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<tbody>
<tr>
<td>ACIR</td>
<td>Australian Childhood Immunisation Register</td>
</tr>
<tr>
<td>AEFI</td>
<td>Adverse Events Following Immunisation</td>
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<td>ASVS</td>
<td>Australian Standard Vaccination Schedule</td>
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<tr>
<td>ATAGI</td>
<td>Australian Technical Advisory Group on Immunisation</td>
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<tr>
<td>DoHA</td>
<td>Department of Health and Aging</td>
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<tr>
<td>Hib</td>
<td>Haemophilus influenzae type b</td>
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<tr>
<td>IPV</td>
<td>Inactivated poliomyelitis vaccine</td>
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<tr>
<td>NCIRS</td>
<td>National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases</td>
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<tr>
<td>NHMRC</td>
<td>National Health &amp; Medical Research Council</td>
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<td>NIC</td>
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<td>OPV</td>
<td>Oral polio vaccination</td>
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<td>PES</td>
<td>Pharmaceutical Evaluation Section</td>
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<td>Therapeutic Goods Administration</td>
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Executive summary

Purpose of the study

Immunisation plays an important role in protecting public health. Immunisation has proved itself to be both medically effective and cost effective in promoting public health.

The purpose of this study is to demonstrate why continued commitment to, and investment in, a Government led immunisation system is needed to maximise future public health outcomes in Australia. The study also reviews the elements comprising the Australian immunisation system against best practice system design principles and then develops proposals to improve the operation of the system in the future.

Context

The current immunisation system in Australia was shaped by the components of the Seven Point Plan, introduced in 1997 under the Immunise Australia Program, which has over time become known as the National Immunisation Program (NIP). The Immunise Australia Program is a joint Commonwealth-State program which aims to increase national childhood immunisation rates so as to reduce the incidence of vaccine preventable diseases in the Australian community.

The Australian immunisation system involves the participation of Commonwealth and State and Territory Government organisations and industry suppliers of vaccines. Vaccine regulation, evaluation, approval and funding are carried out at the Commonwealth level, while vaccine delivery and monitoring involve both Commonwealth and State and Territory activity. Vaccines are developed, manufactured and supplied by industry.

The introduction of the NIP has led to significant improvements in immunisation outcomes in Australia. Effective vaccine supply and usage arrangements and a focus on improving the quality of service delivery have played a key role in achieving these improved outcomes. With increasing immunisation coverage rates the incidence of disease has declined, however, the system requires careful maintenance and further improvements to ensure that disease control continues.

While immunisation outcomes in Australia have improved since the introduction of the NIP in 1997, a number of new challenges for the system are emerging which mean that future good performance of the system cannot be taken for granted.

Emerging challenges

Some key challenges emerging for the Australian immunisation system include:

- the forthcoming availability of a wide range of new vaccines;
- high community expectations; and
- increasing pressures on the Commonwealth health budget.
Challenges from new vaccine development

The advancement of technology and the development of new vaccines is proceeding rapidly. Improved technology has provided new vaccines to:

- simplify the immunisation schedule through the development of combination vaccines;
- improve safety by reducing the risk of adverse effects from vaccines (see for example the lower risks associated with the inactivated poliomyelitis vaccine in combination versus the currently Government funded oral polio vaccination); and
- control other diseases for which there has previously been no preventative therapy (such as varicella).

Currently research is underway on over 60 vaccine candidates against important diseases worldwide. However, vaccines are also becoming technologically more complex and distinctly more expensive than existing vaccines. Due to high barriers to entry (capital costs, transportation requirements, regulatory approval costs and lead times) there is no foreseeable ‘generic’ vaccine market emerging.

The development of a wide range of new vaccines and the continued refinement of existing vaccines presents a particularly significant challenge for existing vaccine assessment, approval and funding processes. Moving forward, it will dramatically increase the number of vaccines requiring assessment, approval and funding.

The traditional focus of the immunisation system has been on providing population wide protection against infectious diseases. However, as the wide range of new vaccines currently under development become available, the role of immunisation in the future is likely to broaden. Several of the new vaccines under investigation represent a different paradigm for vaccination. Therapeutic vaccines, which could be used to combat various forms of cancer, certain allergies or chronic viral diseases are currently being researched. The new paradigm is that the vaccine helps the body to fight a disease already present.

While such therapeutic vaccines will not need to be administered in childhood to the entire population, the higher number of targeted vaccines that will be available and the higher costs associated with these new vaccines will place significant pressures upon the system for vaccine evaluation, approval and acquisition.

Challenges due to high community expectations

There is an increasingly low tolerance for disease risk within the community. This can create a political imperative for potentially expensive action in some key cases (for instance Hib in 1993 and Meningococcal 2002).

In many ways the NIP has created expectations within the community for a fully-funded immunisation system but the rising cost of new vaccines means that it is harder for governments to fund the broad provision of new vaccines. This calls into question the future financial sustainability of the immunisation system in bringing through new vaccines and ensuring appropriate access by patients.

Perhaps an early indicator of consequences of rising funding pressures is that not all vaccines included on the ASVS are currently publicly funded – a situation which may erode public confidence in the quality of the public immunisation system.
Challenges from rising pressure on Government health budget

As government health expenditure continues to rise at rates exceeding inflation, competing demands on the health budget become more pronounced. There is a tendency for short-run “crisis” issues to dominate when decisions are taken on health budget resource allocation. Unless long-term public health programs such as vaccinations are protected from competing short-run expenditure demands, there is a risk of under-investment in such preventive health programs, despite their acknowledged role in promoting long term public health outcomes and the long term financial sustainability of the public health system.

The need for a best practice system

If these challenges are to be successfully addressed the strategy, institutional structures and procedures for the assessment, approval and implementation of vaccines in Australia need to be best practice.

Both general public policy and public health principles can be used to develop a set of best practice principles appropriate for the Australian immunisation system.

To accord with best practice principles, defining features of the Australian immunisation system should include:

- clarity of long-term goals and priorities
- transparency and openness;
- high levels of accountability based on clarity of roles and responsibilities;
- efficiency; and
- financial sustainability.

Bringing the Australian immunisation system in line with best practice system design principles

The Australian immunisation system is not in “crisis”. However, the absence of funding for the latest recommendations included by the NHMRC on the ASVS and the confusion that this is creating is an indicator of the strain that the Australian immunisation program is now under.

There are a number of areas in which the immunisation system does not embody best practice system design principles. Given the emerging challenges facing the system, future strong performance will require best practice principles to be embodied in the immunisation system’s structures and process. Unless best practice principles are implemented Australia’s immunisation system is at risk of falling behind the performance achieved in comparable countries.

In view of the current pressures the immunisation system faces, and the additional pressures it is likely to face in coming years, there is a strong case for taking action now to put the system on a firmer footing. Key areas where action is needed are:

- developing a single over-arching immunisation strategy that comprehensively sets out the goals of the system, how these goals are to be met, and the roles and responsibilities of those involved in vaccine evaluation, approval and implementation;
streamlining the processes for vaccine assessment to avoid duplication of effort and to provide greater clarity of procedures for stakeholders in the system;

- improving the levels of transparency and openness in both the vaccine assessment and approval processes. While a variety of information is available in various forms and locations, processes are not ‘public’ and processes for stakeholder engagement are sometimes unclear or absent;

- ensuring that systems for funding vaccinations in Australia are adequate to allow vaccinations that have been assessed to provide medical benefits in a cost effective manner to be widely available to the Australian public. Given competing pressures for public health expenditure, and both the new vaccines that have recently become available and the considerable number that will become available in coming years, this may require alterations to the current vaccine funding model; and

- maintaining and building upon the system for the implementation of vaccines in Australia.

**Recommendations for action.**

The development of a comprehensive national immunisation strategy that sets out system goals and defines the roles and responsibilities of all those involved in the operation of the system, while a significant undertaking, would be highly desirable. However, in developing recommendations in this report we have, rather than bundling together recommendations under the broad banner of ‘comprehensive immunisation strategy development’, identified a number of discrete improvements to the existing system that, while not representing a complete immunisation strategy, could be expected to be core elements of a best practice immunisation system. Each improvement is worth introducing in its own right.

These improvements, when taken together, would bring the current immunisation system closer to demonstrating the features that would be integral to a comprehensive national immunisation strategy. Six recommendations for action are:

- **Recommendation 1:** establishment of an immunisation priorities framework
- **Recommendation 2:** clarification of the evaluation processes
- **Recommendation 3:** increased transparency of the evaluation processes
- **Recommendation 4:** increased transparency in the approval processes
- **Recommendation 5:** specification of timelines for price negotiations
- **Recommendation 6:** investigation of the potential for a hybrid public/private funding model for new vaccines to be developed

The adoption and implementation of these recommendations would provide greater long term direction to system planning, streamline processes and improve transparency within the system, thereby better positioning the Australian immunisation system to respond to the range of current and future challenges that it faces.
Chapter 1

Introduction

1.1 The Context for the Study

This study will illustrate why continued commitment to, and investment in, government led immunisation systems is needed to achieve improvements in population health. In reviewing the fundamental areas of system management, this study also presents proposals designed to improve the operation of the Australian immunisation system.

Immunisation plays an important role in the public health system in controlling and in some cases effectively eliminating infectious diseases. The public health benefits that have come from progress with the development and application of vaccines have been very large\(^1\) – the World Bank has stated that immunisation should be first among the public health initiatives in which government should invest and that vaccinations programs are the most cost-beneficial health intervention and one of the few that systematically demonstrate far more benefits than costs\(^2\). Scientific progress has meant that over time a growing range of infectious diseases can be effectively prevented in Australia.

Immunisation is a central activity of health protection and a very cost-effective illness prevention measure, protecting millions of children and adults from contracting debilitating, disabling and sometimes fatal infectious diseases.

The Australian Government along with governments in many countries have introduced and supported wide ranging immunisation programs that make vaccines aimed at preventing particular infectious diseases available for the population as a whole and, in particular, for children.

Such programs have been in place over long periods of time. As shown in Appendix A, the Commonwealth Government has operated immunisation programs in one form or another since 1916.

Since the introduction of a national immunisation program in Australia, the immunisation system has evolved through a number of stages which can be broadly characterised as four separate periods:

- The National Immunisation Program: 1997 to present.

\(^1\) These benefits are considered in Chapter 2 of this report.

\(^2\) World Bank, (1993), *Investing in Health*
The Commonwealth Government moved decisively in 1997 to introduce a National Immunisation Program aimed at reinvigorating immunisation performance to world best practice levels. This Program, which is an initiative of the Commonwealth, State and Territory Governments, now provides free vaccine to groups within the Australian community to protect against 12 vaccine-preventable diseases. The Immunise Australia Program builds on initiatives under the Childhood Immunisation Program. These include the supply of free vaccine to all providers; provider and community education programs; and the establishment of the Australian Childhood Immunisation Register (ACIR) whereby records are maintained regarding children’s immunisation status.

The Commonwealth Government contribution to the budget of the National Immunisation Program (NIP) is currently running at about $250 million per annum. The budget reflects a significant increase that occurred in 2003 with the introduction of a three year $100 million per annum Meningococcal C immunisation program.

While the introduction of the NIP has without doubt led to many improvements in the immunisation system, in recent years there have been signs that the immunisation system is coming under stress. The most visible sign of this is that some of the vaccines recommended by advisory bodies for listing the Australian Standard Vaccination Schedule (ASVS) have not as yet been funded by the Commonwealth Government. This means that the Australian public is not currently receiving wide access to some vaccines that have been assessed to effectively provide significant public health benefit. Short run cost containment considerations appear to be driving this outcome.

In many ways the challenges surrounding the immunisation system are similar in nature to those facing the system for approval and reimbursement of prescription medicines. On the one hand the research-based companies are developing a stream of new products, which are in many cases both more effective but also more expensive to develop and produce than existing drugs and vaccines. On the other hand, financing the provision of these new treatments is becoming difficult for Government in a climate of rising overall health care expenditure. This leads to pressures in a number of directions which if not carefully managed can threaten public confidence in the system as a whole, as patient access to beneficial medicines is restricted, and ultimately jeopardise its long term sustainability.

To ensure that the immunisation system in Australia is able to deal with emerging challenges, it is essential that appropriate strategies, structures and funding arrangements are in place. This report assesses current arrangements and makes a number of suggestions regarding how the immunisation system in Australia may be strengthened.

1.2 Understanding of what the immunisation system involves

The immunisation system can be thought of as comprising three main elements. They are the stakeholders, the strategy being followed by governments and the structures that are charged with giving effect to the chosen strategy.
**Stakeholders**

The immunisation system involves a number of stakeholders whose motivations and behaviours have major implications for the outcomes that are produced. The key stakeholders are:

- the Commonwealth and State/Territory Governments;
- the population at large and in particular children and their parents;
- the medical profession and other immunisation providers;
- the developers, manufacturers and suppliers of vaccines; and
- the research community.

The Commonwealth Government decides which vaccines will be made available free to the public. State and Territory Governments administer and finance the application of the vaccines in their jurisdictions. State and Territory Governments may also financially support targeted immunisation strategies particular to their own population needs.

The population at large and in particular children and parents are the main targets for the immunisation program and their participation is essential for the achievement of high rates of take up.

The medical profession and other immunisation providers are involved, through roles as organisation or expert representatives on key evaluation bodies, in the processes by which vaccines are evaluated and approved for inclusion in the program. They are also, of course, involved in the application of the vaccines to the target groups.

The suppliers of vaccines are involved in the development of new vaccines and the production of existing vaccines. With the decision of governments to vacate this function, vaccine suppliers are private companies, which to be viable in the longer term, must make an acceptable return on the capital they employ.

Finally, the research community alongside the vaccine suppliers are involved in the development of new vaccines and improving the effectiveness of existing vaccines. The research community also plays an important role in defining the role of vaccines within the Australian immunisation program.

**Immunisation Strategy**

An effective immunisation system requires that it should be driven by a long term and appropriately funded strategy, as the prevention, and where possible elimination, of infectious diseases is something that needs consistent effort over many years.

The immunisation strategy should articulate:

- the high level goals of the system;
- how these goals should be met;
- the roles and responsibilities of the bodies involved; and
- how the immunisation system is to be funded.
Immunisation Structures

There are three quite distinct steps involved in the process of getting a new vaccine listed on the Australian Standard Vaccination Schedule and put into application in the field. These involve evaluation, approval and implementation.

Evaluation of Vaccines

The three main elements involved with the evaluation of new vaccines are:

- assessment of vaccines to ensure they act in the way they are claimed to act and that they are safe for use in the population group to whom they will be administered;
- assessment of vaccines in terms of their relative medical merits, and the prioritisation of vaccines for listing on the ASVS; and
- assessment of the relative cost effectiveness of vaccines.

As discussed in Chapter 3, there is a case for having these three distinct functions, which require different skills, carried out by different bodies.

Approval of Vaccines

The three elements of the evaluation are then considered by the responsible Commonwealth Minister (the Minister for Health and Ageing).

The Ministerial role is to determine whether the recommendations for vaccine provision will receive funding to support their implementation and delivery to the relevant target groups. The Minister’s decision may also require Cabinet approval. As is discussed further in Chapter 6, whether Cabinet approval is required is dependent on the total projected cost associated with acquisition of the new vaccine.

Implementation Process

Once the decision is taken to add a vaccine to the ASVS, the remaining steps involved in getting the vaccine to the target population are:

- to acquire the vaccine from the suppliers at the best price for delivery to the authorities actually administering the vaccine; and
- to administer and monitor vaccine delivery.

These two functions may or may not be carried out by the same authorities. In Australia, responsibility for negotiation of a national price for vaccines resides with the Commonwealth while the States and Territories play a key role (including the funding of infrastructure) in administering and monitoring vaccine delivery.
1.3 Structure of this report

The report has been structured as follows.

Chapter 2 considers the role and effectiveness of immunisation within the public health system and the public policy case for government intervention.

Chapter 3 details the current Australian immunisation system.

Chapter 4 assesses Australian immunisation outcomes in an international context.

Chapter 5 considers the best practice principles and processes that should apply to immunisation systems.

Chapter 6 evaluates the current Australian immunisation system against best practice principles and proposes courses of action to ensure the Australian immunisation system reflects best practice principles and processes.

Appendix A sets out the evolution of Australian immunisation policy and practice.

Appendix B briefly sets out the immunisation systems in place in a number of comparator countries.
Chapter 2
The role of immunisation in community healthcare

Key points

Immunisation plays an important role in protecting public health.

Immunisation has proved itself to be both medically effective and cost effective in promoting public health.

Technological improvements have led to the recent development of new combination, conjugated and live viral vaccines that allow for the simplification of immunisation schedules, improved safety and for control of diseases for which there was previously no preventative therapy. It is important that the Australia population has wide access to such improved vaccines if public health is to be maximised.

As the wide range of new vaccines currently under development become available, the role of immunisation in the future is likely to broaden from its traditional focus on providing population wide protection against infectious diseases.

Several of the new vaccines under investigation represent a different paradigm for vaccination. Therapeutic vaccines, which could be used to combat various forms of cancer, certain allergies or chronic viral diseases are currently being researched. The new paradigm is that the vaccine helps the body to fight a disease already present.

The higher number of new vaccines that will be available and the higher costs associated with these new vaccines will place pressures upon the system for vaccine evaluation, approval, reimbursement and acquisition.

2.1 Introduction: defining public health objectives

Public health, broadly defined, describes the infrastructure, education, research initiatives and policy interventions employed by a community to protect its collective health and wellbeing. Whereas curative care focuses on restoring health, public health practice includes preventative care, and therefore focuses on the ex ante protection and improvement of community wellness through long term investments in health outcomes.
As one of a broad range of vertical activities linked by the common goal of preserving and improving the health of the population, immunisation programs constitute a vital part of Australia’s co-ordinated strategy to ensure the wellbeing of its population. Figure 2.1 locates immunisation practice within the domain of public health, through its traditional role in protecting against communicable diseases, as defined by the members of the National Public Health Partnership, an organisation co-ordinating the infrastructures and strategies of Commonwealth, State and Territory governments for the purpose of maximising health outcomes within Australia. In the future, as vaccines targeting a range of non-communicable diseases become available, immunisation will also play a role in other areas of public health.

![Figure 2.1: HOUSE OF PUBLIC HEALTH](image)

When these domains are united in their approach, the wellness of the community is maximised. Thus a properly conceived immunisation program is a core component of Commonwealth, State and Territory governments’ long term investment in health of Australian communities.

### 2.4 The benefits of a strong immunisation system

As immunisation has become a routine part of Australian healthcare practices, the benefits and risks of vaccination are often taken for granted.

To better understand the role of immunisation practices within the context of broader public health objectives, this section highlights the benefits and potential costs of immunisation against common vaccine-preventable diseases. Specifically this section will show the benefits to be four-fold:

- direct defence against disease for vaccinated persons;¹

¹ Vaccinations do not provide 100 per cent protection against disease. There still exists a reduced chance that in the event of an outbreak a vaccinated person may contract the disease, although this risk is dramatically reduced by immunisation practice.
• positive externalities manifest in reduced risk of disease contraction by non-vaccinated members of the community (‘herd immunity’);

• increased fiscal sustainability of healthcare programs through the prevention of illness and epidemics; and

• continued economic growth through increased labour participation rates.

Chief benefit of immunisation: community wellness

Immunisation is one of the key foundation for the healthy society that Australians enjoy today. According to the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS), prior to the introduction of vaccines:

• Polio claimed an average of 68 Australian lives per year, leaving hundreds more paralysed.

• Rubella (German Measles), which can result in birth defects and mental retardation in newborns, was contracted by Australians at rates within the range of 15 to 85 persons per 100 000 between 1950 and the commencement of the use of this vaccine in Australia.

• Measles killed an average of 63 people per year.

• Diphtheria was one of the most common causes of death in school aged children, resulting in the deaths of 407 Australians per year.

• A bacterium called *Haemophilus influenzae* type b (Hib), which causes meningitis and epiglottitis, resulted in the hospitalisation of thousands of Australian children, leaving many with permanent brain damage.

• Pertussis (whooping cough) killed thousands of infants.

Vaccination programs have reduced, and in some cases, eradicated many diseases that killed or severely disabled individuals only a few generations ago.

Since the introduction of childhood vaccination for diphtheria in 1932 – and the widespread use of vaccines to prevent tetanus, pertussis, and poliomyelitis in the 1950s, and measles, mumps and rubella in the 1960s – deaths in Australia from these vaccine preventable diseases have declined by more than 99 per cent, despite the Australian population increasing 2.8-fold.


The dramatic success of immunisation programs is due in part to the lack of cures for these diseases. This is true for many diseases currently vaccinated against in Australia: polio, rubella, measles, mumps, and hepatitis A.

However, as noted by Professor Margaret Burgess, Director of the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS), not only do vaccines prevent diseases for which there are no cures, they have also become critically important in the protection against diseases that are becoming increasingly resistant to treatment:

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"In contrast to those diseases for which there are specific therapeutic agents – such as antibiotics, antivirals, or antihypertensives – many vaccine preventable diseases (VPDs), especially those caused by viruses (for example: poliomyelitis, measles, mumps, rubella and hep A) have no specific drug management. Even where specific therapy is available, the emergence of drug-resistant strains of some organisms (for example, Hib and pneumococcal infection) is a growing problem. Therefore, prevention is especially important.”

Prof Margaret Burgess. NSW Public Health Bulletin, Volume 14, Nos 1-2 Jan – Feb 2003

The benefits realised from immunisation practices – manifest in the fall of the incidence of disease outbreaks – are a function of two factors:

- the direct protection vaccination provides to individuals who are immunised; and
- the indirect “herd immunity” provided to non-vaccinated persons within the community.

Because immunising a person slows the transmission of the disease, it mitigates the spread of the virus or bacterium, thereby protecting the health of non-vaccinated persons. Thus, high vaccination coverage levels confer significant positive externalities to the community by fostering reduced rates of disease in unvaccinated populations. Box 2.1 presents evidence on the positive externalities of vaccinations as observed in the UK in 1999.

Box 2.1

**EVIDENCE OF POSITIVE EXTERNALITIES: MENINGOCOCCAL C VACCINATION IN ENGLAND AND WALES, 1999**

In November 1999 the first meningococcal C vaccination was introduced in the UK following an increase in both laboratory-confirmed and clinical notifications of the disease in the mid-1990s.

Carriage studies conducted before and after the introduction of the vaccination to target UK populations, found the prevalence of serogroup C carriage in non-vaccinated UK teenagers was 66 per cent lower one year after the introduction of the Meningococcal C Vaccine. Furthermore the attack rate of the disease in unvaccinated populations also fell: the attack rate in 2001-02 was 67 per cent lower in than had been seen in 1998-99.


This makes immunisation one of the most equitable and cost-effective medical treatments available: the cost of immunising one person provides benefits to the whole community. Box 2.2 provides a salient example of where the introduction of a government-subsidised vaccine has resulted in the dramatic reduction of disease incidence: the introduction of the Hib vaccine to Australian communities in 1993.

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5 An externality describes the case where consumption by one person affects others in the community. Externalities can be either positive or negative. The important point is that there is a divergence between private and social outcomes of particular activities.
Box 2.2
PUBLIC HEALTH SIGNIFICANCE: IMMUNISATION SUCCESSES IN AUSTRALIA

Since the introduction of Hib vaccines, there has been a material reduction in the number of invasive cases of Hib throughout Australia, as illustrated in the graph below.

- Prior to the introduction of vaccine, Hib infections were the most common serious invasive bacterial infections in children.
- Aboriginal children are at a five to six times greater risk of developing Hib disease, as they tended to acquire the disease at a much younger age than other children.
- Immune-suppressed individuals of any age are also at risk of Hib infection.

![Graph showing reduction in Hib notifications](image)

Source: Sustaining National Immunisation Programs, Commonwealth Department of Health and Ageing.

Box 2.2 provides additional evidence that the targeting of high risk groups – such as children, especially Aboriginal and Torres Strait Islander children – has fostered the decline in disease incidence for the whole community, including immune suppressed individuals who may not have received the vaccination.

**Evidence on derivative economic benefits of immunisation**

In addition to the health benefits derived from immunisation practices, immunisation also contributes economic benefits.

While data-based evidence is limited, it has been convincingly argued that economic productivity and growth is linked to the health of a country’s workforce. A study conducted by the Health and Development Satellite of the World Health Organization (WHO)\(^6\), which examined 53 countries from 1965 to 1990, suggested that increased adult survival rates had accounted on average for eight per cent of economic growth realised by those nations in that time period.

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According to the report, the economic growth derived from increased life expectancies was characterised as a function of the following key factors:

- increasing workforce participation rates;
- strengthening of incentives to invest in human and physical capital per capita workforce participation increases; and
- increasing savings rates by individuals for retirement purposes.\(^7\)

This argument is echoed by the World Bank\(^8\) and the Global Alliance for Vaccines and Immunisation whose studies of low- and middle-income countries showed that improved population health contributes to economic growth in four ways:

- it reduces productivity losses caused by worker illness and absence;
- it enables the increased utilization of natural resources;\(^9\)
- it increases enrolment of children in school and makes them better able to learn; and
- it frees for alternative uses resources that would otherwise have to be spent on treating illness.

Therefore, although the primary objective of public health immunisation strategies is to improve the health of Australian communities, it can also be justified on economic grounds. Through the prevention of epidemics, the Commonwealth, State and Territory governments are able to maximise economic productivity and national income growth by preventing a reduction in Australia’s workforce, and by saving or re-allocating resources that, in the event of an outbreak, would have otherwise been spent on the costs of curative care.

**Fiscal benefits arising from immunisation practices**

The monetary returns from disease prevention are not measured in national income growth alone; investments that reduce the incidence of vaccine preventable disease can produce big savings in *ex post* treatment costs.

While again, limited data-based evidence is available on the monetary returns to government through the prevention of disease, Box 2.3 highlights the savings in curative medical treatments measures following the recent introduction of the polio vaccinations to Latin American countries.

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\(^9\) The World Bank has cited the use of land in Sri Lanka and Africa where immunisations against malaria and onchocerciasis (river blindness) allowed persons to farm more land. An economic benefit of this nature is unique to developing countries.
For some diseases the expenditure pays for itself even when all the indirect benefits – such as higher labour productivity and reduced pain and suffering – are ignored. Polio is one example.

Calculations for the Americas made prior to the eradication of polio in the region showed that investing US$220 million over fifteen years to eliminate the disease would prevent 220,000 cases and save between US$320 million and US$1.3 billion (depending upon the number of people treated) in annual treatment costs.

The program’s net return to the government, after discounting at 12 per cent per year, was calculated to be between US$18 million and US$480 million.


It may seem *prima facie* that investments in vaccination made by Australians today are unnecessary due to the absence or low occurrence of vaccine-preventable diseases among its populations. However, many of these vaccine-preventable diseases have not been eradicated outside Australia’s borders and therefore remain a threat. Until vaccine preventable diseases are eradicated worldwide, immunisation practices continue to promote the financial sustainability of Australia’s healthcare system by protecting against the outbreak of imported disease. This in turn saves the Commonwealth significant resources that would otherwise be spent on curative care.

The savings returned to Australia’s healthcare system from vaccination programs have become increasingly important in the last 20 years. Reports by the OECD have shown that the costs of curative care have accelerated for most of its member countries, often at a rate exceeding that of national income growth.

Spending on health care is outpacing economic growth in most OECD countries, forcing governments to find new funds or to pass a larger share of the costs onto individuals. In 2000 and 2001, health spending increased by 4% per year in real terms on average across OECD countries, while real GDP growth averaged just 2.3% per year. This gap led to a further rise in health spending as a share of GDP, reaching 8.4% on average in 2001, up from 7.3% in 1990 and just over 5% in 1970.

OECD, Health at a Glance 2003 - OECD Countries Struggle with Rising Demand for Health Spending

Australia has been no exception. According to the Australian Institute of Health and Welfare (AIHW), health expenditure grew from $692 million in 1960-61 to $66,582 million in 2001-02. This means that health expenditure in Australia as a proportion of GDP has more than doubled over the last four decades, from 4.2% in 1960-61 to 9.3% in 2001-02.

A key factor in the rise in healthcare costs has been the increasing cost of institutional health care costs, especially hospital expenditure by the Commonwealth. Figure 2.2 illustrates the rising expenditure by Australian governments on hospital costs, pharmaceutical treatments and other medical services as reported by the AIHW, which have risen at nominal average annual growth rates of 9.0, 12.8 and 8.6 per cent, respectively – compared with an average annual nominal growth rate of 5.8 per cent in national income over the same period.
Compared to treatment costs, immunisation costs have remained relatively steady, jumping only in 2003-04 with the added cost of the Meningococcal C vaccine, which will provide a catch-up vaccine to every cohort born since 1984 (all children 0 – 19 years of age are eligible for the Meningococcal C vaccine as of 2003). While data on immunisation expenditure from 2000-01 was unavailable at the time of this report, Table 2.1 shows that immunisation expenditure prior to the Meningococcal C vaccine amounted to $183 million in 1998-99 and $153 million in 1999-00, or about 18 per cent of all public and community expenditure.
Table 2.1

NATIONAL EXPENDITURE ON CORE PUBLIC HEALTH CATEGORIES, 1998-99 AND 1999-00

<table>
<thead>
<tr>
<th>Public Health Program</th>
<th>$m in 1998-99</th>
<th>% of 1998-99 Total</th>
<th>$m in 1999-00</th>
<th>% of 1999-00 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Health</td>
<td>$71.7</td>
<td>8.1%</td>
<td>$61.4</td>
<td>6.6%</td>
</tr>
<tr>
<td>Immunisation</td>
<td>183.0</td>
<td>20.6</td>
<td>153.3</td>
<td>16.5</td>
</tr>
<tr>
<td>Other Communicable Disease Control</td>
<td>149.4</td>
<td>16.8</td>
<td>153.5</td>
<td>16.5</td>
</tr>
<tr>
<td>Health Promotion Measures</td>
<td>187.7</td>
<td>21.1</td>
<td>166.0</td>
<td>17.8</td>
</tr>
<tr>
<td>Food Standards and hygiene</td>
<td>22.4</td>
<td>2.5</td>
<td>25.1</td>
<td>2.7</td>
</tr>
<tr>
<td>Breast Cancer Screening</td>
<td>90.8</td>
<td>10.2</td>
<td>97.2</td>
<td>10.4</td>
</tr>
<tr>
<td>Cervical Cancer Screening</td>
<td>80.9</td>
<td>9.1</td>
<td>80.9</td>
<td>8.7</td>
</tr>
<tr>
<td>Research (Commonwealth only)</td>
<td>17.0</td>
<td>1.9</td>
<td>70.3</td>
<td>7.5</td>
</tr>
<tr>
<td>Other Expenditure</td>
<td>85.3</td>
<td>9.6</td>
<td>123.5</td>
<td>13.2</td>
</tr>
<tr>
<td>Total Expenditure</td>
<td>888.2</td>
<td>100.0</td>
<td>931.2</td>
<td>100.0</td>
</tr>
</tbody>
</table>


With costs associated with curative care increasing rapidly, the benefits of maintaining strong immunisation outcomes increases, as each incidence of disease that is prevented represents a higher fiscal saving on curative care costs that would otherwise be incurred.

In the absence of a strong immunisation system, the costs of treating persons who have contracted a vaccine preventable disease, many of whom would require hospitalisation and even possible longer term medical care needs, would apply significant pressure to the already considerable Commonwealth healthcare budget.

**Australian case studies highlighting the cost effectiveness of immunisation programs**

A report completed in 2003 for the Department of Health and Ageing (DoHA) included two brief case studies, which examined the cost-effectiveness of two components of the current NIP, namely:

- vaccination against measles, introduced in 1970; and
- vaccination against Hib, introduced in 1993.

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Compared to curative care, immunisation strategies in both cases have been shown to be highly cost effective methods of intervention. Both the measles and the Hib vaccination programs were found to have net present values that were positive and significant.

The measles immunisation program, which protects against a highly infectious disease, was shown to have delivered net benefits of between (depending on discount rates used) $6.8 billion and $12.6 billion (in mid-1990s dollars).

The Hib immunisation program, which protects against a less infectious disease, was shown to have delivered net benefits of between (depending on discount rates used) $7.4 million and $11.3 million (in mid-1990s dollars).

2.5 Economic argument for immunisation policy intervention

Given the cost-effectiveness and significance of immunisation practices for protecting and improving the overall health and wellbeing of communities within Australia, it is important to consider whether the private market would sufficiently immunise the population in the absence of government intervention. It is clear that if the operation of the private market resulted in optimal vaccination outcomes there would be no need for government intervention in the system. However, as this section will show, due to the presence of market failure, this is not the case.

**Market failure resulting in private under-investment in vaccinations**

Immunisation, as a public health intervention strategy, is an investment in the future health of a population. As already shown, it provides direct benefits to the individuals who are immunised as well as positive externalities to the broader community, whose total risk of contracting avoidable disease is reduced as fewer people are able to transmit the disease.

Thus, a highly immunised society is itself a public good. A public good is marked by two key characteristics:

- It is non-rivalrous, which means that it does not exhibit scarcity. In other words, one person’s use of a disease-free community does not leave less for others to consume.
- It is non-excludable, which means that once the good has been created, it is impossible to prevent certain populations from enjoying the benefits of disease eradication.

Because individuals, when overall rates of immunisation coverage are high, can take advantage of a disease-free society without contributing to its creation, private individuals will under-invest in vaccinations.

This is a satisfactory outcome if the disease has been controlled on a global scale: where a disease has been eradicated, vaccinations are no longer a necessary investment, and the market will unilaterally invest in a satisfactory level of immunisation in that no resources will be allocated to vaccinations against a controlled disease.
However, where a vaccine-preventable disease has not been controlled, there persists the possibility of a future outbreak – even if the risk of contracting the disease within the community is perceived to be zero. Because the disease appears to be eradicated, rational actors within the private market will fail to vaccinate themselves and reallocate resources to other activities.

As more individuals fail to be vaccinated, the risk to the community of an epidemic increases. Government intervention therefore becomes critical to ensure sufficient investment in immunisation and the continued protection of the community against potential illnesses and epidemics. This made clear by Professor Margaret Burgess, Director of the NCIRS:

While many Vaccine Preventable Diseases (VPDs) such as diphtheria, tetanus, and poliomyelitis, are presently controlled by vaccination and are no longer feared by the Australian community, experience overseas has shown that these VPDs can re-emerge if vaccination rates are not maintained. This happened in the newly-independent states of the former Soviet Republic when, between 1990 and 1997, over 150,000 cases of diphtheria occurred and caused more than 5,000 deaths.

Professor Margaret Burgess, NCIRS

Where private markets contribute too little to the creation and sustainment of the public good, as is the case for an immunised society, government intervention is necessary to increase the supply of the good. While Australia continues to control vaccine preventable diseases with high vaccination rates, the risk of future outbreaks and epidemics due to imported diseases – such as wild polio, which continue to affect Africa and parts of Asia – remains remote.

Within Australia, the NIP, which provides for the full-subsidization of most ASVS-listed vaccinations, represents Australia’s method for correcting market failure and enhancing social outcomes. Given the market dynamics of immunisation, it is essential that the NIP remains a core component of the Commonwealth’s strategy for maximising public health outcomes.

2.6 The future role of immunisation in health care

Traditionally, the role of immunisation in health care has been for the population wide prevention of infectious disease. While this role will continue in the future, the role of immunisation is likely to broaden in coming years as a result of the development of new vaccines.

A wide range of new vaccines are now being developed, including:

- varied vaccines against *Neiserria meningitidis* serotypes B and C (bacterial meningitis);
- *Streptococcus pneumoniae* (which causes otitis media, pneumonia, meningitis, septicemia), rotavirus (infant diarrhoea);
- the Epstein-Barr virus (mononucleosis);
- the human papilloma virus (cervical cancer);
- the respiratory syncitial virus (major respiratory infection in new-borns and elderly);

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• Influenza virus (new vaccine with enhanced effectiveness);
• Malaria; and
• AIDS

New immunological vaccine adjuvants are also being studied, designed to induce quicker, stronger and more effective immune response. In some cases they also provide certain types of protective immunity that cannot be obtained using current immunisation methods.

New ways of administering vaccines particularly through the nose or skin are also being studied. These will cause less discomfort and thus encourage disease prevention through vaccination. In some cases they could also produce more effective immune responses.

Technological improvements have already led to the development of new combination, conjugated and live viral vaccines that allow for:

• simplification of the immunisation schedule (through the use of combination vaccines), which promotes higher coverage rates by removing the risk that parents will delay vaccinations in order to avoid having multiple injections on the same day;
• improved safety by reducing the risk of adverse effects from vaccines (see for example the lower risks associated with the inactivated poliomyelitis vaccine in combination versus the currently Government funded oral polio vaccination); and
• control other diseases for which there has previously been no preventative therapy (such as varicella).

The development of such improved, but more expensive, vaccines presents a significant challenge for existing vaccine assessment, approval and funding processes. It is important that the Australia population has wide access to such improved vaccines if public health is to be maximised.

Several of the new vaccines now under investigation represent a different paradigm for vaccination from its traditional role in the prevention of infectious diseases. Therapeutic vaccines, which could be used to combat various forms of cancer, certain allergies or chronic viral diseases are currently being researched. The new paradigm is that the vaccine helps the body to fight a disease already present.

While such vaccines will not need to be administered in childhood to the entire population, the higher number of targeted vaccines that will be available and the higher costs associated with these new vaccines will place pressures upon the system for vaccine evaluation, approval and acquisition.
Chapter 3

Current Australian Immunisation System

Key points
The current system for immunisation in Australia has been shaped by the reforms introduced in 1997 with the introduction of the National Immunisation Program.

The Australian immunisation system involves the participation of multiple Commonwealth and State and Territory Government organisations, industry suppliers of vaccines and public and private sector immunisation providers.

Vaccine regulation, evaluation, approval and funding are carried out at the Commonwealth level, while vaccine delivery and monitoring involve both Commonwealth and State and Territory activity. Vaccines are developed, manufactured and supplied by industry.

3.1 Introduction

The first vaccine used in Australia, the smallpox vaccine, was introduced in 1804. As shown in Appendix A, the Commonwealth Government has operated immunisation programs in one form or another since 1916. Vaccinations have since become a routine practice within Australia and a vital component of the government’s strategy for protecting the health and welfare of Australians.

Australia’s experience with immunisation strategy can be broadly categorised into four periods, distinguished by either disparate policy approaches or funding arrangements:

- **Emerging Immunisation Practice: 1916 – 1988.** In this period, the Commonwealth funded all childhood vaccines, which contributed to the creation of a small vaccination industry and similarly fostered the emergence of a modest private market for vaccines.

- **Fragmented Delivery: 1988 – 1993.** In 1988, the Commonwealth withdrew its direct funding of vaccinations, shifting to a system of vaccine funding based on several grant arrangements with the States and Territories. As a result, wide variations in program implementation emerged between State and Territories, as well as wide variations in the prices paid for vaccines by different jurisdictions, with smaller States and Territories paying significantly higher prices. According to a 1993 report by the National Health and Medical Research Council (NHMRC), this system led to both a decline in immunisation rates and a rise in vaccine-preventable disease outbreaks.

- **Towards a National Approach: 1993 – 1997.** On the advice of the NHMRC, Australia returned to a top-down, national immunisation strategy, defined by indexed-pricing structures and a uniform system of vaccine service delivery. The success of this national strategy was manifest in the rebound of immunisation coverage rates and concomitant the fall in Hib notification rates.
The National Immunisation Program: 1997 to present. Building on the lessons of the 1988 policy failure and the successes the 1993 policy shift, a National Immunisation Program (Immunise Australia or NIP) was instituted under Health Minister Michael Wooldridge. Key features of the 1997 NIP included the Seven Point Plan for increasing vaccination coverage rates and the introduction of an advisory group, the Australian Technical Advisory Group on Immunisation (ATAGI) to assess the benefits to Australia of vaccine adoption to the ASVS.

The 1997 NIP remains Australia’s current program for controlling vaccine preventable disease. To better understand the strengths and limitations of the current system, this chapter aims to outline:

- key features of the NIP as a program for reducing the occurrence of vaccine-preventable disease outbreaks to acceptable levels (Section 3.2); and
- the relevant bodies and processes involved in the approval and funding of vaccines going forward (Section 3.3).

3.2 Australia’s current immunisation program: the NIP

Australia’s NIP is a publicly-funded program designed to co-ordinate, via a Commonwealth policy framework, vaccine pricing by the Commonwealth and immunisation practices designed at the state, territory and local levels. As a nationally integrated approach, the responsibilities of each government body coordinating on the NIP have been defined within a composite set of national program plans, inter-governmental agreements and local management plans related to immunisation and communicable disease control.

Conceived in 1997, the NIP introduced two new features to the Australian immunisation system: the establishment of an advisory body for the technical assessment of a new vaccine’s benefits and costs, and the Seven Point Plan initiatives for improving coverage rates and their surveillance.

The Australian Technical Advisory Group on Immunisation (ATAGI)

A critical initiative of the new NIP was the creation of an advisory body to the Health Minister to provide technical evaluations of the medical benefits of vaccines, as well as a consideration of the costs of the vaccine in light of these potential benefits. This group, which continues to fulfil this function within the NIP today, is ATAGI.

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12 It should be noted, however, that a number of additions to the program have occurred since 1997 – for instance the Q Fever Management Program, Pneumococcal Vaccination Program for children, the Young Adult MMR Program and the Meningococcal C Vaccination Program have all been introduced since 1997.
The rationale for the creation of ATAGI was that before a new vaccine is included in the Commonwealth funded NIP, independent expert assessment should first be made of whether the disease in question is a public health problem or risk and, if it is, whether immunisation is the most practical and effective way of controlling it. Second, the overall costs of introducing the vaccine and maintaining high immunisation coverage should be assessed against the benefits attained through adequate disease control. To determine the relative merit and priority of a vaccine, it was required that a national mechanism for technical advice on the medical and affordability impacts of a new vaccine be created – ATAGI was established to fill this role within the NIP.

Thus, for a vaccine to be included on the ASVS it must be recommended by ATAGI and subsequently endorsed by the NHMRC. Since its establishment, ATAGI recommendations have informed the development and implementation of every technical change to the ASVS and the NIP.

Box 3.1 presents ATAGI’s terms of reference, which were renewed in 2000.

Box 3.4

**ATAGI’S ROLE WITHIN THE NIP**

<table>
<thead>
<tr>
<th>The ATAGI’s current terms of reference were updated in early 2000. Its primary role is to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• provide advice to the Minister for the Department of Health and Ageing (DoHA) on technical issues relating to the NIP and other related issues.</td>
</tr>
<tr>
<td>• operate co-operatively with the NHMRC’s Health Advisory committee to:</td>
</tr>
<tr>
<td>o provide technical advice to the NHMRC on issues related to immunisation as required, and</td>
</tr>
<tr>
<td>o enable NHMRC endorsement of key documents, such as the ASVS;</td>
</tr>
<tr>
<td>o consider vaccines likely to be approved in Australia [by the Therapeutic Goods Administration (TGA)] and provide advice on their use and to consider the burden of disease issues related to immunisation;</td>
</tr>
<tr>
<td>• liaise with the National Immunisation Committee (NIC), the Communicable Diseases Network Australia and the Australian Drug Evaluation Committee on matters related to the implementation of immunisation policies and procedures;</td>
</tr>
<tr>
<td>• liaise with the TGA and the DoHA’s Pharmaceutical Benefits Branch on matters relative to the availability and cost-effectiveness of vaccines intended for inclusion on the ASVS;</td>
</tr>
<tr>
<td>• liaise with the NCIRS on immunisation and related burden of disease issues; and</td>
</tr>
<tr>
<td>• provide advice to DoHA on immunisation policy including funding.</td>
</tr>
</tbody>
</table>


**The Seven Point Plan**

The second element of the NIP approved by Cabinet in 1997 was the Seven Point Plan, the objective of which was to increase vaccination coverage rates within Australia. The seven components of the plan (outlined in greater depth in Box 3.2) consisted of:

• initiatives targeting parents;
• an expanded role for General Practitioners;
• national monitoring, reporting and evaluation of immunisation targets;
IMMUNISATION IN AUSTRALIA: SUSTAINING THE AUSTRALIAN IMMUNISATION SYSTEM

- a series of ‘immunisation days’;
- progressing measles eradication;
- strengthening immunisation related education and research; and
- progressing uniform national school entry requirements.

Box 3.2
THE SEVEN-POINT PLAN

Initiatives for Parents
- The first initiative directed towards parents was the restructuring of the federally funded Maternity Allowance to provide a bonus for parents for ensuring that their child’s immunisation coverage is complete. An additional $68 was provided to parents, increasing the Maternity Allowance from approximately $882 to $950 per eligible child. There were provisions for parents who could not have their children immunised due to medical contraindications or who chose not to have their child vaccinated due to conscientious objection.
- The second initiative directed towards parents was related to childcare rebates. On 27 April 1998, families applying for Childcare Assistance and Childcare Cash Rebate were required to demonstrate that their child was appropriately immunised for age according to the ASVS. Provisions were also made for parents who do not have their children immunised due to medical contraindications or conscientious objection to claim exemption from this requirement.

An expanded role for General Practitioners
- The General Practice Immunisation Incentives Scheme was introduced on 1 July 1998 to provide financial incentives to general practitioners to monitor, as well as to promote and provide age appropriate immunisation services to children under the age of seven years. The aim for the scheme was to achieve 90 percent of GP practices achieving 90 percent immunisation coverage nationally.

Monitoring, reporting and evaluation of immunisation coverage
- With the operationalisation of the ACIR (1993) and the advancement of state and territory initiatives to collect immunisation data, an agreement was made between government health services and immunisation providers to regularly release and report on immunisation rates at a national, state and territory level.

Immunisation Days
- The Commonwealth, in conjunction with the States and Territories piloted a series of immunisation days to increase immunisation coverage rates in geographical areas of low immunisation coverage on 2 August, 4 October and 6 December 1997.

Measles Eradication
- Following success in progress toward poliomyelitis eradication efforts domestically and abroad, a national strategy for measles eradication within Australia was developed. The strategy encompassed four components:
  - long-term, high vaccination coverage – with a two-dose strategy;
  - an effective vaccination coverage monitoring system;
  - enhanced measles case-based surveillance, including urgent notification and confirmation of disease; and
  - a comprehensive rapid response strategy to every measles case.
- In addition to the primary school campaign, efforts at improving measles vaccination in the pre-school age group via General Practitioner services were also undertaken.

Education, Promotion and Research
- A major community education campaign was conducted in 1997, which included television and print media advertising, particularly focusing on the need for whooping cough and measles vaccination. Priority was also given to cultural and linguistically diverse communities.
- A specific strategy for providing campaign information and supporting technical resources to General Practitioners and other immunisation providers was also undertaken.
- To progress a co-ordinated approach to national surveillance and research, the Commonwealth established the National Centre for Immunisation Research and Surveillance (NCIRS).

School Entry Requirements
- The Commonwealth in conjunction with State and Territory Governments developed a model school entry legislation framework to aid states and territories implement such requirements within their jurisdictions. The aim of the legislation is to ensure recording of a child's immunisation history at the time of school enrolment. Provisions exist for school exclusion of non-vaccinated students in the event of an outbreak of a vaccine preventable disease. Legislation has been enacted in New South Wales, Victoria, Tasmania and the Australian...
As a result of Australia’s integrated, national program for immunisation, it has (as discussed in detail in Chapter 4) realised high vaccination coverage rates and disease control for most significant vaccine-preventable diseases.

3.3 The structure of the NIP: key components and processes

This Section considers the basic elements of the NIP system:

- vaccine assessment and recommendation;
- funding approval; and
- vaccine pricing and implementation and delivery arrangements.

**Vaccine assessment and recommendations**

For a vaccine to be listed on the ASVS, the vaccine must be recommended by ATAGI and subsequently endorsed by the NHMRC. Thus, the onus of vaccine assessment and recommendation rests with ATAGI.

However, ATAGI does not perform these functions in isolation. To assess a vaccine, it engages a wide range of stakeholders, in both medical and political spheres, which enables the group to compare the health benefits against the costs of a vaccine. As can be seen in Figure 3.1, the relevant stakeholders for ATAGI consultations include the NCIRS and medical practitioners, as well as the National Immunisation Committee (NIC), which is an intergovernmental management group consisting of NIP managers from each State and Territory and representatives from General Practice and Aboriginal and Torres Strait Islander health authorities.
Once ATAGI has consulted the appropriate stakeholders, it recommends the vaccine for listing on the ASVS. The NHMRC may reject ATAGI’s recommendations, however, by and large, the great majority of ATAGI recommendations are endorsed by the NHMRC and adopted as ‘best practice’ within the ASVS.

This process is not unique to Australia. Today most developed countries have a defined process for reaching a recommendation for adding vaccines to the list of routine vaccines used in national programs.

Considering international approaches to the technical and cost-effectiveness assessments, this review found that many countries with comparable vaccination coverage rates had an advisory group and consultative process similar to the Australian system:

- Canada has a similar federal-based governance system comprising a National Advisory Committee on Immunization (NACI), which, in conjunction with the Governmental Centre for Infectious Disease Prevention and Control, advises on the use and target populations for existing or emerging vaccines. Unlike Australia, however, the NACI also governs vaccine assessment and surveillance for coverage and adverse events.
In similar form to Australia, the United States has an advisory group called the Advisory Committee on Immunization Practices (ACIP). The ACIP provides advice on vaccine preventable disease to the Secretary of the US Department of Health and Human Services and to the Centres for Disease Control and Prevention (CDC). The ACIP’s functions are to provide advice and guidance regarding the applications of vaccine antigens for effective disease control, to review and report on practices, to recommend improvements for the immunisation program and to establish and review the list of vaccines made eligible to children under the Vaccines for Children Program.

New Zealand has an analogous advisory board within its own Department for Health. Separate from the other tasks related to immunisation taken on by the Ministry of Health, New Zealand’s Health Ministry relies on the Immunisation Programme Advisory Committee for advice on its National Immunisation Schedule.

**Funding approval**

While listing on the ASVS is necessary to receive full funding by the Commonwealth, it is not sufficient to ensure full funding of the vaccine by the Commonwealth. The current system makes vaccine funding conditional on the final approval of the Health Minister. In other words, whilst both ATAGI and the NHMRC recommend that “NHMRC-recommended childhood vaccines are offered free, without cost to parent or guardian,” there has never been a defined policy by the Australian Government stating that all recommended vaccines would be automatically and immediately funded.

To illustrate, vaccines currently recommended but not funded for children include:

- inactivated poliomyelitis vaccine (IPV) in combination for all children at age 2 months, 4 months, 6 months, 4 years;
- varicella-zoster vaccine (VZV) for all children at age 18 months and selected adolescents; and
- 7-valent pneumococcal conjugate vaccine (7vPCV) for all Australian infants at age 2 months, 4 months, 6 months.

Australia is, again, not unique in the selective funding of recommended vaccines. Full funding of recommended vaccines occurs in the majority of countries reviewed. However, there are examples – including Canada and the United States – where full subsidisation of recommended vaccines or cohorts do not occur:

- Health care funding in Canada is primarily a provincial or territorial responsibility. Federal support for vaccine funding is subsumed under ‘general health care funding’ and has been limited to:
  - regulating vaccine licensure/release;

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14 IPV is preferred to OPV, subject to the availability of IPV-containing combination vaccines. Both IPV and OPV are acceptable for use in the ASVS.
15 Children with a negative history of varicella disease or vaccination.
16 Access to free 7vPCV is provided to all Aboriginal and Torres Strait Islander children aged to 2 years, Aboriginal children in central Australia aged to 5 years, non-Indigenous children in central Australia aged to 2 years, and all children under 5 years with medical risk factors that predispose them to high rates or severity of pneumococcal infection.
- supporting the National Advisory Committee on Immunization; and
- maintaining a small staff and budget to assist Provinces and territories in coordinating activities.

Canadian guidelines have not been supported by a central national pool of funds for all elements. While vaccination for nine diseases – which can be carried out by either public or private providers – is funded in all Canadian provinces, the provision of newer recommended vaccines (meningococcal C conjugate vaccine, conjugate pneumococcal vaccine, varicella vaccine, and adolescent pertussis vaccine) have not been federally funded. As a result, there is high variation in the provision of these vaccines across different jurisdictions.

- The Vaccines for Children (VFC) program was established in the United States in 1994 and provides vaccines for children who qualify at no charge. The criteria for eligibility to the program are:
  - the child must be eligible for Medicaid;
  - the child must lack health insurance; or
  - the child is a native American or Alaskan native.

An additional criterion is that the child is under-insured for immunisations, however those in this category can only receive through a federally funded health centre or rural health centre. The VFC program purchases vaccines for approximately 35 per cent of the national cohort, at a cost of more than US$500 million per annum (2000 data). In total, just over 50 per cent of all childhood vaccines in the US are purchased in the public sector.

By contrast, immunisation strategies in the UK and New Zealand provide for the full funding of all recommended vaccines. In the United Kingdom the National Health Service Purchase and Supply Agency undertake the procurement of centrally funded vaccines on behalf of the Department of Health, and in New Zealand the Institute of Environmental Science and Research operates a national vaccine store.

Thus, there exists a high degree of variance in the approach to vaccine funding by comparable nations, with Australia aligned with the policy approaches of Canada and the US, who hold funding conditional on Federal government approval.

With the absence of a commitment to fund the latest NHMRC recommended vaccines, the Australian system for vaccine funding is experiencing a shift. It is yet to be ascertained whether this reflects a planned move away from Government commitment to a universal and comprehensive vaccination program, particularly for children, towards a more fragmented system where some vaccines are publicly funded while parents are encouraged to self-fund new ‘best practice’ vaccines. If financial considerations are leading to such a change, this must be made clear to all stakeholders – providers, parents and industry – in the system. If such a change is not being made, the Government should clarify the situation by recommitting to availing ‘best practice’ vaccines to all Australians.
In Australia, the Health Minister provides the final approval for vaccine funding (in some cases Cabinet approval is also required) after consultations with Ministerial policy advisors, who in turn liaise with ATAGI, the NHMRC, the Immunisation Section (DoHA), the Pharmaceutical Evaluation Section (PES)(DoHA) and the NIC. If on the basis of technical and policy consultations the Commonwealth decides to fund a vaccine as part of the NIP, a national price is negotiated at the Commonwealth level and States and Territories then conduct a tender process for vaccine supply. The Commonwealth funds on the basis of expected cohort levels – and in some special cases, such as the meningococcal type C vaccine introduced in 2003, a ‘catch-up’ vaccination can be funded that covers all cohorts born within a specific time period.

Figure 3.2 shows the relationships between key information sources in the process that is used to assess the technical and affordability aspects of a vaccine, including the decision makers charged with providing the final approval for Commonwealth funding of approved vaccines.

Vaccine pricing and implementation and delivery arrangements

The Immunisation Section, in conjunction with PES, negotiates a common national price for acquisition of approved vaccines.

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14 Recently the Commonwealth diverged from the tradition of holding tendering processes at the State/Territory level, holding instead a national tender for the influenza vaccine. The purpose of the national tender is assumed to be to ensure a better price for the vaccine, as well as to consider planning for a potential flu pandemic.
Once a national price has been established, it is the role of the States and Territories to acquire, deliver and monitor the uptake of the vaccine. This is to a degree co-ordinated through the NIC.

The NIC devise implementation plans for the NIP with particular attention to program quality, safety and effectiveness. In addition, it is the role of the Communicable Disease Network Australia – in association with ATAGI, NIC and the NHMRC – to determine disease surveillance and control strategies and policy for vaccine preventable disease in Australia. Specific plans for priority diseases such as measles, pertussis and poliomyelitis are an output of this process. Box 3.3 sets out the role of the NIC within the NIP.

Box 3.3

THE ROLE OF THE NATIONAL IMMUNISATION COMMITTEE WITHIN THE NATIONAL IMMUNISATION PROGRAM

The NIC was established in 1993 to oversee the implementation of the 1993 NHMRC’s National Immunisation Strategy. Today, the NIC is the peak group responsible for overseeing the development, implementation and delivery of the NIP. The original membership of state, territory and Australian government immunisation program managers has been broadened to include representatives of general practice and Indigenous persons.

The NIC’s current terms of reference are:

- Provide leadership and take responsibility for policy development, implementation and review of the NIP;
- Consult and negotiate with stakeholders on the development of national immunisation priorities, strategies and service delivery;
- Establish task-oriented, time-limited working groups as required;
- Collaborate with other peak immunisation-related committees, including ATAGI and the ACIR Management Committee, on issues pertaining to immunisation policy development and program implementation;
- Promote collaboration between local, national and international organizations to inform national immunisation policy; and
- Report to the Australian Health Ministers Advisory Council through the Communicable Disease Network Australia and National Public Health Partnership on immunisation policies and programs.


In addition, as part of the implementation of Commonwealth policy, States and Territories undertake local education, promotion and advocacy as a component of State/Territory (‘district’) planning. This includes strategies for maintaining vaccination coverage, cold-chain compliance and quality/safety plans. All advocacy and communications relating to the NIP are co-ordinated centrally via DoHA. States and Territories may receive funding for specific promotional campaigns and are also funded for all specific promotions of new program implementation initiatives.
A schematic of the NIP

Considering these processes as a whole provides a schematic of the NIP’s structure as a closed system: the jurisdictions monitor the incidence and prevalence of disease as well as coverage rates, which serves to inform the future decisions of ATAGI, as well as the decisions and pricing strategies pursued by the Commonwealth Minister and associated health bodies.
Synthesising the three separate processes identified above we can see a cohesive picture of the NIP, its key bodies and their functions within the immunisation system. This is graphically represented in Figure 3.3 below.

As Figure 3.3 highlights, the NIP involves a wide range of bodies with numerous points of connection to each other.
Chapter 4

Australian immunisation outcomes in an international context

Key points
The introduction of the NIP in 1997 has led to significant improvements in immunisation outcomes in Australia.

Coverage rates have increased and disease incidence have declined, with effective vaccine supply and usage arrangements and a focus on improving the quality of service delivery playing a key role in achieving these improved outcomes. However, the challenge remains to sustain immunisation coverage rates in the future. Particularly in an era where diminishing disease incidence may lead the population to question the value of continued immunisation, the introduction of new vaccines that simplify the immunisation schedule and reduce risks from vaccination will play an important role in sustaining coverage rates.

4.4 Introduction

The NIP has proven to be a highly successful program, bringing Australia in line with best practice in terms of health outcomes for most significant vaccine preventable diseases. Australia now has:

- the highest immunisation coverage ever recorded;
- the lowest rates of measles, rubella and Hib disease; and
- the lowest number of deaths from the diseases for which children are routinely vaccinated.\(^{15}\)

This chapter considers the outcomes of Australia’s current immunisation program and compares them to the performance of other nations’ immunisation programs. Specifically, this chapter measures the outcomes of the NIP by the following criteria:

- coverage rates (Section 4.2);
- the incidence of vaccine-preventable disease notifications (Section 4.3);
- the effective supply and usage of vaccines (Section 4.4); and
- quality of service delivery and monitoring mechanisms (Section 4.5).

4.5 Coverage rates

A chief objective of immunisation programs is to achieve sufficient vaccination coverage so as to effect adequate disease control.

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As discussed in Appendix A, which details the history of Australian immunisation practices, the funding arrangements in place from 1988-1993 resulted in a decline in coverage rates and a corresponding increase in the rates of vaccine-preventable disease outbreaks. To counter what the NHMRC observed to be an ‘unacceptable’ occurrence of disease notifications, a National Immunisation Strategy was conceived and implemented with the goal of controlling the incidence of disease through higher rates of vaccination.

However, despite progress toward meeting the goals and objectives contained in the 1993 Strategy – particularly reforms surrounding funding arrangements and the establishment of a national register – outbreaks of childhood preventable diseases continued, and barriers were still being encountered in attaining optimal vaccination coverage nationally.

The 1997 NIP – which provided for the creation of ATAGI to provide improved advice on the merits of vaccines, of the NCIRS and the ACIR for the improved surveillance of disease and coverage rates, and the Seven Point Plan for increasing vaccination rates – succeeded in significantly improving coverage rates in Australia. Figure 4.1 highlights the increase in coverage rates following the implementation of the NIP’s Seven Point Plan.

Immunisation coverage for vaccines included in the NIP now meet disease control benchmarks for primary vaccination. Furthermore, the increase in national vaccine preventable disease coverage rates observed with the introduction of the NIP has been uniform throughout Australian jurisdictions. All States and Territories have immunisation coverage against diphtheria, tetanus, pertussis, measles, mumps, rubella, poliomyelitis, hepatitis B and Hib 90 per cent or above for children 12 to 15 months of age. This is presented in Table 4.1 below.
Table 4.1
AUSTRALIAN CHILDHOOD IMMUNISATION REGISTER PERCENTAGE OF CHILDREN 12 - 15 MONTHS OF AGE (AS AT 30 JUNE 2003) ASSESSED AS FULLY IMMUNISED

<table>
<thead>
<tr>
<th>State</th>
<th>Number of Children</th>
<th>DTP %</th>
<th>Polio %</th>
<th>HIB %</th>
<th>Hep B %</th>
<th>Fully Immunised %</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT</td>
<td>1 012</td>
<td>92.9</td>
<td>92.8</td>
<td>94.8</td>
<td>95.8</td>
<td>91.6</td>
</tr>
<tr>
<td>NSW</td>
<td>20 945</td>
<td>92.9</td>
<td>92.9</td>
<td>94.5</td>
<td>95.6</td>
<td>91.4</td>
</tr>
<tr>
<td>VIC</td>
<td>14 991</td>
<td>93.7</td>
<td>93.7</td>
<td>95.4</td>
<td>95.2</td>
<td>92.6</td>
</tr>
<tr>
<td>QLD</td>
<td>12 409</td>
<td>92.9</td>
<td>92.8</td>
<td>94.9</td>
<td>95.3</td>
<td>92.1</td>
</tr>
<tr>
<td>SA</td>
<td>4 199</td>
<td>92.8</td>
<td>92.7</td>
<td>95.1</td>
<td>95.6</td>
<td>91.6</td>
</tr>
<tr>
<td>WA</td>
<td>6 068</td>
<td>91.1</td>
<td>90.9</td>
<td>93.9</td>
<td>93.7</td>
<td>89.7</td>
</tr>
<tr>
<td>TAS</td>
<td>1 408</td>
<td>92.6</td>
<td>92.5</td>
<td>95.2</td>
<td>95.2</td>
<td>92.1</td>
</tr>
<tr>
<td>NT</td>
<td>890</td>
<td>92.2</td>
<td>92.0</td>
<td>94.8</td>
<td>96.4</td>
<td>89.9</td>
</tr>
<tr>
<td>AUS</td>
<td>61 922</td>
<td>92.9</td>
<td>92.8</td>
<td>94.8</td>
<td>95.3</td>
<td>91.7</td>
</tr>
</tbody>
</table>

Note: % Fully Immunised = No. children vaccinated/No. children in register x 100. Only vaccines administered to children under 12 months are included in the coverage calculation.


4.6 Disease incidence

While the coverage rates achieved under the NIP appear impressive in their own right, they are only significant to the extent that the rate of disease incidence falls. Therefore, it is useful to also consider the notification rates of disease within Australia and to locate the Australian performance within the international context.

The rates of disease incidence in four comparator countries – the United Kingdom, the United States, Canada and New Zealand – are considered in Table 4.2. These countries are appropriate comparators for Australia as they are developed countries and all have national immunisation strategies whereby most, if not all, of the recommended vaccines have been fully funded by the federal government.16

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16 More detail regarding the immunisation systems in place in these countries is included in Appendix B.

The Allen Consulting Group
As Table 4.2 details, in comparison to countries who also have effective, established immunisation systems, Australia has achieved remarkable levels of disease control for traditional vaccine preventable diseases including Hib and measles. Cases of mumps and rubella are more frequent and are likely to be associated with shifting immunisation policy over time, resulting in some groups (often males or hard to reach populations) missing opportunities to receive the recommended vaccination schedule for that disease.

Comparing disease activity across countries may be complicated by differences in disease case definitions and notification practices. Bearing these factors in mind, however, a NCIRS report published in 2002, states that:

“Nevertheless, it is likely that Australia has a comparatively high pertussis disease burden, including disease and deaths in infants. Children with the highest notification rates in 1999 and 2000 (10 – 14 years of age) were born at a time when the level of completed pertussis immunisation was relatively low and have not been eligible for a pertussis booster before school entry.”


4.7 Effective vaccine supply and usage

In addition to being effective in attaining high coverage and low levels of disease occurrence, another key performance measure for the immunisation system is the efficiency with which the Commonwealth maintains an assured supply of vaccine. Efficient use of available vaccines will be a consequence of effective policies and procedures to ensure maximum usage and is measured by the level of vaccine uptake in defined target groups and the percentage of vaccine wasted through breakage or breaches in the vaccine cold chain.

Within Australia, vaccine wastage is provided for via conditions of vaccine funding between DoHA and State and Territory health departments. States and Territories receive sufficient funding from DoHA to purchase vaccines for the target group and manage vaccine wastage.

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**Table 4.2**

NOTIFICATION RATE COMPARISON PER 100 000 POPULATION FOR FREQUENTLY NOTIFIED VACCINE PREVENTABLE DISEASES, BY COUNTRY OF RESIDENCE

<table>
<thead>
<tr>
<th>Disease</th>
<th>Australia</th>
<th>New Zealand</th>
<th>United States</th>
<th>Canada</th>
<th>England</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hib</td>
<td>0.2</td>
<td>0.4</td>
<td>0.4</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Measles</td>
<td>0.6</td>
<td>4.9</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
<td>0.1</td>
</tr>
<tr>
<td>Mumps</td>
<td>1.4</td>
<td>2.4</td>
<td>0.2</td>
<td>0.4</td>
<td>0.8</td>
</tr>
<tr>
<td>Pertussis</td>
<td>31.0</td>
<td>4.3</td>
<td>2.6</td>
<td>25.1</td>
<td>2.2</td>
</tr>
<tr>
<td>Rubella</td>
<td>1.7</td>
<td>1.6</td>
<td>0.1</td>
<td>0.2</td>
<td>0.1</td>
</tr>
</tbody>
</table>

The efficiency of Australia’s NIP relative to the performance of other nations can theoretically be compared by reference to a set of system performance criteria developed by the World Health Organization. Australia’s performance against these criteria is at an acceptable standard both in terms of its reported level of vaccination uptake and vaccine wastage rates. However, it is not possible to compare Australia’s performance internationally as, with the exception of the USA, other comparator countries do not currently collect the same level of information as Australia regarding efficiency of vaccine usage. This suggests that Australian system monitoring in this area is more advanced than in most other countries.

As previously mentioned, the risks and responsibilities for assuring vaccine supply are differentiated between the Commonwealth Government, State and Territory Governments and vaccine suppliers. Whilst the Commonwealth is the sole funder of vaccines used in the National Immunisation Program, procurement and supply is the primary responsibility of State and Territory health departments who enter into supply contracts with vaccine manufacturers and distributors.

Unless supply side realities are taken into account, vaccine acquisition arrangements are unlikely to support effective vaccine supply and usage. Governments should consider global trends and influences on vaccine supply.

A sustained, assured and efficient supply of vaccines will require a strategic approach to managing risks associated with decreasing numbers of vaccine manufacturers, changing markets and production costs associated with increasing innovation and technologies, for example combination vaccines. A structured and regular dialogue with industry is important in supporting this.

4.8 Quality of service delivery

Ensuring consistent availability of trained staff, injection safety, monitoring adverse events following immunisations (AEFI) and program safety within the system is another critical component of best practice immunisation. Outcomes subsumed under the broader category of quality service delivery include:

- basic program safety, through the scientifically-sound delivery of vaccines;
- adequate risk management, achieved through the appropriate advice from medical groups regarding the balance of disease risk with AEFI risk; and
- adequate monitoring of coverage rates, disease notification and AEFIs.

Basic program safety

A best practice immunisation strategy begins with the safe delivery of the vaccine such that medical ailments independent of the vaccine do not occur as a result of the vaccination. Where the program delivery mechanisms are – or are perceived to be – unsafe, public confidence in the program could fall and with it, coverage rates. Thus, both actual and perceived program safety – captured in the safety levels of injection equipment, disposal equipment and processes, and a safety surveillance/monitoring system – are essential components of a sustainable program.
Australia, like nearly every other developed country, does not engage in multi-dose open vial activities. To minimize the possibility of needle-stick injury or re-use the Australian Immunisation Handbook provides best practice guidance to vaccination providers relating to use of sterile, single-use only equipment and suitable disposal policy and procedures.

These practices are aligned with the practices of other developed nations and are considered best practice.

**Adequate risk management**

Risk management within immunisation programs is essential in both minimising preventable adverse events following vaccination and maintaining public support and confidence in mass vaccination programs. Where the appropriate management of disease and AEFI risks is not understood or not perceived, it can foster a decline in the rates of immunisation among the public. It is therefore a key outcome of a best practice immunisation strategy.

**Risk management: issues arising from ASVS-listed poliomyelitis vaccines**

As discussed in Chapter 3 of this report, not all vaccines listed as best practice in the ASVS following ATAGI recommendation and NHMRC endorsement are funded by the Commonwealth. Among the vaccines not currently funded by the Commonwealth but recommended by the ASVS as best practice immunisation (due to reduced risk of AEFI), is IPV combination vaccines.

It has been observed by members of the NCIRS that as the risk of contracting a disease falls, the risks associated with AEFIs take on a larger role in peoples assessment of the benefits versus risks of immunisation. Currently, the risk of contracting polio is quite low:

- Australia’s last laboratory confirmed case of wild poliomyelitis occurred in 1967;
- the WHO has declared the Western Pacific region to be polio-free; and
- Australia continues to undertake active surveillance for acute flaccid paralysis (AFP) and has succeeded in bettering the benchmark for AFP incidence by 25 per cent.

However, all suspected cases of poliomyelitis notified since 1972 have been investigated and subsequently classified as vaccine associated paralytic poliomyelitis (VAPP) – an acute paralysis caused by a virus similar to that used in live oral Sabin vaccine. Because of the potential of the currently-funded OPV to cause VAPP (and the subsequent undermining of confidence in immunisation that this would follow such an event) and the fact that IPV combination vaccines promote higher coverage rates by removing the risk that parents will delay vaccinations in order to avoid having multiple injections on the same day, many countries – including the United States, New Zealand and the United Kingdom – have, or are planning to, replace OPV vaccine with IPV combination vaccines.

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As the ASVS-listed IPV combination vaccines have not been funded, there is the risk that Australia’s NIP falls short of best practice in the outcome category of risk management. This has important implications for the maintenance of public confidence in the immunisation system and hence the maintenance of high rates of immunisation.

This is due to community concerns regarding the real or perceived side-effects of vaccination rise as the incidence of vaccine preventable diseases declines. Thus it may be the case that coverage rates will fall if the public perceives the risk of vaccination to be too great, compared with the risk of contracting the disease through normal channels of contact.

Figure 4.2 illustrates the evolution of immunisation programs and highlights the fact that as the incidence of a disease falls, a loss of public confidence in immunisation against the disease is likely to increase, resulting in a fall in immunisation rates and a subsequent spike in disease occurrence. The higher the negative side-effects of a vaccine the more likely it is that this pattern of behaviour will occur.

**Surveillance**

Effective vaccine-preventable disease surveillance is an essential component of disease control and national immunisation programs. It is arguable that a significant part of the success reported for the other health outcomes identified in this Chapter is due to the systematic monitoring of vaccination rates and the incidence of AEFIs.
**Vaccination coverage rate surveillance**

Immunisation surveillance and vaccination coverage reports are provided routinely at national and district level via the ACIR. Established under the legislative and operational auspices of the Health Insurance Commission (HIC), the ACIR was developed in response to a decline in childhood immunisation rates in Australia and the continuing significant incidence of preventable childhood diseases. Prior to the introduction of the ACIR, methods used in assessing coverage varied widely in design and quality, with few studies measuring coverage at national or state-wide level.

Today the ACIR provides for the systematic surveillance of immunisation rates. Providers are paid for information provided to the Register regarding NHMRC defined immunisation episodes for children aged less than seven years.

In terms of the international context, Australia shares this centralised-monitoring approach with the United Kingdom. By contrast, other comparator nations such as Canada, New Zealand and the US, either do not have a registry, or have a system of regional registries, with which to monitor immunisation rates.

**Surveillance of disease notification rates**

In terms of surveillance of notification rates, Australia is in large part aligned with the practices of other nations. The Communicable Disease Network Australia holds fortnightly teleconferences to report on notifiable disease activity, which includes zero reporting for measles.

**Surveillance of AEFI**

Ability to routinely monitor and survey for AEFI is the final key quality assurance component subsumed under the broader outcome of effective surveillance, and contributes the adequate risk management within the NIP.

Australia has a passive system of AEFI surveillance. Data is typically collected nationally via General Practitioners and State and Territory health departments, and in some jurisdictions, also collected via validated parent-generated reports. AEFI’s are required to be notified under public health legislation in New South Wales, Western Australia, Queensland and the Northern Territory. Reporting is encouraged in the remaining jurisdictions either via the State/Territory health department or Australian Drug Reactions Advisory Committee (ADRAC). All reported AEFI are assessed by ADRAC and the results published in the *Communicable Diseases Intelligence*.

### 4.9 Conclusion

On balance, the NIP has been shown to achieve vaccination coverage rates and disease incidence rates at best practice levels for a number of, but not all, major vaccine preventable diseases. It does this in a manner that minimises vaccine wastage. Furthermore, it provides for the safe delivery of the vaccines and adequate surveillance of outcomes.

There may be, however, the potential for improvement around risk management strategies as there appear to be inconsistencies in ASVS-listed best practice vaccines and Commonwealth funding. This could lead to a decline in immunisation rates and in turn, poorer outcomes for the NIP system.
Chapter 5

Best practice principles for immunisation system

Key points

While immunisation outcomes in Australia have improved since the introduction of the NIP in 1997, a number of new challenges for the system are emerging.

If these challenges are to be successfully addressed the strategy, institutional structures and procedures for the assessment, approval and implementation of vaccines in Australia will need to be best practice.

Both general public policy and public health principles can be used to develop a set of best practice principles appropriate for the Australian immunisation system.

5.10 Rationale for renewed focus on best practice principles

The assessment of current immunisation outcomes in Australia shows that, since the introduction of the NIP, Australian outcomes have been at international best practice levels for most vaccine preventable diseases. However, a number of challenges are emerging and the current immunisation system is not guaranteed to produce such positive outcomes in the future.

Emerging challenges for the immunisation system include:

- The advancement of technology and the development of new vaccines is proceeding rapidly. Currently research is underway on over 60 vaccine candidates against important diseases worldwide. However, vaccines are also becoming technologically more complex and distinctly more expensive than existing vaccines. Due to high barriers to entry (capital costs, transportation requirements, regulatory approval costs and lead times) there is no foreseeable 'generic' vaccine market emerging.

- There is an increasingly low tolerance for disease risk within the community. This can create a political imperative for potentially expensive action in some key cases (for instance Hib in 1993 and Meningococcal 2002).

- In many ways the NIP has created expectations within the community for full-immunisation. However, the rising cost of new vaccines mean that it is harder for Government to fund broad provision of new vaccines. This brings into question the financial sustainability of the current immunisation system.

- Not all vaccines included on the ASVS are publicly funded (perhaps an early indicator of consequences of rising funding pressures) which may erode public confidence in the quality of the public immunisation system.
• As government health expenditure continues to rise at rates exceeding inflation, competing demands on the health budget become more pronounced. There is a tendency for short-run “crisis” issues to dominate when decisions are taken on health budget resource allocation. Unless long-term public health programs such as vaccinations are protected from competing short-run expenditure demands, there is a risk of under-investment in such programs, despite their acknowledged role in promoting long term public health outcomes and the long term financial sustainability of the public health system.

• Potential gaps are emerging between commercial imperatives and public health needs.

• The development of a range of new vaccines, including vaccines focused on targeted disease prevention in adults. This presents a particularly significant challenge for existing vaccine assessment, approval and funding processes as it will dramatically increase the number of vaccines requiring assessment.

Such challenges will be best met if the elements that make up the Australian immunisation system reflect best practice system design principles. In this Chapter we consider what such best practice system design principles entail.

5.11 System elements

The immunisation system involves stakeholders, strategy and structures/processes. As illustrated in Figure 5.1, within the system there are effectively four functional components:

• an overarching strategy for the system;
• the evaluation process applied to vaccines;
• the approval process for vaccines; and
• the implementation process for vaccines.

Figure 5.6
FUNCTIONAL COMPONENTS OF THE IMMUNISATION SYSTEM

IMMUNISATION STRATEGY
Sets priorities, specifies roles and responsibilities of stakeholders and outlines procedures to be followed in the evaluation, approval and implementation processes.

EVALUATION
This involves answering the following questions

Is the vaccine safe?
Is it effective?
What is its relative medical priority?
How cost effective is it?

APPROVAL
This involves answering the following fundamental question

Will public funding be provided for the provision of the vaccine?

IMPLEMENTATION
This involves the following two steps

Funding of the vaccine
Vaccine acquisition, delivery and monitoring

Source: Allen Consulting Group
5.12 Approach to establishing best practice principles

In developing best practice principles for the different elements of the Australian immunisation system, we have drawn upon both general principles for good public policy and a number of principles that relate more specifically to public health policy and practice.

Relevant general public policy principles

General principles of good public policy that also apply as best practice principles for the immunisation system relate primarily to issues of transparency and accountability.

As noted by the Auditor General for Australia “issues of openness and transparency have to be accepted as essential elements of public sector accountability”\(^\text{18}\). The Australian National Audit Office’s better practice guide to public sector governance\(^\text{19}\) lists accountability and transparency/openness as the first two principles of public sector governance. According to the Audit Office:

- **Accountability** is the process whereby public sector organisation, and the individuals within them, are responsible for their decisions and actions…and submit themselves to external scrutiny. It is achieved by all parties having a clear understanding of those responsibilities, and having clearly defined roles through a robust structure.

- **Transparency/openness** is required to ensure that stakeholders can have confidence in the decision making processes and actions of public sector organisations, in the management of their activities, and in the individuals within them. Being open, through meaningful consultation with stakeholders and communication of full, accurate and clear information, leads to effective and timely action and stands up to necessary scrutiny.

Similarly the Auditor-General notes\(^\text{20}\) that attention to the principles of good governance requires those involved to:

- identify and articulate their responsibilities and relationships;
- to consider who is responsible for what, to whom, and by when; and
- to acknowledge the relationship that exists between stakeholders and those entrusted to manage resources and deliver outcomes.

Commonwealth procurement best practice guidance produced by the Department of Finance and Administration\(^\text{21}\), also provides some important general principles that are applicable to the immunisation system. It identifies achieving “value for money” as the core principle governing Commonwealth procurement and sees this being supported by the underpinning principles of:

- efficiency and effectiveness;
- accountability and transparency;

\(^{18}\) Barrett, P.J., Auditor General for Australia, (2001), *Dealing with risks to ensure greater effectiveness*, Presentation to IIR conference, Canberra, 1\(^{st}\) May 2001

\(^{19}\) ANAO, (2003) *Public Sector Governance, Volume 1, Better Practice Guide*

\(^{20}\) Barrett, op.cit.

\(^{21}\) Department of Finance and Administration, (2002), *Commonwealth Procurement Guidelines and Best Practice Guidance*
It notes that accepting the lowest price is not necessarily an indicator of “value for money”, stressing that a wider range of factors must be considered when assessing the quality of procurement outcomes.

Relevant public health specific principles

In relation to best practice principles of particular relevance within the public health field, the National Public Health Partnership in Australia has identified a number of such principles that we have incorporated. These include:

- the need for clearly stated principles to guide strategy development and implementation;
- that the health outcomes that are to be achieved should be clearly articulated; and
- the need for an evidence-based approach to be adopted in strategy setting and implementation.

The 1993 National Immunisation Strategy proposed a number of strategies focused on improving performance in relation to the efficiency, quality, coverage and accountability of vaccination programs. These were encapsulated in a set of standards that were developed for the immunisation system, including that 22:

- vaccination services are to be readily available;
- there should be no barriers or prerequisites to vaccination services;
- NHMRC-recommended childhood vaccines should be offered free, without cost to parent or guardian;
- providers use accurate and complete recording procedures;
- providers report adverse events following immunisation promptly, accurately and completely as set out in Part 1.6, ‘Adverse events following immunisation (AEFI)’;
- providers adhere to appropriate procedures for vaccine cold-chain management;
- vaccination providers maintain current and easily retrievable vaccination guidelines at all locations where vaccines are administered; and
- vaccines are administered by properly trained individuals who receive ongoing education and training on current vaccination recommendations.

5.13 Best practice principles for immunisation strategy

To ensure that the immunisation system operates in an optimal fashion it is important there is a clear long-term strategy that guides activity within each element of the system.

A best practice immunisation strategy should articulate:

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• the high level goals of the system;
• how these goals are to be met; and
• the roles and responsibilities of those involved in the evaluation, approval and implementation elements of the system.

Potential features of these three elements that could be included within an Australian immunisation strategy are considered in turn.

**High level goals of the system**

The high level goals of the immunisation strategy, which quite properly must be set within the context of the goals of the wider public health system, should be defined in terms of:

1. health outcomes to be achieved;
2. maintenance of high levels of public confidence; and
3. financial sustainability.

While in principle it would be fine to aim to achieve the best possible health outcomes irrespective of their funding implications, in practice there is a resource constraint both for the Government and for individuals/families which must be taken into account. Hence the financial sustainability of the immunisation system is an important high level goal. It would be most destabilising and bad for public confidence if commitments were to be made that could not be financially sustained in the future, necessitating cut-backs of one kind or another.

That said, the long-term commitment needed to operate successful immunisation programs strongly suggests that budgetary provision for immunisation should as much as possible be insulated from the short-run pressures associated with particular annual budgets.

**Articulation of how goals are to be met**

The immunisation strategy should set broad directions regarding how the high level goals are to be achieved. It should, for instance, articulate that the immunisation system will focus on:

1. high priority diseases that are determined through consideration of;
   - the degree of disability associated with the disease,
   - the medical effectiveness of existing disease treatments,
   - the costliness of existing disease treatments, and
   - the Disability Adjusted Life Years profile of at risk groups for the disease.
2. ensuring high risk groups within the population are immunised;
3. that high levels of transparency will be implemented throughout the system to ensure that public confidence in the system is maintained; and
4. implementation of vaccines that enhance the long term financial sustainability of the public health system.
**Specification of roles and responsibilities within the system**

The overarching immunisation strategy should clearly identify those bodies responsible for the conduct of each element of the system and should provide clear guidelines regarding their responsibilities.

### 5.14 Best practice principles for evaluation process

As illustrated in Figure 5.2, the evaluation process consists of three elements:

- regulation/registration;
- medical merit evaluation; and
- cost effectiveness evaluation.

In order for the cost effectiveness evaluation to occur, some preliminary price negotiations will also be needed during the evaluation process so that a realistic final price range can be used in evaluating the cost effectiveness of vaccines. Finalisation of the acquisition price for vaccines within the agreed price range would then occur during the implementation process.

#### Figure 5.7

**BEST PRACTICE ELEMENTS OF THE EVALUATION PROCESS**

<table>
<thead>
<tr>
<th>EVALUATION PROCESS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulation/Registration</strong></td>
</tr>
<tr>
<td>If the vaccine is found to be safe and effective for its target population it receives regulatory approval for use in Australia and the evaluation process continues to the next stage.</td>
</tr>
<tr>
<td><strong>Medical merit evaluation</strong></td>
</tr>
<tr>
<td>If the vaccine is found to be of high medical merit (for instance it prevents a serious disease and has minimal side effects) the evaluation process would continue to the next stage.</td>
</tr>
<tr>
<td><strong>Cost effectiveness evaluation</strong></td>
</tr>
<tr>
<td>If the vaccine is found to be cost effective in the long-term relative to either existing vaccines or disease treatments and recommendation for its public funding would be made.</td>
</tr>
</tbody>
</table>

A number of best practice principles should apply to each of the three evaluation functions. Best practice principles include:

- clarity of the roles and responsibilities – assignment of an appropriate lead body to each of the three evaluation functions and articulation of their responsibilities;
- specification of the time frames – the timeframes within which the nominated lead body for each function should carry out their responsibilities should be specified;
- appropriate resourcing of bodies – responsible bodies should have the appropriate resources to carry out their responsibilities within specified time frames;
• availability of required expertise – responsible bodies should have the required expertise to ensure that they use an evidence-based approach in fulfilling their responsibilities; and

• transparency of process – there should be high public transparency in the assessment criteria used by responsible bodies in their deliberations and in their decisions. This includes providing opportunities for stakeholders to formally submit evidence for the consideration and that clear rationales are provided for the decisions that have been reached.

5.15 Best practice principles for approval process

Following provision of advice by those bodies involved in the evaluation process, the elements of the evaluation are then considered by the responsible Commonwealth Minister (in this case the Minister for Health and Ageing). The Minister (and in some case the Cabinet) must ultimately make a determination regarding whether public funding for a vaccine is to be provided. The following best practice principles should be in place within this approval process for the provision of public funding of vaccines:

• there should be a clear timeframe in place for when decisions on provision of public funding are to be taken following submission of advice to the Minister from the lead bodies involved in the evaluation process; and

• a clear justification for decisions taken should be publicly provided.

5.16 Best practice principles for implementation process

Once the decision is taken to add a vaccine to the ASVS and publicly fund its provision the remaining steps involved in getting the vaccine to the target population are:

• to fund the acquisition of the vaccine from the suppliers at the best price for delivery to the authorities actually administering the vaccine; and

• to acquire vaccines and administer and monitor vaccine delivery.

Best practice principles for the acquisition of vaccines are:

• the price of vaccines being consistent across jurisdictions;

• the Government receiving ‘value for money’ when purchasing vaccines; and

• that funding for the immunisation system is maintained at levels sufficient to deliver desired system outcomes.

Seeking ‘value for money’ does not imply that the Government should seek to obtain vaccines at the lowest possible short-run price (the marginal cost of vaccine production).
When a longer term perspective is taken, value for money also entails the use of pricing arrangements that will allow for a sustainable long-term system for the development and provision of vaccines. Pursuit of short-run cost minimisation will not necessarily represent value for money in the long run as it could lead to pharmaceutical companies reducing investment in the development of new vaccines that would deliver long-term benefits for the financial sustainability of the health system. Assessment of value for money should also involve consideration of the value of the health outcomes that are being purchased through providing wide availability of a vaccine.

Best practice principles for the delivery and monitoring of immunisation include:

- immunisations being readily accessible for all those identified as appropriate immunisation recipients;
- consistent records being kept regarding the immunisation status of the population; and
- quality and safety standards being clearly specified and that adherence to these standards in monitored.

5.17 Schematic of best practice immunisation system structure

When each of the elements of the evaluation, approval and implementation process are considered a schematic of a structure for the immunisation system embodying best practice principles can be developed. An immunisation system structured in such a way that duplication of effort is avoided and clear responsibilities are allocated to each major function is set out in Figure 5.3.

As is discussed in detail in Chapter 6, the current Australian immunisation system differs from a ‘best practice’ structure in a number of areas – especially in relation to the multiple bodies that are currently involved in carrying out medical merit and cost effectiveness evaluations in Australia and limited transparency in decision making processes.
Chapter 6

Assessment of current Australian immunisation system against best practice features and recommendations for action

Key points

The Australian immunisation system is not in “crisis”. However, the absence of funding for the latest recommendations included by the NHMRC on the ASVS is an indicator of the strain that the Australian immunisation program is now under.

There are a number of areas in which the immunisation system does not embody best practice system design principles. Given the emerging challenges facing the system, future strong performance will require best practice principles to be embodied in the immunisation system’s structures and process. Unless best practice principles are implemented Australia’s immunisation system is at risk of falling behind the performance achieved in comparable countries.

In view of the current pressures the immunisation system faces, and the new pressures it will face in coming years, there is a strong case for taking action now to put the system on a firmer footing. The key areas where action should be taken are:

- developing a single over-arching immunisation strategy that comprehensively sets out the goals of the system, how these goals are to be met, and the roles and responsibilities of those involved in vaccine evaluation, approval and implementation;
- streamlining the processes for vaccine assessment to avoid duplication of effort and to provide greater clarity of procedures for stakeholders in the system;
- improving the levels of transparency and openness in both the vaccine assessment and approval processes. While a variety of information is available in various forms and locations, processes are not ‘public’ and processes for stakeholder engagement are sometimes unclear or absent;
- ensuring that systems for funding vaccinations in Australia are adequate to allow vaccinations that have been assessed to provide medical benefits in a cost effective manner to be widely available to the Australian public. Given competing pressures for public health expenditure, given both the new vaccines that have recently become available and the considerable number that will become available in coming years, this may require alterations to the current vaccine funding model; and
- maintaining and building upon the system for the implementation of vaccines in Australia.

Six recommendations for action have been made to strengthen the Australian immunisation system.
6.18 Summary of recommendations for action

The development of a comprehensive national immunisation strategy that sets out system goals and defines the roles and responsibilities of all those involved in the operation of the system, while a significant undertaking, would be highly desirable. However, in developing recommendations in this report we have, rather than bundling together recommendations under the broad banner of ‘comprehensive immunisation strategy development’, identified a number of discrete improvements to the existing system that, while not representing a complete immunisation strategy, could be expected to be core elements of a best practice immunisation system. Each improvement is worth introducing in its own right.

These improvements, when taken together, would bring the current immunisation system closer to demonstrating the features that would be integral to a comprehensive national immunisation strategy.

The six recommendations for action are:

Recommendation 1: establishment of an immunisation priorities framework
Recommendation 2: clarification of the evaluation processes
Recommendation 3: increased transparency of the evaluation processes
Recommendation 4: increased transparency in the approval processes
Recommendation 5: specification of timelines for price negotiations
Recommendation 6: investigation of the potential for a hybrid public/private funding model for new vaccines to be developed

The adoption and implementation of these recommendations would provide greater long term direction to system planning, streamline processes and improve transparency within the system, thereby better positioning the Australian immunisation system to respond to the range of current and future challenges that it faces.

6.19 Assessment of overarching strategy for the system

Maintaining effective and sustainable immunisation programs that respond to developments in technology, emerging disease threats and community attitudes requires a planning and policy framework that is dynamic, has a capacity to introduce new antigens, alter schedules and adopt new disease control strategies. A clear overarching strategy for the system and effective national mechanisms for policy development, implementation, funding and review are needed.

Whilst there are implementation plans for specific funded vaccination and priority vaccine-preventable disease programs in Australia, a comprehensive national immunisation strategy has not been released since the development of the 1993 National Immunisation Strategy. A second strategy development group was convened in 2001-02 but a final strategy document was not produced.

The Immunise Australia Program introduced in 1997, while setting out a number of specific short-to-medium term goals and actions to be taken, does not provide a long-term priorities framework or fully articulate the roles and responsibilities of bodies involved in the immunisation system.
There is, therefore, currently no single over-arching strategy in place for the immunisation system in Australia that both sets out its goals and defines the roles and responsibilities of all those involved in the operation of the system.

In Australia there are, however, ongoing processes relating to planning, assessment and monitoring of technical and programmatic elements of the program in place at both national and regional levels:

- At the Federal level, ATAGI advises the Australian Government and the NHMRC on technical and medical policy and guidelines relating to vaccination procedures and the ASVS.
- The NIC is an intergovernmental management group consisting of NIP managers from each State and Territory and representatives from General Practice and Aboriginal and Torres Strait Islander health authorities. The NIC devise implementation plans for the NIP with particular attention to program quality, safety and effectiveness.

In addition, the Communicable Disease Network Australia in association with ATAGI, NIC and the NHMRC determine disease surveillance and control strategies and policy for vaccine preventable disease in Australia. Specific plans for priority diseases such as measles, pertussis and poliomyelitis are an output of this group.

Notwithstanding the existence of specific plans for particular diseases, the lack of a wider long-term priorities framework for immunisation system is of concern as in its absence stakeholders lack context for their current activities and lack important guidance for their long-term planning.

**Recommendation 1: establishment of an immunisation priorities framework**

The purpose of a long-term priorities framework would be:

- to give greater guidance to those involved in evaluation, approval and implementation processes;
- to give industry greater direction on what vaccines they should focus research upon; and
- to assist public understanding of, and confidence in, the system.

**6.20 Assessment of the evaluation process**

Perspectives regarding the operation of the vaccine evaluation process are likely to differ significantly between those within the system and those that are external to the system. For instance, processes that are clearly understood by those within a evaluation body (‘internal stakeholders’) may be far less clear to industry stakeholders who only periodically deal with such processes (‘external stakeholders’).

The following assessment of the operation of vaccine evaluation processes, which is from the perspective of an ‘external stakeholder’ to the system, are therefore likely differ from the assessment that an ‘internal stakeholder’, who is likely involved in the system on a daily basis, would make.
**Regulation/registration**

The TGA is the sole body responsible for regulation/registration of vaccines as safe and effective and eligible for legal distribution in Australia.

While the timelines involved for the TGA regulation/registration process are not fixed, the regulation/registration process appears to be broadly in line with best practice principles.

**Medical merit evaluation**

ATAGI, the NHMRC, the NIC and the PES are all involved in the medical merit evaluation process. Also, the medical and cost effectiveness evaluations appear to be significantly bundled together.

Major deviations from best practice principles are evident in the medical merit evaluation system, including:

- no clear lead body being responsible for the evaluation;
- duplication of activity occurring;
- no clear timelines being set for the evaluation process;
- no formal and transparent process provided for industry submissions to be made to a lead evaluation body;
- assessment criteria used are not fully publicly available;
- lack of clarity regarding how advice goes to the Minister and the reasons given for recommendations made.

**Cost effectiveness evaluation**

ATAGI, the NHMRC, the PES, the Immunisation Section and the NIC all appear to be involved to some degree in the cost effectiveness evaluation process.

Divergence from best practice principles appears to be widespread in the current cost effectiveness evaluation process which is characterised by:

- no clear lead body being responsible for the evaluation;
- duplication of activity occurring;
- no clear timelines being set for evaluation process;
- no formal and transparent process provided for industry submissions to be made to a lead evaluation body;
- assessment criteria used are not fully publicly available;
- lack of clarity regarding how advice goes to the Minister and the reasons given for recommendations made.
Recommendation 2: clarification of the evaluation processes

This involves clarification of the roles and responsibilities of key bodies in the evaluation process and allocation of a lead body to each core evaluation function. Specifically:

- an overarching document specifying who is responsible for each evaluation function should be developed by DoHA and endorsed by the Minister for Health and Aging;
- one body should be assigned to the regulatory/registration function – preserving the status quo with the TGA fulfilling this role would be appropriate;
- one body should be assigned to the medical merit evaluation function – assigning ATAGI to this function with the NHMRC maintaining a sign-off function would be appropriate;
- one body should be assigned to the cost effectiveness evaluation function – assigning the NCIRS to this function would be appropriate; and
- one body should be assigned to conduct preliminary price negotiations setting a price range to be used in the cost effectiveness evaluation – the Immunisation Section of DoHA could fulfil this function.

Recommendation 3: increased transparency of the evaluation processes

Transparency in each stage of the evaluation process would be improved by:

- providing planning certainty for all those involved in the immunisation system by the development of fixed timeline, endorsed by the Minister, that specify maximum allowable time periods for regulatory/registration processes, medical merit evaluations and cost effectiveness evaluations;
- development of formal processes for industry submissions to the lead bodies;
- assessment criteria being made publicly available by the lead bodies – while this already occurs in relation to ‘levels of evidence’ required by the NHMRC, publicly available criteria relating to other issues, such as implementation, cost and equity issues, should also be provided; and,
- while recognising that some commercial in confidence material may need to be excluded from public documents, nevertheless, reports that sets out recommendations, and the reasons for them, should be produced and publicly released by each of the lead bodies.

6.21 Assessment of the approval process

Responsibility for the approval of public funding for vaccines resides ultimately with the Minister for Health and in some cases the full Cabinet.
Under an earlier decision by Federal Cabinet, vaccines expenditure up to $10 million could be approved by the Federal Health Minister. Amounts between $10 and $20 million could be approved by the Minister for Finance. Amounts over $20 million required full Cabinet approval. This system of vaccine funding was designed to expedite introduction of new vaccines and prioritise the provision of vaccines beyond the regular budget cycle appropriation. It should be noted that the appropriation limit requiring full Cabinet approval was subsequently reduced in 2002 to $10 million.

Currently, the Minister receives non-publicly available advice from a range of sources and within an unspecified time period a decision on whether a vaccine will receive public funding is announced.

The current process is not transparent and there is a risk that short-term budgetary pressures may over-ride evidence-based advice regarding optimal long-term outcomes.

Unless there are clear timelines for decisions to be made once the recommendations of expert advisory bodies have been publicly presented to the Minister, and unless the Minister is required to provide a justification for decisions made regarding provision of public funding, the approval process not reflect best practice principles.

An example of the problems that the current approval process can lead to involves the Meningococcal C vaccine.

*i issues arising from funding of Meningococcal C catch-up vaccine*

In response to a number of small meningococcal outbreaks in NSW, Victoria and Tasmania, which received significant attention by the Australian media, ATAGI was asked to review as a priority the use of Meningococcal C vaccine. In October 2002, ATAGI recommended a 2 dose vaccine schedule with no catch-up component. However, in November 2002 the Prime Minister announced the immediate Commonwealth-funding of a universal vaccine program to prevent Meningococcal C. As of 2003, all children turning 12 months of age became eligible to receive free Meningococcal C vaccine under the NIP. In addition to this, the National Meningococcal C Vaccination Program provides free Meningococcal C vaccine for all one to 19 year olds – a target population actually greater, and hence more costly, than that recommended by ATAGI – over the next four years.

In this case it appears that funding decisions, which may have come at the expense of other subsequent ATAGI recommendations, were based more on public pressure than on evidence-based advice from expert advisory bodies.

**Recommendation 4: increased transparency in the approval process**

The approval process should be made more transparent through:

- introduction of a requirement that justification for decisions be given if they diverge from advice received by expert advisory bodies; and
- establishment of timelines for when decisions must be made by following the Minister receiving written advice from the lead evaluation bodies.
6.22 Assessment of the implementation process

Funding acquisition of vaccines

Consistent pricing of vaccines across jurisdictions

Prior to the NIS in 1993, there was not pricing consistency for vaccines across state and territory jurisdictions. Under the NIS, purchasing was consolidated at the federal level. The best practice principle of consistent pricing across jurisdictions is now being followed in Australia.

Achieving ‘value for money’ when purchasing vaccines

The Commonwealth Government is currently acquiring vaccines at comparable cost to those in other developed countries.

The financial sustainability of the immunisation system

For public confidence in the immunisation system to be maintained, public expectations regarding effectiveness, safety, comprehensiveness and efficiency must be met. To satisfy these expectations in a financially sustainable way requires the Government to consider a range of system financing options.

There are four general options for financing immunisation programs:

- direct allocations from the government budget;
- social insurance and prepayment systems;
- private / non government sector sponsorship; and
- user pays.

These options are used to varying degrees throughout medium to high-income countries and are adopted with consideration to political/policy priorities, ease of implementation, and social equity. In Australia, most vaccines on the ASVS are fully funded by the Commonwealth, while State and Territory Governments fund the delivery and monitoring of vaccinations.

In Australia, the 1998–1999 Commonwealth Budget included an initiative to streamline all childhood vaccine funding as from 1999-00, resulting in funding for all childhood vaccines on the ASVS (up to 15 years of age) being included in the Public Health Outcome Funding Agreements (PHOFAs).

In the same financial year, pneumococcal and influenza vaccine for Indigenous Australians and influenza vaccine for those aged over 65 years were also funded. Federal funding to use DTPa for all 5 infant vaccinations began in February 1999, immediately after the NHMRC recommended the schedule change. In 1999-00, PHOFA funding to purchase enough vaccine for 105 per cent of the eligible cohort for each vaccine (with the current exception of influenza vaccine) was made available. From May 2000, universal infant vaccination with hepatitis B vaccine was recommended and funded. This has been followed over the past 3 years by funding, via the vaccines special appropriation, of the high-risk conjugate pneumococcal vaccination program, national Q Fever screening and vaccination program, and the national meningococcal C vaccination program.
Whilst the ATAGI and the NHMRC recommend that “NHMRC-recommended childhood vaccines are offered free, without cost to parent or guardian” (Standard 3. Standards for Childhood vaccination, Australian Immunisation Handbook 2003), there has never been a defined policy by the Australian Government stating that all recommended vaccines would be automatically and immediately funded.

The current (updated in September 2003) NHMRC endorsed ASVS is defined as incorporating all vaccines recommended as ‘best practice’. The ASVS is therefore not synonymous with the schedule of vaccines funded under the National Immunisation Program. As discussed in Chapter 3.3, vaccines currently recommended but not funded include:

- IPV in combination for all children at age 2 months, 4 months, 6 months, 4 years as a replacement of OPV;
- varicella-zoster vaccine (VZV) for all children at age 18 months and selected adolescents; and
- 7-valent pneumococcal conjugate vaccine (7vPCV) for infants at age 2 months, 4 months, 6 months.

It is not clear whether recent non-funding of some vaccinations listed on the ASVS is a temporary aberration or an indicator of a future trend (where short term budgetary considerations prevent the funding of vaccines that are medically effective and cost efficient). If this situation is a direct result of growing funding pressures within the system, this suggests that system funding arrangements may need to be re-considered. Unless vaccines listed in the ASVS are widely available, confidence in the public immunisation system is likely to be undermined.

With a wider range of new targeted vaccines for non-infectious diseases likely to become available in coming years (as discussed in section 2.5), the Government may need to revisit and broaden system funding arrangements to ensure that the availability of these new vaccines meets public expectations.

**Recommendation 5: specification of timelines for price negotiations**

To provide planning certainty for all those involved in the immunisation system fixed timelines should be developed and endorsed by the Minister that specify maximum allowable time periods for price negotiations for vaccines.

**Recommendation 6: investigation of the potential for a hybrid public/private funding model for new vaccines to be developed**

Given the likely emergence in coming years of a wide range of new, but more expensive, vaccines for both infectious and non-infectious diseases, the Government should investigate whether a hybrid public-private funding model for such vaccines would be appropriate. For some new and more expensive vaccines it may be that only a partial Government subsidy would be appropriate and/or financially sustainable. The introduction of a means tested co-payment system for some vaccines might be one option that the Government should investigate.
Immunisation delivery and monitoring arrangements

Since the introduction of the first NIS significant improvements have been made to the delivery and monitoring of immunisation in Australia.

An example of the improvements that have occurred since the 1993 NIS in the delivery and monitoring of immunisations is the implementation of the ACIR. With the operationalisation of the ACIR in 1996 and the advancement of State and Territory Government initiatives to collect immunisation data, an agreement was made between government health services and immunisation providers to regularly release and report on immunisation rates at a national, state and territory level. ACIR coverage reports are published quarterly in Communicable Diseases Intelligence. Reporting to local level (Local Government Area, Division of General Practice) is also routinely provided to health departments and Divisions of General Practice.

The delivery and monitoring system now in place appears to broadly accord with best practice principles. It is vitally important that the improvements made in this area since the introduction of the NIP are maintained and further built upon.
Appendix A

A History of Australian Immunisation Practices

A.1 Introduction

The first vaccine used in Australia, the smallpox vaccine, was introduced in 1804. But it was not until 1916, when the Commonwealth government established the Commonwealth Serum Laboratories (CSL), that the impact of mass immunisation practices was felt throughout Australian communities.

Since then, vaccinations have become a routine practice within Australia and a vital component of the government’s strategy for protecting the health and welfare of Australians.

This Appendix identifies key developments in the history of Australian immunisation practices, and outlines the current schema for new vaccine approval and funding. Specifically, this Appendix compares the structures and outcomes of various policy and funding arrangement environments, which can be broadly characterised as four separate periods:

- **Emerging Immunisation Practice: 1916 – 1988.** In this period, Commonwealth funds all childhood vaccines, which results in the creation of a small vaccination industry and fosters the emergence of a modest private market for vaccines.

- **Fragmented Delivery: 1988 – 1993.** The Commonwealth withdraws its direct funding of vaccinations in 1988 and replaces national program with several grant arrangements with the States and Territories. As a result, there is a wide variation in program implementation, as well as prices paid by jurisdictions, with smaller States and Territories paying significantly higher prices. Immunisation rates fall and outbreaks rise to unacceptable levels.

- **Towards a National Approach: 1993 – 1997.** On the advice of the NHMRC, Australia returns to a top-down, national immunisation program, defined by indexed-pricing structures and a uniform system of vaccine service delivery. The success of this national strategy is manifest in the rebound of immunisation coverage rates and concomitant the fall in Hib notification rates.

- **The National Immunisation Program: 1997 to present.** Building on the successes and lessons of past policy arrangements, a National Immunisation Program is instituted under Health Minister Michael Woodridge. This lays the foundation for immunisation strategies pursued today.

This retrospective consideration of Australia’s immunisation policy provides a framework for understanding the current system.

A.2 The Introduction of Childhood Vaccine Programs, 1916 – 1988

As noted above, Australian governments were among the first to recognise the public health benefits of mass immunisation and the value of financial investment in population-based vaccination programs.
With the establishment of the CSL in 1916, the mass-production of typhoid, cholera, plague, smallpox and diphtheria vaccines was introduced and a decade later school-based programs had begun to immunise children against diphtheria. In 1956 a vaccine (IPV) against polio was introduced and this provided the foundation of immunisation practice through the 1980s.

At this time the impact on government spending was limited – the standard vaccinations provided were generally limited to childhood vaccines – and as a result, the Australia vaccination industry was small, with a modest private market also emerging.

During the 1960’s the list of diseases for which vaccination was routinely provided remained reasonably constant: diphtheria, tetanus, pertussis, polio and smallpox. The 1970’s saw the introduction of vaccines for the common viral diseases of children, measles and rubella within Australia, and an increased global effort to expand the global vaccination program for a core set of diseases. The success of these earlier programs within Australia can be seen in the reduction of the incidence of disease (Table A.1).

<table>
<thead>
<tr>
<th>Period</th>
<th>Diph.</th>
<th>Pertus.</th>
<th>Tetanus</th>
<th>Polio</th>
<th>Measles*</th>
<th>AUS Pop (000’s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1926-1935</td>
<td>4073</td>
<td>2808</td>
<td>879</td>
<td>430</td>
<td>1102</td>
<td>6 600</td>
</tr>
<tr>
<td>1936-1945</td>
<td>2791</td>
<td>1693</td>
<td>655</td>
<td>618</td>
<td>822</td>
<td>7 200</td>
</tr>
<tr>
<td>1946-1955</td>
<td>624</td>
<td>429</td>
<td>625</td>
<td>1013</td>
<td>405</td>
<td>8 600</td>
</tr>
<tr>
<td>1956-1965</td>
<td>44</td>
<td>58</td>
<td>280</td>
<td>123</td>
<td>210</td>
<td>11 000</td>
</tr>
<tr>
<td>1966-1975</td>
<td>11</td>
<td>22</td>
<td>82</td>
<td>2</td>
<td>146</td>
<td>13 750</td>
</tr>
<tr>
<td>1976-1985</td>
<td>2</td>
<td>14</td>
<td>31</td>
<td>2</td>
<td>62</td>
<td>14 900</td>
</tr>
<tr>
<td>1986-1995</td>
<td>2</td>
<td>9</td>
<td>21</td>
<td>0</td>
<td>32</td>
<td>17 300</td>
</tr>
<tr>
<td>1996-2000</td>
<td>0</td>
<td>9</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

A.3    **A shift in funding arrangements, 1988 – 1993**

Throughout this period, the Commonwealth directly funded States and Territories for all childhood vaccinations. All Commonwealth-funded vaccinations were distributed to providers in the public sector, and private practitioners who gave vaccines were required to issue prescriptions for the private supply of vaccines by a pharmacist.

Then in July 1988, the Commonwealth announced its withdrawal of direct funding of vaccines. Instead, it proposed to increase funding to States and territories through vehicles known as Financial Assistance Grants (FAGs) and Hospital Funding Grants (HFGs). The aim of the policy shift was to cover the bulk of the vaccines on the National Health and Medical Research Council Immunisation (NHMRC) Schedule – regardless of whether the vaccine was publicly or privately provided.

The new funding arrangements fell short of expectations. Notably, there emerged wide variations in the prices that States and Territories paid for vaccines, with the smaller jurisdictions paying higher prices. As increases in vaccination activity above the 1988 level began to place pressure on the available resources, States and Territories began to dispute the level of funding provided under the new arrangements. Furthermore, because the Commonwealth, States and Territories each interpreted details of the funding arrangements in a different manner, there were significant variations in implementation of immunisation programs.

At the time, the NHMRC concluded that based on available data, approximately half of all Australian children received immunisation exclusively from the private sector: the vaccine was purchased by parents on prescription and administered in private consultation with a General Practitioner. The remaining half received immunisation services from a mix of private and public sectors: a primary course delivered in a public clinic and boosters delivered by a GP; or alternately, the full course was delivered by a GP with the vaccine supplied by the state/territory free of charge.

This fragmentation of service delivery rendered surveillance of immunisation programs difficult. In addition, the issue of whether childhood immunisation was a matter for private consultation with a GP or a matter for public health clinics operated by state and territories was unclear. According to the National Health and Medical Research Council (NHMRC), this un-coordinated and fragmented system of vaccination delivery contributed to a low level of immunisation.


Thus, the available evidence indicated that the indirect funding scheme introduced in 1988 had contributed to an unacceptable number of outbreaks of vaccine-preventable disease. The NHMRC cited “unnecessary health care expenditure and other economic costs”\(^{23}\) as the primary motivation for the immediate improvement of immunisation coverage rates.

In light of the major flaws with the FAG/HFG funding arrangement noted above, the NHMRC made recommendations for a National Immunisation Strategy (NIS) in April 1993. The key components of the strategy proposed by the NHMRC were:

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• Clearly differentiated roles for State and Territory and Commonwealth governments such that:
  – the Commonwealth should co-ordinate national policy via a national advisory body;
  – all governments should commit to the public funding of a national childhood immunisation program; and
  – States and territories be responsible for service delivery to meet local needs.

• Improved funding arrangements, such that:
  – the Commonwealth subsidy provided via the HFG’s and FAG’s should be index-adjusted; and
  – States and Territories should administer a funding pool, which includes their own contribution, Commonwealth funding for *Haemophilus influenzae* type b (Hib) vaccine and savings to the PBS and Medicare. In return, the states/Territories should be more accountable for achieving improved immunisation coverage.

• A national system of vaccine purchases, such that
  – governments were able to achieve better value for money. The approach suggested was to be a consortium of State, Territory and Commonwealth governments with independent reporting to the Australian Health Ministers Advisory Committee (AHMAC). State/Territory managed distribution systems would be the sole means of distributing free vaccines, thereby enabling better surveillance of vaccine usage.

In addition, the NIS proposed a number of strategies proposed for improving efficiency, quality, coverage and accountability of vaccination programs. These were encapsulated in a set of standards developed in 1994. Intended as a guide rather than a legal framework for providers and endorsed by the Australian Medical Association, the Royal Australian College of General Practitioners and the Australian College of Paediatrics – the standards provided the basis for quality assurance for immunisation service provision at all levels in the health system.
Box A.1

NHMRC STANDARDS FOR CHILDHOOD VACCINATION (1993)

- Vaccination services are readily available.
- There are no barriers or prerequisites to vaccination services.
- NHMRC-recommended childhood vaccines are offered free, without cost to parent or guardian.
- Vaccination providers utilise all clinical encounters to assess vaccination status and, when indicated, vaccinate children.
- Providers educate parent/caregivers about vaccination.
- Providers question parent/caregivers about contraindications and, before vaccinating a child, inform them in specific terms about the benefits and risks of the vaccines their child is about to receive.
- Providers withhold vaccination only for true contraindications.
- Providers offer and administer, where possible, all vaccines for which a child is due at the one visit.
- Providers use accurate and complete recording procedures.
- Providers report adverse events following immunisation promptly, accurately and completely as set out in Part 1.6, ‘Adverse events following immunisation (AEFI)’.
- Providers adhere to appropriate procedures for vaccine cold-chain management.
- Vaccination providers maintain current and easily retrievable vaccination guidelines at all locations where vaccines are administered.
- Vaccines are administered by properly trained individuals who receive ongoing education and training on current vaccination recommendations.


Furthermore, the first national immunisation strategy also proposed a single national vaccination schedule that identified age-appropriate vaccination to be undertaken across all jurisdictions.

During 1994, the Commonwealth Government moved to fund the purchase of a number of childhood vaccines (DTP, MMR, OPV) via Specific Purpose Payments to States/Territories. To correct the fragmented service delivery seen under the 1988 policy environment, it was mandated that Commonwealth funding be conditional on vaccines being provided to all public and private practitioners, and was formalised via bilateral agreements with each State/Territory.

**NIS heralds increased surveillance**

The beginning of the 1990s also saw the introduction of a number of other major surveillance and vaccination initiatives in Australia. A national disease notification system was established in 1991 under the auspices of State and Territory and Commonwealth communicable diseases program. This surveillance scheme was intended to improve the strategic approach to controlling communicable diseases in Australia, with particular emphasis on identifying and responding to incidence of vaccine preventable disease. The importance of surveillance, made clear by the success of the NIS, has been noted by Margaret Burgess of the NCIRS:

To evaluate the likely benefits of the introduction of the newer vaccines into routine vaccination programs, it is important to have reliable systems of regional and national surveillance to assess the burden of disease (deaths, disabilities and costs) and the effects of the proposed program.
Similarly, the Australian Childhood Immunisation Register (ACIR or Immunisation Register) was developed in response to a decline in childhood immunisation rates in Australia and the continuing significant incidence of preventable childhood diseases. The Register was established under the legislative and operational auspices of the Health Insurance Commission (HIC) and commenced operating on 1 January 1996. This initiative represented one of the major advances in a national immunisation strategy, as many countries had considered the concept of national surveillance of immunisation events, including reminder and recall schemes, as a necessary component of overcoming barriers to high immunisation uptake. Box A.2 describes the operations of the ACIR in greater detail.

Box A.2

UNDERSTANDING THE AUSTRALIAN CHILDHOOD IMMUNISATION REGISTER

The ACIR built upon the HIC’s platform as a health data administrator and payment agency within the health system. The general operating principle for establishing a universal database was that all children aged from birth to six years registered with Medicare would be automatically enrolled on the Register.

The ACIR records details of vaccination events for children aged up to seven years who reside in Australia. Defined information on immunisation encounters is forwarded to the HIC by recognised providers for inclusion in the Register. Although the initial format of transaction between the ACIR and providers was paper-based, the proportion of electronic interface has now increased to be the main mode of data and information exchange.

The ACIR also enables a system of recall and reminder for parents and providers and as the database has matured, has significantly improved surveillance and reporting of immunisation coverage. Prior to the introduction of the ACIR, methods used in assessing coverage varied widely in design and quality, with few studies measuring coverage at national or statewide level.

Bilateral agreements with States and Territories to cost-share an ACIR data collection fee were negotiated and established. Immunisation providers are paid for information provided to the Register regarding NHMRC recommended immunisation episodes. The Commonwealth contributes a $3.00 co-payment encounter fee for each defined episode. From 1 January 1996, States and Territories co-contributed to a maximum encounter fee of $6.00 with the exception being Queensland where providers only receive a $3.00 fee.

Source: Greg Sam analysis

Concurrent with the introduction of the NIS, the Government initiated funding for the Hib vaccination, which had become a major problem for Australia. From both a health and political perspective, the Hib vaccination proved a significant success (Box A.3).
Box A.3

PUBLIC HEALTH SIGNIFICANCE: IMMUNISATION SUCCESSES IN AUSTRALIA

Since the introduction of Hib vaccines, there has been a material reduction in the number of invasive cases of Hib throughout Australia, as illustrated in the graph below.

- Prior to the introduction of vaccine, Hib infections were the most common serious invasive bacterial infections in children.
- Aboriginal children are at a five to six times greater risk of developing Hib disease, as they tended to acquire the disease at a much younger age than other children.
- Immune-suppressed individuals of any age are also at risk of Hib infection.


A.5 The National Immunisation Program: 1997 – Present

Whereas the flawed FAG and HFG funding arrangement had laid the foundation for change in 1993, the successes of the NIS created an impetus for further improvements to immunisation policy and processes within Australia.

Despite progress toward meeting the goals and objectives contained in the 1993 Strategy, particularly reforms surrounding funding arrangements and the establishment of a national register, outbreaks of childhood preventable diseases continued, and barriers were still being encountered in attaining optimal vaccination coverage nationally.
In February 1997, the incoming federal Health Minister, the Hon. Dr. Michael Woodridge, obtained Cabinet approval for a package of initiatives to accelerate an improvement in vaccination coverage and to arrest continuing epidemics of vaccine preventable disease. The package was launched as the Immunise Australia – Seven Point Plan and consisted of:

- initiatives targeting parents;
- an expanded role for General Practitioners;
- national monitoring, reporting and evaluation of immunisation targets;
- a series of ‘immunisation days’;
- progressing measles eradication;
- strengthening related education and research; and
- progressing uniform national school entry requirements.

Box A.4 presents each component of the Seven Point Plan in detail.
Box A.4
THE SEVEN-POINT PLAN

Initiatives for Parents
- The first initiative directed towards parents was the restructuring of the federally funded Maternity Allowance to provide a bonus for parents for ensuring that their child's immunisation coverage is complete. An additional $68 was provided to parents, increasing the Maternity Allowance from approximately $882 to $950 per eligible child. There were provisions for parents who could not have their children immunised due to medical contraindications or chose not to have their child vaccinated due to conscientious objection.
- The second initiative directed towards parents was related to childcare rebates. On 27 April 1998, families applying for Childcare Assistance and Childcare Cash Rebate were required to demonstrate that their child was appropriately immunised for age according to the Australian Standard Vaccination Schedule. Provisions were also made for parents who do not have their children immunised due to medical contraindications or conscientious objection to claim exemption from this requirement.

An expanded role for General Practitioners
- The General Practice Immunisation Incentives (GPII) Scheme was introduced on 1 July 1998 to provide financial incentives to general practitioners to monitor, promote and provide age appropriate immunisation services to children under the age of seven years. The aim for the scheme was to achieve 90 percent of GP practices achieving 90 percent immunisation coverage nationally.

Monitoring, reporting and evaluation of immunisation coverage
- With the operationalisation of the ACIR and the advancement of state and territory initiatives to collect immunisation data, an agreement was made between government health services and immunisation providers to regularly release and report on immunisation rates at a national, state and territory level.

Immunisation Days
- The Commonwealth, in conjunction with the States and Territories piloted a series of immunisation days to increase immunisation coverage rates in geographical areas of low immunisation coverage on 2 August, 4 October and 6 December 1997.

Measles Eradication
- Following success in progress toward poliomyelitis eradication efforts domestically and regionally, a national strategy for measles eradication within Australia was developed. The strategy encompassed four components:
  - long-term, high vaccination coverage, with a two-dose strategy;
  - an effective vaccination coverage monitoring system;
  - enhanced measles case-based surveillance including urgent notification and confirmation of disease; and
  - a comprehensive rapid response strategy to every measles case.
- In addition to the primary school campaign, efforts at improving measles vaccination in the pre-school age group via General Practitioner services were also undertaken.

Education, Promotion and Research
- A major community education campaign was conducted in 1997, which included television and print media advertising, particularly focusing on the need for whooping cough and measles vaccination. Priority was also given to cultural and linguistically diverse communities.
- A specific strategy for providing campaign information and supporting technical resources to General Practitioners and other immunisation providers was undertaken.
- To progress a co-ordinated approach to national surveillance and research, the Commonwealth established the National Centre for Immunisation Research and Surveillance (NCIRS).

School Entry Requirements
- The Commonwealth in conjunction with State and Territory Governments developed a model school entry legislation framework to aid states and territories implement such requirements within their jurisdictions. The aim of the legislation is to ensure recording of a child's immunisation history at the time of school enrolment. Provisions exist for school exclusion of non-vaccinated students in the event of an outbreak of a vaccine preventable disease. Legislation has been enacted in New South Wales, Victoria, Tasmania and the Australian Capital Territory.

Source: NCIRS.
The initiatives of the Seven-Point plan, and the National Immunisation Program more broadly, have been highly successful in improving immunisation outcomes in Australia. According to Margaret Burgess of the NCIRS, Australia now boasts:

- the highest immunisation coverage ever recorded (see Figure A.1);
- the lowest rates of measles, rubella and Hib disease; and
- the lowest number of deaths from the diseases for which children are routinely vaccinated.

![Image of Figure A.1](image-url)

Figure A.1

IMMUNISATION COVERAGE IN AUSTRALIA, MARCH 1997 TO JUNE 2002

The changes to Australia’s immunisation policies and processes implemented in 1997 provide the foundation for current immunisation practices within Australia today.

A.7 Vaccine Funding Arrangements Post The Seven Point Plan

From 1997-1998 funds for vaccination were included in the Public Health Outcomes Funding Arrangements (PHOFAs). However, even with the adoption of the NIP, a number of vaccines continued to be funded via Finance Assistance Grants (OPV doses 1, 2, 3 and 4 and MMR dose 1) and Hospital Funding Grants (ADT). In 1997, the NHMRC recommended that the diphtheria-tetanus-acellular pertussis vaccine (DTPa) be used for the fourth and fifth doses of DTP vaccination. These became funded nationally in September 1997.
The 1998–1999 Commonwealth Budget included an initiative to streamline all childhood vaccine funding as from 1999-00, resulting in funding for all childhood vaccines on the ASVS (up to 15 years of age) being included in the PHOFAs. In the same financial year, pneumococcal and influenza vaccine for Indigenous Australians (Box A.3) and influenza vaccine for those aged over 65 years (Box A.4) were also funded. Existing vaccine funding allocations via FAGs and HFGs were not adjusted, thereby providing some capacity for State/Territory to refocus resources to purchase non-Commonwealth funded vaccines.

Box A.5

**NATIONAL INDIGENOUS PNEUMOCOCCAL AND INFLUENZA IMMUNISATION PROGRAM**

Respiratory diseases are major causes of preventable sickness and death in Aboriginal communities, with some having the highest incidence of invasive pneumococcal disease in the world.

The program provides free influenza and pneumococcal vaccines, through community controlled Aboriginal Medical Services (AMS), State/ Territory immunisation clinics and General Practitioners, for Indigenous people aged over 50 or at high risk, including:

- Adults with chronic debilitating diseases (especially those with chronic cardiac, pulmonary, renal and metabolic disorders, diabetes, alcoholism);
- Adults receiving immunosuppressive therapy; and
- Immuno-compromised persons at increased risk due to HIV infection before the development of AIDS, nephrotic syndrome, multiple myeloma, lymphoma, Hodgkin’s disease and organ transplants Individuals with asplenia or CSF leaks.


Box A.6

**NATIONAL INFLUENZA VACCINE PROGRAM FOR OLDER AUSTRALIANS**

The National Influenza Vaccine Program for Older Australians provides annual influenza vaccination for those persons aged 65 and older. States and territories currently purchase vaccine with Commonwealth funds and distribute via GPs or other aged care services. The federal Government has stated that it intends to restructure the arrangements for procurement of influenza vaccine, and is pursuing a national tender for vaccine supply that services both the over 65’s program and enables access to vaccine supply in the event of an influenza pandemic.


Federal funding to use DTPa for all five infant vaccinations began in February 1999, immediately after the NHMRC recommended the schedule change.
In 1999-00, PHOFA funding to purchase enough vaccine for 105 per cent of the eligible cohort for each vaccine (with the current exception of influenza vaccine) was made available. From May 2000, universal infant vaccination with hepatitis B vaccine was recommended and funded. This has been followed over the past 3 years by funding via the vaccines special appropriation of the high-risk conjugate pneumococcal vaccination program (Box A.5), national Q fever screening and vaccination program (Box A.6), and the national meningococcal C vaccination program (Box A.7).

Box A.7
NATIONAL HIGH RISK CHILDHOOD PNEUMOCOCCAL VACCINATION PROGRAM

The National Childhood Pneumococcal Vaccination Program commenced in 2001. The Program provides access to free pneumococcal vaccine for children who are predisposed to high rates of pneumococcal infection or whom are susceptible to high mortality should they acquire pneumococcal infection. Aboriginal children living in central Australia had the highest rates of pneumococcal infection in the world, with 15 times the chance of acquiring pneumococcal infection than non-indigenous Australians living in urban areas.

Children eligible for free pneumococcal vaccine are:
- all children under 2 years of age living in Central Australia;
- children under 5 years of age with medical risk factors that predispose them to high incidence or high severity of pneumococcal infection;
- all Aboriginal and Torres Strait Islander children under 2 years of age; and
- Aboriginal children in Central Australia and any region likely to have a similar high incidence of pneumococcal infection under 5 years of age.

Source: http://immunise.health.gov.au

Box A.8
NATIONAL Q FEVER MANAGEMENT PROGRAM

The National Q Fever Management Program aims to substantially reduce the burden of disease associated with Q fever in regional Australia. The National Notifiable Diseases Surveillance System shows from 1991 to 2001, 6,597 cases of Q fever have been reported. This averages around 600 cases per year in Australia. The Program comprises a targeted Q fever screening and vaccination program for individuals at high risk of contracting this disease through occupational exposure, and builds on existing Q fever screening and vaccination initiatives supported by industry. The Commonwealth Government has provided funds to State and Territory governments to administer the program and coordinate service delivery.

Phase 1 of the Program, announced in October 2000, is industry-focussed, targeting abattoir workers, those contracted to abattoirs and sheep shearers. Commonwealth funding of $10.6 million over 3 years from 2000-01 to 2002-03 is provided for the skin test, vaccination and a contribution towards the GP and pathology costs associated with immunity testing and vaccination.

Phase 2 of the Program, announced in October 2001, targets cattle and sheep livestock farmers, dairy farmers, their employees and unpaid family members working on farms. Government funding of $8 million over 3 years from 2001-02 to 2003-04 is provided for the purchase of skin tests and Q Fever vaccination. Farmers are able to claim GP and pathology costs as a work related tax deduction.

Source: http://immunise.health.gov.au
Box A.9

NATIONAL MENINGOCOCCAL C VACCINATION PROGRAM

As of 2003, all children turning 12 months of age will be eligible to receive free meningococcal C vaccine under the National Immunisation Program. In addition to this, the National Meningococcal C Vaccination Program will provide free meningococcal C vaccine for all one to 19 year olds, over the next four years.

Source: http://immunise.health.gov.au

A.8 Essential Vaccines Special Appropriation

Funding for essential vaccines used within the NIP is provided by the federal government as a 'special appropriation' under the provisions of Section 9B of the National Health Act 1953. Based on interpretation of this provision, funds appropriated are for the sole purpose of vaccine purchase.

Under the initial decision by Federal Cabinet, vaccines expenditure up to $10 million could be approved by the Federal Health Minister. Amounts between $10 and $20 million could be approved by the Minister for Finance. Amounts over $20 million required full Cabinet approval. This system of vaccine funding was designed to expedite introduction of new vaccines and prioritise the provision of vaccines beyond the regular budget cycle appropriation. It should be noted that the appropriation limit requiring full Cabinet approval was reduced in 2002 to $10 million.

The availability of free vaccines under the national immunisation program has been primarily determined by federal government funding appropriated via the mechanism described above.

A.9 Changes in vaccination practice

The impact of the major strategies over the last decade, 1993 to 2003, has been associated with a period of rapid and accelerated change in vaccination policy and practice in Australia, with major changes to the schedule and continued improvement in vaccination coverage and reporting. Boxes A.8 – A.12 below summarise the changes in vaccination practice for each major vaccine group from 1992 - 2002.
Box A.10

DIPHTHERIA TETANUS PERTUSSIS (DTP) VACCINATION PRACTICE AUSTRALIA 1992-2002

- 1994 - 5th dose of DTP at 4–5 years added to the recommended vaccination schedule (replacing CDT vaccine). Active ADT school vaccination programs commenced in some States for 15–19 year olds.
- 1996 - Diphtheria-tetanus-acellular pertussis vaccine (DTPa) licensed in Australia.
- 1997 - DTPa recommended for 4th and 5th doses of DTP vaccination (due at 18 months and 4–5 years).
- 1998 - 5th dose of DTPa changed from 4–5 years to 4 years of age.
- 1999 - DTPa recommended for all five childhood DTP doses. Combined DTPa-hepatitis B vaccine approved.
- 2000 - Combined Hib-Hepatitis B vaccine available.


Box A.11

HEPATITIS B VACCINATION PRACTICE IN AUSTRALIA, 1992-2002

- 1997 - Vaccination recommended for adolescents aged 10–16 years and an interim recommendation for universal vaccination of infants at birth.
- 1998 - School based programs commenced for 10–16 year olds in South Australia and Victoria. A ‘catch up’ campaign was conducted in the Northern Territory for children 6–16 years of age.
- 2000 - Combined DTPa-hepatitis B vaccine approved. Thiomersal-free paediatric hepatitis B vaccine approved. May: Universal infant vaccination included in childhood schedule with a birth dose of monovalent paediatric hepatitis B vaccine, followed by 3 doses as part of a combination vaccine schedule. Preadolescent vaccination recommended at 10–13 years rather than 10–16 years of age. Booster doses no longer recommended by NHMRC.


Box A.12

MEASLES MUMPS RUBELLA VACCINATION PRACTICE IN AUSTRALIA, 1992-2002

- 1992 (Nov) - NHMRC recommended 2nd dose of MMR vaccine for both sexes to replace schoolgirl rubella vaccination program.
- 1993 (Nov) - Childhood vaccination schedule updated to include second dose of MMR vaccine for 10–16 year olds (replacing schoolgirl rubella vaccination).
- 2000 - MMR rather than rubella vaccine recommended for non-immune women of child-bearing age
Box A.13
POLIO VACCINATION PRACTICE IN AUSTRALIA, 1992-2002

- 1994 - Recommendation for reinforcing dose of OPV to 15 year old adolescents


Box A.14
HAEMOPHILUS INFLUENZAE TYPE B VACCINATION PRACTICE AUSTRALIA, 1992-2002

- 1992 - 1st Hib vaccines (PRP-D, ProHiBIt) licensed in Australia for vaccinating infants aged at least 18 months.
- 1993 - Hib vaccine recommended as part of the childhood vaccination schedule. Hib vaccines: HBOC (HiBtITER), PRP-T (Act-HIB), and PRP-OMP (PedvaxHiB) licensed for infants aged <18 months. PRP-OMP recommended at 2, 4 and 12 months, HBOC and PRP-T at 2, 4, 6 and 18 months.
- 2000 - Combined Hib(PRP-OMP)-hepatitis B vaccine approved. PRP-OMP recommended for all infants (administered separately or in combination with hepatitis B vaccine)


In September 2003, following the delivery of a number of recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI), the NHMRC approved revision of the Australian Standard Vaccination Schedule (Table A.2).
Table A.2

AUSTRALIAN STANDARD VACCINATION SCHEDULE 2003 – NATIONAL HEALTH & MEDICAL RESEARCH COUNCIL

<table>
<thead>
<tr>
<th>AGE</th>
<th>VACCINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth</td>
<td>Hepatitis B&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>2 mths</td>
<td>Hepatitis B&lt;sup&gt;2,3&lt;/sup&gt; DTPa Hib&lt;sup&gt;1,2&lt;/sup&gt; IPV 7vPCV</td>
</tr>
<tr>
<td>4 mths</td>
<td>Hepatitis B&lt;sup&gt;2,3&lt;/sup&gt; DTPa Hib&lt;sup&gt;1,2&lt;/sup&gt; IPV 7vPCV</td>
</tr>
<tr>
<td>6 mths</td>
<td>Hepatitis B&lt;sup&gt;2&lt;/sup&gt;  DTPa Hib&lt;sup&gt;1&lt;/sup&gt; IPV 7vPCV</td>
</tr>
<tr>
<td>12 mths</td>
<td>Hepatitis B&lt;sup&gt;3&lt;/sup&gt;  Hib&lt;sup&gt;1,2&lt;/sup&gt; MMR VZV MenCCV</td>
</tr>
<tr>
<td>18 mths</td>
<td>DTPa Hib&lt;sup&gt;1,2&lt;/sup&gt;  IPV MMR VZV 23vPPV&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>2 yrs</td>
<td>DTPa IPV MMR</td>
</tr>
<tr>
<td>4 yrs</td>
<td>DTPa IPV MMR</td>
</tr>
<tr>
<td>10–13yrs</td>
<td>Hepatitis B&lt;sup&gt;4&lt;/sup&gt;  VZV&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>15–17yrs</td>
<td>dTPa</td>
</tr>
<tr>
<td>50 yrs &amp; over</td>
<td>dT</td>
</tr>
<tr>
<td>65 yrs &amp; over</td>
<td>dT</td>
</tr>
</tbody>
</table>

Schedule key: Hepatitis B<sup>1</sup>: Monovalent hepatitis B vaccine. Hepatitis B<sup>2</sup>: Hepatitis B vaccine given as either monovalent vaccine or in combination with DTPa, 3 doses at 2, 4 and 6 months, in addition to the birth dose for a total of 4 doses. Hepatitis B<sup>3</sup>: Hepatitis B vaccine in combination with Hib (PRP-OMP), 3 doses at 2, 4 and 12 months, in addition to the birth dose for a total of 4 doses. Hepatitis B<sup>4</sup>: Hepatitis B vaccine for 10 to 13 year olds who have not received a primary course. Hib<sup>1</sup>: PRP-T, HbOC (non-Indigenous children).Hib<sup>2</sup>: PRP-OMP (all children).

As at December 2003, the federal government has funded or implemented the following recommendations within the National Immunisation Program:

- the fifth dose of OPV, previously scheduled at 15-17 years of age, is longer required;
- a new 2-dose schedule for the hepatitis B vaccine can be used as an alternative to the standard 3 dose schedule for adolescents aged 11 – 15 years;
- Meningococcal C conjugate vaccine is routinely recommended as a single dose at 12 months of age;
- the fourth dose of DTPa, which was previously given at 18 months of age is no longer required. The fourth dose of DTPa is now recommended at 4 years of age;
- the 7-valent pneumococcal conjugate vaccine (7vPCV) is now recommended for:
  - Aboriginal and Torres Strait Islander infants in a 3 dose series at 2, 4, 6 months of age with a booster dose of the 23 valent pneumococcal polysaccharide vaccine (23vPPV) at 18-24 months of age;
  - All Australian children with underlying predisposing medial conditions at 2, 4 and 6 months of age with a booster dose of 7vPCV at 12 months of age and a booster dose of 23vPPV at 4–5 years of age; and
  - All non-indigenous children residing in central Australia at 2, 4 and 6 months of age; and
- an adult/adolescent formulation pertussis-containing vaccine is available for boosting against pertussis, recommended as a single dose at 15-17 years of age.

By contrast, the federal government has not funded the following recommendations within the NIP:

- replacement of Oral Poliomyelitis Vaccine (OPV) with inactivated poliomyelitis vaccine (in combination with other scheduled antigens so as not to add an additional injection);
- varicella-zoster (chicken-pox) vaccine is recommended for all children at 18 months of age, with a catch-up dose for adolescents without a history of varicella or varicella vaccination; and
- the 7-valent pneumococcal conjugate vaccine (7vPCV) is now recommended for all Australian children as a 3 dose series at 2, 4 and 6 months of age.
Appendix B

Immunisation systems in comparator countries

B.1 Canada

System management
Canada has a federal-based governance system comprising a National Advisory Committee on Immunization (NACI), which in conjunction with the Governmental Centre for Infectious Disease Prevention and Control (CIDPC) advises on the use and target populations for existing or emerging vaccines. The NACI also governs vaccine assessment and surveillance for coverage and adverse events. Recommendations of the NACI are outlined in the “Canadian Immunization Guide”, a publication of Health Canada.

System surveillance
Canada operates a hybrid AEFI surveillance system. Two main AEFI systems operate in Canada, passive system that collects data from health care providers, and an active surveillance system operating through paediatric hospitals, known as IMPACT (Immunization Monitoring Program Active). Thirteen hospitals contribute to this latter system, representing approximately 85% of tertiary care paediatric beds in Canada.

In Canada no single immunisation registry system exists, however a major goal of their current NIP is to implement integration of provincial and territory based registries to facilitate transfer of immunisation records between jurisdictions, improve national surveillance and to enable linking of vaccine-preventable diseases and AEFI.

Approach to funding
Health care funding in Canada is primarily a provincial or territorial responsibility. Federal support for vaccine funding is subsumed under ‘general health care funding’ and has been limited to:

- regulating vaccine licensure/release;
- supporting the National Advisory Committee on Immunization; and
- maintaining a small staff and budget to assist Provinces and territories in coordinating activities.

As with Australia, Canadian guidelines have not been supported by a central national pool of funds for all elements. While vaccination for nine diseases – which can be carried out by either public or private providers – is funded in all Canadian provinces, the provision of newer recommended vaccines (meningococcal c, conjugate pneumococcal vaccine, varicella, and adolescent pertussis vaccine) has not been federally funded. As a result there is high variation in the provision of these vaccines across different jurisdictions.

Information sourced from http://www.hc-sc.gc.ca
B.2 New Zealand

System management
The New Zealand Ministry of Health is responsible for ensuring the adequacy of the immunisation program at the national level through a national co-ordination function and monitoring immunisation coverage, vaccine preventable diseases (including implied vaccine effectiveness) and adverse events following immunisation. It also has the responsibility for purchasing vaccines, health education materials, national promotion of immunisation and auditing the performance of the cold chain. The Ministry of Health’s Immunisation Programme Advisory Committee advises on the National Immunisation Schedule.

System surveillance
New Zealand also has a passive system of AEFI surveillance. In New Zealand severe or unexpected reactions are reported to the Medical Assessor Centre for Adverse Reactions Monitoring, and to the patient’s general practitioner (if the vaccinator is another person).

Up until 2000, New Zealand provided indirect estimates of national immunisation coverage using immunisation benefit claims and information from general practitioners. Currently, work is in progress to improve coverage information through the development of a register. The aim of the National Immunisation Register there will be to provide accurate data on a child’s immunisation status, as well as information on local, regional and national coverage.

Approach to funding
Unlike Australia, the immunisation strategy in New Zealand provides for the full funding of all recommended vaccines. In New Zealand the Institute of Environmental Science and Research (ESR) operates a national vaccine store. The New Zealand approach is similar to that in place in the UK where the National Health Service Purchase and Supply Agency undertake the procurement of recommended vaccines on behalf of the Department of Health.

B.3 United Kingdom

System management
The Department of Health has primary responsibility for determining policy and procedures relating to immunisation in the United Kingdom. Immunisation policies and procedures are published periodically in the Department’s ‘Green Book’ or via stand-alone policies on specific diseases and vaccination programs issued through the UK Health Protection Agency.

The major advisory committee is the Joint Committee on Vaccination and Immunisation (JCVI), an independent expert advisory committee first set up in 1963. The main term of reference for the JCVI is to recommend vaccination policy that considers the need for and impact of vaccines, the quality of vaccines and their safety and the strategies to ensure that the greatest benefit can be obtained from the most appropriate use of vaccines;

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26 Information sourced from http://www.moh.govt.nz
27 Information sourced from http://www.hpa.org.uk
System surveillance

Responsibility for surveillance and reporting of vaccination coverage falls to the Health Protection Agency. The Communicable Disease Surveillance Centre of the Health Protection Agency, in collaboration with CDSC Wales, CDSC Northern Ireland and the Scottish Centre for Infection and Environmental Health, collates UK immunisation coverage statistics from computerised child health systems for children aged one, two and five years of age.

COVER was first piloted in England and Wales in January 1987, with 14 districts contributing data. By May 1989, 175 of the 200 districts in England and Wales were participating. Vaccination data were requested from each district/health board in England, Wales and Northern Ireland for quarterly cohorts of resident children who had recently reached target age for completing vaccination with sentinel antigens. District data was aggregated at the Communicable Disease Surveillance Centre, and regional and national statistics fed promptly back to district immunisation coordinators and regional medical officers. Summary data were also included in the Communicable Disease Report.

With the reorganisation of the NHS in April 2002, COVER data for England is now collected from primary care trusts (PCTs) rather than health authorities. The denominator is defined as the PCT relevant population and includes all children registered with a GP whose practice forms part of the PCT, regardless of where the child is resident, plus any children not registered with a GP, who are resident within the PCT’s statutory geographical boundary. Children resident within the PCT geographical area, but registered with a GP belonging to another PCT, are the responsibility of that other PCT.

Approach to funding

In the United Kingdom all recommended vaccines are currently centrally government subsidised.

Primary care trusts are responsible for the planning, funding and delivery of immunisation services through GP based or public clinics under the direction of the local Medical Officer of Health. Regional Strategic Health Authorities are responsible for health service performance monitoring, including immunisation coverage and vaccine preventable disease control. All vaccines recommended on the UK childhood vaccination are funded by local PCT’s.
B.4 United States

System management
In the United States, the Advisory Committee on Immunization Practices (ACIP) provides advice on vaccine preventable disease to the Secretary of the US Department of Health and Human Services and to the Centers for Disease Control and Prevention (CDC). The ACIP’s functions are to provided advice and guidance regarding the applications of vaccine antigens for effective disease control, to review and report on practices and recommend improvements in the NIP, and to establish and review the list of vaccines made eligible to children under the Vaccines for Children Program. The US NIP has been established under the Public Health Services Act and organised by the CDC. The NIP identifies opportunities to quality assurance activities and provides funds to organise and encourage state-level initiatives to improve vaccination levels through contracting to ensure vaccine supply, information systems, and surveillance.

System surveillance
The United States operates national AEFI surveillance, which is known as the Vaccine Adverse Events Reporting Scheme (VAERS). To address the liability Insurance crisis in the late 1980’s, the US Congress enacted the National Vaccine Injury Compensation Program in 1988. This is a no-fault compensation scheme that provides predetermined compensation for a defined schedule of injuries associated with the vaccines that it covers. Additionally, it is required of all vaccination providers to supply consumers with a Vaccine Information Statement that identifies the AEFI risks inhered with the vaccine.

No single federal registry for immunisation coverage is in operation within the United States. In the US registry funding is primarily from State and local sources, not the CDC. A federal initiative to network state registries was launched in 1997, which provides standards for common definitions.

Approach to funding
In total, just over 50% of all childhood vaccines in the US are purchased in the public sector.

The Vaccines for Children (VFC) program was established in the United States in 1994 and provides vaccines for children who qualify at no charge. The criteria for eligibility to the program are:

- the child must be eligible for Medicaid;
- the child must lack health insurance; or
- the child is a native American or Alaskan native.

An additional criterion is that the child is under-insured for immunisations, however those in this category can only receive through a federally funded health centre or rural health centre. The VFC purchases for approximately 35% of the national cohort, at a cost of more than USD500million per annum (2000 data).

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28 Information sourced from http://www.cdc.gov