

Submission for Reclassification of Influenza Vaccination

Executive Summary

This application requests the extension of the reclassification for influenza vaccination allowing administration to children 13 years and over (from the current 18 years and over) by pharmacists who have completed an approved vaccinator's course and comply with the immunisation standards of the Ministry of Health.

Internationally, there is an increasing trend to allow certified pharmacists to administer vaccinations, particularly influenza vaccinations. Millions of vaccinations have been administered by pharmacists in the United States (US) since the 1990s.¹ Other countries in which pharmacist-vaccinations are occurring include the UK,² Ireland,³ Canada,⁴ and Portugal.² 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^{5,6} and pharmacist-vaccinators have been received well by both healthcare consumers and pharmacists.^{3,7,8} In the US, pharmacist-administered vaccinations have the support of the American College of Physicians and American Society of Internal Medicine,⁹ and the Centers for Disease Control and Prevention (CDC).¹⁰

Pharmacists are increasingly being permitted to vaccinate children, e.g. in parts of Canada,^{11,12} and many states of the US.¹³ Furthermore, the US, Canada and the UK all recommend influenza vaccination in healthy children.

Extending administration of influenza vaccinations by approved pharmacists to children 13 years and above will reduce the barriers for teenagers and their parents in accessing these vaccines. The benefit-risk profile of the influenza 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 influenza vaccination in reducing influenza cases, reducing hospitalisations and reducing mortality are well-known.¹⁴ While risk of hospitalisation from influenza in teenagers is low, it still can occur, as can death (very rarely), and time off school or out-of-school activities can be important for many teenagers. Risks using trained vaccinators with first aid training and appropriate set-up are extremely low.³

Along with General Practice, pharmacists can facilitate an increase in awareness for the public around all vaccines and the importance of discussing funded vaccinations (not just influenza) 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

Influenza vaccination (split virion, inactivated)

2. Proprietary name(s)

Products on the market vary (according to funding for example), and currently include Intanza[®] (age 18-59 only), Fluarix[®], Vaxigrip[®] Fluvax[®], Influvac[®], and FluQuadri[®]. (including FluQuadri[®] Junior for children 6 months to 35 months)

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 strains selected change (usually annually) to reflect the requirements of the Australian Influenza Vaccine Committee and the New Zealand Ministry of Health for the winter. Strains are selected by the World Health Organisation (WHO) see <http://www.medsafe.govt.nz/regulatory/flu.asp>

5. Pack size and other qualifications

The pack size varies with each product and does not need to be specified for the classification.

The product is for injection.

6. Indications for which change is sought

For the prophylaxis against influenza in adults.

7. Present classification of medicine

Prescription only medicine except when administered 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 to a person 13 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

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

Internationally pharmacist-administration of vaccines is becoming common through various mechanisms. In most countries the vaccines remain prescription medicines.

In Canada, influenza vaccinations have been Schedule II since December 1998, equivalent to NZ's Pharmacist-Only Medicine.¹⁵ Trained pharmacists in most parts of Canada can administer vaccinations. In the USA, vaccinations have been available from pharmacies in some states since the 1990s,¹⁶ extended to all states in 2009.

In England, influenza vaccination by accredited pharmacists in pharmacies under Patient Group Direction (PGD) is common, and funding for the vaccine in pharmacy for eligible patients has started.

Vaccinations in community pharmacies are also available in Portugal² and Ireland.³ Pharmacist-administered influenza vaccinations have started in some states in Australia.

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

Approximately 1.2 million vaccines were distributed in 2014.¹⁷

According to the Medsafe website, Fluvax[®] was first consented for use 31 December 1969. Other brands of influenza vaccination have received consent since that time.

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. Additionally, some companies have packaging harmonised with Australia.

12. Proposed warning statements if applicable

Current packaging would remain.

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

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

Part B

Reasons for requesting reclassification change including benefit-risk analysis.

The primary aim of reclassification is to increase the access and convenience of influenza vaccination for teenagers, and reduce the healthcare burden of influenza for teenagers and their families. The benefit-risk of vaccination (with appropriate screening for contraindications and precautions) is positive for this age group.

The extension to 13 years arises from public request. An unpublished survey of 114 pharmacists working in Green Cross pharmacies and doing vaccinations surveyed (July 2015) found that 80% of respondents reported receiving requests for influenza vaccinations in teenagers.

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

Benefits are to teenagers getting vaccinated in reducing the burden of influenza which can include considerable time off school. For children aged 13 years who legally cannot be left at home alone, or where a child seems particularly unwell, parents may need to take time off work. While teenagers tend to have the lowest hospitalisations of all groups, infection is not always without consequence. In the US in an eight year period, 226 influenza-associated deaths occurred in 13-17 year olds.¹⁸ Forty three per cent of all children under 18 years who died had no high risk medical conditions. Rapid clinical decline was common in the healthy children who died.

Children and adolescents shed the virus for longer and are disproportionately affected by influenza, and therefore are the main transmitters of influenza.¹⁹ Benefits might also accrue to the teenager's family, given the transmissibility of influenza. Furthermore, adolescents are frequently used for babysitting young children.

Benefits to the health system may be modest, given the least hospitalisations occurred in teenagers in NZ in 2014, of all age groups,²⁰ but spikes in hospital use during an influenza epidemic stress hospitals and this is an opportunity to relieve the pressure a little.

Benefits to schools include reduced absenteeism which helps teachers work through their curriculum in a timely manner. For boarding schools, an influenza outbreak could affect a large proportion of students at once.

Benefits to families include the convenience of being able to get the influenza vaccination at a time that suits the whole family, often when general practice is not open, e.g. weekends or evenings. Our survey of Green Cross Health pharmacist-vaccinators revealed reports of families wanting teenagers vaccinated 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 after school commitments.

Influenza leads to absence from school, work, tertiary study and sports or other out of school activity. Significant class absences that can result in influenza epidemics will affect teaching. Influenza is spread from person to person. A teenager bringing influenza home can infect siblings, parents, and friends contributing to the burden of influenza in the community.

The CDC website reports that most people getting the 2009 H1N2 influenza virus who were not hospitalised had a fever lasting two to four days. With the CDC recommendation for influenza to stay home for a further 24 hours after the fever has resolved, this would result in three to five days off school or work. The virus can still be shed after that time, but to a lesser extent.

New Zealand experts agree that influenza vaccination is a reasonable measure even in healthy people to prevent illness:

"[Influenza's] still a very dangerous disease for people, most dangerous for those with risk factors, but young people too. You can get a devastating illness in previously healthy people. The message is to get vaccinated. It's crazy not to."

Dr David Galler, Intensive Care Specialist, Middlemore Hospital.
Quoted in NZ Herald, 23 July 2014

"Immunising children (both preschool and school age) could reduce household and community transmission of influenza and is encouraged even for children without underlying medical risk conditions."

Dr Elizabeth Wilson, Auckland DHB paediatrician.
Quoted in Auckland DHB Media Release 15 March 2013

"...everyone should consider vaccination. Even someone who is fit and healthy can become ill with influenza, and risks passing it to family/whanau and friends who may have serious complications."

Dr Jim Miller, Medical Officer of Health,
quoted in Bay of Plenty Times, 8 July 2015

"Just being fit and well does not protect you against the flu nor does it prevent some of the adverse consequences."

Dr Phil Shoemack, Lakes Area Medical Officer of Health,
quoted in Rotorua Daily Post, 13 Sep 2014

"The primary people who should be vaccinated are the very young, the very old, people with existing medical conditions and pregnant women, but if a person doesn't fall into these brackets, it doesn't mean they shouldn't consider getting vaccinated. If you don't want to be off from work for a fortnight or feeling miserable for a fortnight, get vaccinated."

Dr Harry Pert, General Practitioner
quoted in Rotorua Daily Post, 5 August 2014

Emergency Departments and inpatient services are typically stretched in winter, with winter illnesses increasing numbers of patients attending the emergency department, in wards and in intensive care. This leads to hospitals operating above their maximum capacity. When an influenza epidemic adds to this, usage spikes. This is worsened by the need to keep patients with suspected influenza in single rooms, and staff illness over winter. Elective surgery may have to be postponed during the worst times. Although a minority of influenza cases in hospital are teenagers, even a small drop in work load through teenagers not being there, or not infecting family members or contacts who may be in higher risk categories, can help make the load more manageable.

In having more pharmacists immunising adolescents, should mass vaccination be required (e.g. future pandemics or epidemics), the workforce can already vaccinate adolescents. In the meningococcal C outbreak in Northland, this age group were the most difficult to reach,²¹ 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.

Effectiveness of influenza vaccination

The Immunisation Handbook 2014 reports 59% protection in healthy children aged under 16 years.²² The SHIVERS study found that the 2014 vaccine provided 67% protection against a visit to a GP with influenza (when all age groups were combined), and 54% protection against hospitalisation arising from influenza.²³

Influenza vaccination confers protection within 14 days, and lasts at least one influenza season, but annual vaccination is recommended owing to changes in the strain.²⁴

Influenza causes:

- Illness, including secondary infections
- Hospitalisations (average 327/year 1989-2004, but under-reported)^{14,25}
- Deaths (5 – 14 deaths per year, 49 in 2009; modelling suggests an average of 400 deaths per year that are attributable to influenza)¹⁴
- Emergency department over-loading (by contagious patients)
- Time off school or work
- Cost to the taxpayer through the health system costs and reduced productivity

Influenza has an incubation period of 1-3 days, typically, and is communicable from 1-2 days prior to symptoms appearing, until about the fifth day of illness.²² Healthy adolescents suffer from influenza, often at an important time for their learning, in secondary school or university. School absenteeism can reach 10% owing to influenza or influenza-like illness, and school closure for two days the day after reaching a 10% absentee rate helps mitigate influenza outbreaks at school.²⁶ Antibiotics are commonly used in children with influenza like illness (albeit to a lesser extent with older children).²⁷ Reducing usage of antibiotics through prevention of influenza is good antimicrobial stewardship. Influenza-like illness occurs in a household member in 10-43% of children with confirmed influenza, with hospitalisation, antibiotics, and medical visits occurring as a result in that contact.²⁷ Absenteeism involves the sick child, other children in the family, and their parents (owing to influenza themselves, or time off looking after children).²⁷ Vaccination will help reduce the impact of influenza on time off school.

Influenza vaccination is recommended in children in the US (since 2008) and Canada. In Europe, influenza vaccine is recommended in children in Austria, Finland, Latvia, Malta, Poland, Slovakia, Slovenia and the UK, as well as Saxony in Germany.²⁸ Ages in which it is recommended vary. Funded influenza vaccinations in children are available in Finland, Latvia and the UK, although in Finland and Latvia these are in young children.

In summary, benefits of widening access to influenza vaccinations in teenagers through vaccinator-pharmacists potentially include:

- Convenience in being able to easily access the vaccine at a handy location with often no appointment needed
- Increasing uptake in influenza vaccinations
- Reducing time off school (with influenza)
- Potential to reduce illness in other family members
- Reducing complications from the illnesses (potentially decreasing antibiotic use)
- Reducing parental leave
- Reducing cost to the taxpayer (healthcare costs)

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.

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”.⁸ A European survey found only 67% of those intending to have a vaccination actually received a vaccination.²⁹ 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.³⁰ 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.³¹ Most children aged 13-17 will have parents who are working, and the

children will be at school and often with after school activities. Vaccination in a pharmacy will be accessible and convenient.

Public Health England has trialled administration to children in primary schools, noting that: “Results from the first year of the primary school pilots in 2013/14 were encouraging, with reduced numbers of GP attendances in all age groups in pilot areas, compared to non-pilot areas.”³² The expectation in funding the influenza vaccination in children aged two to 17 years is that it will protect children and reduce transmission across the population, reducing levels of flu overall and reducing the burden of flu across the population. Thus, the health system should manage winter better. Private supply of influenza vaccine to adolescents in NZ should reduce transmission within family members of influenza, but will not provide herd immunity.

US Support of Pharmacist Vaccinators

The American College of Physicians and American Society of Internal Medicine stated in 2002:
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“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).¹⁰ In June 2012, CDC in the US wrote to pharmacists to thank them for their “*tremendous efforts this past year to raise immunization rates in the United States.*” CDC noted that “*Pharmacists and community vaccinators are uniquely positioned to promote and provide vaccines to people in a wide range of communities.*”¹⁰ Furthermore, special authority was given to pharmacists in New York to administer influenza vaccinations in children from six months of age (instead of the 18 years minimum at the time) to help manage a severe influenza epidemic in 2012-2013.³³

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

Consumer harm from vaccination is low. There is a very rare chance of anaphylaxis, and a risk of fainting which could lead to hitting the head. 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). See SMARS data from Medsafe.

Pharmacists receive the same vaccination training and assessment as other vaccinators, typically being trained by IMAC or other appropriate organisations. 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. The only change needed for these SOPs would be ensuring the dose of adrenaline has the minimum age from the Resuscitation Guidelines rather than stating Adult dose. This can be communicated to pharmacists.

Pharmacists have been vaccinators for many years in the United States, with considerable support, providing a strong vote of confidence in pharmacists as vaccinators.

Community pharmacies are easily accessible to and used by most of the population, healthy and unwell, and all ages. Healthy 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 influenza vaccinations will have successfully completed the approved vaccinator's course and clinical assessment and meeting the requirements in standards set by the Ministry of Health (see Appendices). 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

There are no other influenza prevention medicines available other than influenza vaccination.

Oseltamivir (for treatment of influenza) became available without prescription in NZ in 2007, under an exemption from prescription when supplied by a pharmacist under certain criteria, including a minimum age of 12 years.³⁴ Accreditation was not required. Qualitative research indicated pharmacists took their responsibilities seriously, and kept the protocol and consultation pad ready for use.³⁴ Non-prescription supply was modest.

Pharmacists provide other preventive medicines, e.g. low dose aspirin for prevention of cardiovascular disease, folic acid for pregnancy, insect repellents to travellers going to malarial areas, and other vaccines, namely: cholera and traveller's diarrhoea vaccine; pertussis vaccine (combined with tetanus and diphtheria); meningococcal vaccine; and shingles vaccine.

5. Local data or special considerations relating to New Zealand

With 1.2 million doses of influenza vaccine distributed in 2014, if all were used, this would represent 26% of the population covered. Thus, at least 74% of the population has not received the influenza vaccination.

In NZ, Māori and Pacific Island and high deprivation index populations are disproportionately affected by influenza hospitalisations.²⁰ 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 adolescents with funded vaccines if necessary will be increased through this extension. Over 500 pharmacists provide vaccinations in New Zealand, a useful and convenient workforce to be able to tap into if necessary for all New Zealanders, and particularly teenagers who have been hard to reach previously,²¹ 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 over 500 pharmacists approved as vaccinators delivering vaccines throughout the country. 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.⁸ Satisfaction with the vaccination was very high with 98% rating it 4 or 5 on the Likert scale.

Most (80.0% of 114) Green Cross 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 parents to be able to have their child vaccinated at the same time as them, at a time that suits, without having to make an appointment.

Health literacy issues exist in New Zealand.³⁵ We therefore have both verbal and written information for patients about their vaccination.

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. Pharmacists are expected to have access to the National Immunisation Register (NIR) by the end of 2015.

NZ government strategy

Administration of influenza 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 patient-centred care, and healthcare workers working to the tops of their scopes of practice. Implementing the Medicines New Zealand action plan (2015-2020) highlights the need to remove barriers to access, and states access should take into account an individual's personal preferences.²² Furthermore, this extension empowers individuals and families/whanau to manage their own medicines and health.

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.³⁶ Extending influenza vaccination to the younger age group ensures pharmacy comfort with this age group in case of an outbreak e.g. of meningococcal disease or pandemic influenza.

6. Interactions with other medicines

The immunological response may be reduced if the patient is taking corticosteroids or immunosuppressants.³⁷

7. Contraindications and precautions

The Immunisation Handbook reports that a history of anaphylaxis to egg has been considered a contraindication to influenza vaccination, but that evidence suggests it can be given safely.¹⁴ However, anyone with allergy to eggs, egg products or chicken proteins will be referred to the doctor.

Anaphylactic hypersensitivity to previous influenza vaccination is a clear contraindication.

Contraindications are vaccine specific also, e.g. Fluvax[®] includes anaphylactic hypersensitivity to neomycin, polymyxin B sulphate, or any constituents or trace residues.³⁷

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. Patients will wait within line of sight in the pharmacy for 20 minutes after being dosed. They will also be given written details of a process to be followed should they become unwell in the following 24 hours post vaccination.

8. Possible resistance

Not applicable.

9. Adverse events - nature, frequency etc.

The adverse events are compatible with availability without prescription. The Immunisation Handbook states that "influenza vaccine is well-tolerated".²² About a third of people will get pain and redness (usually mild) at the injection site.²⁵ Systemic reactions include fever, malaise, and myalgia, which are generally short in duration and mild, and occur in about 1% of adults.^{14,25} Anaphylaxis is very rare (approximately one in a million) and pharmacists doing vaccinations are trained and have adrenaline and other equipment to manage this. Guillain-Barré syndrome is rare and possibly related to influenza vaccination in certain years.¹⁴

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.³⁸ See email

attached in the appendices from an expert resuscitation trainer. SOPs will need to be modified to include the minimum age for the dose of adrenaline provided.

After immunisation the healthcare consumer will be given an information sheet from the National Influenza Specialist Group (NISG) for children for managing adverse events (See appendices).

See the SMARs report from the Medsafe website in the appendices. Since 2000 there have been no deaths reported to CARM associated with influenza vaccination. There have been 11 anaphylactic reactions and 3 anaphylactoid reactions reported. Vomiting was reported by 210 patients. The detailed data examined 2010 onwards did not reveal anything untoward for the new age group 13-17 years (see appendices for this data).

10. Potential for abuse or misuse.

There is no potential for abuse.

Misuse is unlikely. Possibly someone could get two influenza vaccinations in error – e.g. one from their doctor and one from the pharmacy. A vaccination is usually reasonably memorable and will be recent (given the annual basis of this vaccination) so this seems highly unlikely; this problem already exists with workplace immunisations and vaccines provided at boarding schools, for example. Pharmacists will notify doctors of the administration of the vaccination (with patient consent) which minimises this unlikely risk.

11. Other information

Collaboration with GPs

Pharmacist-led influenza vaccination programmes do not replace general practice but offer another option for patients. With patient consent, the GP is notified of the vaccination. This will improve further when the National Immunization Register can include pharmacists have access to it. As is usual in pharmacy, the pharmacist will refer patients onto 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.

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 Simpl Health 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. This electronic format is able to be integrated onto a shared care platform or uploaded onto the NIR.

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 with pharmacists only administering influenza currently. Australia has only just started with pharmacists vaccinating in some states; in Western Australia patients need to be 18 years or over.

Opportunistic screening

A booking for an influenza vaccine typically involves the practice nurse only with no time with the GP or opportunistic screening done. The vaccine is the focus of the appointment. The only possibility is that a child coming into a medical practice could be followed up for other vaccines, but those sufficiently motivated to book and pay for an influenza vaccine will likely be motivated to ensure scheduled vaccinations are obtained, through school or through the doctor.

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. Note an expectation that both the child and the parent will consent.

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. 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 are relatively new to vaccination, but children aged 13-17 pose little extra difficulty. 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.

Various influenza vaccines

In the UK, the live attenuated influenza vaccine delivered nasally is recommended in children owing to greater efficacy.²⁴ However, this is not yet registered in NZ.²² Intanza is only licensed for adults aged 18-59 years, and thus would not be used in children 13-17 years. This will be reflected in the screening tool. The reclassification is not specific to a particular brand and the product used changes each season, so pharmacists will follow IMAC recommendations for products to use. It is expected that pharmacy groups will report IMAC recommendations to their members each year.

Pharmacists' motives to vaccinate

Many pharmacists in New Zealand have taken the time and paid the money to become a qualified vaccinator, with over 500 pharmacists qualified, representing around 20% of community pharmacists. Most of these pharmacists are employees not business owners. 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.³⁹ New Zealand research has found oseltamivir supplies from pharmacists were modest and there was no evidence of commercial priorities unduly affecting supplies.^{34,40,41}

Cost

Cost is not a consideration of the Medicines Classification Committee. This reclassification considers the benefit-risk of whether influenza vaccine should be able to be supplied by pharmacists to children 13 and over. Whether or not it should be funded in children of this age (with chronic conditions, or in all children) in pharmacy is a separate conversation.

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 2009.¹⁶ 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

Pharmacist advocacy even without vaccination administration also significantly increases influenza vaccination rates in at-risk populations.⁴²⁻⁴⁵

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.^{5,6} Vaccinations by pharmacists have been well received by patients, overseas,^{3,31} and in New Zealand.⁸

Summary

While burden of disease in terms of hospitalisation and death is relatively low in adolescents, influenza can cause considerable time off school and non-school activities. NZ health experts recommend influenza vaccination in all ages. Pharmacy delivery of vaccinations to children aged 13 to 18 years has an appropriate benefit-risk equation, and would be welcomed by the public.

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