NATIONAL CENTRE FOR IMMUNISATION RESEARCH & SURVEILLANCE

Evaluation of the National Older Australians Pneumococcal Immunisation Program

Final report

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Abbreviations

ACIR	Australian Childhood Immunisation Register
ADRAC	Adverse Drug Reactions Advisory Committee
ADRS	Adverse Drug Reactions System
ADRU	Adverse Drug Reactions Unit
AEFI	Adverse event following immunisation
AIA	Australian Immunisation Agreement
AIHW	Australian Institute of Health and Welfare
AMS	Aboriginal Medical Service
CATI	Computer assisted telephone interview
CDNA	Communicable Diseases Network Australia
DoHA	Australian Government Department of Health and Ageing
EIPDSWG	Enhanced Invasive Pneumococcal Disease Surveillance Working Group
GP	General practitioner
IPD	Invasive pneumococcal disease
NCIRS	National Centre for Immunisation Research and Surveillance
NHMRC	National Health and Medical Research Council
NIC	National Immunisation Committee
NIP	National Immunisation Program
NIPII	National Indigenous Pneumococcal and Influenza Immunisation
NNDSS	National Notifiable Diseases Surveillance System
7vPCV	7-valent pneumococcal conjugate vaccine
23vPPV	23-valent pneumococcal polysaccharide vaccine
RCT	Randomised controlled trial
SAEFVIC	Surveillance of Adverse Events Following Vaccination in the Community
SBO	State Based Organisations
SBOIC	State Based Organisation immunisation coordinator
TGA	Therapeutic Goods Administration
VE	Vaccine effectiveness

Executive Summary

Background

The Older Australians Pneumococcal Immunisation Program commenced in January 2005. It provided funding for the purchase of 23-valent polysaccharide pneumococcal vaccine for all adults aged ≥65 years and a single revaccination after 5 years. A second revaccination was also recommended for those first vaccinated before 65 years of age. It was introduced simultaneously with the National Childhood Pneumococcal Immunisation Program, and followed several regional vaccination programs for Indigenous adults, the Victorian elderly pneumococcal program from 1998 and the National Indigenous Pneumococcal and Influenza Immunisation Program for Indigenous adults from 1999.

Methods

The evaluation consists of three major components: a process evaluation, system description and outcome/impact analysis. It covers the 4-year period from 1 January 2005 to 31 December 2008.

Results

Program implementation

Key informants reported the program to be successfully implemented, effectively capitalising on the strengths of immunisation service provision in Australia, in particular the Older Australians Influenza Immunisation Program. Commonwealth promotional resources were valued but also supplemented by materials from the jurisdictions. A number of issues and barriers to the delivery of the program were identified. These included the short time-frame for implementation, concern at the lack of an immunisation register for this age group with consequent difficulty in ascertaining vaccination status or coverage in a timely way. The simultaneous rollout of the childhood and the older Australians pneumococcal immunisation programs was also mentioned as an issue, as it caused confusion among providers, with some having difficulty in distinguishing the two vaccines (7-valent pneumococcal conjugate vaccine [7vPCV] and 23-valent pneumococcal polysaccharide vaccine [23vPPV]). There were also some reported instances of Pneumovax 23^{TM} (23vPPV) supplies being discarded after the annual influenza season, due to providers not being aware shelf life was longer than that of influenza vaccine.

The following recommendations are made regarding program implementation:

- Allow a minimum of 9 months for planning program implementation.
- Should the program be expected to continue into the medium term, establish an immunisation register or some other effective means to provide timely coverage data and retrieve vaccination status information on individuals. This is a particular priority for the 23vPPV program, given its relatively complicated revaccination recommendations.
- Promote Pneumovax 23^{TM} vaccination during the whole year.
- Consider having a set time of year for implementation of new programs and/or stagger different vaccines where possible.
- Centrally produce educational and promotional materials available for immunisation providers and clients.

- Promotional materials for the general public should be engaging and attractive, while those for providers should be concise.
- Expand web-based and other online information for quick and easy access by providers.
- Pay special attention to information needs where more than one vaccine is launched.

Available data systems

Three main sources of data were available for evaluating the outcomes and impacts of the Older Australians Pneumococcal Immunisation Program. These were invasive pneumococcal disease (IPD) notifications provided by the Enhanced IPD Surveillance Working Group, national adverse events following immunisation reports provided by the Therapeutic Goods Administration, and vaccination coverage estimates from computer assisted telephone interview surveys conducted by the Australian Government Department of Health and Ageing (DoHA) and some jurisdictions. These sources were vitally important; however, limitations were identified that either restrict or affect the quality of output. The following recommendations have been developed.

- National IPD surveillance, including enhanced data, have provided critically important data for monitoring the impact of pneumococcal vaccination. However, issues remain to be resolved with respect to data completeness, timely collation and reliable transfer to DoHA. The establishment of a single complete historical national dataset that is updated with additional annual datasets in a timely way should be a priority.
- The monitoring of vaccination coverage in adults has been limited by irregular national surveys, with only one post-program survey available for this evaluation, conducted in 2006. In the absence of a national adult or pneumococcal immunisation register as mentioned above, annual surveys should be conducted to enable timely program monitoring.
- Collecting vaccination status data for a vaccine with complicated revaccination recommendations, such as pneumococcal vaccine, requires more attention to data validity than for influenza vaccine, which is recommended annually. Individual studies have provided variable estimates of validity, and an assessment of the exact questions used in the adult vaccination survey, including verification by providers, should be conducted.

Vaccination coverage, vaccine safety and disease impact

The Older Australians Pneumococcal Immunisation Program appears to have resulted in a modest increase in vaccination coverage. In 2004, an estimated 51% of eligible survey respondents had been vaccinated in the previous 5 years, increasing to 62% in 2006. As the estimated national influenza vaccination coverage in 2006 was 78% there is room for improvement of 23vPPV coverage. Reports of adverse events were predominantly mild injection site reactions and consistent with the known safety profile of this vaccine.

There was a 31% decrease in total IPD notification rate in those aged ≥65 years not recorded as Indigenous from Australian jurisdictions excluding Victoria between 2002–2004 and 2007–2008. However, the decrease was limited to serotypes in the 7vPCV, which decreased by 72%, while IPD due to serotypes contained only in the 23vPPV increased by 49%. The most likely explanation for this pattern is a decrease in 7vPCV-type IPD due to herd immunity effects of childhood immunisation, which has been reported in several other countries. Therefore, an impact on notifications of

IPD from the Older Australians program cannot be demonstrated, possibly due to the herd immunity effects of 7vPCV, as well as the modest increase in coverage and the limited effectiveness of the 23vPPV. Estimates of vaccine effectiveness (VE) for 23vPPV in elderly Australians were 32.5% (95%CI: –20 to 62) using the indirect cohort method, as at 2005, and 56.9% (95%CI: 42–68) using the screening method, as at 2005–2006. They are consistent with the extensive international literature on effectiveness of the 23vPPV. However, these estimates may not represent VE in more recent years due to the substantial changes in serotype distribution caused by the use of 7vPCV. New, currently licensed, higher valency conjugate vaccines, if introduced into the National Immunisation Program for children, could also be expected to result in herd immunity effects in the elderly, from a broader range of serotypes, further decreasing the potential benefit of 23vPPV.

CHAPTER 1. Introduction

Pneumococcal disease is caused by the bacterium *Streptococcus pneumoniae* (pneumococcus). Pneumococci are frequently isolated from the upper respiratory tract and can spread directly from the nasopharynx to cause infection in other parts of the respiratory tract (otitis media, sinusitis, pneumonia) or enter the bloodstream. Prior to widespread conjugate pneumococcal vaccination pneumococcus was the most common bacterial cause of acute otitis media in developed countries, which in turn was the most common bacterial infection treated by paediatricians[1], and the cause of approximately 60% of pneumonia, the 6th most common cause of death in Australia.[2] Following bloodstream invasion, clinical manifestations include meningitis, pneumonia and infection at a number of less common sites, as well as septicaemia without focal infection. Invasive pneumococcal disease (IPD) is defined as a sterile site isolate of *Streptococcus pneumoniae*, usually from blood. To date, 90 capsular antigenic types have been recognised, each eliciting type-specific immunity. The age groups with the highest rates of IPD are children <2 years of age and adults >85 years of age. Rates are substantially higher in those with medical or other risk factors such as chronic respiratory or cardiac disease, immunosuppression of any cause, in Indigenous Australians and smokers.

At the commencement of the Older Australians Pneumococcal Immunisation Program, there were two pneumococcal vaccines available in Australia: Pneumovax 23™ (CSL Biotherapies/Merck & Co Inc.) licensed in 1986 and Prevenar™ (Wyeth Australia Ltd) licensed in 2000.[3,4] Pneumovax 23™, a 23-valent polysaccharide pneumococcal vaccine (23vPPV), contains polysaccharide capsule antigens from 23 serotypes of pneumococcus, is effective in reducing the incidence of invasive pneumococcal disease among adults and the immunocompetent elderly, but has a limited response in children <2 years of age. It has substantially reduced effectiveness 5 years after vaccination, little or no impact on nasopharyngeal carriage or non-invasive disease, and does not elicit a booster response. [3,5,6] In contrast, Prevenar™, a 7-valent pneumococcal conjugate vaccine (7vPCV) is a newer technology, containing seven pneumococcal polysaccharide serotypes conjugated to a diphtheria toxin protein. The so-called 'conjugate' vaccines induce a T-cell, or memory, immune response and an effective response in the immature immune system of infants. The 7vPCV is effective in reducing morbidity and mortality from IPD in children <2 years of age and does reduce or eliminate nasopharyngeal carriage of vaccine serotypes. The 7vPCV has demonstrated impacts on non-invasive disease and herd immunity effects in unvaccinated age groups in some settings. It is licensed only for use in children from 2 months to 9 years of age.[1,3] It includes the seven serotypes that were the most common cause of IPD in US children prior to widespread vaccination, all of which are also in the 23vPPV.

Prior to the widespread use of pneumococcal conjugate vaccine, between 2002–2004, approximately 68% of IPD in the elderly was due to the seven serotypes in the conjugate vaccine, and 95% was due to the 23 serotypes in the 23vPPV.

The National Older Australians Pneumococcal Immunisation Program commenced in January 2005, at the same time as the National Childhood Pneumococcal Immunisation Program. The Australian government funded the 23vPPV for adults ≥65 years in all states and territories.[7,8]

The 23vPPV has been available through a range of publicly funded programs prior to the national program for the elderly. In 1991, a pneumococcal immunisation program for Indigenous adults was conducted in some parts of the Kimberley region of Western Australia which became Kimberley-wide from 1996.[9,10] In Queensland, a targeted pneumococcal and influenza program commenced in 1996 for Indigenous adults in Cape York which was extended to the Torres Strait and Cairns in 1997.[11,12] The following year, a state-wide Indigenous pneumococcal and influenza immunisation program funded by Queensland Health commenced.[11,12] The Northern

Territory Government Department of Health and Families has also recommended pneumococcal vaccines for Indigenous adults since the early 1990s but in 1995 actively promoted this vaccine to Indigenous adults, and since May 2000 has funded vaccines to all Indigenous individuals aged ≥15 years.[13] From 1999 onwards, the National Indigenous Pneumococcal and Influenza Immunisation (NIPII) Program funded 23vPPV for Indigenous adults aged ≥15 years with risk factors and all Indigenous adults aged ≥50 years.[14] Since 1997, 23vPPV has been recommended for all individuals aged ≥65 years[3] and available at a subsidised cost through the Government's Pharmaceutical Benefits Scheme. In Victoria, a universal pneumococcal immunisation program for the elderly commenced in 1998.[15,16]

The 23vPPV is also recommended for those aged ≥10 years with medical or other conditions putting them at increased risk of IPD. For those first vaccinated at ≥65 years of age a single revaccination is recommended 5 years after the first dose. For those first vaccinated at <65 years of age, a second revaccination is recommended, either 5 years after the second dose, or at 65 years of age, whichever is later.[3]

Evaluation of the Older Australians Pneumococcal Immunisation Program

The National Centre for Immunisation Research and Surveillance (NCIRS), as part of its responsibilities under the 2005–2009 funding agreement with the Australian Government Department of Health and Ageing (DoHA), has the lead role in evaluations of National Immunisation Program (NIP) vaccines. Evaluations are conducted according to a standard protocol agreed with DoHA, consisting of a Systems description, Process evaluation, and an analysis of Outcomes (adverse events following immunisation, vaccination coverage) and Impacts (morbidity and mortality). Evaluations are conducted in liaison with key stakeholders, in particular the National Immunisation Committee (NIC). The evaluation of the Older Australians Pneumococcal Immunisation Program was conducted during 2009 concurrently with an evaluation of the National Childhood Pneumococcal Immunisation Program.

NCIRS has previously submitted unpublished evaluation reports on the National Indigenous Pneumococcal and Influenza Immunisation (NIPII) Program in 2004,[17] the National Q Fever Immunisation Program (2004), the National Meningococcal C Program (2007), and the National Adolescent Pertussis Immunisation Program (2009), as well as a published report on the National Measles Control Progam.[18]

CHAPTER 2. Process Evaluation

Aims

The purpose of conducting a process evaluation of the pneumococcal immunisation program is to describe the planning, implementation and delivery of the program, the achievements and any obstacles encountered.

Chapter scope and structure

The evaluation was limited to a review of publicly available documents, materials provided by state/territory immunisation program managers and a survey of key informants.

The results section of the report is divided into two major sections:

Part 1 summarises the key aspects of the planning, implementation and delivery of the national program.

Part 2 summarises the strengths and challenges in the planning, implementation and delivery of the program as identified by key informants (based on experience with the program implementation) and informants' recommendations for future immunisation programs.

Methods

Information sources

Sources reviewed to obtain information about the planning and implementation of the pneumococcal immunisation program included: available media releases; information documents written for providers and parents and available on health department websites; reports and data provided by the states and territories; and information obtained from a survey of key informants.

Survey of key informants

The survey was conducted between March and August 2009. The key informants surveyed (listed in the acknowledgements) were staff from the Department of Health and Ageing, state and territory program managers and other relevant staff, and four Divisions of General Practice/State Based Organisation immunisation coordinators (SBOICs). The SBOICs were nominated by Ms Helen Moore; they were involved at the general practice or Divisional level at the time of program commencement, although none were in their current roles as SBOIC at that time. Twenty-two people were surveyed, of whom only 55% (12) were in their current roles in 2005. Those 12 included representatives from six states and territories and one from DoHA. Key informants were sent a questionnaire by email prior to a structured telephone interview, which was audio-digitally recorded with consent of the respondent.

Questionnaire

The structured questionnaire used for the telephone survey of key informants was developed by NCIRS staff based on previous national immunisation program evaluations.[17,19,20] The questionnaire contained both open and closed questions and sought information about:

- program development and planning including funding, the communication strategy, vaccine supply and distribution
- implementation of the program
- surveillance of adverse events following immunisation (AEFI)

- monitoring of vaccine coverage, wastage and leakage
- participants' views regarding the strengths and weaknesses of the pneumococcal immunisation program planning, and their recommendations for future immunisation campaigns.

This information was sought in a series of open questions in the telephone interview (see Appendix). The answers from the telephone interviews were transcribed and drafts sent back to the informants for their comments. All changes and additional information from the informants were incorporated into the final versions of the transcribed questionnaire.

Data analysis

Survey responses were collated in an Excel spreadsheet. Content analysis was conducted to identify prominent themes nominated by key informants regarding strengths and weaknesses of the pneumococcal immunisation program and informants' recommendations for future programs.

Results

Part 1: Planning, implementation and delivery of the program

This section summarises key features of the planning, implementation and delivery of the program including the roles and responsibilities of DoHA, jurisdictions and immunisation providers. However, it was difficult to obtain detailed information on specific roles and responsibilities as only half of all key informants and none of the SBOICs were in their current positions in 2005. Responses were often of a general nature. Any specific information provided in a particular area has been clearly stated in the relevant section.

Funding

The Australian Government allocated funding for the Older Australians Pneumococcal Immunisation Program and the announcement was made by the then federal Minister for Health and Ageing in two media releases, on 11 June and 7 December 2004.[7,8] It was announced that from 1 January 2005 the Australian government would provide free pneumococcal vaccine to all Australians aged ≥65 years.

From 1 January 2005, funds were made available to the states and territories for purchasing Pneumovax 23™, through the usual arrangement under the Australian Immunisation Agreements (AIA). Funding of $28,554,188 was provided to jurisdictions in 2005 to purchase vaccine to cover the period of the AIAs up to 2009. The funds allowed for 85% vaccine coverage of the entire population aged ≥65 years during that period and 15% for wastage and leakage of vaccines. Performance indicators were negotiated between DoHA and the state and territory governments as part of the AIAs. Funds provided by DoHA did not include an allocation for service delivery and state and territory governments provided additional funds for this in some instances.

Communication

The communication strategy included a national component that focused on the broader aspects of the Older Australians Pneumococcal Immunisation Program, a local component that provided information about delivery of the program in each state and territory, and a State Based Organisation/Division of General Practice component.

National communication strategy

DoHA developed a communication campaign that used a combination of mass media and direct communications to notify the Australian public and health professionals about the program. Mass media communication strategies included media releases and interviews by the then Minister for Health and Ageing, Tony Abbott.[7,8] In addition, information for consumers and immunisation providers about pneumococcal disease was posted on the national Immunise Australia website, and provided through the national immunisation telephone help line. The Department of Veterans' Affairs also had promotional activities for pneumococcal vaccinations (e.g. articles in *Vetaffairs*, a newspaper for the veteran community; mail-outs to immunisation providers).

A comprehensive information package was sent by DoHA to all general practitioners (GPs) and practice nurses to inform them of the National Older Australians Pneumococcal Immunisation Program. The package included a tear-off pad (information provided as Q&As for the general public), posters and provider guidelines. The DoHA promotional materials were circulated to NIC for comments prior to distribution. DoHA also utilised the existing strategy for the over 65 year olds influenza vaccinations for promoting the pneumococcal program. The education was targeted at GPs as the 65 year olds and over had proven to be compliant with GP advice.

Jurisdictional communication strategies

The jurisdictional communication strategies varied though all states/territories included information on their health department websites, provided information through their immunisation telephone help lines and did local media releases (Table 1). All jurisdictions, except Victoria, used the DoHA promotional materials. In addition, jurisdictions held educational sessions and disseminated information about the program to immunisation providers through the relevant health department, population health units and the State Based Organisations/Divisions of General Practice.

The program was promoted primarily along with the seasonal influenza program in all states/territories using posters, pamphlets, T-shirts promoting vaccine days, DoHA resources and the resource materials developed by the vaccine companies. In Victoria, as this was the 8th year of their immunisation program, promotional activities from previous years were continued, although less intensive than would be expected at the launch of a new program. Other state/territory health departments also promoted and educated specific healthcare providers in some instances, e.g. NSW Health promoted the program to Justice Health; and the South Australian Department of Health promoted and educated pharmacies and aged care centre staff on maintaining consistency in vaccination recording systems and practices. The inclusion of the pneumococcal vaccine on vaccine order forms developed by the jurisdictions for recording the number of vaccine doses in stock/fridge and the number of doses required by immunisation providers also alerted immunisation providers about the program.

Table1. Communication strategy and materials by states/territories/Division of General Practice/State Based Organisations

Jurisdiction	Communication materials/strategy
Australian Capital Territory	Fact sheets, newsletters Education sessions/information evenings Vaccine company promotional materials (posters, radio ads) Website Health/Immunisation phone help line
New South Wales	Fact sheets, articles in the *NSW Public Health Bulletin* Education (e.g. Justice Health, general practices, nursing homes) Website Health/Immunisation phone help line
Northern Territory	Fact sheets, newsletters Articles in the *NT Disease Control Bulletin* Education sessions Vaccine company promotional materials Website Health/Immunisation phone help line
Queensland	Fact sheets, newsletters Education sessions/workshops Website Health/Immunisation phone help line
South Australia	Fact sheets, newsletters (*Sharp to the Point*) Education (e.g. general practices, aged care centres and pharmacies) Pamphlets Website Health/Immunisation phone help line
Tasmania	Vaccine company promotional materials Education sessions Website Health/Immunisation phone help line
Victoria	Fact sheets, newsletters (*Immunisation Newsletter*) Brochures Information/education sessions Website Health/Immunisation phone help line
Western Australia	Pamphlets, newsletters Brochures Posters, pictures, handouts Training/workshops Advertisement in local newspapers and radio Vaccine company promotional materials Website Health/Immunisation phone help line
State Based Organisations/Divisions of General Practice	Education sessions/information evenings Practice visits Newsletters, emails Information via TV (in the waiting room of GPs) Phone messages (while on hold) Website

State Based Organisations/Divisions of General Practice communication strategies

The State Based Organisations/Divisions of General Practice held regular immunisation face-to-face updates/meetings, information evenings, promotional functions such as BBQs for general practitioners, practice nurses and Aboriginal Medical Service (AMS) staff, and did practice visits. Immunisation providers who were unable to be present for the educational sessions could attend by videoconference. Information was also disseminated via newsletters and emails, though a significant proportion of general practices did not have computer access at that time. Immunisation providers could also order promotional materials if they needed them. Information was also provided in the consultation room or in the treatment room, posted behind toilet doors, via phone messages, by TV advertisements in the waiting area, or by computer printouts.

There was a joint approach (e.g. regular meetings, consultation) between State Based Organisations/Divisions of General Practice and the jurisdictions in the delivery of immunisation programs as reported by all Division of General Practice key informants. Examples of collaborations were reported, between general practitioners, State Based Organisations/Divisions of General Practice, state/territory health departments and/or Aboriginal Medical Services. These were both to deliver the program and to raise patients' awareness of the importance of pneumococcal vaccinations. In the Australian Capital Territory, combined educational sessions (for the childhood and adult pneumococcal immunisation programs) were held on a range of topics. The State Based Organisations/Divisions of General Practice distributed Commonwealth and jurisdictional information resources to inform immunisation providers and prepared them for the rollout of the immunisation program.

The pharmaceutical company had their own information sheets and advertisements for the general public and immunisation service providers. The amount of industry involvement in the dissemination of resource materials varied across states/territories and was most prominent in the Australian Capital Territory, Tasmania, the Northern Territory and Western Australia.

Vaccine

The Australian Government Department of Health and Ageing provided funding to the states/territories to purchase Pneumovax 23™ from 2005 onwards which was similar to the arrangements for other vaccines, as mentioned earlier, and each jurisdiction was responsible for vaccine distribution to local immunisation providers. Existing local distribution and storage systems were used, but due to the large number of vaccines and the joint launch with the childhood program, expansion of these systems was necessary in some jurisdictions.

The number of doses and area of distribution were monitored and an even supply of the vaccine was maintained by the jurisdictions. State/territory health departments collected data on the distribution of Pneumovax 23™, specifically on the number of doses distributed by each general practice by area by month. Wastage was estimated based on the resident age cohort, numbers of doses administered and the numbers of vaccine doses distributed. There was a requirement that leakage and wastage combined was less than 15% for the pneumococcal vaccine (Pneumovax 23™). In addition, jurisdictions collected vaccine coverage information by a range of methods and reported this in the annual AIA acquittal performance report. National computer assisted telephone interview (CATI) surveys collecting pneumococcal coverage data were undertaken in 2004[21] and 2006 (unpublished), and also in New South Wales,[22-26] Western Australia[27] and South Australia.[28-30]

Annually, jurisdictional health departments provided general practice specific data to GPs on the number of doses they used in the previous year. Leakage data was not collected directly, but could be estimated by the majority of jurisdictions (Western Australia, South Australia, the Australian Capital Territory, the Northern Territory and New South Wales) from CATI surveys or other methods. Further details were not available.

Implementation and delivery

Planning for the implementation included jurisdictions ensuring immunisation providers had all supporting documentation (e.g. inclusion of Pneumovax 23^{TM} in forms) and that jurisdictions had communication strategies in place. GPs provided the majority of vaccinations nationally and in most jurisdictions, but Aboriginal Medical Services (AMSs), pharmacies, correctional services, nursing homes and aged care facilities were also involved.

All jurisdictions incorporated components of the Older Australians Pneumococcal Immunisation Program into the existing infrastructure and processes used to deliver NIP vaccines to people aged ≥65 years. The program commenced in January 2005 and was simultaneously implemented across all jurisdictions. An ongoing catch-up strategy was based on age-appropriate recommendations. There was no special committee or changes to reporting for AEFI in all jurisdictions, except Victoria where, after 2007, all AEFI were reported to the Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) system instead of directly to the Adverse Drug Reactions Advisory Committee (ADRAC).

To date, Victoria is the only jurisdiction that has conducted an evaluation of the outcomes and impact of the pneumococcal immunisation program among the elderly.[15,16] However, the evaluation was done prior to the rollout of the national program and did not include a process evaluation.

Part 2: Stakeholder views – strengths, weaknesses and recommendations

There were strengths and challenges in implementation of the program as expressed by key informants.

Funding

Funding was allocated annually for the ongoing program and as a lump sum payment for the catch-up at the beginning of the universal program, part of which was rolled over to following years. There were difficulties referred to by one jurisdiction regarding reporting an under-spend in the first year, rollover of funds, and running out of money in subsequent years. Funding spread over several years may have enabled better management of immunisation services. Most jurisdictional representatives also expressed the need for funding service delivery.

Communication

The Australian Government Department of Health and Ageing communication materials were considered useful and valued by most jurisdictions. The education and resources provided by the state/territory health departments were also an identified strength of the program (the Northern Territory, South Australia, Victoria).

The majority of key informants from the jurisdictions and Divisions of General Practice reported that there were difficulties distinguishing the two vaccines (7vPCV and 23vPPV) and occasional instances where they were used interchangeably, i.e. given to the wrong age group. A Division of General Practice key representative also reported that the complicated recommendations for revaccination (i.e. one revaccination for some, two for others) was not clarified sufficiently in the promotional material. Furthermore, there have been no updated national Indigenous specific resources since 2004.

The strategy of promoting the vaccine (Pneumovax 23^{TM}) to be given during the winter season with the influenza vaccine was successful. However, some jurisdictional and Division of General Practice key informants stressed that this may result in vaccine being discarded prematurely, as its shelf life is about 18 months, and may also lead to missed opportunities to vaccinate during the rest of the year. Hence, there was an emphasis on the importance of promoting the vaccine during the rest of the year.

Seventeen key informants rated the DoHA communication resource materials (Table 2) and provided their comments. The most common rating for all three resources was ‘good’. Fewer respondents provided a rating for the provider guidelines, as respondents felt immunisation providers should be asked to rate those. The majority of the key informants said that the DoHA communication resources were a good thing and representatives from one jurisdiction mentioned that it was regrettable that they were no longer provided in new immunisation programs. Although most key informants said that the content of the educational resources was good, they commented that the layout and format was ‘average’, ‘dull’, ‘not colourful’, ‘bureaucratic’, ‘too wordy’, ‘too clinical’, ‘not exciting’ and ‘boring’. The majority of Divisions of General Practice representatives reported that GPs liked 'minimalist information' since they do not have time to read and preferred to call someone for information (e.g. the Immunisation Help Line).

Most jurisdictional representatives stressed the importance of providing appropriate information to people to avoid confusion, i.e. getting the right information out to the right people at the right time, and that all key stakeholders be involved in the communication strategy to ensure clear communication between them. In addition, key informants advocated clear and concise information in press releases and

promotional materials for providers and in raising community awareness of the immunisation programs. Furthermore, most key informants suggested that the information in DoHA educational resources should be in dot points; more reader friendly; have a summary of short and sharp key messages upfront; be limited to one page; be updated every year; be timely; have a lower level of readability; and have colours and graphics incorporated. The majority of immunisation coordinators from the Divisions of General Practice recommended 'keeping up with the times' (e.g. website information, updating of clinical software) so that the information resources were simple, and easy and quick to access. It was reported that, in the last 5 years, some general practices have been poster-free and brochure-free, so alternative sources of information are needed. In the future, more software development would be needed for providing more online immunisation-related information to providers during consultations.

Table 2. Stakeholder ratings of the DoHA communication resource materials (n=17)

Communication resource materials	Percentage
Older Australians Pneumococcal Immunisation Program – fact sheet	
Very poor	-
Poor	-
Average	11.8
Good	41.2
Very good	23.5
Don't know/did not rate it	23.5
Older Australians Pneumococcal Immunisation Program – tear-off pad	
Very poor	-
Poor	5.9
Average	11.8
Good	41.2
Very good	11.8
Don't know/did not rate it	29.4
Older Australians Pneumococcal Immunisation Program – provider guidelines	
Very poor	-
Poor	-
Average	11.8
Good	23.5
Very good	17.6
Don't know/did not rate it	47.1

Vaccine

The jurisdictional and Divisions of General Practice representatives reported that the vaccinations were well received by adults. However, most jurisdictional and Divisions of General Practice representatives stated that there were logistical issues in distributing vaccine and vaccine management issues (e.g. storage, particularly during influenza season, cold chain maintenance). The provider fridges were inadequate at the time of implementation and storage capacity was strained by the simultaneous introduction of the Childhood and Older Australians Pneumococcal Immunisation Programs. In addition, in the initial months of implementation of the program in 2005, there was a short shelf life ('use-by date') on the Pneumovax 23^{TM} vaccines which led to expired stock and wastage (e.g. in the Australian Capital Territory, New South Wales).

Implementation and delivery

The seasonal influenza immunisation program was a good trigger for uptake of pneumococcal vaccinations annually. The seasonal influenza program enhanced the pneumococcal program. However, most jurisdictional and Division of General Practice key informants reported that it was confusing at times for clients because there was a risk that some adults may have had more Pneumovax 23^{TM} vaccinations than recommended, i.e. received a second dose 1 year later. Though the uptake of pneumococcal vaccinations was facilitated by the influenza immunisation program, there was a reported shortage of the influenza vaccine in 2005 (e.g. the Australian Capital Territory) that could have affected uptake of the adult pneumococcal vaccine.

All jurisdictional representatives and immunisation coordinators from the Divisions of General Practice unanimously reported that there was a short time-frame for the rollout of the program. The 1st of January (just after the Christmas holiday season) was not considered a good time for implementation of immunisation programs that required preparation and considerable resources during December and January. The implementation of the program was 'rushed' and most staff were not able to take leave during the holiday season and had to work harder and longer.

Notwithstanding the information provided nationally and in some instances by others, most jurisdictional and Divisions of General Practice representatives reported that the rollout of both the Childhood and the Older Australians Pneumococcal Immunisation Programs at the same time in January 2005 caused significant confusion among providers. GPs and pharmacists reported confusion and difficulty in distinguishing the two pneumococcal vaccines (7vPCV and 23vPPV), as previously reported. Two jurisdictions did not report this difficulty; in the Northern Territory, the Indigenous childhood and adult programs were already extensive and well established, while in Victoria, there was an adult pneumococcal immunisation program already in place since 1998.

The majority of key informants from the State Based Organisations/Divisions of General Practice recommended that the introduction of new immunisation programs and updating of the immunisation schedule should occur at a known set time in the year rather than in ad hoc stages during the year. This would assist with ongoing planning and education (including development and running of the education programs) before the vaccines arrived in the fridges of general practices. They also suggested separating the introduction of similar adult and childhood programs to avoid provider confusion.

Immunisation register issue

The lack of immunisation records of clients may have affected vaccinations since there was no personal health record card or immunisation register to identify people's vaccination status and the duration of time from the last dose. This information is

more important for 23vPPV than for influenza vaccine, due to its more complicated revaccination recommendations. Hence, there were instances of reported over-vaccination because the adult pneumococcal vaccine was promoted with the seasonal influenza vaccinations, given on a yearly basis. In addition, an issue raised by one Division of General Practice key representative was the impact of changing of paper-based records to electronic health records in general practices, where not all retrospective data of patients may have been entered in the new database and there could have been missing information. All key informants recommended a centralised database or 'whole-of-life' immunisation register that would provide better information, especially for adult immunisation programs.

Discussion, summary and recommendations

Implementation of the national pneumococcal immunisation program was a cooperative effort between DoHA, the state and territory governments, general practitioners, local government and community health providers. It commenced in all jurisdictions on 1 January 2005. The program effectively capitalised on the strengths of immunisation service provision in Australia, in particular the Older Australians Influenza Immunisation Program. Media publicity and professional communication networks were used to inform immunisation providers and the public about the program. While the implementation strategy was effective in making pneumococcal vaccinations available to a large number of adults, a number of issues and barriers to the implementation of the program were identified by key informants that indicated improvements could be made to future programs.

Successful implementation of 23vPPV with influenza vaccination is supported by studies that found influenza vaccination is significantly associated with pneumococcal vaccination status and physician recommendation for vaccination was an important factor in influencing patient behaviour.[31,32] However, there were some reported instances of over-vaccination, and the simultaneous implementation of two adult programs with different revaccination schedules may have contributed to this. All jurisdictional and Division of General Practice key informants reported concern at the lack of an immunisation register and the difficulty of ascertainment of adult pneumococcal vaccination status. This is a particular issue for 23vPPV, which has complicated revaccination recommendations and the risk of harm if over-vaccination occurs. This is consistent with a study of primary care internists and family physicians in the USA that found that one of the reported barriers for adult pneumococcal vaccination was the absence of patient immunisation history.[33] Also, in the absence of a register, jurisdictions rely on infrequent national or state CATI surveys or less robust methods to determine coverage, wastage and leakage. In addition, most jurisdictional key informants reported that the vaccine (Pneumovax 23^{TM}) had a shelf life of 12–18 months and the close association with influenza vaccination resulted in it being discarded unnecessarily early in some instances at the end of the influenza season.

Recommendations:

- Establish an immunisation register to provide vaccination status and coverage information, as a particular priority for 23vPPV, if the program is expected to continue.
- Promote Pneumovax 23^{TM} vaccination during the whole year.

Funding for the program was allocated annually for the ongoing program and as a single lump sum payment for catch-ups in the first year of the program, to cover the period of the AIA till mid-2009. Difficulties with implementing the full catch-up in the

first year and managing the resultant rollovers and a shortage of funds in later years was experienced in at least one jurisdiction. However, funding for catch-ups by single year may also have been complicated to administer. Reported pre-program coverage was substantial, ranging from 42% in Western Australia to 62% in Victoria.[21] As a single booster was recommended after 5 years for those first vaccinated at ≥65 years of age, there would have been considerable variation between jurisdictions in the proportion of the elderly population due for vaccination in any particular year.

The rollout of the Older Australians Pneumococcal Immunisation Program together with the childhood pneumococcal program, with limited preparation time, in the middle of the traditional Christmas holidays, caused significant logistical and communications challenges. Some immunisation providers and pharmacists faced difficulty in distinguishing the two vaccines (7vPCV and 23vPPV), including reports of the vaccines being used in the wrong age groups. This confusion was also reported in a US study, where the infant 7vPCV program was introduced with a pre-existing 23vPPV program for the elderly.[34]

Recommendations:

- Provide centrally produced educational and promotional materials for immunisation providers and clients/patients.
- Promotional materials for the general public should be engaging and attractive, while those for providers should be concise.
- Expand web-based and other online information for quick and easy access by providers.
- Avoid rollout of more than one new immunisation program at one time.
- If dual rollout is conducted, apply special attention to information needs.
- Allocate a minimum of 9 months to preparation for program implementation.
- Consider a set time of year for schedule changes.

Limitations of the report

This study has a number of limitations. The evaluation of the national pneumococcal program was not incorporated into the planning and development phases of the program. Rather, this evaluation was designed after the completion of the pneumococcal immunisation program and information was collected retrospectively.

This process evaluation was conducted in March to August 2009 and over 4 years after the program commenced in January 2005. The consultation process was limited by staff turnover, reducing the number of interviewees who had worked in key positions during the planning and implementation phases of the program, and by recall difficulties amongst those that had been present at that time.

Recommendations:

- Commence planning of evaluations during program implementation planning.
- Commence process evaluations within 1 year of program launch.

Conclusions

The National Older Australians Pneumococcal Immunisation Program was successfully implemented in 2005 and offered to those aged ≥65 years. It was incorporated into an already successful NIP. National promotional materials were widely used. The simultaneous implementation of the adult pneumococcal

immunisation program alongside the influenza immunisation program may also have contributed to higher uptake of the vaccine.[31,32]

Several measures were identified to benefit future programs, including more time to prepare for implementation; the continued availability of national communication materials; the continued promotion of the program during the year and not just during the influenza season; a national register for recording 23vPPV vaccination status; and more timely process evaluations.

CHAPTER 3. System Description

Aims

1. To describe the surveillance systems that collect the following information used in the evaluation: notification data, hospitalisation data, mortality data, adverse events following immunisation (AEFI) data and vaccine coverage data.
2. To review the quality and completeness of data used to evaluate outcomes of the program.

Notification data

The National Notifiable Diseases Surveillance System (NNDSS) was established in 1990 and coordinates the surveillance of more than 60 communicable diseases reported by laboratories and health workers to state and territory authorities under their current public health legislation. Invasive pneumococcal disease (IPD) has been notifiable in a couple of states/territories since the mid 1990s (the Northern Territory since 1995 and Queensland since 1997) and Australia-wide since 2001. State and territory notification criteria are based on the National Health and Medical Research Council (NHMRC) surveillance case definitions.[35] Notification details collected include a unique record number; state or territory identifier; disease code; serogroup/subtype; dates of onset, notification, diagnosis and birth; sex; Indigenous status; patient death; and immunisation status. Cases are de-identified by the state or territory before they are sent to NNDSS.

From 2001 to 2003, the case definition used nationally for IPD was "the isolation from, or detection in, blood, cerebrospinal fluid or other sterile site, of *S. pneumoniae*".[4,36,37] From January 2004, the national case definition was changed slightly, and is shown in the highlighted box below.[38]

Pneumococcal disease – invasive

Reporting

Only confirmed cases should be notified.

Confirmed case

A confirmed case requires laboratory definitive evidence only.

Laboratory definitive evidence

1. Isolation of *Streptococcus pneumoniae* from a normally sterile site by culture

OR

2. Detection of *Streptococcus pneumoniae* from a normally sterile site by nucleic acid testing (NAT).

IPD surveillance is coordinated by the Enhanced IPD Surveillance Working Group (EIPDSWG) of the Communicable Diseases Network Australia (CDNA), which includes relevant surveillance staff from each jurisdiction. 'Core' data fields, that are collected for all notifiable diseases, are transferred to the Australian Government Department of Health and Ageing (DoHA) Surveillance Branch approximately daily. Records may be entered and forwarded as soon as they satisfy the case definition, while data for some fields may be updated as they become available, sometimes months later. Core data unit records for all vaccine preventable diseases are provided to NCIRS monthly.

In addition to the core surveillance data that is routinely collected for all notifiable diseases, additional 'enhanced' data are collected for invasive pneumococcal disease notifications. The enhanced data cover clinical presentation, IPD risk factors, more detailed vaccination history and antibiotic susceptibility of the pneumococcal isolate.[39-41] The collection of enhanced data may also improve the information in core data fields that is often poorly completed, such as vaccination status, Indigenous status and serotype. However, the collection and transfer of enhanced data is more variable. There are differences across jurisdictions in the age groups of enhanced data collection (Table 3). The Australian Capital Territory has been collecting enhanced surveillance data for children aged <5 years only, whereas New South Wales has collected enhanced surveillance data for children aged <5 years and adults aged >50 years since 2002. South Australia and Victoria collected enhanced surveillance data for children aged <5 years and adults aged >64 years from 2002 to 2005 and expanded it to all ages from 2006. The Northern Territory, Western Australia, northern Queensland and Tasmania have collected enhanced surveillance data since 2002 for all age groups. In New South Wales, enhanced data were not collected in some area health services from 2001 to 2003.

Table 3. Enhanced IPD surveillance data collection by states/territories, 2004 to 2006[39-41]

Age	2004	2005	2006
<5 yrs	ACT, NSW, Qld, SA, Vic	ACT, NSW, Qld, SA, Vic	ACT, NSW, Qld*
>50 yrs	NSW	NSW, Qld	NSW
>64 yrs	SA, Vic	SA, Vic	-
All ages	NT, North Qld, Tas, WA	NT, North Qld, Tas, WA	NT, Qld,** Tas, WA, SA, Vic

* South Brisbane Public Health Unit only

** Except South Brisbane Public Health Unit

Enhanced data for calendar years are audited by EIPDSWG and annual reports are prepared and published in *Communicable Diseases Intelligence* once data are finalised. The latest annual report published was for 2006 data. Enhanced data have only been published for single years in annual reports; time trends have not been published due to the unreliability of the data transfer system. Unit record enhanced data are available only following approval by CDNA members, and are not included in this evaluation.

Quality and completeness of notification data

Invasive pneumococcal disease has been notifiable in all states and territories since 2001 but not all notifications were captured from some states and territories in the first year because of delays in changes to state and public health legislation.[39] The total notification numbers are regarded as relatively complete for all jurisdictions since 2002.[39] However, there are variations between jurisdictions in the coverage of enhanced data. There are also issues with the reliability of data transfer to DoHA, and with the completeness of enhanced data fields and the important core data field of vaccination status. These factors mean that analysis of those fields should be done with considerable care, and caution is required in their interpretation.

The key surveillance data from 2004 to 2006 are shown in Table 4.[39-41] In 2006, the surveillance data were better reported than in the previous years: clinical

presentation data were complete for 81% of reported IPD cases, Indigenous status complete for 85% of cases and vaccination status complete for 68% of cases.[41]

Table 4. Surveillance data of invasive pneumococcal disease, 2004 to 2006[39-41]

	2004	2005	2006
	N=2,375*	N=1,680*	N=1,445*
	n (%)†	n (%)†	n (%)†
Clinical presentation	1,219 (51%)	783 (47%)	1,172 (81%)
Vaccination status	1,517 (64%)	1,127 (67%)	983 (68%)
Indigenous status	1,892 (80%)	1,380 (82%)	1,232 (85%)

* Number of notifications

† Percentage of records with complete data

Notification for invasive pneumococcal disease may also be affected by sensitivity of laboratory testing for *Streptococcus pneumoniae*.[42] Both culture and nucleic acid testing (NAT) have been consistent with the case definition since national surveillance began, but NAT was specifically included in 2004. While NAT is regarded as more sensitive than culture, no change in the sensitivity of notifications due to changes in laboratory methods has been documented or reported.

AEFI data

In Australia, adverse events following immunisation (AEFI) are notified to the Adverse Drug Reactions Unit (ADRU), which is part of the Therapeutic Goods Administration (TGA), by state and territory health departments, health professionals, vaccine manufacturers and members of the public. All reports are assessed at the ADRU and entered into the Australian Adverse Drug Reactions System (ADRS) database. Reports are then forwarded to the Adverse Drug Reactions Advisory Committee (ADRAC) for further assessment at 6-weekly committee meetings. ADRAC is an expert committee composed of independent medical experts who have expertise in areas of importance to the evaluation of medicine safety. Current members include an endocrinologist, clinical pharmacologist, specialist physician, neurologist, clinical epidemiologist, specialist immunologist/paediatrician, gastroenterologist and a general practitioner with an interest in complementary medicine.[43] ADRAC reviews adverse drug reactions for prescription medicines, including vaccines, over-the-counter medicines, and complementary medicines (herbal medicines, naturopathic and/or homoeopathic medicines, and nutritional supplements such as vitamins and minerals). Therefore, review of AEFI constitutes only a small component of ADRAC's mandate. De-identified AEFI surveillance data from 2000 is regularly released to NCIRS for analysis.

Annual national AEFI surveillance summaries have been published since 2003. These include all reports received by TGA of adverse events that occurred after the receipt of a vaccine, which contain enough basic information to be a valid report, and where the vaccine cannot be excluded as the cause due to biological implausibility. Prior to review at an ADRAC meeting, AEFI are assigned a causality rating, based on the level of certainty that reported vaccines caused the reaction. Factors that are considered in assigning causality ratings include the timing (minutes, hours, etc) and the spatial correlation (for injection site reactions) of symptoms and signs in relation to vaccination, and whether one or more vaccines were administered.[44] AEFI are defined as 'serious' or 'non-serious' based on information recorded in the ADRAC

database and criteria similar to those used by the World Health Organization (WHO)[45] and the United States Vaccine Adverse Events Reporting System (VAERS).[46] 'Serious' events are those where the record indicates the person had recovered with sequelae, been admitted to a hospital or hospitalisation was prolonged, experienced a life-threatening event, or died. Reactions are re-coded from the reporter's description into standardised terms using the Medical Dictionary for Regulatory Activities (MedDRA®).[47] Individual AEFI reports often list more than one vaccine that were given simultaneously and multiple reactions that occurred following receipt of those vaccines. Also, multiple reports may be received for AEFI following the same vaccination(s).

Quality and completeness of AEFI data

AEFI reports represent only symptoms that manifest after vaccination, which may or may not have been caused by vaccination. While causality is assigned to individual reports by expert review by ADRAC, in the vast majority of cases the causative role of a vaccine cannot be definitively confirmed or excluded. Therefore, the information collated in the ADRS database is primarily intended for signal detection and hypothesis generation. Reporting rates of AEFIs can be estimated using appropriate denominators such as the number of vaccine doses administered. However, they cannot be interpreted as incidence rates due to under-reporting and biased reporting of suspected AEFIs, and the variable quality and completeness of information provided in individual AEFI notifications.[44,48]

Surveillance methods for AEFI have been found to differ between states and territories.[44,49] For example, AEFI are notifiable conditions in New South Wales, the Northern Territory, Queensland and Western Australia. In Tasmania, AEFI are reported directly to the ADRU. This was also the case in Victoria prior to 2007. Since this time, AEFI have been reported to the Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) service at the Royal Children's Hospital, who then forward them to the ADRU and provide quarterly reports to the health department. In all other states and territories, AEFI are reported to the health departments who then forward them to the ADRU.

Vaccine coverage data

Coverage for adults was obtained from national surveys that used the computer-assisted telephone interview (CATI) survey method.[21] A random digit dialling technique, using an electronic directory of residential telephone numbers, generated the sample. The respondents were people aged ≥18 years from the populations of all states and territories. The coverage was calculated as the proportion of the target population vaccinated within the previous 5 years 'for pneumonia'. The CATI method of the survey excluded residents of institutions. Therefore, a survey of aged care residential facilities was undertaken as part of the national survey at the same time as the main CATI survey for adjusting the main results. The survey of aged care residential facilities included questions about pneumococcal vaccination of the residents. Published national coverage estimates are available only for 1 year (2004), immediately prior to the vaccine being added to the National Immunisation Program. Pneumococcal vaccination coverage was also estimated in the survey conducted in 2006 (unpublished), and results are included in this evaluation. The next survey is to be conducted in late 2009. Pneumococcal vaccination coverage data are also collected by CATI in New South Wales,[22-26] Western Australia[27] and South Australia[28-30] producing annual estimates.

Quality and completeness of vaccine coverage data

Coverage estimates from CATI surveys should be interpreted with caution. Vaccination records are not referred to in these surveys, as they are usually not available for adults at the time of interview. While telephone interviews in some settings have included a validation step of contacting providers to validate information provided by participants, this has not been a component of surveys in Australia. Two validation studies of pneumococcal vaccination status measurement have been conducted in Australia, both in Victoria, comparing self-report with medical records. Both found self-reported pneumococcal vaccination status within the previous 5 years to be unreliable for assessing the vaccination status of individual patients, but more reliable for estimating population coverage. In one of the studies, conducted on previous participants in a CATI survey, self-reported pneumococcal vaccination within the previous 5 years under-estimated actual coverage by 5–6%.[16] The other study, conducted on patients hospitalised with pneumonia, showed under-estimation of actual coverage by 1%.[50]

Discussion

The surveillance systems available in Australia for the evaluation of immunisation programs provide vital information for measuring outcomes and the impact of the program on disease burden. However, many of these systems have limitations that either restrict or affect the quality of output for program evaluations. The following recommendations have been developed when considering the pneumococcal immunisation program.

- National IPD surveillance, including enhanced data, have provided critically important data for monitoring the impact of pneumococcal vaccination. However, issues remain to be resolved with respect to data completeness, timely collation and reliable transfer to DoHA. The establishment of a single complete historical national dataset that is updated with additional annual datasets in a timely way should be a priority.
- The monitoring of vaccination coverage in adults has been limited by irregular national surveys. Annual surveys should be conducted to enable timely program monitoring.
- Collecting vaccination status data for a vaccine with complicated revaccination recommendations, such as pneumococcal vaccine, requires more attention to data validity than for influenza vaccine, which is recommended annually. Individual studies have provided variable estimates of validity, and an assessment of the exact questions used in the adult vaccination survey, including verification by providers, should be conducted.
- An adult immunisation register would provide coverage estimates as well as the important benefit of providing information to providers on individual patients, which is particularly important for pneumococcal vaccine's complicated revaccination recommendations.

CHAPTER 4. Outcome/Impact analysis

Aims and Methods

Literature searches

Literature was reviewed on the effectiveness of 23vPPV in preventing IPD in adults, and on the impact of pneumococcal vaccination programs for the elderly on rates of IPD. Population-based studies, rather than studies on patients with specific clinical conditions, were selected. Studies with invasive pneumococcal disease or pneumococcal bacteraemia as the primary outcome of interest were selected, although studies that also reported on pneumococcal pneumonia were also included. The literature search was performed on the PREMEDLINE, MEDLINE, EMBASE, and Cochrane Library databases (including Database of Systematic Reviews, Central Register of Controlled Trials, and Database of Abstracts of Reviews of Effects). Reference lists of published systematic reviews and key studies were also examined.

Adverse events following immunisation

Reported adverse events following immunisation were provided by the Therapeutic Goods Administration, as described in the System description, and analysed at NCIRS. Reporting rates were calculated using coverage estimates from the 2004 and 2006 national coverage surveys as denominators.

Trends in IPD notifications and 23vPPV vaccination coverage

Notifications of IPD were obtained from the National Notifiable Diseases Surveillance System and were included from all years where complete surveillance data were available (2002–2008) and limited to ages ≥65 years. As childhood conjugate vaccine was funded from the same year, notifications were aggregated by serotype grouping to distinguish the impact of these two vaccines – types contained in the 7-valent conjugate vaccine (7v), those contained in the 23-valent polysaccharide vaccine but not in the conjugate (23-non-7v) and those not contained in any vaccine (non-23v). Notifications from Victoria and any notifications recorded as Indigenous were excluded, as their funded programs commenced at different times to the national program (1998 and 1999, respectively). The proportion of notifications that were serotyped increased from 77% in 2002/2003 to 90% in 2008, so serotypes were allocated to untyped cases according to the distribution in typed cases by jurisdiction, by year.

Confidence intervals were calculated using the Poisson distribution of notification numbers. Rates were calculated using yearly total population estimates from the 2006 Census, minus Indigenous population estimates from the 2001 Census.

Vaccination coverage estimates for those aged ≥65 years were provided from the Adult Immunisation Surveys conducted by the Australian Institute of Health and Welfare (AIHW) under contract to the Australian Government Department of Health and Ageing (DoHA) in 2004 and 2006. Estimates were provided by jurisdiction by year, from AIHW on special request.

Estimation of vaccine effectiveness using the indirect cohort method

This study was conducted on notifications of IPD from 2001 to 2005 in people aged ≥15 years, accessed from enhanced surveillance datasets used in the preparation of previously published annual reports.

Vaccination status was categorised as fully vaccinated with 23vPPV according to national recommendations,[51] overdue for revaccination, or never vaccinated. Cases with vaccine serotypes were compared to those with non-vaccine serotypes, while those with vaccine-related serogroups but non-vaccine serotypes were excluded.

Cases reported as Aboriginal and/or Torres Strait Islander were analysed together as 'Indigenous'.

Cases with missing data for a variable of interest were excluded from the vaccine effectiveness (VE) calculations, with the exception of risk factors, since it was not possible to distinguish between those without risk factors and those with missing data. Effectiveness was estimated as one minus the ratio of the odds of having vaccine-type disease in vaccinated versus unvaccinated cases, multiplied by 100, according to the method of Broome.[52] The odds ratio was derived from logistic regression models using the LOGISTIC procedure in SAS.

The models included vaccination status as one of the independent variables predicting the probability of the case being a vaccine serotype. Effect modification was tested by the inclusion of terms for interaction between vaccination status and all other independent variables. The criteria for inclusion of variables or interaction terms in the model were either: 1) a statistically significant ($P < 0.05$) improvement in the model's ability to predict serotype distribution; or 2) a greater than 5% change in the VE estimate. The coding of binary independent variables was centred around zero.[53] Estimates were stratified into two age groups – 15–64 years and ≥65 years.

Statistical analysis was carried out in SAS v9.1.3.[54] Descriptive analyses were conducted on the entire dataset from 2001 to 2005 and the Chi squared test was used to assess statistical significance.

Estimation of vaccine effectiveness using the screening method

The screening method uses the formula VE = 1 – [PCV/(1–PCV)][(1–PPV)/PPV], where PCV is the proportion of cases vaccinated, and PPV is the proportion of the population vaccinated.

PPV was obtained from vaccination coverage estimates of those aged ≥65 years provided from the Adult Immunisation Surveys of 2004 and 2006 as outlined above.

PCV was obtained from enhanced IPD surveillance data provided by DoHA on behalf of the National Pneumococcal Surveillance Working Party. Notifications in those aged ≥65 years were included from 2001 – a year of incomplete national surveillance – to 2006. Notifications reported as Indigenous or with missing serotype or vaccination status were excluded. PCV was taken as the proportion of 23-valent vaccine-type IPD cases recorded as fully vaccinated.

A logistic regression model was fitted using Proc Genmod in SAS v9.1, as described by Torvaldsen 2003,[55] in which the number of vaccinated cases (dependent variable) is regarded as binomially distributed, with PCV used as the parameter and the number of cases as the index. Vaccination coverage was used as an estimate of PPV and logit PPV was specified as an offset in the model. The only parameter in the model was a binomial age variable – 65–74 years, or ≥75 years.

VE was calculated from the model by subtracting the exponentiation of the estimated linear predictor (XBETA in SAS) from one. Confidence intervals were derived in Excel from the covariance matrix, using the standard error of the linear predictor, as previously described by Torvaldsen et al.[55]

Results

Literature reviews

Vaccine effectiveness

There have been many studies on the effectiveness of polysaccharide pneumococcal vaccines since they were first developed in the 1940s; almost 20 controlled trials (intervention studies), more than 20 observational studies and approximately 10 meta-analyses of those studies. Interpretation is complicated by the wide range of populations studied and hence widely differing vaccine effectiveness (VE) estimates, from young adults in high-risk developing country settings to the elderly in developed countries, those with chronic disease and the immunocompromised.

Randomised controlled trials

The majority of randomised controlled trials (RCTs) investigating VE were performed in populations aged ≥55 years or with moderate to high risk conditions. In the majority of these studies, VE against IPD, all-cause pneumonia or pneumococcal pneumonia was not significant. Of those studies that showed significant protective effects,[56,57] the results are questionable due to the use of poor randomisation procedures. In five RCTs performed in young adult populations (mean or median age not provided), VE against IPD or pneumococcal pneumonia was high (77–92%) and significant. These included three trials in South African gold miners,[58,59] a rural population in Papua New Guinea[60] and a military recruit study.[61] In all these cases, attack rates were high due to overcrowding or poor ventilation in housing or mines. A further study in young women with HIV infection in Uganda showed 23vPPV to be ineffective against invasive pneumococcal disease.[62]

RCT meta-analyses

A Cochrane systematic review on 'Vaccines for preventing pneumococcal infection in adults' by Moberley et al., 2007,[63] aimed to assess the effectiveness of pneumococcal polysaccharide vaccination in preventing disease or death in adults. This review updated the previous Cochrane review,[64] addressing whether pneumococcal polysaccharide vaccine is effective in all adult populations, or whether only some groups will benefit. Fifteen randomised and seven non-randomised studies were included in this review, the latter contributing outcomes for culture-confirmed invasive pneumococcal disease only.

Meta-analysis of the randomised trials found pneumococcal polysaccharide vaccination had an effectiveness of 74% (95%CI: 56–85) against IPD (Table 5). However, as the outcomes became less specific, the strength of the evidence for protective benefit reduced, with a point estimate for VE against all-cause pneumonia of 29% (95%CI: 3–38), and there was no significant reduction in all-cause mortality (Odds Ratio 0.87; 95%CI: 0.69–1.10). For each of the primary outcomes considered in the randomised trials, the size of the effect differed in population groups. In particular, the VE against IPD among the sub-group of adults with chronic disease (–56; 95%CI: <0–65) appears poor in comparison to that of otherwise healthy adults in developed (80; 95%CI: 59–90) or developing countries (86; 95%CI: 39–97) (Table 5). In the case of VE against all-cause pneumonia, adults in developing countries was the only sub-group to show a protective effect (46; 95%CI: 33–57). Their meta-analysis of non-randomised studies is discussed in the section below on observational studies.

While the failure to demonstrate efficacy against IPD in adults with chronic illness may be due to lack of power, it is biologically plausible that the vaccine may be less effective amongst this sub-group. The meta-analysis does not provide compelling

evidence to support the routine use of pneumococcal polysaccharide vaccine for the prevention of the less specific outcomes of all-cause pneumonia or mortality. The degree of protection afforded by vaccination is likely to differ across populations according to health status, risk of exposure, susceptibility to disease and serotype distribution.

Five other meta-analyses of trials have been published.[63,65-69] In many of these, only a small number of trials were included, resulting in insufficient power to demonstrate 50% efficacy of the pneumococcal vaccine. Vaccine efficacy against two primary outcomes (IPD and pneumococcal pneumonia) was determined for overall populations as well as individual patient groups, in particular, elderly or high risk adults and young, immunocompetent adults (Table 5). Cornu et al., 2001,[65] Hutchison et al., 1999,[67] and Fine et al., 1994,[66] found statistically significant VE against IPD, but only when trials in young adults in developing countries were included. In all meta-analyses, the VE point estimates against pneumococcal pneumonia were lower than those observed for IPD but, as with VE against IPD, were statistically significant only when trials in young adults from developing countries were included.[65-68]

Meta-analysis of individual patient groups showed that elderly or high risk adults had low vaccine efficacy against IPD and pneumococcal pneumonia compared to young, immunocompetent adults that showed high and significant VE. The confidence intervals were much wider for elderly or high risk groups indicating that there was a lack of power to demonstrate a significant difference between vaccinated and control groups. In contrast to the other meta-analyses, Moberley et al., 2007,[63] showed significant VE in adults from developed countries with no chronic illness, comparable with that observed for adults from developing countries (Table 5).

Table 5. Meta-analysis of trials on pneumococcal vaccine against IPD

Meta-analysis, year published	Patient sub-group	VE (95% CIs)
Moberley et al., 2007[63] (Cochrane Review)	Adults, developed countries	80 (59–90)
	Adults, developed countries with chronic illness	–56 (–594 to 65)
	Adults, developing countries	86 (39–97)
	All studies	74 (56–85)
Watson et al., 2002[69]	Industrialised	47 (–43 to 80)
	High risk	19 (–1116 to 95)
	Elderly	63 (–91 to 93)
	Less industrialised	86 (–14 to 98)
Moore et al., 2000[68]	Elderly or high risk	47 (–94 to 86)
	Immuno-competent, young adults	82 (66–91)
Cornu et al., 2001[65]	Elderly or high risk	42 (0–72)
	All studies	71 (58–80)
Hutchison et al., 1999[67]	Elderly or high risk	–22 (–450 to 73)
	All studies	73 (51–87)
Fine et al., 1994[66]	Elderly or high risk	–23 (–450 to 72)
	Low risk	68 (54–78)
	All studies	66 (52–76)

Observational studies

The majority of observational studies were performed in populations aged ≥55 years or with an underlying risk condition. In these populations, the pneumococcal vaccine showed a protective efficacy against IPD of 50–80%. Only five studies considered VE against pneumonia. VE estimates were lower than those observed for IPD but significant in three of the five studies.[70-72]

Meta-analyses of observational studies

Moberley et al., 2007,[63] performed a meta-analysis of seven observational studies as part of their Cochrane systematic review. Pneumococcal vaccination reduced the risk of IPD with a VE estimate of 52% (95%CI: 39–63) for all serotypes and 55% (95%CI: 38-54) for vaccine type disease. This result was consistent across all study designs (Table 6). Two sub-group analyses involving immunocompetent older adults and immunocompetent adults alone produced similar VE estimates of 68% (95%CI: 53–78) and 59% (95%CI: 48–68), respectively. These results are consistent with those found in a previous systematic review of observational studies on the effectiveness of pneumococcal polysaccharide vaccines in adults (Conaty et al., 2004).[73] In that review, a meta-analysis was performed on 13 observational studies that produced an

overall VE against IPD of 53% (95%CI: 46–59) (Table 6). VE increased slightly to 55% (95%CI: 48–62) when restricted to the elderly or those with chronic disease. The VE estimates were consistent with the non-significant VE estimate observed for the RCT meta-analysis of nine RCTs (38; 95%CI: –4 to 63), although slightly higher, most likely due to selection bias or other unmeasured confounders.

Table 6. Meta-analysis of observational studies on pneumococcal vaccine against IPD

Meta-analysis, year published	Patient sub-group	VE (95% CIs)
Moberley et al., 2007	Immunocompetent older adults	68 (53–78)
	Immunocompetent	59 (48–68)
	All studies	52 (39–63)
Conaty et al., 2004	Elderly or chronic illness	55 (48–62)
	All studies	53 (46–59)

Impact of age

There were many studies in the elderly in developed countries, some of which included young adults with indications for vaccination, and four in young adults in developing countries. The only trial in young otherwise healthy adults in a developed country was by MacLeod et al.,[61] done in 1945 with a tetravalent vaccine. Therefore between-study comparisons of VE in otherwise healthy adults of different age groups are difficult to conduct. Most meta-analyses found lower VE in elderly/high risk populations in developed countries compared with young otherwise healthy adults, mostly in developing countries. Moberley et al., 2007,[63] found no difference in VE from RCTs of otherwise healthy, mainly older adults from developed countries, compared with one study on young healthy adults in a developing country.

The meta-analysis of observational studies by Conaty et al., 2004,[73] also included a separate analysis on elderly or adults with chronic disease. After excluding one study with cases aged >2 years, one of HIV positive adults, one with age unspecified, and one on a Navajo population with a high prevalence of chronic disease, the remaining studies on the elderly with or without risk factors had a similar VE estimate.

Two observational studies that specifically investigated VE against IPD by age, one of which was an indirect cohort study,[74,75] conducted after the Conaty meta-analysis, showed that VE decreased with increasing age.[74-76] The differences between the youngest and oldest age groups were statistically significant in one study,[74,75] and included a wide range of ethnic backgrounds and risk factor prevalence in the different study populations. Adjustments made for risk factors in some of the studies did not alter this decreasing trend in VE with age.

Conclusions regarding effectiveness of 23vPPV in the elderly

It is difficult to separate effects of age and risk factor prevalence on VE due to the fact that very few studies stratified patient groups according to age and the grouping of risk factors varied between studies. VE estimates are generally high in young healthy adults and consistently lower in the elderly, although usually also combined with those that have at-risk and high-risk conditions. The balance of evidence supports effectiveness against IPD in the otherwise healthy elderly of approximately 50%.

Impact of 23vPPV in the elderly in other settings

Six studies were found examining the impact of the 23vPPV – three in the US,[77-79] and one each in Australia,[15] Scotland[80] and Sweden.[81] One study using a mathematical model to predict benefits from 23vPPV vaccination of the elderly is also reviewed.[82]

United States

In the US, the ability to detect any population-level impact was limited by the gradual increase of 23vPPV coverage, and coincidental increase in influenza coverage in the same population. The 23vPPV was subsidised through Medicare from 1983 and recommended by ACIP since 1989.[78] National estimates of 23vPPV coverage (ever vaccinated) increased from 14% in 1989 to 28% in 1993, 45% in 1997, 53% in 2000, and 58% in 2003. Estimated influenza coverage (vaccinated in the previous 12 months) increased from 33% in 1989 to 52% in 1993 and 65% in 1997.[78,83,84]

McBean et al.[78] looked at IPD hospitalisations in the US elderly from 1996 to 2003. Between 1997 and 2000, 23vPPV coverage increased 11% and the IPD hospitalisation rate decreased 3.8%. Compared to 1996–2000, hospitalisation rates declined 22% by 2001/02 and 40% by 2002/03. The large declines in 2001 to 2003 were accompanied by only a 4.7% increase in 23vPPV coverage, and appeared much more likely to be due to the indirect effects of 7vPCV. Using a multiple regression model on Californian data, the decreases were found to be significantly associated with 7vPCV coverage rates in children (P=0.03), but not with coverage rates in the elderly, of either 23vPPV (P=0.31) or influenza (P=0.20).[85]

Redelings et al.[79] report a decrease in deaths coded as due to pneumococcal pneumonia (ICD-9 code 481), or pneumococcal causes of meningitis (320.1), septicaemia (038.2), peritonitis (567.1) or at an unspecified site (041.2), from death registrations from 1989–1998. All-age deaths declined by an average of 2.8% per year for all pneumococcal disease, and 3.0% for invasive disease. Vaccination with 23vPPV may have contributed to this decline, but other factors, including influenza vaccination and the introduction of effective anti-retroviral therapy for the treatment of HIV infection, are also likely to have contributed.

In a study of IPD surveillance data from eight US states, Lexau et al.[77] found that, in those aged ≥50 years, while rates of 7vPCV-type IPD decreased 55% from 1998–1999 to 2002–2003, rates of IPD in 23-non-7v types did not change.

Australia

Andrews et al.[15] found a reduction of 36% in IPD notification rates in those aged ≥65 years in Victoria in a 12-month period after the introduction of funded vaccination for the elderly in Victoria, compared to pre-vaccination levels. Reductions were not seen in younger age groups or a comparison population in New South Wales without funded vaccination.

Scotland

Mooney et al.[80] assessed the impact of the first winter of recommended and actively promoted vaccination for the elderly in Scotland (2003/04). In the first year of vaccination, 23vPPV coverage was 68% in those aged ≥65 years and <10% in younger age groups. Coverage in previous years was not reported. There were incremental increases in influenza coverage from 65% in 2001/02, to 69% in 2002/03 and 73% in 2003/04. IPD rates in 2003/04 were statistically significantly lower than predictions based on data from the previous four winters in the elderly (34%; 95%CI: 23–43), but not in younger age groups. VE estimates for the non-very high risk elderly were 62% (95%CI: 45–73) by the screening method and 51% (95%CI: –278

to 94) by the indirect cohort method. Influenza activity was low in all years included in the study.

Sweden

Spindler et al.[81] studied the impact on IPD of a campaign promoting 23vPPV in those aged ≥65 years, including a reduced vaccine cost, in Stockholm from 1998 to 2000, and compared this with another District in which no such campaign was conducted (Skane). 23vPPV coverage in that age group increased in Stockholm from an unspecified but 'negligible' level in 1997 to 29% in 1998 and 36% in 2000. IPD incidence decreased 20% between 1997–1998 and 2000–2001 in those aged ≥65 years, but not in other age groups. However, this decrease is dependent on high incidence for a single data point for the elderly in 1997. There was no change in Skane over this period, either in vaccine distribution figures or IPD incidence.

Modelling

Fry et al.[82] used modelling to estimate that 23vPPV vaccination in persons over the age of 65 years prevented 11–12% of IPD cases in 1998, with an estimated 46% coverage in 65–75 year olds and 7–8% coverage in those over the age of 75 years. Other assumptions were 85% serotype coverage and vaccine effectiveness which declined with age of receipt and years since vaccination (VE 75% at 65 years, 60% at 74 years and 34% at 85 years, and post-vaccination decreases in VE of 50% from 6–10 years, 75% from 11–15 years and 100% after 15 years). VE was assumed to be 0% in the immunocompromised.

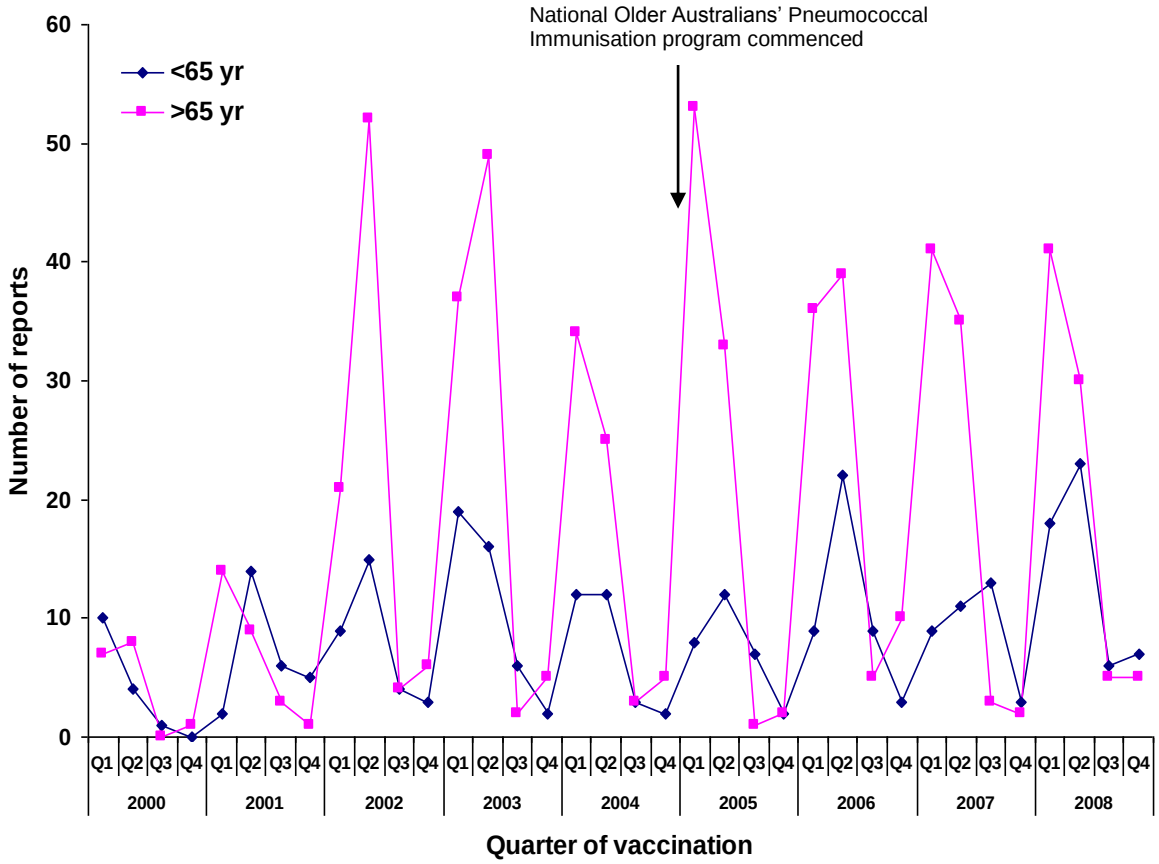
Adverse events following immunisation

Pneumococcal polysaccharide (23vPPV) vaccine

There were a total of 512 reports of AEFI following receipt of 23vPPV during the 2005–2008 period. Sixty-seven per cent (n=341) were from people aged ≥65 years, while 32% (n=162) were for people <65 years of age. The overall reporting rate for people ≥65 years of age for the period of 2005–2008 was 19.8 per 100,000 doses, while dose information was not available for <65 years age group.

The following figure (Figure 1) shows trends over time in the number of reported AEFI following receipt of 23vPPV. The occurrence of peaks and troughs is due to the fact that most people receive 23vPPV along with influenza vaccine, which happens mostly in the first two quarters of the year. The AEFI reporting rate for people ≥65 years of age increased slightly between 2004 and 2005 from 3.3 to 4.0 per 100,000 population, which can be attributed to the commencement of the funded national 23vPPV vaccine program in January 2005, as both years used 2004 coverage estimates as denominator for calculation of reporting rates.

Figure 1. Reports of adverse events following 23vPPV immunisation, ADRAC database, 2004 to 2008, by quarter of vaccination



* The arrow indicates the commencement of the funded national pneumococcal polysaccharide (23vPPV) vaccine program in January 2005.

Reaction types are presented in Tables 7 and 8 below. Table 7 classifies reactions into categories defined in the *Immunisation Handbook*,[3] while Table 8 includes reactions that do not fall into *Handbook* categories. The most commonly reported adverse event was injection site reaction (84%), followed by fever (20%) and allergic reaction (8%) (Table 7).

23vPPV vaccine was the only vaccine reported in 59% (n=303) of records, out of which 142 AEFI records described only one reaction following vaccination. The most frequently reported single reaction following vaccination with only 23vPPV vaccine was injection site reaction (130); others included chills (2), and one report each of angioedema, bacteraemia, convulsions, cellulitis, pneumonia, urticaria, paralysis, tremor, influenza-like illness and pneumococcal bacteraemia.

Table 7. Reactions under routine surveillance* reported for 23vPPV, ADRAC database, 2005 to 2008

Reaction	Number	Per cent†	<65 years	≥65 years
Injection site reaction	428	83.6	123	297
Fever	101	19.7	49	52
Allergic reaction	43	8.4	16	27
Severe allergic reaction‡	4	0.8	2	2
Gastrointestinal reaction§	21	4.1	10	11
Arthralgia	18	3.5	8	10
Rash	12	2.3	5	6
Syncope	12	2.3	4	8
Anorexia	10	1.9	1	9
Lymphadenitis	8	1.6	6	2
Convulsions	2	0.4	2	0
Anaphylaxis	1	0.2	0	1
Arthritis	1	0.2	0	1
Encephalitis	1	0.2	0	1
Sepsis	1	0.2	0	1
Total¶	512	100.0	162	341

* Reaction categories were created for the AEFIs of interest listed and defined in the *Australian Immunisation Handbook* (9th edition).

† Percent of total number of reports

‡ Allergic reaction involving the respiratory and/or circulatory system but not coded as anaphylaxis.

§ Gastrointestinal symptoms of vomiting or diarrhea, with or without other symptoms or signs of an allergic reaction, as defined in *The Australian Immunisation Handbook* (9th edition).

¶ Total number of AEFI records analysed, not the total in each column as categories are not mutually exclusive and an AEFI record may list more than one reaction term.

Table 8. 'Other'* reaction terms reported for 23vPPV, ADRAC database, 2005 to 2008

Reaction	Number	Per cent†	<65 years	≥65 years
Malaise	60	11.7	13	46
Nausea	48	9.4	18	30
Headache	27	5.3	12	14
Myalgia	26	5.1	11	15
Pain	26	5.1	6	20
Oedema	23	4.5	5	18
Increased sweating	13	2.5	6	7
Resp. rate/rhythm change	10	1.9	3	7
Other reactions	70	13.7	33	37
Neurological	12	2.3	4	8
Cardiovascular	8	1.6	1	7
Infections	8	1.6	6	2
Musculo-skeletal	8	1.6	4	4
Respiratory	7	1.4	4	3
General	6	1.2	2	4
Psychological	5	1.0	2	3
Skin	5	1.0	2	3
Haematological and immune	4	0.8	3	1
Eye or ear	2	0.4	1	1
Gastrointestinal	2	0.4	1	1
Metabolic and endocrine	2	0.4	1	1

* Reaction terms not listed in *The Australian Immunisation Handbook* 9th edition but included in AEFI records in the ADRAC database. The top part of the table shows reaction terms included in 1% or more of AEFI records; the bottom part of the table shows reaction terms grouped by organ system that were included in less than 1% of AEFI records.

† Percent of total number of reports

Sixty per cent of all records had causality ratings of either certain (55%) or probable (4.5%), while 40.4% were coded as 'possible'. A total of 8.2% (n=42) of records listed outcomes defined as 'serious' (i.e. recovery with sequelae, hospital admission, life-threatening event or death). There were no reports of death, and one report of recovery with sequelae. There were five reports of life-threatening events and 36 reported hospital admissions.

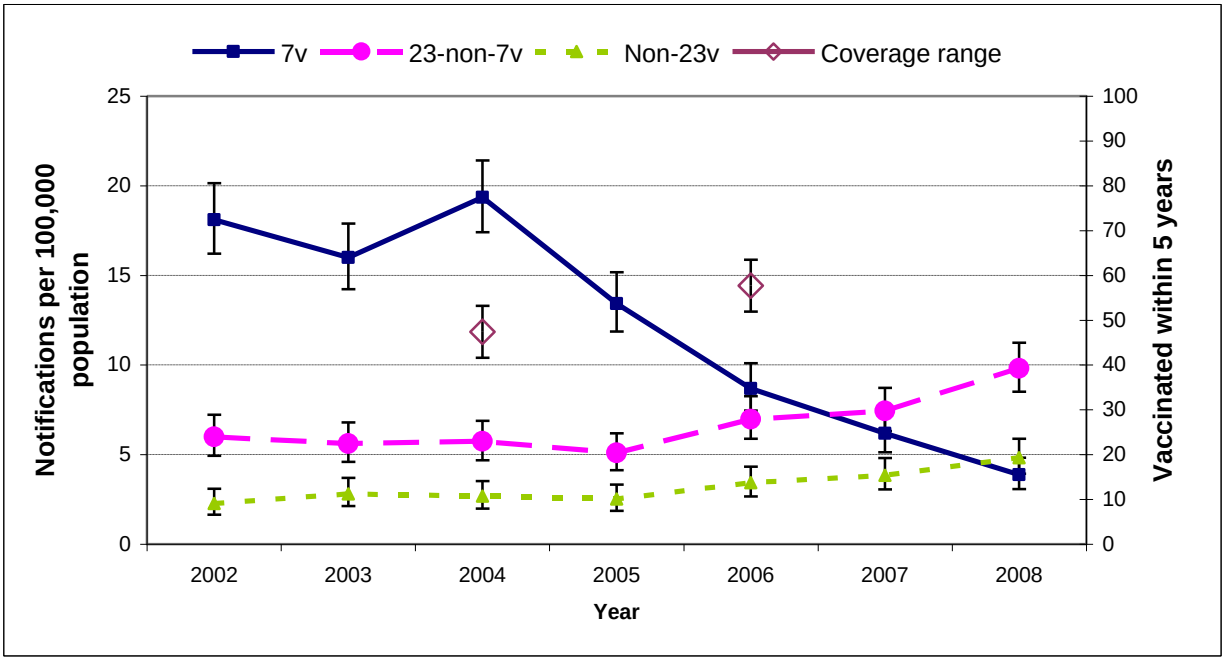
Dose number was recorded for only 45% of AEFI records following 23vPPV among people aged ≥65 years and, out of these, approximately two-thirds indicated that the reaction followed a second dose of 23vPPV.

Vaccination coverage and IPD trends over time in the elderly

Self-reported vaccination coverage estimates for those aged ≥65 years are presented in Figure 2, and in two more detailed age groups in Table 11 (65–74 years and ≥75 years). In 2004, at the national level, 51% of those aged ≥65 years reported receiving pneumococcal vaccine in the previous 5 years, ranging from 42% in Western Australia to 62% in Victoria. This increased to 62% in 2006, ranging from 51% in the Northern Territory to 67% in Victoria. In jurisdictions other than Victoria, coverage increased between 5% and 17% from 2004 to 2006. Coverage was 17% to 19% higher nationally in those aged ≥75 years compared to those aged 65–74 years.

Between 2002 and 2008 there were 3005 IPD notifications among persons aged ≥65 years not recorded as Indigenous from Australian jurisdictions excluding Victoria. The highest total was in 2004 (530) and the lowest in 2007 (357). Annual rates by serotype grouping (serotypes included in 7-valent [7v], 23-valent but not 7-valent [23-non-7v], and other [non-23v]) are presented in Figure 2. A significant decrease was seen in 7vPCV-type cases from 17.8 per 100,000 population in 2002–2004 to 5.0 per 100,000 population in 2007–2008. There was also an increase in the rate of 23-non-7v IPD from 5.8 per 100,000 in 2002–2004 to 8.6 per 100,000 in 2007–2008, and an increase in non-23v types from 2.6 to 4.3 per 100,000 with no overlapping confidence intervals.

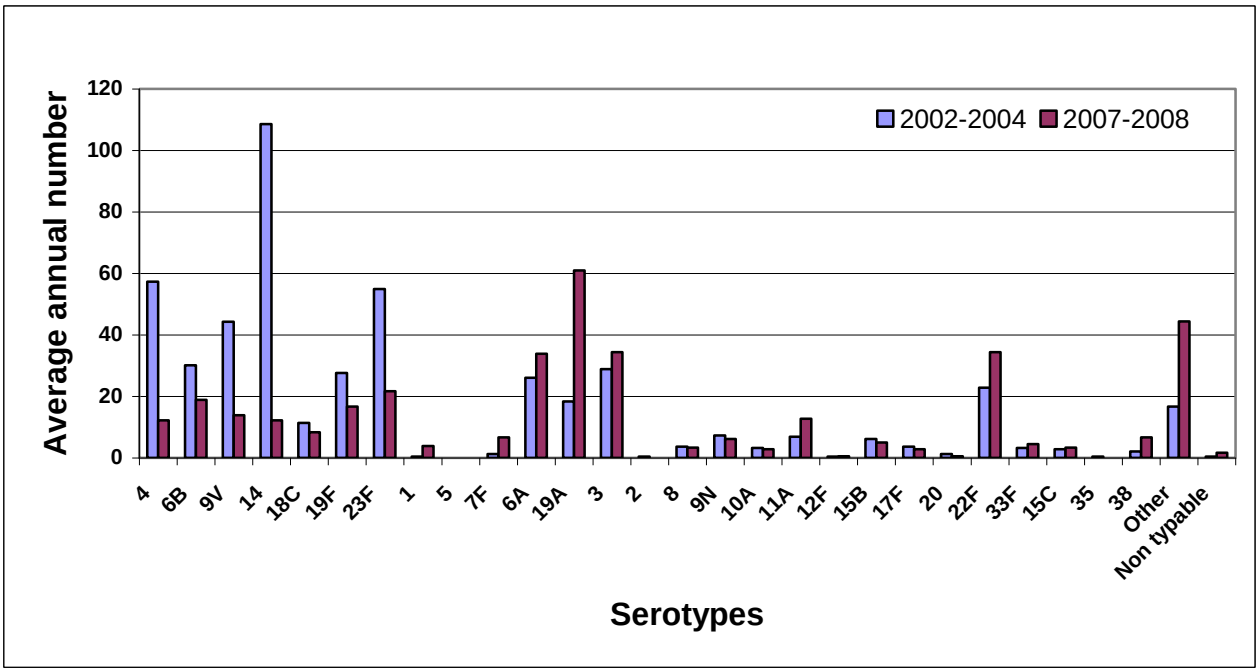
Figure 2. IPD notification rates, not recorded as Indigenous, Australia (minus Victoria), aged ≥65 years, adjusted for untyped cases and self-reported pneumococcal vaccination coverage



Sources: IPD – National Notifiable Diseases Surveillance System; Coverage – Australian Institute of Health and Welfare and Department of Health and Ageing

IPD notifications by individual serotypes are presented in Figure 3, comparing 2007–2008 with the pre-vaccination period of 2002–2004. Decreases were most marked for the 7v-serotypes 14, 4, 9V and 23F. The serotype with the greatest increase was 19A, which was the single most frequently identified serotype in 2007-2008.

Figure 3. Average annual IPD notifications in the non-Indigenous elderly aged ≥65 years, adjusted for untyped cases



Vaccine effectiveness using the indirect cohort method

There were 5,553 cases aged ≥15 years notified from 2001 to 2005. Frequencies and data completeness by Indigenous status are provided in Table 9.

Table 9. Enhanced IPD surveillance notifications, 2001 to 2005

Variable		Age group (years) 15–64 No. (%)	≥65 No. (%)
Indigenous status*†	Indigenous	436 (14.0)	36 (1.5)
	Non-Indigenous	1,985 (63.6)	2,107 (86.7)
	Not stated	701 (22.5)	288 (11.9)
Sex†	Male	1,824 (58.5)	1,271 (52.3)
	Female	1,293 (41.5)	1,159 (47.7)
	Not stated	4 (0.1)	0 (0)
Risk factor†‡	Yes	1,059 (33.9)	1,321 (54.3)
	No	2,063 (66.1)	1,110 (45.7)
Serotype§	Vaccine	2,320 (74.3)	1,827 (75.2)
	Vaccine-related	163 (5.2)	146 (6.0)
	Non-vaccine	88 (2.8)	73 (3.0)
	Not stated	551 (17.7)	385 (15.8)
Vaccination status†	Fully vaccinated	197 (6.3)	539 (22.2)
	Partially vaccinated	181 (5.8)	128 (5.3)
	Never vaccinated	1,312 (42.0)	942 (38.8)
	Not stated	1,432 (45.9)	822 (33.8)

* Includes those reported as Aboriginal and/or Torres Strait Islander.

† $P < 0.05$, chi squared test for comparison of proportions between the 15–64 and ≥65 year age groups.

‡ Risk factors included congenital or chromosomal abnormality, asplenia, immunocompromise, chronic illness and 'other' categories. 'No' includes those with no data on risk factors.

§ 'Vaccine' type – serotypes contained in the 23-valent pneumococcal polysaccharide vaccine: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F; 'Vaccine-related' – serogroups contained in the vaccine, but of different serotypes; 6A, 6C, 7C, 9A, 9B, 9L, 10F, 11D, 11F, 15A, 15C, 18A, 18B, 18F, 19B, 22A, 23A, 23B, 33A, 33B; 'Non-vaccine' type – serogroups not included in the vaccine.

People notified with IPD and aged ≥65 years differed significantly from those aged 15–64 years in the following ways:

- less likely to be male (52% aged ≥65 years versus 58% aged 15–64 years, P<0.0001)
- more likely to have a risk factor reported (54% versus 34% for those aged 15–64 years, P<0.0001)
- more likely to be fully vaccinated (22% versus 6%, P<0.0001)
- less likely to be recorded as Indigenous (1% versus 14%, P<0.0001).

There was no difference in the serotype distribution (75% versus 74% vaccine type, P=0.21).

There were 2,764 (50%) notified cases with complete data in all key fields. Compared to those with missing data, those with complete data were more frequently Indigenous (13% versus 7%, P<0.0001) and older (49% versus 39% ≥65 years, P<0.0001).

Logistic regression results

Of the 2,764 cases with complete data in all relevant fields, 223 cases with vaccine-related serotypes were excluded, leaving 2,541 to be used in VE calculations. Following univariate and multivariate analysis, the variables that remained statistically significantly independently associated with IPD serotype (vaccine versus non-vaccine type) were vaccination status ((P=0.08), Indigenous status (P<0.0001) and having one or more recorded risk factors (P=0.0006). Sex was not significant. No adjustment was made for age as the analysis was stratified by age group.

Interaction terms were added to the base model to test for the impact of other variables on the effect of vaccination status. An interaction term for risk factors with vaccination status was not statistically significant (p=0.25), but resulted in an increase in the adjusted point estimate of VE from 30.6% to 40.9%. The presence of risk factors was therefore an effect modifier of VE. Interaction terms for Indigenous status and sex were non-significant and made negligible difference to VE estimates.

The final VE model included vaccination status, Indigenous status, the presence of a risk factor, and an interaction for risk factors with vaccination status.

Vaccine effectiveness estimates

Crude and adjusted VE estimates, by age group and risk factor status, are presented in Table 10. Crude and adjusted estimates were statistically significantly above zero for those aged 15–64 years, and the point estimates were higher for those vaccinated within the previous 5 years. For those aged ≥65 years, confidence intervals included zero for all VE estimates. However, there was also a strong effect of age within this age group. The unadjusted estimate was statistically significant for those aged 65–74 years and fully vaccinated (66.9%; 95%CI: 7–88), but not for those aged ≥75 years (3.6%; 95%CI: –97 to 53). A similar trend was present for ever being vaccinated – higher for those aged 65–74 years (58.2; 95%CI: –17 to 85) than those aged ≥75 years (0%; 95%CI: –99 to 49).

Table 10. IPD notifications by vaccination status and serotype grouping, and crude and adjusted polysaccharide pneumococcal vaccine effectiveness (VE) estimates* by age group, using indirect cohort method, 2001 to 2005

	15–64 years	≥65 years
Ever vaccinated		
Cases† vaccinated (%)	246/1,249 (19.7)	505/1,186 (42.6)
Controls‡ vaccinated (%)	27/57 (47.4)	24/49 (49.0)
Unadjusted VE (CI)	72.4 (53–84)	23.9 (–33 to 57)
Adjusted VE (CI)	52.5 (5–76)	13.7 (–77 to 58)
Fully vaccinated§		
Cases† vaccinated (%)	118/1,121 (10.5)	410/1,091 (37.6)
Controls‡ vaccinated (%)	19/49 (38.8)	23/48 (47.9)
Unadjusted VE (CI)	81.0 (75–90)	32.5 (–20 to 62)
Adjusted VE (CI)	67.5 (27–85)	28.1 (–48 to 65)

* Estimates adjusted for Indigenous status, risk factor status, and a term for effect modification of risk factors on vaccination.

† IPD cases of serotypes contained in the 23vPPV.

‡ IPD cases of serotypes not contained in the 23vPPV.

§ Up-to-date according to national guidelines, which include a single revaccination after 5 years, and a second revaccination for some high-risk adults.

Vaccine effectiveness using the screening method

The raw data used in the screening method are presented in Table 11. At a national level, the proportion of IPD cases recorded as fully vaccinated was consistently lower than the estimated proportion of the population vaccinated by self-report for each year and age group.

Table 11. Self-reported population pneumococcal vaccination coverage and vaccination status of invasive pneumococcal disease notifications not reported as Indigenous, 2004 and 2006

	2004				2006			
	65–74yrs		≥75yrs		65–74yrs		≥75 yrs	
	Coverage*	CV/N**	Coverage*	CV/N**	Coverage*	CV/N**	Coverage*	CV/N**
NSW	35.2	17/60	58.4	31/117	53.7	19/55	72.3	40/92
Vic	52.9	8/28	73.3	25/48	61.6	10/24	74.1	30/49
Qld	43.3	2/10	56.3	3/11	51.3	4/10	70.3	5/14
SA	43.1	8/8	63.3	9/10	56.7	6/15	73.9	7/11
WA	37.4	3/11	46.8	0/4	52.5	1/2	70.2	0/5
Tas	41.8	0/1	54.2	2/4	57.7	1/6	74.0	1/4
NT	36.7	0/0	56.8	0/0	47.7	1/3	61.6	1/1
ACT	44.6	0/1	61.5	0/0	48.1	0/0	75.4	0/0
Australia	42.3	39/120	61.2	70/194	55.3	43/117	72.5	87/179

* Coverage – percentage reporting pneumococcal vaccination in the previous 5 years, Adult Immunisation Surveys 2004 and 2006, Australian Institute of Health and Welfare, Department of Health and Ageing.

** IPD cases fully vaccinated according to national recommendations (CV)/ total IPD cases (N).

Vaccine effectiveness estimates using the screening method are presented in Table 12. The estimate of effectiveness using vaccination within the previous 5 years as the predictor variable was statistically significantly above zero for those aged ≥65 years and in both age subgroups. The point estimate for those aged ≥75 years was higher than for those aged 65–74 years, and confidence intervals just overlapped. A sensitivity analysis for the impact of accuracy of population coverage estimates yielded an upper estimate of 73.2% (95%CI: 63.8–80.1) if true population coverage was 10% higher than estimated and a lower estimate of 33.6% (95%CI: 10.4–50.8) if true coverage was 10% lower than estimated.

Table 12. Estimates of effectiveness of polysaccharide pneumococcal vaccination within the previous 5 years, in non-Indigenous Australian adults, 2004 and 2006, using the screening method

Age	Vaccine effectiveness
≥65 years*	56.9% (41.8–68.0)
65–74years	45.1% (27.7–58.2)
≥75 years	66.1% (58.2–72.5)

* Adjusted for age

Discussion

Compared to other vaccines there is a relatively large number of studies and meta-analyses on the effectiveness of 23vPPV, conducted over many years. This is to a certain extent a reflection of the characteristics of polysaccharide vaccines, being of lower and shorter-lasting effectiveness, more variable responses in different populations and lack of a booster response, compared with more modern vaccines

such as conjugates. However, the balance of evidence suggests an effectiveness of 23vPPV of approximately 50% in preventing IPD in the otherwise healthy elderly. A modelling study has predicted that, with a modest level of effectiveness, the persistence of disease from serotypes not included in the vaccine, and relatively modest levels of vaccination coverage achieved in the elderly, the decrease in IPD expected from a national vaccination program would also be relatively modest, around 10–15%.[82] In fact, modest decreases were observed in several settings where other pneumococcal vaccines were not in use,[80,81] including Victoria.[86] However, the introduction of conjugate pneumococcal vaccines for children has been accompanied by substantial decreases in IPD in unvaccinated age groups in several settings,[87] attributed to the prevention of nasopharyngeal carriage and subsequent transmission by children to others. This appears to have also occurred in Australia, where decreases in IPD in the non-Indigenous elderly outside Victoria were seen only in serotypes contained in the conjugate vaccine, and IPD due to serotypes only in the polysaccharide vaccine actually increased. Increases in non-7vPCV type IPD have been seen in many settings after the introduction of 7vPCV, including Australia, most markedly in children but also in other age groups. While there is a theoretical possibility that the use of polysaccharide vaccine may eliminate or reduce this effect, such an impact has not been clearly demonstrated. In addition, the increase in coverage associated with the commencement of the national program appears to have been relatively modest (5–17%), as measured by national telephone surveys. This appears to be due to a combination of the relatively high coverage achieved over years of availability through the Pharmaceutical Benefits Scheme, and the difficulties in general in achieving high coverage in the elderly. However, reported 23vPPV coverage is consistently lower than that for influenza, suggesting additional factors specific to 23vPPV are also relevant.

Reported adverse events following immunisation increased moderately with the introduction of the national program, consistent with the history or prior use in Australia and modest increase in coverage seen after the commencement of the national program. They were predominantly mild and consistent with reports from other settings.[88] The reporting rate is higher than for influenza vaccine,[89] and this is predominantly due to reports of injection site reactions. It has been reported that injection site reactions occur more frequently following revaccination compared with first vaccination,[90] but other studies have shown relatively little difference in the rate of medical consultation for injection site reaction following a first, second or third dose of 23vPPV.[91]

However, the result of factors mentioned above is that a clear impact of 23vPPV on IPD in the elderly in Australia following the introduction of the national program cannot be demonstrated. Point estimates of VE were greater than zero by the indirect cohort method (32.5%; 95%CI: –20 to 62) and the screening method (56.9%; 95%CI: 42–68), as they were in other settings of population programs for the elderly (Table 13). However, the VE estimates in this evaluation were calculated in the early years of the national program – 2005 and 2006. In fact, almost all studies of 23vPPV effectiveness were carried out in the absence of 7vPCV. Given the continuing trends in IPD in recent years of decreases in serotypes contained in the 7vPCV and increases in non-vaccine serotypes, the VE estimates may not reflect more recent performance of the 23vPPV. However, there are substantial difficulties in calculating more recent VE estimates. The impact of 7vPCV renders the indirect cohort method invalid, due to potential biases from serotype replacement. The screening method requires current population coverage estimates, which were not available during this evaluation, but may be in 2010.

Table 13. Estimates of 23vPPV effectiveness (95% CI) in the elderly, United Kingdom and Australia

Country	Method	Age group (years)			
		62–73	**74–79**	**≥80**	**All**
England & Wales*	Screening†	24% (14–24)	37% (28–45)	38% (32–44)	34% (29–38)
	Indirect cohort†	40% (13–59)	25% (–12 to 49)	8% (–21 to 30)	23% (6–36)
		65–74	**75+**		**All**
Scotland[80]	Screening†	54 (20–74)	69 (52–80)		62 (45–73)
	Indirect cohort†				51% (–278 to 94)
Australia	Screening‡	45% (28–58)	66% (58–73)		57% (42–68)
	Indirect cohort‡	67% (7–88)	4% (–97 to 53)		33% (–20 to 62)
	Indirect cohort†	58% (–17 to 85)	0% (–99 to 49)		24% (–33 to 57)

* Unpublished data provided by E. Miller and N. Andrews, Health Protection Agency, United Kingdom

† Ever vaccinated

‡ Fully vaccinated, according to *Handbook* recommendations

The currently licensed higher-valency conjugate vaccines (10-valent and 13-valent), if introduced into the NIP for children, may also produce herd effects in the elderly, in a greater range of serotypes.

Conclusions

The Older Australians Pneumococcal Immunisation Program appears to have resulted in only a modest increase in vaccination coverage in jurisdictions that did not have a funded vaccination program already in place, with scope for further improvements in coverage. Reports of adverse events were predominantly mild injection site reactions and consistent with the known safety profile of this vaccine. An impact on IPD from this program cannot be demonstrated, possibly due to a combination of several factors including the modest increase in coverage, the limited effectiveness of the vaccine and the simultaneous herd immunity impacts from the use of 7vPCV in children. Estimates of vaccine effectiveness, calculated as at 2005 and 2006, were greater than zero, but may not be reflective of vaccine effectiveness in more recent years.

References

1. Black S, Eskola J, Whitney C, Shinefield H. Pneumococcal conjugate vaccine and pneumococcal common protein vaccines. In: Plotkin SA, Orenstein WA, Offit P, eds. Vaccines. 5th ed. Philadelphia: Saunders Elsevier, 2008.

2. Australian Bureau of Statistics. 3318.0- Mortality Atlas, Australia, 1997 to 2000. 2002. Available at: http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/3318.0Media%20Release11997%20to%202000?opendocument&tabname=Summary&prodno=3318.0&issue=1997%20to%202000&num=&view= (accessed Dec 2009).

3. National Health and Medical Research Council. The Australian immunisation handbook. 9th ed. Canberra: Australian Government Department of Health and Ageing, 2008.

4. Roche P, Krause V, for the Enhanced Pneumococcal Surveillance Group of the Pneumococcal Working Party of the Communicable Diseases Network Australia. Invasive pneumococcal disease in Australia, 2001. *Communicable Diseases Intelligence* 2002;26:505-19.

5. Centers for Disease Control and Prevention (CDC). Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR - Morbidity & Mortality Weekly Report* 1997;46(RR-08):1-24.

6. Jackson LA, Neuzil KM. Pneumococcal polysaccaride vaccines. In: Plotkin SA, Orenstein WA, Offit P, eds. Vaccines. 5th ed. Philadelphia: Saunders Elsevier, 2008.

7. Abbott T (Minister for Health and Ageing). Commonwealth government to provide pneumococcal vaccine for both young and old. Media Release ABB078/04, 11 June 2004. Available at: http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2004-ta-abb078.htm?OpenDocument&yr=2004&mth=6 (accessed Jun 2009).

8. Abbott T (Minister for Health and Ageing). Free pneumococcal vaccine from 1 January 2005. Media Release ABB188/04, 7 December 2004. Available at: http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2004-ta-abb188.htm?OpenDocument&yr=2004&mth=12 (accessed Jun 2009).

9. Mak D, Plant AJ, Rushworth RL. Where the data are deficient: a field evaluation of the effectiveness of the pneumococcal vaccination in remote Australia. *Australian Journal of Rural Health* 2001;9:38-46.

10. Mak D. Invasive pneumococcal disease in the Kimberley, 1995–2001. *Australian Journal of Rural Health* 2004;12:237-40.

11. Hanna JN, Young DM, Brookes DL, Dostie BG, Murphy DM. The initial coverage and impact of the pneumococcal and influenza vaccination program

for at-risk Indigenous adults in Far North Queensland. *Australian and New Zealand Journal of Public Health* 2001;25:543-6.

12. Hanna JN, Humphreys JL, Murphy DM. Invasive pneumococcal disease in Indigenous people in north Queensland, 1999–2004. *Medical Journal of Australia* 2006;184:118-21.

13. Stewart D, Markey P. Review of the NT adult pneumococcal vaccine database. *The Northern Territory Disease Control Bulletin* 2002;9:23-7.

14. Wooldridge M (Minister of Health and Ageing). National program to fight flu in Indigenous communities. Media Release, 3 February 1999. Parliament House, Canberra. Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-mediarel-yr1999-mw-mw99008.htm (accessed Jun 2009).

15. Andrews RM, Counahan ML, Hogg GG, McIntyre PB. Effectiveness of a publicly funded pneumococcal vaccination program against invasive pneumococcal disease among the elderly in Victoria, Australia. *Vaccine* 2004;23:132-8.

16. Andrews RM. Assessment of vaccine coverage following the introduction of a publicly funded pneumococcal vaccine program for the elderly in Victoria, Australia. *Vaccine* 2005;23:2756-61.

17. National Centre for Immunisation Research and Surveillance (NCIRS). Evaluation of the National Indigenous Pneumococcal and Influenza Immunisation Program, 2003. Confidential report to the Australian Government Department of Health and Ageing. 2004.

18. Let's work together to beat measles. A report on Australia's Measles Control Campaign. Canberra: Commonwealth Department of Health and Aged Care, Immunisation and Vaccine Preventable Diseases Section, 2000.

19. Boomer M, Lawrence G, McIntyre P. Evaluation of the Australian meningococcal C immunisation program. Part 2: Process evaluation of program planning, implementation and delivery. Confidential report to the Australian Government Department of Health and Ageing. 2007.

20. Quinn H, Dey A, Glasswell A, Deeks S, Menzies R, McIntyre P. Evaluation of the national adolescent dTpa immunisation program. Confidential report to the Australian Government Department of Health and Ageing. 2009.

21. Australian Institute of Health and Welfare (AIHW). 2004 Adult Vaccination Survey: summary results. Canberra: AIHW & DoHA, 2005. Available at: http://www.aihw.gov.au/publications/phe/avssr04/avssr04.pdf (accessed Sep 2009).

22. Centre for Epidemiology and Research. 2002-2005 Report on adult health by country of birth from the New South Wales Population Health Survey. Sydney: NSW Department of Health, 2006. Available at: http://www.health.nsw.gov.au/pubs/2006/pdf/cobreport2005.pdf (accessed Oct 2009).

23. Centre for Epidemiology and Research. 2005-2007 Summary report on adult health by Division of General Practice from the New South Wales Population Health Survey. Sydney: NSW Department of Health, 2008. Available at: http://www.health.nsw.gov.au/resources/publichealth/surveys/hsa_07dgp_summary.pdf (accessed Oct 2009).

24. Centre for Epidemiology and Research. 2006 Report on adult health from the New South Wales Population Health Survey. Sydney: NSW Department of Health, 2007. Available at: http://www.health.nsw.gov.au/pubs/2007/pdf/adulthealthreport06.pdf (accessed Oct 2009).

25. Centre for Epidemiology and Research. 2007 Report on adult health from the New South Wales Population Health Survey. Sydney: NSW Department of Health, 2008. Available at: http://www.health.nsw.gov.au/resources/publichealth/surveys/hsa_07.pdf (accessed Oct 2009).

26. Centre for Epidemiology and Research. 2008 Report on adult health from the New South Wales Population Health Survey. Sydney: NSW Department of Health, 2009. Available at: http://www.health.nsw.gov.au/resources/publichealth/surveys/hsa_08.pdf (accessed Oct 2009).

27. Wood N, Smith B, Stevens PT, Daly A. Health and wellbeing of adults in Western Australia 2007: overview of results. Western Australia: Department of Health, 2008. Available at: http://www.health.wa.gov.au/publications/documents/Health_and_wellbeing_of_adults_in_western_australia_2007.pdf (accessed Oct 2009).

28. Centre for Population Studies in Epidemiology. South Australian Monitoring and Surveillance System (SAMSS): business case. Government of South Australia, 2002. Available at: http://www.health.sa.gov.au/pros/portals/0/samss-business-case-02.pdf (accessed Oct 2009).

29. Centre for Population Studies in Epidemiology. South Australian Monitoring and Surveillance System (SAMSS). Government of South Australia, 2004. Available at: http://www.health.sa.gov.au/pros/portals/0/samss-tech-paper1-method.pdf (accessed Oct 2009).

30. South Australia Department of Health. South Australia: our health and health services. Adelaide: SA Department of Health, 2008. Available at: https://www.library.health.sa.gov.au/Portals/0/south-australia-our-health-and-health-services.pdf (accessed Oct 2009).

31. Ridda I, Motbey C, Lam L, Lindley IR, McIntyre PB, MacIntyre CR. Factors associated with pneumococcal immunisation among hospitalised elderly persons: A survey of patient's perception, attitude, and knowledge. *Vaccine* 2008;26:234-40.

32. Christenson B, Lundbergh P. Comparison between cohorts vaccinated and unvaccinated against influenza and pneumococcal infection. *Epidemiology and Infection* 2002;129:515-24.

33. Szilagyi PG, Shone LP, Barth R, Kouides RW, Long C, Humiston SG, et al. Physician practices and attitudes regarding adult immunizations. *Preventive Medicine* 2005;40:152-61.

34. Bundy DG, Shore AD, Morlock LL, Miller MR. Pediatric vaccination errors: application of the "5 Rights" framework to a national error reporting database. *Vaccine* 2009;27:3890-6.

35. Public Health Committee, NHMRC. Surveillance case definitions. Canberra: AGPS, 1994.

36. Roche P, Krause V, Andrews R, Carter L, Coleman D, Cook H, et al. Invasive pneumococcal disease in Australia, 2002. *Communicable Diseases Intelligence* 2003;27:466-77.

37. Roche P, Krause V, Bartlett M, Coleman D, Cook H, Counahan M, et al. Invasive pneumococcal disease in Australia, 2003. *Communicable Diseases Intelligence* 2004;28:441-54.

38. Australian Government Department of Health and Ageing. Pneumococcal disease (invasive) case definition. 2004. Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-casedefs-cd_pnuemo.htm (accessed Mar 2009).

39. Roche PW, Krause VL, Bartlett M, Coleman D, Cook H, Davis C, et al. Invasive pneumococcal disease in Australia, 2004. *Communicable Diseases Intelligence* 2006;30:80-92.

40. Roche PW, Krause VL, Cook H, Bartlett M, Coleman D, Davis C, et al. Invasive pneumococcal disease in Australia, 2005. *Communicable Diseases Intelligence* 2007;31:86-100.

41. Roche PW, Krause VL, Cook H, Barralet J, Coleman D, Sweeny A, et al. Invasive pneumococcal disease in Australia, 2006. *Communicable Diseases Intelligence* 2008;32:18-30.

42. Pneumococcal Accelerated Development and Introduction Plan (PneumoAdip) at Johns Hopkins Bloomberg School of Public Health. Laboratory approaches for detection of pneumococcal disease. 2009. Available at: http://www.pneumoadip.org/activities/surveillance_and_research/upload/08_id5_0952_v6.pdf (accessed Mar 2009).

43. Australian Government Department of Health and Ageing, Therapeutic Goods Administration. Adverse Drug Reactions Advisory Committee (ADRAC). 2008. Available at: http://www.tga.gov.au/adr/adrac.htm (accessed Oct 2008).

44. Lawrence G, Menzies R, Burgess M, McIntyre P, Wood N, Boyd I, et al. Surveillance of adverse events following immunisation: Australia, 2000–2002. *Communicable Diseases Intelligence* 2003;27:307-23.

45. Uppsala Monitoring Centre. WHO Collaborating Centre for International Drug Monitoring. WHO. 2009. Available at: http://www.who-umc.org/ (accessed Feb 2009).

46. Zhou W, Pool V, Iskander JK, English-Bullard R, Ball R, Wise RP, et al. Surveillance for safety after immunization: Vaccine Adverse Event Reporting System (VAERS)–United States, 1991-2001. [erratum appears in MMWR Morb Mortal Wkly Rep. 2003 Feb 14;52(06):113]. *MMWR - Morbidity & Mortality Weekly Report* 2003;52(SS-1):1-24.

47. Brown EG, Wood L, Wood S. The medical dictionary for regulatory activities (MedDRA). *Drug Safety* 1999;20:109-17.

48. Varricchio F, Iskander J, DeStefano F, Ball R, Pless R, Braun MM, et al. Understanding vaccine safety information from the Vaccine Adverse Event Reporting System. *Pediatric Infectious Disease Journal* 2004;23:287-94.

49. Lawrence G. National Vaccine Safety Workshop: summary and draft recommendations. *Communicable Diseases Intelligence* 2006;30:378-80.

50. Skull SA, Andrews RM, Byrnes GB, Campbell DA, Nolan TM, Brown GV, et al. ICD-10 codes are a valid tool for identification of pneumonia in hospitalized patients aged >=65 years. *Epidemiology and Infection* 2008;136:232-40.

51. National Health and Medical Research Council. The Australian immunisation handbook. 8th ed. Canberra: Australian Government Department of Health and Ageing, 2003.

52. Broome CV, Facklam RR, Fraser DW. Pneumococcal disease after pneumococcal vaccination. *New England Journal of Medicine* 1980;303:549-52.

53. Kraemer HC, Blasey CM. Centring in regression analyses: a strategy to prevent errors in statistical inference. *International Journal of Methods in Psychiatric Research* 2004;13:141-51.

54. The SAS institute Inc. SAS for Windows v 9.1.3. Cary, NC, USA: The SAS Institute Inc., 2002.

55. Torvaldsen S, Simpson JM, McIntyre PB. Effectiveness of pertussis vaccination in New South Wales, Australia, 1996–1998. *European Journal of Epidemiology* 2003;18:63-9.

56. Gaillat J, Zmirou D, Mallaret MR, Rouhan D, Bru JP, Stahl JP, et al. Clinical trial of an antipneumococcal vaccine in elderly subjects living in institutions [French]. *Revue d Epidemiologie et de Sante Publique* 1985;33:437-44.

57. Kaufman P. Pneumonia in old age: active immunisation against pneumonia with pneumococcus polysaccharide, results of a 6-year study. *Archives of Internal Medicine* 1947;79:518-31.

58. Austrian R, Douglas RM, Schiffman G, Cietzee AM, Koornhof HJ, Hayden-Smith S. Prevention of pneumococcal pneumonia by vaccination. *Transactions of the Association of American Physicians* 1976;89:184-94.

59. Smit P, Oberholzer D, Hayden-Smith S, Koornhof HJ, Hilleman MR. Protective efficacy of pneumococcal polysaccharide vaccines. *JAMA: The Journal of the American Medical Association* 1977;238:2613-6.

60. Riley ID, Tarr PI, Andrews M, Pfeiffer M, Howard R, Challands P, et al. Immunisation with a polyvalent pneumococcal vaccine. Reduction of adult respiratory mortality in a New Guinea Highlands community. *Lancet* 1977;1:1338-41.

61. MacLeod CM, Hodges RG, Heidelberger M, Bernhard WG. Prevention of pneumococcal pneumonia by immunization with specific capsular polysaccharides. *Journal of Experimental Medicine* 1945;82:445-65.

62. French N, Nakiyingi J, Carpenter LM, Lugada E, Watera C, Moi K, et al. 23-valent pneumococcal polysaccharide vaccine in HIV-1-infected Ugandan adults: double-blind, randomised and placebo controlled trial. *Lancet* 2000;355:2106-11.

63. Moberley SA, Holden J, Tatham DP, Andrews RM. Vaccines for preventing pneumococcal infection in adults. *Cochrane Database of Systematic reviews* 2008;(1):Art. No.: CD000422. DOI: 10.1002/14651858.CD000422.pub2.

64. Dear K, Holden J, Andrews R, Tatham D. Vaccines for preventing pneumococcal infection in adults. *Cochrane Database of Systematic reviews* 2003:CD000422.

65. Cornu C, Yzebe D, Leophonte P, Gaillat J, Boissel JP, Cucherat M. Efficacy of pneumococcal polysaccharide vaccine in immunocompetent adults: a meta-analysis of randomized trials. *Vaccine* 2001;19:4780-90.

66. Fine MJ, Smith MA, Carson CA, Meffe F, Sankey SS, Weissfeld LA, et al. Efficacy of pneumococcal vaccination in adults: a meta-analysis of randomised controlled trials. *Archives of Internal Medicine* 1994;154:2666-77.

67. Hutchison BG, Oxman AD, Shannon HS, Lloyd S, Altmayer CA, Thomas K. Clinical effectiveness of pneumococcal vaccine. Meta-analysis. *Canadian Family Physician* 1999;45:2381-93.

68. Moore RA, Wiffen PJ, Lipsky BA. Are the pneumococcal polysaccharide vaccines effective? Meta-analysis of the prospective trials. *BMC Family Practice* 2000;1:1.

69. Watson L, Wilson BJ, Waugh N. Pneumococcal polysaccharide vaccine: a systematic review of clinical effectiveness in adults. *Vaccine* 2002;20:2166-73.

70. Christensen B, Lundberg P, Hedlund J, Ortqvist A. Effects of a large scale intervention with influenza and 23-valent pneumococcal vaccines in adults aged 65 years or older. *The Lancet* 2001;357:1008-11.

71. Gable CB, Holzer SS, Engelhart L, Friedman RB, Smeltz F, Schroeder D, et al. Pneumococcal vaccine: efficacy and associated cost savings. *JAMA: The Journal of the American Medical Association* 1990;264:2910-5.

72. Nichol KL. The additive benefits of influenza and pneumococcal vaccinations during influenza seasons among elderly persons with chronic lung disease. *Vaccine* 1999;17(Suppl 1):S91-S93.

73. Conaty S, Watson L, Dinnes J, Waugh N. The effectiveness of pneumococcal polysaccharide vaccines in adults: a systematic review of observational studies and comparison with results from randomised controlled trials. *Vaccine* 2004;22:3214-24.

74. Singleton RJ, Butler JC, Bulkow LR, Hurlburt D, O'Brien KL, Doan W, et al. Invasive pneumococcal disease epidemiology and effectiveness of 23-valent pneumococcal polysaccharide vaccine in Alaska Native adults. *Vaccine* 2006;25:2288-95.

75. Menzies R, McIntyre P, Krause V, Roche P. The effectiveness of the 23-valent pneumococcal polysaccharide vaccine in Indigenous and non-Indigenous adults. *Draft* 2007

76. Shapiro ED, Berg AT, Austrian R, Schroeder D, Parcells V, Margolis A, et al. The protective efficacy of polyvalent pneumococcal polysaccharide vaccine. *New England Journal of Medicine* 1991;325:1453-60.

77. Lexau C, Lynfield R, Danila RN, Pilishvili T, Facklam RR, Farley MM, et al. Changing epidemiology of invasive pneumococcal disease among older adults in the era of pediatric pneumococcal conjugate vaccine. *JAMA* 2005;294:2043-51.

78. McBean AM, Park YT, Caldwell DYX. Declining invasive pneumococcal disease in the US elderly. *Vaccine* 2005;23:5641-5.

79. Redelings MD, Sorvillo F, Simon P. A population-based analysis of pneumococcal disease mortality in California, 1989–1998. *Public Health Reports* 2005;120:157-64.

80. Mooney JD, Weir A, McMenamin J, Ritchie LD, Macfarlane TV, Simpson CR, et al. The impact and effectiveness of pneumococcal vaccination in Scotland for those aged 65 and over during winter 2003/2004. *BMC Infectious Diseases* 2008;8:53.

81. Spindler C, Hedlund J, Jasir A, Normark BH, Ortqvist A. Effects of a large-scale introduction of the pneumococcal polysaccharide vaccine among elderly persons in Stockholm, Sweden. *Vaccine* 2008;In press

82. Fry AM, Zell ER, Schuchat A, Butler JC, Whitney CG. Comparing potential benefits of new pneumococcal vaccines with the current polysaccharide vaccine in the elderly. *Vaccine* 2002;21:303-11.

83. Centers for Disease Control and Prevention (CDC). Influenza and pneumococcal vaccination coverage levels among persons aged >65 years – United States, 1973–1993. *MMWR - Morbidity & Mortality Weekly Report* 1995;44:506-14.

84. Centers for Disease Control and Prevention (CDC). Influenza and pneumococcal vaccination levels among adults aged >65 Years – United States, 1997. *MMWR - Morbidity & Mortality Weekly Report* 1998;47:797-802.

85. McBean AM, Jung K, Hebert PL. Decreasing invasive pneumococcal disease in the elderly: a state-level analysis. *Vaccine* 2006;24:5609-14.

86. Andrews RM, Counahan ML, Hogg GG, McIntyre PB. Effectiveness of a publicly funded pneumococcal vaccination program against invasive pneumococcal disease in Victoria, Australia. *Vaccine* 2004;23:132-8.

87. Whitney CG, Farley MM, Hadler J, Harrison LH, Bennett NM, Lynfield R, et al. Decline in Invasive Pneumococcal Disease after the Inroduction of Protein-Polysaccharide Conjugate Vaccine. *New England Journal of Medicine* 2003;348:1737-46.

88. National Health and Medical Research Council. The Australian immunisation handbook - 9th Edition. 9th ed. Canberra: Australian Government Department of Health and Ageing, 2008.

89. Lawrence G, Gold MS, Hill R, Deeks S, Glasswell A, McIntyre PB. Annual report: surveillance of adverse events following immunisation in Australia, 2007. *Communicable Diseases Intelligence* 2008;32:371-87.

90. Jackson L, Benson P, Sneller VP, Butler JC, Thompson RS, Chen RT, et al. Safety of revaccination with pneumococcal polysaccharide vaccine. *JAMA* 1999;281:243-8.

91. Jackson LA, Nelson JC, Whitney CG, Neuzil KM, Benson P, Malais D, et al. Assessment of the safety of a third dose of pneumococcal polysaccharide vaccine in the Vaccine Safety Datalink population. *Vaccine* 2006;24:151-6.

Appendix

Process Evaluation Questionnaire

The National Centre for Immunisation Research and Surveillance NCIRS is currently undertaking an evaluation of the Pneumococcal vaccination program for older Australians. The evaluation will provide information on the processes used by each State and Territory to plan and manage the Program to inform future vaccination programs. A separate evaluation of the Childhood Pneumococcal program is also being conducted.

The following questionnaire has been provided prior to your telephone interview to allow for collation of program specific information.

Any information you provide in this questionnaire will be confidential. Information contained in the final report will be a summary of all information provided by interviewees. You will be provided with a copy of the relevant sections of the draft report and permission sought to identify your organisation in the final report if required.

The questionnaire will cover the following topics:

- ✓ Your role during the program
- ✓ Pneumococcal vaccination activities prior to the 2005 program
- ✓ Program funding, planning and delivery
- ✓ Communication strategies
- ✓ Strengths and challenges of the program
- ✓ Outcome data

1. Details of stakeholder:

1.1. Name:

1.2. Job title:

1.3. Were you in your current position during the planning and delivery of the National pneumococcal vaccination program for older Australians (2005/6)? Yes/No

1.4. What was your role in the implementation of the 2005 program ?

1.5. Please describe your responsibilities in the implementation of the 2005 program.

1.6. Is there another person from your organisation who could provide additional information regarding the implementation of the program? Yes/No

If Yes:

1.6.i. Name:

1.6.ii. Job title during program:

1.6.iii. Role in implementation of pneumococcal program:

1.6.iv. Contact details:

2. Pneumococcal vaccination <u>BEFORE</u> 2005

2.1. Did your jurisdiction provide funded vaccine to adults **before** the 2005 program? Yes/No

2.1.i. If yes, please specify who eligible

2.2. Please outline the strategy to vaccinate Indigenous and at risk people **before** the 2005 program in your jurisdiction?

2.3. What information do you have about uptake for Indigenous and non-Indigenous people of the vaccine **before** the 2005 program?

3. Pneumococcal vaccination <u>AFTER</u> 2005

3.1. When was the funded older Australian pneumococcal program commenced in your jurisdiction? (d/mm/yyyy)

4. Program Funding

<u>Planned</u>

4.1. What was the ***anticipated*** or planned funding formula for the 2005 program for your jurisdiction?

4.2. Was service delivery funding included in the formula? Yes/No

4.3. What was the anticipated (planned) funding component to be allocated for your jurisdiction for the 2005 program:

4.3.i. for vaccine:

4.3.ii. for service delivery:

4.3.iii. in total:

Actual

4.4. What was the *actual* funding allocated for the program?

4.4.i. By the Australian Government in total:

4.4.ii. By your State/Territory Government in total:

4.5. When did the funding start? (d/mm/yyyy)

4.6. Did the service delivery funding cover the costs of infrastructure and personnel? Yes/No Yes

4.6.i.a. If no, what was the shortfall?

5. Communication Strategy BEFORE 2005

What was the communication strategy for pneumococcal vaccination **before** the 2005 program in your jurisdiction? (Timing, media*, providers, seminars, industry involvement)*

6. Communication Strategy AFTER 2005

6.1. Did your jurisdiction develop promotion materials for the ***general public*** for the 2005 program? (eg. Timing, radio, television, print, posters etc.) Yes/No

6.1.i. If yes, please describe

6.2. Did your jurisdiction develop promotion materials for ***service providers*** for the 2005 program (eg. print, posters etc.) Yes/No

6.2.i. If yes, please describe

6.3. In promoting the program, did your jurisdiction use the communication materials provided by the Commonwealth? Yes/No

6.4. Which materials were used:

6.4.i. Pneumococcal vaccination program fact sheet ☐

6.4.ii. Pneumococcal vaccination program poster ☐

6.4.iii. Pneumococcal vaccination provider guidelines ☐

6.5. How would you rate these materials?

6.5.i. Pneumococcal vaccination program fact sheet

Very Poor ☐ Poor ☐ Average ☐ Good ☐ Very Good ☐
Don't Know ☐

How could it be improved?

6.5.ii. Pneumococcal vaccination program poster

Very Poor ☐ Poor ☐ Average ☐ Good ☐ Very Good ☐
Don't Know ☐

How could it be improved?

6.5.iii. Pneumococcal vaccination provider guidelines

Very Poor ☐ Poor ☐ Average ☐ Good ☐ Very Good ☐
Don't Know ☐

How could it be improved?

7. Service Delivery (Prompts: timing, issues confronted with, provider types, AEFI)

Planned

7.1. What was planned regarding delivery of the 2005 program in your jurisdiction?

7.2. What was planned regarding the mop-up strategy in your jurisdiction?

7.3. Did your jurisdiction plan an evaluation of the program?

7.3.i. If yes, please describe?

Actual (Prompts: timing, issues confronted with, provider types, AEFI)

7.4. How was the program delivered in your jurisdiction? (*Was the process of delivery staged or simultaneously implemented across the jurisdiction?)*

7.5. Was the program delivery consistent across your jurisdiction? Yes/No

7.5.i. If No, please describe:

7.6. Please describe any specific issues or problems with the service delivery of the program?

7.7. If your jurisdiction implemented a mop-up strategy for eligible adults how was this managed?

7.8. Please describe any planning or logistical issues during implementation of the program? *(Was vaccine storage capacity adequate, was it necessary to develop new systems/processes to implement the program, were additional people employed to plan or implement the program?)*

7.9. Did the pneumococcal program impact on, or was the program impacted by an existing vaccination program (eg flu)? Yes/No

7.9.i. If yes, please describe:

7.10. Please describe any specific issues associated with the simultaneous implementation the childhood and adult pneumococcal immunisation programs? *(identification of target group, vaccine delivery, communication strategy, provider information)*

7.11. Please describe any current or unresolved issues regarding the program?

8. Vaccine supply

8.1. Please describe any logistical issues in distributing vaccine or maintaining cold chain during the program?

8.2. Please describe any issues with vaccine supply that affected the program?

8.3. Was data collected regarding the distribution of vaccine? Yes/No

8.3.i. If yes, what was collected?

9. Strengths and challenges

9.1. What, if any, were the strengths of the implementation of the program in the jurisdiction?

9.2. What, if any, were the challenges of the implementation of the program in the jurisdiction?

9.3. Have your experiences with this program informed how you implemented another targeted vaccination program? Yes/No

9.3.i. If yes, please describe:

9.4. Please describe any recommendations for future vaccination programs?

10. Outcome data

10.1. How many doses of Pneumovax 23 were purchased for the program by the jurisdiction (timeframe)?

10.2. How many doses of Pneumovax 23 were administered during the program by the jurisdiction (timeframe)?

10.3. Was vaccine wastage data collected or estimated in your jurisdiction?

10.4. Was vaccine leakage data collected or estimated in your jurisdiction?

10.5. How was vaccine coverage information collected in your jurisdiction for this age group?

10.5.i. Who collated the data?

10.6. How was the information managed?

10.7. What reports and analysis are available?