Undergraduate Vaccination Training Program for Pharmacy Students: Development and Validation

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A thesis submitted for the degree of

Doctor of Philosophy

Faculty of Engineering, Health, Science and the Environment

Charles Darwin University

2015
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Thesis Declaration

I hereby declare that the work herein, now submitted as a thesis for the degree of Doctor of Philosophy at Charles Darwin University, is the result of my own investigations, and all references to ideas and work embodied in this thesis has not already been accepted in substance for any degree, and is not being currently submitted in candidature for any other degree. This thesis is presented in the format of a series of journal papers which have been, or are in the process of being published. All work was completed during the period of doctoral degree candidature, between March 2011 and June 2015. All research was performed and coordinated by the candidate.

Mary-Jessimine Ann Bushell
Acknowledgements

This thesis is the culmination of many years of work and invariably, many people have provided me with support to enable its completion.

I would first like to thank my principle supervisor Professor Patrick Ball. Patrick has provided me with quality editorial feedback on drafts in a timely manner. I believe, Patrick exemplifies cultural appropriateness and much of what he has taught me in this area during my candidature will be carried throughout my career.

Thank you also to my Associate Supervisor, Dr Hana Morrissey whose drive, initiative and persistence assisted to open many doors that may have remained closed without her support. I would like to make a special acknowledgment and thank you to Patrick and Hana for supporting me on both of my trips to Sri Lanka to deliver the vaccination training program.

To my friend, colleague and Associate Supervisor Dr Kwang Choon Yee, thank you for your patience, assistance and expertise with all things related to formatting and statistics.

To librarians, Bernadette Royal and Jayshree Mamtora for assisting me endnote queries and how to locate, find and retrieve all sources of literature. Your support over the last five years has been amazing.
To Lynette Lowe, you are pleasure to work alongside and I thank you most sincerely for your technical support, ensuring that all equipment is ordered, organised and cleaned up after each training session.

To Dan Hartney and Erin Lawson for the development of the multimedia content to support student learning and Kate Freestone for the generation of high quality photographs and images used in the workbooks and PowerPoint presentations.

Further, I wish to thank and acknowledge Dr. M. Rodrigo and Dr Praboda for assessing students in Sri Lanka, your support and donation of time are greatly appreciated.

To the nurses Nicole Norman, Kobi Schultz and Meagan Gaskett for your assistance in the development of the training program by providing me with real life techniques, tips and pointers about administering vaccinations. For laughing with me not at me as I learn a new skill, that is the skill of injection. I wish to specifically acknowledge the continued assistance of Nicole Norman throughout the project and her donation of time to assess Australian students on the skills of injections.

Thanks to my American collaborators, Dr Wesley Nuffer and Dr Samuel Ellis for the collation of American data and assisting me on my travels in the US. Thank you also to Dr Eisha Waidyarathne and Mr Shukry Zawahir for local support in Sri Lanka.

Thank you to my best friend and husband Byron Bushell, for recognizing this journey as something I need to achieve and providing me with the continued support
to do so. Thank you to my two beautiful children, Billy and Sophie both born during my candidature, who were read pharmacy literature in the womb instead of Dr. Seuss and who have endured long hours in day care and weeks without mum while I travel abroad to collect data and present findings.
Abstract

In Australia, pharmacists have traditionally been involved with vaccine education, advocacy and distribution. An emerging role for pharmacists in Australia is the administration of vaccines. Consequently it is appropriate that undergraduate curricula evolve simultaneously to ensure graduate preparedness.

A comprehensive vaccination training program was designed and developed by the author after detailed study and mapping of existing programs in Australia and overseas. The intended program was then validated through the use of four focus groups, which were conducted by the author in three countries (Australia, The United States of America and Sri Lanka) to verify the appropriateness and reliability of the developed program. The program, featuring nested injection skills training was piloted in 2015. It was delivered to pharmacy students in Australia and Sri Lanka and competency was assessed by established vaccinators, using validated Objective Structured Clinical Assessments (OSCA). Student knowledge of theory was assessed utilizing multiple choice questionnaires. For comparison, pharmacy students in the United States of America completing their established program undertook identical assessment. The applied content of the vaccination training program was delivered to fourth year students and first year students enabling comparison of understanding.

The developed program allowed Australian students to demonstrate comparable skill competency and appropriate knowledge, to that of the USA students completing an established injection skill and vaccination training program. There is a perceived value in early introduction of injection skills training.
The developed training program validated by established vaccinators and academics nationally and internationally, may be adopted by pharmacy schools in Australia and overseas.
Publications contributing to this thesis


Bushell M-JA, Morrissey H, Nuffer W, Ellis S, Ball PA. Development and design of a vaccination training program with nested injection skills training targeted for Australian pharmacy students. *Currents in Pharmacy Teaching and Learning* 2015;7(6) (*in press*).


Publications completed during candidature- but not included in this thesis


Contribution

This thesis by publication consists of nine chapters, of which six are substantively reprints of published and peer-reviewed articles authored by the candidate.

Unpublished, original work comprises the entirety of Chapter One (the Introduction to the study) and the Conclusions chapter.

New and original work is also interspersed between article-based chapters, primarily but not exclusively within the prefaces of each; these prefaces explain to the reader the purpose of incorporating individual papers, or parts thereof, and to link successive chapters and their themes.

My supervisors Professor Patrick Ball, Dr Hana Morrissey, Dr Kwang Choon Yee, Dr Eisha Waidyarathne provided supervision feedback, editing and their contribution is recognized in co-authorship as is the help, facilitation and assistance provided in the United States of America and Sri Lanka by Dr Wesley Nuffer, Dr Samuel Ellis and Mr Shukry Zawahir.

The explicit nature of co-author contributions to the incorporated articles are detailed prior to each publication in this thesis.
Statement of ethical clearances

The research presented and reported in this thesis was conducted within the guidelines for research ethics.

Ethical clearances were obtained for qualitative and quantitative research presented in this thesis by formal application to the Charles Darwin University Human Research Ethics Committee (HREC) using the National Ethics Application Form (H14067).

In addition ethics approval for the project was obtained from the University of Ruhuna Sri Lanka Ethics Committee (3.13).
### Terms and Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>APPE</td>
<td>advanced pharmacy practice experiences</td>
</tr>
<tr>
<td>ASCIA</td>
<td>Australasian Society of Clinical Immunology and Allergy</td>
</tr>
<tr>
<td>AED</td>
<td>automated external defibrillator</td>
</tr>
<tr>
<td>AEFI</td>
<td>adverse event following immunisation</td>
</tr>
<tr>
<td>AMA</td>
<td>Australian Medical Association</td>
</tr>
<tr>
<td>A.C.T.</td>
<td>Australian Capital Territory</td>
</tr>
<tr>
<td>APC</td>
<td>Australian Pharmacy Council</td>
</tr>
<tr>
<td>APNA</td>
<td>Australian Practice Nurses Association</td>
</tr>
<tr>
<td>AHW</td>
<td>aboriginal health workers</td>
</tr>
<tr>
<td>CPR</td>
<td>Cardiopulmonary Resuscitation</td>
</tr>
<tr>
<td>CRS</td>
<td>congenital rubella syndrome</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>Hib</td>
<td><em>Haemophilus influenza</em> type B</td>
</tr>
<tr>
<td>IgE</td>
<td>immunoglobulin E</td>
</tr>
<tr>
<td>IPPE</td>
<td>introductory pharmacy practice experience</td>
</tr>
<tr>
<td>ISTP</td>
<td>injection skills training program</td>
</tr>
<tr>
<td>LMS</td>
<td>Learning Management System</td>
</tr>
<tr>
<td>LO</td>
<td>Learning outcome</td>
</tr>
<tr>
<td>MIMS</td>
<td>Monthly Index of Medical Specialities</td>
</tr>
<tr>
<td>MMR</td>
<td>measles-mumps-rubella</td>
</tr>
<tr>
<td>NIP</td>
<td>National Immunisation Program</td>
</tr>
<tr>
<td>NMP</td>
<td>National Medicines Policy</td>
</tr>
<tr>
<td>N.S.W</td>
<td>New South Wales</td>
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</table>
N.T  Northern Territory
PAV  pharmacist administered vaccination
PSA  Pharmaceutical Society of Australia
PGA  Pharmacy Guild of Australia
QPIP  Queensland Pharmacist Immunisation Pilot
TGA  Therapeutic Goods Administration
UK  United Kingdom
U.S.A  United States of America
VPDs  vaccine preventable diseases
VTP  vaccination training program
W.A.  Western Australia
Chapter 1: Introduction

Background to the study

“In 1736 I lost one of my sons, a fine boy of four years old, by the small-pox, taken in the common way. I long regretted bitterly, and still regret that I had not given it to him by inoculation. This I mention for the sake of parents who omit that operation, on the supposition that they should never forgive themselves if a child died under it; my example showing that the regret may be the same either way, and that, therefore, the safer should be chosen.”

— Benjamin Franklin

A vaccine is a biological preparation containing live, attenuated, modified, or killed microorganisms, or tumour antigens, which when administered into the body confers immunity against a specific infectious disease. (1) Immunisation using vaccines is among the greatest public health initiatives, according to one author:

“next to clean water, no single intervention has had so profound an effect on reducing mortality from childhood diseases as the widespread introduction of vaccines” (Institute of Medicine 1991).

Since the introduction of organised vaccination programs, eleven diseases that were once widespread and responsible for causing large-scale morbidity and mortality have been greatly reduced and in the case of smallpox, eradicated globally.

Immunisation data published in July 2014 by The World Health Organisation (WHO) reported worldwide immunisation coverage prevented between two to three
million deaths in 2013, however is it estimated a further 1.5 million deaths could have been prevented by vaccinations (World Health Organization 2014).

Internationally, there is significant experience of pharmacist administered vaccination services and pharmacy immunisation training programs. International experience demonstrates that vaccination rates increase and there are cost benefits when pharmacists can contribute to the provision of immunisations (Prosser 2008).

In Australia, pharmacists have been traditionally involved with vaccine education, advocacy and distribution within governmental departments, research institutions, hospital pharmacy and community pharmacy settings. In December 2013 a case for pharmacist administered vaccinations was published (Bushell, Yee & Ball 2013) and the Pharmacy Board of Australia announced via a communiqué that vaccination is within the current scope of practice for pharmacists in Australia (Pharmacy Board of Australia 2013). Accordingly an emerging role for Australian pharmacists is the administration of vaccines.

**Stakeholders call for integration of vaccination training in undergraduate Australian pharmacy curricula**

The Australian Medical Association (AMA) and the Australian Practice Nurses Association (APNA) have voiced their opposition to the introduction of pharmacist administered vaccinations. The then President of the Australian Medical Association Steve Hambleton stated in January 2013 "*With regard to pharmacist-administered immunisations services ... the AMA would not support any future legislative change to allow pharmacists to administer injections until this was included in pharmacists’ core training — and not just as an adjunct*" (Paul Smith 2013). This voiced concern
prompted much of the work contained in this thesis and the focus on the development and validation of an *undergraduate pharmacy school* vaccination training program and not an adjunct vaccination training program for practicing pharmacists.

**American Undergraduate Vaccination Training Program for Pharmacy Students**

Pharmacists have been administering vaccinations in America since 1994 (Hogue et al. 2006). An increasing number of American pharmacy schools have incorporated vaccination training as part of their curricular requirements (Welch, Olenak & Culhane 2009). By 2009, 38% of colleges and pharmacy schools had incorporated immunisation education and training as part of their core curricula (Bain & Cullison 2009). Statements and viewpoints, published in the American Journal of Pharmaceutical Education since 2009, have called for all pharmacy schools to mandate immunisation education and for universal adoption of an approved and validated undergraduate vaccination training program (Bain & Cullison 2009; Romanelli & Freeman 2012). Such an initiative would ensure all pharmacy graduates have a baseline knowledge and minimal competency in vaccination information and administration upon graduation.

Romanelli and Freeman (2012) state that an increase in pharmacy student numbers with baseline immunisation administration knowledge will improve immunisation uptake and assist the US health care system to achieve quality health indicators as targeted in Healthy People 2020 initiatives. Turner et al. (2007) states there is value in integrating vaccination training for pharmacy students early in the curriculum. The
study by Turner et al. (2007) identified that introducing the skill of injection in second and third year levels, improved students maturity as they were able to recognize from early in the degree they could play an active role in disease mitigation. The study identified demonstration of competency in the skill of injection was comparable between second year students and third year students taught the same material. The USA experience and literature suggest that, as pharmacists commence administering vaccines in Australia, vaccination uptake may improve and contribute to the reduction of vaccine preventable diseases, particularly in pandemic events (Hogue et al. 2006).

**Domestic Undergraduate Vaccination Training Program for Pharmacy Students**

The Australian Pharmacy Council, responsible for accrediting pharmacy schools and programs has voiced approval to integrate injection and vaccination skills into undergraduate curricula in response to the peak professional bodies calling for the inclusion of vaccination assessed competency (Australian Pharmacy Council 2015).

In recognition of recently changed jurisdictional regulations in Australian to allow pharmacist administered vaccinations, there is value in adequately up skilling pharmacy students to deliver such a patient care service (New South Wales Department of Health 2015, Northern Territory Department of Health 2015, Western Australia Department of Health 2015). Such competence will be achieved through the successful completion of an approved national undergraduate pharmacy vaccination training program.
Research Questions

The primary objective of this thesis was to design, develop and author a pharmacy student specific, validated vaccination training program with nested injection skills training and integrate the training program into core curriculum at Charles Darwin University.

This Thesis brings together research carried out between 2011 and 2015. Specifically, it addresses the following research questions:

1. Is it important to have an undergraduate pharmacy specific vaccination training program to produce core knowledge and skill?
2. How should the program be integrated into curriculum to best achieve the appropriate learning outcomes and graduate attributes?
3. Can the training program be adopted and contribute to pharmacist core competencies?
4. How can the vaccination training program be validated and evaluated?

Significance of this research

The developed and validated vaccination training program can be nationally adopted to provide an appropriate integrated learning experience throughout the pharmacy degree years and produce core knowledge for registered pharmacists similar to that gained by aboriginal health, nursing and medical practitioners.
**Rationale for countries chosen**

The USA has an established history of pharmacy administered vaccination. For another comparator country it was desirable to have one where the language of instruction is English, and the pharmacy system fundamentally based on similar principles and legislation to the UK and Australia. A collaborative relationship in pharmacy was already in existence between Charles Darwin University and the University of Ruhuna in Galle, Sri Lanka. Building on this relationship provided a suitable second comparator.

**Outline of thesis**

Chapter two first published in the *Journal of Pharmacy Practice and Research*, in December 2013, provides an evidenced based case for the expansion of pharmacist service delivery to include vaccination administration. The chapter provides an introduction to vaccines, vaccination and immunisation in Australia and details current vaccination uptake and trends. It discusses the then current developments and future role of the pharmacist in pharmacist-administered vaccinations and how the delivery of the professional service is in line with government policy. The chapter looks at international examples, both the success and limitation of service delivery and the impact on vaccination uptake and subsequent improvement of health outcomes. The chapter concludes by discussing the barriers to pharmacist administered vaccinations and highlights the concerns voiced by other health professional organizations.
Chapter three published in the *Journal of Pharmacy Practice and Research*, in May 2015, is a research article discussing how pharmacists should manage vaccine-associated anaphylaxis in the pharmacy. Chapter three was originally written as a learning module, as part of the larger vaccination training program developed by the author with the aim to educate pharmacy students. Mindful that the chapter was originally written to inform and educate, the chapter discusses the definition and features of anaphylaxis, vaccine-associated anaphylaxis, anaphylaxis management including the contents of pharmacy anaphylaxis kits and the development of a written emergency protocol. It also covers appropriate training for pharmacists and pharmacy students in how to report an adverse event following vaccination, the mandatory observation period and how to differentiate anaphylaxis from vasovagal syncope. The chapter further creates an evidence-based argument for how vaccine-associated anaphylaxis should be managed in the pharmacy setting, which differs from that outlined in the Australian Immunization Handbook (Australian Government Department of Health and Ageing 2013).

This chapter, along with chapter two, has been published twice. Both chapter two and chapter three were invited secondary publications in the *Australian Journal of Pharmacy*. Both chapters were used as continuing education pieces to inform practice and educate registered and provisionally registered Australian pharmacists.

Chapter four published in February 2015 in *Pharmacy Education*, is a short communication which outlines the development, validation and evaluation of the Australian, pharmacy student specific, vaccination training program to be integrated within undergraduate pharmacy training, as identified modules with assessed
competency. The chapter articulates how the training program was developed with consideration of the learner context, teaching context, subject matter and strategic approach.

Chapter five articulates the robust systematic approach that was employed to develop the Australian undergraduate vaccination training program with nested injection skills training. It outlines how a set of learning outcomes, assessable knowledge and assessable skills was developed following a critical review of relevant literature. Further, it introduces how the new teaching and learning concepts are to be integrated and delivered via a spiral curriculum. It discusses how knowledge and skills should progressively improve as students advance through the pharmacy course. It articulates why core injection skills training will be assessed on a number of occasions. The chapter further discusses the rationale behind integrating and embedding modules into the first, third and fourth year of the pharmacy program.

Chapter six, published in April 2015 in *Pharmacy*, provides delineation of how qualitative focus groups which were conducted by the author to validate the entire draft vaccination training program including modes of delivery and assessment and pedagogical strategies prior to the embedding of the training program into pharmacy school curricula. Further this chapter concludes by discussing the success and limitations of using focus group methodology to validate training programs.

Chapter seven, published in February 2015 in *Pharmaceutical Regulatory Affairs*, reports on one of the four focus groups conducted to validate the vaccination training program, specifically the focus group which was conducted in Sri Lanka with six Sri
Lankan medical and pharmacist experts. As the newly developed vaccination training program was to be delivered at the University of Ruhuna in Sri Lanka it was imperative the study identified the cultural appropriateness and wider usability of the training program beyond the Australian health care environment.

Chapter eight discusses the delivery and student evaluation of the newly developed training program in Australia and Sri Lanka. In 2015 the vaccination training program, developed by the author, was delivered to, first, third and fourth year undergraduate pharmacy students in Australia and first and fourth year students in Sri Lanka as a pilot program. Student competency was assessed by established vaccinators (doctors and nurses) using validated Objective Structured Clinical Assessments (OSCA) as used by other professions. This chapter reports on the results of the Objective Structured Clinical Assessments and multiple choice questionnaires designed to assess student knowledge and understanding. Results are compared with American first year pharmacy students completing a proven vaccination and injection skills training program. All students underwent identical assessment of competency and knowledge to allow comparison.

Chapter eight further quantifies the outcomes of teaching the applied content of the vaccination training program to students earlier than fourth year. The findings support that validated in the focus groups as outlined in chapter six and seven, that is applied content should not be introduced in the first year of the curriculum.

Chapter nine discusses how the full cycle of implementation will be achieved over a four year period with final evaluation of the entire course and delivery in 2018. It
synthesizes the significant findings from the previous chapters reflecting on the thesis’s contribution to pharmacy practice and proposes a number of potential avenues for further research and recommendations.

As this is a thesis by publication, the spelling used in each individual chapter reflects the usage of the country where the manuscript was submitted and published. For example, the manuscripts published in *Pharmacy Education* use ‘British English’ spelling and terminology while the manuscript submitted to the *Currents in Pharmacy Teaching and Learning* has ‘American English’ and terminology. There are subtle differences in terminology between chapters and publications; for example the term ‘undergraduate student’ is not commonly used in North America, so in American journals ‘pharmacy student’ is adopted as the preferred terminology. The referencing at the conclusion of each chapter is in line with that required by each journal. Further formatting is consistent with that required by each journal and therefore is not uniform throughout the thesis.
Figure 1 (1.1): Overview of PhD Project
Aus = Australia; SL = Sri Lanka; USA = United States of America; IST = Injection Skills Training (nested component of VTP; VTP = Vaccination Training Program)
*Red coloured text = Active control group.
References


Bushell, M-JA, Yee, KC & Ball, PA 2013, 'Case for pharmacist administered vaccinations in Australia', *Journal of Pharmacy Practice and Research*, vol. 43, no. 4, p. 292.


Romanelli, F & Freeman, T 2012, 'Immunization training: right or privilege?', *American journal of pharmaceutical education*, vol. 76, no. 4.


Welch, AC, Olenak, JL & Culhane, N 2009, 'Incorporating an immunization certificate program into the pharmacy curriculum', *American journal of pharmaceutical education*, vol. 73, no. 1.

Chapter 2: A Case for Pharmacist Administered Vaccinations in Australia

Title: A Case for pharmacist administered Vaccinations in Australia

This work has been previously published in- **Bushell M-JA**, Yee KC and Ball PA. Case for pharmacist administered vaccinations in Australia. *Journal of Pharmacy Practice and Research*, 2013;43(4): 292-296.

Statement of contributions of each author:

Bushell, conceptualised and designed the study, performed the literature review and produced and authored the manuscript. Ball and Yee edited and guided the writing of the manuscript.

Consent has been granted by all co-authors for use of this publication in my PhD thesis (Appendix 1).
**Contribution to practice**

One of the most significant achievements in modern medicine is the prevention of disease by the administration of vaccinations. Internationally, there is significant experience of pharmacist delivered vaccination services and pharmacy immunisation training programs. However at the commencement of this thesis by publication in 2011, jurisdictional regulation in every Australian State and Territory prevented pharmacists from administering vaccinations and the scope of practice for pharmacists had not yet been expanded to include vaccine administration. It was therefore innovative and forward thinking to suggest that Australian pharmacists, like pharmacists practicing in America, Portugal, New Zealand, Ireland, Canada and parts of the United Kingdom, would be administering vaccinations as early as 2014. The first publication of this thesis makes an evidence based case for pharmacist administered vaccinations in Australia.
Developments since publication

This publication helped to inform legislation changes nationally and at the time of thesis submission in July 2015, jurisdictional regulations have now been modified to enable appropriately trained and certified competent pharmacists to administer vaccinations in most States and Territories. As anticipated the professional service delivery has, and continues to gain momentum. This thesis by publication has made a substantial contribution to informing pharmacy practice and reads as an evolving document.
Chapter 3: Managing Vaccine Associated Anaphylaxis in the Pharmacy

Chapter 3- Title: Managing vaccine-associated anaphylaxis in the pharmacy

This work has been previously published in- Bushell M-JA, & Ball PA. Managing vaccine-associated anaphylaxis in the pharmacy. Journal of Pharmacy Practice and Research. 2015;45(1):24-30.

Statement of contributions of each author:

Bushell, conceptualised and designed the study, performed the literature review and authored and produced the manuscript. Ball edited and guided the writing of the manuscript.

Consent has been granted by the co-author for use of this publication in my PhD thesis (Appendix 1).
Contribution to practice

At the time of writing, one of the Australian Medical Association's strongest objections to pharmacist-administered vaccination was that pharmacists will not be able to manage life-threatening anaphylaxis. This chapter, first published in the Journal of Pharmacy Practice and then as an invited secondary publication in the Australian Journal of Pharmacy, presents a series of recommendations on how pharmacists can best be prepared for and competently treat anaphylaxis. A media release was published alongside this publication (Appendix 10) and a subsequent radio interview followed discussing the recommendations. It also must be stated that with an incidence of around 1:1,000,000 for all vaccinations, and that, as is the case with all other non-medical vaccinators, pharmacists will refer all patients with a history of vaccine-associated reactions to appropriate facilities. It is a real risk, for which pharmacists must be appropriately prepared but like vaccinators from other professions, most pharmacist-vaccinators will be unlikely ever to see a case in their career.
Chapter 4: Vaccination Training in Australian Undergraduate Pharmacy Curricula

Chapter 4- Title: Vaccination training in Australian undergraduate pharmacy curricula

This work has been previously published in- Bushell M-JA, Morrissey H, Yee KC, Ball PA. Vaccination training in Australian undergraduate pharmacy curricula. *Pharmacy Education*. 2015;15(1):54-6.

Statement of contributions of each author:

Bushell, conceptualised and designed the study and authored and produced the manuscript. Ball and Morrissey edited and guided the writing of the manuscript.

Consent has been granted by all co-authors for use of this publication in my PhD thesis (Appendix 1).
Contribution to practice

This chapter starts and contributes to the national conversation of embedding vaccination training in undergraduate pharmacy curriculum. The paper argues that vaccination training needs to be integrated into curriculum in a considered, systemic, validated and pedagogical framework. The paper starts to answer the call for vaccination and injection skills to be recognised as part of core skills for pharmacists.
Abstract

Context
Recently, legislation has been modified to allow pharmacist administered vaccinations in some Australian jurisdictions. Therefore it is appropriate that pharmacy students are appropriately trained and certified competent to deliver such a service to patients. Such competence will be achieved through the successful completion of an approved and validated undergraduate vaccination training program.

Description
This short description outlines the progress to date on the development of an Australian, pharmacist specific, validated vaccination training program (VTP) to be integrated within undergraduate pharmacy training, as identified modules with assessed competency. The training program has been developed with consideration of the learner context, teaching context, subject matter and strategic approach.

Evaluation
To validate the developed undergraduate vaccination training program, four focus groups for consultation are in progress.

Future plans and implementation
The developed validated undergraduate vaccination training program will be delivered to Australian and Sri Lankan pharmacy students in 2015. On completion, pharmacy students will be surveyed, with the aim to identify participant satisfaction with program delivery. Collection and analysis of survey and assessment data will then be analysed.
Successful completion of the embedded training program will contribute to pharmacy student graduate preparedness to administer vaccinations in a safe, competent and ethical manner.

**Keywords**

Training, undergraduate, vaccination, injection skills


**Introduction**

An emerging role for Australian pharmacists is the administration of vaccines. In December 2013 the Pharmacy Board of Australia announced that vaccination is within the current scope of practice for pharmacists in Australia (The Pharmacy Board of Australia, 2013). In January 2014 Queensland legislation changes approved by the Department of Health, enabled pharmacists to administer vaccinations after completion of a vaccination training program and enrolment in Queensland Pharmacist Immunisation Pilot program (Queensland Government, 2014). In May 2014, Northern Territory (NT) jurisdictional regulation was amended enabling pharmacists to administer influenza and measles vaccines after completion of an approved training program (Northern Territory Department of Health, 2014). Therefore it is appropriate that pharmacy students are appropriately trained and certified competent to deliver this health service innovation. Such competence will be achieved through the successful completion of an approved undergraduate vaccination training program.

The primary objective of this short description is to detail the progress of a research project proposing, a pharmacist specific, validated vaccination training program (VTP) with incorporated generic injection skills training, to be integrated within Australian undergraduate pharmacy training as identified modules with assessed competency.
Description

A training program has been designed after extensive review of all current and discontinued Australian and international immunisation/vaccination/injection training programs for health professionals. When developing the teaching rational for the vaccination training program a number of elements were considered including learning objectives, the learner and teaching context, the subject matter and the different styles of student learning.

The training program has been developed with reference to current Australian pharmacy curricula and addresses published concerns raised by key stakeholders and professional associations in the past five years, particularly the recommendation that vaccination training be an identifiable unit within training. The vaccination training program (VTP), including all educational material, has been designed and developed purposively for the Australian context.

The injection skills training integrates a variety of education pedagogies, including simulation. Simulation is a learner-centred educational pedagogy that facilitates learning by exposing the learner to a situation which is based on or mimics a real life event. It provides the student with a safe environment to problem-solve and learn prior to practising in the professional setting. Further the use of simulation as an educational tool enables experiential learning and constructivism (Papert and Harel, 1991). Simulation provides students an opportunity to create their own meaning and co-construct knowledge in a safe environment.
The training program will be integrated into undergraduate curricula in three parts. First year pharmacy practice students will be taught and competency assessed in the skills of injection administration, infection control and anaphylaxis management. Collectively the three components have been titled ‘injection skills training’.

Third year pharmacy students will again complete ‘injection skills training’ and have their competency reassessed. Fourth year pharmacy students will complete a vaccination training program, delivered over six weeks via weekly lectures, tutorials and workshops. The vaccination training program will deliver and assess concepts pertinent to the judicious and safe administration of vaccines. Further the VTP will cover, public health and the evolving role of the pharmacist, immunology and vaccination, epidemiology of vaccine preventable diseases, objections to vaccinations: myths and realities, logistics of vaccine supply, and how to conduct a vaccination service in the pharmacy setting in line with current professional recommendations and legislation. The three components of ‘injection skills training’ will be once more assessed.

**Evaluation**

To validate the proposed vaccination training program, four focus groups will be consulted, the first will take place in the United States of America where credentialed pharmacists are authorised to administer vaccinations in all fifty States under specific jurisdictional prescribing arrangements including, standing orders, protocols, collaborative agreements and written and/or verbal prescriptions.
The focus group conducted in America will be comprised of five participants, including pharmacist vaccinators and pharmacy academics involved in the delivery of vaccination training to current American pharmacy students. The American focus group provides expert consultation and validation of the content and core skills included in the developed training program. Focus group participants will identify if the material and delivery modes are sufficient for student learning and comprehension of the concepts of both injections and vaccinations and allow skill retention and demonstration of competency.

The second and third focus group will be held in the Northern Territory, Australia. Focus group participants will include, indigenous health practitioners, psychologists, medical doctors, nurse vaccinators and community and hospital pharmacists. The two Australian focus groups aim to validate and ensure the content is contextualised to the Australian setting. Further, Australian participants will identify if the completion of the developed training program allows student participants to achieve the same competency standards as required by other health professionals.

The final focus group will be held in Sri Lanka. The focus group to be held in Sri Lanka will include participants with medical and pharmacy qualifications and experience (practice, industry and academic). This final focus group will add a further layer of expert validation to the content and delivery of the training program.

Learning material will be revised as appropriate following the final focus group. A final draft copy of the training program will be sent electronically to all focus group members for final feedback.
After the final revision the primary investigator will ‘train the trainer’, that is the primary investigator will teach lecturers and demonstrators in Australia and Sri Lanka how to deliver the content of the training program to ensure that graduates in both cohorts can achieve the same level of knowledge and skill. Trainers will be interviewed after train the trainer sessions, enabling yet another iteration of feedback for the developer of the training program.

The injection skills training and vaccination training program will then be delivered to pharmacy students at an Australian and Sri Lankan University. After the delivery of the IST, student competency will be assessed via the demonstration of the skills of injection. Assessment will be conducted by an external assessor using a validated objective structured clinical examinations (OSCE) rubric. The rubric was designed in collaboration with established vaccinators (Australian nurses and American pharmacy academics) and piloted by completion and demonstration of competency with four academics new to the skill of injection. Assessment has been designed specifically for pharmacy students. Additionally, students will undertake a multiple choice questionnaire which aims to test knowledge and understanding of concepts taught. Assessment data will be analysed.

Immediately following the training programs pharmacy student participants will then be invited to participate in a student evaluation questionnaire aiming to identify participant satisfaction with the program and its delivery.
Future plans and implementation

University degrees aim to provide students with the knowledge, skills and graduate attributes for professional and workplace preparedness (Marriott et al., 2008). Universities globally are up skilling pharmacy students to deliver innovative professional and clinical services. The development and inclusion of a validated Australian vaccination and injection skills training program in undergraduate curricula will improve student preparedness as the profession embraces innovative professional practice and pharmacist administered vaccinations.
References


Northern Territory Department Of Health. 2014. Medicines, Poisons and Therapeutic Goods Act: Prescribed qualifications to supply or administer or possess vaccinations [Online]. Available:


The Pharmacy Board of Australia. 2013. Communiqué [Online]. Available:
Developments since publication

The Australian Pharmacy Council, responsible for accrediting pharmacy schools and programs has voiced approval to integrate injection and vaccination skills into undergraduate curricula in response to the peak professional bodies calling for the inclusion of vaccination assessed competency. This publication provides a delineation for how injection skills and vaccination training should be introduced into pharmacy school curriculum.
Chapter 5: Development and Design of a Vaccination Training Program with Nested Injection Skills Training Targeted for Australian Undergraduate Pharmacy Students

Chapter 6- Title: Development and design a vaccination training program with nested injection skills training targeted for Australian undergraduate pharmacy students

This work has been accepted for publication in - Bushell M-JA, Morrissey H, Nuffer W, Ellis S, Ball PA. Development and design of a vaccination training program with nested injection skills training targeted for Australian pharmacy students. Currents in Pharmacy Teaching and Learning 2015; 7(6) (in press).

Statement of contributions of each author:

Bushell, conceptualised and designed the study and produced the manuscript. Nuffer and Ellis collaboratively developed the rubrics and assessment items with Bushell. Ball and Morrissey edited and guided the writing of the manuscript.

Consent has been granted by all co-authors for use of this publication in my PhD thesis (Appendix 1).
Abstract

Introduction

In 2014, vaccination was included within the scope of practice for Australian pharmacists. A number of Australian pharmacy schools have either commenced or are planning to incorporate vaccination training into pharmacy curricula. The primary objective of this article is to articulate the process undertaken to develop an Australian vaccination training program with nested injection skills training for pharmacy students.

Material and methods

A set of learning outcomes, assessable knowledge and assessable skills was developed following a critical review of relevant literature, guided by the Australian Pharmacy Council Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines. This ensures that the modules will enable students to demonstrate competency required for vaccination, similar to that of current Australian vaccinators; doctors, nurses and pharmacists.

Results

A vaccination training program with nested injection skills training was developed and validated. The new teaching and learning concepts will be integrated and delivered via spiral curriculum. Knowledge and skills should progressively improve as students advance through the pharmacy course. Core skills will be assessed on a number of occasions. Integrated modules are embedded into the first year, third year and fourth year of the pharmacy program.

Discussion

To develop the program, a robust systematic approach was employed. This promotes optimal knowledge retention and skill competence. Following a cyclical approach it
was possible to produce a program that is unique, blended and progressive. As technology in vaccine formulations and packaging is changing rapidly, annual revision amending content to reflect current information will be essential.

**Conclusion**

A vaccination training program with nested injection skills training was developed for Australian pharmacy students.

**Keywords:** Pharmacy, pharmacy education, vaccination, injection, validation
Introduction

In December 2013, the Pharmacy Board of Australia ruled that vaccination is within the current scope of practice for pharmacists.\(^1\) To date, legislation has been modified to allow pharmacist administered vaccinations in most Australian jurisdictions. As the scope of practice for Australian pharmacists evolves and expands, it is imperative that pharmacy school curricula evolve and expand simultaneously to ensure graduate preparedness. Further, incorporating such education into core training helps to address concerns raised by established vaccinator professional bodies, such as the Australian Medical Association. In 2013, Dr Steve Hambleton, the then president of the Australian Medical Association stated in response to pharmacists vaccinating, "the AMA has warned the move is premature, and pharmacists should not be permitted to administer injections until such procedures are included in core training, and were not just an adjunct."\(^2\)

It is anticipated that the scope of the Australian pharmacist will continue to expand, to enable pharmacists to administer a number of parenteral medications. Pharmacy student competence to administer vaccinations will be achieved via the successful completion a vaccination training program (VTP), which includes a nested injection skills training program (ISTP). This article outlines the process undertaken to develop, validate and integrate a vaccination training program into pharmacy curricula at one Australian University. After several years of development and validation, the inaugural delivery of the training program commenced in semester one, 2015.
Developing the vaccination training program with nested injection

skills training

Concept

The first stage in the development of the vaccination training program was a thorough review of existing international literature, firstly in competency-based education and secondly in vaccination training. In addition, literature outlining how innovative clinical skills were being integrated into pharmacy curricula globally was assessed. Similarly, existing Australian vaccination training programs across health professions including nursing, medicine and Indigenous Australian health were studied for similarities and differences in content, delivery modes and assessment strategies. This review process identified a number of similarities and a number of subtle differences amongst material and delivery. Notable similarities included the requirement for not only a face-to-face component but also practical application, where the skills of injection, specifically intramuscular and subcutaneous injection, would be taught and assessed. The treatment of anaphylaxis and the importance of infection control were also consistent themes.

Three main components including, administering injections, managing anaphylaxis and infection prevention and control, were evident in every vaccination training program irrespective of professional background. The authors identified the skills of administering injections, emergency response management and knowing how to prevent the spread of blood borne pathogens, as ‘core skills.’ Delivery of this content will enable students to attain competency in the administration of injections, including vaccines.
When looking specifically at vaccination training programs delivered to pharmacy students in the United States of America (USA) and to medicine students in Australia, there was an apparent consensus in the foundation skills and concepts taught and subsequently assessed.

Immunology and vaccine development were central topics in vaccination training in both curricula. Further, an Australian medicine students and American pharmacy students are assessed in their abilities to explain and discuss which diseases are vaccine preventable, as well as their pathogenesis, clinical signs and symptoms and epidemiology. Health professionals should be able to act as vaccine advocates, so a common theme amongst training programs was recognizing vaccination myths and refuting them with evidence. The importance of ensuring the stability of vaccine products and the maintenance of the cold chain was incorporated into most training programs. All training programs were at least in part, contextualised to the country in which they were taught. Training programs were also contextualised for individual professions and the practice setting where injections were to be enacted. Vaccination education consistently reflected on, and referred to, relevant jurisdictional legislation and current professional guidelines. The critical review and mapping of existing training programs, identified core topics essential in pharmacy curricula to ensure students could obtain knowledge and skill acquisition comparable to students completing an established degree with incorporated vaccination training.
Curriculum structure - assigning the content of modules to appropriate year levels

Examination of existing injection skills training in Australian nursing school curricula identified that the skills of administering injections could be introduced early in the degree, allowing for mastery of such skills while on placement in the clinical setting. It was noted that nursing students do not undertake vaccination training. Registered nurses, complete vaccination training as an elective adjunct course upon completion of their nursing degree. However, nursing students must be recognised as competent to administer both subcutaneous and intramuscular injections for successful completion of individual nursing units and subsequently the nursing degree. The skills of injection are commonly taught in the second year of an Australian nursing degree.

In the USA, where vaccination training has been incorporated into pharmacy curricula in some schools since 2004, students are commonly taught the skills of injection either late in their first year or in the second year of the curriculum. In an environment where competency-based assessment is widely applied, this enables students to be certified as competent in the skills of injection prior to placement. As a result, ‘credentialed’ students completing introductory pharmacy practice experience (IPPE) or advanced pharmacy practice experiences (APPEs) (wherein students are placed in practice settings as part of their training) are available to administer vaccinations, under the supervisor of a registered pharmacist. It has been identified that having such a clinical skill, is of value to the sites where students undertake their placement.
Noting the emphasis on mastery in the skills of administering injections, recognizing and managing anaphylaxis, and minimizing the risk of blood borne pathogen exposure, when developing the Australian vaccination training program the authors felt it essential to introduce these ‘core skills’ early in the pharmacy curriculum and allow for reassessment of the skills taught throughout the curricula (Table 1). The ‘core skills’ are collectively titled the injection skills training program (ISTP). On completion of the ISTP pharmacy students will have comparable competency in the skills of injections as Australian nursing students. Such early integration and assessment of skills is in line with a spiral curriculum. In a spiral-designed curriculum students revisit topics and build on concepts taught in preceding years. Topics visited are addressed in successive levels of difficulty. During concept development it was identified that some skills required a larger foundation of knowledge for application of new concepts, or required higher order thinking. For example, in studying the epidemiology and pathogenesis of vaccine preventable diseases, for best understanding, a foundation knowledge of anatomy and physiology, microbiology and infectious diseases are all required. Teaching such concepts to first year students would not be ideal. However, fourth year students have the foundation knowledge to build on and apply the concepts of the pathophysiology of vaccine preventable diseases. As such it was decided, in line with the spiral curriculum, that the more complex vaccination topics would be introduced to fourth year students once the foundation units had been successfully completed. Students would also revisit topics (infection control, administering injections and emergency management) covered in the injection skills training program providing the opportunity to demonstrate maintained or progressive gain in ‘core skills’
competence. Topics to be covered in the fourth year of the curriculum are outlined in Table 6 (5.2).

Given the length of time that elapses between learning in first and fourth year, it was decided third year students will be reassessed on the ‘core skills’. The second year of the pharmacy curriculum does not currently host a pharmacy practice unit in which the core skills could be reassessed and built on. In the third year of the degree, updated injection skills concepts will be taught and any new learning will be linked back to previous learning.

**Learning outcome development**

Learning outcomes (LOs) allow students to ascertain an academics intention for their learning. The rationale for clearly identifying learning outcomes is that they provide students with useful guidance to focus their study, maximize understanding of the content delivered and identify assessable knowledge, activities and skills. Therefore it was imperative learning objectives were defined and aligned with internal and external standards prior to content development. Each individual module commenced with clearly articulated learning outcomes. Each learning outcome started with an active verb such as, define, recognise and identify.

**Alignment with graduate attributes**

Intended learning outcomes in each module were aligned to the broader unit learning outcomes in which the training was embedded. Further, how the acquisition of knowledge and skills contributed to achieving appropriate university graduate attributes and competency in professional practice standards, specifically the
National Competency Standards Framework for Pharmacists in Australia\textsuperscript{11} was articulated. When released in November 2014, content was aligned with the Australian Pharmacy Council (APC) Standards for the accreditation of programs to support pharmacist administration of vaccines.\textsuperscript{12} The APC is an external government body which accredits pharmacy courses across Australia, and it is therefore essential that modules are mapped to professional standards ensuring student preparedness upon graduation in an evolving scope of professional practice.

**Modes of delivery**

At the date of writing, Australian pharmacy practice units in concert with Australian Pharmacy Council guidelines should be delivered via contact mode at the university campus. These guidelines influenced the mode of delivery selected for the teaching and learning of the vaccination training for pharmacy students.

A blended mode of delivery was chosen to deliver both the vaccination training and nested injection skills training. Blended delivery included one weekly lecture (2 hours) accompanied by one weekly tutorial (2 hours) and one workshop (3 hours) per module. Tutorial and workshop classes are ideal for small class sizes and help to foster student learning with active engagement between the students and demonstrator. Recordings of some live lectures are to be posted to the course Learning Management System (LMS) to allow some flexibility of revision of content delivered. Five multimedia video clips were produced, in collaboration with the universities 3D Animation & Multimedia Developer, demonstrating the following skills; pre vaccination screening and counselling, administering a subcutaneous injection, administering an intramuscular injection, drawing up from a vial (including
reconstitution of powdered medication), drawing up from an ampoule and post vaccination care.

The injection skills training program incorporating ‘core skills’ assessment will be delivered over three weeks to first year students integrated into a unit titled “Fundamentals of Pharmacy Practice.” The vaccination training program will be delivered over six weeks to 4th year pharmacy students integrated into the unit titled “Innovative Pharmacy Practice.”

Students will be provided with a workbook reiterating concepts taught during lectures. The inability to provide a contextualized Australian vaccination textbook specific for pharmacy students made the workbook a central component of material development for the vaccination training program with nested injections skills training. The selected textbooks for the VTP were The Australian Immunisation Handbook,13 Myths and Realities: Responding to arguments against vaccination14 and National Vaccine Storage Guidelines -Strive for 5.15 All three books are published by the Australia government as universal resources and guidance for vaccinators across health professions.

Content development

Once topics to be covered were identified, written modules and PowerPoint™ presentations were developed in consultation with experts who had authored and delivered postgraduate immunisation training programs in Australia and experts who had delivered vaccination programs in pharmacy schools in the United States of
America. Each module was developed, based on a comprehensive literature review on the topic addressed in that module listed in table 1 and 2. This approach ensured the information was contemporary and evidenced based. Further the literature review format was appropriate given the lack of contextualised Australian educational material for pharmacy students and pharmacists on injection skills and vaccination training. In this way the author avoided adopting overseas modules, which might not be applicable to the Australian health practice environment and legislation, hence optimizing the relevance of the content of the training program. Additionally the modules were delivered at a stage in the pharmacy program where other units at that level supported the required learning outcomes (table 6.(5.2)).

Modules were written for Australian students, contextualized from the initial draft for the Australian pharmacy setting reflecting current jurisdictional regulations and peak professional body standards and guidelines. As a further layer of consultation the core content of two modules, the authors believe the most novel for Australian pharmacy practice, were published in peer reviewed journals. Two modules have also been published in a widely read Australian pharmacy journal and delivered as accredited continuing education for completion by pharmacists.

**Educational strategies**

From the outset all modules were developed with reference to educational pedagogy. Prior to development of the training sound rationale and methodologies were identified and chosen for individual teaching and learning modules. The elements
that were considered included the learner context (audience), teaching context, subject matter, strategic approach and resources available.

Constructivist theory suggests that learners use their own activity to construct their own knowledge and it acknowledges that a learner’s knowledge is built on prior experiences. It focuses on knowledge construction, not knowledge reproduction. It is known to be a humanistic approach to teaching where the aim is to engage students in active learning. Simulated learning devices, such as wearable injection pads provide students with an opportunity to create their own meaning and co-construct knowledge in a safe environment. Using simulated situations and wearable injection pads as a learning and assessment tool, students are able to practice and learn by doing. Perusal of existing immunization and injection skills training identified the widespread success and implementation of simulation as a learning tool when teaching the art and science of vaccination.

Simulation has been used increasingly as a teaching and learning tool in both medical and nursing schools globally over the past decade. A report outlining the use of simulation in Pharmacy School Curricula in Australia has recently identified that simulated learning is being integrated into pharmacy curricula nationwide. It has been identified that simulated learning in pharmacy practice units may assist students develop clinical, communication, inter-professional learning and interaction and professional services skills. Universities agree that simulation in pharmacy school curricula will continue to increase and impact positively on the preparedness of students for actual professional practice.
**Knowledge and Skills Assessment**

Validation of the assessment and marking rubrics was conducted by established vaccinators. Pharmacy academics in USA and nursing academics in Australia, all of whom are established vaccinators, were involved in validating the marking rubrics. It was agreed by all reviewers that assessment of competency in the individual skills of injection should be shown via objective structured clinical assessment, for an example see (table 4). The rubrics were refined as required to ensure a reliable and valid demonstration of competency could be ascertained irrespective of the examiner. For example during the OSCA rubric validation process, US academics wanted to emphasize that the needle goes into the sharps container right after administration, before any Band-Aids are placed or anything else is done with the patient. As such, the author modified the OSCA so the requirement for sharps disposal was moved into the administration section and the requirement to apply a Band-Aid was moved down to the post-injection section of the rubric.

Students will know prior to any assessment the specific criteria that will be used to assess their performance. Prior to examiner assessment of competency, students will be divided into groups of three, allowing one student to demonstrate the skill, one student to observe and one student to peer assess. Each student is to have a turn assessing, observing and demonstrating the skills of injection prior in the group of three.

Knowledge assessment of material delivered to first year students will be tested via weekly mini-tests and a final examination conducted during the universities centralized examination period.
**Assessing knowledge and communication skills**

Fourth year students will have their written and verbal communication skills assessed with respect to vaccination record keeping and to taking and recording patients’ medical medication and social histories. Additionally, students’ knowledge will be tested regarding their ability to A) identify patients with a contraindication to vaccine administration B) locate appropriate vaccination sites C) manage thermos-labile pharmaceutical products and D) appropriately dispose of used vaccination supplies. Examiners of competency will be established practicing vaccinators.

**Validation**

Review of the training program was integrated at all steps of development. Peer review is an essential component of ensuring validity of the training. Through the initial phases with expert consultation, via peer reviewed publication of modules and finally via four focus groups for validation. Focus groups were held in America, Australia (x 2) and in Sri Lanka. Each focus group had at minimum five expert participants most with experience administering vaccinations. Focus group participants provided a layer of content and construct validity. The reasoning behind conducting a focus group in USA was to seek validation of the training program from experts who had integrated vaccination training into pharmacy school curricula, while the reasoning behind conducting the focus group in Sri Lanka was to identify the wider usability of the training program. Focus group feedback was collated and
used to inform required amendments to the original vaccination training program with nested injections skills training. Major amendments included introducing the concept of informed consent in the first year of the training (originally this concept was taught in year four), adding a module on needle phobia, and incorporating serology interpretation education.

**Limitations**

There was sufficient Australian literature on vaccination training for nurses and medical doctors, however there was only limited literature available that was specifically targeted for Australian pharmacists.

**Reflections and future developments**

Annual revision of content and student evaluation via de-identified surveys will be conducted. The content will be amended accordingly to capture new evidenced based knowledge and raised student concerns. Changes will be implemented prior to the delivery of the program for the following year, reflecting an ongoing evaluation cycle (figure 1).
### Table 5 (5.1) - Core skills taught in year 1

<table>
<thead>
<tr>
<th>Learning module</th>
<th>Core skills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection prevention and control in the pharmacy</td>
<td>Hand washing, Hand rubbing, Preventing needle stick injury, Disposal of used ampoules and swabs contaminated with blood</td>
</tr>
<tr>
<td>Administering Injections</td>
<td>Drawing medicine out of an ampoule, Drawing medicine out of a vial, Administering an intramuscular injection into the deltoid, Administering a subcutaneous injection</td>
</tr>
<tr>
<td>Anaphylaxis and emergency response</td>
<td>Administering an Epipen®, Administering an Anapen®, Administering adrenaline via needle, syringe and ampoule</td>
</tr>
<tr>
<td>Module</td>
<td>Learning Outcomes</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Public Health, vaccination and the evolving role of the pharmacist</td>
<td>• Discuss the effect vaccinations have had on vaccine-preventable diseases both globally and in Australia</td>
</tr>
<tr>
<td></td>
<td>• Discuss the benefits immunisation has both at the individual and societal level</td>
</tr>
<tr>
<td></td>
<td>• Explain current trends in immunisation in Australia</td>
</tr>
<tr>
<td></td>
<td>• Discuss the current Australian vaccination schedules (National Immunisation Program Schedule)</td>
</tr>
<tr>
<td></td>
<td>• Discuss how pharmacist administered vaccinations are in line with Australian government priorities</td>
</tr>
<tr>
<td></td>
<td>• Describe strategies for pharmacists to advocate for pharmacist administered vaccination</td>
</tr>
<tr>
<td></td>
<td>• Identify reputable resources that are useful for immunisation providers and resources that can be recommended for the general public</td>
</tr>
<tr>
<td>Immunology and vaccination</td>
<td>• Identify basic concepts in immunology (organisation of the immune system, nonspecific immunity, specific/adaptive immunity)</td>
</tr>
<tr>
<td></td>
<td>• Describe active and passive immunity</td>
</tr>
<tr>
<td></td>
<td>• Describe the role immunisation plays in providing disease protection</td>
</tr>
<tr>
<td></td>
<td>• Describe the different types of vaccines (live/attenuated vaccine strains, inactivated, non-replicating vaccine,</td>
</tr>
<tr>
<td>Objections to vaccinations: Myths and the realities</td>
<td>Vaccine preventable diseases</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>• Discuss the history of conscientious objection</td>
<td>• Describe how to detect evidence of immunity or past infection</td>
</tr>
<tr>
<td>• Discuss how vaccines are manufactured and tested</td>
<td>• Discuss the epidemiology, pathology of and clinical signs and symptoms of vaccine preventable diseases</td>
</tr>
<tr>
<td>• Identify common safety concerns individuals may have about vaccines</td>
<td>• Discuss the evidence that discredits the safety concern that mercury in vaccines can cause autism</td>
</tr>
<tr>
<td>• Discuss how the MMR vaccine was thought to cause autism and the scientific evidence about the alleged link</td>
<td>• Identify the resources that are available for individuals who have safety concerns about vaccines</td>
</tr>
<tr>
<td>• Demonstrate the skills relative to retrieving, evaluating and presenting information suitable for enquiries encountered on vaccine safety concerns</td>
<td>• Critically review pharmacy, medical, and promotional literature to apply the principles of evidence-based medicine to pharmacy practice</td>
</tr>
</tbody>
</table>
| Logistics of vaccine supply | • Describe the importance of maintaining a cold chain  
|                           | • Describe the Strive for 5 guidelines and Quality Care Pharmacy Program cold chain requirements  
|                           | • Describe how to monitor the effectiveness of the cold chain upon receipt of temperature labile medications and when you are transporting such medications  
|                           | • Describe how to maintain the correct temperature of cold chain equipment  
|                           | • Describe how to monitor refrigerator temperature  
|                           | • Outline a contingency plan in the event of power failure to maintain cold chain  
|                           | • Identify how to report cold chain breaches  
| Conducting a vaccination service in the pharmacy setting | • Describe the infrastructure and equipment requirements for hosting or delivering a vaccination service in the community pharmacy setting  
|                           | • Describe and identify protocols that must be displayed within the designated vaccination area in order to conform with Australian law  
|                           | • Communicate effectively with the consumer and their carers when administering vaccinations  
|                           | • Demonstrate preparing consumers for immunisation including questioning and pre-screening as per the Australian Immunisation Handbook  

• Document a clear, complete and accurate patient history
• Develop an awareness of safety to self and consumers in the pharmacy setting
• Participate in appropriate referrals to other health care professionals
• Describe current documentation and registry requirements for authorised pharmacist immunisers in the Northern Territory and other Australian jurisdictions
• Identify, recommend and initiate immunisations as part of routine preventative health
• Demonstrate cultural sensitivity in the management of consumers from a variety of backgrounds
• Demonstrate an understanding of and commitment to the legal requirements and ethical principles as they apply to the confidentiality of consumer information
Table 7 (5.3) - Injection and vaccination training embedded across the undergraduate curricula

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Injection Skills Training Program</strong></td>
<td><strong>Pharmacy program units taught:</strong></td>
<td><strong>Injection Skills Training and Emergency Response</strong></td>
<td><strong>Vaccination Training Program</strong></td>
</tr>
<tr>
<td>Module 1: Infection prevention and control in the pharmacy</td>
<td>Pharmacology units</td>
<td>Core skills reassessed</td>
<td>Module 1: Public health, vaccinations and the evolving role of the Australian pharmacist</td>
</tr>
<tr>
<td>Module 2: Administering injections</td>
<td>Pharmacists units</td>
<td><strong>Pharmacy program units taught concurrently:</strong></td>
<td>Module 2: Immunology and vaccination</td>
</tr>
<tr>
<td><strong>Pharmacy program units taught concurrently:</strong></td>
<td>Medicinal chemistry units</td>
<td>Therapeutics units</td>
<td>Module 3: Epidemiology and vaccine preventable disease</td>
</tr>
<tr>
<td>Pharmacy foundation unit</td>
<td>Biochemistry units</td>
<td>Infectious disease unit</td>
<td>Module 4: Objections to vaccinations: Myths and the Realities</td>
</tr>
<tr>
<td>Anatomy and Physiology units</td>
<td></td>
<td></td>
<td>Module 5: Logistics of vaccine supply</td>
</tr>
<tr>
<td>Microbiology unit</td>
<td></td>
<td></td>
<td>Module 6: Conducting a vaccination service in the Australian pharmacy setting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Injection Skills Training Program</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Core skills reassessed</strong></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td><strong>Pharmacy program units taught concurrently:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical pharmacy units</td>
<td></td>
</tr>
</tbody>
</table>
Figure 2 (5.1): Cycle of training program development

1. Concept development
2. Learning outcomes and student attribute alignment
3. Curriculum structure & Modes of delivery
4. Content development
5. Educational strategies
6. Knowledge and skills assessment
7. Evaluation and implementation of changes
References

1. Pharmacy Board of Australia. Communiques. 


Chapter 6: Sri Lankan Perspectives on Pharmacist Administered Vaccinations

Chapter 7- Title: Sri Lankan Perspectives on Pharmacist Administered Vaccinations

This work has been previously published in- Bushell M-JA, Morrissey H, Waidyarathne E, Zawahir S, Ball PA. Sri Lankan Perspectives on Pharmacist Administered Vaccinations. Pharmaceut Reg Affairs 2015;4:135.

Statement of contributions of each author:
Bushell, conceptualised and designed the study, conducted the focus groups, analysed the data and produced the manuscript. Ball and Morrissey verified data analysis and edited the manuscript. Waidyarathne and Zawahir facilitated the focus group in Sri Lanka. Waidyarathne represented Bushell locally on the Sri Lankan ethics committee.

Consent has been granted by all co-authors for use of this publication in my PhD thesis (Appendix 1).
**Contribution to practice**

This paper contributes to the volume of knowledge about the Sri Lankan health care system. Further it provides Sri Lankan health practitioners with a voice about pharmacist administered vaccination and about the inclusion of injection skills and vaccination training in Sri Lankan pharmacy school curriculum.

The paper may be used to help inform future directions and prior approvals when considering the incorporation of clinical skills into pharmacy curriculum. This body of work provides context as to why training programs cannot be universally adopted without modification to reflect the cultural context in which they are delivered.
Abstract

Background
Globally, the administration of vaccines by pharmacists is gaining momentum and incorporation of vaccination and injection skills in pharmacy school curricula is becoming more common.

Objectives
This paper reports on one of four focus groups conducted to validate an Australian developed undergraduate Vaccination Training Program (VTP) and its wider application beyond the Australian health care environment.

Methods
A focus group discussion was conducted with six Sri Lankan medical and pharmacist experts following the development of a vaccination training program.

Results
Participants voiced that prior to incorporation of the VTP into undergraduate Sri Lankan curricula, approval should be sought from the Ministry of Health and established vaccinators. The issue of certificates of competency was deemed inappropriate to be issued to Sri Lankan students. Additionally the assessment of competency was seen to be essential on a yearly basis throughout the curricula.
Concern was expressed about the management of vaccine associated anaphylaxis in the context of minimal pre-hospital care. Participants voiced that vaccination training should be piloted prior to formal incorporation into Sri Lankan undergraduate pharmacy curricula.
Conclusion

While there is wide interest in the introduction of clinical skills into pharmacy curricula, the results of this study raise questions about the inclusion of injection and vaccination training in Sri Lankan undergraduate curricula.

Keywords: Focus groups; vaccination; Sri Lanka; Pharmacy practice; Clinical pharmacy
Introduction

In many countries including, the United States of America (USA) and Canada, administration of vaccines by pharmacists is an established role, while in other countries, including Australia and New Zealand [1], it is an emergent role and in other countries the vaccination service delivery by pharmacists remains a foreign concept. In Sri Lanka the role of the pharmacist is evolving, however it does not currently include the administration of vaccines.

The title ‘pharmacist’ in Sri Lanka may at present be applied to a person who has completed a two year certificate of proficiency in pharmacy, or a two year certificate of efficiency in pharmacy, or a four year bachelor degree either as a two year Bachelor of Science followed by two year specialisation in Pharmacy or as the four year Bachelor of Pharmacy. In Sri Lanka, registrations of pharmacists who fulfil the prescribed requirements are registered by the Sri Lanka Medical Council (SLMC) [2].

Currently the majority of pharmacists hold the proficiency or efficiency certificate in pharmacy, as the first Bachelor of Pharmacy degree was established in 2006 [3]. The certificate system had previously satisfied Sri Lanka’s needs however with the emerging changes in pharmacists’ role around the world particularly in clinical pharmacy; Sri Lanka wants to expand the knowledge and skill base of future pharmacists and is also moving towards the degree program. It was made clear from the outset, that such extended roles for pharmacists were only being considered for those with a four year qualification. Field experience or placements for real life training is now incorporated into Sri Lankan undergraduate curricula bringing them
in line with mainstream pharmacy education standards. One element still in gestation is clinical pharmacy; both education and practice, however there is a strong intention to integrate aspects of clinical pharmacy into the Sri Lankan pharmacy undergraduate curriculum [3]. Currently there is no compulsory internship year, prior to practicing as a registered or listed pharmacist.

Sri Lanka has highly developed medical education and many medical staffs have worked in countries where clinical pharmacy services are well-developed. They can see the value and support the concept to expand the role of the pharmacist to include clinical services. Administration of vaccines by pharmacists has been considered as a clinical skill that undergraduate pharmacists can learn, but the idea of actual practice of vaccinations after graduation is not yet established.

At present the majority of nurses practicing in Sri Lanka are hospital trained; two cohorts have graduated from a newly established Bachelor of Nursing Degree. Thus, historically nurses’ responsibilities rarely extend beyond traditional patient care [4,5]. Currently, nurse administered vaccinations must be done under the direct supervision of a medical doctor.

Medical education in Sri Lanka is consistent with the education requirements of medical students in most countries. Students must successfully complete a five-year undergraduate Bachelor of Medicine and Bachelor of Surgery (MBBS), followed by an internship and supervised practice. Doctors must continue to maintain currency of practice completing mandatory Continuing Professional Development (CPD). Physicians must also undertake specialisation before the age of 35, or remain as
general practitioners (which is in itself a specialisation). Medical academics are permitted to continue to practice professionally while they are in an academic teaching role.

Pre-hospital care is another emerging concept in Sri Lanka and most ambulance services offer simple patient transport with first aid, but no advanced trauma equipped ambulance vehicles are currently in service, and they do not carry paramedics.

The Ministry of Health is the decision making authority for all immunisation related activities in the country [6]. All vaccinations should be administered at centres which are registered and accredited by the Ministry of Health. Vaccinations are currently offered via immunisation clinics under the supervision of Medical Officer of Health (MOH); physicians and trained Public Health Inspectors or Government Health Midwives may administer vaccinations [7]. Some, vaccinations are offered in the government and private hospital setting. In the private hospital such vaccinations are offered at patient request, the private hospital caters for caters to 5-10% of the country’s in-patients [8]. In government hospitals vaccinations are most often offered when a person has a pre-existing condition that requires hospital access or have an injury that requires for example, a tetanus vaccine. Vaccination offered at government hospitals and Ministry of Health immunisation clinics are free of charge.

Collaboration between the pharmacy disciplines at Charles Darwin University and the University of Ruhuna, was established in 2014 and this facilitated the formation of a focus group to discuss and validate a pharmacy undergraduate vaccination
program that can be jointly introduced as a new clinical skill for pharmacy students through a pilot study in both universities.

**Aim**

This paper reports on one of four focus groups conducted to validate an Australian developed undergraduate Vaccination Training Program (VTP) and its broader application outside the Australian health care environment.

**Method**

The study adopted a mixed descriptive and explorative method in innovation of teaching, through a number of activities that included development of training module material, multidisciplinary focus groups to validate the training module, then evaluation of the achieved students attributes by students and multidisciplinary practitioners. The part discussed in this paper is the outcome of the Sri Lankan focus group activities. Focus groups were chosen to assist in the validation of the Australian developed undergraduate pharmacy specific vaccination training program, as they allow a panel of multidisciplinary experts to voice their concerns and provide constructive feedback on the content and the wider usability of the educational material and modes of delivery. A total of six participants were recruited. Criteria for inclusion included having an extensive knowledge in vaccination administration and a medical or pharmacy qualification. It was intended to have a similar expertise composition to that of the focus groups conducted in the USA and two focus groups conducted in Australia. Participants included the manager of a large pharmaceutical corporation (pharmacist), a consultant physician (hospital practice), two senior
medical academics (one a general practitioner), one practicing general practitioner and a senior pharmacist academic. Participants were electronically sent a copy of a plain language statement outlining the study and a consent form. Individual consent forms were signed by each participant prior to the commencement of the focus group. No difficulties were experienced with recruitment; supporting the assertion that there is wide interest in the introduction of clinical skills into undergraduate pharmacy curricula in Sri Lanka.

The focus group was moderator by the developer of the vaccination training program. The primary responsibility of the moderator was to encourage open discussion and to keep the discussion on track, without biasing the participants’ thoughts and opinions.

Ten open-ended guide questions had been developed and were asked in a predetermined order. The focus group meeting was audio recorded (with consent from all participants), transcribed verbatim, and then manually analysed for themes. In addition, each guide question was published on an A3 laminated poster and participants were colour coded and provided with self-adhesive note pads (sticky notes). Participants were encouraged to write any thoughts on the provided sticky note pads and then asked to attach the written note to the corresponding guide question during the discussion. Statements and feedback written by participants was then analysed for themes alongside the audio recording.

Note was taken of whether emerging and identified themes were a consensus among participants or if themes were the view point of one or two participants. Apparent
factions and group disparities were manually coded. Coding was validated by the project supervisor.

The focus group session ran for 170 minutes, with 10 minutes for opening and 5 minutes for closing remarks and one 30 minute break.

**Results**

The analysis revealed four themes

Approvals prior to incorporation any vaccination training program into Sri Lankan pharmacy degree curricula was a dominant theme and several subthemes could be identified including the assessment of competency, piloting and contextualisation of content and role of pharmacists in anaphylaxis.

Approval by the Ministry of Health

This was the most-discussed topic. It was obvious that participants were in agreement that Ministry of Health support for the inclusion of the clinical skill into pharmacy curricula is required. The general rule and practice to introduce any new module into an existing curriculum is that the new module should be submitted with justification at the university’s faculty curriculum development and evaluation committee and then subsequently forwarded to University council for approval via the relevant faculty board. However, practicing these skills in the future is still a question for the Ministry of Health as administration of vaccination by pharmacists is not currently practiced in Sri Lanka. Additionally, if the clinical service is to be introduced, it will have implications on a number of professional boundaries, graduate supply and other resource implications. “You should not do anything
without government approval, I think if not it will create problems, I think the education is a basic concept, but if you are going to teach these students to provide this service for the country you need minister approval” *Doctor1* “Before implemented in Sri Lanka it needs to be addressed in government policies before it is introduced into our system” *Doctor 2*

While such comments were articulated by physicians there was universal consensus around the table that there was a need for approval from external regulatory bodies for inclusion of any vaccination training program or injection skills outside the pilot.

**Approval from established vaccinators**

Participants reported that endorsement by established vaccinators was important, prior to inclusion into the undergraduate curricula. The skill was recognised as being new to pharmacy students and the pharmacy profession and therefore other professionals needed to be informed.

“If you incorporate this thing in Sri Lanka, with competency after four years, other doctors, other professionals need to be advised” *Doctor1*

“It is not incorporated into any other B. Pharm in Sri Lanka so other health professionals need to know” *Pharmacist A*
Assessment and recognition of competency

Integrated and repeated assessment: Participants expressed that assessment must be repeated and ongoing; however initial delivery of the skills would be preferred as a one week intensive teaching session in one identified module.

“One intensive week course - I personally feel is better in our set up as the curriculum is already full, however assessment wise, skills, there should be something put in regularly, even in second year, otherwise they will forget everything” Doctor 3

Certificate of competency

Participants expressed concern about the issuing of a certificate of competency in the skills of injection. Both physician and pharmacist participants mentioned this would be interpreted as being qualified to administer injections, such as penicillin and other antibiotics. There was a uniform consensus that a certificate of competency should not be issued to students.

“By offering a certificate of competency you are offering a pass out and pharmacy students will start vaccinating” Doctor 4

Pilot training program and recognition of the Sri Lankan context

The researchers detected some hesitancy about the delivery of the vaccination training program as a pilot in Sri Lanka from some medical doctor participants. However verbally the group was in agreement that the training program needs to be conducted as a pilot program initially, possibly on a number of occasions and
preferably as multidisciplinary classes involving medical, nursing and pharmacy students and then evaluated prior to incorporation into the curricula.

“Before incorporating it into the curriculum can it be run as a trial” Doctor2

A recurring theme throughout the focus group was the need for the developed vaccination training program to recognise the unique characteristics of Sri Lanka’s health care system, including the diverse pharmacists’ and nursing qualifications, the patterns of health demand and the manual prescribing, dispensing and health records.

“Our set up is completely different” Doctor3

The Sri Lankan focus group also identified that the topics in modules should be separated as chapters and that pharmacists should be competent in their knowledge about all vaccines not only those they are allowed to administer. Additionally the group recommended the delivery of the material through-out the four years of the pharmacy course not only three and an additional competency assessment annually thereafter if the student vaccinator did not perform a certain number of actual vaccinations. Additionally the current Bachelor Degrees in Sri Lanka are accredited under total credit points as in Australia, the pharmacy course using all allowable credit points for other theory and foundation knowledge units and it will be required to shift or replace some topics to allow the inclusion of the vaccination modules.
Role of pharmacists in anaphylaxis

Medical participants voiced concerns about the critical nature of anaphylaxis. Many participants expressed concern about the ability of the pharmacist to appropriately respond to the medical emergency anaphylaxis for many reasons:

• The diverse qualifications of pharmacists
• The current community pharmacies’ floor plans and size
• The inability to have an ambulance dedicated to the place where vaccination will be conducted
• The inability to have the vaccinating pharmacist directly supervised by physician as is currently the case with vaccinating nurses
• The lack of pre-hospital care

This concern was amplified by a case report.

“Sri Lanka we have problems there was a case one or two years back, fatality from anaphylaxis” Doctor 1

Participants appeared relieved when it was articulated that it was not currently under consideration that pharmacists would administer antibiotics such as penicillin, a medication more strongly correlated with a prevalence of inducing anaphylaxis.

“Are you planning for pharmacists to administer other medications?” Doctor 2, participant interjects “antibiotics should not be administered by pharmacists” Doctor 1

It was recognised that administering adrenaline in case of anaphylaxis is considered as an injection other than vaccination, however this will be the only medication
allowed to be administered by pharmacists and its administration is included in the undergraduate training program.

**Discussion**

As the role of the pharmacist expands in Australia to embrace this patient care service it is integral that pharmacy students, like any other health professionals, are educated and deemed competent to safely and appropriately administer vaccines [9]. Such competence should be achieved via successful completion of a validated vaccination training program. Focus group discussion was used to explore the newly developed training program and gather perspectives on the usability for both students studying a Bachelor of Pharmacy in and outside Australia. This article attempts to answer the research question on the global usability of the newly developed vaccination training program. Themes that arose that are discussed here include:

- Approvals prior to incorporation into Sri Lankan curricula
- Assessment of competency
- Piloting and contextualisation of content
- Role of pharmacists in anaphylaxis

The group interaction facilitated participants to develop and define their beliefs voicing their positions in presence of others from different disciplines as they explained their view points.

This focus group was the final focus group in a series of four, the first focus group being held in USA and the second and third held in Australia. It was felt there was value in reporting on this focus group separately, in addition to combined with the
other three, for several reasons. Pharmacy student vaccination training and pharmacist administered vaccination are well-established and accepted concepts in the USA. However, while it is not yet an established practice in Australia, the acceptance of pharmacist administered vaccinations is gaining momentum as jurisdictional regulations are rapidly being amended to enable pharmacists to administer vaccines. Further, it has been identified by the Pharmacy Board of Australia that the administration of vaccines is within the scope of the Australian pharmacist practice. Thus participants involved in the Australian and the USA focus groups were more accepting of the concept shifting their focus to the practicality and applicability of the content of the developed vaccination training program for undergraduate pharmacy students rather than the novelty of the concept of pharmacists vaccinating. On the other-hand, the Sri Lankan focus group provided great benefit to validating the concept of pharmacists vaccinating with constrains that were not previously considered. The focus group identified themes surrounding the incorporation of the vaccination training program outside Australia in the Sri Lankan pharmacy degree program.

**Conclusion**

Vaccination is a new skill for pharmacists in Australia. It has been identified that Sri Lankan health professionals and academics see value in incorporating clinical skills into their newly established undergraduate Bachelor of Pharmacy programs. Vaccination is one such clinical skill that is being considered. However prior to the introduction of vaccination and injection skills training in Sri Lanka, approval and endorsement external to university pharmacy schools should be sought. This focus group identified that the Ministry of Health should be consulted and government
policies modified, furthermore representatives from established vaccinator professions should be informed. Such consultation and collaboration would provide a foundation for successful introduction of the skill of vaccination to be taught in undergraduate pharmacy curricula, contributing to pharmacy profession readiness should the clinical skill be incorporated into the practice scope of pharmacists in Sri Lanka.

**Acknowledgement**

Participants in the focus group and the pharmacy staff at the University of Ruhuna, Sri Lanka.
References


Developments since publication

A memorandum of understanding and plans for future collaborations are in place to further support the inclusion of clinical pharmacy skills at the University of Ruhuna.
Chapter 7: Using Focus Groups to Validate a Pharmacy Vaccination Training Program

This work has been previously published in- Bushell M-J, Morrissey H, Ball PA. Using Focus Groups to Validate a Pharmacy Vaccination Training Program. 


Statement of contributions of each author:

Conceptualization, focus group conduction, data interpretation and write up by Bushell. Validation of data interpretation, structural and editorial input of publication by Morrissey and Ball.

Consent has been granted by all co-authors for use of this publication in my PhD thesis (Appendix 1).
Abstract

Introduction

Focus group methodology is commonly used to quickly collate, integrated views from a variety of different stakeholders. This paper provides an example of how focus groups can be employed to collate expert opinion informing amendments on a newly developed training program for integration into undergraduate pharmacy curricula.

Materials and methods

Four focus groups were conducted, across three continents, to determine the appropriateness and reliability of a developed vaccination training program with nested injection skills training. All focus groups were comprised of legitimate experts in the field of vaccination, medicine and/or pharmacy.

Results

Themes that emerged across focus groups informed amendments giving rise to a validated version of a training program.

Discussion

The rigorous validation of the vaccination training program offers generalizable lessons to inform the design and validation of future training programs intended for the health sector and or pharmacy curricula. Using the knowledge and experience of focus group participants fostered collaborative problem solving and validation of material and concept development. The group dynamics of a focus group allowed synthesis of feedback in an interprofessional manner.
Conclusions

This paper provides a demonstration of how focus groups can be structured and used by health researchers to validate a newly developed training program.

Keywords: pharmacy; focus groups; multidisciplinary; inter-professional; pharmacy curriculum
**Introduction.**

Focus groups are a qualitative research methodology used for a variety of purposes including identifying peoples’ attitudes, behaviours, experiences and opinions and thoughts.\(^1\)\(^-\)\(^2\) They are a method of group interview that draws advantage from communication and group interaction among participants in order to generate data.\(^3\)

Focus groups have long been used as a methodology in health care research to examine a range of issues including, interactions between health professionals and patients, the changing roles of health professions and the organisation of health services.\(^4\) The concept of using focus groups to evaluate both undergraduate and postgraduate educational material is not novel.\(^5\) However adoption of the technique generally occurs once a training program, course or curriculum has been delivered to student learners.\(^6\) This article articulates how focus groups were used to inform development and validate newly authored educational material to be delivered in undergraduate pharmacy curriculum.

In this context, the term focus group is not synonymous with working group or consultation group. Consultation groups are primarily used to elicit advice or exchange views on a guideline or policy. Working groups refer to a group of people working together temporarily until some goal is achieved; these are most commonly used to brainstorm or generate ideas. Neither a consultation group nor a working party requires prior ethical approval. Neither type involves systematic analysis of verbatim transcripts to identify themes.
There appears to be paucity in the literature delineating how undergraduate training programs or courses, once developed, are evaluated and or validated prior to delivery. Published accounts of developed programs for undergraduate curricula commonly report evaluation post student completion of the training program. Undergraduate students commonly complete pre and post training assessments and/or surveys yielding quantitative data. This commonly quantifies an increase in student knowledge, understanding, skill generation or attitudinal change after program completion. While some publications describe how content was developed, it is consistently shown that training programs are developed in a silo fashion, with at best ad hoc consultation with one to two perceived and available subject matter experts. The process of development of a course or training program routinely lacks depth, transparency and transferability. As such there is a lack of published examples of how training programs are validated prior to initial delivery.

Undergraduate students are commonly asked to provide their perceptions of the value of a new course or training program via evaluation surveys post course completion. Qualitative data obtained via student interviews post course completion has also been used identify student perception of course delivery and content.

**Inter-professional focus group**

As pharmacists are part of a broader primary health care team and patient-centred care can be optimised if health professionals’ work as a cohesive team, the researchers saw value in conducting an inter-professional focus group. It was suggested that each focus group member could help contribute their knowledge, skills, and attitudes to augment and support the contributions of other participants and improve the value of feedback on the training program. Further, as the pharmacy
profession embraces and expands its roles and responsibilities to include services already delivered by other health professions, it is important to liaise with those professions to reduce confusion and conflicts.

**Experimental Section**

**Materials and methods**

To validate the proposed vaccination training program (VTP) with nested injection skills training, four focus groups were consulted, the first was conducted in the United States of America (where vaccination by pharmacists has been established for some years), the second and third focus groups took place in the Northern Territory, Australia (the country where the vaccination training program was to be embedded in undergraduate pharmacy curriculum) and the final focus group took place in Sri Lanka, South-East Asia (where the VTP would be delivered as a pilot informing future curricula directions). The focus groups consisted of; America (5), Sri Lanka (6), Australia Group 1 (3), Australia Group 2 (4), giving 18 persons overall. Each individual focus group discussion lasted approximately three hours. All were audio recorded and transcribed verbatim. In addition, the title of each discussion topics was printed on paper sized 297mm x 420mm (one sheet of A3 sized paper per discussion topic). Participants were encouraged to contribute their thoughts on each discussion topic verbally and/or in writing by attaching Post It Note™ comments to the appropriate sheets of A3 paper. The Post It Note™ memo paper was colour-coded to each participant. Notes fostered further discussion on topics and easily identified when participants presented contrasting opinions or were in unison on a topic. Feedback from all four focus groups was collated and manually coded and examined for themes. Where there was consensus in feedback, such as the suggestion to add a
certain topic, or change a module title, the author of the training program revised the content to reflect focus group consensus (see table 1). When focus groups voiced approval of the content or concept, the material was not changed, and the content was considered validated in its initial form. All amendments made and the final draft copy of the training program was sent electronically to all focus group members for final feedback.
<table>
<thead>
<tr>
<th>Guide Questions</th>
<th>USA Focus Group</th>
<th>Australia Focus Group 1</th>
<th>Australia Focus Group 2</th>
<th>Sri Lanka Focus Group</th>
<th>Suggestion incorporated training program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is it clear to the user how to use the manual?</td>
<td>Clear</td>
<td>Clear</td>
<td>Clear</td>
<td>Clear</td>
<td>More images have been incorporated into the modules and PowerPoint presentations</td>
</tr>
<tr>
<td>Module introductions, do they introduce the reader to the topic?</td>
<td>Clear</td>
<td>Clear</td>
<td>Clear</td>
<td>Clear</td>
<td>Glossary, abbreviations list &amp; forward now included</td>
</tr>
<tr>
<td>Titles do they reflect the content of the modules?</td>
<td>Module entitled ‘anaphylaxis’ suggested to be ‘retitled to anaphylaxis and emergency management’ All other titles appropriate</td>
<td>Clear</td>
<td>From module title- not clear where immunisation schedules are taught</td>
<td>Clear</td>
<td>Module revised and retitled ‘Managing vaccine-associated anaphylaxis in the pharmacy’</td>
</tr>
<tr>
<td>Skills taught in year 1, 3 &amp; 4</td>
<td>Appropriate</td>
<td>Must revisit skills competency if introduced in first year</td>
<td>Need to revisit injections skills, a strength of the program</td>
<td>Good but if ever introduced in Sri Lanka a workshop format</td>
<td>n/a</td>
</tr>
</tbody>
</table>
| Competencies and the ways they are proposed to be assessed | Introduce informed consent in module one-three  
Objective Structured Clinical Examinations should incorporate more than skill assessment, must assess communication before and after injection | Peer assessment prior to demonstrator assessment good.  
Peer assessment teaches them ‘preceptorship’  
Established vaccinators assessing a strong point of the training program | Approved the use of Objective Clinical Skills Examinations  
Must reassess how to manage anaphylaxis not just the skills of injections in 1st, 3rd and 4th year  
Peer review and validation a good idea  
Students should have an oral assessment where they talk about two vaccines in depth | OSCE modified in collaboration with USA academics  
Practical exercise for Cold chain expanded to include ‘managing cold chain in challenging environments’ |
|---|---|---|---|---|
| The appropriateness of the selected skills and knowledge included in each of the modules and their suitability for student learning | Good Australian specific  
Injection skill introduction gets students thinking that pharmacy comes with clinical skills from the commencement of the degree  
More case study stories | Query how students are going to practice in real life when they will be upskilled before registered pharmacists | Must assess knowledge of adverse events specific to each vaccine | Two additional case studies embedded in lectures and workshops |
| The depth of topics within each module | ‘scaffolding’ | Good | Credit hours to be assigned
What must be removed from the course to make space for the new material | n/a |
<table>
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</thead>
<tbody>
<tr>
<td>Infection control module too extensive</td>
<td>Infection control appropriate for first year and students will take the module with them throughout the curricula and into professional practice. Liked how it was population specific and regulation specific. Agreement that the modules should be updated as the practice of vaccination evolves</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skills, concepts, knowledge that might be missing</td>
<td>Needle phobia Informed consent needs to be introduced in first not fourth year In fourth year complete a mock biohazard incident report as an exercise Via practical activity assess students’ knowledge on how to report an error vaccines – more depth</td>
<td>Needle phobia and acknowledgement that some pharmacists may not feel comfortable vaccinating</td>
<td>List of abbreviations List of terminology</td>
</tr>
<tr>
<td>Comments on the order the training material is presented</td>
<td>Starting with hand washing and needle stick injury is a great choice Anaphylaxis module should come after the injection skills module</td>
<td>Anaphylaxis module should come after the injection skills module</td>
<td>Good</td>
</tr>
<tr>
<td>Other</td>
<td>You tube clips to support student learning Needle phobia, not all pharmacists will want to vaccinate</td>
<td>Linking opportunity to practice skills while on placement as nursing students do. Skill of injection itself is not hard Cold chain management a difficult concept</td>
<td>The skill of injection is not hard Pharmacists shouldn’t be vaccinating, anaphylaxis is a concern</td>
</tr>
</tbody>
</table>
over a term. The intensive should be compulsory. Certificates of competency should not be given in Sri Lanka until approved by government. Vaccination training should be approved by the Health Ministry prior to inclusion in curricula outside of pilot. Should be multidisciplinary workshops with medical students invited.
Participant Selection

The aim of conducting focus groups for validation was to ensure that the content of the training program included all current information on vaccination, that content was sufficient for student learning and comprehension of the concepts of both injections and vaccinations and allowed for skill retention and demonstration of competency. Also that it would allow students to achieve the competency standards identified by the overarching key or professional representative organisations, such as the Australian Council of Pharmacy and the Pharmaceutical Society of Australia.\textsuperscript{11-12} Further relevant competency standards for established vaccinator health professionals could also be met.\textsuperscript{13} Thus the aim and objectives influenced participant selection criteria. Given that there is limited experience of pharmacists administering vaccinations\textsuperscript{14} and subsequently developing or delivering vaccination training in Australia, the initial focus group in November 2014, for training program validation was held in The United States of America (USA), where pharmacist administered vaccinations is an established concept.\textsuperscript{15} In the USA, all focus group participants had experience in either delivering or recently completing a vaccination training program(See Table 9 (7.2)). Focus group participants included two pharmacy academics both of whom deliver vaccination training to pharmacy students, two credentialed pharmacist vaccinators one responsible for up skilling pharmacists completing adjunct vaccination training, the other a pharmacy owner-operator responsible for integrating and delivering the professional service within their pharmacy. One participant in the focus group was a Doctor of Pharmacy student (Pharm.D.) who had recently completed vaccination training embedded in pharmacy curricula and had administered vaccinations while on placement.
Table 9 (7.2) Composition of the Focus Groups

<table>
<thead>
<tr>
<th>America</th>
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<tbody>
<tr>
<td>Pharmacy academic and pharmacist</td>
<td>I</td>
</tr>
<tr>
<td>Pharmacy academic and pharmacist</td>
<td>II</td>
</tr>
<tr>
<td>Pharmacist vaccinator and educator</td>
<td>III</td>
</tr>
<tr>
<td>Pharmacy owner/operator who offers vaccination service</td>
<td>IV</td>
</tr>
<tr>
<td>Pharm D student (completed vaccination training)</td>
<td>V</td>
</tr>
<tr>
<td>Australia 1</td>
<td></td>
</tr>
<tr>
<td>Community Pharmacist</td>
<td>1</td>
</tr>
<tr>
<td>Nurse vaccinator</td>
<td>2</td>
</tr>
<tr>
<td>Aboriginal health professional /Clinical psychologist</td>
<td>3</td>
</tr>
<tr>
<td>Medical Doctor – no show</td>
<td>n/a</td>
</tr>
<tr>
<td>Australia 2</td>
<td></td>
</tr>
<tr>
<td>Clinical Pharmacist</td>
<td>A</td>
</tr>
<tr>
<td>Department of Health Pharmacist</td>
<td>B</td>
</tr>
<tr>
<td>Community Pharmacist</td>
<td>C</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>D</td>
</tr>
<tr>
<td>Aboriginal health professional</td>
<td>E</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td></td>
</tr>
<tr>
<td>Manager of a large pharmaceutical corporation (pharmacist)</td>
<td>i</td>
</tr>
<tr>
<td>Consultant physician (hospital practice)</td>
<td>ii</td>
</tr>
<tr>
<td>Senior medical academics</td>
<td>iii</td>
</tr>
<tr>
<td>Senior medical academics and general practitioner</td>
<td>iv</td>
</tr>
<tr>
<td>General practitioner</td>
<td>v</td>
</tr>
<tr>
<td>Senior pharmacist academic</td>
<td>vi</td>
</tr>
</tbody>
</table>
The two Australian focus groups were made up of participants selected based on their current scope of clinical practice and expertise (See table 9.(7.2)). Illustrative of established vaccinators in the Australian Health Care System, the focus groups had representation from the nursing, medical and Aboriginal health professionals. To help validate the training program for the Australian pharmacy setting, four registered practicing pharmacists (one clinical, two community and one employed with department of health) participated in the focus group. The inter-professional design of the focus groups allowed consultation, collaborative feedback from all current health professions involved in vaccine administration and patient care.

In Sri Lanka, focus group participants represented the medical, pharmacy and pharmaceutical industry and included the manager of a large pharmaceutical corporation (pharmacist), a consultant physician (hospital practice), two senior medical academics (one a general practitioner), one practicing general practitioner and a senior pharmacist academic. Each focus group was conducted approximately one month apart.

Participants were purposively selected to ensure representation of important elements of the research question. American and Sri Lankan participants were identified using a primary contact person who resided in each country. The contact person in both countries, via their connections was able to select participants who met inclusion criteria and who could best and most broadly inform the research question(s). All focus groups were comprised of both male and female participants and gender representation reflected the current gender trends within represented professions as such, for nursing and pharmacy more females participated than males while physician participants were mostly male. A semi-structured discussion guide was
developed and pretested in a pilot focus group with experts who had previously delivered post graduate vaccination training in Australia.

The focus group moderator was the researcher who had authored and developed the vaccination training program. The moderator assisted in directing and moving the discussion along and drawing out reticent responders. At the end of each discussion, the moderator verified the data collected by summarizing themes and highlighting themes that had been posted on the A3 pages. The moderator asked participants if they felt any key points had been missed. Each focus group session was electronically recorded and transcribed verbatim.

**Ethical considerations**

The study was conducted after approval was obtained from Charles Darwin University Human Research Ethics Committee (HREC) H14067 and Faculty of Medicine University of Ruhuna Ethical Review Committee (3.13). All focus group participants were informed of the study design and the aims of the project via a written plain language statement and verbal explanation. Written informed consent was received from all participants prior to focus group commencement. It was reiterated at the commencement of each focus group that participants were free to leave at any point if they did not wish to continue to be a part of the study.

**Results**

**Support for blended modes of delivery**

One theme across the focus groups was the requirement of blended modes of delivery to optimise student learning. In general, participants liked the written modules; however they wanted to see more pictures to illustrate concepts.
“The modules could benefit from more pictures, especially of the skills “

Aus. Pharmacist A

Participants also felt the incorporation of videos and using online multiple choice questionnaires enabling automatic feedback for answers would improve student outcomes and knowledge retention.

“There should be ‘You Tube®’ clips to support student learning”

USA Pharmacist II. All other USA focus group participants agreed with this statement.

Omission of material to be delivered

One theme consistent across both of the Australian focus groups raised by pharmacist participants was the omission or acknowledgement of needle phobia. Two pharmacists did not personally want to administer vaccinations, and strongly advocated that not every pharmacist should have to perform the clinical skill or participate in training to administer injections. There was concern that students may feel the same way as they entered a degree not anticipating direct physical patient care.

“I hate needles, wouldn’t hold a needle wouldn’t inject a needle...I personally find it scary, daunting and it does make me nervous - and if I had an option I wouldn’t”

Australian Pharmacist C

“Students shouldn’t be forced”

Australian Pharmacist A

“There needs to be education on needle phobia, it is a real fear”

Australian Aboriginal health professional 3 – Australian Pharmacist 1 interjects
“yes that’s something that should be covered, students may not be expecting to vaccinate as pharmacists aren’t seen as vaccinators”

At the time of development, the module titled “Epidemiology and Vaccine Preventable Diseases” only covered in detail the vaccine preventable diseases that Australian pharmacists could currently administer vaccinations for. All four focus groups suggested the module would be improved by providing material, education and assessment on all vaccine preventable diseases or at least those identified on the current Australian immunisation schedule.

“You need to cover all vaccine preventable diseases in the training program; it is not good enough to cover only the select few that you may administer vaccines for currently”

Australian Pharmacist A

‘Even if some diseases are covered in other units you need to go over the content in a vaccination training program’

Australian Pharmacist I

“You should cover all diseases and orally assess students on their knowledge on a sample”

Sri Lankan Medical Academic iii

Further education participants identified should be covered in greater detail included; serology and how to screen for the evidence of immunity and vaccine preventable diseases. In addition it was suggested the written modules incorporated both a forward and a glossary.
Support for the use of spiral curriculum

Across the four focus groups there was strong support for the use of spiral curricula to teach the clinical skills and applied knowledge.

“I like infection control first because it has applications in other areas of practice”

USA Pharmacist I

There was some concern that introducing the skills of injection in the first year of the degree was too early.

“injectable coincides with anatomical sites so to understand the importance of the placement of the vaccine, you have to understand the underlying anatomy to make those decisions, that’s why we have it in second year cause in first year they learn the underlying anatomy”

Australian Nurse 2 - Pharmacist 1 interjects

“First year is huge course content it can be just pushed to the side and you know like anything else creates stress so in the third and fourth year they can revisit it... refresh”

“I am concerned again about the retention from 1st to 4th year you need the assessment again in 3rd year, especially as I assume they are currently unable to demonstrate competency while on placement”

American Pharmacist I

“I like the fact the skills are reinforced and retested”

American Pharmacist III

Three focus groups voiced that the material in modules four through nine could not be taught earlier than fourth year, that is students had to have the underpinning foundation knowledge prior to undertaking the modules.
Participants voiced their approval for the learning outcomes at the commencement of each module. Further participants thought that the learning outcomes were aligned with assessments and would allow for the achievement of competency in the specified skills.

Further, a strength that was voiced across three focus groups was the contextualisation of content in the country it was to be delivered. As the author had authored each individual module, participants approved the current and Australian specific content, and thought the modules could be used not only to teach pharmacy students, but teach pharmacists wishing to complete vaccination training and maintain their skills.

“It’s good how it is population and regulation specific”

Australian Pharmacist 1

Discussion

This study has drawn on participant expertise to help validate a vaccination training program with nested injection skills. The first emerging theme from participants was the articulated support for the blended modes of delivery embedded throughout the training program. Blended learning is not novel in pharmacy courses or higher education and it is being increasingly utilised to optimise learning outcome achievement. The literature describes numerous accounts where blended learning programs have been shown to be superior to single delivery mode programs. In addition to pedagogical techniques already embedded in the training program, participants voiced that additional educational technologies could be included or increased to enrich the vaccination training program. Participants suggested that the training program should include narrated visual presentations of key skills, such as
drawing up from a vial and an ampoule. Consistent with what is scribed in the literature, participants further voiced making knowledge assessment online would allow for greater and timelier feedback enhancing student learning and outcomes.\textsuperscript{19}

The group dynamics of the focus groups allowed synthesis of feedback in an inter-professional manner. In day to day practice health care professionals work and learn together to deliver quality patient-centred health care. Pharmacists do not work in isolation but are part of a broader health care team. Further, while the skill of administering injections is new for Australian pharmacists it is not at all novel for Australian doctors or appropriately credentialed nurses.\textsuperscript{14} Inter-professional practice aligned with inter-professional education has been identified as a means of promoting broad levels of expertise. Participants collectively presented a broad level of expertise which worked well to help inform amendments and validation of the training program. The methodology helped provide inter-professional critique that highlighted strengths and weaknesses including omissions in the training program that should be addressed.

The deliberate attention of the focus group on the validation of the vaccination training program content, delivery and educational strategies, utilised participant skills and expertise without asking or drawing on participants perceptions about the broadening scope of practice for pharmacists in Australia. At the time the focus groups were conducted (late 2014 and early 2015) the change in scope of practice and changing jurisdictional regulations to enable pharmacists to legally vaccinate, was being debated and opposed by professional bodies such as The Royal College of General Practitioners via position statements and media appearances.\textsuperscript{20-21}
Focus group participants identified material that should be included when teaching Australian students vaccination training with nested injection skills. Participants across focus groups voiced there should be learning, teaching and knowledge assessment on all vaccine preventable diseases. This is consistent with vaccination training delivered to American students who complete the American Pharmacists Association's (APhA) Pharmacy-Based Immunization Delivery. 22

The omission of education on needle phobia in the training program was not inadvertent, the concept was not thought of by the author. It was not until the focus groups and the repeated discussion on needle phobia by all Australian pharmacist participants, which the author thought it important to incorporate such education. Needle phobia affects between 3.5% and 10% of the population, invariably pharmacists may be affected by the disorder. 23-24 Historically, Australian pharmacists have provided care without physical contact. It became evident via the focus groups that pharmacists had commenced study and entered the pharmacy profession without envisaging that would have to administer injections. The unanticipated shift in the scope of practice pharmacists may not be well received by everyone in the profession. Further research is needed to quantify the incidence of needle phobia amongst pharmacy students and pharmacists.

There was widespread support for the use of spiral curriculum, that is, the considered iterative revisiting of topics in greater depth throughout the pharmacy degree. This was not surprising given that spiral curriculum has been successfully employed and widely applied to teach nursing, dentistry and medicine education and skills. 25

Using the knowledge and experience of focus group participants fostered collaborative problem solving and validation of material and concept development.
Content was validated for the designated level and appropriateness of difficulty. Content was further validated for the alignment with learning outcomes and integration with prior teaching and learning. As a result of feedback from focus group participants a new learning module has been developed (needle phobia) and existing modules expanded to include key concepts (epidemiology of all vaccine preventable diseases taught). The authors believe the use of focus group methodology to validate education materials and programs offers a sound way of validating a program prior to delivery and can be adopted by other courses external to pharmacy.

**Limitations**

One limitation of the study was the difficulty in recruiting Australian general practitioners (GPs) to participate in the focus group. This may be attributed in part to the opposition voiced by peak professional medical bodies such as the Australian Medicines Association and The Royal Australian College of General Practitioners have against pharmacist administered vaccinations. However research has indicated in Australia that recruitment of GPs to participate in any research project is problematic.\(^{26}\) This was not a limitation faced when recruiting Sri Lankan focus group participants; in contrast most participants were medical doctors. Ease of recruitment of medical doctors into the focus group may be a result of the primary contact person for recruiting participants was a longstanding, respected medical doctor in South East Asia.
Conclusions

This study outlines observations on a method for development and validation of a vaccination training programme. The study demonstrates focus group methodology can be successfully used to validate a training program prior to delivery to students.

Acknowledgments

The authors thank everyone who participated in the focus groups.

Author contributions

Conceptualization, focus group conduction, data interpretation and write up by Mary Bushell. Validation of data interpretation, structural and editorial input of publication by Hana Morrissey and Patrick Ball. All authors have approved the submitted manuscript.

Conflicts of Interest

“The authors declare no conflict of interest”.
References


13. NT Department of Health. Guidelines for the "About Giving Vaccines" course. Available online:


Chapter 8: Australian Undergraduate Pharmacy

Vaccination Training Program with Nested Injection Skills Training: Delivery and Evaluation

This work is submitted.

Bushell M-JA, Morrissey H, Yee KC, Nuffer W, Ellis S, Ball PA. Development and design of a vaccination training program with nested injection skills training targeted for Australian pharmacy students. (submitted)

Statement of contributions of each author:

Bushell designed the study, analysed the data and drafted the paper. Yee verified the analysis of data interpretation. Ball, Morrissey, Yee, Nuffer and Ellis reviewed the paper. Ball and Morrissey assisted Bushell to deliver the training program in Australia and Sri Lanka. Nuffer and Ellis collected USA data.

Consent has been granted by all co-authors for use of this publication in my PhD thesis (Appendix 1).

Acknowledgements

The authors would like to acknowledge Dr Eisha Waidyarathne and Mr Shukry Zawahir for their support and facilitation to deliver the training program to their students at the University of Ruhuna, Sri Lanka. Further, we would like to
acknowledge Dr. M. Rodrigo and Dr. L.B.L. Praboda and Nicole Norman for
donating their time and expertise to assess the pharmacy students using the OSCAs.
Abstract

Background
Many pharmacy schools globally and in Australia are expanding their curriculum to include additional skills that are entering into pharmacy practice. Injection administration, initially for vaccination administration is one of those skills. However, to date, there is no consensus on when such programs should commence within the pharmacy course.

Aims
To evaluate a nine module vaccination training program with nested injection skills training program.

Method
A novel program with nested injection skills training was piloted in 2015. It was delivered to first year pharmacy students in Australia and Sri Lanka and competency was assessed by established vaccinators, using a validated Objective Structured Clinical Assessments (OSCA). Student knowledge of theory was assessed utilizing a multiple choice questionnaire. For comparison, USA first year pharmacy students completing their established program undertook identical assessment. The applied content of the vaccination training program was delivered to fourth year students and first year students enabling comparison of understanding.

Results
Student competency and knowledge assessment data were compared and analyzed. Result stratification identified no significant difference in the Injection Skills Knowledge Test scores between students from different year levels (one way ANOVA p=0.45). Applied knowledge tested with the Vaccination Training
Knowledge Test identified that fourth year students significantly out-performed first year students ($t= -7.968, p < 0.001$).

**Conclusion**

The developed program allowed Australian students to demonstrate comparable skills and knowledge competency to that of the USA students completing an established injection skill and vaccination training program. There is a perceived value in early introduction of training.
Introduction

During the last two years, most Australian States and Territories have modified jurisdictional regulations to enable pharmacist-administered vaccinations.\textsuperscript{1-4} In addition, the role and the scope of practice of appropriately credentialed Australian pharmacists has been expanded, enabling the delivery of this patient-care service from approved premises’.\textsuperscript{5} Many university courses in Australia and globally are developing vaccination courses with incorporated injection skills training.\textsuperscript{6-8} However, there is no consistent approach of when vaccination training should commence or how long such training should be in pharmacy school curricula.

For example in Australia, Griffith University School of Pharmacy incorporates vaccine administration teaching into the first year of their Master of Pharmacy Program. The entry point into the Master’s program is graduation from a three year Bachelor of Pharmaceutical Science.\textsuperscript{7} While Charles Sturt University incorporates vaccination training into the fourth year of a Bachelor of Pharmacy degree program.\textsuperscript{9} In the United States of America (USA), where vaccination training has been incorporated into pharmacy curricula in some schools since 2004\textsuperscript{10}, pharmacy students are commonly taught the skills of injection either late in their first year or in the second year of their curriculum.

Nursing students are commonly taught and assessed on the skills of injection in the second year of an Australian nursing degree and must be competent to administer both subcutaneous and intramuscular injections to patients. However nursing students do not currently complete vaccination training. This suggests that the skills of injection may be introduced and assessed early in Australian university curricula.
It has been proposed that incorporation of injection skills early in the pharmacy degree will better prepare pharmacy students for the broadened scope of practice the profession is now embracing.\textsuperscript{10}

\textbf{Rationale and Objectives}

A novel, in-depth Australian pharmacy school vaccination training program with nested injection skills was developed and validated prior to delivery, through four focus groups and peer review.\textsuperscript{11} One unique aspect of the training program, when compared to current or previously delivered programs, is the concept of ‘nesting’ the injection skills training as part of a larger vaccination training program.\textsuperscript{12} Nested training is when a complete teaching block is delivered within a larger step-up training program. This facilitates multiple assessment points in the larger training program and enables versatility as the foundation training package may be used for a variety of other advanced skills.

One rationale for ‘nesting’ the injection skills training, is that as the scope of practice for the Australian pharmacist expands to include the administration of vaccines, it is inevitable that the role of the pharmacist will expand to include the administration of other parental therapies. Recognised stand-alone competence in the skills of administering injections may ensure students are prepared to administer injections other than vaccinations as the practice scope of the pharmacist continues to evolve.

This study aimed to evaluate a newly developed vaccination training program with nested injections skills training. The vaccination training program is comprised of nine modules of which the first three constitute the injection skills training program.
Further, it aimed to identify the effectiveness of the curricular approach of ‘nesting’ the injections skills training and introducing the initial three modules in the first year of the pharmacy course.

The developed program consists of two parts and nine modules. Three modules (Infection Prevention and Control, Injection skills, and Managements of Anaphylaxis in the Pharmacy Setting) are delivered and assessed in the first year; collectively the three modules make up the first part and the nested component of the larger program. The final six modules (Public Health Vaccinations and the Evolving Role of the Pharmacist, Immunology and Vaccination, Epidemiology and Vaccine Preventable Diseases, Objections to Vaccinations: Myths and the Realities, Logistics of Vaccine Supply and Conducting a Vaccination Service in the Pharmacy Setting) are intended to be delivered and assessed in the fourth year.

Specifically this study examines if Australian and Sri Lankan first year pharmacy students could demonstrate assessed competency in the skills of administering injections comparable to first year pharmacy students in America, where they already complete an established training program. Further, this study aimed to identify the most suitable year to introduce the applied vaccination training modules (modules four through nine) in the Bachelor of Pharmacy degree program (year level one or four).

**Materials and methods**

The injection skills component was delivered to 68 pharmacy students in 2015. It was delivered in February as a short two day intensive course (duration 12 hours) to
28 first year and nine fourth year students at the University of Ruhuna, Sri Lanka and 15 first year, seven third year and nine fourth year pharmacy students over a period of three weeks (duration 12 hours), in March at Charles Darwin University.

Following delivery the students completed a series of assessments. Student competency in the skills of administering injections was assessed using collaboratively designed Objective Structured Clinical Assessments or OSCAs. The OSCAs had been designed by Australian and American academics. The OSCA was conducted by established vaccinators comprised of Sri Lankan physicians and Australian nurses since, at the time of this course there were no certified pharmacist vaccinators in Sri Lanka nor in the Northern Territory of Australia. Assessors used the OSCA to identify if students practiced appropriate infection prevention and control, were competent to draw up medication from a glass ampoule, reconstitute and draw up powdered medication from a vial and to administer both subcutaneous and intramuscular injections into a wearable injection pad in a safe and appropriate manner. In addition to skill assessment, students undertook a multiple choice survey, consisting of 25 questions which aimed to test knowledge and understanding of the concepts taught in the injection skills training (infection prevention, management of anaphylaxis in the pharmacy setting, administering injections). As an active control, 35 first year pharmacy students at the University of Colorado USA, who had completed established injection skills training, were given the same OSCA and knowledge assessment. Assessment data was analyzed allowing comparison of the three cohorts.
The applied component (modules four through to nine) was delivered to 46 students in 2015. It was delivered to 28 first year and 9 fourth year students as a one day intensive (6 hour duration) at the University of Ruhuna, Sri Lanka. The applied content modules were also delivered to 9 fourth year Australian students over a period of 2 weeks (6 hour duration). All students were then asked to complete knowledge assessment comprising 25 multiple choice questions.

Following delivery of the two components, Sri Lankan and Australian pharmacy student participants were invited to complete a student evaluation questionnaire aiming to identify participant satisfaction with each program and its delivery.

**Ethics approval**

Ethics approval was granted by both the Charles Darwin University Human Research Ethics Committee (H14067) and the University of Ruhuna, Faculty of Medicine Ethical Review Committee (3.13).

**Results**

The information about students who undertook the Injection Skills Training Knowledge Assessment is summarized in table 10 (8.1).

The results show that students studying pharmacy in Sri Lanka have a significantly lower score that students studying in both Australia and the USA (one-way ANOVA test; \( p < 0.001 \)). However no significant difference was observed between students studying in Australia and in the USA undertaking the identical knowledge assessment (2-tailed t-test; \( p = 0.096 \)). The results are demonstrated in figure 3 (8.1).
After the injection skills training program it became evident that due to differing health protocols between countries, two questions in the original multiple choice questionnaire were not appropriate outside Australia. The data was reanalyzed after removal of the two invalid questions. The results identified that students from Sri Lanka still performed significantly lower, however the mean differences between countries was reduced (-4.59; 95%CI (-3.55,5.64) to -3.49; 95%CI (-2.51,-4.48)). The results are demonstrated in figure 4 (8.2).

**Results stratification by student cohort**

The results show that regardless of the year level of students, performance in the Injection Skills Knowledge Assessment are similar after completion of the injection skills training or equivalent vaccination training program with injection skills training (One-way ANOVA test; $p = 0.294$ and $p=0.340$) for original questionnaire and adjusted questionnaire respectively. For details of original questionnaire score stratification refer to figure 5 (8.3).

Result stratification is further analysed considering the country of origin of students. It was observed that there is no difference in the scores between student year cohorts after completing the same injection skills training program (from both Australia and Sri Lanka). The results are comparable to students studying pharmacy in the USA who have completed a different training program. The results are summarized in table 11 (8.2).
Sub analysis by category of questions

Three modules were taught and assessed in the injection skills training program; infection prevention and control, managing anaphylaxis in the pharmacy setting and administering injections. Overall student performance in each category of questions was 75.30%. See table 12 (8.3).

Sub analysis based on categories of questions did not show notable difference from the general analysis of the questionnaire as a whole. The performance in all three sections was found to be consistent with the overall scores. Students from Sri Lanka did not demonstrate any focal weakness.

Objective assessment of clinical skills

All students completing a training program were identified as competent in the skills of injection using OSCA rubrics. However two students in USA, three students in Australia and two students in Sri Lanka were noted by assessors as needing more practice to promote confidence.

Vaccination Training Program: Applied Knowledge Assessment

Comparing knowledge between first year and fourth year students after completion of the Vaccination Training Program

Nine fourth year and 28 first year Sri Lankan students completed the applied vaccination training. Out of 25 possible marks, first year students had a mean score of 12.14, while fourth year students had a mean score of 20.11. An independent samples t-test showed that fourth year Sri Lankan pharmacy students scored significantly higher on the proficiency test than the first year students (t = -7.968, p < 0.001). See table 13 (8.4).
Comparing knowledge between Australian and Sri Lankan fourth year pharmacy students

A total of 19 fourth year students completed the vaccination training program, 10 students from Australia and 9 students from Sri Lanka. The scores from both cohorts are not statistically significant (p = 0.306), refer to table 14 (8.5).

Student feedback evaluation

Injection Skills Training (modules 1-3)

Sri Lankan students reported lower levels of understanding when compared to Australian students using a 10 point numerical reading scale, 7.25 and 9.08 respectively (p < 0.01), where 1 = very difficult to understand and 10 = very easy to understand. Other questions collecting data on students’ perception of the presentation of the material and its relevance appear to be similar.

As Australian academics delivered the training program, the difference in accent compared to their tutors and possibly the pace of the oral presentations presented language difficulties. Sri Lankan students wrote the following comments in the text box at the completion of the evaluation questionnaire.

“It would be 100% understandable if there isn’t any language problems” Student A

“This is a very useful course but I could not understand some English words – however this is a very useful and creative programme” Student B

“Note taking was somewhat difficult” Student C
**Vaccination Training Program (modules 4-9)**

Student feedback on the applied content component indicated that it was easy to understand, well presented and relevant, where the average score from 10 point numerical reading scale is 7.53, 8.84 and 8.64 respectively. The feedback does not appear to be markedly different between countries or between student cohorts.

**Discussion**

There is a perceived value in introducing the skills of administering injections as early as first year in the undergraduate Pharmacy degrees. Results from this study demonstrated that skill and knowledge acquisition was comparable between final year and first year pharmacy students in both Australia and Sri Lanka. Introducing the skills early in the curriculum enables opportunities to practice and reassess the skills later in the curriculum. This may help to promote confidence in injection administration in the real life pharmacy setting. Further, it will facilitate Australian pharmacy students to be placement ready, for when Australian jurisdictional regulations allow students to take part in the provision of vaccination in community pharmacies, as is currently the case in the USA. In the USA and Canada appropriately trained and ‘credentialed’ students can administer injections under supervision of a vaccination accredited registered pharmacist.\textsuperscript{13-14}

While this study supports the early introduction of injection skills training in first year, it questions the teaching and assessment of applied vaccination concepts, such as the epidemiology of vaccine preventable disease and immunology at this level. These appear best dealt with in the therapeutics units in the pharmacy curriculum starting in year three.
First year Australian pharmacy students found the injection skills training easy to understand. In contrast, although in many ways more enthusiastic and motivated, Sri Lankan students appeared to have found some of the concepts presented difficult to understand. There may be number of reasons behind this; first is the fact that the content was delivered in two consecutive days and the volume of knowledge might be greater than first year students can retain, compared to three four hour sessions delivered over three weeks as occurred in Australia. Secondly, language issues, while all Sri Lankan students spoke English with proficiency, and English is the language of instruction in their University, for everyone present it is a second language. Students come from a Sri Lankan background, culture and education system, and this may give rise to what we believe to be clear messages to someone from an Australian background, being misunderstood because of idioms and colloquialisms that inevitably become incorporated in our materials. In our ‘train the trainers model’ academic and technical service staff at the University of Ruhuna were trained simultaneously on the same material, future cohorts may report higher levels of understanding and lower language barriers as their native instructors deliver the training program. This will be watched with interest in future years.

Most Australian and Sri Lankan students reported they would like more practice prior to administering injections in the community setting. In Sri Lanka, where all students were identified as competent, established vaccinator assessors identified ongoing yearly or biennial assessment of the skill on injection in later years would support student confidence. This supports the reiteration of skills and knowledge assessment throughout the degree. It further highlights that at the completion of a
single training program pharmacy students may be competent but not comfortable nor confident to administer injections to a real human. In the developed training program students will be introduced and assessed on the skills of administering injections in first year, and reassessed in third and fourth year. It should be considered in fourth year that students demonstrate competency in the skills of injection by administering injections into each other, as occurs in adjunct training completed by registered pharmacists. Perhaps performing the skills of injections on a real individual may improve student confidence.

The disparity between the average score for first and fourth year students on the applied component supports the hypothesis that it cannot be introduced in the first year of the curriculum. Rather that students should have completed foundation units including anatomy and physiology, infectious diseases and microbiology before learning and assessment of applied concepts delivered in the vaccination training. This supports the application and understanding of the content taught in the vaccination training program.

The results of the experiment conducted with Sri Lankan students may not exactly mirror outcomes for Australian students undertaking paced teaching and assessment of the vaccination training program (covering the material over a series of weeks in lectures and tutorials). However given the statistical significance between the mean scores for the knowledge test it could be assumed that in principle learning outcomes of the applied vaccination training program would be better achieved by fourth year students. The achievement of learning outcomes is aligned with profession preparedness.
Conclusions

This program allowed for the same competency and knowledge acquisition by first year pharmacy students with similar demographic and cultural backgrounds. The wider usability of the training program has been demonstrated but as expected for it to achieve equal outcomes across cultural and language differences further fine tuning will be required.

There is value in introducing the skill of injection early in the undergraduate Bachelor of Pharmacy. However applied knowledge concepts, such as the epidemiology of vaccine preventable disease and immunology should not be taught in first year. Aligning with the changing scope of practice for Australian pharmacists, it was considered advisable not to narrow ‘injections skills’ to be synonymous with ‘vaccination administration skills,’ as this fails to facilitate future growth and development of the curriculum to reflect trends in professional practice.
References


### Table 10 (8.1): Student stratification for injection skills training knowledge assessment

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<tr>
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<td>9</td>
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Table 11 (8.2): Result stratification examining student year level and country of study

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<td></td>
<td>Students</td>
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<tr>
<td>Australia (n=31)</td>
<td>15</td>
<td>7</td>
<td>9</td>
<td>p=0.45</td>
</tr>
<tr>
<td>Mean</td>
<td>19.60</td>
<td>18.71</td>
<td>18.77</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>18.52</td>
<td>17.05</td>
<td>17.46</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>20.68</td>
<td>20.38</td>
<td>20.10</td>
<td></td>
</tr>
<tr>
<td>Upper</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sri Lanka (n=37)</td>
<td>28</td>
<td>-</td>
<td>9</td>
<td>p=0.59</td>
</tr>
<tr>
<td>Mean</td>
<td>14.64</td>
<td>-</td>
<td>16.44</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>13.79</td>
<td>-</td>
<td>14.14</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>15.50</td>
<td>-</td>
<td>18.75</td>
<td></td>
</tr>
<tr>
<td>Upper</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>35</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>18.06</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>17.28</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>18.83</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Upper</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 12 (8.3): Sub analysis based on categories of questions

<table>
<thead>
<tr>
<th></th>
<th>Infection Prevention and Control</th>
<th>Managing anaphylaxis in the pharmacy setting</th>
<th>Administering Injections</th>
<th>Adjusted Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of questions</td>
<td>4</td>
<td>8</td>
<td>11</td>
<td>23</td>
</tr>
<tr>
<td>Mean score</td>
<td>2.91</td>
<td>5.88</td>
<td>8.52</td>
<td>17.32</td>
</tr>
<tr>
<td>95% CI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>2.75</td>
<td>5.63</td>
<td>8.21</td>
<td>16.80</td>
</tr>
<tr>
<td>Upper</td>
<td>3.08</td>
<td>6.14</td>
<td>8.82</td>
<td>17.85</td>
</tr>
<tr>
<td>Mean Percentage</td>
<td>72.75</td>
<td>73.63</td>
<td>77.45</td>
<td>75.30</td>
</tr>
<tr>
<td>95% CI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>68.69</td>
<td>70.27</td>
<td>74.67</td>
<td>72.90</td>
</tr>
<tr>
<td>Upper</td>
<td>77.18</td>
<td>76.70</td>
<td>80.05</td>
<td>77.59</td>
</tr>
</tbody>
</table>
Table 13 (8.4): Sri Lankan first and fourth year pharmacy students applied knowledge vaccination training assessment scores

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean (SD)</th>
<th>T-test (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First year students</td>
<td>28</td>
<td>12.14</td>
<td>Mean difference</td>
</tr>
<tr>
<td>Fourth year students</td>
<td>9</td>
<td>20.11</td>
<td>-7.97 (95%CI -10.21,-5.72)</td>
</tr>
</tbody>
</table>

* Indicates statistical significance with 95% CI

† Indicates statistical significance with 99% CI
Table 14 (8.5): Australian and Sri Lankan fourth year pharmacy students applied knowledge vaccination training assessment scores

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean (SD)</th>
<th>T-test (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian students</td>
<td>10</td>
<td>18.90</td>
<td>Mean difference</td>
</tr>
<tr>
<td>Sri Lankan students</td>
<td>9</td>
<td>20.11</td>
<td>-1.21 (95%CI 1.21,-3.64)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>( t = -1.06 )</td>
</tr>
</tbody>
</table>
Figure 3 (8.1) Mean scores for injection skills knowledge test between countries
Figure 4 (8.2) Adjusted scores for injection skills knowledge test between countries
Figure 5 (8.3): Scores for injection skills knowledge test between year levels
Developments since study

Prior to the commencement of this study none of the training of graduates or undergraduates in injection had involved administration to human subjects. Consequently, in this study ethics approval was not sought or granted, nor was it covered by university insurance for students to administer injections into a live volunteer. During the period of candidature, regulations were issued requiring the training of registered pharmacists to include an actual injection into living volunteers, but this was mandated too late to change the basis of this project. It is anticipated that in fourth year that students will in future demonstrate competency in the skills of injection by administering injections into each other, as occurs in adjunct training completed by registered pharmacists. Perhaps performing the skills of injections on a real individual may improve student confidence.
Chapter 9: Discussion and Conclusion

This thesis developed and validated a pharmacy specific vaccination training program with nested injection skills which can be more widely adopted to provide an appropriate integrated learning experience throughout the pharmacy degree years. Invariably, all research projects have a number of limitations associated with their findings. So before discussing this project's contribution to knowledge, final recommendations and conclusion, the limitations are discussed.

Full cycle of implementation

To date, delivery and evaluation of this vaccination training program in its entirety to the same cohort of students over four years has yet to be completed. The definitive evaluation of the training program cannot be conducted until 2018, when the first year cohort (who in 2015 completed the initial injection skills training) will progress to their fourth and final year of study.

This overarching project aims to validate the effectiveness of the nested injections skills training commencing in the first year, followed by reassessment of skills in third and fourth year. This will fall outside the period of candidature for this degree. However, the trials conducted to date on year three and year four students have demonstrated acquisition of skills where in reality they are fundamentally designed to reinforce skills previously acquired. This is encouraging.
**Contribution to knowledge**

During both the literature review and module development, several knowledge gaps were identified:

- In most Australian jurisdictions, pharmacists must complete an independent post graduate vaccination training program to enable administration of vaccines. Australian pharmacy students do not currently complete recognised, embedded injection skills and competency training in Pharmacy degree programs.

- Considering the uniqueness of Australian pharmacy practice, an appropriate and accepted method to validate and evaluate pharmacy undergraduate competencies could not be identified.

- The scope of pharmacy practice is generally generic and individual clinical services provided are not minutely defined.

- In Australia, a clear framework for pharmacist professional development in the area of vaccinations could not be identified.

This body of work has added a substantial contribution to pharmacy practice in Australia by:

- Developing a validated vaccination training program with nested injection skills which is embedded in a systematic manner within an undergraduate pharmacy
program at an Australian university. Student competency to administer injections will be assessed on a number of occasions at different academic levels.

- Pharmacy is part of a multidisciplinary team and as such any provision of clinical services must fit as part of holistic patient care. The concept of focus groups was tailored to have a series of primary health care teams formed to evaluate and validate the content of the modules from the viewpoint of employability attributes. Themes that emerged across focus groups informed amendments giving rise to a validated version of a training program.

- Publications generated in this body of work, supported and contributed to the evidence-base for the broadening of the scope of practice for pharmacists to include vaccinations.

- This body of work produced seven peer-reviewed publications, two invited secondary publications and one conference presentation. It is believed this represents a substantial contribution to scholarly knowledge.

**Future research**

At the time of writing there are no qualified pharmacist vaccinators in the jurisdiction the Australian university is located. There has been discussion of how students will practice the skill of injection in the pharmacy setting. In contrast to American pharmacy students and Australian nursing and medical students who have the opportunity to practice the skill of injection while on clinical placement in their respective professional setting, Australian pharmacy students are currently not
permitted to administer injections while on placement. One reason for this is that pharmacy students have been upskilled prior to registered pharmacists who will be their supervisors and therefore to date, appropriate supervision does not exist. In the future it is inevitable that a large number of pharmacists will complete an approved vaccination training program enabling supervision by appropriately credentialed pharmacists. However it remains to be ascertained whether pharmacy students in the future will graduate without the requirement to complete adjunct training to administer vaccinations.

This body of work provides the Australian Pharmacy Council with evidence to include injection/vaccination training as new competencies within the current pharmacy students’ competency standards. Hence pharmacy students nationwide should graduate with this as one of their core skills. This will enable graduating pharmacy students to practice the skill of administration of vaccinations under the supervision of an appropriately credentialed pharmacist during their internship. Such an initiative will enrich the pharmacy profession with a generation of suitably qualified early career pharmacist vaccinators in Australia.

**Recommendations**

**Recommendation 1**

Vaccination Training should be embedded in pharmacy undergraduate programs throughout the course with multiple assessment points. Vaccination training should not simply be introduced in the final year with one assessment of skill.
**Recommendation 2**

The undergraduate and internship competency standards for pharmacists authored by the Australian Pharmacy Council should include injection skills for the purpose of vaccination as a core competency.

**Recommendation 3**

The post graduate program should only be used to upskill current practicing pharmacists. In the future post graduate programs should move to be refresher courses for continuous professional development and not used as introductory training for vaccination.

**Recommendation 4**

Aligning with the changing scope of practice for Australian pharmacists, it is considered advisable not to narrow ‘injections skills’ to be synonymous with ‘vaccination administration skills,’ as this fails to facilitate future growth and development of the curriculum to reflect trends in professional practice.
Concluding statement

This thesis has made important contributions to the theory and practice of Pharmacy. It has designed a validated and piloted vaccination training program with nested injection skills. The thesis has made practical contributions to the methods that can be used to validate a newly developed training program. This thesis identifies that the skills of injection may be introduced early in pharmacy school curricula. Further, when developing a vaccination training program, relevant primary care professions and organisations should work collaboratively to develop core competencies.
Appendices
Appendix 1

Consent from co-authors for use of publications in PhD

I consent to the PhD candidate Mary-Jessimine Bushell using the above publication as part of her PhD thesis.

<table>
<thead>
<tr>
<th>Co-author name</th>
<th>Signature</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>P Ball</td>
<td></td>
<td>22/06/2015</td>
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<tr>
<td>H Morrissey</td>
<td></td>
<td>22/06/2015</td>
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<tr>
<td>K C Yee</td>
<td></td>
<td>22/06/2015</td>
</tr>
</tbody>
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I consent to the PhD candidate Mary-Jessimine Bushell using the above publication as part of her PhD thesis.

<table>
<thead>
<tr>
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<td></td>
<td>22/06/2015</td>
</tr>
<tr>
<td>K C Yee</td>
<td></td>
<td>22/06/2015</td>
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</tbody>
</table>
**Bushell M-JA, Morrissey H, Nuffer W, Ellis S, Ball PA.** Development and design of a vaccination training program with nested injection skills training targeted for Australian pharmacy students. *Currents in Pharmacy Teaching and Learning* 2015; 7(6) (*in press*).

I consent to the PhD candidate Mary-Jessimine Bushell using the above publication as part of her PhD thesis.

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<td>22/06/2015</td>
</tr>
<tr>
<td>H Morrissey</td>
<td></td>
<td>22/06/2015</td>
</tr>
<tr>
<td>W Nuffer</td>
<td></td>
<td>25/06/2015</td>
</tr>
<tr>
<td>S Ellis</td>
<td></td>
<td>23/06/2015</td>
</tr>
</tbody>
</table>

I consent to the PhD candidate Mary-Jessimine Bushell using the above publication as part of her PhD thesis.

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<td></td>
<td>22/06/2015</td>
</tr>
<tr>
<td>H Morrissey</td>
<td></td>
<td>22/06/2015</td>
</tr>
<tr>
<td>E Waidyarathne</td>
<td></td>
<td>23/06/2015</td>
</tr>
<tr>
<td>S Zawahir</td>
<td></td>
<td>23/06/2015</td>
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<tr>
<td>P Ball</td>
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</tr>
<tr>
<td>H Morrissey</td>
<td></td>
<td>22/06/2015</td>
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</tbody>
</table>
Appendix 2

Recruitment Invitation for Focus Group
Recruitment Invitation
Focus Group for Validation

Undergraduate Vaccination Training Program for Pharmacy Students: Development and Evaluation

Dear __________________________

RE: Invitation to participate in focus group for validation

My name is Mary-Jessimine Bushell and I am currently completing a PhD under the supervision of Professor Patrick Ball. The primary objective of my PhD is to propose a pharmacist specific, validated Australian undergraduate vaccination training program optimised for integration within undergraduate pharmacy training as identified modules with assessed competency.

I am nearing the end of educational material development. To evaluate the newly developed training program, I will be facilitating a series of consultation focus groups. The aim of the focus groups is to explore and identify if the newly developed educational material and modes of delivery are sufficient for student learning and understanding of concepts and allow for demonstration of competency.

I have been provided your contact details as I understand you have been nominated as having an area of expertise or an interest in the administration of vaccinations.

I would like to extend an invitation to participate in a focus group for consultation.

The focus group would be asked to comment on:
- What should the entire program be titled (right content, title of the profession)
- Introduce the topic to the user
- Tell the user how to use the manual
- Does the title reflect the content of the modules
- The order of which the training material is presented
- The depth of topics within each module
- The appropriateness of the selected skills and knowledge included in each of the modules and their suitability for student learning (ease of understanding)

DEPARTMENT NAME

T. +61 8 8946 7490  F. +61 8 8946 7490  M. 04170 63 083  E. mary.bushell@cdu.edu.au

CHANGE YOUR WORLD

201
The outlined competencies and the way they are proposed to be assessed
Any other skills/concepts/knowledge that might be missing

The focus group will be held on the Thursday 11th of December 2014 at DoubleTree by Hilton 116
The Esplanade Darwin from 6.00pm to 9.00pm.

The consultation group will go for approximately 3 hours. Dinner and drinks will be provided. A
small honorarium is offered in the form of a $100 gift card for participating in the consultation focus
group.

As you will be participating in a discussion group, there is impossibility of complete confidentiality
of your involvement. However, all information collected from consultation focus group participants
will be non-identifiable in final summaries and publications.

All hard copy data collected from focus groups will be stored in a locked cabinet in the primary
investigators office located within the pharmacy department at Charles Darwin University.
Electronically recorded data will be password protected on the primary investigators Charles
Darwin University drive.

Please RSVP to mary.bushell@cdu.edu.au by the 30th November 2015.

Sincerely,

Mary

Mary-Jessimine Bushell
PhD Candidate
Lecturer in Pharmacy
B. Pharm (Hons), AACPA, GCTLHE, MPS, AFACP
Appendix 3

Plain Language Statement for Focus Group Participants
PLAIN LANGUAGE STATEMENT

Focus Groups for Consultation

RESEARCH PROJECT: Undergraduate Vaccination Training Program for Pharmacy Students: Development and Validation

RESEARCHER: Ms Mary-Jessimine Bushell PhD Candidate, Charles Darwin University, Australia.

SUPERVISOR: Professor Patrick Ball Pharmacy Theme, Charles Darwin University, Australia.

PURPOSE OF THE STUDY: The objective of this study is to propose a pharmacist specific, validated undergraduate Australian vaccination training program optimised for integration within undergraduate pharmacy training as identified modules with assessed competency over the four years course duration.

BENEFITS OF THE STUDY: Pharmacy students and pharmacy academics and tutors will benefit from skill generation and knowledge of concepts.

The training program will aim to provide pharmacy students with new skills in the area of injections and vaccination to enable them to administer vaccines in a safe, professional and ethical manner taking into account the importance of appropriate vaccination recording process. Therefore student participants will benefit from skill generation and knowledge of new concepts. Students will develop an understanding of the evolving role of the pharmacist in communicable disease prevention and primary health care.

WHAT WOULD BE EXPECTED OF YOU?: If you agree to participate in this project you will be asked to join a consultation focus group. You will be asked questions to help validate the developed vaccination training program. You will be asked questions that help us to identify if the developed educational material and modes of delivery are sufficient for student learning and understanding of vaccination concepts and allow for demonstration of competency.

Constructive positive or negative feedback will be welcomed as the main focus is on producing a workable module.

With your permission the consultation focus group will be audiotaped for the purpose of governance and to allow the researcher to confirm recommended changes. The consultation focus group would last for a maximum of 4 hours.

RISKS: There are no identified risks associated with participating in this project. If you have concerns with the conduct of the study please contact the Executive Officer of the CDU.
Human Research Ethics Committee on (08) 8946 6498, toll free on 1800 466 215, or email Ethics@cdu.edu.au to have your concerns raised with the appropriate officers within the University.

CONFIDENTIALITY: As you will be participating in a discussion group, there is impossibility of complete confidentiality of your involvement. However, any identifying data will be removed once the data is analyzed. Pseudonyms will be used for location and for persons. All hard copy data collected from focus groups will be stored in a locked cabinet in the primary investigators office located within the pharmacy department at Charles Darwin University. Electronically recorded data will be password protected on a computer at CDU accessible only to the researchers.

PARTICIPATION: Your participation in this project is entirely voluntary and you are free to decline to participate.

RESULTS OF THE STUDY: In January 2016, you will have the opportunity to review a summary of the results on the Charles Darwin University Pharmacy Website (http://www.cdu.edu.au/ehs/health/pharmacy). Alternatively you can contact the principal researcher, Mary-Jessamine Bushell on email mary.bushell@cdu.edu.au or (08) 89 46 74 90 and request a copy of any publications related to the study.

PERSON TO CONTACT: If you require further clarification or have questions about this project, please do not hesitate to contact the principal researcher, Mary-Jessamine Bushell on email mary.bushell@cdu.edu.au or (08) 89 46 74 90 or the Primary Supervisor Professor Patrick Ball on patrick.ball@cdu.edu.au.

If you have concerns regarding this study at any stage, please contact the Executive Officer of the CDU Human Research Ethics Committee on (08) 8946 6498, toll free on 1800 466 215, or email Ethics@cdu.edu.au. The executive officer will be able to notify the appropriate person with the University about your concerns.

ETHICAL GUIDELINES: This project will be executed in accordance with the Australian Code for the Responsible Conduct of Research, as defined by the National Health and Medical Research Council of Australia.

Thank you for dedicating some of your time to reading this statement, and considering its contents.

This form can be printed and kept for your personal record.
Appendix 4

Plain Language Statement for Sri Lankan Focus Group Participants

(with local contacts)
PLAIN LANGUAGE STATEMENT

Focus Groups for Consultation

RESEARCH PROJECT: Undergraduate Vaccination Training Program for Pharmacy Students: Development and Validation

RESEARCHER: Ms Mary-Jessimine Bushell PhD Candidate, Charles Darwin University, Australia.

SUPERVISOR: Professor Patrick Ball Pharmacy Theme, Charles Darwin University, Australia.

LOCAL SUPERVISOR: Dr Etha Waidyaratna, University of Ruhuna, Sri Lanka.

PURPOSE OF THE STUDY: The objective of this study is to propose a pharmacist specific, validated undergraduate Australian vaccination training program optimised for integration within undergraduate pharmacy training as identified modules with assessed competency over the four years course duration.

BENEFITS OF THE STUDY: Pharmacy students and pharmacy academics and tutors will benefit from skill generation and knowledge of concepts.

The training program will aim to provide pharmacy students with new skills in the area of injections and vaccination to enable them to administer vaccines in a safe, professional and ethical manner taking into account the importance of appropriate vaccination recording process. Therefore student participants will benefit from skill generation and knowledge of new concepts. Students will develop an understanding of the evolving role of the pharmacist in communicable disease prevention and primary health care.

WHAT WOULD BE EXPECTED OF YOU?: If you agree to participate in this project you will be asked to join a consultation focus group. You will be asked questions to help validate the developed vaccination training program. You will be asked questions that help us to identify if the developed educational material and modes of delivery are sufficient for student learning and understanding of vaccination concepts and allow for demonstration of competency.

Constructive positive or negative feedback will be welcomed as the main focus is on producing a workable module.

With your permission the consultation focus group will be audiotaped for the purpose of governance and to allow the researcher to confirm recommended changes. The consultation focus group would last for a maximum of 4 hours.
RISKS: There are no identified risks associated with participating in this project. If you have concerns with the conduct of the study please contact the Executive Officer of the CDU Human Research Ethics Committee on (08)8946 6498, toll free on 1800 466 215, or email Ethics@cdu.edu.au to have your concerns raised with the appropriate officers within the University.

CONFIDENTIALITY: As you will be participating in a discussion group, there is impossibility of complete confidentiality of your involvement. However, any identifying data will be removed once the data is analyzed. Pseudonyms will be used for location and for persons. All hard copy data collected from focus groups will be stored in a locked cabinet in the primary investigators office located within the pharmacy department at Charles Darwin University. Electronically recorded data will be password protected on a computer at CDU accessible only to the researchers.

PARTICIPATION: Your participation in this project is entirely voluntary and you are free to decline to participate.

RESULTS OF THE STUDY: In January 2016, you will have the opportunity to review a summary of the results on the Charles Darwin University Pharmacy Website (http://www.cdu.edu.au/ehs/health/pharmacy/). Alternatively you can contact the principal researcher, Mary-Jessimine Bushell on email: mary.bushell@cdu.edu.au or (08) 89 46 74 90 and request a copy of any publications related to the study.

PERSON TO CONTACT: If you require further clarification or have questions about this project, please do not hesitate to contact the principal researcher, Mary-Jessimine Bushell on email: mary.bushell@cdu.edu.au or (08) 89 46 74 90 or the Primary Supervisor Professor Patrick Ball Patrick.Ball@cdu.edu.au

If you have concerns regarding this study at any stage, please contact the Executive Officer of the CDU Human Research Ethics Committee on (08)8946 6498, toll free on 1800 466 215, or email Ethics@cdu.edu.au. The executive officer will be able to notify the appropriate person with the University about your concerns.

ETHICAL GUIDELINES: This project will be executed in accordance with the Australian Code for the Responsible Conduct of Research, as defined by the National Health and Medical Research Council of Australia.

Thank you for dedicating some of your time to reading this statement, and considering its contents.

This form can be printed and kept for your personal record.
Appendix 5

Consent Form for Focus Group Participants
Consent form
Focus group participants
(Please print and complete the following form, scan and email to
mary.bushell@cdu.edu.au or hand-over the paper copy to Mary Bushell on the
day the focus group is scheduled)

Undergraduate Vaccination Training Program for Pharmacy Students:
Development and Validation

I

of

consent to participate in a study to be undertaken by Mary-Jessimine Bushell a PhD
candidate with Charles Darwin University and I understand the purpose of the
research is to help validate an undergraduate vaccination training program for
pharmacy students.

I acknowledge that:

• The aims, methods, and anticipated benefits and possible risks of the study, have
been explained to me by Ms Mary-Jessimine Bushell.

• I voluntarily and freely give my consent to participate in this study.

• I understand that group results will be used for research purposes and may be
published in peer reviewed publications.

• Individual results will not be released to any person except at my request and on
my authorisation.

• I am free to withdraw my consent at any time during the study, in which event my
participation in the research study will immediately cease.

Signature: ___________________________ Date ____________________
Appendix 6

Plain Language Statement for Student Evaluation Survey
PLAIN LANGUAGE STATEMENT

Ruhuna University Student Evaluation Survey

RESEARCH PROJECT: Undergraduate Vaccination Training Program for Pharmacy Students: Development and Validation

RESEARCHER: Ms Mary-Jessimine Bushell PhD Candidate, Charles Darwin University, Australia.

MAIN SUPERVISOR: Professor Patrick Ball Pharmacy Theme, Charles Darwin University, Australia.

LOCAL SUPERVISOR: Dr Eisha Waidyarathne, Ruhuna University

PURPOSE OF THE STUDY: The objective of this study is to propose a pharmacist specific, validated undergraduate vaccination training program optimised for integration within undergraduate pharmacy training as identified modules with assessed competency over the four years course duration.

BENEFITS OF THE STUDY: Ruhuna University pharmacy students and pharmacy academics and tutors will benefit from skill generation and knowledge of concepts.

The training program aims to provide pharmacy students with new skills in the area of injections and vaccination to enable them to administer vaccines in a safe, professional and ethical manner taking into account the importance of appropriate vaccination recording process. Therefore student participants will benefit from skill generation and knowledge of new concepts. Students will develop an understanding of the evolving role of the pharmacist in communicable disease preventative and primary healthcare.

WHAT WOULD BE EXPECTED OF YOU? For this year the program is delivered in Ruhuna University as a pilot. While the participation in the workshop is not elective, providing feedback on the workshop is. If you agree to provide feedback on this project you will be asked to complete an evaluation form at the end of the vaccination/injections training program you attended.

You will be asked questions to help identify if the developed educational material and modes of delivery were sufficient for your learning and understanding of vaccination concepts and allowed you to demonstrate competency.

RISKS: There are no identified risks associated with participating in this project. If you have concerns with the conduct of the study please contact the Executive Officer of the CDU Human Research Ethics Committee on (08)8946 8498, toll free on 1800 466 215, or email ethics@cdu.edu.au to have your concerns raised with the appropriate officers within the University.
CONFIDENTIALITY: The data provided on the survey will be confidential. Only group data from assessment results and the evaluation questionnaire will be analyzed and reported.

All hard copy data collected from the evaluation survey and assessment marks will be stored in a locked cabinet in the primary investigators office located within the pharmacy department at Charles Darwin University. Electronically recorded data will be password protected on a computer at CDU accessible only to the researchers.

PARTICIPATION: Your participation in the student evaluation survey is entirely voluntary and you are free to decline to participate.

RESULTS OF THE STUDY: In January 2016, you will have the opportunity to review a summary of the results on the Charles Darwin University Pharmacy Website (http://www.cdu.edu.au/shp/health/pharmacy). Alternatively you can contact the principal researcher, Mary-Jessimine Bushell on email: mary.bushell@cd.edu.au or (08) 89 46 74 90 and request a copy of any publications related to the study.

PERSON TO CONTACT: If you require further clarification or have questions about this project, please do not hesitate to contact the principal researcher, Mary-Jessimine Bushell on email: mary.bushell@cd.edu.au or (08) 89 46 74 90 or the primary supervisor Professor Patrick Ball: patrick.ball@cd.edu.au or Eishan Waidyarathne.

If you have concerns regarding this study at any stage, please contact the Executive Officer of the CDU Human Research Ethics Committee on (08)8946 8406, toll free on 1800 466 215, or email ethics@cdu.edu.au. The executive officer will be able to notify the appropriate person with the University about your concerns.

ETHICAL GUIDELINES: This project will be executed in accordance with the Australian Code for the Responsible Conduct of Research, as defined by the National Health and Medical Research Council of Australia.

Thank you for dedicating some of your time to reading this statement, and considering its contents.

This form can be printed and kept for your personal record.
Appendix 7

Plain Language Statement for Student Evaluation Survey for Sri Lankan students

(in Tamil language)
அமைக்கப்பட்ட ஆக மாதம் தமிழ் பதிப்பில் பின் கிருட்டியாலும் மாதம் பாதுகாக்கப் பட்டிட வேளை திறன்.

சந்தை மாதம் பாதுகாப்பாக்கிய இறைய்க் கொடுக்கும் மாதம் நூற்றாண்டு வருடம் சந்தை. பாதுகாப்பான உதவிக்கும் பலம் மற்றும் அனைத்து நடையில் பெரும் வம்பிக்கை போன்ற விளக்கும் தொடர்பு.

மிகுதிக் கல்வி புராணமும்: ஒரு குழும் கொண்டாட்டம் கை மூலம் பணமுத்துக்குரியது அறியப்படும். பல்லவ வண்ண சேர்க்க விளக்கம் ஒருசுருக்கமும், பல்லவ என்ன கொண்டாட்டம் வீடியோ முறை. சிற்றில வழிகோள் வேளை பொருந்து வந்து பெரும் வம்பிக்கை குழாய் / ஆக பல்லவ பிரிவில் முடிவு கொண்டு வரும் தொடர்பு விளக்கும் தகவல்களுள்.

மிகுதிக் குழாய் புராணம் மதுமாதான விளக்கமாக பலவை கை மூலம் மாதம் தமிழ் வாணிகள் புரிந்து செல்வதற்குப் பயன்பாடும். சந்தையான செய்யுள்ள பலவை செருமான் குழாய் / பெரும் வம்பிக்கை அளிக்காமல் பெரும் தொடர்பு விளக்கு வந்து வரும் தகவல்களுள்.

சந்தையான: ஒரு கி பிசாந்த பலவை எடுத்துக்கொள்வதற்கு வேளையான அனைத்து வாணிகள் பொருந்தும். மிகுதிக் குழாய் பெரும் வம்பிக்கை பயன்பாடும் நூலில் குறிப்பிட்டு விளக்கும் கையாள் எண்ணிக்கை 1800 466 215 மற்றும், (08) 8946 6498 மற்றும் சந்தையான CDU பலவை எடுத்துக்கொள்வது குழாய் / பெரும் வம்பிக்கை அளிக்காமல் பெரும் தொடர்பு விளக்கும். எந்தும் காலந்து பலவை எடுத்துக்கொள்வது எண்ணிக்கை ethics@cdu.edu.au பெரும் வம்பிக்கை விளக்கும் அளிக்காமல்.
சுருக்கம்: 2016 வருடம் முதல் வரை செயல்நிலையில் புது கல்லூரியாக உள்ளது. முறையே பல முறைகள் தொடங்கிய வருடத்தில் முக்கிய மாற்றங்களைப் பெரும்பானே குறிப்பிட்டு கொண்டுள்ளன. இது வல்லுனர்களுக்கு அடிப்படையாக எள்ளச்செயல்பாடு அறிவுசெய்திகளை குறிப்பிட்டுள்ளது. உள்ளூர் கல்லூரியைப் பயணிகள் புதுக்கல்லூரிகளின் கூட்டமான பல்வேறு தொழிகளில் CDU செயல்நிலைத் தொடங்கிய வருடத்திற்கு முந்தைய காலத்தில் பயணிகள் பதிவுசெய்யும் தொழில் தொடங்கியது. 

புதுக்கல்லூரின் முறையே பிள்ளையர் கல்லூரியை பதிவு செய்யும் நிலைகளை மறுகூறும் நிலையில் பதிவு செய்யும் செயல்பாடுகள் கூடுதலாக செய்யப்பட்டுள்ளது. 

ஆராய் செயல்கள்: தொடர்பு வழங்கும் நிறுவனம் பல்கலைக் கழகச் செயல்வாய்ந்தது (http://www.cdu.edu.au/ehs/health/pharmacy/) (மார்ன்றூர் கல்லூரிகள் மற்றும் செயல்பாடுகள்). பல்கலைக் கழகம் பிரிவுகளை பெரும்பானே அணுகுமையாளர்கள்; மார்ன்றூர் Jessimine Bushell குழுப்பான் தளபதி: mary.bushell@cdu.edu.au அல்லது (08) 89 46 74 90

மறுகூறு: mary.bushell@cdu.edu.au அல்லது (08) 89 46 74 90; பிள்ளையர் பதிவு செய்யும் நிலைகளைப் பதிவு செய்யும் செயல்பாடுகள். செயல்வாய்ந்த நிறுவனம்; Jessimine Bushell குழுப்பான் தளபதி: mary.bushell@cdu.edu.au அல்லது (08) 89 46 74 90; பதிவு செய்யும் செயல்பாடுகள். 

Patrick Ball, Waidyaratne
அமைதி.

தில்லியர் நூற்றாண்டு கட்டட விளக்கம் பிரதானக் குறிப்பிட்டுள்ளது சூட்டுவது நிலையாக விளக்கம், 1800 466 215, அமைதி நிலைத்து எதிர்காலம் ethics@cdu.edu.au என்று (08) 8346 6408, கல்விக்குழு

CDU மீது முற்பாக உரையாட்டு உரையாட்டு குறிப்பிட்டு அறிக்கை வழிபாடு பல்கலை. உரையாட்டு அறிக்கை வழிபாடு குறிப்பிட்டு பல்கலை முற்பாக அதிகாரிகள் வழிபாடு.

குறுக்கான விளக்கங்கள்: சீடம் கால்கா வண்ணம்
அண்டர்என்ஸ் முக்கியத்துவம் அறிக்கை அலைந்திட்
மண்டமுக்கியப்படுத்தும் ஒரு கிளை அன்பரிக்கு என்ன மற்றும் குறிப்பிட்டு வழிபாட்டு

நிலையாக தேசிய முற்பாக நூற்றாண்டு கட்டட விளக்கம்
சீடம் கால்கா வண்ணம் மற்றும் குறிப்பிட்டு வழிபாட்டு

சீடம் அறிக்கை வழிபாடு குறிப்பிட்டு வழிபாடு
சீடம் கால்கா வண்ணம் மற்றும் குறிப்பிட்டு வழிபாடு

CHANCE YOUR WORLD

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Appendix 8

Formal approval from Australian Ethics Committee
16 October 2014

Mary-Jessimine Bushell
School of Psychological and Clinical Sciences
Charles Darwin University
Darwin NT 0909

Dear Ms Bushell,

RE: H14067 – Undergraduate Vaccination Training Program for Pharmacy Students: Development and Validation

Human Research Ethics Committee - Project Application Approval

The Charles Darwin University Human Research Ethics Committee (HREC) considered your application for ethics clearance for the abovementioned project out of session.

The HREC has approved this application.

Please find attached a notice of clearance.

The expiry date of ethics approval for your project is 16/10/2015. It is the responsibility of the researcher to ensure that ethics approval is renewed prior to the expiry date. If renewal is necessary, you will need to submit a progress report including a statement of compliance with ethical requirements and details of any proposed or actual changes to the project that may affect its ethical acceptability. Renewal/Final Report forms are available from the Web at: http://www.cdu.edu.au/research/ori/human-ethics

If any significant alterations to your project are contemplated, or if any matters arise which may conceivably affect the continued ethical acceptability of the project, you are required to immediately notify the Human Research Ethics Committee by letter or email.

Our best wishes for the success of your project.

Yours sincerely

Dr Bev Turnbull
Chair, Human Research Ethics Committee
NEW PROPOSAL

HREC REFERENCE: H14067

PROJECT TITLE: Undergraduate Vaccination Training Program for Pharmacy Students: Development and Validation

CHIEF INVESTIGATOR(S): Mary-Jessimine Bushell

The Charles Darwin University Human Research Ethics Committee has considered your project.

The Committee is satisfied that the research proposed in this project conforms with the general principles set out in the current National Health and Medical Research Council regulations, and with the policy of the Charles Darwin University.

It should be noted that data must be stored securely on campus. Storage in a central facility [with limited access if necessary] is available. Researchers should address any queries concerning data storage to their relevant Faculty.

Expiry date: 16th October 2015

Please Note:

- Ethical Clearance is provided for a period of one year.
- A Final Report is due on completion of this project.
- A renewal must be submitted before the expiry date if the project is to continue.
- Any requests to vary the project should be submitted in writing.
- The HREC is unable to provide retrospective approval. Approval is granted from the date on this notice only.

APPROVED

Chair,
CDU Human Research Ethics Committee

Dated
Appendix 9

Formal approval from Sri Lankan Ethics Committee
19/02/2015

Ms. Mary-Jessimine Bushell,
Pharmacy Discipline,
School of Psychological and Clinical Sciences,
Faculty of Engineering, Health, Science and Environment,
Charles Darwin University, Casuarina Campus, Darwin.

Dear Ms. Bushell,

Reference number : 26/02/2015: 3.13

Undergraduate Vaccination Training Program for Pharmacy students: Development and Validation. Mary-Jessimine Bushell, Prof. P Ball, Dr H Morrissey, Dr E Waidyaratne

I am pleased to inform that the Ethical Review Committee having reviewed the proposal granted ethical approval for the study.

Yours sincerely,

[Signature]

Chairperson
Ethical Review Committee
Faculty Of Medicine
University Of Ruhuna
Galle, Sri Lanka

Copies : Secretary, ERC
Appendix 10

Media Release Professional Awareness
Pharmacy Practice and Research

MEDIA RELEASE: EMBARGOED until 12 am AEDT Tuesday 10 March 2015

Pharmacists: prepare to manage vaccine-associated anaphylaxis

Pharmacists who inject vaccines must be prepared to give adrenaline using an auto-injector if a patient suffers the extremely rare side effect of anaphylaxis, say researchers. This advice comes as pharmacists across Australia will soon be administering vaccines to patients, depending on state legislation.

Using an auto-injector differs from advice in the Australian Immunisation Handbook, which recommends using adrenaline ampoules and measuring the dose with a syringe.

"Auto-injectors are easy to use and allow rapid, sterile administration of adrenaline without removal of clothing. We believe this is faster and has less potential for error than drawing from ampoules. We will still support training people in the use of both," explained Mary Bushell.

Using adrenaline auto-injectors is just one of the recommendations made by Ms Bushell and her colleague Professor Patrick Ball from Charles Darwin University, who researched the current evidence for treating anaphylaxis and published their recommendations in the latest issue of the Journal of Pharmacy Practice and Research.

One of the Australian Medical Association's strongest objections to pharmacists giving vaccinations is pharmacists will not be able to manage life-threatening anaphylaxis.

Ms Bushell explains, "If pharmacists—who are required to also have current certification in first-aid, including CPR—have completed approved vaccination training, Australian Society of Clinical Immunology and Allergy (ASCIA) training and demonstrated competency using both adrenaline auto-injectors, and administering adrenaline by needle and syringe, they are as prepared as any other health professional to provide immediate emergency management of anaphylaxis within the community pharmacy setting. Pharmacists are trained to ensure appropriate follow up and referral.

"Vaccination in pharmacies has been safe, effective and successful in increasing vaccination coverage in a number of other countries. Universities throughout Australia are embedding undergraduate injection skills and emergency management training into undergraduate training. All health professionals must demonstrate and maintain competency. Pharmacists are no different in this."

Other recommendations in the paper:
- Screen for people at a higher risk of anaphylaxis—if at risk don’t give, refer to a setting with resuscitation facilities.
- Have an anaphylaxis kit.
- If anaphylaxis is suspected, give adrenaline using an auto-injector
- Undergo appropriate anaphylaxis training.
- Have a written emergency protocol.
- Report adverse events.
- Observe the patient for at least 15 minutes after vaccination.

More information
Dr Chris Alderman +61 3 9486 0177 jppr@shpa.org.au
Appendix 11

CPD activity for registered pharmacists

Learning objectives:
1. Discuss some of the current trends regarding immunization and its uptake in Australia.
2. Describe factors that may impact on the case for pharmacist administered vaccinations in Australia.

Pharmacist competency standards* addressed include:
Standard 6.3 Contribute to public and preventative health.
Standard 7.3 Influence patterns of medicine use.

*National competency standards framework for pharmacists in Australia, 2010

Accreditation: This activity has been accredited for 1 hour of Group 2 CPD (or 2 CPD credits) suitable for inclusion in a pharmacist’s CPD plan (if self-assessment questions are completed after reading the journal article).

Accreditation Number: 2014/13

Questions:

Q1. According to data collated by Medicare local catchment areas, the percentage of 5 year old Aboriginal and Torres Strait Islander children fully immunized is:

a) 65-70%

b) 70-95%

c) 85-94%

d) <85%

Answer: b
Rationale: See "Trends in Immunization"
Appendix 12

Certificate of Achievement for Mary Bushell

*Pharmacy-Based Immunisation Delivery*
Certificate of Achievement

This acknowledges that

Mary Bushell

has successfully completed Pharmacy-Based Immunization Delivery,
a 20 hour, national certificate training program for pharmacists providing
comprehensive immunization education and training.

11/7/2014

Thomas E. Menighan, BPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO
American Pharmacists Association

Shelby Engleit, Senior Director of Education
American Pharmacists Association

This Certificate of Achievement is invalid unless accompanied by written proof of current certification
In Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS)
Appendix 13

Electronic Link to Publications

Chapter 2


Chapter 3


Chapter 4


Chapter 6


Chapter 7