

November 27<sup>th</sup>, 2006

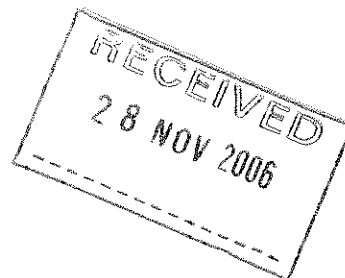
UNIVERSITY  
of  
OTAGO



Te Whare Wānanga o Ōtago

The Hon Pete Hodgson  
Minister of Health  
Parliament Buildings  
PO Box 18 888  
Wellington

Keith  
ackn.  
biching - Dec 14  
rec from MofH about  
where to meet.



Dear Mr Hodgson,

Re: The National Immunisation Schedule for 2008

Immunisation is one of the most effective available public health interventions. I would therefore welcome the opportunity to meet with you and to discuss the recent availability of newly developed and safe vaccines. This now means that more diseases can be prevented than ever before and includes vaccines to protect against strains of:

1. *Streptococcus pneumoniae*, a bacterium capable of causing life-threatening infections, such as meningitis, blood poisoning (sepsis) and pneumonia
2. Human papilloma virus, which can result in cervical cancer
3. Varicella, the agent leading to chickenpox
4. Rotavirus, the most common cause of severe gastroenteritis in young children.

Health professionals have welcomed the licensure of these vaccines, as have health consumer groups, both here and overseas. As New Zealand has relatively high rates of infectious diseases, the availability of novel vaccines provides an opportunity to improve the health of New Zealanders by reducing disease burden and decreasing health disparities for Maori and disadvantaged groups in our community.

The Ministry of Health Immunisation Technical Working Group met recently to provide advice on the 2008 National Immunisation Schedule. A summary of recommendations is appended. This is an exciting time in vaccinology and I hope we can meet to discuss these developments and our recommendations.

Yours sincerely,

Keith Grimwood ONZM MD FRACP  
**Chair, Immunisation Technical Working Group**

cc. Mr Stephen McKernan, Director General of Health  
Dr Don Matheson, Deputy Director General, Public Health  
Dr Alison Roberts, Senior advisor on Public Health Medicine

Department of Paediatrics & Child Health

Wellington School of Medicine & Health Sciences  
Main Street, Newtown, Wellington, PO Box 7343, Wellington South, New Zealand.  
Tel 64 4 385 5999 • Fax 64 4 385 5898

[www.wnmeds.ac.nz](http://www.wnmeds.ac.nz)

DUNEDIN • CHRISTCHURCH • WELLINGTON • AUCKLAND

## **APPENDIX 1**

### **Final prioritised recommendations for the 2008 National Immunisation Schedule**

#### **New vaccines**

1. Pneumococcal conjugate vaccine for infants with four doses beginning at age 6 weeks, 3 and 5 months, and a booster dose at 15 months.
2. Human papilloma virus (HPV) vaccine - it is recommended that a primary immunisation series of 3 doses be given to girls at age 15 years if no catch up is planned. However, if funding is available, the HPV vaccine should be given to girls at age 11 or 13 years as a Schedule vaccine with a catch up programme for girls aged 12 to 15 years (see below).
3. Measles, mumps, rubella and varicella (MMRV) vaccine given as 1 dose at age 15 months (subject to licensure of the vaccine).
4. Rotavirus – 2 or 3 doses (dependent upon the vaccine and its licensure) at 6 weeks, 3 (and 5) months.

#### **Catch up for new vaccines**

Note – catch up for new vaccines was of a lower priority than implementation of the new vaccines to the appropriate age cohort.

5. HPV – catch up for girls aged 12 to 15 years (if the primary series is given to girls at age 11 or 13).
6. Pneumococcal conjugate vaccine catch up programme for those aged under 2 years.
7. Varicella vaccine for children aged 11-15 years who have not previously been immunised against varicella and are without a history of chickenpox.

#### **Additional Recommendations**

8. (8<sup>th</sup> equal) Maintain the existing influenza vaccine recommendations and extend funding of the influenza vaccine to household members where there is a person eligible for funded influenza vaccine.
8. (8<sup>th</sup> equal) Health care workers working with children vulnerable to severe illness from pertussis (neonates and others at risk) should be immunised with the adult pertussis vaccine.

If the pneumococcal conjugate vaccine is introduced into the national schedule, the hexavalent vaccine, DTaP-HBV-IPV/Hib, should also be used at age 6 weeks, 3 and 5 months. This is to limit the number of injections at each of these visits and to address concerns over interference between the pneumococcal conjugate vaccine and the hepatitis B vaccine used at 5 months in the present immunisation schedule.

The recommended 2008 National Immunisation Schedule is outlined below:

	DTaP-IPV- Hib-HepB	PCV7	RV (oral)	Hib	MMRV	MMR	dTap	HPV	MeNZB
6 weeks	X	X	X						X
3 months	X	X	X						X
5 months	X	X	?X						X
10 months									X
15 months		X		X	X				
4 years	DTaP-IPV					X			
11 years							X		
Girls 11/13/15 years								3X	

- Note - RV at age 5 months would depend on the vaccine used – 2 or 3 doses.  
 - The age at which HPV vaccine is administered to girls may not be at age 11 or 13 years; HPV could be administered at age 15 years if catch up is not funded.

These recommendations are based upon the assumptions that all the candidate vaccines will be licensed (including MMRV and rotavirus vaccines) and the economic analyses submitted by the manufacturers are independently verified. The importance of national surveillance programmes monitoring the effectiveness of these vaccines is emphasised, recognising that for each vaccine different surveillance methods will be necessary.

## APPENDIX 2

### New vaccines considered by the Immunisation Technical Working Group

#### Pneumococcal conjugate vaccine (7vPCV) - children

- Compared with other industrialised countries, New Zealand children have a relatively high burden of invasive pneumococcal disease. In Auckland, the annual rates of invasive disease in children under 2-years of age are 191 per 100,000 with Pacific and Maori having rates of 296 and 217 per 100,000 children respectively. Within this age group pneumococcal meningitis is an important life-threatening infection, occurring at an annual rate of 30 cases per 100,000 children. A prospective national survey of childhood pneumococcal meningitis is currently being conducted. Hospitalisation data also identify pneumonia as an important childhood illness, particularly during the first 5-years of life.
- A 7-valent pneumococcal conjugate vaccine (7vPCV) is currently licensed in New Zealand for infants and children aged 6-weeks to 9-years. It contains the polysaccharide capsular antigens of serotypes 4, 6B, 9V, 14, 18C, 19F and 23F. Between 1998 and 2005, these serotypes caused 81% of invasive disease in children under the age of 2-years. Rates of penicillin-resistance amongst pneumococcal isolates remained stable during this period and were most commonly detected in children under 5-years of age. In this age group all resistant strains were one of the serotypes included in the conjugate vaccine.
- Since the introduction of 7vPCV in the United States, invasive pneumococcal disease caused by vaccine types has reduced by 94%, and from all serotypes by 75%, in children aged younger than 5-years. These benefits have been matched in importance by indirect effects with twice the number of cases of vaccine type invasive disease prevented by a herd immune effect in unvaccinated older age groups, especially in those over the age of 65-years. Furthermore, across all age groups the rates of invasive disease caused by penicillin-resistant strains declined by almost 60%. These impressive gains have been slightly offset by an increase in replacement disease by non-vaccine-type strains and in particular by serotype 19A infections. Similar benefits are being observed in Australia following targeted vaccination of high-risk groups and more recently by universal immunisation.
- A recent economic analysis submitted to the Ministry of Health by Wyeth suggested that when including the indirect herd immunity protective effects of a universal 7vPCV infant immunisation programme (3-dose primary immunisation series, followed by a second year booster dose) the incremental cost per life year gained for the New Zealand population would be \$NZ25,000.
- Currently in New Zealand, 7vPCV is funded only for a small group of high-risk children.

- 7vPCV may be safely administered with DTaP-HBV- IPV/Hib (Hib as PRP-T), but it is not currently recommended for co-administration with the hepatitis B vaccine, which is given at 5-months of age in the present national immunisation schedule

### **Human papillomavirus (HPV)**

- HPV causes genital warts and most preinvasive and invasive cancers of the lower anogenital tract. Of the more than 100 types of HPV, more than 40 infect the genital mucosa, of which 15 are deemed to be high-risk for cancer, including HPV types 16 and 18, which worldwide cause more than 70% of cervical carcinoma.
- One or more genital HPV types will infect most sexually active women at some point in time. However, most HPV infections are acquired soon after initiation of sexual activity and are transient. About 1% of sexually active adults develop genital warts, almost always from the low-risk types 6 and 11. Although high-risk HPV types will infect many women, in the absence of intervention only about 2% will develop precancerous lesions that might progress to cancer.
- In New Zealand cervical cancer is the third most common cancer and the fourth leading cause of cancer-related death amongst Maori women. Among non-Maori women, cervical cancer is the ninth most common cancer, but a less common cause of death. On average, each year in New Zealand about 200 women are diagnosed with cervical cancer and another 80 will die. There are limited data on the predominant HPV types associated with cervical cancer in New Zealand.
- Two inactive, recombinant vaccines containing HPV L1 virus-like particles (VLPs) have been developed and trialled successfully. One is a bivalent prophylactic HPV16/18 vaccine, while the other is a quadravalent HPV 6/11/16/18 vaccine. Each is administered by intramuscular injection at 0, 2 and 6-months. The vaccines are safe, immunogenic and highly protective against type-specific HPV infection. Efficacy rates of about 90% for vaccine-type persistent infection and 100% for prevention of clinical disease associated with HPV 6, 11, 16 or 18 over 36-months are reported.
- In New Zealand, the quadravalent vaccine was licensed in July 2006 and approved for females aged 9-26 years.
- The ITWG discussed with representatives from the Royal New Zealand College of General Practitioners, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the National Cervical Cancer Screening Unit issues surrounding (i) the importance of determining the prevalence of HPV types causing clinical disease in New Zealand women, (ii) public education for the link between HPV, sexual activity and cervical cancer, (iii) the continuing

importance of cervical screening and how this must be conveyed to vaccinated women, (iv) age of immunisation (before sexual debut) and where a vaccine programme is best delivered, (v) possible future immunisation of males, and (vi) cost benefit analyses of HPV vaccines where benefits may not be realised for two or more decades.

## **Varicella**

- It is estimated that each year approximately 50,000 New Zealand children develop chickenpox, of which in recent years 250-300 are hospitalised, one to two cases result in long-term disability or death and 0.5-1 cases are severe congenital varicella. Much of the severe disease burden is borne by otherwise healthy children.
- The United States introduced universal varicella immunisation in 1995 and in the following decade when slightly more than 80% of toddlers were vaccinated against chickenpox, there was a reduction in varicella hospitalisation rates by almost 90%, nearly 60% in ambulatory visits and 74% in direct health care costs. Other countries, including Australia and Canada, have recently introduced varicella vaccines into their national immunisation schedules.
- The theoretical risk of a temporary increase in herpes zoster following universal varicella immunisation from a lack of boosting adult immunity has not been seen, although it is still too early to confidently exclude this possibility. A vaccine against zoster was recently licensed in the United States. In elderly adults who received this vaccine and who were studied over almost 3-years, the burden of zoster was decreased by almost 60% in this population.
- An economic analysis published in 1999 indicated that a varicella vaccine would likely be cost saving in the New Zealand context if both direct health and society (from a work loss perspective) cost savings were taken into consideration. The analysis was vaccine cost-sensitive.
- Previously, the ITWG has recommended the universal introduction of the varicella vaccine when the combination MMRV vaccine becomes available. This vaccine is now awaiting licensure in New Zealand.

## **Rotavirus**

- At least 2% of all New Zealand children are hospitalised by 3-years of age following a severe rotavirus infection. Most admissions occur during Winter and Spring, a time when “all cause” hospitalisation rates are greatest because of respiratory related illness and staff absenteeism is at its greatest.

- Two oral live-attenuated rotavirus vaccines (P[8]G1 and P[8]G1-G4) have recently completed large field trials in both industrialised and emerging countries. These vaccines were well tolerated and unlike the original first generation rotavirus vaccine there was no observed increase in intussusception. They reduced the risk of rotavirus diarrhoea of any severity by about 75%, but importantly they demonstrated 85-98% protective efficacy against severe infection, including family doctor and Emergency Department visits and hospitalisation. Both vaccines were associated with a 41-59% reduction of “all cause” gastroenteritis admissions in young children. The vaccines proved effective against the main rotavirus serotypes circulating in New Zealand.
- Rotavirus vaccines are now licensed in more than 30 countries, including Australia and the United States.
- As an oral vaccine, this is unlikely to lead to major administration difficulties.

## APPENDIX 3

### Changes to current vaccine recommendations

#### Interpandemic influenza

- Each year New Zealand experiences a winter epidemic of influenza. Obtaining accurate data for the true burden of influenza is difficult. For example hospital data are likely to under-estimate the number of admissions from influenza as not all cases are recognised clinically or confirmed by laboratory testing, while discharge coding combines influenza and pneumonia believed to be secondary to influenza, but where pneumonia is the primary diagnosis. In 2002/2003 there were 12,191 hospitalisations from influenza and pneumonia. During 2003 there were also 424 deaths attributed to influenza and pneumonia. Modelling of New Zealand data from 1980-1992 suggested that for every death attributed to influenza there were another 7.7 deaths from influenza that went unrecognised.
- Rates of influenza are highest among children, but rates of serious illness and infection are greatest amongst the elderly, those under 2-years of age and individuals with chronic medical conditions placing them at increased risk of influenza complications. Ironically, it is the very young, the elderly and those with compromised immunity who have the poorest immune responses to the current licensed influenza vaccines.
- Currently, in New Zealand, influenza vaccines are publicly funded for all persons aged 65-years and over, and for those aged 6-months to 64-years with selected chronic medical conditions associated with a high risk of influenza-related complications.
- Other countries adopt different strategies. The latest recommendations from the American Advisory Committee on Immunization Practices (ACIP) on influenza immunisation include offering annual vaccination to (i) all children aged 6-59 months, (ii) those who are pregnant during the influenza season, (iii) to persons aged 50-years and over, (iv) to individuals of any age with certain high-risk medical conditions, and (v) to persons who live with or care for persons at high risk (household contacts and health-care workers). In contrast, in Japan previous mass immunisation of school children was associated with decreased morbidity and mortality in the very young and the elderly.
- The ITWG considered universal immunisation of infants and young children. The reduced immunogenicity of the trivalent influenza vaccine in young children, the need for annual vaccination because of antigenic drift, the requirement for two doses of vaccine to children aged under 9-years in the first year they are immunised and questions surrounding cost-effectiveness, efficacy and feasibility of immunising healthy children in primary care meant that no such recommendation could currently be made.

- Persons who are clinically or asymptotically infected can transmit influenza to persons at high-risk for complications. Vaccination reduces the risk of transmission and, in nursing homes, immunising health care workers is associated with reduced frequency of outbreaks and deaths.

## **Pertussis**

- New Zealand continues to have a relatively large disease burden from pertussis. During the last 2-years (2004-05) more than 6,000 cases were notified, including 173 hospitalisations and at least one death. Last year the highest rates recorded were during infancy (225 per 100,000) and in 10-14 year olds (124 per 100,000).
- Enhanced active surveillance of infants hospitalised in New Zealand with pertussis during a 12-month period beginning July 2004 found rates of hospitalisation in Maori and Pacific infants were 2.5 to 3 times greater than those for European/other infants less than 12-months of age (296 and 358 vs 117 per 100,000 infants respectively). One quarter of those hospitalised were younger than 6-weeks of age and too young to have been immunised, while almost half of those hospitalised and old enough to be immunised had not received any vaccines. Almost all of these cases had household contacts with a cough, of whom half were adults.
- It is too early to determine the impact upon pertussis of introducing the dTap vaccine into the immunisation schedule at age 11-years in February 2006.