National Immunisation Strategy for Australia
2013-2018

Department of Health
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A joint Australian, State and Territory Government initiative
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EXECUTIVE SUMMARY

There have been many changes to the National Immunisation Program (NIP) in recent years. Additional vaccines have been added to the NIP Schedule and the cohorts have expanded, new vaccine purchasing arrangements have been implemented and there is a greater focus on improving monitoring to ensure vaccine safety. It is now time to take stock, build on the strengths and identify areas for further improvement.

The focus of the Strategy is the NIP, an established collaborative program involving the Australian Government and the state and territory governments. Under the NIP, essential vaccines are available free of charge to eligible infants, children, adolescents and adults. Australia has a strong and internationally recognised NIP, with a national average of over 90% coverage for most childhood vaccines. Australia’s achievements in immunisation meet international goals set by the World Health Organization (WHO) under the Global Immunization Vision and Strategy (GIVS). The Strategy articulates action areas to maintain the successful delivery of the NIP, including addressing current issues to further improve national immunisation and vaccine delivery.

The Strategy is consistent with Commonwealth, state and territory government efforts to reform the health system and encourage a greater focus on health rather than illness as well as contributing to a better preventive health system in Australia. Its aim is to prevent disease and severe outcomes by maximising immunisation coverage in people of all ages.

The Strategy comprises eight (8) Strategic Priority Areas to complement and strengthen the NIP:

• Improve immunisation coverage
• Ensure effective governance of the National Immunisation Program
• Ensure secure vaccine supply and efficient use of vaccines for the National Immunisation Program
• Continue to enhance vaccine safety monitoring systems
• Maintain and ensure community confidence in the National Immunisation Program through effective communication strategies
• Strengthen monitoring and evaluation of the National Immunisation Program through assessment and analysis of immunisation register data and vaccine-preventable disease (VPD) surveillance
• Ensure an adequately skilled immunisation workforce through promoting effective training for immunisation providers
• Maintain Australia’s strong contribution to the region

This Strategy document addresses each of those strategic priorities and the key actions to be undertaken within each area.

1 DTPa, hepatitis B, MMR, Hib and polio
SUMMARY OF STRATEGIC PRIORITIES AND KEY ACTIONS

Strategic Priority 1: Improve immunisation coverage

Key Actions

- Maintain or improve immunisation coverage in accordance with the National Immunisation Program (NIP) Schedule.
- Improve immunisation coverage for high risk population groups.
- Identify geographic areas or cohorts of low coverage and implement strategies to improve immunisation coverage.
- Ensure equity of access to immunisation services for all Australians regardless of financial or geographical barriers.
- Maintain and monitor the effectiveness of childhood vaccination awareness and promotion campaigns and incentives.
- Implement strategies to improve and better understand adolescent immunisation coverage.
- Improve influenza and pneumococcal vaccination rates.
- Through disease surveillance, identify the risks posed by unvaccinated cohorts in the population.
- Develop an agreed position on the provision of free catch-up immunisation schedules.

Strategic Priority 2: Ensure effective governance of the National Immunisation Program

Key Actions

- Ensure governance arrangements for vaccination in Australia are clear, accountable and effective, with regular processes in place to monitor and evaluate performance and provide feedback.
- Develop a map of the NIP that shows the roles and responsibilities of the Commonwealth, states and territories and other key stakeholders.
- Prepare and publish an Annual Report for the NIP, which provides a summary of key activities, achievements and challenges in the previous year.
Strategic Priority 3: Ensure secure vaccine supply and efficient use of vaccines for the National Immunisation Program

Key Actions

• Implement the Essential Vaccine Procurement Strategy.
• Review the indicator for wastage and leakage of vaccine under the National Partnership for Essential Vaccines.
• Develop an Australian Standard for purpose built vaccine refrigerators and promote their utilisation.
• Review and revise the National Vaccine Storage Guidelines.
• Review the factors that impact on vaccine wastage and leakage to better understand and, if required, identify opportunities to minimise wastage and leakage.

Strategic Priority 4: Continue to enhance vaccine safety monitoring systems

Key Actions

• Continue to work with key stakeholders to implement the recommendations from the Horvath Review.
• Continue to work with key stakeholders to improve the timeliness and completeness of adverse events following immunisation surveillance in collaboration with the newly established Advisory Committee on the Safety of Vaccines.
• Assess the need for, and implement where required, a specific vaccine safety plan for the release of each new vaccine or existing vaccine to new cohort for the NIP.
• Raise community and health professional awareness of vaccine safety systems to improve confidence in the program and reporting of adverse events.
• Investigate opportunities for linkages between the Australian Childhood Immunisation Register (ACIR) and the HPV Register to other data collections to better assess and ensure vaccine safety.
**Strategic Priority 5: Maintain and ensure community confidence in the National Immunisation Program through effective communication strategies**

**Key Actions**

- Identify ways to strengthen the current communications strategy, particularly for population groups with low and/or delayed immunisation coverage.
- Develop a media reference pack to encourage accurate and responsible reporting of immunisation.
- Monitor and revise communications resources and campaigns to improve the reach of immunisation awareness and confidence for key target groups.
- Identify ways to utilise current and emerging social marketing tools/technology to reach target audiences.
- Develop a specific communications strategy for vaccine safety to promote community confidence in the process of monitoring and responding to vaccine safety issues.

**Strategic Priority 6: Strengthen monitoring and evaluation of the National Immunisation Program through assessment and analysis of immunisation register data and vaccine-preventable disease (VPD) surveillance**

**Key Actions**

- Investigate opportunities for linkages between ACIR the National HPV Vaccination Program Register (HPV Register) and other data collections to better assess program outcomes, vaccine safety and vaccine efficacy.
- Undertake a review of the ACIR and the HPV Register to assess their potential for expansion to include other vaccines and provide immunisation coverage data for other age groups.
- Use data on immunisation coverage in ACIR, the HPV Register and other sources to better identify groups at risk of delayed and/or gaps in immunisation coverage compared to the NIP Schedule.
- Identify ways to streamline and rationalise surveillance of VPDs to improve timeliness, effectiveness and efficiency of current surveillance systems.
- Ensure supported laboratory infrastructure in place to support high quality surveillance via VPD detection and characterisation.
- Monitor potential opportunities to improve and strengthen the immunisation system using eHealth and other technological initiatives.
Strategic Priority 7: Ensure an adequately skilled immunisation workforce through promoting effective training for immunisation providers

Key Actions

- Undertake an evaluation of the Australian Immunisation Handbook and other communication resources for providers to ensure these meet the needs of the range of providers.
- Identify ways to strengthen and support a range of immunisation service providers.
- Review and update competencies for immunisation providers.
- Investigate how to ensure national harmonisation of the credentialing and recognition of immunisation providers and transferability of skills and qualifications.

Strategic Priority 8: Maintain Australia’s strong contribution to the region

Key Actions

- Continue to be an active participant in the WHO WPRO Enhanced Programme on Immunisation, particularly in relation to:
  - achieving measles elimination;
  - maintaining polio elimination;
  - strengthening hepatitis B control; and
  - continuing to contribute to National Immunisation Technical Advisory Groups (NITAG).
INTRODUCTION

The National Immunisation Program

“Immunisation is one of the most successful and cost effective health interventions ever”. The low incidence of vaccine-preventable diseases (VPDs) in Australia attests to the effectiveness of our immunisation services, programs and policies. Since the introduction of routine immunisations in Australia in the 1950s, death or disability from many once-common infectious diseases is now rare.

Australia’s high quality immunisation system is internationally recognised. Routine immunisation of infants in Australia began in the 1950s and the first nationally funded infant program for diphtheria, tetanus and polio started in 1975. Since this time the immunisation program has grown to be a major public program funded by state and federal governments. Coinciding with the introduction of immunisation in Australia, the incidence of VPDs has dramatically declined.

Some of the successful outcomes of the National Immunisation Program (NIP) to date include high immunisation coverage rates (Figure 1), good control of vaccine-preventable diseases, access to all required vaccines, a contemporary national schedule for vaccinations, and national registers of childhood and some adolescent immunisations.

The current NIP consists of a schedule of recommended vaccines, the NIP Schedule, which is a national standard of vaccines by age group funded by the Australian Government and made available free of charge to all Australians in those age groups. To date, the NIP Schedule covers 16 diseases, including hepatitis B, diphtheria, tetanus, pertussis (whooping cough), Haemophilus influenzae type b (Hib) disease, poliomyelitis, pneumococcal, rotavirus, measles, mumps, rubella, meningococcal C, varicella (chickenpox), hepatitis A, human papillomavirus (HPV) and influenza (Appendix 2). Due to the success of the immunisation program many diseases such as tetanus, diphtheria, Hib and measles are now extremely rare in Australia. However, the lack of visibility of these diseases in the community has its own challenges and can lead to complacency amongst consumers and health providers.

The appropriate administration of vaccines is underpinned by the Australian Immunisation Handbook, which is developed by the Australian Technical Advisory Group on Immunisation (ATAGI). The Handbook is an essential resource for those involved in the delivery of immunisation services throughout Australia. It provides comprehensive information about all vaccines approved for use in Australia. This includes routine vaccination of infants, young children, adolescents, and older people; vaccination for special risk groups (e.g. Aboriginal and Torres Strait Islander people); those undertaking international travel; and groups with special vaccination requirements (e.g. pregnant women and people who are immunocompromised).

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Historical Context

Immunisation, as a public health issue, was traditionally the responsibility of the states and territories in line with the Federal system in Australia. As demand for and availability of immunisation increased in the latter half of the 20th Century, a range of disparities appeared between states and territories regarding the funding of and access to vaccines for the population, with national surveys in the 1980s suggesting that only about 53% of Australian children were adequately immunised. This gave rise to the first National Immunisation Strategy in 1993, the establishment of the ACIR in 1994, initially as a pilot, and adopted in 1996, and the introduction of the Immunise Australia Program, also known as the NIP in 1997.

The data held in the ACIR has enabled detailed tracking of immunisation coverage, issuing of reminders for overdue immunisation and provision of consolidated immunisation histories for parents and providers.

The Immunise Australia Program outlined a Seven Point Plan, to improve immunisation coverage across the nation. Since the introduction of the Immunise Australia Program, childhood immunisation coverage increased dramatically and reached 90% of the eligible population of 1 year olds in 2002, 2 year olds in 2003, and 90% of all children at 5 years of age in 2010 (Figure 1).

A range of arrangements for the funding and management of the NIP have been in place since its inception in 1997 and these have enhanced co-ordination between Commonwealth, state and territory governments leading to consistent funding for all vaccines on the NIP. Initially funding was agreed under the Public Health Outcome Funding Agreements (PHOFAs) and subsequently the Australian Immunisation Agreements.

Following changes to the federal financial arrangements between the Commonwealth and the states and territories as a result of the Intergovernmental Agreement on Federal Financial Relations and the 2009 Federal Financial Relations Act, the Australian Immunisation Agreements were replaced with the National Partnership Agreement on Essential Vaccines (NPEV) in 2009.

The NPEV describes the transitional and ongoing arrangements for the funding and delivery of a national, coordinated and integrated approach to maintaining and improving effective immunisation coverage for VPDs funded under the NIP. It delineates the roles and responsibilities of the Commonwealth and states and territories in the delivery of the NIP and provides for facilitation and reward payments to states and territories to support program delivery and achievement of performance indicators.

Funding for vaccine purchasing has increased from $10 million per annum in the mid-1970s to over $350 million in 2011-2012.

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Figure 1: Childhood Immunisation Coverage in Australia

The NIP Schedule is much more complex than it was when the NIP was established in 1997 with 9 childhood vaccines on the Schedule. Today, the Schedule reflects the life-course approach of contemporary population health policy and includes over 16 vaccines for infants, children, young adults, vulnerable adults (such as Aboriginal and Torres Strait Islander peoples and pregnant women) and older people.

Aboriginal and Torres Strait Islander peoples are an important population group for whom immunisation rates could still be improved. This objective is reflected in the performance indicators of the NPEV. Ensuring high immunisation coverage rates for Aboriginal and Torres Strait Islander peoples is also an important contribution to Closing the Gap in Indigenous health outcomes.

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9 Source: Data from the Australian Childhood Immunisation Register, prepared by the National Centre for Immunisation Research and Surveillance

Governance

The current governance arrangements for the NIP reflect the collaborative, whole of government approach between the Commonwealth, states and territories that has characterised the program since its introduction in 1997.

The National Immunisation Committee (NIC)\(^{11}\) was established in 1992 with a goal to achieve national consistency in the availability and pricing of vaccines and to develop national policies. The NIC leads policy development and evaluation on the implementation of the NIP and provides advice on strategic directions. The NIC reports to the Australian Health Protection Principal Committee (AHPPC) of the Australian Health Ministers Advisory Council (AHMAC) through the Communicable Diseases Network Australia (CDNA). In line with the importance of collaborative and cooperative relationships to the success of the NIP, NIC has members from all the key stakeholder groups in immunisation, including health professionals, consumers and researchers, as well as representatives from the Commonwealth, state/territory and local governments.\(^{12}\)

Technical advice on the operation of the NIP is provided by the ATAGI\(^{13}\), which was also established in 1997. ATAGI provides technical advice to the Minister for Health on the medical administration of vaccines available in Australia, including those on the NIP. In addition to technical experts, ATAGI’s membership includes a consumer and general practitioners.

The NIP is consistent with the objectives of the National Medicines Policy, which are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry\(^{14}\).

In 2005, the National Health Act (1953) was amended to provide for the evaluation of cost-effectiveness of vaccines by the Pharmaceutical Benefits Advisory Committee (PBAC) in order to provide a more consistent and transparent process for recommending vaccines for Australian Government funding.

Under these arrangements, the National Health Act 1953 requires that before a vaccine is provided for free through the NIP or subsidised under the Pharmaceutical Benefits Scheme, the PBAC must undertake a thorough and objective assessment of the

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11 Terms of Reference and further information is available at the Immunise Australia website [www.immunise.health.gov.au/](http://www.immunise.health.gov.au/)


clinical efficacy and cost-effectiveness (value-for-money) of medicines, in comparison with other available treatments. The PBAC then provides appropriate advice to the Minister for Health. The Act does not allow for Ministerial or departmental discretion to list a vaccine on the NIP in the absence of this recommendation. As part of these legislative changes existing vaccines on the NIP were listed on the National Health (Immunisation Program – Designated Vaccines) Determination (the Determination). PBAC recommendations are given in response to vaccine sponsor submissions. With these legislative changes ATAGI was given a strengthened role in providing technical advice to PBAC on new vaccines, expertise on vaccines was provided for on PBAC and cross membership between the two committees was established.

International Focus on Immunisation

Immunisation has been a specific focus globally over the past decade, particularly for organisations such as the United Nations Children’s Fund (UNICEF) and the WHO. In 2006 the WHO and UNICEF jointly developed the Global Immunization Vision and Strategy GIVS, which provides a four point strategic framework and 24 specific strategies for countries to choose from to strengthen their immunisation programs.

The strategic framework comprises:

- Protecting more people in a changing world;
- Introducing new vaccines and technologies;
- Integrating immunisation, other linked health interventions and surveillance in the health systems context; and
- Immunising in the context of global inter-dependence.

As a result of work already commenced or undertaken through the NIP and the key action areas outlined in this National Immunisation Strategy, Australia is well placed to achieve the 2015 GIVS goals.

Australia is an active partner in the WHO Western Pacific Region (WPRO) Enhanced Programme on Immunisation and contributes to strengthening the WPRO’s efforts to control hepatitis B through immunisation, eliminate measles in the region and continue to maintain WPRO’s polio free status through a range of efforts within Australia and with our partners in the region. In 2012 Australia was declared by WPRO as having achieved the regional goal of reducing chronic hepatitis B infection rates to less than 1% among children of at least 5 years of age.

While it is considered that Australia has eliminated endemic measles since at least 2005 we are actively engaged in the Regional verification process and have established a National Verification Committee to review and submit our evidence to the WPRO.

Further information on the goals and other aspects of the GIVS (www.who.int/immunization/givs/en/index.html.)
Australian Health Reform

In addition to the developments and changes to the global immunisation landscape outlined above, there has been considerable reform in the Australian health system as a whole. Those of specific relevance to immunisation include a greater emphasis on preventive health strategies and a commitment to Closing the Gap in Indigenous disadvantage.

Medicare Locals have been established to coordinate primary health care delivery and tackle local health care needs and service gaps. They will drive improvements in primary health care and ensure that services are better tailored to meet the needs of local communities. One of the key reporting areas of Medicare Locals is to maintain or improve immunisation coverage rates for children.

Development of the National Immunisation Strategy

At the Australian Health Ministers’ Conference (AHMC) held 22 July 2008, it was agreed that a National Immunisation Strategy be developed. The NIC was given responsibility for overseeing the development of the Strategy.

In 2010, a contractor was engaged to develop a proposal for a National Immunisation Strategy. This involved:

- a series of consultations with state and territory health departments and peak bodies;
- a National Forum held in December 2010 involving key immunisation experts and a wide range of stakeholders; and
- the development of a discussion paper outlining the proposed areas for future improvement which had been identified through the consultations.

The proposal for the Strategy was presented to AHPPC in 2011.

The key priority areas and actions within these areas were identified in consultation with the NIC. Additional consultations were undertaken during 2011 and the early part of 2012 with further drafting of the Strategy in late 2012.

Strategic Priorities

The consultation process identified the following eight (8) Strategic Priorities for inclusion in the Strategy:

- Improve immunisation coverage.
- Ensure effective governance of the National Immunisation Program.

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• Ensure secure vaccine supply and efficient use of vaccines for the National Immunisation Program.

• Continue to enhance vaccine safety monitoring systems.

• Maintain and ensure community confidence in the National Immunisation Program through effective communication strategies.

• Strengthen monitoring and evaluation of the National Immunisation Program through assessment and analysis of immunisation register data and vaccine-preventable disease (VPD) surveillance.

• Ensure an adequately skilled immunisation workforce through promoting effective training for immunisation providers.

• Maintain Australia’s strong contribution to communicable disease control through immunisation in the region.
STRATEGIC PRIORITY 1: IMPROVE IMMUNISATION COVERAGE

The continued success of the NIP is dependent on continuing to maintain and improve vaccination rates for all eligible Australians. Governments have a role to play through the funding and delivery of vaccines, implementation and management of registers and surveillance systems, and communications strategies to promote immunisation more broadly as well as to specific population groups.

GPs and other health practitioners also have an important role to play in promoting and delivering immunisation to their patients.

Childhood Vaccination

While Australia has an excellent record in childhood immunisation coverage, achieving at or above 90% average coverage for children at 12 months, 24 months and 60 months of age (Appendix 5). A high national coverage rate can mask geographic areas and population groups that have low coverage. It will continue to be important to maintain and improve these rates over the next five years. Many countries in the world report coverage rates at around 95%.

The proportion of the population that has to be immune to interrupt disease transmission differs for each vaccine-preventable disease. For measles, this is 95% and emphasises the need to ensure that high coverage rates are achieved not only at a national level, but local levels. A recent outbreak of measles in Sydney during 2012, in which 170 cases were identified, illustrates the importance of achieving high vaccination coverage rates.

The success also has embedded within it the risk of complacency as incidence of VPDs becomes rare. There has been a growing trend of parents who hesitate or delay having their children vaccinated. Recent research suggests that as many as 3% of parents delay having their children vaccinated at the appropriate time. Such delay, if short, may not be apparent in coverage rates assessed some months after immunisations are due however delay may be placing some children at risk of contracting VPDs.

The number of children whose parent or guardian has decided not to vaccinate their child on non-medical grounds as recorded on the ACIR has grown over the past 13 years from 0.23% (n=4271) in December 1999 to 1.44% (n=30,880) in May 2012. While these numbers are small, they reflect an increase and if concentrated in geographic areas or close knit groups potentially present a risk to disease control efforts.

17 Annual report Immunisation coverage, 2007 Brynley Hull, Shelley Deeks, Rob Menzies, Peter McIntyre
The Australian Government has introduced reforms to Australia’s childhood immunisation arrangements that aim to increase the immunisation rates of Australian children. From 1 July 2012, parents need to have had their children fully vaccinated during the financial years that each child turns one, two and five years of age to be eligible to receive the Family Tax Benefit Part A supplement (for each child each year). In addition, immunisation is already a condition for eligibility for Australian Government child care payments.

**Adolescent Vaccination**

Adolescent vaccination is delivered in high school based programs conducted by states and territories. The current schedule provides for hepatitis B (catch-up), diphtheria-tetanus-pertussis, varicella and HPV. With the exception of HPV, accurate national coverage rates for adolescent vaccines are not available.

HPV vaccine immunisation rates for girls are at a high level, reaching about 70% in school-aged girls.¹⁹ HPV vaccine has been introduced for 12-13 year old boys in 2013, along with a catch up program for boys to 15 years, and this should help further protect the Australian population against HPV infection and the risk of HPV related cancer such as cervical and anal cancer as well as HPV related disease.

**Vaccination for Older Australians**

Vaccination rates for older Australians aged 65 and over for influenza and pneumococcal disease have improved over time but remain relatively low. The 2009 Adult Vaccination Survey estimated that, for the population aged ≥65 years, 74.6% were vaccinated against seasonal influenza and 54.4% against pneumococcal disease.²⁰ Adults with chronic conditions such as diabetes, chronic lung disease and renal failure, and those taking immuno-suppressive medications are also under-immunised.²¹ It is important to continue to monitor vaccination uptake in older Australians and consider ways to improve vaccination rates in this important population group.

**High Risk Population Groups**

One of the key challenges to improving immunisation coverage is to target immunisation to at-risk population groups. In Australia these include Aboriginal and Torres Strait Islander people, pregnant women and specific age cohorts. In some cases, people working in high risk of transmission areas such as healthcare or aged or childcare facilities. The responsibility for workplace vaccination is with the employers through workplace health and safety programs.

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Under the NPEV, the states and territories have agreed (*inter alia*) to maintain or improve vaccination coverage:

- for Aboriginal and Torres Strait Islander peoples;
- in areas of agreed low immunisation coverage; and
- for four year olds.\(^{22}\)

It is important to identify and monitor specific groups within the Australian population who are at high risk of infection with VPDs and determine the most appropriate course of action.

There have been calls to provide immunisation programs for refugees as many arrive from countries with fragile primary health care and may have missed out on vaccines.

In Australia, individuals who have been issued with a Medicare Card are eligible to receive free vaccines listed in the Determination and included on the NIP Schedule. Most refugees and asylum seekers hold a Medicare Card and are therefore also eligible for vaccines on the NIP Schedule.

*Catch up vaccination*

The Australian Immunisation Handbook advises that every opportunity should be taken to review a person’s vaccination history and to administer the appropriate vaccine(s). If a person has not had documented receipt of vaccines scheduled in the NIP appropriate for their age, a catch-up schedule should be planned. If receipt of prior vaccination cannot be confirmed, it should generally be assumed that the vaccine(s) required have not been given.

Catch-up schedules for vaccines available under the NIP are provided by most states and territories for children up to 7 years of age. The Determination also explicitly provides for some catch-up programs (e.g. HPV vaccination program for males).

Notwithstanding the desire to ensure that all people should be fully protected against VPDs, there needs to be a better understanding of the potential risk to the individual and the community posed by unvaccinated cohorts on public health.

**Key Actions:**

- Improve immunisation coverage in accordance with the NIP Schedule.
- Maintain or improve immunisation coverage for high risk population groups.
- Identify geographic areas or cohorts of low coverage and implement strategies to improve immunisation coverage in these areas.

• Ensure equity of access to immunisation services for all Australians without financial or geographical barriers.

• Maintain and monitor the effectiveness of childhood vaccination awareness and promotion campaigns and incentives.

• Implement strategies to improve and better understand adolescent immunisation coverage.

• Improve influenza and pneumococcal vaccination rates.

• Through disease surveillance, identify the risks posed by unvaccinated cohorts in the population.

• Develop an agreed position on the provision of free catch-up immunisation schedules.
STRATEGIC PRIORITY 2: ENSURE EFFECTIVE GOVERNANCE OF THE NATIONAL IMMUNISATION PROGRAM

There has been a concerted focus in recent years to strengthen governance arrangements in the public sector and to improve openness and transparency of committee and other advisory processes. In the case of population health and health protection policy, this has specifically been driven by the recommendations in two reviews released in 2011: the Review of Australia’s Health Sector Response to Pandemic (H1N1) 2009: Lessons identified, and the Review of the management of adverse events associated with Panvax and Fluvax.

These reviews have identified the need to both clarify and strengthen governance arrangements in relation to both health protection more generally and improved monitoring of vaccine safety in the case of the latter review. Since the release of these reviews, there has been considerable work undertaken to streamline and strengthen governance structures in health protection more generally, and the vaccine safety arrangements for the NIP in particular.

The governance arrangements for immunisation in Australia are complex, reflecting the range of responsibilities of Commonwealth, state/territory and local governments as well as the roles of many other stakeholders involved in the design, delivery and uptake of immunisation. Recently, the House of Representatives Standing Committee on Health and Ageing’s ‘Report on the inquiry into health issues across international borders – Diseases have no borders’ stated:

‘the national immunisation program and Australia’s ability to maintain nationally low levels of vaccine preventable disease in Australia is an example of strong national coordination between the Commonwealth and state and territory governments’

The Committee also considered that the national coordination of immunisation issues should be considered by the Commonwealth as model for national coordination on infectious diseases more broadly.

While the existing governance arrangements work quite well, these could be better articulated and made readily available to stakeholders and the community to improve transparency and confidence in the program. Appendix 4 provides a broad outline of existing arrangements; however this could be expanded upon and made publically available on the Immunise Australia website.

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23 Review of Australia’s Health Sector Response to Pandemic (H1N1) 2009: Lessons identified, Commonwealth of Australia, 2011

24 Horvath, J, Review of the management of adverse events associated with Panvax and Fluvax, Commonwealth of Australia, 2011

In line with improving and strengthening governance, a number of Australian Government organisations and committees with key roles to play in the NIP have recently reviewed and updated their governance structures. This has included the Therapeutic Goods Administration’s (TGA) implementation of the key recommendations of its transparency review to improve the public’s knowledge of regulatory decision-making and to enhance public understanding of the benefits and risks of therapeutic goods so that the Australian community can understand how the TGA operates and the reasons for its key decisions. In late 2012, the TGA made its database on adverse events reports available and searchable to the public, which will make it easier to find information about suspected adverse events following immunisation. The Department of Health is also planning to review the governance and operational management structures in place for ATAGI.

There are a number of reports about immunisation and the NIP made available throughout the year in various publications. These include, but are not limited to:

- Immunisation coverage figures published on the Medicare Australia website which is being incorporated into the Department of Human Services website;
- Reports of immunisation coverage, VPD surveillance and review of adverse events in Communicable Disease Intelligence;
- Updates to the vaccine schedule and electronic copies of the Australian Immunisation Handbook;
- Results of ad hoc adult vaccination surveys; and
- HPV vaccination coverage reports.

To improve the openness and transparency of the NIP, an Annual Report should be prepared and published on the Immunise Australia website to provide a central consolidated summary of key activities, achievements and challenges for the NIP in the previous year.

**Key Actions:**

- Ensure governance arrangements for vaccination in Australia are clear, accountable and effective, with regular processes in place to monitor and evaluate performance and provide feedback. Develop a map of the NIP that shows the roles and responsibilities of the Commonwealth, states and territories and other key stakeholders.
- Prepare and publish an Annual Report for the NIP, which provides a summary of key activities, achievements and challenges in the previous year.

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28 Department of Human Services (www.humanservices.gov.au)
STRATEGIC PRIORITY 3: ENSURE SECURE VACCINE SUPPLY AND EFFICIENT USE OF VACCINES FOR THE NATIONAL IMMUNISATION PROGRAM

National Procurement of Essential Vaccines

Under the NPEV the Commonwealth is taking over responsibility for purchasing all essential vaccines on behalf of the states and territories. The states and territories have agreed to work to ensure the cost-effective delivery of vaccination services, including the minimisation of wastage (loss of vaccines due to cold chain breach or other damage) and leakage (unauthorised use of vaccines), in return for incentive and reward payments.

The Commonwealth has developed an Essential Vaccine Procurement Strategy to secure the continual supply of essential vaccines in Australia and to guide the continued joint Commonwealth, state and territory collaboration on the planned procurement process. The Strategy outlines the tendering process and provides a proposed schedule for tenders and purchasing arrangements to help provide clarity for the vaccine industry.

Vaccine wastage and cold chain maintenance

One of the key risks associated with the NIP is the maintenance of the cold chain, and the safe transport and storage of vaccines. The National Vaccine Storage Guidelines, released in 2005 were targeted at vaccine providers and encouraged them to “Strive for 5” (degrees) to maintain the safety and viability of vaccines. Accreditation of GP practices includes compliance with “Strive for 5” guidelines. “Strive for 5” is well accepted and utilised by immunisation providers. The tools and resources included in “Strive for 5” can be used by GP practices to ensure they meet accreditation requirements. With the availability of purpose-built vaccine refrigerators it is appropriate that these Guidelines be reviewed. Work is currently progressing on this review and on the development of an Australian Standard for purpose built vaccine refrigerators.

Vaccine wastage is currently managed by states and territories but the level of wastage at a national level is not routinely collected. The NPEV includes a performance indicator for wastage and leakage: to meet this benchmark, a jurisdiction’s wastage or leakage in the assessment period must be equal to or less than 10 per cent. This performance indicator is based on self-report by states and territories and requires some verification. The data do not provide a national picture on level of wastage and leakage experienced in the NIP and whether the levels are acceptable or action is required.


Key Actions

• Implement the Essential Vaccine Procurement Strategy.
• Review the indicator for wastage and leakage of vaccine under the NPEV.
• Develop an Australian Standard for purpose built vaccine refrigerators and promote their utilisation.
• Review and revise the National Vaccine Storage Guidelines.
• Review the factors that impact on vaccine wastage and leakage to better understand and, if required, identify opportunities to minimise wastage and leakage.
STRATEGIC PRIORITY 4: CONTINUE TO ENHANCE VACCINE SAFETY MONITORING SYSTEMS

An area of concern for the public is the safety of the vaccines, and minimising adverse events following immunisation (AEFI). Assessment of vaccine safety considers the balance between the benefits and the risks of the vaccine noting that no vaccine or medicine is completely without side effects. However delivery of immunisation to well population groups means that vaccine safety considerations are paramount.

*The Horvath Review of the management of adverse events associated with Panvax and Fluvax* (the Horvath Review) examined the vaccine safety system in Australia following adverse events associated with seasonal influenza vaccine in children in 2010. The review found that the existing Australian system of passive surveillance for monitoring adverse events has a number of strengths: it was able to detect the safety signal associated with the use of the 2010 seasonal influenza vaccine, take appropriate action and undertake a rigorous investigation. The review made seven recommendations to further improve and strengthen the safety of immunisation in Australia and these are currently being implemented. This Strategy will monitor the effects of implementing improvements in the vaccine safety system. Activities in this area include:

- Improved governance - the Advisory Committee on the Safety of Vaccines (ACSOV) is being established to advise both the Office of Health Protection, which has administrative responsibility for the NIP, and the TGA on vaccine safety issues in relation to the NIP and regulatory matters in relation to all registered vaccines.

- Improving the national system for more timely reporting and monitoring of adverse events - A national minimum data set has been agreed, a national AEFI reporting form is being developed and closer liaison between the TGA and state and territory immunisation program managers has been established. Specific details are being finalised with the states and territories.

- Raising community and health professional awareness of vaccine safety - coinciding with establishment of the Advisory Committee and improvements to the timely reporting of AEFI, improvements are being planned in the way the assessment and monitoring of vaccine safety is communicated to the public and immunisation providers, including increased transparency and better awareness of the risks and benefits of immunisation.

- National protocols for program action in the event of an identified vaccine safety issue on the NIP – these have developed in conjunction with states and territories to ensure a nationally consistent response to safety issues involving a NIP vaccine.

Work should continue to implement the recommendations from the Horvath Review and sustain improvements in a comprehensive vaccine safety system.

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Key Actions

- Continue to work with key stakeholders to implement the recommendations from the Horvath Review.

- Continue to work with key stakeholders to improve the timeliness and completeness of AEFI surveillance in collaboration with the newly established Advisory Committee on the Safety of Vaccines.

- Assess the need for, and implement where required, a specific vaccine safety plan for the release of each new vaccine or existing vaccine to new cohort for the NIP.

- Raise community and health professional awareness of vaccine safety systems to improve confidence in the program and reporting of adverse events.

- Investigate opportunities for linkages between the ACIR and the HPV Register to other data collections to better assess and ensure vaccine safety.
STRATEGIC PRIORITY 5: MAINTAIN AND ENSURE COMMUNITY CONFIDENCE IN THE NATIONAL IMMUNISATION PROGRAM THROUGH EFFECTIVE COMMUNICATION STRATEGIES

The ongoing success of the NIP depends on a high level of community confidence in immunisation, both amongst consumers and health professionals. As the immunisation coverage rate remains high, and outbreaks of VPDs are rare, it becomes more and more important to ensure community support to maintain sufficiently high levels of immunisation coverage to protect the whole population.

Media coverage of immunisation issues can have an important impact on the community’s confidence in and support for immunisation. Given this, a media pack to promote factual, responsible reporting of immunisation issues should be developed.

Childhood Immunisation

Parents who delay immunising their children at the appropriate time should be reassured about the safety of childhood vaccines and of the measures in place to prevent, monitor and respond to vaccine safety concerns.

While a range of resources are available to parents and health professionals on the NIP, there is a need for more specific resources and tools to assist health professionals to sensitively and respectfully discuss issues of concern about immunisation with parents. Such resources could provide ready access to scientific information about the risks, benefits and safety of specific childhood vaccines. The currency of the range of issues and concerns being raised by parents should be assessed and monitored to continue to inform the development of communications during the term of the Strategy.

Vaccine Safety

The other key communications challenge is to ensure community confidence in the methods for identifying and responding to vaccine safety issues. The Horvath Review provided recommendations to improve not only the way AEFI are identified, monitored, reported and responded to, but also how best to communicate that improved system to all stakeholders to improve awareness of, and confidence in, the vaccine safety assessment and monitoring system. Development of an agreed communications strategy would achieve improved community confidence in the way the NIP manages potential vaccine safety issues.

Specific Target Groups

The NIP has a strong communications program to promote immunisation to target groups, such as mothers and their children, Aboriginal and Torres Strait Islander peoples, and health professionals. Promotional materials associated with the existing communications program are available for each target population and in various languages. There is a need to review current and emerging coverage and other data to
develop appropriate communications strategies to promote immunisation to specific target groups such as adolescents, older Australians and Aboriginal and Torres Strait Islander peoples. The NIP Communications Strategy could be updated and methods identified to take advantage of social media and other technological opportunities (such as viral marketing and smartphone applications) to improve the delivery of communications efforts with hard to reach groups.

**Key Actions**

- Identify ways to strengthen the current communications strategy, particularly for population groups with low and/or delayed immunisation coverage.
- Develop a media reference pack to encourage accurate and responsible reporting of immunisation.
- Monitor and revise communications resources and campaigns to improve the reach of immunisation awareness and confidence for key target groups.
- Identify ways to utilise current and emerging social marketing tools/technology to reach target audiences.
- Develop a specific communications strategy for vaccine safety to promote community confidence in processes to evaluate, monitor and respond to vaccine safety issues.
STRATEGIC PRIORITY 6: STRENGTHEN MONITORING AND EVALUATION OF THE NATIONAL IMMUNISATION PROGRAM THROUGH ASSESSMENT AND ANALYSIS OF IMMUNISATION REGISTER DATA AND VACCINE-PREVENTABLE DISEASE (VPD) SURVEILLANCE

Communicable Disease Control Framework

Under the auspices of the Communicable Diseases Network Australia, the Commonwealth, states and territories are developing a joint Communicable Disease Control Framework (the Framework) which spans the prevention, detection, surveillance, response and control of communicable diseases, including vaccine-preventable diseases in Australia. One of the key points of focus for the Framework is to strengthen and streamline the National Notifiable Diseases Surveillance Systems and other surveillance systems that support national data collection and reporting to ensure that there is a nationally agreed surveillance and monitoring plan to support control strategies for infectious diseases, including vaccine-preventable diseases. This National Immunisation Strategy will ensure the NIP is consistent with the vision and key directions of the Framework and particularly that a comprehensive monitoring plan is in place when a new vaccine is introduced.

Vaccine-Preventable Diseases Surveillance Systems in Australia

Australia has a well-established and comprehensive surveillance system for VPDs which includes a national sero-surveillance program to measure population immunity over time, case-based surveillance of incident cases through the National Notifiable Diseases Surveillance System, hospitalisation data accessed via the Australian Institute of Health and Welfare’s (AIHW) National Hospital Morbidity Database, and mortality data from the Australian Bureau of Statistics and the AIHW General Record of Incidence of Mortality. Other national and state based surveillance systems capture additional surveillance data such as severe cases of selected VPDs or their complications in children through the Australian Paediatric Surveillance Unit and the Paediatric Active Enhanced Disease Surveillance program, sentinel information on influenza and sentinel information on the circulating genotypes of rotavirus causing hospitalisation in children through the Australian Rotavirus Surveillance Program and resistance patterns in meningococcal disease isolates through the Australian Meningococcal Surveillance Program.

Better utilisation of immunisation coverage data

One of the key areas for action in this Strategy is to consider the unrealised advantages of the existing childhood immunisation register, the HPV Register and opportunities afforded by data linkage between these high quality data sets and other health data sets. Data linkage and better use of the immunisation registers data has a range of
potential benefits including improved program evaluation, understanding of and better quantification of adverse events and assessment of vaccine efficacy in a national program setting.

**eHealth Developments**

Technological advances in information communications systems are happening at a rapid rate throughout the world, and health systems technology is one of the areas that is reaping benefits from these advances. The Strategy notes the introduction of the Personally Controlled Electronic Health Record (PCEHR). Including vaccines given to individuals in their personally controlled electronic health record from a range of administrative data sets needs to be progressed. This will provide individuals and their health care providers information about vaccines administered and those overdue.

Over time there may be further opportunities to improve and strengthen the immunisation system using eHealth and other technological advances.

**Vaccine-Preventable Diseases Laboratory Testing**

Confirmation of VPDs requires close collaboration of clinicians, public health professionals and laboratories to create a coordinated public health laboratory network. Appropriate specimen collection, transport and laboratory testing are essential. Laboratory testing also supports enhanced surveillance processes through monitoring of strains and to compare the circulating strains with the components within the vaccine. Introduction of new vaccines or antigens requires support of laboratory surveillance.

**Key Actions**

- Investigate opportunities for linkages between ACIR, the HPV Register and other data collections to better assess program outcomes, vaccine safety and vaccine efficacy.
- Undertake a review the ACIR and the HPV Register to assess their potential for expansion to include other vaccines and provide immunisation coverage data for other age groups.
- Use data on immunisation coverage in ACIR, the National HPV Register and other sources to better identify groups at risk of delayed and/or gaps in immunisation coverage compared to the NIP Schedule.
- Identify ways to streamline and rationalise surveillance of VPDs to improve timeliness, effectiveness and efficiency of surveillance systems.
- Ensure supported laboratory infrastructure in place to support high quality surveillance via VPD detection and characterisation.
- Monitor potential opportunities to improve and strengthen the immunisation system using eHealth and other technological initiatives.
STRATEGIC PRIORITY 7: ENSURE AN ADEQUATELY SKILLED IMMUNISATION WORKFORCE THROUGH PROMOTING EFFECTIVE TRAINING FOR IMMUNISATION PROVIDERS

Immunisation in Australia is provided by a range of health professionals, including general practitioners, nurses, local government and Aboriginal and Torres Strait Health Workers working in different health care settings. The availability of a diverse network of providers helps to ensure immunisation services are accessible and enables consumers to select their preferred immunisation provider.

Immunisation providers have a key role in ensuring that their patients are well informed on the benefits of immunisation. The Australian Immunisation Handbook provides evidence-based clinical practice guidelines for health professionals on the safe and effective use of all vaccines available in Australia. It is a valuable tool to help immunisation providers explain the benefits of immunisation to their patients.

Specialist training and credentialing is required in most jurisdictions to demonstrate the health professional’s capacity to administer immunisations safely and effectively. Currently, a vaccine provider with extensive experience in administering vaccines in one state or territory may not be permitted to administer vaccines in another jurisdiction unless further training and credentialing is undertaken.

Given the pressures on the health workforce in Australia, this is a significant barrier to the efficient delivery of vaccination in Australia, particularly in remote areas. It is also at odds with national health workforce registration legislation in Australia that harmonises the recognition of certain health practitioners’ registration so that it is recognised all over the country.

The training and expertise required to be a safe and effective immunisation provider is universal. This Strategy will seek to develop nationally agreed core standards and competencies for the delivery of immunisation services and promote the recognition of these in all states and territories.

A range of providers administer vaccines across Australia and the mix varies between jurisdictions. A better understanding of vaccine providers and their various roles in different settings will enhance the targeting of communication messages and identification of training needs.

Key Actions

- Undertake an evaluation of the Australian Immunisation Handbook and other communication resources for providers to ensure these meet the needs of the range of providers.
- Identify ways to strengthen and support a range of immunisation service providers.
• Review and update competencies for immunisation providers.
• Investigate how to ensure national harmonisation of the credentialing and recognition of immunisation providers and transferability of skills and qualifications.
STRATEGIC PRIORITY 8: MAINTAIN AUSTRALIA’S STRONG CONTRIBUTION TO THE REGION

The prevention and control of VPDs is a global issue, and Australia is an active partner with the WHO member states in the Western Pacific and other regions. This includes under the Enhanced Programme on Immunisation (EPI) and contributes to: strengthening the WPRO’s efforts to control hepatitis B, rotavirus and bacterial meningitis through immunisation; eliminate measles in the region and; continue to maintain WPRO’s polio free status through a range of efforts within Australia and with our partners in the region.

In addition, Australia funds the GAVI Alliance. GAVI a public/private partnership that works in collaboration with other international organisations, donor governments, developing countries, financing institutions and vaccine manufacturers committed to protecting people’s health through increasing access to immunisation. By the end of 2011 GAVI had supported the immunisation of more than 325 million children.

AusAID also funds the United Nations Children’s Fund (UNICEF) which supports child health, including immunisation. In 2011 UNICEF helped vaccinated 10 million children against measles.

This support reflects Australia’s commitment to minimising the incidence of VPDs in the Asia-Pacific region. AusAID’s contribution to immunisation programs has helped achieve remarkable improvement in vaccination rates and health and development outcomes in countries in the region. It is important for Australia to be part of the global effort to prevent and control VPDs in an increasingly mobile world, where international travel and trade has become the norm for most countries and such a large proportion of the world’s population.

As part of the WHO Western Pacific Region EPI, Australia has met the regional 2012 targets for:

• reducing chronic hepatitis B infection to less than 1% among children at least 5 years of age;
• elimination of measles and establishing a National Verification Committee; and
• contributing to poliomyelitis eradication through ensuring that Australia has adequate surveillance for wild polioviruses and undertaking a risk assessment for the transmission of wild poliovirus in Australia.

Key Actions

• Continue to be an active participant in the WHO Western Pacific Region Enhanced Programme on Immunisation, particularly in relation to:
  - achieving measles elimination;

Further information is available at Gavi Alliance (www.gavialliance.org/)

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- maintaining polio elimination;
- strengthening hepatitis B control; and
- continuing to contribute to National Immunisation Technical Advisory Groups (NITAG).
APPENDICES

Appendix 1 – Development of the Strategy

Although Australia has had success in establishing and normalising immunisation, there is a need to ensure that we do not become complacent about the importance of maintaining and continually improving upon these achievements and ongoing vigilance of VPDs is necessary. For example, control of pertussis is a source of concern with reports of high rates of pertussis infection across Australia, between 2008 and 2011. At the request of the Australian Health Ministers’ Conference held 22 July, 2008, it was agreed that a National Immunisation Strategy be developed. This document has been produced on behalf of the Commonwealth Department of Health (the Department).

The NIC was given responsibility for overseeing the development of the Strategy. The NIC comprises all states and territories, the Therapeutic Goods Administration, a consumer representative and expert advisors from a range of peak organisations (including the Australian Association of Maternal Child and Family Health Nurses (AAMCFHN), the Australian College of Midwives (ACM), the Australian Local Government Association (ALGA), the Australian Medical Association (AMA), Australian Medicare Local Alliance (AML Alliance), the Australian Practice Nurses Association (APNA), the National Aboriginal Community Controlled Health Organisations, the Royal Australian College of General Practitioners (RACGP) and the Rural Doctors Association of Australia (RDAA) and committees (including the Australian Technical Advisory Group on Immunisation and the Communicable Disease Network of Australia). The National Immunisation Strategy is focused on key areas of improvement, identified through a range of research and consultation processes conducted over the last two years, incorporating Commonwealth, state and territory governments, health department officials, private sector and experts on immunisation.

In 2010, Professor Michael Frommer, Sydney Medical School, School of Public Health, University of Sydney was engaged to develop a proposal for a National Immunisation Strategy. This involved:

• a series of consultations with state and territory health departments and peak bodies;
• a National Forum held in December 2010 involving key immunisation experts; and
• the development of a discussion paper outlining the proposed areas for future improvement which had been identified through the consultations.

The proposal for the Strategy was presented to AHPPC in 2011.

The key priority areas and actions within these areas were identified in consultation with the NIC. Further consultations were undertaken during 2011 and the early part of 2012.

The Strategy was drafted in late 2012 and early 2013.
# National Immunisation Program Schedule

## From 1 July 2013

### Child programs

<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccine</th>
</tr>
</thead>
</table>
| Birth    | • Hepatitis B (hepB)  
• Diphtheria, tetanus, acellular pertussis (whooping cough),  
  *Haemophilus influenzae* type b, inactivated poliomyelitis (polio) (hepB-DTPa-Hib-IPV)  
• Pneumococcal conjugate (13vPCV)  
• Rotavirus |
| 2 months | • Hepatitis B, diphtheria, tetanus, acellular pertussis (whooping cough),  
  *Haemophilus influenzae* type b, inactivated poliomyelitis (polio) (hepB-DTPa-Hib-IPV)  
• Pneumococcal conjugate (13vPCV)  
• Rotavirus |
| 4 months | • Hepatitis B, diphtheria, tetanus, acellular pertussis (whooping cough),  
  *Haemophilus influenzae* type b, inactivated poliomyelitis (polio) (hepB-DTPa-Hib-IPV)  
• Pneumococcal conjugate (13vPCV)  
• Rotavirus |
| 6 months | • Hepatitis B, diphtheria, tetanus, acellular pertussis (whooping cough),  
  *Haemophilus influenzae* type b, inactivated poliomyelitis (polio) (hepB-DTPa-Hib-IPV)  
• Pneumococcal conjugate (13vPCV)  
• Rotavirus |
| 12 months| • *Haemophilus influenzae* type b (Hib)  
• Meningococcal C (MenCCV)  
• Measles, mumps and rubella (MMR) |
| 18 months| • Measles, mumps, rubella and varicella (chickenpox) (MMRV) |
| 4 years  | • Diphtheria, tetanus, acellular pertussis (whooping cough) and inactivated poliomyelitis (polio) (DTPa-IPV)  
• Measles, mumps and rubella (MMR) (to be given only if MMRV vaccine was not given at 18 months) |

### School programs

10–15 years (contact your State or Territory Health Department for details)

<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months and over</td>
<td>• Influenza (flu) (people with medical conditions placing them at risk of serious complications of influenza)</td>
</tr>
</tbody>
</table>
| 12 months            | • Pneumococcal conjugate (13vPCV)  
  (medically at risk) |
| 12–18 months         | • Pneumococcal conjugate (13vPCV) (Aboriginal and Torres Strait Islander children in high risk areas)  
  (medically at risk) |
| 12–24 months         | • Hepatitis A (Aboriginal and Torres Strait Islander children in high risk areas)  
  (medically at risk) |
| 4 years              | • Pneumococcal polysaccharide (23vPPV)  
  (medically at risk) |
| 15 years and over    | • Influenza (flu) (Aboriginal and Torres Strait Islander people)  
• Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander people medically at risk) |
| 50 years and over    | • Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander people) |
| Pregnant women       | • Influenza (flu)  
• Pneumococcal polysaccharide (23vPPV) |
| 65 years and over    | • Influenza (flu)  
• Pneumococcal polysaccharide (23vPPV) |

* Please refer to reverse for footnotes
Footnotes to the National Immunisation Program (NIP) Schedule

a. Hepatitis B vaccine: should be given to all infants as soon as practicable after birth. The greatest benefit is if given within 24 hours, and must be given within 7 days.
b. Rotavirus vaccine: third dose of vaccine is dependent on vaccine brand used. Contact your State or Territory Health Department for details.
c. Hepatitis B and Varicella vaccine: contact your State or Territory Health Department for details on the school grade eligible for vaccination.
d. HPV vaccine: is for all adolescents aged between 12 and 13 years. A catch-up program for males aged between 14 and 15 years is available until December 2014. Contact your State or Territory Health Department for details on the school grade eligible for vaccination.
e. Pneumococcal vaccine:
   i. Medically at risk children require: a fourth dose of 13vPCV at 12 months of age; and a booster dose of 23vPPV at 4 years of age (but less than 6 years of age).
   ii. Infants born at less than 28 weeks gestation require: a fourth dose of 13vPCV at 12 months of age.
   iii. Aboriginal and Torres Strait Islander children require: a fourth dose of pneumococcal vaccine (13vPCV) at 12 months of age (but not more than 18 months) for children living in high risk areas (Queensland, Northern Territory, Western Australia and South Australia). Contact your State or Territory Health Department for details.
f. Hepatitis A vaccine: two doses of Hepatitis A vaccine for Aboriginal and Torres Strait Islander children living in high risk areas (Queensland, Northern Territory, Western Australia and South Australia). Contact your State or Territory Health Department for details.

Further information

Further information and immunisation resources are available from the Immunise Australia Program website at www.immunise.health.gov.au or by contacting the Infoline on 1800 671 811.

You should contact your State or Territory Health Department for further information on the program specific to your State or Territory:

<table>
<thead>
<tr>
<th>State/Territory</th>
<th>Contact Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Capital Territory</td>
<td>(02) 6205 2300</td>
</tr>
<tr>
<td>New South Wales</td>
<td>1300 066 055</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>(08) 8922 8044</td>
</tr>
<tr>
<td>Queensland</td>
<td>13 HEALTH (13 4325 84)</td>
</tr>
<tr>
<td>South Australia</td>
<td>1300 232 272</td>
</tr>
<tr>
<td>Tasmania</td>
<td>1800 671 738</td>
</tr>
<tr>
<td>Victoria</td>
<td>1300 882 008</td>
</tr>
<tr>
<td>Western Australia</td>
<td>(08) 9321 1312</td>
</tr>
</tbody>
</table>
### Appendix 3 – Key dates when vaccines first came into widespread use in Australia

<table>
<thead>
<tr>
<th>Year</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1945</td>
<td>Tetanus toxoid</td>
</tr>
<tr>
<td>1953</td>
<td>Diphtheria-tetanus-pertussis, whole-cell (DTPw)</td>
</tr>
<tr>
<td>1956</td>
<td>Poliomyelitis (Salk) (inactivated poliomyelitis vaccine [IPV])</td>
</tr>
<tr>
<td>1966</td>
<td>Poliomyelitis (Sabin) (live attenuated oral poliomyelitis vaccine [OPV])</td>
</tr>
<tr>
<td>1970</td>
<td>Measles</td>
</tr>
<tr>
<td>1971</td>
<td>Rubella</td>
</tr>
<tr>
<td>1975</td>
<td>Child diphtheria-tetanus (CDT)</td>
</tr>
<tr>
<td>1982</td>
<td>Adult diphtheria-tetanus (ADT)</td>
</tr>
<tr>
<td>1982</td>
<td>Measles-mumps</td>
</tr>
<tr>
<td>1982</td>
<td>Hepatitis B (hepB) (serum-derived vaccine)</td>
</tr>
<tr>
<td>1987</td>
<td>Hepatitis B (recombinant vaccine)</td>
</tr>
<tr>
<td>1989</td>
<td>Measles-mumps-rubella (MMR)</td>
</tr>
<tr>
<td>1993</td>
<td>Hib (<em>Haemophilus influenzae</em> type b)</td>
</tr>
<tr>
<td>1994</td>
<td>Hepatitis A</td>
</tr>
<tr>
<td>1997</td>
<td>Diphtheria-tetanus-pertussis, acellular (DTPa)</td>
</tr>
<tr>
<td>1999</td>
<td>Influenza</td>
</tr>
<tr>
<td>1999</td>
<td>23-valent pneumococcal polysaccharide (23vPPV)</td>
</tr>
<tr>
<td>2000</td>
<td>DTPa-hepB</td>
</tr>
<tr>
<td>2000</td>
<td>Hib(PRP-OMP)-hepB</td>
</tr>
<tr>
<td>2001</td>
<td>7-valent pneumococcal conjugate (7vPCV)</td>
</tr>
<tr>
<td>2003</td>
<td>Varicella</td>
</tr>
<tr>
<td>2003</td>
<td>Meningococcal C conjugate</td>
</tr>
<tr>
<td>2004</td>
<td>Diphtheria-tetanus-pertussis, acellular; reduced antigen content formulations (dTpa and dTpa-IPV)</td>
</tr>
<tr>
<td>2005</td>
<td>Pentavalent and hexavalent combination DTPa vaccines (DTPa-hepB-IPV-Hib; DTPa-IPV; DTPa-hepB-IPV; DTPa-IPV-Hib)</td>
</tr>
<tr>
<td>2007</td>
<td>Human papillomavirus (HPV)</td>
</tr>
<tr>
<td>2007</td>
<td>Rotavirus</td>
</tr>
<tr>
<td>2009</td>
<td>10-valent pneumococcal conjugate (10vPCV)</td>
</tr>
<tr>
<td>2011</td>
<td>13-valent pneumococcal conjugate (13vPCV)</td>
</tr>
<tr>
<td>2013</td>
<td>Measles-mumps-rubella-varicella (MMRV)</td>
</tr>
</tbody>
</table>

This table provides only some dates; for specific details on vaccine registration, funding, recommendations and program use please see complete information in the ‘NCIRS Vaccination History Tables’ available from the NCIRS website (http://www.ncirs.edu.au/immunisation/history/index.php).

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Appendix 4 - Vaccination Expenditure

Australia’s Investment in Immunisation

The scale and cost of immunisation for all Australians is a vital consideration to the Strategy. Annual expenditure on vaccines alone has risen from $13 million in 1996-97 to an estimated $323 million in 2010-11. This does not include the costs of immunisation service delivery, information provision, professional and community immunisation incentives or monitoring and surveillance. This is only a small proportion for medicines, considering the total Government expenditure on the Pharmaceutical Benefits Scheme (PBS) is currently just over $9 billion.

Facilitation of the requirements for the vaccine industry is important. With a resident population of approximately 22.6 million, Australia is a relatively small market for vaccines. The interest of the vaccine industry in investing in this market – and hence the interest of pharmaceutical companies in sustaining a reliable supply of vaccines for Australia – is likely to be affected by uncertainty of market access and by procurement processes that entail high transaction costs.

Currently, the Australian Government provides funding for:

- Purchasing vaccines listed on the NIP.
- Medicare Australia for:
  - ACIR;
  - Subsidising individual private consultations which involve immunisation through the Medicare Benefits Schedule (MBS);
- The Victorian Cytology Service for the administration of the National HPV Vaccination Program Register; and
- Support for the National Centre for Immunisation Research and Surveillance.

On 26 March 2008, COAG agreed that the NIP should become a Commonwealth Own Purpose Expense. The NPEV outlines the transitional and ongoing arrangements for the funding and delivery of a national, coordinated and integrated approach to maintaining and improving effective immunisation for VPDs funded under the NIP. Essential Vaccines are those listed in a determination (as amended) under section 9b of the National Health Act 1953 (Commonwealth). New vaccines and new cohorts may, from time to time, be added to the Schedule of Essential Vaccines. Under the new arrangements, Governments agreed to change the process through which vaccines are purchased. The Commonwealth will purchase directly from vaccine suppliers and states and territories will continue to order vaccines and distribute to vaccine providers.

From 1 July 2012, the Commonwealth aligned eligibility for payments to families of the


36 Council of Australian Governments, National Partnership Agreement on Essential Vaccines
Family Tax Benefit (FTB) Part A supplement to children aged 1, 2 and 4 years being fully immunised. This change replaced the former ‘Maternity Immunisation Allowance’. From 1 July 2013, children will also be required to receive vaccines for meningococcal C, pneumococcal and varicella (chicken pox) to be assessed as fully immunised. Immunisation is also currently a stipulation for receiving the Child Care Benefit. The General Practice Immunisation Incentive (GPII) ceases on 1 May 2013. Discontinuing the GPII will reduce incentive payments where there are already other processes in place to improve immunisation of Australian children, including funding to Medicare Locals, payments to practitioners and GPs and family payments as above.

According to the *Health Expenditure Australia 2010-11* report, between 2000–01 and 2010–11, estimated government expenditure on public health activities grew at an average rate of 3.8% per year, with organised immunisation (this includes immunisation clinics, school immunisation programs, immunisation education, public awareness, immunisation databases and information systems) being one of the areas with one of the highest average annual growth rates at 6%. Much of the growth in expenditure on organised immunisation resulted from costs associated with the implementation of the HPV vaccination program (AIHW 2012).  

As the graph in Figure 2 shows, vaccine expenditure generally increases with the introduction of new vaccines (and any associated catch-up programs such as the HPV program); peaks in the graph reflect additional expenditure associated with time limited catch-up programs.

Although continued advances in vaccine technology and the development of vaccines against diseases that are not currently vaccine-preventable are likely to bring important benefits, they will inevitably come at a substantial cost. These are inherent considerations for any proposed actions identified in improving vaccination service and delivery.

The figure below shows that funding for vaccine purchasing has increased from [source](#).
$10 million per annum in the mid-1990s to over $350 million in 2011 – 2012.

The peaks in the figure represent the provision of new funding associated with the introduction of new vaccines and time-limited catch-up programs.

**Figure 2 Vaccine expenditure under the NIP**
### State Summary by age group 1 January 2012 to 31 December 2012

<table>
<thead>
<tr>
<th>State</th>
<th>Age Group months</th>
<th>Number In State</th>
<th>% Fully immunised</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT</td>
<td>12–&lt;15</td>
<td>5,231</td>
<td>92.83</td>
</tr>
<tr>
<td>NSW</td>
<td></td>
<td>97,525</td>
<td>91.40</td>
</tr>
<tr>
<td>VIC</td>
<td></td>
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<td>298,213</td>
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<tr>
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<td>304,487</td>
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Source: Data from the Australian Childhood Immunisation Register, prepared by the National Centre for Immunisation Research and Surveillance
* ‘Fully immunised’ is defined as, for:

- 12-<15 months age: diphtheria tetanus pertussis, polio, Hib and hepatitis B.
- 24-<27 months age: includes all of the vaccines from the lower age group, plus the measles mumps rubella vaccines.
- 60-<63 months age: DTP, polio and MMR vaccines only

At 12 months, 24 months and 4 years of age, over 90% of children in Australia are listed as ‘fully immunised’. At 6 years of age the figures are slightly less at just over 88%. Nationally, age-specific immunisation rates for Indigenous children are lower than the corresponding figures for the Australian population at 12 months of age and four years of age. Indigenous children are more likely to receive their immunisation past the recommended timeframe. Immunisation coverage rates for the Indigenous population, although improved, are not yet on par with that of the non-Indigenous population.

Appendix 6 – Coverage reports for adolescent HPV vaccines

National HPV Vaccination Coverage (3 dose) for girls turning 15 years in 2011

<table>
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<tr>
<th>State</th>
<th>ACT</th>
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<th>NT</th>
<th>QLD</th>
<th>SA</th>
<th>TAS</th>
<th>VIC</th>
<th>WA</th>
<th>NAT</th>
</tr>
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<tr>
<td>No. Doses</td>
<td>5,137</td>
<td>104,037</td>
<td>4,027</td>
<td>67,926</td>
<td>22,582</td>
<td>7,115</td>
<td>80,420</td>
<td>30,950</td>
<td>322,194</td>
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<tr>
<td>%</td>
<td>73.2%</td>
<td>72.7%</td>
<td>79.5%</td>
<td>70.2%</td>
<td>66.0%</td>
<td>64.0%</td>
<td>74.5%</td>
<td>64.8%</td>
<td>71.2%</td>
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</tbody>
</table>

Notes:

- Data extracted from the HPV Register as at 3 July 2012
- Includes only eligible consumers and vaccinations given as part of the National HPV Vaccination Program
- Includes valid doses and too close doses for Clinically Complete Consumers
- Population is Estimated Resident Population provided by the Australian Bureau of Statistics - Cat 3101.0
- Australian Demographic Statistics, Tables 51 to 58:
- Estimated Resident Population By Single year of Age by State and Territory, published 2011.
- Age is age as at date of Estimated Resident Population estimate
- Coverage is calculated as doses administered and reported to the HPV Register / estimated resident population expressed as a percentage
Appendix 7 – NIP listing process

Overview of process for the listing of a vaccine on the NIP

There is a legislative requirement for all vaccines provided under the NIP or the PBS to undergo a thorough and objective assessment process. The initial step is the requirement under the Therapeutic Goods Act 1989 that medical products to be imported into or supplied in Australia be included in the Australian Register of Therapeutic Goods (ARTG).

For a product to be included in the ARTG, a sponsoring company is required to make an application accompanied by data to support the quality, safety and efficacy of the product for its intended use.

Australia has a number of agreements with other countries relating to mutual recognition of therapeutic agents including the recognition of Good Manufacturing Practice compliance. If vaccines have already received approval from the European Medicines Agency and the U.S. Food and Drug Administration the TGA requirements for the approval process in Australia are shortened.

Once a vaccine is registered on the ARTG, the vaccine sponsor can make an application to the PBAC to list the vaccine on either the PBS and/or the NIP schedule. The vaccine sponsor can seek pre-submission technical advice from the ATAGI on matters relating to the strength of evidence of safety and effectiveness of vaccines and use in Australian populations, taking into account the epidemiology of the disease. A flow diagram of this process is outlined below.

The PBAC considers the clinical and economic data in the application to determine whether the use of the vaccine will provide value for taxpayers’ money.

Once a vaccine has been recommended by PBAC, a number of processes need to be completed before the medicine can be listed on the NIP. These include:

- consideration by the Pharmaceutical Benefits Pricing Authority (PBPA);
- finalisation of the details for listing the vaccine on the NIP;
- quality and availability checks; and
- consideration by Government for funding.

The role for the PBPA in vaccine assessment is to ensure there is a reliable supply of vaccine at the most reasonable cost to Australian taxpayers and consumers. The PBPA recommends prices for new items which then becomes the Nationally Negotiated Price (NNP) of the vaccine. Companies can also apply to the PBPA for a review of the NNP.

All PBAC recommendations are considered by Government.

Following agreement to funding by Government, the Department of Health progresses implementation of the new vaccine on the NIP. Activities may include:
• addition of vaccine to the ACIR;
• implementation planning with states and territories;
• procurement of vaccine through a tender process;
• communication activities; and
• amendments to the National Health Act 1953 (Immunisation Program – Designated Vaccines) (the Determination).

The timeframe for implementing a vaccine on the NIP following Government allocation of funding will depend on progressing all these activities. The department will meet with industry to discuss supply and potential timeframes soon after a Government decision is announced.

As a result of the national procurement being undertaken by the Commonwealth, a vaccine may be listed on the Determination, but where there are a range of potential vaccines for a specific schedule point, there is no guarantee that a listed vaccine will be successful in an RFT process.

The ongoing monitoring of vaccine safety and adverse events is through input from the states and territories and through the TGA (Office of Medicines Safety Monitoring) where all adverse event reports are reviewed by technical staff. Any serious adverse events involving new medicines are also reviewed by the Advisory Committee on the Safety of Medicines (ACSOM).

It is anticipated that during the life of the procurement strategy new vaccines may be added to the NIP.
Figure 4: Vaccine Listing Process

Disease Surveillance

ATAGI Scoping Phase
- Horizon scanning
- Interaction with companies
- Interactions with PBD
- Pre-PBAC submission advice (to both PBAC and Company)

PBAC Phase
- Company submission to PBAC for NIP listing
- Economic Subcommittee (ESC)
- Discussion with NIC on implementation issues
- Further specific advice from ATAGI

Positive recommendation from PBAC

Commence Program Planning

PBPA Evaluation
Nationally Negotiated Price Set

Agreed Start Date for Commencement of Program

Post PBAC Phase
Program Planning
- Australian Childhood Immunisation Register modification
- State and Territory Negotiation
- Communication Strategy
- Legislation
- Vaccine Procurement
- Vaccine Safety Plan
- Vaccine Supply
- Disease Surveillance
- Adverse Event Monitoring

New Vaccine Funded
NIP or PBS

Government Decision on PBAC Recommendation
## Appendix 8 – List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACIR</td>
<td>Australian Childhood Immunisation Register</td>
</tr>
<tr>
<td>ACSOM</td>
<td>Advisory Committee on the Safety of Medicines</td>
</tr>
<tr>
<td>ACSOV</td>
<td>Advisory Committee on the Safety of Vaccines</td>
</tr>
<tr>
<td>AEFI</td>
<td>Adverse Event Following Immunisation</td>
</tr>
<tr>
<td>AHMAC</td>
<td>Australian Health Ministers’ Advisory Council</td>
</tr>
<tr>
<td>AHMC</td>
<td>Australian Health Ministers’ Conference</td>
</tr>
<tr>
<td>AHPPC</td>
<td>Australian Health Protection Principal Committee</td>
</tr>
<tr>
<td>AIA</td>
<td>Australian Immunisation Agreement</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
</tr>
<tr>
<td>AMA</td>
<td>Australian Medical Association</td>
</tr>
<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
</tr>
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<td>ATAGI</td>
<td>Australian Technical Advisory Group on Immunisation</td>
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<td>CCB</td>
<td>Child Care Benefit</td>
</tr>
<tr>
<td>CDNA</td>
<td>Communicable Diseases Network Australia</td>
</tr>
<tr>
<td>COAG</td>
<td>Council of Australian Governments</td>
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<tr>
<td>COPE</td>
<td>Commonwealth Own Purpose Expense</td>
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<tr>
<td>dTpa</td>
<td>Adult/adolescent formulation diphtheria-tetanus-acellular pertussis vaccine</td>
</tr>
<tr>
<td>DTPa</td>
<td>Diphtheria-tetanus-acellular pertussis (vaccine)</td>
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<td>EPI</td>
<td>Expanded Programme on Immunisation</td>
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<td>FTB</td>
<td>Family Tax Benefit</td>
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<tr>
<td>GAVI</td>
<td>Global Action on Vaccines and Immunisation</td>
</tr>
<tr>
<td>GIVS</td>
<td>Global Immunization Vision and Strategy</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>GPII</td>
<td>General Practice Immunisation Incentive (Scheme)</td>
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<td>Hep A</td>
<td>Hepatitis A</td>
</tr>
<tr>
<td>Hep B</td>
<td>Hepatitis B</td>
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<tr>
<td>Hib</td>
<td>Haemophilus influenzae type b (disease)</td>
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<tr>
<td>HPV</td>
<td>Human Papillomavirus</td>
</tr>
<tr>
<td>IA</td>
<td>Immunise Australia</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
<td>-------------</td>
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<tr>
<td>MBS</td>
<td>Medicare Benefits Schedule</td>
</tr>
<tr>
<td>MIA</td>
<td>Maternity Immunisation Allowance</td>
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<td>ML</td>
<td>Medicare Locals</td>
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<tr>
<td>MMR</td>
<td>Measles, Mumps, Rubella (vaccine)</td>
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<td>NACCHO</td>
<td>National Aboriginal Community Controlled Health Organisation</td>
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<td>NCIRS</td>
<td>National Centre for Immunisation Research and Surveillance</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NHPVR</td>
<td>National Human Papillomavirus Program Register</td>
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<td>NIC</td>
<td>National Immunisation Committee</td>
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<td>NIP</td>
<td>National Immunisation Program</td>
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<td>NITAG</td>
<td>National Immunisation Technical Advisory Group</td>
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<td>NNDSS</td>
<td>National Notifiable Diseases Surveillance System</td>
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<td>NNP</td>
<td>Nationally Negotiated Price</td>
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<td>NPEV</td>
<td>National Partnership Agreement on Essential Vaccines</td>
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<td>OHP</td>
<td>Office of Health Protection</td>
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<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee</td>
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<td>PBPA</td>
<td>Pharmaceutical Benefits Pricing Authority</td>
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<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<td>Personally Controlled Electronic Health record</td>
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<td>13PCV</td>
<td>Pneumococcal conjugate</td>
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<tr>
<td>PHOFAs</td>
<td>Public Health Outcome Funding Agreements</td>
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<td>23PPV</td>
<td>Pneumococcal Polysaccharide</td>
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<td>RONGs</td>
<td>Refusal to vaccinate on Non-medical Grounds</td>
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<td>SCoH</td>
<td>Standing Council on Health</td>
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<td>SPP</td>
<td>Special Purpose Payment</td>
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<td>Therapeutic Goods Administration</td>
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<td>UNICEF</td>
<td>United Nations Children's Fund</td>
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<td>VPD</td>
<td>Vaccine-preventable disease</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WHO WPRO</td>
<td>World Health Organization Western Pacific Regional Office</td>
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