

Immunisation Subcommittee of PTAC
Meeting held 3 September 2014

(minutes for web publishing)

Immunisation Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note:

- that this document is not necessarily a complete record of the Immunisation Subcommittee meeting; only the relevant portions of the minutes relating to Immunisation Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Immunisation Subcommittee may:

- (a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
- (b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
- (c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 7 & 8 February 2015, the record of which is now available.

Summary of recommendations

- The Subcommittee reiterated the **recommendation** that the term “epidemic” be removed from restriction criteria for the vaccination of pregnant women against pertussis.
- The Subcommittee **recommended** PHARMAC investigate numbers of patients on disease-modifying antirheumatic drugs (DMARDs) and those living with household immunosuppressed patients with a view to possibly recommending funding of the influenza vaccine for these patients/household contacts.
- The Subcommittee **recommended** the following changes to the access criteria for the influenza vaccine (additions in bold, deletions in strike through):

A) is available each year for patients who meet the following criteria, as set by PHARMAC:

- a) all people 65 years of age and over;
- b) people under 65 years of age who:
 - i) have any of the following cardiovascular diseases:
 - a) ischaemic heart disease,
 - b) congestive heart disease **failure**,
 - c) rheumatic heart disease,
 - d) congenital heart disease, or
 - e) cerebo-vascular disease;
 - ii) have either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function;
 - iii) have diabetes;
 - iv) have chronic renal disease;
 - v) have any cancer, excluding basal and squamous skin cancers if not invasive;
 - vi) have any of the following other conditions:
 - a) autoimmune disease,
 - b) immune suppression **or immune deficiency**,
 - c) HIV,
 - d) transplant recipients,
 - e) neuromuscular and CNS diseases/**disorders**,
 - f) haemoglobinopathies,
 - g) are children on long term aspirin,
 - h) have a cochlear implant (pre or post implant),**
 - (i) inborn errors of metabolism at risk of major metabolic decompensation,**
 - (j) pre and post splenectomy, or**
 - (k) down syndrome;**
 - vii) are pregnant;
- vii) people under 18 years of age living within the boundaries of the Canterbury District Health Board;
- viii) children aged four **years** and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness.

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease,

B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

C) Individual DHBs may fund patients over and above the above criteria. The claiming process for these additional patients should be determined between the DHB and Contractor.

D) Stock of the seasonal influenza vaccine is typically available from February until late July with suppliers being required to ensure supply until at least 30 June. Exact start and end dates for each season will be notified each year.

- The Subcommittee noted that Canterbury had begun planning for next season's influenza vaccine. The Subcommittee **recommended** that next year should be the last year for including people under 18 years of age living within the boundaries of the Canterbury District Health Board in the access criteria, unless the need for continuing access for them in particular can be justified.
- The Subcommittee **recommended** changes be made to the access criteria for a number of antigens as detailed in the minutes below.
- The Subcommittee **recommended** PHARMAC request evidence from Canterbury District Health Board on administering three doses of Haemophilus Influenzae Type B vaccine as part of its post BMT protocols.
- The Subcommittee **recommended** PHARMAC investigate appropriate funding of the Hepatitis B Recombinant vaccine for prisoners, as a high risk group.
- The Subcommittee **recommended** PHARMAC investigate current access to the Hepatitis B Recombinant vaccine for intravenous drug users.
- The Subcommittee **recommended** PHARMAC investigate funding the Pneumococcal (PPV23) Polysaccharide and conjugate (PCV13) vaccines for high risk adults for discussion at the next meeting of the Subcommittee.
- The Subcommittee **recommended** PHARMAC present a paper at the next meeting analysing the feasibility of funding HPV for 11-13 year old males.
- The Subcommittee noted that the United Kingdom offered zoster vaccine at ages either 70 or 79. The Subcommittee **recommended** that PHARMAC gather prescribing data on medications for shingles and bring it to the next meeting along with ethnicity and age data.

1 Record of Previous Subcommittee meeting

- 1.1 The Subcommittee **recommended** that the term "epidemic" be removed from item 2.12 in the minutes of the previous meeting held on 10 February 2014.

2 Currently funded childhood vaccines

- 2.1 The Subcommittee noted that post the outbreak in Auckland, MMR vaccination rates in non-funded age groups increased significantly over the three month period January to March 2014 inclusive. Vaccination rates in the one year (15

months) and four year old age groups did not change markedly over the same period.

- 2.2 The Subcommittee noted that in February 2014 there was a small outbreak of hepatitis A in the Hutt Valley. Approval was gained for the vaccination of children and adults from two Pacific Island families and the children and teachers of a Pacific Island Preschool. A total of 45 children and 15 adults were vaccinated.
- 2.3 The Subcommittee noted that the BCG vaccine was expected to be registered shortly. Members noted that the BCG vaccine was undergoing a priority assessment at Medsafe. The Subcommittee also noted that it was being supplied under Section 29 at present. Members noted that the vaccine supplied had not changed but the supplier had found that the registration had not been maintained.
- 2.4 The Subcommittee noted that the tetanus diphtheria vaccine was in short supply and that it may be unavailable for a short period of time in some areas. Members noted that PHARMAC had resolved to allow Tdap to be supplied to patients as a replacement during the shortage and the market was notified on 2 September 2014.

3 Review of access criteria for at risk groups

The Subcommittee reviewed that access criteria for each of the currently funded vaccines:

Influenza

- 3.1 The Subcommittee noted that PHARMAC had received enquiries regarding influenza vaccination for patients who were pre and post splenectomy, for patients with functional or anatomic asplenia, Down Syndrome and inborn errors of metabolism at risk of major metabolic decomposition.
- 3.2 The Subcommittee noted that influenza has a high level of transmission within households and that poses a risk for immunocompromised patients even if they have been vaccinated. The Subcommittee considered that caregivers and family members of housebound patients who were receiving active chemotherapy or immunosuppressive therapy and caregivers and household members of frail, elderly people should be vaccinated against influenza. The Subcommittee noted that this patient population could be large.
- 3.3 The Subcommittee **recommended** that PHARMAC investigate the possible number of household contacts of housebound or hospitalised transplant and chemotherapy patients; housebound patients receiving disease modifying drugs; children with primary immune diseases or chronic respiratory disease; housebound patients who are severely immunocompromised and household members who are under the age of 65 and live with frail elderly people.

3.4 The Subcommittee **recommended** with a high priority the following changes to the access criteria for the influenza vaccine (deletions in strikethrough; additions in bold):

A) is available each year for patients who meet the following criteria, as set by PHARMAC:

- a) all people 65 years of age and over;
- b) people under 65 years of age who:
 - i) have any of the following cardiovascular diseases:
 - a) ischaemic heart disease,
 - b) congestive heart disease~~failure~~,
 - c) rheumatic heart disease,
 - d) congenital-heart disease, or
 - e) cerebo-vascular disease;
 - ii) have **any** either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function;
 - iii) have diabetes;
 - iv) have chronic renal disease;
 - v) have any cancer, excluding basal and squamous skin cancers if not invasive;
 - vi) have any of the following other conditions:
 - a) autoimmune disease,
 - b) immune suppression **or immune deficiency**,
 - c) HIV,
 - d) transplant recipients,
 - e) neuromuscular and CNS ~~diseases~~**disorders**,
 - f) haemoglobinopathies,
 - g) are children on long term aspirin,
 - h) have a cochlear implant,**
 - (i) inborn errors of metabolism at risk of major metabolic decompensation,**
 - (j) pre and post splenectomy, or**
 - (k) Down syndrome;**
 - vii) are pregnant;
 - viii a) people under 18 years of age living within the boundaries of the Canterbury District Health Board;**
 - ix a) children aged four years and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness.**

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease,

B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

C) Individual DHBs may fund patients over and above the above criteria. The claiming process for these additional patients should be determined between the DHB and Contractor.

D) Stock of the seasonal influenza vaccine is typically available from February until late July with suppliers being required to ensure supply until at least 30 June. Exact start and end dates for each season will be notified each year.

3.5 The Subcommittee **recommended** PHARMAC investigate the possibility of sourcing a live attenuated influenza vaccine (nasal spray) for use in children.

3.6 The Subcommittee noted that Canterbury had begun planning for next season's influenza vaccine. The Subcommittee **recommended** that next year should be the last year for including people under 18 years of age living within the boundaries of the Canterbury District Health Board in the access criteria, unless the need for continuing access for them in particular can be justified.

Diphtheria, Tetanus and Pertussis Vaccine

- 3.7 The Subcommittee **recommended** with a high priority the following changes be made to the access criteria to the Diphtheria, Tetanus and Pertussis vaccine (deletions in strike through, additions in bold):

- 1) A single vaccine for pregnant woman between gestational weeks 28 and 38; or
- 2) A course of up to four vaccines is funded for children from age 7 **up to under 18** 47 years to complete full primary immunisation; or
- 3) ~~A course of up to four vaccines is funded for children from age 7 to 17 years inclusive for reimmunisation following immunosuppression.~~

3) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens.

Notes: Tdap is not registered for patients aged less than 10 years. Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Hexavalent vaccine

- 3.8 The Subcommittee **recommended** with a high priority the following changes be made to the access criteria to the Diphtheria, Tetanus, Pertussis, Polio, Hepatitis B and Haemophilus Influenzae Type B vaccine with high priority (deletions in strike through, additions in bold):

- 1) Up to four doses for children up to **and under** the age of 10 for primary immunisation; or
- 2) ~~Up to four doses (as appropriate) for children **individuals** are funded for (re)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; renal dialysis and other severely immunosuppressive regimens; or~~

2) An additional four doses (as appropriate) are funded for (re-)immunisation for children up to and under the age of 10 who are patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens.

- 3) Up to five doses for children up to **under** 10 years receiving solid organ transplantation.

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to **and under** the age of 10 years) to complete full primary immunisation.

Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Haemophilus influenzae type B vaccine

- 3.9 The Subcommittee **recommended** the following changes be made to the access criteria to the Haemophilus Influenzae Type B vaccine (deletions in strike through, additions in bold):

One dose for patients meeting any of the following:

- 1) For primary vaccination in children; or
- 2) ~~For revaccination of children following immunosuppression; or~~

3) For children aged 0-18 years with functional asplenia; or

4) For patients pre and post splenectomy; or

2) An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens.

3) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

The Subcommittee **recommended** PHARMAC request evidence from the Haematology Department at Christchurch Hospital for its requirement for allogenic bone marrow transplant (BMT) recipients to receive three doses of Haemophilus Influenzae Type B vaccine as part of the post BMT protocol.

Hepatitis A Vaccine

3.10 The Subcommittee **recommended** the following changes be made to the access criteria to the Hepatitis A vaccine (deletions in strike through, additions in bold):

1) Two vaccinations for use in transplant patients **and patients with HIV**; or

2) Two vaccinations for use in children with chronic liver disease; or

3) One dose of vaccine for close contacts of known hepatitis A cases; or

4) ~~One dose for any of the following on the recommendation of a local medical officer of health:~~

a) ~~Children, aged 1-4 years inclusive who reside in Ashburton district; or~~

b) ~~Children, aged 1-9 years inclusive, residing in Ashburton; or~~

c) ~~Children, aged 1-9 years inclusive, who attend a preschool or school in Ashburton; or~~

d) ~~Children, aged older than 9 years, who attend a school with children aged 9 years old or less, in Ashburton funded for children in Ashburton.~~

3.11 The Subcommittee **recommended** the following changes be made to the access criteria to the Hepatitis B Recombinant vaccine (additions in bold):

Funded for patients meeting any of the following criteria:

1) for household or sexual contacts of known **acute hepatitis B patients or** hepatitis B carriers; or

2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or

3) for children up to **under** 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination; or

4) for HIV positive patients; or

5) for hepatitis C positive patients; or

6) for patients following non-consensual sexual intercourse; or

7) for patients following immunosuppression;

8) for transplant patients; or

9) following needle stick injury.

- 3.12 The Subcommittee **recommended** PHARMAC investigate appropriate funding of the Hepatitis B Recombinant vaccine for prisoners, as a high risk group, and for intravenous drug users.

Human Papillomavirus (6, 11, 16 and 18) Vaccine

- 3.13 The Subcommittee **recommended** the following changes be made to the access criteria to the Human Papillomavirus (6, 11, 16 and 18) Vaccine (additions in bold):

a) Maximum of three doses for patients meeting any of the following criteria:

- i) Females aged under 20 years old; or
- ii) Patients aged under 26 years old with confirmed HIV infection; or
- iii) For use in transplant (**including stem cell**) patients

b) An additional dose post chemotherapy for patients under 26 years of age who have been immunised prior to chemotherapy

Measles, Mumps and Rubella Vaccine

- 3.14 The Subcommittee **recommended** the following changes be made to the access criteria to the Measles Mumps and Rubella vaccine (additions in bold):

A maximum of two doses for any patient meeting the following criteria:

- 1) For primary vaccination in children; or
- 2) For revaccination before or after the end of immunosuppression;
- 3) For any individual susceptible to measles, mumps or rubella; or
- 4) **A maximum of three doses for children who have had their first dose prior to 12 months.**

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Meningococcal Conjugate Vaccines (monovalent and quadravalent)

- 3.15 The Subcommittee **recommended** the following changes be made to the access criteria to the Meningococcal Conjugate Vaccine (deletions in strike through, additions in bold):

Any of the following:

- 1) Up to three doses **and a booster every five years** for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, **HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant;** or
- 2) ~~One dose every five years for patients with HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant; or~~

- 2) One dose for close contacts of meningococcal cases; or
- 3) A maximum of two doses for bone marrow transplant patients; or
- 4) A maximum of two doses for patients preferably before the start of immunosuppression*.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Note: **Infants under one year of age require a primary course of two doses, a booster dose in the second year of life, a further booster dose in three years, then every five years. Previously unvaccinated** children aged one year to under seven years of age require **two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly. a second dose three years after the first and then five yearly.**

Pneumococcal (PCV13) Vaccine

- 3.16 The Subcommittee **recommended** the following changes be made to the access criteria to the Pneumococcal (PCV13) Vaccine (deletions in strike through, additions in bold):

Any of the following:

- 1) A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or
- 2) Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV10; or
- 3) One dose is funded for high risk children **(over the age of 17 months up to under 18 years)** who have previously received four doses of PCV10; or
- 4) Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients with HIV, for patients post **haematopoietic stem cell transplantation**HSCT, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, **complement deficiency (acquired or inherited), cochlear implants, primary immunodeficiency** and other severely immunosuppressive regimens ~~up to under the age of 18; or~~
- 5) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes

Pneumococcal (PPV23) Polysaccharide Vaccine

- 3.17 The Subcommittee **recommended** PHARMAC investigate funding the Pneumococcal (PPV23) Polysaccharide and conjugate PCV13 Vaccine for high risk adults

Varicella

- 3.18 The Subcommittee noted that, at the March 2013 meeting, it had reviewed an application for funding varicella vaccination for infants as part of the universal childhood vaccination programme with a high priority, but that PTAC at its August 2014 meeting had recommended to decline the application. The Subcommittee noted that PTAC had recommended declining the application due to concerns

regarding the risks of varicella infection at a later age and a potential increase in the incidence of herpes zoster in the elderly. The Subcommittee noted that recent publications following the introduction of universal varicella vaccination in Australia and the US had not reported any increased incidence of herpes zoster or varicella infection in older susceptible individuals.

- 3.19 The Subcommittee considered that, if varicella vaccination were to be introduced, it should be administered separately to MMR for the first dose as there is a small increase in febrile convulsion risk if the combined MMRV vaccine is used in toddlers. The Subcommittee noted that if varicella were to be introduced at age 15 months, young children would be receiving four separate injections which may mean a reduction in the uptake of one of the other three: consideration of a second toddler visit would be required.
- 3.20 The Subcommittee noted that the varicella had a short refrigerator shelf life with a reduction in the number of viruses over the life of the product. Members noted that stock rotation would be important to ensure high potency vaccine was available. The Subcommittee also noted that there would be cost implications associated with implementation if varicella vaccination were to be funded and that these would be in addition to the vaccine cost.

Zoster

- 3.21 The subcommittee noted that PTAC were to review an application for the funding of zoster vaccination at its' August 2014 meeting.
- 3.22 The Subcommittee noted that the United Kingdom offered zoster at ages 70 and at age 79. The Subcommittee **recommended** that PHARMAC gather prescribing data on medications for shingles and bring a paper with age and ethnicity data to the next meeting to assist any recommendations that may be made in regard to funding zoster vaccinations.

Pneumococcal 23

- 3.23 The Subcommittee noted that an application for funding pneumococcal 23 vaccine for all people over the age of 65 was reviewed by PTAC at its February 2014 meeting. The Subcommittee noted that PTAC recommended declining the application due to low quality evidence. The Subcommittee noted that PTAC considered that if PPV23 were funded it would be given in conjunction with the influenza vaccine which may increase the uptake to ~ 70% over the next 5-10 years. The Committee noted that while the elderly and those with chronic disease are at the greatest risk of pneumococcal disease, these are also the groups with the least evidence for efficacy.
- 3.24 The Subcommittee considered that the evidence was not robust but that there was some evidence that if pneumococcal (PP23) polysaccharide vaccine was given simultaneously with the influenza vaccine there was a lower incidence of heart attacks and strokes.

- 3.25 The Subcommittee noted a recent paper on severe community acquired pneumonia in which the average age of patients was 50 years and half of these patients had co-morbidities. The Subcommittee considered that vaccination with PCV13 followed by PPV23 greater than 8 weeks later may reduce the rate of community acquired pneumonia in patients with co-morbidities
- 3.26 The Subcommittee **recommended** that the Subcommittee further discuss the pneumococcal 23 and PCV 13 vaccines for adults at the next Immunisation Subcommittee meeting.