# PHARMACIST PRESCRIBING IN THE AUSTRALIAN CONTEXT: DEVELOPMENT AND VALIDATION OF COMPETENCY STANDARDS AND IDENTIFICATION OF PHARMACISTS' EDUCATIONAL NEEDS


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***ERRATA***

p. xi (para 3, line 4): Delete apostrophe after “Pharmacists”.
p. 2 (para 2, line 8): Delete “, that includes” and add colon after “prescriber”.
p. 3 (para 3, line 1): Change “practiced” to “practised”.
p. 18 (para 2, line 1): Delete “was” and “to”. Change “determine” to “determined”.
p. 19 (para 3, line 3): Delete “but”
p. 23 (para 3, line 1): Delete “Previous”
p. 23 (para 3, line 3): Add comma after “studies”. Delete “,” after reference “73”.
p. 24 (para 2, line 1): Delete colon after reference “73”. Add colon after “areas”.
p. 51 (Table 7, Column: Establishing options) line 23: Delete asterisk after “diagnosis”.
p. 52 (Table 7, Column: Establishing options) line 28: Delete asterisk after “preferences”.
p. 53 (Table 8, Column: Prescribing safely) line 11: Delete asterisk after “specialist” and line 33 after “notes”.
p. 56 (para 2, line 2): Change “pharmacist” to “pharmacists”.
p. 58, Table 12:
(Table title): Delete “The” before “summary”.
(Table heading): Delete “the” before “description”.
(Column: 9.1 Prescribe Safely): Line 1: Add “competency” before “unit” and line 4: Change “consist” to “consists”.
(Column: 9.2 Prescribe Effectively): Line 1: Delete “functional area includes units that address” and replace with “competency unit addresses” and line 3: Change “consist” to “consists”.
(Column: 9.3 Prescribe Professionally): Line 1: Add “competency” before “unit” and line 4: Change “consist” to “consists”.
(Column: 9.4 Prescribe to the Accepted Standard): Line 1: Change “describe” to “describes”, “standard” to “standards” and “pharmacist” to “pharmacists”; line 2: Change “patients” to “patients‘“ and “problem” to “problems” and line 4: Change “consist” to “consists”.
(Column: 9.5 Participate in the Development of Prescribing Practice) Line 1: Change “describe” to “describes” delete “on” before “ways”, line 2: Change “the” to “their“ and “other” to “others” and line 3: Change “consist” to “consists”.
p. 64 (para 2, line 5): Add “of” after “consideration”.
p. 65 and 66, Table 13:
p. 65 (Column 9.1 Prescribe Safely, elements, (First draft): Add “apply” before “safety”
p. 65 (Column 9.3 Prescribe Safely, elements, (Amended version): Add “apply” before “safety”.
p. 65 (Column 9.1 Prescribe Safely, elements (first draft), line 2: Add “Apply” before “safety”.
p. 65 (Column 9.4 Prescribe Safely, elements (Amended version), line 3: Add “Apply” before “safety”.
p. 65 (Column: 9.4 Prescribe Professionally, elements (Amended version), line 1: Change “works” to “work”
p. 66 (Column: 9.4 Prescribe Professionally, elements (Amended version), line 3: “takes” to “take”.
p. 66 (Column 9.5 Participate in the Development of Prescribing Practice, elements (Amended version, line 1): Change “participates” to “participate”.
p. 66 (Column 9.6 Apply Communication Skills, elements (Amended version) line 3: Change “undertakes” to “undertake”, line 5: “negotiates” to “negotiate” and line 6: “gives” to “give”.
p. 66 (Column 9.7 Provide Medicines and Health Information and Education, elements (Amended version) line 1: Change “understands” to “understand”, line 4: “appraises” to “appraise”, line 6: “applies” to “apply” and line 8: “reviews” to “review”.
p. 67 (para 1, line 4): Add “in” before “Table 14”.
p. 68 to 89 (Functional Area 9: Prescribe Medicines):
p. 68 (para 1, line 1): Change “Prescribe Medicine” to “Prescribe Medicines”.
p. 69 (Column: Performance criteria, line 22): Change “Understand” to “Understands”.
p. 70 (Column: Evidence Guide, line 10): Add “Ability to” before review and change “identifies” to “identify”.
p. 72 (Column: Evidence Guide, line 1 and 6): Add hyphen to “no treatment”.
p. 73 (Column: Evidence Guide) line 4: Delete “a” and add “the” before “patient”, line 9: Change “patients” to “patient” line 2, 5, 8: Add apostrophe after “patient”.
p. 74 (Column: Evidence Guide, line 4): Delete “Demonstrated”.
p. 75 (Column: Performance Criteria, line 14): Change “Assess” to “Assesses” and “interpret” to “interprets”.
p. 76 (Column: Element, line 1): Add “Apply” before “safety”.
p. 77 (Column: Performance Criteria, line 17): Change “Use” to “Uses”.
p. 78 (Column: Element, line 1): Change “works” to “work”.
p. 79 (Column: Evidence Guide, line 11): Change “Recognises and respects” to “Ability to recognise and respect”.
p. 80 (Column: Performance Criteria, line 3 and 6): Change “maintain” to “maintains”.
p. 81 (Column: Element, line 1): Change “takes” to “take”.
p. 82 (Column: Element, line 1): Change “participates” to “participate”.
p. 82 (Column: Evidence Guide, line 19): Change “Response and acting” to “Ability to act”.
p. 82 (Column: Performance Criteria, line 5): Add apostrophe after “others”.
p. 83 (Column: Performance Criteria) line 1: Change “challenge” to “challenges”, line 3: Change “establish” to “establishes”.
p. 83 (Column: Element, line 6): Change “reports” to “report”.
p. 83 (Column: Evidence Guide, line 27): Add “Ability to” before “establishes”. Change “establishes” to “establish”.
p. 84 (Competency Unit 9.6: Column: Performance Criteria, line 1): Change “understand” to “understands”.
p. 84 (Competency Unit 9.6: Column: Evidence Guide, line 4): Change “Recognises and respects” to “Ability to recognise and respect”.

p. 85 (Column: Element, line 1): Change “undertakes” to “undertake”.
p. 85 (Column: Evidence Guide, line 26): Delete “Demonstrate the “.
p. 86 (Column: Element) line 1: Change “negotiates” to “negotiate”, line 3: Change “gives” to “give”.
p. 86 (Column: Performance Criteria), line 2: Delete “that” and add “with” after “consultation”, line 4: delete “with”, line 9: Change “assist” to “assists”.
p. 87 (Column: Element) line 1: Change “understands” to “understand”, line 10: Change “appraises” to “appraise”.
p. 88 (Column: Element) line 1: Change “applies” to “apply”, line 5: Change “reviews” to “review”.
p. 88 (Column: Performance Criteria) line 13: Change “apply” to “applies”.
p. 88 (Column: Evidence Guide) line 19: Delete “demonstrated”, line 29: Change “Accesses or develops and uses” to “Ability to access, develop and “use”, line 30: Change “assists” to “assist”.
p. 91 (Chapter 4, summary) line 3: Change “two” to “three”, line 6 and 9: Change “using” to “use of”, line 9: Delete “was refined” and add “to refine” after “panel”.
p. 92 (Section 4.1, para 1, line 10): Delete “the” and ‘in some of the potential areas”.
p. 120 (Section 5.3.6, line 1): Change “was” to “were”.
p. 120 (Section 5.4) line 1: Change “survey” to “the questionnaire”, line 3: Change “survey” to “questionnaire”.
p. 136 (Section 6.2.5, line 7): Add “the” before “questionnaire”.
p. 138 (Section 6.3) line 1: Change “survey” to “the questionnaire”, line 3: Change “surveys” to “questionnaires”.
p. 185 (Section 7.4.2.1 Case Study A, line 7): Delete “to”.
p. 189 (Section 7.4.2.2 Case Study B, line 4): Delete “to”.
p. 191 (para 1, line 3): Change “has” to “have”.
p. 221 (Section b. appropriate management, coding, line 2): Not changed in the text because the quote is accurate.
p. 222 (para 1, line 2): Change ‘arrthymias” to “arrhythmias”.

***ADDENDUM***

p. xi (para 2, line 9): Add “Barriers found were related to patient safety, privacy and security issues, organisational issues, professional responsibility, and the relationship between patients and medical practitioners” after “implementation of pharmacist prescribing”.

p. xi (para 3, line 4): Add “via mail survey” after “were ascertained”.

p. 7 (Section 1.3.5 para 1 line 2): Add “In Australia the Fifth Community Pharmacy Agreement (2010-2015) has provision for this to occur (Medication Continuance) as one of several specific programs for priority funding.” after “doctor”.

p. 12 (para 1, line 1): Add “New Zealand” after “USA”.

p. 14 (Section 1.4.3.1 para 1, line 3): Change “…containing the legislative framework for advanced pharmacist practitioners.” to “…describing the scope of practice and competency standards for pharmacist prescribers.”

p. 14 (Section 1.4.3.1 para 1, line 4): Update reference 44 to: Pharmacy Council of New Zealand 2012. Pharmacist Prescribers: Pharmacist Prescriber Scope of Practice Overview.
http://www.pharmacycouncil.org.nz/cms_display.php?sn=225&st=1&pg=2259 (accessed 16th April 2013)

p. 27 (Section 1.6.3 para 3, line 1): Add “Because of legal issues, prescriptions needed to be countersigned by doctors.” after “…Australia”.

p.40 (Section 2.1.5.1 para 1, line 6): Add “In addition, the document ‘Advanced Pharmacy Practice Framework for Australia’ was published in October 2012, coordinated by the PSA.” after “pharmacists”.

p. 40 (Section 2.1.6 para 1, line 4): Add “National Competency Standards for the Nurse Practitioner (2006) is also available.” after “(Table 5)”.

p. 49 (Chapter 3, section 3.2): Add after “…work conducted.”:
“In the context of this study, advantages of expert panels compared to individual interviews are:

1) decisions can be made based on consensus among experts;
2) efficiency is achieved by receiving multiple individual inputs at a single time; and
3) broad questions, which elicit varied responses, help the researcher determine critical problem dimensions.

Disadvantages include:

1) Potential for domination and unbalanced participation by certain panellists; and
2) Depth of individual feedback may be less due to time constraints.[98, Ref” ] *(Ref: Andrew H. Van de Ven and Andre L. Delbecq. The Nominal Group as a Research Instrument for Exploratory Health Studies. A.J.P.H March, 1972; 337- 342.)*

p.120 (Section 5.4, para 1, line 5): Change “questionnaire” to “questionnaires” and add “Three hundred and five questionnaires were received. Forty respondents returned uncompleted questionnaires, justifying their reasons for not participating in the survey; many were either retired or not interested.” after “participants,”

p.122 (Section 5.4.2, para 1, line 1): Delete “Three hundred and five questionnaires were received. Forty of the respondents returned uncompleted questionnaires, justifying their reasons for not participating in the survey. Most of them were either retired or not interested.”

p. 134 (Chapter 6, section 6.2): Add ‘Survey methodology has been previously discussed in section 5.2.” after “…described in detail”.

p. 138 (Section 6.2.6.3): Add new para at end of section:
“Multiple single item regression was chosen since the purpose of the analysis was to identify predictors of confidence across the group that may inform the planning of education and training for the prescribing role. The general disadvantage of the univariate approach is the assumption that the outcome variable is influenced by only one other variable, whereas multivariate analysis assumes that it is influenced by a number of variables, which may be inter-related. In this case, the inter-relationship was not of interest.

The purpose of multivariate scoring is to predict an outcome for an individual, e.g. to provide a quantitative measure of risk,[Ref] which was not the intent of the analysis in this study. *Ref: Sullivan LM, Massaro JM, D’Agostino BR Sr. Presentation of multivariate data for clinical use: The Framingham Study risk score functions. Statistics in Medicine 2004; 23(10):1631-60.*

p. 166 (Chapter 7, section 7.2): Add new para at the beginning of the section:
“Qualitative research was chosen as the best approach to inquiry. Nominal group technique, Delphi technique and interviews are commonly used methods in qualitative research. Nominal group technique is a process that allows the target group to identify, rank and rate critical problem dimensions. It provides a means to aggregate individual judgments and allows for multiple individual inputs at a single time.[1] The Delphi technique is an approach used to gain consensus among a panel of experts. This is normally achieved through a series of rounds where information is fed back to panel members using questionnaires.[2] Interviews use predetermined questions that are expected to elicit the subjects’ thoughts, opinions and attitudes about the issues. For the study purpose, the aim was to compare approaches to patient management between medical practitioners and pharmacists by exploring their thoughts process on what they would usually do in their daily practice. Therefore, one to one interview was the method chosen for this study since it enabled the researcher to differentiate the confidence and level of thinking between professions which may be influenced by their designation and experience individually.[125] Nominal group technique and Delphi technique were not chosen because these methods are best used to gather consensus among the study subjects on the research issues discussed. However, this is not the main purpose of this study.”
*Ref 1: Andrew H. Van de Ven and Andre L. Delbecq. The Nominal Group as a Research Instrument for Exploratory Health Studies. A.J.P.H March, 1972; 337- 342.*
*Ref 2: Sinead Keeney, Felicity Hasson, Hugh P. McKenna. A critical review of the Delphi technique as a research methodology for nursing. International Journal of Nursing Studies 38 (2001) 195-200.*

p. 166 (Chapter 7, section 7.2): Add new para after “....not the main purpose of this study.”
“There are five qualitative approaches to inquiry; narrative, phenomenological, grounded theory, ethnographic and case studies. Narrative study is understood as a spoken or written text giving an account of an event/ action or series of events/ actions, chronologically connected i.e autobiography. Phenomenological study describes the meaning for several individuals of their lived experiences of a concept or a phenomenon. It describes what all participants have in common as they experience a phenomenon. A grounded theory study is to move beyond description and to generate or discover a theory. Ethnographic study focuses on the shared and learned patterns of values, behaviours, beliefs and language of a culture-sharing group. Case study research is a qualitative approach in which the investigator explores a bounded system (a case) or multiple bounded systems (cases) and reports a case description and case-based themes.[125] This study was meant to explore the differences in the thought processes involved in history taking and decision making among pharmacists and medical practitioners in order to elucidate pharmacists’ knowledge and skill gaps for prescribing. For this purpose, specific case vignettes were developed with different levels of complexity to explore the similarities and differences and to suggest potential prescribing models for implementation in the shorter term. Case study research was determined to be the most appropriate method for this study since it enables the researcher to explore the similarities and differences in patient management among medical practitioners and pharmacists within the same case and between cases. Other approaches were not chosen because this study was not meant to report subjects’ series of events through autobiography, their lived experiences of a concept, discovering a theory or shared and learned patterns of values among culture-sharing group.”

p.166 (Section 7.2, para 1, line 3): Delete “Case study research is a qualitative approach in which the investigator explores a bounded system (a case) or multiple bounded systems (cases) and reports a case description and case-based themes.[125]”

p.167 (Section 7.2, para 1): Delete “Interview is a commonly used method in qualitative research; structured interviews use predetermined questions that are expected to elicit the subjects’ thoughts, opinions and attitudes about the issues.[125]”

Section 7.3.4.2, p. 183, line 3: Add “from the coding. Coding is the step taken during analysis to organise and make sense of textual data. In a case study, codes exist for the context and description of the case to analyse similarities and differences within and cross cases.” after “…elucidate the themes”.

p230: Add “Conclusion: A set of competency standards for pharmacist prescribing in the Australian context (“the standards”) was developed, and validated by medical practitioners in Victoria, who confirmed all the areas listed in “the standards” to be important for prescribing.” after heading 8.1. Change heading for 8.1.1 from “Summary” to “Discussion”

p231: Add “Conclusion: Generally, pharmacists perceived that they possess the clinical skills and knowledge in most of the areas important to prescribing. Pharmacists with extra qualifications were more confident. Differences were seen in the management processes used by pharmacists and medical practitioners. Areas identified for further education and training were performing clinical assessments and using appropriate techniques and equipment.” after heading 8.2. Change heading for 8.2.1 from “Summary” to “Discussion”

p.232: Add: “8.3.3: International Development of Nonmedical Prescribing

“The process of development and validation of competency standards described in this thesis, and involving major stakeholders, could be used by others internationally to develop and validate standards for the expanded professional role of prescribing in the context of their healthcare systems. In particular, the multifaceted validation has not been used elsewhere. Attitudinal research, such as described in this thesis, would be important to undertake to identify barriers and facilitators to the introduction of nonmedical prescribing in countries where this is a new professional activity.

The approach is not limited to pharmacist prescribing, but could be applied by any profession seeking prescribing rights. A stronger argument, however, is that competency standards relevant for prescribing apply to all professions that have or are seeking the right to prescribe. In Australia, this was the approach taken by the National Prescribing Service when developing the NPS “Competencies required to prescribe medicines.[96]”

p.235, update reference 43 to:
Pharmacy Council of New Zealand 2010. Prescribing competency framework and standards. Pharmacist Prescriber Scope of Practice. http://www.pharmacycouncil.org.nz/cms_show_download.php?id=258 (accessed 7th April 2013).

## Copyright Notices

### Notice 1



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# ABSTRACT

Significant changes have been observed in the development of nonmedical prescribing globally, especially in the United Kingdom. Development of appropriate competency standards is important in ensuring pharmacists are well equipped to perform the task and in informing the development of educational programmes for pharmacist prescribing.

The first aim of this study was to develop and validate a draft set of competency standards for pharmacist prescribing in the Australian context ("the standards"). Areas important in prescribing were identified from the UK Competency Framework and Competency Standards for Pharmacists in Australia documents. "The standards" were developed by identifying gaps in the Australian document with regards to competencies required for prescribing, as articulated in the UK document, and were formatted to be compatible with the Australian document. Expert panel discussions among pharmacists and medical practitioners were conducted to refine "the standards" and to identify barriers to implementation of pharmacist prescribing. "The standards" were validated by medical practitioners within Victoria who found all the areas listed in "the standards" to be important for prescribing.

The second aim was to identify educational needs to inform the development of educational programmes for pharmacist prescribing in the Australian context. Pharmacists' perceptions of their knowledge and clinical skills in the areas important for prescribing were ascertained and factors influencing their perceptions were identified. Pharmacists' perceived that they possess the knowledge and clinical skills in most of the areas. Those with extra qualifications were more confident in their knowledge and clinical skills. Generally, pharmacists felt they needed further training in performing clinical assessment and using appropriate techniques and equipment.

Case study vignettes were used to compare medical practitioners' and pharmacists' approaches to patient management. In general, pharmacists were found to be confident in history taking and patient management within their area of practice defined by the current legal limits. Pharmacists were more receptive to accepting cases with a confirmed diagnosis and would gather history related to the confirmed diagnosis. They were

confident in managing acute simple cases and were capable of prescribing medications within their legal scope or according to protocol and of managing a confirmed case of stable chronic disease.

This is the first study to identify and validate the required competencies for Australian pharmacists to perform the extended role of prescribing and to develop appropriate competency standards. This is also the first study to make direct comparisons of patient management approaches between pharmacists and medical practitioners, in addition to surveying pharmacists' opinions.

It is recommended that:

- "the standards" be used to inform policy development regarding nonmedical prescribing;

- educational programmes be developed based on the available overseas literature, findings from this research and further discussion with relevant stakeholders; and

- recognition of prior learning and acknowledgement of a recognised level of skills and experience should be considered prior to a pharmacist commencing an educational programme.

# DECLARATION

I, the undersigned, Adliah Mhd Ali, candidate for the Doctor of Philosophy degree in the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University Australia declare that this thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other institution and affirm that to the best of my knowledge the thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Adliah Mhd Ali

# ACKNOWLEDGEMENT

*"O you who have believed, seek help through patience and prayer. Indeed, Allah is with the patient."* 2:153. *"For indeed, the hardship (will be) eased."* 94:5.

In the name of Allah the Most Merciful, I am blessed and grateful that He provided me the strength in continuing this journey until the end.

I would like to express my sincere thanks and gratitude to both my supervisors Associate Professor Jennifer Marriott and Associate Professor Kay Stewart for their continuous guidance, patience and support in assisting me throughout the project until completion. It is really difficult for me to express with words how much I appreciate and value them, only God knows deep inside my heart.

I would like to thank Universiti Kebangsaan Malaysia for providing me the opportunity to pursue for my study. Without the funding, I will not be able to gain invaluable knowledge and life experiences outside Malaysia.

Thank you to all the pharmacy practice staff and postgraduate friends at Monash University Australia, especially Rachel Soon, Cik Yin Lee, Alex Chen, Kitty Yu, Tabish Zaidi, Greg Weeks, Kevin Mc Namara, Liz Morabito, Johnson George, Jenny McDowell, Safeera Hussainy and Janet Leeder for your kind help and support during the project.

Thank you to my Malaysian friends and colleagues especially Professor PT Thomas, Associate Professor Dr Jamia Azdina Jamal and Dr Norazrina Azmi, who understand my situation and encourage me and my fantastic work team Dr Mohd Makmor Bakry, Dr Nur Akmar Taha, Dr Adyani Redzuan, Dr Noraida Mohamed Shah, Dr Endang Kumolosasi and Mrs Siti Azdiah who are able to help with my work when I was away in Australia. Without your help, it will be difficult for me to come to Australia to complete my study. I do really appreciate your kind help. Thank you to Hailan Abdul Halim for assisting me with the formatting of the thesis.

Mum and Dad, there are times that I have to juggle my time between work commitment and whenever I have the opportunity I will be away in Australia to complete my study. I promise after this, I will spend more of my quality time with both of you, my beloved niece Qihah, my brothers Firdaus and Naim, and my sister in-law Linda. Thank you for your love, prayer, blessing and understanding.

Special thank you to my dearest friends when I was in Australia and Malaysia especially Azmarul Aziz, Awan Ismail, Andrew Loo, Deena Sherena, Ema Izati Zullkepili, Esther Chan, Faizlinda Razak, Hamza Alzubaidy, Mahadir Ahmad, Rizalawati Ismail, Rohi Ghazali, Siti Fatimah Idris, Siti Munirah Jusoh, Syed Azmi Alhabshi and Zuratul Ain Hamid with whom I have shared the ups and downs in life, who continuously support, understand and always believe in me and I really treasure the friendships.

For Amie and Badrul; Awin and Herman: thank you for being kind and great hosts during my stays in Australia. I wish you all the best for your study as well.

# COMMUNICATION ARISING FROM THIS RESEARCH

***Publication***

1. A. Mhd Ali, J. Marriott and K. Stewart. Pharmacists' views on their current skills for the potential role of supplementary prescribing: a case study in Victoria, Australia. Int J Pharm Pract 2009; Supplement 2 A31.

***Conference presentations***

Oral presentations

1. A. Mhd Ali, J. Marriott and K. Stewart. Pharmacists' views on their current skills for the potential role of supplementary prescribing: a case study in Victoria, Australia. British Pharmaceutical Conference (BPC). Manchester, United Kingdom; 2009.
2. Mhd Ali, A., Marriott, J. & Stewart, K. Competency Standards for Supplementary Prescribing in Australia. 15th International Social Pharmacy Workshop. Queenstown, New Zealand; 2008.

Poster presentations

1. Mhd Ali, A., Marriott, J. & Stewart, K. Development of competency standards for supplementary prescribing by pharmacists in Australia**.** VCP 2nd Annual Post Graduate Research Symposium, Melbourne, Australia; 2007.
2. Mhd Ali, A., Marriott, J. & Stewart, K. Development of Competency Standards for Supplementary Prescribing in Australia. Australian Pharmaceutical Sciences Association National Conference (APSA). Sydney, Australia; 2007.

# ABBREVIATIONS

| | |
|---|---|
| AACP | Australian Association of Consultant Pharmacy |
| ANTA | Australian National Training Authority |
| CDTM | Collaborative Drug Therapy Management |
| CI | Confidence Interval |
| CMP | Clinical Management Plan |
| CPD | Continuing Professional Development |
| DH | Department of Health |
| DN | District Nurses |
| GP | General Practitioners |
| HIC | Health Insurance Commission |
| HMR | Home Medicine Review |
| IT | Information Technology |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| NHMRC | National Health and Medical Research Council |
| NP | Nurse Practitioner |
| NPC | National Prescribing Centre |
| OR | Odds ratio |
| PBS | Pharmaceutical Benefits Scheme |
| PGD | Patient Group Direction |
| PMA | Pharmaceutical Manufacturers Association |
| PSA | Pharmaceutical Society of Australia |
| RACF | Residential Aged Care Facilities |
| RPSGB | Royal Pharmaceutical Society of Great Britain |
| SCERH | Standing Committee on Ethics in Research Involving Humans |
| SD | Standard Deviation |
| S2 | Schedule 2 (Non-prescription medicines the safe use of which may require advice from a pharmacist |

| | |
|---|---|
| S3 | Schedule 3 (Non-prescription medicines for supply by pharmacists only) |
| S4 | Schedule 4 (Prescription only medicines) |
| SHPA | Society of Hospital Pharmacists |
| TGA | Therapeutic Goods Administration |
| "the standards" | The preliminary draft of the competency standard that was developed based on two main documents – the UK document "Maintaining Competency in Prescribing" and the Australian document "Competency Standards for Pharmacists in Australia". |
| UK | United Kingdom |
| USA | United States of America |
| USC | University of Southern California |

# Chapter 1: Nonmedical Prescribing: Experiences and Challenges

**Summary**

- This chapter presents an overview of the global developments in prescribing including experiences and challenges in implementing nonmedical prescribing.

- The literature review focuses on the barriers perceived to be the main challenges in the implementation of nonmedical prescribing.

- Studies related to nonmedical prescribing in the Australian context are discussed and potential areas for research identified.

## 1.1 Prescribing

In the prescribing context, it is important to understand the definition and components of prescribing. According to Galt[1] prescribing is defined as the decision to "initiate treatment, select the specific treatment, decide the initial dose, frequency, route and duration of administration of a drug, modify the dose, frequency, route and duration of administration and discounting the therapy". Traditionally, physicians have had the authority to initiate a variety of treatments. Prescribing medications, ordering laboratory tests, conducting and supervising procedures consistent with the patient's diagnosis have been highly visible parts of their practice. These activities demonstrate the physician's knowledge, skill and concern for the patient's well being.[2]

In Australia, pharmacists already prescribe to the extent that they recommend and sell to patients, on a daily basis, a certain range of medications restricted to pharmacy. According to Therapeutic Goods Administration (TGA), pharmacists are allowed to supply Schedule 2 (S2) and Schedule 3 (S3) medicines.[3] S2 (Pharmacy Medicines) is defined as nonprescription medicines the safe use of which may require advice from a pharmacist and S3 (Pharmacist-only Medicines) as nonprescription medicines for supply by pharmacists only. Schedule 4 (S4 - Prescription Medicines) covers medicines which can be dispensed by pharmacists on receipt of a prescription from an authorised prescriber, that includes medical practitioners, podiatrists, optometrists and nurse practitioners. Currently, there are no established policies in Australia on extending the role of pharmacists to allow them to prescribe S4 medicines.

## 1.2 Global Changes in Prescribing Practice

Although major global changes in prescribing have been observed in recent years, the concept of pharmacist prescribing has existed for more than 25 years; the United States of America (USA) was among the first to pioneer authorising prescribing by pharmacists.[4] Extensive changes in prescribing practice in the United Kingdom (UK) has been observed with the introduction of various prescribing models among nonmedical prescribers. These

changes started in 1997 when the UK government established a review of prescribing, supply and administration chaired by Dr June Crown. This review resulted in greater use of the skills and experience of various professions in primary and secondary care to undertake new roles in prescribing, supplying and administration of medicines.[5] This report led to the introduction of pharmacist prescribing in UK, where the first pharmacists obtained the necessary accreditation and began prescribing in early 2004.[4] Even though it is well known that pharmacists have long been prescribing at a certain level, especially in the community setting, the context of pharmacist prescribing what are generally considered prescription only medicines, differs between countries based on local law and regulation.

## 1.3 The International Development of Prescribing

Kay and Brien[6] published a literature review on pharmacist prescribing in 2004. They evaluated relevant literature published from 1974 to 2004 in various countries and concluded that additional research is needed to assess clinical, humanistic and economic outcomes for pharmacist prescribers, as only less well designed studies were available evaluating the positive outcomes of pharmacist prescribing. Four years later, a thematic review was published by Cooper et al.[7], however, the papers reviewed related to supplementary prescribing by nurses and pharmacists in the UK. The review was mainly focused on empirical research in the areas of practitioners' perspectives, views of other healthcare professionals, patients' and the public's perspectives, professional relationships, and education and training. Anecdotal literature, clinical applications, facilitators and barriers, independent prescribing and grey literature were also explored. The authors concluded that, generally, supplementary prescribing is well accepted; however, challenges were encountered mainly at the implementation level. Further research was suggested concerning the impact on the healthcare system and issues related to safety, costs and patients' experience. Both literature reviews were mainly focused on the issue of proving the positive outcomes related to pharmacist prescribing but did not discuss the trends or classification of various models available around the world.

The sole, suitable and clear classification of prescribing models currently practiced around the globe was found in the literature review conducted by Emmerton et al.[8] This study

included newly introduced prescribing models as well as prescribing models that pharmacists have traditionally been practising. According to the authors, eight models of pharmacist prescribing implemented internationally have been identified (**Figure 1**). These prescribing models were divided into dependent prescribing, independent prescribing and collaborative prescribing, with dependent prescribing sub-classified into prescribing by protocol, Patient Group Direction (PGD), prescribing by formulary, prescribing by patient referral, repeat prescribing and supplementary prescribing. The purpose of exploring the differences in these prescribing models was to gather a clear understanding of the advantages and disadvantages as well as the feasibility of suitable pharmacist prescribing models to be implemented in the future.

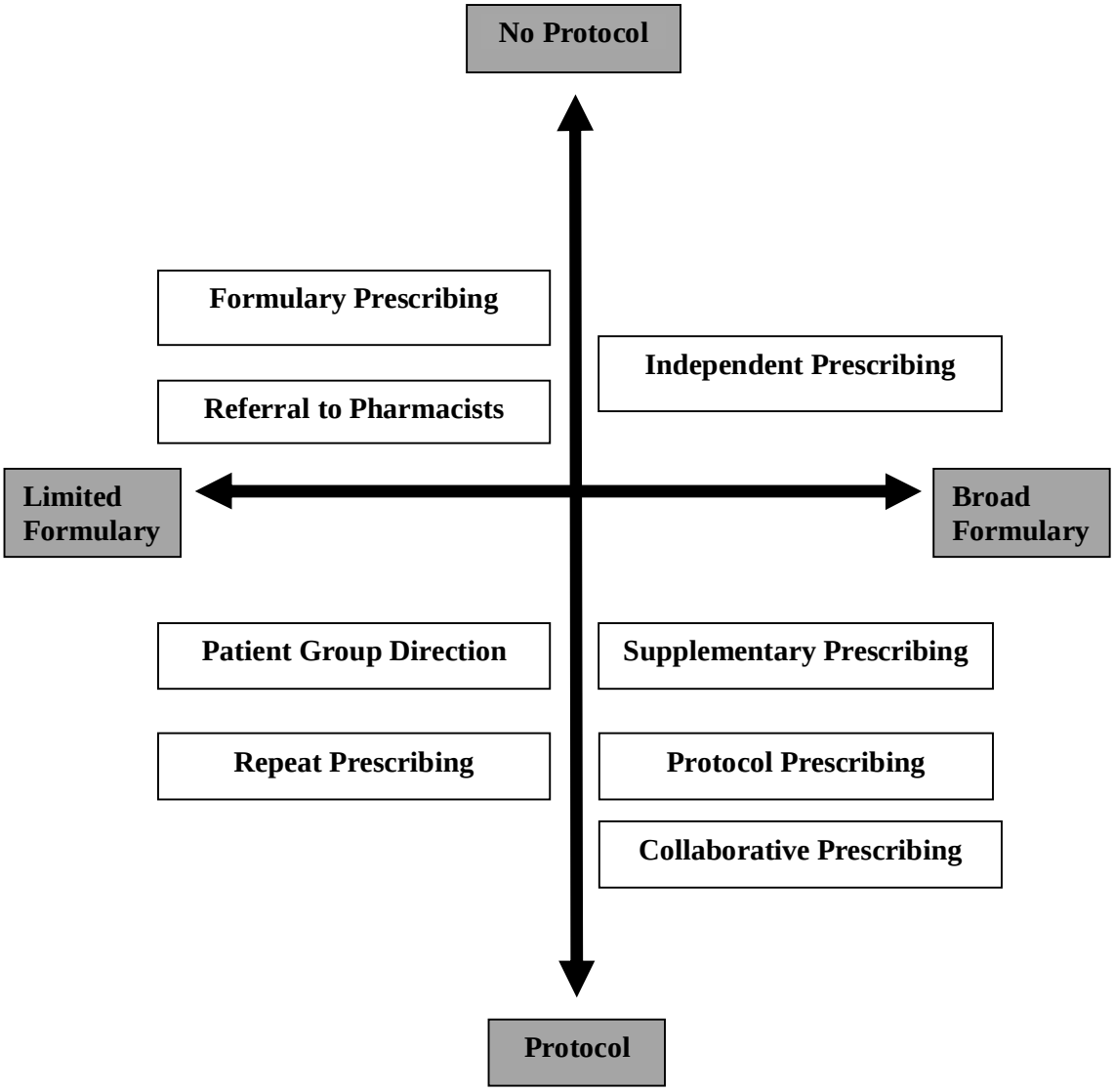


**Figure 1: The relationship between the models of pharmacist prescribing[8]**

### *1.3.1 Dependent Prescribing: Prescribing by Protocol*

In this prescribing model, the independent prescriber will delegate authority, which involves a formal agreement based on a protocol – a detailed document listing the tasks that the pharmacist is allowed to undertake within specified limits. The protocol includes information regarding the diseases and drug categories, the procedure that the pharmacist should follow, the physician's and pharmacist's agreement, the time limit for the agreement, the responsibilities for the parties involved, the documentation and procedure involved and the policies for review and revision purposes.[9-11] Usually, physicians will determine the level of authority for pharmacists to prescribe within the limits of protocol prescribing, based on mutual agreement between both professions.[12] Some of the commonly used drug groups that have been found suitable for protocol prescribing are anticoagulants, analgesics, antiemetics and antihypertensives.[10,12-14] Protocol prescribing has been shown to reduce drug costs and medical practitioner visits and improve integration with medication reviews and access to medicines. [13] On the down-side, protocol prescribing could lead to more errors as it may reduce the communication between the dependent prescriber and the physician undertaking the diagnosis. It may also create extra workload and complicate the reimbursement procedure, because the process involves more professionals in the prescribing process.[13-15]

### *1.3.2 Dependent Prescribing: Patient Group Direction*

Patient Group Direction (PGD) is defined as written instructions for the supply or administration of medicines to a group of patients, who may not be individually identified before presentation for treatment.[5,16] Healthcare professionals who were allowed to prescribe under this category of prescribing in the UK were ambulance paramedics, chiropodists (podiatrist), dieticians, health visitors, midwives, nurses, occupational therapists, optometrists, pharmacists, physiotherapists, prosthetists and orthotists, radiographers, and speech and language therapists.[16] In PGD, the class, dosage and dosage forms, route and frequency of dosing, period of administration, warnings and quantity restrictions, circumstances in which the medicine is allowed to be supplied, counselling procedure, follow-up, records, and the valid period for the PGD should be clearly

indicated. Some of the medications that are allowed to be prescribed under this model include emergency hormonal contraception, combined oral contraceptives and antihistamines.[17-19]

### *1.3.3 Dependent Prescribing: Prescribing by Formulary*

In formulary prescribing, the physician delegates the prescribing authority for a limited list of medicines.[10,11] This prescribing model is less explicit than protocol prescribing and is more flexible for the pharmacist to prescribe.[10,11] It consists of the list of treatable symptoms, length of treatment, criteria for referrals and limitations for prescribing.[19] In this model, local formularies are agreed between medical practitioners and pharmacies.[5] Pharmacists are also required to keep records and with the right policy, over-prescribing to patients by different pharmacists could be avoided.

### *1.3.4 Dependent Prescribing: Prescribing by Patient Referral*

In this prescribing model, patients would be individually referred to a pharmacist by a physician. These patients would be referred for the management of specific medication therapy to achieve a specific therapeutic outcome. The ambulatory care setting within a healthcare facility is considered to be a good example of prescribing by patient referral.[10, 11]

### *1.3.5 Dependent Prescribing: Repeat Prescribing*

Repeat prescribing is defined as the pharmacist providing a medication refill prescription for patients who have run out of medication before their next appointment with the doctor.[8] This prescribing model has usually involved refill prescriptions for medical centre clinics. Pharmacists assess the patient and their therapy. They are responsible for consulting the appropriate physician about any problems, writing refill prescriptions to be dispensed at another pharmacy or refilling the medication with sufficient quantity until the next appointment.[12,20] In Australia, under the Pharmaceutical Benefits Scheme (PBS), repeat prescriptions can be written by medical practitioners for a new prescription.[21] For management of chronic conditions, this usually means that the patient only needs to visit

their doctor every six months. The main criticism of pharmacist prescribing under this model relates to the process, in which the repeat prescription might be considered as merely transcribing from the previous script provided by the medical practitioner.[21]

### *1.3.6 Dependent Prescribing: Supplementary Prescribing*

Supplementary prescribing is a voluntary partnership between an independent prescriber and a supplementary prescriber to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement.[5,22] This prescribing model may involve more than one-to-one prescriber partnerships, in which the independent prescribers consist of doctors or dentists and the supplementary prescribers consist of the other healthcare professionals including nurses and pharmacists.[5] In this prescribing model, the independent prescriber is responsible for undertaking the initial assessment and the supplementary prescriber is able to write prescriptions based on the agreement with the independent prescriber.[5,22-23] Supplementary prescribers are responsible for CMP monitoring, changing the medication when needed and referring the case to the independent prescriber whenever appropriate.[5] Apart from that, they also need to record any clinically important and relevant information. The main difference supplementary prescribing in the UK compared to the other prescribing models is that this model involves patient-specific CMPs. The CMP is evidence-based and in accordance to the clinical guidelines agreed by prescribers and the patient. The unique feature of supplementary prescribing is it that involves the patient in the decision making, including giving their consent for the transfer of their clinical information between prescribers. The prescribing and dispensing processes should be separated for safety reasons. This prescribing model is unlikely to be used for acute conditions since it requires the CMP for continuation of therapy in chronic disease management.[16] The main difference between the CMP in supplementary prescribing and the PGD is that CMPs are developed for individual patients whereas PGDs relate to a group of patients who may not be individually identified before presentation for treatment.[16]

### *1.3.7 Independent Prescribing*

This type of prescribing provides the highest level of authority for the practitioners to prescribe compared to the other prescribing models. The main difference of this model is that the practitioners are solely responsible for patient assessment, diagnosis and clinical management. Traditionally, the medical professions have been solely responsible for independent prescribing, but in the UK, this prescribing model was opened up to nonmedical prescribers, mainly nurses and pharmacists, who need to fulfil certain requirements to be accredited as independent prescribers.[24] Pharmacists in Australia prescribe independently for medicines classified under S2 and S3, which is in fact a limited formulary.

### *1.3.8 Collaborative Prescribing*

This prescribing model is currently being practised in the USA and Canada. It requires collaboration between pharmacist and physician or a practice group with the legal authority to prescribe medications.[10] In collaborative prescribing, the physician will make the initial diagnosis and treatment decisions. Pharmacists will then select, initiate, monitor, modify and decide to either continue or discontinue patients' therapy to achieve the agreed patient outcomes.[8] In this model, both physician and pharmacist share the risk and responsibility in the decision making and patient outcomes.

## 1.4 Nonmedical Prescribing Experiences

In this section, nonmedical prescribing experiences from selected countries are explored. Only countries undergoing significant or recent transformation in the nonmedical prescribing arena are discussed. The nonmedical prescribers discussed under this section include pharmacists, nurses and optometrists. Since the major transformations have occurred in pharmacist and nurse prescribing, the description of nonmedical prescribing will be focused mainly on these two professions. This section discusses the background of the models according to the countries, the research conducted in the area and the implications of the models after the introduction into the current healthcare systems. Clear

understanding of these experiences will enable adoption in the Australian context in the future.

### *1.4.1 Supplementary Prescribing to Independent Prescribing – United Kingdom*

#### 1.4.1.1 Pharmacist Prescribing

Supplementary prescribing was implemented in the UK in 2003, based on the recommendations in the final report of the Review of Prescribing, Supply and Administration of Medicines (Crown Report 1999).[5] It provides an opportunity for the pharmacy profession to enhance its contribution to primary care. After the implementation of supplementary prescribing, significant change occurred in pharmacist prescribing practice in the UK, allowing pharmacists to expand their role to independent prescribing.

Cooper et al.[7] have published the most comprehensive thematic review on studies related to supplementary prescribing among pharmacists and nurses to date. Most of the studies conducted involved surveys, interviews and focus groups exploring healthcare providers' perspectives through their experiences, perceptions and opinions. George et al.[25-27] published several studies in the area of early experiences, perceptions and opinions of pharmacists as supplementary prescribers which found that most of the pharmacists reported benefits in patient management but perceived challenges in certain areas, such as funding, information technology (IT) support and lack of awareness of supplementary prescribing. The author and his colleagues also published a paper in the area of awareness, views and attitudes of independent prescribing.[28] Most of the independent prescribers were prior supplementary prescribers and several institutions in the UK were accredited to deliver an educational prescribing programme for independent prescribing as well as a conversion programme from supplementary to independent prescribing.[29]

#### 1.4.1.2 Nurse Prescribing

The Crown Report[5] also recommended that nurses holding district nurse (DN) or health visitor qualifications, who undertook additional training, should be allowed to prescribe from a limited formulary, supply medicines within a group protocol for a particular clinical service and adjust the timing and dosage of medicines within a patient specific protocol. Extensive research is ongoing in the various areas of prescribing among nurses in the UK context, related to their perceptions, barriers and training issues.[30-33] Since the introduction of independent prescribing in 2002, more than 28,000 DNs have become qualified to prescribe independently.[34]

Subsequently to the introduction of this role among nurses, Courtenay et al.[35] conducted a survey among nurses who practise as supplementary and independent prescribers to provide an overview on their practices as well as factors facilitating or inhibiting their practice. The main strength of this study was that it is a national study with 868 responses from qualified independent and supplementary nurse prescribers, which allows generalisability of the results. Most of the nurses (87%) used independent prescribing and only 35% used supplementary prescribing to treat a range of chronic conditions. The majority of them worked in primary care. Nurses in general practice perceived the highest number of barriers to their prescribing, mainly due to IT issues and the implementation of CMPs. They perceived the need for more continuous professional development (CPD), including updates on prescribing policy and the management of various conditions. The same authors published another paper from the same study focusing on respondents' confidence in educating and assessment as mentors.[36] It was found that qualification affected confidence level; the higher the qualification or the more access they had to continuing professional development (CPD), the more confident they were in their role. This is supported by Cooper et al.[7] in their studies in the area of supplementary prescribing among pharmacists and nurses.

#### 1.4.1.3 Optometrist Prescribing

In the USA and certain areas in Australia and Canada, licensed optometrists may prescribe medications to treat certain eye conditions, which is not the case for the European optometrists.[37,38] In the UK, in addition to pharmacists and nurses, optometrists were also given the right to manage and prescribe independent therapeutic management of certain acute eye conditions and dependent management of certain chronic conditions in which the treatment has been initiated by an ophthalmologist.[37] Following the changes in prescribing practice among optometrists, a postal survey was conducted to explore how optometric practice might change with the introduction of therapeutic prescribing.[38] Ten percent of registered optometrists in UK (n=758) were randomly selected to respond to a questionnaire, Scope for Optometrist Prescribing (AESOP). Responses were received from 432 (57%), which is sufficient for generalisability of the results. More than 80% agreed that optometrists should be suitable for training as therapeutic prescribers. Most of the respondents were willing to undergo training and re-accreditation, as well as continuing education. Respondents anticipated that the introduction of optometrist prescribing would significantly reduce referrals to general practitioners (GPs) and, to a lesser degree, referral to ophthalmologists via GPs. They also perceived that participating in prescribing would increase patient access to therapeutic ocular treatment.[38] This information was based on opinion only; well-designed research to measure optometrist performance in this new task is needed to establish whether the introduction of this system brings benefits compared to the current situation.

### *1.4.2 Collaborative Prescribing – United States of America and Canada*

#### 1.4.2.1 Pharmacist Prescribing

Collaborative prescribing commenced in the late 1970s in the USA.[39] The federal government and about thirty-nine states permit collaborative drug therapy management (CDTM) through legislation, regulation and boards of pharmacy.[39] The USA has a clear

policy to reduce unnecessary costs due to inefficiency and duplication of effort in the healthcare system.[39] To achieve this objective, pharmacists were given wider responsibility in making changes in prescribed care plans under this prescribing model to improve medication management and continuity of care. Pharmacists were expected to agree to take responsibility, as well as monitoring the response to medication therapy and making changes to optimise patient care.[1] The main difference between this prescribing model and independent prescribing in the UK is that no state in the USA recognises full independent prescribing for pharmacists. The physician is responsible for coordinating overall patient care.[39]

In Canada, as in the USA, there is a desire to reduce costs by reducing patient length of stay in hospital and preventing inefficiencies and duplication of effort.[40,41] In 2001, a significant number of hospitals reported that pharmacists were involved in prescribing, such as therapeutic interchange programmes, clarification of orders, and ordering of nonprescription drugs.[40,41] One hundred and twenty-seven hospitals (55%) reported that they had policies allowing pharmacists to rewrite orders when the incorrect dose or dosage form of a medication was written for a patient by a physician.[40,41] "Meds as at home policies" were reported to be in place at 84 hospitals (36.4%), where the pharmacist was allowed to clarify the medication regimen with the patient and write all of the appropriate medication orders during hospitalisation. For nonprescription medications, four hospitals (1.7%) allowed the pharmacist to initiate treatment with all nonprescription medications, eight hospitals (3.5%) allowed the pharmacist to initiate treatment with specific nonprescription medications, and 91 hospitals (39.4%) allowed the pharmacist to modify treatment with a nonprescription medication. The survey demonstrated a broad range of pharmacist involvement in collaborative drug therapy programmes in Canadian hospitals.[40,41]

#### 1.4.2.2 Nurse Prescribing

In the USA, 49 states allowed nurse prescribing but limit the setting or the type of drugs that can be prescribed by nurse practitioners. In some states, nurses may only prescribe

within protocols that are clearly supervised by physicians. In most states, nurse prescribers must undergo mandatory continuing education and audit.[42]

### *1.4.3 Development of Nonmedical Prescribing – New Zealand*

#### 1.4.3.1 Pharmacist Prescribing

Some movement from the current conservative role of pharmacists towards the extended role in prescribing has occurred in New Zealand, although to a lesser degree than in the UK. The Pharmacy Council of New Zealand produced a document containing the legislative framework for advanced pharmacist practitioners.[43] Subsequently, pharmacists were given prescribing rights with the two schools of pharmacy at the University of Otago and the University of Auckland offering prescribing courses.[44]

#### 1.4.3.2 Nurse Prescribing

Similarly to pharmacists, the issue of prescribing rights for advanced practice nurses has been under consideration for a number of years. The Minister for Health has indicated support for extending prescribing rights to nurses and other professionals under certain conditions. Some work towards introducing limited prescribing rights for nurses working in two particular scopes of practice (child/family health and aged care) has already begun.[42]

### *1.4.4 European Experience*

#### 1.4.4.1 Nurse Prescribing

Since 1994, DNs in Sweden have been permitted to prescribe a limited list of medications. Several issues arose from the introduction of this new system, especially among medical practitioners who opposed to the idea. Wilhelmsson and Foldevi conducted a study to gain understanding of the various opinions about DN prescribing and to explore the impact of the reform on primary care among DNs and general practitioners.[45] Generally, DNs were very positive towards prescribing and gained new knowledge through the training courses.

They perceived prescribing drugs as a serious responsibility and recognised the need to be careful in performing this task. They also recognised that they need to have a certain level of knowledge to prescribe drugs. They perceived that they gained knowledge they had been lacking in the training courses in pharmacology and drug treatment. There was a mixture of opinion in terms of cooperation; they experienced both positive and negative aspects. As in other overseas studies involving nonmedical prescribers, barriers from medical practitioners were raised.[46,47] It was reported that, in some of the health centres, DNs were not allowed to take part in training courses. There is limited literature regarding nurse prescribing in Europe in general compared to nurse prescribing in the UK.

## 1.5 Perceived Barriers – Lessons to Learn

There was a mixture of reactions before the introduction of pharmacist prescribing in the UK, especially among those who would be affected by this new system. Most of the barriers and challenges related to uncertainty whether this new system would contribute to better outcomes compared to the conventional system. This section will focus mainly on the perceived barriers prior to the implementation of pharmacist prescribing and early experiences. Understanding of the issues could prevent or minimise the similar barriers for future implementation in the Australian context.

### *1.5.1 Stakeholder Early Views*

#### 1.5.1.1 United States of America Experience

This section discusses acceptance at the organisational level from the USA experience before the expanded role of pharmacists prescribing was implemented. The study published by Segal and Grines[48] aimed to identify attitudes of organised pharmacy and pharmaceutical industry about prescribing authority for pharmacists. The study found that there were considerable differences in the organisational views of the legislative bill for pharmacists. It was found that hospital pharmacy associations and boards of pharmacy supported the idea. Those who were not members of the Pharmaceutical Manufacturers Association (PMA), generic manufacturers and state pharmacy associations were neutral. Medical associations and PMA-member companies were opposed to the idea. In fact, the

medical associations believed that the bill would not be passed in majority of states within the next five years. Opposition from the medical association perspective was found to be similar in the Australian context in 2008.[49] Given this similarity, it will be important to learn from the USA experience in addressing the organisational views on pharmacist prescribing when moving to implement it in Australia.

#### 1.5.1.2 United Kingdom Experience

The introduction of supplementary prescribing in the UK had led to a mixture of opinions among those affected by these changes. Most of the studies conducted in this area have been survey-based. Holden and Wolfdon[50] conducted a study to evaluate the attitudes of GPs and community pharmacists to prescribing matters. Generally, both doctors and pharmacists agreed in their attitudes towards prescribing where the quality of prescribing was a legitimate subject of concern for local health authorities. Most of the community pharmacists favoured a wider role, with GPs generally being more conservative. Both professions expressed concern to improve the quality of prescribing and some believed that prescribing was currently of poor quality.

Most of the studies conducted on pharmacist prescribing indicated that barriers were perceived from the medical practitioners prior to the implementation of pharmacist prescribing. Child et al.[51] published a study in 1998 to evaluate the healthcare professionals' views on hospital pharmacist prescribing in the United Kingdom. The surveys, sent to 195 doctors, 200 nurses and 87 pharmacists with 57.7% response rate, found that the majority of medical practitioners and nurses agreed that would be beneficial if pharmacists were allowed to write prescriptions and prescribe drug treatment. The main opposition was medical practitioners' concern that pharmacists were not competent or well enough trained to perform this new role.[51] They suggested that only pharmacists fulfilling certain criteria (e.g. postgraduate education or training, routine attachment to the clinical area) should be allowed to perform the task.

Following the 1998 study by Child et al., Child and Cantrill[47] conducted a study in 1999 to examine the reasons behind hospital doctors' perceived barriers to pharmacist prescribing

by using a survey in a similar setting to the previous study. The response rate was slightly lower than the earlier study, 49% compared to 57.7%. Thirty-eight from fifty-two respondents described the reasons behind their idea that pharmacists should not be permitted to transcribe or prescribe drug treatment, which related to pharmacists' awareness of clinical and patient details, potential communication problems, perceived belief that a doctor should write the initial inpatient prescription, division of the clinical responsibility and loss of the opportunity to review drug treatment. Eleven respondents added supportive comments and the remainder were neutral. It was noted that some doctors had misconceptions regarding the division of responsibility related to drug treatment. Due to the low number of participants and the nature of the sample (which only consisted of hospital doctors), the results might not be the representative of the general views of medical practitioners.

A study conducted by Spencer and Edwards[52] used a survey to gather GPs' views of the extended role of community pharmacists in the Northern, West Midlands and Oxford regions. A total of 1087 questionnaires were distributed, within overall response rate of 68.4% (Oxford 75.6%, Northern 70.4% and West Midlands 62.7%). The majority were in favour of pharmacists reporting adverse drug reactions but against their supervising repeat prescriptions. It was found that most doctors would favour an extension of the activities of community pharmacists, which is similar to the findings of Holden and Wolfdon[50] in which most of the community pharmacists favoured a wider role. In Spencer's study[52], general practitioners generally were conservative in the area of the role expansion, which is supported by Holden's study[50], where concerns were raised about the pharmacists' role in screening and counselling patients and in prescribing.

Jones et al.[53] explored pharmacists' views on supplementary prescribing. This exploratory study found positive views among the pharmacists, but issues about the pharmacist/GP relationship emerged in the discussions. Another study conducted by Hughes and McCann[54] also noted perceived barriers between pharmacists and general practitioners. A comment recently published in the Australian context by a medical practitioner carried the similar views of pharmacist prescribing.[55] Other studies have also found similar views in this area, related either to pharmacists or nurse prescribing.[56,57] Therefore, careful planning

and consideration need to be emphasised in this area in the course of implementation of pharmacist prescribing.

A study was published in 2009[58] to determine the awareness, views and attitudes of the general public toward nonmedical prescribing, with an emphasis on pharmacist prescribing. This survey was mailed to a random sample of 5000 members of the general public aged 18 and over in Scotland and achieved a response rate of 37.1%. More than half of the respondents (56.6%) were aware that trained health professionals could write prescriptions for medications previously prescribed only by physicians. Comfort levels for nonmedical prescribing were highest for pharmacists, followed by nurses, and lowest for radiographers. More than half of the respondents supported pharmacist prescribing; however concerns were expressed regarding the lack of privacy in a pharmacy, despite acknowledging its enhanced convenience. Several issues related to the aspects of the clinical governance were highlighted, specifically education and data handling.

Child et al.[51] published a study in 1998 evaluating healthcare professionals' views on hospital pharmacist prescribing in the UK. In this study, questionnaires were sent to all the health professionals working in five hospitals in Birmingham, which included medical practitioners, nurses and pharmacists. The survey found that the majority of the medical practitioners and nurses agreed that would be beneficial if pharmacists were allowed to write prescriptions and prescribe drug treatment. Possible barriers perceived to pharmacist prescribing included pharmacists' willingness to accept this new role, education and training, familiarity with the patients, communication between healthcare professionals and legal accountability and resource implications.

#### 1.5.1.3 Professional Accountability and Clinical Responsibility

Due to significant changes in the prescribing role, practitioners are taking responsibility for the care of patients which requires awareness of limitations within their area of expertise to prescribe. This is an important principle of supplementary prescribing in the UK, which states that prescribers need to be aware of their own limitations and know when to refer back to the independent prescriber.[5] According to the Code of Ethics and Standards of the

Royal Pharmaceutical Society of Great Britain (RPSGB)[22], pharmacists are required to be professionally accountable for all their activities and decision making. They should only accept work that they have the skills and confidence to perform.

An example of this is the difference between independent and supplementary prescribers in the UK. Since the introduction of independent prescribing in the UK, there has been a movement for supplementary prescribers to extend their role to become independent prescribers. Therefore, it is important that pharmacists do not accept responsibility for managing a condition or for prescribing medicines with which they are unfamiliar. They should only prescribe within the limits of their competence. Competency was highlighted as one of the important areas that need to be well addressed to ensure that the prescribing tasks are performed by pharmacists who are competent in the area of practice. It is understood that a professional person would be judged against the standards to be expected from a responsible body of his or her peers.

It is important that pharmacist prescribers should understand the basic principles of the law of negligence to maintain patient safety. Although they will still be practising within their clinical area of expertise, but with the new system, their roles and clinical responsibility will be expanded. Usually, as the number of prescribers increases so do the mixed messages and misunderstandings and reasonable steps must be introduced to monitor, manage and minimise danger. This issue was address by Newdick[59] in his article regarding the legal implications that arise from pharmacists being allowed to prescribe.

Currently in Australia, the separation of dispensing and prescribing works well as an important mechanism for checks and balances. The system helps to ensure the quality use of medicines by decreasing the overuse or misuse of drugs. Firstly, the system contributes to maintaining patient safety, since the process for medication prescription and supply involves several stages and more than one authorised individuals, allowing cross checking.[60,61] Secondly, if the prescriber also supplies the medicine, there is potential for the temptation to prescribe medicines that provide better income for the supplier. Currently, as stated previously (Section 1.3.7), pharmacists prescribe and dispense for minor ailments without any significant problems; pharmacists in Australia are allowed to

dispense S2 and S3 medications without medical practitioners' prescription. Extending the right to prescribe more potent or costly medication, however, may require consideration of this issue. If pharmacists who prescribe are not allowed to dispense, the introduction of pharmacist prescribing will have an impact on pharmacist manpower.[62,63]

## 1.6 Nonmedical Prescribing in the Australian Context

This section describes aspects of the current Australian healthcare system and discusses studies exploring the views of pharmacists and medical practitioners of pharmacist prescribing and the possibility of implementing this in the Australian context. This section also discusses pilot studies exploring potential areas for a prescribing role for pharmacists in Australia.

### *1.6.1 Development of Pharmacist Prescribing in the Australian Context*

The report by Bessell et al.[64] on the development of pharmacy practice models to improve access to prescription medicines in the context of the Australian healthcare system has made a significant contribution to the discussion of possible solutions to issues around medication access by patients. The proposed models for expanding the pharmacist's role to prescribing were medication maintenance, clinical management, protocol management and pharmacist formulary. Data were collected using semi-structured interviews involving stakeholder organisations, focus groups comprising consumers, pharmacists and medical practitioners from both rural and metropolitan areas to evaluate the applicability of the proposed models. A range of benefits, harms, barriers and facilitators were discussed for each of the models. Details of the models are described below.

#### 1.6.1.1 Model 1: Medication Maintenance

In this proposed model, pharmacists would be able to provide PBS prescriptions to continue supply of chronic medications for patients in residential aged care facilities (RACFs). Currently, medical practitioners need to attend RACFs regularly to write prescriptions for ongoing medication. A problem that commonly arises relates to the supply of the medication when the prescription runs out. When this occurs, the nurses

usually request the pharmacist to supply medication in advance of receiving the prescription – usually referred to as the 'script owing' system. This system, however, is not legal under the Health Insurance Commission (HIC) regulations. The medication management model would enable pharmacists to legally supply the medicine by generating a PBS reimbursable form to authorise a month's supply of medicine and send a copy of the form to the treating doctor.[65] This proposed model is similar to the dependent prescribing model for repeat prescribing listed by Emmerton et al.[8] as described in Section 1.3.5.

#### 1.6.1.2 Model 2: Clinical Management

This model involves improving access to medicines in discharge planning. In the clinical management model, prescriber and supplementary practitioner (pharmacist), implement an agreed patient specific plan for discharge from hospital. The model was proposed to circumvent delays in the discharge process. Currently, the registrars or interns usually write the discharge prescriptions but this task is often given low priority due to other urgent matters to which they need to attend leading to delayed delivery of the discharge prescription to the pharmacy. Due to the time pressure, this can result in transcription and other related errors, as well as dispensing errors by pharmacist. Delays in patient discharge may cause unnecessary additional cost due to longer than necessary hospitalisation. This has been demonstrated in two 2008 studies in the Australian setting using a survey and focus groups, that confirmed time lag as the main issue encountered in providing discharge medication and that health professionals were of the opinion that pressure with discharge prescriptions usually leads to errors.[66,67] In the clinical management model, when the consultant decides to discharge the patient, he/she will recommend the discharge and document any final medication changes in the patient chart. Instead of the registrar or intern, the ward pharmacist will check the changes, determine the appropriate dose form and duration, write the order onto a prescription and return the prescription to the pharmacy for dispensing. The ward pharmacist can also counsel the patients and the patient can be discharged at the appropriate time. Based on Emmerton et al.[8] classification, discharge prescribing would be classified under the dependent prescribing model (**Figure 1**).

#### 1.6.1.3 Model 3: Protocol Management

Significant issues have been encountered in the supply of medicines to people living in rural and remote areas due to the less access to qualified practitioners. Indigenous Health Workers and Nurse Practitioners have the right to write prescriptions for a range of medicines, but this is currently not the case for pharmacists. This model proposes that pharmacists also be given the authority to provide prescription medication in the rural setting without further consultation within an agreed formulary. In protocol management, a defined stepwise procedure will be reciprocated in determining the therapy for an agreed formulary similar to other rural health workers. This proposed model is similar to the dependent prescribing model for protocol prescribing listed by Emmerton et al.[8] and described in Section 1.3.1.

#### 1.6.1.4 Model 4: Pharmacist Formulary

This model involves more autonomy in the therapeutic process and access to a selection of the Prescription Medicines (S4), with relevant restrictions. The pharmacist requires legally defined levels of knowledge and skill that are usually monitored through a licensing process.[64] This proposed model is similar to the dependent prescribing model for formulary prescribing listed by Emmerton et al.[8] and described in Section 1.3.3.

### *1.6.2 Views of Nonmedical Prescribing*

Published studies conducted in the Australian setting have been focused mainly on the pharmacist views of nonmedical prescribing[6,68,69] or pilot projects conducted to identify potential areas for pharmacist prescribing.[64,67,70,71,72] Hanes and Bajorek[69] published an early study in 2005 to explore views of Australian hospital pharmacists to the issue of prescribing privileges, followed in 2006 by a study by Kay et al.[73] to obtain their opinions on the feasibility of pharmacist prescribing in their area of practice, as well as their awareness of the international prescribing practices. In 2008, Weeks and Marriott[68] published the results of a survey of Society of Hospital Pharmacists (SHPA) pharmacists' views on collaborative prescribing, which suggested that views of nonmedical prescribing

could be divided into benefits and barriers in the implementation of this new prescribing model. This topic is further discussed in the next section.

### 1.6.2.1 Benefits of Nonmedical Prescribing

The study by Hanes and Bajorek[69] explored Australian pharmacists' perspectives on pharmacist prescribing models overseas; the potential niche for pharmacist prescribing in Australia; the appropriateness of the overseas prescribing models; and the benefits of prescribing to routine practice. In that study, several prescribing models were explored to identify the most appropriate and useful models in which pharmacists could engage. Pharmacists thought that they could engage in repeat prescribing for stabilised patients with chronic conditions; prescribe from a limited formulary agreed upon collaboratively by physician and pharmacist; prescribe discharge medication; adjust quantity and frequency as per jointly-developed protocols; order laboratory tests and modify drug therapy accordingly; and implement agreed patient-specific clinical management plans. As only fifteen pharmacists participated in the survey, the sample size is a major limitation to generalising the findings. Participants noted that they engaged in 'unofficial' prescribing on a regular basis, which was similarly found by Weeks and Marriott in their later study.[68] Weeks and Marriott[68] found that the most appropriate models elucidated were within the context of discharge and pre-admission clinics, which was similar to earlier work by Bessell et al.[64] and Marriott and Bessell.[67]

### 1.6.2.2 Barriers to Nonmedical Prescribing

Previous overseas experience had suggested concerns relating to the barriers in implementation of the prescribing models. This was found to be similar in the Australian-based studies[64,68, 69, 73], which identified the following concerns:

- opposition from doctors,
- restrictions of current practice acts and legislation,
- workload,
- legal and ethical responsibility,
- opposition from the pharmaceutical industry,

- the capability of pharmacist to perform the role,
- the need for appropriate training,
- the need to have a specified framework to guide prescribing,
- time, space and resource constraints,
- the potential for conflict with doctors,
- conflict of interest between prescribing and dispensing activities,
- defining the boundaries of prescribing activities,
- importance of access to and communication about relevant clinical information,
- cost implications of a new prescribing model,
- performing tasks outside of their clinical practice,
- liability,
- remuneration issues,
- their current busy schedule; and
- low self-belief in their confidence to perform the task

These barriers can be divided into several areas[64,68, 69, 73]:

- competency,
- funding and training,
- patient safety,
- professional responsibility, and
- professional relationships

If prescribing privileges were granted, pharmacists would need to undertake special training or accreditation through clinical internship or formal examination. One of the three major themes from the focus group conducted in the Hanes and Bajorek study[69] was that participants were concerned that they lacked sufficient training to diagnose, mainly in relation to decision-making in therapy management, and suggested a specified framework to guide prescribing.[69] This study, however, was conducted only in one state (New South Wales) with a very small sample. A later study by Weeks et al.[74] was a pilot in Australia of a RPSGB accredited nonmedical prescribing course. This confirmed that Australian

pharmacists perceived the need to improve the running of the course and developing a local course. The main suggestions related to the need for Australian content, improve period of learning in practice and rigorous competency assessment.

Another study was conducted to gather information from Australian pharmacists about prescribing activities. An electronic survey was conducted to obtain their opinion on the feasibility of pharmacist prescribing privileges in their area of practice, as well as their awareness of prescribing practices internationally.[73] Only 268 pharmacists (6.4%) completed the census survey. The majority agreed that pharmacists should be granted dependent prescribing authority and believed that they could identify their own limitations as well as justifying their decisions as a dependent prescriber. The pharmacists were more in favour of the dependent prescribing model compared to independent prescribing. Since this study was conducted in 2004, only half of the respondents were aware of the international prescribing models for pharmacists. Six main points were raised relating to the barriers to pharmacist prescribing[73]:

- time, space and resource constraints;
- the potential for conflict with doctors;
- conflict of interest between prescribing and dispensing activities;
- defining the boundaries of prescribing activities;
- the importance of access to and communication about relevant clinical information; and
- cost implications of a new prescribing model

In the 2008 study by Weeks and Marriott[68] exploring the views of SHPA members on collaborative prescribing, 1367 members were invited to participate in a survey, to which 40% responded. Three-quarters of them said they would prefer to become pharmacist prescribers in their clinical area of practice, provided that legal and credentialing frameworks existed to support the role, while the remainder were either undecided or would prefer not to undertake the role. Participants admitted to already undertaking *de facto* prescribing and supported the importance of pharmacists taking an active role in discharge prescribing. The result was consistent with the findings of the studies conducted

by Marriott and Bessell[67] on discharge prescribing and Hanes and Bajorek[69] on activities in *de facto* prescribing.

Vracar and Bajorek[49] published a study in 2008 investigating Australian general practitioners' (GPs) views on pharmacist prescribing. The purpose of this study was to explore their views regarding the appropriateness of pharmacist prescribing models. This study was conducted using questionnaires and interviews in Sydney with GPs randomly recruited from two Sydney Divisions of General Practice (response rate 15%). Repeat prescribing and prescribing by referral were found to be the most favoured models. The major themes that emerged in the discussion were related to safety issues, lack of awareness of pharmacists' training and capabilities, division of professional/clinical responsibility, conflict in definition of prescribing versus treating, interference with the general practitioner-patient relationship and remuneration. Some of these concerns are similar to those of pharmacists in the studies conducted by Hanes and Bajorek[69] and Weeks and Marriott.[68]

There is no current legislation allowing the extended role of pharmacist prescribing in Australia; home medicines review (HMR) is the only currently accredited extended role available for Australian pharmacists. Prior to the introduction of HMRs, while GPs generally supported this programme, some concerns were raised. Although the pharmacist's role in HMR is different from prescribing, medical practitioners might have some reservations about nonmedical prescribing in the Australian context. This was supported by a study conducted by Van et al.[75] to explore the perceptions of Australian GPs towards extended pharmacy services, and to investigate the modes and extent of collaboration between community pharmacists and GPs. This study involved semi-structured interviews in Sydney and surrounding areas. GPs were generally positive about the HMR service, information gathering, and monitoring. There were certain areas in which GPs were less in favour of pharmacists contributing e.g. screening and immunisation services. The GPs also felt that the collaboration was useful, but that extended services provided by pharmacists should be within the pharmacist's capability.

### *1.6.3 Pilot Studies of Nonmedical Prescribing*

Various issues have been described earlier based on published papers related to the implementation of pharmacist and nurse prescribing overseas. This section discusses published studies in the Australian setting, mostly pilot studies involving specific hospitals or institutions. As mentioned earlier, currently there are no established policies for the implementation of pharmacist prescribing.

Several pilot studies related to pharmacist prescribing in the Australian setting have been undertaken, one of which was the study by Birdsey et al.[70] to determine whether pharmacist-initiated electronic discharge would decrease discharge times for selected cardiology patients and improve the accuracy of prescribing by limiting deviations from the intended therapeutic plan. This pilot study showed that an experienced pharmacy specialist using an electronic discharge prescribing system can significantly reduce the time elements of the discharge medication pathway. In addition, errors of omission that deviate from evidence-based practice were reduced. This electronic discharge prescribing was supported by similar research conducted in discharge prescribing by Marriott et al.[66,67] and Weeks and Marriott[68].

Various pharmacist pilot projects have been conducted in Australia. One project by Weeks et al. evaluated a pharmacist-led lipid clinic for patients with peripheral vascular disease.[76] Bajorek et al. explored the niche area of warfarin prescribing.[71,72] Nguyen and Bajorek[71] investigated the clinical utility and capacity of a small sample of Sydney hospital pharmacists prescribing warfarin therapy. These studies have shown that pharmacists are capable of undertaking a variety of supplementary prescribing roles. In 2009, a workshop on pharmacist prescribing concluded that pilot studies had used different models, methods and evaluation frameworks. Consensus was reached among participants that there was a need to develop a consistent 'evaluation framework' for future research.[77]

### *1.6.4 Nurse Practitioner Prescribing*

The introduction of the "nurse practitioner (NP)" has enabled expanded roles for nurses in Victoria. In the report of the "The Victorian Nurse Practitioner Project"[42], the nurse

practitioner was defined as "a registered nurse with appropriate accreditation who practices within the professional role with autonomy in the work setting and the freedom to make decisions consistent with his/her scope of practice and the freedom to act on those decisions".[42] The recommendations of the Task Force are shown in **Table 1**.

**Table 1: Recommendations for nurse practitioners based on Victorian Nurse Practitioner Report[42]**

| | Recommendation | Description |
|---|---|---|
| 1 | Recognition of the role of nurse practitioners | Recognised as a registered nurse educated for advanced practice.<br>Recognised as legitimate providers of healthcare services in Victoria.<br>Core component: advanced clinical practice, education, counselling, research, quality improvement, administration and management.<br>Position of nurse practitioner to be remunerated in line with the knowledge, skills, competencies and responsibilities required for the position. |
| 2 | Regulation, endorsement and educational preparation of nurse practitioners | Approved by the Nurses Board of Victoria to regulate the use of the title 'nurse practitioner'.<br>Prevent any persons who have not met the requirements from using the title.<br>Use existing processes for the accreditation of courses.<br>Title to be restricted to that of nurse registered in divisions 1, 3 or 4 of the register, with the identified area of practice attached to the title.<br>Extensions to nursing practice such as prescribing should be included as core components of the courses.<br>Department of Human Services to provide funding to a consortium of universities for the development of appropriate nurse practitioner courses.<br>Minimum educational requirement for recognition: accredited masters level program with strong clinical focus and a research project component.<br>Transition process of 10 years for the attainment of the minimal educational requirement of a master for nurse |

| | Recommendation | Description |
|---|---|---|
| | | practitioner recognition.<br>Department of Human Services to have additional funds available for registered nurses wishing to undertake studies leading to recognition as nurse practitioner.<br>Department of Human Services to fully fund a clinical chair to provide leadership in nurse practitioner practice, research, education and policy development in Victoria. |
| 3 | Standards/ competencies of nurse practitioners | Framework be developed that enables core and/or specific standards/competencies to be developed that are nationally and internationally consistent in relation to nurse practitioner.<br>Minister of Health to request the Nurses Board of Victoria to facilitate the processes necessary for the development of a framework for standards/competencies for nurse practitioners that are nationally consistent and internationally compatible.<br>Funding for the development of a national framework for standards/ competencies for nurse practitioners. |
| 4 | Credentialing of nurse practitioners | Nursing profession monitor the outcome of the current national project funded by the Commonwealth examining the feasibility of credentialing and appropriate action to be taken.<br>Establishing criteria for the assessment of continuing competence of nurse practitioners. |
| 5 | Best practice | Follow the guidelines for the development, implementation and evaluation of clinical practice guidelines to be used for the development of best practice clinical guidelines for nurse practitioner services. |
| 6 | Professional indemnity for nurse practitioners | Nurse practitioners demonstrate adequate professional indemnity insurance cover.<br>Department of Human Services to provide professional indemnity insurance facility for nurse practitioner to ensure that the cost of professional indemnity insurance does not limit the implementation of the nurse practitioner role in any area of practice. |
| 7 | Additional legislative requirements | Drugs Poisons and Controlled Substances Act 1981 be amended to provide for limited prescribing authorisation for nurse practitioners.<br>The nurse practitioner be authorised to prescribe from a formulary corresponding to the context of practice of the nurse practitioner. |

| | Recommendation | Description |
|---|---|---|
| | | That the Department of Human Services facilitate the process for the development of a prescribing formulary and guidelines consistent with NHMRC[2] guidelines taking into account the variety of contexts of nurse practitioner practice.<br>That the Department of Human Services facilitate the process for the development of guidelines consistent with NHMRC[2] for specific diagnostic services which nurse practitioners may initiate in relation to the context of practice and for the systems necessary to manage the results.<br>That referral to a medical specialist from a nurse practitioner be coordinated by the client's nominated GP in consultation with the nurse practitioner. Where a client does not nominate a GP, the nurse practitioner should be guided by locally agreed referral policies and protocols.<br>That the Department of Human Services facilitate the process for the development of guidelines for nurse practitioners requiring admitting rights and authority to approve absence from work certificates.<br>That all relevant legislation, including but not limited to the Nurses Act 1993 and the Drugs Poisons and Controlled Substances Act 1981, be reviewed and amended according to the context of the nurse practitioner role. |
| 8 | Extended nursing practice | Prescribing rights: benefits in extending to advanced practice nurse in the areas listed below:<br><br>Improved client care<br>Increased convenience for clients<br>Improved nurse-client relationship<br>Improved collaborative practice<br>Potential reduction in costs<br><br>Prescribing rights: concerns and potential risks in extending to advanced practice nurses<br>Prescribing and diagnostics: legitimising and developing the role of the advanced clinical nurse |

Currently in Victoria, nurses who have been appointed by an employer to become NPs are referred to as nurse practitioner candidates.[78] They are registered nurses under division 1, 3

or 4, engaged to undertake a course of study and clinical experience leading to endorsement as a NP. Among the states in Australia, Queensland was the first state to authorise a NP to prescribe.[78]

### *1.6.5 Summary of the Development of Nonmedical Prescribing Practice in Australia*

In addition to nurses, optometrists and podiatrists also have limited prescribing rights in Australia.[79,80] While there is no current legislation supporting the extended role of pharmacist prescribing, there is however, a groundswell of interest in this area, with several pilot studies having been conducted. An interesting opinion was published in an Australian pharmacy journal, the Journal of Pharmacy Practice and Research, by Stewart, a UK researcher in nonmedical prescribing.[81] He commented that pharmacists, as 'experts in medicines', should be the key players in nonmedical prescribing. Studies exploring views of pharmacists and medical practitioners on nonmedical prescribing issues and the experiences of implementing various models in other countries are valuable in informing implementation in Australia. In particular, development of appropriate competency standards for pharmacist prescribers in the Australian healthcare context was identified as vitally important in ensuring pharmacists are well equipped to perform the prescribing role and to identify the educational needs for pharmacists when developing education and training programmes to equip them as competent prescribers.

# Chapter 2: Competencies and Related Educational Needs for Nonmedical Prescribers

**Summary**

- In the previous chapter, issues related to competence were shown to be an early barrier to implementation of nonmedical prescribing.

- Therefore, identifying the appropriate competencies for nonmedical prescribers was recognised as the vital first step, prior to identifying educational needs and developing education and training in the Australian setting.

- This chapter, therefore, analyses the literature around the required competencies and the educational needs for nonmedical prescribers, based on overseas experience.

The previous chapter discussed the literature regarding the global changes, early experiences and barriers to nonmedical prescribing. Most of these early studies identified challenging issues in appropriate planning; the capability of nonmedical prescribers, including pharmacists, to perform the task; and the outcomes of the new model of prescribing. Post-implementation evaluation identified the barriers to introducing the services, views of nonmedical prescribers' confidence to perform the task and issues related to the education and training of pharmacist prescribers.

## 2.1 Competency Standards

The report of the Royal Pharmaceutical Society of Great Britain (RPSGB)[82] **(Table 2)** highlighted the lack of competency assessment, both before and after qualification as a supplementary prescriber, as the first of a number of priority areas that needed further action. This report was produced one year after the implementation of supplementary prescribing. These issues need to be taken into careful consideration when implementing the appropriate model of pharmacist prescribing in the Australian context, since similar concerns might arise.

**Table 2: Key issues identified one year after implementation of supplementary prescribing in the United Kingdom[82]**

| | Key issues in the order of priority |
|---|---|
| 1 | Lack of competency assessment both before and after qualification as a supplementary prescriber |
| 2 | Limitations of supplementary prescribing when trying to incorporate it into existing practice |
| 3 | Lack of a support network to provide updates relating to supplementary prescribing |
| 4 | Lack of information technology support from general practitioner computer software systems for supplementary prescribing |
| 5 | Issues relating to funding, from remuneration of the role itself, to education and training, access to prescribing budgets and indemnity insurance |
| 6 | Difficulties with clinical management plans (CMPs), particularly for patients with co-morbidities |
| 7 | Poor understanding of the supplementary prescribing role among other health professionals and the public, in part caused by the complexity of nonmedical prescribing models |

| | Key issues in the order of priority |
|---|---|
| 8 | Problems arising from the lack of access to patient records in both primary and secondary care, but particularly in community pharmacy |

Recommendations from the RPSGB report to address these key issues are highlighted in **Table 3**. Therefore, the focus of this section is to explore some of these challenges and barriers perceived in the areas of prescribing.

**Table 3: Key recommendations identified one year after implementation of supplementary prescribing in the United Kingdom[82]**

| | Key recommendations |
|---|---|
| 1 | Bring supplementary prescribing materials together into one resource pack |
| 2 | Promote the role of supplementary prescribers among other professions and the public |
| 3 | Define exactly where pharmacists add value as supplementary prescribers |
| 4 | Simplify the supplementary prescribing model |
| 5 | Encourage multidisciplinary work between national professional bodies, and between pharmacists and nurses at a local level |
| 6 | Set up a good practice database |
| 7 | Establish a system that allows new supplementary prescribers to be mentored by existing supplementary prescribers |
| 8 | Improve communication between the RPSGB and supplementary prescribers |
| 9 | Provide more support and regular updates to supplementary prescribers |

The defining of competencies is important to inform the development of the education and training, assessment and continuing professional development (CPD) among nonmedical prescribers. An important barrier that will be discussed in this chapter relates to the assessment of competency as part of the educational needs component.

### *2.1.1 Competency*

Defining competence is difficult and very subjective. According to Rethans et al.[83] competency-based assessment measures what a person can do in controlled representations of professional practice and performance-based assessment measures what a person does in actual professional practice. The author explained this according to Miller's pyramid of competence (**Figure 2**), which shows the essential facets of clinical competence consisting

of several levels. Understanding these levels is important in designing the educational needs and assessment appropriately for nonmedical prescribing.

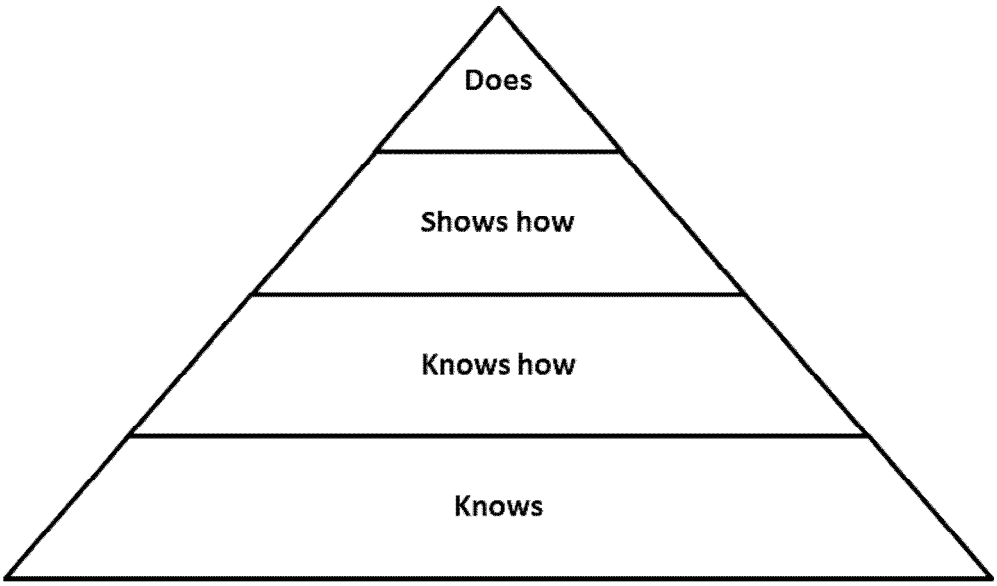


**Figure 2: Miller's pyramid of competence[84]**

In the context of the pharmacist prescribing, it may be that all registered pharmacists have the expertise required to undertake prescribing tasks without further intensive education, other than knowledge of the appropriate prescribing process. It is important that all pharmacists undertaking prescribing roles should meet a minimum standard of competence. Without a clear understanding of the required competencies and the appropriate level of performance, suitable assessment cannot be designed to assure the quality of practitioners.

### *2.1.2 Pharmacist Competency Standards – United Kingdom*

In United Kingdom, the competency framework for nonmedical prescribing was commissioned by the Department of Health (DH) in conjunction with the RPSGB, the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Prescribing Centre (NPC). The first UK competency framework document developed for nonmedical prescribers (allied health professionals, including pharmacists) was published

in 2004 to support supplementary prescribing.[85] In 2006, the second edition of the competency framework was published due to the introduction of the independent prescribing among pharmacist prescribers.[86] It is clearly stated in the document that the competency framework is intended as an aid for education and development as listed below:

- "To inform the development of the curriculum.
- To help providers of initial educational and training programmes to identify learning outcomes.
- As a self assessment tool for healthcare professionals to evaluate their own level of competency when considering an education and/or training programme.
- To help managers and pharmacist prescribers to identify ongoing education, training and development needs.
- To provide an ongoing way of structuring CPD." [86]

This document was used as the main reference for the education and training for nonmedical prescribing. It contains three areas of competency: the consultation, prescribing effectively and prescribing in context. Each of these areas is accompanied by statements which further describe what the competency is about (**Table 4**).

**Table 4: The basic structure of the competency framework**

| Areas | Competencies | Number of statements |
|---|---|---|
| The Consultation | Clinical and pharmaceutical knowledge | 10 |
| | Establishing options | 14 |
| | Communicating with patients | 11 |
| Prescribing Effectively | Prescribing safely | 9 |
| | Prescribing professionally | 8 |
| | Improving prescribing practice | 7 |
| Prescribing In Context | Information in context | 6 |
| | The NHS in context | 5 |
| | The team and individual context | 7 |

### *2.1.3 Pharmacist Competency Standards – United States of America*

USA was among the first countries to authorise prescribing among nonmedical practitioners. Stimmel was one of the early researchers who conducted studies in the area of pharmacists' competence to perform the extended role of prescribing.[87,88,89] The University of Southern California (USC) pilot project was conducted for pharmacist prescribers in the USA to evaluate whether pharmacists could prescribe as appropriately as physicians.[87] In this project, prescriber trainees were required to complete an education programme and pass a written certifying examination before they began prescribing. Each trainee had to have an identified supervising physician, supervisory meetings were held, and every prescription written by a trainee was reviewed by the supervising physician to assess safety and quality of prescribing. This is similar to the UK prescribing training experience in which pharmacists undergo a certain period of training under the supervision of mentors.[24] In the study by Stimmel and McGhan[87], the only formal training required for these pharmacists to prescribe and evaluate drug therapy was a physical assessment skills course, which was taught by a physician who provided lectures and practical experience for the pharmacist prescribers. The focus of the course was not on differential diagnosis but rather on assessment of disease state change as a function of drug response and drug-induced adverse effects. The course served only as an introduction to physical assessment, with refinement of skills to occur in the practice setting with the supervising physician.

Study by Stimmel and McGhan[87] was meant to evaluate the appropriateness of pharmacist prescribing in the USA, which found pharmacist prescribing in pilot studies had been safe, effective and either equal or superior to physician prescribing. However, negative aspects of pharmacist prescribing included that not all pharmacists are competent to prescribe, pharmacists are not trained in diagnosis, physicians do not want pharmacists to interfere, patient care would be further fragmented if pharmacists prescribe (which would increase the cost), and pharmacists do not have access the information necessary for them to competently prescribe drug therapy. Based on these arguments, it was recommended that

legislation regulating pharmacist prescribing should impose certain limits: certification to prescribe should be based on demonstrated competence, pharmacists who prescribe must have access to medical records, pharmacists must prescribe within established working relationships with physicians, and pharmacist prescribing should be limited to long term therapy for chronic disease and therapy for acute self-limiting illnesses that are not diagnostically complex.

A further study was conducted by these investigators to evaluate drug prescribing for inpatients by three certified pharmacist prescribers and two psychiatrists in a mental health facility in California.[88] The pharmacist prescribers were assigned diagnosed patients whose treatment plan was primarily medication-based. For each prescriber, 60 prescriptions were randomly selected. A panel of four judges independently evaluated the appropriateness of each prescription. The certified pharmacist prescribers in this study prescribed drugs for psychiatric inpatients as safely and appropriately as the physicians.

### *2.1.4 Pharmacist Competency Standards – Alberta, Canada*

Significant change was also observed in 2006 in Alberta when the government introduced new regulations that expanded pharmacists' practice, including the authority to prescribe Schedule 1 drugs, defined as **"**Drugs that require a prescription as a condition of sale." The expert panel involved in the document development recommended an assessment that would determine whether the pharmacist applicants have the necessary competencies to prescribe safely, effectively and responsibly. Pharmacists who undertake prescribing must practice in accordance with all applicable legislation and standards in Alberta.[90]

### *2.1.5 Competency Standards – The Australian Context*

In Australia, competency standards in the workplace are based on the Australian National Training Authority (ANTA) guidelines[91], which are based on the concept of industry relevant competency – the broad concept of competency concerns the ability to perform particular tasks and duties to the standard of performance expected in the workplace. Competency requires the application of specified skills, knowledge and attitudes relevant

to effective participation in an industry, industry sector or enterprise. It covers all aspects of workplace performance and involves performing individual tasks; managing a range of different tasks; responding to contingencies or breakdowns; and dealing with the responsibilities of the workplace, including working with others. The relevant skills, knowledge and attitudes need to be applied consistently over time, and in the required workplace situations and environments.

As described under the ANTA guidelines[91], units of competency are the nationally agreed statements of the skills and knowledge required for effective performance in a particular job, or job function, which describe work outcomes as agreed by the particular industry. As such, they do not describe the procedures necessary to perform a particular role, but rather, identify the skills and knowledge, as outcomes, that contribute to the whole job function. Each unit of competency describes a specific work activity, conditions under which the activity is conducted, and the evidence that needs to be gathered to determine whether the activity is being competently performed. In developing the unit of competency, developers need to clearly understand the:

- "work activity and what it involves,
- particular skills (and level of skills) that are needed to perform the work activity,
- conditions under which the work activity may be conducted,
- evidence that needed to demonstrate that a person is competent in the work activity,
- knowledge and skills required to perform the work activity,
- generic work skills (or employability skills) required,
- evidence that should be considered in assessing competency, and
- resources that may be needed to gather the evidence" [91]

#### 2.1.5.1 Competency Standards for Australian Pharmacists

The document "Competency Standards for Pharmacists in Australia"[92] published in 2003 was designed to provide pharmacists, their professional organisations and the registering authorities with a basis for ensuring competent professionals capable of providing quality pharmacy services.[92] The "National Competency Standards Framework for Pharmacists in Australia 2010", released after completion of this project, is the current competency standards document available for pharmacists.[93]

Currently in Australia, the Australian Association of Consultant Pharmacy (AACP) specifies competency requirements for pharmacists seeking accreditation to undertake medication management reviews, including supplementary performance criteria relevant to this role. The AACP was established and accredited to develop a national approach to the practice of consultant pharmacy as an expansion of the professional role of pharmacy in Australia.[94] The AACP is jointly owned by the Pharmaceutical Society of Australia (PSA) and The Pharmacy Guild of Australia (The Guild). Its primary role is to define and develop new professional or consultant services and accredit pharmacists to provide them. These services will range from medication review and management of the frail aged living in residential care or at home, through to specific services provided by community pharmacists. It is logical, therefore, to use this document as the starting point for the development of competency standards for pharmacist prescribers in the Australian context.

### *2.1.6 Competency Standards – Nurse Practitioners*

As described in Chapter 1, the recommendations for nurse practitioners in Victoria included developing standards/competencies and credentialing as listed below (**Table 5**)[42] These areas were considered to be important for the assessment and integrity of the programme.

**Table 5: Recommendation for competencies and credentialing for nurse practitioners in Victoria[42]**

| | |
|---|---|
| Standards/ competencies of nurse practitioners | That a framework be developed that enables core and/or specific standards/competencies to be developed that are nationally and internationally consistent in relation to nurse practitioner.<br>That the Minister of Health request the Nurses Board of Victoria to facilitate the processes necessary for the development of a framework for standards/competencies for nurse practitioners that are nationally consistent and internationally compatible.<br>That funding be made available for the development of a national framework for standards/ competencies for nurse practitioners. |
| Credentialing of nurse practitioners | That the nursing profession monitor the outcome of the current national project funded by the Commonwealth examining the feasibility of credentialing and appropriate action to be taken.<br>That criteria be established for the assessment of continuing competence of nurse practitioners. |

## 2.2 Education and Training for Nonmedical Prescribers

### *2.2.1 Overview of United Kingdom Pharmacist Prescribing Programmes*

In the UK, education and training courses for pharmacists to become supplementary and independent prescribers have been accredited in several institutions. The supplementary prescribing curriculum was developed in November 2002 and the pharmacist independent prescribers' curriculum was subsequently derived from the supplementary prescribers' curriculum and published in August 2006.[24] As described earlier (Section 1.3.7), the main difference between supplementary and independent prescribers is that the independent prescriber is responsible for making autonomous prescribing decisions based on clinical assessment of patients, which includes clinical concerns about which the patient is consulting the pharmacist and also other clinical problems that require attention or referral by the pharmacist.

Currently, pharmacists who wish to become prescribers must complete an accredited education programme. Independent prescribing programmes last the equivalent of 26 days over three to six months, with an additional 12 days learning in practice supervised by a

medical practitioner.[24] Pharmacists who successfully complete the accredited programme and the period of learning in practice are considered competent to practise as supplementary prescribers.

According to the RPSGB curriculum outline published in 2006[24] the curriculum was based on the applied therapeutics that pharmacists acquire from their initial education and through experience in practice. In their undergraduate education, pharmacists have been exposed to the basic foundations of pharmacodynamics, pharmacology, pharmacokinetics and toxicity of medicines and how they may be used to prevent and treat illness, relieve symptoms or assist in the diagnosis of disease. Entrance into pharmacist prescriber education and training programmes depends on pharmacists' area of practice and their level of experience. pharmacists' expertise, experience and skills.

Before accepting the extended role of prescriber, pharmacists need to demonstrate evidence of relevant CPD and that they will update and extend their prescribing skills. This is clearly defined by the Royal Pharmaceutical Society's Code of Ethics and Standards in which pharmacists are obliged to ensure that their knowledge, skills and performance are of high quality.

Requirements that the RPSGB has clearly outlined for pharmacists who wish to convert from supplementary to independent prescribing are:

- "hold current registration with RPSGB or Pharmaceutical Society of Northern Ireland as a practising pharmacist with annotation as a supplementary prescriber for not more than five years;
- currently practising as a supplementary prescriber or registered as a supplementary prescriber for not more than five years and able to provide evidence of relevant patient orientated practice;
- able to provide a statement of support from a medical practitioner that confirms competence as a supplementary prescriber;

- demonstrate how they reflect on their own performance and take responsibility for their own CPD;
- demonstrate how they have developed their own networks for support, reflection and learning, including prescribers from other professions." [24]

This programme was also supported by the institutions that were accredited to deliver pharmacist prescribing programmes in the UK (**Table 6)**.[29]

**Table 6: Institutions accredited to deliver pharmacist independent prescribing programmes in the United Kingdom updated to November 2009[29]**

| Institution | Accredited independent prescribing programme | Accredited conversion programme to allow supplementary prescribers to also qualify as independent prescribers |
|---|---|---|
| Anglia Ruskin University | √ | |
| Bangor University | √ | √ |
| University of Bath | √ | |
| University of Bolton | √ | √ |
| University of Bradford | √ | √ |
| University of Brighton | √ | √ |
| Cardiff University | √ | √ |
| University of Central Lancashire | √ | √ |
| University of Chester | √ | √ |
| DeMontfort University | √ | √ |
| University of Derby | √ | √ |
| University East Anglia | √ | |
| Edge Hill University | √ | |
| University of Glamorgan | √ | √ |
| Glyndwr University | √ | √ |
| University of Hertfordshire | √ | √ |
| University of Hull | √ | √ |
| Keele University | √ | √ |
| King's College London | √ | √ |
| University of Leeds | √ | |
| London Metropolitan University | √ | |
| London South Bank University | √ | √ |
| Medway School of Pharmacy | √ | √ |
| University of Nottingham | √ | |

| Institution | Accredited independent prescribing programme | Accredited conversion programme to allow supplementary prescribers to also qualify as independent prescribers |
|---|---|---|
| University of Portsmouth | √ | √ |
| Queen's University, Belfast | √ | √ |
| University of Reading | √ | √ |
| Robert Gordon University | √ | √ |
| University of Strathclyde | √ | √ |
| University Campus Suffolk | √ | |
| University of Sunderland | √ | √ |
| Swansea University | √ | √ |

### *2.2.2 United Kingdom Pharmacist Prescribing Training Experience*

The previous section outlined the importance of appropriate curriculum development for education and training programmes for pharmacist supplementary and independent prescribers in the UK. In this section, studies exploring nonmedical prescribers' experiences and views related to prescribing education and training will be discussed.

Dawoud[95] conducted a study to identify how the first cohort of pharmacists attending prescribing courses at two institutions in the south east of England perceived the supplementary prescribing system and the education and training courses. The study found that the majority of pharmacists trained as supplementary prescribers in the first cohort at the two institutions felt they already had the competencies required for supplementary prescribing prior to the course.[95] They highlighted, however, the importance of redesigning the courses to involve more physical examination and consultation skills.[95]

A study conducted by George et al.[28] investigated Scottish community pharmacists' awareness, views and attitudes related to independent prescribing by community pharmacists and their perceptions of competence and education and training needs for the management of some common conditions. While the majority of respondents perceived

themselves to be competent in diagnosing and selecting appropriate drugs for the condition studied, only a quarter of them were confident about their knowledge of evidence-based treatment for the conditions. Despite feeling competent in diagnosing and treating the various conditions studied, many respondents perceived the need for education and training in relation to the diagnosis of the conditions and drugs used for treating those conditions before undertaking prescribing responsibilities. Gaining communication and consultation skills were also regarded as important prior to undertaking independent prescribing.

## 2.3 Need for Research

From the literature review (Chapters 1 and 2), it can be concluded that there are various issues related to pharmacist prescribing that need to be explored before moving to implementation. Competency standards and associated assessment were highlighted as important in the studies conducted overseas. After the implementation of supplementary prescribing in the UK, competency was identified as the key issue that needed to be addressed. Development and validation of competency standards for prescribing in Australia is therefore important. Identifying the educational needs for pharmacist prescribers in the Australian context is also important. Most of the studies conducted in the Australian context have been about the views of pharmacists and medical practitioners on nonmedical prescribing (Section 1.6.2). Some of the studies were pilot projects of potential areas or prescribing models that could be implemented in the Australian setting (Section 1.6.3). Therefore, the following issues needed to be examined:

- The competencies needed for pharmacists to perform prescribing in Australia;
- The perceived barriers to implementation;
- Current prescribers' perceptions of the areas of competency important in prescribing;
- Pharmacists' perception of their current level of knowledge and skill for the extended role of prescribing;
- Factors influencing pharmacists' confidence level in prescribing; and
- Identification of the educational needs for curriculum development.

## 2.4 Aims and Objectives

Therefore the aims of this study were:

- To develop and validate a draft set of competency standards for pharmacists to perform prescribing in the Australian context.
- To identify educational needs to inform the development of the education and training programmes for pharmacist prescribing in the Australian context.

The objectives of the first aim of the study were:

- To identify the areas important in prescribing by using the UK document "Maintaining Competency in Prescribing: An outline framework to help pharmacist prescribers"[86] and "Competency Standards for Pharmacists in Australia 2003"[92] as the basis.
- To develop a draft set of competency standards by identifying the gaps in the Australian document in regard to competencies required for prescribing as articulated in the UK document and to format the draft standards to be compatible with the Australian document.
- To refine the draft standards and to identify the associated barriers to implementation of pharmacist prescribing using a series of expert panel discussions among pharmacists and medical practitioners.
- To validate the components of the standards with medical practitioners.

The objectives of the second aim of the study were:

- To ascertain pharmacists' perceptions of their clinical skills and knowledge in the areas important in prescribing and identify factors influencing their perceptions.
- To compare the differences in approach to patient management between medical practitioners and pharmacists.

# Chapter 3: Development of Competency Standards for Nonmedical Prescribing

**Summary**

- This chapter describes the process of development of competency standards for pharmacist prescribing ("the standards") in the Australian context.

- The development process comprised three stages:

  Stage 1: Identification of the appropriate competencies for nonmedical prescribing.

  Stage 2: Development of "the standards" in a format compatible with the existing "Competency Standards for Pharmacists in Australia 2003".

  Stage 3: Refining the draft of "the standards" using an expert panel.

## 3.1 Background

From the second chapter of the literature review, competency was highlighted as one of the important areas to be addressed while considering the possibility of implementing prescribing models in Australia. Identification of related competencies was important prior to the development of an educational module for the extended role of prescribing by pharmacists in the Australian context.

### *3.1.1 Aim*

The aim was to identify the areas important in prescribing and develop a draft set of competency standards.

## 3.2 Development Process for Australian Pharmacist Prescribing Competency Standards

The development process for Australian Pharmacist Prescribing Competency Standards involved three different stages. The draft document will be referred to throughout this thesis as "the standards". The first stage of the development process involved identification of the appropriate competencies for pharmacists to perform extended roles of prescribing. This step is important to gather the important competencies needed for this purpose. At the time of conducting this study in 2006, only the UK "Maintaining Competency in Prescribing"[86] and "The Competency Standards for Pharmacists in Australia 2003"[92] were published and available.

> NOTE: The current competency standards documents available for pharmacist prescribing are "Guide to receiving additional prescribing authorization" (Alberta, Canada)[90] and "Proposed Advanced Scope of Practice and Qualifications for Pharmacists" (New Zealand)[43] documents. In Australia, the "National Competency Standards Framework for Pharmacists in Australia 2010" document is the current competency standards available for pharmacists.[93] In 2012 the National Prescribing

Service published "Competencies required to prescribe medicines".[96] These competencies relate to all prescribers, not just pharmacists, similar to a UK document recently published in May 2012 "A single competency framework for all prescribers"[97], however they were not available at the time this study was conducted.

ANTA guidelines are prepared for the purpose of guiding training bodies in their development of training courses to prepare, and if necessary, credential participants for their workplace.[91] The second stage of the study involved the development of the standards according to the ANTA guidelines, as used by the Pharmaceutical Society of Australia in developing "The Competency Standards for Pharmacists in Australia 2003". This document describes the knowledge, skills and attributes necessary for a pharmacist to practice in Australia. Therefore it covers the areas where the majority of pharmacists practise.[92] Following the ANTA format is important to ensure the document is consistent.

The last stage involved review and amendment by expert panels. They are usually convened to deal with policy issues and can generate ideas to move a project forward, address issues which need further work behind the proposal or improve technical aspects of the project.[98] They are commonly used to provide feedback on the work conducted. All the documents related to pharmacists prescribing mentioned in Section 3.2 underwent the same process during development. The process is summarised in **Figure 3** and the details of the stages will be discussed in this chapter.

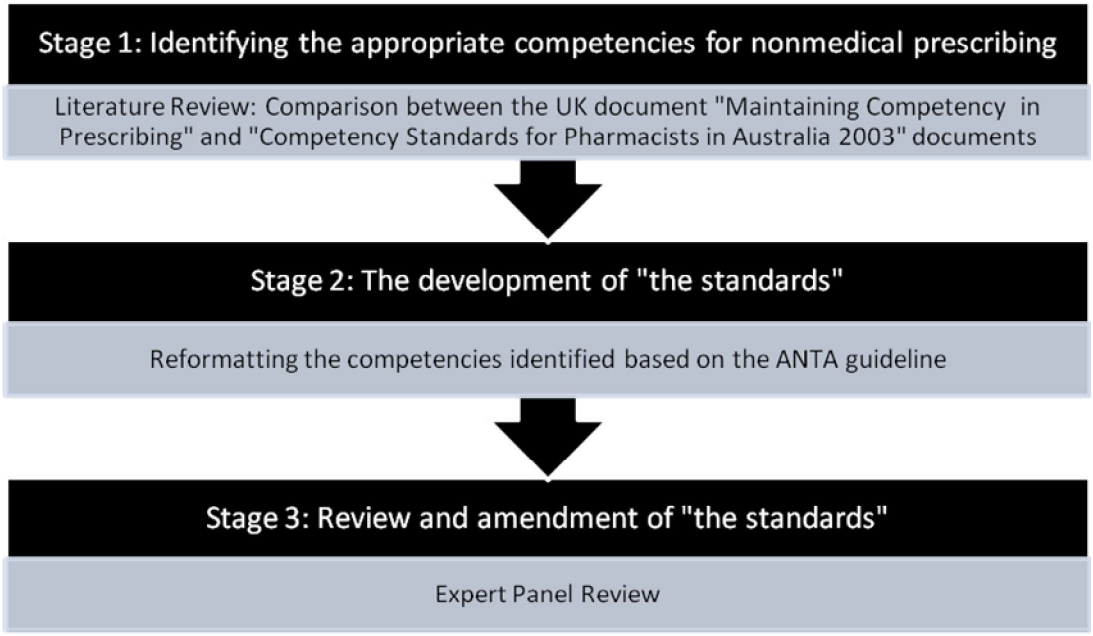


**Figure 3: The process of development of "the standards"**

### *3.2.1 First Stage – Identifying the Appropriate Competencies for Nonmedical Prescribing*

The UK document "Maintaining Competency in Prescribing"[86] was compared to the "Competency Standards for Pharmacists in Australia 2003"[92], the current standards for pharmacists in Australia, to identify common areas and aspects lacking in the Australian document related to pharmacists' prescribing. The structure of the UK document "Maintaining Competency in Prescribing"[86] is illustrated in **Table 7, Table 8,** and **Table 9**.

**Table 7: The structure of the UK "Maintaining Competency in Prescribing"[86] under the competency area of the consultation**

| THE CONSULTATION | | |
|---|---|---|
| **CLINICAL AND PHARMACEUTICAL KNOWLEDGE** | **ESTABLISHING OPTIONS** | **COMMUNICATING WITH PATIENTS (carers, parents and / or advocates where appropriate)** |
| ***Has up-to-date clinical and pharmaceutical knowledge relevant to own area of practice*** | ***Makes / reviews a diagnosis, generates treatment options for the patient and follows up treatment.*** | ***Establishes a relationship based on trust and mutual respect. Sees patients as partners in the consultation. Applies the principles of concordance*** |
| Understands the conditions being treated, their natural progress and how to assess their severity | Takes a comprehensive medical history and medication history (including complementary medicines, herbal remedies, over-the-counter medicines) | Listens to and understands patients' beliefs, ideas, concerns and expectations |
| Understands different non pharmacological and pharmacological approaches to modifying conditions and promoting health, desirable and undesirable outcomes and how to identify and assess them | Assesses the clinical condition using appropriate techniques and equipment | Understands the cultural and religious implications of the diagnosis / prescribing |
| Understands the mode of action and pharmacokinetics of medicines, how these mechanisms may be altered(e.g. by age, renal impairment) and how this affects dosage | Accesses and interprets all relevant patient records to ensure knowledge of the patient's management | Undertakes the consultation in an appropriate setting and adapts to meet the needs of different patients (e.g. language, level of understanding, physical impairments) |
| Understands the potential for unwanted effects, (e.g. adverse drug reactions [ADRs], drug interactions, allergy), and how to avoid/minimise and manage them | Identifies the nature, severity and significance of the clinical problem (i.e. formulates a 'working' diagnosis from differential diagnosis)* | Deals sensitively with patients' emotions and concerns |
| Maintains an up-to-date knowledge of relevant products (e.g. doses, formulations, pack sizes, storage conditions and cost) | Requests, and interprets, relevant investigations | Creates a relationship which does not encourage the expectation that a prescription will be supplied |
| Appreciates the misuse potential of drugs | Views and assesses the patient's needs holistically (e.g. psychosocial, physical) | Explains the nature of the patient's condition, the rationale behind and potential risks and benefits of management options |

| THE CONSULTATION | | |
|---|---|---|
| **CLINICAL AND PHARMACEUTICAL KNOWLEDGE** | **ESTABLISHING OPTIONS** | **COMMUNICATING WITH PATIENTS (carers, parents and / or advocates where appropriate)** |
| ***Has up-to-date clinical and pharmaceutical knowledge relevant to own area of practice*** | ***Makes / reviews a diagnosis, generates treatment options for the patient and follows up treatment.*** | ***Establishes a relationship based on trust and mutual respect. Sees patients as partners in the consultation. Applies the principles of concordance*** |
| Applies the principles of evidence-based medicine, and clinical and cost-effectiveness | Considers no treatment, non-drug and drug treatment options (including referral and preventive measures) | Enables patients to make informed choices about their management |
| Understands how medicines are licensed, sourced, supplied and monitored (e.g. how ADRs are reported) | Assesses the effect of multiple pathologies, existing medication and contraindications on treatment options | Negotiates an outcome of the consultation that both patient and prescriber are satisfied with |
| Understands the public health issues related to medicines and their use | Assesses the risks and benefits to the patient of taking/not taking a medicine (or using/not using a treatment) | Encourages patients to take responsibility for their own health and self manage their conditions |
| Is aware of infection control procedures | Selects the most appropriate drug, dose and formulation for the individual patient and prescribes appropriate quantities | Gives clear instructions about the medication (e.g. what it is for, how to use it, where to get it from, possible unwanted effects) |
| | Monitors effectiveness of treatment and potential unwanted effects | Checks the patients' understanding of, and commitment to, their management and follow-up |
| | Makes changes to the treatment plan in light of ongoing monitoring and the patient's condition and preferences* | |
| | Establishes and maintains a plan for reviewing the therapeutic objective, discharge or end point of treatment | |
| | Ensures that patients can access ongoing supplies of their medication | |

**Table 8: The structure of the UK "Maintaining Competency in Prescribing"[86] under the competency area of prescribing effectively**

| | PRESCRIBING EFFECTIVELY | |
|---|---|---|
| **PRESCRIBING SAFELY** | **PRESCRIBING PROFESSIONALLY** | **IMPROVING PRESCRIBING PRACTICE** |
| ***Is aware of own limitations. Does not compromise patient safety. Justifies prescribing decisions*** | ***Works within professional, regulatory and organisational standards*** | ***Actively participates in the review and development of prescribing practice to improve patient care*** |
| Knows the limits of own knowledge and skill, and works within them | Accepts personal responsibility for own prescribing and understands the legal and ethical implications of doing so | Learns and changes from reflecting on own practice |
| Knows when and how to refer to, or seek guidance from, another member of the team or a specialist* | Makes prescribing decisions, based on the needs of patients and not the personal considerations of the prescriber | Shares and debates own and others prescribing practice |
| Only prescribes a medicine with adequate, up-to-date knowledge of its actions, indications, contraindications, interactions, cautions, dose and side-effects | Understands how current legislation affects prescribing practice | Challenges inappropriate practice constructively |
| Checks doses and calculations to ensure accuracy and safety | Prescribes within current professional and organisational codes of practice/standards | Develops own networks for support, reflection and learning |
| Keeps up-to-date with advances in practice and emerging safety concerns | Maintains patient confidentiality | Understands and uses tools to improve practice (e.g. data, audit and feedback) |
| Knows about common types of medication errors and how to prevent them | Takes responsibility for own continuing professional development | Reports prescribing errors and near misses, reviews practice to prevent recurrences |
| Makes prescribing decisions often enough to maintain confidence and competence | Keeps prescriptions safely and knows what to do if they are stolen/lost | Establishes multi-professional links with practitioners working in the same specialist area |
| Understands the need for and makes accurate, clear and timely records and clinical notes* | Protects the security of own access to electronic medical records and prescribing systems | |
| Generates legible, clear and complete prescriptions, which meet legal requirements | | |

**Table 9: The structure of the UK "Maintaining Competency in Prescribing"[86] under the competency area of prescribing in context**

| PRESCRIBING IN CONTEXT | | |
|---|---|---|
| **INFORMATION IN CONTEXT** | **THE NHS IN CONTEXT** | **THE TEAM AND INDIVIDUAL CONTEXT** |
| ***Knows how to access relevant information. Can critically appraise and apply information in practice*** | ***Understands, and works within, local and national policies that impact on prescribing practice. Sees how own practice impacts on wider NHS*** | ***Works in partnership with colleagues for the benefit of patients. Is self-aware and confident in own ability as a prescriber*** |
| Understands the advantages and limitations of different information sources | Knows how local health service and partner organisations work and interact | Thinks and acts as part of a multidisciplinary team to ensure that continuity of care is not compromised |
| Uses relevant, up-to-date information | Follows relevant local and national guidance for medicines use (e.g. local formularies, care pathways, NICE guidance) | Establishes relationships with colleagues based on understanding, trust and respect for each others roles |
| Critically appraises the validity of information sources (e.g. promotional literature, research) | Works within the NHS / organisational code of conduct when dealing with the pharmaceutical industry | Establishes and maintains credibility with colleagues in the health care team |
| Applies information to the clinical context (linking theory to practice) | Understands budgetary constraints at local and national levels | Recognises and deals with pressures that might result in inappropriate prescribing (e.g. pharmaceutical industry, patients and colleagues) |
| Uses relevant patient record systems, prescribing and information systems, and decision-support tools | Understands national NHS frameworks relevant to medicines use (e.g. clinical governance, IT strategy) | Is proactive, adaptable, flexible and responsive to change |
| Regularly reviews evidence behind therapeutic strategies | | Negotiates the appropriate level of support for role as a prescriber |
| | | Seeks and/or provides support and advice to other prescribers, team members or support staff where appropriate |

At the time of this research, there were eight functional areas in the existing Australian document[92] which describe the general areas that pharmacists are expected to perform, illustrated in **Table 10**.

**Table 10: The summary of the "Competency Standards for Pharmacists in Australia 2003"[92]**

| | Functional Area | Competency Unit |
|---|---|---|
| 1 | Practise pharmacy in the professional and ethical manner | Unit 1.1 Practise legally<br>Unit 1.2 Practise to accepted standards<br>Unit 1.3 Pursue life-long professional learning and contribute to the development of others |
| 2 | Manage work issues and interpersonal relationships in pharmacy practice | Unit 2.1 Apply communication skills<br>Unit 2.2 Participate in negotiations<br>Unit 2.3 Address problems<br>Unit 2.4 Manage conflict<br>Unit 2.5 Apply assertiveness skills |
| 3 | Promote and contribute to optimal use of medicines | Unit 3.1 Participate in therapeutic decision making<br>Unit 3.2 Provide ongoing pharmaceutical management<br>Unit 3.3 Promote rational drug use |
| 4 | Dispense medications | Unit 4.1 Assess prescriptions<br>Unit 4.2 Evaluate prescribed medicines<br>Unit 4.3 Supply prescribed medicines |
| 5 | Prepare pharmaceutical products | Unit 5.1 Consider requirements for preparing a product<br>Unit 5.2 Compound pharmaceutical products<br>Unit 5.3 Prepare cytotoxic drug products |
| 6 | Provide primary health care | Unit 6.1 Assess primary health care needs<br>Unit 6.2 Address primary health care needs of patients<br>Unit 6.3 Promote good health in the community |
| 7 | Provide medicines and health information and education | Unit 7.1 Retrieve information<br>Unit 7.2 Evaluate and synthesise information<br>Unit 7.3 Disseminate information |
| 8 | Apply organisational skills in the practice of pharmacy | Unit 8.1 Plan and manage work time<br>Unit 8.2 Manage own work contribution<br>Unit 8.3 Supervise staff<br>Unit 8.4 Work in partnership with others<br>Unit 8.5 Plan and manage pharmacy resources<br>Unit 8.6 Plan and manage pharmacy services and the work environment |

### *3.2.2 Second Stage – The Development of "the standards"*

The additional competency standards required to cover pharmacist prescribing were then written according to the ANTA guidelines to be compatible with the existing Australian

document. Following the ANTA guideline[91], the components of the competencies in "the standards" consist of functional areas, units of competency, elements, performance criteria and evidence guide.

Functional areas bring together a number of units that are all associated with a general area of responsibility for practising pharmacist. [91] In "the standards", the functional area is defined as functional area nine "Prescribe Medicines" in addition to the eight existing functional areas. Units of competency reflect the major functions of the profession and each unit describes an area of professional performance. Units are subdivided into smaller segments called elements of competency that describe in more detail the range of roles and activities in the professional workplace. They integrate the knowledge, skills, attitudes and other important attributes of professional performance in the workplace. Units and elements are written in active form to describe the activities. Performance criteria specify the appropriate level of performance required. Evidence guides provide 'cues' for the assessor to further clarify the standard of competency expected.[91]

### *3.2.3 Results and Discussion for Stage 1 and 2*

The first stage of the study involved comparison of the statements in the UK Competency Framework[86] and the "Competency Standards for Pharmacists in Australia 2003"[92]. An excerpt of the comparison is shown in **Table 11** and the full version is available in (**Appendix 1**). Following the first stage of the study, the common areas and aspects lacking in the Australian document related to pharmacists' prescribing were identified and restructured based on the ANTA guidelines.[91] The first draft of "the standards" consisted of one functional area, five competency units, twelve elements, thirty-eight performance criteria and sixty-nine evidence guides. The summary of the first draft of "the standards" is shown in **Table 12** and the full version is available as (**Appendix 2)**.

**Table 11 : The comparison on the similarity of the statements in the UK Competency Framework document and the "Competency Standards for Pharmacists in Australia 2003" document**

| UK Competency Framework Statement | Competency Standards for Pharmacists in Australia 2003 | **Guide *** (Refer to Competency Standards for Pharmacists in Australia 2003) |
|---|---|---|
| **CONSULTATION** | | |
| **A. Clinical and Pharmaceutical Knowledge** | | |
| **Has up to date clinical and pharmaceutical knowledge relevant to own area of practice** | | |
| ***1. Understands the conditions being treated, their natural progress and how to assess their severity*** | **PC2:**<br>Understand the pathophysiology of the medical conditions/diseases of patients whose medication is reviewed and how it may influence optimal choices of medicines<br>**Evidence guide:**<br>Ability to explain clinical aspects of diseases/medical conditions of individual patients and the signs and symptoms commonly associated with them | **F3, C3.1, E2, PC2** |

*F: Functional area, C: Competency unit, E: Element, PC: Performance criteria

**Table 12: The summary of the first draft of "the standards"**

| Competency Unit and the Description |
|---|
| **9.1 Prescribe Safely** |
| • This unit is concerned with pharmacists' ability to prescribe in an appropriate manner. It encompasses skills and knowledge as well as responsibility for safe prescribing.<br>• This competency unit consist of:<br>5 Elements<br>12 Performance Criteria<br>16 Evidence Guide |
| **9.2 Prescribe Effectively** |
| • This functional area includes competency units that address the skills and knowledge that pharmacist need to acquire to prescribe in the most effective way.<br>• This competency unit consist of:<br>2 Elements<br>5 Performance Criteria<br>9 Evidence Guide |
| **9.3 Prescribe Professionally** |
| • This unit is concerned with pharmacists' ability to prescribe in the professional way. It encompasses the standards of practice that pharmacists need to follow to prescribe professionally.<br>• This competency unit consist of:<br>3 Elements<br>9 Performance Criteria<br>15 Evidence Guide |
| **9.4 Prescribe to the Accepted Standard** |
| • This competency unit describe various standard that pharmacist need to achieve when reviewing patients clinical problem before making the decision to prescribe.<br>• This competency unit consist of:<br>1 Element<br>9 Performance Criteria<br>16 Evidence Guide |
| **9.5 Participate in the Development of Prescribing Practice** |
| • This competency unit describe on ways to improve the prescribing practice from the own and other prescribing practice.<br>• This competency unit consist of:<br>1 Element<br>3 Performance Criteria<br>13 Evidence Guide |

### *3.2.4 Third Stage – Review and Amendment of "the standards"*

An expert panel was convened to discuss the draft of "the standards" to establish its face and content validity. Pharmacists were selected for the first expert panel to ensure that the discussion would cover the important areas of prescribing from the pharmacists' point of view. Since the panellists were not research subjects, ethical approval was not required.

#### 3.2.4.1 Participation Selection

Participants were chosen for their experience and familiarity with the development and application of the current "Competency Standards for Pharmacists in Australia 2003" document[92] via convenience sampling. Pharmacists who were eligible were identified and approached based on their contribution in various practice areas. They were approached via email and phone to invite participation in the discussion. Pharmacists who agreed to be involved voluntarily emailed the researcher.

The first expert panel members comprised pharmacists from different areas of practice: three hospital pharmacy Directors, a hospital Chief Pharmacist, a representative from the Society of Hospital Pharmacists of Australia (SHPA) and a pharmacist involved in research about pharmacist prescribing in the UK. Therefore, pharmacists involved in the review were mostly senior pharmacists who were assumed to have experience and familiarity with pharmacy practice development and policy.

Information was sent to the panellists prior to the meeting to explain the purpose and expectations of the discussion (**Appendix 3**). The documents supplied were the first draft of "the standards"(Section 3.2.3), the UK competency framework[86] and the "Competency Standards for Pharmacists in Australia 2003".[92] The panellists were expected to go through "the standards" and discuss related issues in the meeting. A copy of the document that was used to compare the components in the Australian and the UK document in the development of "the standards" was provided at the meeting for further clarification (Section 3.2.3).

The researcher facilitated the expert panel meeting using a structured discussion, assisted by an independent note-taker (**Appendix 4**). The discussion was audio-taped and transcribed verbatim. Data were managed using NVIVO (QSR NVivo; version 2.0, QSR International) and analysed to elucidate themes.

Following the meeting, expert panel members were sent a summary of the meeting and consequent planned actions (**Appendix 5**).

### *3.2.5 Results for Stage 3*

The themes emerged from the discussion of the expert panel review were categorised as the outline of "the standards" and the applicability of "the standards". Details of the results will be elaborated under the themes mentioned.

#### 3.2.5.1 Themes Emerging from the Expert Panel Review

**A) The outline of "the standards"**

The panel felt that the competency document addressed important issues and articulated its goals and design clearly, although concerns were expressed regarding the scope and terminology. The panellists suggested minor changes to improve clarity, such as rewording of some of the statements.

***1) The scope and terminology***

Panellists expressed concern about the term "Prescribe Medicines". They maintained that 'prescribing' was just one aspect of the overall prescribing process and therefore that the functional area should be expressed in broader terms, not just focused on the act of writing a prescription for medication. There was also concern that this term would imply independent prescribing and that it would be more appropriate to specify 'supplementary prescribing'. They felt that this should be defined very clearly, as should the distinction between simply transcribing medication orders and actual prescribing.

The panellists also expressed concern about the intended scope of "the standards" whether it was meant to cover only supplementary prescribing or also allow for independent prescribing. Panellists cautioned that some terms needed to be clearly defined so that "the standards" would be able to facilitate the measurement of what is supposed to be measured e.g. screening and monitoring, which should not be interpreted as overlapping with the physician's diagnostic role.

> *"... prescribing is just one aspect in the whole process… we should probably use the broader terms not just narrow it down to prescribing."* **(Panellist 4)**

> *"I think it is actually quite crucial. I think we need a broad definition of supplementary prescribing but you do not [have one]."* **(Panellist 1)**

> *"What I am saying is [with] this document we need to understand where we are suggesting the limits are. Because if you put something in about people doing 'physical examination' that's a very crude term."* **(Panellist 1)**

### *2) The structure of "the standards"*

The panellists commented that they had found it difficult to compare the UK competency framework document, the Australian document and "the standards" when trying to determine whether all the relevant aspects of the UK document were covered. One panellist expressed concern that there appeared to be many areas covered in the UK document that were not apparent in "the standards".

Panellists expressed uncertainty as to whether or not "the standards" for prescribing should be integrated into the existing "Competency Standards for Pharmacists in Australia 2003" document. Some panellists felt that this was the appropriate approach, but others disagreed, arguing that a stand-alone document would be clearer.

If the draft of "the standards" were to be integrated into the existing document, panellists felt that links should be clearly articulated so that aspects crucial to prescribing, such as negotiation/communication skills, would be made obvious to the reader or user.

> *"If it is already in the Australian document but is crucial to this functional area, the link needs to be made. It is not obvious to the reader or to the user … People take that chapter on primary care and read that or they ignore the chapter on primary care because they don't do primary care. So you can't assume that people have read the whole thing ... So you've got to make sure that it is all there."* **(Panellist 1)**

### B) The applicability of "the standards"

The panel expressed the belief that the document provided accurate information on the parameters that it was supposed to measure, but that its usefulness was not able to be adequately determined without illustrative case scenarios. They suggested that appropriate context-specific scenarios would enable better understanding of the applicability of the competencies in community or hospital settings e.g. repeat prescribing would be more relevant in the community setting and discharge prescribing in the hospital setting.

#### *1) The proposed prescribing model*

Panellists suggested prescribing models that might be applicable in the current Australian setting, including pre-admission and in-patient prescribing for regular medications, discharge prescribing, emergency prescribing or prescribing by protocol. Clear linking to the competency standards was seen to be important to describe the competencies for these various roles. One panellist with experience of the UK system commented that, in his experience, not all UK pharmacists may be prepared to undertake fully independent prescribing.

One panellist suggested that a stand-alone document, not linked to the "Competency Standards for Pharmacists in Australia 2003" document, but focused on the use of medicines and interprofessional interactions would have the potential for application to any health professional involved in prescribing.

> *"That's the reason to make it a stand-alone document that is not pharmacist specific but the focus is on the use of medicine and the interaction between that professional and whoever is managing things and the patient. Could leave the word 'pharmacist' out of it."* **(Panellist 1)**

### *3.2.6 Discussion for Stage 3*

The development of "the standards" for pharmacist prescribing in Australia is an important process. This study utilised related documents with different styles and backgrounds to produce a new document suitable for use in the Australian setting. This process contributed to some concerns raised by the expert panellists, due to lack of familiarity with some of the documents involved.

Some comments made by panellists when comparing the UK competency framework and the Australian document related directly to the different formats in which the two documents are written. Omissions from the new functional areas were intended, as many of these aspects were already covered under other functional areas in the Australian document; however, this highlights the difficulty of portraying the full scope of required competencies. Panellists expressed difficulty comprehending the scope of "the standards" and locating and comparing important elements from the UK document. The researchers had reworded some of the statements in the UK document to conform to the structure of the "Competency Standards for Pharmacists in Australia 2003" without changing the intrinsic meaning, which may have contributed to this difficulty.

A specific area of concern involved standards for communication skills that were considered to be adequately described in the existing Australian competency document. Based on the panellists' feedback, it was agreed that specific skills pertaining to consultation should be included in "the standards". Prescribing courses in the UK have highlighted extended consultation skills as an important area. Supplementary prescribers viewed that exploratory, collaborative skills were not usually involved in a traditional pharmacist consultation.[99]

Concerns relating to the applicability of "the standards" were addressed by addition of a Ranges of Variables, as in other areas within the Australian document, to place the competency unit into appropriate practice contexts to improve understanding. The term "Prescribe Medicines" was considered to be the most appropriate term, as, according to the

ANTA guidelines, the description of a competency requires use of an active verb that is broad enough to encompass all the elements required for its action and no more suitable term was found.[91] In May 2012, NPS Better Choices ▸Better Health launched a broad national framework for prescribing competencies which uses a similar term.[96]

Some panellists expressed the view that "the standards" for pharmacist prescribing should be a stand-alone document, similar to the UK Competency Framework. Different sets of competencies have been developed for pharmacists and for other health professional prescribers in UK at the time this study was conducted.[85,86,100,101] The decision to keep the competency standards for prescribing integrated is supported by consideration the precedent set by the AACP which integrated competency standards for Home Medicines Review (HMR) into the Competency Standards for Pharmacists in Australia format. The aim of producing the draft document of "the standards" was to establish the concept within the Australian pharmacy profession. It is therefore important that these competency standards should be part of the Competency Standards for Pharmacists in Australia document so that they are accessible by the whole profession. This means that there is no need to repeat sections already in the current document, although consideration could be given to cross-linking relevant existing competencies with the "Prescribe Medicines" functional area.

The panel also suggested that as other nonmedical groups were involved in prescribing, the competency standards could be written to include these groups. To write competencies for all prescribing professions would require a broader understanding of how prescribing would be undertaken within each professional context. While this idea is laudable it was not the aim of the current project.

### *3.2.7 "The standards" Amendment*

As mentioned earlier, all the panellists agreed on the importance of the competencies listed in "the standards". As a result of issues that arose in certain areas, amendments were made to the first draft to change the order of the statements and to add extra competency units.

The final draft of the competency units comprises 'Prescribe effectively, Prescribe to the accepted standard, Prescribe safely, Prescribe professionally, Participate in the development of prescribing practice, Apply communication skills and Provide medicine, health information and education' as listed in Section 3.2.7.1. **Table 13** summarises the changes in the amended version.

**Table 13: Comparison of the first draft and the amended version of "the standards"**

| **Competency Unit (First draft)** | **Competency Unit (Amended version)** |
|---|---|
| **9.1 Prescribe Safely** | **9.1 Prescribe Effectively** |
| **Elements**<br>• Review prescribing process<br>• Safety issues in prescribing<br>• Apply knowledge and skills to prescribe in an appropriate manner<br>• Assess clinical condition<br>• Use appropriate techniques and equipment | **Elements**<br>• Confirm availability of medicines<br>• Update knowledge<br>• Prescribe in appropriate manner |
| **9.2 Prescribe Effectively** | **9.2 Prescribe to the Accepted Standard** |
| **Elements**<br>• Confirm availability of medicines<br>• Update knowledge | **Elements**<br>• Review patient clinical problem<br>• Review therapy options<br>• Select treatment |
| **9.3 Prescribe Professionally** | **9.3 Prescribe Safely** |
| **Elements**<br>• Work within professional, regulatory and organisational standards<br>• Work in partnership towards benefit of patients<br>• Behave in a professional and ethical manner | **Elements**<br>• Review prescribing process<br>• Update patient information<br>• Safety issues in prescribing<br>• Apply knowledge and skills to prescribe in an appropriate manner<br>• Assess progress of clinical condition |
| **9.4 Prescribe to the Accepted Standard** | **9.4 Prescribe Professionally** |
| **Elements**<br>• Review patient clinical problems | **Elements**<br>• Works within professional, regulatory and organisational standards<br>• Work in partnership towards benefit of patients |

| Competency Unit (First draft) | Competency Unit (Amended version) |
|---|---|
| | • Behave in a professional and ethical manner<br>• Takes responsibility for own continuing professional development in relation to prescribing |
| **9.5 Participate in the Development of Prescribing Practice** | **9.5 Participate in the Development of Prescribing Practice** |
| • Participate in the review of prescribing practice | • Participates in the review of prescribing practice<br>• Develop own networks<br>• Use tools to improve practice<br>• Reports prescribing errors |
| | **9.6 Apply Communication Skills** |
| | • Understand and respect the 'uniqueness' of individuals.<br>• Undertakes the consultation in an appropriate manner<br>• Negotiates an outcome<br>• Gives clear instructions about the medication<br>• Follow up |
| | **9.7 Provide Medicines and Health Information and Education** |
| | • Understands the readily available information sources<br>• Use relevant, up to date information<br>• Critically appraises the validity of information sources<br>• Applies information to the clinical context<br>• Reviews evidence |

### 3.2.7.1 Final Version of "the standards" after the Expert Panel Review

**Proposed Competencies for Supplementary Prescribing**

Functional area 9 applies to pharmacists who wish to obtain additional accreditation for advanced practice in supplementary prescribing. This is an additional functional area that may be added to the existing "Competency Standards for Pharmacists in Australia 2003"[92] document. Listed below **Table 14** are major competencies that are relevant to prescribing that are included in the current "Competency Standards for pharmacists in Australia 2003"[92] document. All pharmacists wishing to undertake advanced practice in supplementary prescribing would be required to be competent in these areas which need to be applied in the prescribing context.

**Table 14: Current major competency areas relevant to prescribing by pharmacists**

| **Functional Area 1: Practise pharmacy in a professional and ethical manner** | |
|---|---|
| **Competency Unit** | 1.1 Practise legally |
| | 1.2 Practise to accepted standards |
| | 1.3 Pursue life-long professional learning and contribute to the development of others |
| **Functional Area 2: Manage work issues and interpersonal relationships in pharmacy practice** | |
| **Competency Unit** | 2.1 Apply communication skills |
| | 2.2 Participate in negotiations |
| | 2.3 Address problems |
| | 2.4 Manage conflict |
| | 2.5 Apply assertiveness skills |
| **Functional Area 3: Promote and contribute to optimal use of medicines** | |
| **Competency Unit** | 3.1: Participate in therapeutic decision making |
| | 3.2: Provide ongoing pharmaceutical management |
| | 3.3: Promote rational drug use |
| **Functional Area 6: Provide primary health care** | |
| **Competency Unit** | 6.1: Assess primary health care needs |
| | 6.2: Address primary health care needs of patients |
| | 6.3: Promote good health in the community |

| **Functional Area 7: Provide medicines and health information and education** | |
|---|---|
| **Competency Unit** | 7.1 Retrieve information |
| | 7.2 Evaluate and synthesise information |
| | 7.3 Disseminate information |
| **Functional Area 8: Apply organisational skills in the practice of pharmacy** | |
| **Competency Unit** | 8.1 Plan and manage work time |
| | 8.2 Manage own work contribution |
| | 8.3 Supervise staff |
| | 8.4 Work in partnership with others |
| | 8.5 Plan and manage pharmacy resources |
| | 8.6 Plan and manage pharmacy services and the work environment |

**FUNCTIONAL AREA 9: PRESCRIBE MEDICINES**

Prescribe Medicine is defined as the collaborative partnership between an independent prescriber and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement. In a supplementary prescribing partnership, the independent prescriber makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing ongoing care within agreed parameters, to the supplementary prescriber. Supplementary prescribers contribute to this aim by monitoring patients with long term conditions and prescribing medicines that are appropriate for the patient's condition. They are allowed to order in writing the supply of a medicine for a named patient after the diagnosis has been made by the independent prescriber. Pharmacists who wish to undertake this supplementary prescribing need to be competent in various areas as listed in this document. This functional area includes competency units that address the clinical skills and knowledge pharmacists need to perform supplementary prescribing.

**Competency Unit 9.1 Prescribe Effectively**

This functional area includes competency units that address the skills and knowledge that pharmacists need to acquire to prescribe in the most effective way.

| **Element (3)** | **Performance Criteria (6)** | **Evidence Guide (11)** |
|---|---|---|
| Confirm availability of | Establishes any special circumstances or supply arrangements impacting | Ability to describe the requirements (including legal requirements where relevant) applicable to medicines with specific terms of supply (e.g. |

| Element (3) | Performance Criteria (6) | Evidence Guide (11) |
|---|---|---|
| medicines | on availability of the prescribed medicine | PBS and private prescriptions, Section 100 supplies, Special Access Scheme (SAS) and emergency supply medicines, hospital formulary versus non-formulary medicines |
| | Suitable products held in stock or available from a supplier | Ability to interpret brand bioequivalence notes in PBS Schedule of Benefits for products from different manufacturers<br><br>Ability to use authoritative reference sources and supplier catalogues to clarify required product and its availability |
| | Ensures that patients can access ongoing supplies of their medication | Ability to identify factors which may affect the ongoing supply of medication<br><br>Ability to identify ways to avoid the factors which may affect the ongoing supply of medication |
| | Understands how medicines are licensed, sourced, supplied and monitored (e.g. how ADRs are reported) and contributes to information on frequency and nature of adverse drug reactions associated with drug use | Ability to describe how medicines are licensed, supplied and monitored<br><br>Ability to demonstrate applied knowledge of how medicines are licensed, supplied and monitored<br><br>Ability to describe and/or use formal ADR reporting systems (e.g. institutional reporting systems) or report to Adverse Drug Reaction Advisory Committee (ADRAC) of the Therapeutic Goods Administration (TGA) |
| Update knowledge | Maintains an up to date knowledge of relevant products | Ability to demonstrate up to date knowledge of doses, formulations, pack sizes, storage conditions and cost of medication |
| Prescribe in appropriate manner | Understand the cost concern in prescribing | Ability to explain the importance of cost effectiveness in prescribing<br><br>Ability to demonstrate the knowledge of cost maintenance in prescribing |

**Range of Variables**

This work environment applies to supplementary prescribers (pharmacists) practising in any setting.

Availability of the medication and information on the relevant products are essential to prescribing in the most effective way. This is to ensure that patient should be able to receive the appropriate medication. The information can be acquired from various resources depending on the setting. Information on updates of relevant products should also be made available.

**Competency Unit 9.2 Prescribe to the accepted standard**

This competency unit describes various standards that pharmacists need to achieve when reviewing a patient's clinical problem before making the decision to prescribe. Pharmacists need to have up-to-date clinical and pharmaceutical knowledge relevant to their own area of practice.

| Element (3) | Performance Criteria (14) | Evidence Guide (27) |
|---|---|---|
| Review patient clinical problem | Understands the conditions being treated, their natural progress and how to assess their severity | Ability to understand the pathophysiology of the medical conditions/diseases of patients whose medication is reviewed and how it may influence optimal choices of medicines<br><br>Ability to explain clinical aspects of diseases/medical conditions of individual patients and the signs and symptoms commonly associated with them |
| | Identifies the nature, severity and significance of the clinical problem | Review/identifies nature of severity and significance of clinical problems |
| Review therapy options | Understands the pharmacological and/non pharmacological approaches to modifying conditions | Ability to explain the nonpharmacological approach to promote health, desirable and undesirable outcomes<br><br>Ability to explain the medication treatment regimen in terms of the pharmacological |

| Element (3) | Performance Criteria (14) | Evidence Guide (27) |
|---|---|---|
| | | actions and therapeutic uses of the medications and the medical conditions/ diseases of the patient to promote health, desirable and undesirable outcomes |
| | Understands the mode of action and pharmacokinetics of medicines and how these mechanisms may be altered | Ability to identify the pharmacokinetics parameters of medicines and factors which may affect the medication<br><br>Ability to identify patient factors such as medical conditions/ disease states, age, weight, allergies, pregnancy and lactation that are likely to impact on the pharmacokinetics of the medication |
| | Identifies clinically significant potential or actual drug related problems in the current medication treatment | Ability to use professional judgement to identify potential or actual medication related problems in the current medication treatment that are likely to be clinically significant (e.g. interactions, contraindications, incompatibilities, allergies, adverse drug reactions)<br><br>Ability to demonstrate the understanding of how to avoid/minimise and manage them |
| | Requests, and interprets relevant investigations and evaluate the significance of common laboratory tests and investigations performed on individual patients | Ability to describe the use and limitations of commonly ordered laboratory tests and investigations that influence medication treatment<br><br>Ability to order laboratory tests relevant to the area of practice<br><br>Ability to assess the clinical significance to medication treatment of results of common laboratory tests and investigations that are outside the normal or desired range (e.g. renal function, liver function and serum electrolytes) |

| Element (3) | Performance Criteria (14) | Evidence Guide (27) |
|---|---|---|
| | Considers no treatment, nondrug and drug treatment options (including referral and preventive measures) | Ability to identify no treatment options, pharmacological and nonpharmacological treatment options/strategies as well as those for which there may be a relative or absolute contraindication<br><br>Ability to discuss on no treatment or treatment options in terms of nature of coexisting diseases/ conditions and current medication treatment, presenting symptoms, their duration and the extent to which previous efforts have been successful |
| | Assesses the effect of multiple pathologies, existing medication and contraindications on treatment options | Ability to describe the impact of existing factors such as comorbidities and current medication that will contribute to the selection of appropriate treatment options |
| | Assesses the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment) | Ability to identify the impact for the patient of receiving or not receiving the treatment choice |
| | Applies the principles of evidence-based medicine, and clinical cost effectiveness | Ability to describe and apply a logical and effective search strategy for accessing clinical documentation required to support a specific review (to understand how the drug should be used and why and to access the most relevant guidelines, standards and/or criteria)<br><br>Ability to consider cost of medication on choosing therapy |
| Select treatment | Selects the most appropriate drug, dose and formulation for the individual patient and prescribes appropriate quantities | Ability to determine the most appropriate drug, dosage and formulation for the patient |

| Element (3) | Performance Criteria (14) | Evidence Guide (27) |
|---|---|---|
| | Establishes and maintains a plan for reviewing the therapeutic objective or end point of treatment | Ability to develop an individualised plan for a patient<br><br>Ability to apply the individualised plan for a patient |
| | Monitors effectiveness of treatment and potential unwanted effects and assess whether medication treatment is achieving therapeutic goals/ outcomes | Ability to describe disease processes and the relevance of monitoring activities for assessing disease management<br><br>Ability to clearly describe the therapeutic goals for individual patients whose treatment is being monitored (e.g. desired INR, blood glucose, cholesterol or blood pressure reading)<br><br>Ability to collaborate with the patient and other healthcare professionals to share information relevant to assessment of whether treatment is achieving therapeutic goals |
| | Makes changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences | Ability to identify factors which affect patients clinical outcome while receiving the treatment<br><br>Ability to evaluate factors which affect patients clinical outcome while receiving the treatment<br><br>Ability to identify solutions and make changes to improve patients clinical outcome while receiving the treatment |

**Range of Variables**

All supplementary prescribers practising in various settings should be responsible and capable of selecting the best possible management for the patient.

Most of the competencies listed in this competency unit are related to Functional Area 3 - Promote and contribute to optimal use of medicine. In this new role pharmacists accept responsibility by reviewing the patients' clinical conditions and selecting the best therapy options for the patient with the agreement of the independent prescriber according to the clinical management plan. Ordering and interpretation of advanced laboratory tests are more applicable in the hospital setting.

The supplementary prescribers are also responsible for evaluating the patients' management plan and following up on the patients' management. In this overall setting, patient consent is essential to maintain the agreement before the management being made by the supplementary prescriber.

**Competency Unit 9.3 Prescribe Safely**

This unit is concerned with pharmacists' ability to prescribe in an appropriate manner with consideration of their own limitations. It encompasses skills and knowledge as well as responsibility for safe prescribing. It does not compromise patient safety and justifies prescribing decisions.

| **Element (5)** | **Performance Criteria (17)** | **Evidence Guide (27)** |
|---|---|---|
| Review prescribing process | Knows the limits of own knowledge and skill, and works within them | Ability to identify and describe the work tasks or aspects of practice for which they are responsible<br><br>Demonstrated ability to take responsibility for the outcomes of their work effort (direct and indirect) and respond to poor outcomes or situations likely to lead to poor outcomes (e.g. errors or misinformation) |
| | Knows when and how to refer to, or seek guidance from, the independent prescriber, another member of the team or a specialist | Ability to refer patients appropriately to the independent prescriber for further management when needed based on the supplementary prescribing guideline |
| | Prescribes a medicine using adequate, up to date knowledge | Ability to apply knowledge of the actions, indications, contraindications, interactions, cautions, dose and side effects of the medication when making a decision to |

| Element (5) | Performance Criteria (17) | Evidence Guide (27) |
|---|---|---|
| | | prescribe for a patient, based on the supplementary prescribing guideline |
| | Decides the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine and checks doses and calculations to ensure accuracy and safety | Ability to decide on the appropriateness of the prescribed drug, dose form and dosing regimen for a specific patient, taking into account relevant patient and drug factors |
| | Makes accurate, clear and timely records | Ability to describe the important factors/requirements to be written in the patient notes<br><br>Ability to communicate with other members of the health professional team about care provided to the patient for information sharing |
| Update patient information | Takes a comprehensive history | Ability to develop an accurate medication history from the patient and/or carer (and other healthcare professionals and patient notes when necessary) that includes detail of current and previous medications, relevant medical and social history and test results, previous adverse drug reactions and known allergies and sensitivities<br><br>Ability to describe what additional information needs to be obtained and why it is relevant to selecting an appropriate therapy (e.g. nonprescription and complementary therapies to complete medication record) |
| | Assess and interpret all relevant patient records to ensure knowledge of the patient's management | Ability to use readily available information sources to clarify or confirm information or meet additional information needs |

| Element (5) | Performance Criteria (17) | Evidence Guide (27) |
|---|---|---|
| | | Ability to discuss the value and limitations of readily available information sources for supporting the development of a complete and accurate patient history |
| Safety issues in prescribing | Keeps up to date with advances in practice and emerging safety concerns | Ability to describe the common types of medication errors with regards to prescribing<br><br>Ability to apply knowledge of safety concerns to prescribing practice |
| | Establishes systems on responding when error occurred during prescribing | Ability to describe the steps need to be taken when error occurred during the prescribing process<br><br>Ability to describe the steps need to be taken to minimise the possible error due to prescribing |
| | Establishes systems for reporting and responding to medication errors | Ability to describe error reporting systems and documentation in terms of key information elements needed to respond to an error to prevent or minimise the risk of recurrence (e.g. what happened, what were the contributing factors, what action has already been taken) |
| | Generates legible, clear and complete prescriptions, which meet legal requirements | Ability to explain the key legal requirements of a valid prescription as specified by relevant State or Territory legislation (e.g. drugs, poisons and controlled substances legislation, Pharmacy Act and Regulations) and National Health Act and Regulations<br><br>Ability to describe and/or promptly access information on the professional conventions and obligations applicable to prescribing, including for those medicines that are subsidised under the PBS |

| Element (5) | Performance Criteria (17) | Evidence Guide (27) |
|---|---|---|
| | Uses documentation and systems that support prescription validation | Ability to develop, review and maintain documentation, including standard operating procedures, for prescription validation (PBS claims rules, contacts for suspected fraudulent prescriptions) |
| Apply knowledge and skills to prescribe in an appropriate manner | Makes prescribing decisions with confidence and competence | Ability to demonstrate knowledge contributing to personal prescribing decision with confidence |
| Assess progress of clinical condition | Understands the disease state management | Ability to describe factors which may influence the management of current disease states |
| | Understands the conditions being treated, their natural progress and how to assess their severity | Ability to understand the pathophysiology of the medical conditions/diseases of patients whose medication is reviewed and how it may influence optimal choices of medicines<br><br>Ability to explain clinical aspects of diseases/medical conditions of individual patients and the signs and symptoms commonly associated with them |
| | Performs clinical assessment for various clinical conditions in appropriate areas | Ability to perform clinical assessment in accordance with Clinical Management Plan<br><br>Ability to monitor of clinical progress |
| | Use appropriate techniques and equipment | Ability to describe the knowledge and requirements for use of various medical equipment and devices<br><br>Ability to perform clinical assessment using specific medical equipment or devices |

**Range of Variables**

All supplementary prescribers (pharmacists) need to work in the appropriate manner. In this competency unit, supplementary prescribers are expected to work in an ethical manner. Understanding the responsibility for the decisions made as a supplementary prescriber is essential to maintain patient safety as the first priority.

In terms of ongoing clinical assessment, supplementary prescribers in the hospital setting are expected to have more advanced clinical skills according to their specialisation or area of practice. In the community setting, supplementary prescribers have the role of screening and more generalised clinical skills.

All of the supplementary prescribers are expected to know the actions to be taken if an error occurs in the prescribing process. This is the most crucial part in this competency unit to maintain patient safety.

**Competency Unit 9.4 Prescribe Professionally**

This unit is concerned with pharmacists' ability to prescribe in the professional way. It encompasses the standards of practice that pharmacists need to follow to prescribe professionally.

| **Element (4)** | **Performance Criteria (13)** | **Evidence Guide (22)** |
|---|---|---|
| Works within professional, regulatory and organisational standards | Accepts personal responsibility for own prescribing | Ability to describe own responsibility towards prescribing<br><br>Ability to describe the legal and ethical implications of own responsibility towards prescribing |
| | Makes prescribing decisions based on patient-related factors | Ability to recognise and describe the prescribing decision based on the needs of patients and not the personal considerations of the prescriber<br><br>Ability to apply the knowledge of prescribing based on the needs of patients and not the personal considerations of the prescriber |

| Element (4) | Performance Criteria (13) | Evidence Guide (22) |
|---|---|---|
| | Prescribes to the accepted standards | Ability to apply current professional and organisational codes of practice/standards to prescribing |
| Work in partnership towards benefit of patients | Negotiates with members of the prescribing team | Ability to demonstrate negotiation skills in communication with the independent prescriber and the patient to develop and agree on clinical management plans |
| | Ensures that the patient has agreed to be managed within a prescribing partnership | Ability to explain to the patient what management within a prescribing partnership will mean for their care |
| | Understands the cultural and religious implications of the diagnosis/ prescribing | Recognises and respects the values, beliefs and cultural backgrounds of patients and other health professionals<br><br>Demonstrated sensitivity to and ability to elicit information relating to values, beliefs and cultural backgrounds that may influence the way in which professional services are provided<br><br>Demonstrated positive attitude to providing flexibility in the way in which services are provided to accommodate as far as practicable the values, beliefs and cultural backgrounds of patients and other health professionals |
| Behave in a professional and ethical manner | Understands how current legislation affects prescribing practice | Ability to describe the legislation involved in prescribing<br><br>Ability to prescribe in a legal manner |
| | Understands the scope of own prescribing responsibility | Ability to describe and recognise own role in the prescribing decision within the context of a shared clinical management plan |

| Element (4) | Performance Criteria (13) | Evidence Guide (22) |
|---|---|---|
| | | Ability to apply the knowledge of own role in the prescribing decision within the context of a shared clinical management plan |
| | Maintains patient confidentiality | Ability to explain the steps taken to protect patient privacy and maintain confidentiality of personal information<br><br>Ability to demonstrate the procedure for patient consent before prescribing according to the clinical management plan |
| | Maintain security of prescribing stationery or computer security systems | Ability to understand the importance of keeping prescription stationery/systems secure<br><br>Ability to explain the steps needed to be taken when a prescription pad is lost or computer security is breached |
| | Maintain the security and confidentiality of data being transferred | Ability to describe the steps that need to be taken during the data transferring to maintain the confidentiality of data only by the appropriate personnel<br><br>Ability to describe the steps need to be taken to minimise the breaching on data transferring |
| | Recognises and deals with pressure that might result in inappropriate prescribing | Ability to identify the implications/consequences of inappropriate prescribing (e.g. pharmaceutical industry, patients and colleagues)<br><br>Ability to identify the solutions of inappropriate prescribing (e.g. pharmaceutical industry, patients and colleagues) |

| Element (4) | Performance Criteria (13) | Evidence Guide (22) |
|---|---|---|
| Takes responsibility for own continuing professional development in relation to prescribing | Refer to the elements, performance criteria and evidence guides in Functional area 1, Competency Unit 1.3 | |

**Range of Variables**

All supplementary prescribers (pharmacists) need to work with professional standards. In this competency unit, supplementary prescribers are expected to work in a professional and ethical manner for benefit of the patient.

Professional standards and guidelines issued by professional associations and pharmacy registering authorities provide the framework to guide professional practice. Continuous learning and development of professional capability is central to pharmacists' professional practice and ability to manage career change. Identification of learning needs may arise from the inclusion of new roles (supplementary prescriber) into an existing position statement or from pharmacist planning for career advancement (supplementary prescriber).

Continuous Professional Development (CPD) is essential for the advanced role of supplementary prescribing. Pharmacists are able to attend CPD conducted by professional associations or pharmacy registering authorities. Receiving and giving performance feedback is another way in which pharmacists can identify their learning and development needs and assist others to identify their own needs.

The elements, performance criteria and evidence guides under Competency Unit 1.3 'Pursue life-long professional learning and contribute to the development of others' are relevant here. The major difference is the continuous professional development under this competency unit will be tailored to the prescribing context.

**Competency Unit 9.5 Participate in the development of prescribing practice**

This competency unit describes ways to improve prescribing practice from one's own experience and that of others. The development of a network is essential in establishing support and learning for prescribing practice.

| Element (4) | Performance Criteria (8) | Evidence Guide (22) |
|---|---|---|
| Participates in the review of prescribing practice | Learns and changes from reflecting on own practice | Ability to explain own prescribing practice<br><br>Ability to identify the strength and weaknesses of own prescribing practice<br><br>Ability to develop and change own prescribing practice |
| | Shares and debates own prescribing practice | Ability to identify the strengths and weaknesses of own prescribing practice<br><br>Ability to describe the factors which contribute to the strengths and weaknesses of own prescribing practice<br><br>Ability to identify the solutions to problems with own prescribing practice<br><br>Ability to apply the solutions to the problems with own prescribing practice<br><br>Ability to explain the strengths and weaknesses and ways to manage them for own prescribing practice<br><br>Response and acting on the feedback on own prescribing practice |
| | Shares and debates others prescribing practice | Ability to identify the strengths and weaknesses of the prescribing practice of others<br><br>Ability to describe the factors which contribute to the weaknesses of others' prescribing practice |

| Element (4) | Performance Criteria (8) | Evidence Guide (22) |
|---|---|---|
| | | Ability to identify the solutions to the problems with the prescribing practice of others<br><br>Ability to apply the solutions to the problems of the prescribing practice of others<br><br>Ability to explain the strengths and weaknesses and ways to manage them for others' prescribing practice |
| | Challenge inappropriate practice constructively | Ability to describe and apply strategies known to be effective in changing or reinforcing changes in prescribing or other drug related clinical practice behaviours |
| Develop own networks | Establish the support, reflection and learning from own networks | Ability to support the learning and professional development of others and oneself in the workplace<br><br>Ability to provide and receive professional advice and guidance to others consistent with the limits of own expertise |
| | Establishes multiprofessional links with practitioners working in the same specialist area | Demonstrated positive attitude to working collaboratively with others, including as a member of a team<br><br>Ability to promote and engender teamwork with others in the workplace |
| Use tools to improve practice | Understands and knows the types of dissemination tools/strategies that can be used to share information on review findings and recommendations for change | Ability to describe a range of dissemination tools or strategies |
| Reports prescribing errors | Reports prescribing errors and near misses, reviews practice to prevent | Establishes systems for reporting and responding to medication errors |

| Element (4) | Performance Criteria (8) | Evidence Guide (22) |
|---|---|---|
| | recurrences | Ability to describe error reporting systems and documentation in terms of key information elements needed to respond to an error to prevent or minimise the risk of recurrence (e.g. what happened, what were the contributing factors, what action has already been taken) |

**Range of Variables**

In this work environment all supplementary prescribers (pharmacists) are encouraged to learn from their own and others' prescribing practice.

Development of a network is essential for the reflection of one's own and others' prescribing patterns. The role of mentor (independent prescriber) is to assist supplementary prescribers in this learning process.

In the hospital setting, supplementary prescribers are expected to learn and develop their prescribing practice based on their area of specialisation in their daily practice.

**Competency Unit 9.6 Apply communication skills**

This unit addresses the ability of pharmacists to communicate effectively during the prescribing process. The aim is to establish a relationship based on trust and mutual respect and sees patients as partners in the consultation.

| Element (5) | Performance Criteria (10) | Evidence Guide (15) |
|---|---|---|
| Understand and respect the 'uniqueness' of individuals | Understand patients' beliefs, ideas, concerns and expectations | Ability to demonstrate sensitivity to the needs, values, beliefs and cultural background of others |
| | Understands the cultural and religious implications of the diagnosis/ prescribing | Recognises and respects the values, beliefs and cultural backgrounds of patients and other health professionals |

| Element (5) | Performance Criteria (10) | Evidence Guide (15) |
|---|---|---|
| | | Demonstrated sensitivity to and ability to elicit information relating to values, beliefs and cultural backgrounds that may influence the way in which professional services are provided<br><br>Demonstrated positive attitude to providing flexibility in the way in which services are provided to accommodate as far as practicable the values, beliefs and cultural backgrounds of patients and other health professionals |
| Undertakes the consultation in an appropriate manner | Undertakes the consultation in an appropriate setting and adapts to meet the needs of different patients and understands that special communication needs exist in some circumstances | Ability to identify and/or describe circumstances where special communication needs exist, especially for patients and carers (e.g. culturally and linguistically diverse background, emotional distress, deafness, blindness, mental incapacity, communication through a third party) |
| | Deals sensitively with patients' emotions and concerns | Ability to demonstrate sensitivity to patient needs on the clinical management<br><br>Ability to demonstrate a relationship which does not encourage the expectation that a prescription will be supplied |
| | Explains the nature of the patient's condition, the rationale behind and potential risks and benefits of management options | Demonstrate the capability to ensure that the patient and/or carer understand the reasons for the plan<br><br>Ability to communicate effectively with patient and/or carer to clearly explain the reasons for and potential benefits of agreed follow-up |
| | Enables patients to make informed choices about their management | Ability to demonstrate respect for the patient's right to participate in decision making |

| Element (5) | Performance Criteria (10) | Evidence Guide (15) |
|---|---|---|
| | | Ability to discuss the importance of consumer involvement in health service delivery and their role as partners in delivery of care (e.g. their right to control their personal information and make their own choices about who to involve in their care and whether to accept or decline advice, services or products) |
| Negotiates an outcome | Negotiates an outcome of the consultation that both patient and prescriber are satisfied with | Ability to recognise and describe an outcome that is mutually acceptable to those involved in the negotiation process |
| Gives clear instructions about the medication | Encourages patients to take responsibility for their own health and self-manage their conditions | Ability to explain to the patient the impact of not taking care of their health and current management for the disease condition |
| | Assist patient understanding of their medical condition and/or medication treatment | Ability to provide concise, accurate and relevant verbal and/or written health and medicines information (including reinforcement of indications, dosing regimen and administration technique, storage requirements and adverse effects) to patients to meet their information needs |
| Follow up | Checks the patients' understanding and commitment to their management and follow-up | Ability to communicate effectively with patient and/or carer to clearly explain the reasons for and potential benefits of agreed follow-up |

**Range of Variables**

All of the competencies addressed in this competency unit are in Competency Unit 2.1 'Apply communication skills' in the 'Competency Standards for Pharmacists in Australia 2003'. The major difference addresses the advanced skills required for the new consultation role of supplementary prescribers.

The type of information and negotiation shared between the supplementary prescribers, independent prescribers, patients and the prescribing team will be different with the introduction of this new role (supplementary prescriber).

**Competency Unit 9.7 Provide medicines and health information and education**

This competency unit address the role pharmacists have in researching and delivering medicines and/or health information and education to other health professionals/facility personnel, patients and members of the general public.

| Element (5) | Performance Criteria (10) | Evidence Guide (17) |
|---|---|---|
| Understands the readily available information sources | Understands the advantages and limitations of different information sources | Ability to list and describe the scope (e.g. their usefulness and limitations) of legally required or recommended texts (e.g. APF, AusDI, Martindale, Australian Prescription Products Guide) |
| | Knows what other information sources can provide relevant information | Ability to discuss the independence, appropriateness of value of other reference materials (e.g. Merck Manual, Australian Medicines Handbook, AusDI and Therapeutic Guidelines) for types of information most usually sought<br><br>Ability to access appropriate other reference sources (hard copy and electronic) both directly and indirectly via other location |
| Use relevant, up to date information | Formulates recommendations for changes to medication treatment against the latest evidence and information on new medicines | Ability to access information on recent research and/or new drugs released to treat conditions or diseases commonly encountered in a specialised area of practice (e.g. gerontology, cardiology, endocrinology, intensive care or paediatrics) |
| Critically appraises the validity of information sources | Critically evaluates the research findings | Demonstrated understanding of key economic concepts such as cost effectiveness and cost benefit |

| Element (5) | Performance Criteria (10) | Evidence Guide (17) |
|---|---|---|
| | | Ability to assess evidence for strength, size of effect and relevance<br><br>Ability to identify and differentiate between the promotional literature and research |
| | Uses primary and secondary information sources to critically evaluate the efficacy and safety of medicines | Ability to interpret data relating to pharmacology, pharmacokinetics, precautions, administration and dosing, dosage forms and economic issues in primary and secondary information sources |
| | Critically evaluates the reliability and accuracy of new information in primary information sources | Ability to explain the impact of significance of new information from primary sources on therapy or dosing decisions<br><br>Ability to apply evidence to clinical/ healthcare situations to determine benefit/harm and cost effectiveness |
| | Calculates and manipulates clinical data and associated costs accurately | Demonstrated ability to carry out additional calculations and manipulations accurately |
| Applies information to the clinical context | Apply information sources Shares research findings with pharmacy colleagues and other health professionals/ facility personnel whose care processes may be affected | Ability to undertake appropriate dissemination activities from a broad range of options ('in-house' newsletters, professional journals and local, national or international meetings)<br><br>Ability to demonstrate the applied knowledge from theory into practice |
| Reviews evidence | Uses relevant patient record systems, prescribing and information systems, and decision support tools | Accesses or develops and uses tools and resources that assists the conduct of review of medications<br><br>Ability to identify existing tools (e.g. software, personal digital assistance) or develop additional resources (e.g. proforma record sheets, patient |

| Element (5) | Performance Criteria (10) | Evidence Guide (17) |
|---|---|---|
| | | information brochure) that will facilitate the conduct of reviews of medication treatment |
| | Works collaboratively with clinicians to prepare or revise medication treatment protocols, guidelines, criteria and/or standards | Ability to access relevant research and other information from which the evidence base for revision of drug treatment guidelines or protocols may be drawn<br><br>Ability to discuss and agree the evidence base for revising existing guidelines or protocols and to undertake revisions to create concise, unambiguous and easy to use treatment protocols or guidelines |

**Range of Variables**

Pharmacists have a pivotal role in promoting quality use of medicine (QUM). Therefore this competency unit highlights the importance of health information in order to prescribe appropriate, safe and effective therapeutic treatment regimens and/or treatment options for individual patients or groups of patients.

These competencies are addressed in Functional Area 7 'Provide medicines and health information and education' in the "Competency Standards for Pharmacists in Australia 2003". The major difference addresses the information required for the advanced skills needed for the new role of supplementary prescriber.

With this new role, supplementary prescribers are expected to acquire the information, evaluate and synthesise information and disseminate information reflecting one's own prescribing practice. This is the major difference that needs to be demonstrated compared to the conventional role of the pharmacist.

### *3.2.8 Conclusion*

If pharmacist prescribing is to be introduced in Australia, competency standards for this practice must be developed with broad professional consultation to ensure that they are general and flexible and can be applied to a wide variety of practice settings. From the feedback received, it was found that the outline of "the standards" needed further refinement to ensure the clarity of the statements in the document and the competency units rearranged. Amendments were consequently made. Panellists had difficulty with the applicability of "the standards" in the practice setting. Therefore, the next chapter will focus on the refinement and barriers related to the implementation of "the standards" via expert panel discussion by using case-based scenarios with different prescribing models.

# Chapter 4: Identifying the Barriers to Implementation of the Competency Standards

**Summary**

- This chapter focuses on identifying the barriers to the implementation of "the standards" in the Australian context.

- The development process comprised two stages:

  Stage 1: The development of case-based scenarios for the various prescribing models.

  Stage 2: Using case-based scenarios for the various prescribing models in order to identify acceptable prescribing models and barriers to the development and implementation of "the standards" using an expert panel.

  Stage 3: Using the same expert panel the draft of "the standards" was refined.

## 4.1 Background

The first chapter of the thesis presented a literature review related to pre- and post-implementation barriers for pharmacist prescribing. The pre-implementation barriers were associated with the early views of the stakeholders, mainly opposition or mixed opinion from medical practitioners and pharmacists (Section 1.5.1). These mixed opinions related to the changes to the profession's current responsibility, accountability and the capability of pharmacists to perform the extended role. The mixed opinions concerned misconceptions and perceived complexity of the new system, safety concerns for patients, and data transfer involved in pharmacist prescribing. Most of the studies conducted in the Australian context were focused on the views of prescribing models among the stakeholders (Section 1.6.2), potential barriers to implementation and the pilot projects in some of the potential areas (Section 1.6.3). Since most of the literature highlighted the barriers related to this new prescribing model, it is expected that similar issues might be observed in the development process of "the standards".

In the previous chapter concerns were expressed regarding the outline and the applicability of "the standards" in the practice setting. During the first expert panel discussion, (Chapter 3), feedback received from the pharmacist panellists included difficulty visualising and conceptualising the statements in the proposed standards. Due to the abstract nature of statements in "the standards", the pharmacist panellists suggested using clinical case scenarios associated with various prescribing models to further clarify and refine them.

### *4.1.1 Aim*

The aim was to develop case scenarios based on various prescribing models and use these to identify barriers related to the implementation of "the standards", in order to further refine them.

## 4.2 Method

Three steps were involved in identifying barriers to implementation of "the standards".

### *4.2.1 Step One – Identification of Case-based Scenarios for Various Prescribing Models*

The first step involved identification of case-based scenarios for the various prescribing models. This step is important to gather the stakeholders' views on the prescribing models that are currently proposed for implementation in the Australian setting. The prescribing models and cases were identified from the report by Bessell et al.[64] and modified slightly. This report, published in 2005, aimed to improve access to prescription medicine in the Australian context by investigating models of nonmedical prescribing. From the report, four pharmacy practice models were developed, as highlighted in the Chapter 1. Case-based scenarios supporting the various prescribing modes in the report were used to predict the possible future prescribing practice in the Australian context.

The case scenarios were based on prescribing by protocol, prescribing by patient group direction, prescribing by advanced practitioner, community liaison pharmacy, medication management prescribing, collaborative prescribing and independent prescribing as described in the report.[64] The cases used in these models included the management of a patient with uncontrolled asthma, palliative care management, warfarin management, a patient undergoing a surgical procedure, and other chronic disease management.

### *4.2.2 Step Two – Identifying the Acceptable Prescribing Models and Barriers*

The second step of the study involved using an expert panel including medical practitioners and pharmacists to identify acceptable prescribing models and potential barriers. As mentioned in (Section 3.2) expert panels are usually convened to deal with policy issues and can generate ideas to move a project forward, address issues which need further work behind the proposal or improve technical aspects of the project. They are commonly used to provide feedback on the work conducted. For this research, the expert

panel was used to address issues which needed further work prior to the implementation of "the standards". Identifying the acceptable prescribing models and barriers are important to ensure the future success of the prescribing model implementation.

#### 4.2.2.1 Participant Selection

Medical practitioners and pharmacists were selected by purposive sampling based on their area of specialisation related to the case scenarios identified in the first step. Since most of the cases involved respiratory conditions, in mature adults with multiple diseases, consultants specialising in this area were invited to participate in the discussion. Other consultants involved were specialists in geriatrics, and general practitioners for cases involving the community setting. Contact details were available in the public domain and potential participants were approached via email and phone. Those who agreed were sent information before the meeting to explain the purpose and expectations of the discussion (**Appendix 6** and **7**). The documents supplied were the amended version of "the standards"(Section 3.2.7.1), the UK competency framework and the Australian document.[86,92] A set of clinical case scenarios illustrating various prescribing models developed in the first stage of this study (Section 4.2.1) was also provided. The panellists were requested to go through all the documents prior to discussion at the meeting.

#### 4.2.2.2 Data Collection

The first expert panel consisted of five medical practitioners from different areas of practice and ranging from consultants to general practitioners. The second expert panel consisted of six pharmacists practising in hospital and community settings. The members of the expert panel involved in this project were different from those involved in the previous pharmacist expert panel (Section 3.2.4.1).

The researcher, assisted by an independent note-taker facilitated the expert panel meetings using structured guides (**Appendix 8** and **9**). The discussion was audio-taped and transcribed verbatim. Data were managed using NVIVO (QSR NVivo; version 2.0, QSR International) and analysed to elucidate themes.

### *4.2.3 Step Three – Review of "the standards"*

The last stage involved review of the amended version of "the standards" by the same expert panels involved in step two to establish its face and content validity, as discussed in Section 3.2. A similar method was used here, involving the second review of "the standards" by pharmacists and medical practitioners after the feedback received from the first expert panel review.

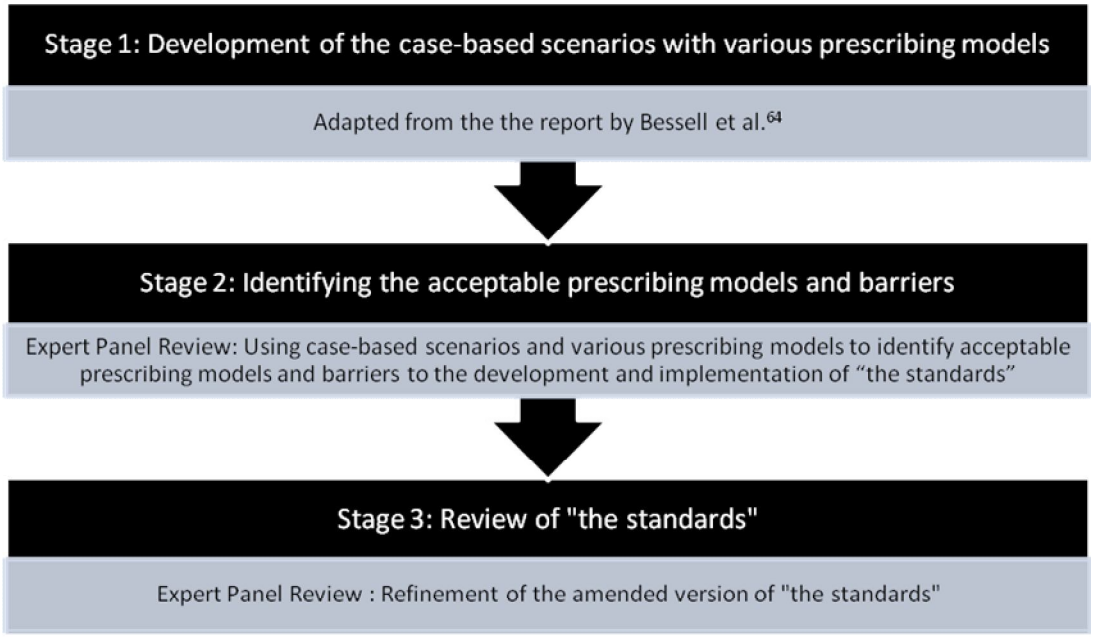


**Figure 4: The process used in identifying the barriers related to "the standards".**

## 4.3 Results

The case scenarios that illustrate various prescribing models identified in the first stage of the study are listed below.

### *4.3.1 Step One – Identification of Case-based Scenarios for Various Prescribing Models*

#### 4.3.1.1 Protocol

The following two scenarios illustrate protocol prescribing in a community and hospital settings respectively.

**Scenario 1**

Tanya is a 17 year-old who presents to the pharmacy on her way home from school. The pharmacy is close to the bus stop and is convenient to her as it is always open when she catches the bus. She requests a Ventolin (salbutamol) inhaler. David, the pharmacist, remembers that she bought one only last week. He decided that this is a good time to intervene. He asked Tanya why she needs another inhaler – did she lose the last one? She tells him that she didn't lose it, but is getting through them more frequently lately. He asked how her asthma is, and she tells him she has had frequent mild symptoms. Tanya's inhaler technique is good – he checked it last week.

When Tanya was diagnosed with asthma her GP wrote a treatment plan for her and transmitted it to David. The doctor decided that as her symptoms were mild, she could commence on a Ventolin inhaler only. If her symptoms worsened, as indicated by either increased reliance on the Ventolin or a decrease in her peak flow measurement, then she should commence fluticasone Accuhaler, twice daily. If she continued to rely on her Ventolin then a salmeterol inhaler could be added with review by her GP scheduled.

David judged that, according to her treatment protocol, she should commence treatment with a Flixotide Accuhaler twice daily. He wrote the prescription for her to have dispensed and asked her to come to see him in a few days with her peak flow meter readings to monitor her progress.

**Scenario 2**

Mr Smith is a 69 year-old smoker who has recently been hospitalised with a pulmonary embolus. His discharge medication included warfarin tablets and he has therefore been referred to David, the pharmacist at the anticoagulation clinic, for ongoing management.

His INR is to be maintained within the range 2-3. He comes to David today with an INR of 1.89. He has been taking 4mg daily. Warfarin dosage is to be adjusted using the protocol below. David therefore increases the dose to 4.5mg, by prescribing 1mg tablets and adding a half a 1mg tablet to the 2 x 2mg tablets Mr Smith has been taking, to be reviewed again next week. David makes a note in Mr Smith's 'Blue book' and an appointment for next week.

**Target INR:** ❑ 2.0-3.0 **or** ❑ 2.5-3.5

**INR Frequency:**
- ✓ Weekly after each dosage change until 2 consecutive INRs are within target range.
- ✓ Monthly thereafter as long as the INR remains in the target range.
- ✓ As necessary when a medication is started or stopped that is documented to interact with warfarin.

| **INR GOAL OF 2.0 - 3.0** | |
|---|---|
| **If INR is:** | |
| ≤1.9 | • Increase weekly dose by approximately 15-20%. |
| 2.0 - 3.0 | • No dosage change |
| 3.1 - 3.5 | • Decrease weekly dose by approximately 15-20%. |
| 3.6 - 3.9 | • Hold 1 dose, then decrease weekly dose by approximately 15-20%. |
| 4.0 - 5.9 | • Notify the physician; suggest holding 2 or more doses and decreasing weekly dose by 15-20%. |
| 6.0 - 9.9 | • Hold Warfarin. Notify the physician and suggest giving Vitamin K 1 – 2 mg orally; repeat INR in 24 hours. Further action is determined by the physician based on the INR level. |
| ≥ 10.0 | • Hold Warfarin. Notify the physician and suggest referral to acute care for Fresh Frozen Plasma. |

#### 4.3.1.2 Patient Group Direction

**Scenario 3**

At a meeting with David's local general practice clinic, The Park Medical Practice, it was determined that David could manage clients with asthma according to the National Asthma Council Australia recommendations. The doctors prefer to use dry powder inhalers for prevention and MDIs for acute symptom control. Together, David and the doctors discussed the pros and cons of different devices and of inhaled corticosteroids. The group decided that fluticasone should be the inhaled corticosteroid of choice for a variety of evidence-based reasons, but patients already stabilised on another agent should not be changed over unless they are having difficulty managing their current inhaler device. The dose and frequency and the upper dosage limit to be prescribed are documented. All patients are to be reviewed at six-monthly intervals by their GP. All aspects are documented and signed by all parties.

When Tanya Brown presents to the pharmacy requesting a Ventolin inhaler, David is concerned that she is using the medication too frequently, indicating poor control of her underlying disease. Tanya is a patient of Dr Jones at The Park Medical Practice. After checking her inhaler technique and medical history, David decided that Tanya needs to commence an inhaled corticosteroid. He prescribed low dose fluticasone twice daily via an Accuhaler and counsels Tanya on what this is for and how she should use it. He asks her to call to see him in a week. He faxed Dr Jones a copy of the prescription for his records.

#### 4.3.1.3 Advanced Practitioner

**Scenario 4**

Mrs James is admitted to Smallville hospital for an elective hip replacement. David is her pharmacist. He is called to see her when she is admitted. When he arrives on the ward, he checks the standardised drug chart that has been populated with medications prescribed by the pharmacist at her pre-admission clinic visit.

David introduces himself to Mrs James and checks that all medications on her chart are still correct, doses have not changed and no new medications have been added. He endorses the chart as correct. He also notes for the doctor which medication should be ceased prior to surgery, and notes for the nursing staff when medication that is ceased for surgery should be restarted.

When Mrs James is ready for discharge, David, who has attended ward rounds with the team, checks which medications are to be continued following discharge, which are to be ceased (such as the narcotic for pain relief) and any new drugs to be commenced. He writes the discharge prescription and transmits it electronically to the pharmacy for dispensing.

Within 1-2 hours of being told she is ready to go home, Mrs James is counselled by David about her medications and is ready to leave. A copy of the discharge prescription is transmitted electronically into her health record that is accessible by her GP and community pharmacist.

#### 4.3.1.4 Community Liaison Pharmacy (CLP)

**Scenario 5**

Mrs James has been discharged from Smallville hospital following a hip replacement. As she is over 55, lives alone and has >5 current medications, she is eligible for a CLP visit.

Thomas, her hospital pharmacist, contacts Parkside Pharmacy, which is Mrs James' designated community pharmacy, to inform them of her discharge and transmit her discharge information. Parkside Pharmacy sends David, a consultant pharmacist, to visit Mrs James within five days of her discharge. David has received a copy of the discharge information and contacted Thomas to clarify a couple of minor points.

David has contacted Mrs James and made an appointment to see her.

During the visit, David checks the medicines that Mrs James has stored at home and checks that all medicines she was taking before her hospitalisation were prescribed on admission. This was the case, because she had been to the pre-admission clinic. David then checked for expired medicines and medicines no longer required. He then checked how Mrs James was managing with her new medications, asked about any unwanted effects and provided her with education concerning her new medication. During this discussion David learnt that Mrs James was experiencing some dizziness that was possibly due to her metoprolol. He made an appointment for Mrs James with her GP to have this assessed and made a note in his report for the GP.

Following his visit, David prepared a report that he transmitted to her GP and community pharmacist.

#### 4.3.1.5 Medication Management Prescribing

The following three scenarios illustrate medication management prescribing involving various chronic diseases in different settings.

**Scenario 6**

Tanya has attended her local GP for a check-up following exacerbation of her asthma symptoms. He has prescribed fluticasone Accuhaler in addition to her use of Ventolin when required. He has also prescribed a salmeterol inhaler for her to use if her symptoms and PEFR don't improve after several weeks of fluticasone therapy. He then tells her to attend her local pharmacy for ongoing prescription of these medications. Tanya makes contact with her pharmacist, David. He records her diagnosis and files a copy of her treatment plan so that her asthma treatment can be continued without further need for input from her GP unless problems arise. David will periodically (3/12 or when a change occurs) send a report to the GP of current management progress and will advise Tanya to see the GP for review every 12 months.

**Scenario 7**

Mrs James takes glibenclamide and metformin for her type 2 diabetes mellitus. Every six months, she attends the local pathology laboratory for an HbA1c test. The pathology laboratory sends a copy of the results to both her GP and nominated pharmacy. Mrs James attends the pharmacy and David, the pharmacist, prescribes ongoing therapy, adjusting the doses of these two agents to maintain the HbA1c <7% and to minimise any side-effects Mrs James may be experiencing. At each visit, David communicates any changes to her therapy to her GP.

**Scenario 8**

The Smallville Clinic looks after 15 of the patients at the Resteasy Aged Care facility. These patients are taking medication for a variety of conditions including hypertension, hyperlipidaemia, diabetes, COPD, arthritis and depression. David, the pharmacist, meets annually with the Smallville clinic doctors and documents an agreed course of action for each of these patients, which includes an overall management plan and therapeutic goals. David has a signed and documented agreement with the doctors at the clinic for management of these patients, which includes when they should be referred for review; the frequency of dose increases, maximum dose and what level of side effects is tolerable. Each month, David is responsible for seeing these patients, assessing their status, prescribing ongoing medication and sending a report to their GPs. New medications may be prescribed according to the treatment plan, but new symptoms are reviewed by the treating doctor to make/confirm a diagnosis and develop a new management plan in consultation with the pharmacist. Any new problems are managed by the GP and handed over when the GP decides the patient is stable. David can ask the GP to review the patient any time within the 12 months, but otherwise ongoing care of the patient rests with David.

#### 4.3.1.6 Collaborative Prescribing

The following two scenarios illustrate collaborative prescribing in different settings.

**Scenario 9**

Tanya calls in to her local pharmacy on her way home from school. It is close to the bus stop and is convenient to her as it is always open when she catches the bus. Tanya wants to talk to the pharmacist about her shortness of breath. David, the pharmacist, suspects that Tanya has symptoms of asthma and refers Tanya to her local doctor for diagnosis and assessment. The doctor makes this diagnosis and refers Tanya back to her pharmacy for ongoing management. In consultation with her, David prescribes a low dose inhaled corticosteroid and a beta agonist for occasional symptom relief and to use prior to sport. He asks Tanya to call in regularly so that he can assess the effectives of her prescribed therapy and modify it if necessary and so that he can monitor and correct her inhaler

technique. Every three months, David sends a report of Tanya's progress to her GP and once a year she has a full GP review.

**Scenario 10**

Mrs James is now 75. Unfortunately she has developed cancer and although she had treatment it was not successful and she is in the terminal stages of care. She is currently living with her daughter. She is being cared for by the Smallville palliative care service. This is a team-based service that includes a palliative care doctor, nurses and the palliative care pharmacist.

The pharmacist, David, has contacted Mrs James and made an appointment to see her and her daughter in her daughter's home.

During his visit, David checks Mrs James' medicines that she has at home and checks all medicines Mrs James is taking. He then checks how Mrs James is managing with her new medications, asks about any unwanted effects and provides her with education concerning her new medication. David checks that Mrs James, or her daughter, is able to obtain adequate supplies of medication, knows how they should be stored and that they are comfortable with some of the new devices used to administer the medication. The palliative care nurses visit to administer the injections and to change the medication in the syringe driver.

David monitors side effects such as sedation, constipation and dry mouth and recommends strategies or products that will help alleviate those problems.

Following his visit David prepares a report that he transmits to her GP and community pharmacist.

#### 4.3.1.7 Independent Prescribing

**Scenario 11**

Tanya is a 17 year-old. She presents to the pharmacy in her school uniform after getting off the bus, on her way home. Tanya requests a Ventolin inhaler. David, the pharmacist remembers that Tanya bought one only last week and decides that this is a good time to intervene. David asks Tanya why she needs another inhaler – did she lose the last one? She tells him that she didn't lose it, but is getting through them more frequently lately. When asked how her asthma is she tells him she has had frequent mild symptoms.

Tanya's inhaler technique is good – David checked it last week. David judges that it would be appropriate to commence Tanya on a low dose inhaled corticosteroid, explaining to Tanya the reason she needs to a use a corticosteroid, what that will mean in terms of asthma management and side effects. David discussed the different devices available with Tanya and decided on a delivery system she feels she can manage. He writes a prescription for fluticasone dry powder inhaler and asks Tanya to call by in a few days, on her way home, so that he can see how she is managing with the new device. The prescription is dispensed by the technician and a counselling pharmacist explains to Tanya how she should use it, and what to do in case of an emergency.

### *4.3.2 Step Two – Identifying Barriers to Prescribing Models*

The identified barriers to the implementation of "the standards" were divided into the prescribers' issues of concern, pharmacists' issues of concern and joint issues of concern. The results will be discussed based on the barriers to the implementation of "the standards" and the suitability of the prescribing models.

#### 4.3.2.1 Barriers in Implementation of "the standards"

**A) Prescribers' issues of concern**

***1) Capability of pharmacist to identify underlying important issues (Red Flags)***

One of the major issues of concern was the capability of pharmacists to identify critical issues (referred to as 'red flags'). Identifying red flags is important since it is a critical point for referral to the appropriate medical practitioner for further assessment. Thorough history taking skills are needed to identify 'red flags', which medical practitioners did not believe was a skill possessed by pharmacists. Medical practitioners expressed concern that pharmacists were not properly trained to be able to identify 'red flags' in acute or stabilised chronic disease states.

> *"It looks to me as though the pharmacists are trying to take on the medical role without having the appropriate training and we are talking about what competencies would be required. A great deal is required in actually learning how to take a full history apart from the medication history. Doing appropriate clinical examination and making the judgement where the medications fit into that whole thing about the approach to managing the person's situation. You don't look at in isolation."* **(Medical Practitioner 4)**

> *"There are lots and lots of traps for new players in this sort of situation. I have been caught out by the most bizarre sort of things."* **(Medical Practitioner 1)**

### *2) Value-adding role of the pharmacists*

Another issue of concern was the value-adding role of the pharmacists in performing this new task. The medical practitioners expressed concern regarding the benefits that could be obtained from the pharmacists' new task and whether there would be any difference compared to the current system.

> *"Patient will be seeing the GP with the type II diabetes at least every 6 months. We would normally check it every time ..., if you are expecting to see a GP that frequently, what is the pharmacist going to be adding to that?"* **(Medical Practitioner 1)**

## B) Pharmacists' issues of concern

### *1) Additional education and training for the new task*

Most of the pharmacists expressed concerns about their level of confidence in prescribing Schedule 4 medications. Even though they have been prescribing Schedule 3 ('Pharmacist Only medicines'), they expressed concern in the area of prescribing for chronic disease management. They emphasised that additional education and training would be needed for them to be able to perform this new task with confidence.

> *"I would say not all pharmacists … they sort of need some sort of specific knowledge and skills to be able to manage different types of cases."* **(Pharmacist 1)**

> *"… it would need to be a lot more training. Again I suppose really we are trained in minor illness or major disease. We are looking for those key factors which means they need to be referred on again."* **(Pharmacist 1)**

### *2) Manpower issues*

The other issue of concern related to manpower and whether pharmacists would be willing and capable to perform the prescribing tasks in addition to the current tasks for which they are responsible. This concern was expressed especially in the community setting.

> *"I think it would only work if you had a larger team. Based in a one assistant store, it wouldn't work in full capacity. In our store where I work, we have minimum three pharmacists. And I generally do a lot of the interaction, so where I am at the moment I can see it fitting in, but it would take some adjustment."* **(Pharmacist 6)**

## C) Joint issues of concern

### *1) Patient safety*

A safety issue of concern was the need for separation between pharmacists performing the prescribing and dispensing tasks.

> *"It would be great in the scenario in a pharmacy where there were two pharmacists, or where there were a prescribing pharmacist and another pharmacist there so that the second pharmacist could check what the prescribing pharmacist was doing. Because obviously with the doctor pharmacist scenario, there is a pharmacist checking the doctor. But then who is there to check the pharmacist?"* **(Pharmacist 5)**

### *2) Privacy and security issues*

Some issues were raised in regard to patient privacy and security associated with the implementation of this new prescribing role. There will be more people involved in the transfer of data between doctors and pharmacists; therefore, there could be problems with patient privacy. The other area related with privacy was the space provided for patient counselling in community pharmacy that may not be conducive.

> *" ... what I am talking is about the security of the information on the* [prescribing] *system."* **(Medical Practitioner 5)**

> *"...what about patient privacy issues. We are going to the pharmacy now and they ask you in public, so I think that's very important and I think that it could be asked."* **(Medical Practitioner 4)**

### *3) Organisational level*

Another concern was regarding the training of the pharmacists as supplementary prescribers, such as which institution would be responsible for conducting the training and the appropriate duration of training. Reimbursement issues were raised; both pharmacists and doctors speculated on the cost involved in the implementation of this new prescribing model. The expert panellists believed that the benefits should clearly outweigh the risks of the proposed prescribing models. There were also doubts as to whether there would be any benefits in implementing the proposed models compared to the current healthcare system.

> *"The issue of reimbursement and relative reimbursement to each GP and pharmacist and relative out-of-pocket expenses to the patient may be actually a driver of good practice or not."* **(Medical Practitioner 1)**

> *"…you might actually end up with this costing more by having frequent unnecessary, although cheaper, individual services. You never know how it would play out."* **(Medical Practitioner 2)**

### *4) Professional responsibility and relationship*

Issues were raised in terms of the dynamic change implications of the new prescribing role for pharmacists. Not only will there be changes in the current role of the profession but this would also impact on relationships among patients and medical practitioners. Therefore the proposed role and system need to be clearly defined to ensure the professions would be clear about their responsibilities and when to refer a patient to other healthcare professionals.

> *"So one of the concerns more broadly, in terms of young people, is if pharmacists are taking on a broader role now, the question is would she go to the GP anyway and is this adding an opportunity for engagement with general practitioners which would be positive, but it might detracting from seeing the GP who could be providing more holistic care."*
> **(Medical Practitioner 1)**

> *"...you would have to look at the role and relationship very carefully, really clearly defined, because something could fall over."***(Medical Practitioner 4)**

> *"I think communication is most important in healthcare because mistakes can be made because of miscommunication. Simple thing."* **(Pharmacist 1)**

> *"I'm also worried whether at each visit David* [the pharmacist] *communicates any changes to his GP. Does that mean David tells the GP or David discusses with the GP? Is it a collaborative decision that is made? Or is it the decision made by the pharmacist supplementary prescriber that is then transmitted to the independent prescriber?* **(Medical Practitioner 2)**

> *"I guess you have to have very clear parameters such as when do they need to refer back and whether that is for certain clinical signs rather than symptoms having improved after a period of time. But it does need to be very clear in additional agreement, and obviously the competency of the pharmacist being able to access those* [test results] *also needs to be essential."* **(Pharmacist 3)**

#### 4.3.2.2 Suitability of the Prescribing Models

Generally the medical practitioners had some reservations about pharmacist prescribing, despite the prescribing models proposed.

Protocol prescribing was generally considered to be acceptable; however, there were even concerns about this model relating to its inflexibility for individual patients and the tendency to rigidly adhere to the protocol. Warfarin was deemed to be the safest and most acceptable for protocol prescribing compared to other medications, diseases or models.

> *"... warfarin is a good example of a drug that can be prescribed according to the strict protocol within a nice safety domain ... and there are a very few other examples like that."* **(Medical Practitioner 1)**

> *"… basically what we are saying here is, if things are going well according to protocol, supplementary prescribing may have a place. But when things go wrong it is basis for a clinical intervention. … we do a lot of protocol driven care and the protocol says that when things are going well follow the protocol and when things are going bad you work out why they are going bad. And often there are a lot of traps for young, new players".* **(Medical Practitioner 5)**

> *"I really have a problem with the whole concept that you can set up protocol with everything that people just follow almost blindly, regardless of what competencies they gather."* **(Medical Practitioner 4)**

There was a mixture of opinions regarding supplementary prescribing, and independent prescribing was opposed by all the panellists.

> *"I think that the role of a supplementary prescriber would be to manage those conditions where drugs are the only answer, and where there are no other issues to consider, and I find those are very small set to consider. I find it very hard to imagine that there are never other diagnostic issues or other management strategies to consider and where drugs are the sole therapeutic issue. I think that the behavioural, the lifestyle issues are so important in almost everything we do."* **(Medical Practitioner 2)**

> *"So being able to prescribe for someone who is stable and going well, I've got no problem with the pharmacist doing that."* **(Medical Practitioner 3)**

> *"I wouldn't be saying that it is the place for a pharmacist to be independently prescribing... That would be a place* [for the] *pharmacist discussing with the patient and with the treating team, which might include also the nurse, about the diet and exercise or physio also about how you get walking despite your bad knees. So it might be part of the team but I don't see that they have to* [have an] *independent prescribing role. Why would you need that?"* **(Medical Practitioner 2)**

### *4.3.3 Step Three – Review of "the standards"*

The third stage involved the refinement of "the standards" to ensure face and content validity after amendments consequent to the first expert panel review. The emerging themes from the discussion among both groups were found to be similar to those of the first expert panel discussion (Chapter 3).

#### A) Medical practitioners' group

##### *1) The terms used for functional area nine "Prescribe Medicines"*

Most of the members of the medical practitioners group expressed concern about the terms used in the proposed competency standards. The term "prescribe medicines" was considered not suitable to be used in the context of supplementary prescribing as this might lead to the false understanding that pharmacists will be conducting total independent prescribing without the consultation from the medical practitioners.

##### *2) Statements in "the standards"*

The medical practitioners expressed concern about pharmacists performing some of the tasks. This was similar to the first expert panel discussion presented in Chapter 3.

> *"'Understand the conditions being treated and assesses the severity'. That sounds like totally medicine."* **(Medical Practitioner 2)**

## 4.4 Discussion

From the expert panel discussion, there were differences and similarities between issues of concern expressed by both groups. The main issue related to pharmacists' ability to perform the task of identifying patient-related issues in a holistic way. Medical practitioners had the impression that pharmacists mainly focused on medication management in the clinical cases. They had the impression that pharmacists were only trained in medication management and therefore did not have the knowledge and skills to undertake a comprehensive patient management role. This is supported by a study in the UK, where medical practitioners expressed their concerns regarding pharmacists' capability in diagnosis, awareness of patient clinical problems as well as communication barriers that most likely will occur with the implementation of the new role.[102] However, these perceived barriers from the medical practitioners were noted before the implementation of pharmacist prescribing.

During the conduct of the expert panel discussion, issues were raised regarding the term "prescribe medicines" among medical practitioners. This led to the negative perception among medical practitioners of the proposed idea of pharmacists expanding their current role in prescribing. The message portrayed was that pharmacists will be taking over the current medical practitioners' task to prescribe medicine independently without thorough supervision by the medical practitioners. This was also observed from the non-verbal expression from medical practitioners where they felt uncomfortable with the general idea of prescribing by pharmacists. The researcher decided to continue to use this term as there were no other words that could be used to describe this domain using an 'active' verb. The recent document "Competencies required to prescribe medicines" by NPS has also used this term.[96]

Issues focusing on barriers in implementation of pharmacist prescribing have been described in studies conducted either overseas or in Australia.[26,27,49,64,68,69,73,103] The study conducted in Australia by Bessell et al. identified a number of potential barriers to the implementation of pharmacist prescribing models in Australia, including professional issues, the clinical impact of changes to medication prescribing, economic issues, workforce issues and legal issues.[64] Kay et al. explored Australian pharmacists' views on feasibility and utility of pharmacist prescribing privileges within their current practice.[73] Some of the barriers noted were concerns about time and space, potential conflicts with the doctors, conflict of interest between prescribing and dispensing, defining boundaries of prescribing activity, importance of access to communication among healthcare professionals and cost implications of the new prescribing models.[73] The study conducted by Weeks et al. among hospital pharmacists, found that those who are either not interested or undecided about prescribing raised concerns about practising outside their clinical area, legal liability, remuneration, lack of confidence in their personal ability, limited vision for a career in hospital pharmacy, disagreement with pharmacists' prescribing, lack of interest in further study, retiring soon and lack of identified benefit for patients.[68] In 2010 Hoti et al.[104], evaluated Australian pharmacists' attitudes on expanding their prescribing role and found that issues related to cost, patient assessment, diagnosis and monitoring and other barriers were among the negative predictors in expanding roles to include prescribing. Despite the different methods used in the current study the findings are consistent with those obtained by others, highlighting many of the same barriers to implementation.

The issues raised in the Australian studies were based mainly on the opinions among healthcare professionals, including pharmacists, regarding the proposed role.[49,68,69,73] The main difference between the Australian studies and the studies conducted in UK was that the barriers identified in the UK were based on actual experience performing the new role. Lloyd and Hughes conducted a series of focus group discussions among pharmacists and their mentors who were involved in a pharmacist prescribing course.[103] The study was conducted in Northern Ireland and focuses on their views and context after the implementation of pharmacist prescribing. The barriers noted in the focus group discussion were pharmacists' concern that there was lack of a safety net for them in prescribing

practice. There were also some reservations noted with the implementation of independent prescribing among both pharmacists and mentors. There was concern regarding the deskilling of junior doctors since pharmacists will be taking greater responsibility in prescribing. Postal surveys among pharmacist prescribers in the UK found that the barriers they experienced were mainly financial and organisational.[25,26,105] These issues were related to reimbursement and funding to undergo the prescribing course. Pharmacists felt that they needed additional support, in terms of infrastructure, to perform the prescribing task. Since this study explored the early experiences of pharmacists undergoing supplementary prescribing in Great Britain, these issues were perceived as important barriers for the early group of pharmacist prescribers. Similar concerns were expressed during the expert panel discussion in the current study.

### *4.4.1 Study Limitations*

Expert panels are widely used for the development of guidelines in the medical settings.[106-109]The purpose of conducting the expert panel discussion was to provide feedback and comments on the proposed standards that had been developed. One limitation of expert panels is that members of such groups are unlikely to be representative of all pharmacists and all medical practitioners, hence introducing bias and reducing generalisability. There was also potential bias in that the meeting was conducted in one geographical area in Victoria, Australia, which may have imposed a limitation on the views expressed; however, pharmacy and medical practice are substantially the same across Australia and therefore the views expressed were likely to be similar to those of pharmacists and medical practitioners in other areas of Australia.

The expert panel meeting was facilitated by one of the researchers (AMA). The advantage of this was that the researcher had in-depth understanding of the UK and Australian documents as well as the draft document. Being aware of the potential to bias the discussion, the facilitator was careful to act only as the facilitator and not to impose her views. An independent person made notes during the discussion.

## 4.5 Conclusion

This preliminary study is an important part of the process of developing competency standards for pharmacist prescribing in Australia. The expert panel provided constructive guidance in refining the draft document and identifying issues of concern with the document and general issues in prescribing. Barriers identified in this study were found to be consistent with the other studies conducted in the Australian context and overseas. (Section 1.5) Subsequent chapters provide a description of the validation of these competencies (Chapter 5) and identification of the educational needs for pharmacists who wish to undertake a prescribing role (Chapter 6 and 7).

# Chapter 5: Validation of “the Standards” by Medical Practitioners

**Summary**

- This chapter describes the validation process for “the standards”.
- The validation process involved a medical practitioner survey that aimed to rank the areas that current prescribers considered important in prescribing.

## 5.1 Background

The development of "the standards" involved several steps from identification of existing competency standards via the literature review to using an expert panel to provide constructive feedback about "the standards" (Chapters 3 and 4).

In this study, medical practitioners were surveyed to determine their views of each of the performance criteria proposed for "the standards" for pharmacist prescribing. Since medical practitioners are the current prescribers, their opinions on the areas important in prescribing are fundamental to validation of "the standards".

### *5.1.1 Aim*

The aim of this step in validation of "the standards" was to ensure that all the proposed performance criteria were considered by current prescribers to be important in the prescribing process.

## 5.2 Survey

Careful attention is needed in selecting the most appropriate survey method. Several types of survey methods are commonly used in research – mail, phone, self-administered and web-based surveys.[110] Factors such as the population being studied, the cost incurred, manpower issues and the facilities involved will significantly affect the selection of the survey method.[110]

Mail survey is inexpensive and is able to be conducted with a large number of respondents. However, the disadvantage in conducting mail surveys is that there is no opportunity to clarify ambiguous replies and a high probability of incomplete surveys. With telephone surveys, well-trained interviewers are able to explain unclear terms to respondents, keep them motivated and probe incomplete or inadequate answers. Therefore, there is a possibility of a higher complete response rates with telephone interviews and researcher-administered surveys compared to the other techniques. However, if a large number of

potential respondents are involved, careful attention needs to be given to recruiting trained interviewers to ensure consistency in conducting the survey. Nowadays, there is an increasing trend towards the use of online surveys. Even though they are easy to administer, only respondents with internet access are able to respond to the survey leading to the possibility of a biased group of respondents. There is also the possibility of the survey not being delivered to the correct mailbox and the researcher being unaware, while mail surveys will usually be returned to sender thereby alerting the researcher.

Increasing response rates to mail questionnaires in large samples is one of the issues that need to be addressed when conducting mail surveys. The commonly used protocol to increase the response rate in mail survey research was developed by Dillman.[110,111] The procedures can be divided into five different aspects – questionnaire format, follow-up, anonymity, appeals and personalisation.

Questionnaire format must be planned carefully to cut mail costs and to reduce the length of the questionnaire. It can be printed on both sides or printed in booklet form. According to Dillman[110], follow-up includes sending a post card one week after the questionnaire was sent, three weeks later informing each nonrespondent that the researcher has not heard from them and a seven weeks letter sent by certified mail containing a replacement questionnaire. According to the protocol, only nonrespondents should be contacted to reduce follow-up expense. However, this is not possible with anonymous surveys.[111]

Other studies have been conducted focusing on issues such as of providing rewards, compensation or tokens to increase respondents' motivation to complete the survey.[112] A meta-analysis conducted by Church[112] classified rewards in previous studies into monetary and nonmonetary and whether the reward was delivered initially with the questionnaire or on the returned response. According to Dillman[110], rewards can be provided in several ways such as by showing positive regard, saying thank you, asking for advice, giving tangible rewards, making the questionnaire interesting, giving social validation and informing respondents that opportunities to respond are scarce. He also listed several ways to reduce social cost such as avoiding subordinating language, avoiding embarrassment, avoiding inconvenience, making questionnaires appear short and easy, minimising requests

to obtain personal information and keeping requests similar to other requests to which a person has already responded.

### *5.2.1 Justification for Using Mail Survey*

In this phase of the study, a mail survey of prescribers was selected to validate "the standards". Since the questionnaire items were newly developed and were not validated, it was crucial to determine the face and content validity of the survey. In the design of the survey research, choices must be made with regard to the wording of the questions, the response scale, the question context and the technique of data collection.[113] Thus, the process of questionnaire development is important in determining the success of the survey.

Although there was a possibility of a higher response rate by using researcher-administered or phone survey, these techniques were not considered to be the most suitable method for this study due to the large number of participants required. The location of participants throughout Victoria also precluded use of a researcher-administered survey.

Conducting an online survey would require informing participants about how to access the survey via internet. Although most of the potential participants would have internet access since they are working professionals, email addresses were not readily available. Therefore, a mail survey was chosen for this project.

## 5.3 Method: Study Flow

The medical practitioner survey consisted of six steps which are summarised in **Figure 5** and will be described in detail below.

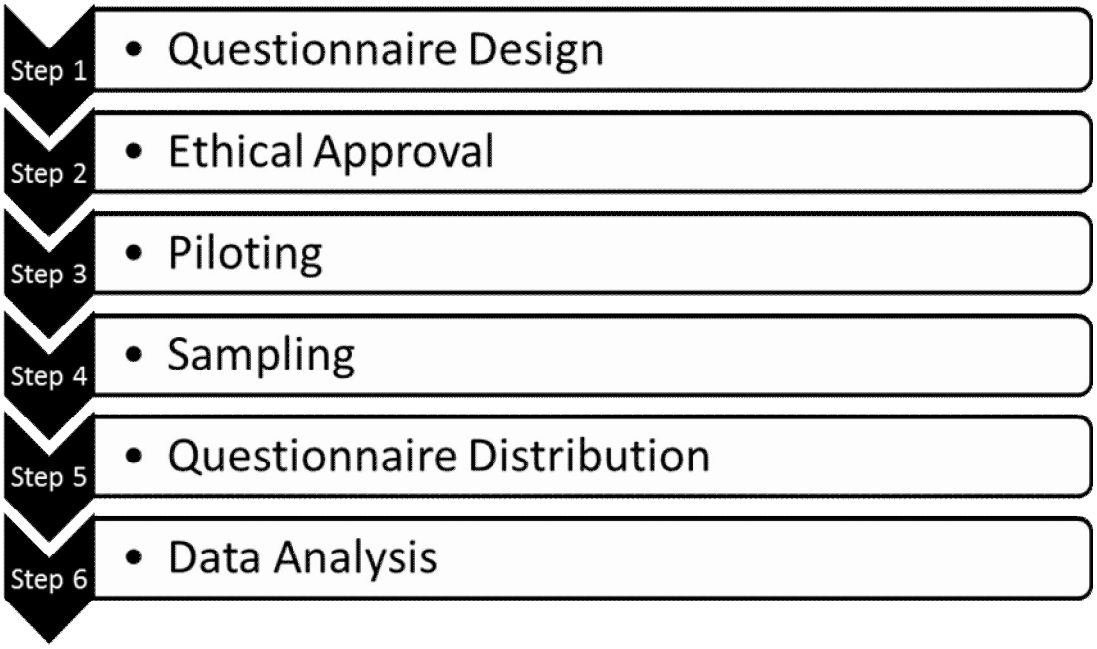


**Figure 5: Flow chart for medical practitioners' survey**

### *5.3.1 Step 1: Questionnaire Design*

The questionnaire was based on "the standards" developed at the earlier stage of the project (Chapter 3 and 4). Fundamental areas listed in the competency unit, elements and performance criteria were extracted and included as the survey items.

The questionnaire (**Appendix 10**) sought information from medical practitioners about their:

1) Demographics: gender, age, current practice location, area of practice, work description, country pertaining to the degree and the duration of practice.

2) Level of agreement, using a 5-point Likert scale, on 82 statements associated with the six identified areas of prescribing in "the standards". Values on the scale ranged from one 'strongly agree' to five 'strongly disagree'. Free-text comment columns were provided for each of the prescribing areas.

### *5.3.2 Step 2: Ethical Approval*

This study was approved by Monash University Standing Committee on Ethics in Research Involving Humans (SCERH) (**Appendix 11**).

### *5.3.3 Step 3: Piloting*

The questionnaire was pilot tested with two general practitioners, two pharmacists and two postgraduate pharmacy students to ensure the format and appearance of the questionnaire were user friendly and easy to understand and complete. Minor changes were made to the wording as the result of the comments from them.

### *5.3.4 Step 4: Sampling*

The register of medical practitioners in Victoria, purchased from the Medical Practitioners Board of Victoria, listed 20,281 registrants. For a population of this size, to ensure that the sample proportions would be within ±5% of the 'true' population prevalences with a 95% level of confidence, 379 responses were required.[114] To allow for an estimated 20% response rate, as response rates are generally low in research involving medical practitioners, 2000 potential participants were selected using random numbers generated by Microsoft Office Excel 2003.

### *5.3.5 Step 5: Questionnaire Distribution*

The survey was conducted from August to November 2008. The explanatory statement (**Appendix 12**) and the questionnaire (**Appendix 10**) were sent and a modified Dillman protocol[111] was followed to increase the response rate to the survey. Reminders were sent to all respondents since the survey was anonymous and participants who returned the survey were unable to be identified. The postcard reminder (**Appendix 13**) that was sent to the participants two weeks after the survey distribution contained information to encourage participation and information for correspondence with the researcher, including email and landline numbers to obtain a replacement copy of the questionnaire. A second reminder was sent two weeks after the first reminder.

### *5.3.6 Step 6: Data Analysis*

Quantitative data was analysed using the Statistical Package for the Social Sciences (SPSS for Windows: version 17.0, SPSS Inc.)

#### 5.3.6.1 Reliability Analysis

Reliability is a measure of reproducibility or consistency of a test. Internal consistency is mainly used to assess the response against a given construct or idea. It evaluates individual questions in comparison with one another for their ability to give consistently appropriate results. Different questions that test the same construct should give consistent results in this reliability testing. Therefore, internal consistency was conducted in this study to evaluate areas that were important in prescribing by using Cronbach's alpha. Consistency was considered acceptable at levels greater than 0.80.[115]

#### 5.3.6.2 Descriptive Analysis

Descriptive analysis is used to describe the basic features of the data in a study. It provides simple summaries about the sample and the measures. Likert scale scores for the areas involved in prescribing are presented using percentage and median.

## 5.4 Results

Of the two thousand copies of survey that were distributed, 139 were returned to the sender unopened. The main reason for return was that the medical practitioner was no longer working at that address. The returned surveys were replaced with a further random sample of 139. After the second reminder, another 125 questionnaires were returned. These were also replaced with questionnaire sent to a further 125 randomly chosen participants. The process is summarised in **Figure 6**; a response rate of 13.3% (n=265/2000) was achieved.

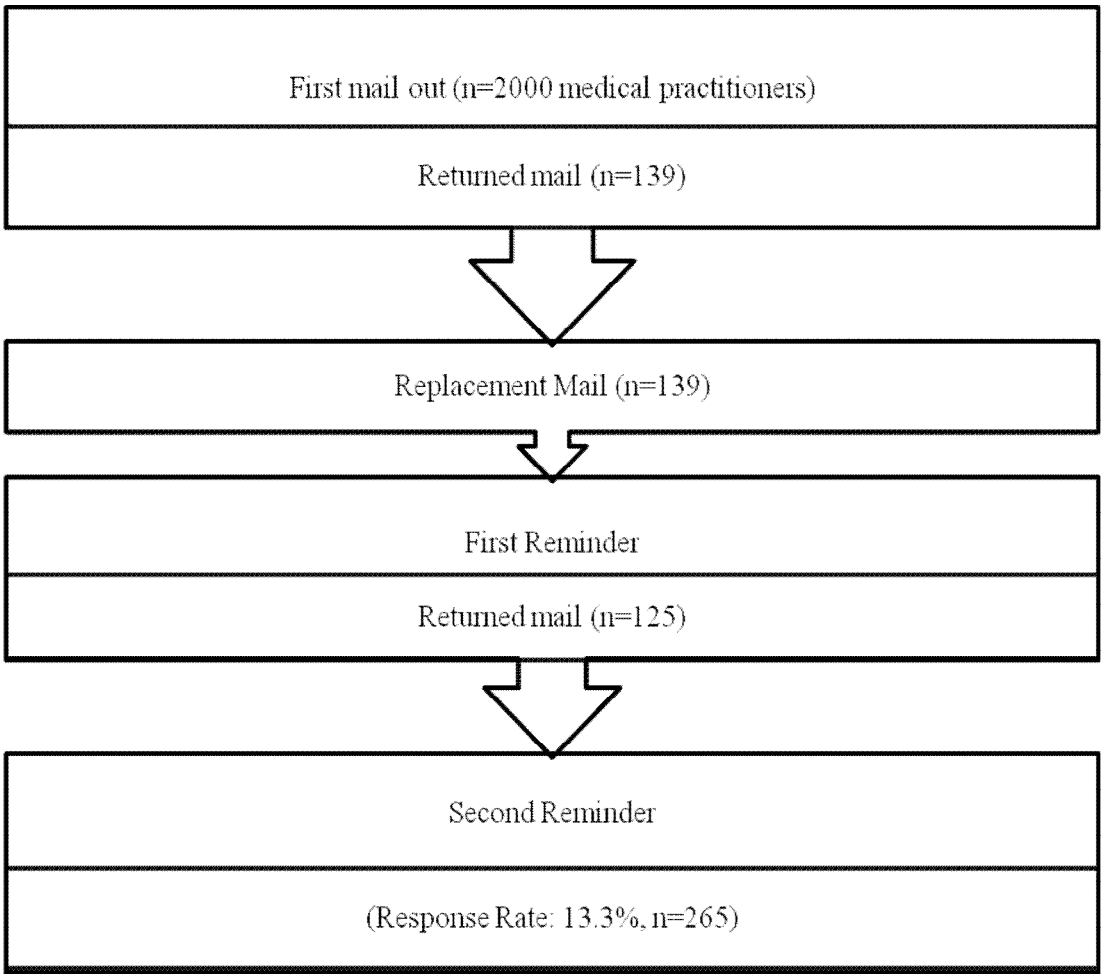


**Figure 6: Flow chart of the process for the medical practitioners' survey**

The results are presented in two sections. The first section presents the reliability analysis followed by demographic data for survey participants. The second section consists of results exploring the descriptive analysis based on the demographic characteristics that might be influencing participants' perceptions of prescribing. The summary of the result is available in Table 15.

### *5.4.1 Part A: Reliability Analysis*

**Table 15: Reliability analysis for each of the competency unit for functional area 9**

| Competency Unit | Cronbachs' alpha value |
|---|---|
| Section A: Prescribe effectively | 0.764 |
| Section B: Prescribe to an acceptable standard | 0.916 |
| Section C: Prescribe safely | 0.952 |
| Section D: Prescribe professionally | 0.920 |
| Section E: Participate in the development of prescribing practice | 0.904 |
| Section F: Communicate effectively with patients | 0.932 |
| Section G: Provide medicines, health information and education | 0.922 |

Internal consistency was checked with Cronbach's alpha by using the total scores of 1 (strongly agree) to 5 (strongly disagree) for each of the statement responses. Among all of the seven sections, only section A 'Prescribe Effectively' was associated with alpha value of less than 0.8. The other sections of the survey had alpha value of more than 0.8, which confirms the reliability of the items in "the standards" proposed. The low reliability in Section A compared to the other sections could be explained by the nature of items covered in the section, e.g. confirming the availability of medicine.

### *5.4.2 Part B: Descriptive Analysis of Demographic Characteristics*

Three hundred and five questionnaires were received. Forty of the respondents returned uncompleted questionnaires, justifying their reasons for not participating in the survey. Most of them were either retired or not interested in participating. Two hundred and sixty-five (13.3%) useable responses were received, which was much lower than anticipated in the sample size calculation. More than half of the respondents were male (60.6%). The majority of the medical practitioners (74.6%) were practising in the Melbourne metropolitan area. Of the participating medical practitioners, 45.8% were specialists; 44.3% worked in the hospital setting. The duration of practice ranged from six months to sixty years. The details of the demographic and other characteristics are shown in **Table 16** and **Table 17**.

**Table 16: Characteristics of respondents (n=265)**

| Demographic Characteristics | | % (n) |
|---|---|---|
| Gender | Male<br>Female | 60.6% (n= 160)<br>39.4% (n=104) |
| Practice Location | Capital city<br>Large regional centre<br>Rural/remote<br>Other | 74.6% (n=197)<br>15.5% (n=41)<br>8.3% (n=22)<br>1.5% (n=4) |
| Work description | Intern<br>Registrar<br>Resident<br>General practitioner<br>Specialist<br>Academic<br>Other | 1.5% (n=4)<br>13.3% (n=35)<br>6.1% (n=16)<br>28.0% (n=74)<br>45.8% (n=121)<br>2.7% (n=7)<br>2.7% (n=7) |
| Practice settings | Hospital only<br>Community only<br>Both hospital and community<br>Other | 44.3% (n=117)<br>23.9% (n=63)<br>27.7% (n=73)<br>4.2% (n=11) |
| Country of graduation | Australia<br>Overseas | 75% (n=198)<br>25% (n=66) |

**Table 17: Characteristics of respondents (n=265)**

| Characteristics | Range | Mean (SD) |
|---|---|---|
| Age | 24-84 years old | 46.1 years old (13.01) |
| Duration of registration | 0.5-60 years | 21.4 years (13.00) |
| Duration of practice | 0.5-60 years | 18.4 years (13.29) |

### *5.4.3 Part C: Descriptive Analysis of Medical Practitioners' Perceptions of Prescribing*

The results are presented as medians; the lower the median, the stronger the agreement with the statement. Results indicated that medical practitioners agreed that most of the items in "the standards" were important in prescribing. This was evidenced by the high percentage of the Likert scale scores that had a median value of less than three. Least agreement was observed in section A ('Prescribe Effectively'), where two of six items had medians of three. The overall descriptive results are shown in **Table 18.**

**Table 18: Responses to the statements related with prescribing for functional area 9**

| **Competency Unit (n=265)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing value (n) | Median score |
|---|---|---|---|---|---|---|---|
| **Section A: Prescribe effectively** | | | | | | | |
| *confirming availability of medicines by* | | | | | | | |
| 1) establishing any special circumstances or supplying arrangements impacting on availability of the prescribed medicine | 21.2 | 44.3 | 23.5 | 9.1 | 1.9 | 1 | **2** |
| 2) confirming that suitable products are held in stock or available from a supplier | 11.4 | 34.8 | 32.6 | 15.9 | 5.3 | 1 | **3** |
| 3) ensuring that patients can access ongoing supplies of their medication | 19.7 | 50.8 | 17.8 | 10.2 | 1.5 | 1 | **2** |
| 4) understanding how medicines are licensed, sourced, supplied and monitored | 11 | 37.1 | 29.2 | 16.3 | 6.4 | 1 | **3** |
| *updating knowledge by* | | | | | | | |
| 5) maintaining an up-to-date knowledge of relevant products | 56.3 | 40.2 | 2.7 | 0.8 | 0 | 4 | **1** |
| *prescribing in an appropriate manner by* | | | | | | | |
| 6) understanding cost concerns relevant to prescribing | 25.1 | 62.2 | 8.5 | 4.2 | 0 | 6 | **2** |
| **Section B: Prescribe to an acceptable standard** | | | | | | | |
| *reviewing patient clinical problems by* | | | | | | | |
| 1) understanding the conditions being treated, their natural progress and how to assess their severity | 85.7 | 14.0 | 0.4 | 0 | 0 | 0 | **1** |
| 2) identifying the nature, severity and significance of the clinical problem | 84.9 | 14.3 | 0.8 | 0 | 0 | 0 | **1** |
| *reviewing patient therapy options by* | | | | | | | |
| 3) understanding the pharmacological and/non-pharmacological approaches to modifying conditions | 60.6 | 35.6 | 3.4 | 0.4 | 0 | 1 | **1** |
| 4) understanding the mechanism of action and pharmacokinetics of medicines and how these mechanisms may be altered | 43.4 | 47.2 | 9.1 | 0.4 | 0 | 0 | **2** |
| 5) identifying clinically significant potential or actual drug related problems in the current medication treatment | 66.7 | 32.2 | 1.1 | 0 | 0 | 1 | **1** |

| **Competency Unit (n=265)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing value (n) | Median score |
|---|---|---|---|---|---|---|---|
| 6) requesting common laboratory tests and investigations performed on individual patients | 42.6 | 48.7 | 7.5 | 1.1 | 0 | 0 | **2** |
| 7) interpreting relevant investigations and evaluating the significance of common laboratory tests and investigations performed on individual patients | 54.7 | 43.0 | 1.9 | 0.4 | 0 | 0 | **1** |
| 8) considering no treatment, non-drug and drug treatment options (including referral and preventive measures) | 58.9 | 35.1 | 5.3 | 0.8 | 0 | 0 | **1** |
| 9) assessing the effect of multiple pathologies, existing medication and contraindications on treatment options | 65.8 | 33.8 | 0.4 | 0 | 0 | 2 | **1** |
| 10) assessing the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment | 60.4 | 36.2 | 3 | 0.4 | 0 | 0 | **1** |
| 11) applying the principles of evidence-based medicine | 48.7 | 43.4 | 7.2 | 0.8 | 0 | 0 | **2** |
| 12) applying the principles of clinical cost effectiveness | 23.5 | 52.3 | 21.2 | 2.3 | 0.8 | 0 | **2** |
| *selecting treatment by* | | | | | | | |
| 13) selecting the most appropriate drug, dose and formulation for the individual patient and prescribe appropriate quantities | 74 | 24.5 | 1.1 | 0.4 | 0 | 0 | **1** |
| 14) establishing and maintaining a plan for reviewing the therapeutic objective or end point of treatment | 54.5 | 42 | 3 | 0.4 | 0 | 1 | **1** |
| 15) monitoring effectiveness of treatment and potential unwanted effects and assess whether medication treatment is achieving therapeutic goals/ outcomes | 60 | 36.2 | 3.8 | 0 | 0 | 0 | **1** |
| 16) making changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences | 60.8 | 36.5 | 2.7 | 0 | 0 | 2 | **1** |
| **Section C: Prescribe safely** | | | | | | | |
| *reviewing the prescribing process by* | | | | | | | |
| 1) knowing the limits of my own knowledge and skill to prescribe safely | 70.5 | 27.7 | 1.5 | 0.4 | 0 | 1 | **1** |
| 2) knowing when and how to refer to, or seek guidance from another member of the team or a specialist | 75.4 | 23.5 | 1.1 | 0 | 0 | 1 | **1** |

| **Competency Unit (n=265)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing value (n) | Median score |
|---|---|---|---|---|---|---|---|
| 3) prescribing a medicine using adequate, up-to-date knowledge | 67.4 | 31.4 | 0.8 | 0.4 | 0 | 1 | **1** |
| 4) deciding on the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine | 64.1 | 35.1 | 0.4 | 0.4 | 0 | 3 | **1** |
| 5) checking doses and calculations to ensure accuracy and safety | 66.7 | 30.7 | 2.3 | 0.4 | 0 | 1 | **1** |
| 6) making accurate, clear and timely records | 64 | 32.6 | 3.4 | 0 | 0 | 1 | **1** |
| *updating patient information by* | | | | | | | |
| 7) taking a comprehensive history | 67.3 | 31.2 | 1.1 | 0 | 0.4 | 2 | **1** |
| 8) assessing and interpreting all relevant patient records to ensure knowledge of the patient's management | 58.7 | 37.9 | 2.3 | 0.8 | 0.4 | 1 | **1** |
| *applying safety issues in prescribing by* | | | | | | | |
| 9) keeping up to date with advances in practice and emerging safety concerns | 54.9 | 43.2 | 1.5 | 0 | 0.4 | 1 | **1** |
| 10) establishing systems for responding when an error occurs during prescribing | 48.1 | 42.8 | 7.6 | 1.1 | 0.4 | 1 | **2** |
| 11) establishing systems for reporting and responding to medication errors | 47 | 42.8 | 8.7 | 1.1 | 0.4 | 1 | **2** |
| 12) generating legible, clear and complete prescriptions, which meet legal requirements | 66.2 | 30.8 | 2.3 | 0.4 | 0.4 | 2 | **1** |
| 13) using documentation and systems that support prescription validation | 45.5 | 41.7 | 11.4 | 1.1 | 0.4 | 1 | **2** |
| *applying knowledge and skills to prescribe in an appropriate manner by* | | | | | | | |
| 14) making prescribing decisions with confidence and competence | 55.9 | 40.2 | 3.4 | 0 | 0.4 | 4 | **1** |
| *assessing progress of the clinical condition by* | | | | | | | |
| 15) understanding disease state management principles | 62.1 | 33.3 | 4.2 | 0 | 0.4 | 1 | **1** |
| 16) understanding the conditions being treated, their natural progress and how to assess their severity | 66.9 | 32.3 | 0.4 | 0 | 0.4 | 2 | **1** |
| 17) performing clinical assessment for various clinical conditions in appropriate areas | 59.5 | 38.3 | 1.9 | 0 | 0.4 | 1 | **1** |
| 18) using appropriate techniques and equipment | 51.3 | 42.2 | 5.7 | 0.4 | 0.4 | 2 | **1** |
| **Section D: Prescribe professionally** | | | | | | | |
| *working within professional, regulatory and organisational standards by* | | | | | | | |
| 1) accepting responsibility for my own prescribing | 71.6 | 26.4 | 1.9 | 0 | 0 | 4 | **1** |

| **Competency Unit (n=265)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing value (n) | Median score |
|---|---|---|---|---|---|---|---|
| 2) making prescribing decisions based on patient-related factors | 64.4 | 33.3 | 2.3 | 0 | 0 | 4 | **1** |
| 3) prescribing to an acceptable standard | 63.6 | 34.5 | 1.9 | 0 | 0 | 4 | **1** |
| *working in partnership towards benefit of patients by* | | | | | | | |
| 4) being able to negotiate with members of the prescribing team | 33.1 | 45.4 | 20 | 1.2 | 0.4 | 0 | **2** |
| 5) ensuring that the patient has agreed to be managed within a partnership | 29.1 | 40.3 | 24 | 4.7 | 1.9 | 7 | **2** |
| 6) understanding the cultural and religious implications of the diagnosis/ prescribing | 27.9 | 47.3 | 20.2 | 3.4 | 1.1 | 3 | **2** |
| *behaving in a professional and ethical manner by* | | | | | | | |
| 7) understanding how current legislation affects prescribing practice | 41.4 | 50.6 | 6.5 | 1.5 | 0 | 2 | **2** |
| 8) understanding the scope of my own prescribing responsibility | 50.6 | 49 | 0.4 | 0 | 0 | 2 | **1** |
| 9) maintaining patient confidentiality | 68.8 | 28.9 | 2.3 | 0 | 0 | 2 | **1** |
| 10) maintaining security of prescribing stationary or computer security systems | 49.2 | 42.4 | 6.9 | 1.1 | 0.4 | 3 | **2** |
| 11) maintaining the security and confidentiality of data being transferred | 51.3 | 42.6 | 5.3 | 0.4 | 0.4 | 2 | **1** |
| 12) recognising and dealing with pressures that might result in inappropriate prescribing | 46.8 | 48.3 | 3.8 | 0.8 | 0.4 | 2 | **2** |
| 13) taking responsibility for my own continuing professional development in relation to prescribing | 55.9 | 41.1 | 2.7 | 0.4 | 0 | 2 | **1** |
| **Section E: Participate in the development of prescribing practice** | | | | | | | |
| *participating in the review of prescribing practice by* | | | | | | | |
| 1) learning and changing through reflecting on my own practice | 27.4 | 57.9 | 12.4 | 1.9 | 0.4 | 6 | **2** |
| 2) sharing my own prescribing practice | 16.2 | 48.5 | 31.2 | 3.1 | 1.2 | 5 | **2** |
| 3) sharing and debating others' prescribing practice | 16.5 | 39.6 | 35 | 7.3 | 1.5 | 5 | **2** |
| 4) challenging inappropriate practice constructively | 25.4 | 56.2 | 15.8 | 2.3 | 0.4 | 5 | **2** |
| *using own networks by* | | | | | | | |
| 5) developing networks for mutual support, reflection and learning | 18.5 | 51.5 | 25.4 | 3.5 | 1.2 | 5 | **2** |
| 6) establishing multiprofessional links with practitioners working in the same practice area | 20.1 | 54.4 | 21.2 | 3.9 | 0.4 | 6 | **2** |
| *using tools to improve practice by* | | | | | | | |

| **Competency Unit (n=265)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing value (n) | Median score |
|---|---|---|---|---|---|---|---|
| 7) understanding and knowing the types of dissemination tools/strategies that can be used to share information or review findings and recommendations for change | 17.8 | 51.6 | 25.6 | 3.1 | 1.9 | 7 | **2** |
| *reporting prescribing errors by* | | | | | | | |
| 8) reporting prescribing errors and near misses that I am aware of | 32.3 | 51.4 | 12.8 | 3.1 | 0.4 | 8 | **2** |
| 9) reviewing my practice to prevent error recurrences | 41.5 | 53.1 | 5.4 | 0 | 0 | 7 | **2** |
| **Section F: Communicate effectively with patients** | | | | | | | |
| *understanding and respecting the uniqueness of individuals by* | | | | | | | |
| 1) understanding patients' beliefs, ideas, concerns and expectations | 49.8 | 47.1 | 3.1 | 0 | 0 | 4 | **2** |
| 2) understanding the cultural and religious implications of the diagnosis/ prescribing | 39.5 | 48.7 | 11.1 | 0.8 | 0 | 4 | **2** |
| *undertaking the consultation in an appropriate manner by* | | | | | | | |
| 3) undertaking it in an appropriate setting and adapting it to meet the needs of different patients | 45.2 | 48.7 | 6.1 | 0 | 0 | 4 | **2** |
| 4) dealing sensitively with patients' emotions and concerns | 56.2 | 41.5 | 1.9 | 0.4 | 0 | 5 | **1** |
| 5) explaining the nature of the patient's condition, the rationale behind and potential risks and benefits of management options | 63.2 | 35.6 | 1.1 | 0 | 0 | 4 | **1** |
| 6) enabling patients to make informed choices about their management | 57.7 | 36.5 | 5.4 | 0.4 | 0 | 5 | **1** |
| *negotiating an outcome by* | | | | | | | |
| 7) through consultation that both patient and prescriber are satisfied with | 45.8 | 47.7 | 5.8 | 0.4 | 0.4 | 5 | **2** |
| *giving clear instructions about the medication by* | | | | | | | |
| 8) encouraging patients to take responsibility for their own health and self manage their conditions | 55.4 | 38.1 | 5.4 | 1.2 | 0 | 5 | **1** |
| 9) assisting patients' understanding of their medical condition and/or medication treatment | 58.8 | 40 | 0.8 | 0.4 | 0 | 5 | **1** |
| *following up by* | | | | | | | |
| 10) checking the patients' understanding and commitment to their current and ongoing management | 47.9 | 45.2 | 6.5 | 0.4 | 0 | 4 | **2** |
| **Section G Provide medicines, health information and education** | | | | | | | |
| *understanding the readily available information sources by* | | | | | | | |

| **Competency Unit (n=265)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing value (n) | Median score |
|---|---|---|---|---|---|---|---|
| 1) recognising the availability of information sources that can provide relevant information | 33.3 | 57.5 | 8.8 | 0.4 | 0 | 4 | **2** |
| 2) understanding the advantages and limitations of various information sources | 35.2 | 55.9 | 8 | 0.8 | 0 | 4 | **2** |
| *using relevant, up to date information by* | | | | | | | |
| 3) formulating recommendations for changes to medication treatment based on the latest evidence and information on new medicines | 39.2 | 52.3 | 8.5 | 0 | 0 | 5 | **2** |
| *critically appraise the validity of information sources by* | | | | | | | |
| 4) critically evaluating research findings | 35.4 | 46.2 | 14.6 | 3.5 | 0.4 | 5 | **2** |
| 5) using primary and secondary information sources to critically evaluate the efficacy and safety of medicines | 31.5 | 48.8 | 16.2 | 3.1 | 0.4 | 5 | **2** |
| 6) critically evaluating the reliability and accuracy of new information in primary information sources | 32.4 | 49.4 | 15.1 | 2.3 | 0.8 | 6 | **2** |
| 7) calculating and manipulating clinical data and associated costs accurately | 17.8 | 41.1 | 29.8 | 8.5 | 2.7 | 7 | **2** |
| *applying information in the clinical context by* | | | | | | | |
| 8) information sources, sharing research findings with colleagues and other health professionals/ facility personnel whose care processes may be affected | 25.6 | 51.6 | 19.4 | 3.1 | 0.4 | 7 | **2** |
| *reviewing evidence by* | | | | | | | |
| 9) using relevant patient record systems, prescribing and information systems, and decision support tools | 27.9 | 49.6 | 19.4 | 2.7 | 0.4 | 7 | **2** |
| 10) working collaboratively with other clinicians to prepare or revise medication treatment protocols, guidelines, criteria and/or standards | 29.3 | 54.4 | 13.1 | 2.3 | 0.8 | 6 | **2** |

## 5.5 Discussion

The purpose of conducting the medical practitioners' survey was to validate "the standards" developed for pharmacists' prescribing through a quantitative approach. Since medical practitioners are the current prescribers, their judgement of the areas important in prescribing was sought.

Medical practitioners agreed that all areas included in the proposed standards were important in prescribing. This is demonstrated by median scores of less than three for most of the prescribing areas. These findings validated that the items included in "the standards" are important in prescribing. If the median score for an item had been higher than three, indicating respondents' disagreement with this statement it would have been removed from "the standards" proposed. No item scored higher than three and therefore none were removed.

## 5.6 Conclusion

All the items in "the standards" were found to be important in prescribing and therefore no amendments were required.

"The standards" were then used to identify pharmacists' perceptions of their current knowledge and skills for nonmedical prescribing (Chapter 6).

# Chapter 6: Pharmacists' Perceptions of their Current Knowledge and Skills for Nonmedical Prescribing

**Summary**

- This chapter describes a mail survey ascertaining pharmacists' perceptions of their current knowledge and skills in the areas important in prescribing.

- Factors influencing their perceptions will inform future development of educational programmes for nonmedical prescribers.

## 6.1 Background

Identifying the important areas in prescribing is fundamental to ascertain the educational needs for structuring prescribing courses. This was clearly stated in the UK competency framework document that is used "as an aid in training and development to inform the development of the curriculum, to help providers of initial training programmes to identify learning outcomes, as a self assessment tool for healthcare professionals to evaluate their own level of competency when considering a training and development programme, to help managers and pharmacist prescribers to identify ongoing training and development needs and to provide an ongoing way of structuring CPD".[86]

The importance of appropriate training and educational needs, especially in the areas of diagnosing, treating various conditions and consultation[28,99] was highlighted by pharmacists after the introduction of supplementary prescribing in the UK, as elaborated in the literature review (Chapter 2). In the USA, clinical pharmacists have been performing physical assessment in monitoring drug therapy response.[87] The US pharmacists' experience, however, is slightly different from that of pharmacists in the conventional UK healthcare system prior to the introduction of nonmedical prescribing.

Relating educational needs to required competencies is important prior to the development of training programmes for pharmacists to prescribe in the Australian context.

### *6.1.1 Aims*

The aims of this study were to:

1) Ascertain pharmacists' perceptions of their current knowledge and skills in the areas important for prescribing Prescription Only Medicine.

2) Identify demographic characteristics that may influence these perceptions.

It was hypothesised that the following characteristics may be influential:

- Gender
- Practice location (hospital/community)
- Practice setting (urban/rural/remote)
- Extra qualifications
- Age
- Duration of practice

## 6.2 Method

A mail survey of pharmacists was used, the methodology for which consisted of six steps, as summarised in **Figure 7** and subsequently described in detail.

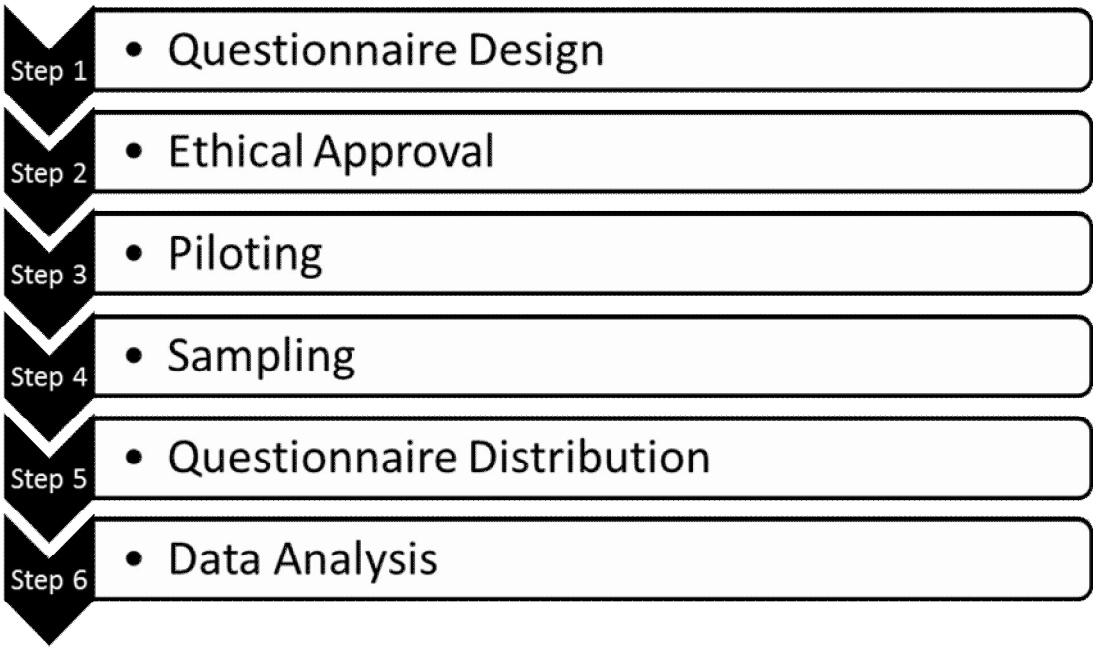


**Figure 7: Flow chart for pharmacists' survey**

### *6.2.1 Step 1: Questionnaire Design*

The questionnaire was developed to ascertain pharmacists' perceptions of their current level of knowledge and skills in the areas important to prescribing, as set out in "the standards" (Chapters 3 and 4). The questionnaire was similar in structure to that used in the study conducted among medical practitioners to validate "the standards" (Chapter 5), but the wording of the questions differed to ascertain perception rather than opinion. The face and content validity of the items in the questionnaire was previously established (Chapters 3, 4 and 5).

The questionnaire (**Appendix 14**) sought information from pharmacists about their:

1) Demographics: gender, age, current practice location, area of practice, basic pharmacy qualifications, additional pharmacy-related qualifications and duration of practice.

2) Level of agreement, using a 5-point Likert scale, on 82 statements associated with the six areas of prescribing in "the standards". Values on the scale ranged from one 'strongly agree' to five 'strongly disagree'. Free-text comment columns were provided for each of the prescribing areas.

### *6.2.2 Step 2: Ethical Approval*

This study was approved by Monash University Standing Committee on Ethics in Research Involving Humans (SCERH) (**Appendix 11**).

### *6.2.3 Step 3: Piloting*

The questionnaire was pilot tested among five pharmacists to ensure the format and appearance of the questionnaire was user friendly, easy to understand and complete. Minor changes were made to the wording as the result of the comments received.

### *6.2.4 Step 4: Sampling*

The list of registered pharmacists (n = 5498) was obtained from the Pharmacy Board of Victoria. From this list, the 4981 pharmacists holding general registration were included in the sampling frame. Pharmacists registered under other registration categories, including those 'not practising', were excluded from the study because the purpose was to obtain the opinions of practising pharmacists. For a population of this size, to ensure that the sample proportions would be within ±5% of the 'true' population prevalences with a 95% level of confidence, 357 responses were required.[114] Factoring in an estimated 45% response rate, 800 potential participants were selected using random numbers generated by Microsoft Office Excel 2003.

### *6.2.5 Step 5: Questionnaire Distribution*

The survey was conducted from August to November 2008. The explanatory statement (**Appendix 15**) and the questionnaire (**Appendix 14**) were sent and the Dillman[111] protocol was followed for conduct of the survey. A postcard reminder was sent to the participants two weeks after the original survey distribution. The postcard reminder contained information to encourage participation and information for correspondence to the researcher, including email and landline numbers for them to contact if they needed a new copy of questionnaire (Chapter 5).

### *6.2.6 Step 6: Data Analysis*

Quantitative data were analysed using the Statistical Package for the Social Sciences (SPSS for Windows: version 17.0, SPSS Inc.)

#### 6.2.6.1 Reliability Analysis

Reliability analysis is used to ascertain whether the same set of items would elicit the same responses if the same questions were re-administered to the same respondents. Variables derived from test instruments are declared to be reliable only when they provide stable and

reliable responses over repeated administration of the test. The internal consistency of the questionnaire was measured using Cronbach's alpha. Values greater than 0.80 are regarded as desirable.[115] Reliability analysis is described in Chapter 5, Section 5.3.6.1.

#### 6.2.6.2 Descriptive Analysis

Descriptive statistics (percentages and means) were used to describe the demographic characteristics of the sample and pharmacists' level of agreement with the statements about their confidence the areas of prescribing. Analysis of Likert scale data from this survey is presented as mean. Strictly, Likert scale data are ordinal rather than continuous, as it is debatable that the intervals between the points on the scale are equal – or similarly interpreted by all respondents. While the most robust interpretation of Likert scale data is the median (as reported in Chapter 5, **Table 18**), it is a coarse measure and provides little variability in results. In this study, the aim was to differentiate areas of need for education and training for pharmacists to undertake the prescribing role, so the mean was used to provide more variability. Reporting means is a controversial practice[116,117,118] but it is not uncommon in educational research.[119,120]

#### 6.2.6.3 Ordinal Logistic Regression Analysis

The items in the survey were ranked using Likert scales, with values ranging from one, 'strongly agree', to five, 'strongly disagree'. Ordinal logistic regression analysis was used to identify factors affecting pharmacists' agreement with statements regarding their perceived confidence in the areas important in prescribing. Factors that were included in the prediction of the outcome were gender, practice location, practice setting, extra qualification, age and duration of practice. The results are presented in tables with odds ratios, confidence intervals and significant p values ($<0.05$).

Backward stepwise regression analysis was used, whereby variables were eliminated from the model in a stepwise process. The model was tested after the elimination of each variable to ensure that the model still adequately fitted the data. The analysis was complete when there were no more variables that could be eliminated. The odds ratio is a way of

representing probability, using the ratio of the probability that the event of interest occurs to the probability that it does not. It is one of a range of statistics used to assess the risk of a particular outcome if a certain factor is present.[121] Firstly, odds ratios provide an estimate (with confidence interval) for the relationship between two binary ("yes" or "no") variables. Secondly, they enable examination of the effects of other variables on that relationship, using logistic regression.[122] In this study, the odds ratio was used to examine the effects of other variables on the relationship.

## 6.3 Results

Of the eight hundred copies of survey that were distributed, twelve were returned to the sender unopened. The main reason for return was that the pharmacist was no longer working at that address. The returned surveys were replaced with a further random sample of 12. After the second reminder, another six questionnaires were returned and three declined to participate. These were also replaced with questionnaires sent to a further six randomly chosen participants. The distribution process is summarised in **Figure 8**. A response rate of 20% (n=160/800) was achieved.

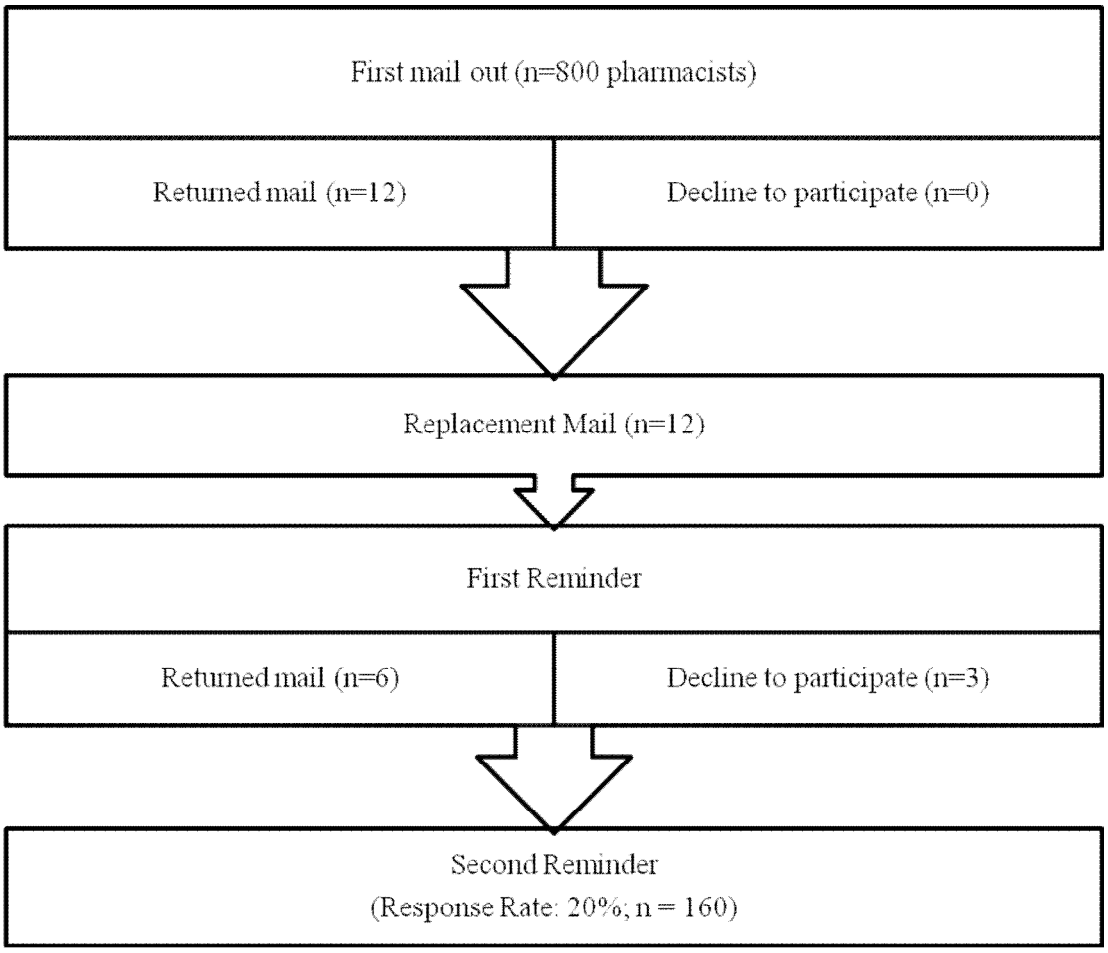


**Figure 8: Flow chart of the process for the pharmacists' survey**

### *6.3.1 Part A: Reliability Analysis*

Internal consistency was evaluated using Cronbach's alpha. High reliability was established, as the value of Cronbach's alpha was more than 0.9 in all of the sections (**Table 19**).

**Table 19: Reliability analysis for competency units in functional area 9**

| Competency Unit | Cronbach's alpha value |
|---|---|
| Section A: Prescribe effectively | 0.902 |
| Section B: Prescribe to an acceptable standard | 0.958 |
| Section C: Prescribe safely | 0.948 |
| Section D: Prescribe professionally | 0.926 |
| Section E: Participate in the development of prescribing practice | 0.948 |
| Section F: Communicate effectively with patients | 0.933 |
| Section G: Provide medicines, health information and education | 0.953 |

### *6.3.2 Part B: Descriptive Analysis of Demographic Data*

The details of the results are presented in **Table 20.** More than half of the respondents were female and two-thirds were working in the capital city. Three-quarters were currently practising in the community setting at least some of the time. Almost all had graduated from an Australian university and more than one-third had a pharmacy qualification beyond a basic pharmacy degree. Respondents' duration of practice ranged from 0.5 to 54 years with a mean and standard deviation of 21.63 ±14.59.

**Table 20: Characteristics of respondents (n=160)**

| Demographic Characteristics | | % (n) |
|---|---|---|
| Gender | Male<br>Female | 38.4% (n=61)<br>61.6% (n=98) |
| Practice location | Capital city<br>Large regional centre<br>Rural/remote area | 66.7% (n=106)<br>21.4% (n=34)<br>11.9% (n=19) |
| Practice settings | Hospital only<br>Community only<br>Both hospital and community<br>Other | 17% (n=26)<br>62.1% (n=95)<br>9.8% (n=15)<br>11.1% (n=17) |

| Demographic Characteristics | | % (n) |
|---|---|---|
| Practice category – Hospital | Grade 1 | 13.3% (n=6) |
| | Grade 2 | 31.1% (n=14) |
| | Grade 3 | 26.7% (n=12) |
| | Grade 4 | 24.4% (n=11) |
| | Other | 4.4% (n=2) |
| – | Retail pharmacist | 89.1% (n=106) |
| Community | Consultant pharmacist | 7.6% (n=9) |
| | Other | 3.4% (n=4) |
| Country of graduation | Australia | 94.3% (n=50) |
| | Overseas | 5.7% (n=3) |
| Extra qualification | Yes | 37.1% (n=59) |
| | No | 62.9% (n=100) |

### *6.3.3 Part C: Pharmacists' Perceptions of their Current Clinical Knowledge and Skills in Prescribing*

Most respondents perceived that they already possess the clinical knowledge and skills for prescribing, Prescription Only Medicines, as shown by the high percentages of responses on the Likert scale in the 'strongly agree' and 'agree' categories, with consequent mean values of less than three in all of the areas important for prescribing and less than 2.5 in most (**Table 21**).

**Table 21: Responses of perceptions to statements related to prescribing**

| Competency Unit (n=160) | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing (n) | Mean score (/5) |
|---|---|---|---|---|---|---|---|
| **Section A: Prescribe effectively** | | | | | | | |
| *confirming availability of medicines by* | | | | | | | |
| 1) establishing any special circumstances or supplying arrangements impacting on availability of the prescribed medicine | 54.1 | 37.1 | 6.9 | 1.3 | 0.6 | 1 | **1.6** |
| 2) confirming that suitable products are held in stock or available from a supplier | 72.3 | 25.2 | 1.3 | 0.6 | 0.6 | 1 | **1.3** |
| 3) ensuring that patients can access ongoing supplies of their medication | 67.3 | 30.8 | 0.6 | 0.6 | 0.6 | 1 | **1.4** |
| 4) understanding how medicines are licensed, sourced, supplied and monitored | 58.9 | 30.4 | 8.2 | 1.9 | 0.6 | 2 | **1.6** |
| *updating knowledge by* | | | | | | | |
| 5) maintaining an up-to-date knowledge of relevant products | 48.7 | 48.1 | 2.5 | 0 | 0.6 | 2 | **1.6** |
| *prescribing in an appropriate manner by* | | | | | | | |
| 6) understanding cost concerns relevant to prescribing | 51.6 | 40.1 | 5.7 | 1.9 | 0.6 | 3 | **1.6** |
| **Section B: Prescribe to an acceptable standard** | | | | | | | |
| *reviewing patient clinical problems by* | | | | | | | |
| 1) understanding the conditions being treated, their natural progress and how to assess their severity | 19.6 | 46.2 | 17.7 | 13.9 | 2.5 | 2 | **2.3** |
| 2) identifying the nature, severity and significance of the clinical problem | 18.4 | 38.6 | 25.3 | 16.5 | 1.3 | 2 | **2.4** |
| *reviewing patient therapy options by* | | | | | | | |
| 3) understanding the pharmacological and/non-pharmacological approaches to modifying conditions | 26.6 | 51.3 | 13.9 | 6.3 | 1.9 | 2 | **2.1** |
| 4) understanding the mechanism of action and pharmacokinetics of medicines and how these | 30.4 | 48.1 | 13.9 | 5.7 | 1.9 | 2 | **2.0** |

| **Competency Unit (n=160)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing (n) | Mean score (/5) |
|---|---|---|---|---|---|---|---|
| mechanisms may be altered | | | | | | | |
| 5) identifying clinically significant potential or actual drug related problems in the current medication treatment | 36.1 | 53.2 | 6.3 | 3.2 | 1.3 | 2 | **1.8** |
| 6) requesting common laboratory tests and investigations performed on individual patients | 20.3 | 24.1 | 26.6 | 25.3 | 3.8 | 2 | **2.7** |
| 7) interpreting relevant investigations and evaluating the significance of common laboratory tests and investigations performed on individual patients | 17.2 | 24.2 | 29.3 | 25.5 | 3.8 | 3 | **2.8** |
| 8) considering no treatment, non-drug and drug treatment options (including referral and preventive measures) | 27.8 | 41.1 | 22.2 | 6.3 | 2.5 | 2 | **2.2** |
| 9) assessing the effect of multiple pathologies, existing medication and contraindications on treatment options | 17.3 | 38.5 | 25.6 | 16.7 | 1.9 | 4 | **2.5** |
| 10) assessing the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment | 26.6 | 52.5 | 14.6 | 5.1 | 1.3 | 2 | **2.0** |
| 11) applying the principles of evidence-based medicine | 32.3 | 48.7 | 13.3 | 4.4 | 1.3 | 2 | **1.9** |
| 12) applying the principles of clinical cost effectiveness | 27.2 | 44.9 | 18.4 | 8.2 | 1.3 | 2 | **2.1** |
| *selecting treatment by* | | | | | | | |
| 13) selecting the most appropriate drug, dose and formulation for the individual patient and prescribe appropriate quantities | 34.2 | 40.5 | 13.9 | 10.1 | 1.3 | 2 | **2.0** |
| 14) establishing and maintaining a plan for reviewing the therapeutic objective or end point of treatment | 27.8 | 36.1 | 20.9 | 13.3 | 1.9 | 2 | **2.3** |
| 15) monitoring effectiveness of treatment and potential unwanted effects and assess whether medication treatment is achieving therapeutic goals/ outcomes | 27.2 | 46.8 | 13.9 | 10.1 | 1.9 | 2 | **2.1** |
| 16) making changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences | 27.2 | 32.3 | 22.8 | 14.6 | 3.2 | 2 | **2.3** |

| Competency Unit (n=160) | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing (n) | Mean score (/5) |
|---|---|---|---|---|---|---|---|
| **Section C: Prescribe safely** | | | | | | | |
| *reviewing the prescribing process by* | | | | | | | |
| 1) knowing the limits of my own knowledge and skill to prescribe safely | 53.1 | 40 | 5 | 1.3 | 0.6 | 0 | **1.6** |
| 2) knowing when and how to refer to, or seek guidance from another member of the team or a specialist | 47.8 | 45.9 | 4.4 | 1.3 | 0.6 | 1 | **1.6** |
| 3) prescribing a medicine using adequate, up-to-date knowledge | 29.4 | 52.5 | 11.3 | 5.6 | 1.3 | 0 | **2.0** |
| 4) deciding on the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine | 40.3 | 42.1 | 12.6 | 3.1 | 1.9 | 1 | **1.8** |
| 5) checking doses and calculations to ensure accuracy and safety | 58.5 | 35.8 | 4.4 | 0.6 | 0.6 | 1 | **1.5** |
| 6) making accurate, clear and timely records | 63.5 | 31.4 | 4.4 | 0 | 0.6 | 1 | **1.4** |
| *updating patient information by* | | | | | | | |
| 7) taking a comprehensive history | 43.1 | 32.5 | 13.8 | 10 | 0.6 | 0 | **1.9** |
| 8) assessing and interpreting all relevant patient records to ensure knowledge of the patient's management | 35 | 41.9 | 11.9 | 10 | 1.3 | 0 | **2.0** |
| *applying safety issues in prescribing by* | | | | | | | |
| 9) keeping up to date with advances in practice and emerging safety concerns | 33.1 | 48.1 | 12.5 | 5.6 | 0.6 | 0 | **1.9** |
| 10) establishing systems for responding when an error occurs during prescribing | 40 | 42.5 | 10.6 | 6.3 | 0.6 | 0 | **1.9** |
| 11) establishing systems for reporting and responding to medication errors | 42.8 | 42.1 | 9.4 | 5 | 0.6 | 1 | **1.8** |
| 12) generating legible, clear and complete prescriptions, which meet legal requirements | 58.5 | 32.7 | 5 | 1.9 | 1.9 | 1 | **1.6** |
| 13) using documentation and systems that support prescription validation | 48.1 | 36.1 | 11.4 | 3.8 | 0.6 | 2 | **1.7** |
| *applying knowledge and skills to prescribe in an appropriate manner by* | | | | | | | |
| 14) making prescribing decisions with confidence and competence | 24.7 | 37.3 | 20.3 | 15.2 | 2.5 | 2 | **2.3** |
| *assessing progress of the clinical condition by* | | | | | | | |

| Competency Unit (n=160) | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing (n) | Mean score (/5) |
|---|---|---|---|---|---|---|---|
| 15) understanding disease state management principles | 19.5 | 38.4 | 23.9 | 17 | 1.3 | 1 | **2.4** |
| 16) understanding the conditions being treated, their natural progress and how to assess their severity | 16.5 | 38.6 | 24.7 | 17.1 | 3.2 | 2 | **2.5** |
| 17) performing clinical assessment for various clinical conditions in appropriate areas | 15.7 | 25.8 | 27 | 28.3 | 3.1 | 1 | **2.8** |
| 18) using appropriate techniques and equipment | 18.4 | 22.8 | 28.5 | 27.2 | 3.2 | 2 | **2.7** |
| **Section D: Prescribe professionally** | | | | | | | |
| *working within professional, regulatory and organisational standards by* | | | | | | | |
| 1) accepting responsibility for my own prescribing | 47.8 | 38.4 | 8.8 | 3.1 | 1.9 | 1 | **1.7** |
| 2) making prescribing decisions based on patient-related factors | 39.6 | 38.4 | 15.1 | 5.0 | 1.9 | 1 | **1.9** |
| 3) prescribing to an acceptable standard | 39.6 | 36.5 | 15.1 | 7.5 | 1.3 | 1 | **1.9** |
| *working in partnership towards benefit of patients by* | | | | | | | |
| 4) being able to negotiate with members of the prescribing team | 46.5 | 40.3 | 10.7 | 1.9 | 0.6 | 1 | **1.7** |
| 5) ensuring that the patient has agreed to be managed within a partnership | 42.8 | 45.9 | 10.1 | 0.6 | 0.6 | 1 | **1.7** |
| 6) understanding the cultural and religious implications of the diagnosis/ prescribing | 29.6 | 39 | 18.2 | 10.7 | 2.5 | 1 | **2.2** |
| *behaving in a professional and ethical manner by* | | | | | | | |
| 7) understanding how current legislation affects prescribing practice | 39.4 | 45.6 | 10 | 5 | 0 | 0 | **1.8** |
| 8) understanding the scope of my own prescribing responsibility | 50 | 38.8 | 8.1 | 2.5 | 0.6 | 0 | **1.7** |
| 9) maintaining patient confidentiality | 74.4 | 25 | 0.6 | 0 | 0 | 0 | **1.3** |
| 10) maintaining security of prescribing stationery or computer security systems | 70.6 | 25.6 | 3.1 | 0.6 | 0 | 0 | **1.3** |
| 11) maintaining the security and confidentiality of data being transferred | 68.1 | 27.5 | 3.8 | 0.6 | 0 | 0 | **1.4** |
| 12) recognising and dealing with pressures that might result in inappropriate prescribing | 43.8 | 41.3 | 11.3 | 3.8 | 0 | 0 | **1.8** |
| 13) taking responsibility for my own continuing professional development in relation to prescribing | 59.4 | 33.1 | 6.9 | 0.6 | 0 | 0 | **1.5** |
| **Section E: Participate in the development of prescribing practice** | | | | | | | |
| *participating in the review of prescribing practice by* | | | | | | | |

| **Competency Unit (n=160)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing (n) | Mean score (/5) |
|---|---|---|---|---|---|---|---|
| 1) learning and changing through reflecting on my own practice | 34.4 | 43.1 | 12.5 | 9.4 | 0.6 | 0 | **2.0** |
| 2) sharing my own prescribing practice | 29.4 | 35 | 26.3 | 8.8 | 0.6 | 0 | **2.2** |
| 3) sharing and debating others' prescribing practice | 26.9 | 36.3 | 26.9 | 9.4 | 0.6 | 0 | **2.2** |
| 4) challenging inappropriate practice constructively | 26.9 | 36.9 | 25.6 | 10 | 0.6 | 0 | **2.2** |
| *using own networks by* | | | | | | | |
| 5) developing networks for mutual support, reflection and learning | 22.6 | 40.3 | 27.7 | 8.8 | 0.6 | 1 | **2.3** |
| 6) establishing multiprofessional links with practitioners working in the same practice area | 24.5 | 40.9 | 23.3 | 10.7 | 0.6 | 1 | **2.2** |
| *using tools to improve practice by* | | | | | | | |
| 7) understanding and knowing the types of dissemination tools/strategies that can be used to share information or review findings and recommendations for change | 16.4 | 39.6 | 27.7 | 15.1 | 1.3 | 1 | **2.5** |
| *reporting prescribing errors by* | | | | | | | |
| 8) reporting prescribing errors and near misses that I am aware of | 36.5 | 44.7 | 17 | 1.9 | 0 | 1 | **1.8** |
| 9) reviewing my practice to prevent error recurrences | 40.5 | 44.3 | 13.3 | 1.9 | 0 | 2 | **1.8** |
| **Section F: Communicate effectively with patients** | | | | | | | |
| *understanding and respecting the uniqueness of individuals by* | | | | | | | |
| 1) understanding patients' beliefs, ideas, concerns and expectations | 37.7 | 48.4 | 10.1 | 3.1 | 0.6 | 1 | **1.8** |
| 2) understanding the cultural and religious implications of the diagnosis/ prescribing | 30.2 | 39.6 | 16.4 | 10.7 | 3.1 | 1 | **2.2** |
| *undertaking the consultation in an appropriate manner by* | | | | | | | |
| 3) undertaking it in an appropriate setting and adapting it to meet the needs of different patients | 34.4 | 43.1 | 15 | 6.9 | 0.6 | 0 | **2.0** |
| 4) dealing sensitively with patients' emotions and concerns | 44.4 | 42.5 | 10.6 | 2.5 | 0 | 0 | **1.7** |
| *5)* explaining the nature of the patient's condition, the rationale behind and potential risks and benefits of management options | 35.6 | 42.5 | 15.6 | 6.3 | 0 | 0 | **1.9** |
| 6) enabling patients to make informed choices about their management | 37.5 | 48.8 | 9.4 | 4.4 | 0 | 0 | **1.8** |

| **Competency Unit (n=160)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing (n) | Mean score (/5) |
|---|---|---|---|---|---|---|---|
| *negotiating an outcome by* | | | | | | | |
| 7) through consultation that both patient and prescriber are satisfied with | 36.9 | 45 | 14.4 | 3.1 | 0.6 | 0 | **1.9** |
| *giving clear instructions about the medication by* | | | | | | | |
| 8) encouraging patients to take responsibility for their own health and self manage their conditions | 45.6 | 48.8 | 5.6 | 0 | 0 | 0 | **1.6** |
| 9) assisting patients' understanding of their medical condition and/or medication treatment | 48.8 | 46.9 | 3.8 | 0.6 | 0 | 0 | **1.6** |
| *following up by* | | | | | | | |
| 10) checking the patients' understanding and commitment to their current and ongoing management | 40.3 | 50.3 | 7.5 | 1.3 | 0.6 | 1 | **1.7** |
| **Section G Provide medicines, health information and education** | | | | | | | |
| *understanding the readily available information sources by* | | | | | | | |
| 1) recognising the availability of information sources that can provide relevant information | 44.7 | 43.4 | 8.8 | 3.1 | 0 | 1 | **1.7** |
| 2) understanding the advantages and limitations of various information sources | 40.3 | 45.9 | 11.3 | 2.5 | 0 | 1 | **1.8** |
| *using relevant, up to date information by* | | | | | | | |
| 3) formulating recommendations for changes to medication treatment based on the latest evidence and information on new medicines | 32.1 | 42.8 | 17.6 | 7.5 | 0 | 1 | **2.0** |
| *critically appraise the validity of information sources by* | | | | | | | |
| 4) critically evaluating research findings | 23.3 | 33.3 | 27 | 15.1 | 1.3 | 1 | **2.4** |
| 5) using primary and secondary information sources to critically evaluate the efficacy and safety of medicines | 25.2 | 37.1 | 24.5 | 11.9 | 1.3 | 1 | **2.3** |
| 6) critically evaluating the reliability and accuracy of new information in primary information sources | 25.3 | 36.1 | 24.1 | 13.3 | 1.3 | 2 | **2.3** |
| 7) calculating and manipulating clinical data and associated costs accurately | 17.6 | 30.2 | 31.4 | 18.2 | 2.5 | 1 | **2.6** |
| *applying information in the clinical context by* | | | | | | | |
| 8) information sources, sharing research findings with colleagues and other health professionals/ facility personnel whose care processes may be affected | 25.2 | 32.1 | 27.7 | 12.6 | 2.5 | 1 | **2.4** |

| **Competency Unit (n=160)** | Strongly agree (%) | Agree (%) | Neither agree nor disagree (%) | Disagree (%) | Strongly disagree (%) | Missing (n) | Mean score (/5) |
|---|---|---|---|---|---|---|---|
| *reviewing evidence by* | | | | | | | |
| 9) using relevant patient record systems, prescribing and information systems, and decision support tools | 30.8 | 37.1 | 22.6 | 7.5 | 1.9 | 1 | **2.1** |
| 10) working collaboratively with other clinicians to prepare or revise medication treatment protocols, guidelines, criteria and/or standards | 34 | 34.6 | 20.1 | 9.4 | 1.9 | 1 | **2.1** |

### *6.3.4 Part D: Factors Influencing Pharmacists' Confidence Level in their Current Clinical Knowledge and Skills in Prescribing*

#### 6.3.4.1 Ordinal logistic regression analysis

**Table 22** presents the full set of performance criteria, and highlights the items significantly influenced by the demographic characteristics. Only two factors, 'gender' and 'extra qualification' demonstrated significant association with the outcomes. Significance levels and odds ratios (with confidence intervals) for these significant factors are shown in **Table 23** and **Table 24.**

In Section A (Prescribe Effectively), 'extra qualification' was significantly related to the level of agreement for two items **(Table 22,** Section A), "*updating knowledge by maintaining an up-to-date knowledge of relevant products"* (OR = 3.02, 95% CI 0.434-1.775; p=0.001) and "*prescribing in an appropriate manner by understanding cost concerns relevant to prescribing"* (OR = 3.06, 95% CI 0.443-1.795; p=0.011) (**Table 24,** Section A).

In Section B (Prescribe to an Acceptable Standard), four items was significantly influenced by 'gender' and almost all items were significantly influenced by 'extra qualification' **(Table 22**, Section B). For the items significantly influenced by 'gender', male pharmacists perceived themselves as more confident compared to female pharmacists (**Table 23**, Section B). Pharmacists with extra qualifications were more confident in their abilities (**Table 24**, Section B).

In Section C (Prescribe Safely), 'extra qualification' was found to significantly influence the level of agreement for all items (**Table 22**, Section C). Item number 4, "*deciding on the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine*", was found to have the highest odds ratio of 4.40 (**Table 24**, Section C). In the element "*assessing progress of the clinical condition*", two items "*performing clinical assessment for various clinical conditions in*

*appropriate areas*" and "*using appropriate techniques and equipment*" were significantly influenced by both 'extra qualification' and 'gender' (**Table 22**, Section C). Female pharmacists were less confident than males (OR = 0.51 and 0.36 respectively; **Table 23**, Section C) and pharmacists with extra qualifications were more confident than those without (OR = 2.44 and 2.46 respectively; **Table 24**, Section C).

Almost half of the items in the elements "*working within professional, regulatory and organisational standards"*, *"working in partnership towards benefit of patients"* and *"behaving in a professional and ethical manner"* listed under Section D (Prescribe Professionally) were found to be significantly influenced by 'extra qualification', (**Table 22**, Section D) with odds ratios ranging between 2 and 4 (**Table 24**, Section D).

Similar findings were noted in Section E (Participate in the Development of Prescribing Practice), in which half of the items were found to be significantly influenced by 'extra qualification' (**Table 22**, Section E**).**

In the area of 'Communicating Effectively with Patients' (Section F), pharmacists with extra qualifications were more confident in their clinical skills and knowledge in this area for the elements "*undertaking the consultation in an appropriate manner*" and "*negotiating an outcome*"(**Table 22**, Section F) with significant odds ratios for all of the items (**Table 24**, Section F).

Only three of the 10 items in Section G (Provide medicines, health information and education), were significantly influenced by 'extra qualification' (**Table 22**, Section G**).** Item number 3, "*formulating recommendations for changes to medication treatment based on the latest evidence and information on new medicines*", was the area most influenced by 'extra qualification', (OR = 3.58) (**Table 24**, Section G). This was the only item in the element *"using relevant, up to date information"*.

**Table 22: Items that significantly influenced pharmacists' level of agreement with units and elements of functional area 9 by demographic characteristics**

| | Gender | Practice Location | Practice Setting | Extra Qualification | Age | Duration of practice |
|---|---|---|---|---|---|---|
| **Section A Prescribe effectively** | | | | | | |
| *confirming availability of medicines by* | | | | | | |
| 1) establishing any special circumstances or supplying arrangements impacting on availability of the prescribed medicine | | | | | | |
| 2) confirming that suitable products are held in stock or available from a supplier | | | | | | |
| 3) ensuring that patients can access ongoing supplies of their medication | | | | | | |
| 4) understanding how medicines are licensed, sourced, supplied and monitored | | | | | | |
| *updating knowledge by* | | | | | | |
| 5) maintaining an up-to-date knowledge of relevant products | | | | S | | |
| *prescribing in an appropriate manner by* | | | | | | |
| 6) understanding cost concerns relevant to prescribing | | | | **S** | | |
| **Section B Prescribe to an acceptable standard** | | | | | | |
| *reviewing patient clinical problems by* | | | | | | |
| 1) understanding the conditions being treated, their natural progress and how to assess their severity | **S** | | | | | |
| 2) identifying the nature, severity and significance of the clinical problem | | | | | | |
| *reviewing patient therapy options by* | | | | | | |
| 3) understanding the pharmacological and/non-pharmacological approaches to modifying conditions | **S** | | | **S** | | |
| 4) understanding the mechanism of action and pharmacokinetics of medicines and how these mechanisms may be altered | | | | | | |

| | Gender | Practice Location | Practice Setting | Extra Qualification | Age | Duration of practice |
|---|---|---|---|---|---|---|
| 5) identifying clinically significant potential or actual drug related problems in the current medication treatment | | | | S | | |
| 6) requesting common laboratory tests and investigations performed on individual patients | | | | S | | |
| 7) interpreting relevant investigations and evaluating the significance of common laboratory tests and investigations performed on individual patients | | | | S | | |
| 8) considering no treatment, non-drug and drug treatment options (including referral and preventive measures) | S | | | S | | |
| 9) assessing the effect of multiple pathologies, existing medication and contraindications on treatment options | | | | | | |
| 10) assessing the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment) | | | | S | | |
| 11) applying the principles of evidence-based medicine | | | | S | | |
| 12) applying the principles of clinical cost effectiveness | | | | S | | |
| *selecting treatment by* | | | | | | |
| 13) selecting the most appropriate drug, dose and formulation for the individual patient and prescribe appropriate quantities | | | | S | | |
| 14) establishing and maintaining a plan for reviewing the therapeutic objective or end point of treatment | S | | | S | | |
| 15) monitoring effectiveness of treatment and potential unwanted effects and assess whether medication treatment is achieving therapeutic goals/ outcomes | | | | S | | |
| 16) making changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences | | | | S | | |
| **Section C Prescribe safely** | | | | | | |

| | Gender | Practice Location | Practice Setting | Extra Qualification | Age | Duration of practice |
|---|---|---|---|---|---|---|
| *reviewing the prescribing process by* | | | | | | |
| 1) knowing the limits of my own knowledge and skill to prescribe safely | | | | S | | |
| 2) knowing when and how to refer to, or seek guidance from another member of the team or a specialist | | | | S | | |
| 3) prescribing a medicine using adequate, up-to-date knowledge | | | | S | | |
| 4) deciding on the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine | | | | S | | |
| 5) checking doses and calculations to ensure accuracy and safety | | | | S | | |
| 6) making accurate, clear and timely records | | | | S | | |
| *updating patient information by* | | | | | | |
| 7) taking a comprehensive history | | | | S | | |
| 8) assessing and interpreting all relevant patient records to ensure knowledge of the patient's management | | | | S | | |
| *applying safety issues in prescribing by* | | | | | | |
| 9) keeping up to date with advances in practice and emerging safety concerns | | | | S | | |
| 10) establishing systems for responding when an error occurs during prescribing | | | | S | | |
| 11) establishing systems for reporting and responding to medication errors | | | | S | | |
| 12) generating legible, clear and complete prescriptions, which meet legal requirements | | | | S | | |
| 13) using documentation and systems that support prescription validation | | | | S | | |
| *applying knowledge and skills to prescribe in an appropriate manner by* | | | | | | |
| 14) making prescribing decisions with confidence and competence | | | | S | | |
| *assessing progress of the clinical condition by* | | | | | | |
| 15) understanding disease state management principles | | | | S | | |
| 16) understanding the conditions being treated, their natural progress and how to assess their severity | | | | S | | |

| | Gender | Practice Location | Practice Setting | Extra Qualification | Age | Duration of practice |
|---|---|---|---|---|---|---|
| 17) performing clinical assessment for various clinical conditions in appropriate areas | S | | | S | | |
| 18) using appropriate techniques and equipment | S | | | S | | |
| **Section D Prescribe professionally** | | | | | | |
| *working within professional, regulatory and organisational standards by* | | | | | | |
| 1) accepting responsibility for my own prescribing | | | | S | | |
| 2) making prescribing decisions based on patient-related factors | | | | S | | |
| 3) prescribing to an acceptable standard | | | | | | |
| *working in partnership towards benefit of patients by* | | | | | | |
| 4) being able to negotiate with members of the prescribing team | | | | S | | |
| 5) ensuring that the patient has agreed to be managed within a partnership | | | | | | |
| 6) understanding the cultural and religious implications of the diagnosis/ prescribing | | | | | | |
| *behaving in a professional and ethical manner by* | | | | | | |
| 7) understanding how current legislation affects prescribing practice | | | | | | |
| 8) understanding the scope of my own prescribing responsibility | | | | S | | |
| 9) maintaining patient confidentiality | | | | S | | |
| 10) maintaining security of prescribing stationery or computer security systems | | | | | | |
| 11) maintaining the security and confidentiality of data being transferred | | | | | | |
| 12) recognising and dealing with pressures that might result in inappropriate prescribing | | | | S | | |
| 13) taking responsibility for my own continuing professional development in relation to prescribing | | | | S | | |
| **Section E Participate in the development of prescribing practice** | | | | | | |
| *participating in the review of prescribing practice by* | | | | | | |
| 1) learning and changing through reflecting on my own practice | | | | S | | |
| 2) sharing my own prescribing practice | | | | S | | |

| | Gender | Practice Location | Practice Setting | Extra Qualification | Age | Duration of practice |
|---|---|---|---|---|---|---|
| 3) sharing and debating others' prescribing practice | | | | | | |
| 4) challenging inappropriate practice constructively | | | | | | |
| *using own networks by* | | | | | | |
| 5) developing networks for mutual support, reflection and learning | | | | **S** | | |
| 6) establishing multiprofessional links with practitioners working in the same practice area | | | | **S** | | |
| *using tools to improve practice by* | | | | | | |
| 7) understanding and knowing the types of dissemination tools/strategies that can be used to share information or review findings and recommendations for change | | | | | | |
| *reporting prescribing errors by* | | | | | | |
| 8) reporting prescribing errors and near misses that I am aware of | | | | | | |
| 9) reviewing my practice to prevent error recurrences | **S** | | | | | |
| **Section F Communicate effectively with patients** | | | | | | |
| *understanding and respecting the uniqueness of individuals by* | | | | | | |
| 1) understanding patients' beliefs, ideas, concerns and expectations | | | | | | |
| 2) understanding the cultural and religious implications of the diagnosis/ prescribing | | | | | | |
| *undertaking the consultation in an appropriate manner by* | | | | | | |
| 3) undertaking it in an appropriate setting and adapting it to meet the needs of different patients | | | | | | |
| 4) dealing sensitively with patients' emotions and concerns | | | | **S** | | |
| 5) explaining the nature of the patient's condition, the rationale behind and potential risks and benefits of management options | | | | **S** | | |
| 6) enabling patients to make informed choices about their management | | | | **S** | | |
| *negotiating an outcome by* | | | | | | |
| 7) through consultation that both patient and prescriber are satisfied with | | | | **S** | | |

| | Gender | Practice Location | Practice Setting | Extra Qualification | Age | Duration of practice |
|---|---|---|---|---|---|---|
| *giving clear instructions about the medication by* | | | | | | |
| 8) encouraging patients to take responsibility for their own health and self manage their conditions | | | | | | |
| 9) assisting patients' understanding of their medical condition and/or medication treatment | | | | | | |
| *following up by* | | | | | | |
| 10) checking the patients' understanding and commitment to their current and ongoing management | | | | | | |
| **Section G Provide medicines, health information and education** | | | | | | |
| *understanding the readily available information sources by* | | | | | | |
| 1) recognising the availability of information sources that can provide relevant information | | | | **S** | | |
| 2) understanding the advantages and limitations of various information sources | | | | | | |
| *using relevant, up to date information by* | | | | | | |
| 3) formulating recommendations for changes to medication treatment based on the latest evidence and information on new medicines | | | | **S** | | |
| *critically appraise the validity of information sources by* | | | | | | |
| 4) critically evaluating research findings | | | | | | |
| 5) using primary and secondary information sources to critically evaluate the efficacy and safety of medicines | | | | | | |
| 6) critically evaluating the reliability and accuracy of new information in primary information sources | | | | | | |
| 7) calculating and manipulating clinical data and associated costs accurately | | | | | | |
| *applying information in the clinical context by* | | | | | | |
| 8) information sources, sharing research findings with colleagues and other health professionals/ facility personnel whose care processes may be affected | | | | | | |
| *reviewing evidence by* | | | | | | |
| 9) using relevant patient record systems, prescribing and information systems, and decision support tools | | | | **S** | | |

| | Gender | Practice Location | Practice Setting | Extra Qualification | Age | Duration of practice |
|---|---|---|---|---|---|---|
| 10) working collaboratively with other clinicians to prepare or revise medication treatment protocols, guidelines, criteria and/or standards | | | | | | |

(S): Items with p value <0.05

**Table 23: Ordinal regression analysis indicating significant items for functional area 9 based on gender**

| Competency Unit | Items significantly influenced by gender | Female ( $p < 0.05$) OR=Odds ratio CI= 95% Confidence Interval |
|---|---|---|
| **Section A Prescribe effectively** | Nil | |
| **Section B Prescribe to an acceptable standard** | *reviewing patient clinical problems by:* understanding the conditions being treated, their natural progress and how to assess their severity | **p = 0.045 OR = 0.54 CI = -1.221- (-0.014)** |
| | *reviewing patient therapy options by:* understanding the pharmacological and/non-pharmacological approaches to modifying conditions | **p = 0.026 OR = 0.48 CI = -1.375-(-0.087)** |
| | *reviewing patient therapy options by:* considering no treatment, non-drug and drug treatment options (including referral and preventive measures) | **p = 0.008 OR = 0.43 CI = -1.481-(-0.217)** |
| | *selecting treatment by:* establishing and maintaining a plan for reviewing the therapeutic objective or end point of treatment | **p = 0.016 OR = 0.47 CI = -1.383-(-0.145)** |
| **Section C Prescribe safely** | *assessing progress of the clinical condition by:* performing clinical assessment for various clinical conditions in appropriate areas | **p = 0.027 OR = 0.51 CI = -1.268-(-0.076)** |
| | *assessing progress of the clinical condition by:* using appropriate techniques and equipment | **p = 0.001 OR = 0.36 CI = -1.629-(-0.408)** |
| **Section D Prescribe professionally** | Nil | |
| **Section E Participate in the development of prescribing practice** | *reporting prescribing errors by:* reviewing my practice to prevent error recurrences | **p = 0.015 OR = 0.46 CI = -1.400-(-0.154)** |
| **Section F Communicate effectively with patients** | Nil | |
| **Section G Provide medicines, health information and education** | Nil | |

**Table 24: Ordinal regression analysis indicating significant items for functional area 9 based on qualification**

| Competency Unit | Items significantly influenced by extra qualification | Extra qualification ( $p < 0.05$) OR=Odds ratio CI= 95% Confidence Interval |
|---|---|---|
| **Section A Prescribe effectively** | *updating knowledge by:* maintaining an up-to-date knowledge of relevant products | **p = 0.001 OR = 3.02 CI = 0.434-1.775** |
| | *prescribing in an appropriate manner by:* understanding cost concerns relevant to prescribing | **p = 0.001 OR = 3.06 CI = 0.443 -1.795** |
| **Section B Prescribe to an acceptable standard** | *reviewing patient therapy options by:* understanding the pharmacological and/non-pharmacological approaches to modifying conditions | **p < 0.001 OR = 3.80 CI = 0.661-2.009** |
| | identifying clinically significant potential or actual drug related problems in the current medication treatment | **p = 0.001 OR = 2.99 CI = 0.441-1.747** |
| | requesting common laboratory tests and investigations performed on individual patients | **p < 0.001 OR = 4.54 CI = 0.891-2.135** |
| | interpreting relevant investigations and evaluating the significance of common laboratory tests and investigations performed on individual patients | **p < 0.001 OR = 3.78 CI = 0.713-1.946** |
| | considering no treatment, non-drug and drug treatment options (including referral and preventive measures) | **p < 0.001 OR = 4.13 CI = 0.759-2.079** |
| | assessing the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment) | **p < 0.001 OR = 3.43 CI = 0.580-1.889** |
| | applying the principles of evidence-based medicine | **p < 0.001 OR = 3.44 CI = 0.589-1.881** |
| | applying the principles of clinical cost effectiveness | **p = 0.001 OR = 2.99 CI= 0.466-1.722** |
| | *selecting treatment by:* selecting the most appropriate drug, dose and formulation for the individual patient and prescribe appropriate quantities | **p = 0.001 OR = 3.04 CI= 0.486-1.738** |
| | establishing and maintaining a plan for reviewing the therapeutic objective or end point of treatment | **p < 0.001 OR = 4.14 CI= 0.771-2.071** |
| | monitoring effectiveness of treatment and potential unwanted effects and assess whether medication treatment is achieving therapeutic goals/ outcomes | **p < 0.001 OR = 3.37 CI= 0.575-1.855** |

| Competency Unit | Items significantly influenced by extra qualification | Extra qualification ( $p < 0.05$) OR=Odds ratio CI= 95% Confidence Interval |
|---|---|---|
| | making changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences | **p = 0.003 OR = 2.46 CI = 0.301-1.503** |
| **Section C Prescribe safely** | *reviewing the prescribing process by:* knowing the limits of my own knowledge and skill to prescribe safely | **p = 0.004 OR = 2.68 CI = 0.323-1.652** |
| | knowing when and how to refer to, or seek guidance from another member of the team or a specialist | **p = 0.014 OR = 2.69 CI = 0.197-1.781** |
| | prescribing a medicine using adequate, up-to-date knowledge | **p = 0.033 OR = 2.33 CI = 0.070-1.617** |
| | deciding on the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine | **p < 0.001 OR = 4.40 CI = 0.821-2.143** |
| | checking doses and calculations to ensure accuracy and safety | **p = 0.003 OR = 2.93 CI = 0.375-1.774** |
| | making accurate, clear and timely records | **p = 0.003 OR = 3.00 CI = 0.365-1.829** |
| | *updating patient information by:* taking a comprehensive history | **p = 0.001 OR = 2.77 CI = 0.393-1.642** |
| | assessing and interpreting all relevant patient records to ensure knowledge of the patient's management | **p = 0.005 OR = 2.43 CI = 0.272-1.501** |
| | *applying safety issues in prescribing by:* keeping up to date with advances in practice and emerging safety concerns | **p = 0.006 OR = 2.40 CI = 0.250-1.497** |
| | establishing systems for responding when an error occurs during prescribing | **p = 0.014 OR = 2.09 CI = 0.157-1.400** |
| | establishing systems for reporting and responding to medication errors | **p = 0.013 OR = 2.21 CI = 0.168-1.419** |
| | generating legible, clear and complete prescriptions, which meet legal requirements | **p = 0.025 OR = 2.16 CI = 0.098-1.438** |
| | using documentation and systems that support prescription validation | **p = 0.007 OR = 2.39 CI = 0.234-1.509** |

| Competency Unit | Items significantly influenced by extra qualification | Extra qualification ( $p < 0.05$) OR=Odds ratio CI= 95% Confidence Interval |
|---|---|---|
| | *applying knowledge and skills to prescribe in an appropriate manner by:* making prescribing decisions with confidence and competence | **p = 0.015 OR = 2.10 CI = 0.144-1.344** |
| | *assessing progress of the clinical condition by:* understanding disease state management principles | **p = 0.001 OR = 2.82 CI = 0.427-1.649** |
| | understanding the conditions being treated, their natural progress and how to assess their severity | **p = 0.003 OR = 2.52 CI = 0.316-1.530** |
| | performing clinical assessment for various clinical conditions in appropriate areas | **p = 0.004 OR = 2.44 CI = 0.282-1.501** |
| | using appropriate techniques and equipment | **p = 0.004 OR = 2.46 CI = 0.284-1.515** |
| **Section D Prescribe professionally** | *working within professional, regulatory and organisational standards by:* accepting responsibility for my own prescribing | **p = 0.023 OR = 2.08 CI = 0.100-1.367** |
| | making prescribing decisions based on patient-related factors | **p = 0.014 OR = 2.16 CI = 0.156-1.387** |
| | *working in partnership towards benefit of patients by:* being able to negotiate with members of the prescribing team | **p = 0.030 OR = 2.01 CI = 0.068-1.332** |
| | *behaving in a professional and ethical manner by:* understanding the scope of my own prescribing responsibility | **p = 0.003 OR = 2.74 CI = 0.354-1.663** |
| | maintaining patient confidentiality | **p = 0.005 OR = 3.55 CI = 0.380-2.156** |
| | recognising and dealing with pressures that might result in inappropriate prescribing | **p = 0.007 OR = 2.39 CI = 0.240-1.500** |
| | taking responsibility for my own continuing professional development in relation to prescribing | **p < 0.001 OR = 4.00 CI = 0.652-2.123** |
| **Section E Participate in the development of prescribing practice** | *participating in the review of prescribing practice by:* learning and changing through reflecting on my own practice | **p = 0.004 OR = 2.46 CI = 0.282-1.515** |
| | sharing my own prescribing practice | **p = 0.006 OR = 2.30 CI = 0.235-1.435** |

| Competency Unit | Items significantly influenced by extra qualification | Extra qualification ( $p < 0.05$) OR=Odds ratio CI= 95% Confidence Interval |
|---|---|---|
| | *using own networks by:* developing networks for mutual support, reflection and learning | **p = 0.001 OR = 2.83 CI = 0.425-1.653** |
| | establishing multiprofessional links with practitioners working in the same practice area | **p = 0.004 OR = 2.44 CI = 0.282-1.498** |
| **Section F Communicate effectively with patients** | *undertaking the consultation in an appropriate manner by:* dealing sensitively with patients' emotions and concerns | **p = 0.002 OR = 2.73 CI = 0.365-1.646** |
| | explaining the nature of the patient's condition, the rationale behind and potential risks and benefits of management options | **p = 0.019 OR = 2.07 CI = 0.118-1.341** |
| | enabling patients to make informed choices about their management | **p = 0.005 OR = 2.49 CI = 0.279-1.544** |
| | *negotiating an outcome by:* through consultation that both patient and prescriber are satisfied with | **p = 0.009 OR = 2.29 CI = 0.206-1.449** |
| **Section G Provide medicines, health information and education** | *understanding the readily available information sources by:* recognising the availability of information sources that can provide relevant information | **p = 0.012 OR = 2.26 CI =0.180-1.449** |
| | *using relevant, up to date information by:* formulating recommendations for changes to medication treatment based on the latest evidence and information on new medicines | **p < 0.001 OR = 3.58 CI = 0.643-1.910** |
| | *reviewing evidence by:* using relevant patient record systems, prescribing and information systems, and decision support tools | **p = 0.001 OR = 2.74 CI = 0.397-1.617** |

## 6.4 Discussion

Careful interpretation of the results is needed, since this survey has ascertained only pharmacists' perceived confidence in their ability and this might not truly reflect their level of clinical skills and knowledge in practice.

Pharmacists perceived high levels of confidence in most of the areas important in prescribing. Having an extra qualification (an additional educational qualification in a pharmacy-related area or accreditation from AACP) was found to play an important role in influencing their confidence level in many of the areas.

Most of the respondents (89%) in the survey were community pharmacists. This is in line with the high proportion of pharmacists practising in the community setting in Australia. Recent pharmacy workforce data show that community pharmacists represented 78% of the pharmacists in Australia, followed by those working in hospital (15.4%), industrial (1.5%), administration (1.1%), teaching (1%) and other settings (3.1%).[123] The results of this study showed that practice setting did not significantly affect the level pharmacists' confidence level in the areas important in prescribing.

One of the purposes of the survey was to identify potential areas of educational need for pharmacists to become competent to prescribe in the Australian context. As discussed in Chapter 2, previous studies in the UK identified that pharmacists needed further training in diagnosis of conditions and communication and consultation skills.[28,99,124] These studies were conducted after the pharmacists had undergone the initial prescribing course. In the current survey, lack of confidence was reported for the element "*assessing progress of clinical condition*" in Section C (Prescribe Safely), which involves performing clinical assessment and using appropriate techniques and equipment, but not in the area of communication negotiation skills under Section F (Communicate Effectively with Patients).

Given that extra qualifications were associated with greater confidence relating to prescribing competencies, an issue arises whether prior learning associated with other qualifications needs to be recognised when entering a prescribing course, and what aspects would be relevant for consideration.

### *6.4.1 Limitations*

The low response rate (n=160; 20%) in this survey meant that the target number of responses (357) was not achieved, thus compromising the representativeness of the sample. A low level of interest in the research topic can lead to low response rates, which may have been a factor in this study. The length of the survey may also influenced the response rate.

Because of the low response rate, the results may be biased towards the opinions of the respondents. It may be that the respondents were those who were interested in pharmacist prescribing, which could have led to the highly positive level of agreement in most of the areas. This was suspected from the free-text comments received in which most of the feedback related to pharmacist prescribing research was positive. Two respondents, who did not complete the survey and returned it to the researcher, commented that they declined to participate because they opposed the idea of pharmacist prescribing.

While it would have been preferable to conduct the study with pharmacists throughout Australia, this was not possible because of inconsistencies in accessibility of contact information for pharmacists from the eight pharmacy registering authorities that were in operation across the states and territories in Australia at the time; therefore, the study was conducted only within Victoria**.** This limits the generalisability of the results to the population of Australian pharmacists. As the practice of pharmacy in Australia, particularly in the community setting, is largely governed by national legislation, it does not differ significantly among the states and territories. In addition, the results showed that practice location and setting did not significantly influence pharmacists' confidence level in prescribing. It is therefore likely that the assumption made regarding the standard of practice across Australia is valid.

## 6.5 Conclusion

Generally, pharmacists perceived that they possess the clinical skills and knowledge in most of the areas important to prescribing and pharmacists with extra qualifications were found to be more confident in their clinical skills and knowledge to prescribe.

It was noted that pharmacists were less confident and needed further training in performing clinical assessment and using appropriate techniques and equipment. It may be advisable to recognise prior learning, before entry into a prescribing course.

# Chapter 7: Identifying the Educational Needs for Pharmacists to become Prescribers

**Summary**

- This chapter builds on the study findings in Chapters 4 and 6.
- Case-based scenarios were used in interviews conducted with pharmacists and medical practitioners.
- The purpose of conducting these interviews was to further elucidate the gaps in knowledge and skills for pharmacists in areas needed for prescribing.

# Chapter 7: Identifying the Educational Needs for Pharmacists to become Prescribers

## 7.1 Background

During the review and validation of "the standards" (Chapter 4), concerns were expressed about pharmacists' capability in history-taking and in identifying critical points in the patient history, commonly referred to as 'red flags'. Medical practitioner panellists based their concerns on the assumption that there is a lack of training for pharmacists in this area. These findings were consistent with barriers related to pharmacist prescribing, either prior to or during implementation, discussed in Chapter 1.

Because of these concerns, a study was conducted to explore the differences in medical practitioners' and pharmacists' approaches to patient management in order to elucidate the gaps in knowledge and skills for pharmacists in undertaking the extended role of prescribing.

### *7.1.1 Aims*

The purposes of this study were to:

1. Compare approaches to patient management between medical practitioners and pharmacists.

2. Identify the educational needs for pharmacists to become prescribers.

## 7.2 Method

A series of case vignettes were used, through structured interviews, to identify the differences in patient management approaches between medical practitioners and pharmacists. Case study research is a qualitative approach in which the investigator explores a bounded system (a case) or multiple bounded systems (cases) and reports a case description and case-based themes.[125]

Interview is a commonly used method in qualitative research; structured interviews use predetermined questions that are expected to elicit the subjects' thoughts, opinions and attitudes about the issues.[125] A summary of the study methodology is illustrated in **Figure 9**.

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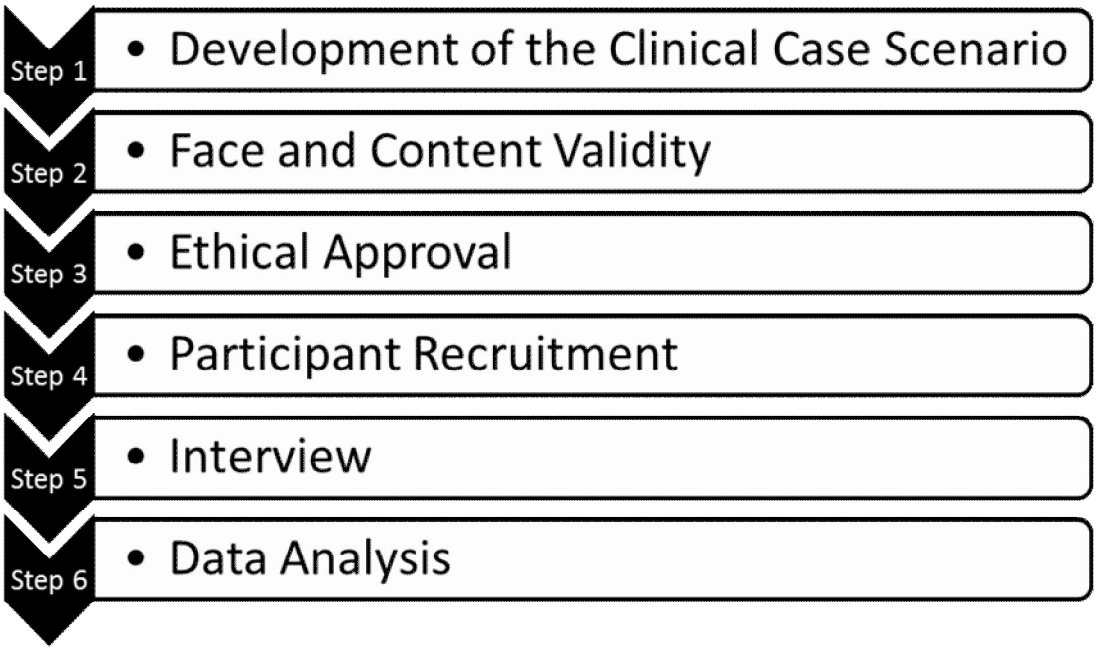


**Figure 9: Flow chart for the patient management study**

### *7.2.1 Development of the Clinical Case Scenarios*

The case scenarios were developed using medical and pharmacotherapeutic clinical references.[126,127] The ten case scenarios ranged from acute to chronic diseases with different levels of complexity involving both hospital and community settings, in order to explore differences in the approach to patient management at different levels of complexity.

In each of the cases, several questions explored both sets of professions' general approach and confidence in managing the cases. A question to explore their usual approach allowed participants to verbalise their thoughts about what they would usually do in their normal daily practice if they encountered such a case. While all of the questions developed about the cases were designed to explore the general differences in approach between medical practitioners and pharmacists, questions were developed in some cases specifically to differentiate certain levels of thinking and confidence in patient management. The specific aims and outcomes expected for each of the case scenarios used in the interviews are listed in **Table 25**.

**Table 25 : Case scenarios**

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| A | Acute exacerbation of childhood asthma (Community) | The aims of this case were to explore the ability to take a thorough history, to identify trigger factors for the current problem and to manage a patient with a history of childhood asthma.<br><br>Category: Acute simple case | **A) History taking:**<br>▪ Establish rapport<br>▪ Elucidate onset, factors triggering asthma<br>▪ Elicit medication history<br>**B) Problem Identification:**<br>**Assessment:**<br>▪ Seek permission to examine (medical practitioners)<br>▪ Ask for examination findings (pharmacist)<br>▪ Physical observation and laboratory investigation<br>**C) Appropriate Management:**<br>• **Management:**<br>▪ Pharmacotherapy including the decision to dispense Pharmacist Only medicine for asthma (pharmacist)<br>▪ Non-pharmacotherapy, including lifestyle modifications<br>• **Referral:**<br>▪ The point of referral to a medical practitioner (pharmacist) or respiratory physician (medical practitioner) |
| B | Acute management of back pain (Community) | The aims of this case were to explore the ability to take a thorough history, identify issues related to the symptoms and make decisions on appropriate management and referral for a case of acute back pain. | **A) History taking:**<br>▪ Establish rapport<br>▪ Elucidate site, duration and severity of pain<br>▪ Identify the cause of pain<br>▪ Elicit medication history |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | Category: Acute simple case due to possible chronic underlying problem | **B) Problem Identification:**<br>▪ **Assessment:**<br>▪ Seek permission to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Physical observation based on history taking<br>**C) Appropriate Management:**<br>▪ **Management:**<br>▪ Pharmacotherapy including OTC or Pharmacist Only medicine for pain management (pharmacist)<br>▪ Nonpharmacotherapy including referral to an allied health practitioner.<br>• **Referral:**<br>▪ The point of referral to medical practitioner (pharmacist) or neurologist (medical practitioner) |
| C | Protocol management for warfarin (Hospital) | The aims of this case were to explore the level of agreement for managing a patient using protocol-based prescribing, the ability to take a thorough history, to identify issues related with protocol-based management and the ability to manage a case using protocol-based prescribing of warfarin.<br><br>Category: Unstable to stable chronic case (protocol prescribing) | **A) History taking:**<br>▪ Establish rapport<br>▪ Elicit medication history<br>▪ Elucidate start, onset and duration of warfarin therapy<br>▪ Establish other treatments and diseases<br>**B) Problem Identification:**<br>▪ **Assessment:**<br>▪ Seek permission to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist) |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | ▪ Physical observation based on history taking<br>▪ Interpret appropriateness of the management based on the warfarin level<br>**C) Appropriate Management:**<br>▪ **Management:**<br>▪ Pharmacotherapy including the monitoring of safety and efficacy of warfarin.<br>▪ Identify other medication affecting warfarin level and disease condition.<br>▪ Nonpharmacotherapy including lifestyle changes and other factors that affect warfarin level and disease condition.<br>▪ **Referral:**<br>▪ The point of referral to medical practitioner (pharmacist only) or cardiologist (medical practitioner and pharmacist) |
| D | Acute exacerbation of underlying congestive heart failure (Hospital) | The aims of this case were to explore the ability to identify the underlying issues, to take a thorough history and appropriately refer a patient with a provisional diagnosis of congestive heart failure.<br><br>Category: Acute severe case due to chronic underlying problem | **A) History taking:**<br>▪ Establish rapport<br>▪ Based on the symptoms e.g. breathlessness, orthopnoea, identify the possible causes of the problem e.g. disease complications, drug-induced<br>▪ Elicit medication history<br>**B) Problem Identification:**<br>• **Assessment:**<br>▪ Seek permission to conduct examination (medical |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Establish the possible diagnosis based on symptoms, physical examination (medical practitioner), observation and history taking<br>**C) Appropriate Management:**<br>▪ **Management:**<br>▪ Pharmacotherapy including identifying drug-related problems<br>▪ Recommendations for problem management<br>▪ **Referral:**<br>▪ Urgent hospital referral (pharmacist and medical practitioner)<br>▪ Follow-up by cardiologist |
| E | Chronic case of rhinorrhoea (Community) | The aims of this case were to explore the ability to take a thorough history, identify possible causative factors, establish a provisional diagnosis and appropriately refer a case of chronic rhinorrhoea.<br><br>Category: Chronic underlying problem | **A) History taking:**<br>▪ Establish rapport<br>▪ Establish onset and duration of the symptoms<br>▪ Identify the possible causes of the problem<br>▪ Elicit medication history<br>**B) Problem Identification:**<br>• **Assessment:**<br>▪ Seek permission to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Identify the possible diagnosis based on the symptoms, |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | physical examination (medical practitioner), observation and history taking<br>**C) Appropriate Management:**<br>▪ **Management:**<br>▪ Pharmacotherapy including recommendation for symptomatic and long-term management of the patient's problem<br>▪ **Referral:**<br>▪ The point of referral to medical practitioner (pharmacist) or otolaryngologist (medical practitioner) |
| F | Uncontrolled diabetes mellitus (Community) | The aims of this case were to explore the ability to take a thorough history, to identify factors related to uncontrolled disease, medicine-related issues, goals of patient therapy, management, monitoring and patient education and the point of referral for a patient with uncontrolled diabetes mellitus.<br><br>Category: Chronic unstable case | **A) History taking:**<br>▪ Establish rapport<br>▪ Identify uncontrolled diabetes symptoms e.g. polydipsia, polyuria, vaginal candidiasis and random blood glucose<br>▪ Identify the possible causes of the problem<br>▪ Identify prior pharmacotherapy and nonpharmacotherapy management<br>▪ Identify the severity of the disease<br>▪ Identify other complications related to the disease<br>**B) Problem Identification:**<br>• **Assessment:**<br>▪ Seek permission to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Identify the possible diagnosis based on the symptoms, |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | physical examination (medical practitioner), observation and history taking<br>▪ Identify the severity of the disease<br>▪ Identify other complications related to the disease<br>**C) Appropriate Management:**<br>• **Management:**<br>▪ Identify the goals of therapy<br>▪ Suggest pharmacotherapy and lifestyle modifications<br>▪ Suggest appropriate monitoring for diabetes mellitus and home glucose monitoring<br>• **Referral:**<br>▪ The point of referral to medical practitioner (pharmacist) or endocrinologist (medical practitioner) |
| G | Chronic migraine with possible underlying issues (Community) | The aims of this case were to explore the ability to take a thorough history, identify the underlying problems, make a provisional diagnosis, select appropriate treatment and appropriately refer a patient with a provisional diagnosis of migraine.<br><br>Category: Acute severe case due to possible underlying problem | **A) History taking:**<br>▪ Establish rapport<br>▪ Elicit description of headache<br>▪ Elicit onset, duration and severity of headache<br>▪ Identify factors triggering the pain<br>▪ Elicit medication history<br>**B) Problem Identification:**<br>• **Assessment:**<br>▪ Seek permission to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Establish a provisional diagnosis based on the symptoms, |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | physical examination (medical practitioner), observation and history<br>**C) Appropriate Management:**<br>• **Management:**<br>▪ Pharmacotherapy management including recommendation for symptomatic migraine and long-term management for migraine.<br>• **Referral:**<br>▪ The point of referral to medical practitioner (pharmacist) or neurologist (medical practitioner) |
| H | Acute abdominal pain with possible chronic underlying problems (Community) | The aims of this case were to explore the ability to take a thorough history, identify the underlying factors leading to the current problem, to establish a provisional diagnosis and appropriately referral a case of abdominal pain.<br><br>Category: Acute severe case due to underlying problem. | **A) History taking:**<br>▪ Establish rapport<br>▪ Elicit description of abdominal pain<br>▪ Establish onset, duration, location and severity of abdominal pain<br>▪ Establish factors triggering the pain<br>▪ Establish other symptoms associated with the pain<br>▪ Elicit medication history<br>**B) Problem Identification:**<br>• **Assessment:**<br>▪ Seek permission to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Identify the possible diagnosis based on the symptoms, physical examination (medical practitioner), observation |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | and history taking<br>▪ Identify differential diagnosis for acute abdominal pain<br>**C) Appropriate Management:**<br>• **Management:**<br>▪ Pharmacotherapy including recommendation for symptomatic acute abdominal pain and long-term management for other underlying problems.<br>• **Referral:**<br>▪ The point of referral to medical practitioner (pharmacist) or gastroenterologist (medical practitioner) |
| I | Acute disease management of childhood diarrhoea (Community) | The aims of this case were to explore the ability to take a thorough history, identify the underlying factors leading to the current problem, establish a provisional diagnosis and appropriately refer a case of paediatric diarrhoea.<br><br>Category: Acute severe paediatric case | **A) History taking:**<br>▪ Establish rapport<br>▪ Elicit a description of the diarrhoea<br>▪ Establish the onset, duration and severity of diarrhoea<br>▪ Identify factors triggering the diarrhoea<br>▪ Elicit other symptoms associated with diarrhoea<br>▪ Elicit medication history<br>**B) Problem Identification**<br>• **Assessment:**<br>▪ Seek permission from parent/guardian to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Identify the possible diagnosis based on the symptoms, physical examination (medical practitioner), observation and history taking |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | ▪ Identify possible differential diagnosis<br>**C) Appropriate Management**<br>• **Treatment decision:**<br>▪ Pharmacotherapy management including recommendations for treatment of acute diarrhoea and long-term management for chronic diarrhoea.<br>• **Referral:**<br>▪ Appropriate referral to medical practitioner (pharmacist) or paediatrician (medical practitioner) |
| J | Multiple chronic disease management in the elderly (Home Medicine Review) (Community) | The aims of this case were to explore the ability to take a thorough history, and to identify the current problems, medicine-related issues, disease- and lifestyle-related issues, patient monitoring and education and appropriate referral of an elderly patient with multiple chronic conditions.<br><br>Category: Acute severe exacerbation of chronic unstable condition | **A) History taking:**<br>▪ Establish rapport<br>▪ Establish frequency, timing and injuries associated with fainting<br>▪ Identify factors triggering the faint e.g. disease, treatment or other factors<br>▪ Elicit other symptoms experienced<br>▪ Current outcome on the other disease condition<br>▪ Elicit medication history<br>**B) Problem Identification:**<br>• **Assessment:**<br>▪ Seek permission to conduct examination (medical practitioner)<br>▪ Ask for examination findings (pharmacist)<br>▪ Identify the possible diagnosis based on the symptoms, physical examination (medical practitioner), observation |

| | Case scenarios (Practice setting) | Case Description (Category) | Expected Outcomes (Domains: History Taking, Problem Identification, Appropriate Management) |
|---|---|---|---|
| | | | and history taking<br>▪ Identify underlying problems<br>▪ Establish differential diagnosis related to the problems<br>**C) Appropriate Management:**<br>• **Management:**<br>▪ Pharmacotherapy management including identifying drug-related problems, discontinuing related medication, recommending appropriate alternative long-term management.<br>▪ Nonpharmacotherapy management including lifestyle modifications<br>• **Referral:**<br>▪ Appropriate referral to medical practitioner (pharmacist) or geriatrician (medical practitioner) |

## 7.3 Face and Content Validity

Cases were derived from a commonly-used current international pharmacotherapeutic clinical reference.[126] To ensure that the cases were applicable in the local setting, a local source was consulted.[127]

Five pharmacists working in community and hospital settings and a pharmacist with academic background confirmed the face and content validity of the case scenarios. Some modifications were made to the original case scenarios after feedback, mainly related to ordering of the case scenarios, wording of the questions and the setting of the case. Rather than ordering the cases from the least complex to the most complex, as originally presented, the ordering was made random to prevent bias in participant responses if they perceived a logical order in case complexity. In order to create a relaxed atmosphere for the interview, it was emphasised that the study was being conducted to explore participants' usual approach to patient management and was not an assessment of their performance.

### *7.3.1 Ethical Approval*

This study was approved by Monash University Standing Committee on Ethics in Research Involving Humans (SCERH) (**Appendix 16**).

### *7.3.2 Participant Recruitment*

The project was conducted from February until November 2008 and was advertised in professional newsletters to encourage recruitment (**Appendix 17**). Interested potential participants were invited to contact the researcher through the contact details provided in the advertisement.

Due to the low response rate through this recruitment process, an amendment was made in the sampling method, which was approved by the SCERH. Snowball sampling was used to increase participation by both medical practitioners and pharmacists. Medical practitioners

and pharmacists who participated were asked to convey information about the study to other potential participants. Low response rates were encountered in both professions but mainly with medical practitioners; therefore, an additional strategy was used whereby pharmacists working in various Divisions of General Practice distributed the study information among medical practitioners. An advertisement similar to the printed leaflet was sent via email and potential participants were asked to contact the researcher through the contact details provided in the advertisement.

Regardless of the means of recruitment, the researcher sent the explanatory statement (**Appendix 18**) via email or post to the interested individuals. The date and venue of the face-to-face interview was mutually agreed upon between the researcher and each participant. Signed consent (**Appendix 19**) was received prior to the commencement of the interview. The recruitment process is summarised in **Figure 10**.

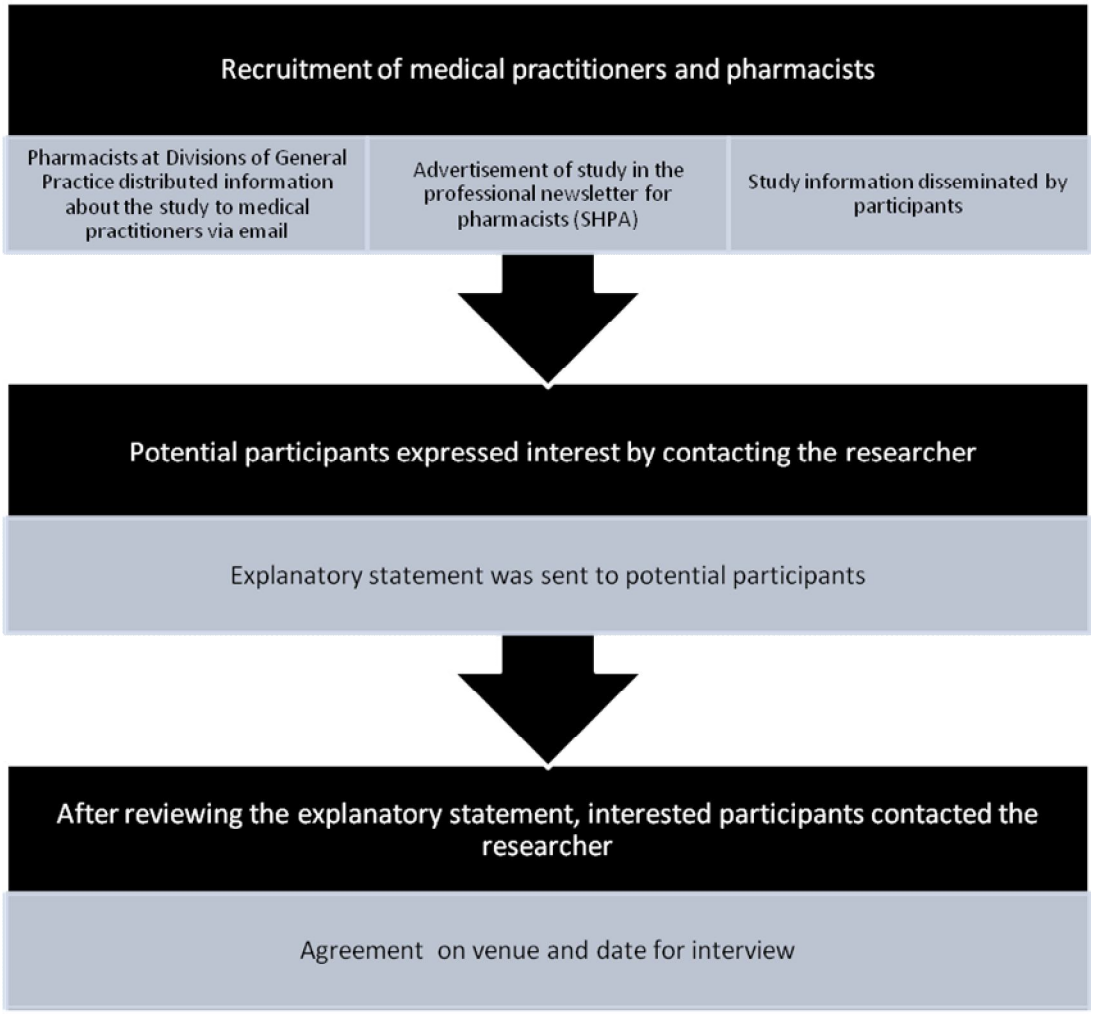


**Figure 10: Participant recruitment process**

### *7.3.3 Interview*

There are generally six types of questions that may be asked of people during an interview. These questions are experience and behaviour questions, opinion and values questions, feeling questions, knowledge questions, sensory questions and background/demographic questions.[128] In the interviews conducted in this research, the types of the questions asked

were combinations of experience and behaviour questions based on the participants' daily practice, opinion and values questions, and knowledge questions.

### *7.3.4 Data Analysis*

The analytical framework process approach was used.[128] One of the main purposes of this approach is to describe important processes involved in decision-making.[128] This is consistent with the purpose of this study to explore the differences in the history-taking and decision-making processes for patient management among medical practitioners and pharmacists.

#### 7.3.4.1 Framework Analysis

Prescribing is an important area which contributes to patient management. It is expected that not all of the decisions in clinical cases will lead to prescribing. There are other factors contributing to decision making, which lead to different approaches among individuals and cases.

The stepwise approach to patient management involves history taking to identify issues that lead patients to seek medical or pharmacist attention, before deciding on management (**Figure 11**). History taking consists of several factors that will later determine the decision-making process for the patient. The details of the factors in the history-taking and decision-making process are shown in **Table 26**.

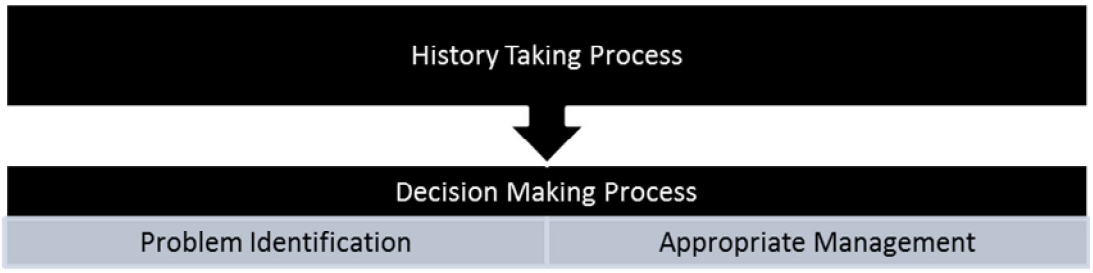


**Figure 11 : The patient management process**

**Table 26: General patient management process**

| History-taking process | Decision-making process | |
|---|---|---|
| | Problem identification | Appropriate management |
| History of presenting symptoms<br>Previous medication history<br>Previous medical history<br>Previous medical referral<br>Social history<br>Family history<br>Physical examination<br>Laboratory test results<br>Allergy history | Based on history taking<br>Based on confirmed diagnosis<br>- *Diagnostic test*<br>- *Physical examination*<br>Unable to confirm the diagnosis<br>- *Further investigations*<br>- *Referral* | Definite management decision<br>- *Initiate new medication*<br>- *Continue current medication without amendment*<br>- *Continue current medication with amendment*<br>- *Stop the current medication*<br>- *Not recommending medications*<br>- *Nonpharmacotherapy management*<br>- *Education (counselling and monitoring)*<br>- *Follow up*<br>- *Referral - if not authorised to prescribe*<br>Uncertain about management<br>- *Further investigations*<br>- *Referral* |

#### 7.3.4.2 Reliability of the Analysis

The interviews were conducted by one researcher (AMA), audio-taped and transcribed verbatim. Data were managed using NVIVO (QSR NVivo; version 2.0, QSR International) and analysed to elucidate the themes. Analysis was conducted by one researcher (AMA) and then presented to the other two researchers (JM and KS) for their input. Discussions were conducted until agreement was reached in the analysis of the case scenarios. This method was used to consolidate the findings by having multiple people give an assessment. It can be used to confirm the coding.

## 7.4 Results

### *7.4.1 Demographic Characteristics*

Forty-two health practitioners participated in the semi-structured interviews: 31 pharmacists and 11 medical practitioners. The pharmacists came from both hospital and community settings; the medical practitioners were working in different areas at various levels of practice. The details of the demographic characteristics of both pharmacists and medical practitioners are shown in **Table 27.**

**Table 27: Demographic characteristics of participants**

| Demographic characteristics | Medical practitioners (n=11) | Pharmacists (n=31) |
|---|---|---|
| Participants | 26.2 % | 73.8% |
| Gender | Female (63.6%, n=7) | Female (58.1%, n=18) |
| Age | Mean =36.9±8.5 | Mean value =33.2±9.7 |
| Area of practice | Community (9.1%, n=1)<br>Hospital (63.6%, n=7)<br>Other (9.1%, n=1)<br>Not indicated (18.2%, n=2) | Community (25.8%, n=8)<br>Hospital (41.9%, n=13)<br>Other (32.3%, n=10) |
| Practice location | Capital city (72.7%, n=8)<br>Large regional centre (27.3%, n=3)<br>Rural/remote (0%, n=0) | Capital city (77.4%, n=24)<br>Large regional centre (19.4%, n=6)<br>Rural/remote (3.2%, n=1) |
| Current work | Intern (0%, n=0)<br>Registrar (27.3%, n=3)<br>Resident (27.3%, n=3)<br>General practitioner (18.2%, n=2)<br>Specialist (27.3%, n=3)<br>Academic (0%, n=0) | |
| Graduate | Australia (72.7%, n=8)<br>Overseas (27.3%, n=3) | Australia (87.1%, n=27)<br>Overseas (12.9%, n=4) |
| Additional qualifications | Yes (45.5%, n=5)<br>No (54.5%, n=6) | Yes (32.3%, n=10)<br>No (58.1%, n=18)<br>Not indicated (9.7%, n=3) |
| Duration of practice (Years) | Mean value=12.20±8.44 | Mean value=10.73±10.27 |

### *7.4.2 Framework Analysis*

#### 7.4.2.1 Case Study A

Paul is a 20 year-old man who came into your pharmacy. He is about to start a painting and decorating apprenticeship. Paul had asthma as a child but has been well since. Four weeks ago he had a viral upper respiratory tract infection. Since then he has had a cough, which is keeping him awake at night. He is short of breath and has to stop playing soccer after only ten minutes. He gets some wheeze during exercise.

Question:

1) How would you approach to the case? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case.

**Case Description:** This is a simple case of acute exacerbation of asthma in a patient with a history of childhood asthma. The case description and expected outcomes are presented in **Table 25.**

**Result:**

1) **History-taking process**

Both pharmacists and medical practitioners were confident in gathering information based on the elements in the history-taking process. They asked for more information regarding the symptoms, the onset of the symptoms and factors triggering the symptoms.

> *"So I would ask him … more about this sort of shortness of breath. Does he get any other symptoms? Does he have difficulty breathing otherwise? Or in terms of his wheezing, is it there at other times – he mentioned that he wheezes during exercise – but then at other times? How about any other symptoms, like what is the cough – is it productive or is it just dry?"* **Pharmacist 13**

> *"We'll talk about … any allergies, if he smokes, what kind of pets he has at home and whether he's got any sensitivities to painting, the paints and things like that."* **Medical Practitioner 7**

Other elements were discussed in the area of medication history.

> *"I will ask him has he got or used anything to help. What makes it better, what makes it worse?... I would ask if he is still on an asthma reliever and to see if it helps with the situation."* **Pharmacist 1**

> *"You would ask a bit more about his asthma. If he's normally on any medication for asthma, if he's on a preventer or a symptom reliever and how many times he gets his asthma, whether he has any hospital admissions"* **Medical Practitioner 7**

**2) Decision-making process**

**a. Problem identification**

Most of the pharmacists identified the issues based on the history. Some pharmacists were more cautious and wanted more detailed investigations to assist their decision making. Medical practitioners however, were more confident in decision making, identifying the issues based on the history and confirming the diagnosis through physical examination or diagnostic testing.

> *"(I) would probably assume that it is viral induced asthma. Because he has the predisposition for asthma anyway, so the virus may have brought it back."* **Pharmacist 1**

> *"Some people sort of think that they get over asthma – or whether it's a disease you might always have. So from that, my view would be, I would suggest he would need to get a check up, including spirometry, to make sure it's not an obstructive airway (disease). I mean it sounds like it's just going to be exercise-induced asthma and a viral component has caused it, but I'd want to make sure there's no obstructive capacity there as well."* **Pharmacist 21**

> *"So from there you go on to examination. So you have to have a look at his chest and see if there is any evidence of long term asthma, a deformed chest. And then listen to his breathing, looking at the rate of breathing, whether he's got a wheeze at the moment. Listen to his cough to see if he coughs anything up. And listen to his lungs and see if there is anything else going on, whether he could have an infection. So take his temperature, blood pressure and pulse rate."* **Medical Practitioner 7**

**b. Management Decision**

Most of the pharmacists were confident of the appropriate management for this case, based on the information gathered. They were confident in dispensing Ventolin for treatment of the current acute problem, but would also refer the case for further assessment and management.

> *"Yes, I would definitely sell him a Ventolin or Bricanyl, but I would definitely advise that he sees his doctor. I might even make an appointment for him or call the doctor for him and discuss … my belief and my diagnosis of the problem."* **Pharmacist 1**

> *"As a pharmacist, in that case, if I was doing what I could now, I would refer to a doctor. All right, it is something that you know he might have asthma, ... could be exercise induced. I could give him a Ventolin inhaler to try, but sometimes, the concern I have is if that you give someone a Ventolin and it works and so they just keep using the Ventolin, they don't actually get properly assessed."* **Pharmacist 7**

The medical practitioners were confident in the management of this case since the problem was identified based on their history taking and confirmed diagnosis.

> *"... figure out your differential diagnoses, perhaps use some investigation looking at his peak flows or if you think he needs a chest x-rays or some blood tests. So history, examination, investigations, if you think he needs any, and diagnose him. And then if you do think ... he has asthma - then you'd think about giving him some Ventolin."* **Medical Practitioner 2**

**Summary of Case A**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **ND** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **ND** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **ND** | **D** | **ND** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** Minor differences were noted in the decision-making processes between professions. Most of the medical practitioners would identify the problems based on history taking and confirm with physical examination. Pharmacists, however, would identify the problem based on history taking and not undertake physical examination, as this is not currently part of the pharmacists' role. Pharmacists were confident to dispense 'Pharmacist Only Medication' but would refer to a medical practitioner if the case involved more complex underlying problems or if the patient needed prescription-only medicine.

### 7.4.2.2 Case Study B

A 43 year-old patient came to your pharmacy complaining of back pain and requested you to provide a pain killer for her problem.

Questions:

1) How would you approach to the case? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case.
2) What could be causing the back pain? Please explain what you know about the problem.
3) If you were to manage this patient, what do you think would be the most appropriate management?
4) If you were allowed to manage this patient, would you be comfortable to do so? When would you refer this patient to a doctor or general practitioner?

**Case Description:** This is a case of pain management with the aim of exploring the decision-making process for pharmacists in identifying issues related to back pain and the point at which they would refer. The case description and expected outcomes are presented in **Table 25.**

**Result:**

**1) History-taking process**

Most of the pharmacists were confident in gathering information during the history-taking process, specifically in regard to medication history.

> *"You would want to ask if she was taking any other medication, if she has any other health condition, so in terms of osteoporosis or something like that."* **Pharmacist 7**

> *"What's causing the back pain ... if it is a mechanical thing? Or it is a muscular thing? But if she had an ongoing pain syndrome and she got back pain, then I need to know what she is actually taking ... I still want to know what she is on, whether she is actually taking it ... There may be some issues with the compliance."* **Pharmacist 8**

> *"I will look whether this is a chronic back pain condition or something that happened recently … I want to know what pain killer she is or has been using."* **Pharmacist 9**

There was a difference, however, in that some senior pharmacists acquired more detailed information regarding the onset, location, factors triggering the symptoms and the types of pain experienced by the patient.

> *"Does she have chronic back pain, has she had anything yet, the nature of the pain, is it just localised to the one area or is it anywhere else? Now, what can be causing the back pain? Well it could it be musculoskeletal, whether she had any back problem specifically, any trauma that could be causing it."* **Pharmacist 10**

> *"I'd ask her whereabouts on her back. Is it lower back or up mid to high back? I'd ask how long she'd had this pain, what is the nature of the pain, so whether it is a dull ache or a sharp pain. I'd probably get her to do on a scale of one to ten … how painful she would rate this back pain. I'd ask when it started, if she possibly had been involved in any different sports or doing some gardening, or if it could be something physical that she's done. It's normally muscular if it's a normal healthy 43 year-old patient."* **Pharmacist 25**

**2) Decision-making process**

**a. Problem identification**

Most of the pharmacists identified the problem based on the history; however, the medical practitioners identified the issues, using history and confirmed diagnosis based on physical examination and diagnostic tests.

> *"Now, we need to all find out has she used anything before, so has she used any other pain killers or medications to relieve the symptoms. Does she take any medication including prescription and over the counter. Did she has any medical condition and also did she have any allergies? And that's going to then determine what I recommend for her."* **Pharmacist 3**

> *"So firstly I'd like to know the history of his back pain, how quickly did it come on, whether there was an event, whether it's a chronic issue. I'd like to know whether there's neurological deficit relating to that, and I would certainly be examining anyone like this properly, a full neurological examination, to ensure that there's nothing to suggest a neurological compromise."***Medical Practitioner 10**

> *"I would really be sticking them in hospital if they have any neurological deficits or any systemic problems, you know, if there's any loss of anal tone or sensation or whatever, that's indicating that there's … or if you suspect a fracture or something that's sinister. But generally, most of the time, it is a simple musculoskeletal pain, if they strain their back or whatever, or even if it is say sciatica."* **Medical Practitioner 2**

Even though some of the pharmacists were capable of distinguishing the severity and complexity of the case based on history taking, they were more cautious in their decision making.

> *"Managing the patient should be something simple, and then to know red flags or has she try anything yet but didn't respond … if it didn't then I would refer. And if she is already in the chronic problem and then you've got a lot more to look (at) based on the time, because she needs something, an S4 medication (prescription-only) probably."* **Pharmacist 10**

> *It's possible that the pain was just related to exercise in the gym. Could also mean nerve involvement. I would be recommending the patient to see doctors to get further examination and need to have some X-ray or scan to look at what's going on – to get a proper diagnosis of the cause of the pain. And once you have done the diagnosis, you will feel more comfortable in recommending treatment.* **Pharmacist 15**

**c. Appropriate management**

Based on the assumption of the community pharmacy setting, most of the pharmacists were comfortable to dispense simple analgesic medication over the counter for acute

symptomatic relief and would refer the patient to a medical practitioner or chiropractor for further assessment.

> *"We can start over-the-counter for her analgesics, some paracetamol. If no contraindication to non-steroidal anti-inflammatory, you could use that for the shortest possible time at this stage it's going to help, and if it didn't help in certain period of time, to seek further advice.* **Pharmacist 10**

> *"But, if she would like some pain relief in the meantime, we could give her, being a muscle strain possibly, some ibuprofen, 200 milligram, two tablets every four or six hours just for a couple of days, and hopefully she will have gone to the doctor just to get it checked out in between."* **Pharmacist 25**

Pharmacists were less confident managing the case if it involved more complex underlying problems that they were unable to identify through history taking, and would refer the case to a medical practitioner to confirm the diagnosis and follow up with appropriate management.

> *"If it's more in the spinal region, right in her bones and things, I'd definitely be referring her. I don't actually know what kind of thing would cause that kind of bone pain unless it's some sort of very bad cancer, but that doesn't seem to sit with that scenario".* **Pharmacist 25**

> *"I think if they had previously been assessed, if it's an ongoing condition they get from time to time, I guess I'd be comfortable suggesting heat or paracetamol for a time, unless it was worse than normal. I guess I'd refer it if it was new or worse than normal or affecting them more than normal".* **Pharmacist 27**

Medical practitioners, especially those based in hospitals, were more confident in managing the patients because of the availability of other facilities.

> *"But generally with back pain I like to use diazepam and NSAIDs, if it's a musculoskeletal problem. If it's really, the back pain is intractable, then you'd go onto opiates whether it be oral or even IM stuff if it's to the point where they cannot move and they're in agony."* **Medical Practitioner 2**

> *"So if none of the red flags are present, then I am going to go forward with more of the direct management of simple analgesia, activities, maybe refer to a physio, get them active as soon as possible and then review them in an*

*appropriate amount of time. If I think it's really simple I will tell them to come back if they don't improve."* **Medical Practitioner 3**

**Summary of Case B**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **D** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **D** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **ND** | **D** | **D** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** Minor differences were noted in the history-taking process among pharmacists. Senior pharmacists were more thorough in gathering information during history taking compared to the other pharmacists. Differences were noted between pharmacists and medical practitioners in problem identification, because medical practitioners were able to identify the problem based on history taking and physical examination. In the management process, pharmacists were confident to dispense simple analgesics but would refer to the medical practitioners for more complex underlying problems.

### 7.4.2.3 Case Study C

Mr Smith is a 69 year-old smoker who has recently been hospitalised with a pulmonary embolus. His discharge medication included warfarin tablets and he has therefore been referred to you, the pharmacist at the anticoagulation clinic, for ongoing management.

His INR is to be maintained within the range 2-3. He comes to you today with an INR of 1.89. He has been taking 4mg daily. Warfarin dosage is to be adjusted using the protocol (Section 4.3.1.1, scenario 2). You therefore increase the dose to 4.5mg, by prescribing 1mg tablets and adding a half a 1mg tablet to the 2 x 2mg tablets Mr Smith has been taking. You make a note in Mr Smith's 'Blue book' and an appointment for review next week.

Question:

1) Do you agree with the patient management? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case.
2) Would you feel confident to manage this patient if there is a treatment protocol?
3) What are the other clinical areas beside warfarin dose adjustment do you think pharmacists can contribute with protocol driven management?

**Case Description:** This is a case of warfarin management using protocol prescribing. The case description and expected outcomes are presented in **Table 25**.

**Result:**

**1) History-taking process**

The history-taking process in this case was relatively brief for both medical practitioners and pharmacists, mainly involving the history of warfarin consumption to reconfirm the results of the INR.

*"I want to make sure that he has actually been taking 4mg as prescribed, meaning that if his INR of 1.89 or 1.9 is today but his dose adjustment had*

> *been yesterday, again I will be adjusting his dose until it depends on that scenario whether I am happy to change things."* **Pharmacist 8**

> *"So if he was 1.9 on discharge from hospital and he was taking 4mg, now he's 1.89, you would be saying 'alright the dose needs to be bumped up a little bit.' If he was 1.2 on leaving hospital and now he's 1.8, so it's actually on the way up, you would be a lot more careful. If it was 2.5 and he's been on 4mg and now he's down to 1.8, that trend is very important."* **Medical Practitioner 3**

**2) Decision-making process**

**a. Problem identification**

Participants correctly assumed that the diagnosis was made prior to warfarin commencement and therefore, skipped the process for provisional diagnosis of the case.

**b. Appropriate management**

Almost all pharmacists were able to manage the patient on warfarin using protocol prescribing, although some were confident in managing cases only within their area of practice. This was also found to be similar for the medical practitioners.

> *"If this is the protocol that they use, well it looks quite reasonable to increase slightly. My normal practice is that I don't need to prescribe the dose. In the hospital that should be prescribed by the doctor, so I am not very confident in suggesting a dose."* **Pharmacist 5**

> *"An interesting question this one because, along with many GPs, I don't usually manage warfarin and INRs ... it's managed by the pathology company. So it's not a clinical situation which I'm very familiar with."* **Medical Practitioner 5**

Generally both of the professions demonstrated similar level of agreement in the warfarin management using protocol prescribing.

> *"So yeah, as long as there is nothing too dramatic. And I think increasing it by just 15% or 20% isn't going to make too much of a difference. I mean*

> *the INR won't jump up too much, so I don't think this is a big problem."* **Medical Practitioner 7**

> *" ... so should add 15 to 20 percent. Yeah I think that's all right 'cause that's what doctors will do anyway. It's more flexible to make a decision like that."* **Pharmacist 14**

In gathering opinions related to protocol prescribing, most of the medical practitioners agreed with the concept, but expressed some reservations that not all clinical conditions could be managed effectively in this way.

> "*I mean a protocol is a guideline, you always individualise treatment for each patient. I've never used this one before but it's kind of what you would do anyway. But it's nice to have it there where you can refer to it.* **Medical Practitioner 2**

> *" ... other common things, like hypertension and high cholesterol, I think would probably be a bit too complicated* [for pharmacists to adjust] *because it's not just a matter of increasing one drug to match a test and it's taking into account the whole clinical scenario for which a pharmacist probably hasn't got the training to examine the patient and come up with an appropriate response there.* **Medical Practitioner 10**

**Summary of Case C**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **ND** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **ND** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **ND** | **ND** | **ND** |
| **ND= No difference** | | | |

**Conclusion:** No difference was noted in the history-taking and decision-making process between the professions. Medical practitioners were more reserved about applying protocol prescribing to other chronic diseases.

#### 7.4.2.4 Case Study D

A 70 year-old patient has had a 3-month history of increasing breathlessness. The breathlessness was now brought on by minor exertion such as dressing and he can only walk approximately 50m before having to stop. His medical history is unremarkable. He said he once took tablets for high blood pressure but gave these up some years ago. He sleeps badly and finds it more comfortable to sleep or rest sitting up. He takes indomethacin for arthritis and does not smoke.

Questions:

1) What would you usually do in your daily practice if you encountered this type of case?
2) What are the common causes of breathlessness in a man of this age?
3) Is there anything in the history that points to one of these potential diagnoses?
4) Is the medication likely to be relevant?

**Case Description:** This is a case of acute symptoms for a potential diagnosis of congestive heart failure. The case description and expected outcomes are presented in **Table 25**.

**Result:**

**1) History-taking process**

Minor differences in the approach among pharmacists in the history-taking process for this case were noted. Most of the senior pharmacists would refer this case immediately to a medical practitioner for further investigation or urgent management without taking a further history; however, some pharmacists wanted further history before referring the case.

> *"Again breathlessness on minor exertion would mean pulmonary oedema possibly. So the fact that he has 3 months of increasing breathlessness, I*

*would want to refer him to a specialist as soon as possible because he's old. He is 70 and so his health will be more fragile and most of the time delicate and it has been going on for certain period of time."* **Pharmacist 13**

*"Well, I'd definitely refer him to a doctor. Having increase breathlessness, well you don't know whether it is due to the heart. He might have CCF, he doesn't smoke but I will normally refer him to a doctor."* **Pharmacist 5**

*"... is he a smoker? I'd want to know when he last went to the doctor ... I'd take a history including where he worked, was he working with things like asbestos and all those sort of things ... he's probably going to have congestive cardiac failure but you want to make sure. I would refer him because it is something that should be checked out, you just can't assume it's going to be because he's old. I mean it's coming on very quickly for three months."* **Pharmacist 21**

**2) Decision-making process**

**a. Problem identification**

In problem identification, additional questions were used to further elucidate the differences in the thought process in this case. Most of the pharmacists were able to identify the issues based on thorough history taking, especially related to medication.

*"I would definitely be worrying that he has some sort of heart failure with the breathlessness, and his compliance obviously meant that he stopped taking his tablets for blood pressure; maybe had hadn't been educated on the blood pressure. The sleeping badly could be due to this breathlessness as well. I don't know if this is an obese patient, but possibly with sleep apnoea could be there, but I think it's more pulmonary oedema. Possibly there's some sort of renal impairment with the indomethacin, but I'd be wanting to know is he taking indomethacin regularly, is he needing it all the time for his arthritis?"* **Pharmacist 25**

Medical practitioners used history taking, physical examination and diagnostic tests for problem identification.

*"So I would take a full history and examination again, and I would do a chest x-ray and an ECG and I would probably also do an Echo*

> *because I really do want to see what's going on in his heart."* **Medical Practitioner 6**

> *"And then investigations-wise you would want to do a chest x-ray on him ... I guess another differential could be a tumour, but that's pretty rare. Yeah, I'd be doing blood tests to see if it's an infective cause. A chest x-ray will give you differentials if it's either a chest infection or COAD and heart failure as well."* **Medical Practitioner 2**

Some senior hospital pharmacists were able to distinguish the issue by observing physical signs, based on their current clinical experience in the related area.

> *"If it's COPD, I've never seen it come on that fast in my entire life. So I'm assuming it's got to do with a fluid overload, so I'd be looking at oedema with his ankles and the rest of him, skin complexion, pallor, those sort of things ... "* **Pharmacist 21**

**b. Appropriate management**

Most of the pharmacists were unable to manage this acute case of potential heart failure due to the complexity of the case.

> *"It's not something I would be treating."* **Pharmacist 21**

Most participants were able to identify the possible issues, but would refer the case for appropriate management. This included general practitioners, who would refer the case to the hospital.

> *"I'm assuming it's a cardiac related thing, it's not sort of like asthma started ... and if I was ringing the doctor, I'd summarise that discussion through to the doctor as well for the doctor to take a detailed history to make sure that he did get those same points."* **Pharmacist 21**

> *"So if I encountered this case in retail* [pharmacy]*, I'd be saying 'Go to your GP' and giving him advice … you've got shortness of breath, possibly due to indomethacin or something else and that needs to be checked out and we also need to get you an appropriate treatment for your arthritis."* **Pharmacist 26**

*"I would be thinking about sending him to the Emergency Department. Something significant has happened and he needs to be sorted out immediately. If I was some distance away from a hospital I would be trying to get some blood tests and an X-Ray, but I think I would send him straight to hospital."* **Medical Practitioner 3**

**Summary of Case D**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **D** | **D** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **D** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **D** | **D** | **ND** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** Minor differences were noted in the history-taking and decision-making processes among pharmacists. Some senior hospital pharmacists were confident in identifying the problems based on history and physical observation compared to the other pharmacists. Differences were noted between pharmacists and medical practitioners in problem identification. Medical practitioners used physical examination and diagnostic testing to confirm potential problems identified based on history. In the management process, both pharmacists and GPs felt unable to manage the case and would refer the patient to the hospital.

### 7.4.2.5 Case Study E

A 35 year-old woman has bilateral watery nasal discharge (rhinorrhoea). The discharge is present all year round, although it is worse in the spring. She has a poor sense of smell and has not responded to inhaled nasal steroids.

Questions:

1) What would you usually do in your daily practice if you encountered this type of case?
2) What examinations should be carried out?
3) What is the likely diagnosis?

**Case Description:** This is a case of chronic rhinorrhoea with the possibility of other underlying issues. The case description and expected outcomes are presented in **Table 25**.

**Result:**

1) **History-taking process**

It was found that medical practitioners' history taking was mainly focused on the onset and the duration of symptoms experienced by the patient and the history of allergy. However, pharmacists' history-taking was more focused on the medication history prior to seeking medical attention.

> *"So again I want to find out a bit more about why, how long it has been going on for, whether it has been going on for years and years and years. What kind of environment she's in at home, at work, so like if she's allergic to anything else. What other medical history does she have, whether she's got eczema, asthma, something else that points towards allergic sinusitis, what medication she's on at the moment?"* **Medical Practitioner 7**

> *"First thing I will do is I check how she is using the inhaled steroid, which we only do PRN, and is she actually physically using the device correctly ... and I* [would] *check if there was other medication like antihistamines and things like that ... and to try to ask her if there is anything else that made it worse or made it better."* **Pharmacist 7**

**2) Decision-making process**

**a. Problem identification**

Most of the pharmacists were uncertain when questioned about the provisional diagnosis and possible examinations for a patient experiencing chronic bilateral watery discharge, but were able to manage a case of simple allergic rhinitis.

> *"... so examination ... I don't know whether examinations carried out are okay. Or is it something local? I don't know. And the likely diagnosis I am not sure."* **Pharmacist 16**

> *"I would assume she's got some form of atopic hay fever … but the fact that it is present all year round perhaps is a little unusual. That is worse in spring and there is an allergic component...but the fact that she's got chronic rhinorrhoea is a bit unusual and I would have tried her on an inhaled steroid. The fact that hasn't worked means that I would probably refer her."* **Pharmacist 6**

Similarly to some of the medical practitioners, some pharmacists were more confident in identifying the case.

> *" ... could have turbinoids, where mucous eventually deposits, then hardens so they really block. Probably need the turbinoids to be done ... So when you go to an ENT* [specialist] *they will do the examination of the nose, will check her throat and, really, the likely diagnosis, I think, is she's got turbinoids, because she's got poor sense of smell as well."* **Pharmacist 3**

> *"And examination wise, just to have a look and see if the nose is actually blocked and look ... in the nose and see if there is any evidence of inflamed, enlarged turbinoids. Have a look at the lymph nodes, see if there is any evidence of infection. See if she's got any facial pain, so whether she's got sinusitis at the moment, and probably just test her hearing as well ..."* **Medical Practitioner 7**

**b. Appropriate management**

In general, pharmacists were familiar with managing a simple case of allergic rhinitis, but expressed the need for referral to an Ear Nose and Throat (ENT) specialist to manage more

chronic and complex cases. They were unsure of the appropriate management if the patient failed earlier therapy, and would request further investigation.

> *"I'd probably, if she hasn't been using the cortisones for a period of time, I would suggest that she go back onto it for a period of time using the appropriate technique. If that didn't work after a couple of weeks, then for her to see the doctor, because there may actually be something else causing it."* **Pharmacist 21**

Both medical practitioners and pharmacists were more cautious in managing this patient in case it involved more chronic underlying issues.

> "*She should see her GP and try to get referral to an ENT because if her turbinoids are all blocked …".* **Pharmacist 3**

> *"I think she might have chronic sinusitis. Maybe a scan of her sinuses or something like that. Poor sense of smell yeah, I'm afraid that ENT is not my special area. I give up."* **Medical Practitioner 6**

**Summary of Case E**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **ND** | **D** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **D** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **D** | **D** | **ND** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** Minor differences were noted in the history-taking process between pharmacists and medical practitioners. Most of the pharmacists' history taking was more focused on medication history compared to the medical practitioners. Difference was also noted in problem identification among pharmacists. Most of the pharmacists were able to

identify the simple case based on the history; however, senior pharmacists were capable of identifying more complex issues similarly to medical practitioners. In general, it was found that both pharmacists and medical practitioners would refer the case to a specialist if it involved more complex underlying problems.

#### 7.4.2.6 Case Study F

LH, a 50 year-old moderately obese woman was diagnosed with diabetes type II a year ago. She came to see you for recurrent vaginal thrush infections. Subsequently on two separate occasions she was found to have a random plasma glucose of 12 mmol/L and 13.1 mmol/L. LH denies any symptoms of polydipsia or polyuria, although lately she has been more thirsty than usual. She does complain of lethargy and often takes afternoon naps.

Laboratory assessment reveals a fasting plasma glucose of 8.3 mmol/L (normal <7 mmol/L)

Questions:

1) How would you approach the case both initially and long term? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case.
2) What should the goals of therapy be for LH? Which biochemical indices should be monitored?
3) How should LH be managed initially?
4) LH is interested in learning how to perform blood glucose testing. What are the advantages and disadvantages of self monitored blood glucose (SMBG) tests? When and how often should LH be instructed to test her blood glucose concentrations?

**Case Description:** This is a case of uncontrolled diabetes mellitus due to poor compliance. The case description and expected outcomes are presented in **Table 25.**

**Result:**

**1) History-taking process**

Difference was noted in the history taking between medical practitioners and pharmacists. Most of the pharmacists used the history-taking process to acquire more information on medication-related issues, rather than acquiring information to confirm other possible problems or diagnoses.

> *"I need to know what medication she is on. So if she can't remember,. I need to call her doctor … Because she's been more thirsty, she's been tired, taking afternoon naps, it all indicates to me her sugar levels aren't well controlled and her medications need adjusting."* **Pharmacist 3**

> *"So I think just check what medication she is on, compliance is one of them, and maybe should refer her to see the doctor, because if it is a recurrent vaginal thrush, I think she'd better be checked out. Maybe it is just the sugar is not well controlled."* **Pharmacist 5**

> *"So ... past history, whether she's got high blood pressure, whether she smokes, cholesterol, because she might be at risk of heart disease. So it sounds like she's got poor control of her diabetes and I need to know what medication she's on for diabetes and how often she checks her own sugars, things like that. Whether she's got any complications, so any reduced sensation in her fingers, whether she's noticed that, any trouble with her vision, whether she's had her eyes tested or things like that."* **Medical Practitioner 7**

**2) Decision-making process**

**a. Problem identification**

Most of the pharmacists were able to identify the problem as due to the uncontrolled diabetes mellitus from the symptoms described by the patient in the history-taking process.

> **"***I would explain that probably her diabetes has caused the vaginal thrush. That is usually one of the indicators of recurrent vaginal thrush.… I will ask*

> *the patient to see the doctor because that could be a diabetic complication."* **Pharmacist 1**

Most of the pharmacists were confident to suggest appropriate laboratory tests although it is outside their current role.

> *"The main biochemical indices to be monitored here – certainly need to have that fasting glucose – will tell you whether she is acutely diabetic* [sic], *but her long-term control would be* [measured by] *HbA1c, so she needs that to be done. Normal sodium, potassium. She needs serum lipids, triglycerides, LDL, HDL and cholesterol … and she needs to have her urine protein tested* [to determine] *if she's got any evidence of microalbuminuria and therefore renal failure."* **Pharmacist 6**

> *"Examination wise, check her weight, blood pressure, do all that. Listen to the chest and her lungs and do sensation tests with a microfilament and do a dipstick of her urine and see if she's got an infection there or whether she's got ketones. She shouldn't have ketones but she'll probably have lots of sugar. Do a quick eye test. Just basic screening for diabetes."* **Medical Practitioner 7**

**b. Appropriate management**

In general, pharmacists were confident in discussing appropriate patient management in diabetes, based on medication therapy, education and counselling; however, they were limited in their ability to implement management due to current legal restrictions.

> *"I would refer her on to a dietician, a diabetic educator ... I would recommend exercise ... I would explain the implications of not controlling the diabetes, how important it is to keep her blood sugar low ... I would recommend that she sees an optometrist to get her eye check at least once a year. Go see the podiatrist regularly... if anything happens to her toes, she needs to check. She definitely needs to lose weight. I will recommend ways of helping her to reduce weight like diet and exercise and maybe something like prescribe medication to help her lose weight. Put her on metformin to begin with if I could."* **Pharmacist 1**

> *"If she was on metformin, you need to find out the dose for that. Possibly increase the dose. If she was just on metformin, I would probably suggest to*

*the doctor adding a sulphonylurea. And this thing will happen step by step over consecutive months."* **Pharmacist 3**

Medical practitioners also acknowledged that the case needs a multidisciplinary approach.

*"Look this is actually quite a difficult thing. She is moderately obese. We know that lifestyle changes, weight reduction, change in diet can make a huge difference within someone with type II diabetes.....So I know there's a huge role for education within this person. And she needs to be seeing a diabetes educator on a regular basis. She needs to be seeing a dietician. At 50 years of age I would be trying to link her in with some of the local gym programmes, the Live Longer, Live Stronger program, which is for people over the age of 50.....You need to make sure that she understands what diabetes is, that she's self-monitoring and self-managing. There are a group of people that don't self-manage very well, in which case then they need to be supported through case management and usually that's done by a diabetes educator, or a practice nurse."* **Medical Practitioner 3**

**Summary of Case F**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **ND** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **ND** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **D** | **ND** | **ND** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** The pharmacists again were more focused on medication history than were medical practitioners. Most of the pharmacists were able to identify the problem and discuss the appropriate management but, due to current legal restrictions, they would refer the case to a medical practitioner for prescription of appropriate medication.

### 7.4.2.7 Case Study G

Kl, a 29 year-old woman, came to your pharmacy complaining of left-sided pulsatile head pain recurring on a weekly basis. Her headaches are usually preceded by flashes of light bilaterally and a sensation of light-headedness. The ensuing pain is always unilateral and is commonly associated with nausea, vomiting and photophobia. The headache is not relieved by two tablets of either aspirin 300mg or ibuprofen 200mg and generally lasts all day unless she is able to lie in a dark room and sleep. The headaches usually interfere with her ability to continue work.
Questions:

1) What is the problem of this patient?
2) How would you approach to the case? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case.
3) What subjective data from the above description are consistent with the possible diagnosis that you made?
4) What further laboratory or diagnostic tests should be ordered for Kl?
5) What should be the general approach to the treatment of Kl's headache attacks?
6) When would you refer this patient to a doctor?

**Case Description:** This is a case of chronic migraine with potential underlying issues. The case description and expected outcomes are presented in **Table 25**.

**Result:**

**1) History-taking process**

Both pharmacists and medical practitioners had similar opinions in gathering information based on the elements in the history-taking process.

> *"… have there been any changes or anything specific that she noticed that triggered it off, because it's starting to happen on a regular basis now. What's going on? What's changed? Is she on the pill? Has she had any focal symptoms? All the things that we need to sort out when we are talking about the severity of the migraine. Make sure if she's on the pill that she goes off the pill, whether that could be a precipitating factor. So if her examination came back all normal, blood pressure was all normal, there was nothing to suggest anything nasty going on."* **Medical Practitioner 3**

> *"I think she would have got a migraine, so I want to know again more of the history, make sure she doesn't have any neurological abnormalities with it, see if she's on the pill, and any other past medical history or family history. So if it's just a simple migraine - well she's getting them pretty often - and try and find out if there's any precipitating factors to her migraines, and if there is … ask her to avoid those.* **Medical Practitioner 4**

> *"I would ask her what other medication she is on that could trigger her migraine as well. Maybe she is taking OTC or any complimentary medication"* **Pharmacist 1**

> *"I think she's got migraine. But I think you need to exclude ... a tumor..."* **Pharmacist 6**

**2) Decision-making process**

**a. Problem identification**

Medical practitioners were generally more confident in identifying the other possible diagnoses related to the symptoms associated with headache compared to the pharmacists, and discussed needed physical examination. Some pharmacists only considered the symptoms experienced by the patient and concluded that she was suffering from chronic migraine; whereas others would refer her to a medical practitioner for further assessment.

> *"If it's a fairly new patient, you still have to go through all the history. You would do a full examination, you would be checking her blood pressure, you would be doing a CNS examination, you would be checking her eyes ... So you would still check to make sure that it's nothing else nasty going on, but you would be leaning fairly quickly too. It sounds like a migraine."***Medical Practitioner 3**

> *"Okay, well … I think the nausea and photophobia are fairly a give-away and also that she gets the flashes of light bilaterally. That is known as the migraine aura"* **Pharmacist 11**

> *"I think this patient has migraine. Definitely, because all the signs … pulsatile pain, unilateral ... seeing the flashes of light and also nausea and vomiting, photophobia"* **Pharmacist 13**

> *"Because it is interfering with her work ... it's becoming weekly ... quite frequent. I would send her to a doctor straight away."* **Pharmacist 1**

**b. Appropriate management**

In this process, most of the pharmacists were cautious in their patient-management approach, based on the decision-making process.

> *"She would need to, maybe they would do some CT scans. And then the doctor might prescribe something to prevent the migraine. So you know … a range of medication, beta blocker, something like Norvasc as well, calcium channel blocker. That is just a prevention."* **Pharmacist 3**

Most of them were confident to recommend medication that could be used in the interim; however, they would refer the patient to the medical practitioners for further management.

> *"Initially I would just recommend for her to try something like Mersyndol - Mersyndol has paracetamol, codeine and doxylamine. I will explain the dose to her, I will explain how it works but at the same time she needs to see her doctor."* **Pharmacist 3**

> *"I could give her something with ibuprofen or something. But I will be referring as she needs medical attention."* **Pharmacist 1**

**Summary of Case G**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **ND** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **ND** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **ND** | **D** | **D** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** Minor differences were noted in the decision-making processes between medical practitioners and pharmacists. In general, pharmacists were more focused on issues related to migraine symptoms. Although questions in this case were designed to focus on the decision-making process, medical practitioners were more detailed in discussing other possible issues related to the headache. In regard to management, pharmacists were confident to dispense simple analgesics but would refer to medical practitioners if there were more complex underlying problems requiring prescription medication.

#### 7.4.2.8 Case Study H

| |
|---|
| Mr EC works in the local hotel. He came to your pharmacy because of bad abdominal pain. He thought that it might be due to a gastric problem. He took an over-the-counter antacid a few days previously, but the pain has not resolved.<br><br>Question:<br>1) How would you approach to the case? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case. |

**Case Description:** This is a case of abdominal pain with potential chronic underlying problems. The case description and expected outcomes are presented in **Table 25**.

**Result:**

**1) History-taking process**

There was a difference, in that some senior pharmacists acquired more detailed information regarding the onset, location, factors triggering the symptoms and the types of pain experienced by the patient. Otherwise, information gathering by pharmacists was similar to that by medical practitioners.

> *"Is there any nausea and vomiting involved? Is he taking any other medication? … If he works from the local hotel has he been drinking the*

> *beer? You know, if the job is causing the problem …. Did the antacids work? What makes it worse, what makes it better?"* **Pharmacist 1**

> *"I'd maybe ask him about what he'd eaten in the last few days. What kind of pain this is: is it a dull ache, is it an acute sharp pain? And whereabouts it is? Is it lower in the gut or is it up under where the rib cage meets there, under the sternum. I'd ask when it hurts. Is it at night or is during the day? Is it after eating? Just to find out whether we've got an ulcer happening, whether it's oesophageal, or whether it's gastric. How long it's been going on for? It could have been for the last month and he's only just taken an antacid, or it could have been just in the last week or so. That might be directly due to food. I'd find out which antacid he's taken."* **Pharmacist 25**

> *"… when you say abdominal pain, abdominal pain is a whole myriad of things. Are we talking about abdominal pain of things like reflux, which I gather is how you are trying to angle it here, but is it abdominal pain of something like an appendix? Has he got a problem with his liver? Has he got, is he a real binge drinker and he's got alcoholic hepatitis or something? Has he got pancreatitis? You would sit this bloke down and you would go through the whole history of the pain and often it's the patient that will tell you … they will go through the pain and will often point you to the diagnosis, because the way people describe pain, actually it's usually pretty good."* **Medical Practitioner 3**

**2) Decision-making process**

**a. Problem identification**

Difference was noted in the problem identification process between pharmacists and medical practitioners. Pharmacists identified potential problems associated with abdominal pain based on history and the limited observations available to them within their scope of practice, whereas medical practitioners identified the problems using the history and also observation, physical examination and the results of laboratory tests that they would undertake.

> *"So he's got gastric* [pain],*, so it could be his pancreas or bile or it could be his liver dying* [sic]*. Yeah, so that would indicate to me that his alcohol problem could be a little bit worse than what he's letting on. ... What's his skin colour? Is he looking a bit yellow, are the whites of his eyes, how are they? Because my main concern is ... you're not going to tell if the stools are black. You'd want a stool sample because if he is pale, has he got*

*bleeding? Is it an ulcer due to the excess alcohol consumption? If his pallor is yellow it might indicate early jaundice due to liver disease. I'd say it may well be just simple abdominal* [pain]. *So if it's just a radiating pain, it's not cramping or anything like that, it's likely to be something he's eaten."* **Pharmacist 21**

*"Bad abdominal pain, it is so general, very difficult to make a diagnosis. I would ask lots of questions especially to pin point where the pain was and sometimes that helps, you know, if it is upper. If he is saying near the lung could be gastro-oesophageal reflux."* **Pharmacist 1**

*"The biggest thing is whether he's got an acute abdomen as well. And differentiating … between whether it's a cardiac-related chest pain or whether it is a true abdominal pain. So you'd want an ECG pretty much straight off when he comes in. And if he's got any other problems, whether the antacid did help or if it didn't, because it can indicate that it is his tummy. And the ones that you want to be worried about, if the antacid did help, if he's got any bleeding ulcers or anything like that, and if he's got any blood in his stools."* **Medical Practitioner 2**

*"If he has focal tenderness, in particular if he has right upper quadrant tenderness, or if he's got epigastric tenderness I'd be interested in getting some blood tests, including liver function tests, and potentially involving a surgeon if there's a suggestion that there may be a surgical condition. But I certainly wouldn't be just treating his pain with analgesics without that work-up."* **Medical Practitioner 10**

**b. Appropriate management**

Most of the pharmacists were cautious in their management approach. Generally, they were confident in managing the case if it involved a simple gastric problem e.g. reflux, by recommending appropriate medication, but would refer if these measures were not effective.

"[If] *he's just got a bit of indigestion, he's got some wind and stuff, I could recommend something like Degas, which is going to get rid of the wind. If he has tried an antacid, I could recommend a different one. So let's say he tried Mylanta in the mixture, I would recommend Gaviscon, provided there are no contraindications, and see if that helps. If he tells me it's more crampy and colicky, I could give him Buscopan. And what's going to make me more confident about – like if he gets reflux, if he has those burning*

> *symptoms in his throat ... Nevertheless, whatever it is, if it doesn't get better in a couple more days, I'd (tell him to) go and see the doctor and he might need like a gastroscopy done and have it checked out."* **Pharmacist 3**

If the case involved more complex underlying disease, and they felt unable to manage it, pharmacists would refer the case to the medical practitioner for further investigation.

> *"Definitely I will refer this patient to a doctor. … because I am not very sure, I think the best is to refer the patient to see the doctor rather than just give him antacid or Buscopan or something like that. And yeah, because it has been a few days, you never know ... just want to know what are the causes, any appendicitis or things like that. You never know ... because he has history of excessive alcohol, sometimes it might be alcohol-induced pancreatitis. Something you just don't want to use over-the-counter Buscopan* [for]. *So refer straight away to the doctor."* **Pharmacist 5**

Medical practitioners' management decisions were based on the findings of their investigations.

> *"And it depends, if we think it is a gastric problem and he's stable, then I'd probably send him home ... then organise the outpatient gastroscope. If I think it is a true abdominal problem, then I'd want to do, whether it's now or later, do an ultrasound or a CT of the abdomen depending on how bad, like if he's got acute abdomen we'd do a CT straight away and get the surgeons down. If I think it's a cardiac related chest pain then I'd be doing ECGs and enzymes."* **Medical Practitioner 1**

**Summary of Case H**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **D** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **ND** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **ND** | **D** | **D** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** There were differences in the history-taking and decision-making processes among pharmacists and between pharmacists and medical practitioners. Some pharmacists identified the problem based on history; however, not all pharmacists were confident in differentiating the severity of the problem from the history alone. Medical practitioners used more observation and investigation for problem identification and management decisions compared to pharmacists. In the area of management, pharmacists were confident to dispense medications for simple conditions but would refer to a medical practitioner for more complex underlying problems.

### 7.4.2.9 Case Study I

Brandon is a lively 2 year-old boy. He has been a patient at the local doctors' surgery since he was born and has attended only for coughs and colds and immunisations. His growth has been along the 75$^{th}$ percentile.
Today Julie has come to see you at the pharmacy because Brandon is having continuing diarrhoea.

Question:
1) How would you approach to the case? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case.

**Case Description:** This is a case of chronic diarrhoea in a paediatric patient. The case description and expected outcomes are presented in **Table 25**.

### 1) History taking process

Pharmacists were mostly thorough in obtaining information about the symptoms and the course of the diarrhoea in the history-taking process.

> *"I need to know for how long? Has it been 24 hours? Has it been 2 to 3 days? Need to ask his mum what his stool looks like. Are they just explosive? Is it completely runny or is it a little bit of stools. They're like smelly? Is it completely watery? Because that's going to indicate to me what kind of diarrhoea and what could be the possible cause. Assuming I can see Brandon, a sign of dehydration in a child, I need to look at that, sunken eyes. Is he energetic or he is completely drained out?"*
> **Pharmacist 3**

However, history-taking among medical practitioners was more comprehensive in relation to possible underlying causes.

> *"Oh, if there's some continuing diarrhoea - It doesn't say how long he's been having it for. But again, in this case you want to figure out whether he's just septic, septic problem with the diarrhoea… and, acutely, you want to see whether he's hydrated or not. I guess hydration is the most important thing. And then you want to assess the diarrhoea, see what's causing it, whether it's septic ... or whether it's … stuff like milk intolerance or not. He's a bit old to have that ... he's onto solids and everything now ... whether they've been overseas, whether his siblings have it, does it sound like a viral illness? Did the family eat something that's affected him, or whatever?"*
> **Medical Practitioner 2**

### 2) Decision-making process

#### a. Problem identification

Neither pharmacists nor medical practitioners were able to identify the problem by history alone. Medical practitioners highlighted the need for further clinical and laboratory investigations to identify the possible issues.

> *"If it's continuing diarrhoea, I assume it's going for more than sort of three or four days or even a week, so you'd want to do stool samples as*

> *well. I guess Giardia is something that you want to exclude in him and then I guess you think of all the other crazy autoimmune causes … I guess you just do the more acute things, see if there's anything that you can exclude right there and then, but you can do the other autoimmune tests later on and just make sure."* **Medical Practitioner 2**

**b. Appropriate management**

Most of the pharmacists would refer the case if the problem continued for a long period of time. They were cautious with treating a case involving a paediatric patient.

> *"Looking at dehydration, if he's got cold hands, cold feet, he'd go straight into hospital."* ***Pharmacist 21***

> *"Well I guess I probably only would refer them to the doctor if he looked extremely unwell or it had been going on for say three or four days rather than just a couple of days."* **Pharmacist 27**

Medical practitioners were also cautious in managing the case of chronic diarrhoea involving a paediatric patient. They were confident managing an acute case of paediatric diarrhoea, particularly if the underlying cause was clear, but would refer the patient to the hospital if the problem persists.

> *"In this case it's highly likely that this kid's picked up either – it could be a very persistent virus ... it's more likely to be a Giardia or one of those, so he needs a stool* [sample tested] *and specific treatment if something's picked up."* **Medical Practitioner 5**

> *"I'd be asking a paediatrician to come and see the patient because I would be aware that I'm a little bit limited when it comes to two year olds."* **Medical Practitioner 10**

**Summary of Case I**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **ND** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **ND** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **D** | **D** | **ND** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** Minor difference was noted in the history-taking process among pharmacists and medical practitioners. A difference was noted between pharmacists and medical practitioners in their approach to problem identification. Medical practitioners identified the problem based on history in conjunction with laboratory examination, whereas pharmacists mainly relied on the history. In regard to management, both pharmacists and medical practitioners would refer the patient if there were possibly more complex underlying problems.

### 7.4.2.10 Case Study J

You went to see TM, an 80 year-old lady, for HMR (Home Medicine Review). She complains that she feels 'sluggish' and has had several episodes of fainting. She has a number of chronic medical problems, including coronary artery disease, heart failure, hypertension, diabetes and hyperlipidaemia. She has seen several general practitioners for the management of her various disease states and takes "a lot of medications" whose names she does not know. She admits to skipping her medications periodically. She was on:

glibenclamide 2.5mg bd,
hydrochlorothiazide 25mg,
propranolol 20mg qid,
niacin 500mg tds,
digoxin 0.25 d,
isosorbide dinitrate 20mg qid,
sublingual GTN 0.4 mg prn,
captopril 25 mg tds,
frusemide 40mg bd,
paracetamol 500mg prn,
verapamil 60 mg qid,
calcium carbonate 500mg tds,
ibuprofen 200mg prn,
rosiglitazone 2mg bd.
She also drinks a glass of red wine with dinner and several cups of liquorice tea with breakfast and lunch.

Questions:

1) How would you approach to the case? Please verbalise your thoughts and what you would do in your normal daily practice if you encountered this case.
2) If you were allowed to manage this patient, what are some of the pharmacotherapeutic issues that need to be brought for special attention to the general practitioners?

**Case Description:** This is a case of multiple chronic disease management in an elderly patient. The case description and expected outcomes are presented in **Table 25**.

**1) History-taking process**

In the history-taking process, pharmacists, not surprisingly, were focused on medication history taking because this elderly patient is on multiple medications with multiple problems and the purpose of the visit was stated to be for a HMR.

> *"I'd want to check that all of this here* [in the medication list] *is what is in the dispensing history, and that the instructions are the same, and whether or not they're from the same pharmacy to see who the prescribing doctors are. And I would ask her about each medication individually, how she's taking them, because she says that she does skip them periodically, so there might be some - yeah, by asking her about each one individually, she might say "Oh I often forget that one", and I'd find out whether she's having them with food, say the oral hypoglycaemic, glibenclamide. I would be asking her if she had any concerns* [about her medications] *at the moment, as she's being managed by several general practitioners, for the various disease states."* **Pharmacist 25**

Medical practitioners, however, were more concerned about gathering details of the current medical and holistic issues experienced by the patient, in order to identify underlying problems.

> *"First of all I want to know how dependant she is, whether she's from a residential* [aged-care facility], *whether she's incontinent, double incontinent, or if she can give me a good history from the nursing home or residential aged care, from the family. Take thyroid history, whether she's got cardiovascular, respiratory, GI problems. Examine her thoroughly, every system. Because it could be one of the other things, it could be drugs, drug interaction problems, level problems ... She looks like she's got heart problems, whether it's not a new problem. Sluggish and fainting, I'll be worried about new arrhythmias or AMIs ... if there's no new neurology or neuro symptoms."* **Medical Practitioner 11**

> *"Okay so this is a typical patient whom we see in ED. So immediately with an elderly patient with all these problems going on and multiple medication, so first thing is whether her sugar is checked (she's a diabetic). What's her sugar normally like and have the sugars been checked. So I would like to address each of these comorbilities separately. Like with regard to her diabetes ... has she been healthy and has she been under regular follow-up with all the other team members like podiatrist, ophthalmologist ... And hypertension also, normal blood pressure control. And with regard to the heart failure, any heart attacks, angina, how often has she been hospitalised with heart failure. And then to look into these fainting episodes which she has had - so ask her about things which happen before fainting, during fainting and after fainting. So how was she feeling before fainting, was she aware that she was going to*

> *fall down or did she feel like her vision was getting blurred and then she had the fall or was she feeling like the room is spinning around her and then had a fall or did she suddenly have, was she looking pale and then suddenly a flushing episode and then have a fall, and then how long did every episode last and did she lose her consciousness after each of the falls and after the fainting episodes? Does she remember everything, whatever has happened, and how does she feel."* **Medical Practitioner 9**

**2) Decision-making process**

**a. Problem identification**

Within the HMR process, pharmacists were seeking to identify medication-related problems. They did this using their pharmacotherapeutic knowledge in conjunction with the documented laboratory findings and symptoms experienced by the patient.

> *"If she has heart failure she shouldn't be on the ibuprofen. Rosiglitazone can also increase risk of coronary heart disease."* **Pharmacist 1**

> *"... and then digoxin, a high dose for a lady. So maybe check her pulse."* **Pharmacist 4**

Medical practitioners, in exploring medical and holistic issues, identified problems based on history, laboratory tests and physical examinations that they would perform, as described by medical practitioner #9 in the previous section.

**b. Appropriate management**

Generally, pharmacists were confident in identifying medication related-issues and in recommending appropriate changes; however, they would refer the case to a medical practitioner for changes to prescribed medication, due to not being legally able to prescribe themselves.

> *"So you definitely suggest the doctor stop the rosiglitazone for the first thing. Stop ibuprofen is possible. If she needs any pain killer just continue normal paracetamol.* [Check] *what is the indication of verapamil with the doctor, because it doesn't look like she has any real indication for verapamil here, but it can worsen the heart*

*failure. And* [we] *don't use it very much with hypertension anymore. It is more for those arrthymias. So frusemide is fine, captopril, yeah, it's fine. Well because she's got heart failure,* [if there are medications for which doses need to be increased, we need to] *see how well she can tolerate. ... Well, she is quite old, (she is on the big dose of digoxin) So maybe it is worth ordering TDM just to check the digoxin level."* **Pharmacist 5**

*"... she is on rosiglitazone and ibuprofen, which are probably not the ideal choice for someone with heart failure. ...* [For] *heart failure turns, a beta blocker - something like metoprolol, carvedilol or bisoprolol - is indicated, not propranolol. Hyperlipidaemia - she is on niacin, she's got a history of coronary artery disease, she'd probably be better off with a statin."* **Pharmacist 7**

**Summary of Case J**

| Comparative Group | History-taking process | Decision-making process | |
|---|---|---|---|
| | | Problem Identification | Appropriate Management |
| **Comparison between pharmacists (P-P)** | **ND** | **ND** | **ND** |
| **Comparison between medical practitioners (MP-MP)** | **ND** | **ND** | **ND** |
| **Comparison between pharmacists and medical practitioners (P-MP)** | **D** | **D** | **ND** |
| **ND= No difference; D= Difference** | | | |

**Conclusion:** Differences were noted in the history-taking process between medical practitioners and pharmacists. Pharmacists were more focused on gathering information related to medication history. Differences were also noted between pharmacists and medical practitioners in the process of problem identification, with medical practitioners identifying problems based on medical history and physical examination and pharmacists

mainly by the medication history. In terms of management, pharmacists would refer the patient to a medical practitioner for recommended changes in prescribed medication.

### *7.4.3 Cross-Case Themes Analysis*

The preceding analysis of the approaches of pharmacists and medical practitioners to the case vignettes in light of the case category is summarised in **Table 28**.

**Table 28 : Cross-case themes analysis**

| Case | Category | History-taking process | Decision-making process | |
|---|---|---|---|---|
| | | | Problem identification | Appropriate Management |
| | | P-MP | P-MP | P-MP |
| A | Acute simple case | ND | D | ND |
| B | Acute simple case due to possible chronic underlying problem | ND | D | D |
| C | Unstable to stable chronic case (protocol prescribing) | ND | ND | ND |
| D | Acute severe case due to chronic underlying problem | D | D | ND |
| E | Chronic underlying problem | D | D | ND |
| F | Chronic unstable case | D | ND | ND |
| G | Acute severe case due to possible underlying problem | ND | D | D |
| H | Acute severe case due to underlying problem | ND | D | D |
| I | Acute severe paediatric case | D | D | ND |
| J | Acute severe exacerbation of chronic unstable condition | D | D | ND |

## 7.5 Discussion

This study was designed to explore the differences in the thought processes involved in history taking and decision making among pharmacists and medical practitioners in order to elucidate pharmacists' knowledge and skill gaps for prescribing. To the best of our knowledge, no other research has been published that makes direct comparisons of patient management approaches.

During the conduct of the interviews, nonverbal expressions were noted in order to assist with interpreting the transcripts. The most significant differences observed by the interviewer were in terms of the approach to the cases. All participants responded confidently to cases within their scope of practice. Generally speaking, medical practitioners appeared more familiar with the clinical case scenario approach compared to pharmacists, as pharmacists were more cautious in responding. Differences were also observed along the continuum of novice to expert for both pharmacists and medical practitioners in completion of the case scenarios and the confidence in managing the cases.

In general, pharmacists were found to be confident in history taking and patient management within their current area of practice, as limited by legal barriers e.g. to ordering pathology tests and to prescribing.

Differences were noted in the history-taking process between medical practitioners and pharmacists, particularly in cases of unstable chronic conditions or chronic underlying problems. Generally, pharmacists' history-taking was more focused on the medication history within their current scope of practice, compared to that undertaken by medical practitioners, which was more holistic. Pharmacists were more receptive to accepting cases with a confirmed diagnosis and would gather history related to the confirmed diagnosis. Pharmacists' history taking was focused on the success and failure of the drug treatment and patient adherence. The medical practitioners identified other possible issues by collecting further information during history taking, even though the diagnosis had been confirmed. These findings were similar to the concerns raised in the expert panel

discussion among medical practitioners (Chapter 4), which related to the capability of pharmacists to conduct thorough history taking and in the study by Weeks et al. which found that some pharmacists also lacked faith in their competence to deal with issues outside their experience.[74]

Most of the pharmacists identified problems based largely on history taking (particularly medication history) with limited physical observation and results of laboratory tests if available. Medical practitioners undertook a more comprehensive patient evaluation including physical examination and laboratory tests to identify problems for the clinical cases that they commonly dealt with in their normal practice. As noted in case E, involving the specialised area of ear, nose and throat, they were more likely to refer the patient to a specialist for confirmation. Most of the pharmacists were confident in identifying problems involving simple acute cases. Although some were able to identify more complex problems, based on their current areas of experience, they would refer cases to medical practitioners if they felt they lacked expertise.[129]

In most cases, no differences were observed between pharmacists and medical practitioners in regard to management, either because they were both confident to manage the case or because they both felt the need to refer. Pharmacists were comfortable managing acute simple cases and were capable of prescribing medications within legal boundaries. They were also confident with protocol prescribing and with managing a confirmed case of stable chronic disease. However, when the cases involved more complex underlying problems, they would refer the case to a medical practitioner. Medical practitioners were more confident managing patients with complex underlying diseases compared to the pharmacists. Pharmacists focused on the pharmacotherapy management approach, whereas medical practitioners took a more holistic management approach.

Specific education for pharmacists should be designed to fulfil their needs in the areas where they are lacking in knowledge and/or skills as prescribers. History taking and problem identification are some of the potential areas in which pharmacists require more thorough training. A study of the first cohort of pharmacist supplementary prescribers

trained at two institutions in the UK, identified the importance of training pharmacists in the areas of communication and performing clinical examinations.[95] That study found that the majority felt they already had the competencies required for supplementary prescribing prior to the course. They highlighted, however, the importance of redesigning the courses to involve more physical examination and consultation skills.[95] A later series of semi-structured interviews conducted among supplementary prescribers who underwent the course found that they perceived communication skills teaching and learning to be positive.[99] This is similar to the findings conducted by Weeks et al.[74]

It is likely that different levels of skills would be needed in performing supplementary prescribing, collaborative prescribing, protocol prescribing or independent prescribing. The type(s) of prescribing models implemented in the future may influence the educational needs. The study suggests that protocol prescribing and supplementary prescribing are potential models for implementation in the shorter term. Pharmacists would be able to refer cases back to the independent prescribers if issues identified were not within their agreed skills and scope of practice.

Generally, both pharmacists and medical practitioners were confident in managing cases related to their area of practice. It was expected that participants might approach the cases differently based on their level of experience and their area of specialty within their current practice setting and the limitations imposed by current legal barriers. Differences in the approach were noted among experts and novices for both professions. Most of the medical practitioners at the specialist level approached the cases with more confidence by quickly identifying the target issues; however, this might be influenced by their level of interest and work pressures, since most of the interviews were conducted in the work setting. These confounding factors would need to be considered in further identification of pharmacists' educational needs.

### *7.5.1 Limitations*

Generally, pharmacists and medical practitioners who participated in the study showed a significant level of interest and volunteered to participate in the project. Low response was

initially an issue and therefore the sampling method was amended to increase the response by snowball sampling. There are arguments in the literature regarding the use of snowball sampling in research; most relate to the nonrandom selectivity of the participants and the potential for bias in selection.[130] This would be a major issue in quantitative studies, especially those involving hypothesis testing but is not relevant in a qualitative study, where the aim is to recruit a wide variety of participants in order to explore the broad range of opinions.

The importance of communication skills could not be captured using the case studies, since the purpose was to explore the thinking processes for both professions.

The study was also not designed to evaluate whether the approaches of both professions were ideal in patient management. Since this was an exploratory study, the results can be used to generate hypotheses and further research questions.

The interviewer was not from an Australian background and English was not her first language; therefore, in order to improve the efficiency of the interview process, the questions were designed in a structured way and were provided to the participants during the conduct of the interview so that the interviewees were aware of the expectations of the interview. This ensured that the interviews were successful in obtaining reliable information from the participants and avoided unnecessary confusion. This approach is commonly used in structured and semi-structured interviews. [131]

A noisy and busy environment is not a conducive environment in which to conduct an interview. Because many of the interviews were conducted at the workplace, due to the interviewee's preference, interruptions did occur; however this did not adversely affect the quality of the information obtained.

## 7.6 Conclusion

In general, differences were observed among pharmacists and medical practitioners in their approach to patient management in the areas of history taking and decision making. Management based on protocol prescribing and stable chronic disease management were found to be promising areas to explore for initiation of pharmacist prescribing.

In developing educational programmes for nonmedical prescribers in the future, it is suggested that the programme should put special emphasis on the areas involving the history-taking process, focusing on the holistic approach and the problem-identification process, focusing on performing relevant physical examination and laboratory tests. The importance of communication and consultation skills should not be overlooked when developing educational programmes.

# Chapter 8: Conclusion, Recommendations and Future Directions

**Summary**

- This chapter provides the conclusion to this research with recommendations for the future.

# Chapter 8: Conclusion, Recommendation and Future Directions

## 8.1 Development of Competency Standards

### *8.1.1 Summary*

Developing appropriate competencies for pharmacist prescribing is an important process. It is essential that all the relevant areas of nonmedical prescribing are identified to ensure appropriate levels of practice in future Australian pharmacist prescribing.

This is the first study to identify and validate the required competencies for Australian pharmacists to perform the extended role of prescribing and to develop the appropriate competency standards. The identification process involved comparing competency standards and literature from overseas and local sources and developing "the standards" for the Australian context. "The standards" were refined and validated using several processes from expert panel discussion to a medical practitioner survey.

In the development phase of this study, the "Competency Standards for Pharmacists in Australia, 2003"[92], which was the accepted set of competency standards for Australian pharmacists at the time, was used as the main reference. The prescribing competency standards ("the standards") developed and validated in this project were formatted as an adjunct to the 2003 document. Recently, a revised document was released entitled the "National Competency Standards Framework for Pharmacists in Australia 2010"[93] which solidified and strengthened the previous version. Both documents were endorsed and adopted for the profession as a whole by the Pharmaceutical Society of Australia, The Pharmacy Guild of Australia, the Association of Hospital Pharmacists, the Association of Professional Engineers, Scientists and Managers Australia, the Australian Association of Consultant Pharmacy, the Australian College of Pharmacy, the Australian Pharmacy Council, the Council of Pharmacy Schools Australia and New Zealand and the Society of Hospital Pharmacists of Australia.

Recently, since completion of this project, the National Prescribing Service Limited have published "Competencies required to prescribe medicines", developed using an advisory

group and expert reference group for health professions. This framework consists of seven competencies, five of which are specific to prescribing and the other two are related to general professional competencies.[96] The components in the framework are covered in "the standards" although wording and formatting is different. "The standards" were developed specifically for pharmacist prescribers; the NPS document has been designed for all autonomous prescribers, a point raised in Chapter 3.2.5.

### *8.1.2 Recommendation: Development of Policy*

That "the standards" be used to inform policy development regarding nonmedical prescribing.

## 8.2 Identifying Educational Needs

### *8.2.1 Summary*

Exploring pharmacists' opinions of their current level of clinical skills and knowledge was important to evaluate their confidence, and factors affecting their confidence, to perform the extended role of prescribing. Identifying differences in knowledge and approaches to clinical management between pharmacists and medical practitioners was also important to inform educational programme development. This is the first study to make direct comparisons of patient management approaches between pharmacists and medical practitioners, in addition to surveying pharmacists' opinions.

Understanding the knowledge gaps and the areas of concern related to prescribing is important in influencing syllabus development for educational programmes for pharmacist prescribers. This study has shown that some pharmacists lacked confidence in their knowledge or skills in some areas that are important to prescribing, such as holistic history taking, physical examination, and laboratory tests, and that differences exist in the management process between the professions. Pharmacists with extra qualifications were more confident in making decisions within their scope of practice.

### *8.2.2 Recommendation: Development of Educational Programmes*

That educational programmes be developed based on the available overseas literature, findings from this research and further discussion with relevant stakeholders, such as the Pharmacy Board of Australia, responsible for pharmacist registration, and the Australian Pharmacy Council, responsible for accreditation of educational programmes. The newly published "Competencies required to prescribe medicines" [96] should also be used to inform an educational curriculum for prescribing, as the document itself suggests.

That recognition of prior learning and acknowledgement of a recognised level of skills and experience should be considered prior to a pharmacist commencing an educational programme.

## 8.3 Future Directions

### *8.3.1 Evaluation of Educational Programmes*

Further research to evaluate any educational programmes that are developed will be required.

### *8.3.2 Development of Competency Assessment for Pharmacist Prescribers*

A competency assessment framework would need to be developed to complement the proposed competency standards for pharmacist prescribers.

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**Appendix 1: Comparison of competency documents**

The comparison of the similarity between the statements in the UK Competency Framework document and the "Competency Standards for Pharmacists in Australia 2003".

| UK Competency Framework Statement | Competency Standards for Pharmacists in Australia 2003 | Guide (Refer to Competency Standards for Pharmacists in Australia 2003)<br>F: Functional area<br>C: Competency unit<br>E: Element<br>PC: Performance criteria |
|---|---|---|
| **CONSULTATION** | | |
| **A. Clinical and Pharmaceutical Knowledge** | | |
| **Has up to date clinical and pharmaceutical knowledge relevant to own area of practice** | | |
| ***1. Understands the conditions being treated, their natural progress and how to assess their severity*** | **PC2:**<br>Understand the pathophysiology of the medical conditions/diseases of patients whose medication is reviewed and how it may influence optimal choices of medicines<br>**Evidence guide:**<br>Ability to explain clinical aspects of diseases/medical conditions of individual patients and the signs and symptoms commonly associated with them | **F3, C3.1, E2, PC2** |

| | | |
|---|---|---|
| ***2. Understands different non pharmacological and pharmacological approaches to modifying conditions and promoting health, desirable and undesirable outcomes and how to identify and assess them*** | **PC3:**<br>Understands the pharmacological and/or therapeutic basis for the medication treatment regimen of individual patients.<br>**Evidence guide:**<br>Ability to explain the medication treatment regimen in terms of the pharmacological actions and therapeutic uses of the medications and the medical conditions/ diseases of the patient. | **F3, C3.1, E2, PC3** |
| ***3. Understands the mode of action and pharmacokinetics of medicines, how these mechanisms may be altered (e.g. by age, renal impairment) and how this affects dosage*** | **PC7:**<br>Considers the appropriateness of use of each medicine in the current medication treatment of individual patients.<br>**Evidence guide:**<br>Ability to discuss the appropriateness of the dosing (dose, dosage form, methods of administration, frequency and duration of dosing) and use of each medicine in a patient's medication treatment regimen, taking into account relevant patient factors (e.g. medical conditions/ disease states, age, weight, allergies, pregnancy and lactation) and drug factors (e.g. bioavailability, pharmacokinetics, efficacy, toxicity and interactions) that are likely to impact on the efficacy or safety of treatment of an individual patient. | **F3, C3.1, E2, PC7** |
| ***4. Understands the potential unwanted effects, (e.g. adverse drug reactions (ADRs), drug interactions, allergy, and how to avoid/minimize and manage them*** | **PC8:**<br>Identifies clinically significant potential or actual drug related problems in the current medication treatment<br>**Evidence guide:**<br>Ability to use professional judgement to identify potential or actual medication related problems in the current medication treatment that are likely to be clinically significant (e.g. interactions, contraindications, incompatibilities, allergies, adverse drug reactions). | **F3, C3.1, E2, PC8** |

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| ***5. Maintains an up to date knowledge of relevant products (e.g. doses, formulations, pack sizes, storage conditions and cost)*** | **Nil** | |
| ***6. Appreciates the misuse potential of drugs*** | **Nil** | |
| ***7. Applies the principles of evidence-based medicine, and clinical cost effectiveness*** | **PC4S :**<br>Applies a systematic search strategy for identifying key documents and/or material needed to support the development and conduct of a specific review process.<br>**Evidence guide:**<br>Ability to describe and apply a logical and effective search strategy for accessing clinical documentation required to support a specific review (to understand how the drug should be used and why and to access the most relevant guidelines, standards and/or criteria). | **F3, C 3.3, E2, PC4S** |
| ***8. Understands how medicines are licensed, sourced, supplied and monitored (e.g. how ADRs are reported)*** | ***Incomplete statement***<br>**PC3:**<br>Contributes to information on frequency and nature of adverse drug reactions associated with drug use.<br>**Evidence guide:**<br>Ability to describe and/or use formal ADR reporting systems (e.g. institutional reporting systems or report to Adverse Drug Reaction Advisory Committee (ADRAC) of the Therapeutic Goods Administration (TGA). | **F3, C3.3, E1, PC3** |
| ***9. Understands the public health issues related to medicines and their use*** | **Nil** | |

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| ***10. Is aware of infection control procedures*** | **Nil** | |
| **B. Establishing Options** | | |
| **Reviews diagnosis, generates treatment options for the patient and follows up treatment within the scope of the clinical management plan** | | |
| ***1. Takes a comprehensive medical history and medication history (including complementary medicines, herbal remedies, over the counter medicines)*** | **PC2:**<br>Obtains additional relevant clinical and medication related information from patients and/or carers or healthcare professionals (with patient consent)<br>**Evidence guide:**<br>Ability to interview patients and/or carers, including those where sensitivity to cultural issues must be observed (e.g. Aboriginal or Torres Strait Islander people) or special communication needs exist (e.g. physical or cognitive impairment or culturally and linguistically diverse background).<br><br>Ability to develop an accurate medication history from the patient and/or carer (and other healthcare professionals and patient notes when necessary) that includes detail of current and previous medications, relevant medical and social history and test results, previous adverse drug reactions and known allergies and sensitivities | **F3, C3.1, E1, PC2** |

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| | Ability to describe what additional information needs to be obtained and why it is relevant to selecting an appropriate therapy (e.g. nonprescription and complementary therapies to complete medication record). | |
| ***2. Assess the clinical condition using appropriate techniques and equipment*** | **Nil** | |
| ***3. Assess and interprets all relevant patient records to ensure knowledge of the patient's management*** | **PC3:**<br>Uses readily available information sources as needed to clarify or confirm information or meet additional information needs.<br><br>**Evidence guide:**<br>Ability to discuss the value and limitations of readily available information sources for supporting the development of a complete and accurate patient history. | **F3, C3.1, E1, PC3** |
| ***4. Reviews/ identifies the nature, severity and significance of the clinical problem (i.e. formulates a working diagnosis from a differential diagnosis)*** | **Nil** | |
| ***5. Requests, and interprets relevant investigations*** | ***Incomplete statement***<br>**PC6:**<br>Evaluates the significance of common laboratory tests and investigations performed on individual patients.<br>**Evidence guide:**<br>Ability to describe the use and limitations of commonly ordered laboratory tests and investigations that influence medication treatment. | **F3, C3.1, E2, PC6** |

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| | Ability to assess the clinical significance to medication treatment of results of commonly laboratory tests and investigations (e.g renal function, liver function and serum electrolytes) that are outside the normal or desired range. | |
| ***6. Views and assesses the patient's needs holistically (e.g. psychosocial, physical)*** | **Nil** | |
| ***7. Considers no treatment, non drug and drug treatment options (including referral and preventive measures)*** | ***This statement refers to F6: Provide primary healthcare Statement should be applied in a different setting***<br>**PC2:**<br>Identifies possible pharmacological and non-pharmacological treatment strategies and options<br>**Evidence guide:**<br>Ability to identify a range of pharmacological and non pharmacological treatment options/strategies as well as those for which they may be a relative or absolute contraindication.<br><br>Ability to discuss treatment options in terms of nature of coexisting diseases/ conditions and current medication treatment, presenting symptoms, their duration and the extent to which previous efforts have been successful. | **F6,C6.1,E2, PC2** |
| ***8. Assesses the effect of multiple pathologies, existing medication and contraindications on treatment options*** | **Nil** | |
| ***9. Assesses the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a*** | **Nil** | |

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| ***treatment)*** | | |
| ***10. Selects the most appropriate drug, dose and formulation for the individual patient and prescribes appropriate quantities*** | **Nil** | |
| ***11. Monitors effectiveness of treatment and potential unwanted effects*** | ***This statement refers to F3: Promote and contribute to optimal use of medicines**<br>**Statement should be applied in different setting***<br>**PC6S:**<br>Participates in the assessment of whether medication treatment is achieving therapeutic goals/ outcomes.<br>**New statement:**<br>Conduct the assessment of whether medication treatment is achieving therapeutic goals/ outcomes.<br>**Evidence guide:**<br>Ability to describe disease processes and the relevance of monitoring activities for assessing disease management.<br><br>Ability to clearly describe the therapeutic goals for individual patients whose treatment is being monitored (e.g. desired INR, blood glucose, cholesterol or blood pressure reading).<br><br>Ability to collaborate with the patient and other healthcare professionals to share information relevant to assessment of whether treatment is achieving therapeutic goals. | **F3, C3.2, E2, PC6S** |
| ***12. Makes changes within the clinical management plan in light of ongoing monitoring and the patient's condition*** | **Nil** | |

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| ***and preferences*** | | |
| ***13. Establishes and maintains a plan for reviewing the therapeutic objective, discharge or end point of treatment*** | **Nil** | |
| ***14. Ensures that patients can access ongoing supplies of their medication*** | **Nil** | |
| **C. Communicating with Patients** | | |
| **Establishes a relationship based on trust and mutual respect. Sees patients as partners in the consultation. Applies the principles of concordance.** | | |
| ***1. Listens to and understands patients' beliefs, ideas, concerns and expectations*** | **PC3:**<br>Respects the 'uniqueness' of individuals.<br>**Evidence guide:**<br>Ability to demonstrate sensitivity to the needs, values, beliefs and cultural background of others. | **F2, C2.1,E1, PC3** |
| ***2. Understands the cultural and religious implications of the diagnosis/ prescribing*** | **PC4:**<br>Recognises and respects the values, beliefs and cultural backgrounds of patients and other health professionals<br>**Evidence guide:**<br>Demonstrated sensitivity to and ability to elicit information relating to values, beliefs and cultural backgrounds that may influence the way in which professional services are provided | **F1, C1.2,E2, PC4** |

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| | Demonstrated positive attitude to providing flexibility in the way in which services are provided to accommodate as far as practicable the values, beliefs and cultural backgrounds of patients and other health professionals | |
| ***3. Undertakes the consultation in an appropriate setting and adapts to meet the needs of different patients (e.g. language, level of understanding, physical impairments)*** | **PC6:**<br>Understands that special communication needs exist in some circumstances<br><br>**Evidence guide:**<br>Ability to identify and/or describe circumstances where special communication needs exist, especially for patients and carers (e.g culturally and linguistically diverse background, emotional distress, deafness, blindness, mental incapacity, communication through a third party) | **F2, C2.1, E1, PC6** |
| ***4. Deals sensitively with patients' emotions and concerns*** | **PC3:**<br>Respects the 'uniqueness' of individuals.<br>**Evidence guide:**<br>Ability to demonstrate sensitivity to the needs, values, beliefs and cultural background of others. | **F2, C2.1,E1, PC3** |
| ***5. Creates a relationship which does not encourage the expectation that a prescription will be supplied*** | **Nil** | |
| ***6. Explains the nature of the patient's condition, the rationale behind and potential risks and benefits of management options*** | **PC5:**<br>Ensures the patient and/or carer understands the reasons for the plan.<br>**Evidence guide:**<br>Ability to communicate effectively with patient and/or carer to clearly explain the reasons for and potential benefits of agreed follow-up. | **F3, C3.1, E5, PC5** |

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| ***7. Enables patients to make informed choices about their management*** | **PC5:**<br>Respects the patient's right to participate in decision making<br>**Evidence guide:**<br>Ability to discuss the importance of consumer involvement in health service delivery and their role as partners in delivery of care (e.g. their right to control their personal information and make their own choices about who to involve in their care and whether to accept or decline advice, services or products) | **F1, C1.2,E2, PC5** |
| ***8. Negotiates an outcome of the consultation that both patient and prescriber are satisfied with*** | **PC5:**<br>Identifies a position that meets the objectives of the parties to the negotiation.<br>**Evidence guide:**<br>Ability to recognise and describe an outcome that is mutually acceptable to those involved in the negotiation process. | **F2, C2.2, E2, PC5** |
| ***9. Encourages patients to take responsibility for their own health and self manage their conditions*** | **Nil** | |
| ***10. Gives clear instructions about the medication (e.g. what it is for, how to use it, where to get it from, possible unwanted effects)*** | **PC3:**<br>Assist patient understanding of their medical condition and/or medication treatment.<br>**Evidence guide:**<br>Ability to provide concise, accurate and relevant verbal and/or written health and medicines information (including reinforcement of indications, dosing regimen and administration technique, storage requirements and adverse effects) to patients to meet their information needs. | **F3, C3.1, E4, PC3** |
| ***11. Checks the patients' understanding of, and commitment to,*** | **PC5:**<br>Ensures the patient and/or carer understands the reason for the plan | **F3, C3.1, E5, PC5** |

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| ***their management and follow up*** | **Evidence guide:**<br>Ability to communicate effectively with patient and/or carer to clearly explain the reasons for and potential benefits of agreed follow-up. | |

| **UK Competency Framework Statement** | **Competency Standards for Pharmacists in Australia 2003** | Guide: (Refer to Competency Standards for Pharmacists in Australia 2003)<br>F: Functional area<br>C: Competency unit<br>E: Element<br>PC: Performance criteria |
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| **PRESCRIBING EFFECTIVELY** | | |
| **A. Prescribing Safely** | | |
| **Is aware of own limitations. Does not compromise patient safety. Justifies prescribing decisions.** | | |
| ***1. Knows the limits of own knowledge and skill, and works within them*** | **PC2:**<br>Accepts responsibility for own work tasks, actions and decisions and their outcomes.<br>**Evidence guide:**<br>Ability to identify and describe the work tasks or aspects of practice for which they are responsible | **F1, C1.2, E1, PC2** |

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| | Demonstrated ability to 'own' the outcomes of their work effort (direct and indirect) and respond to poor outcomes or situations likely to lead to poor outcomes (e.g. errors or misinformation) | |
| ***2. Knows when and how to refer to, or seek guidance from, the independent prescriber, another member of the team or a specialist*** | **Nil** | |
| ***3. Only prescribes a medicine with adequate, up to date knowledge of its actions, indications, contraindications, interactions, cautions, dose and side effects*** | **Nil** | |
| ***4. Checks doses and calculations to ensure accuracy and safety*** | ***This statement refers to F4: Dispense Medicine Statement should be applied in different setting***<br>**PC4:**<br>Considers the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine.<br>**Evidence guide:**<br>Ability to decide on the appropriateness of the prescribed drug, dose form and dosing regimen for a specific patient, taking into account relevant patient and drug factors | **F4, C4.2, E2, PC4** |
| ***5.Keeps up to date with advances in practice and emerging safety concerns*** | ***Incomplete statement***<br>**PC5S:**<br>Formulates recommendations for changes to medication treatment against the latest evidence and information on new medicines | **F3, C3.1, E3, PC5S** |

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| | **Evidence guide:**<br>Ability to access information on recent research and/or new drugs released to treat conditions or diseases commonly encountered in a specialized area of practice (e.g. gerontology, cardiology, endocrinology, intensive care or paediatrics) | |
| ***6. Knows about common types of medication errors and how to prevent them*** | ***This statement refers to F4: Dispense Medicine Statement should be applied in different setting***<br>**4S:**<br>Establishes systems for reporting and responding to medication errors.<br>**Evidence guide:**<br>Ability to describe error reporting systems and documentation in terms of key information elements needed to respond to an error to prevent or minimize the risk of recurrence (e.g. what happened, what were the contributing factors, what action has already been taken) | **F4, C4.3, E2, PC4S** |
| ***7. Makes prescribing decisions often enough to maintain confidence and competence*** | **Nil** | |
| ***8. Understands the need for and makes accurate, clear and timely records in shared patient notes*** | **Nil** | |
| ***9. Generates legible, clear and complete prescriptions, which meet legal requirements*** | **Nil** | |

| **B. Prescribing professionally** | | |
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| **Works within professional, regulatory and organisational standards** | | |
| ***1. Accepts personal responsibility for own prescribing and understands the legal and ethical implications of doing so*** | **Nil** | |
| ***2. Makes prescribing decisions, based on the needs of patients and not the personal considerations of the prescriber*** | **Nil** | |
| ***3. Understands how current legislation affects prescribing practice*** | **Nil** | |
| ***4. Prescribes within current professional and organisational codes of practice/standards*** | **Nil** | |
| ***5. Maintains patient confidentiality*** | **PC8:**<br>Acts to protect patient privacy and maintain patient confidentiality of personal information<br>**Evidence guide:**<br>Ability to explain the steps taken to protect patient privacy and maintain confidentiality of personal information | **F1, C1.2, E2, PC8** |
| ***6. Takes responsibility for own continuing professional development*** | **PC2:**<br>Understands the expectations of the registering authorities and professional associations in relation to maintenance of competence and ongoing professional development<br>**Evidence guide:** | **F1, C1.3, E1, PC2** |

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| | Ability to discuss the role pharmacy registering authorities have for protecting the public and the scope of professional development activities/opportunities provided by professional associations and other organizations (e.g. National Prescribing Service) | |
| ***7. Keeps prescriptions safely and knows what to do if they are stolen/ lost*** | **Nil** | |
| ***8. Protects the security of own access to electronic medical records and prescribing systems*** | **PC4S:**<br>Establishes and maintains a secure patient record storage system<br>**Evidence guide:**<br>Ability to describe the security arrangement | **PC3, C3.2, E3, PC4S** |
| ***9. Understands the scope of own prescribing responsibility in the context of a shared clinical management plan*** | **Nil** | |
| ***10. Ensures that the patient has agreed to be managed by a prescribing partnership*** | **Nil** | |
| **C. Improving prescribing practice** | | |
| **Actively participates in the review and development of prescribing practice to improve patient care** | | |
| ***1. Learns and changes from reflecting on own practice*** | **Nil** | |
| ***2. Shares and debates own and others prescribing practice*** | **Nil** | |
| ***3. Challenges inappropriate practice constructively*** | **PC5S:**<br>Promotes practice changes that arise from specific reviews | **F3, C3.3, E3, PC5S** |

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| | **Evidence guide:**<br>Ability to describe and apply strategies known to be effective in changing or reinforcing changes in prescribing or other drug related clinical practice behaviours. | |
| ***4. Develops own networks for support, reflection and learning*** | **PC3:**<br>Supports the learning and professional development of others in the workplace<br>**Evidence guide:**<br>Ability to provide professional advice and guidance to others consistent with the limits of own expertise. | **F1, C1.3, E3, PC3** |
| ***5. Understands and uses tools to improve practice (e.g. data, audit and feedback)*** | **3S:**<br>Knows the types of dissemination tools/strategies that can be used to share information on review findings and recommendations for change.<br>**Evidence guide:**<br>Ability to describe a range of dissemination tools or strategies. | **F3,C3.3,E3,PC3S** |
| ***6. Reports prescribing errors and near misses, reviews practice to prevent recurrences*** | ***This statement refers to F4: Dispense Medicine Statement should be applied in different setting***<br>**4S:**<br>Establishes systems for reporting and responding to medication errors.<br>**Evidence guide:**<br>Ability to describe error reporting systems and documentation in terms of key information elements needed to respond to an error to prevent or minimize the risk of recurrence (e.g. what happened, what were the contributing factors, what action has already been taken) | **F4, C4.3, E2, PC4S** |

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| ***7. Establishes multi professional links with practitioners working in the same specialist area*** | **PC1:**<br>Accepts the value of partnerships and teamwork<br>**Evidence guide:**<br>Demonstrated positive attitude to working collaboratively with others, including as a member of a team<br>Ability to promote and engender teamwork with others in the workplace | **F8, C8.4, E3, PC1** |

| **UK Competency Framework Statement** | **Competency Standards for Pharmacists in Australia 2003** | Guide: (Refer to Competency Standards for Pharmacists in Australia 2003)<br>F: Functional area<br>C: Competency unit<br>E: Element<br>PC: Performance criteria |
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| **PRESCRIBING IN CONTEXT** | | |
| **A. Information in context** | | |
| **Knows how to access relevant information. Can critically appraise and apply information in practice** | | |
| ***1. Understands the advantages and limitations of different information sources*** | **PC1:**<br>Identifies the most useful of the readily available information sources for providing the required information. | **F7, C7.1, E4, PC1** |

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| | **Evidence guide:**<br>Ability to list and describe the scope (i.e. their usefulness and limitations) of legally required or recommended texts (e.g. APF, AusDI, Martindale, Australian Prescription Products Guide). | |
| | **PC2:**<br>Knows what other information sources can provide relevant information<br>**Evidence guide:**<br>Ability to discuss the independence, appropriateness of value of other reference materials (e.g. Merck Manual, Australian Medicines Handbook, AusDI and Therapeutic Guidelines) for types of information most usually sought.<br><br>Ability to access appropriate other reference sources (hard copy and electronic) both directly and indirectly via other location. | **F7, C7.1, E4, PC2** |
| ***2. Use relevant, up to date information*** | **PC5S:**<br>Formulates recommendations for changes to medication treatment against the latest evidence and information on new medicines<br>**Evidence guide:**<br>Ability to access information on recent research and/or new drugs released to treat conditions or diseases commonly encountered in a specialized area of practice (e.g. gerontology, cardiology, endocrinology, intensive care or paediatrics) | **F3, C3.1, E3, PC5S** |
| ***3. Critically appraises the validity of information sources (e.g. promotional literature, research)*** | **PC6S:**<br>Critically evaluates the research findings<br>**Evidence guide:**<br>Demonstrated understanding of key economic concepts such as cost effectiveness and cost benefit. | **F7, C7.2, E2, PC6S** |

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| | Ability to assess evidence for strength, size of effect and relevance. | |
| | **PC7S:**<br>Uses primary and secondary information sources to critically evaluate the efficacy and safety of medicines.<br>**Evidence guide:**<br>Ability to interpret data relating to pharmacology, pharmacokinetics, precautions, administration and dosing, dosage forms and economic issues in primary and secondary information sources. | **F7, C7.2, E2, PC7S** |
| | **PC8S:**<br>Critically evaluates the reliability and accuracy of new information in primary information sources.<br>**Evidence guide:**<br>Ability to explain the impact of significance of new information from primary sources on therapy or dosing decisions.<br><br>Ability to apply evidence to clinical/ healthcare situations to determine benefit/harm and cost effectiveness. | **F7, C7.2, E2, PC8S** |
| | **PC9S:**<br>Calculates and manipulates clinical data and associated costs accurately.<br>**Evidence guide:**<br>Demonstrated ability to carry out additional calculations and manipulations accurately. | **F7, C7.2, E2, PC9S** |
| ***4. Applies information to the clinical context (linking theory to practice)*** | **PC2S:**<br>Shares research findings with pharmacy colleagues and other health professionals/ facility personnel whose care processes may be affected.<br>**Evidence guide:** | **F7, C7.3, E1, PC2S** |

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| | Ability to undertake appropriate dissemination activities from a broad range of options ('in house' newsletters, professional journals and local, national or international meetings). | |
| ***5. Uses relevant patient record systems, prescribing and information systems, and decision support tools*** | ***Incomplete statement***<br>**PC4S:**<br>Accesses or develops and uses tools and resources that assists the conduct of review of medications<br>**Evidence guide:**<br>Ability to identify existing tools (e.g. software, personal digital assistance) or develop additional resources (e.g. proforma record sheets, patient information brochure) that will facilitate the conduct of reviews of medication treatment | **F3, C3.1, E2, PC4S** |
| ***6. Regularly reviews evidence behind therapeutic strategies*** | **PC6S:**<br>Works collaboratively with clinicians to prepare or revise medication treatment protocols, guidelines, criteria and/or standards.<br><br>Ability to access relevant research and other information from which the evidence base for revision of drug treatment guidelines or protocols may be drawn.<br><br>Ability to discuss and agree the evidence base for revising existing guidelines or protocols and to undertake revisions to create concise, unambiguous and 'easy to use' treatment protocols or guidelines. | **F3, C3.3, E3,PC6S** |
| **B. The NHS in context** | | |
| **Understands, and works within, local and national policies that impact on prescribing practice. Sees how own practice impacts on wider NHS** | | |

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| ***1. Knows how local health service and partner organizations work and interact*** | **Nil** | |
| ***2. Follows relevant local and national guidance for medicines use (e.g. local formularies, care pathways, NICE guidance)*** | **Nil** | |
| ***3. Works within the NHS/ organisational code of conduct when dealing with the pharmaceutical industry*** | **PC1:**<br>Considers the obligations created by codes of conduct/ethics for professional practice<br>**Evidence guide:**<br>Ability to describe and explain the obligations created by the codes of conduct/ ethics | **F1, C1.2, E2, PC1** |
| | **PC2:**<br>Interprets and applies the requirements imposed by relevant codes of conduct/ ethics for specific services or situations<br>**Evidence guide:**<br>Ability to interpret the obligations created by relevant codes in terms of specific services or situations<br><br>Demonstrated conduct or professional behaviour toward patients, other health professionals and the public that is consistent with codes of conduct/ ethics | **F1, C1.2, E2, PC2** |
| ***4. Understands budgetary constraints at local and national level*** | **Nil** | |

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| ***5. Understands national NHS frameworks relevant to medicines use (e.g clinical governance, IT strategy)*** | **Nil** | |
| ***6. Understands the framework of supplementary prescribing and how it is applied in practice*** | **Nil** | |
| **C. The team and individual context** | | |
| **Works in partnership** | | |
| ***1. Thinks and acts as part of a multidisciplinary team to ensure that continuity of care is not compromised*** | **PC6:**<br>Considers the rights, responsibilities, duty of care and/or legislative obligations applicable to other health professionals/ facility personnel with whom they cooperate in the delivery of the professional services.<br>**Evidence guide:**<br>Ability to describe factors relevant to professional service delivery that arise from the legislative obligations, rights and responsibilities or duty of care of collaborating health professionals/ facility personnel (e.g. doctors and registered and enrolled nurses). | **F1, C1.2, E2, PC6** |
| | **PC7:**<br>Collaborates with other healthcare professionals to enable patients to achieve the best health outcomes<br>**Evidence guide:**<br>Ability to maintain rapport and work in partnership (share information, with patient consent, and work cooperatively on patient health goals) with other health professionals to achieve therapeutic goals. | **F1, C1.2, E1, PC7** |

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| ***2. Establishes relationships with colleagues based on understanding, trust and respect for each others roles*** | **PC5:**<br>Respects and preserves the relationships that other health professionals have with patients<br>**Evidence guide:**<br>Demonstrated ability to discuss the role of other members of the healthcare team (including with patients) in a way that engenders understanding and confidence in the team and its members | **F1, C1.2, E1, PC5** |
| ***3. Establishes and maintains credibility with colleagues in the healthcare team*** | **PC4:**<br>Maintain relevant professional boundaries.<br>**Evidence guide:**<br>Ability to describe roles and activities undertaken in relation to own expertise and the expectations of the collaborating health professionals | **F1, C1.2, E1, PC4** |
| ***4. Recognises and deals with pressure that might result in inappropriate prescribing (e.g. pharmaceutical industry, patients and colleagues)*** | **Nil** | |
| ***5. Is proactive, adaptable, flexible and responsive to change*** | **Nil** | |
| ***6. Negotiates the appropriate level of support for role as a prescriber*** | **Nil** | |
| ***7. Seeks and/or provides support and advice to other prescribers, team members or support staff where appropriate*** | **PC2:**<br>Works in partnership with others in the delivery of services to patients and other clients<br>**Evidence guide:**<br>Ability to assist colleagues (e.g. provide advice, offer professional assistance) to undertake work activities. | **F8, C8.4, E3, PC2** |

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| | Ability to maintain respectful and cooperative relationships with work colleagues and other health professionals and carers involved in the care of patients, to deliver pharmacy services to specific patients. | |
| | **PC1:**<br>Encourages improvement in the professional capability of others in the workplace<br>**Evidence guide:**<br>Demonstrated ability to maintain a positive attitude to continuous learning and professional development | **F1, C1.3, E3, PC1** |
| | **PC2:**<br>Assists others to create a professional development plan and identify relevant learning opportunities<br>**Evidence guide:**<br>Ability to work with others to develop a professional development plan and suggest ways in which the plan may be progressed through relevant training and/or experiential learning opportunities. | **F1, C1.3, E3, PC2** |
| | **PC3:**<br>Supports the learning and professional development of others in the workplace<br>**Evidence guide:**<br>Ability to provide professional advice and guidance to others consistent with the limits of own expertise. | **F1, C1.3, E3, PC3** |
| ***8. Negotiates with the independent prescriber to develop and agree clinical management plans*** | **Nil** | |
| ***9. Relates to the independent prescriber as a partner*** | **PC1:**<br>Accepts the value of partnerships and teamwork | **F8, C8.4, E3, PC1** |

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| | **Evidence guide:**<br>Demonstrated positive attitude to working collaboratively with others, including as a member of a team<br>Ability to promote and engender teamwork with others in the workplace | |
| ***10. Maintains the integrity of the prescribing partnership*** | **Nil** | |

**Appendix 2: Proposed standards**

The proposed competency standards discussed during the first expert panel meeting.

**Guide:**

**Red colour font: refers to the statement that is contained in the Australian Pharmacists Competency document WITH modifications**

**Brown colour font: refers to the statement that is contained in the Australian Pharmacists Competency document WITHOUT modifications**

**Blue colour font: refers to statement that is contained in the UK supplementary prescribing framework WITHOUT modifications**

**Pink colour font: refers to statement that is contained in the UK supplementary prescribing framework WITH modifications**

**Black colour font: refers to the statement that I have developed for supplementary prescribing in Australia**

This functional area applies for pharmacists who wish to obtain additional accreditation for advanced practice in supplementary prescribing.

**FUNCTIONAL AREA 9: PRESCRIBE MEDICINES**

This functional area includes competency units that address the clinical skills and knowledge pharmacists need to perform supplementary prescribing. Supplementary prescribing is defined as a voluntary partnership between the independent prescriber and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement. The competency units in this functional area apply to pharmacy practice either in hospital or community based practice.

**Competency Unit 9.1 Prescribe Safely**

This unit is concerned with pharmacists' ability to prescribe in an appropriate manner. It encompasses skills and knowledge as well as responsibility for safe prescribing.

| Element (5) | Performance Criteria (12) | Evidence Guide (16) |
|---|---|---|
| Review prescribing process | Knows when and how to refer to, or seek guidance from, the independent prescriber, another member of the team or a specialist | Ability to refer patients appropriately to the independent prescriber for further management when needed based on the supplementary prescribing guideline |
| | Prescribes a medicine using adequate, up to date knowledge | Ability to apply knowledge of the actions, indications, contraindications, interactions, cautions, dose and side effects of the medication when making a decision to prescribe for a patient, based on the supplementary prescribing guideline |
| | Checks doses and calculations to ensure accuracy and safety<br>OR<br>Refer to Functional area 4: Dispense Medicine<br><br>Statement should be applied in the prescribing scenario<br><br>Functional area 4, Competency Unit 4.2, Element 2, Performance Criteria 4<br><br>Considers the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine. | Ability to decide on the appropriateness of the prescribed drug, dose form and dosing regimen for a specific patient, taking into account relevant patient and drug factors |
| | Makes accurate, clear and timely records in shared patient notes | Ability to describe the important factors/requirements to be written in the shared patient notes |

| Element (5) | Performance Criteria (12) | Evidence Guide (16) |
|---|---|---|
| | | |
| Safety issues in prescribing | Keeps up to date with advances in practice and emerging safety concerns | Ability to describe the common types of medication errors with regards to prescribing.<br><br>Ability to apply knowledge of safety concerns to prescribing practice |
| | Refer to Functional area 4: Dispense Medicine<br><br>Statement should be applied in the prescribing scenario<br><br>Functional area 4, Competency Unit 4.3, Element 2, Performance Criteria 4S<br><br>Establishes systems for reporting and responding to medication errors. | Ability to describe error reporting systems and documentation in terms of key information elements needed to respond to an error to prevent or minimise the risk of recurrence (e.g. what happened, what were the contributing factors, what action has already been taken) |
| | Generates legible, clear and complete prescriptions, which meet legal requirements<br>OR<br>Confirms that written prescription comply with all legal requirements and professional conventions | Ability to explain the key legal requirements of a valid prescription as specified by relevant State or Territory legislation (e.g. drugs, poisons and controlled substances legislation, Pharmacy Act and Regulations) and National Health Act and Regulations.<br><br>Ability to describe and/or promptly access information on the professional conventions and obligations applicable to prescribing, including for those medicines that are subsidised under the PBS. |
| | Uses documentation and systems that support prescription validation | Ability to develop, review and maintain documentation, including standard operating procedures, for prescription validation (PBS |

| Element (5) | Performance Criteria (12) | Evidence Guide (16) |
|---|---|---|
| | | claims rules, contacts for suspected fraudulent prescriptions). |
| Apply knowledge and skills to prescribe in an appropriate manner | Makes prescribing decisions with confidence and competence | Ability to demonstrate knowledge contributing to personal prescribing decision with confidence |
| Assess clinical condition | Understands the disease state management | Ability to describe factors which may influence the management of current disease states |
| | Performs clinical assessment for various clinical conditions in appropriate areas | Ability to perform examination of head, ears, eyes, nose, throat, abdomen, pulmonary (chest), nervous system, skin, head and neck, eyes and vascular system. |
| Use appropriate techniques and equipment | Demonstrates the ability to perform clinical assessment using specific medical equipment and devices | Ability to describe the knowledge and requirements for use of various medical equipment and devices.<br><br>Ability to apply the knowledge of various medical equipments and devices to their use.<br><br>Ability to perform clinical assessment using specific medical equipment or devices. |

**Competency Unit 9.2 Prescribe Effectively**

This functional area includes competency units that address the skills and knowledge that pharmacist need to acquire to prescribe in the most effective way.

| Element (2) | Performance Criteria (5) | Evidence Guide (9) |
|---|---|---|
| Confirm availability of medicines | Refer to Functional area 4: Dispense Medicine<br><br>Statement should be applied in the prescribing scenario<br><br>Functional area 4, Competency Unit 4.1, Element 3, Performance Criteria 1<br><br>Establishes any special circumstances or supply arrangements impacting on availability of the prescribed medicine | Ability to describe the requirements (including legal requirements where relevant) applicable to medicines with specific terms of supply (e.g. PBS and private prescriptions, Section 100 supplies, Special Access Scheme (SAS) and emergency supply medicines, hospital formulary versus non-formulary medicines |
| | Refer to Functional area 4: Dispense Medicine<br><br>Statement should be applied in the prescribing scenario<br><br>Functional area 4, Competency Unit 4.1, Element 3, Performance Criteria 2<br><br>Identifies suitable products held in stock or available from a supplier | Ability to interpret brand bioequivalence notes in PBS Schedule of Benefits for products from different manufacturers.<br><br>Ability to use authoritative reference sources and supplier catalogues to clarify required product and its availability. |
| | Ensures that patients can access ongoing supplies of their medication | Ability to identify factors which may affect the ongoing supply of medication.<br><br>Ability to identify ways to avoid the factors which may affect the ongoing supply of medication. |

| Element (2) | Performance Criteria (5) | Evidence Guide (9) |
|---|---|---|
| | Understands how medicines are licensed, sourced, supplied and monitored (e.g. how ADRs are reported)<br>OR<br>Refer to Functional area 3, Competency Unit 3.3, Element 1, Performance Criteria 3<br><br>Contributes to information on frequency and nature of adverse drug reactions associated with drug use. | Ability to describe how medicines are licensed, supplied and monitored<br><br>Ability to demonstrate applied knowledge of how medicines are licensed, supplied and monitored<br><br>Ability to describe and/or use formal ADR reporting systems (e.g. institutional reporting systems) or report to Adverse Drug Reaction Advisory Committee (ADRAC) of the Therapeutic Goods Administration (TGA). |
| Update knowledge | Maintains an up to date knowledge of relevant products | Ability to demonstrate up to date knowledge of doses, formulations, pack sizes, storage conditions and cost of medication |

**Competency Unit 9.3 Prescribe Professionally**

This unit is concerned with pharmacists' ability to prescribe in the professional way. It encompasses the standards of practice that pharmacists need to follow to prescribe professionally.

| Element (3) | Performance Criteria (9) | Evidence Guide (15) |
|---|---|---|
| Works within professional, regulatory and organisational standards | Accepts personal responsibility for own prescribing | Ability to describe own responsibility towards prescribing<br><br>Ability to describe the legal and ethical implications of own responsibility towards prescribing |

| Element (3) | Performance Criteria (9) | Evidence Guide (15) |
|---|---|---|
| | Makes prescribing decisions based on patient related factors | Ability to recognise and describe the prescribing decision based on the needs of patients and not the personal considerations of the prescriber<br><br>Ability to apply the knowledge of prescribing based on the needs of patients and not the personal considerations of the prescriber |
| | Prescribes to the accepted standards | Ability to apply current professional and organisational codes of practice/standards to prescribing |
| Work in partnership towards benefit of patients | Negotiates with members of the prescribing team | Ability to demonstrate negotiation skills in communication with the independent prescriber to develop and agree on clinical management plans |
| | Ensures that the patient has agreed to be managed within a prescribing partnership | Ability to explain to the patient what management within a prescribing partnership will mean for their care. |
| Behave in a professional and ethical manner | Understands how current legislation affects prescribing practice | Ability to describe the legislation involved in prescribing<br><br>Ability to prescribe in a legal manner |
| | Understands the scope of own prescribing responsibility | Ability to describe and recognise own role in the prescribing decision within the context of a shared clinical management plan<br><br>Ability to apply the knowledge of own role in the prescribing decision within the context of a shared clinical management plan |

| Element (3) | Performance Criteria (9) | Evidence Guide (15) |
|---|---|---|
| | Maintain security of prescribing stationary or computer security systems | Ability to understand the importance of keeping prescription stationary/systems secure<br><br>Ability to explain the steps needed to be taken when a prescription pad is lost or computer security is breached |
| | Recognises and deals with pressure that might result in inappropriate prescribing | Ability to identify the implications/consequences of inappropriate prescribing (e.g. pharmaceutical industry, patients and colleagues)<br><br>Ability to identify the solutions of inappropriate prescribing (e.g. pharmaceutical industry, patients and colleagues) |

**Competency Unit 9.4 Prescribe to the accepted standard**

This competency unit describe various standard that pharmacist need to achieve when reviewing patients clinical problem before making the decision to prescribe.

| Element (1) | Performance Criteria (9) | Evidence Guide (16) |
|---|---|---|
| Review patient clinical problem | Identifies the nature, severity and significance of the clinical problem | Ability to formulate a working diagnosis from differential diagnoses |
| | Requests, and interprets relevant investigations<br>OR<br>Refer to Functional area 3, Competency Unit 3.1, Element 2, Performance Criteria 6 | Ability to describe the use and limitations of commonly ordered laboratory tests and investigations that influence medication treatment. |

| Element (1) | Performance Criteria (9) | Evidence Guide (16) |
|---|---|---|
| | Evaluates the significance of common laboratory tests and investigations performed on individual patients. | Ability to assess the clinical significance to medication treatment of results of common laboratory tests and investigations that are outside the normal or desired range (e.g. renal function, liver function and serum electrolytes). |
| | Considers no treatment, non drug and drug treatment options (including referral and preventive measures)<br>OR<br>Refer to Functional area 6: Provide primary healthcare<br><br>Statement should be applied in the hospital scenario as well<br><br>Functional area 6, Competency Unit 6.1, Element 2, Performance Criteria 2<br><br>Identifies possible pharmacological and non-pharmacological treatment strategies and options | Ability to identify a range of pharmacological and non-pharmacological treatment options/strategies as well as those for which there may be a relative or absolute contraindication.<br><br>Ability to discuss treatment options in terms of nature of coexisting diseases/ conditions and current medication treatment, presenting symptoms, their duration and the extent to which previous efforts have been successful |
| | Assesses the effect of multiple pathologies, existing medication and contraindications on treatment options | Ability to describe the impact of existing factors and current medication that will contribute to the selection of appropriate treatment options |
| | Assesses the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment) | Ability to identify the impact for the patient of receiving or not receiving the treatment choice |

| Element (1) | Performance Criteria (9) | Evidence Guide (16) |
|---|---|---|
| | Selects the most appropriate drug, dose and formulation for the individual patient and prescribes appropriate quantities | Ability to determine the most appropriate drug, dosage and formulation for the patient |
| | Monitors effectiveness of treatment and potential unwanted effects<br><br>OR<br><br>Refer to Functional Area 3: Promote and contribute to optimal use of medicines<br><br>Statement should be applied in the prescribing scenario<br><br>Functional area 3, Competency Unit 3.2, Element 2, Performance Criteria 6S<br><br>Assessment of whether medication treatment is achieving therapeutic goals/ outcomes. | Ability to describe disease processes and the relevance of monitoring activities for assessing disease management.<br><br>Ability to clearly describe the therapeutic goals for individual patients whose treatment is being monitored (e.g. desired INR, blood glucose, cholesterol or blood pressure reading).<br><br>Ability to collaborate with the patient and other healthcare professionals to share information relevant to assessment of whether treatment is achieving therapeutic goals. |
| | Makes changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences | Ability to identify factors which affect patients clinical outcome while receiving the treatment<br><br>Ability to evaluate factors which affect patients clinical outcome while receiving the treatment<br><br>Ability to identify solutions and make changes to improve patients clinical outcome while receiving the treatment |

| Element (1) | Performance Criteria (9) | Evidence Guide (16) |
|---|---|---|
| | Establishes and maintains a plan for reviewing the therapeutic objective, discharge or end point of treatment | Ability to develop an individualized plan for a patient<br><br>Ability to apply the individualized plan for a patient |

**Competency Unit 9.5 Participate in the development of prescribing practice**

This competency unit describe on ways to improve the prescribing practice from the own and other prescribing practice.

| Element (1) | Performance Criteria (3) | Evidence Guide (13) |
|---|---|---|
| Participates in the review of prescribing practice | Learns and changes from reflecting on own practice | Ability to explain own prescribing practice<br><br>Ability to identify the strength and weaknesses of own prescribing practice<br><br>Ability to develop and change own prescribing practice |
| | Shares and debates own prescribing practice | Ability to identify the strengths and weaknesses of own prescribing practice<br><br>Ability to describe the factors which contribute to the strengths and weaknesses of own prescribing practice<br><br>Ability to identify the solutions to problems with own prescribing practice |

| | | |
|---|---|---|
| | | Ability to apply the solutions to the problems with own prescribing practice<br><br>Ability to explain the strengths and weaknesses and ways to manage them for own prescribing practice |
| | Shares and debates others prescribing practice | Ability to identify the strengths and weaknesses of the prescribing practice of others<br><br>Ability to describe the factors which contribute to the weaknesses of others' prescribing practice<br><br>Ability to identify the solutions to the problems with the prescribing practice of others<br><br>Ability to apply the solutions to the problems of the prescribing practice of others<br><br>Ability to explain the strengths and weaknesses and ways to manage them for others' prescribing practice |

**Appendix 3: Explanatory statement for the first expert panel (pharmacists)**

MONASH University

**Development of the Competency Standards for Pharmacists to Perform Supplementary Prescribing in Australia.**

**Information for Expert Panels**

My name is **Adliah Mhd Ali** and I am conducting a research project with **Dr. Jennifer Marriott and Associate Professor Kay Stewart** in the Department of **Pharmacy Practice** towards a **Doctor of Philosophy** at Monash University.

**The aim/purpose of the research**

The aim of this study is to develop Competency Standards for pharmacists who may undertake supplementary prescribing in Australia in the future. Supplementary prescribing is defined as the voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement. Supplementary prescribing was introduced in the United Kingdom in 2004 with the intention of improving health services and patient care by making it easier for patients to get the medicines they need through best use of the skills of health professionals. Pharmacist prescribers contribute to this aim by monitoring patients with long term conditions and prescribing medicines that are appropriate for the patient's condition. In a supplementary prescribing partnership, the medical practitioner makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing ongoing care within agreed parameters, to the pharmacist prescriber.

Following the implementation of pharmacist prescribing in the United Kingdom, it became apparent that there were inconsistencies regarding competency assessment both before and after qualification as a supplementary prescriber. This key issue is highlighted as a high priority in the report by The Royal Pharmaceutical Society of Great Britain[1]. Literature reviews have also indicated that pharmacists feel that they are not competent in certain areas, particularly related to clinical assessment and monitoring.

In Australia, pharmacy practice models have been developed to improve access to prescription medicines. The introduction of the proposed models may lead to the extension of supplementary prescribing rights to pharmacists, with doctors acting as the main independent prescribers. Before supplementary prescribing models are introduced in Australia, the issues related to pharmacists' competency to prescribe need to be addressed. Various competencies have been identified from the literature and supplementary prescribing courses conducted overseas. These have been adapted to develop Competency Standards for Prescribing Pharmacists based on the existing Competency Standards for Pharmacists in Australia published in 2003.

**Expert Panels**

Expert panels will be convened to discuss proposals for Competency Standards for Pharmacist Prescribers –composed of pharmacists.

The expert reference group discussion will be of approximately 2 hours duration, conducted on 23rd January 2007 from 10.30 a.m to 12.30 p.m followed by a light lunch at the Victorian College of Pharmacy, Monash University located at the Dean's Meeting Room (Sissons Building Ground Floor). A small honorarium of $150 will be provided to compensate for the time involved. Participants will also have the opportunity to be involved at a later stage in the development of the educational programme for pharmacists who wish to be qualified as supplementary prescribers.

**Explanation for the Expert Reference Group Discussion**

There are 3 separate documents that will be used for the discussion.

1. The first document contains the competency framework developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006.

2. The second document is the Competency Standards for Pharmacists in Australia 2003. This was prepared by the Pharmaceutical Society of Australia on behalf of the Australian pharmacy profession to describe the knowledge, skills and attributes necessary for a pharmacist to practice in Australia. They cover areas of practice in which the majority of pharmacists practice, as well as areas in which not all pharmacists practice.

3. The third document contains the proposed competencies that have been developed for pharmacists to perform supplementary prescribing that will be incorporated into the Competency Standards for Pharmacists in Australia 2003 in the future.

Members of the expert panel are asked to review the three documents before the meeting. On the day of the meeting, members will discuss the suitability of the functional area and competency units for the various competencies that have been developed for supplementary prescribing. Members will also discuss and comment on the suitability of the content for the element, performance criteria and evidence guide for the proposed competency units. The Competency framework document developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006 will be used as a reference document since supplementary prescribing has been implemented in the United Kingdom. The Competency Standards for Pharmacists in Australia 2003 document is used as a guide since the content of the proposed competencies for pharmacists to perform supplementary prescribing should follow the format of this document.

Thank you.

**Adliah Mhd Ali**

**Reference**

1. Practice Division. (2006). Supplementary Prescribing One Year On. Royal Pharmaceutical Society of Great Britain. April 2006. http://www.rpsgb.org.uk/pdfs/supplpresconf05.pdf. Last updated 27th August 2006.

**Appendix 4: First expert panel review agenda**

Title: Development of the Competency Standards for Pharmacists to Perform Supplementary Prescribing in Australia

Date: 23rd January 2007

Time: 10.30 a.m to 12.30 p.m

Venue: Dean's Meeting Room, Ground Floor, Sissons Building,
Victorian College of Pharmacy, Monash University

**Programme**

10.00-10.30: Arrive

10.30-12.30: Discussion

12.30-1.30: Lunch

**15 minutes Introduction (10.30 a.m-10.45 a.m)**

1. Welcome
2. Thanks for attending
3. Get people (round robin) to introduce themselves (name and brief description, from which organization, what you do)
4. Explain the method of payment
5. Purpose of the discussion (Refer to the information of the expert panel)
    a. to develop Competency Standards for pharmacists who may undertake supplementary prescribing in Australia in the future
    b. proposed competencies for supplementary prescribing has been developed and the purpose of today discussion is to comment and to get some feedback on the proposed competencies
    c. expert panels are convened to discuss the proposal for Competency Standards for Pharmacist Prescribers which composed of pharmacists practicing in different area
6. Explain the documents which will be discussed (make sure that all the members have all the documents with the correct number of pages)

a. UK Competency Framework developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006 (16 pages)
b. Competency Standards for Pharmacists in Australia 2003 prepared by the Pharmaceutical Society of Australia on behalf of the Australian pharmacy profession to describe the knowledge, skills and attributes necessary for a pharmacist to practice in Australia. (144 pages)
c. Proposed Competencies for Supplementary Prescribing that has been developed for pharmacists that will be incorporated into the Competency Standards for Pharmacists in Australia 2003 in the future (11 pages)
    i. Units of competency: reflect the major functions of the profession, each unit describing an area of professional performance
    ii. Elements: aim to integrate the knowledge, skills, attitudes and other important attributes of professional performance in the workplace
    iii. Performance criteria ascribed to the elements specify the appropriate level of performance required of the professional in the workplace
    iv. Evidence guide assist with the interpretation and assessment of units and elements. It may cover aspects such as context for assessment

7. Ground rules
    a. audio taping
    b. one person speak at a time
    c. please say name before speaking (initially)
    d. no names will be used in the reporting of the study (confidentiality)
    e. negative and positive views wanted
    f. Liz Morabito will be taking notes during our discussion and this will assist with the transcribing work
    g. Agenda
        i. 5-10 minutes discussion for the suitability of the terms used for functional area and competency units
        ii. Discuss and comment on the suitability of the content for the element, performance criteria and evidence guide (time allocated is 15 minutes for each unit). Depending on the situation, might need the voting for the consensus

iii. 20 minutes (final discussion and conclusion)

**10 minutes Discussion (10.45 a.m-10.55 a.m)**

1. Discussion on the functional area and competency unit
    - Refer to page 1 (functional area)
    - Refer to page 1, 4, 6, 7 and 10 (competency units)
    - Do you agree with the terms used for the functional area and competency unit?
    - Any issues regarding the terms used?
    - Is there anything else missing?
    - If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
    - If the statement is appropriate, then move straight to no 2

**1 hour 15 minutes Discussion (10.55 a.m-12.10 p.m)**

1. Discussion on the element, performance criteria and the evidence guide for each of the competency unit

**15 minutes discussion**

a) Competency Unit 9.1: Prescribe Safely
    - Refer to page 1
    - Are the statements appropriate? What do you think?
    - Choose the most suitable performance criteria
        - page 2, line 2
        - page 3, line 2
    - If the statements are appropriate, then move straight to no 2b.
    - If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
    - Serial discussion for clarification
    - Any other issues concerned will be noted
    - Make sure that everyone is happy with the consensus
    - Is there anything else missing? Any comments?

Depending on the situation, might need the voting for the consensus

- Preliminary vote on item importance
- Discussion on the voting
- Final vote

Notes on chart: Liz Morabito

**15 minutes discussion**

b) Competency Unit 9.2: Prescribe Effectively

- Refer to page 4
- Are the statements appropriate?
- Choose the most suitable performance criteria
  - page 5, line 3
- If the statements are appropriate, then move straight to no 2c.
- If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
- Serial discussion for clarification
- Any other issues concerned will be noted
- Make sure that everyone is happy with the consensus
- Is there anything else missing?

Depending on the situation, might need the voting for the consensus

- Preliminary vote on item importance
- Discussion on the voting
- Final vote

Notes on chart: Liz Morabito

**15 minutes discussion**

c) Competency Unit 9.3: Prescribe Professionally

- Refer to page 6
- Are the statements appropriate?
- If the statements are appropriate, then move straight to no 2d.
- If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
- Serial discussion for clarification

- Any other issues concerned will be noted
- Make sure that everyone is happy with the consensus
- Is there anything else missing?

Depending on the situation, might need the voting for the consensus

- Preliminary vote on item importance
- Discussion on the voting
- Final vote

Notes on chart: Liz Morabito

**15 minutes discussion**

d) Competency Unit 9.4: Prescribe to the accepted standard

- Refer to page 7
- Are the statements appropriate?
- Choose the most suitable performance criteria
  - page 8, line 1
  - page 8, line 2
  - page 9, line 3
- If the statements are appropriate, then move straight to no 2e.
- If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
- Serial discussion for clarification
- Any other issues concerned will be noted
- Make sure that everyone is happy with the consensus
- Is there anything else missing?

Depending on the situation, might need the voting for the consensus

- Preliminary vote on item importance
- Discussion on the voting
- Final vote

Notes on chart: Liz Morabito

**15 minutes discussion**

e) Competency Unit 9.5: Participate in the development of the prescribing practice

- Refer to page 10
- Are the statements appropriate?
- If the statements are appropriate, then move to no 4
- If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
- Serial discussion for clarification
- Any other issues concerned will be noted
- Make sure that everyone is happy with the consensus
- Is there anything else missing?

Depending on the situation, might need the voting for the consensus

- Preliminary vote on item importance
- Discussion on the voting
- Final vote

Notes on chart: Liz Morabito

**20 minutes Conclusion (12.10 p.m-12.30 p.m)**

1. Any other issues concerned will be noted
    a. Make sure that everyone is happy with the consensus
    b. Is there anything else missing?
2. Outcomes of the meeting (summarize everything)
3. Thanks everyone for participating (useful positive and negative comments) and Liz Morabito for taking the notes
4. Invited everyone again for the future project on supplementary prescribing

Useful phrases:

- Other people agree with that
- That's a whole different discussion on it's own, by the sound of it

- I’m aware of the time so we probably need to move on
- Since everyone agree with the statement, can we move on to the next

**Appendix 5: Summary of the first expert panel review**

**Summary of the Meeting**

Attached are some of the useful suggestions and important points that have been raised during the meeting and the action taken.

1. Suggestions: Decision has to be made concerning whether the proposed document has to be as a stand alone document or as part of the Australian Competency Standard

Action: The document will stand as part of the Australian Competency Standard so that it is accessible to all the profession. However proper linking on the missing points from the UK document will be made available.

2. Suggestions: The document needs to be extended not only to the pharmacist but also to the other healthcare professionals.

Action: The extension of the document to the other healthcare professionals requires more detailed research to be conducted with the other allied health professionals. Since this is a PhD project that needs to be finished within a certain required time the competencies developed would only be extended for the pharmacists at the time being. Collaboration with other professional groups could be considered at some time in the future as a collaborative research project.

3. Suggestions: Some concerns have been raised on the scope and content of the proposed document. The concern is that it is not stringent enough compared to the UK document

Actions: Some of the crucial area such as consultation and communication skills in the UK document will be taken into consideration and will be reworded in the proposed document in an appropriate manner. It will be written as extra S for advanced pharmacy practitioner and 'Range of Variables' will be added to the proposed document. The range of variables seek to place the competency unit into the appropriate practice contexts, including those involving the application of the supplementary Performance Criteria. The appropriate practice ranges from the community setting, repeat supply of chronic medications in the residential aged care facilities, discharge prescribing in the hospital settings, provision of prescription under protocols in remote areas and pharmacists formulary.

4. Suggestions: Difficulty to match the United Kingdom document with the existing Australian Competency Standard document

Actions: Some of the statements in the UK documents will be reworded before being introduced into the Australian Competency Standard context without changing the intrinsic meaning.

5. Suggestions: Concerns on the boundaries and content of the supplementary prescribing within the Australian setting.

Actions: The document will be written in such a way that covers the independent prescribing model as well. The competencies will then cover prescribing in all contexts.

6. Suggestions: Difficult to define and incorporate the prescribing competencies into appropriate Australian scenarios (community setting, repeat supply of chronic medications in the residential aged care facilities, discharge prescribing in the hospital settings, provision of prescription under protocols in remote areas and pharmacists formulary)

Actions: Prescribing within appropriate scenarios will be included in the 'Range of Variables' for a clear understanding of the reader.

7. Suggestions: Concerns on the more suitable term used rather than "Prescribe medicine"

Actions: The terms prescribe medicine will be maintained as the most appropriate term to be used in the document. The Competency requires use of an 'active' verb that is broad enough to encompass all the elements required for its action.

8. Suggestions: Contents of the proposed document

Actions: All the suggestions for the contents of the proposed document that have been discussed and agreed during the meeting will be taken into considerations.

**Appendix 6: Explanatory statement for the second expert panel (medical practitioners)**

MONASH University

## Development of the Competency Standards for Pharmacists to Perform Supplementary Prescribing in Australia.

### Information for Expert Panels

My name is **Adliah Mhd Ali** and I am conducting a research project with **Dr. Jennifer Marriott and Associate Professor Kay Stewart** in the Department of **Pharmacy Practice** towards a **Doctor of Philosophy** at Monash University.

**The aim/purpose of the research**

The aim of this study is to validate the competency standard that has been developed for pharmacists who may undertake supplementary prescribing in Australia in the future. Supplementary prescribing is defined as the voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement. Supplementary prescribing was introduced in the United Kingdom in 2004 with the intention of improving health services and patient care by making it easier for patients to get the medicines they need through best use of the skills of health professionals. Pharmacist prescribers contribute to this aim by monitoring patients with long term conditions and prescribing medicines that are appropriate for the patient's condition. In a supplementary prescribing partnership, the medical practitioner makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing ongoing care within agreed parameters, to the pharmacist prescriber.

Following the implementation of pharmacist prescribing in the United Kingdom, it became apparent that there were inconsistencies regarding competency assessment both before and after qualification as a supplementary prescriber. This key issue is highlighted as a high priority in the report by The Royal Pharmaceutical Society of Great Britain[1]. Literature reviews have also indicated that pharmacists feel that they are not competent in certain areas, particularly related to clinical assessment and monitoring.

In Australia, pharmacy practice models have been developed to improve access to prescription medicines. The introduction of the proposed models may lead to the extension of supplementary prescribing rights to pharmacists, with doctors acting as the main independent prescribers. Before supplementary prescribing models are introduced in Australia, the issues related to pharmacists' competency to prescribe need to be addressed. Various competencies have been identified from the literature and supplementary prescribing courses conducted overseas. These have been adapted to develop Competency Standards for Prescribing Pharmacists based on the existing Competency Standards for Pharmacists in Australia published in 2003.

**Expert Panels**

Expert panels will be convened to discuss proposals for Competency Standards for Supplementary Prescribers –composed of doctors.

The expert reference group discussion will be of approximately 2 hours duration, conducted on 13th April 2007 from 11 a.m to 1 p.m followed by a light lunch at the Victorian College of Pharmacy, Monash University located at the Dean's Meeting Room (Sissons Building Ground Floor). A small honorarium of $150 will be provided to compensate for the time involved. Participants will also have the opportunity to be involved at a later stage in the development of the educational programme for pharmacists who wish to be qualified as supplementary prescribers.

**Explanation for the Expert Reference Group Discussion**

There are 4 separate documents that will be used for the discussion.

1. The first document contains the case studies that will be used to identify the competencies needed to perform supplementary prescribing and thus to further validate the proposed competencies that has been developed for pharmacist to perform supplementary prescribing.

2. The second document contains the proposed competencies that have been developed for pharmacists to perform supplementary prescribing that will be incorporated into the Competency Standards for Pharmacists in Australia 2003 in the future.

3. The third document is the competency framework developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006.

4. The fourth document is the Competency Standards for Pharmacists in Australia 2003. This was prepared by the Pharmaceutical Society of Australia on behalf of the Australian pharmacy profession to describe the knowledge, skills and attributes necessary for a pharmacist to practice in Australia. They cover areas of practice in which the majority of pharmacists practice, as well as areas in which not all pharmacists practice.

5. Members of the expert panel are asked to review the four documents before the meeting. On the day of the meeting, case studies will be used to discuss and explore the knowledge and skills that are needed for supplementary prescribers. This will then be used to further validate the suitability of the functional area and competency units for the various competencies that have been developed for supplementary prescribing. Members will also discuss and comment on the suitability of the content for the element, performance criteria and evidence guide for the proposed competency units. The Competency framework document developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006 will be used as a reference document since supplementary prescribing has been implemented in the United Kingdom. The Competency Standards for Pharmacists in Australia 2003 document is used as a guide since the content of the proposed competencies for pharmacists to perform supplementary prescribing should follow the format of this document.

Thank you.

**Adliah Mhd Ali**

**Reference**

1. Practice Division. (2006). Supplementary Prescribing One Year On. Royal Pharmaceutical Society of Great Britain. April 2006. http://www.rpsgb.org.uk/pdfs/supplpresconf05.pdf. Last updated 27th August 2006.

**Appendix 7: Explanatory statement for the second expert panel (pharmacists)**

MONASH University

**Development of Competency Standards for Pharmacists to Perform Supplementary Prescribing in Australia.**

**Information for Expert Panels**

My name is **Adliah Mhd Ali** and I am conducting a research project with **Dr. Jennifer Marriott and Associate Professor Kay Stewart** in the Department of **Pharmacy Practice** towards a **Doctor of Philosophy** at Monash University.

**The aim/purpose of the research**

The aim of this study is to refine the proposed competency standards that have been developed for pharmacists to undertake supplementary prescribing in Australia in the future. Supplementary prescribing is defined as the voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement. Supplementary prescribing was introduced in the United Kingdom in 2004 with the intention of improving health services and patient care by making it easier for patients to get the medicines they need through best use of the skills of health professionals. Pharmacist prescribers contribute to this aim by monitoring patients with long-term conditions and prescribing medicines that are appropriate for the patient's condition. In a supplementary prescribing partnership, the medical practitioner makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing for ongoing care within agreed parameters, to the pharmacist prescriber.

Following the implementation of pharmacist prescribing in the United Kingdom, it became apparent that there were inconsistencies regarding competency assessment both before and after qualification as a supplementary prescriber. This key issue is highlighted in the report by The Royal Pharmaceutical Society of Great Britain[1]. Literature reviews have also indicated that pharmacists feel that they are not competent in certain areas, particularly those related to clinical assessment and monitoring. Perhaps particularly because things are moving quickly in UK, there are some concerns with the competencies, assessment and educational programmes they have developed.

In Australia, pharmacy practice models have been developed to improve access to prescription medicines. The introduction of the proposed models may lead to the extension of supplementary prescribing rights to pharmacists, with doctors acting as the main independent prescribers. Access to medical care is more critical in the UK, which is why they investigated widening prescribing rights. However there have been concerns that with the limited number of doctors and the increasing ageing population, there are indications that access might be the problem in the future in Australia. At the moment, there are no plans or processes in place to introduce supplementary prescribing in Australia, but the fact that this is happening overseas in the UK, USA and Canada is an indication that it might happen in Australia in the future. If supplementary prescribing were to be introduced in Australia, it needs to be done in a more consultative way to make it work for the benefit of all with consideration of safety issues. When prescribing was introduced overseas this work was not done beforehand. It is therefore imperative that consideration is given to developing appropriate competency standards, policies and procedures and associated standards and education. Therefore various competencies have been identified from the literature and supplementary prescribing courses conducted overseas. These have been adapted to develop Competency Standards for Prescribing Pharmacists based on the existing Competency Standards for Pharmacists in Australia published in 2003.

**Expert Panels**

Expert panels will be convened to discuss proposals for Competency Standards for Supplementary Prescribers. This research is to look at the process involved in the development of competency standards so that education can be developed for possible use in the future and to inform the profession. People's names will not be mentioned in any papers published from this research, only themes and the recommendations that are discussed.

The expert reference group discussion for prescribers will be of approximately two hours duration, conducted on 23rd May 2007 from 11 a.m to 1 p.m followed by a light lunch at the Victorian College of Pharmacy, Monash University, in the Dean's Meeting Room (Sissons Building Ground Floor). A small honorarium of $150 will be provided to compensate for the time involved. Participants will also have the opportunity to be involved at a later stage in the development of the educational programme for pharmacists who wish to be qualified as supplementary prescribers.

**Explanation for the Expert Reference Group Discussion**

Four separate documents will be used for the discussion.

1. The first document contains case studies that will be used to identify the competencies needed to perform supplementary prescribing and thus to further validate the proposed competencies that have been developed for pharmacists to perform supplementary prescribing.

2. The second document contains the proposed competencies that have been developed for pharmacists to perform supplementary prescribing in Australia in the future.

3. The third document is the competency framework developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006.

4. The fourth document is the Competency Standards for Pharmacists in Australia 2003. This was prepared by the Pharmaceutical Society of Australia on behalf of the Australian pharmacy profession to describe the knowledge, skills and attributes necessary for a pharmacist to practice in Australia. They cover areas of practice in which the majority of pharmacists practice, as well as areas in which not all pharmacists practice.

5. Members of the expert panel are asked to review the four documents before the meeting. On the day of the meeting, case studies will be used to discuss the knowledge and skills that are needed for supplementary prescribers. Therefore, the case studies are intended for discussion to gather pharmacists' perspectives on the different levels of responsibility to determine what they can do, what they could do with extra training and what they absolutely should not do. Therefore the intention of the meeting is to discuss what these limits are and to explore why they are limits. There will also be an opportunity to discuss other issues of concern. This will then be used to further validate the suitability of the functional area and competency units for the various competencies that have been developed for supplementary prescribing. Members will also discuss the suitability of the elements, performance criteria and evidence guides for the proposed competency units. The competency framework document developed by the National Prescribing Centre in the United Kingdom will be used as a reference document since supplementary prescribing has been implemented in the United Kingdom. The Competency Standards for Pharmacists in Australia 2003 will be used as a guide since the content of the proposed competencies for pharmacists to perform supplementary prescribing complements the content and follows the format of this document.

Thank you.

**Adliah Mhd Ali**

**Reference**

1. Practice Division. (2006). Supplementary Prescribing One Year On. Royal Pharmaceutical Society of Great Britain. April 2006. http://www.rpsgb.org.uk/pdfs/supplpresconf05.pdf. Last updated 27th August 2006.

**Appendix 8 : Second expert panel review agenda (medical practitioners)**

**Expert Panel Review Discussion**

Title: Development of the Competency Standards for Pharmacists to Perform Supplementary Prescribing in Australia

Date: 13th April 2007

Time: 11.00 a.m to 1 p.m

Venue: Dean's Meeting Room, Ground Floor, Sissons Building,
Victorian College of Pharmacy, Monash University

**Programme**

10.00-10.30: Arrive

10.30-12.30: Discussion

12.30-1.30: Lunch

**15 minutes Introduction (11.00 a.m-11.15 a.m)**

1. Welcome
2. Thanks for attending
3. Get people (round robin) to introduce themselves (name and brief description, from which organization, what you do)
4. Explain the method of payment
5. Purpose of the discussion (Refer to the information of the expert panel)
    a. to develop Competency Standards for pharmacists who may undertake supplementary prescribing in Australia in the future
    b. proposed competencies for supplementary prescribing has been developed and the purpose of today discussion is to comment and to get some feedback on the proposed competencies
    c. expert panels are convened to discuss the proposal for Competency Standards for Supplementary Prescribers which composed of doctors practicing in different area

6. Explain the documents which will be discussed (make sure that all the members have all the documents with the correct number of pages)
    a. UK Competency Framework developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006 (16 pages)
    b. Competency Standards for Pharmacists in Australia 2003 prepared by the Pharmaceutical Society of Australia on behalf of the Australian pharmacy profession to describe the knowledge, skills and attributes necessary for a pharmacist to practice in Australia. (144 pages)
    c. Proposed Competencies for Supplementary Prescribing that has been developed for pharmacists that will be incorporated into the Competency Standards for Pharmacists in Australia 2003 in the future (11 pages)
        i. Units of competency: reflect the major functions of the profession, each unit describing an area of professional performance
        ii. Elements: aim to integrate the knowledge, skills, attitudes and other important attributes of professional performance in the workplace
        iii. Performance criteria ascribed to the elements specify the appropriate level of performance required of the professional in the workplace
        iv. Evidence guide assist with the interpretation and assessment of units and elements. It may cover aspects such as context for assessment

7. Case studies
8. Ground rules
    a. audio taping
    b. one person speak at a time
    c. please say name before speaking (initially)
    d. no names will be used in the reporting of the study (confidentiality)
    e. negative and positive views wanted
    f. Liz Morabito will be taking notes during our discussion and this will assist with the transcribing work
    g. Agenda
        i. 5-10 minutes discussion for the suitability of the terms used for functional area and competency units

ii. Discuss and comment on the suitability of the content for the element, performance criteria and evidence guide (time allocated is 15 minutes for each unit). Depending on the situation, might need the voting for the consensus
iii. 20 minutes (final discussion and conclusion)

1) Based on your judgement as a prescriber, do you think that in this scenario, is it appropriate for pharmacist to manage the patient in this way?

a) If yes,

1) What sort of knowledge, skills and ability that the pharmacist need to obtain to perform the task?
2) What are the advantages and disadvantages with this?
3) Do you think that this will help to improve the medicine management pathway?

b) If no, any reason for that?

1) What needs to happen?
2) Who could do this?

After going through all the scenarios, I would like all of you to have a look at the proposed competency standards that has been circulated earlier.

2) Do you think that the proposed pharmacist supplementary prescribing role would help to improve the medicine management pathway and patient care?

**15 minutes Discussion (12.40 p.m- 12.55 p.m)**

After going through all the case studies (summarise the types of competencies the group has come up with during discussion of cases), I would like you to look at the proposed competency standards.

1. Do you think that the proposed competency standards cover all the appropriate areas for pharmacists to perform this new task as a supplementary prescriber?
2. Discussion on the functional areas and competency units

- Do you agree with the terms used for the functional area and competency unit?
- Any issues regarding the terms used?
- Is there anything else missing?
- If there is an issue, round robin recording of ideas on a chart (Liz Morabito)

3. Discussion on the elements, performance criteria and the evidence guides for each of the competency unit
    a. Are the statements appropriate? What do you think?
    b. If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
    c. Any other issues concerned will be noted
    d. Make sure that everyone is happy with the consensus
    e. Is there anything else missing? Any comments?

4. Depending on the situation, might need voting for consensus

    Notes on chart: Liz Morabito

**5 minutes Conclusion (12.55 p.m-1.00 p.m)**

1. Any other issues of concern will be noted
    a. Make sure that everyone is happy with the consensus
    b. Is there anything else missing?
2. Outcomes of the meeting (summarize everything)
3. Initiate to make further comment later if they think of something.
4. Thanks everyone for participating (useful positive and negative comments) and Liz Morabito for taking the notes

**Useful phrases:**

- Other people agree with that
- That's a whole different discussion on it's own, by the sound of it
- I'm aware of the time so we probably need to move on
- Since everyone agrees with the statement, can we move on to the next

**Appendix 9: Second expert panel review agenda (pharmacists)**

**Expert Panel Review Discussion**

Title: Development of Competency Standards for Pharmacists to Perform Supplementary Prescribing in Australia

Date: 23rd May 2007

Time: 11.00 a.m to 1 p.m

Venue: Dean's Meeting Room, Ground Floor, Sissons Building,
Victorian College of Pharmacy, Monash University

**Programme**

10.30-11.00: Arrive

11.00-1.00: Discussion

1.00-1.30: Lunch

**10 minutes Introduction (11.00 a.m-11.10 a.m)**

1. Welcome
2. Thanks for attending
3. Get people (round robin) to introduce themselves (name and brief description, from which organization, what you do)
4. Explain the method of payment
5. Purpose of the discussion (Refer to the information of the expert panel)
    a. to discuss the 9 case studies to identify potential pharmacist role in managing patients with long term chronic conditions
    b. to get some feedback on the proposed Competency Standards for supplementary prescribing in Australia in the future
    c. expert panels are convened to discuss the case studies and the proposal for Competency Standards for Supplementary Prescribers which composed of doctors practicing in different area

6. Explain the documents which will be discussed (make sure that all the members have all the documents with the correct number of pages)
    a. Case studies involving pharmacists managing patient in a different scenario (11 pages)
    b. Proposed Competencies for Supplementary Prescribing that have been developed for pharmacists that could be incorporated into the Competency Standards for Pharmacists in Australia 2003 in the future (23 pages)
        i. Units of competency reflect the major functions of the profession, each unit describing an area of professional performance
        ii. Elements aim to integrate the knowledge, skills, attitudes and other important attributes of professional performance in the workplace
        iii. Performance criteria ascribed to the elements specify the appropriate level of performance required of the professional in the workplace
        iv. Evidence guides assist with the interpretation and assessment of units and elements. They cover aspects such as the context for assessment
    c. Supplementary documents for referral:
        i. UK Competency Framework developed by the National Prescribing Centre in the United Kingdom (2nd edition) published in October 2006 (16 pages)
        ii. Competency Standards for Pharmacists in Australia 2003 prepared by the Pharmaceutical Society of Australia on behalf of the Australian pharmacy profession to describe the knowledge, skills and attributes necessary for a pharmacist to practice in Australia. (144 pages)
7. Ground rules
    a. audio taping
    b. one person speak at a time
    c. please say name before speaking (initially)
    d. no names will be used in the reporting of the study (confidentiality)
    e. negative and positive views wanted

f. Liz Morabito will be taking notes during our discussion and this will assist with the transcribing work
g. Agenda
    i. 1 ½ hours discussion on case studies
    ii. 15 minutes discussion on the appropriateness of the proposed competency standards
    iii. 5 minutes conclusion

**1 ½ hours Discussion (11.10 a.m -12.40 p.m)**

Case studies (10 minutes discussion on each of the case studies)

**1) Based on your judgement as a potential supplementary prescriber (pharmacist), do you think that in this scenario, is it appropriate for pharmacist to manage the patient in this way?**

A) If yes,

i. What sort of knowledge, skills and ability does the pharmacist need to perform the task?
ii. Do you think that the pharmacists already have all the knowledge, skills and ability to perform the task?
iii. If there is an issue, round robin recording of ideas on a chart (Liz Morabito)

B) If no, why not?

i. What needs to happen in this case?
ii. Who could do the prescribing in this case?
iii. Do you think that if pharmacists undergo appropriate training they would be competent to perform the task? What would they need in the training?
iv. If there is an issue, round robin recording of ideas on a chart (Liz Morabito)

**2) Do you think that the proposed pharmacist supplementary prescribing role would help to improve the medicine management pathway and patient care?**

**15 minutes Discussion (12.40 p.m- 12.55 p.m)**

After going through all the case studies (summarise the types of competencies the group has come up with during discussion of cases), I would like you to look at the proposed competency standards.

1. Do you think that the proposed competency standards cover all the appropriate areas for pharmacists to perform this new task as a supplementary prescriber?

2. Discussion on the functional areas and competency units

    - Do you agree with the terms used for the functional area and competency unit?
    - Any issues regarding the terms used?
    - Is there anything else missing?
    - If there is an issue, round robin recording of ideas on a chart (Liz Morabito)

3. Discussion on the elements, performance criteria and the evidence guides for each of the competency unit
    a. Are the statements appropriate? What do you think?
    b. If there is an issue, round robin recording of ideas on a chart (Liz Morabito)
    c. Any other issues concerned will be noted
    d. Make sure that everyone is happy with the consensus
    e. Is there anything else missing? Any comments?

4. Depending on the situation, might need voting for consensus

    Notes on chart: Liz Morabito

**5 minutes Conclusion (12.55 p.m-1.00 p.m)**

1. Any other issues of concern will be noted
    a. Make sure that everyone is happy with the consensus

   b. Is there anything else missing?
2. Outcomes of the meeting (summarize everything)
3. Initiate to make further comment later if they think of something.
4. Thanks everyone for participating (useful positive and negative comments) and Liz Morabito for taking the notes

Useful phrases:

- Other people agree with that
- That's a whole different discussion on it's own, by the sound of it
- I'm aware of the time so we probably need to move on
- Since everyone agrees with the statement, can we move on to the next

## Appendix 10: Prescribing survey (medical practitioners)

# Prescribing Survey for Doctors

**HOW TO COMPLETE THIS QUESTIONNAIRE**
The questionnaire contains **5** pages and will take approximately **20** minutes

Please indicate your answers by COMPLETELY FILLING a response of your chosen answers.
Make heavy marks that fill the circle. Do NOT use highlighters.
Be sure to answer each statement by filling in only one response.

Please fill the circles completely as illustrated ● O O O O

**Your completed questionnaire should be returned to the researcher in the enclosed reply-paid envelope.**

## Part 1: Demographic Information

**Please fill in the details or indicate ● for the most appropriate response**

| | | |
|---|---|---|
| **1) Gender** | O Male | O Female |
| **2) Age** | _____ years | |
| **3) Current location of practice** | O Capital city<br>O Large regional centre<br>O Rural/remote<br>O Other please specify _____<br>O | |
| **4) Area of practice** | O Hospital ONLY<br>O Community ONLY<br>O BOTH hospital and community<br>O Other please specify _____<br>O | |
| **5) Current work** | O Intern<br>O Registrar<br>O Resident<br>O General practitioner<br>O Specialist<br>O Academic<br>O Other please specify _____ | |
| **6) Basic Medical Degree or equivalent** | A) Country of graduation<br>o Australia<br>o Overseas, please indicate country _____<br><br>B) Number of years since initial registration _____ years | |
| **7) Duration of practise within the Australian Health Care System** | _____ years | |

## Part 2: Prescribing Survey

Each statement indicates an aspect of prescribing practice. ***Indicate your level of agreement*** with each of the following statements based on judgment as a prescriber. Please select only **ONE** rating for each statement.

**A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree**

| SECTION A | | | | | |
|---|---|---|---|---|---|
| **In order for me to prescribe <u>effectively</u>, I need to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **confirm availability of medicines by** | | | | | |
| *1) establishing any special circumstances or supplying arrangements impacting on availability of the prescribed medicine.* | O | O | O | O | O |
| *2) confirming that suitable products are held in stock or available from a supplier.* | O | O | O | O | O |
| *3) ensuring that patients can access ongoing supplies of their medication.* | O | O | O | O | O |
| *4) understanding how medicines are licensed, sourced, supplied and monitored.* | O | O | O | O | O |
| **update knowledge by** | | | | | |
| *5) maintaining an up-to-date knowledge of relevant products.* | O | O | O | O | O |
| **prescribe in an appropriate manner by** | | | | | |
| *6) understanding cost concerns relevant to prescribing.* | O | O | O | O | O |
| **Comments concerning section A** | | | | | |

| SECTION B | | | | | |
|---|---|---|---|---|---|
| **In order for me to prescribe to an <u>acceptable standard</u>, I need to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **review patient clinical problems by** | | | | | |
| *1) understanding the conditions being treated, their natural progress and how to assess their severity.* | O | O | O | O | O |
| *2) identifying the nature, severity and significance of the clinical problem.* | O | O | O | O | O |
| **review therapy options by** | | | | | |
| *3) understanding the pharmacological and/non-pharmacological approaches to modifying conditions.* | O | O | O | O | O |
| *4) understanding the mechanism of action and pharmacokinetics of medicines and how these mechanisms may be altered.* | O | O | O | O | O |
| *5) identifying clinically significant potential or actual drug related problems in the current medication treatment.* | O | O | O | O | O |
| *6) requesting common laboratory tests and investigations performed on individual patients.* | O | O | O | O | O |
| *7) interpreting relevant investigations and evaluating the significance of common laboratory tests and investigations performed on individual patients.* | O | O | O | O | O |
| *8) considering no treatment, non-drug and drug treatment options (including referral and preventive measures).* | O | O | O | O | O |
| *9) assessing the effect of multiple pathologies, existing medication and contraindications on treatment options.* | O | O | O | O | O |
| *10) assessing the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment).* | O | O | O | O | O |
| *11) applying the principles of evidence-based medicine.* | O | O | O | O | O |
| *12) applying the principles of clinical cost effectiveness.* | O | O | O | O | O |
| **select treatment by** | | | | | |
| *13) selecting the most appropriate drug, dose and formulation for the individual patient and prescribe appropriate quantities.* | O | O | O | O | O |
| *14) establishing and maintaining a plan for reviewing the therapeutic objective or end point of treatment.* | O | O | O | O | O |
| *15) monitoring effectiveness of treatment and potential unwanted effects and assess whether medication treatment is achieving therapeutic goals/ outcomes.* | O | O | O | O | O |
| *16) making changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences.* | O | O | O | O | O |
| **Comments concerning section B** | | | | | |

| SECTION C | | | | | |
|---|---|---|---|---|---|
| **In order for me to prescribe safely, I need to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **review the prescribing process by** | | | | | |
| *1) knowing the limits of my own knowledge and skill to prescribe safely.* | O | O | O | O | O |
| *2) knowing when and how to refer to, or seek guidance from another member of the team or a specialist.* | O | O | O | O | O |
| *3) prescribing a medicine using adequate, up-to-date knowledge.* | O | O | O | O | O |
| *4) deciding on the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine.* | O | O | O | O | O |
| *5) checking doses and calculations to ensure accuracy and safety.* | O | O | O | O | O |
| *6) making accurate, clear and timely records.* | O | O | O | O | O |
| **update patient information by** | | | | | |
| *7) taking a comprehensive history.* | O | O | O | O | O |
| *8) assessing and interpreting all relevant patient records to ensure knowledge of the patient's management.* | O | O | O | O | O |
| **apply safety issues in prescribing by** | | | | | |
| *9) keeping up to date with advances in practice and emerging safety concerns.* | O | O | O | O | O |
| *10) establishing systems for responding when an error occurs during prescribing.* | O | O | O | O | O |
| *11) establishing systems for reporting and responding to medication errors.* | O | O | O | O | O |
| *12) generating legible, clear and complete prescriptions, which meet legal requirements.* | O | O | O | O | O |
| *13) using documentation and systems that support prescription validation.* | O | O | O | O | O |
| **apply knowledge and skills to prescribe in an appropriate manner by** | | | | | |
| *14) making prescribing decisions with confidence and competence.* | O | O | O | O | O |
| **assess progress of the clinical condition by** | | | | | |
| *15) understanding disease state management principles.* | O | O | O | O | O |
| *16) understanding the conditions being treated, their natural progress and how to assess their severity.* | O | O | O | O | O |
| *17) performing clinical assessment for various clinical conditions in appropriate areas.* | O | O | O | O | O |
| *18) using appropriate techniques and equipment.* | O | O | O | O | O |
| **Comments concerning section C** | | | | | |

| SECTION D | | | | | |
|---|---|---|---|---|---|
| **In order for me to prescribe professionally, I need to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **work within professional, regulatory and organisational standards by** | | | | | |
| *1) accepting responsibility for my own prescribing.* | O | O | O | O | O |
| *2) making prescribing decisions based on patient-related factors.* | O | O | O | O | O |
| *3) prescribing to an acceptable standard.* | O | O | O | O | O |
| **work in partnership towards benefit of patients by** | | | | | |
| *4) being able to negotiate with members of the prescribing team.* | O | O | O | O | O |
| *5) ensuring that the patient has agreed to be managed within a partnership.* | O | O | O | O | O |
| *6) understanding the cultural and religious implications of the diagnosis/ prescribing.* | O | O | O | O | O |
| **behave in a professional and ethical manner by** | | | | | |
| *7) understanding how current legislation affects prescribing practice.* | O | O | O | O | O |
| *8) understanding the scope of my own prescribing responsibility.* | O | O | O | O | O |
| *9) maintaining patient confidentiality.* | O | O | O | O | O |
| *10) maintaining security of prescribing stationery or computer security systems.* | O | O | O | O | O |
| *11) maintaining the security and confidentiality of data being transferred.* | O | O | O | O | O |
| *12) recognising and dealing with pressures that might result in inappropriate prescribing.* | O | O | O | O | O |
| *13) take responsibility for my own continuing professional development in relation to prescribing* | O | O | O | O | O |
| **Comments concerning section D** | | | | | |

| SECTION E | | | | | |
|---|---|---|---|---|---|
| **In order for me to participate in the development of prescribing practice, I need to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **participate in the review of prescribing practice by** | | | | | |
| *1) learning and changing through reflecting on my own practice.* | O | O | O | O | O |
| *2) sharing my own prescribing practice.* | O | O | O | O | O |
| *3) sharing and debating others' prescribing practice.* | O | O | O | O | O |
| *4) challenging inappropriate practice constructively.* | O | O | O | O | O |
| **use own networks by** | | | | | |
| *5) developing networks for mutual support, reflection and learning.* | O | O | O | O | O |
| *6) establishing multi-professional links with practitioners working in the same practice area.* | O | O | O | O | O |
| **use tools to improve practice by** | | | | | |
| *7) understanding and knowing the types of dissemination tools/strategies that can be used to share information or review findings and recommendations for change.* | O | O | O | O | O |
| **report prescribing errors by** | | | | | |
| *8) reporting prescribing errors and near misses that I am aware of.* | O | O | O | O | O |
| *9) reviewing my practice to prevent error recurrences.* | O | O | O | O | O |
| **Comments concerning section E** | | | | | |

| SECTION F | | | | | |
|---|---|---|---|---|---|
| **In order for me to communicate effectively with patients, I need to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **understand and respect the uniqueness of individuals by** | | | | | |
| *1) understanding patients' beliefs, ideas, concerns and expectations.* | O | O | O | O | O |
| *2) understanding the cultural and religious implications of the diagnosis/ prescribing.* | O | O | O | O | O |
| **undertake the consultation in an appropriate manner by** | | | | | |
| *3) undertaking it in an appropriate setting and adapting it to meet the needs of different patients.* | O | O | O | O | O |
| *4) dealing sensitively with patients' emotions and concerns.* | O | O | O | O | O |
| *5) explaining the nature of the patient's condition, the rationale behind and potential risks and benefits of management options.* | O | O | O | O | O |
| *6) enabling patients to make informed choices about their management.* | O | O | O | O | O |
| **negotiate an outcome** | | | | | |
| *7) through consultation that both patient and prescriber are satisfied with.* | O | O | O | O | O |
| **give clear instructions about the medication by** | | | | | |
| *8) encouraging patients to take responsibility for their own health and self manage their conditions.* | O | O | O | O | O |
| *9) assisting patients' understanding of their medical condition and/or medication treatment.* | O | O | O | O | O |
| **follow up by** | | | | | |
| *10) checking the patients' understanding and commitment to their current and ongoing management.* | O | O | O | O | O |
| **Comments concerning section F** | | | | | |

| SECTION G | | | | | |
|---|---|---|---|---|---|
| **In order for me to provide medicines and health information and education, I need to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **understand the readily available information sources by** | | | | | |
| *1) recognizing the availability of information sources that can provide relevant information.* | O | O | O | O | O |
| *2) understanding the advantages and limitations of various information sources.* | O | O | O | O | O |
| **use relevant, up to date information by** | | | | | |
| *3) formulating recommendations for changes to medication treatment based on the latest evidence and information on new medicines.* | O | O | O | O | O |
| **critically appraise the validity of information sources by** | | | | | |
| *4) critically evaluating research findings.* | O | O | O | O | O |
| *5) using primary and secondary information sources to critically evaluate the efficacy and safety of medicines.* | O | O | O | O | O |
| *6) critically evaluating the reliability and accuracy of new information in primary information sources.* | O | O | O | O | O |
| *7) calculating and manipulating clinical data and associated costs accurately.* | O | O | O | O | O |
| **apply information in the clinical context by** | | | | | |
| *8) information sources, sharing research findings with colleagues and other health professionals/ facility personnel whose care processes may be affected.* | O | O | O | O | O |
| **review evidence by** | | | | | |
| *9) using relevant patient record systems, prescribing and information systems, and decision support tools.* | O | O | O | O | O |
| *10) working collaboratively with other clinicians to prepare or revise medication treatment protocols, guidelines, criteria and/or standards.* | O | O | O | O | O |
| **Comments concerning section G** | | | | | |

**Part 3: Other comments**

***Please check that you have answered all the questions.***

***Thank you for your time.***

## Appendix 11: Ethical approval (prescribing survey)

MONASH University

**Standing Committee on Ethics in Research Involving Humans (SCERH)**
Research Office

**Human Ethics Certificate of Approval**

| | | |
|---|---|---|
| **Date** | **20-FEB-2008** | |
| **Project Number** | **CF08/0260 - 2008000099** | |
| **Project Title** | **Prescribing survey** | |
| **Chief Investigator** | **Dr Jennifer Marriott** | |
| **Approved** | **From: 20-FEB-2008** | **To: 20-FEB-2013** |

**Terms of approval**

1. Approval is only valid whilst you hold a position at Monash University.
2. It is the responsibility of the Chief Investigator to ensure that all pending information (such as permission letters from organisations) is forwarded to SCERH. Research cannot begin at an organisation until SCERH receives a permission letter from that organisation and confirms that research can start.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by SCERH.
4. You should notify SCERH immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project:** Requires the submission of a Request for Amendment form to SCERH and must not begin without written approval from SCERH. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. SCERH should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by SCERH at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

Dr Souheir Houssami
Executive Officer, Human Research Ethics (on behalf of SCERH)

Cc: Assoc Prof Kay Stewart; Miss Adliah Mhd Ali

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +61 3 9905 5490 Facsimile +61 3 9905 1420
Email scerh@adm.monash.edu.au www.monash.edu/research/ethics/human/index/html
ABN 12 377 614 012 CRICOS Provider #00008C

**Appendix 12: Explanatory statement (medical practitioners survey)**

MONASH University

**Explanatory Statement**

**Prescribing Survey**

**This information sheet is for you to keep.**

**My name is** Adliah Mhd Ali **and I am conducting a research project with** Dr Jennifer Marriott **and** Associate Professor Kay Stewart **in the Department of** Pharmacy Practice **towards a** Doctor of Philosophy **at Monash University. This means that I will be writing** a thesis which is the equivalent of a 300 page book.

**Why did you choose this particular person/group as participants?**

The purpose of the survey is to evaluate doctors' perceptions of competencies needed for prescribing, therefore medical practitioners are invited to participate in this survey. A sample of medical practitioners has been selected by systematic random sampling from the publicly available Medical Practitioners Board of Victoria.

**The aim/purpose of the research**

Supplementary prescribing was introduced in the United Kingdom in 2004 with the intention of improving health services and patient care by making it easier for patients to get the medicines they need through best use of the skills of health professionals. Pharmacist prescribers contribute to this aim by monitoring patients with long-term conditions and prescribing medicines that are appropriate for the patient's condition. In a supplementary prescribing partnership, the medical practitioner makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing for ongoing care within agreed parameters, to the pharmacist prescriber.

In Australia, pharmacy practice models have been proposed to improve access to prescription medicines in a range of settings. The introduction of these models may lead to the extension of supplementary prescribing rights to Australian pharmacists in the future, with doctors remaining as the main independent prescribers.

Following the implementation of pharmacist prescribing in the United Kingdom, it became apparent that there were inconsistencies regarding competency assessment both before and after qualification as a supplementary prescriber. Therefore a set of competencies have

been developed for Australia to ensure pharmacists have the appropriate knowledge, skills and attitudes to undertake this role.

The aim of this study is to validate the competencies for prescribing with a view to identifying the educational needs for pharmacists if they were to undertake this supportive role.

**Possible benefits**

The long-term benefit of this work is that, by identifying the educational needs for pharmacists to undertake a role in prescribing, courses can be developed to address these needs with a view to producing competent pharmacists who can participate in supplementary prescribing thus improving access to medicines both safely and effectively.

**What does the research involve?**

The research involves completion of an anonymous mail questionnaire. The first part of the questionnaire consists of demographic data and the second part seeks opinions on various competencies identified as needed in prescribing.

**How much time will the research take?**

The questionnaire will take about 20 minutes to complete. A reminder will be sent to you 2 weeks after the original questionnaire distribution. A reply-paid envelope will be provided for return of the questionnaire.

**Inconvenience/discomfort**

As this research only involves completion of an anonymous (non-identifiable) questionnaire, it is unlikely that any inconvenience or discomfort will occur.

**Payment**

Involvement in this survey is voluntary and there will be no payment to participate in this study.

**Can I withdraw from the research?**

Because this study is voluntary you are under no obligation to participate. Return of the completed questionnaire will indicate consent to participation. Since the questionnaire is anonymous, it will not be possible to withdraw once the questionnaire has been submitted to the researcher.

**Confidentiality**

All data will be kept securely and in a confidential manner. It is not possible for the investigators to identify the participants due to the anonymous nature of the survey. Involvement of this survey is anonymous and publications based on data collected will at all times maintain the confidentiality and anonymity of individuals.

**Storage of data**

Storage of the data collected will adhere to the University regulations and will be kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

**Use of data for other purposes**

If applicable, the anonymous data may be used for other purposes and, because it is anonymous data, nobody will be named and they will not be identified in any way.

**Results**

**If you would like to be informed of the aggregate research finding, please contact** Dr Jennifer Marriott **on** [redacted] **or email** [redacted]**. The findings are accessible for** 12 months.

| | |
|---|---|
| **If you would like to contact the** researchers **about any aspect of this study, please contact the Chief Investigator:** | **If you have a** complaint **concerning the manner in which this research** <insert your project number here, i.e. 2006/011> **is being conducted, please contact:** |

| | |
|---|---|
| Dr Jennifer Marriott<br>Department of Pharmacy Practice<br>Victorian College of Pharmacy<br>Monash University<br>381 Royal Parade<br>Parkville 3052<br>Tel: [redacted]<br>Fax: [redacted]<br>E-mail:<br>[redacted] | Human Ethics Officer<br>Standing Committee on Ethics in Research Involving Humans (SCERH)<br>Building 3e Room 111<br>Research Office<br>Monash University VIC 3800<br>Tel: +61 3 9905 2052 Fax: +61 3 9905 1420<br><br>Email: scerh@adm.monash.edu.au |

Thank you

[redacted]

Dr. Jennifer Marriott

## Appendix 13: Postcard reminder (prescribing survey)

[redacted]

Dear colleagues,

[redacted]

You may recall a questionnaire entitled "Prescribing Survey" which was sent to you in the last 2 weeks.

[redacted]

If you have already replied to the questionnaire, I would like to thank you for your time. If you have not responded to the questionnaire, I am still very interested in your opinions and would appreciate it if you could fill in and return the questionnaire as soon as possible. If you need a new copy of the questionnaire, please contact Ms Adliah Mhd Ali by telephone ([redacted]) or email [redacted]

[redacted]

May I thank you in anticipation of your co-operation. It is greatly appreciated.

[redacted]

Yours sincerely,

[redacted]

Adliah Mhd Ali B.Pharm.(Hons), M.Pharm (Clin), Rph

[redacted]

## Appendix 14: Prescribing survey (pharmacists)

# Prescribing Survey for Pharmacists

**HOW TO COMPLETE THIS QUESTIONNAIRE**

The questionnaire contains **5** pages and will take approximately **20** minutes

Please indicate your answers by COMPLETELY FILLING a response of your chosen answers.
Make heavy marks that fill the circle. Do NOT use highlighters.
Be sure to answer each statement by filling in only one response.

Please fill the circles completely as illustrated ● O O O O

**Your completed questionnaire should be returned to the researcher in the enclosed reply-paid envelope.**

## Part 1: Demographic Information

**Please fill in the details or indicate ● for the most appropriate response**

| | | |
|---|---|---|
| **1) Gender** | O Male | O Female |
| **2) Age** | _____ years | |
| **3) Current location of practice** | O Capital city<br>O Large regional centre<br>O Rural/ remote<br>O Other please specify _____ | |
| **4) Area of practice** | O **HOSPITAL *ONLY***: answer **4A**<br>O **COMMUNITY *ONLY***: answer **4B**<br>O **BOTH** : answer **4A and 4B**<br>O Other please specify _____ | |
| | **A) HOSPITAL**<br>○ Grade 1<br>○ Grade 2<br>○ Grade 3<br>○ Grade 4<br>○ Other please specify _____ | **B) COMMUNITY**<br>○ Retail pharmacist<br>○ Consultant pharmacist<br>○ Other please specify _____ |
| **5) Basic pharmacy qualification** | A) Country of graduation (Bachelor of Pharmacy or equivalent)<br>○ Australia<br>○ Overseas, please indicate country _____ | B) Number of years since initial registration<br>_____ years |
| **6) Do you have ADDITIONAL pharmacy related qualifications?** | ○ **NO** | ○ **YES**<br>Qualification 1:<br>a) Your qualification _____<br>b) Number of years of graduation _____years<br>c) Country of graduation<br>○ Australia<br>○ Overseas please indicate country _____<br>Qualification 2:<br>a) Your qualification_____<br>b) Number of years of graduation _____years<br>c) Country of graduation<br>○ Australia<br>Overseas please indicate country _____ |
| **7) Duration of practise within the Australian Health Care System** | _____ years | |

## Part 2: Prescribing Survey

Each statement indicates an aspect of competency needed for prescribing in a range of areas. ***If you were allowed to prescribe* 'Prescription Only' medications** within your area of practice in partnership with an independent prescriber (doctor or dentist), ***please indicate your current level of knowledge and skill*** in each area. In this prescribing partnership, the medical practitioner makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing for ongoing care within agreed parameters, to the pharmacist prescriber. Please select only **ONE** rating for each statement.

**A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree**

| SECTION A | | | | | |
|---|---|---|---|---|---|
| **In order to prescribe effectively, I CURRENTLY have the appropriate level of knowledge and skills to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **confirm availability of medicines by** | | | | | |
| *1) establishing any special circumstances or supplying arrangements impacting on availability of the prescribed medicine.* | O | O | O | O | O |
| *2) confirming that suitable products are held in stock or available from a supplier.* | O | O | O | O | O |
| *3) ensuring that patients can access ongoing supplies of their medication.* | O | O | O | O | O |
| *4) understanding how medicines are licensed, sourced, supplied and monitored.* | O | O | O | O | O |
| **update knowledge by** | | | | | |
| *5) maintaining an up-to-date knowledge of relevant products.* | O | O | O | O | O |
| **prescribe in an appropriate manner by** | | | | | |
| *6) understanding cost concerns relevant to prescribing.* | O | O | O | O | O |
| **Comments concerning section A** | | | | | |

| SECTION B | | | | | |
|---|---|---|---|---|---|
| **In order to prescribe to an acceptable standard, I CURRENTLY have the appropriate level of knowledge and skills to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **review patient clinical problems by** | | | | | |
| *1) understanding the conditions being treated, their natural progress and how to assess their severity.* | O | O | O | O | O |
| *2) identifying the nature, severity and significance of the clinical problem.* | O | O | O | O | O |
| **review therapy options by** | | | | | |
| *3) understanding the pharmacological and/non-pharmacological approaches to modifying conditions.* | O | O | O | O | O |
| *4) understanding the mechanism of action and pharmacokinetics of medicines and how these mechanisms may be altered.* | O | O | O | O | O |
| *5) identifying clinically significant potential or actual drug related problems in the current medication treatment.* | O | O | O | O | O |
| *6) requesting common laboratory tests and investigations performed on individual patients.* | O | O | O | O | O |
| *7) interpreting relevant investigations and evaluating the significance of common laboratory tests and investigations performed on individual patients.* | O | O | O | O | O |
| *8) considering no treatment, non-drug and drug treatment options (including referral and preventive measures).* | O | O | O | O | O |
| *9) assessing the effect of multiple pathologies, existing medication and contraindications on treatment options.* | O | O | O | O | O |
| *10) assessing the risks and benefits to the patient of taking/ not taking a medicine (or using/ not using a treatment).* | O | O | O | O | O |
| *11) applying the principles of evidence-based medicine.* | O | O | O | O | O |
| *12) applying the principles of clinical cost effectiveness.* | O | O | O | O | O |
| **select treatment by** | | | | | |
| *13) selecting the most appropriate drug, dose and formulation for the individual patient and prescribe appropriate quantities.* | O | O | O | O | O |
| *14) establishing and maintaining a plan for reviewing the therapeutic objective or end point of treatment.* | O | O | O | O | O |
| *15) monitoring effectiveness of treatment and potential unwanted effects and assess whether medication treatment is achieving therapeutic goals/ outcomes.* | O | O | O | O | O |
| *16) making changes within the clinical management plan in light of ongoing monitoring and the patient's condition and preferences.* | O | O | O | O | O |
| **Comments concerning section B** | | | | | |

| SECTION C | | | | | |
|---|---|---|---|---|---|
| **In order to prescribe safely, I CURRENTLY have the appropriate level of knowledge and skills to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **review the prescribing process by** | | | | | |
| *1) knowing the limits of my own knowledge and skill to prescribe safely.* | O | O | O | O | O |
| *2) knowing when and how to refer to, or seek guidance from, the independent prescriber, another member of the team or a specialist.* | O | O | O | O | O |
| *3) prescribing a medicine using adequate, up-to-date knowledge.* | O | O | O | O | O |
| *4) deciding on the appropriateness of the dose, dose form, dosing regimen, route of administration and duration of treatment of the prescribed medicine.* | O | O | O | O | O |
| *5) checking doses and calculations to ensure accuracy and safety.* | O | O | O | O | O |
| *6) making accurate, clear and timely records.* | O | O | O | O | O |
| **update patient information by** | | | | | |
| *7) taking a comprehensive history.* | O | O | O | O | O |
| *8) assessing and interpreting all relevant patient records to ensure knowledge of the patient's management.* | O | O | O | O | O |
| **apply safety issues in prescribing by** | | | | | |
| *9) keeping up to date with advances in practice and emerging safety concerns.* | O | O | O | O | O |
| *10) establishing systems for responding when an error occurs during prescribing.* | O | O | O | O | O |
| *11) establishing systems for reporting and responding to medication errors.* | O | O | O | O | O |
| *12) generating legible, clear and complete prescriptions, which meet legal requirements.* | O | O | O | O | O |
| *13) using documentation and systems that support prescription validation.* | O | O | O | O | O |
| **apply knowledge and skills to prescribe in an appropriate manner by** | | | | | |
| *14) making prescribing decisions with confidence and competence.* | O | O | O | O | O |
| **assess progress of the clinical condition by** | | | | | |
| *15) understanding disease state management principles.* | O | O | O | O | O |
| *16) understanding the conditions being treated, their natural progress and how to assess their severity.* | O | O | O | O | O |
| *17) performing clinical assessment for various clinical conditions in appropriate areas.* | O | O | O | O | O |
| *18) using appropriate techniques and equipment.* | O | O | O | O | O |
| **Comments concerning section C** | | | | | |

| SECTION D | | | | | |
|---|---|---|---|---|---|
| **In order to prescribe professionally, I CURRENTLY have the knowledge and skills to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **work within professional, regulatory and organisational standards by** | | | | | |
| *1) accepting responsibility for my own prescribing.* | O | O | O | O | O |
| *2) making prescribing decisions based on patient-related factors.* | O | O | O | O | O |
| *3) prescribing to an acceptable standard.* | O | O | O | O | O |
| **work in partnership towards benefit of patients by** | | | | | |
| *4) being able to negotiate with members of the prescribing team.* | O | O | O | O | O |
| *5) ensuring that the patient has agreed to be managed within a prescribing partnership.* | O | O | O | O | O |
| *6) understanding the cultural and religious implications of the diagnosis/ prescribing.* | O | O | O | O | O |
| **behave in a professional and ethical manner by** | | | | | |
| *7) understanding how current legislation affects prescribing practice.* | O | O | O | O | O |
| *8) understanding the scope of my own prescribing responsibility.* | O | O | O | O | O |
| *9) maintaining patient confidentiality.* | O | O | O | O | O |
| *10) maintaining security of prescribing stationery or computer security systems.* | O | O | O | O | O |
| *11) maintaining the security and confidentiality of data being transferred.* | O | O | O | O | O |
| *12) recognising and dealing with pressures that might result in inappropriate prescribing.* | O | O | O | O | O |
| *13) take responsibility for my own continuing professional development in relation to prescribing* | O | O | O | O | O |
| **Comments concerning section D** | | | | | |

| SECTION E | | | | | |
|---|---|---|---|---|---|
| **In order to participate in the development of prescribing practice, I CURRENTLY have the appropriate level of knowledge and skills to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **participate in the review of prescribing practice by** | | | | | |
| *1) learning and changing through reflecting on my own practice.* | O | O | O | O | O |
| *2) sharing my own prescribing practice.* | O | O | O | O | O |
| *3) sharing and debating others' prescribing practice.* | O | O | O | O | O |
| *4) challenging inappropriate practice constructively.* | O | O | O | O | O |
| **use own networks by** | | | | | |
| *5) developing networks for mutual support, reflection and learning.* | O | O | O | O | O |
| *6) establishing multi professional links with practitioners working in the same practice area.* | O | O | O | O | O |
| **use tools to improve practice by** | | | | | |
| *7) understanding and knowing the types of dissemination tools/strategies that can be used to share information or review findings and recommendations for change.* | O | O | O | O | O |
| **report prescribing errors by** | | | | | |
| *8) reporting prescribing errors and near misses that I am aware of.* | O | O | O | O | O |
| *9) reviewing my practice to prevent error recurrences.* | O | O | O | O | O |
| **Comments concerning section E** | | | | | |

| SECTION F | | | | | |
|---|---|---|---|---|---|
| **In order to communicate effectively, I CURRENTLY have the appropriate level of knowledge and skills to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **understand and respect the uniqueness of individuals by** | | | | | |
| *1) understanding patients' beliefs, ideas, concerns and expectations.* | O | O | O | O | O |
| *2) understanding the cultural and religious implications of the diagnosis/ prescribing.* | O | O | O | O | O |
| **undertake the consultation in an appropriate manner by** | | | | | |
| *3) undertaking it in an appropriate setting and adapting it to meet the needs of different patients.* | O | O | O | O | O |
| *4) dealing sensitively with patients' emotions and concerns.* | O | O | O | O | O |
| *5) explaining the nature of the patient's condition, the rationale behind and potential risks and benefits of management options.* | O | O | O | O | O |
| *6) enabling patients to make informed choices about their management.* | O | O | O | O | O |
| **negotiate an outcome** | | | | | |
| *7) through consultation that both patient and prescriber are satisfied with.* | O | O | O | O | O |
| **give clear instructions about the medication by** | | | | | |
| *8) encouraging patients to take responsibility for their own health and self manage their conditions.* | O | O | O | O | O |
| *9) assisting patients' understanding of their medical condition and/or medication treatment.* | O | O | O | O | O |
| **follow up by** | | | | | |
| *10) checking the patients' understanding and commitment to their current and ongoing management.* | O | O | O | O | O |
| **Comments concerning section F** | | | | | |

| SECTION G | | | | | |
|---|---|---|---|---|---|
| **In order to provide medicines and health information and education, I CURRENTLY have the appropriate level of knowledge and skills to** | | | | | |
| **A= Strongly agree B= Agree C= Neither agree nor disagree D= Disagree E= Strongly disagree** | **A** | **B** | **C** | **D** | **E** |
| **understand the readily available information sources by** | | | | | |
| *1) recognizing the availability of information sources that can provide relevant information.* | O | O | O | O | O |
| *2) understanding the advantages and limitations of various information sources.* | O | O | O | O | O |
| **use relevant, up to date information by** | | | | | |
| *3) formulating recommendations for changes to medication treatment based on the latest evidence and information on new medicines.* | O | O | O | O | O |
| **critically appraise the validity of information sources by** | | | | | |
| *4) critically evaluating research findings.* | O | O | O | O | O |
| *5) using primary and secondary information sources to critically evaluate the efficacy and safety of medicines.* | O | O | O | O | O |
| *6) critically evaluating the reliability and accuracy of new information in primary information sources.* | O | O | O | O | O |
| *7) calculating and manipulating clinical data and associated costs accurately.* | O | O | O | O | O |
| **apply information in the clinical context by** | | | | | |
| *8) using information sources, sharing research findings with colleagues and facility personnel whose care processes may be affected.* | O | O | O | O | O |
| **review evidence by** | | | | | |
| *9) using relevant patient record systems, prescribing and information systems, and decision support tools.* | O | O | O | O | O |
| *10) working collaboratively with clinicians to prepare or revise medication treatment protocols, guidelines, criteria and/or standards.* | O | O | O | O | O |
| **Comments concerning section G** | | | | | |

**Part 3: Other comments**

***Please check that you have answered all the questions.***

***Thank you for your time.***

**Appendix 15: Explanatory statement (pharmacists survey)**

MONASH University

**Explanatory Statement**

**Prescribing Survey**

**This information sheet is for you to keep.**

**My name is** Adliah Mhd Ali **and I am conducting a research project with** Dr Jennifer Marriott **and** Associate Professor Kay Stewart **in the Department of** Pharmacy Practice **towards a** Doctor of Philosophy **at Monash University. This means that I will be writing** a thesis which is the equivalent of a 300 page book.

**Why did you choose this particular person/group as participants?**

The purpose of this survey is to identify the education needs of pharmacists for a potential role in prescribing, therefore pharmacists from community and hospital backgrounds are invited to participate. A sample of pharmacists has been selected by systematic random sampling from the publicly available Pharmacy Board of Victoria register of pharmacists.

**The aim/purpose of the research**

Supplementary prescribing was introduced in the United Kingdom in 2004 with the intention of improving health services and patient care by making it easier for patients to get the medicines they need through best use of the skills of health professionals. Pharmacist prescribers contribute to this aim by monitoring patients with long-term conditions and prescribing medicines that are appropriate for the patient's condition. In a supplementary prescribing partnership, the medical practitioner makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing for ongoing care within agreed parameters, to the pharmacist prescriber.

In Australia, pharmacy practice models have been proposed to improve access to prescription medicines in a range of settings. The introduction of these models may lead to the extension of supplementary prescribing rights to Australian pharmacists in the future, with doctors remaining as the main independent prescribers.

Following the implementation of pharmacist prescribing in the United Kingdom, it became apparent that there were inconsistencies regarding competency assessment both before and after qualification as a supplementary prescriber. Therefore a set of competencies have

been developed for Australia to ensure pharmacists have the appropriate knowledge, skills and attitudes to undertake this role.

The aim of this study is to evaluate pharmacists' perceptions of the competencies needed for prescribing, with a view to identifying their educational needs to undertake this role.

**Possible benefits**

The long-term benefit of this work is that, by identifying the educational needs for pharmacists to undertake a role in prescribing, courses can be developed to address these needs with a view to producing competent pharmacists who can participate in supplementary prescribing thus improving access to medicines both safely and effectively.

**What does the research involve?**

The research involves completion of an anonymous mail questionnaire. The first part of the questionnaire consists of demographic data and the second part seeks opinions on various competencies identified as needed in prescribing.

**How much time will the research take?**

The questionnaire will take about 20 minutes to complete. A reminder will be sent to you 2 weeks after the original questionnaire distribution. A reply-paid envelope will be provided for return of the questionnaire.

**Inconvenience/discomfort**

As this research only involves completion of an anonymous (non-identifiable) questionnaire, it is unlikely that any inconvenience or discomfort will occur.

**Payment**

Involvement in this survey is voluntary and there will be no payment to participate in this study.

**Can I withdraw from the research?**

Because this study is voluntary you are under no obligation to participate. Return of the completed questionnaire will indicate consent to participation. Since the questionnaire is anonymous, it will not be possible to withdraw once the questionnaire has been submitted to the researcher.

**Confidentiality**

All data will be kept securely and in a confidential manner. It is not possible for the investigators to identify the participants due to the anonymous nature of the survey. Publications based on data collected will at all times maintain the confidentiality and anonymity of individuals.

**Storage of data**

Storage of the data collected will adhere to the University regulations and will be kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

**Use of data for other purposes**

If applicable, the anonymous data may be used for other purposes and, because it is anonymous data, nobody will be named and they will not be identified in any way.

**Results**

**If you would like to be informed of the aggregate research finding, please contact** Dr Jennifer Marriott **on** [redacted] **or email** [redacted] **. The findings will be accessible for *12 months.***

| **If you would like to contact the** researchers **about any aspect of this study, please contact the Chief Investigator:** | **If you have a** complaint **concerning the manner in which this research is being conducted, please contact:** |
|---|---|
| **Dr Jennifer Marriott**<br>**Department of Pharmacy Practice**<br>**Victorian College of Pharmacy**<br>**Monash University**<br>**381 Royal Parade**<br>**Parkville 3052**<br>**Tel:** [redacted]<br>**Fax:** [redacted] | **Human Ethics Officer**<br>**Standing Committee on Ethics in Research Involving Humans (SCERH)**<br>**Building 3e Room 111**<br>**Research Office**<br>**Monash University VIC 3800**<br>**Tel: +61 3 9905 2052**<br>**Fax: +61 3 9905 1420** |

| | |
|---|---|
| E-mail: [redacted] | Email: scerh@adm.monash.edu.au |

Thank you.

[redacted]
Dr. Jennifer Marriott

## Appendix 16: Ethical approval (evaluation of doctors' and pharmacists' approach to patient management)

MONASH University

**Standing Committee on Ethics in Research Involving Humans (SCERH)**
Research Office

**Human Ethics Certificate of Approval**

| | |
|---|---|
| **Date** | **23-October-2007** |
| **Project Number** | **CF07/4097 - 2007001876** |
| **Project Title** | **Evaluation of doctors' and pharmacists' approach to patient management** |
| **Chief Investigator** | **Ms Jennifer Marriott** |
| **Approved** | **From: 23-October-2007 To: 23-October-2012** |

**Terms of approval**

1. Approval is only valid whilst you hold a position at Monash University.
2. It is the responsibility of the Chief Investigator to ensure that all pending information (such as permission letters from organisations) is forwarded to SCERH. Research cannot begin at an organisation until SCERH receives a permission letter from that organisation.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by SCERH.
4. You should notify SCERH immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project:** Requires the submission of a Request for Amendment form to SCERH and must not begin without written approval from SCERH. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. SCERH should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by SCERH at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Dr Souheir Houssami
Executive Officer, Human Research Ethics (on behalf of SCERH)

Cc: Assoc Prof Kay Stewart; Miss Adliah Mhd Ali

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +61 3 9905 5490 Facsimile +61 3 9905 1420
Email scerh@adm.monash.edu.au www.monash.edu/research/ethics/human/index/html
ABN 12 377 614 012 CRICOS Provider #00008C

**Appendix 17: Invitation to participate (evaluation of doctors' and pharmacists' approach to patient management)**

**You are invited to participate in an interview to discuss on doctors' and pharmacists' approaches to patient management**

**Purpose of the project**

Evaluate doctors' and pharmacists' approaches to patient management and to explore the differences between them for future development of the extended role of pharmacists.

**What is involved?**

Case studies reflecting the common scenarios in real practice will be discussed during the interview. The interview will take less than an hour; time and venue can be arranged as per your convenience.

**Participation needed from:**

Doctors and pharmacists

**Have any queries? Interesting in participating?**

**Please contact *Adliah Mhd Ali***

**Telephone:** [redacted]

**Fascimile:** [redacted]

**Mobile:** [redacted]

**E-mail:** [redacted]

We value your thoughts and opinions and hence would like to hear from you.

This project is contributing towards a Doctor of Philosophy degree. Your participation is greatly appreciated.

**From:**

**The Project Team**


| | |
|---|---|
| Dr. Jennifer Marriott | Victorian College of Pharmacy, Monash University |
| Associate Professor Kay Stewart | Victorian College of Pharmacy, Monash University |
| Adliah Mhd Ali | Victorian College of Pharmacy, Monash University |

**Appendix 18: Explanatory statement (evaluation of doctors' and pharmacists' approach to patient management)**

MONASH University

**Explanatory Statement**

**Title: Evaluation of doctors' and pharmacists' approach to patient management**

This information sheet is for you to keep.

My name is **Adliah Mhd Ali** and I am conducting a research project with **Dr. Jennifer Marriott** and **Associate Professor Kay Stewart** towards a **Doctor of Philosophy** at Monash University in the Department of **Pharmacy Practice**. This means that I will be writing **a thesis which is the equivalent of a 300 page book.**

**Why did you choose this particular person/group as participants?**

Doctors consisting of consultants, registrars, medical officers, general practitioners and pharmacists from community and hospital backgrounds are invited to participate in a semi-structured interview. Case studies have been adapted and developed by the researcher to evaluate doctors' and pharmacists' approach to patient management. The interview will be conducted among these groups of professionals to validate the clinical cases based on the current situation in Australia. The cases will be used for the next phase of the project to evaluate the difference in terms of doctors' and pharmacists' approach in patient management.

**The aim/purpose of the research**

Supplementary prescribing was introduced in the United Kingdom in 2004 with the intention of improving health services and patient care by making it easier for patients to get the medicines they need through best use of the skills of health professionals. Pharmacist prescribers contribute to this aim by monitoring patients with long-term conditions and prescribing medicines that are appropriate for the patient's condition. In a supplementary prescribing partnership, the medical practitioner makes the diagnosis and directs the overall management of the patient but delegates aspects of management, such as prescribing for ongoing care within agreed parameters, to the pharmacist prescriber.

Following the implementation of pharmacist prescribing in the United Kingdom, it became apparent that there were inconsistencies regarding competency assessment both before and after qualification as a supplementary prescriber. This key issue is highlighted in the report by The Royal Pharmaceutical Society of Great Britain. Literature reviews have also indicated that pharmacists feel that they are not competent in certain areas, particularly those related to clinical assessment and monitoring. Perhaps particularly because things are moving quickly in UK, there are some concerns with the competencies, assessment and educational programmes they have developed.

In Australia, pharmacy practice models have been developed to improve access to prescription medicines. The introduction of the proposed models may lead to the extension of supplementary prescribing rights to pharmacists, with doctors acting as the main independent prescribers. Access to medical care is more critical in the UK, which is why they investigated widening prescribing rights. However there have been concerns that with the limited number of doctors and the increasing ageing population, there are indications that access might be the problem in the future in Australia. At the moment, there are no plans or processes in place to introduce supplementary prescribing in Australia, but the fact that this is happening overseas in the UK, USA and Canada is an indication that it might happen in Australia in the future. If supplementary prescribing were to be introduced in Australia, it needs to be done in a more consultative way to make it work for the benefit of all with consideration of safety issues. When prescribing was introduced overseas this work was not done beforehand. It is therefore imperative that consideration is given to developing appropriate competency standards, policies and procedures and associated standards and education. Therefore various competencies have been identified from the literature and supplementary prescribing courses conducted overseas.

Therefore the purpose of the interview is to explore doctors' and pharmacists' perspective in patient management. Discussion with case studies which reflect the daily case scenarios will be used to identify competencies needed for advanced pharmacists' role in managing patient with acute and long term chronic conditions. The discussion will be based without the inclusion of the current constraints such as the PBS and the other legal implication.

**Possible benefits**

The purpose of the interview is to discuss, refine and validate whether the scenarios reflect daily practice. The results of this study will be used for the development of the next phase of this project to evaluate doctors' and pharmacists' approach to patient management. Once the data analysis is complete, we will inform you of the study findings.

**What does the research involve?**

Should you volunteer and contact the researcher from the information provided in the advertisement, you will be involved in a semi-structured interview. Before you begin with

the interview, a consent form will be given to you by the researcher. You need to read and agree to participate in this study. The interview will be audio-taped to ensure that no information is missed. If you want a specific section of the interview not to be audio taped or if you do not wish to answer any particular questions, feel free to inform the researcher. At the end of the session you need to fill in the information on your background practice.

**How much time will the research take?**

The interview will be less than 60 minutes duration. It will be conducted at a place and time convenient for you during or after working hour at your working environment during day time.

**Inconvenience/discomfort**

It is always possible that participants in a sample as small as this may be able to identified, but the research methodology has been designed to ensure that the risk of this is minimal. Use of codes or pseudonyms as opposed to real names during the recording of information will ensure protection of confidential information. The only perceived risk is associated with ensuring confidentiality, however, the investigators will adopt procedures to ensure complete confidentiality at all times, subject to legal limitations.

**Payment**

A small token will be given to your time. The gift will be given to you after the completion of the interview.

**Can I withdraw from the research?**

Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may only withdraw prior to the running of the interview.

**Confidentiality**

All data will be kept securely and in a confidential manner. It is always possible that participants in a sample as small as this may be able to identified, but the research methodology has been designed to ensure that the risk of this is minimal. Use of codes or pseudonyms as opposed to real names during the recording of information will ensure protection of confidential information. Other details considered non-essential to the data

collection may also be altered in order to preserve the anonymity of the participants. Once collected, data will be de-identified. A copy of transcripts of the interview (where applicable) will be provided to you for verification.

**Storage of data**

Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

**Use of data for other purposes**

In certain situation the anonymous data may be used for other purposes and nobody will be named and they will not be identified in any way.

**Results**

If you would like to be informed of the aggregate research finding, please contact **Dr. Jennifer Marriott** on [redacted] or email [redacted].The findings are accessible for **12 months**.

| If you would like to contact the **researchers** about any aspect of this study, please contact the Chief Investigator: | If you have a **complaint** concerning the manner in which this research is being conducted, please contact: |
|---|---|
| Dr Jennifer Marriott<br>Department of Pharmacy Practice<br>Victorian College of Pharmacy<br>Monash University<br>381 Royal Parade<br>Parkville 3052<br>Tel: [redacted]<br>Fax: [redacted]<br>E-mail:<br>[redacted] | Human Ethics Officer<br>Standing Committee on Ethics in Research Involving Humans (SCERH)<br>Building 3e Room 111<br>Research Office<br>Monash University VIC 3800<br><br>Tel: +61 3 9905 2052 Fax: +61 3 9905 1420 Email: scerh@adm.monash.edu.au |

Thank you.

**Dr. Jennifer Marriott**

**Appendix 19: Consent form (evaluation of doctors' and pharmacists' approach to patient management)**

**Consent Form**

**Title: Evaluation of doctors' and pharmacists' approach to patient management**

**NOTE: This consent form will remain with the Monash University researcher for their records**

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep a copy for my records. I understand that agreeing to take part means that I am willing to:

**allow the interview to be audio-taped and/or video-taped** ☐ Yes ☐ No

**and**

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

**and**

I understand that any data that the researcher extracts from the interview for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

**and**

I understand and agree that the results of the interview will be used for the development of future research by the researcher

**and**

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

**and**

I understand that data from the interview will be kept in a secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

**Participant's name:**

**Signature:**

**Date:**

**Researcher's name:**

**Signature:**

**Date:**