



Queensland University of Technology
Brisbane Australia

This is the author's version of a work that was submitted/accepted for publication in the following source:

[Nissen, Lisa](#), Glass, Beverley, [Lau, Esther](#), & Rosenthal, Michelle
(2015)

Queensland pharmacist immunisation pilot phase 1 pharmacist vaccination - Influenza final report.

This file was downloaded from: <http://eprints.qut.edu.au/91903/>

© Copyright 2015 The Author(s)

Notice: *Changes introduced as a result of publishing processes such as copy-editing and formatting may not be reflected in this document. For a definitive version of this work, please refer to the published source:*

Queensland Pharmacist Immunisation Pilot

Phase 1

Pharmacist Vaccination - Influenza

Final Report



Prepared by Professor Lisa Nissen and Professor Beverley Glass

Assisted by Dr Esther Lau and Ms Michelle Rosenthal



Acknowledgements

We wish to acknowledge the input and support for the Queensland Pharmacist Immunisation Pilot (QPIP) from the steering committee representatives listed below and the collaboration between the Queensland Branches of the Pharmaceutical Society of Australia (PSA) and the Pharmacy Guild of Australia (PGA), which has made the pilot possible.

We would also like to acknowledge and thank the 157 individual pharmacists and 80 pharmacies across Queensland who have blazed a trail for the rest of the pharmacy profession in Australia by participating in this ground-breaking pilot.

We would also like to thank the Honourable Lawrence Springborg, Opposition Leader, then Minister for Health Queensland, and the Chief Health Officer, Dr Jeannette Young for their unwavering support for Queensland pharmacists, recognising the contribution they can make to preventative care in the wider community through this type of professional service provision.

Financial support for Pilot

We wish to acknowledge the generous support for the QPIP pilot implementation from the Queensland Branches of the PSA and PGA who provided financial support for a part-time research assistant at Queensland University of Technology and James Cook University respectively for the duration of the pilot.

Queensland Pharmacists Immunisation Pilot (QPIP) Steering Committee

- Prof Lisa Nissen – Queensland University of Technology and Pharmaceutical Society of Australia, QLD Branch (Chair)
- Mr Tim Logan – Pharmacy Guild of Australia, QLD Branch
- Ms Nicole Floyd – Pharmacy Guild of Australia, QLD Branch
- Dr Chris Freeman – Pharmaceutical Society of Australia, QLD Branch
- Ms Michelle Rosenthal – Pharmaceutical Society of Australia, QLD Branch
- Mr Chris Campbell – Terry White Management
- Mr Gilbert Yeates – Pharmaceutical Defence Limited, QLD Director
- Mr Brett Simmonds – Pharmacy Board of Australia, QLD Director
- Prof Beverley Glass – James Cook University
- Dr Stephen Lambert – Queensland Department of Health
- Dr Susan Ballantyne – Queensland Department of Health
- Mr Bill Loveday – Queensland Department of Health

Acknowledgement

The QPIP steering committee would also like to thank Ms Megan DeIDot for her time and contribution to the development of the training modules and Mr Damian Gray for his assistance in implementation of the training program. Also thanks to Ms Lynda Cardiff and Mr Aaron Drovandi for their contribution as research assistants at Queensland University of Technology and James Cook University respectively.

Table of Contents

1. Executive Summary.....	6
2. Background	7
3. Governance.....	9
4. Protocol Design.....	9
5. Data Collection.....	11
6. Constraints.....	12
7. Vaccination Training and Credential for Pharmacists.....	14
8. Results and Evaluation.....	19
(i) QPIP1 Sites	19
(ii) Who was vaccinated?.....	20
(iii) When were they vaccinated?.....	21
(iv) Were there any problems with the vaccinations?	23
(v) What did they think of pharmacist vaccination?	25
(vi) Facilities.....	28
9. Pilot Protocol	29
10. Appendices	36

Table of Appendices

Appendix 1	Anaphylaxis Management - Example
Appendix 2	Initial Anaphylaxis Response Management - Example
Appendix 3	Pharmacist Administered Vaccination Equipment Checklist
Appendix 4	Patient Pre-vaccination Checklist for Pharmacist – Influenza (Example)
Appendix 5	Patient Consent - GuildCare Screenshot
Appendix 6	Vaccination Recording Service Report - GuildCare Screenshot
Appendix 7	Frequently Asked Questions - GuildCare Screenshot
Appendix 8	Sample GP Notification - GuildCare Screenshot
Appendix 9	Patient Record of Immunisation - GuildCare Screenshot
Appendix 10	Customer satisfaction questionnaire
Appendix 11	Post-immunisation follow-up Survey
Appendix 12	Adult Vaccines available for administration by route (refer to CMI)
Appendix 13	QPIP Pharmacist consent
Appendix 14	QPIP Pharmacy consent
Appendix 15	QPIP Patient consent
Appendix 16	Pharmacists Role in Patient Journey
Appendix 17	Patients Journey
Appendix 18	Clinical Champions Role in the Patients Journey
Appendix 19	QUT Human Ethics Approval for QPIP
Appendix 20	Section 18(1) Approval for QPIP
Appendix 21	QPIP 1 Approved Site List
Appendix 22	Approved Pilot Site Certificate - Example

1. Executive Summary

The results of the pilot demonstrated that a pharmacist delivered vaccinations services is feasible in community pharmacy and is safe and effective. The accessibility of the pharmacist across the influenza season provided the opportunity for more people to be vaccinated, particularly those who had never received an influenza vaccine before.

Patient satisfaction was extremely high with nearly all patients happy to recommend the service and to return again next year. Factors critical to the success of the service were:

1. Appropriate facilities
2. Competent pharmacists
3. Practice and decision support tools
4. In-store implementation support

We demonstrated in the pilot that vaccination recipients preferred a private consultation area. As the level of privacy afforded to the patients increased (private room vs. booth), so did the numbers of patients vaccinated. We would therefore recommend that the minimum standard of a private consultation room or closed-in booth, with adequate space for multiple chairs and a work / consultation table be considered for provision of any vaccination services. The booth or consultation room should be used exclusively for delivering patient services and should not contain other general office equipment, nor be used as storage for stock.

The pilot also demonstrated that a pharmacist-specific training program produced competent and confident vaccinators and that this program can be used to retrofit the profession with these skills. As vaccination is within the scope of pharmacist practice as defined by the Pharmacy Board of Australia, there is potential for the universities to train their undergraduates with this skill and provide a pharmacist vaccination workforce in the near future. It is therefore essential to explore appropriate changes to the legislation to facilitate pharmacists' practice in this area.

Given the level of pharmacology and medicines knowledge of pharmacists, combined with their new competency of providing vaccinations through administering injections, it is reasonable to explore additional vaccines that pharmacists could administer in the

community setting. At the time of writing, QPIP has already expanded into Phase 2, to explore pharmacists vaccinating for whooping cough and measles. Looking at the international experience of pharmacist delivered vaccination, we would recommend considering expansion to other vaccinations in the future including travel vaccinations, HPV and selected vaccinations to those under the age of 18 years.

Overall the results of the QPIP implementation have demonstrated that an appropriately trained pharmacist can deliver safely and effectively influenza vaccinations to adult patients in the community. The QPIP showed the value that the accessibility of pharmacists brings to public health outcomes through improved access to vaccinations and the ability to increase immunisation rates in the general population. Over time with the expansion of pharmacist vaccination services this will help to achieve more effective herd immunity for some of the many diseases which currently have suboptimal immunisation rates.

2. Background

Suboptimal uptake of vaccinations is an ongoing global issue. Pharmacist delivered vaccinations in the community setting have become part of the solution in the United Kingdom, United States, Canada, Portugal and most recently New Zealand. Some of these countries have seen pharmacists administering vaccines for over a decade. The type of vaccines delivered varies by country, but includes influenza, travel vaccinations, HPV, measles and whooping cough. Pharmacists may develop their competency to deliver vaccinations and provide immunisation services through either their undergraduate qualification, or undertake pharmacist specific training programs designed specifically to retrofit the profession in each country.

Within the Australian context there have been several key barriers to pharmacists providing immunisation services:

1. Lack of legislative framework
2. Competency gaps
3. Attitudes of other health professionals

Community pharmacies across Australia have started providing immunisation services through the delivery of a Nurse-Immuniser model. This model limits pharmacies to able to providing one day or variable short sessions across an entire influenza season. This restricted access to the service in the community and provided limited options for spontaneous or opportunistic vaccination.

Early 2013 saw the release of the Pharmaceutical Society of Australia Guidelines for the provision of immunisation services in community pharmacy, covering the current Australian standard of care, being the Nurse-Immuniser model. Given that pharmacist immunisation is standard practice in other western countries the Pharmacy Guild of Australia (Qld) and Pharmaceutical Society of Australia (Qld) continued to raise the possibility with the Government the amendments to legislation could be made that would allow Australian pharmacists, initially in Queensland in this case, to offer this service. Similar conversations were had in jurisdictions around Australia by the professional organisations.

Leading into 2013, there were record numbers of influenza cases and several measles outbreaks across the country. The Grattan Institute report on Australia's health workforce, released in September 2013, identified the possibility of expanding the scope for pharmacists' practice to include vaccination to assist in alleviating the shortfall in services in rural areas. This was seen as a potentially valuable addition to the preventative healthcare mix.

Late September 2013 saw a communication from the Chief Health Officer of the Queensland Department of Health, Dr Jeanette Young, received by the Presidents of the Qld Branches of Pharmaceutical Society of Australia and Pharmacy Guild of Australia. She invited the organisations to consider the possibility of a trial of pharmacist-administered influenza vaccinations in community pharmacy. This trial was to be targeted at consumers not covered under the National Immunisation Program (NIP), with appropriate evaluation on safety, feasibility, training, infrastructure and governance. This was the genesis of Qld Pharmacist Immunisation Pilot (QPIP) for influenza.

3. Governance

The Governance of the pilot was discussed at the outset between the Presidents of the Pharmaceutical Society of Australia (Qld) and Pharmacy Guild of Australia (Qld) Branches, and representatives from the Department of Health. It was considered crucial that all key stakeholders were involved to provide input into both the design and implementation of the pilot. It was also considered important for the credibility of the data produced, that the academic community should take the lead in the research design of the pilot. The professional organisations provided a small amount of funding and other resources needed to assist the universities with the implementation of the pilot and analysis of the data.

A steering committee of key stakeholders (membership noted in acknowledgements) was formed and invitations were sent, with the first meeting held in November 2013. Prof Lisa Nissen was nominated as Chair of the Steering Committee in her role as Professor and Head of Clinical Sciences, Queensland University of Technology (QUT), supported academically by Prof Beverley Glass, Chair of Pharmacy, James Cook University (JCU).

James Cook University was chosen as the academic partner as it is the seat of Rural Pharmacy education and their expertise would be valuable for the design focus on rural and regional access.

4. Protocol Design

Phase 1 of QPIP (QPIP1) was designed to evaluate in an Australian context, the international experience that vaccination by pharmacists in a community pharmacy setting was not only feasible, but also safe and acceptable to the general public. The evaluation of the QPIP was approved by QUT's Human Research Ethics Committee (Appendix 19).

The protocol sought to address the following questions:

1. Are pharmacists as immunisers, as effective as the current standard of care in community pharmacy (i.e. nurse-immunisers)?
2. Does previous delivery of immunisation services by nurse immunisers make any difference to the implementation of pharmacist vaccination?

3. Is there a difference in the delivery of the service between metropolitan areas and regional or rural settings?
4. Are there any barriers to change from the Nurse-Immuniser model to that of a Pharmacist-lead model for delivering vaccinations in community pharmacy?

In QPIP1, pharmacies were purposively recruited to target specific criteria to ensure the data needed to address the study questions could be obtained. To facilitate this, the QPIP1 pilot was divided into two arms.

Arm one allowed for a comparison of an existing model of service delivery in community pharmacy, namely nurse immunisers, against the pilot model of pharmacist immunisers. For this arm, the research team worked with the Terry White Chemist group (TWC) to leverage from their established in-pharmacy nurse immunisation program to collect data from pharmacist immunisers in their pharmacies in the South-East Qld (SEQ) sector. In 2013, TWC collected patient evaluation data of their nurse-delivered service. This provided the baseline information about the in-pharmacy service and the acceptability of nurse-immunisers. Arm one will be referred to as the 'SEQ arm' hereafter.

This also provided an opportunity to utilize approximately 50 TWC pharmacies in SEQ who had previously used this nurse-delivered service as sites in QPIP1. This essentially provided pump-primed sites that were familiar with the processes and requirements for an immunisation service. The difference would be that a pharmacist was now administering the vaccination. Thus, in comparing the patient feedback it would be possible to evaluate if pharmacists performed as well as the nurse vaccinators.

The second arm was designed to evaluate barriers and facilitators to implementation of the pilot model of a pharmacist administered immunisation service, particularly in regional and rural areas. For the second arm, an expression of interest (EOI) was called for across North Qld (NQ) - North of the Tropic of Capricorn, for pharmacies that had **not** previously hosted an in-pharmacy immunisation service. The EOIs were circulated through the branch memberships of PGA-Qld and PSA-Qld. The aim was to recruit approximately 50 sites giving a total pilot number of approximately 100 pharmacies. Arm two will be referred to as the 'NQ arm' hereafter.

The SEQ and NQ arms both evaluated safety, adverse drug reactions (ADRs), patient satisfaction and improvements in vaccination access (Section 1 – Pilot Protocol, and Appendix 1-18). Pharmacies and pharmacist from both arms were required to meet the inclusion criteria listed below:-

Inclusion Criteria for QPIP1: Individual pharmacists:

- Registered Pharmacist with Pharmacy Board of Australia (NOT INTERN)
- Undergone appropriate immunisation training
 - Provided by PSA-Qld for the QPIP trial
- Current First Aid Certificate, and cardio pulmonary resuscitation (CPR) certification
- Appropriate professional indemnity cover for immunisation scope of practice

Inclusion Criteria for QPIP1: Pharmacies:

- Authorised pharmacy premise (immunisation to occur only in QPIP approved site)
- QCPP (Quality Care Pharmacy Program) accredited pharmacy
- Access to GuildCare® software
- Appropriate indemnity cover for the business for immunisation scope of practice
- A least TWO pharmacists on duty when immunisation is being provided
- Appropriate facilities to host immunisation (ADR management, infection control, privacy)

5. Data Collection

It was anticipated there would be over 10,000 vaccinations provided during the course of the pilot. Community pharmacy is a busy environment and it was thus necessary to provide data collection tools to assist the pharmacists in delivering their service, whilst not imposing a constraint that would make the service cumbersome and unworkable.

The GuildCare® proprietary software had an existing module for the delivery of a nurse immunisation service in community pharmacy. This software also had the capacity for its data to be interrogated from the back end and be de-identified. Given the time constraints,

it was decided the pilot would use an adapted version of the existing proprietary software, which would contain a module that supported pharmacist delivered vaccination services. The software would also form a patient record and decision support tool for the pharmacist. Prof Lisa Nissen (QUT) and Mr Chris Campbell (TWC) assisted in with modification to the module to combine it with the documentation and data required in the QPIP protocol. However, not all data collection could be automated and patient satisfaction surveys and 7-day follow up surveys were required to be completed manually.

6. Constraints

(i) Legislative Framework

Influenza vaccines are a Schedule 4 'Prescription Only' medicine and so supply would normally be upon presentation of a prescription from an authorized person, which did not include pharmacists at the time of the pilot. In addition, pharmacists are not able to "administer" medications other than methadone via controlled means.

To enable a pharmacist to provide influenza vaccinations, an application under Section 18 of the Health Drugs and Poisons Regulation was submitted in December 2013 to the Office of the Chief Health Officer. The approval was granted for pharmacists to "supply and administer influenza" vaccinations according to the QPIP1 protocol (Section 1 - Plot Protocol, and Appendix 1-18). This allowed pharmacists who completed QPIP training to provide and administer influenza vaccinations only at an approved QPIP site (Appendix 20).

(ii) Competency gaps and training

A factor critical to the success of the pilot was ensuring pharmacists participating in the pilot were competent in providing vaccinations. The Pharmacy Board of Australia (PBA) had recently mapped the competencies for pharmacists with those of nurse immunisers, and identified there was significant overlap. The competency gaps identified were required to be addressed by the training programs, with the addition of the key competency; administration of injections. The result of the mapping reflected the existing knowledge pharmacists possessed in medication management, including vaccination administration, the declining patient and cold chain considerations.

Given the need for a tailored training program to address pharmacist-specific competency gaps and the short timeline for implementation of the pilot, the decision was made to consult Canadian colleagues who have been training pharmacists for the administration of injections, including vaccinations for many years. The Alberta Pharmacists Association's "Administering Injection and Immunisation Preparation Course" was used as a basis for the development of an Australianised training program for QPIP1 pharmacists.

This course has a proven track record in retrofitting the profession for this new service, and providing the relevant and specific competencies required by currently practicing pharmacists. This training course was to provide registered pharmacists in Qld who met the pre-requisite requirements, with the knowledge, skills and competencies to establish and deliver a successful immunisation service in community pharmacy, including administration of injections. The Pharmaceutical Society of Australia (Qld) Branch facilitated the design, development and implementation of the pharmacist training for QPIP1.

(iii) Attitudes of other Health Professionals

There was opposition to the concept of pharmacists vaccinating expressed in the media by various medical organizations, though this was not unexpected given our previous experiences with health practitioner scope of practice expansion. However, within the context of QPIP1, there was a significant impact on the implementation from the aggressive and relentless campaign run by the "Revive" nurse clinic group from Western Australia who sought to have the QPIP stopped. Revive are a private company who supplied nurse immunisation services to pharmacies and other workplaces. The steering committee and research team were surprised that opposition had come from this part of the sector, but understood that the existing business model provided for pharmacy of nurse-delivered services was now being challenged.

(iv) Timing

A start date of 1 April 2014 was selected to ensure the general public had adequate access to influenza vaccinations in time for the 2014 influenza season. We acknowledge that starting earlier may have allowed pharmacists to catch the first part of the season. However, the April 1st date still only provided a lead time of six months to design the pilot, obtain regulatory approvals, obtain ethics approval, recruit pharmacies, design, write and deliver

training for over 150 pharmacists, and design practice support tools for use in community pharmacy. The successful launch on April 1st was the result of all organisations and stakeholders striving to achieve a common goal and the hard work of all those involved in the implementation stage.

7. Vaccination Training and Credential for Pharmacists

Vaccination training and credentialing for pharmacists was provided by PSA-Qld. Through consultation with the steering group, it was decided that pharmacists should receive a “credential” to participate in QPIP1, and be authorized to vaccinate under the Section 18 approval. The training was one part of this credential, as a current First Aid certificate, Australasian Society of Clinical Immunology and Allergy (ASCIA) training and being a registered pharmacist provided the pre-requisite background to which the newly trained competencies could be added.

An outline of the credential developed, the training and evaluation that PSA-Qld Branch delivered to QPIP1 participants, and pharmacist satisfaction and evaluation of the training is described below:-

(i) Components of the QPIP1 Credential

To obtain the FINAL credential, participants were required to:-

- Be a registered pharmacist with the Pharmacy Board of Australia
- Hold a current certificate in HLTAID003 Provide First Aid or HLTF311A Apply First Aid
- Hold a current certificate in HLTAID001 Provide Cardiopulmonary Resuscitation or HLTCPR211A Perform CPR
- Hold a current certificate in the ASCIA anaphylaxis e-training for pharmacists or health professionals (ASCIA)
- ***Successfully complete the pre-reading module 1 and module 2 and achieve a pass mark of 80% on the multiple-choice questions (PSA-Qld)***
- ***Successfully complete the face-to-face workshop assessment (PSA-Qld)***

A Certificate of Credential was only issued once all the components were completed and PSA staff or the QPIP Research Assistant sighted the First Aid, CPR and ASCIA training certificates. As the duration of the pilot was to be for the 2014 influenza season, the credential for each pharmacist was given an initial expiry date of 31 October 2014. This had the possibility to be renewed in the event of legislative change or extension of the pilot and on confirmation of the required training standards for pharmacists by the Australian Pharmacy Council.

(ii) The Training Course

The training part of the credential was delivered in two sections. The first section provided a knowledge update on diseases and vaccines, and covered practical considerations of implementing the service in a community pharmacy. This was delivered through an online module. The second section provided the new practical skills required, and reviewed the management of the declining patient through active role-plays simulating a community pharmacy setting.

a) Section ONE – Pre-study online (13 Group 2 CPD Credits)

The Pre-Study included reading material (Module 1 and Module 2) and a multiple-choice test. To successfully complete the Pre-Study, participants had to achieve at least 80% on the multiple-choice test. The learning objectives of the Pre-Study were:-

Module One – Diseases and Vaccines

1. Discuss immunisation and the public health benefits
2. Discuss immunity including the different immune responses
3. Identify the different vaccine constituents
4. Describe the classification and types of vaccines, including their spacing, dosing and timing and the onset and duration of immunity
5. Review Australia's immunisation strategy and the epidemiology of vaccine preventable disease in Australia
6. Discuss the key organisations and resources in immunisation in Australia, including The Australian Immunisation Handbook
7. Discuss the NIP schedule and its impact on vaccine preventable disease in Australia

8. Discuss the myths and realities associated with immunisation

Module Two – Practical Considerations

1. Discuss the role of the pharmacist in immunisation
2. Explain the principles and procedures for vaccine procurement, storage, and handling, including cold chain breaches
3. Identify workplace health and safety issues, including hand hygiene, the handling and disposal of sharps and the prevention and management of needle stick injuries.
4. Recognise the importance of consumer consent, confidentiality and privacy
5. Describe a system for an immunisation service in a community pharmacy including administering vaccines and documentation requirements
6. Discuss the different methods of administration of vaccines and recommended injection sites
7. Recognise the importance of consumer aftercare including the provision of vaccination statements and reporting to immunisation registers
8. Explain the procedures for medication error and ADR reporting including, anaphylaxis diagnosis and management

b) Section TWO – Workshop (7 Group 2 CPD Credits)

The Workshop included theory, discussion, demonstration, guided practice, and assessment in relation to delivering immunisation *via* injections. Before attending the face-to-face workshop participants were required to:-

- Hold a current certificate in the ASCIA anaphylaxis e-training for pharmacists or health professionals (ASCIA)
 - Successfully complete the pre-reading Module 1 and Module 2 and achieve a pass mark of 80% on the multiple choice questions
1. The learning objectives of the Workshop were:-Describe the structure and assessment requirements of QPIP
 2. Describe the legal framework that the pilot is operating within and your role as a pharmacist and immunisation provider during the pilot
 3. Identify the importance of valid consumer consent, privacy and confidentiality

4. Identify, report and manage medication errors and adverse events following immunisation
5. Describe the process of identifying and treating emergencies such as anaphylaxis:
 - a. *Policies*
 - b. *Procedures*
 - c. *Equipment*
6. Demonstrate how to prepare the necessary equipment to vaccinate a consumer, including the application of infection control methods
7. Demonstrate how to withdraw medication from an ampoule and a vial
8. Demonstrate the skill of injections:
 - a. *Discuss preparation of medications for intradermal, subcutaneous and intramuscular injections*
 - b. *Discuss how to evaluate potential injection sites*
 - c. *Demonstrate the location of appropriate sites for subcutaneous, and intramuscular injections*
 - d. *Describe differences in technique in giving subcutaneous and intramuscular injections*
9. Discuss ways to decrease patient anxiety/discomfort related to injections

(iii) Practical Evaluation

To successfully complete the Workshop and receive a Certificate of Completion and Continuing Professional Development (CPD) credits, a workshop participant under supervision of a credentialed nurse immuniser was required to:-

1. Correctly demonstrate preparation of a medication from a vial and an ampoule
2. Work in pairs and correctly administer one subcutaneous injection (locate site and inject into each other) and record the administration
3. Work in pairs and correctly administer one intramuscular injection into the deltoid muscle (locate site and inject into each other) and record the administration.

(iv) Training satisfaction and evaluation

A total of 157 pharmacists completed the QPIP1 credential through 14 face-to-face training sessions across Qld. Following the training, participants were asked to complete a questionnaire that considered aspects of the pre-workshop preparation (online modules), and the face-to-face workshop component of the training. In particular, participants were asked how the training mapped to the learning objectives provided and how it developed their confidence to inject / immunise patients following the course.

A total of 154 evaluations were received. A 5-point Likert scale was used in the evaluation questionnaire. The Likert-scale for questions 1-5 had the anchors 'not at all' to 'entirely', and questions 6 -11 used the anchors 'poor' to 'excellent'. Overall the participants were satisfied with the training, and commented that the pre-reading and face-to-face modules met their expectations and was relevant to their practice (Figure 1). When asked "Now that you have completed all elements of the QPIP credential, what is your level of confidence to administer injections to patients?" participants responded positively, rating their confidence as 'very good' to 'excellent'.

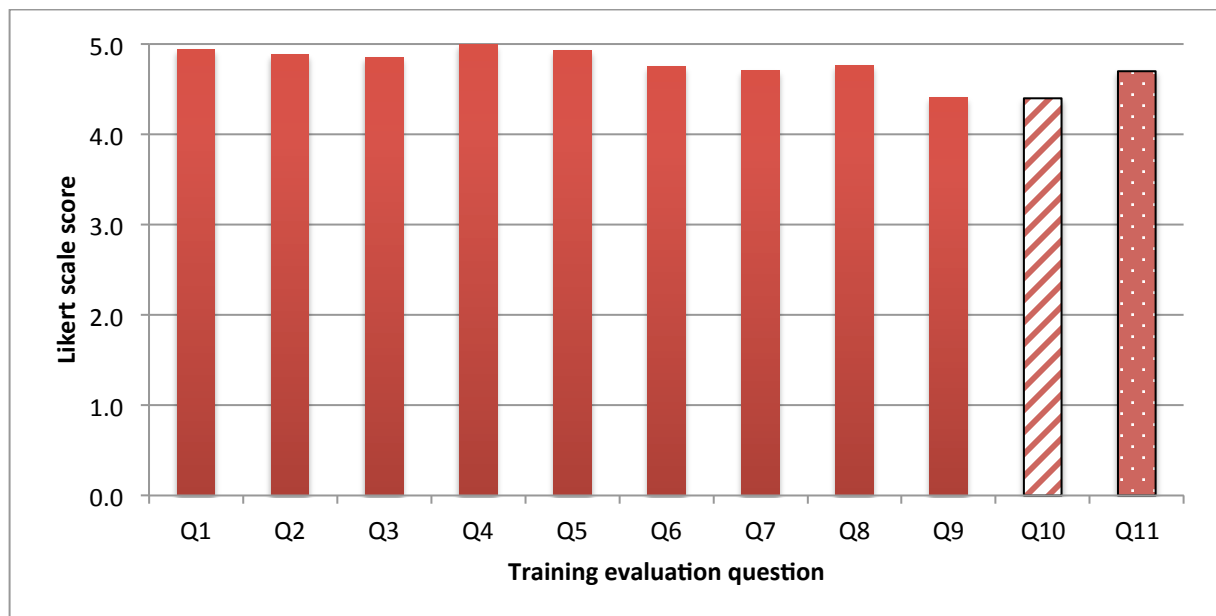


Figure 1. Likert scale scores from training evaluation questions (n=154/157). The anchors were 1 = not at all, to 5 = entirely (Q1-5); and 1 = poor, to 5 = excellent (Q6-11).

Legend:

Q1	To What extent were the learning objectives for the pre-reading modules met?
Q2	To what degree were the pre-reading modules relevant to your practice?
Q3	Rate your overall satisfaction with the content of the pre-reading modules?
Q4	To what extent were the learning objectives for the practical training met?
Q5	To what degree was the practical training relevant to your practice?
Q6	Rate your satisfaction with the anaphylaxis and adverse event section of the practical training?
Q7	Rate your satisfaction with the patient management section of the practical training?
Q8	How did you find the style of the interactive parts of the practical training?
Q9	What was your level of comfort with giving and receiving injections during the practical training?
Q10	Now that you have completed all elements of the QPIP credential, what is your level of confidence to administer injections to patients?
Q11	Considering both the pre-reading and the practical training as a whole, what is your overall satisfaction with the training program for the QPIP credential?

It was also important to note that while participants were initially apprehensive about giving and receiving injections during the training they were aware that this was a critical component of the workshop. They commented that although having even more practice under controlled conditions in the course would always be good, they felt their level of confidence was still high even without more practice (Figure 1). The trainers also noted that through injecting each other, the participants visibly gained self-confidence in their ability to perform their new skill and left the training excited and eager to begin.

8. Results and Evaluation

(i) **QPIP1 Sites**

A total of 80 pharmacies participated in QPIP1, 51 TWC pharmacies in the SEQ arm and 29 in the NQ arm (Appendix 21). All sites were required to display their site certificate (Appendix 22). The recruitment of NQ sites was limited by the need to have two registered pharmacists on duty when vaccinating, and issues around relationships with local general practitioners (GP).

Pharmacy locations and type ranged from shopping centre and medical centre pharmacies to suburban strip pharmacies. The mix included banner group and independently operated premises. The top three pharmacies per volume of vaccinations provided in QPIP1 was TWC

Clifford Gardens (n = 705), TWC Myer Centre (n = 430), and TWC Brookside (n = 383). The key point of difference to note is that Clifford Gardens is a regional site (Toowoomba), Myer Centre is a metropolitan site in the Brisbane CBD, and Brookside is in a suburban shopping centre in the outer Brisbane suburbs. This highlights the value the diversity community pharmacy locations provided in providing access for consumers to vaccination services.

The average number of vaccinations delivered per store was 194 and 34 in the SEQ and NQ arms respectively. This suggested that the previous experience with immunisation services by nurse immunisers in the SEQ arm might have enabled them to implement the pharmacist immunisation service faster. Anecdotally this has been reported by the smaller NQ pharmacies. However, further evaluations of sites are required to determine more specific barriers and facilitators to implementation of the pharmacist immunisation service, and to determine if this was the case across all pharmacies.

(ii) **Who was vaccinated?**

There were 10,889 vaccinations delivered in the pilot. More females than males were vaccinated with 63% of vaccinations administered to females and 37% to males. The largest age group vaccinated was the 45 – 65 year group with a mean age of 49 years (Figure 2). It was noteworthy that 10% of people overall were eligible for free vaccines under the NIP, but still elected to have their influenza vaccine in the community pharmacy, despite being offered referral to their GPs.

Approximately half of the patients had been vaccinated in the previous year. Almost 15% had **never** received an influenza vaccination before, and approximately one-third of the patients had previously received an influenza vaccination, but did not get the vaccination every year, with some not having been vaccinated in over five years (Figure 3). There were no differences seen in any of the socio-demographic categories between regional/rural regions and metropolitan sites or SEQ and NQ.

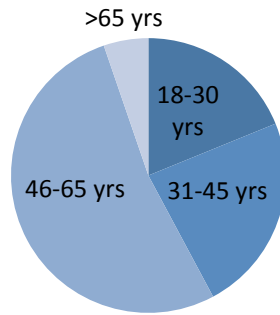


Figure 2. Age demographics of patients that received vaccinations from pharmacists in QPIP1.

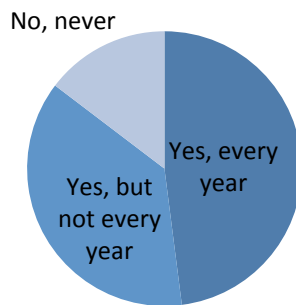


Figure 3. Patient's reported experience on whether they have received an influenza vaccine previously, and how frequently they were vaccinated against influenza.

(iii) When did the vaccinations take place?

In the pilot design, the SEQ arm featured TWC pharmacies that had previously provided a vaccination service in their pharmacy. TWC were experienced with an online booking system, and this provided an opportunity to capture booking data. From the TWC booking data, Tuesdays and Thursdays were the most popular day for appointments, followed closely by Wednesday, with an overall preference for midweek bookings (Figure 4). The most popular time was the morning, at 10:00 am, followed by 9:00 am and 11:00 am respectively (Figure 5).

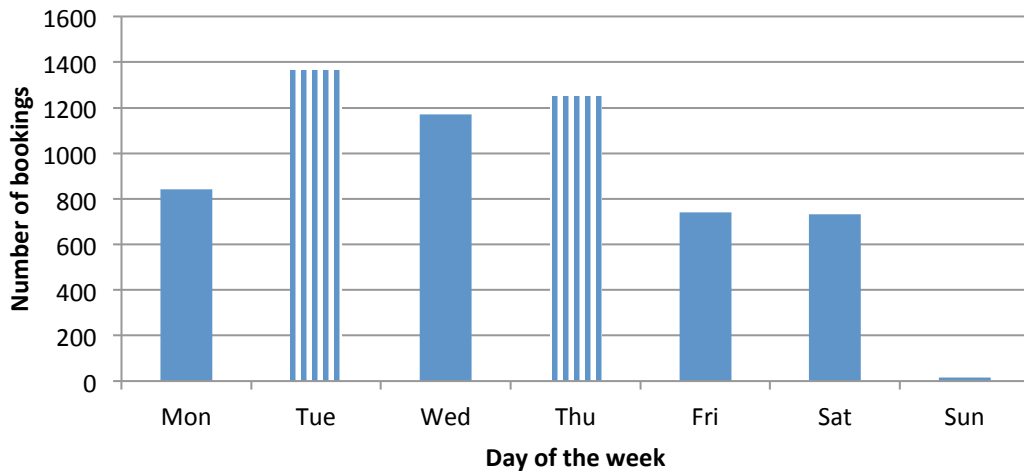


Figure 4. Terry White Chemist group online booking data, comparing the number of bookings with the day of the week the appointment was made for.

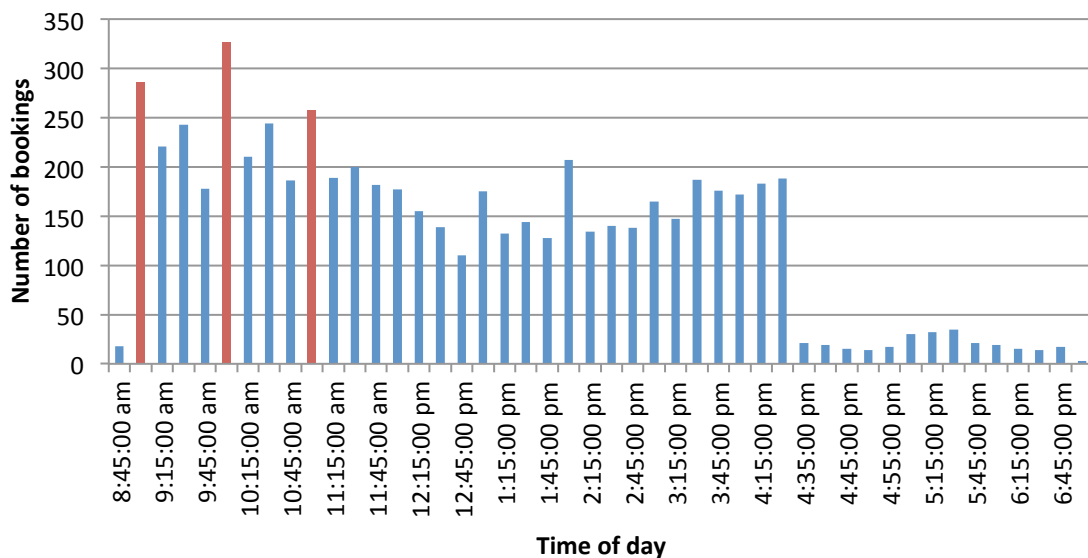


Figure 5. Terry White Chemist group online booking data, comparing the number of bookings with the time of day the appointment was made for.

There was a strong uptake of the service at the beginning of the pilot, with the peak being reached mid-June. The presence of a booking system with complementary advertising increased the penetration rates of vaccination. Nevertheless, approximately half of all the vaccinations delivered in TWC were generated in store with either a vaccine delivered on the spot (“walk in”), or with a prospective appointment made in store (Figure 6). As such,

the presence of an online booking system appeared to increase the efficiency of vaccine service delivery for the TWC group.

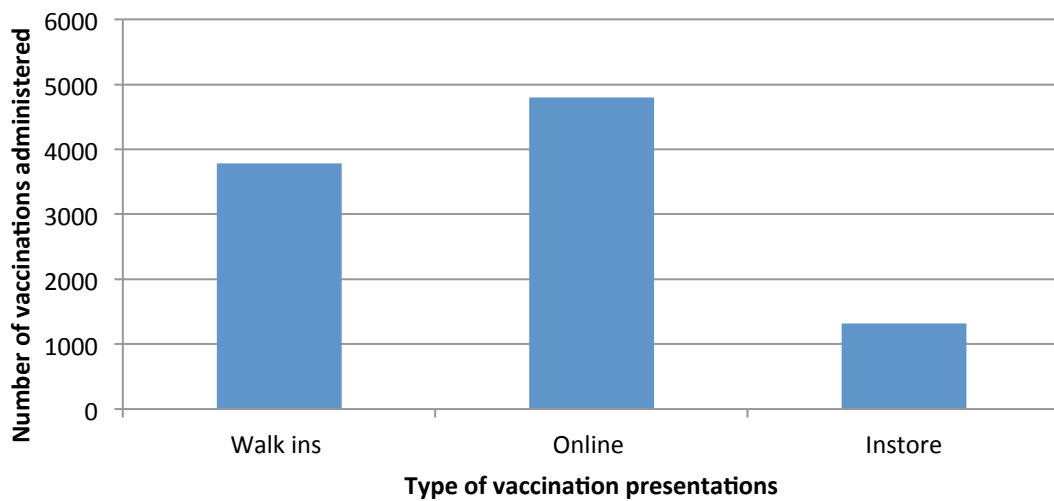


Figure 6. Comparison of the frequency in the way people presented for their influenza vaccination at the Terry White Chemist group, i.e. walk-ins where the vaccination was delivered ‘on the spot’, *versus* online bookings *versus* in store bookings.

(iv) Were there any problems with the vaccinations?

A selection of patients (target 10%) was followed-up one week post-vaccination to ascertain whether there were any adverse consequences to note from the QPIP service. The side effects reported in QPIP1 are consistent with those expected from the influenza vaccine (

Table 1). No serious adverse events were encountered in the pilot. There were a small number of vasovagal responses in-store, and the majority of these patients had already indicated to the pharmacist that this was a likely response prior to the vaccination. It was interesting to note that patients who had previously had an influenza vaccination reported a lower rate of adverse events than those who were first time recipients.

Table 1. Comparison of the reported adverse effects from influenza vaccine between people who had previously received an influenza vaccine, versus those who were ‘vaccine-naïve’.

Adverse Event	Received influenza vaccination before (%)	Not received influenza vaccination before (%)
	N=307	N=87
Pain at injection site	20.9	33.3
Redness at injection site	14.0	28.7
Itchiness at injection site	9.1	11.5
Skin infection at injection site	0.0	1.2
Shivering and/or chills	1.0	1.2
Nausea, vomiting, diarrhoea	0.3	1.2
Headache	4.2	4.6
Fever	1.3	3.5
Cough, running nose, sore throat	5.5	8.1
Muscle and/or joint pain	3.3	5.8
Excessive fatigue (more than normal)	1.3	2.3
Chest infection	0.3	0.0
Guillian Barre Syndrome	0.0	0.0
Nerve AE (pins and needles, nerve pain, etc)	0.0	0.0
Allergic reaction	0.0	0.0
Severe allergy requiring urgent treatment/hospitalisation	0.0	0.0

(v) What did they think of pharmacist vaccination?

The results from the pilot of pharmacist administered vaccinations compared favourably with the current “standard care” model currently in pharmacies i.e. nurse immunisers. The data used for the baseline information about the acceptability of nurse immunisers in community pharmacies is sourced from the TWC patient evaluation data from 2013. In this survey, 2690 patients completed the questionnaire, of which 91% indicated that they would be comfortable with a pharmacist administering the influenza vaccine should that be an option in the future.

The broader evaluation data collected during QPIP confirmed that patients were happy to receive their vaccination from pharmacists, with 95% of patients happy to return in the future (Figure 7); compared to the 78% from the 2013 TWC group who reported they would be happy to come back again. Patients were also satisfied with the professionalism of the pharmacist who delivered the vaccination service (Figure 8), and 97% of patients would recommend the service to others (Figure 9).

The level of acceptance from patients was extremely high. Overall the patient satisfaction with the service was 96% with the remaining 4% being neutral (0.6%), not satisfied (0.05%), or did not answer the question (Figure 10). Patients consistently commented that this was a “great service, and I hope it continues”. In particular, many patients were happy that they could “drop-in” and access this service on an impulse. This saw people who usually would not get vaccinated because they could not be bothered with appointments, receive a vaccination, as was demonstrated by almost 15% never having been vaccinated before. Patients also advised that they would like to see the service be advertised more broadly and that more awareness of the service should be created. There was also difference in any of the patient feedback between rural/regional, and metropolitan sites.

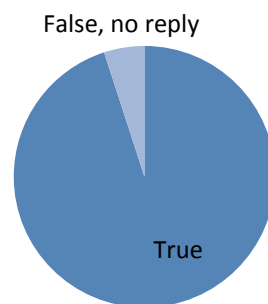


Figure 7. Patients’ response when surveyed if they were comfortable with returning to a pharmacy to receive their influenza vaccination in the future.

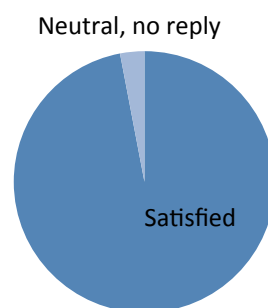


Figure 8. Patients’ response when asked to rank their vaccination experience in relation to the professionalism of the pharmacist administering their vaccination.

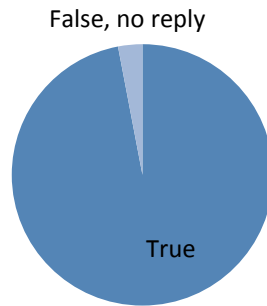


Figure 9. Patients' response when surveyed if they would recommend the pharmacist administered vaccination service to others.

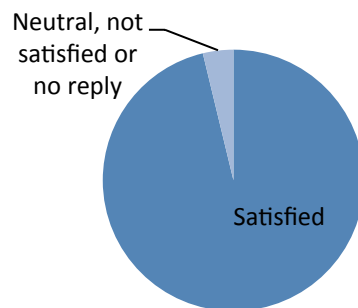


Figure 10. Overall patient satisfaction with the pharmacist administered vaccination experience.

(vi) Facilities

While a variety of private consultation facilities were allowed in the QPIP pilot, the most popular was the consultation room. All facilities needed to be private, but a separate room with a door was not mandatory. The patient's preference in their post satisfaction survey was by far for the consultation room as this afforded the highest level of privacy. Stores that had private rooms performed better on vaccination volume than stores that had a private area/booth, which performed better than stores that used a screen to partition off a private area.

Overall 94% of patients were satisfied with the premises and the facilities. When specifically asked about the premises and the facilities provided, both those who were completely satisfied and the small amount of people who were less satisfied, noted that improvements could be:

1. Increase the number of chairs and ensure they are comfortable
2. Increase the privacy
3. Increase the space
4. Ensure the space is utilized for consultations
5. Make sure there is less clutter and make the area more relaxing
6. Ensure it is not visible to the public
7. Provide a waiting area that has more privacy.

9. Pilot Protocol

Overview

This protocol was developed to support pharmacists administering influenza vaccination to enable them to assess patient suitability, record patient consent and relevant details of the vaccinations administered in their pharmacy, whilst ensuring that they adhered to legislative requirements and that the patient receives a quality service.

This document was developed with reference to information from the PSA's Practice guidelines for the provision of immunisation services within pharmacy (<https://www.psa.org.au/download/practice-guidelines/immunisation-guidelines.pdf>) and relevant international literature and protocols.

The information contained in the following section was provided to the pharmacists to guide the implementation of the pilot within their individual pharmacies. It includes details for staff training, storage of vaccines, management of patient presentations and emergencies. This document was linked to the training provided.

Glossary of Terms

Term	Definition
Patient	Consumer who visits store and requests a vaccination
Vaccination/vaccine	An antigenic substance prepared from the causative agent of a disease or a synthetic substitute, used to provide immunity against one or several diseases e.g. influenza
Pharmacist	Pharmacist qualified and trained in providing the vaccine
Immunisation service area	Private area where the patient receives a vaccination

Required Resources

TITLE	AUTHOR/SOURCE	LINK
Australian Immunisation Handbook	Australian Government Department of Health and Ageing, National Health and Medical Research Council	http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home
Immunise Australia Program	Australian government Department of Health and Ageing	http://www.immunise.health.gov.au/
eMIMS Annual	MIMS	http://www.mims.com.au/index.php/products/emims
Health (Drugs and Poisons) Regulation 1996	Australian Health Ministers Council	http://www.austlii.edu.au/au/legis/qld/consol_reg/hap_r1996340/

Queensland Health Immunisation Program	Queensland Health	http://www.health.qld.gov.au/immunisation/health_professionals/qhip.asp
National Vaccine Storage Guidelines – Strive for 5 (2 nd edition)	Australian Government	http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/IMM77-cnt

Staff roles and training

To allow for appropriate workflow and consistent delivery of this service, it is advised to inform, and where appropriate, train staff members about the service the pharmacy is providing patients and their role in the pharmacy’s procedure. A “Clinical Champion” within the pharmacy can aid in the workflow and service delivery (Appendix 18).

The pharmacist will:

- assess the patient’s suitability for vaccination using a screening checklist (Appendix 4)
- obtain the patient’s consent to be vaccinated
- ensure only a pharmacist who has undertaken QPIP training administer vaccines to patients
- observe the patient for 15 minutes after administering the vaccine to ensure that no adverse reaction occurs
- ensure there is adequate provision of staff time and resources to promote and explain the vaccination service to customers.

Note: Either a pharmacist or trained staff member can enter the initial patient details into the GuildCare® software – BUT only the pharmacist can complete the consenting process

The pharmacist will be a registered pharmacist and have undertaken a course receiving the following Australian recognised qualifications or equivalent:

- Perform CPR: HLTCPR211A
- Apply First Aid: HLTF311A (Includes CPR)
- Emergency Management of Anaphylaxis: 22099VIC

It is recommended that additional staff be educated/trained in:

- their role in emergency response procedures
- the pharmacist’s role in administering the vaccine

- the immunisation service delivery, including appointment arrangements, referral of customer enquiries and handling of customer complaints
- policies and procedures for collecting patient information
- privacy information
- cultural safety.

It is strongly advised that all pharmacy staff are educated about the signs of anaphylaxis. Refer to Appendix 1 for more information.

Professional Indemnity Insurance

Pharmacists (and the pharmacy) must have professional indemnity insurance, which covers immunisation as within the scope of practice, and ensure that it is appropriate for them to administer the vaccines in the pharmacy.

Facilities required

Each vaccination should be conducted in a screened area or private room and allow for confidential discussions with a patient to be conducted and in a place where their conversations (when at normal speaking levels) cannot be overheard by other patients. The area should be of sufficient size and layout to accommodate an efficient workflow to allow for the patient, the carer (if applicable), the pharmacist, as well as consumables, equipment and documentation for the service. It is important to ensure that there is sufficient space and appropriate surfaces for the pharmacist to treat potential adverse events. Appropriate hand-washing facilities should meet Queensland's health requirements and be available within the pharmacy.

Adverse reactions/emergency response

There should be an area for the patient to wait after vaccination, so the pharmacist can observe the patient for 15 minutes to ensure no adverse reactions occur. These areas should not be within the dispensary and will need to ensure there is adequate seating (a recommendation is adjacent to the immunisation area).

Pharmacists should use discreet identifiers to enable a quick identification of patients who have received the vaccination should they require further assistance. Refer to Appendix 1 for Anaphylaxis Management.

If anaphylaxis is present, the Initial Anaphylaxis Response Management Chart (Appendix 2) or equivalent should be followed. After the patient has been taken to hospital, **ensure that all emergency equipment is restocked and refilled, as soon as possible, and before another vaccination is administered.**

Emergency equipment should be checked regularly.

Any Adverse Reaction or Effect must be recorded using GuildCare® ADR module and noted in the Patients Vaccination Record on GuildCare® (Appendix 6)

Equipment required

All pharmacies must have appropriate equipment for storing vaccines and vaccine products, including a reliable and stable refrigerator compliant with QCPP cold chain requirements. This may be available in either the immunisation area or in the dispensary, but access to vaccines and vaccine products is restricted as per the State prescribed legislation for storing controlled substances.

Equipment for the appropriate disposal of sharps and medical waste must be available in the immunisation service area, as described in the current edition of the *Australian Immunisation Handbook*. Appropriate resources to treat consumers in case of an emergency (including a displayed emergency response protocol and emergency response kit) should be readily available in the immunisation service area.

Refer to Appendix 3 for a full list of required equipment, which is the Pharmacist Administered Vaccination Equipment Checklist.

Storage and handling the Vaccine

To ensure the correct process for receiving and storing vaccines, pharmacists should be familiar with the *National Vaccine Storage Guidelines: Strive for 5*. Staff will also need to be educated on the storing of vaccines and monitoring of the refrigerator temperature. For the purposes of a quality control audit for the QPIP project the following QCPP documents and procedures should be followed in regard to vaccine refrigerator temperature records:-

- P5A: Monitoring Refrigerator Temperature Procedure
- T5C: Refrigerator Temperature Record

- T5B Equipment Calibration/Maintenance Schedule and Record.

At least two pharmacists should be responsible for receipting and storing the flu vaccine.

The vaccination will arrive in a secure cold chain storage packaging. Externally the packaging will have a date and time label that advises when it was dispatched from the manufacturer. This should be checked immediately upon arrival to ensure that the arrival time is within 24 hours of the packing date and time.

The delivered vaccines will need to be removed from the cold chain packaging. (Note: the vaccines should never be stored within the fridge without removing them from the cold chain packaging).

To ensure that the hazardous waste is disposed of correctly, QCPP's Infection Control procedure will need to be followed.

Assessing patient suitability for a vaccination

The pharmacist should complete a Patient Pre-vaccination Checklist for Pharmacist form to assess each patient's suitability for the vaccination (Appendix 4). Patients identified as being at risk should be given information on the vaccination and be referred to their primary health care provider for further discussion (a referral letter can be provided).

Patients travelling to areas of considerable risk or those who have chronic diseases that place them at increased risk of disease or illness during their trip should also be referred to their primary health provider.

Pharmacists must only provide advice within the limits of their professional knowledge and experience and ensure that they are up to date with the latest policy advice and scientific evidence around the immunisation.

See Appendix 4, for an Example Patient Pre-vaccination Checklist for Pharmacist – Influenza.

Part of assessing patient's suitability for the vaccine will require the patient to complete and sign the *Patient Consent* form, printed via Guildcare® (Appendix 5) and completion of a *Vaccination Recording Service Report* – using GuildCare® software (Appendix 6).

For the purposes of the QPIP patients will also need to complete the designated consent form to participate in the research study by signing the provided separate documentation. (Appendix 15)

Administering the vaccination (Appendix 16 / 17)

1. Take the patient into a private room or area, which is equipped with seating, and a hazardous waste bin to discard used injection syringe.
2. Describe the injection system used (intradermal, subcutaneous or intramuscular). If using the intradermal vaccination, describe with emphasis on the fact that the different injection system achieves the same efficacy as alternative injection apparatus (i.e. intradermal injection only needs a short needle, but achieves the same vaccination efficacy as longer needles, different brands, etc.).
3. Discuss the need to wait in the pharmacy for 15 minutes after vaccination (in the unlikely event of an anaphylactic reaction), and ensure that the customer has time to do this.
4. Explain potential anaphylactic reaction symptoms. See Appendix 1 for a list of anaphylactic symptoms. It is recommended you have a stand-alone display chart with these details available e.g. Appendix 1.
5. Check that the patient is not eligible for a government-funded vaccination or has been informed, if they are eligible. Refer them to their GP or carer if they are eligible and want to pursue the funded option.
6. Check that the Patient Consent Form and the QPIP consent form are completed and signed off.
7. Check that the vaccine is the correct one chosen for use. Document the vaccination name, batch number and expiry the GuildCare® Vaccination Recording Service Report.
8. Thoroughly wash and dry your hands before starting the procedure. Refer to Hand Hygiene Procedure (T3M - QCPP).
9. Before administering the vaccine into the deltoid region in the arm, ensure that the vaccine is in date and has been stored under correct storage conditions (refer to National Vaccine Storage Guidelines – Strive for 5 (2nd edition) and aforementioned QCPP documents).

10. If using intradermal flu vaccination follow the instructions provided by the manufacturer (pictorial and text) for administering intradermal vaccination.
11. If using an intramuscular flu vaccination follow the instructions provided by the manufacturer (pictorial and text) for administering the intramuscular vaccination.
12. Dispose of the used injector immediately, by putting in the hazardous waste bin. Wash and dry hands.
13. Advise the customer that they must remain in the pharmacy for 15 minutes in case of an adverse reaction to the vaccine. Request that they complete a post-vaccination satisfaction questionnaire while waiting (Appendix 10).
14. Note the time of administration and end of the 15 minute wait time. During this period, check that the customer is feeling well and is not having an adverse reaction. **Keep patient in line of sight at all times.**
15. Ensure that the patient's vaccination record is entered in Guildcare and complete a Patient Record of Immunisation (Appendix 9). Including documentation of any ADRs (and their management) in the 15min observation period.
16. Ensure that the likely post-vaccination effects and how to deal with them have been discussed and that the patient has been given 'Frequently Asked Questions' (Appendix 7) and the GP notification letter for them to give to their doctor (Appendix 8), if requested, before they leave the pharmacy.
17. At the end of the 15 minutes, check back with the patient, and if they are feeling well, notify them that they can leave the pharmacy.

During the QPIP project 10% of patients immunised will receive a follow-up call from the pharmacist to collect information regarding their responses to the immunisation, experienced beyond the initial 15min in-pharmacy period. Appendix 11.

10. Appendices

Appendix 1: Anaphylaxis Management - Example

Signs and Symptoms of Anaphylaxis

**Ensure that all pharmacy staff members know the signs and symptoms of anaphylaxis. See table below for reference. **

Time Scale	Signs and symptoms	Severity
Early warning signs (within a few minutes)	Dizziness, perineal burning, warmth, pruritus, flushing, urticaria, nasal congestion, sneezing, lacrimation, angioedema	Mild to moderate
Early warning signs (within a few minutes)	Hoarseness, nausea, vomiting, substernal pressure	Moderate to severe
Early warning signs (within a few minutes)	Laryngeal oedema, dyspnoea, abdominal pain	Moderate to severe
Late and life threatening symptoms	Bronchospasm, stridor, collapse, hypotension, dysrhythmias	Severe

Most life threatening anaphylactic events begin within 10 minutes of vaccination. Pharmacy shop staff may be the first people to notice potential symptoms while the patient is waiting in the pharmacy. If anaphylaxis occurs direct a specific person to call an ambulance while other staff manage the patient.

Distinguishing anaphylaxis from a faint (vasovagal reaction)

**Ensure that all authorised vaccinators know the difference in symptoms between anaphylaxis and fainting.*

*See table below for reference. **

	Faint (vasovagal reaction)	Anaphylaxis
Onset	Usually at the time or soon after the injection	Usually a delay of 5 – 30 minutes after injection
System		
Skin	Pale, sweaty, cold and clammy	Red, raised and itchy rash; swollen eyes and face; generalised rash
Respiratory	Normal to deep breaths	Noisy breathing due to airways obstruction (wheeze or stridor); respiratory arrest
Cardiovascular	Bradycardia; transient hypotension	Tachycardia; hypotension; dysrhythmias; circulatory arrest
Gastrointestinal	Nausea/vomiting	Abdominal cramps
Neurological	Transient loss of consciousness; good response once supine/flat	Loss of consciousness; little response once supine flat

Be prepared for an anaphylactic emergency and ensure that all staff members know the initial response/emergency procedure for anaphylaxis. Designate which staff roles will look after other customers and who will call the ambulance.

Appendix 2: Initial Anaphylaxis Response/Management - Example

Initial anaphylaxis response/management chart

CALL FOR HELP – send for professional assistance (ambulance, doctor). Never leave the individual alone.

ASSESS – if unconscious, place in recovery position and institute standard procedures for basic life support (airway, breathing, circulation). If cardiorespiratory arrest occurs, administer age-appropriate CPR and life support measures.

ADMINISTER ADRENALINE – dosage: 1:1000 (adrenaline 1:1000 = 0.01mg per 0.01mL).

<u>Approximate age and weight</u>	<u>Adrenaline dose</u>
-----------------------------------	------------------------

<1 year (approx. 5–10 kg)	0.05–0.1 mL
---------------------------	-------------

1–2 years (approx. 10 kg)	0.1 mL
---------------------------	--------

2–3 years (approx. 15 kg)	0.15 mL
---------------------------	---------

4–6 years (approx. 20 kg)	0.2 mL
---------------------------	--------

7–10 years (approx. 30 kg)	0.3 mL
----------------------------	--------

10–12 years (approx. 40 kg)	0.4 mL
-----------------------------	--------

>12 years and adult (over 50 kg)	0.5 mL
----------------------------------	--------

Route: deep IM. Where possible administer in a non-injected limb, in either the deltoid or vastus lateralis.

You can expect to see some response to the adrenaline within 1 – 2 minutes. If necessary, adrenaline can be repeated at 5 – 15 minute intervals, to a maximum of three doses, while waiting for assistance. Use alternate sites/limbs for additional doses.

ADMINISTER OXYGEN (if available) at high flow rates where there is respiratory distress, stridor or wheeze.

IF HYPOTENSIVE, ELEVATE LEGS

IF STRIDOR IS PRESENT, ELEVATE HEAD AND CHEST

RECORD VITAL SIGNS even 5 – 10 minutes. All observations and interventions need to be clearly documented in medical notes and should accompany the individual to hospital.

ADMIT TO HOSPITAL – all cases of anaphylaxis should be admitted to hospital for observation. Rebound anaphylaxis can occur 12 – 24 hours after the initial episode.

Note: only medical practitioners should administer IV adrenaline, and then only 1:10,000 dilution at a dose of 0.1mg/kg and volume of 1:10,000 of 0.1mL/kg.

Appendix 3: Pharmacist Administered Vaccination Checklist

Pharmacist Administered Vaccination Checklist

Equipment

- Fridge
- Phone access
- Min. 3x ANAPEN/EPIPEN **or**
 - Adrenaline 1:1000 (three ampoules)
 - Adrenaline 1:1000 dose chart
 - Syringes 1.0ml Tuberculin, not insulin syringes (insulin needles are too short for an IM injection)
 - Needles – range including 23 or 25 G x 25mm, 22G x 38mm
- Sharps container
- Alcohol swabs
- Cotton balls
- Gauze
- Thermometer (for taking patient temperature) optional
- Blood pressure monitor optional
- Influenza vaccine
- Fridge temp: data monitor/Min-max thermometer
- Disposable gloves
- Hand sanitiser
- Timer (to monitor customer waiting times once they have had the vaccination)
- Latest copy of Immunisation Handbook
- Hazardous waste bin and a replacement
- Esky, polystyrene foam, shredded paper and ice blocks (if there is a power outage)
- Wash basin and soap
- Saline (if vaccine is in contact with eye)
- Tape/Band-Aids
- Pens
- Paper
- Garbage bin
- Room with two chairs, desk and computer with internet access if possible
- Waiting area
- Latest version of GuildCare Software

Documentation

- Patient consent
- Fridge temperature document (QCPP -T5C)
- Pre-vaccination checklist
- How to recognise anaphylaxis Poster
- Emergency equipment checklist
- Posters
- Letter to doctors
- Letter to local business
- Booking Schedule
- Factsheet to give to customers
- Booking instructions
- Instructions for Use
- Current First Aid, completed QPIP training course certificate, CPR certificate (or documentation showing these courses have been completed)
- Frequently Asked Questions

Appendix 4: Patient Pre-vaccination Checklist for Pharmacist – Influenza (Example)

Patient Pre-vaccination Checklist for Pharmacist – Influenza

A trained pharmacist must conduct the pre-vaccination consultation, consent process and vaccine administration.

Date: ___/___/___ Customer name: _____

Phone number: _____ DOB: ___/___/___

Customer address: _____

GP name/address/phone number: _____

CONSULTATION QUESTIONS	RECORD YES/NO	WHEN TO REFER
Is the customer younger than 18?		If yes, refer to GP
Is the customer older than 59 years?		If yes: intramuscular injection route is required. If older than 65 years, the patient is eligible for a funded vaccination.
Is the customer younger than 65 years and have a chronic illness or are pregnant?		If yes to age criteria and health condition, refer to GP for funded vaccine.
Is the customer allergic to eggs, egg products or chicken proteins?		If yes, refer to GP
Is the customer allergic to neomycin or other vaccine components?		If yes, refer to GP
Is the customer unwell today? (NB: okay to vaccinate if they are mildly unwell but afebrile, i.e. temperature less than 38 degrees C).		If yes, refer to GP
Has the customer ever had a severe reaction to any vaccine?		If yes, refer to GP
Is the customer taking immunosuppressant medicines?		If yes, refer to GP
Has the customer had a severe allergic reaction from any cause? (Excluding insect bites and bee stings.)		If yes, refer to GP
Does the customer have any neurological conditions? (Potential risk of recurrence of Guillain-Barre syndrome, neuritis, encephalomyelitis and other)		If yes, refer to GP.

Appendix 5: Patient Consent – GuildCare Screenshot

Patient Details:			
Name:	Daisy Browne	Gender:	Female
Address:	66 Campbells River Road, CONIMBIA, NSW, 2829		
Contact #:	(02)40328208	Date/Time:	12/02/2014 03:45 AM
Medicare #:	69369770216	Date of Birth:	12/04/1969
Email:	DaisyBrowne@example.com.au		

Vaccine Details:	
Vaccine Administered:	<input type="text" value="Vaxigrip"/>
Vaccinating against:	<input type="text" value="Influenza"/>
<input checked="" type="checkbox"/> Patient has received this vaccine before; last received	<input type="text" value="2013"/>

Suitability for vaccination:	
Please answer the following by ticking the box if you:	
<input type="checkbox"/>	are unwell today
<input type="checkbox"/>	have had a severe reaction following a vaccine
<input type="checkbox"/>	have any allergies (to anything)
<input type="checkbox"/>	have had any vaccine in the past month
<input type="checkbox"/>	are pregnant or anticipating pregnancy
<input type="checkbox"/>	are having treatment which lowers immunity (oral steroid medicines such as cortisone or prednisolone, radiotherapy, chemotherapy)
<input type="checkbox"/>	are taking any other medications
<input type="checkbox"/>	have a disease which lowers immunity (eg. Leukaemia, cancer, HIV/AIDs)
<input type="checkbox"/>	have a severe or chronic illness
<input type="checkbox"/>	have a history of Guillain-Barré syndrome
<input type="checkbox"/>	have a bleeding disorder
<input type="checkbox"/>	have had an injection of immunoglobulin, or received any blood products or a whole blood transfusion within the past year

Pharmacy Declaration:	
<input checked="" type="checkbox"/>	Screening checklist completed and patient assessed as suitable for vaccination

Consent:	
I have read and understood the frequently asked questions and information provided regarding possible side effects of the vaccine. If I have any further questions I will ask the person administering the vaccine prior to being vaccinated. I request to have this vaccination and understand that it is completely voluntary.	
Patient Name:	Daisy Browne
Signature:	
Date:	12/02/2014

Appendix 6: Vaccination Recording Service Report - GuildCare Screenshot

Patient Details:	
Name:	Daisy Browne
Address:	66 Campbells River Road, CONIMBIA, NSW, 2829
Contact #:	(02)40328208
Medicare #:	69369770216
Email:	DaisyBrowne@example.com.au
Gender:	Female
Date/Time:	12/02/2014 03:45 AM
Date of Birth:	12/04/1969

Vaccine Details:	
Vaccinating against:	Influenza
Vaccine Administered:	Vaxigrip
<input checked="" type="checkbox"/> Patient has received this vaccine before; last received	2013

Suitability for vaccination:
<p>Please answer the following by ticking the box if you:</p> <p><input type="checkbox"/> are unwell today</p> <p><input type="checkbox"/> have had a severe reaction following a vaccine</p> <p><input type="checkbox"/> have any allergies (to anything)</p> <p><input type="checkbox"/> have had any vaccine in the past month</p> <p><input type="checkbox"/> are pregnant or anticipating pregnancy</p> <p><input type="checkbox"/> are having treatment which lowers immunity (oral steroid medicines such as cortisone or prednisolone, radiotherapy, chemotherapy)</p> <p><input type="checkbox"/> are taking any other medications</p> <p><input type="checkbox"/> have a disease which lowers immunity (eg. Leukaemia, cancer, HIV/AIDS)</p> <p><input type="checkbox"/> have a severe or chronic illness</p> <p><input type="checkbox"/> have a history of Guillain-Barré syndrome</p> <p><input type="checkbox"/> have a bleeding disorder</p> <p><input type="checkbox"/> have had an injection of immunoglobulin, or received any blood products or a whole blood transfusion within the past year</p>

Vaccination Needs Assessment:
<p>Please tick the box and tell your nurse or pharmacist if you:</p> <p><input type="checkbox"/> are 65 or older</p> <p><input type="checkbox"/> identify as Aboriginal or Torres Strait Islander</p> <p><input type="checkbox"/> do not have a functioning spleen</p> <p><input type="checkbox"/> live with someone who has a disease which lowers immunity (eg. Leukaemia, cancer, HIV/AIDS) or is having treatment which lowers immunity (oral steroid medicines such as cortisone or prednisolone, radiotherapy, chemotherapy)</p>

Appendix 7: Frequently Asked Questions - GuildCare Screenshot

What is influenza?

Influenza, or "the flu", is a viral illness caused by the Influenza A and B viruses. It is highly infectious and spreads through infected droplets in the air after sneezing or coughing, or via hands which have been in contact with the virus. It should not be confused with the "common cold".

Symptoms of influenza include sudden fever, muscle aches, sore throat and joint pains which can last up to 7-10 days. Complications such as bronchitis and pneumonia can also develop following onset of influenza in some people, and can result in hospitalisation and/or death in some at risk people such as those with chronic illnesses and the elderly.

Can I receive free influenza vaccine under the National Immunisation Program?

Free vaccine is available from your GP (though a consultation fee may apply) for the following people who are at high risk of severe flu or complications from flu:

- People aged 65 years and over
- Aboriginal and Torres Strait Islander people from 15 years of age
- Pregnant women
- People with one or more of the following conditions:
 - heart disease; severe asthma; chronic lung condition; chronic illness requiring medical follow-up or hospitalisation in the past year; diseases of the nervous system; impaired immunity; or diabetes

You cannot receive a free vaccine from a community pharmacy.

What are the possible side effects from the influenza vaccine?

Common side effects following seasonal influenza vaccination include soreness, redness, itching pain or swelling at the injection site. Occasionally, people can develop a slight fever 1-2 days after the injection. These side effects are usually mild and resolve quickly without any treatment. If a high temperature above 38.5°C persists, contact your doctor or seek medical assistance. The person who administers your vaccine will require you to stay for 15 minutes after your vaccination to monitor you for any immediate allergies or side effects.

Can I get influenza from the vaccination?

No you cannot. The vaccine does not contain live virus particles, only inactivated particles, and will not cause influenza.

I received an influenza vaccine last year, do I still need to get one this year?

Yes. Each year, the flu vaccine will protect against the three strains of flu virus most likely to circulate over the winter period in the Southern Hemisphere, as predicted by the World Health Organisation. The formulation of the vaccine changes each year. Your immunity will gradually decrease over time and vaccination is needed each year to ensure you continue to be protected. Vaccination is recommended in autumn to allow time for an immune response before influenza season starts.

I had the vaccine last year and I still got influenza, why?

There are many strains of the influenza virus and the three strains within the vaccine each year are the 'most likely' to circulate. If a strain that has not been in the vaccine in recent years circulates, you may still develop influenza, although it may be a less severe case if you have received an influenza vaccine.

Appendix 8: Sample GP Notification - GuildCare Screenshot

JD MC
Dr John
Doe
555 5555
02 5555 5555
John@doe.com

Dear Dr John,

I am writing to you about Daisy Browne, DOB 12/04/1969, of 66 Campbells River Road, CONIMBIA, NSW, 2829.

Daisy has received the following vaccination here at the pharmacy. Could you please update your records to reflect this?

Vaccine Administered: Vaxigrip
Vaccinating against: Influenza
Date/Time of vaccination: 12/02/2014; 12:00 AM
Site of Administration: Right arm
Batch number: 5555555

Regards,

C

Pharmacist
12/02/2014

Appendix 9: Patient Record of Immunisation - GuildCare Screenshot

Patient Details:	
Name:	Daisy Browne
Address:	66 Campbells River Road, CONIMBIA, NSW, 2829
Contact #:	(02)40328208
Medicare #:	69369770216
Email:	DaisyBrowne@example.com.au
Gender:	Female
Date/Time:	12/02/2014 03:45 AM
Date of Birth:	12/04/1969

Vaccine Details:	
Vaccinating against:	Influenza
Vaccine Administered:	Vaxigrip
<input checked="" type="checkbox"/> Patient has received this vaccine before; last received	2013

Vaccination Details:	
Person administering vaccine:	Nathaniel Santillan
Contact #:	1300 Mirixa
Qualifications:	Nurse Administrator
Date/Time of Vaccination:	12/02/2014 12:00 AM
Date Next Vaccination Due:	
Site of Administration:	Right arm
Batch Number:	5555555

Important Information
<p>What are the possible side effects from the influenza vaccine? Common side effects following seasonal influenza vaccination include tiredness, muscle aches and pain, redness, itching or swelling at the injection site. Occasionally, people can develop a slight fever 1-2 days after the injection. These side effects are usually mild and resolve quickly without any treatment. If a high temperature above 38.5°C persists, contact your doctor or seek medical assistance.</p> <p>How long after the influenza vaccine can these reactions occur? Generally, reactions occur within the first 24 to 48 hrs. These reactions commonly begin 6 to 12 hours after vaccination.</p> <p>If I get an unusual side effect after influenza vaccine, where can I report it? It is easiest to contact the pharmacy where you received the vaccine and inform them, and the pharmacist will be able to give you advice and answer your questions. Alternatively, you can report side effects to your doctor, or to the Therapeutic Goods Administration (TGA) Adverse Medicine Events Line on 1300 134 237.</p> <p>Severe allergic reaction (anaphylaxis) is a rare side effect of vaccines. It occurs suddenly, usually within 15 minutes but can occur within hours of vaccine administration. Early signs of anaphylaxis include significant redness and/or itching of the skin, swelling of the face, lips or tongue, and breathing difficulties.</p> <p>The person who administers your vaccine will require you to stay for 15 minutes after your vaccination to monitor you for any immediate allergies or side effects. If you have any concerns or questions, please speak to your doctor, nurse or pharmacist.</p>

Appendix 10: Participant Satisfaction Questionnaire

Queensland Pharmacist Immunisation Pilot (QPIP)		
Participant Satisfaction Questionnaire		
QUT Ethics Approval Number 1400000098		
Important Information About You	Please tick	
1. What is your age?	18 – 30 years	
	31 – 45 years	
	46 – 65 years	
	Older than 65 years	
2. Have you received a flu vaccination before?	Yes, every year	
	Yes, but not every year	
	No – go to question 4	
3. Where have you previously received your flu vaccination?	GP Clinic	
	Work	
	Home visit – by GP/community nurse	
	Other (please specify)	
4. What were the main reasons for you NOT receiving the flu vaccination in previous years? <i>Please tick the most important reasons to you (there may be more than one)</i>	Not applicable – I get my vaccination every year	
	Too busy	
	Inconvenience of attending a clinic/doctor's surgery	
	Unsure where to get the vaccination from	
	Fear of side effects after the vaccination	
	Didn't feel it was necessary – I am fairly fit and strong	
	Other (please specify)	
5. Why are you receiving a flu vaccination this year?	My GP recommended I do so	
	My pharmacist recommended I do so	
	My friends suggested it may be an idea	
	I feel it is a good idea	
	I had the 'flu' last year and don't want it again	
	Other (please specify)	

Your QPIP Vaccination Experience

Please rate your overall satisfaction with the vaccination experience according to the following scale:

- 1- Completely dissatisfied 2 - Partially dissatisfied 3- Neutral
 4- Partially satisfied 5- Completely satisfied

Question	Satisfaction Rating				
	1	2	3	4	5
1. Were the details of the vaccination process explained adequately?					
Comment					
	1	2	3	4	5
2. Was the vaccination provided in a professional manner?					
Comment					
	1	2	3	4	5
3. Did you feel comfortable with the skills of the professional providing the immunisation?					
Comment					
	1	2	3	4	5
4. Overall, how satisfied are you with your vaccination experience?					
Comment					
5. Were other aspects of your health discussed with you?	<i>Tick as applicable</i>				
Other medications I usually take and why					
Concerns I have regarding my health					
My general health					
My allergies					
Other (Please describe)					
6. If this vaccination service WAS NOT available, where would you have received your flu vaccination this year?	<i>Tick as applicable</i>				
I would not have had a vaccination					
GP clinic / surgery					
At work					
Home visit – GP or community nurse					
Other (please describe)					
7. What was the main reason for choosing to receive your flu vaccination here today?	<i>Tick as applicable</i>				
Convenient location					
Easy to get an appointment					
Friendly and relaxed environment					
Health professional that I trust					
Other (please describe)					

8. Would you be happy to receive your flu vaccination in a pharmacy in the future? <i>Please tick as appropriate</i>	Yes	
	No	
Comments		
9. Would you recommend this service to others? <i>Please tick as appropriate</i>	Yes	
	No	
Comments		
10. What was the best aspect of the vaccination service? <i>Please rank (where 1 is the highest – or best)</i>	Ranking	
Convenience		
No appointment necessary		
The opportunity to discuss my medications and other health issues with a professional		
The friendly staff		
The service was quick and easy		
Other (please describe)		

How Can We Improve This Service?

We are very keen to make sure we provide the best possible immunisation experience for everyone involved. We welcome your thoughts regarding how we can improve the service in the future.

1. Were the facilities (e.g. the chairs, consulting rooms) adequate? <i>Please tick as appropriate</i>	Yes	
	No	
Comments		
2. How could we improve the facilities? <i>Please describe</i>		
3. Did you feel comfortable while you waited after the vaccination was given? <i>Please tick as appropriate</i>	Yes	
	No	
4. If not, how could we have made you more comfortable?		
5. Can you think of anything we could do to improve the vaccination program? <i>Please describe</i>	Yes	
	No	
6. Final comments		

Thank you for your assistance with this research.

Appendix 11: Post-immunisation follow-up survey

Queensland Pharmacist Immunisation Pilot (QPIP)
Participant Post-vaccination Survey
 QUT Ethics Approval Number 1400000098

Instructions:

- This follow-up interview is intended to provide data regarding adverse events experienced by the participant during the first week after vaccination.
- The interview is to be conducted by phone approximately one week after the participant received their influenza vaccination.
- To protect the privacy of the participant, no specific identifiers should be recorded on this form.
- Responses to the interview questions are to be manually recorded and provided to the research team for analysis. Details of how to forward responses to the research team will be provided as part of the study preparations.
- At the start of the phone call, please introduce yourself and let the participant know the intention of the phone call is to provide a follow-up service as part of the QPIP study (the details of this are included in the consent which all participants have agreed to). Check you have called at a suitable time.
- Please feel free to add comments in the table below e.g. to clarify what was said or to quote details provided by the participant.

Interview Questions:

Question	Response	Comment
1. Have you previously received a flu vaccination (i.e. prior to 2014)?	Yes – every year <input type="checkbox"/> Yes – but not every year <input type="checkbox"/> No (go to question 3) <input type="checkbox"/>	
2. When you previously had a flu vaccination (prior to 2014), did you experience any of the following side effects after the vaccination?		
a. Pain at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
b. Redness at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
c. Itchiness at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
d. Skin infection at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
e. Shivering and/or Chills	Yes <input type="checkbox"/> No <input type="checkbox"/>	
f. Nausea, Vomiting and/or Diarrhoea	Yes <input type="checkbox"/> No <input type="checkbox"/>	
g. Headache	Yes <input type="checkbox"/> No <input type="checkbox"/>	
h. Fever	Yes <input type="checkbox"/> No <input type="checkbox"/>	
i. Cough, runny nose or sore throat	Yes <input type="checkbox"/> No <input type="checkbox"/>	
j. Muscle and/or joint pain	Yes <input type="checkbox"/> No <input type="checkbox"/>	
k. Excessive fatigue (more than normal)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
l. Chest infection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
m. Guillain-Barre syndrome	Yes <input type="checkbox"/> No <input type="checkbox"/>	
n. Side effects affecting the nerves e.g. 'pins and needles', nerve pain, difficulty moving, convulsions/seizures, infections affecting the nervous system	Yes <input type="checkbox"/> No <input type="checkbox"/>	
o. Allergic reaction (provide details)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
p. Severe allergy requiring urgent treatment or hospitalisation e.g. anaphylaxis	Yes <input type="checkbox"/> No <input type="checkbox"/>	
3. Did you experience any of the following symptoms in the week after you received the vaccination in 2014?		
a. Pain at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
b. Redness at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
c. Itchiness at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
d. Skin infection at the site of the injection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
e. Shivering and/or Chills	Yes <input type="checkbox"/> No <input type="checkbox"/>	
f. Nausea, Vomiting and/or Diarrhoea	Yes <input type="checkbox"/> No <input type="checkbox"/>	
g. Headache	Yes <input type="checkbox"/> No <input type="checkbox"/>	
h. Fever	Yes <input type="checkbox"/> No <input type="checkbox"/>	
i. Cough, runny nose or sore throat	Yes <input type="checkbox"/> No <input type="checkbox"/>	
j. Muscle and/or joint pain	Yes <input type="checkbox"/> No <input type="checkbox"/>	
k. Excessive fatigue (more than normal)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
l. Chest infection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
m. Guillain-Barre syndrome	Yes <input type="checkbox"/> No <input type="checkbox"/>	
n. Side effects affecting the nerves e.g. 'pins and needles', nerve pain, difficulty moving, convulsions/seizures, infections affecting the nervous system	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Question	Response	Comment
o. Allergic reaction (provide details)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
p. Severe allergy requiring urgent treatment or hospitalisation e.g. anaphylaxis	Yes <input type="checkbox"/> No <input type="checkbox"/>	
4. Did you experience any other effects not discussed so far today? Please provide details.	Yes <input type="checkbox"/> No <input type="checkbox"/> (If "no" go to question 6)	
5. Did any of the side effects require you to seek medical attention? Please detail – the side effect and who was consulted.	Yes <input type="checkbox"/> No <input type="checkbox"/>	
6. Do you have any questions or comments regarding your vaccination experience?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Appendix 12: Adult Vaccines available for administration by route (refer to CMI)

Vaccines for intramuscular administration

- **Agrippal** – Novartis Vaccines and Diagnostics Pty Ltd (inactivated influenza virus). Each 0.5 mL pre-filled syringe contains 15 µg haemagglutinin of each of the three recommended strains. May contain traces of kanamycin, neomycin, formaldehyde, barium sulphate, cetrimeronium bromide (CTAB), polysorbate 80 and egg protein.
- **Fluarix** – GlaxoSmithKline (inactivated influenza virus). Each 0.5 mL pre-filled syringe contains 15 µg haemagglutinin of each of the three recommended strains. May contain traces of formaldehyde, gentamicin, polysorbate 80, octoxinol 10 and egg protein.
- **Influvac** – Abbott Products Pty Ltd (inactivated influenza virus). Each 0.5 mL pre-filled syringe contains 15 µg haemagglutinin of each of the three recommended strains. May contain traces of formaldehyde, CTAB, polysorbate 80, gentamicin and egg protein.
- **Vaxigrip** – Sanofi Pasteur Pty Ltd (inactivated influenza virus). Each 0.5 mL pre-filled syringe contains 15 µg haemagglutinin of each of the three recommended strains. May contain traces of formaldehyde, octoxinol 9, neomycin and egg protein.
- **Fluvax** – CSL Limited (inactivated influenza virus). Each 0.5 mL pre-filled syringe contains 15 µg haemagglutinin of each of the three recommended strains. May contain traces of neomycin, polymyxin B, β-propiolactone, sodium taurodeoxycholate and egg protein.

Adults aged ≥65 years

- **Fluad** – Novartis Vaccines and Diagnostics Pty Ltd (inactivated influenza virus). Each 0.5 mL pre-filled syringe contains 15 µg haemagglutinin of each of the three recommended strains, adjuvanted with MF59C.1 (which contains squalene and polysorbate 80). May contain traces of kanamycin, neomycin, formaldehyde, barium sulphate, CTAB and egg protein.

Vaccines for intradermal administration

Adults aged 18–59 years

- **Intanza** 9 µg – Sanofi Pasteur Pty Ltd (inactivated influenza virus). Each 0.1 mL pre-filled purpose-designed Micro-Injection System contains 9 µg haemagglutinin of each of the three recommended strains. May contain traces of formaldehyde, octoxinol 9, neomycin and egg protein.

Appendix 13: QPIP Pharmacist Consent



Queensland University of Technology
Brisbane Australia



Pharmaceutical
Society of Australia



The Pharmacy
Guild of Australia



Queensland Pharmacist Immunisation Pilot (QPPI) Evaluation

Pharmacist Information Sheet and Consent Form

QUT Ethics Approval Number 1400000098

The Queensland Pharmacist Immunisation Pilot (QPPI) aims to evaluate the benefits of registered pharmacists providing influenza vaccines to members of the public in the setting of a community pharmacy. Data collected from this study will be reviewed and analysed by a research team located at Queensland University of Technology (QUT) and James Cook University (JCU).

The research team responsible for the QPIP evaluation would like your assistance with the collection of data generated by the QPIP. Your participation as a pharmacist in QPIP is entirely voluntary. Your decision to participate or not participate will in no way affect your employment.

Project Details

- The QPIP is an initiative of the Queensland Branches of the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia, in collaboration with QUT and JCU.
- The research evaluation of the QPIP has been approved by the Human Research Ethics Committees at both QUT and JCU.
- Data generated by the QPIP will be used to determine both the benefits and difficulties associated with pharmacists administering influenza vaccines. This information will be formulated into a report for the Chief Health Officer.

What is required for pharmacists to administer vaccines during QPIP?

All pharmacists who provide vaccinations, as part of the QPIP, must undertake approved training and demonstrate an acceptable level of both knowledge and skill associated with the administration of vaccines.

Is it legal for pharmacists to administer vaccines during QPIP?

Yes. Pharmacists are covered by specific legislation (Amendment 18(1) of the Health (Drugs and Poisons) Regulations 1996) that enables administration of vaccines as part of the QPIP.

What do I need to do as part of the Evaluation?

By participating in this research, you will be asked to:

- Provide information about QPIP and its evaluation to participants and obtain consent from participants for their vaccination details to be used by the research team.
 - * **Note:** This consent is in addition to the consent form you will be required to obtain (via the Guildcare software) for the actual vaccination itself. (i.e. patient will complete two consent forms)
- Provide the research team with the de-identified details of the episodes of care for those participants who have consented to their data being collected and evaluated (these data will be recorded by the Guildcare software).

As part of the research evaluation, you will also request that participants complete a feedback form regarding their QPIP vaccination experience at the conclusion of their visit. This is to be completed during the 15min post-vaccination waiting period. In addition, you will undertake a follow-up interview (conducted by phone) with approximately 10% of participants a week after their vaccination. This will enable data to be collected on the outcomes of the vaccination once the participant has left your pharmacy.

All information collected as part of the episode of care involving administration of the influenza vaccination needs to be kept as part of the patient's record for at least 2 years from the time of administration. Only de-identified information from the QPIP participants will be provided to the research team for evaluation. Study data will be stored securely as defined by QUT's Management of Research Data Policy, which will be provided to all participating pharmacies. Patient surveys will be stored securely in the pharmacy before they are collected by the research team.

Who do I contact if I have any questions?

If you would like further information you can contact the QPIP research coordinator: Professor Lisa Nissen, QUT School of Clinical Sciences on 07 3138 4404.



Consent to participate in the Queensland Pharmacist Immunisation Pilot (QPIP)

- I have been provided with information about the Queensland Pharmacist Immunisation Pilot (QPIP). I am aware that my participation is entirely voluntary.
- For patients who provide consent, I agree to the research team accessing data associated with the administration of the influenza vaccination for the purpose of evaluating the QPIP.
- Before signing this document, I was given the opportunity to ask any questions about the immunisation service to be delivered by the community pharmacist, the type of information that is to be collected, and how the information collected will be used.
- I understand that any information or personal details gathered in the course of this research about my patients, the pharmacy or its staff are confidential and that neither my name nor any other identifying information will be used or published without my written permission. I understand that any data collected for the purpose of the study will remain strictly confidential and not be used to identify any health professional or patient involved in the study.
- I understand that this information cannot be collected, stored or analysed for use for any other purposes apart from the QPIP.
- I have been informed of my right to question any part of the QPIP or to withdraw from the project at any time. I understand that withdrawal from QPIP will not affect my relationship with the collaborating organisations or my employment. In the event of withdrawal, data collected as part of the study may be withdrawn.
- I understand that my withdrawal from the QPIP would prevent me from continuing to administer immunisations.

Name: _____

Pharmacy Address _____

Signature: _____

Date: _____

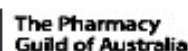
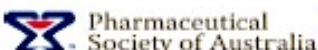
Witness Name: _____

Witness Signature: _____

Date: _____

Thank you for assisting with this research project.

Appendix 14: QPIP Pharmacy Consent



Queensland Pharmacist Immunisation Pilot (QPPI) Evaluation

Site Information and Consent

QUT Ethics Approval Number 140000098

The Queensland Pharmacist Immunisation Pilot (QPPI) aims to investigate the benefits of registered pharmacists providing influenza vaccines to members of the public in the setting of a community pharmacy. Data collected from this study will be reviewed and analysed by a research team located at Queensland University of Technology (QUT) and James Cook University (JCU).

The research team responsible for the QPPI evaluation would like your assistance with the collection of data generated by the QPPI. Your participation in this project is entirely voluntary.

Project Details

- The QPPI is an initiative of the Queensland Branches of the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia, in collaboration with QUT and JCU.
- The research evaluation of the QPPI has been approved by the Human Research Ethics Committees at both QUT and JCU.
- Data generated by the QPPI will be used to determine both the benefits and difficulties associated with pharmacists administering influenza vaccines. This information will be formulated into a report for the Chief Health Officer.

What is required for pharmacists to administer vaccines during QPPI?

All pharmacists who provide vaccinations, as part of the QPPI, must undertake an approved course of study and demonstrate an acceptable level of both knowledge and skill associated with the administration of vaccines

Is it legal for pharmacists to administer vaccines during QPPI?

Yes. Pharmacists are covered by specific legislation (Amendment 18(1) of the Health (Drugs and Poisons) Regulations 1996) that enables them to administer vaccines as part of the QPPI.

What does this pharmacy need to do as part of the evaluation?

By participating in this research, your pharmacists will be asked to:

- Provide information about QPPI and its evaluation to participants and obtain consent from participants for their vaccination details to be used by the research team.
***Note:** This consent is in addition to the consent form your pharmacists will be required to obtain (via the Guildcare software) for the actual vaccination itself. (i.e. patient will complete two consent forms)
- Provide the research team with the de-identified details of the episodes of care for those participants who have consented to their data being collected and evaluated (these data will be recorded by the Guildcare software).
- Ensure hard copies of the data generated by the QPPI are stored securely and confidentially until such time as it is required by the research team.

All information collected as part of the episode of care involving administration of the influenza vaccination needs to be kept as part of the patient's record for at least 2 years from the time of administration. Only de-identified information from the QPPI participants will be provided to the research team for evaluation. Study data will be stored securely as defined by QUT's Management of Research Data Policy, which will be provided to all participating pharmacies. Patient surveys will be stored securely in the pharmacy before they are collected by the research team.

Who do I contact if I have any questions?

If you would like further information you can contact the QPPI research coordinator: Professor Lisa Nissen, QUT School of Clinical Sciences on 07 3138 4404.

Consent to participate in the Queensland Pharmacist Immunisation Pilot (QPIP)

- I have been provided with information about the Queensland Pharmacist Immunisation Pilot (QPIP). Details of the project have been clearly explained by the research team. I have been issued with an information sheet. I am aware of the purpose of the project and what my pharmacies' involvement entails and that my participation is entirely voluntary.
- Before signing this document, I was given the opportunity to ask any questions about the immunisation service to be delivered by the community pharmacist, the type of information that is to be collected, and how the information collected will be used.
- I understand that any information or personal details gathered in the course of this research about my patients, pharmacy and staff are confidential and that neither my name nor any other identifying information will be used or published without my written permission. I understand that any data collected for the purpose of the study will remain strictly confidential and not be used to identify any health professional or patient involved in the study.
- I understand that this information cannot be collected, stored or analysed for use for any other purposes apart from the QPIP.
- I have been informed of my right to question any part of the QPIP or to withdraw from the project at any time. I understand that withdrawal from QPIP will not affect my relationship with the collaborating organisations. In the event of withdrawal, data collected as part of the study may be withdrawn.
- I understand that withdrawal would stop my pharmacy from having pharmacists administer immunisations during the QPIP.

Owner / Delegate / Manager: _____

Pharmacy Name: _____

Pharmacy Address: _____

Signature: _____

Date: _____

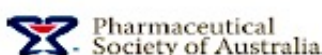
Witness Name: _____

Witness Signature: _____

Date: _____

Thank you for assisting with this research project.

Appendix 15: QPIP Patient Consent



Queensland Pharmacist Immunisation Pilot (QPPI) Evaluation

Participant Information Sheet and Consent Form

QUT Ethics Approval Number 1400000098

The Queensland Pharmacist Immunisation Pilot (QPPI) aims to investigate the benefits of registered pharmacists providing influenza vaccines to members of the public in the setting of a community pharmacy. Data collected from this study will be reviewed and analysed by a research team located at Queensland University of Technology (QUT) and James Cook University (JCU).

The research team would like to use data collected from your immunisation visit to assist with this study. If you agree to this, details of your immunisation visit will be made available to the research team for analysis. The data will be de-identified and the research team will NOT be able to identify you specifically in any way from the data they receive.

Your agreement to allow your data to be used is entirely voluntary and your decision will in no way impact upon your current or future relationship with your community pharmacist or your immunisation. If you do agree to participate you can withdraw your consent prior to receiving the vaccination. The research team will be unable to identify you from the information collected as part of the study. Consequently, after you have received your vaccination, withdrawal of your data from the study will not be possible.

Project Details

- The QPIP is an initiative of the Queensland Branches of the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia
- QUT and JCU will be evaluating the data collected as part of the QPIP
- The evaluation and analysis of QPIP data has been approved by the Human Research Ethics Committees at both QUT and JCU.
- Selected pharmacies throughout Queensland will participate in the study. To do so, pharmacies must agree to all the requirements of the study. These requirements include:
 - ✓ An **appropriately trained pharmacist** available to administer the vaccination
 - ✓ The ability to ensure the safety of all participants enrolled in the study by carefully selecting appropriate patients, monitoring patients for adverse events associated with administration of the vaccination and thoroughly documenting all activities undertaken as part of the project
 - ✓ Appropriate facilities to ensure patients are safe and comfortable
 - ✓ Adequate support staff to provide the immunisations safely and efficiently
 - ✓ Adequate equipment for storing the vaccines and disposing of sharp equipment and medical waste
- Data generated by the QPIP will be used to determine both the benefits and difficulties associated with pharmacists administering influenza vaccines. This information will be formulated into a report for the Chief Health Officer.

What training do pharmacists require to administer vaccines during QPIP?

The training undertaken by pharmacists to enable them to administer vaccines is in addition to their usual training to become a pharmacist. All pharmacists who provide vaccinations, as part of the QPIP, must undertake an approved course of study and must demonstrate an acceptable level of both knowledge and skill associated with the administration of vaccines.

Is it legal for pharmacists to administer vaccines during QPIP?

Yes. Pharmacists are covered by specific legislation (Amendment 18(1) of the Health (Drugs and Poisons) Regulations 1996) that enable them to administer vaccines as part of the QPIP.

Am I at any risk by allowing my details to be provided to the research team?

No. There is no risk to you by allowing the research team to access your specific immunisation details. The research team will not be able to identify you specifically from the data in any way.

What do I need to do?

The pharmacist has assessed your suitability to participate in the QPIP and you have agreed to receive the vaccination. Please now consider whether you are happy to agree to the research team accessing the information associated with your vaccination for the purposes of evaluating the value of the service.

What information will the research team have access to?

The research team will be able to access details related only to your immunisation. For example:

- Whether you have previously had an influenza vaccine (and experienced any adverse effects from that vaccine).
- Whether you have any allergies or illnesses.
- Who administered the vaccine during your QPIP visit.
- Whether you experienced any adverse effects after receiving the vaccine as part of the QPIP.
- Your comments regarding the service (in the form of a survey you will be asked to complete after receiving the immunisation).

All information collected as part the study, will be kept on record by your pharmacist – with only de-identified information from the QPIP participants being provided to the research team for analysis. Study data will be stored securely as defined by QUT's Management of Research Data Policy, which is available for you to read on request.

At the conclusion of your QPIP visit, you will also be asked to complete a feedback form regarding your QPIP vaccination experience. The information you provide in this form will contribute to the project analysis however your personal details will **not** be available to the QPIP project team.

In order to review the outcomes of the vaccination service for QPIP participants once they leave the pharmacy, the pharmacist may ask to telephone you approximately a week after your vaccination. Once again, the information you provide during this telephone call will contribute to the QPIP analysis and will not identify you in any way.

What will happen after the QPIP is completed?

The results of the study will be provided to the Chief Health Officer to inform future planning of vaccination programs in Queensland. A summary of the report may be obtained from your pharmacist on request.

Who do I contact if I have any questions?

Your pharmacist should be able to provide answers to all of your questions about the QPIP, however if you would like further information you can contact the QPIP research coordinator: Professor Lisa Nissen, Head, QUT School of Clinical Sciences on 07 3138 4404.

Thank you for helping with this research project. Please keep this sheet for your information.

Consent to participate in the Queensland Pharmacist Immunisation Pilot (QPIP)

- I have been provided with information about the Queensland Pharmacist Immunisation Pilot (QPIP).
- Details of the project have been clearly explained by the pharmacist and I have agreed to receive my influenza immunisation today as part of the study. I am happy for the research team to have access to the data associated with that vaccination for the purpose of evaluating the QPIP.
- I understand that allowing the research team to access my immunisation details is entirely voluntary.
- Before signing this document, I was given the opportunity to ask any questions about the immunisation service delivered by the community pharmacist, the type of information that is to be collected, and how the information collected will be used.
- I understand that any information or personal details gathered in the course of this research about me are confidential and that neither my name nor any other identifying information will be used or published without my written permission. I understand that any data collected for the purpose of the study will remain strictly confidential and not be used to identify any health professional or patient involved in the project.
- I understand that this information cannot be collected, stored or analysed for use for any other purposes apart from the QPIP.
- I have been informed of my right to question any part of the QPIP or to withdraw from the project at any time. I understand if I withdraw from the study after I have received my vaccination, my data may still be included. I understand that withdrawal from QPIP will not affect my usual pharmacist care.

Participant Name: _____

Address: _____

Participant Signature: _____

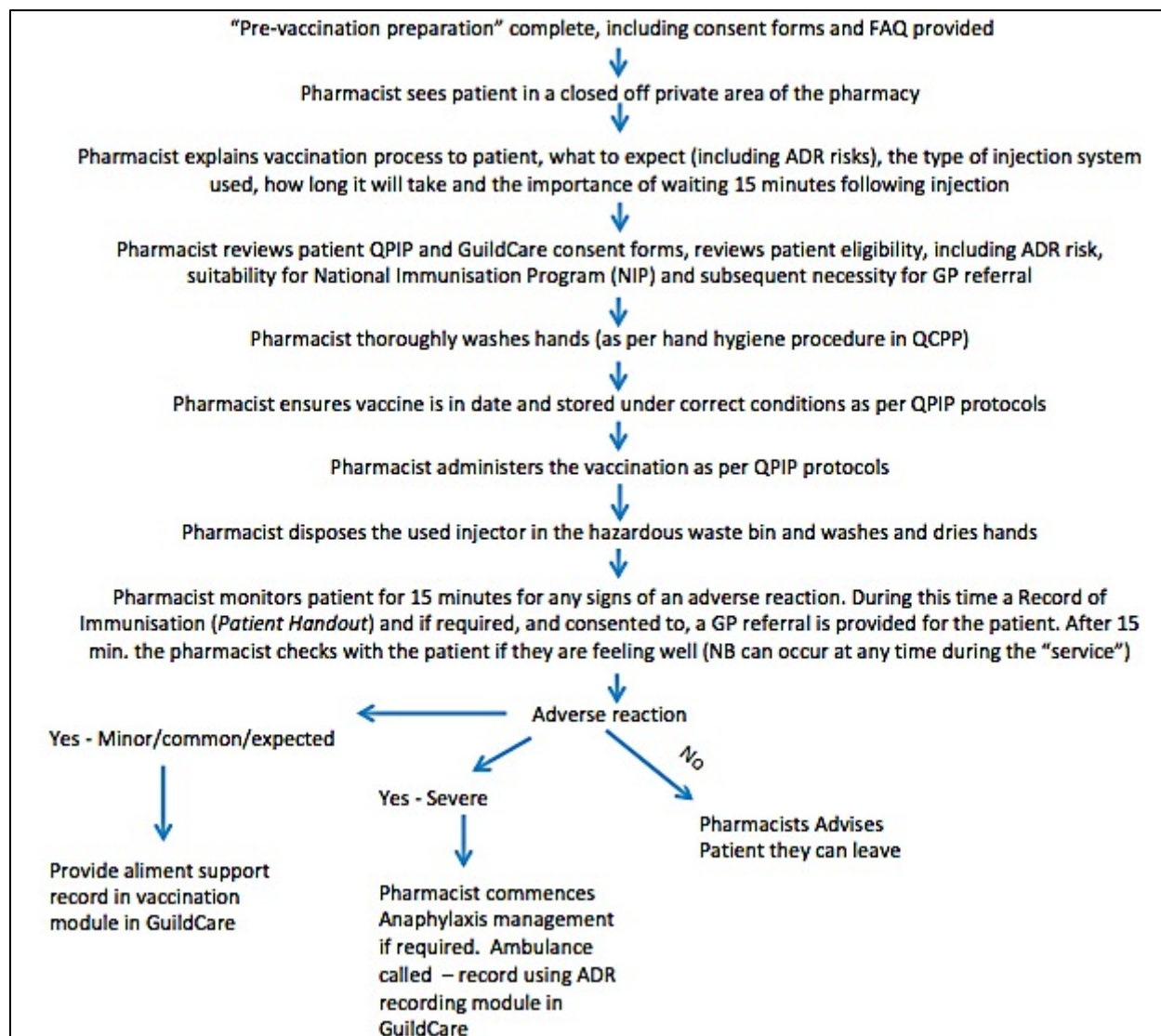
Date: _____

Witness Name: _____

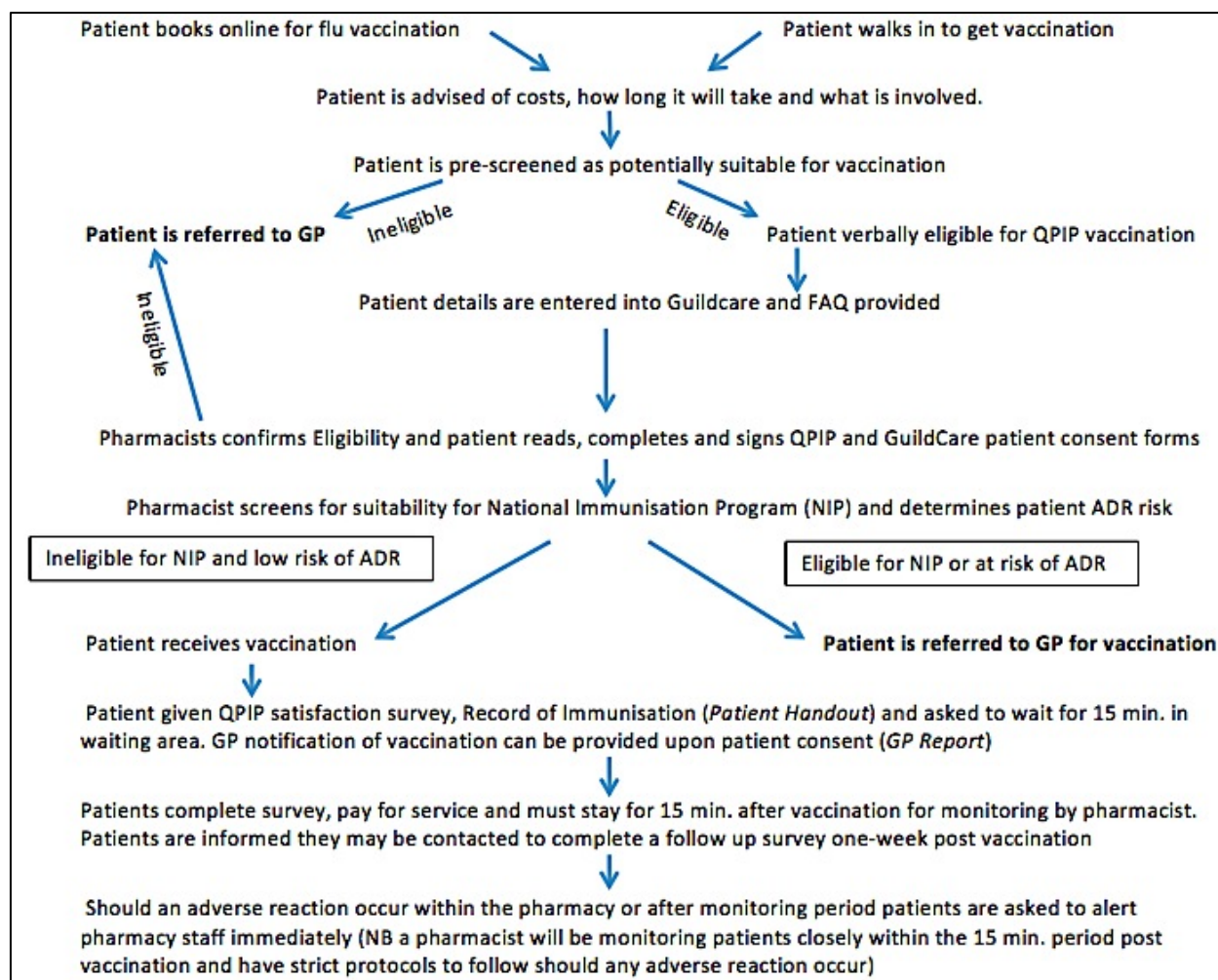
Witness Signature: _____

Date: _____

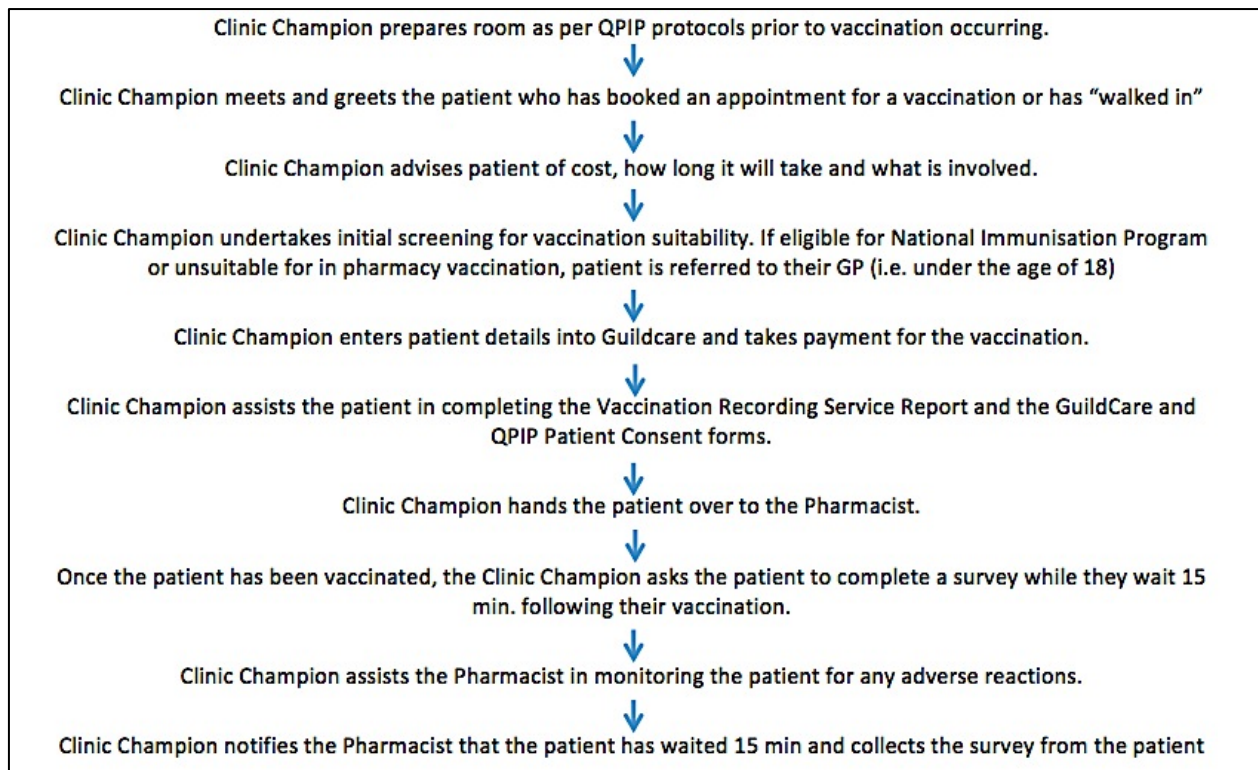
Appendix 16: Pharmacists Role in Patient Journey



Appendix 17: Patient Journey



Appendix 18: Clinic Champion Role in the patient Journey



Appendix 19: QUT Human Ethics Approval for QPIP



University Human Research Ethics Committee
HUMAN ETHICS APPROVAL CERTIFICATE
NHMRC Registered Committee Number EC00171

Date of Issue: 28/3/14 (supersedes all previously issued certificates)

Dear Prof Lisa Nissen

A UHREC should clearly communicate its decisions about a research proposal to the researcher and the final decision to approve or reject a proposal should be communicated to the researcher in writing. This Approval Certificate serves as your written notice that the proposal has met the requirements of the *National Statement on Research involving Human Participation* and has been approved on that basis. You are therefore authorised to commence activities as outlined in your proposal application, subject to any specific and standard conditions detailed in this document.

Within this Approval Certificate are:

- * Project Details
- * Participant Details
- * Conditions of Approval (Specific and Standard)

Researchers should report to the UHREC, via the Research Ethics Coordinator, events that might affect continued ethical acceptability of the project, including, but not limited to:

- (a) serious or unexpected adverse effects on participants; and
- (b) proposed significant changes in the conduct, the participant profile or the risks of the proposed research.

Further information regarding your ongoing obligations regarding human based research can be found via the Research Ethics website <http://www.research.qut.edu.au/ethics/> or by contacting the Research Ethics Coordinator on 07 3138 2091 or ethicscontact@qut.edu.au

If any details within this Approval Certificate are incorrect please advise the Research Ethics Unit within 10 days of receipt of this certificate.

Project Details

Category of Approval: Human Negligible-Low Risk
Approved From: 28/03/2014 **Approved Until:** 28/03/2016 (subject to annual reports)
Approval Number: 1400000098
Project Title: Queensland Pharmacist Immunisation Pilot (QPIP)
Experiment Summary: The project aims to investigate the benefits of suitably trained registered pharmacists administering influenza vaccinations to members of the general public in the setting of a community pharmacy.

Investigator Details

Chief Investigator: Prof Lisa Nissen

Other Staff/Students:

Investigator Name	Type	Role
Mr Tim Logan	External	Partner Investigator
Prof Beverley Glass	External	Partner Investigator
Ms Lynda Cardiff	Internal	Research Assistant

Appendix 20: Section 18(1) for QPIP

Enquiries to: Bill Loveday
Medicines Regulation & Quality
Telephone: (07) 3328 9820
Facsimile: (07) 3328 9821
CH009653

HEALTH (DRUGS AND POISONS) REGULATION 1996

APPROVAL UNDER SECTION 18(1)

I, Jeannette Rosita YOUNG, delegate of the Chief Executive, Queensland Health, approve:-

Pharmacists participating in the Queensland Pharmacists Immunisation Pilot

to supply and administer the restricted drugs (influenza vaccines) without a prior instruction from an authorised prescriber, subject to the following conditions:

1. That the Queensland Pharmacists Immunisation Pilot (QPPI) protocol is granted ethical approval by a recognised Human Research Ethics Committee.
2. That influenza vaccines are only administered by pharmacists who are participating in the QPIP to adult persons who have consented to take part in the trial.
3. That the participating pharmacist:
 - Is registered with the Pharmacy Board of Australia;
 - Has undergone appropriate immunisation training, including the management of adverse drug reactions, in accordance with the QPIP protocol;
 - Has a current First Aid Certificate and Cardiopulmonary Resuscitation (CPR) certification;
 - Has appropriate professional indemnity cover for immunisation practice; and
 - Is practicing at premises with the facilities required by the QPIP protocol.
4. That vaccines are administered to each individual person according to the QPIP protocol and
 - The potential for actual severe adverse reactions as specified in the current edition of the National Health and Medical Research Council (NHMRC) Australian Immunisation Handbook is considered and evaluated;
 - Contraindications to the administration of a vaccine as specified in the current edition of the NHMRC Australian Immunisation Handbook are considered and evaluated;
 - The dose and route of administration of vaccines is as specified in the current edition of the NHMRC Australian Immunisation Handbook or recommended/approved by the NHMRC.

Office


Postal
Locked Bag 21
Fortitude Valley QLD 4006

Phone
(07) 323 89808

Fax
(07) 323 89821

5. That records are kept in accordance with the QPIP protocol. Records of the administration of vaccines to individuals are to be retained for at least two years from the latest date of administration; records may be in an electronic form.
6. This approval is effective 1 January 2014 and shall remain in force for the duration of the QPIP or two years, unless sooner suspended, cancelled, replaced or surrendered, whichever occurs first.

Given under my hand at Brisbane this 20th day of December 2013.



Dr Jeannette Young
Chief Health Officer
Delegate of the Chief Executive
Department of Health

No. MRQ-0005

Please note that no expiry reminder advice is issued. Should you wish this approval to be reissued then a fresh application should be made.

NOTICE

Health (Drugs and Poisons) Regulation 1996

Section 18(3)

Notice is given to pharmacists administering influenza vaccines that the conditions included on approval MRQ-0005 have been imposed for the reasons stated below.

REASONS:

- | | |
|-------------------|---|
| Conditions 1 & 2: | Ensures that ethics approval is obtained prior to commencement of the trial, and that the vaccine is only administered to appropriate patients. |
| Condition 3: | Ensures that participating pharmacists are appropriately registered and trained. |
| Condition 4: | Ensures that the influenza vaccines are only administered under an approved protocol. |
| Condition 5: | Ensures accountability and traceability of the influenza vaccines and the patients to whom they are administered. |
| Condition 6: | Limits the life of the approval and restricts the approval holder to supplying and administering influenza vaccines on the current approval only. |

You may appeal against the imposition of these conditions within 28 days to a Magistrates Court.

Appendix 21: QPIP1 Approved Site List

South East Queensland arm (TWC):-

Australia Fair	Kippa-Ring
Bellbowrie	Lutwyche
Booval Fair	Margate
Brookside	Maroochydore 1
Browns Plains	Maroochydore 2
Buranda Centro	Mermaid Waters
Burpengary	Mt Gravatt Plaza
Calamvale	Mt Ommaney (Shop 1)
Caloundra	Mt Ommaney (Shop 44)
Capalaba	Myer Centre
Carindale Lower	Narangba
Carindale Upper	Nerang
Carseldine	Noosa
Chermside	North Lakes
Cleveland	Pacific Fair
Clifford Gardens	Park Ridge
Coorparoo	Redcliffe
Corinda	Robina
Fairfield Gardens	Runaway Bay
Garden City	Stafford
Gasworks	Sunnybank Plaza
Highfields	Underwood
Indooroopilly	Valley Metro
Kawana Waters	West End
Kawana Waters 2	Windsor
	Wynnum Plaza

North Queensland arm:-

Alive Discount Pharmacy - Abbott Street

Kuranda Pharmacy

V Pharmacy - Smithfield

Yungaburra Pharmacy

Calanna Pharmacy Woree

Calanna Pharmacy Edmonton

Marlin Coast Amcal

Discount Drug Stores Pease Street

Annandale Pharmacist Advice Pharmacy

Amcal Pharmacy Cannonvale

Amcal Robert Poole's Pharmacy

Bluewater Pharmacy

Calanna Pharmacy Kirwan

Calanna Pharmacy Aitkenvale

Alive Pharmacy JCU

Liveline Pharmacy Airlie Beach

AFS Friendly Care Pharmacy

Dupuy's Pharmacy

Healthpoint Northside Mater Pharmacy

Healthpoint Northern Beaches Mackay

Healthpoint Day and Night Mackay

Bowen Plaza Pharmacy

Bowen Healthcare Pharmacy

Emerald Pharmacy First

Amcal Max Yeppoon Central Pharmacy

LiveLife Pharmacy Keppel Plaza

LiveLife Pharmacy Gracemere

Gracemere Amcal Pharmacy

Mt Isa Pharmacy First

Queensland Pharmacist Immunisation Pilot (QPIP)

APPROVED PILOT SITE

***Pharmacist Administered
Influenza Vaccinations***

TERRY WHITE AUSTRALIA FAIR

**This pharmacy is an approved site for the
Queensland Pharmacist Immunisation Pilot**

Pharmacists administering the influenza vaccination as part of the pilot in this approved pharmacy are registered Health Professionals who have undertaken approved training and are credentialed to provide immunisations

This pilot has been legally authorized by the granting of an approval by the Queensland Department of Health under Section 18 of the *Health (Drugs and Poisons) Regulation 1996*



Queensland University of Technology Ethics Approval Number: 1400000098
QPIP Research Coordinator: Professor Lisa Nissen, School of Clinical Sciences
Queensland University of Technology Phone - 07 3138 4404