Submission for extension of current classification of Tetanus-Diphtheria Pertussis (Tdap) Vaccination

Green Cross Health Ltd and Natalie Gauld Ltd

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Executive Summary

This application requests the extension of the current classification status for pharmacist-supply of the tetanus-diphtheria-pertussis vaccination (Tdap). This extension allows administration by pharmacists to adults and teenagers 18 years and over (as currently occurs), and also to pregnant women of 13 years and over. Pharmacists will still be required to have completed an approved vaccinator's course and comply with the immunisation standards of the Ministry of Health.

Internationally, accredited pharmacists are increasingly being used to administer vaccinations. Millions of vaccinations are administered by pharmacists in the United States (US) where pharmacists first did vaccinations in the 1990s.[1] Pharmacist-administered vaccinations are also occurring in the United Kingdom (UK),[2] Ireland,[3] Canada,[4] Portugal,[2] and Australia.[5] This move recognises the accessibility and convenience of pharmacy and the advocacy of pharmacists as health professionals, both of which increase awareness of and opportunities for consumers to become vaccinated. Vaccination rates improve[6-9] and pharmacist-administered vaccinations have been positively received by healthcare consumers,[8,10] including in New Zealand.[11] In New Zealand, a survey undertaken by Professor Sarah Hook,[11] from the School of Pharmacy, the University of Otago, found that of those consumers surveyed who had their flu vaccination in a pharmacy 42% had not received a flu vaccine the year before. This highlights the opportunity to target those who remain unprotected from serious diseases. Pharmacists have been positive about vaccination,[10] and in New Zealand over 25% of community pharmacists have undertaken this qualification, despite the first vaccine only being reclassified in 2012.

In the US, pharmacist-administered vaccinations have the support of the American College of Physicians, American Society of Internal Medicine,[12] and the Centers for Disease Control and Prevention (CDC).[13]

Pharmacists are increasingly being permitted to vaccinate adolescents and children, e.g. in parts of Canada,[14,15] many states of the US,[16] and in the UK.[8]

The Tdap vaccine is used to prevent tetanus, diphtheria and pertussis. In childhood, the stronger version (full dose tetanus, full dose diphtheria, and full dose acellular pertussis, DTaP) is given according to the childhood immunisation schedule. At age 11, a booster is given (the adult, lower strength, Tdap). This booster is now also recommended for use during pregnancy at 28-38 weeks' gestation to protect the infant from pertussis before their initial series of vaccines are completed. The burden of pertussis is greatest in young infants, who are most likely to suffer from serious illness including needing hospitalisations or intensive care.[17] Māori and Pacific ethnicities are disproportionately affected, and so are those in the highest deprivation groups. The disease is most likely to be fatal in infants under six months.

A significant challenge in New Zealand is in attaining high vaccination rates with Tdap during pregnancy. The current vaccination rate is not certain, but has been estimated at only 30% (personal communication Dr Helen Petousis-Harris, University of Auckland, November 2016), and others have described the uptake as low or poor.[18]

The current situation allows only those 18 years and over to get Tdap administration in pharmacy. Extending administration of Tdap vaccinations by approved pharmacists to pregnant women 13 years and over has clear benefit in access. There is also benefit to have the discussion with those who are in households with young children. The benefit-risk profile of the Tdap vaccination given by an appropriately trained health professional is consistent with (or better than) other pharmacist-only medicines or medicines with exemption to supply through pharmacists. Benefits of Tdap vaccination in pregnancy in reducing Tdap cases and reducing hospitalisations have recently been proven.[19] Risks of the vaccination using trained vaccinators with first aid training and appropriate set-up are extremely low.[3]

Along with General Practice, pharmacists can continue to facilitate an increase in awareness for the public around all vaccines and the importance of discussing funded vaccinations with their practitioners.

The pharmacy process will be comprehensive including thorough screening, record-keeping, notification to the healthcare consumer's GP (with consent), and reporting of adverse events to the GP and the Centre for Adverse Reactions Monitoring (CARM). Pharmacy is willing and able to play a greater role in public health.

Part A

1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine

Combined diphtheria-tetanus-acellular pertussis vaccine

2. Proprietary name(s)

Three vaccinations are provided in a single injection called combined diphtheria-tetanus-acellular pertussis (dTap or Tdap) vaccine. Products on the market are Boostrix®, and Adacel®.

Note: The formulation used in over seven year olds is commonly known as Tdap or dTap (pertussis and diphtheria are at considerably lower doses than the version used in young children and infants, and tetanus is around half strength).

The formulation used in children up to the age of seven is known as DTaP (showing all three vaccinations are in high strength). The age limitation in the classification statement would mean that this vaccine would not be used by pharmacists.

3. Name of company/organisation/individual requesting reclassification

Green Cross Health Ltd, the parent company for Life and Unichem Pharmacies in New Zealand, and Natalie Gauld Ltd. Neither are sponsors for the medicine.

4. Dose form(s) and strength(s) for which a change is sought

Single dose injection. The strength does not need to be specified in the classification statement, as the age is used instead and only certain strengths are available in adults.

The Boostrix data sheet reports that 1 dose (0.5 mL) contains:
Diphtheria toxoid* not less than 2 International Units (IU) (2.5 Lf)
Tetanus toxoid* not less than 20 International Units (IU) (5 Lf)
Bordetella pertussis antigens
- Pertussis toxoid* 8 micrograms
- Filamentous Haemagglutinin* 8 micrograms
- Pertactin* 2.5 micrograms

* adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$) 0.3 milligrams Al^{3+}
and aluminium phosphate ($AlPO_4$) 0.2 milligrams Al^{3+}

5. Pack size and other qualifications

The product is only for single dose use and is for injection. No pack size qualification is needed.

6. Indications for which change is sought

For booster vaccination against diphtheria, tetanus and pertussis.

7. Present classification of medicine

Diphtheria, tetanus and pertussis (acellular, component) vaccine; prescription except when administered in a single dose to a person 18 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health.

8. Classification sought

Prescription only medicine except when administered in a single dose to a person 18 years of age or over or to pregnant women 13 years and above by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health.

NB: we do not recommend including the gestation stage, this is better managed in the screening tool so that it can be updated quickly should the recommendation in NZ change.

9. Classification status in other countries (especially Australia, UK, USA, Canada)

Internationally pharmacist-administration of vaccines is becoming common through various mechanisms, sometimes through reclassification, but in some areas by other initiatives such as local state laws in the US which may allow the pharmacist to be a prescriber of the vaccine. Typically, pharmacists need to have additional training in vaccination and resuscitation and maintain that knowledge.

Table 1 Country and availability

Country	Availability
Canada	Schedule II (equivalent to pharmacist-only). Variation by province occurs. British Columbia allows pharmacists to give Tdap in people 5 years and over, for example. [20]
USA	Pharmacists can provide Tdap in the majority of states without a prescription. Ages vary by state, with many states allowing vaccination administration
UK	Prescription classification but available through pharmacists under different mechanisms
Australia	Prescription only but available through pharmacists without prescription in some states of Australia (e.g. Victoria, 18 years and over)

In 2015, few US states had a minimum age for a child being vaccinated in the pharmacy of 14 years or over (three states); 18 years or over (eight states).[21]

10. Extent of usage in New Zealand and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Sales figures for Tdap are unknown. Given this is used for a funded booster at 11 years, and the NZ birth cohort is around 65,000, but it is used for other booster shots, particularly during

pregnancy; it is expected that the sales would be over 80,000 units per year. There are concerns about low uptake of Tdap in pregnancy.[22]

According to the Medsafe website, Adacel® was first consented for use on 31 May 2007 and Boostrix® on 9 November 2000. Diphtheria vaccine was first available in NZ in 1926, tetanus vaccine in 1940, and pertussis in 1945 (but initially was whole-cell; the acellular vaccine is associated with less adverse effects).

11. Labelling or draft labelling for the proposed new presentation(s)

There would be no change to labelling for the proposed change in classification. This medicine is not going to be self-administered so consumer labelling is unnecessary. Companies may have packaging harmonised with Australia.

12. Proposed warning statements if applicable

Current packaging would remain with no new warning statements.

13. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

Any adult Tdap vaccination that is registered on the NZ market will be affected.

Part B

Reasons for requesting reclassification change including benefit-risk analysis.

Please note the following abbreviations commonly used with this vaccination:

Td = Tetanus and diphtheria (high strength tetanus and low strength diphtheria)

Tdap = Tetanus, diphtheria and acellular pertussis (medium strength tetanus and low strength diphtheria and pertussis). This vaccination is used for the 11 year old booster (funded), and for later boosters if required. This is the vaccination pharmacy would administer. This vaccination is also used for the primary vaccinations from 7 years of age onwards for tolerability reasons.

DTaP = Diphtheria, tetanus and acellular pertussis (all in high strengths). This vaccination is provided only to children under 7 years and is used as the primary vaccinations at 6 weeks, three months, five months, and four years

The primary aim of this application is to increase the access and convenience of Tdap vaccination for pregnant teenagers below 18 years of age, and reduce the healthcare burden of pertussis for infants. In NZ, rates of hospitalisation of infants with pertussis are approximately three-fold higher than in Australia and the United States.[23]

In NZ, Tdap uptake in pregnancy is sub-optimal[18] (estimated at around 30%, personal communication, Dr Helen Petousis-Harris, Nov 2016). The current Tdap vaccination classification allows pharmacists to administer the vaccination only in those 18 years and older. Currently, if a pregnant woman who is younger than 18 asks a pharmacy for a pertussis vaccine, or is recommended it in the pharmacy, she will be turned away. However, there is no additional safety risk with administration in pharmacy in a pregnant woman under 18 years. Thus, it is inequitable for a person under 18 years to be denied this vaccine from pharmacy.

The initial rationale for a minimum age of 18 years for pharmacist administration (versus the 16 years initially proposed) was because there was funding for the booster through general practice up to and including 18 years, to complete the full childhood vaccination recommendation. However, the difficulty this creates is that pregnant women 18 years and over can have the Tdap vaccine in the pharmacy, but women who are 17 years or age or lower cannot.

This application has arisen in part from the funding by Waikato District Health Board (DHB) of pharmacy administration of Tdap vaccine in pregnant women which started 1 November 2016. This funding has been implemented to try to increase uptake of Tdap vaccine during pregnancy. There is a need to ensure that teenage mothers, particularly those of Māori and Pacific ethnicity and those in high deprivation groups, where the need has been highlighted even more, have the highest possible chance of getting this vaccine. A teenage mother will probably be more likely to be sharing a house with other family members, with her infant more likely to be exposed to pertussis than infants of older mothers. We need to remove existing barriers to access for such women.

1. Benefits to the consumer, public and others expected from the proposed change

Benefits of widening access to Tdap vaccinations in pregnant teenagers through vaccinator-pharmacists potentially include:

- Convenience in being able to easily access the vaccine at a handy location
- Reducing the barrier of needing an appointment
- Increasing uptake in Tdap vaccinations in a hard to reach age group, probably reaching more vulnerable groups
- Potential to reduce morbidity and mortality in infants and therefore hospitalisations and intensive care usage
- Reducing cost to the taxpayer (healthcare costs)
- Further enhanced collaboration with GP's in sharing information on the care of patients

Use in pregnancy

In New Zealand and many other countries, vaccination is recommended in pregnancy for pertussis.[24,25] The pertussis vaccine in pregnancy is for the benefit of the infant. It passes antibodies across the placenta into the infant. It also reduces the likelihood of transmission from the mother to the infant if the mother is infected at some time after birth. The vaccine is recommended to be administered in every pregnancy.

Infants are most vulnerable to serious illness with pertussis in the first few months of life,[17] when they are too young to have received the complete three-dose infant pertussis vaccine series. A single dose of acellular pertussis vaccine, given during pregnancy, provides protection to this vulnerable age group.[19,26,27] Pertussis immunisation in pregnant women (from 28 to 38 weeks' gestation) is now recommended and fully funded in NZ,[24] i.e. there is no cost to the woman. General practice and hospitals throughout New Zealand provide these free vaccines. In Waikato, pharmacy is also now funded (as of 1 November 2016) to provide this vaccine in pregnancy.

Funded pertussis vaccine uptake during pregnancy in NZ was estimated (in 2014) at only 13%.[22] It was described as 'poor' in 2015, with suggestions that DHBs and the Ministry of Health need to improve this uptake.[28] A more recent estimate is around 30% (personal communication, Dr Helen Petousis-Harris, Nov 2016). NZ is not alone in the low rates, with some other countries or regions also relatively low, e.g. parts of London in the UK had a 26% uptake.[29] Like NZ, other countries have described disparities with the impact of pertussis greater in more deprived areas.[30] In NZ approximately 50% of the children requiring intensive care unit admission because of life threatening pertussis live in households that are in the most deprived 20% of all households in NZ.[31] The Child and Youth Mortality Review Committee[17] called for addressing barriers to immunisation service access through national policies aiming to achieve equitable and on-time immunisation coverage "by providing pertussis booster vaccinations in a broad range of settings."

From 2003 to 2013, 1465 children in New Zealand were hospitalised with pertussis infection, and 65 children were admitted to a paediatric intensive care unit.[32] Data to 2009 showed a

pertussis hospitalisation rate in NZ that was three times that in the US and Australia.[23] The estimated inflation-adjusted cost of this was $8.3 million, and the epidemic years of 2012 and 2013 were responsible for over 40% of the cost.[32] Most of these children (78% of those hospitalised, and 98% of those in intensive care) were aged under one year. There would be 1465 families with disrupted lives, affected by their child's hospitalisation. The epidemic years of 2012 and 2013 occurred despite 75% of infants being up-to-date with pertussis vaccination at six months.[28]

Infants are most affected by the morbidity and mortality. Annual hospitalisations in people 10 years and older are very small, only seven persons per year across that whole age group on average.[17]

Families of Māori or Pacific ethnicity or in high deprivation are disproportionately affected by pertussis.[31,32] Infants in very high deprivation areas are less likely to be up-to-date on vaccinations at six months.[28] Teenage pregnancies are more likely in these ethnicities, and there is a link between social disadvantage and teenage births,[33] thus, having additional barriers to Tdap access in pregnant women under 18 years of age (compared to those 18 and over) will impact on those groups whose babies are at highest risk.

Benefits of reducing the age of Tdap in pharmacy include convenience to a wider range of New Zealanders. Pharmacies are often open extended hours compared to general practice and the usual hours many people work or have schooling. Young people may be less likely to have a car than those 18 and over, and therefore need to rely on other family members (who may be working) for transport. Our unpublished survey of Green Cross Health pharmacist-vaccinators revealed reports of families wanting teenagers vaccinated for influenza in the pharmacy, and being referred to general practice where they need to make an appointment at a time that may require juggling (or missing) work, school and other commitments. This should also apply for Tdap.

Adolescents can be hard to reach with vaccinations. In the meningococcal C outbreak in Northland, this age group were the most difficult to reach,[34] with walk-in mobile clinics eventually set up to help access this population. In the future, the DHB could use pharmacies instead to get to this group of people.

Patients should be under a lead maternity carer (LMC) during their pregnancy and may not present at the general practice during their pregnancy. If they do present at the general practice, they may not see the practice nurse/s who provide vaccinations, and their doctor may have delegated vaccination to them so may be less informed about the need for Tdap vaccine in pregnancy. There may be urgent needs within the consultation that preclude a proactive approach about vaccination. Having pharmacists able to vaccinate young pregnant women (as well as the current situation of 18 years and over) would help inform patients of the need for vaccination, provide an opportunity for any concerns to be discussed with a health professional with training in vaccination, and provide an ability to immediately vaccinate should the patient wish it and it be in the recommended time period for vaccination.

Cocooning

Cocooning involves vaccinating those people in close contact with young infants, including household members and caregivers. This provides indirect protection. The Global Pertussis Initiative recommends vaccination during pregnancy as a primary protection, owing to efficacy, safety and logistic advantages over cocooning.[25] In NZ, cocooning is recommended but such vaccinations are not funded.

Tdap vaccination in pregnancy and adolescence for pertussis

Tdap dosing in pregnancy is a relatively new initiative internationally. In 2010, it was noted that safety and efficacy data were lacking,[35] however, this has since been remedied.[19,36-38]

Adding the 11 year Tdap booster to the vaccine schedule in the US in 2006 was associated with reductions in hospitalisations for pertussis for three of the four years studied.[39] However, the authors noted the need to maximise uptake in this age group (it was 78% in 2011) to improve the potential benefits. New Zealand also added in the Tdap booster at 11 years in 2006, with Grant and Reid expecting that this dose "is potentially of greater significance for protecting vulnerable infants from household exposure in NZ given the age profiles and crowding…"[35] We are not aware of the uptake rates for the 11 year old booster.

Pharmacy vaccinations

Pharmacy delivery of vaccines may be one of the best opportunities for increasing consumer access given the accessibility and extended hours for pharmacies, and that no appointment is needed. Pharmacy immunisation delivery has become increasingly popular in the United States of America, and Canada, with the UK, NZ and Australia more recently becoming involved in this area. Such availability has been associated with a positive impact on uptake of vaccinations,[40,41] including with funding of the service in pharmacies.[42] High rates of consumer satisfaction have been reported.[11,42]

In a NZ study in which consumers were surveyed after being vaccinated in pharmacies, 42% of participants vaccinated for influenza had not received the vaccine the year before.[11]

Recent qualitative research in NZ showed that most women with an infant under one year were positive about the idea of receiving funded pertussis vaccine at a pharmacy, for reasons of accessibility, no need for an appointment, and increasing likelihood that pregnant women would be informed of the recommendation.[43]

We anticipate that most vaccinations through pharmacy will be incremental gains, e.g. teenagers who never get around to booking in with their doctor. Most community pharmacies are open at least six days a week, and many are open long hours. An appointment will often not be necessary. There are over 900 pharmacies around the country, conveniently located for most of the population. Increasing numbers of these pharmacies are providing vaccinations.

A survey of adults who received an influenza vaccination from the pharmacist in New Zealand found that 42% of respondents had not received an influenza vaccine the previous year, often because they were "too busy".[11] A European survey found only 67% of those intending to have a vaccination actually received a vaccination.[44] In Australia, time and inconvenience were cited by a quarter of adults under 65 years with chronic medical conditions who did not get an influenza vaccination.[45] Convenient location and convenient opening hours were cited by people in the UK eligible for funded vaccination who chose to pay for their vaccine in a pharmacy instead.[46] Most children aged 13-17 will have parents who are working, and the children will be at school. Vaccination in a pharmacy will be accessible and convenient.

In NZ, pharmacists who have undergone additional training in vaccinations started vaccinating about five years ago. Around 20% of community pharmacists were approved vaccinators by 2015, and rapid growth is evident in the number of pharmacists who are approved vaccinators.[47] Pharmacists can deliver influenza, pertussis (as Tdap), meningococcal, and shingles vaccines. However, pharmacists in NZ have not typically delivered vaccines to pregnant women, primarily because these vaccines are funded through other providers (e.g. the general practitioner) and not pharmacies. Influenza vaccine in people 65 years and over is funded in a limited number of district health boards, including Waikato. Waikato has just started funding Tdap and influenza vaccinations in pregnancy through pharmacy (as of 1 November 2016, with influenza starting when stock becomes available in 2017).

US Support of Pharmacist Vaccinators

The American College of Physicians and American Society of Internal Medicine stated in 2002:[12]

> *"ACP-ASIM supports the use of the pharmacist as immunization information source, host of immunization sites and immunizer, as appropriate and allowed by state law. ACP-ASIM will work with pharmacy organizations to increase immunization awareness."*

No concerns about pharmacist-immunisation were outlined by these doctor groups who noted:

- The potential benefit of non-physician immunisation
- Pharmacists increase access to immunisation through extended opening hours and locations
- Benefits expected include decreased antibiotic resistance and increased adult immunisation

In the US, pharmacist-administered vaccinations also have the support of the Centers of Disease Control and Prevention (CDC).[13] CDC noted that *"Pharmacists and community vaccinators are uniquely positioned to promote and provide vaccines to people in a wide range of communities."*[13]

2. Potential risk of harm to the consumer as a result of the proposed change, and factors to mitigate this risk.

Safety of the Tdap vaccination in pregnancy is good.[38,48] It is not a live vaccine. A NZ observational study involving a telephone interview at 48 hours and four weeks post-vaccination in 793 women concluded that: "Vaccination with Tdap in pregnant women was well tolerated with no SAE [serious adverse events] likely to be caused by the vaccine."[37]

Consumer harm from Tdap vaccination is low. There is a very rare chance of anaphylaxis, and a risk of fainting which could lead to hitting the head. The Tdap vaccine can be painful. Other adverse events tend to be short-lived. These reactions are managed through training and equipment for CPR, sitting the patient for the vaccination, and drawing up doses out of sight to minimise fainting (see standard operating procedures used in pharmacy). During the informed consent process contraindications and precautions are checked for and adverse effects are discussed. Written information is provided which includes management of adverse effects. See SMARS data from Medsafe.

Pharmacists receive the same vaccination training and assessment as other vaccinators, typically being trained by IMAC. The IMAC training includes that they are observed for two vaccinations in their assessment, and other aspects of the requirements are reviewed including cold chain accreditation. Pharmacies have a full suite of Standard Operating Procedures (SOPs) for vaccinations. Templates for these procedures are available from Green Cross Health, or the Pharmacy Guild of New Zealand, and have been reviewed by IMAC. There will be no change required for the SOPs as pharmacists should already have the dose of adrenaline for the 13 year age group from the Resuscitation Guidelines given the influenza vaccine reduction in minimum age.

Community pharmacies are easily accessible to and used by most of the population, healthy and unwell, and all ages. Healthy pregnant teenagers on minimal or no medication are not enrolled in a single pharmacy, so can use the one most conveniently located for them at the time.

3. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated

The only pharmacists able to provide Tdap vaccinations will have successfully completed the approved vaccinator's course and clinical assessment and be meeting the requirements in standards set by the Ministry of Health. Establishing appropriate persons to vaccinate will be straight-forward for these trained pharmacists. The pre-vaccination checklist and consent form attached (See Appendices) will be used by the pharmacist, recording each consultation. Those fulfilling referral criteria would be referred to the GP, those answering no to all questions will be vaccinated if they consent.

4. Relevant comparative data for like compounds

Pharmacist administration of influenza vaccine was changed from a minimum age of 18 years to 13 years in February 2016. No data has been collected on the uptake in the younger age group.

5. Local data or special considerations relating to New Zealand

Pertussis vaccine was first given alone from 1945, from 1960 it was given as Diphtheria, tetanus and whole-cell pertussis triple vaccine.[24] Acellular pertussis vaccine replaced whole-cell pertussis vaccines in 2000 to reduce adverse effects. Since January 2013, funding for Tdap vaccine has extended to pregnant women, although some regions provided this earlier, e.g. Canterbury.

The current NZ childhood immunisation schedule includes DTaP at ages 6 weeks, 3 months, 5 months and 4 years, then the lower-strength Tdap is given at 11 years.

The Immunisation Handbook notes that Tdap is recommended but not government-funded for:

- Lead maternity carers and other health providers in neonatal units and other clinical settings with exposure to infants (with a booster dose at 10-year intervals)
- Household contacts of newborns
- Early childhood workers (with a booster dose at 10-year intervals)

In NZ, Māori and Pacific Island and high deprivation index populations are disproportionately affected by pertussis hospitalisations.[17] While pharmacy would like to help address this disparity, reclassification is a separate decision from funding. The ability of pharmacy to be able to step in at short notice to vaccinate pregnant adolescents with funded vaccines if necessary will be increased through this extension. This is particularly important given that a new pertussis epidemic could happen at any time now.

Local data[43,49,50] suggests that multiple barriers exist to getting Tdap vaccination in pregnancy, particularly lack of awareness of the Tdap vaccination in pregnancy; fear of side effects, and doubt about effectiveness. Misinformation or lack of information from health professionals has contributed to low uptake. Hill's study in Canterbury women post-partum found that the 55% of respondents who reported receiving encouraging information about Tdap vaccination in pregnancy were more likely to receive it from midwives (55%) than GPs (38%) or practice nurses (12%). Discouraging information was most likely to come from GPs (41%), much higher than whanau and friends (2%) or the internet (3%). Of women not receiving the Tdap vaccine in pregnancy, 60% reported receiving discouraging GP information. Twenty-two per cent of women who did not receive Tdap said the inconvenience of getting to the GP was a potential influencing factor. Note that this quantitative study occurred in 2013 in Canterbury, in the early days of funded Tdap in pregnancy.

A Ministry of Health commissioned qualitative research project by Litmus[50] reported that:

> *"The pathway for pregnant women receiving immunisation is not convenient and women face many barriers accessing immunisation through their general practice. Māori and Pacific pregnant women face more barriers to accessing immunisation through their general practice than Pākehā pregnant women. These barriers include transportation, arranging childcare and time off work. Some women are also reluctant to visit their general practice, if they owe money for consultations and prescriptions."*

Pharmacists have been identified in NZ as an additional advocate in prevention of pertussis.[18] A Ministry of Health workshop regarding pertussis control held in 2015 noted that pharmacists could promote immunisation when folic acid vitamin supplements and pregnancy tests are purchased. A qualitative study in 2015 found that women with an infant aged under 12 months supported pharmacists providing the pertussis vaccine (preferably funded). The rationale for this support was that they thought it would aid the likelihood of women being recommended to have the vaccine in pregnancy and would aid access.[43]

Over 25% of community pharmacists provide vaccinations in New Zealand, a useful and convenient workforce to be able to tap into if necessary for all New Zealanders. Having teenagers able to be vaccinated by pharmacists will reduce barriers for a hard to reach group,[34] or for whom access may be difficult, when an epidemic or pandemic occurs.

Provision of vaccinations through community pharmacy in NZ started with Pharmacy 547 in Hamilton having pharmacist-vaccinators in 2010, then 22 pharmacists were authorised in mid-2011 administering 400 vaccines in this short period of time. We now have around 700 pharmacists approved as vaccinators delivering vaccines throughout the country.

Pharmacy administration provides incremental gains. A New Zealand survey of adults receiving an influenza vaccination from a pharmacist found that 42% of respondents had not received an influenza vaccine the previous year.[11] Satisfaction with the vaccination was very high with 98% rating it 4 or 5 on the Likert scale.

As reported to the Medicines Classification Committee in 2015, most (80.0% of 114) Green Cross Health pharmacists who vaccinate and responded to our (unpublished) survey conducted in July 2015 reported that they had received requests for vaccinations in teenagers. It is convenient for caregivers to vaccinate their teenagers at a time that suits, without having to make an appointment.

Informed consent is a requirement in New Zealand health provision. Pharmacists will provide information for patients about their vaccination and gain their consent (and parent/guardian assent for those under 16 years) prior to giving the vaccination. Written information will also be provided. Health literacy issues exist in New Zealand,[51] and pharmacists receive under-graduate and continuing education on this topic.

Fragmentation of care has been raised as an issue in New Zealand, so pharmacists inform the general practitioner of vaccinations with patient consent, minimising this risk. Work has progressed on getting pharmacists' information on vaccination administration onto the MoH Immunise Now, web portal with an ongoing pilot phase, and this electronic recording is being used in six Waikato pharmacies providing Tdap to pregnant women.

NZ government strategy

Administration of Tdap vaccinations by approved pharmacists both provides public health benefits and potential benefits to the taxpayer as outlined above. This extension remains in line with NZ government strategy of closer to home, patient-centred and patient-empowered care, and healthcare workers working to the tops of their scopes of practice.[52] Implementing

the Medicines New Zealand action plan (2015-2020) highlights the need to remove barriers to access, and states that access should take into account an individual's personal preferences.[24] Furthermore, this extension empowers individuals and families/whanau to manage their own medicines and health in the way that they choose.

Population growth, an aging population and developments in health are increasing demand for health services in a constrained fiscal environment. These require better use of the existing health workforce, including extending existing roles.[53] Extending Tdap vaccination to the younger age group who are pregnant, along with the previous extension of influenza vaccination ensures pharmacy comfort with this age group in case of an outbreak e.g. of meningococcal disease.

6. Interactions with other medicines

If Tdap is to be given at the same time as another injectable vaccine or immunoglobulin, the products should always be administered at different sites. It is possible that pregnant women will receive an influenza vaccine and Tdap at the same visit to the health care provider, particularly in Waikato DHB where funding is in place for both through pharmacy. This will be included on the screening tool.

The vaccine should not be mixed with other vaccines.

7. Contraindications and precautions

The Immunisation Handbook reports that a history of immediate severe anaphylactic reaction to the vaccine or any component of the vaccine is the only contraindication for this vaccine.

These will be covered in the vaccination checklist, and pharmacists will have received the comprehensive training and completed vaccinator requirements including first aid training to the equivalent of level 4 (as per the Immunisation Handbook). Pharmacies offering the vaccinations will have a private area for consultation available and will have the necessary emergency equipment available, and the pharmacist-administered vaccination will be advised to the patient's GP as previously discussed. Six pharmacies in the Waikato (and soon to be rolled out to other Vaccinating pharmacists) will be using the MoH Immunise Now web portal which means that Tdap vaccines in pregnancy can be electronically documented for other providers to see. Patients will wait within line of sight in the pharmacy for 20 minutes after being dosed no different to what occurs currently across all vaccination administration. They will also be given written details of a process to be followed should they become unwell in the following 24 hours post-vaccination as well as information on the importance of vaccinating others in the family who will come into close contact with the newborn.

The Immunisation Handbook notes the following precaution specific to Tdap: children with an evolving neurological disorder (e.g. uncontrolled epilepsy or deteriorating neurological state), and very premature babies. Persons 13 years and over presenting in pharmacy will not fall into either category.

For all vaccines, the Immunisation Handbook provides the following general precautions: thrombycytopenia or bleeding disorder, and acute febrile illness (but not minor infection). It recommends that the vaccine is postponed where there is a fever over 38°C.

The Boostrix datasheet notes a contraindication of encephalopathy of unknown aetiology within seven days after previous pertussis-containing vaccination. A further contraindication is noted with a history of transient thrombocytopenia or neurological complications after an earlier immunisation against diphtheria and/or tetanus.

The Boostrix datasheet includes the following precautions:

- Temperature ≥40°C within 48 hours of pertussis-containing vaccine administration, not due to another identifiable cause
- Collapse or shock-like state within 48 hours of pertussis-containing vaccine administration
- Persistent, inconsolable crying lasting 3 hours or longer occurring within 48 hours of pertussis-containing vaccine administration
- Convulsions with or without fever, within 3 days of vaccination
- Immunodeficiency or immunosuppressive therapy may affect the immunologic response

8. Possible resistance

Not applicable.

9. Adverse events - nature, frequency etc.

The adverse events are compatible with availability without prescription. The Immunisation Handbook [24] states that:

> *The adult reduced-concentration Td and Tdap (Boostrix) vaccines have been found to have no safety concerns in those aged 10–64 years and those aged over 65 years. Administration of Tdap to pregnant women did not identify any concerning patterns in maternal, infant, or fetal outcomes.*

Tdap administered to adolescents causes:[24]

- Pain (75%)
- Swelling at the injection site (21%)
- Redness at the injection site (23%)
- Fever >38°C (5%)
- Headache* (16%)
- Fatigue* (14%)
- Gastrointestinal symptoms* (10%)

*sufficient to interfere with normal activity

Major adverse reactions are uncommon and the incidence is not provided for adolescents in the Immunisation Handbook. These reactions include anaphylaxis (very rare), and seizures. There is no need for any further training around resuscitation above what is already done for vaccinators which is the equivalent of a level 4 (as per the Immunisation Handbook, 2014). The dose of adrenaline remains the same, and resuscitation process is the same for the 13 year plus children.[54]

After immunisation the healthcare consumer will be given an information sheet that includes adverse events and what to do if they occur.

See the SMARs report from the Medsafe website in the appendices. The SMARs report which comprises 10530 reports notes no deaths between 1 Jan 2000 to 31 Dec 2016. There have been 7 anaphylactic reactions and 1 anaphylactoid reactions reported. There were no reports of Guillain-Barre syndrome. A single case report of Guillain-Barre syndrome a few days following Tdap vaccine has been reported in the medical literature.[55]

10. Potential for abuse or misuse.

There is no potential for abuse.

Misuse is unlikely. Possibly someone could get two Tdap vaccinations in error – e.g. one from their general practice or the hospital and one from the pharmacy. This concern already exists with hospital and general practice administration. Pharmacists will notify doctors of the administration of the vaccination (with patient consent) which minimises this unlikely risk. If the patient is in doubt as to what has been received, the pharmacist could contact their general practice or the hospital to confirm vaccination status.

11. Other information

Collaboration with GPs and LMC's

Pharmacist-led Tdap vaccination programmes do not replace general practice but offer another option for communities to consider. With patient consent, the GP and LMC (where relevant) will be notified of the vaccination. This will improve further when the National Immunization Register can include pharmacist access. As is usual in pharmacy, the pharmacist will refer patients to their GP where they feel appropriate (including for funded vaccines as per Standard Operating Procedures and the screening tool), and as identified through the history taking/consent process. This is a process that occurs currently within Pharmacy for other vaccines administered.

An internal Green Cross Health review of 76 pharmacies providing vaccination services in 2013 found that 95% of consumers accessing the influenza vaccine from their pharmacist consented to their general practitioner receiving notification.

Green Cross Health together with Whanau Tahi have developed an online electronic consent form that notes all the key information of the screening tool and based on the information collected on the NIR. However, the introduction of the Immunize Now web Portal by the MoH will ensure that vaccine administration is recorded electronically in the future.

Minimum ages elsewhere

Many states in the US, regions in the UK and provinces in Canada use pharmacists to administer vaccines to children. These can include injectable vaccines. See Appendices for more details. Ireland has a minimum age of 18 years. Australia has only just started with pharmacists vaccinating in some states; in Western Australia patients need to be 18 years or over.

Administration of vaccine to children 13 and over

Parental consent is needed in children under 16 years, and this will be included in the screening tool, in addition to the child consenting.

Some children who are late developers may be very small at 13 years. They can still be vaccinated in the same way as older children. The muscle can be bunched if necessary, and a shorter needle is available for this purpose if required. Pharmacists are already vaccinating elderly people who may have very little muscle mass.

Fainting might be more common in young people, and has already been managed well in SOP templates from Green Cross and the Pharmacy Guild. Fainting already occurs in pharmacy for other reasons.

Pharmacists in NZ are already able to vaccinate in children over 13 years and older for influenza. Experts we have discussed this with, including IMAC, have agreed that pharmacist vaccination without any further training is suitable in this age group.

We surveyed 114 vaccinating pharmacists through Green Cross Health (out of a pool of over 350 pharmacists) in July 2014. When asked what age they would be comfortable vaccinating, the minimum given was 0 years, and the average was 11.5 years. Only 9 respondents (8% of 113 answering this question) wanted a minimum age of 18 to remain. The respondents had on average 2.6 vaccinator pharmacists on their staff, so a pharmacist who is uncomfortable with vaccinating a younger teenager is likely to be able to refer to a co-worker, or ask the patient to come back or refer them elsewhere for the vaccination.

Pharmacists' motives to vaccinate

Many pharmacists in New Zealand have taken the time and paid the money to become a qualified vaccinator and paid for pharmaceutical fridges as well as all emergency equipment. Anecdotal feedback from NZ pharmacists who have done vaccinator training has shown enthusiasm for helping their community and learning and applying new skills. This is in line with international research, for example, a survey of vaccinating pharmacists found that "desire to improve the health care of the public and personal satisfaction" were important factors encouraging pharmacists to train for vaccination provision.[56] New Zealand research has found indicated modest supplies and referrals occurring instead of supply as indicated for reclassified medicines such as trimethoprim and oseltamivir with no evidence of commercial priorities unduly affecting supplies.[57-61] This is as expected given the Code of Ethics for pharmacists who are health care professionals.

International research and experience of pharmacist-administered vaccinations

In the US, pharmacists have administered vaccinations to adults since the 1990s, expanding to all states in 2009.[62] In Walgreens alone (a large community pharmacy chain) more than 4.5 million seasonal influenza vaccinations were pharmacist-administered in the 2009/2010 season, including 1.7 million in medically underserved areas.[1]

Vaccinations by pharmacists have been well received by patients, overseas,[3,46] and in New Zealand.[11] Vaccinations in pharmacies can increase vaccination rates. US studies have shown increased uptake of influenza vaccination, particularly in certain groups (e.g. over 65 and those not vaccinated the previous year) in states with community pharmacist-vaccination versus states without.[6,7] Pharmacist advocacy even without vaccination administration also significantly increases vaccination rates in at-risk populations.[63-66]

Diphtheria and tetanus

Diphtheria and tetanus components are included in this vaccine, but the group for this extension is pregnant women, and the reason for provision is for protection from pertussis. The potential protection from diphtheria and tetanus will provide little if any added benefit in pregnant women who are up-to-date with their vaccinations. The Immunisation Handbook provides more detail on both components should they be of interest. Pertussis vaccine is not marketed on its own in NZ, and the recommendation is for Tdap in pregnancy, with trials typically using Tdap.

Note that Tdap can be used in pregnancy to protect against pertussis even if the primary series has not been had. However, should this occur, the patient will be referred to her GP to get the full primary series to ensure coverage for tetanus and diphtheria.

Summary

Women who are pregnant and under 18 years should not have more barriers to access for Tdap vaccine than women who are 18 years and over. It is important for health equity and aiding uptake in a vulnerable group to remove this barrier to access and lower the minimum age for pharmacist administration to 13 years for pregnant women, consistent with influenza vaccination, and the benefit-risk profile of this vaccine. We have a new epidemic for pertussis due soon and it is vital that we remove this barrier promptly before the epidemic starts.

It is also important to note that the aim of introducing pharmacist vaccinators is to raise the awareness of the importance of immunization and assist in increasing the number of pregnant women accessing the Tdap vaccine which earlier in this submission has been shown to be around 30%. Evidence would show that pharmacists are aiming to increase the number of people vaccinated (as has been evident with flu vaccine) not switch them from one health professional to another. Pharmacists alongside other health professionals work collaboratively to ensure a consistent immunization message is promoted and use the opportunity to triage our communities to general practice where appropriate, again a practice that community pharmacists display currently.

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