



National Health Amendment (National HPV Vaccination Program Register) Bill 2007

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National Health Amendment (National HPV Vaccination Program Register) Bill 2007

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Links:

The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

The purpose of the Bill is to amend the *National Health Act 1953* in order to establish and maintain a National Human Papillomavirus (HPV) Vaccination Program Register. It also allows for payments to be made to General Practitioners for the provision of vaccination information on the Register.

Background

Cervical cancer kills around 200 women in Australia each year, although the incidence and mortality of the disease in recent years has been decreasing. In 2004 the mortality rate for cervical cancer was 1.8 per 100,000 women, compared to 4.0 per 100,000 in 1991, the year the National Cervical Cancer Screening Program (NCSP) commenced.¹ Australia has one of the lowest incidences of cervical cancer, largely attributable to the NCSP, which it is estimated prevents around 70 per cent of squamous cervical cancers.²

The NCSP, a joint program of the Australian and state and territory governments, aims to reduce morbidity and deaths from cervical cancer, cost-effectively, by encouraging women to have regular Pap smears which can detect cervical abnormalities. The Program includes

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1. Australian Institute of Health and Welfare, [Cervical Screening in Australia 2004-05](#), Canberra, AIHW, 2007, p. ix.
 2. National Health and Medical Research Council, [Screening to prevent cervical cancer: guidelines for the management of asymptomatic women with screen detected abnormalities](#), Canberra, NHMRC, 2005, p. 5.

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a nationally agreed screening policy, Pap test registers in each State and Territory, accreditation of pathology laboratories and quality management strategies across the screening pathway.³ The NCSP total cost to governments is around \$89.1 million per year.⁴

Cervical cancer can be caused by infection with certain strains of the Human Papilloma Virus (HPV). HPV is a sexually transmitted virus which is extremely common among people who have had sexual contact—it has been estimated that 4 in 5 people will have experienced infection with HPV.⁵ Although DNA from HPV is found in 99.7 per cent of cervical cancers, cervical cancer is a rare outcome of HPV infection.⁶ Most infected women do not go on to develop cervical cancer.

In June 2006 the first vaccine that protects against some of the cancer causing strains of HPV, Gardasil®, was registered for use in Australia by the Therapeutic Goods Administration (TGA) for the prevention of cervical cancer in women and girls aged 9 to 26 years (and prevention of HPV infection in males aged 9 to 15).⁷ On 30 March 2007 Cervarix® (manufactured by GlaxoSmithKline) became the second HPV vaccine to obtain TGA approval, in this case, for the prevention of cervical cancer in women aged 10 to 45 years.⁸ Both vaccines protect against the two HPV strains responsible for 70 – 80 per cent of cervical cancers – types 16 and 18.

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3. Department of Health and Ageing, *National Cervical Screening Program*, URL: <http://www.cervicalscreen.health.gov.au/internet/screening/publishing.nsf/Content/cervical-about>, accessed 2/7/07.
 4. Australian Institute of Health and Welfare, *National Public Health expenditure report 2001-02 to 2003-04*, Canberra, AIHW, 2006, p. 10.
 5. Department of Health and Ageing, 'The National HPV Vaccination Program-Frequently asked questions for young women' webpage, URL: <http://www.health.gov.au/internet/standby/publishing.nsf/Content/young-women-faq#3>, accessed 29/6/07.
 6. NHMRC, op. cit, p. 9.
 7. Therapeutic Goods Administration, Australian Drug Evaluation Committee (ADEC) '[ADEC 246th Meeting recommendations: Resolution no. 8971](#)', Commonwealth of Australia *Gazette*, No. GN 25, 28 June 2006.
 8. Therapeutic Goods Administration, Australian Drug Evaluation Committee (ADEC) '[ADEC 251st meeting recommendations: Resolution no. 9058](#)' Commonwealth of Australia *Gazette*, No. GN 15, 18 April 2007.

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Gardasil® is manufactured and distributed in Australia by CSL Limited, which has granted the worldwide license to Merck.⁹ The vaccine's development was based in part on research by former Australian of the Year, Professor Ian Frazer. The vaccine protects against four of the more than 100 strains of HPV, including two of the cancer causing strains.¹⁰ It also protects against 90 per cent of strains that cause genital warts.¹¹

An application to list Gardasil® on the National Immunisation Program (NIP) was made by the sponsor, CSL Limited, to the Pharmaceutical Benefits Advisory Committee (PBAC) in early November 2006. PBAC is the independent expert body which advises the government on listing drugs under the Pharmaceutical Benefits Scheme (PBS), and, from January 2006, makes decisions to fund vaccines under the NIP (prior to this the Australian Technical Advisory Group on Immunisation (ATAGI) performed this function).

The initial application to list the vaccine was rejected by PBAC 'on the basis of uncertainty about duration of effect and unfavourable cost effectiveness.'¹² The price to government was reportedly \$625 million over four years.¹³ Further, PBAC had not been satisfied on the long term effectiveness of the vaccine, whether a booster would be required and how women requiring a booster would be identified, and the long term effects of the vaccine on the incidence of cervical cancer.¹⁴ PBAC also expressed concerns over possible 'unintended harmful consequences' if vaccinated girls and women decide to not participate in the NCSP.¹⁵

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9. CSL Ltd, *Half Yearly Report 2005-06* p. 4, URL: http://www.csl.com.au/Half_Year_Reports.asp accessed 3/7/07.
 10. NHMRC, *op. cit.*, p. 10.
 11. Hon. Bruce Billson, National Health Amendment (National HPV Vaccination Program Register) Bill 2007, [Second Reading Speech](#), House of Representatives *Hansard*, 20 June, 2007, p. 7.
 12. Pharmaceutical Benefits Advisory Committee 'November 2006 PBAC Outcomes - 1st time decisions not to recommend' URL: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbacrec-nov06-1st_time.
 13. Annabel Stafford, '[Cancer vaccine too costly](#),' *The Age* 9 November, 2006, p. 1.
 14. Hon. Tony Abbott, '[PBAC advice on Gardasil](#),' *Media Release*, 8 November, 2006.
 15. Pharmaceutical Benefits Advisory Committee, *Public summary document for Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) recombinant vaccine, injection, 0.5 mL, Gardasil®* November 2006, URL:

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Following a request from the Health Minister, PBAC agreed to consider a new application from CSL, in which some of the main concerns raised by PBAC were addressed. The second application included a price reduction, additional information about its long-term effectiveness, and the provision of 'risk-share arrangement' for possible booster doses.¹⁶ Gardasil® was subsequently approved for inclusion on the NIP at an extraordinary PBAC meeting in late November 2006.¹⁷

When the Health Minister announced the vaccine's approval, he made assurances that the accelerated time frame of the approval process had not compromised the quality of the PBAC decision-making, and emphasised the need for women to continue to undergo regular Pap smears.¹⁸ Current guidelines recommend routine screening with Pap smears every two years for women who have no history of cervical abnormalities, from the age of 18 (or within a year of commencement of sexual activity).¹⁹

Basis of policy commitment

HPV vaccine

As noted above, in November 2006 the government announced it would fund the HPV vaccine Gardasil® for girls and young women aged 12 to 26 years old through the National Immunisation Program (NIP).²⁰ Under the NIP the Australian government funds the states and territories to purchase vaccines listed in the National Vaccine Schedule (NVS). In 2006-07 vaccine expenditure through the NIP totalled \$283 million.²¹

<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbac-psd-gardasil-nov06>, accessed 2/7/07.

16. PBAC, *Public summary document*, op. cit, p. 5.
17. Pharmaceutical Benefits Advisory Committee 'Recommendation made by the extraordinary PBAC Meeting - November 2006', URL: <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbacrec-nov06-extra>.
18. Hon. Tony Abbott, '[Government funds Gardasil](#),' *Media Release*, 29 November, 2006.
19. Department of Health and Ageing, *National Cervical Screening Program – Policy Overview*, URL: <http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cervical-11p>, accessed 2/7/07.
20. Hon. Tony Abbott, '[Government funds Gardasil](#),' op. cit.
21. Hon. Bruce Billson, op. cit.

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The five-year HPV vaccination program with revised funding of \$475.9 million to 2010-11 has since commenced in all states and territories.²² The HPV vaccine is being administered to girls aged between 12 and 13 years in three injections over a period of six months. Vaccination is not compulsory, with consent required before the vaccine is administered.²³ Media reports suggest that uptake of the school vaccination program has been high.²⁴

Clinical evidence from trials of the vaccine show that Gardasil® is most effective in preventing pre-cancerous lesions (CIN 2 and 3) when administered before sexual activity commences. Effectiveness declines as the number of sexual partners increases.²⁵

In addition, from July 2007 until July 2009, the vaccine will also be available free to girls and women aged up to 26 years, through GPs and community providers.²⁶ The PBAC estimates that in the first four years of the HPV Program more than 200,000 doses of Gardasil® would be administered.²⁷

HPV Vaccination Program Register

When government funding for Gardasil® was announced, it was also announced that CSL had agreed to assist with the costs of any future booster program (if required) and in the establishment of a national HPV register to link vaccination data with later cervical screening records.²⁸ In its initial rejection of Gardasil® PBAC had expressed concerns about the long-term efficacy of the vaccine and the need for a mechanism (such as a

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22. Hon. Bruce Billson, op cit. The original funding announcement was for \$436 million over four years.
 23. Department of Health and Ageing, 'The National HPV Vaccination Program: Frequently asked Questions' webpage, URL: <http://www.health.gov.au/internet/standby/publishing.nsf/Content/parents-faq>, accessed 29/6/07.
 24. Rada Rouse, '[Vaccine uptake highest ever](#),' *Medical Observer*, 29 June 2007, p. 1.
 25. George F Sawaya, Karen Smith-McCune, '[HPV Vaccination – more answers, more questions](#)' *New England Journal of Medicine*, May 10, 2007, p. 1992.
 26. Department of Health and Ageing, 'The National HPV Vaccination Program – Young women in the community', webpage, URL: <http://www.health.gov.au/internet/standby/publishing.nsf/Content/young-women>, accessed 29/6/07.
 27. Pharmaceutical Benefits Advisory Committee, *Public summary document*, op. cit, p. 4.
 28. Hon. Tony Abbott, 'Government funds Gardasil', op. cit.

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registry) to identify females who may subsequently need a booster dose. CSL's commitment to a 'risk-share arrangement' to provide for a booster program was a factor in the PBAC decision to recommend the vaccine for the NIP.²⁹

In March 2007 the government announced \$100 million in funding to the states and territories to implement the HPV program, establish the HPV Register and run an education campaign.³⁰

The main purposes of the HPV Register as outlined in the Second Reading speech include:

- the recording of the details of individuals who participate in the HPV program which will allow statistics on participation rates to be compiled
- the recording of vaccination information which can be compared with information recorded in Pap smear, cervical cytology and cervical cancer registers so as to assess the effectiveness of the HPV program over time
- enabling the notification of participants of the HPV program if booster doses are required, or determine vaccination status or to certify completion of the vaccination course
- collecting statistics to inform health authorities, health care providers and the public about the HPV program
- informing participants (or parents of participants) of developments with the HPV program
- recording details of vaccination providers, and
- allowing for a participant (or parent of a participant) in the HPV program to have personal details removed when a request is made in writing.³¹

Indigenous status will also be recorded on the Register (although this field will be optional).

GPs administering the vaccine to individuals in the 12 to 18 year age group will be eligible for an administrative payment. Similar payments to GPs are provided under the General

29. See the PBAC, *Public Summary Document*, op. cit, p. 5.

30 Hon. Tony Abbott, '[Funding to the states for HPV vaccination program](#),' *Media Release*, 7 March, 2007.

31. Hon. Bruce Billson, op. cit.

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Practice Immunisation Incentives Scheme to encourage GPs to provide immunisation services to children under seven.³²

The Bill provides for the establishment, functioning and maintenance of the proposed HPV Register.

Position of significant interest groups/press commentary

HPV Vaccine

There has been a considerable level of commentary concerning the HPV vaccine (but little on the issue of the HPV Register). Much of the early commentary was in response to the initial decision by PBAC to reject listing Gardasil®. Concerns over safety and the appropriateness of vaccinating young girls have also been raised.

The initial PBAC decision to reject the application to list the vaccine was met with considerable criticism. A cross-party group of 22 women parliamentarians were so concerned that they wrote to the Prime Minister, who subsequently expressed his view that the drug would be subsidised.³³

Some argued that the high cost of the vaccine was justified. Julia Gillard MP described the estimated \$34 million annual cost of a school immunisation program as ‘good value for money’, and Professor Ian Frazer disputed the PBAC view that the vaccine was not cost-effective, arguing that the vaccine could reduce costs ‘by preventing up to 15,000 surgical operations a year’.³⁴ In response, the Chair of the PBAC Professor Lloyd Sansom defended their decision, warning that ‘if we have only 10 years until a booster is needed, then it’s not such a good health outcome we’re buying’.³⁵ Professor David Henry of the University of Newcastle went as far as to accuse critics of the PBAC as ‘playing into the hands of the drug companies’.³⁶ The Health Minister also defended the PBAC, saying ‘it’s only because of the PBAC that drug companies can’t demand blank cheques’.³⁷

32. Around \$18.8 million in payments were made to GPs in 2005-06. Medicare Australia, *Annual Report 2005-06*, Canberra, Medicare Australia, 2006, p. 116.

33. Michelle Grattan ‘On health, women Senators march together to do battle’ *Sun Herald*, 12 November, 2006, p. 31. See also Cathy O’Leary, ‘PM promises cash for cervical cancer vaccine’ *West Australian* 10 November, 2006.

34. Annabel Stafford, ‘Cancer vaccine too costly,’ op. cit.

35. Annabel Stafford, ‘[No proof cancer drug lasts](#)’ *The Age* 11 November, 2006, p. 8.

36. Annabel Stafford, ‘[Cancer drug firms to rake in millions](#)’ *The Age* 10 November, 2006, p. 2.

37. Annabel Stafford, ‘No proof cancer drug lasts’ op. cit.

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The commercial interests at stake during the period when CSL was trying to negotiate an agreement with government also received comment. In November 2006 one pharmaceutical industry newsletter noted ‘there is a lot at stake’ because if CSL could persuade the government to ‘fund a sole supplier four year HPV program...it will effectively keep rival product Cervarix out of the market.’³⁸ A report had also emerged in *The Age* that rival Cervarix® may offer longer lasting protection against cervical cancer.³⁹ The commercial pressure on CSL was also recognised by the Health Minister.⁴⁰ However, the re-application process was quickly resolved in favour of the listing of Gardasil®, with CSL making a number of concessions, including on price.

In response to a question over the government’s perceived ‘intervention’ in the listing process, the Health Minister described the negotiating process with CSL as ‘very good’ resulting in ‘important ongoing concessions’.⁴¹ Some commentators have continued to question the speed of the approval process, its commercial implications for CSL, and the experimental nature of HPV vaccination.⁴² One commentator noted that the approval process highlights a ‘very, very uncomfortable relationship between the pharmaceutical industry and the PBAC’.⁴³

Other commentary has focused on safety concerns and issues around sexuality, following the commencement of the HPV vaccination program. Safety issues were raised in the media when reports emerged of school girls who had been vaccinated suffering adverse effects. These effects were reportedly serious enough to require hospitalisation in at least five cases in Melbourne.⁴⁴ Some side effects were already known. According to the Consumer Medicine Information leaflet, common reported adverse effects include local

38. ‘Political pressure and the PBAC’, *Pharma in Focus*, 27 Nov – 3 Dec, 2006.

39. [‘Rival vaccine “better”](#) *The Age*, 23 November 2006, p. 8.

40. Mark Metherall and Edmund Tadros [‘Abbott warns of vaccine competitor’](#) *Sydney Morning Herald* 15 November, 2006, p. 5.

41. [‘Transcript of the Prime Minister the Hon John Howard MP Joint Press Conference with the Hon Tony Abbott MP, Minister for Health and Ageing, Parliament House Canberra’](#), 29 November, 2006.

42. Melinda Tankard Reist and Renate Klein [‘Why are we experimenting with drugs on Australian girls?’](#), *The Age*, 25 May, 2007, p. 13.

43. M. Stevens, [‘Howard rescues Gardasil from Abbott poison pill’](#), *Weekend Australian*, 11 November 2006.

44. Rachel Kerbaj, Cath Hart [‘Cancer jab puts girls in hospital’](#) *The Australian* 23 May 2007, p. 3.

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redness and swelling around the injection site, fever, dizziness, nausea, and vomiting. Less common effects include difficulty breathing and fainting.⁴⁵ Notwithstanding these reports of known adverse effects, the government has assured parents that the vaccine is safe.⁴⁶

But questions over the longer term effects of the vaccine remain. Recent trial evidence reported in the *New England Journal of Medicine* found that while incidence of cancers caused by HPV types 16 and 18 declined in a vaccinated group, overall incidence of disease continued to increase. This has raised concerns that other cancer causing HPV strains may be filling the 'biologic niche' left after the elimination of types 16 and 18.⁴⁷

Concerns over the ages of girls targeted for vaccination have also been raised. In March this year the Right to Life Association in WA raised concerns that the vaccine might create 'not only moral dilemmas but physical dilemmas' for young girls regarding the appropriate age for the onset of sexual activity, and was advising parents of girls under 18 not to participate in the program.⁴⁸ There followed reports that some parents in WA were withholding consent to have their daughters vaccinated through the school programs. Although parents were concerned about side effects, it was also reported that some parents thought that the vaccine was only necessary if their daughter was sexually active⁴⁹. In South Australia reports emerged that two private schools had decided not to make the vaccine available because of the schools' 'beliefs'.⁵⁰

Opposition to HPV vaccination in the United States has focused on the moral dimension of mandated vaccination of young girls, for example, parental concern that vaccination will have a 'disinhibiting effect' and promote promiscuity in their daughters.⁵¹ It has also been argued that opposition to vaccination also reflects a wider trend in parental concern over vaccination more generally.⁵²

45. [Gardasil Consumer Medicine Information](#), National Prescribing Service, accessed 5/7/07.

46. Department of Health and Ageing, *The National HPV Vaccination Program – Frequently asked questions for parents of girls in school*, op. cit.

47. George F Sawaya and Karen Smith-McCune, op. cit.

48. Debbie Guest '[Anti-cancer jabs rile Right to Life](#)' *West Australian* 21 March 2007, p. 5.

49. Alison Batcheler, Yasmine Phillips, '[Religious bar to sex cancer jab](#)' *West Australian*, 14 May 2007, p. 3.

50. Laura Anderson, '[Cancer drug leads to sex, say schools](#)' *The Advertiser*, 23 May 2007, p. 3.

51. R. Alta Charo. '[Politics, parents and prophylaxis – mandating HPV vaccination in the United States](#),' *New England Journal of Medicine*, May 10, 2007, p. 1907.

52. *ibid.*

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Nevertheless, these moral concerns do not appear to be widely replicated in the Australian context. Uptake of the vaccination program has been high, with unconfirmed reports that the consent rate so far exceeds 80 per cent.⁵³

HPV Register

As noted above, there has been little commentary concerning the HPV Register itself. There was some discussion at Senate Estimates hearings in May concerning the ‘lag’ in time between the rollout of the HPV vaccination program and the introduction of legislation to establish the Register.

Senator MOORE—Minister, this may well be a question for you rather than for the department. With a program like this, where we knew it was happening and we knew we would have to collect data, I am interested that the register legislation was not in place at least at the same time as the rollout started. I want to find out whether it is common to have a lag like that. All immunisation is subject to public scrutiny because people have very strong views about it, as everybody here knows. But this one in particular has caused a degree of discussion leading up to the time of implementation. My expectation was that the processes around capturing the information and also ensuring that everybody knows what is going on would have been in place.⁵⁴

The Senate Committee also asked on notice for an explanation as to the reason a separate Register was required, and for details of the cost.

Senator MOORE—I will not labour the point—it is just that my interest has been caught by this. But in terms of the process there are existing school based immunisation programs. I would imagine that data is being collected on those and passed on. I am interested as to why there needs to be specific legislation and the kind of register discussion that you have mentioned today to add Gardasil.⁵⁵

The HPV Register will allow health authorities to compare participation rates of vaccinated women in the national cervical cancer screening program (NCSP) to see if the rate of participation declines over time. Concerns that the HPV vaccine program may undermine the highly successful cervical cancer screening program were raised by PBAC when it first reviewed Gardasil®. PBAC was concerned that the risk of contracting cervical cancer may actually increase, if vaccination were to replace screening.

53. Rada Rouse, op. cit.

54. Senate Standing Committee on Community Affairs, Health and Ageing Portfolio, ‘[Estimates Discussion](#)’, *Hansard*, 30 May 2007, p. 4.

55. *ibid.*

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There is a risk of unintended harmful consequences to patients if vaccinated females do not continue to participate in the NCSP, even though this would also tend to reduce the overall costs of screening, including managing pre-cancerous health states. For instance, if vaccination were to substitute for cervical screening, costs savings would occur, but the cervical cancer lifetime risk would increase from 0.78% (cervical screening only) to 1.173% (vaccination only).⁵⁶

Other medical experts argued that a mass vaccination program could address inequities in the current cervical screening program whereby certain groups, such as indigenous women, have lower participation in the NCSP.⁵⁷ The need to monitor the effectiveness of the vaccination program, and address the incorporation of vaccination status into state and territory cervical cytology registers were both highlighted in a recent issue of the *Medical Journal of Australia*.⁵⁸ The same article also questioned the future role of the NCSP, in an environment where a mass vaccination program is available, and the capacity of the cytology workforce to manage the NCSP may be limited.⁵⁹

Some concerns have emerged in the medical sector concerning the delayed establishment of the HPV Register and the impact this may have on GPs. GPs who have commenced administering the HPV vaccine as part of the program, are being advised by the Divisions of General Practice to record vaccination data in order to be able to claim remuneration from the government after the legislation has passed.⁶⁰

Key issues

The HPV vaccine has been shown to be highly effective against the HPV types that cause the vast majority of cervical cancer, when administered early. If vaccination is delayed, its effectiveness declines. However, questions remain over the long term effectiveness of the vaccine, its impact on the NCSP, and future adverse effects.

HPV safety and efficacy

Recent evidence, outlined above, suggesting that other cancer causing strains may occupy the biological niche left after the elimination of HPV types 16 and 18, was not available to

56. PBAC, *Public summary document*, op. cit, p. 4.

57. Gerard V Wain, '[Cervical cancer prevention: the saga goes on, but so much has changed!](#),' *Medical Journal of Australia*, Vol. 185 (9), 6 November, 2006, p. 476.

58. *ibid.* Pap smear, cervical cytology or cervical registers are maintained by the states and territories.

59. *ibid.*

60. Rada Rouse, 'HPV register not ready', *Medical Observer*, 6 July 2007, p. 1.

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the PBAC. But the emergence of such evidence underscores the PBAC view that a Register is necessary in order to monitor the effectiveness of the vaccine over time. As noted above, CSL's commitment to assist with the establishment of the HPV Register was a major factor in the PBAC's approval of the vaccine.

Concerns that the HPV vaccine program may undermine the highly successful cervical cancer screening program were raised by PBAC when it first reviewed Gardasil®. However, the HPV Register will allow health authorities to see if participation rates of vaccinated women in the screening program declines over time.

Questions have been raised over the future viability of the NCSP where mass vaccination is available. The NCSP which costs around \$90 million annually, is considered cost-effective. The PBAC expressed concern that vaccination may unintentionally lower participation rates in the NCSP and lead to an increase in cervical cancer lifetime risk.

Nevertheless, a significant proportion of women do not participate in cervical cancer screening (around 39 per cent of women aged 20-69).⁶¹ Those unscreened may be at risk of contracting disease. These women may consider vaccination a preferable intervention. However, as neither Gardasil® nor Cervix® currently protect against all forms of cancer causing HPV, ongoing screening is recommended. The information held on the HPV Register will allow for a campaign promoting the benefits of screening to be directly targeted to those women who may choose to forego screening.

However, in order to address ongoing concerns over safety and efficacy, particularly among parents of school aged girls, a broader ongoing education and communication campaign may be required.

Issues of consent and privacy

The Explanatory Memorandum explains that because of the 'tight time frame' in which the school based HPV vaccination program was implemented, issues around consent and privacy were not fully addressed. Although receiving little attention in any commentary, concerns over consent and privacy may yet emerge. While written consent is required for vaccination, no consent was sought to have personal vaccination details recorded on the Register itself prior to the rollout of the school based vaccination program.

However, the Bill allows for women, or parents of vaccinated girls, to have their details removed from the HPV Register, if an explicit request is made in writing – the so-called 'opt off' provision. Unless a written request is made to 'opt off' the Register, personal details of those vaccinated under the program will be automatically recorded on the

61. Australian Institute of Health and Welfare, *Cervical screening in Australia 2004-05*, op. cit, p. ix.

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Register. This ‘opt off’ provision may raise some concerns, although it is unclear if it would deter anyone from proceeding with vaccination.

The Explanatory Memorandum notes there is a ‘strong argument’ to provide an ‘opt off’ provision for the Register, as opposed to an ‘opt in’ provision.⁶² This is because when presented with a choice to ‘opt in’ many may choose to do nothing, thus reducing the level of data collected and eroding the effectiveness of the Register.

Overseas evidence supporting the ‘opt off’ consent model, (which in this particular case was for consent to store patient’s clinical medical records electronically), show that overwhelmingly, few patients had concerns at having their records stored in this manner, with only a small number choosing to opt off such a system.⁶³ State cytology and cervical cancer registers already allow for women to decline to have their details recorded (that is, to ‘opt off’), but evidence shows that only a small percentage elect to ‘opt off’ (around one or two per cent).⁶⁴

This model of consent, it is argued, can also reduce the administrative burden on the program, because the patient’s consent does not need to be explicitly sought or recorded.⁶⁵

On the other hand, an ‘opt in’ system can give patients more control over what personal details are recorded because it requires patients to give explicit permission to have their personal details entered on the database. The advantage of an ‘opt in’ system for the Register is that patients are able to weigh the risks and benefits of consent, just as they are given this opportunity when asked to consent to the vaccination itself. Patients who may be sensitive about the recording of their personal data can choose to not have their data recorded, yet see the benefits of protection and proceed with vaccination. A system of consent that allows for a patient to ‘opt in’ can therefore provide the patient with greater confidence in the security of the system, reduce their anxiety and encourage their ongoing participation in the program over time.

Although the Bill provides for an ‘opt off’ system of consent regarding personal details being entered on the Register, GPs who participate in the HPV Program are being encouraged to seek consent: ‘Immunisation providers are encouraged to register patients

62. [Explanatory Memorandum](#), p. 7.

63. John Halamka, Nigel Watson, Jan Wilkinson, ‘[For and against: patients should have to opt out of national electronic care records](#)’, *British Medical Journal*, 1 July, 2006, p. 39.

64. Australian National Audit Office, *The National Cervical Cancer Screening Program*, Canberra, ANAO, 2001, p. 42.

65. Halamka, op. cit.

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on the HPV register, subject to them providing their consent'.⁶⁶ This approach could be seen to be at odds with the principles of the 'opt off' system applied to the school vaccination phase of the program, although the Department confirmed that the 'opt off' provision in the Bill will apply to all participants in the program once the legislation comes into effect.⁶⁷ However, some may question whether the speedy implementation of the vaccination program has resulted in an erosion of choice.

Information held on the Register will be used mainly to evaluate the HPV vaccination program on cervical cancer rates, issue reminders and contact participants if booster doses are required. However, personal information may also be used in future longitudinal studies. In such circumstances, the Explanatory Memorandum explains, the handling of such information will be subject to appropriate guidelines. Further, the privacy provisions of the Bill provide that only prescribed bodies or persons can access data on the Register.

Privacy legislation prevents the disclosure of personal information held by a record keeper. However, it provides for disclosure when authorised by law. This Bill allows for disclosure to be made to a body or person provided these are prescribed in separate regulations, or under the *Health Insurance Act 1973* (HIA). Section 46E of the HIA already allows for personal information that is held on the Australian Childhood Immunisation Register to be disclosed to specified persons or bodies.

Information on the safety and efficacy of a drug after it is released to the market, or post-marketing surveillance, is an important tool for pharmaceutical companies. Such information can assist the further development of the drug or in developing new drugs. Although pre-marketing clinical trials assess the safety and performance of a drug, information gathered in the post-marketing phase reflects the performance of the drug in the real world, rather than under controlled trial conditions, and provides valuable information to the drug maker.

The type of information held on the Register could, therefore, have high commercial value, as well as its value in informing public policy. There is no evidence that access to any data on the Register would be granted to a commercial body – only those bodies prescribed through regulation or under the HIA Act have access to the data. Nevertheless, given the controversy surrounding the PBAC approval process and questions over the influence of commercial interests in the process, confidence in the confidential nature of the Register may need to be further strengthened. For example, access to data on the

66. Department of Health and Ageing 'Fast facts for General Practitioners' URL: <http://www.health.gov.au/internet/standby/publishing.nsf/Content/general-practitioners-faq#19>, accessed 24/7/07.

67. Personal communication.

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Register could be overseen by an ethics committee where requests to access data for research purposes are received.

Cost sharing of Register

As noted above, the government obtained a commitment from CSL to assist in the cost of establishing and maintaining the HPV Register, and this commitment was a factor in the PBAC's approval of Gardasil®.

The Explanatory Memorandum estimates the cost of the Register to be between \$8 to 11 million. So far, however, there is no indication as to what contribution, if any, CSL has provided to the establishment of the Register. Nor is it clear if the manufacturer of the second HPV vaccine approved for use in Australia will also be making a contribution to the cost of the Register or other aspects of the program. At this time Cerverix® has not received approval from the PBAC to be listed on the National Immunisation Program.

Financial implications

The Explanatory Memorandum states that there is no financial impact as funding for the Register was approved by the Prime Minister in February 2007, as part of a \$103.5 million funding package to the states and territories for the implementation of the HPV program. A total cost of \$8 to \$11 million to establish and operate the Register is allocated, according to the Explanatory Memorandum.

Main provisions

The Bill proposes to insert new **section 9BA** into the *National Health Act 1953*, to establish the National HPV Vaccination Program Register. The provisions of the Bill are detailed in the Explanatory Memorandum, and summarised below.

Schedule 1 – Amendments

New subsections **9BA(1) and 9BA(2)** establish and describe the content of the HPV Register. Content may include personal details, address and Medicare number, details about the administration of the HPV vaccine, the immunisation provider and the vaccine used.

New **subsection 9BA(3)** describes the purpose of the Register. This is to ensure the successful implementation of the National HPV Vaccination Program, by establishing and maintaining an electronic database of records of vaccination participants, which can monitor the effectiveness of the HPV vaccine, notify participants if doses are missed or boosters required, certify completion of vaccination, promote health by providing information and pay GPs who enter details in the Register.

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New **subsection 9BA(4)** details the ‘opt out’ provision of the Bill. It allows for a person or parent or guardian of a child, to request in writing that their details be removed from the Register.

New subsections **9BA(5)** and **9BA(6)** address privacy issues, allowing the disclosure of personal information held on the Register to prescribed bodies, either through regulation or as prescribed in the *Health Insurance Act 1973*, or to a vaccination provider.

Conclusion

The Bill seeks to establish and maintain a National HPV Vaccination Program Register, to support the rollout of the government funded National HPV vaccination program. The need for a Register was noted by the independent pharmaceutical advisory body which approved the HPV vaccine Gardasil® for the National Immunisation Program, because of ongoing safety and efficacy issues relating to the vaccine.

Information held on the Register will be used by government to evaluate the effectiveness of the HPV program in reducing cervical cancer rates, and inform the future policy direction of the national cervical screening program. There is a suggestion that the NCSP be reviewed in light of the HPV vaccination program, although regular Pap smears are still recommended.

Information held on the Register will be used to provide information to participants in the HPV program, remind them of missed doses or inform them of the requirement for booster doses. In addition personal information held on the Register may be made available to prescribed bodies or persons for longitudinal analysis. Although privacy provisions apply, confidence that personal information will remain confidential and not be accessed inappropriately may need to be further strengthened. Although participants in the HPV Vaccination Program can ‘opt off’ the Register at any time by making a written request, the absence of consent in the initial phase may raise concerns.

The funding of the HPV vaccine Gardasil® was widely welcomed in the community, although concerns over the long term safety and efficacy of the vaccine remain. The moral and ethical dimensions of vaccinating young girls have also been raised. Such issues can resonate in the community, especially where they involve children and the onset of sexual activity.

The ongoing cost of the Register is a small component of the total cost of the HPV Program. In any case the manufacturer has undertaken to contribute to the establishment and maintenance of the Register. The cost-sharing commitment from CSL was a factor in the PBAC’s approval of the vaccine, but the exact nature of their contribution remains unclear. This lack of clarity over the contribution of the vaccine manufacturer may contribute to criticism of the approval process, and further highlights the continuing sensitivity around relationships between governments and pharmaceutical companies.

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