From:
To: Community Affairs, Committee (SEN)
Subject: No Jab No Pay - some info that Senator Moore was after.
Date: Wednesday, 4 November 2015 10:17:52 PM
Attachments: NHMRC rescinded Hep B paper.pdf

Dear Sir/ Madam,

During Monday's hearing for the No Jab No Pay bill, Senator Moore was interested in how/why the Hepatitis B vaccine was on the schedule of vaccines recommended for children.
Below is a link to a NHMRC document for the recommendations for Hepatitis B immunisation. Page 15 summarises the advantages and disadvantages of universal infant immunisation.
https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cd11.pdf

I have also attached it as a file, just in case that is easier for you.

Hope this is of assistance.

Kind regards,
Liça Bienholz

Recommendations on hepatitis B immunisation

Report by NHMRC Hepatitis B Working Party

Endorsed at the 121st session of the
National Health and Medical Research Council

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Introduction

The purpose of hepatitis B immunisation is to either eliminate hepatitis B infection or to reduce the transmission of the virus and thereby reduce infection, the development of the hepatitis B carrier state and the development of long-term sequelae.

In October 1991, the World Health Organization (WHO) made a resolution on the elimination of hepatitis B infection and recommended that hepatitis B immunisation should be integrated into the national immunisation programs of all countries with a hepatitis B carrier prevalence of 8 per cent or greater by 1995 and in all countries by 1997. WHO also stated that 'countries with a lower prevalence than 2 per cent may consider immunisation of all adolescents as an addition or alternative to infant immunisation'[1].

Universal infant immunisation against hepatitis B has been incorporated into the list of vaccines recommended in the WHO Expanded Program on Immunisation. National hepatitis B immunisation programs have been implemented in over 50 countries including most of those in western and southern Europe. Universal infant immunisation has been introduced in Canada[2], the United States and Italy. France has introduced universal adolescent immunisation. In January 1996, the United Kingdom hepatitis B immunisation policy was reported to be 'under review' with no plans for the introduction of universal infant hepatitis B immunisation.[3]

The National Health and Medical Research Council (NHMRC) established the Hepatitis B Working Party with the following terms of reference:

- to examine the epidemiology and options for control of hepatitis B in Australia, including the case for and against different options for hepatitis B vaccination (including the need for and timing of booster doses);
- to consider cost-benefit issues of hepatitis B control; and
- to report to the NHMRC through the Communicable Diseases Standing Committee and the National Health Advisory Committee.

Membership of the Working Patty

Dr Graham Rouch (Chairman)	Chief Health Officer, Department of Human Services (Victoria), Melbourne
Dr Jim Butler	Senior Fellow (Health Economics), National Centre for Epidemiology and Population Health, Canberra
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i Formerly of the National Centre for Epidemiology and Population Health, Australian National University, Canberra.

Dr Ian Steven	Assistant Secretary (Research), Royal Australian College of General Practitioners, Adelaide
Dr Lance Sanders (Scientific Secretary)	Principal Scientist, Commonwealth Department of Health and Family Services, Canberra.

Recommendations

Recommendation 1

The NHMRC recommends the implementation of universal hepatitis B immunisation for **both** infants and pre-adolescents, in addition to more vigorous implementation of selective hepatitis B vaccination recommendations.

- The infant immunisation schedule will be developed by the Immunisation Working Party as part of the *NHMRC Standard Immunisation Schedule*.
- Pre-adolescent vaccination should be administered in Year/Grade 6.

Recommendation 2

A system for monitoring the implementation of antenatal screening programs should be developed, to ensure that carrier mothers are identified at least at delivery, if antenatal screening did not occur.

Recommendation 3

The *Australian Childhood Immunisation Register* (ACIR) should monitor vaccination of all hepatitis B immunisation of children under 6 years of age. Additionally, consideration should be given to expanding the ACIR to include the pre-adolescent group, in an endeavour to ensure that all three doses of the vaccine are administered.

Recommendation 4

Evaluation of the effectiveness of immunisation programs in reaching high risk infants should be undertaken, as these children often have limited access to health care and low vaccination rates for other vaccines in the immunisation schedule.

Recommendation 5

Evidence on the duration of hepatitis B immunity of vaccinated children should be monitored, in order to determine whether pre-adolescent immunisation should continue once the cohort of children vaccinated as neonates reaches Year/Grade 6.

Recommendation 6

Issues of surveillance of vaccine immunogenicity and efficacy should be considered *in the National Disease Surveillance Strategy* being developed by the Commonwealth.

1. The epidemiology of hepatitis B in Australia

In adults, hepatitis B infection is frequently symptomatic, while in young children (particularly those under 1 year of age) infection is usually asymptomatic. Of those with acute infection, about 5 per cent of adults and most infants become carriers; they are a potential source of infection for others and have a significantly increased risk of chronic hepatitis and primary liver cancer in later life[4].

Transmission occurs through percutaneous or permucosal exposure to infective body fluids such as blood, saliva, semen and vaginal fluid. The infection is most commonly acquired from:

- an infected mother to child at or around the time of birth;
- an infected sexual partner;
- shared injection equipment; and
- carriers living in the same household.

In countries with a high prevalence of hepatitis B infection, most infection occurs in infancy or childhood. Infection is most common in young adults in countries with a lower prevalence of the disease[5].

In considering the epidemiology of hepatitis B in Australia, NHMRC's Working Party reviewed the following three papers:

- *Hepatitis B position paper* (1990) by Carey[6]. This report was prepared for the Health Department of New South Wales to assist in policy development and considered the epidemiology of hepatitis B in Australia and New South Wales.
- *The changing pattern of hepatitis B infection in Australia* (1995) by Cossart[7] which considered the effects of the changing composition of the Australian population, immigration, and immunisation policies on the epidemiology of hepatitis B in Australia.[ii]
- *Hepatitis B infection in Australia: an epidemiological overview* (1995) by Kaldor et al[8] which considered research and surveillance reports providing data on the incidence and prevalence of hepatitis B in Australia[iii]. This paper reviewed evidence that some population subgroups in Australia have been found to have hepatitis B infection rates comparable to or higher than those found in some (so called) high prevalence countries. Transmission rates for hepatitis B virus (HBV) in newborns, children and adults were estimated under a range of assumptions. These data were used as the basis for the cost-effectiveness study carried out by Dr Jim Butler[9].

These studies highlight the gaps in the data on the incidence and prevalence of hepatitis B infection, rates of vaccine uptake and completion of the course of vaccination, the immunogenicity and efficacy of the vaccines, and the duration of immunity. Despite these gaps, the NHMRC Working Party considered that there was now sufficient knowledge of the epidemiology of the disease in Australia to proceed with recommendations on a revised immunisation policy.

The NHMRC notes that the Commonwealth is developing a *National Disease Surveillance Strategy* and that issues of surveillance of vaccine immunogenicity and efficacy have not been considered. The NHMRC recommends that this deficiency be addressed.

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ii This paper is the work of the individual author(s) and not the Working Party itself, although the paper was used by the Working Party as the basis for the development of policy

iii See footnote ii

2. Immunogenicity and protective efficacy of hepatitis B vaccines

The evidence is clear that both hepatitis B vaccines marketed in Australia (Engerix-B and H-B-Vax II) are highly immunogenic. Published data show that where adequate titres of antibody are attained after a primary vaccination course, the vaccines provide protection against symptomatic infection and seroconversion to the carrier state.

The currently approved schedules for these vaccines are set out below.

Vaccine	Schedule
Engerix B	• 3 doses, given at 0, 1 and 6 months; and . 4 doses, given at 0, 1, 2 and 12 months.
H-B-Vax II	· 3 doses, given at 0, 1 and 6 months.

3. Adverse reactions to hepatitis B vaccination

In considering the data on adverse events temporally associated with hepatitis B vaccination, members evaluated data published *in* a recent US report *Adverse events associated with childhood vaccines - evidence bearing on* causality[10]. While the Working Party recognised that there are no vaccines for which there are no side effects, they agreed with the findings of that report, which concluded that hepatitis B vaccine is very safe.

The *Serious Adverse Events Following Vaccination Scheme* has been established under the auspices of the *National Childhood Immunisation Program* for the purpose of monitoring adverse effects of vaccination and may be a suitable method of monitoring adverse reactions to hepatitis B vaccination[11].

4. Options reviewed

The Working Party evaluated several options for immunisation strategies to reduce the incidence and prevalence of hepatitis B infection and its sequelae in Australia. The options considered were **in addition to** the present level of implementation of existing policy, These options were:

- the present level of existing hepatitis B immunisation (antenatal screening and vaccination, assuming 50 per cent coverage of infants of foreign-born mothers[iv]);
- a more vigorous implementation of the existing program (antenatal screening and vaccination and assuming 100 per cent implementation of vaccination programs for infants of foreign-born mothers);
- universal vaccination at birth (in addition to existing antenatal screening and vaccination);
- universal vaccination at birth plus universal pre-adolescent vaccination (in addition to existing antenatal screening and vaccination); and
- pre-adolescent vaccination (in addition to antenatal screening and vaccination and assuming 100 per cent implementation of vaccination programs for infants of foreign-born mothers).

iv As data on the proportion of births to high risk households is not available, the cost-effectiveness analysis have been prepared using data for infants born to all foreign-born mothers).

5. Cost-effectiveness analysis

In making the above recommendations, consideration was given to the safety and efficacy of hepatitis B vaccine, the expanding high risk populations within Australia[7,12], the overall incidence of infection and the evidence that compliance with existing policy has been only of the order of 50 per cent for selected high risk groups[13].

The cost-effectiveness analysis performed by Dr Jim Butler (1995)[9] was produced to compare specific vaccination strategies considered by the NHMRC Working Party with the assumption that antenatal screening for hepatitis B surface antigen (HBsAg) (to allow administration ofhepatitis B immunoglobulin (HBIG) and hepatitis B vaccine to infants of HBsAg positive mothers) would need to continue regardless of additional strategies. A summary of the results of the cost-effectiveness analysis is presented at Appendix 1.

The conclusion drawn from this analysis is that the best health gain, measured in increased years of life saved, resulted from universal infant vaccination combined with universal pre-adolescent vaccination.

Ranking	Option	Years of life saved	Cost saving	Cost saving per life year saved*
1	Infant plus pre-adolescent vaccination	443	$1.63m	$17,430
2	Infant vaccination	114	$5.11m	$75,392
3	Pre-adolescent vaccination	404	$4.57m	$10,558

* Assumes 100% coverage of all newborns, continued screening of pregnant women and provision of HBV and HBIG to infants of HBsAg positive mothers.

Should a much higher coverage of high risk infants be obtained, and if limitation of resources dictated, then the addition of universal pre-adolescent vaccination alone would be the most cost-effective strategy.

The NHMRC Working Party has assumed for the purpose of its deliberations that universal infant vaccination would result in much higher coverage of infants in high risk families than occurs at the present time.

The Working Party also noted a study on the cost-effectiveness of alternative hepatitis B vaccination strategies in England and Wales, which found that, with no discounting of future health gains, universal vaccination was more cost-effective than selective vaccination in a low prevalence country. However, if future health gain was discounted, selective immunisation combined with universal pre-adolescent vaccination became more, cost-effective.[14]

6. Advantages and disadvantages of universal childhood immunisation and universal pre-adolescent vaccination

Universal infant immunisation

Advantages

- Reduces recruitment to the pool of hepatitis B carriers
- Universal immunisation policies are generally logistically easier to implement than selective policies which must identify and reach high risk groups.
- The vaccine can be given at the same time as other routine immunisations.
- The population is accessible, which will allow for high coverage levels comparable to those for Diphtheria-tetanus-pertussis (DTP), polio and *Haemophilus influenzae* type b (Hib) vaccines.
- The population at highest risk of becoming carriers of hepatitis B would be protected, ie infants of carrier mothers who are missed by antenatal screening programs would be vaccinated.
- With the increased volume of vaccine required, the cost of individual doses of vaccine may be reduced.
- It is consistent with World Health Organization recommendations.

Disadvantages

- The overall incidence of disease is extremely low in young children and many infants will be vaccinated against a disease which they are at low risk of contracting.
- Booster doses may be needed when the cohort reaches adolescence and/or adulthood when risks related to lifestyle become a factor.
- The complexity of the immunisation schedule is likely to increase.
- The number of injections required may reduce parental and immunisation provider acceptance of the immunisation schedule.
- The primary impact of the program (the reduction of long-term sequelae) will not be felt for a decade or more, which may affect acceptance by parents, health care professionals and health authorities.
- The program will be more costly than the current selective program.
- If all infants are immunised at birth, antenatal screening may be seen as less important and there could be a decrease in the proportion of infants born to carrier mothers who receive hepatitis B immunoglobulin at birth.

Universal pre-adolescent immunisation

Advantages

- It can be delivered through schools to maximise access.
- The effect of the program on disease incidence will be noted earlier.

- Vaccine is administered at a time when risks related to lifestyle (injecting drug experimentation and sexual activity) are beginning to become a factor.
- The number of life-years saved will be maximised (see Appendix 1, Table 1).

Disadvantages

- The cost is higher than with universal infant immunisation (see Appendix 1).
- Additional resources are needed to administer three doses of vaccine within a school system.
- There may be difficulties in achieving satisfactory uptake levels of three doses of vaccine in this age group.

7. Recommendations for hepatitis B immunisation

Based on the available evidence, the NHMRC recommends that the best and most cost-effective protection against hepatitis B is achieved by **universal hepatitis B immunisation of both infants and pre-adolescents.** Immunisation of preadolescents should occur during Year/Grade 6 of primary school, and should occur only until the cohort of children that were vaccinated as infants reaches Year/Grade 6, at which time consideration would be given to administering a booster, if necessary. The program of immunisation of pre-adolescents could then be terminated.

The NHMRC stresses that the introduction of universal immunisation for infants and pre-adolescents should be **in addition to** the more vigorous implementation of selective hepatitis B vaccination recommendations[4]. These are:

- routine antenatal screening for HBsAg with administration of both hepatitis B vaccine and HBIG at birth to children of carrier (HBsAg positive) mothers; and
- vaccination of
  - infants and young children in community groups with a hepatitis B carrier rate of over 2 per cent (this includes individuals from most countries in Asia, Africa, Oceania, central and south America, eastern Europe, and the Mediterranean region; pre-vaccination testing is not recommended for this group);
  - individuals who are sexual partners of acute cases or carriers, or who are long term household contacts of carriers (including close family members of HBsAg positive immigrants; pre-vaccination HBsAg testing of members of families who have immigrated from high prevalence countries is recommended);
  - individuals who are at occupational risk of exposure, such as health care workers and embalmers (this risk depends upon the carrier rate among the population served and the degree of exposure to human blood or tissue); and
  - individuals with significant lifestyle risk of hepatitis B such as: clients of STD clinics; men who have sex with men; injecting drug users; haemodialysis patients; haemophiliacs; residents of institutions for the intellectually disabled; close residential contacts of deinstitutionalised intellectually disabled individuals who are carriers of hepatitis B; and inmates of long term correctional facilities.

The NHMRC also recommends that a system for monitoring the implementation of antenatal screening and vaccination programs should be established. In instances where antenatal hepatitis B screening has not been carried out, the mother should be tested at delivery and hepatitis B vaccine and HBIG administered if indicated.

The NHMRC notes that the *Australian Childhood Immunisation Register* (ACIR), which commenced data collection on 1 January 1996, would provide useful data on vaccine uptake in children under 6 years of age. However, it was noted that, in the ACIR's current form, data on hepatitis B vaccinations relates preferentially to high risk children, since a fee is only paid for notification of hepatitis B vaccinations for which there is a clinical indication.

The NHMRC recommends that, with the introduction of universal infant hepatitis B immunisation, the ACIR should monitor vaccination of all hepatitis B immunisation of children in this age group. In addition, consideration should be given to expanding the ACIR to include pre-adolescent hepatitis B vaccination, in an endeavour to ensure that all three doses of vaccine are administered.

One of the assumptions underlying the introduction of universal infant immunisation was that this would improve vaccine uptake in high risk infants. The NHMRC considers that evaluation of the effectiveness of immunisation

programs in reaching infants at high risk of infection should be undertaken, since these children often have limited access to health care and low vaccination rates for other vaccines on the immunisation schedule.

The NHMRC's Working Party also considered that the alternative approaches would reduce the incidence and carriage of hepatitis B in Australia. In order of preference these options are:

- universal infant immunisation; and
- universal pre-adolescent vaccination.

Regardless of which hepatitis B immunisation policy is implemented, more vigorous implementation of current selective immunisation policies is essential.

Immunisation schedule

During second stage consultation on these recommendations, there was strong **in principle** support for the introduction of a combination of universal infant and universal pre-adolescent vaccination. However, there was considerable debate about the details of the implementation of the recommendations.

Immunisation schedule for infants

The primary debate centred on the timing of the introduction of the recommendations (ie whether to wait for the introduction of a multivalent vaccine) and the exact vaccination schedule to be used. A variety of schedules were suggested to either minimise the number of injections administered at one visit or minimise the number of visits. A second element in the debate concerned the timing of the administration of the first dose of vaccine, ie whether the initial dose of vaccine should be administered at birth for all infants or only for those in high risk groups.

The NHMRC considers that **either** a schedule of 0 (at risk infants only), 2, 6, and 12 months of age **or** of 0, 2, and 6 months of age for all infants may be feasible. Regardless of the schedule the NHMRC's position is that any hepatitis B vaccination administered at birth must use a monovalent vaccine.

The NHMRC recognises that the exact vaccination schedule needs to be determined within the context of the immunisation schedule as a whole. This schedule is under review by the NHMRC Pertussis Working Party and the NHMRC Immunisation Working Party, which is also revising the current edition of the *Australian Immunisation Procedures Handbook.* This includes a review of the advice on booster doses and pre- and post-vaccination serology testing. In moving from a targeted hepatitis B vaccination program to a universal one, it is important to ensure that the *Standard Schedule* incorporates a schedule for hepatitis B vaccination that is both immunogenic and convenient. The revised *NHMRC Standard Immunisation Schedule* will be considered by Council in November 1996.

Pre-adolescent vaccination schedule

The Working Party discussed logistical problems of vaccine administration to pre-adolescents and the most appropiate age to administer vaccine. Administration of vaccine in Year/Grade 7 or 8 (following appropiate education programs) was considered. However, the NHMRC's preference was for administration of hepatitis B vaccination in Year/Grade 6.

Hepatitis B vaccine became available in the early 1980s. Data on the duration of hepatitis B immunity in vaccinated children is limited by availability of long term studies. Published evidence on a population of Yupik Eskimos[15], indicates that in people who developed adequate titres of antibody after a primary course of vaccine, protective efficacy may be maintained for at least 7 years.

The NHMRC recommends that boosters should not be administered to children under 10 years of age who were vaccinated as neonates or young children[4]. It is further recommended that evidence on the duration of hepatitis B immunity of vaccinated children be kept under review to determine whether pre-adolescent immunisation should continue once the cohort of children vaccinated as neonates reaches Year/Grade 6.

8. Implementation of these recommendations

The NHMRC considers that the implementation of the recommendations needs to be carried out in the context of the review of the broader immunisation schedule and that this review should be accomplished as soon as is practicable.

It is acknowledged that current impediments to implementation include:

- lack of availability of suitable multivalent vaccines which would reduce the number of injections required at any one visit;
- me cost of multivalent vaccines is not known at present, but is anticipated to be high in comparison to other vaccines;
- lack of advice about the place of hepatitis B vaccination within the context of the current immunisation schedule. (This will be developed by the Immunisation Working Party in its review of the immunisation schedule).

The NHMRC recognises that implementation of infant and pre-adolescent vaccination programs will not be straight forward and that several key issues, including logistical details of program delivery, vaccine uptake, information provision to pre-adolescents and funding, will need to be addressed for effective implementation to occur. The NHMRC further notes that implementation of the recommendations should not necessarily be dependant upon the introduction of a multivalent vaccine, but that this issue should be considered in conjunction with other aspects of immunisation.

The NHMRC recommends that any introduction of universal infant vaccination and universal pre-adolescent vaccination should be **in addition to** improved implementation of the current selective programs, particularly antenatal screening of pregnant women and neonatal vaccination of high risk infants with the administration of HBIG to children of carrier mothers.

The NHMRC considered that, while details of implementation of these recommendations are being finalised, improvements in the administration of antenatal screening programs could be achieved without excessive cost implications. Issues that could be addressed on a regional basis include structural issues in obstetric hospitals and the provision of information on antenatal screening to obstetricians.

In the short-term, adding universal infant and universal pre-adolescent vaccination to the existing selective vaccination programs will result in a reduction in the incidence of acute hepatitis B infection, chronic carriage of the disease and a reduction in the transmission of the disease to those who have not been immunised. Effects of the policy change on the incidence of sequelae such as cirrhosis and primary liver cancer will not be seen for some time.

Appendix 1: Summary of results of cost-effectiveness analysis

The following tables, taken from the cost-effectiveness analysis undertaken by Dr Jim Butler, summarise the results of the cost-effectiveness analysis of the various alternative immunisation strategies considered by the NHMRC Working Party.

The analysis includes two specifications of the baseline program against which the alternative immunisation strategies are then compared. These are:

- Program A: Based on existing NHMRC policy and assumes that 50 per cent of infants born to HBsAg negative foreign-born mothers are immunised against Hepatitis B; and
- Program A+: Based on the same policy but assumes that 100 per cent of this group are immunised.

Three alternative Programs are then considered:

- Program B: Universal vaccination at birth;
- Program C: Universal vaccination at birth **plus** a universal pre-adolescent program; and
- Program D: Addition of a universal pre-adolescent program to the baseline Program A+.

In Table 1, each of the alternative programs is compared with baseline Program A and baseline Program A+. The lines in Table 1 labelled 'Change over existing policy ...', show the additional costs/cost savings, and the estimated number of life years saved, achieved by a particular policy in comparison with baseline Program A and Program A+. Tables 2 and 3 show the parameters used in developing this cost-effectiveness data.

The estimated years of life saved with each policy are discounted at 5 per cent per annum. Thus with an assumed mean age at death from hepatitis B infection among adults of 45 years and a remaining life expectancy at age 45 of 33 years, the present value of 33 years of life saved commencing in 45 years time is two years. If the mean age at death were 55 years, the present value of years of life saved for a person in this group would be one year.

In comparison with Program A, universal vaccination at birth together with a universal pre-adolescent program (Program C) saves 443 years of life and yields a net cost saving of $1.63 million. While the vaccination cost for one year is estimated to be $19.5 million, treatment cost savings in the future are estimated at $21.1 million. Universal vaccination at birth alone (Program B) has a greater net cost saving ($5.11 million) but saves only 114 years of life.

It should also be noted that expanding Program A to achieve 100 per cent coverage of infants born to HBsAg negative foreign-born mothers would achieve net cost savings of $8.05 million and save 75 years of life. This is shown in the comparison of Program A+ with Program A in Table 1.

If Program A+ is taken as the baseline, a universal infant vaccination program (Program B) saves an additional 39 years of life at a net cost of $75,392 per life year saved. Combining this with a universal pre-adolescent program would save 368 years of life at a cost per life-year saved of $17,430.

Taken together, these results suggest that, in comparison with a situation where only 50 per cent of infants born to HBsAg negative foreign-born mothers are vaccinated (Program A), extending coverage of these high-risk infants to 100 per cent and implementing a universal preadolescent program, saves more costs and yields almost as many Me-years saved as universal vaccination at birth combined with a universal pre-adolescent program (Program C). This is because most of the benefits of universal vaccination at birth accrue from the coverage obtained in the higher-risk sub-group of infants born to HBsAg negative foreign-born mothers. If coverage in this group can be lifted to 100 per cent, and a universal pre-adolescent program is implement& 404 years of life would be saved with a net cost saving of $4.57 million (see Program D in Table 1).

Table 1 Cost-effectiveness data for hepatitis B immunisation policy options

Program	Total screening cost	Total immunisation cost			Total treatment cost*	Total cost*	Life-years lost	Incremental Life-years saved	Cost per Life-year saved	cost savings
		Vaccine cost	Admin cost	Total						
A. Existing policy with 50% coverage.** No pre-adolescent program.	$3,575,000	$882,120	$804,304	$1,686,424	$33,338,411	$38,599,835	633			
A+ Existing policy with 100% coverage.** No pre-adolescent program.	$3575,000	$1,495,111	$1447,377	$2,942,488	$24,033,032	$30,550,520	558			
Change over existing policy A	$0	$612,991	$643,073	$1,256,064	($9,305,379)	($8,049,315)		75		$8.05m
B. Universal vaccination at birth.*** No pre-adolescent program.	$3,575,000	$5,307,640	$5447,000	$10,754,640	$19,164,595	$33,494,235	519			
Change over existing policy A	$0	$4,425,520	$4,642,696	$9,068,216	($14,173,815)	($5,105,600)		114		$5.11m
Change over existing policy A+	$0	$3,812,529	$3,999,623	$7,812,152	($4,868,437)	$2,943,715		39	$75,392	
C. B + universal pre-adolescent program	$3,575,000	$10,380,020	$10,768,300	$21 148,320	$12,248,273	$36,971,593	190			
Change over existing policy A	$0	$9,497,900	$9,963,996	$19,461,896	($21,090,138)	($1,628,242)		443		$1.63m
Change over existing policy A+	$0	$8,884,909	$9,320,923	$18,205,832	($11,784,759)	$6,421,073		368	$17,430	
D. Existing policy A+ with universal pre-adolescent program	$3,575,000	$6,567,491	$6,768,677	$13,336,168	$17,116,710	$34,027,878	229			
Change over existing policy A	$0	$5,685,371	$5,964,373	$11,649,744	($16,221,701)	($4,571,957)		464		$4.57m
Change over existing policy A+	$0	$5,072,380	$5,321,300	$10,393,680	($6,916,322)	$3,477,358		329	$10,558	

A bracketed figure indicates a reduction in cost.

** The percentages covered in Programs A and A+ refer to the proportion of infants born to HBsAg negative foreign-born women who are immunised. Program A+ represents a more vigorous implementation of existing policy than Program A.

*** Universal vaccination at birth assumes 100% coverage of all newborns, and would continue the present policy of screening pregnant women and providing HBV vaccine and HBIG to infants of HBsAg negative women.

Table 2 Parameter values used in the hepatitis B cost-effectiveness model

Parameter	Explanation/default value
Number of newborns	Number of births in Australia in a year. Default value = 260,000[16].
Proportion of births to foreign-born mothers	25%[17]
Carrier rate in mothers	Foreign-born - 0.037 (3.7%). Australian-born - 0.001 (0.1%). Weighted mean carrier rate - 0.01 (1.0%).
Sensitivity of HBsAg test	**0.98**[18]
Proportion of mothers tested	Default value = 1.0 (100%).
Proportion of children to HBsAg negative foreign-born mothers immunised	50%[7]
Probability of perinatal transmission	Calculated as the weighted mean of probabilities of perinatal transmission in HBeAg positive and HBeAg negative mothers, where the weights are the proportions of mothers e-antigen positive and negative. Defaultvalues: Proportion HBeAg positive = 0.2. Probability of vertical transmission = 0.9. Proportion HBeAg negative = 0.8. Probability of vertical transmission = 0.15. Weighted mean probability of transmission = 0.30.[19]. (This compares with a probability of vertical transmission of 0.378 used in Krahn & Detsky 1993[20]).
Probability of horizontal transmission during first 10 years of life	Foreign-born household - 0.0257. Australian-born household - 0.0022. Weighted mean = 0.008[18].
Number of 10 year olds	Default value = 254,000[17]
Probability of horizontal transmission for adolescents	0.025[18]
Proportions of newborns and adolescents experiencing sub-clinical outcomes etc	See Table 3.
Unit cost data - outcome states	See Table 3.
Life-years lost per death	Assumed mean age at death = 45[19]. Life expectancy at age 45 = 33 years. Life expectancy at birth = 76 years[21]. Present value of 33 years of life saved commencing in 45 years time at 5% discount rate = 2 years. Present value of 76 years of life saved commencing this year at 5% discount rate = 20 years.
Decrease in effectiveness (non-compliance etc)	HBV vaccine - 25% HBV vaccine with HBIG - 16%
Unit cost of HBIG	$15 (indicative only)
Unit cost of HBV vaccine	Retail pharmacy prices (3 doses): Child $41.50, Adult $67.00 On mass immunisation schedule (3 doses): Child $14.70, Adult $24.60
Unit cost of administration of HBV vaccine	$6 per dose
Vaccine formulation for adolescent program	Paediatric
Unit cost of HBsAg test	$13.75 (MBS Item no. 69243, Schedule fee)

Table 3 Outcome proportions and unit costs

	Birth cohort		Adolescent cohort	
	Outcome proportions	Lifetime unit cost of treatment	Outcome proportions	Lifetime unit cost of treatment
Proporation experiencing sub-clinical outcome	0.98	$0	0.657	$5
No sequelae	0.1	$0	0.92	$0
Chronic carrier	0.45	$746	0.04	$746
Chronic persistent hepatitis	0.2	$1,271	0.02	$1,271
Chronic active hepatitis	0.25		0.02	
Alive	0.75	$53,002	0.5	$53,002
Cirrhosis/hepatocellular carcinoma	0.25	$81,010	0.5	$81,010
Proportions experiencing clinical infection	0.01999	$714	0.34	$552
No sequelae	0.1	$5	0.92	$0
Chronic carrier	0.45	$746	0.04	$746
Chronic persistent hepatitis	0.2	$1,271	0.02	$1,271
Chronic active hepatitis	0.25		0.02	
Alive	0.75	$53,002	0.5	$53,002
Cirrhosis/hepatocellular carcinoma	0.25	$81,010	0.5	$81,010
Proportion experiencing fulminant infection	0.00001	$12,331	0.003	$9,522
Deaths, given fulminant infection	0.78		0.78	
Of those surviving:				
No sequelae	0.96	$0	0.96	$0
Chronic carrier	0.02	$746	0.02	$746
Chronic persistent hepatitis	0.014	$1,271	0.014	$1,271
Chronic active hepatitis	0.006		0.006	
Alive	0.75	$53,002	0.5	$53,002
Cirrhosis/hepatocellular carcinoma	0.25	$81,010	0.5	$81,010

Source: Bloom et al 1993, Table 1[19]

Appendix 2: List of submissions received from public consultation

Aboriginal and Torres Strait Islander Commission, Social and Cultural Division, General Manager, John Eldridge

Australian College of Paediatrics, Immunisation Standing Committee, Chair, John Ziegler

Australian College of Paediatrics, President, Dr PD Phelan

Australian Council of Local Government Officers, Secretary, Adrian O'Loughlin

Australian Defence Force, Headquarters, Office of the Surgeon General Australian Defence Force, Director General Clinical Services, Lieutenant Colonel C Castles

Australian Funeral Directors Association, Executive Director, RG Richardson

Australian Gastroenterology Institute, Honorary Secretary, Brendan Crotty

Australian Government Health Service, Policy and Marketing, Director, Dr R Griffin

Australian Infection Control Association, President, Mrs Madeline McPherson

Australian Institute of Environmental Health, Executive Officer, Bob Langdon

Australian Medical Association Ltd, Health Services, Assistant Director, Phillip Taylor

Australian Society for HIV Medicine, President, Dr Marilyn McMurchie

Canterbury Division of General Practice Ltd, Immunisation Committee, Chairman, Alex Lewis

Child and Youth Health, Immunisation Unit, Planning and Development, Director of Nursing, Nan Davies

City of Darebin, Preston District Office, Medical Officer of Health, Dr RT Howsam

Commonwealth Department of Human Services and Health, National Childhood Immunisation Committee, Secretary, Monica Johns

Community and Health Services (Tas), Population Health, Public Health Branch, Director, Dr Mark Jacobs

Corrections Health Service, Corrections Health Service Board, Chairman, Professor Ronald Penny

Cowan, Dr Alan N

CSL Ltd, Dr Brian Feery

Dandenong District Division of General Practice, Director, Ms Anne Peek

Department for Education and Children's Services, Chief Executive, Denis Ralph

Department of Education (Qld), Director General of Education, F J Peach

Department of Education and the Arts (Tas), Senior Curriculum Officer (Health), Chris McNamara

Department of Health and Community Care (ACT): Chief Health Officer, Dr Doris Zonta; Director Communicable Disease Control, Ms Irene Parraris; Community Infection Control, Ms Helen Bedford; Immunisation Coordinator, Ms Ann Kempe; MAE Student, Dr Eddie O'Brien.

Department of Health and Community Services (Vic), Infectious Diseases Unit, Manager, Dr J Camie

Division of General Practice Northern Tasmania, Dr Maree O'Sullivan

Farrell, Peter J

Haemophilia Foundation, Executive Director, Jennifer Ross

Health Department of Western Australia, Disease Control, Director, Dr Jag Gill

Hunter Area Health Service (NSW), Public Health Physician, Dr Thaïs Miles

Macfarlane Burnet Centre for Medical Research, Epidemiology and Social Research Unit, Deputy head, Dr Sandy Thompson

Macfarlane Burnet Centre for Medical Research, Director, John Mills Macfarlane Burnet Centre for Medical Research, Tilman Ruff

Medical Officers of Health Association, Chairperson, Dr RJ Howsam

Melbourne Division of General Practice, Linda Burke and Project Manager, Dr Jane Collins

National Centre for Epidemiology and Population Health, Visiting Fellow, Robert Hall

National Council of Women of Australia Inc Ltd, National Health Convenor, Elizabeth Newman

NSW Health Department, AIDS/Infectious Diseases Branch, Director, Ross O'Donoughue

Nurses Board of South Australia, Chief Executive Officer/Registrar, Helen Tolstoshev

Nursing Board of Tasmania, Executive Officer/Registrar, Geoff Clark

Osborne Division of General Practice, Director, Dr Richard Hosking

Prince Henty Hospital (NSW), Professor & Consultant Emeritus, CR Boughton

Princess Alexandra Hospital for Children, Department of Immunology and Infectious Diseases, Head, David Isaacs

Public Health Association of Australia, Executive Director, Margaret Conley

Royal Alexandra Hospital for Children, Associate Professor of Paediatrics and Child Health, Physician in Preventive Medicine, Associate Professor Margaret Burgess

Royal Australian College of Physicians, Dr David Tiller

Royal Brisbane Hospital, Department of Pathology, Dr JL Faoagali

Royal College of Nursing, Executive Director, Elizabeth C Percival

Royal College of Pathologists of Australasia, Honorary Secretary, Colin McLeod

South Australian Health Commission, Communicable Diseases Control Unit, John Carrangis

South Eastern Sydney Area Health Service, Dr Mark Ferson

Spencer, Dr Rodney

St Vincent's Hospital, Department of Gastroenterology, Deputy Director, Dr Katrina Watson

St Vincent's Hospital, Department of Gastroenterology, Gastroenterologist/Hepatologist, Dr Simone Strasser

Swan Hill Division of General Practitioners Ltd, Coordinator, Dr Colin Hughes

Territory Heath Services (NT), Chief Health Officer, Dr Malcolm Dunjey

University of Melbourne, Microbiology Diagnostic Unit, Dr Geoff Hogg

Vaccination Information Network Qld Inc, President, Mrs Norma Love

Victorian Infectious Diseases Reference Laboratory, Director, Associate Professor Stephen Locarnini

Viral Hepatitis Prevention Board, Associate Professor Peter Hollingsworth

Westmead Hospital, Department of Medicine, Robert W Storr Professor of Hepatic Medicine, Professor G Farrell

Women in Medical Science, President, Margaret Sawyer

Women's and Children's Hospital, Microbiology and Infectious Disease Services, Senior Consultant Clinical Microbiologist, Paul N Goldwater

World Health Organization, Regional Office for the Western Pacific

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