill for pharmacists practicing at an advanced level.

### ***How do pharmacists know they are practicing at an advanced level?***

The focus group project described in Chapter 6, identified portfolio review, peer review and direct observation of practice as preferred methods for assessment of advanced practice. The advanced practice assessment project described in Chapter 9, piloted six different potential assessment methods to evaluate advanced pharmacy practice. A total of 36 pharmacists from four Australian paediatric hospitals initially enrolled in the project and 24 completed the study. Portfolio review and peer review were both confirmed as appropriate assessment methods, as they provided reliable assessment scores and were strongly supported by participants and evaluators for both formative and summative assessment. An oral interview (or viva voce) was also supported by pharmacists and evaluators as a means of structured analysis of portfolio evidence and had reliable scores across all competency clusters. Direct observation of practice using the GLF or shpaclinCAT was supported as a development tool for formative assessment but *not* as a fair evaluation tool for summative assessment of advanced practice. This moderates some of the findings in the GLF assessment research described in Chapter 8. Knowledge assessments using postgraduate qualifications and CPD records are suitable for inclusion in a professional portfolio but not as separate methods of assessment of advanced practice.

### ***What does advanced pharmacy practice mean for children?***

The majority of the research into the value or impact of pharmacists on patient care has been based on prevention of adverse medication events. Hence this research investigated activities and skills to improve medication safety in hospitalised children.

The initial adverse medication event study described in Chapter 4 investigated six months of administrative coding (using ICD-10) in combination with clinical incident reports and pharmacist

interventions to identify adverse medication events. This study found that each case identification method detected different events with very little overlap. Pharmacist interventions identified the most error, but few cases involving harm, as these were largely near-miss events where the pharmacist resolved the error before it reached the patient. Incident reports identified events involving error, and some occasions of harm, with little duplication with other sources. ICD-10 coding identified the most events involving harm but few instances of error, therefore did not detect potentially preventable adverse medication events. The time required to investigate ICD-10 coded events using manual chart review was prohibitive for ongoing use for the subsequent research within this project where focus was on error reduction and safety improvement.

This project demonstrated the large number of documented pharmacist interventions that improve the safety of medication use in children. These interventions were largely changes in therapy for individual patients where the knowledge and skills required (such as knowledge of appropriate medication doses and identification and resolution of medication related problems) are expected of pharmacists early in their career. In contrast, the more complex and broader changes at a system or institutional level required more advanced skills. The use of intervention reports to demonstrate the skill progression over time towards advanced practice was investigated in Chapter 7, as described above.

Activities to improve safety and prevention of adverse medication events were investigated in more depth in Chapter 5. This research in one paediatric hospital investigated eight years of medication related events identified by clinical incident and pharmacist intervention reports. The nearly 11,000 separate recorded events identified trends in types of medications, risk characteristics and proximal causes of errors and harm. A proportion of total reported events were used for analysis to minimise the impact of reporting bias. A significant reduction in reported chemotherapy-protocol-related prescribing errors was identified, suggesting the positive effect of prescribing restrictions, education, standardised charts, and electronic prescribing systems to decrease errors. A downward trend in reported errors involving potassium also demonstrated the impact of increased awareness, forcing functions, clinical guidelines and multidisciplinary involvement.

These positive changes in safety required significant multidisciplinary involvement and strong executive endorsement. Importantly, the skills required of health practitioners (including pharmacists) to increase medication safety and decrease risk were investigated. These were found to include leadership, education, risk management, project management, teamwork, communication

and skills in research methodology such as evaluation, analysis and reporting. These skills are the same as those described for an advanced practice pharmacist, including in the paediatric setting.

The research projects involving adverse medication events demonstrated more than just the positive influence on safety for individual patients, they also demonstrated the changes pharmacists have contributed towards improvement in quality of care at a system level and the advanced skills required to undertake these quality improvement activities.

### **10.3 Recommendations for future research**

This research project has confirmed that formal recognition of advanced pharmacy practice is suitable and appropriate for Australian pharmacists. Progress towards this has already been made, utilising the early results of this research project. It is recommended that evaluation of advanced practice should include portfolio review using an electronic format, peer review using suitable assessors, and a viva voce using structured questioning with an expert panel. Further evaluation should be undertaken regarding the reliability of these measures using larger groups of pharmacists.

Once a cohort of advanced practitioners has been identified, further research is recommended into the direct patient benefits achieved by advanced pharmacy practitioners as part of the healthcare team. This research should include paediatric settings. Another consideration to be included is the different needs and considerations in regional hospitals versus specialist metropolitan hospitals, taking into account the gaps identified in the GLF research described in this thesis.

Future work should include adaptation of the current Paediatric ALF into a paediatric curriculum for pharmacy. This curriculum should be incorporated into educational opportunities available to pharmacists across all sites, including regional and community settings. Work has already started in this area in response to the findings of this research thesis, with development and launching of an online Paediatric Pharmacy Learning Package available via the education platform of the Society of Hospital Pharmacists of Australia. Future work should also include formal postgraduate training in paediatrics, with multidisciplinary involvement and collaboration with international colleagues and organisations.

Future research on quality and safety of medicines use should include multiple case identification methods. Automated trigger tools and ICD-10 coding should be used alongside voluntary reporting where electronic medical records enable feasibility on an ongoing basis. Pharmacists have a clear and important role in medication safety at an individual patient and system-wide level, and should be key members of patient safety groups within organisations. Specific training in patient safety,

including data analysis and change management strategies, should be available to accelerate skill development for pharmacists new to this area.

Development of research skills in pharmacists was also a significant gap identified in these research projects. Pharmacists are clearly performing at a high level, contributing to significant improvements in individual patient care and to significant system improvement. However sharing important cases and success factors from quality improvement activities can be an important learning opportunity for all health practitioners. Improved research skills within the profession will also improve the overall quality of improvement activities even though these may not have been routinely considered 'research'. Work is underway in this area with research content in professional conferences increasing over the past two years and the first Research Seminar by the Society of Hospital Pharmacists of Australia is scheduled for November 2014. Improved research culture within the pharmacy profession, formal linkages with research institutions and access to research training provided by professional, academic and research organisations may assist in this area.

Analysis of publications arising from paediatric conference presentations should be repeated in coming years to determine whether positive impact has been made on research output by the paediatric pharmacy profession.<sup>384</sup>

As mentioned above, it is important that future research focuses on measurement of direct patient outcomes, such as harm, readmission rates, length of stay, and biochemical markers, in addition to analysis of the needs of hospitalised children and their families; rather than limiting research analysis to audits or merely counting errors and adverse events.



## **10.4 Conclusion**

This research project has reinforced the important contribution paediatric pharmacists make to improve safety and quality of care for hospitalised children. The components of advanced practice were found to include more than merely knowledge of how drugs work, but include high-level leadership, communication, education, risk management and research skills. Assessment methods of pharmacists on the journey towards advanced practice were investigated, with portfolio review, peer review and viva voce identified as the most reliable and acceptable methods of summative assessment of advanced pharmacy practice.

It is clear from this research that as pharmacists progress in development of advanced practice their contribution to patient care increases; from prevention of adverse drug events at an organisational level or broader, education of others at a multidisciplinary and tertiary level, and leading and contributing to research activities to advance knowledge and patient care practice.

## 11 References

1. Coombes I, Bates I, Duggan C, Galbraith K. Developing and Recognising Advanced Practitioners in Australia: An Opportunity for a Maturing Profession? *J Pharm Pract Res* 2011.41(1):17-20.
2. Bates I, Davies G, Carter S, Quinn J, McRobbie D, Hall G, et al. Advancing and improving practice in pharmacy: "elitism" a dirty word? *Pharm J* 2009.283:149.
3. United Nations. *Global Strategy for Women's and Children's Health*. New York: United Nations; 2010.
4. World Health Organisation. *Promoting Safety of Medicines for Children*. Geneva: World Health Organisation; 2007.
5. Hill MK, Pawsey M, Cutler A, Holt JL, Goldfeld SR. Consensus standards for the care of children and adolescents in Australian health services. *Med J Aust* 2011.194(2):78-82.
6. Freed GL, Sewell JR, Spike NA. Challenges to children's health care in an ageing Australia. *Med J Aust* 2011.195(8):436-7.
7. Jacobi A. Introduction. *Am J Dis Child* 1911.1(1):1-5.
8. Lindell-Osuagwu L, Sepponen K, Farooqui S, Kokki H, Hameen-Anttila K, Vainio K. Parental reporting of adverse drug events and other drug-related problems in children in Finland. *Eur J Clin Pharmacol* 2013.69(4):985-94.
9. Rashed AN, Wong ICK, Cranswick N, Hefele B, Tomlin S, Jackman J, et al. Adverse Drug Reactions in Children - International Surveillance and Evaluation (ADVISE): A Multicentre Cohort Study. *Drug Saf* 2012.35(6):481-94.
10. Cousins D, Clarkson A, Conroy S, Choonara I. Medication Errors in Children – an Eight Year Review Using Press Reports. *Paediatr Perinat Drug Ther* 2002.5(2):52-8.
11. Queensland Health. *Clinical Incident Management Implementation Standard (CIMIS)*. Brisbane: Queensland Health; 2009.
12. Institute for Safe Medication Practices. *Frequently Asked Questions* [Internet]. 2012 [cited 2012 Jul 22]; Available from: <http://www.ismp.org>
13. National Coordinating Council for Medication Error Reporting and Prevention. *What is a Medication Error?* [Internet]. 2011 [cited 2011 Oct 07]; Available from: <http://www.nccmerp.org>
14. Dean B, Barber N, Schachter M. What is a prescribing error? *Qual Health Care* 2000.9(4):232-7.
15. Ghaleb MA, Barber N, Franklin BD, Wong ICK. The incidence and nature of prescribing and medication administration errors in paediatric inpatients. *Arch Dis Child* 2010.95(2):113-8.

16. Ghaleb MA, Barber N, Dean Franklin B, Wong ICK. What constitutes a prescribing error in paediatrics? *Qual Saf Health Care* 2005.14(5):352-7.
17. Wakefield J. *Patient Safety: From Learning to Action. First Queensland Health Report on Clinical Incidents and Sentinel Events*. Brisbane: Queensland Health; 2007.
18. Patient Safety and Quality Improvement Service. *Patient safety: from learning to action 2012*. Brisbane: State of Queensland (Queensland Health); 2012.
19. Morimoto T. Adverse drug events and medication errors: detection and classification methods. *Qual Saf Health Care* 2004.13(4):306-14.
20. Griffin FA, Resar RK. *IHI Global Trigger Tool for Measuring Adverse Events (Second Edition)*. Cambridge: Institute for Healthcare Improvement; 2009.
21. Klopotoska JE, Wierenga PC, de Rooij SE, Stuijt CC, Arisz L, Kuks PF, et al. The effect of an active on-ward participation of hospital pharmacists in Internal Medicine teams on preventable Adverse Drug Events in elderly inpatients: protocol of the WINGS study (Ward-oriented pharmacy in newly admitted geriatric seniors). *BMC Health Serv Res*. 2011;11(1):124. DOI: 10.1186/1472-6963-11-124
22. Klopotoska JE, Wierenga PC, Stuijt CCM, Arisz L, Dijkgraaf MGW, Kuks PFM, et al. Adverse drug events in older hospitalized patients: results and reliability of a comprehensive and structured identification strategy. *PLoS ONE*. 2013;8(8):e71045. DOI: 10.1371/journal.pone.0071045
23. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. Relationship between medication errors and adverse drug events. *J Gen Intern Med* 1995.10(4):199-205.
24. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 1995.274(1):29-34.
25. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995.274(1):35-43.
26. Holdsworth MT, Fichtl RE, Behta M, Raisch DW, Mendez-Rico E, Adams A, et al. Incidence and impact of adverse drug events in pediatric inpatients. *Arch Pediatr Adolesc Med* 2003.157(1):60-5.
27. Runciman WBW, Roughead EEE, Semple SJS, Adams RJR. Adverse drug events and medication errors in Australia. *Int J Qual Health Care* 2003.15:i49-i59.
28. Aronson JK, Ferner RE. Clarification of terminology in drug safety. *Drug Saf* 2005.28(10):851-70.
29. Cimino MA, Kirschbaum MS, Brodsky L, Shaha SH. Assessing medication prescribing errors in pediatric intensive care units. *Pediatr Crit Care Med* 2004.5(2):124-32.
30. Kaushal R. Using chart review to screen for medication errors and adverse drug events. *Am J Health-Syst Pharm* 2002.59(23):2323-5.

31. Potts A, Barr F, Gregory D, Wright L, Patel N. Computerized physician order entry and medication errors in a pediatric critical care unit. *Pediatrics* 2004.113:59-63.
32. King WJ, Paice N, Rangrej J, Forestell GJ, Swartz R. The effect of computerized physician order entry on medication errors and adverse drug events in pediatric inpatients. *Pediatrics* 2003.112:506-9.
33. World Health Organisation. *International Drug Monitoring: The Role of National Centres*. Geneva: World Health Organisation; 1972.
34. Aronson JK. Medication errors: definitions and classification. *Br J Clin Pharmacol* 2009.67(6):599-604.
35. Kunac DL, Kennedy J, Austin N, Reith D. Incidence, preventability, and impact of Adverse Drug Events (ADEs) and potential ADEs in hospitalized children in New Zealand: a prospective observational cohort study. *Paediatr Drugs* 2009.11(2):153-60.
36. World Health Organisation. *Glossary of terms used in Pharmacovigilance*. Geneva: World Health Organisation; 2011.
37. Gazarian M, Graudins LV. Long-Term Reduction in Adverse Drug Events: An Evidence-Based Improvement Model. *Pediatrics*. 2012;129(5):e1334-e42. DOI: 10.1542/peds.2011-1902
38. SHPA Committee of Specialty Practice in Clinical Pharmacy. *SHPA Standards of Practice for Clinical Pharmacy*. *J Pharm Pract Res* 2005.35(2):122-46.
39. Bürkle T, Müller F, Patapovas A, Sonst A, Pfistermeister B, Plank-Kiegele B, et al. A new approach to identify, classify and count drug-related events. *Br J Clin Pharmacol* 2013.76 Suppl 1:56-68.
40. Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington: National Academies Press; 2000.
41. Australian Commission on Safety and Quality in Health Care. *Literature Review: Medication Safety in Australia*. Sydney: Commonwealth of Australia; 2013.
42. Folli HL, Poole RL, Benitz WE, Russo JC. Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals. *Pediatrics* 1987.79:718-22.
43. Kaushal R, Bates DW, Landrigan C, McKenna KJ, Clapp MD, Federico F, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001.285(16):2114-20.
44. Huynh C, Jani Y, Wong ICK, Dewchand B, Tomlin S. What is the current practice of medicines reconciliation in children nationally in the UK? *Int J Pharm Pract* 2012.21(1):62-5.
45. Huynh C, Wong ICK, Tomlin S, Terry D, Sinclair A, Wilson K, et al. Medication discrepancies at transitions in pediatrics: a review of the literature. *Paediatr Drugs* 2013.15(3):203-15.

46. Terry DRP, Solanki GA, Sinclair AG, Marriott JF, Wilson KA. Clinical significance of medication reconciliation in children admitted to a UK paediatric hospital: observational study of neurosurgical patients. *Paediatr Drugs* 2010.12(5):331-7.
47. Barber ND, Batty R, Ridout DA. Predicting the rate of physician-accepted interventions by hospital pharmacists in the United Kingdom. *Am J Health-Syst Pharm* 1997.54(4):397-405.
48. Wong ICK, Ghaleb MA, Franklin BD, Barber N. Incidence and nature of dosing errors in paediatric medications: a systematic review. *Drug Saf* 2004.27(9):661-70.
49. Fernandez-Llamazares CM, Calleja-Hernández M-Á, Manrique-Rodríguez S, Pérez-Sanz C, Durán-García E, Sanjurjo-Sáez M. Prescribing errors intercepted by clinical pharmacists in paediatrics and obstetrics in a tertiary hospital in Spain. *Eur J Clin Pharmacol* 2012.68:1339-45.
50. Matlow AG, Baker GR, Flintoft V, Cochrane D, Coffey M, Cohen E, et al. Adverse events among children in Canadian hospitals: the Canadian Paediatric Adverse Events Study. *Can Med Assoc J* 2012.184(13):E709-18.
51. Conroy S, Sweis D, Planner C, Yeung V, Collier J, Haines L, et al. Interventions to reduce dosing errors in children: a systematic review of the literature. *Drug Saf* 2007.30(12):1111-25.
52. Kozer E. Medication Errors in Children. *Pediatr Clin North Am* 2006.53(6):1155-68.
53. Lesar TS. Errors in the use of medication dosage equations. *Arch Pediatr Adolesc Med* 1998.152(4):340-4.
54. Levine SR, Cohen M, Blanchard N, Federico F, Magelli M, Lomax C, et al. Guidelines for preventing medication errors in pediatrics. *J Pediatr Pharmacol Ther* 2001.6:426-42.
55. Wong ICK, Wong LYL, Cranswick NE. Minimising medication errors in children. *Arch Dis Child* 2009.94(2):161-4.
56. Rowe C, Koren T, Koren G. Errors by paediatric residents in calculating drug doses. *Arch Dis Child* 1998.79(1):56-8.
57. Davis T. Paediatric prescribing errors. *Arch Dis Child* 2011.96(5):489-91.
58. Lesar TS. Tenfold medication dose prescribing errors. *Ann Pharmacother* 2002.36(12):1833-9.
59. Doherty C, Mc Donnell C. Tenfold Medication Errors: 5 Years' Experience at a University-Affiliated Pediatric Hospital. *Pediatrics* 2012.129(5):916-24.
60. Chappell K, Newman C. Potential tenfold drug overdoses on a neonatal unit. *Archives of Disease in Childhood - Fetal and Neonatal Edition* 2004.89(6):F483-F4.
61. Baber N, Pritchard D. Dose estimation for children. *Br J Clin Pharmacol* 2003.56(5):489-93.
62. Sanghera N, Chan P-Y, Khaki ZF, Planner C, Lee KKC, Cranswick NE, et al. Interventions of hospital pharmacists in improving drug therapy in children: a systematic literature review. *Drug Saf* 2006.29(11):1031-47.

63. Koren G, Barzilay Z, Greenwald M. Tenfold errors in administration of drug doses: a neglected iatrogenic disease in pediatrics. *Pediatrics* 1986.77(6):848-9.
64. Crouch BI, Caravati EM, Moltz E. Tenfold therapeutic dosing errors in young children reported to U.S. poison control centers. *Am J Health-Syst Pharm* 2009.66(14):1292-6.
65. Simpson JH. Reducing medication errors in the neonatal intensive care unit. *Arch Dis Child Fetal Neonatal Ed* 2004.89(6):F480-F2.
66. Shirkey H. Editorial comment: therapeutic orphans. *J Pediatr* 1968.72(1):119-20.
67. Hoppu K, Anabwani G, Garcia-Bournissen F, Gazarian M, Kearns GL, Nakamura H, et al. The status of paediatric medicines initiatives around the world—what has happened and what has not? *Eur J Clin Pharmacol* 2011.68(1):1-10.
68. Beggs S. Australian Report on Pediatric Medication Issues. *Paediatr Drugs* 2009.11(1):38-40.
69. Conroy S. Unlicensed and off-label drug use: issues and recommendations. *Paediatr Drugs* 2002.4(6):353-9.
70. Conroy S, McIntyre J, Choonara I. Unlicensed and off label drug use in neonates. *Arch Dis Child Fetal Neonatal Ed* 1999.80(2):F142-4.
71. Turner S, Longworth A, Nunn AJ, Choonara I. Unlicensed and off label drug use in paediatric wards: prospective study. *BMJ* 1998.316:343-5.
72. Conroy S. Association between licence status and medication errors. *Arch Dis Child* 2011.96(3):305-6.
73. Mason J, Pirmohamed M, Nunn T. Off-label and unlicensed medicine use and adverse drug reactions in children: a narrative review of the literature. *Eur J Clin Pharmacol* 2011.68(1):21-8.
74. Phan H, Leder M, Fishley M, Moeller M, Nahata M. Off-label and unlicensed medication use and associated adverse drug events in a pediatric emergency department. *Pediatr Emerg Care* 2010.26(6):424-30.
75. Mukattash T, Trew K, Hawwa AF, McElnay JC. Children's views on unlicensed/off-label paediatric prescribing and paediatric clinical trials. *Eur J Clin Pharmacol* 2011.68(2):141-8.
76. Committee on Drugs. Off-Label Use of Drugs in Children. *Pediatrics* 2014.133(3):563-7.
77. Schaad UB. Drug therapy in children: still more art than science. *Curr Opin Infect Dis* 2001.14(3):301-2.
78. Paediatric Medicines Advisory Group. Outcome Statement of the Paediatric Medicines Advisory Group meeting [Internet]. Department of Health and Ageing; 2011 [updated 2011 Sep 20; cited 2012 May 29]; Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-pmag-public-documents-20-sept11>



79. Sinha YK, Craig JC, Barclay P, Taitz J, South M, Coulthard K, et al. Drug approval processes in Australian Paediatric Hospitals. *Arch Dis Child* 2010.95(9):739-44.
80. Kearns GL, Abdel-Rahman SM, Alander SW, Blowey DL, Leeder JS, Kauffman RE. Developmental Pharmacology -- Drug Disposition, Action, and Therapy in Infants and Children. *N Engl J Med* 2003.349(12):1157-67.
81. Steering Committee on Quality Improvement and Management and Committee on Hospital Care American Academy of Pediatrics. Policy Statement - Principles of Pediatric Patient Safety: Reducing Harm Due to Medical Care. *Pediatrics* 2011.127(6):1199-210.
82. Fabiano V, Mameli C, Zuccotti GV. Adverse drug reactions in newborns, infants and toddlers: pediatric pharmacovigilance between present and future. *Expert Opin Drug Saf* 2012.11(1):95-105.
83. Kunac DL, Kennedy J, Austin NC, Reith DM. Risk Factors for Adverse Drug Events and Medication Errors in Paediatric Inpatients: Analysis by Admission Characteristics. *J Pharm Pract Res* 2010.40(4):290-3.
84. Kunac DL, Reith DM. Preventable medication-related events in hospitalised children in New Zealand. *NZMJ* 2008.121(1272):17-32.
85. Clavenna A, Bonati M. Adverse drug reactions in childhood: a review of prospective studies and safety alerts. *Arch Dis Child* 2009.94(9):724-8.
86. Bourgeois FT, Mandl KD, Valim C, Shannon MW. Pediatric Adverse Drug Events in the Outpatient Setting: An 11-Year National Analysis. *Pediatrics* 2009.124(4):744-50.
87. Clarkson A, Choonara I. Surveillance for fatal suspected adverse drug reactions in the UK. *Arch Dis Child* 2002.87(6):462-6.
88. Moore TJ, Weiss SR, Kaplan S, Blaisdell CJ. Reported Adverse Drug Events in Infants and Children Under 2 Years of Age. *Pediatrics*. 2002;110(5):e53. DOI: 10.1542/peds.110.5.e53
89. Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. *Br J Clin Pharmacol* 2007.63(2):136-47.
90. Buck ML, Connor JJ, Snipes CJ, Hopper JE. Comprehensive pharmaceutical services for pediatric patients. *Am J Hosp Pharm* 1993.50(1):78-84.
91. Provost GP. Opportunities for the pharmacist in pediatric drug therapy. *Am J Hosp Pharm* 1969.26(5):251.
92. Ellis M. The clinical pharmacist on a pediatric unit. *Hosp Top* 1969.47(11):81-9.
93. Nahata MC. Evolution of Pediatric Clinical Pharmacy. *Ann Pharmacother* 2006.40(6):1170-1.
94. Levin RH. Clinical Pharmacy Practice in a Pediatric Clinic. *Drug Intell Clin Pharm* 1972.6:171-6.

95. Munzenberger P, Sister E, Heins M. The role of a pharmacist on the pediatric unit of a general hospital. *Am J Hosp Pharm* 1972.29(9):755-60.
96. Stucky ER, American Academy of Pediatrics Committee on Drugs, American Academy of Pediatrics Committee on Hospital Care. Prevention of medication errors in the pediatric inpatient setting. *Pediatrics* 2003.112(2):431-6.
97. Sullivan JE, Buchino JJ. Medication errors in pediatrics - the octopus evading defeat. *J Surg Oncol* 2004.88(3):182-8.
98. Leape LL, Cullen DJ, Clapp MD, Burdick E, Demonaco HJ, Erickson JI, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999.282(3):267-70.
99. Stacey SR, Turner SC, Coulthard KP, Miller H. Paediatric pharmacy in Australia: Where have we come from and where do we need to go? *J Pharm Pract Res* 2013.43(1):45-8.
100. Board of Pharmacy Specialties. Specialties: Pediatric Pharmacy Washington: Board of Pharmacy Specialties (BPS)2014 [updated 2014 May 10; cited 2014 Apr 10]; Available from: <http://www.bpsweb.org/specialties/pediatricpharmacy.cfm>
101. International Pharmaceutical Federation (FIP). FIP reference paper on the effective utilization of pharmacists in improving maternal, newborn and child health. Hyderabad: International Pharmaceutical Federation; 2011.
102. Conroy S. Paediatric pharmacy - drug therapy. *Hospital Pharmacist* 2003.10:49-57.
103. Pesaturo KA, Ramsey EZ, Johnson PN, Taylor LM. Introduction to pediatric pharmacy practice: reflections of pediatrics practitioners. *Am J Health-Syst Pharm* 2008.65(14):1314-9.
104. Turner S. A spoonful of sugar makes the medicine go down? *Australian Pharmacist* 2001.20:386-91.
105. Bhatt-Mehta V, Buck ML, Chung AM, Farrington EA, Hagemann TM, Hoff DS, et al. Recommendations for meeting the pediatric patient's need for a clinical pharmacist: a joint opinion of the Pediatrics Practice and Research Network of the American College of Clinical Pharmacy and the Pediatric Pharmacy Advocacy Group. *Pharmacotherapy* 2013.33(2):243-51.
106. Kennedy M, Phan H, Benavides S. The Role of the Pediatric Pharmacist in Personalized Medicine and Clinical Pharmacogenomics for Children: Pediatric Pharmacogenomics Working Group. *J Pediatr Pharmacol Ther* 2011.16(2):118-22.
107. Worthington R, Corbett M. Pharmacy Services to a Paediatric Cystic Fibrosis Clinic. In: Paper presented at: Seventh Australasian Cystic Fibrosis Conference; 2007 Aug 11-14; Sydney, Australia; 2007.
108. Brook S. Why is the regulation of advanced practice essential? *Br J Nurs* 2011.20(16):996-1000.
109. Nursing and Midwifery Board of Australia. Endorsement as a nurse practitioner registration standard. Melbourne: Australian Health Practitioner Regulation Agency; 2012.



110. The Royal Australasian College of Physicians. Advanced Training in General Paediatrics. 2012 Program Requirements Handbook Sydney: The Royal Australasian College of Physicians; 2012.
111. Bond C. An evidence base for professional competence. *Int J Pharm Pract* 2009.17(2):77.
112. Joint Partners Credentialing Task Group. Professional recognition and professional advancement: For our practitioners, for our profession and for our patients. London: Royal Pharmaceutical Society; 2013.
113. Australian Pharmacy Council. Advanced and Extended Pharmacy Practice: An Environmental Snapshot. Canberra: Australian Pharmacy Council; 2013.
114. Meadows N, Webb D, McRobbie D, Antoniou S, Bates I, Davies G. Developing and validating a competency framework for advanced pharmacy practice. *Pharm J* 2004.273:789-92.
115. Competency Development and Evaluation Group. Advanced to Consultant Level Framework. London: CoDEG; 2005.
116. Department of Health. Adult Critical Care: Specialist Pharmacy Practice. London: Department of Health; 2005.
117. Middleton H, Sanders S, Christou M, Lau S, Sowter J. Education and training - a professional development framework. *Hospital Pharmacist* 2008.15:175-6.
118. Adams V, Blake D, Corlett S, Godward D, Low J, McMurray A, et al. Competency Framework for Specialist Oncology Pharmacists. London: British Oncology Pharmacy Association 2004.
119. Royal Pharmaceutical Society. The RPS Advanced Pharmacy Framework (APF). London: Royal Pharmaceutical Society; 2013.
120. Avery AJ, Pringle M. Extended prescribing by UK nurses and pharmacists. *BMJ* 2005.331(7526):1154-5.
121. Nissen L. Pharmacist prescribing: What are the next steps? *Am J Health-Syst Pharm* 2011.68:e57-61.
122. Fittock A. Non-medical prescribing by nurses, optometrists, pharmacists, podiatrists and radiographers - A quick guide for commissioners. Liverpool: National Prescribing Centre; 2010.
123. Accreditation Council for Pharmacy Education. Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree. Chicago: Accreditation Council for Pharmacy Education; 2011.
124. Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Rockville: Office of the Chief Pharmacist. U.S. Public Health Service; 2011.

125. American Society of Health-System Pharmacists. ASHP Accreditation Standard for Postgraduate Year One (PGY1) Pharmacy Residency Programs. Bethesda: American Society of Health-System Pharmacists; 2012.
126. Pharmacy Board of Australia. ~~Intern~~ Intern pharmacist guide. Melbourne: Australian Health Practitioner Registration Agency; 2012.
127. American Society of Health-System Pharmacists. Educational Outcomes, Goals, and Objectives for Postgraduate year Two (PGY2) Pharmacy Residencies in Pediatrics. Bethesda: American Society of Health-System Pharmacists; 2008.
128. Board of Pharmacy Specialties. 2012 Candidate's Guide. Washington: Board of Pharmacy Specialties; 2012.
129. Board of Pharmacy Specialties. 2012 Recertification Guide. Washington: Board of Pharmacy Specialties; 2012.
130. Council on Credentialing in Pharmacy. Credentialing in Pharmacy: a resource paper. Washington: Council on Credentialing in Pharmacy; 2010.
131. American College of Clinical Pharmacy, Shord SS, Schwinghammer TL, Badowski M, Banderas J, Burton ME, et al. Desired professional development pathways for clinical pharmacists. *Pharmacotherapy*. 2013;33(4):e34-42. DOI: 10.1002/phar.1251
132. Pharmaceutical Society of Australia. National Competency Standards Framework for Pharmacists in Australia. Deakin: Pharmaceutical Society of Australia; 2010.
133. Stacey S, Turner S, Tait P, Worthington R, Graudins L, Bogovic A, et al. Development of an Advanced Level Competency Framework for Paediatric Pharmacists. In: Paper presented at: Medicines Management 2008, The 34th SHPA National Conference; 2008 Sep 4-7; Adelaide, Australia.
134. Stacey S, Avent M, Coombes I, Coombes J. Four years' experience with the advanced level framework - what have we learned and has it made a difference? In: Paper presented at: Medicines Management 2011, The 37th SHPA National Conference; 2011 Nov 10-13; Hobart, Australia.
135. Stacey S, Coombes J. Integration of paediatric pharmacy training from undergraduate to advanced practice - implementation of a paediatric advanced level competency framework. In: Paper presented at: Medicines Management 2010, The 36th SHPA National Conference; 2010 Nov 11-14; Melbourne, Australia.
136. Carrington C, Weir J, Smith P. The development of a competency framework for pharmacists providing cancer services. *J Oncol Pharm Pract* 2011.17(3):168-78.
137. Donegan E. An advanced practice framework and learning package for emergency medicine pharmacists: what the new kids on the block will need to know. In: Paper presented at: Medicines Management 2011: The 37th SHPA National Conference, 2011 Nov 12; Hobart, Australia. p. 41.
138. Porter S. Advanced level framework for the development of cardiology pharmacists. In: Paper presented at: the Medicines Management 2010: The 36th SHPA National Conference, 2010 Nov 13; Melbourne, Australia. p. 60.

139. Southern Health Pharmacy Department. Advanced Level Competency Framework Infectious Diseases. Melbourne: Southern Health Pharmacy Department; 2009.
140. Ciabotti L, Hodgkinson M, Larmour I, Senturk-Raif R. Structured training, education and professional development for pharmacists - implementation of general level and advanced level competency frameworks (GLF and ALF). In: Paper presented at: Medicines Management 2009: The 35th SHPA National Conference, 2009 Nov 06; Perth, Australia. p. 198.
141. Advanced Pharmacy Practice Framework Steering Committee. An Advanced Pharmacy Practice Framework for Australia. Deakin West: Pharmaceutical Society of Australia; 2012.
142. Advanced Pharmacy Practice Framework Steering Committee. Communique from the Advanced Pharmacy Practice Framework Steering Committee [Internet]. 2012 [updated 2012 Nov 9; cited 2012 Nov 12]; Available from: <http://www.psa.org.au/archives/7131>
143. The Royal Australasian College of Physicians. General Paediatrics Advanced Training Curriculum. Sydney: The Royal Australasian College of Physicians; 2010
144. Women's and Children's Health Network. Diploma in Child Health South Australia. Adelaide: Women's and Children's Health Network; 2012.
145. Children's Hospital at Westmead, University of Sydney. Diploma in Child Health. Sydney: University of Sydney; 2012.
146. Daly WMW, Carnwell RR. Nursing roles and levels of practice: a framework for differentiating between elementary, specialist and advancing nursing practice. *J Clin Nurs* 2003.12(2):158-67.
147. Australian Nursing Federation. Competency standards for the advanced registered nurse. Rozelle: Australian Nursing Federation; 2004.
148. Australian Confederation of Paediatric and Child Health Nurses. Competencies for the Specialist Paediatric and Child Health Nurse. Sydney: Australian Confederation of Paediatric and Child Health Nurses; 2006.
149. Australian Physiotherapy Association. APA Physiotherapist Title Program. Camberwell: Australian Physiotherapy Association; 2012.
150. Knoppert D, Arenas-Lopez S, McArtney R. The infancy of an international pediatric pharmacy network. *Paediatr Drugs* 2008.10(2):71-3.
151. Poole RL. The History of PPAG: The First 30 Years. *J Pediatr Pharmacol Ther* 2010.15(2):72-80.
152. Tomlin S. Neonatal and Paediatric Pharmacists Group (NPPG). *Paediatr Perinat Drug Ther* 2001.4(3):101-2.
153. Royal Pharmaceutical Society, Neonatal and Paediatric Pharmacists Group. Neonatal and Paediatric Care: Expert Professional Practice Curriculum. London: Royal Pharmaceutical Society Faculty; 2014.

154. Kunac DL, Turner S. Initial Experience with a Paediatric Pharmacy E-Mail Network. *Aust J Hosp Pharm* 2001.31(2):139-42.
155. Graudins LV, Turner S, Kunac D. Paedpharm: Paediatric Pharmacy Network. *J Pharm Pract Res* 2009.39(4):290-2.
156. Meyers RS, Costello-Curtin J. Implementing a pediatric pharmacy educational program for health-system pharmacists. *Am J Pharm Educ.* 2011;75(10 ):Article 205. DOI: 10.5688/ajpe7510205
157. Conard LAE, Fortenberry JD, Blythe MJ, Orr DP. Pharmacists' attitudes toward and practices with adolescents. *Arch Pediatr Adolesc Med* 2003.157(4):361-5.
158. Munzenberger PJ, Thomas RL, Edwin SB, Tutag-Lehr V. Pharmacists' Perceived Knowledge and Expertise in Selected Pediatric Topics. *J Pediatr Pharmacol Ther* 2011.16(1):47.
159. Stewart D, Rouf A, Snaith A, Elliott K, Helms PJ, McLay JS. Attitudes and experiences of community pharmacists towards paediatric off-label prescribing: a prospective survey. *Br J Clin Pharmacol* 2007.64(1):90-5.
160. Low JK, Baldwin JN, Greiner GE. Pediatric Pharmacy Education for U.S. Entry-Level Doctor of Pharmacy Programs. *Am J Pharm Educ* 1999.63(3):323-7.
161. Lavoie A, Gerber P. Pediatric pharmacotherapy content of Canadian undergraduate pharmacy curricula. *Canadian Pharmacists Journal* 2008.141(4):228-33.
162. Prescott WA, Dahl EM, Hutchinson DJ. Education in Pediatrics in US Colleges and Schools of Pharmacy. *Am J Pharm Educ.* 2014;78(3):Article 51. DOI: 10.5688/ajpe78351
163. Flynn EA, Barker KN, Pepper GA, Bates DW, Mikeal RL. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health-Syst Pharm* 2002.59(5):436-46.
164. Snyder RA, Fields W. A model for medication safety event detection. *Int J Qual Health Care* 2010.22(3):179-86.
165. Perez B, Knych SA, Weaver SJ, Liberman A, Abel EM, Oetjen D, et al. Understanding the barriers to physician error reporting and disclosure: a systemic approach to a systemic problem. *Journal of Patient Safety* 2014.10(1):45-51.
166. Wakefield JG, McLaws M-L, Whitby M, Patton L. Patient safety culture: factors that influence clinician involvement in patient safety behaviours. *Qual Saf Health Care* 2010.19(6):585-91.
167. Brill R, McClead RE, Crandall WV, Stoverock L, Berry JC, Wheeler TA, et al. A comprehensive patient safety program can significantly reduce preventable harm, associated costs, and hospital mortality. *The Journal of Pediatrics* 2013.163(6):1638-45.
168. Muething SE, Goudie A, Schoettker PJ, Donnelly LF, Goodfriend MA, Bracke TM, et al. Quality improvement initiative to reduce serious safety events and improve patient safety culture. *Pediatrics.* 2012;130(2):e423. DOI: 10.1542/peds.2011-3566

169. Guy J, Persaud J, Davies E, Harvey D. Drug Errors: What Role do Nurses and Pharmacists have in Minimizing the Risk? *Journal of Child Health Care* 2003.7(4):277-90.
170. Mangino PD. Role of the pharmacist in reducing medication errors. *J Surg Oncol* 2004.88(3):189-94.
171. Dean B, Schachter M, Vincent C, Barber N. Prescribing errors in hospital inpatients: their incidence and clinical significance. *Qual Saf Health Care* 2002.11(4):340-4.
172. Williams SD, Phipps DL, Ashcroft DM. Understanding the attitudes of hospital pharmacists to reporting medication incidents: A qualitative study. *Research in Social and Administrative Pharmacy* 2012.9(1):80-9.
173. Patterson ME, Pace HA, Fincham JE. Associations between communication climate and the frequency of medical error reporting among pharmacists within an inpatient setting. *Journal of Patient Safety* 2013.9(3):129-33.
174. Barker KN, Flynn EA, Pepper GA. Observation method of detecting medication errors. *Am J Health-Syst Pharm* 2002.59(23):2314-6.
175. Schneider MP, Cotting J, Pannatier A. Evaluation of nurses' errors associated in the preparation and administration of medication in a pediatric intensive care unit. *Pharm World Sci* 1998.20(4):178-82.
176. Bruce J, Wong I. Parenteral drug administration errors by nursing staff on an acute medical admissions ward during day duty. *Drug Saf* 2001.24(11):855-62.
177. Baines RJ, Langelaan M, de Bruijne MC, Asscheman H, Spreeuwenberg P, van de Steeg L, et al. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Quality & Safety* 2013.22(4):290-8.
178. Lemon V, Stockwell DC. Automated Detection of Adverse Events in Children. *Pediatr Clin North Am* 2012.59(6):1269-78.
179. Forster AJ, Jennings A, Chow C, Leeder C, van Walraven C. A systematic review to evaluate the accuracy of electronic adverse drug event detection. *J Am Med Inform Assoc* 2011.19(1):31-8.
180. Bates DW. Using information technology to screen for adverse drug events. *Am J Health-Syst Pharm* 2002.59(23):2317-9.
181. Franklin BD, Birch S, Savage I, Wong I, Woloshynowych M, Jacklin A, et al. Methodological variability in detecting prescribing errors and consequences for the evaluation of interventions. *Pharmacoepidemiology and Drug Safety* 2009.18(11):992-9.
182. Takata GS, Mason W, Taketomo C, Logsdon T, Sharek PJ. Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. *Pediatrics* 2008.121(4):e927-35.
183. Tham E, Calmes HM, Poppy A, Eliades AB, Schlafly SM, Namtu KC, et al. Sustaining and Spreading the Reduction of Adverse Drug Events in a Multicenter Collaborative. *Pediatrics* 2011.128(2):e438-e45.

184. Kirkendall ES, Kloppenborg E, Papp J, White D, Frese C, Hacker D, et al. Measuring adverse events and levels of harm in pediatric inpatients with the Global Trigger Tool. *Pediatrics* 2012.130(5):e1206-14.
185. Stausberg J. International prevalence of adverse drug events in hospitals: an analysis of routine data from England, Germany, and the USA. *BMC Health Serv Res.* 2014;14:125. DOI: 10.1186/1472-6963-14-125
186. Stausberg J, Hasford J. Drug-related admissions and hospital-acquired adverse drug events in Germany: a longitudinal analysis from 2003 to 2007 of ICD-10-coded routine data. *BMC Health Serv Res.* 2011;11:134. DOI: 10.1186/1472-6963-11-134
187. Bates DW, Evans RS, Murff H, Stetson PD, Pizziferri L, Hripcsak G. Detecting Adverse Events Using Information Technology. *J Am Med Inform Assoc* 2003.10(2):115-28.
188. Hohl CM, Karpov A, Reddekopp L, Stausberg J. ICD-10 codes used to identify adverse drug events in administrative data: a systematic review. *J Am Med Inform Assoc.* 2013;0:1-11. DOI: 10.1136/amiajnl-2013-002116
189. Honigman B, Lee J, Rothschild J, Light P, Pulling RM, Yu T, et al. Using computerized data to identify adverse drug events in outpatients. *Journal of the American Medical Informatics Association : JAMIA* 2001.8(3):254-66.
190. Brvar M, Fokter N, Bunc M, Mozina M. The frequency of adverse drug reaction related admissions according to method of detection, admission urgency and medical department specialty. *BMC Clin Pharmacol* 2009.9(1):8 doi:10.1186/472-6904-9-8.
191. Jha AK, Kuperman GJ, Teich JM, Leape L, Shea B, Rittenberg E, et al. Identifying adverse drug events: development of a computer-based monitor and comparison with chart review and stimulated voluntary report. *Journal of the American Medical Informatics Association : JAMIA* 1998.5(3):305-14.
192. Nwulu U, Nirantharakumar K, Odesanya R, McDowell SE, Coleman JJ. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: An evaluation of two trigger tools. *Eur J Clin Pharmacol* 2013.69(2):255-9.
193. Christiaans-Dingelhoff I, Smits M, Zwaan L, Lubberding S, van der Wal G, Wagner C. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *BMC Health Serv Res* 2011.11(1):49.
194. Olsen S, Neale G, Schwab K, Psaila B, Patel T, Chapman EJ, et al. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *BMJ Quality & Safety* 2007.16(1):40-4.
195. Koren G. Trends of medication errors in hospitalized children. *J Clin Pharmacol* 2002.42(7):707-10.
196. Isa NM, Taylor MW, Helms PJ, McLay JS. How well are general practice trainees prepared for paediatric prescribing? *Br J Clin Pharmacol* 2009.67(3):370-3.

197. Likic R, Maxwell SRJ. Prevention of medication errors: teaching and training. *Br J Clin Pharmacol* 2009.67(6):656-61.
198. Davey AL, Britland A, Naylor RJ. Decreasing paediatric prescribing errors in a district general hospital. *Qual Saf Health Care* 2008.17(2):146-9.
199. Conroy S, Carroll WD. Prescribing in paediatrics. *Archives of Disease in Childhood - Education and Practice* 2009.94(2):55-9.
200. Sullivan KM, Suh S, Monk H, Chuo J. Personalised performance feedback reduces narcotic prescription errors in a NICU. *BMJ Quality & Safety* 2013.22(3):256-62.
201. Kidd L, Shand E, Beavis R, Taylor Z, Dunstan F, Tuthill D. Prescribing competence of junior doctors: does it add up? *Arch Dis Child* 2010.95(3):219-21.
202. Kozer E, Scolnik D, Macpherson A, Rauchwerger D, Koren G. The effect of a short tutorial on the incidence of prescribing errors in pediatric emergency care. *Canadian Journal of Clinical Pharmacology* 2006.13(3):e285-91.
203. Kamarudin G, Penm J, Chaar B, Moles R. Educational interventions to improve prescribing competency: a systematic review. *BMJ Open* 2013.3(8):3291.
204. Brennan N, Mattick K. A systematic review of educational interventions to change behaviour of prescribers in hospital settings, with a particular emphasis on new prescribers. *Br J Clin Pharmacol* 2013.75(2):359-72.
205. Maxwell S, Mucklow J. e-Learning initiatives to support prescribing. *Br J Clin Pharmacol* 2012.74(4):621-31.
206. McQueen DS, Begg MJ, Maxwell SRJ. eDrugCalc: an online self-assessment package to enhance medical students' drug dose calculation skills. *Br J Clin Pharmacol* 2010.70(4):492-9.
207. Antoniou S, Webb DG, McRobbie D, Davies JG, Wright J, Quinn J, et al. A controlled study of the general level framework: Results of the South of England competency study. *Pharmacy Education* 2005.5(3-4):201-7.
208. Burrows J, Kirkpatrick C, Coombes I, Cardiff L, Lum E. The impact on clinical practice of a postgraduate clinical pharmacy programme, incorporating competency-based performance evaluation. *Pharmacy Education* 2013.13(1):177-82.
209. Coombes I, Avent M, Cardiff L, Bettenay K, Coombes J, Whitfield K, et al. Improvement in Pharmacist's Performance Facilitated by an Adapted Competency-Based General Level Framework. *J Pharm Pract Res* 2010.40(2):111-8.
210. Mills E, Farmer D, Bates I, Davies G, Webb DG. The General Level Framework: use in primary care and community pharmacy to support professional development. *Int J Pharm Pract* 2008.16(5):325-31.
211. Meštrović AA, Staničić ZZ, Hadžiabdić MOM, Mucalo II, Bates II, Duggan CC, et al. Individualized education and competency development of Croatian community pharmacists using the general level framework. *Am J Pharm Educ* 2012.76(2):Article 23.

212. Fortescue EB, Kaushal R, Landrigan CP, McKenna KJ, Clapp MD, Federico F, et al. Prioritizing Strategies for Preventing Medication Errors and Adverse Drug Events in Pediatric Inpatients. *Pediatrics* 2003.11:722-9.
213. Kaushal R, Goldmann D, Keohane C, Christino M, Honour M, Hale A, et al. Adverse Drug Events in Pediatric Outpatients. *Ambul Pediatr* 2007.7(5):383-9.
214. Frey B, Buettiker V, Hug M, Waldvogel K, Gessler P, Ghelfi D, et al. Does critical incident reporting contribute to medication error prevention? *Eur J Pediatr* 2002.161(11):594-9.
215. Merry AF, Anderson BJ. Medication errors - new approaches to prevention. *Pediatr Anesth* 2011.21(7):743-53.
216. Weant KA, Humphries RL, Hite K, Armitstead JA. Effect of emergency medicine pharmacists on medication-error reporting in an emergency department. *Am J Health-Syst Pharm* 2010.67(21):1851-5.
217. Costello JL, Torowicz DL, Yeh TS. Effects of a pharmacist-led pediatrics medication safety team on medication-error reporting. *Am J Health-Syst Pharm* 2007.64(13):1422-6.
218. Dean B, Schachter M, Vincent C, Barber N. Causes of prescribing errors in hospital inpatients: a prospective study. *The Lancet* 2002.359:1373-8.
219. Roehr B. US hospital incident reporting systems do not capture most adverse events. *BMJ* 2012.344:e386.
220. Steering Committee on Quality Improvement and Management and Committee on Hospital Care. Principles of Pediatric Patient Safety: Reducing Harm Due to Medical Care. *Pediatrics* 2011.127(6):1199-210.
221. Westbrook JI, Baysari MT, Li L, Burke R, Richardson KL, Day RO. The safety of electronic prescribing: manifestations, mechanisms, and rates of system-related errors associated with two commercial systems in hospitals. *Journal of the American Medical Informatics Association : JAMIA* 2013.20(6):1159-67.
222. Jani YH, Barber N, Wong ICK. Paediatric dosing errors before and after electronic prescribing. *Qual Saf Health Care* 2010.19(4):337-40.
223. Walsh KE, Landrigan CP, Adams WG, Vinci RJ, Chessare JB, Cooper MR, et al. Effect of Computer Order Entry on Prevention of Serious Medication Errors in Hospitalized Children. *Pediatrics* 2008.121(3):e421-e7.
224. Han YY. Unexpected Increased Mortality After Implementation of a Commercially Sold Computerized Physician Order Entry System. *Pediatrics* 2005.116(6):1506-12.
225. Del Beccaro MA. Computerized Provider Order Entry Implementation: No Association With Increased Mortality Rates in an Intensive Care Unit. *Pediatrics* 2006.118(1):290-5.
226. van Rosse F, Maat B, Rademaker CMA, van Vught AJ, Egberts ACG, Bollen CW. The Effect of Computerized Physician Order Entry on Medication Prescription Errors and Clinical Outcome in Pediatric and Intensive Care: A Systematic Review. *Pediatrics* 2009.123(4):1184-90.



227. Kozer E. Medication errors in children. *Paediatr Drugs* 2009.11(1):52-4.
228. Buehler JW, Smith LF, Wallace EM, Heath CW, Kusiak R, Herndon JL. Unexplained deaths in a children's hospital. An epidemiologic assessment. *N Engl J Med* 1985.313(4):211-6.
229. Wong I, Conroy S, Collier J, Haines L, Sweis D, Yeung V, et al. Co-operative of Safety of Medicines in Children (COSMIC): Scoping study to identify and analyse interventions used to reduce errors in calculation of paediatric drug doses. London: University of London; 2014.
230. Manrique-Rodriguez S, Sánchez-Galindo A, Fernandez-Llamazares CM, Lopez-Herce J, Echarri-Martinez L, Escudero-Vilaplana V, et al. Smart pump alerts: All that glitters is not gold. *Int J Med Inf* 2012.81:344-50.
231. Manrique-Rodríguez S, Sánchez-Galindo AC, de Lorenzo-Pinto A, Gonzalez-Vives L, López-Herce J, Carrillo-Álvarez A, et al. Implementation of smart pump technology in a paediatric intensive care unit. *Health Informatics Journal*. Forthcoming 2014.DOI: 10.1177/1460458213518058.
232. Walsh KE, Kaushal R, Chessare JB. How to avoid paediatric medication errors: a user's guide to the literature. *Arch Dis Child* 2005.90(7):698-702.
233. Kaushal R, Bates DW, Abramson EL, Soukup JR, Goldmann DA. Unit-based clinical pharmacists' prevention of serious medication errors in pediatric inpatients. *Am J Health-Syst Pharm* 2008.65(13):1254-60.
234. Wang JK, Herzog NS, Kaushal R, Park C, Mochizuki C, Weingarten SR. Prevention of pediatric medication errors by hospital pharmacists and the potential benefit of computerized physician order entry. *Pediatrics* 2007.119(1):e77-85.
235. Isaac R, Gerrard A. PICU pharmacist interventions: what can they tell us? *Arch Dis Child* 2011.45(e1):1-2.
236. Kalina M, Tinkoff G, Gleason W, Veneri P, Fulda G. A multidisciplinary approach to adverse drug events in pediatric trauma patients in an adult trauma center. *Pediatr Emerg Care* 2009.25(7):444-6.
237. Fernandez-Llamazares CM, Calleja-Hernandez MA, Manrique-Rodriguez S, Perez-Sanz C, Duran-Garcia E, Sanjurjo-Saez M. Impact of clinical pharmacist interventions in reducing paediatric prescribing errors. *Arch Dis Child* 2012.97:564-8.
238. Fernandez-Llamazares CM, Pozas M, Feal B, Cabañas MJ, Villaronga M, Hernández-Gago Y, et al. Profile of prescribing errors detected by clinical pharmacists in paediatric hospitals in Spain. *Int J Clin Pharm* 2013.35(4):638-46.
239. Zhang C, Zhang L, Huang L, Luo R, Wen J. Clinical Pharmacists on Medical Care of Pediatric Inpatients: A Single-Center Randomized Controlled Trial. *PLoS ONE* 2012.7(1):e30856.
240. Chisholm-Burns MA, Graff Zivin JS, Lee JK, Spivey CA, Slack M, Herrier RN, et al. Economic effects of pharmacists on health outcomes in the United States: A systematic review. *Am J Health-Syst Pharm* 2010.67(19):1624-34.

241. Dooley MJ, Allen KM, Doecke CJ, Galbraith KJ, Taylor GR, Bright J, et al. A prospective multicentre study of pharmacist initiated changes to drug therapy and patient management in acute care government funded hospitals. *Br J Clin Pharmacol* 2004.57(4):513-21.
242. Graham N. An economic analysis of Clinical Pharmacy Interventions in a government funded paediatric specialist hospital: a pilot study [Masters thesis]. St Lucia, Qld: University of Queensland; 2007.
243. Graham N, Cottrell N, Stacey S, Dade M, Stephens J-A. An economic analysis of Clinical Pharmacy Interventions in a government funded paediatric specialist hospital: a pilot study. In: Paper presented at: The Society of Hospital Pharmacists of Australia 28th Federal Conference; 2007 Nov; Sydney, Australia; 2007.
244. Krupicka MI, Bratton SL, Sonenthal K, Goldstein B. Impact of a pediatric clinical pharmacist in the pediatric intensive care unit. *Crit Care Med* 2002.30(4):919-21.
245. Larochelle JM, Ghaly M, Creel AM. Clinical pharmacy faculty interventions in a pediatric intensive care unit: an eight-month review. *J Pediatr Pharmacol Ther* 2012.17(3):263-9.
246. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical Pharmacists and Inpatient Medical Care: A Systematic Review. *Arch Intern Med* 2006.166(9):955-64.
247. Suehs BT, Mican LM, Campbell AH. Retrospective evaluation of an inpatient psychiatric pharmacist consultation service. *J Am Pharm Assoc* 2011.51(5):599-604.
248. Young S, Young S, Bishop L, Bishop L, Twells L, Twells L, et al. Comparison of pharmacist managed anticoagulation with usual medical care in a family medicine clinic. *BMC Family Practice* 2011.12(1):88.
249. Stemer G, Lemmens-Gruber R. Clinical pharmacy activities in chronic kidney disease and end-stage renal disease patients: a systematic literature review. *BMC Nephrol* 2011.12(1):35.
250. González-Martin G, Joo I, Sánchez I. Evaluation of the impact of a pharmaceutical care program in children with asthma. *Patient Educ Couns* 2003.49(1):13-8.
251. de Vries TW, van den Berg PB, Duiverman EJ, de Jong-van den Berg LTW. Effect of a minimal pharmacy intervention on improvement of adherence to asthma guidelines. *Arch Dis Child* 2010.95(4):302-4.
252. Chen C, Lee DSH, Hie SL. The impact of pharmacist's counseling on pediatric patients' caregiver's knowledge on epilepsy and its treatment in a tertiary hospital. *Int J Clin Pharm* 2013.35(5):829-34.
253. Cies JJ, Varlotta L. Clinical pharmacist impact on care, length of stay, and cost in pediatric cystic fibrosis (CF) patients. *Pediatr Pulmonol* 2013.48(12):1190-4.
254. El Borolossy R, El Wakeel L, El Hakim I, Badary O. Implementation of clinical pharmacy services in a pediatric dialysis unit. *Pediatr Nephrol* 2014.29(7):1259-64.
255. Marconi GP, Claudius I. Impact of an Emergency Department Pharmacy on Medication Omission and Delay. *Pediatr Emerg Care* 2012.28(1):30.

256. Kennedy I. Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. London: The Stationary Office; 2001.
257. Hill LH, Delafuente JC, Sicat BL, Kirkwood CK. Development of a competency-based assessment process for advanced pharmacy practice experiences. *Am J Pharm Educ* 2006.70(1):Article 01.
258. Cervero R. Professional practice, learning, and continuing education: an integrated perspective. *International Journal of Lifelong Education* 1992.11(2):91-101.
259. Benner P. From novice to expert : excellence and power in clinical nursing practice. Menlo Park, Calif: Addison-Wesley Pub. Co., Nursing Division; 1984.
260. Cantillon P, Sargeant J. Giving feedback in clinical settings. *BMJ* 2008.337:a1961.
261. Miller GE. The assessment of clinical skills/competence/performance. *Academic Medicine* 1990.65(9 Suppl):S63-S7.
262. Epstein RM, Hundert EM. Defining and assessing professional competence. *JAMA* 2002.287(2):226-35.
263. Jefferies A, Simmons B, Ng E, Skidmore M. Assessment of multiple physician competencies in postgraduate training: utility of the structured oral examination. *Adv Health Sci Educ Theory Pract* 2011.16(5):569-77.
264. Epstein RM. Assessment in medical education. *N Engl J Med* 2007.356(4):387-96.
265. Matheson C. The educational value and effectiveness of lectures. *The Clinical Teacher* 2008.5(4):218-21.
266. Prober CG, Heath C. [REMOVED] Lecture Halls without Lectures — A Proposal for Medical Education. *N Engl J Med* 2012.366(18):1657-9.
267. Crouch MA. An advanced cardiovascular pharmacotherapy course blending online and face-to-face instruction. *Am J Pharm Educ* 2009.73(3):Article 51.
268. Flowers SK, Vanderbush RE, Hastings JK, West D. Web-based multimedia vignettes in advanced community pharmacy practice experiences. *Am J Pharm Educ* 2010.74(3):39.
269. White AM, Albertson B, Muncey L. Development and implementation of a clinical pharmacist training and assessment program. *Am J Health-Syst Pharm* 2012.69:278-81.
270. Morris JLJ, Knoderer CAC. Assessment of web-based training modules on learning facilitation for advanced pharmacy practice experiences in pediatrics. *J Pediatr Pharmacol Ther* 2011.16(3):210-5.
271. Gordon M, Chandratilake M, Baker P. Improved junior paediatric prescribing skills after a short e-learning intervention: a randomised controlled trial. *Arch Dis Child* 2011.96(12):1191-4.
272. Govaerts MJB, Wiel MWJ, Schuwirth LWT, Vleuten CPM, Muijtjens AMM. Workplace-based assessment: raters' performance theories and constructs. *Adv Health Sci Educ Theory Pract* 2013.18.

273. Reece A, Klaber R. Maximising learning on ward rounds. *Archives of Disease in Childhood - Education and Practice* 2012.97(2):61-7.
274. Challis M. AMEE Medical Education Guide No. 11 (revised): Portfolio-based learning and assessment in medical education. *Med Teach* 1999.21(4):1-17.
275. Wilkinson TJ, Challis M, Hobma SO, Newble DI, Parboosingh JT, Sibbald RG, et al. The use of portfolios for assessment of the competence and performance of doctors in practice. *Med Educ* 2002.36(10):918-24.
276. Royal College of General Practitioners. The use of portfolio-based learning in continuing medical education. In: *Occasional Paper 63: Portfolio-based Learning in General Practice*: Royal College of General Practitioners; 1993. p. 19-20.
277. Nagler A, Andolsek K, Padmore JS. The unintended consequences of portfolios in graduate medical education. *Acad Med* 2009.84(11):1522-6.
278. Mathers NJ, Challis MC, Howe AC, Field NJ. Portfolios in continuing medical education--effective and efficient? *Med Educ* 1999.33(7):521-30.
279. Roberts C, Newble DI, O'Rourke AJ. Portfolio-based assessments in medical education: are they valid and reliable for summative purposes? *Med Educ* 2002.36(10):899-900.
280. Garrett BM, MacPhee M, Jackson C. Evaluation of an eportfolio for the assessment of clinical competence in a baccalaureate nursing program. *Nurse Educ Today* 2013.33(10):1207-13.
281. Nursing and Midwifery Board of Australia. [Endorsement as a nurse practitioner](#). Guide for submitting a portfolio: Pathway 2. Melbourne: Australian Health Practitioner Regulation Agency; 2012.
282. Briceland LL, Hamilton RA. Electronic reflective student portfolios to demonstrate achievement of ability-based outcomes during advanced pharmacy practice experiences. *Am J Pharm Educ* 2010.74(5).
283. McDuffie CH, Sheffield MC, Miller MS, Duke LJ, Rogers SP. Web-based portfolios for pharmaceutical care plans during advanced pharmacy practice experiences. *Am J Pharm Educ* 2010.74(4):59.
284. Office of the Queensland Parliamentary Counsel. *Health Practitioner Regulation National Law Act 2009*. State of Queensland; 2010. p. 1-311.
285. Pharmacy Board of Australia. *Continuing professional development registration standard*. Melbourne: Pharmacy Board of Australia; 2010.
286. McKenzie C, Borthwick M, Thacker M, Shulman R, Offord R, Tomlin M, et al. Developing a process for credentialing advanced level practice in the pharmacy profession using a multi-source evaluation tool. *Pharm J* 2011.286:1-5.
287. Purcell K. Use of performance portfolios for pharmacy personnel. *Am J Health-Syst Pharm* 2009.66(9):801-4.

288. Singh T, Modi JN. Workplace based assessment: a step to promote competency based postgraduate training. *Indian Pediatr* 2013.50(6):553-9.
289. Jubraj B, Innes A, Kavanagh R. Dispel the myths and see the benefits of workplace-based assessments<sup>[66]</sup>. *Pharm J* 2011.287:467.
290. Hayden SR, Dufel S, Shih R. Definitions and competencies for practice-based learning and improvement. *Acad Emerg Med* 2002.9(11):1242-8.
291. Norcini J, Burch V. Workplace-based assessment as an educational tool: AMEE Guide No. 31. *Med Teach* 2007.29(9):855-71.
292. Moonen-van Loon JMW, Overeem K, Donkers HJLM, van der Vleuten CPM, Driessen EW. Composite reliability of a workplace-based assessment toolbox for postgraduate medical education. *Advances in Health Sciences Education* 2013.18(5):1087-102.
293. McRobbie D, Webb D, Bates I, Wright J, Davies J. Assessment of clinical competence: designing a competence grid for junior pharmacists. *Pharmacy Education* 2002.1(2):67-76.
294. Goldsmith GM, Bates IP, Davies JG, McRobbie D, Webb DG, Wright J, et al. A Pilot Study to Evaluate Clinical Competence in Junior Grade Pharmacy Practitioners. *Pharmacy Education* 2003.3(2):127-34.
295. Costello J, Cardiff L, Coombes I. Practice evaluation and identification of learning and development needs using the General Level Framework – are we meeting pharmacists needs? *Pharmacy Education* 2013.13(1):129-33.
296. Rutter V, Wong C, Coombes I, Cardiff L, Duggan C, Yee M-L, et al. Use of a general level framework to facilitate performance improvement in hospital pharmacists in Singapore. *Am J Pharm Educ* 2012.76(6):Article 107.
297. Society of Hospital Pharmacists of Australia. shpaclinCAT. Clinical Competency Assessment Tool for Australian Pharmacists. Collingwood: The Society of Hospital Pharmacists of Australia; 2010. p. 1-45.
298. Alderman C. Clinical Pharmacy and Competency Assessment. *J Pharm Pract Res* 2010.40(1):6-7.
299. Norcini JJ, Blank LL, Duffy FD, Fortna GS. The mini-CEX: a method for assessing clinical skills. *Ann Intern Med* 2003.138(6):476-81.
300. Hawkins RE, Margolis MJ, Durning SJ, Norcini JJ. Constructing a Validity Argument for the Mini-Clinical Evaluation Exercise: A Review of the Research. *Academic Medicine* 2010.85(9):1453-61.
301. Nair BR, Alexander HG, McGrath BP, Parvathy MS, Kilsby EC, Wenzel J, et al. The mini clinical evaluation exercise (mini-CEX) for assessing clinical performance of international medical graduates. *Med J Aust* 2008.189(3):159-61.
302. The Royal Australasian College of Physicians. PREP Advanced Training in Paediatric Emergency Medicine Program Requirements Handbook. Sydney: The Royal Australasian College of Physicians; 2012.

303. Basu I, Parvizi S, Chin K. The perception of online work-based assessments. *The Clinical Teacher* 2013.10(2):73-7.
304. Tomisato S, Venter J, Weller J, Drachman D. Evaluating the Utility, Reliability, and Validity of a Resident Performance Evaluation Instrument. *Acad Psychiatry* 2014.38(4):458-63.
305. Abdulla A. A critical analysis of mini peer assessment tool (mini-PAT). *J R Soc Med* 2008.101(1):22-6.
306. Archer JC, Norcini J, Davies HA. Use of SPRAT for peer review of paediatricians in training. *BMJ* 2005.330(7502):1251-3.
307. Archer J, Norcini J, Southgate L, Heard S, Davies H. mini-PAT (Peer Assessment Tool): A Valid Component of a National Assessment Programme in the UK? *Adv Health Sci Educ Theory Pract* 2006.13(2):181-92.
308. Whitehouse A, Hassell A, Bullock A, Wood L, Wall D. 360 degree assessment (multisource feedback) of UK trainee doctors: Field testing of team assessment of behaviours (TAB). *Med Teach* 2007.29(2-3):171-6.
309. Burford B, Illing J, Kergon C, Morrow G, Livingston M. User perceptions of multi-source feedback tools for junior doctors. *Med Educ* 2010.44(2):165-76.
310. Murphy DJ, Bruce DA, Mercer SW, Eva KW. The reliability of workplace-based assessment in postgraduate medical education and training: a national evaluation in general practice in the United Kingdom. *Advances in Health Sciences Education* 2009.14(2):219-32.
311. Patel JP, West D, Bates IP, Eggleton AG, Davies G. Early experiences of the mini-PAT (Peer Assessment Tool) amongst hospital pharmacists in South East London. *Int J Pharm Pract* 2009.17(2):123-6.
312. Patel JP, Sharma A, West D, Bates IP, Davies JG, Abdel-Tawab R. An evaluation of using multi-source feedback (MSF) among junior hospital pharmacists. *Int J Pharm Pract* 2011.19(4):276-80.
313. Archer JC, McAvoy P. Factors that might undermine the validity of patient and multi-source feedback. *Med Educ* 2011.45(9):886-93.
314. Vivekananda-Schmidt P, MacKillop L, Crossley J, Wade W. Do assessor comments on a multi-source feedback instrument provide learner-centred feedback? *Med Educ* 2013.47(11):1080-8.
315. Coombes JA, McGuire TM, Harrhy KL, McRobbie D, Davies JG, Fleming G. Piloting an Objective Structured Clinical Examination to Evaluate the Clinical Competency of Pre-Registration Pharmacists. *J Pharm Pract Res* 2003.33(3):194-8.
316. McRobbie D, Fleming G, Ortner M, Bates I, Davies JG. Evaluating skills and competencies of pre-registration pharmacists using objective structured clinical examinations (OSCEs). *Pharmacy Education* 2006.6(2):133-8.
317. Barman A. Critiques on the Objective Structured Clinical Examination. *Ann Acad Med Singapore* 2005.34(8):478-82.

318. Haines ST, Andrus MR, Badowski M, Bradbury MM, Canales AE, Cavanaugh JM, et al. Board Certification of Pharmacist Specialists. *Pharmacotherapy* 2011.31(11):1146-9.
319. Westanmo A, Wu X, Carmichael JM, Dennis SJ. Improvement of competence after preparation for board certification examination. *Am J Health-Syst Pharm* 2012.69(3):186-90.
320. Murdoch-Eaton D, Sandars J. Reflection: moving from a mandatory ritual to meaningful professional development. *Arch Dis Child* 2014.99(3):279-83.
321. Brown JO. Know Thyself: The Impact of Portfolio Development on Adult Learning. *Adult Educ Quarterly* 2002.52(3):228-45.
322. Cobourne MT. What's wrong with the traditional viva as a method of assessment in orthodontic education? *J Orthod* 2010.37(2):128-33.
323. Macan T. The employment interview: A review of current studies and directions for future research. *Human Resource Management Review* 2009.19(3):203-18.
324. Barrick MR, Shaffer JA, DeGrassi SW. What you see may not be what you get: Relationships among self-presentation tactics and ratings of interview and job performance. *J Appl Psychol* 2009.94(6):1394-411.
325. Eva KW, Macala C. Multiple mini-interview test characteristics: 'tis better to ask candidates to recall than to imagine. *Med Educ* 2014.48(6):604-13.
326. Hull L, Birnbach D, Arora S, Fitzpatrick M, Sevdalis N. Improving surgical ward care: development and psychometric properties of a global assessment toolkit. *Ann Surg* 2014.259(5):904-9.
327. Homer M, Setna Z, Jha V, Higham J, Roberts T, Boursicot K. Estimating and comparing the reliability of a suite of workplace-based assessments: an obstetrics and gynaecology setting. *Med Teach* 2013.35(8):684-91.
328. Costa MH, Shulman R, Bates I. A credentialing process for advanced level pharmacists: participant feedback. *Pharm J* 2012.288:1-5.
329. Breen KJ. Revalidation - what is the problem and what are the possible solutions? *The Medical journal of Australia* 2014.200(3):153-6.
330. Stacey S, Coombes I, Wainwright C, Klee B, Miller H, Whitfield K. Characteristics of adverse medication events in a children's hospital. *Journal of Paediatrics and Child Health*. Forthcoming. 2014. DOI: 10.1111/jpc.12684
331. Noble DJ, Pronovost PJ. Underreporting of patient safety incidents reduces health care's ability to quantify and accurately measure harm reduction. *Journal of Patient Safety* 2010.6(4):247-50.
332. Cox AR, Anton C, Goh CH, Easter M, Langford NJ, Ferner RE. Adverse drug reactions in patients admitted to hospital identified by discharge ICD-10 codes and by spontaneous reports. *Br J Clin Pharmacol* 2001.52(3):337-9.

333. Australian Commission on Safety Quality in Health Care. National Safety and Quality Health Service Standards. Sydney: ACSQHC, Commonwealth of Australia; 2011.
334. Le J, Nguyen T, Law AV, Hodding J. Adverse drug reactions among children over a 10-year period. *Pediatrics* 2006.118(2):555-62.
335. Goldstein LH, Berlin M, Saliba W, Elias M, Berkovitch M. Founding an adverse drug reaction (ADR) network: a method for improving doctors spontaneous ADR reporting in a general hospital. *J Clin Pharmacol* 2013.53(11):1220-5.
336. National Coordinating Council for Medication Error Reporting and Prevention. NCC MERP Index for Categorizing Medication Errors: National Coordinating Council for Medication Error Reporting and Prevention; 2001 [updated 2001 Feb 20; cited 2014 Jul 31]; Available from: <http://www.nccmerp.org/medErrorCatIndex.html>
337. Kale A, Keohane CA, Maviglia S, Gandhi TK, Poon EG. Adverse drug events caused by serious medication administration errors. *BMJ Quality & Safety* 2012.21(11):933-8.
338. High Risk Medicines Working Party. High risk medicines — feeling the PINCH! Melbourne: Department of Health, Victoria; 2006.
339. Rashed AN, Wong ICK, Cranswick N, Tomlin S, Rascher W, Neubert A. Risk factors associated with adverse drug reactions in hospitalised children: international multicentre study. *Eur J Clin Pharmacol* 2011.68(5):801-10.
340. Hodgkinson MR, Dirnbauer NJ, Larmour I. Identification of Adverse Drug Reactions Using the ICD-10 Australian Modification Clinical Coding Surveillance. *J Pharm Pract Res* 2009.39(1):19-23.
341. Takata GS, Taketomo CK, Waite S. Characteristics of medication errors and adverse drug events in hospitals participating in the California Pediatric Patient Safety Initiative. *Am J Health-Syst Pharm* 2008.65(21):2036-44.
342. Smyth RMD, Gargon E, Kirkham J, Cresswell L, Golder S, Smyth R, et al. Adverse Drug Reactions in Children—A Systematic Review. *PLoS ONE* 2012.7(3):e24061.
343. Wilson DG, McArtney RG, Newcombe RG, McArtney RJ, Gracie J, Kirk CR, et al. Medication errors in paediatric practice: insights from a continuous quality improvement approach. *Eur J Pediatr* 1998.157(9):769-74.
344. Fernandez CV, Gillis-Ring J. Strategies for the prevention of medical error in pediatrics. *The Journal of Pediatrics* 2003.143(2):155-62.
345. Otero P, Leyton A, Mariani G, Ceriani Cernadas JM, Committee atPS. Medication Errors in Pediatric Inpatients: Prevalence and Results of a Prevention Program. *Pediatrics* 2008.122(3):e737-e43.
346. Wakefield J. Patient Safety: From Learning to Action IV. Fourth Queensland Health Report on Clinical Incidents and Sentinel Events in the Queensland Public Health System 2008/9. Brisbane: Queensland Health; 2011.



347. Kozer E, Seto W, Verjee Z, Parshuram C, Khattak S, Koren G, et al. Prospective observational study on the incidence of medication errors during simulated resuscitation in a paediatric emergency department. *BMJ* 2004.329(7478):1321-0.
348. Kozer E, Scolnik D, Macpherson A, Keays T, Shi K, Luk T, et al. Variables Associated With Medication Errors in Pediatric Emergency Medicine. *Pediatrics* 2002.110(4):737-42.
349. Ross LM, Wallace J, Paton JY. Medication errors in a paediatric teaching hospital in the UK: five years operational experience. *Arch Dis Child* 2000.83(6):492-7.
350. Long AL, Horvath MM, Cozart H, Eckstrand J, Whitehurst J, Ferranti J. Tailoring adverse drug event surveillance to the paediatric inpatient. *Qual Saf Health Care* 2010.19(5):e40.
351. Coombes ID, Stowasser DA, Reid C, Mitchell CA. Impact of a standard medication chart on prescribing errors: a before-and-after audit. *Qual Saf Health Care* 2009.18(6):478-85.
352. Coombes ID, Reid C, McDougall D, Stowasser D, Duiguid M, Mitchell C. Pilot of a National Inpatient Medication Chart in Australia: improving prescribing safety and enabling prescribing training. *Br J Clin Pharmacol* 2011.72(2):338-49.
353. Herzer KR, Mirrer M, Xie Y, Steppan J, Li M, Jung C, et al. Patient safety reporting systems: sustained quality improvement using a multidisciplinary team and "good catch" awards. *Joint Commission journal on quality and patient safety / Joint Commission Resources* 2012.38(8):339-47.
354. Rinke ML, Bundy DG, Velasquez CA, Rao S, Zerhouni Y, Lobner K, et al. Interventions to Reduce Pediatric Medication Errors: A Systematic Review. *Pediatrics* Forthcoming 2014.10.1542/peds.2013-3531.
355. Stacey SR, Coombes I, Wainwright C, Cardiff L, Whitfield K. What does advanced practice mean to Australian paediatric pharmacists? A focus group study. *Int J Pharm Pract* Forthcoming 2014.10.1111/ijpp.12113.
356. Coombes I, Kirsa SW, Dowling HV, Galbraith K, Duggan C, Bates I. Advancing pharmacy practice in Australia: The importance of national and global partnerships. *J Pharm Pract Res* 2012.42(4):261-3.
357. Duggan C. The Society has plans afoot that will help you to stand out from the crowd. *The Pharmaceutical Journal* 2013.290:25.
358. College of Pharmacy Practice and Faculty of Neonatal and Paediatric Pharmacy. *General Paediatric Competencies*. London: College of Pharmacy Practice and Faculty of Neonatal and Paediatric Pharmacy; 2006.
359. Maddux MS. Preliminary Request for the Board of Pharmacy Specialties to Consider a New Specialty. Lenexa: American College of Clinical Pharmacy; 2011.
360. Advanced Pharmacy Practice Framework Steering Committee. *Advanced Pharmacy Practice. A Consultation Paper for the Pharmacy Profession*. Deakin West: Pharmaceutical Society of Australia; 2012.
361. Burch VC, Seggie JL. Use of a structured interview to assess portfolio-based learning. *Med Educ* 2008.42(9):894-900.

362. Rutter PM. The introduction of observed structured clinical examinations(OSCEs) to the M. Pharm degree pathway. *Pharmacy Education* 2002.1(3):173-80.
363. Board of Pharmacy Specialties. Board of Pharmacy Specialties Announces New Specialties in Critical Care Pharmacy and Pediatric Pharmacy 2013 [updated 2013 Apr 15; cited 2013 Apr 24]; Available from: [http://bpsweb.org/news/pr\\_041513.cfm](http://bpsweb.org/news/pr_041513.cfm)
364. O'Leary KM, Kirsa SW, Dowling HV, Allinson YM, Coombes I. A Professional Development Framework for Pharmacists. *J Pharm Pract Res* 2012.42(4):259-61.
365. SHPA Committee of Specialty Practice in Clinical Pharmacy. Standards of Practice for Clinical Pharmacy Services. Overview: Standards of Practice for Clinical Pharmacy Services. *J Pharm Pract Res* 2013.43(2 (suppl)):S2-S5.
366. Pharmaceutical Society of Australia. Standard and guidelines for pharmacists performing clinical interventions. Deakin West: Pharmaceutical Society of Australia; 2011.
367. SHPA Committee of Specialty Practice in Clinical Pharmacy. Standards of Practice for Clinical Pharmacy Services. Chapter 13. Documenting Clinical Activities. *J Pharm Pract Res* 2013.43(2 (suppl)):S42-S6.
368. Dunbar JA, Reddy P, Beresford B, Ramsey WP, Lord RSA. In the wake of hospital inquiries: impact on staff and safety. *Med J Aust* 2007.186(2):80-3.
369. Van Der Weyden MB. The Bundaberg Hospital scandal: the need for reform in Queensland and beyond. *Med J Aust* 2005.183(6):284-5.
370. Jenkins N. Hospital talk: SHPA identifying learning needs with competency assessment tools. *AJP: The Australian Journal of Pharmacy* 2013.94(1118):42.
371. O'Leary KM, Allinson YM. Snapshot of the Australian Public Hospital Pharmacy Workforce in 2007. *J Pharm Pract Res* 2009.39(1):28-33.
372. Keen N. Clinical Pharmacy and Competency Assessment. *J Pharm Pract Res* 2010.40(1):6-7.
373. Australian Pharmacy Council. Evaluation and Credentialing of Advanced Practice Pharmacists: First Round Consultation. Australian Pharmacy Council; 2014 Jun.
374. Lawrence J. Recognising pharmacy's professional role models: the first Faculty members. *The Pharmaceutical Journal* 2013.291:456.
375. Stacey S, Coombes I, Wainwright C, Whitfield K. Using the "General Level Framework" to identify gaps in knowledge and skills to prioritise professional development activities for paediatric pharmacists. In: Paper presented at: Neonatal and Paediatric Pharmacists Group 19th Annual Conference; 2013 Nov 09; London, United Kingdom.
376. McGill DA, van der Vleuten CPM, Clarke MJ. Supervisor assessment of clinical and professional competence of medical trainees: a reliability study using workplace data and a focused analytical literature review. *Advances in Health Sciences Education* 2011.16(3):405-25.

377. McGill DA, van der Vleuten CPM, Clarke MJ. A critical evaluation of the validity and the reliability of global competency constructs for supervisor assessment of junior medical trainees. *Advances in Health Sciences Education* 2013.18(4):701-25.
378. Levashina J, Hartwell CJ, Morgeson FP, Campion MA. The Structured Employment Interview: Narrative and Quantitative Review of the Research Literature. *Personnel Psychology* 2013.67(1):241-93.
379. Prideaux D, Roberts C, Eva K, Centeno A, McCrorie P, McManus C, et al. Assessment for selection for the health care professions and specialty training: consensus statement and recommendations from the Ottawa 2010 Conference. *Med Teach* 2011.33(3):215-23.
380. Siu E, Reiter HI. Overview: what's worked and what hasn't as a guide towards predictive admissions tool development. *Adv in Health Sci Educ* 2009.14(5):759-75.
381. Pau A, Jeevaratnam K, Chen YS, Fall AA, Khoo C, Nadarajah VD. The Multiple Mini-Interview (MMI) for student selection in health professions training - a systematic review. *Med Teach* 2013.35(12):1027-41.
382. Huffcutt AI, Van Iddekinge CH, Roth PL. Understanding applicant behavior in employment interviews: A theoretical model of interviewee performance. *Human Resource Management Review* 2011.21(4):353-67.
383. Mak VSL, Clark A, March G, Gilbert AL. The Australian pharmacist workforce: employment status, practice profile and job satisfaction. *Aust Health Rev* 2013.37(1):127-30.
384. Grzeskowiak LE, Thomas AE. Paediatric and Perinatal Health Abstracts at SHPA National Conferences: Trends in Presentation and Subsequent Publication. *J Pharm Pract Res* 2014.44(1):22-5.

## Appendix A: Paediatric ALF (Section 1.1 Professional Practice – Expert Knowledge)

1. Professional Practice				
Improving standards of paediatric pharmaceutical care				
Competency Level Descriptors				
No.	Competency	Foundation (Rotational)	Excellence (Advanced/Specialist)	Mastery (Expert/Consultant)
1.1	Expert Knowledge	The following are examples of the knowledge expected of a paediatric pharmacist at each level of career. A specialist pharmacist would be expected to have all the knowledge listed for a rotational pharmacist in addition to the majority of the specialist level knowledge base. An expert paediatric pharmacist would be expected to have a reasonable understanding of all of the knowledge criteria listed for a specialist pharmacist (with the understanding that an expert in one or two specialities e.g. oncology and parenteral nutrition would not be expected to have specialist or expert knowledge of all other specialities). An expert paediatric pharmacist is expected to be taking the knowledge listed under specialist (and expert if stated) and applying it to larger groups of patients to improve patient care		
		Demonstrates general pharmaceutical knowledge in core areas.	Demonstrates specialist pharmaceutical knowledge in defined area(s).	Advances the knowledge base in the defined area
1.1.1	<b>Knowledge: Child Health Issues</b>  (Core Knowledge)	Demonstrates an understanding of the concepts of family-centered care  Demonstrates a good knowledge of concordance in children and their carers, including issues surrounding medicines in school.  Explains how disease processes impact medication therapy (including drug handling, concordance and quality of life).  Understanding of common child health issues and priorities locally and globally.  Demonstrated understanding of the ethics of medical care in children (including consent for treatment, research and clinical trial design).	Demonstrates a high level understanding of the challenges of adolescence including transition to adult care, dealing with chronic illness, concordance and sexual health.  Demonstrates a high level understanding of the complexity of ethics in paediatric medical care (see also cluster 6).	
		<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
		<i>SHPA Paediatrics Seminar</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>	<i>Records of consultation requests from clinicians and pharmacists interstate and internationally</i>	<input type="checkbox"/>
		<i>Observational assessment (Paed GLF or equivalent)</i>	<input type="checkbox"/>	<i>Records of consultation requests from clinicians and pharmacists locally</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>
		<i>Postgraduate qualifications (with paediatric content)</i>	<input type="checkbox"/>	<i>Active member of PaedPharm network</i>	<input type="checkbox"/>	<i>Interventions at an expert level</i>	<input type="checkbox"/>
		<i>Member of PaedPharm network</i>	<input type="checkbox"/>	<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>		
	Individual examples						
1.1.2	<b>Knowledge: Drug Administration</b> (Core Knowledge)	Demonstrate an understanding of the challenges of drug administration in children (e.g. palatability, extemporaneous formulations)		Demonstrates a high level understanding of the issues surrounding drug administration problems in paediatrics and how they can be addressed.			
		Demonstrate a practical understanding of routes of administration of drugs in children, including parenteral administration, and various venous access devices and IV delivery systems (e.g. IV push, infusion, piggyback, Y site, syringe pumps).					
	Demonstrates a basic knowledge of enteral feeds, PEGs and NGTs and implications for drug administration.						
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>		<i>Case presentations to ground rounds, conferences</i>		<i>Education on topic at a high level - university, conferences, seminars</i>	
		<i>Clinical rotations in paediatric areas</i>		<i>Active teaching role within institution</i>			
		<i>Case presentations to department</i>		<i>SHPA Advanced Paediatrics Seminar or Workshop</i>		<i>Member of, or provide advice to, a state, national or international group or committee</i>	
		<i>Examples of interventions documented</i>		<i>Member of, or provide advice to a local group or committee</i>			
		<i>SHPA Paediatrics Seminar</i>		<i>Records of consultation requests from clinicians and pharmacists locally</i>		<i>Records of consultation requests from clinicians and pharmacists interstate and internationally</i>	
		<i>Observational assessment (Paed GLF or equivalent)</i>		<i>Active member of PaedPharm network</i>		<i>Published research</i>	
<i>Postgraduate qualifications (with paediatric content)</i>			<i>Interventions at a specialist/advanced level</i>				
<i>Member of PaedPharm network</i>				<i>Interventions at an expert level</i>			

1. Professional Practice						
Improving standards of paediatric pharmaceutical care						
Competency Level Descriptors						
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)
	Individual examples					
1.1.3	<b>Knowledge: Child Development, Growth and Nutrition</b> (Core Knowledge)	Knowledge of usual weights for age and acceptable ranges, along with the implications of extremes of body weight on drug dosing.  Be familiar with the growth and development of a healthy child, including body size, sensory changes, eating, behaviour and sleep.  Demonstrate a basic understanding of specialised nutritional formulas used in children.  Demonstrate a basic understanding of the safe use of parenteral nutrition in children.		Understanding of TPN requirements for neonates and children and how to monitor and adjust regimens including compatibilities.		
		Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i> <input type="checkbox"/>	<input type="checkbox"/>
		<i>Clinical rotations in paediatric areas</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Certified Nutrition Support Pharmacist (e.g. BCNSP or CNSC)</i> <input type="checkbox"/>	<input type="checkbox"/>	
		<i>Case presentations to department</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Active teaching role within institution</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i> <input type="checkbox"/>
		<i>Examples of interventions documented</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i> <input type="checkbox"/>	<input type="checkbox"/>	
		<i>Postgraduate qualifications (with paediatric content)</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Active member of PaedPharm</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Published research</i> <input type="checkbox"/>
		<i>Member of PaedPharm network</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Interventions at a specialist/advanced level</i> <input type="checkbox"/>	<input type="checkbox"/>	<i>Interventions at an expert level</i> <input type="checkbox"/>
	Individual examples					
1.1.4	<b>Knowledge: Drug Handling</b> (Core Knowledge)	Demonstrate a basic knowledge of the pharmacokinetic and pharmacodynamic changes in children of different ages. Explains the differences in drug absorption, distribution, metabolism and elimination for neonatal, paediatric and adolescent patients compared to adult patients. Describes		Demonstrate an advanced level of understanding and application of pharmacokinetics and pharmacodynamics in children. (e.g. different metabolic pathways, adaptation of renal function in neonates,		

1. Professional Practice								
Improving standards of paediatric pharmaceutical care								
Competency Level Descriptors								
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)		
		how these processes mature. Explains why younger children have a different potential for Adverse Drug Reactions. Demonstrated understanding of how obesity effects drug handling in children.		protein binding).				
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>		<i>Case presentations to ground rounds, conferences</i>		<i>Education on topic at a high level - university, conferences, seminars</i>		
		<i>Clinical rotations in paediatric areas</i>						
		<i>Case presentations to department</i>		<i>Active teaching role within institution</i>		<i>Member of, or provide advice to, a state, national or international group or committee</i>		
		<i>Examples of interventions documented</i>		<i>Member of, or provide advice to a local group or committee</i>				
		<i>Postgraduate qualifications (with paediatric content)</i>		<i>Active member of PaedPharm</i>		<i>Published research</i>		
		<i>Member of PaedPharm network</i>		<i>Interventions at a specialist/advanced level</i>		<i>Interventions at an expert level</i>		
Individual examples								
1.1.5	<b>Knowledge: Clinical Governance &amp; Medication Safety</b> (Core Knowledge)	Have an understanding of the issues related to equity of access of medicines in children (e.g. unlicensed and off-label use). Demonstrate an understanding of the medication safety challenges in childhood, and the strategies to prevent or reduce medication misadventure. (e.g. oral syringes, paediatric medication chart, smart pumps, child resistant packaging). Lists high risk medications in neonates, infants and children if inappropriately prepared or administered.		Demonstrated knowledge of current local and international medication safety priorities in paediatrics, including the Medication Safety Self-Assessment. Active involvement in local medication safety initiatives.		Identifies medication safety issues at a local, state or national level, drives safety improvement initiatives and shares results with peers and appropriate forums.		
		<i>Child Health Learning Package</i>		<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>		<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>
		<i>Assistance with medication chart audits</i>		<input type="checkbox"/>	<i>Review of Australian and international</i>		<input type="checkbox"/>	

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
				<i>literature (e.g. ISMP Bulletins)</i>			
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Active teaching role within institution</i>	<input type="checkbox"/>	<i>Member of, or provide advice to, a state national, or international group or committee (e.g. CHA Medication Safety ERG)</i>	<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee (e.g. Drug and Therapeutics Committee, Medication Safety Committee)</i>	<input type="checkbox"/>		
		<i>Attendance at Human Error and Patient Safety Course, Root Cause Analysis training (or equivalent)</i>	<input type="checkbox"/>	<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>	<i>Published research (especially practice-based)</i>	<input type="checkbox"/>
				<i>Review of institutional smart pump data-set</i>	<input type="checkbox"/>	<i>Interventions at an expert level</i>	<input type="checkbox"/>
	Individual examples						
1.1.6	<b>Knowledge: Fluids &amp; Electrolytes</b>  (Core Knowledge)	Knowledge of the basic fluid requirements of children in terms of volume and content. Knows the potential for fluid overload from IV administration, particularly in neonates, and children on TPN.  Knowledge of appropriate IV fluids in children.		Demonstrate a good knowledge of issues surrounding intravenous therapy: compatibility, extravasation, displacement volumes, types of lines, methods of administration, pumps			
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>
		<i>Clinical rotations in paediatric areas</i>	<input type="checkbox"/>	<i>Active teaching role within institution</i>	<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>		
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>
						<i>Interventions at an expert level</i>	<input type="checkbox"/>
		Individual examples					



1. Professional Practice						
Improving standards of paediatric pharmaceutical care						
Competency Level Descriptors						
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)
1.1.7	<b>Knowledge: Pain &amp; Sedation</b>  (Core Knowledge)	Understand the basic concepts of pain management and procedural sedation in paediatrics, including drugs and doses appropriate in different inpatient and outpatient settings.  Familiar with common pain scores and assessments used in children.		Understand concepts of: Patient Controlled Analgesia, Nurse Controlled Analgesia, Epidural, Nerve Blocks etc.  Be aware of the treatment options and overall management of the palliative patient.  Demonstrated understanding of current theories on pain management in children – including use of minimally invasive pharmacological and non-pharmacological therapies.		
		Examples of evidence: (tick boxes)		<i>Child Health Learning Package</i> <input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i> <input type="checkbox"/>	
			<i>Clinical rotations in paediatric areas (e.g. PICU, post-surgery, emergency medicine, pain clinics)</i> <input type="checkbox"/>	<i>Active teaching role within institution</i> <input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i> <input type="checkbox"/>	
			<i>Case presentations to department</i> <input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i> <input type="checkbox"/>	<i>Published research</i> <input type="checkbox"/>	
			<i>Examples of interventions documented</i> <input type="checkbox"/>	<i>Interventions at a specialist/advanced level</i> <input type="checkbox"/>	<i>Interventions at an expert level</i> <input type="checkbox"/>	
	Individual examples					
1.1.8	<b>Knowledge: Primary Care, Public Health and Preventative Medicine</b>  (Core Knowledge)	Be aware of the current National Immunisation Schedule, including cold chain requirements.  Be aware of the issues related to indigenous health, including family dynamics, infectious diseases (scabies, rheumatic fever, ear infections), belief systems and spirituality.  Demonstrated understanding of the common (often minor) paediatric illnesses which present to primary care physicians and how to manage (see also emergency		Be capable and confident to discuss the issues surrounding public health strategies such as immunisation.  Active involvement in injury prevention at a local level (e.g. poisoning prevention, child resistant packaging etc).		

1. Professional Practice									
Improving standards of paediatric pharmaceutical care									
Competency Level Descriptors									
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)			
		medicine section)							
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>		
		<i>Clinical rotations in paediatric areas</i>	<input type="checkbox"/>		<i>Active teaching role within institution</i>		<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>		<input type="checkbox"/>	<i>Published research</i>		<input type="checkbox"/>
		<i>Cultural Awareness Training</i>	<input type="checkbox"/>			<i>Interventions at a specialist/advanced level</i>			<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>						
		<i>Postgraduate qualifications (with paediatric content)</i>	<input type="checkbox"/>						
Individual examples									
1.1.9	<b>Knowledge: Emergency Medicine</b>  (Core Knowledge)	Knowledge of the simple management of burns.		Knowledge of the epidemiology of childhood injury, including poisoning, envenomation and strategies for injury prevention in children.					
		Knowledge of the management of common childhood illnesses such as febrile illnesses, otitis media, asthma, URTI, croup, gastroenteritis. (see also infectious diseases, immunology, gastroenterology and respiratory sections).		Knowledge of current protocols for resuscitation of the collapsed child.					
	Demonstrate a sound knowledge of the management of dehydration and fluid replacement in children.								
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>		
		<i>Clinical rotations in paediatric emergency care</i>	<input type="checkbox"/>		<i>Active teaching role within institution</i>		<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>		<input type="checkbox"/>	<i>Published research</i>		<input type="checkbox"/>
<i>Examples of interventions documented</i>		<input type="checkbox"/>	<i>Interventions at a specialist/advanced level</i>			<input type="checkbox"/>			
<i>SHPA Emergency Medicine Seminar</i>	<input type="checkbox"/>								

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
						<i>Interventions at an expert level</i> <input type="checkbox"/>	
	Individual examples						
1.1.10	<b>Knowledge: Respiratory</b>	Demonstrate a good understanding of paediatric asthma and the treatment options (including devices) available.		Demonstrates an advanced understanding and application of the current management of cystic fibrosis and emerging evidence for treatment options.			
		Demonstrate an understanding of the treatment of common respiratory disorders such as cough, hayfever, bronchiolitis and croup.		Demonstrates an advanced knowledge of the management of severe asthma, bronchiolitis and bronchiectasis.			
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>		<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>		<input type="checkbox"/>
		<i>Clinical rotations in paediatric respiratory areas</i>		<input type="checkbox"/>	<i>Attendance at Cystic Fibrosis Conferences</i>		<input type="checkbox"/>
		<i>Case presentations to department</i>		<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>		<input type="checkbox"/>
		<i>Examples of interventions documented</i>		<input type="checkbox"/>	<i>Active teaching role within institution</i>		<input type="checkbox"/>
					<i>eCystic Fibrosis Review (<a href="http://www.hopkinscme.net/ofp/eCysticFibrosisReview/index.html">http://www.hopkinscme.net/ofp/eCysticFibrosisReview/index.html</a>)</i>		<input type="checkbox"/>
			<i>Interventions at a specialist/advanced level</i>		<input type="checkbox"/>		
	Individual examples						
1.1.11	<b>Knowledge: Nephrology and Genito-urinary Disorders</b>	Knowledge of the acute management of urinary tract infections, basic knowledge of the diagnosis and treatment of vesico-ureteric reflux and current recommendations for prophylaxis.  Demonstrate a sound knowledge of the management of enuresis.		Demonstrate a general knowledge of haemolytic uraemic syndrome and nephrotic syndrome and their treatment.  Demonstrate a general knowledge and application of dialysis and dose adjustment in renal failure.		Demonstrate a high level knowledge of renal replacement therapy (e.g. dialysis).	

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
		Demonstrate a basic understanding of the management of acute glomerulonephritis.		Demonstrate an understanding of the management of renal transplantation.			
	Examples of evidence: (tick boxes)	Child Health Learning Package	<input type="checkbox"/>	Case presentations to ground rounds, conferences	<input type="checkbox"/>	Education on topic at a high level - university, conferences, seminars	<input type="checkbox"/>
		Clinical rotations in paediatric nephrology areas	<input type="checkbox"/>		Active teaching role within institution		<input type="checkbox"/>
		Case presentations to department	<input type="checkbox"/>	Member of, or provide advice to a local group or committee		<input type="checkbox"/>	Published research
		Examples of interventions documented	<input type="checkbox"/>		Interventions at a specialist/advanced level	<input type="checkbox"/>	
	Individual examples						
1.1.12	<b>Knowledge: Neurology</b>	Demonstrate a good understanding of the the types of seizures in children, and the treatment of paediatric epilepsy and febrile convulsions.		Demonstrate an understanding of the management of more complex neurological disorders, e.g. brain injury, cerebral palsy, movement disorders, Ventriculo-peritoneal (VP) shunts, Guillian Barre and other neuromuscular disorders, headache and migraine in children, and management of neurodevelopmental delay.			
		Child Health Learning Package	<input type="checkbox"/>	Case presentations to ground rounds, conferences	<input type="checkbox"/>	Education on topic at a high level - university, conferences, seminars	<input type="checkbox"/>
	Clinical rotations in paediatric neurology areas	<input type="checkbox"/>	Active teaching role within institution		<input type="checkbox"/>		Member of, or provide advice to, a state, national or international group or committee
	Case presentations to department	<input type="checkbox"/>		Member of, or provide advice to a local group or committee	<input type="checkbox"/>	Published research	
	Examples of evidence: (tick boxes)	Examples of interventions documented	<input type="checkbox"/>		Interventions at a specialist/advanced level		<input type="checkbox"/>

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
	Individual examples						
1.1.13	Knowledge: Mental Health	Demonstrate an understanding of Attention Deficit Hyperactivity Disorder and the current treatment options.		Demonstrate an understanding of the complexities of the management of eating disorders, including re-feeding syndrome.			
		Demonstrate a basic understanding of the common treatment options for anorexia nervosa and depression in children and adolescents.		Demonstrate a good working knowledge of the current evidence for pharmacotherapy of major psychiatric disorders affecting children (e.g. anxiety, depression, psychoses, autistic spectrum disorder)			
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>
		<i>Clinical rotations in paediatric mental health areas</i>	<input type="checkbox"/>				
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Active teaching role within institution</i>	<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>		
				<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>
				<i>Interventions at an expert level</i>	<input type="checkbox"/>		
	Individual examples						
1.1.14	Knowledge: Endocrinology	Demonstrate a basic understanding of the management of Type 1 diabetes and the implications for treatment options in children.		Be able to describe the treatment of the complications of diabetes such as diabetic ketoacidosis, hypo- and hyperglycaemia.		Demonstrate an understanding of the rationale behind the common endocrinology tests and what the results represent.	
		Demonstrate a basic understanding of the monitoring and treatment of growth disorders in children.		Demonstrate an understanding of the management of more complicated endocrine disorders, e.g. bone diseases (including osteogenesis imperfecta, management of AVN and osteoporosis), congenital adrenal hyperplasia, diabetes insipidus, Turners			
		Demonstrate a basic understanding of the physiology of puberty.					

1. Professional Practice									
Improving standards of paediatric pharmaceutical care									
Competency Level Descriptors									
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)			
				Syndrome. Demonstrate an understanding of the risk factors of long term steroid use and appropriate treatment in period of stress.					
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>		
		<i>Clinical rotations in paediatric endocrinology areas</i>	<input type="checkbox"/>		<i>Active teaching role within institution</i>		<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>		<input type="checkbox"/>	<i>Published research</i>		<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>			<i>Interventions at a specialist/advanced level</i>			<input type="checkbox"/>
	Individual examples								
1.1.15	<b>Knowledge: Gastroenterology</b>	Understand the principles of rehydration		Demonstrate an understanding of the management of inflammatory bowel disorders.		Demonstrate an understanding of the treatment options for short gut syndrome.			
		Understand the pharmacology behind the treatment of gastro-oesophageal reflux and colic in children.		Demonstrate an understanding of the management of significant GI bleeds.					
		Demonstrate an understanding of the management of nausea, vomiting, constipation and encopresis.		Demonstrate an understanding of the management of liver disorders and the management of liver transplantation.					
Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>			
	<i>Clinical rotations in paediatric gastroenterology areas</i>	<input type="checkbox"/>		<i>Active teaching role within institution</i>		<input type="checkbox"/>	<i>Member of, or provide advice</i>	<input type="checkbox"/>	
	<i>Case presentations to department</i>	<input type="checkbox"/>							

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>	<i>to, a state, national or international group or committee</i>	
				<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>
						<i>Interventions at an expert level</i>	<input type="checkbox"/>
	Individual examples						
1.1.16	<b>Knowledge: Rheumatology</b>			Understand the treatment of juvenile arthritis, including pain management.			
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>
		<i>Clinical rotations in paediatric rheumatology areas</i>	<input type="checkbox"/>				
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Active teaching role within institution</i>	<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>
				<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>		
					<i>Interventions at an expert level</i>	<input type="checkbox"/>	
Individual examples							
1.1.17	<b>Knowledge: Immunology</b>	Demonstrate an understanding of common allergies in children and the basic management of allergy and anaphylaxis.		Show an understanding of the disease state and treatment of Kawasaki Disease and Chronic Granulomatous Disease.			
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>
		<i>Clinical rotations in paediatric immunology areas</i>	<input type="checkbox"/>				
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Active teaching role within institution</i>	<input type="checkbox"/>	<i>Member of, or provide advice</i>	<input type="checkbox"/>

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>	<i>to, a state, national or international group or committee</i>	
				<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>
						<i>Interventions at an expert level</i>	<input type="checkbox"/>
	Individual examples						
1.1.18	<b>Knowledge: Haematology and Oncology (See also Cancer Services Competency Framework)</b>	Demonstrate a basic understanding of the management of children with cancer, including standard management of febrile neutropenia.  Demonstrate an understanding of supportive care, mouth care and infective prophylaxis.  Demonstrate a basic understanding of bleeding disorders as they present in children.		Demonstrate a sound understanding of Acute Lymphoblastic Leukaemia (ALL) and its treatment.  Demonstrate knowledge of the treatment of febrile neutropenia, sickle cell disease, anaemia.  Demonstrate an understanding of the treatment options and management required for bone marrow transplantation.  Demonstrate an understanding of the appropriate use of antithrombotic therapy in children, including monitoring.  Demonstrate an understanding of tumour lysis syndrome, and contemporary therapies.		Demonstrate an understanding of current common clinical trials underway in paediatric oncology, including an understanding of the reasoning behind treatment options.	
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>
		<i>Clinical rotations in paediatric oncology and haematology areas</i>	<input type="checkbox"/>				
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Active teaching role within institution</i>	<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>		
		<i>Attendance at SHPA Oncology Seminars</i>	<input type="checkbox"/>	<i>Attendance at ANZSIG, ISOPP, COSA and/or COG</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>



1. Professional Practice									
Improving standards of paediatric pharmaceutical care									
Competency Level Descriptors									
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)			
				<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>	<i>Interventions at an expert level</i> <input type="checkbox"/>			
	Individual examples								
1.1.19	<b>Knowledge: Cardiology</b>	Demonstrate a basic understanding of the common types of congenital heart defects including Patent Ductus Arteriosus.		Demonstrate an understanding of the management of hypertensive crisis, pulmonary hypertension, arrhythmias and rheumatic heart disease.					
		Demonstrates a basic understanding of appropriate use of SBE prophylaxis.		Demonstrate an understanding of the management of cardiac transplant.					
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>		
		<i>Clinical rotations in paediatric cardiology areas</i>	<input type="checkbox"/>		<i>Active teaching role within institution</i>		<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>		<input type="checkbox"/>	<i>Published research</i>		<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>			<i>Interventions at a specialist/advanced level</i>			<input type="checkbox"/>
	Individual examples								
1.1.20	<b>Knowledge: Infectious Diseases</b>	Have a basic understanding of common childhood bacterial and viral infections, including treatment and prophylaxis. (e.g. URTI, UTI, pneumonia, meningitis, surgical prophylaxis).  Demonstrate a sound understanding of the acute and chronic management of otitis media, otitis externa and glue ear in children.  Understand the management of fever in children, including appropriate use of antipyretics and treatment of pyrexia of		Demonstrate an understanding of the management of chronic, severe and/or less common paediatric infections (eg sepsis, TB, HIV, CMV).  Demonstrate an understanding of the causes and management of common tropical diseases presenting in children.		Demonstrate an understanding of the theory and application of antibiotic governance in the paediatric setting.			

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
		unknown origin. Have an understanding of the standard management of bone, skin and joint infections in children.					
	Examples of evidence: (tick boxes)	Child Health Learning Package	<input type="checkbox"/>	Case presentations to ground rounds, conferences	<input type="checkbox"/>	Education on topic at a high level - university, conferences, seminars	<input type="checkbox"/>
		Clinical rotations in paediatric areas	<input type="checkbox"/>	Active teaching role within institution	<input type="checkbox"/>	Member of, or provide advice to, a state, national or international group or committee	<input type="checkbox"/>
		Case presentations to department	<input type="checkbox"/>	Member of, or provide advice to a local group or committee	<input type="checkbox"/>	Published research	<input type="checkbox"/>
		Examples of interventions documented	<input type="checkbox"/>	Interventions at a specialist/advanced level	<input type="checkbox"/>	Interventions at an expert level	<input type="checkbox"/>
Individual examples							
1.1.21	<b>Knowledge: Metabolic Disorders and Genetics</b>	Have a basic understanding of common genetic variations in drug handling (e.g. G6PD deficiency)		Demonstrate an understanding of common metabolic disorders such as phenylketonuria, urea cycle disorders and glycogen storage disorders.		Demonstrate an understanding of complex metabolic disorders and treatment options available.	
	Examples of evidence: (tick boxes)	Child Health Learning Package	<input type="checkbox"/>	Case presentations to ground rounds, conferences	<input type="checkbox"/>	Education on topic at a high level - university, conferences, seminars	<input type="checkbox"/>
		Clinical rotations in paediatric metabolic diseases areas	<input type="checkbox"/>	Active teaching role within institution	<input type="checkbox"/>	Member of, or provide advice to, a state, national or international group or committee	<input type="checkbox"/>
		Case presentations to department	<input type="checkbox"/>	Member of, or provide advice to a local group or committee	<input type="checkbox"/>	Published research	<input type="checkbox"/>
		Examples of interventions documented	<input type="checkbox"/>	Interventions at a specialist/advanced level	<input type="checkbox"/>	Interventions at an expert level	<input type="checkbox"/>
Individual examples							

1. Professional Practice								
Improving standards of paediatric pharmaceutical care								
Competency Level Descriptors								
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)		
1.1.22	<b>Knowledge: Obstetrics and Neonatology</b>	Understand the developmental changes in the neonate, with particular regard to drug metabolism and excretion.		Demonstrated understanding of common neonatal problems and their treatment: e.g. Respiratory Distress Syndrome, Patent Ductus Arteriosus, neonatal abstinence syndrome, neonatal apnoea, necrotising enterocolitis.				
		Explains how disease processes impact medication therapy, especially conditions frequently encountered in premature infants.		Advanced knowledge of drugs in pregnancy & breastfeeding, including risk assessment and patient focused advice.				
		Familiar with the standard prophylaxis of haemorrhagic disease of the newborn, neonatal immunisation, routine management of neonatal jaundice & neonatal abstinence syndrome, and standard neonatal screening tests (e.g. APGAR).		Demonstrated understanding of common advanced obstetric complications (e.g. pre-term labour, premature rupture of membranes, gestational diabetes, hypertension, PUPPS, postpartum haemorrhage and substance abuse), and their management and implications for the neonate.				
		Identify the organisms associated with both early onset and late onset neonatal sepsis and the appropriate empiric therapy.		Demonstrated understanding of management of pre-existing chronic medical conditions during pregnancy to minimise risk to the mother and baby (e.g. renal & cardiac disease, epilepsy)				
		Have a basic understanding of drugs in breast milk, and safety of medicines in pregnancy, including awareness of the most useful references for drugs in pregnancy and lactation.						
		Awareness of common obstetric conditions (e.g. hyperemesis, constipation) and their appropriate management to minimise risk to the neonate.						
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>		<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>		<input type="checkbox"/>	
<i>Clinical rotations in neonatology areas</i>		<input type="checkbox"/>			<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>		
<i>Case presentations to department</i>		<input type="checkbox"/>	<i>Active teaching role within institution</i>		<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>	
<i>Examples of interventions documented</i>		<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>		<input type="checkbox"/>			
			<i>Interventions at a specialist/advanced level</i>		<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>	
						<i>Interventions at an expert level</i>	<input type="checkbox"/>	
Individual examples								

1. Professional Practice							
Improving standards of paediatric pharmaceutical care							
Competency Level Descriptors							
No.	Competency	Foundation (Rotational)		Excellence (Advanced/Specialist)		Mastery (Expert/Consultant)	
1.1.23	Knowledge: Critical Care	Demonstrate an understanding of the standard treatment requirements for a ventilated child, including prophylaxis for stress ulceration, and sedation.		Demonstrate an understanding of the appropriate use of inotropes, management of multi-organ failure (e.g. CVVHDF) and the impact of this on medication use..		Demonstrate a sound understanding of the patient journey in the intensive care unit, including use of prognostic scoring and end of life decisions.  Demonstrate an understanding of resuscitation broadly in a paediatric environment – e.g. fluids, adrenaline, alternate routes of administration (e.g. intraosseus, endotracheal)	
	Examples of evidence: (tick boxes)	<i>Child Health Learning Package</i>	<input type="checkbox"/>	<i>Case presentations to ground rounds, conferences</i>	<input type="checkbox"/>	<i>Education on topic at a high level - university, conferences, seminars</i>	<input type="checkbox"/>
		<i>Clinical rotations in paediatric critical care areas (e.g. PICU, NICU)</i>	<input type="checkbox"/>				
		<i>Case presentations to department</i>	<input type="checkbox"/>	<i>Active teaching role within institution</i>	<input type="checkbox"/>	<i>Member of, or provide advice to, a state, national or international group or committee</i>	<input type="checkbox"/>
		<i>Examples of interventions documented</i>	<input type="checkbox"/>	<i>Member of, or provide advice to a local group or committee</i>	<input type="checkbox"/>		
				<i>Interventions at a specialist/advanced level</i>	<input type="checkbox"/>	<i>Published research</i>	<input type="checkbox"/>
				<i>Interventions at an expert level</i>	<input type="checkbox"/>		
Individual examples							

## **Appendix B: shpaclinCAT**

The following pages show a selection of the shpaclinCAT competency assessment tool, indicating the level of performance criteria included.

---

# shpaclinCAT

## Clinical Competency Assessment Tool for Australian Pharmacists

---

### Assessment Tool with Evaluation

Version 2010

Pharmacist Details		Evaluator Details	
<b>Name</b>		<b>Name</b>	
<b>Position</b>		<b>Position</b>	
<b>Site</b>			
<b>Date of Evaluation</b>			

#### Frequency Ranges for Assessment Ratings

Rating	Definitions	Percentage expression
<b>Consistently</b>	Consistently demonstrates the expected standard practice, with very rare lapses	85-100%
<b>Usually</b>	Demonstrates expected standard practice with occasional lapses	51-84%
<b>Sometimes</b>	Demonstrates expected standard practice less than half of the time observed. Much more haphazard than "mostly"	25-50%
<b>Rarely</b>	Very rarely meets the standard expected. No logical thought process appears to apply	0-24%

---

Published by: The Society of Hospital Pharmacists of Australia, Suite 3, 65 Oxford Street, Collingwood 3066, Australia  
ABN 54 004 553 806

© The Society of Hospital Pharmacists of Australia, 2010.

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced without prior written permission from the Society of Hospital Pharmacists of Australia.

## Part One: Delivery of Patient Care

### Competency Unit 1.1: Medication History

Element	Performance Criteria & Evidence Guide						
<b>1.1.1 Relevant patient background</b>	<p><b>Retrieve relevant information</b></p> <p>Obtain and contextualise the following patient information as applicable:</p> <ul style="list-style-type: none"> <li>▪ Age –consider patient’s likely ability to metabolise/excrete medicines, and implications for appropriate selection of medicine and dosage</li> <li>▪ Gender – consider impact of gender on therapeutic decision making</li> <li>▪ Height and weight</li> <li>▪ Pregnancy/lactation status</li> <li>▪ Immunisation status</li> <li>▪ Ethnic background/religion– consider pharmaceutical implications including pharmacogenetic factors</li> <li>▪ Social background – consider impact on patient’s ability to manage their medicines</li> <li>▪ Details of regular general practitioner/community pharmacy/other as appropriate</li> <li>▪ Patient’s ability to communicate (cognitive function, alertness, mental acuity, psychological state) and requirements for communication aids e.g. glasses, hearing aids, need for interpreter service</li> <li>▪ Presenting condition – consider the possibility of adverse drug reactions, poor adherence, inadequate dosing, inappropriate therapy as a contributor to hospital presentation/morbidity</li> <li>▪ Working diagnosis - consider appropriate evidence based therapy</li> <li>▪ Previous medical history – identify potential medicine and/or disease contraindications and ensure that management of the presenting complaint does not compromise a co-morbidity</li> <li>▪ Relevant laboratory or other findings (if available) - focus on findings that will affect decisions regarding medicines, including                             <ul style="list-style-type: none"> <li>▪ renal function</li> <li>▪ electrolytes</li> <li>▪ liver function</li> <li>▪ full blood count</li> <li>▪ cardiac markers</li> <li>▪ general observations</li> <li>▪ relevant previous therapeutic drug monitoring results</li> </ul> </li> <li>▪ Utilise appropriate sources to obtain information e.g.                             <ul style="list-style-type: none"> <li>▪ ward handover sheet</li> <li>▪ health care professionals (including pharmacists, nurses, doctors, allied health professionals)</li> <li>▪ medical notes (including advance care directive) and transfer summaries from referring institution</li> <li>▪ laboratory results systems</li> </ul> </li> </ul>						
	<b>Self</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment	
	<b>Comment</b>						
	<b>Evaluation</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment	
	<b>Comment</b>						

Element	Performance Criteria & Evidence Guide					
<b>1.1.2 Introduction to consultation</b>	<b>Provide clear introduction to the consultation</b>					
	<ul style="list-style-type: none"> <li>▪ Greet patient</li> <li>▪ Establish patient identity</li> <li>▪ Introduce self and other colleagues as applicable</li> <li>▪ Confirm time is convenient</li> <li>▪ Establish a rapport with the patient and/or carer to support ongoing communication</li> <li>▪ Respect the patient's right to decline an interview or consultation, or to choose a more appropriate time</li> </ul>					
	<b>Self</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment
	<b>Comment</b>					
	<b>Evaluation</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment
	<b>Comment</b>					
	<b>Agree on an agenda with the patient</b>					
	<ul style="list-style-type: none"> <li>▪ Explain purpose of discussion e.g. taking a medication history, medicine specific counselling or a medication chart review</li> </ul>					
	<b>Self</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment
	<b>Comment</b>					
<b>Evaluation</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment	
<b>Comment</b>						
<b>1.1.3 Questioning technique</b>	<b>Use appropriate questioning to obtain relevant information from the patient</b>					
	<ul style="list-style-type: none"> <li>▪ Determine who the most appropriate person is to discuss the patient's medications with</li> <li>▪ Use appropriate nonverbal language e.g. adopt a suitable position, maintain eye contact, actively listen</li> <li>▪ Use appropriate language i.e. non judgmental, non alarmist, reassuring and using terminology and phrasing the patient/carer will understand (avoid use of medical jargon)</li> <li>▪ Ask relevant and succinct questions using an appropriate technique i.e. a mixture of open and closed questions</li> <li>▪ Avoid interrupting the patient/carer</li> <li>▪ Avoid leading or negative questions</li> </ul>					
	<b>Self</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment
	<b>Comment</b>					
	<b>Evaluation</b>	Rarely	Sometimes	Usually	Consistently	Unable to Comment
<b>Comment</b>						



## Appendix C: Feedback Questions for Advanced Practice Assessment Participants

1. What level of practice did you consider yourself before you started the project, and what level of practice do you consider yourself now you have completed the project. (With Level 1 being foundation or general level practice, and Level 3 being "Mastery" or "Advanced" level)
  - Before you started the project
  - After you completed the project
  
2. The portfolio was presented electronically via an internet storage provider (dropbox). What is your preferred format to present your portfolio?
  - Electronic, personal (e.g. USB stick or similar)
  - Electronic, internet based (e.g. dropbox or similar)
  - Paper based (e.g. printed copies provided to panel members)
  - Other
  
3. Overall, I found the portfolio review to be: (5 point Likert scale from Strongly agree to Strongly Disagree for each of the following statements)
  - A positive experience that allowed me to reflect honestly on my practice and future development.
  - An extremely taxing process that provided little benefit to me.
  - An inspiring experience that has given me renewed enthusiasm for pharmacy practice.
  - A fair method of evaluation of advanced practice
  
4. Overall, I found the oral viva to be... (5 point Likert scale from Strongly agree to Strongly Disagree for each of the following statements)
  - A positive experience that allowed me to reflect honestly on my practice and future development.
  - An extremely taxing process that provided little benefit to me.
  - An inspiring experience that has given me renewed enthusiasm for pharmacy practice.
  - A fair method of evaluation of advanced practice

5. Overall, I found the Mini-PAT to be... (5 point Likert scale from Strongly agree to Strongly Disagree for each of the following statements)
- A positive experience that allowed me to reflect honestly on my practice and future development.
  - An extremely taxing process that provided little benefit to me.
  - An inspiring experience that has given me renewed enthusiasm for pharmacy practice.
  - A fair method of evaluation of advanced practice
6. Overall, I found knowledge assessments... (5 point Likert scale from Strongly agree to Strongly Disagree for each of the following statements, separate questions for CPD recording and postgraduate qualifications)
- A positive experience that allowed me to reflect honestly on my practice and future development.
  - An extremely taxing process that provided little benefit to me.
  - An inspiring experience that has given me renewed enthusiasm for pharmacy practice.
  - A fair method of evaluation of advanced practice
7. Overall, I found direct observation of practice to be... (5 point Likert scale from Strongly agree to Strongly Disagree for each of the following statements)
- A positive experience that allowed me to reflect honestly on my practice and future development.
  - An extremely taxing process that provided little benefit to me.
  - An inspiring experience that has given me renewed enthusiasm for pharmacy practice.
  - A fair method of evaluation of advanced practice
8. What do you consider are the MOST useful pieces of evidence to demonstrate level of practice? This could be what you found most useful, or what you might consider useful in the future. (Multiple selections can be chosen)
- Advanced Level Framework (adding evidence against the different competencies)
  - Mini-PAT (the summarised peer review from your colleagues)
  - ClinCAT or GLF (direct observation of your practice)
  - Thank-you or other acknowledgements (e.g. emails from colleagues)
  - Presentations or lectures given

- Student or learner feedback (as an educator)
  - CPD records
  - Written references
  - Intervention reports or case based demonstrations
  - Project Reports
  - Research - published articles
  - Research - conference or seminar abstracts, posters or presentations
9. What do you consider are the LEAST useful pieces of evidence to demonstrate level of practice? (Multiple choices can be selected)
- (same options as for Question 8 above)
10. Do you have any other comments regarding the project, or suggestions on how to improve advanced practice assessment in the future? (free text)

Oral Viva Participants were also asked the additional questions:

1. What format was the oral viva you participated in?
  - Face to face
  - Videoconference (via Webex)
  - Videoconference (via FaceTime)
  - Telephone
2. How many people were in your evaluation panel? (Not counting Sonya Stacey as an observer)
3. How did you feel before the oral viva?
  - Quite anxious
  - A little apprehensive
  - Neutral
  - Comfortable
  - Confident

4. How did you feel after the oral viva?
  - Much better
  - A little better
  - The same
  - A little worse
  - Much worse
  
5. Did you feel the oral viva gave you the opportunity to provide additional information or evidence to support your level of practice (above presenting your portfolio alone)?
  - Yes, No or Not Sure
  
6. What other comments do you have, or suggestions on how to improve the oral viva process for the future? (free text)

# Appendix D: Multi Source Peer Review Survey (Mini-PAT)

## 1. Introduction

Welcome to the Advanced Pharmacy Practice 360 degree appraisal form for paediatrics.

You have been asked to complete this because a pharmacist is undergoing an evaluation and has designated you as a referee for part of the process. At present, this type of evaluation is infrequent, you are unlikely to be inundated with such requests in future. The candidate is evaluated in a number of different assessments, of which this is just one part.

This appraisal survey is structured according to the format of a competency framework developed by the Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Paediatrics.

Competencies are clustered into 6 main areas with three levels of advanced practice for each area. There is a paragraph with some explanatory sentences for each of the three levels, which are a condensed version of the competency framework and provided to help you gauge the likely level of practice of the candidate pharmacist.

The 6 areas are:

- Expert Professional Practice
- Building Working Relationships
- Leadership
- Management
- Education, Training and Development
- Research and Evaluation

You will be asked about each area in turn.

In each area, please indicate the level of practice the pharmacist routinely works at (in your opinion) by clicking on one box. Please note that it is unusual for a pharmacist to attain the

highest level of practice in all areas, and it is not necessary to have achieved all of the explanatory points to be considered working at that specific level.

Please also write brief comments in each of the areas where possible. The comments from all the referees will be consolidated together anonymously and fed back to the candidate.

There is also a text box for suggestions that you may have about development opportunities available to the candidate.

## **2. About you**

Please could you indicate how long you have known the candidate?

Please indicate which professional group you would describe yourself as belonging to:-

- Doctor
- Nurse
- Pharmacist
- Allied Health Professional
- Other (please specify)

### 3. Expert Professional Practice

Please assign a level of competence for the candidate by clicking on ONE BUTTON ONLY. Examples of practice that suggest the candidate is working at a particular level are provided to assist you.

If you do not believe the candidate meets level 1, or you feel that that you cannot comment on this aspect of the framework, then please state this in the comments box and do not select a button.

The candidate does not have to perform all listed activities to achieve a rating at that level, but should perform activities that are generally of the same level of complexity or require the same depth of knowledge / skill as the examples given.

Please also add comments in the text boxes below (e.g. brief examples of the candidates practice that support the grade assigned, strengths and weaknesses). This is optional, but comments are exceptionally helpful for the evaluation panel when reviewing the candidate's performance and as consolidated feedback to the pharmacist themselves.

LEVEL 1: Demonstrated general pharmaceutical knowledge in paediatric patients. Able to plan, manage, monitor, advise and review pharmaceutical care programs for general paediatric patients at an individual patient level. Able to make decisions, problem-solve, prioritise in a timely manner and within organisational constraints.

LEVEL 2: Demonstrates in depth pharmaceutical knowledge in paediatric patients. Able to plan, manage, monitor, advise and review specialist pharmaceutical care plans for groups of paediatric patients, including high acuity patients. Able to problem-solve and make decisions in complex situations in a timely manner, where limited information is available and multiple factors are involved. Able to describe reasoning and evidence behind recommendations to others.

LEVEL 3: Able to identify knowledge gaps and advances the knowledge base in paediatrics. Advances pharmaceutical care programmes for large groups of paediatric patient groups, including development and implementation of new policies and procedures for use in the paediatric environment. Able to advocate on behalf of individual patients or service groups at a state or national level. Able to use skills to manage difficult and dynamic situations, make

decisions in the absence of evidence or data or when there is conflicting information, and resolve large scale or complex service problems.

Having reviewed the candidate against the examples above, are there any initiatives / projects in your location that the candidate could become involved with that aids their professional development and / or improves patient care?

#### **4. Building Working Relationships**

Please assign a level of competence for the candidate by clicking on ONE BUTTON ONLY. Examples of practice that suggest the candidate is working at a particular level are provided to assist you.

If you do not believe the candidate meets level 1, or you feel that that you cannot comment on this aspect of the framework, then please state this in the comments box and do not select a button.

The candidate does not have to perform all listed activities to achieve a rating at that level, but should perform activities that are generally of the same level of complexity or require the same depth of knowledge / skill as the examples given.

Please also add comments in the text boxes below (e.g. brief examples of the candidates practice that support the grade assigned, strengths and weaknesses). This is optional, but comments are exceptionally helpful for the evaluation panel when reviewing the candidate's performance and as consolidated feedback to the pharmacist themselves.

**LEVEL 1:** Demonstrates use of appropriate communication with individual patients, colleagues and clinicians as part of a multidisciplinary team. Able to communicate where the content of the discussion is clear. Able to persuade others about individual episodes of care, and negotiates effectively. Able to communicate effectively with children and families in a developmentally appropriate fashion, including respectful listening, empathy and appropriate reassurance. Effective and proactive member of the multidisciplinary team and of other professional groups.

**LEVEL 2:** Demonstrates the use of appropriately selected communication skills with small groups of patients, colleagues, senior clinicians and managers within the organization. Able to communicate effectively with children and families in an empathetic and respectful manner in



complex situations using appropriate verbal and body language. Able to persuade or influence and negotiate with the multidisciplinary team with regard to complex cases, organizational change, guidelines and protocols. Active member of multidisciplinary and specialty professional groups with acknowledged expertise in the defined area of practice.

LEVEL 3: Demonstrates ability to present complex, sensitive or contentious information to large groups of patients, clinicians and senior managers. Motivates the multidisciplinary and pharmacy team. Able to utilize high level negotiation and conflict management skills and communicate effectively in a hostile, antagonistic or highly emotive atmosphere. Acknowledged within a multidisciplinary team as a leader in the defined area of practice, and sought as an opinion leader from within and outside the organization. Works across geographical and professional boundaries to build relationships, share information, plans and resources.

Having reviewed the candidate against the examples above, are there any initiatives / projects in your location that the candidate could become involved with that aids their professional development and / or improves patient care?

## **5. Leadership**

Please assign a level of competence for the candidate by clicking on ONE BUTTON ONLY. Examples of practice that suggest the candidate is working at a particular level are provided to assist you.

If you do not believe the candidate meets level 1, or you feel that that you cannot comment on this aspect of the framework, then please state this in the comments box and do not select a button.

The candidate does not have to perform all listed activities to achieve a rating at that level, but should perform activities that are generally of the same level of complexity or require the same depth of knowledge / skill as the examples given.

Please also add comments in the text boxes below (e.g. brief examples of the candidates practice that support the grade assigned, strengths and weaknesses). This is optional, but comments are exceptionally helpful for the evaluation panel when reviewing the candidate's performance and as consolidated feedback to the pharmacist themselves.

LEVEL 1: Understands local organizational structures and service delivery, governance and partnerships. Ensures compliance with local policies. Understands and contributes to department and unit vision and service improvement activities. Able to motivate self to achieve goals. Implements local changes and service improvement projects agreed by the unit or organization.

LEVEL 2: Understands culture and climate and can plan with the whole organization in mind. Able to incorporate national healthcare policy into local practice. Raises and/or deals with identified issues at a unit level. Creates clear vision for the future. Develops and implements innovation from outside the organization. Able to motivate individuals in the team.

LEVEL 3: Plans long term and actively participates in creating national healthcare guidelines and policies. Convinces and motivates others to share the vision at higher level (beyond the team), develops and leads innovation strategies at an organizational level to demonstrably improve service delivery.

Having reviewed the candidate against the examples above, are there any initiatives / projects in your location that the candidate could become involved with that aids their professional development and / or improves patient care?

## 6. Management

Please assign a level of competence for the candidate by clicking on ONE BUTTON ONLY. Examples of practice that suggest the candidate is working at a particular level are provided to assist you.

If you do not believe the candidate meets level 1, or you feel that that you cannot comment on this aspect of the framework, then please state this in the comments box and do not select a button.

The candidate does not have to perform all listed activities to achieve a rating at that level, but should perform activities that are generally of the same level of complexity or require the same depth of knowledge / skill as the examples given.

Please also add comments in the text boxes below (e.g. brief examples of the candidates practice that support the grade assigned, strengths and weaknesses). This is optional, but comments are

exceptionally helpful for the evaluation panel when reviewing the candidate's performance and as consolidated feedback to the pharmacist themselves.

LEVEL 1: Understands the process for resource utilization at a departmental level, including necessity for managing own time and conflicting priorities. Understands and conforms to local standards of practice. Proactively manages own data collection for financial, risk management, performance indicators as required by organization. Able to carry out small individual projects without guidance.

LEVEL 2: Demonstrates ability to effectively manage resources including personal time a small team. Able to supervise students and less experienced pharmacists and performance manage a small team. Develops, implements and monitors standards of practice at a team level, including management of risk management issues and policies and protocols for the team. Able to successfully manage a small project and/or change process for the team.

LEVEL 3: Demonstrates ability to manage, allocate and reconfigure available resources and understands competing factors at an institutional, state and national level. Able to performance manage a large team or department. Sets and monitors standards of practice at a departmental and/or institutional level, including resolution of risk management issues and development of policies and procedures. Able to successfully plan, supervise and manage the implementation a project or change management process beyond the team/workplace or across disciplines.

Having reviewed the candidate against the examples above, are there any initiatives / projects in your location that the candidate could become involved with that aids their professional development and / or improves patient care?

## **7. Education, Training and Development**

Please assign a level of competence for the candidate by clicking on ONE BUTTON ONLY. Examples of practice that suggest the candidate is working at a particular level are provided to assist you.

If you do not believe the candidate meets level 1, or you feel that that you cannot comment on this aspect of the framework, then please state this in the comments box and do not select a button.

The candidate does not have to perform all listed activities to achieve a rating at that level, but should perform activities that are generally of the same level of complexity or require the same depth of knowledge / skill as the examples given.

Please also add comments in the text boxes below (e.g. brief examples of the candidates practice that support the grade assigned, strengths and weaknesses). This is optional, but comments are exceptionally helpful for the evaluation panel when reviewing the candidate's performance and as consolidated feedback to the pharmacist themselves.

LEVEL 1: Role model to junior pharmacists, technicians and peers. Teaches within pharmacy and to nursing staff and other allied health professionals. Reflects on the effectiveness of teaching conducted. Maintains own CPD portfolio and evaluates own learning.

LEVEL 2: Role model at a local level and externally. Mentors others within the team. Teaches to wider multidisciplinary team, senior staff, and undergraduate and postgraduate students. Able to plan and deliver an effective learning experience, and assess the performance and learning needs of others. Ongoing participation in professional development activities including postgraduate qualifications.

LEVEL 3: Role model for pharmacy and wider multidisciplinary team and able to develop role model behavior in others. Able to mentor other advanced level pharmacists, including outside the organization and the profession. Recognised as a peer reviewer of clinical practice within specialty area. Able to design and manage a course of study including appropriate teaching, assessment and study methods. Shapes and contributes to professional development and education for the profession or other disciplines, including state/national level. Commitment to own professional development via higher postgraduate qualifications.

Having reviewed the candidate against the examples above, are there any initiatives / projects in your location that the candidate could become involved with that aids their professional development and / or improves patient care?

## 8. Research and Evaluation

Please assign a level of competence for the candidate by clicking on ONE BUTTON ONLY. Examples of practice that suggest the candidate is working at a particular level are provided to assist you.

If you do not believe the candidate meets level 1, or you feel that that you cannot comment on this aspect of the framework, then please state this in the comments box and do not select a button.

The candidate does not have to perform all listed activities to achieve a rating at that level, but should perform activities that are generally of the same level of complexity or require the same depth of knowledge / skill as the examples given.

Please also add comments in the text boxes below (e.g. brief examples of the candidates practice that support the grade assigned, strengths and weaknesses). This is optional, but comments are exceptionally helpful for the evaluation panel when reviewing the candidate's performance and as consolidated feedback to the pharmacist themselves.

LEVEL 1: Able to critically evaluate published evidence. Can give examples of evidence gaps. Performs audits and presents results locally. Understands research governance and works as a member of the research team at supply and clinical information level.

LEVEL 2: Able to critically evaluate published evidence in the context of paediatric specialty practice. Able to formulate research questions within the specialty for use within the team to direct research efforts. Submits work to peer reviewed national conferences. Writes evidence based guidelines that are implemented at a local level. Contributes to research supervision in collaboration with others. Involved in clinical trials at planning/implementation level.

LEVEL 3: Undertakes peer review activities within the specialty (e.g. journal publications, conference abstracts, guidelines). Able to design a successful strategy to address research questions within the specialty. Demonstrates authorship of primary evidence and outcomes in peer-reviewed media. Member of clinical governance team, working parties or service improvement groups. Writes or co-writes evidence based guidelines that are implemented at a state or national level. Supervises students undertaking postgraduate research. Works with researchers and/or clinical trials teams at a state and national level, making a contribution to large and/or multi-centre research studies.

Having reviewed the candidate against the examples above, are there any initiatives / projects in your location that the candidate could become involved with that aids their professional development and / or improves patient care?

## **9. Finish**

Thank you for completing this evaluation. Your answers will provide valuable information for the evaluation panel when assessing this candidate.

We appreciate that the referee process takes time and effort to complete. We are constantly trying to make this process more efficient. If you have any comments or suggestions to make about the format of this evaluation form please add them to the text box below.

## **10. Thank you!**

---

---

---

---