NCIRS

National Centre
for Immunisation
Research and
Surveillance

Evaluation of the National Shingles Vaccination Program Process and early impact evaluation

Final Report

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Government and associated committees/advisory groups

- Australian Government Department of Health
- National Immunisation Committee
- Australian Government Department of Human Services
- State and territory departments of health
- Advisory Committee on Vaccines

Peak professional/practitioner groups

- Australian Medical Association
- Royal Australian College of General Practitioners
- Australian College of Rural and Remote Medicine
- Royal Australasian College of Physicians

- Australian Primary Health Care Nurses Association

Community-based groups/practitioners

- Primary health networks
- General practitioners
- Local councils
- Aboriginal Medical Services
- Other immunisation providers
- Consumers/consumer representatives
- Practice nurses
- Local council and community health nurses

Executive summary

Background

Shingles vaccination using the live-attenuated zoster vaccine (Zostavax®, CSL/Merck) commenced under Australia's National Immunisation Program (NIP) from November 2016 for individuals 70 years of age, with a catch-up program to the age of 79 years funded until 2021. Prior to this, Zostavax® was available on the private market from 2008 in Australia, although in limited supply.

This is the first major new vaccine program introduced for older Australians in more than one decade and the first time that a live-attenuated vaccine has been provided at a wide-scale population level in this age group. Population-level zoster vaccine programs also began in the United Kingdom in 2013 and in the USA from 2006.

This evaluation aimed to examine implementation of the National Shingles Vaccination Program in Australia, including an assessment of vaccine coverage and safety data.

Evaluation component methods

1. Process evaluation

The process evaluation aimed to capture views and experiences of relevant groups, representative at national level, during the first year of the program rollout.

The process evaluation was conducted in three modules: Module 1 – Survey of key program delivery stakeholders; Module 2 – Survey of a national sample of general practitioners (GPs) and other primary health care staff; and Module 3 – Survey of a national sample of consumers.

In Module 1, 48 stakeholders were interviewed between July and October 2017, including representatives of the Immunisation Branch, Australian Government Department of Health (Department of Health) and the Therapeutic Goods Administration (TGA), jurisdictional immunisation program representatives, representatives of 13 peak professional bodies and associations, medical sub-specialists, representatives of Primary Health Networks (PHNs) and Public Health Units (PHUs) and nominees of the vaccine manufacturer Seqirus and the AusVaxSafety surveillance initiative.

Module 2 comprised an online survey, conducted from October to November 2017, of 1,567 GPs, practice nurses/managers and other professionals working in the primary

healthcare area, using the database of HealthEd (a private national health education provider).

Module 3 comprised a telephone survey in September 2017 of 403 consumers aged 70–79 years across Australia, using random digit dialling and Computer Assisted Telephone Interviewing (CATI).

2. Vaccination coverage

Early impact of the shingles vaccination program was evaluated using Australian Immunisation Register (AIR) data to estimate coverage of Zostavax® in adults aged 70–79 years in Australia. Coverage was assessed between 1 November 2016 and 31 March 2018.

3. Vaccine safety

Adverse events following immunisation (AEFI) data from the Adverse Events Management System (AEMS) of the TGA were analysed and reported from the first 16 months of the rollout of the shingles vaccination program, that is, from 1 November 2016 to 28 February 2018.

AusVaxSafety data from the first 19 months of the shingles vaccination program, that is, from 1 November 2016 to 3 June 2018 were reviewed and summarised.

Key findings

1. Process evaluation

Module 1 – Key stakeholder survey

Strengths

- The age group targeted by the program is a strong acceptor of vaccination, confirming findings from survey data before program rollout. Interest in the vaccine was high, as the age group had good appreciation of shingles and its adverse health impacts.
- Communication and the vaccine safety plan (VSP) were comprehensive. In particular, the VSP recognised high prevalence of chronic medical conditions and use of multiple medications in this age group and there was a well-coordinated response to an important safety event.
- Extensive collaboration with states and territories, key immunisation stakeholders and manufacturer (Seqirus) on the implementation of the program.

- Sufficient lead time was perceived as a strength of the program by all jurisdictional respondents (from New South Wales, Western Australia, Queensland, Victoria, Tasmania, Australian Capital Territory and the Northern Territory) and all 13 stakeholders from peak bodies who participated in the evaluation.
- Stakeholders considered the shingles vaccination program to have been well-promoted, well-delivered and well-received.

Challenges

- Some immunocompromised individuals received the vaccine despite prior warnings and alerts. One man died as a result of receiving the vaccine despite being contraindicated due to immunocompromise.
- Demand for the vaccine was higher than anticipated, resulting in service delivery stresses and public dissatisfaction.
- Managing public expectations of age-eligibility for vaccine, including communication around the limited efficacy in individuals aged >79 years and their exclusion from the funded program.
- Incomplete recording of vaccinations in the AIR, noting that recording of doses is dependent on practitioners.
- 3 jurisdictional program representatives and 5 PHU/PHN representatives felt there were instances of data entered in general practice not reaching the AIR and that provider access to and understanding of the AIR was not optimal.
- Periods of low supply of the shingles vaccine were considered a major challenge by all jurisdictional program representatives, 8/13 representatives of peak professional bodies and all 13 PHU/PHN representatives.
- Stakeholders felt high demand was driven by strong promotion, which, in the view of some (7/8 program managers, 8/13 peak professional body representatives and 5/13 PHU/PHN representatives), amounted to excessive marketing by Seqirus which resulted in demand outstripping supply for a period.

Module 2 – Online survey of GPs and other primary healthcare staff

Strengths

Strengths of the program perceived by GPs and other primary healthcare staff were:

- vaccine available for free
- raised public awareness
- support for the vaccine among this elderly age group
- good awareness raising before the rollout

Challenges

- vaccine supply problems
- difficulty of applying the age criteria in general practice

- lack of detailed information about contraindications at the beginning of the program

Module 3 – Consumer interviews

- The mean age of participants was 73.9 years, 53% were female and 1.2% identified as Aboriginal and/or Torres Strait Islander.
- Consumer awareness of shingles was high, with 96% having heard of shingles or reporting knowing someone who had had shingles, and about a third reporting having had shingles themselves.
- The vaccine was popular among this age group, consistent with reports from healthcare providers.
- More than half the consumers surveyed reported receiving the vaccine, with most others stating intention to receive it at their next GP visit.
- Most information about and awareness of the vaccine was reported as coming from the consumer's own GP, with only a third of consumers referring to resources such as posters or brochures.
- Consumer knowledge about the disease and age eligibility for free vaccine was good.
- A few consumers were uncertain about specific areas, including shingles risk; relationship of shingles risk to chickenpox; access to the vaccine; vaccine safety, efficacy and side effects. Knowledge tended to be lower among males.

2. Vaccination coverage

Reported shingles vaccination coverage, as recorded on the AIR, in the first 17 months of the program was low (33.9% for adults aged 70 years and 25.8% for the catch-up program for adults aged 71–79 years). This may be partly attributable to under-reporting to the AIR and shortage of Zostavax® in the initial months of the program implementation. There were 1,370,395 doses of Zostavax® distributed under the NIP during this period, as reported by the Department of Health, but our analysis shows that only 489,605 doses were recorded in the AIR. While not all vaccines distributed would have been administered, the large discrepancy suggests underreporting. AIR zoster vaccination data completeness would be expected to improve over time as GP practice management software packages are updated and initiatives to improve data entry and transfer are implemented. The lower than anticipated coverage may have also been contributed to by the shortage of vaccine in the first 6 months of the program. In adults aged 70 years, an average of around 4,500 doses per month were recorded as given nationally in the first 5 months of the program from November 2016 to March 2017. Uptake improved to 6,813 doses in April 2017, with a further increase in May 2017 (9,140 recorded doses). This increase is likely due to availability of shingles vaccine after a period of shortage along with concomitant GP visits for influenza vaccination.

Coverage was higher in Aboriginal and/or Torres Strait Islander people, particularly those aged 70 years (43.3% versus 33.8% compared with non-Indigenous Australians). In addition, shingles vaccination coverage was 9.4 percentage points higher in females compared to males (38.6% versus 29.2%).

These coverage estimates are similar to those reported from the United States of America, where shingles vaccine coverage among adults aged ≥60 years was 28% in 2014, despite vaccine being available and recommended since 2006. Higher uptake has been seen in England where a publicly funded population-level program began in 2013. Coverage in England in 2015–2016 was 55% in the routine cohort (aged 70 years) and 56% for the catch-up cohort (one birth cohort, aged 79 years).

3. Vaccine safety

Analyses of data from the TGA's Adverse Events Management System (AEMS) and AusVaxSafety (active participant-based surveillance system) demonstrated a low rate of adverse events following shingles vaccination, consistent with existing knowledge of the vaccine's safety profile. There was a higher level of AEFI reporting to the AEMS in the initial months of the program than in later months. While there is anecdotal evidence that some individuals received two doses of zoster vaccine, we were unable to assess the frequency of double dosing. An early increase in AEFI reporting often occurs when a new vaccine is introduced, as immunisation providers are more likely to report milder, less serious AEFI for vaccines with which they are less familiar. A reduction in and stabilisation of reporting rates over time typically occur thereafter.

Both surveillance systems (AEMS and AusVaxSafety) reported similar types of AEFI such as injection site reactions and rash. However, rare serious adverse events and vaccination errors, including vaccination of immunocompromised persons, were also reported to both systems. One death due to disseminated varicella zoster vaccine virus infection following inappropriate vaccination of an immunocompromised person was reported. This very unfortunate event generated additional communication and education activities to reinforce information on vaccine contraindications and the need for pre-vaccination screening.

Summary and recommendations

This evaluation provides data on a range of program implementation and early outcome indicators for the program.

Feedback from key stakeholders, primary care providers and the public on the shingles vaccine program implementation generally found the program to be well-promoted, well-delivered and well-received. A number of program strengths

were identified. Key recommendations arising from the feedback obtained during the process evaluation include:

- Early assessment of vaccine procurement, supply and marketing via greater communication between the Department of Health and Seqirus and jurisdictions, and other stakeholders where relevant. Improvements in management of vaccine supply and demand are recommended.
- More clinical education for GPs, practice nurses, specialists and immunisation providers about the risks of administering the live vaccine in this elderly age group who are likely to have comorbidities, likely to be taking several medications and at risk of immunocompromise. Better educational resources about clinical risk assessment of individual patients to determine suitability for vaccination, such as via more webinars for professional education, particularly in rural and remote regions, are recommended.
- For consumers, greater consumer-based education about the potential vaccine risks/contraindications is recommended as well. A greater focus on cultural suitability of educational activities for Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse (CALD) groups is also recommended.
- Plain English summaries of the Australian Immunisation Handbook advice so that it is easier to read. Consider extension of eligibility for the funded vaccine to younger and older age groups, in particular to Aboriginal and Torres Strait Islander people aged <70 years (this would need to be progressed through appropriate pathways).

Reported coverage of shingles vaccination among the target and catch-up cohort of adults aged 70–79 years was less than optimal, although it was higher in Aboriginal and Torres Strait Islander people compared with non-Indigenous people. Strategies to increase vaccination uptake in the NIP target population should be considered, especially for the catch-up cohorts (aged 71–79 years) who are only eligible to receive the funded vaccine till October 2021.

The occurrence of adverse events related to inappropriate use of the vaccine in immunocompromised people reinforces the importance of continued communication and education about vaccine contraindications. A pre-screening tool to assess immunocompromising conditions and medication use, to avoid adverse events resulting from the live vaccine virus, has been promoted for use in general practice. Consideration of evaluating the use of this or other similar tools may be warranted.

This report’s findings emphasise the need to examine the vaccine program’s impact on herpes zoster and post-herpetic neuralgia which, to date, has not been done in Australia and may be challenging, given no disease impact/surveillance plan has yet been finalised.

Another theme that emerged from the evaluation was use of Zostavax®, a live-attenuated vaccine, does not address the burden of disease in those who are at high risk for herpes zoster and post-herpetic neuralgia, such as immunocompromised adults (including those aged <70 years of age) in whom this vaccine is contraindicated and Aboriginal and Torres Strait Islander people aged 60–69 years who were not funded under the NIP despite some evidence of a similar risk of herpes zoster to that in non-Indigenous people aged 70–79 years.

Full program evaluation with respect to impact on disease burden is also needed to understand the current epidemiology of herpes zoster and post-herpetic neuralgia to assess the potential impact of the non-live adjuvanted sub-unit herpes zoster vaccine (Shingrix®, GSK) which was registered in Australia on 2 July 2018.

Abbreviations

ACRRM	Australian College of Rural & Remote Medicine
ACV	Advisory Committee on Vaccines
AIR	Australian Immunisation Register
ALGA	Australian Local Government Association
AMA	Australian Medical Association
AMS	Aboriginal Medical Service
APNA	Australian Primary Health Care Nurses Association
ATAGI	Australian Technical Advisory Group on Immunisation
CATI	Computer Assisted Telephone Interviewing
CATSINaM	Congress of Aboriginal and Torres Strait Islander Nurses Association and Midwives
EMA	European Medicines Agency
GPRT	General Practice Roundtable
HZ	Herpes zoster
MCHN	Maternal and child health nurse
NACCHO	National Aboriginal Community Controlled Health Organisation
NIC	National Immunisation Committee
NIP	National Immunisation Program
PBAC	Pharmaceuticals Benefits Advisory Committee
PHN	Primary Health Network
PHU	Public Health Unit
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RDAA	Rural Doctors Association of Australia
TGA	Therapeutic Goods Administration
VZV	Varicella zoster virus

Introduction

Herpes zoster, or shingles, results from the reactivation of latent varicella–zoster virus (VZV) infection and typically presents as a painful rash.[1, 2] Shingles is more common in older adults and people who are immunocompromised.[3, 4] Immunocompromised people are more likely to have complications from herpes zoster.[1-4] Post-herpetic neuralgia is the most common incapacitating complication of herpes zoster – pain can persist for extended periods and be refractory to treatment. Antiviral therapy can reduce the duration of herpes zoster rash but has not been shown to decrease the incidence of post-herpetic neuralgia.[3,4]

The overall incidence of herpes zoster in Australia is approximately 490 cases per 100,000 population (all ages), with estimates ranging from 330 to 830 per 100,000 population depending on the data source.[3, 4] Incidence increases markedly with age.[5,6]

A recent study using general practice data from 2000 to 2006 and pharmaceutical prescribing, hospital morbidity and emergency department data from 1998 to 2005 found that in the Australian population aged ≥50 years, there was an annual average herpes zoster–related burden per person of 0.06 hospitalisations, 1.61 general practitioner (GP) visits, 1.96 prescriptions filled and 0.11 emergency department (ED) visits.[6] The burden of herpes zoster–associated hospitalisations was highest in adults aged ≥80 years; for GP visits it was highest in those aged 60–69 years; and for prescriptions and ED visits, it was highest in those aged 70–79 years.[6] The substantial healthcare costs of herpes zoster and post-herpetic neuralgia highlight the potential benefits of shingles vaccination.[5-8]

In Australia, the registered vaccine, Zostavax®, contains a live-attenuated strain of VZV and is thought to induce primarily T-cell-mediated immunity against VZV.[7] Vaccination has been shown to reduce the incidence of herpes zoster by 51% and the incidence of post-herpetic neuralgia by 67% over a median of more than 3 years follow-up.[9] The vaccine has been shown to be more efficacious in reducing herpes zoster in people aged 60–69 years than in those aged 70–79 years (64% compared with 41% efficacy), although efficacy against post-herpetic neuralgia is similar in both age groups.[9] Vaccination of people aged 70–79 years is estimated to prevent two thirds of post-herpetic neuralgia cases in this population.[9] In vaccinated people who experience an episode of shingles, the pain, severity and duration is reduced by 50%.[9] Routine vaccination of people aged 70–79 years is expected to provide the greatest population-based benefits against shingles and its complications, noting that vaccine efficacy wanes with time.[3,10] This observation is based on the vaccine efficacy demonstrated in this age group and their increased risk of shingles and post-herpetic neuralgia compared with those aged 50–69 years.[3, 9, 10]

The safety profile of the vaccine, following 10 years of post-marketing use, has been favourable and consistent with that observed in clinical trials and post-licensure studies.[11] During the course of clinical development, it was demonstrated that Zostavax® was well tolerated in over 58,000 vaccine recipients aged ≥50 years with a diverse range of comorbid medical conditions, generally reflective of the adult population, although excluding significantly immunocompromised individuals in whom the vaccine is contraindicated.[12]

The vaccine is currently licensed in >55 countries.[12] Although the vaccine has been available and recommended in the United States since 2006, the first publicly funded population-level shingles vaccine program began in the United States in 2013.[11,13] In the United Kingdom, the shingles vaccine program was introduced for adults aged 70 years with a phased catch-up program for those aged 71–79 years in 2013.[11,13] In the first 3 years of the program, the incidence of herpes zoster fell by 35% and of post-herpetic neuralgia by 50%.[14] Reductions in herpes zoster and post-herpetic neuralgia have also been observed in the United States.[15-17]

In Australia, Zostavax® was registered in 2007. While the Pharmaceutical Benefits Advisory Committee (PBAC) provided a positive recommendation for inclusion on the National Immunisation Program (NIP) in 2009, there were supply issues, resulting in the vaccine not being available until 2013. The PBAC subsequently reviewed a number of submissions from bioCSL (now Seqirus) and gave a positive recommendation for the vaccine to be included on the NIP at its November 2014 meeting.[18]

Australia's shingles vaccination program commenced from 1 November 2016 for people aged 70 years, with a 5-year catch-up program for those aged 71–79 years.[4]

Aims

1. Process evaluation

This report presents a survey-based process evaluation of the National Shingles Immunisation Program in its first year of operation. The evaluation aimed to:

1. describe and assess program implementation, including the communication strategy, vaccine procurement and program delivery
2. identify strengths and challenges of the program through engagement with key stakeholder groups
3. make recommendations relevant to current and future programs.

Methods

1. Process evaluation

The process evaluation compromised 3 modules:

- **Module 1:** Key stakeholder surveys and interviews
- **Module 2:** Survey of general practitioners and other primary healthcare staff using an online survey
- **Module 3:** Survey of consumers using computer assisted telephone interviewing (CATI)

The above-mentioned modules are presented in the first chapter in this report.

The evaluation study design and protocol were approved by the Sydney Children's Hospitals Network Human Research Ethics Committee (**Appendix A**)

2. Vaccination coverage

Coverage was assessed using the Australian Immunisation Register (AIR) data for adults aged 70–79 years between 1 November 2016 and 31 March 2018**.**

3. Vaccine safety

Vaccine safety data from the Adverse Events Management System (AEMS) of the Therapeutic Good Administration (TGA) were analysed and reported for the first 16 months of rollout of the program, that is, 1 November 2016 to 28 February 2018.

AusVaxSafety data were reviewed for the first 19 months of rollout of the program, that is, 1 November 2016 to 3 June 2018. Data from two data systems (SmartVax and Vaxtracker) that feed into AusVaxSafety were used in this review.

CHAPTER 1: PROCESS EVALUATION

Module 1: Key stakeholder surveys

Aims

The objectives were to assess among key stakeholders:

- awareness of herpes zoster and post-herpetic neuralgia disease burden and state- and territory-wide shingles immunisation program initiatives
- knowledge and understanding of relevant shingles immunisation–related issues (age eligibility for funded vaccine, vaccine efficacy against herpes zoster and post-herpetic neuralgia, contraindications and vaccine safety)
- attitudes to shingles immunisation and related implementation issues (vaccine efficacy against herpes zoster and post-herpetic neuralgia, duration of protection, contraindications and vaccine safety, cost-effectiveness)
- use of available resources (communication resources developed by Commonwealth and state/territory governments, human resources, funding)
- relationships and networks which facilitated implementation of the shingles immunisation program
- feedback on specific implementation issues, including vaccine ordering, supply and distribution, wastage, leakage, reporting and recording of vaccine receipt on the AIR
- feedback on any vaccine safety issues.

Methods

Stakeholder survey and semi-structured interviews

A mixed methods approach was used. Both qualitative and quantitative data were collected from stakeholder questionnaires and interviews.

As the zoster program is a large new program for an age group not previously specifically targeted under the NIP, and the first time a live vaccine has been used at a population level in the elderly, a greater number and breadth of stakeholders was surveyed – see stakeholder sampling matrix in **Appendix B**.

Tailored questionnaires were prepared for specific stakeholder groups – see example in **Appendix C.**

Key stakeholder groups invited to nominate interviewees:

Government and associated committees/advisory groups

- Australian Government Department of Health (Department of Health)
- National Immunisation Committee (NIC)
- State and territory departments of health
- Advisory Committee on Vaccines (ACV)
- Therapeutic Goods Administration (TGA)
- AusVaxSafety

Peak professional/practitioner groups

- Australian Medical Association (AMA)
- Royal Australian College of General Practitioners (RACGP)
- Australian College of Rural & Remote Medicine (ACRRM)
- Royal Australasian College of Physicians (RACP)
- Australian Primary Health Care Nurses Association (APNA)
- National Aboriginal Community Controlled Health Organisation (NACCHO)
- Rural Doctors Association of Australia (RDAA)
- The Congress of Aboriginal and Torres Strait Islander Nurses Association and Midwives (CATSINaM)
- Australian Local Government Association (ALGA)

Community-based groups/practitioners

- Primary Health Networks (PHNs)
- Public Health Units (PHUs)
- GPs and practice nurses/managers
- Local councils
- Aboriginal Medical Services (AMSs)
- Other immunisation providers
- Consumers Health Forum

Engagement with stakeholders

Stakeholder representatives were consulted via the NIC and professional organisations to obtain expert advice during the development and implementation of the evaluation plan, and to help with dissemination of evaluation findings when complete.

The draft evaluation plan and progress of the shingles vaccination program evaluation were tabled at the NIC meeting on 24 March 2017 for provision of feedback to NCIRS. Also, the draft questionnaires were distributed to NIC members

'out of session' for comments on 26 June 2017. NCIRS received comments from NIC members on 10 July 2017.

Analysis

1. Descriptive analyses of frequencies within gender groups were undertaken using SPSS V24. A 5-point Likert scale was used to ascertain knowledge attitudes and behaviours. Graphical presentations were derived using Microsoft Excel, Version 10.

2. Thematic analysis of comments from all stakeholder groups was undertaken. These included jurisdictional managers and relevant staff, along with representatives of peak professional bodies and associations, Seqirus, the TGA, Department of Health, AusVaxSafety, medical specialists and PHUs/PHNs. The scope of comments included program planning, communication and resources, strengths, challenges and recommendations about implementation of the National Shingles Vaccination Program.

Results

Semi-structured telephone interviews were conducted with each group of stakeholders regarding planning and implementation activities; communication and resources; collaboration; vaccine characteristics (coverage, adverse events, supply); and program attributes (strengths, challenges and recommendations).

A summary of participation from each stakeholder group is outlined below and is summarised in **Table 1.1**.

- **Jurisdictional immunisation program managers and other relevant staff**
  A total of 14 representatives were invited across all states/territories and 8 participated (1 from the Australian Capital Territory (ACT), 2 from New South Wales [NSW], 1 from the Northern Territory [NT], 1 from Queensland [QLD], 1 from Tasmania [TAS], 1 from Victoria [VIC] and 1 from Western Australia [WA]).

- **Department of Health**
  Two representatives of the Department of Health provided a consolidated written response.

- **TGA**
  Two representatives from the TGA were interviewed.

- **AusVaxSafety**
  Three representatives from AusVaxSafety were interviewed.

- **Representatives of professional peak bodies**
  A total of 25 representatives were invited. A total of 13 people agreed to be interviewed from the AMA; RACGP; ACRRM; RACP (geriatricians, neurologists, rehabilitation medicine); Consumers Health Forum; APNA; NACCHO; CATSINaM; RDAA; Indigenous Immunisation Coordinator (NCIRS).

- **PHUs and PHNs**
  Participants from 15 PHUs were invited, as per the sampling matrix (**Appendix B**), and 9 participated (3 from QLD, 2 each from NSW and WA and 1 each from TAS and the NT).
  Participants from 13 PHNs were invited, as per the sampling matrix (**Appendix B**), and 6 participated (2 from Hunter New England and Central Coast and 1 each from Northern Sydney, South Western Sydney, Western NSW and Eastern Melbourne).

- **Specialists**
  A total of 8 relevant medical sub-specialists were invited through the RACP and 2 participated (1 rheumatologist and 1 haematologist).

- **Seqirus**
  Two staff nominated by Seqirus participated in the interview.

- **Immunisation expert**
  A nominated immunisation expert from NCIRS was interviewed.

The participating stakeholders are summarised in **Table 1.1**.

Table1.1. Description of the 48 stakeholders who participated in interviews

Type of stakeholder	Number Interviewed	Percentage, %
Jurisdictional immunisation program managers and other relevant staff	8	17
Australian Government Department of Health	2	4
The Therapeutic Goods Administration	2	4
Representatives of professional peak bodies	13	27
Seqirus employees	2	4
AusVaxSafety staff	3	6
Public Health Unit staff	9	19
Primary Health Network staff	6	13
Medical specialists	2	4
Immunisation expert	1	2

Program planning

In response to the question "How and when were you advised about the National Shingles Vaccination Program?" all ***jurisdictional immunisation program managers and other relevant staff*** considered consultation and lead time adequate –

> *We were advised a long time before it happened*
>
> *We knew by March … that it was coming*

All noted no change of state or territory policies was required for implementation:

> *So they (immunisation program nurses) didn't have to make any changes to actually implement this new shingles program*

However, jurisdictional immunisation program managers/other relevant staff also agreed there was a great need to both raise awareness and provide information to various stakeholders and target groups. These included, but were not limited to, immunisation program nurses, PHUs, PHNs, GPs, AMSs, Aboriginal and Torres Strait Islander health councils, community nurses, pharmacists, aged care organisations and seniors groups. Planning and implementation activities with stakeholders and target groups were conducted by jurisdictional program managers via face-to-face meetings, teleconferences, letters, emails/faxes and website postings.

Professional body representatives did not report any involvement in planning for the implementation of the national shingles vaccination program beyond distribution of information about the rollout and educational resources produced by their own organisations (AMA) and from the Commonwealth, NCIRS and Seqirus.

> *AMA made members aware of resources and how to access them ….articles regarding NSVP prepared by AMA were posted on AMA website and several articles appeared in 'doctorportal' (a comprehensive online resource for AMA members) before, during and after the November 2016 launch of NSVP*
>
> *We put out news items that the program was coming, and any information coming through was sent out to members (RACGP)*
>
> *Communiqué which can be circulated through the weekly bulletin… It's got a wide, very wide coverage (RACP)*

PHN and PHU representatives described their role in planning and implementation strategies for the national shingles program. Collaboration between PHNs and PHUs in provision of educational materials and information to GPs, practice nurses and AMS was a common theme.

> *Main planning activities….informing GPs…through immunisation coordinator via our local Immunisation Committee with the Primary Health Network*

Agreement with the Primary Health Network to send it out through their faxes…. whoever's on their list. In the past mailed out…now all online……

In October we sent fact sheets out on the Zostavax® program and key points on contraindications and precautions including immune-compromised ……also sent Queensland Health information sheet. We planned three evening sessions across our area for November (PHN QLD)

State/territory websites were used, as were the Commonwealth and NCIRS communication materials. Communication about implementation was largely via circulation of Commonwealth, state or NCIRS-developed resources to GP practices.

The ***Department of Health representatives*** highlighted their key role in planning. They advised that implementation of any new program under the NIP takes approximately 12–18 months; that an implementation plan was developed to provide high-level guidance; and separate (more detailed) plans were drafted to outline specific activities, such as procurement, vaccine safety, communications and program evaluation.

The Department of Health plans are included as appendices: **Appendix D** (Implementation plan), **E** (Vaccine safety plan) and **F** (Communication strategy).

Key activities of the Department of Health's implementation plan included:

Safety surveillance (refer to **Appendix E** for more details)
Develop a vaccine safety plan (VSP) for shingles vaccine:

- Implementing AusVaxSafety
- responding to significant adverse events and signals
- monitoring to detect population-specific, rare, late-onset or unexpected adverse events.

Surveillance and monitoring
The surveillance and monitoring plan has been developed and will be finalised in late 2018/early 2019.
Data collection and mechanisms:

- Sentinel surveillance systems for shingles will be added to notifications through National Notifiable Diseases Surveillance System (NNDSS).
- Parameters to be monitored:
  - age-specific vaccine coverage achieved in the eligible population
  - prevalence and severity overall, and in Aboriginal and Torres Strait Islander people
  - incidence of post-herpetic neuralgia in the eligible population
  - vaccine failures
  - circulating genotypes.

Procurement

- Procurement approach
- Request for Tender documentation, including state and territory agreements
- Tender assessment processes
- Contract negotiations
- Execution of vaccine agreements (Commonwealth and states/territories)

Communications strategy **(Appendix F)**

- Clinical advice and communication materials to increase uptake of the vaccine.

AIR capabilities

- Functional changes were made by the Department of Human Services in September 2016 to enable the AIR to record Zostavax® immunisation for the start of the program from 1 November 2016.

Program evaluation – post implementation

- Develop post-implementation evaluation in consultation with NCIRS (i.e. this and subsequent scheduled reports)

Table 1.2. Timeline for introduction of the National Shingles Vaccination Program (as reported by the Department of Health)

Date	Planning activities
7 November 2014	PBAC recommended that Zostavax® be included on the NIP
12 May 2015	Funding for the National Shingles Vaccination Program announced in the 2015–16 Budget
June 2015	Development of implementation arrangements commenced
24 November 2015	Implementation plan (**Appendix D**) endorsed by the NIP Implementation Steering Committee. Included senior officers in the Immunisation Branch responsible for communications, evaluation, procurement, vaccine safety and immunisation registers as set out on page 5 of the plan
20 April 2016	The Australian Government released tender for purchase of vaccine
1 July 2016	National Health (Immunisation

	Program – Designated Vaccines) Determination 2014 amended to include Zostavax®
1 August 2016	Australian Immunisation Handbook updated to include Zostavax®
September 2016	Stakeholders consulted on the development of communication materials, distributed before program commencement. Included letter from the Chief Medical Officer to immunisation providers. Safety plan and Communication strategy developed (**Appendices E** and **F**)
30 September 2016	AIR enhanced to capture all adult immunisations.
3 October 2016	Vaccine delivery to states and territories commenced. Providers advised to commence vaccination as soon as the vaccine arrived
1 November 2016	Program commenced
2 November 2016	The Minister for Health launched Shingles Program and the AusVaxSafety national vaccine safety surveillance system

Communication and resources

Department of Health initiatives

1. Communication strategy (**Appendix F**)
2. Suite of resources to support uptake of the program, including:
    - letter from the Chief Medical Officer
    - fact sheet for vaccination providers
    - consumer poster
    - consumer brochure
    - Aboriginal and Torres Strait Islander specific poster
    - Aboriginal and Torres Strait Islander specific brochure
    - social media content and graphics.

Consumer brochures advised certain people may be unable to have the vaccine, particularly those with a weakened immune system, and to seek advice from their GP.

The *vaccination provider fact sheet* included a section titled 'Contraindications' which stated that Zostavax® is contraindicated in people who are significantly immunocompromised and referred providers to the Australian Handbook. These fact sheets were provided to all GPs in Australia.

Vaccination providers received *correspondence from the Chief Medical Officer* in late October 2016, including two posters promoting the vaccine (mainstream and Aboriginal and Torres Strait Islander), a fact sheet for vaccination providers and a brochure for consumers.

Consumer brochure: translated into a range of languages for people from non–English-speaking backgrounds (available for download from Immunise Australia). The Department of Health provided electronic copies of materials for distribution through key stakeholder networks (NIC, GP Roundtable, NATSIIN and Primary Health Networks).

Vaccine contraindications: After the Zostavax®-related death of an NSW man who was immunocompromised and received the vaccine despite contraindications, the Department of Health coordinated development and dissemination of the Zostavax® checklist to help providers make decisions about using Zostavax® in immunocompromised people. The Department of Health worked with ACV, ATAGI and NCIRS on an alert detailing use of vaccine in immunocompromised patients, distributed by states/territories to vaccine providers, using detailed information from the NCIRS fact sheet.[10]

Jurisdictional immunisation program managers and other relevant staff

<u>*Commonwealth National Shingles Vaccination Program resources:*</u> All jurisdictional immunisation program staff who participated in the evaluation reported using these and linking them via their state or territory websites. All of the program staff (8/8) had seen the 'Protect yourself against shingles' brochure, posters and fact sheets and all reported that they were useful resources.

> *Commonwealth resources, we used all of them, yep. We sent out all of the posters and we sent out the fact sheets, we used the Commonwealth ones We thought they were fine, generally. I think they provided all the information people needed to know… providers did not indicate any problems with them*

<u>*Other communication with stakeholders*</u> included information about the program via regular meetings and teleconferences as well as mail-out of an information pack, which included cover letter to providers, new/revised order forms, new/revised schedule, new/revised cold chain breach forms, vaccine fact sheets and alerts.

> *We usually provide a covering letter that explains that there's a new addition to the schedule, it's a National Shingles Vaccination Program, it's for this group. We advise start vaccinating 70-year-olds in the first instance and then it's a 5-year program, so you can work your way through the other age groups*

Several jurisdictional program staff and NCIRS experts delivered webinars for GPs and practice nurses as well as GP/nurse education sessions via local PHNs.

Communication post critical incident: In March 2017, following the Zostavax®-related death, program managers sent a one-page alert to GPs, hospitals and specialists about risks among immunocompromised patients.

Representatives from professional colleges and peak professional organisations

Webinars: All (13/13) considered webinars useful for informing and educating –

> *Webinars are good because you have a greater capacity for doctors and nurses to participate without having to travel….leave their practices…*
>
> *Webinars are very good because they reach so well into remote settings (and)… …offer CPD points*

Educational materials from the Commonwealth, NCIRS and Seqirus were well-used:

> *Yes, I have **brochure** in the practice….handing it out patients as they came in, so that they could think about it, discuss the vaccine with GPs….I think that's the story that you'll get from most practices……..*
>
> ***Factsheets** for providers, we've sent them through……...As they've been available through the electronic network, we've sent out to our members….*
>
> *The college is very good at disseminating resources. We received and disseminated……the **pre-vaccination checklist***

One professional association recommended the use of **online chat spaces** for trainees to participate in Q&A sessions as part of educational programs.

> *For example our trainees, they come through in cohorts depending on the stage of their development. They have a chat forum there. We can certainly facilitate those... useful way to engage in an active manner …*

PHU and PHN staff

Recognition of the 'Protect yourself against shingles' posters and brochures was reported by three PHUs, but 5/9 (56%) reported not seeing or using these resources. Similarly, of 6 PHNs interviewed, only 3 reported seeing/using the materials.

In addition to Commonwealth and state/territory resources and websites for providers, PHUs and PHNs used resources from Seqirus.

> *They (Seqirus) wanted to do the education so we let them do it …. Dr XX did the education session, using PowerPoint – we (PHN staff) attended and backed any calls from service providers over the phone, to provide any*

additional information. We had good attendance at that evening where the education session was delivered….lots of doctors and lots of nurses……

Collaboration

Department of Health

Noted that the approach to the communication materials was informed by the results of market research conducted by *Snapcracker in 2016*. This research, directed at understanding knowledge, behaviour and intentions regarding immunisation among target audiences, included some from the target age-group for the shingles vaccination program, yielding information about their information needs, gaps and overall preferences.

Furthermore, the Department of Health advised that the communication approach developed (**Appendix F**) was also informed by qualitative and quantitative research *commissioned by Seqirus* on patients' and GPs attitudes and intentions regarding shingles and the shingles vaccine. The research, conducted by *Forethought Research from 2013 to 2015*, was provided to the Department of Health by Seqirus.

Subsequently, the Department of Health consulted extensively with the states and territories (through JICs) to develop final communication resources. NCIRS, NIC and NATSIIN also provided technical and cultural advice on the draft materials. The Department of Human Services was also engaged to promote the shingles vaccination program through its publications and social media channels.

Other key stakeholders, peak professional bodies and organisations

Reported collaborating with several different community groups to inform and educate providers and consumers. Collaborative partnerships specified:

- The Council on the Ageing (COTA) Australia is an advocacy organisation which lobbies for action at a national level on issues affecting seniors. COTA was advised of the program via discussions with the AMA.
- The GP Roundtable (GPRT) includes representatives of the Australian Practice Nurses Association, the Australian Practice Managers Association, the Pharmacists Guild and the AMA.
- The Indigenous team and a rural team within the college (RACGP) provided input as members of NIC.
- The AMA has representatives from a number of organisations and has representation on NIC.
- AMA, as a member of GPRT, worked with members of the TGA Advisory Committee on Vaccines and members of Australian Technical Advisory Group on Immunisation (ATAGI) to prepare a pre-vaccination checklist for patient screening in March–April 2017.
- The AMA reported that pharmacists had been supportive.

- The AMA, PHNs and PHUs all reported that they had collaborated and cooperated with the AMS in their areas.

Also reported collaborations between stakeholders from state and territory health departments and PHNs/PHUs, as well as with NCIRS and Seqirus

> *The main collaboration is with NCIRS*
>
> *I had Seqirus come and they did a presentation. I had a one-on-one with Seqirus - they bought a tool kit that went to all the Practice Support Officers*

PHUs and PHNs also reported working together with the following organisations –

- local/regional immunisation committees
- aged care facilities
- practice support officers
- local government
- RACGP
- Pharmacy Guild & Pharmaceutical Society of Australia

Supply

Department of Health

A request for tender (RFT) to secure vaccine supply was released on 5 May 2016 and it closed on 17 June 2016. In response to the RFT, a tender was received from Seqirus, the only provider in Australia, to supply their product Zostavax®. The vaccine supply contract was executed on 4 October 2016.

Pre-implementation estimates were based on the program being demand-driven. It was anticipated that approximately 240,000 70-year-olds would be eligible each year, with 1.4 million 71–79-year-olds eligible for the 5-year catch-up.

Upon commencement of the program on 1 November 2016, demand for the shingles vaccine was much higher than anticipated. The Department of Health worked closely with the supplier, and states and territories, to ensure national distribution met demand. By June 2017 (7 months into the program), supply had increased to meet NIP requirements.

Managers and immunisation staff from all jurisdictions

All reported that supply problems interfered with the rollout, resulting in lower initial coverage and frustration for providers.

> *I don't think we've ever rolled out a program……..where vaccine was short at the beginning for a number of months following….. It's never going to be a good way to roll out a program.*

There was limited supply until 30 May 2017. This is unacceptable for a National program.

Both providers and the public became very unhappy…... we spent a lot of time responding to their concerns, answering numerous Ministerial, complaints through RACGP and Public Health Hotline complaints…

Supply issues are covered in detail under "Challenges" below as a major problem during the rollout. Nevertheless, despite these problems, by 5 October 2017, the program had distributed over 1.3 million doses of shingles vaccine across Australia.

Coverage

Department of Health

The AIR commenced collecting information on vaccine doses given to adults in late September 2016. It was inevitable that initially adult vaccination information held in the AIR would be incomplete, but expected that as providers became more familiar with use of AIR, reporting would steadily increase.

Jurisdictional program managers and providers

Notwithstanding this background, coverage issues were mentioned by all jurisdictional managers, who expressed frustration with delays in data recording.

Coverage - we collect data and transfer it to AIR…..those service providers who have electronic software packages upload data directly…..then we collect everybody else manually, put it onto our database and upload that to AIR.

Supply problems were also considered to have directly reduced coverage.

Were uptake coverage targets set in jurisdictions? No, they weren't …. we thought we'd give 70-80% but we didn't have enough vaccine

Adverse events

Passive surveillance of adverse events was undertaken by the TGA. In all states and territories (except Tasmania) it is preferred that reporting of AEFI for NIP vaccines is via the local health authority, which then sends reports to the TGA.

The Department of Health funds AusVaxSafety, an active participant-based sentinel surveillance system, to actively monitor AEFI with NIP vaccines, including Zostavax®. The majority of AusVaxSafety surveillance occurs at 3 days post vaccination and therefore (unlike the passive system in which reporting can occur at

any time) may not pick up adverse events that are identified after this time frame. The Department of Health advised that Zostavax® has been monitored since 1 November 2016, with no safety signals identified to date.

Death post shingles vaccine

A Zostavax®-related death was reported to the TGA in January 2017.[19] An immunocompromised man in NSW received the shingles vaccine in December 2016 and died in January 2017 from disseminated varicella-zoster virus infection, with his death subsequently confirmed as due to the vaccine strain.[20] Clinical reviews by public health officials confirmed that this was an administration error by the GP, contrary to recommendations. Further investigations by the TGA and AusVaxSafety have identified a number of immunocompromised individuals who have received the vaccine, although no other deaths have been recorded.[21]

Following notification by the TGA of the death to the Department of Health and state/territory managers, multiple subsequent actions were undertaken, including:

- alert issued via the Commonwealth and all states and territories reminding providers to not vaccinate immunocompromised people with Zostavax® and providing links to resources and other support for follow up if required.
- the Chief Medical Officer teleconference with the GP Roundtable on strategies for minimising the risk of Zostavax® administration to immunocompromised individuals
- the Department of Health worked with ACV as well as ATAGI and NCIRS to develop more detailed guidance on categories of immunocompromise which contraindicate Zostavax®, released on 9 March 2017
- in August 2017, a Zostavax® pre-vaccination checklist was distributed to immunisation providers
- increased communication and education activities
- the Australian Immunisation Handbook update with more information on need for prevaccination assessment.

In light of these events, concerns were expressed by all jurisdictional program managers and ACRRM:

> *We had a death ….we have had a number of other reports of it being given incorrectly, and including given to a child.* (Jurisdictional Program Manager)

> *We had a couple of people who got (Zostavax®) given more than once…one had to come into hospital …she did have some underlying medical conditions (*Jurisdictional Program Manager)

> *We noted there were cases of administering the vaccine twice… mainly due to providers not checking the AIR. (*Jurisdictional Program Manager)

*They (GP providers) …….just wanted an easy access flashcard for questions to ask and side-effects…came after the unfortunate event with the death of that man. (*Jurisdictional Program Manager)

Assessing a patient's level of immunocompromise due to illness and/or medication has been problematic. (Jurisdictional Program Manager)

The comment 'seek specialist advice' is not helpful in rural and remote areas where there are no specialists other than the GP. (ACRRM)

All stakeholders commented that the risk associated with the administration of a live vaccine to immunocompromised patients needs to be addressed via education.

Strengths, challenges and recommendations

Strengths

Department of Health

People in the age group targeted by the program are strong acceptors of vaccination, confirmed by survey data before program rollout. Interest in the vaccine has been high, as the age group had good appreciation of shingles and the adverse health impacts that can follow from it.

Communication and vaccine safety plans are now comprehensive (**Appendix D** and **E**). In particular, the VSP recognises prevalence of comorbidities, chronic medical conditions and use of multiple medications in this age group.

Collaborated extensively with states and territories and key immunisation stakeholders on implementation of the program.

Worked closely with manufacturer Seqirus before, during and after the program implementation.

Managers and immunisation staff from all jurisdictions

Sufficient lead time was perceived as a strength of the program by all 8 jurisdictional immunisation program staff and all 13 stakeholders from peak bodies who participated in the survey. **Table 1.3** lists the major themes regarding strengths of the program from the stakeholder interviews.

Table 1.3. Stakeholder themes related to program strengths

Stakeholder group	Strengths (number reporting)
Jurisdictional immunisation program managers and other relevant staff (n=8)	• Target population already aware and engaged in immunisation (5/8) • Elderly are used to getting annual influenza vaccine (4/8) • Elderly keen to get new free vaccine (5/8) • Awareness and support among GPs was high (3/8)
Representatives of peak bodies (n=13)	• GP providers support the new free vaccine (3/13) • Offer free vaccine to susceptible age group (5/13) • High-quality educational resources from NCIRS, the Department of Health and Seqirus were helpful (5/13) • Elderly patients are engaged with immunisation (6/13) • Potential to prevent post-herpetic neuralgia (3/13) • Webinars were very helpful (6/13)
PHU staff (n=9) **PHN staff (n=6)** **Total staff (n=15)**	• High quality of educational resources provided to GP providers from NCIRS, the Commonwealth and Seqirus (8/9 PHUs) (6/6 PHNs) • Resources and seminars from all sources Commonwealth, NCIRS and Seqirus (9/9 PHUs) (5/6 PHNs) • Face-to-face and webinars were helpful (7/9 PHUs)

Challenges

Department of Health

- Immunocompromised individuals received the vaccine despite prior warnings and alerts.
- Since the commencement of the program on 1 November 2016, demand for the vaccine has been higher than anticipated, resulting in service delivery stresses and public dissatisfaction.
- There were challenges associated with managing public expectations of the eligibility of the vaccine and its efficacy in adults aged >79 years.
- Records in the AIR are not complete.
- Further communication about the program required.

Other stakeholders

Low supply of the Zostavax® vaccine

Major challenge expressed by 8 JIC/program managers, 8 peak professional bodies and 13 PHU/PHNs. View among the majority of stakeholders that high demand driven by strong promotion, arguably excessive marketing by Seqirus which resulted in demand outstripping supply (7 jurisdictional immunisation program managers and other relevant staff, 8 peak professional bodies and 5 PHU/PHNs).

AIR

Challenges reported for AIR (3 jurisdictional immunisation program staff and 5 PHU/PHNs) included data entered in general practice not reaching the AIR and lack of access to AIR.

Additional challenges are listed in **Table 1.4**.

Table 1.4. Stakeholder themes related to major challenges

Stakeholder group	Major challenges (Number reporting)
Jurisdictional immunisation program managers and other relevant staff (n=8)	• Need for GP and specialist education regarding administration of this new live vaccine to immunocompromised patients (5/8) • GP education about patient immunosuppression and misadministration of the vaccine (7/8) • Managing complaints - jurisdictional managers reported receiving complaints from GPs, PHUs, PHNs, consumers (5/8) on supply issues • Desire to expand eligibility for free vaccine to younger age groups e.g. 60–70 years (4/8)
Representatives of peak professional bodies (n=13)	• Need for GP and specialist education regarding administration of this new live vaccine (8/13). More specific education for GPs about patient immunosuppression. • Should be available for Aboriginal and Torres Strait Islander people at younger age (5/13)
Representatives of Seqirus (n=2)	• Should be available for Aboriginal and Torres Strait Islander people at a younger age (2/2) • Education for GPs about immunosuppression and misadministration of the vaccine (2/2)
PHU staff (n=9) **PHN staff (n=6)** **Total staff (n=15)**	• GP and nurse education is a large task for PHUs and PHNs (9/9PHUs) (4/6 PHNs) • GP and nurse knowledge about immunocompromise and vaccine eligibility was lacking (5/6 PHNs) • Educational resources were good, but not available early enough (7/9 PHUs)) (4/6PHNs) • Should be available for Aboriginal people at a younger age (4/9 PHUs) (4/6 PHNs) • Lack of detailed information in the Handbook (3/6 PHNs) • Handbook not helpful to GPs – needs to be summarised (3/6 PHNs)

Recommendations of stakeholders

Stakeholders provided recommendations on how to improve the existing shingles vaccination program and also on implementation of future vaccination programs.

Department of Health

Recommendations for future new national vaccination programs:

1. more effective and transparent supply planning with the manufacturer, especially if the supplier undertakes extensive promotion of the vaccine
2. lessons learnt from the introduction of the first new vaccine for older people in 15 years - the interests and willingness to vaccinate very different
3. continued strategic use of AusVaxSafety to augment passive adverse event reporting.

Other stakeholders

Three major recommendations for specific areas below and in **Table 1.5**:

1. Vaccine procurement, supply and marketing should be better managed to balance vaccine availability and demand from general public and GPs.

2. More clinical education for GPs, specialists and nurses about administration of a live vaccine among elderly population who have a much higher proportion of individuals with comorbidities, immunosuppressive conditions and who are receiving medications with immunosuppressive effects.

3. Expanded availability of the shingles vaccine to consumers, particularly for Aboriginal people aged <70 years.

Table 1.5. Recommendations and relevant comments from stakeholders

Stakeholder group	Recommendations and relevant comments (Number mentioning)
Jurisdictional immunisation program managers and other relevant staff (n=8)	**Procurement, supply and marketing better managed**
	• Supply needs to be secured well ahead of time (8/8)
	• Planning of supply requires better consultation (5/8)
	• Marketing of vaccine should be calibrated to supply (8/8)
	• Commonwealth and Seqirus responsibility to assess supply needs based on advice from states and territories (3/8)
	More clinical education particularly around immunocompromise

	• Commonwealth education about adverse risks of a live virus in immunocompromised before problems identified (4/8)
	• Education to upskill GPs (8/8)
	• GP and nurse education about vaccine eligibility for immunosuppressed was lacking and should be improved (5/8)
	• Commonwealth should take advice from states and territories about educational resources (3/8)
	• Engage more with specialists in regard to adverse effects (2/8)
	• Commonwealth and Seqirus should provide education and resources to diverse language and cultural groups (3/8)
	• Posters should be more culturally diverse (2/8)
	• Form implementation committee of JIC to handle planning/implementing for future national programs (1/8)
	Age-eligibility of the shingles vaccine should be expanded
	• Should be available on NIP from age 60 years and over 80 year olds also, although lower efficacy in this age group (3/8)
	• Aboriginal people should receive shingles vaccine at a younger age – suggested age 50 years (7/8)
Representatives of peak professional bodies (n=13)	**Procurement, supply and marketing better managed**
	• Supply, demand and education better managed (8/13)
	• Marketing of this vaccine should be more responsible (6/13)
	Availability to consumers should be expanded
	• Aboriginal people at a younger age – 50 years (5/13)
	• Involvement of PHUs and PHNs in educating providers and consumers and other organisations early (7/13)
	• Funding to employ more Aboriginal immunisation staff (1/15)
	More clinical education, particularly around immunocompromise
	• Target health providers and general public separately (3/13)
	• Educational resources should inform about the disease shingles and show a picture of the shingles rash (3/13)
	• Resources that provide information about level of protection, use of live vaccine, risks for immunocompromised (6/13)
	• GP and nurse education on risks of this live vaccine (4/13)
	• GP education via NCIRS (2/13)
	• Advice and support for rural or remote GPs is required (1/13)
	• Materials about immunosuppressive medications (1/13)
	• Better consultation with general practice (1/13)
	• Involve NCIRS in education (5/13)
	• Flashcard for GPs to quickly assess immunological risk (3/13)
	• Brochures and other resources in consultation with Aboriginal people to make more culturally appropriate (2/13)
	• Education for health professionals via webinars (8/13)

Representatives of Seqirus (n=2)	**Procurement, supply and marketing better managed** **Availability of vaccine to consumers should be expanded to younger and older age cohorts**
PHU staff (n=9) **PHN staff (n=6)**	**Education about administration of this live vaccine**
	• Education for GPs about eligibility, contraindications, medications (9/9 PHUs) 3/6PHNs)
	• GP education about checking AIR (5/6 PHNs)
	• Resources sent out to PHNs/PHUs early (8/9 PHNs)
	• Handbook made more user friendly in plain English(3/9 PHNs)
	• Webinars before the rollout would be helpful (5/9 PHNs) Seqirus education seminars informative and attracted a lot of people – these should be encouraged in future (5/9 PHNs)
	Availability expanded
	• Younger people and Aboriginal people at a younger age (3/9 PHUs/) (2/6PHNs)

Summary

Strengths of the program included availability of a new and needed vaccine for the prevention of shingles among a demographic of older consumers who traditionally support vaccination. All stakeholders reported being made aware of the vaccine availability well before the rollout and receiving communication resources and educational materials in a timely manner. Collaboration between stakeholders was often cited as helpful. GP providers especially commented on useful resources from the Commonwealth, NCIRS and Seqirus.

The main challenge, cited by all stakeholders alike, was delay in supplying the vaccine, with lack of supply creating frustration and confusion among providers and consumers in the first months of rollout. For providers, lack of comprehensive, detailed information about contraindications, especially relating to clear definition of the degree of immunocompromise contraindicating vaccine use at the outset of the program was a significant deficit. A checklist and/or a flashcard was preferred for this purpose.

The use of a pre-vaccination screening checklist was implemented after the vaccine-related death. Use of other detailed information, such as the NCIRS fact sheet, adapted for state/territory/Department of Health communication after this incident, was viewed as helpful. Also, there was strong support among some peak bodies for NCIRS role in the education of providers.

Module 2: Online survey of GPs and other primary healthcare staff

Aims

The aims of the survey of GPs and other primary health care staff were to examine:

- issues in the rollout of the national shingles vaccination program, in context of diversity of practice types and settings
- knowledge, attitudes and behaviours on background of moderate efficacy of the vaccine and potential side effects.

Methods

An online survey of GPs, practice nurses and practice managers, and other professionals working in the primary healthcare area across Australia, was conducted using *SurveyMonkey*® via the HealthEd network during the 3 weeks from 16 October to 3 November 2017 (refer to **Appendix G**). HealthEd has approximately 20,500 email addresses on its national electronic database, the majority of which are of GPs. HealthEd runs a rolling national series of educational events aimed at GPs, practice nurses/managers and other professionals working in primary healthcare areas.

The HealthEd survey provided the following data on GP and practice nurses/managers: demographics; type of practice/number of GPs in practice; provision of services to aged care facilities; administration of the shingles vaccine; knowledge, beliefs and attitudes about the shingles vaccine; and awareness of the program communication resources.

Results

A total of 1,567 responses (response rate 8%) were obtained from the online survey, with a gender split of 82% female (1,283) and 18% male (284).

This sample included, proportionate to population, major representation from the three large eastern states (83%) but included respondents from all states and territories (**Figure 2.1**), a cross-section of age groups (**Figure 2.2**) and professional roles within general practice (**Figure 2.3**). Not all respondents answered all questions and hence denominators presented vary across questions.

Figure 2.1 Distribution of online survey respondents by state and territory N=1,567

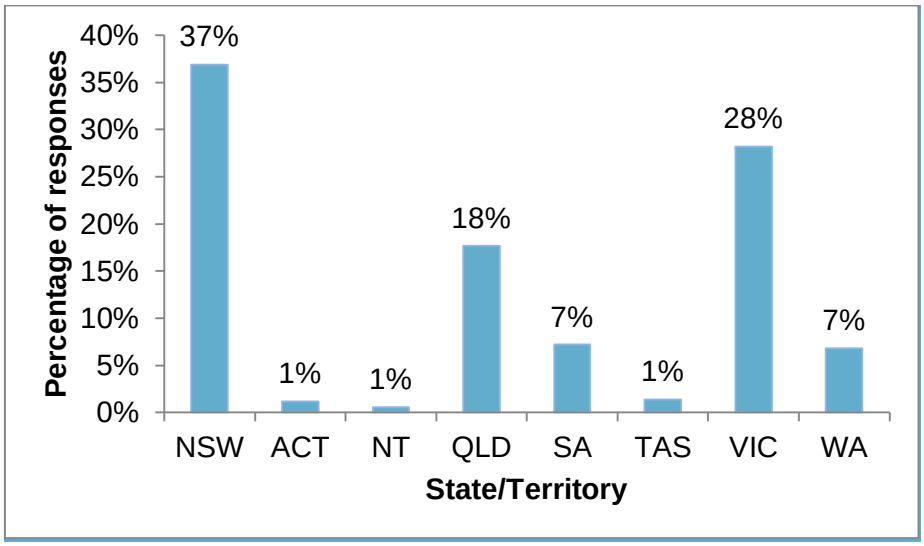


Figure 2.2 Distribution of online survey respondents by age group N=1,567

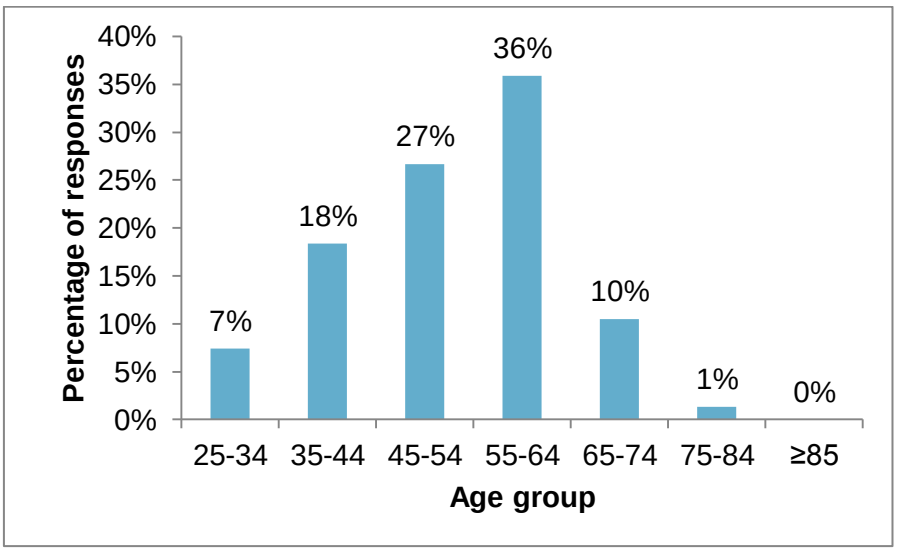
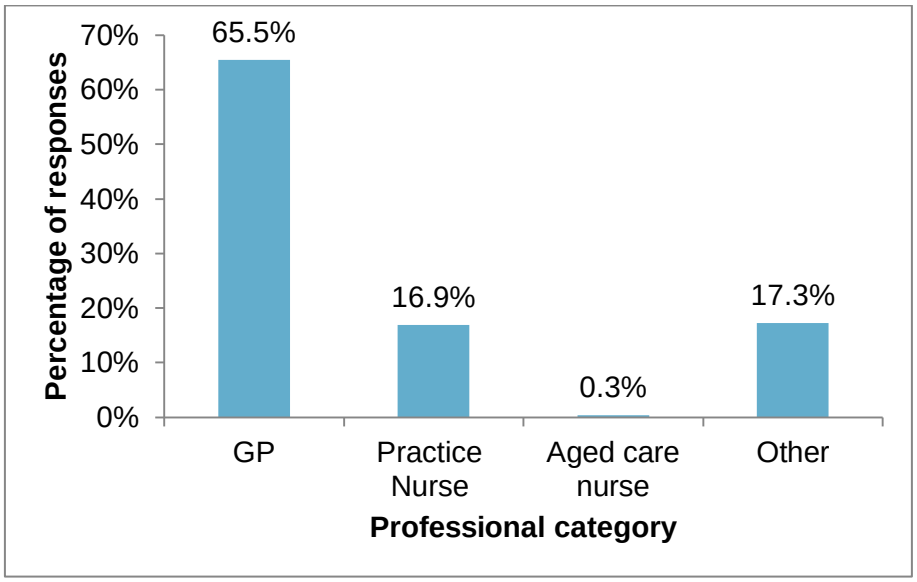


Figure 2.3. Distribution of online survey respondents by professional category N=1,567



The majority of participants were GPs (65.5%), followed by practice nurses/managers (16.9%). The 'Other' group consisted of various healthcare professionals, including registered nurses (RNs), midwives, maternal and child health nurses (MCHN) and allied health practitioners.

The majority of practices (**Table 2.1**) were private, independent group practices of 5–9 GPs (33%, 529), followed by 10 or more (20%, 306) or 2–4 GPs (19%, 304).

Table 2.1. Type of GP practice (n=1,567)

Type of GP practice	Number (%)
Private, independent group practice (5–9 GPs)	529 (33)
Private, independent group practice (10 or more GPs)	306 (20)
Private, independent group practice (2–4 GPs)	301 (19)
Other	213 (13)
Private, independent solo practice	109 (7)
Hospital-based clinic	89 (6)
Aboriginal Medical Service	20 (2)

Those working in 'Other' locations identified their workplace as a community health centre, university clinic, local government clinic, PHNs, health service, women's health centre or Maternal and Child Health (MCH) centre.

Responses from GPs and other primary healthcare staff are summarised in **Table 2.2**.

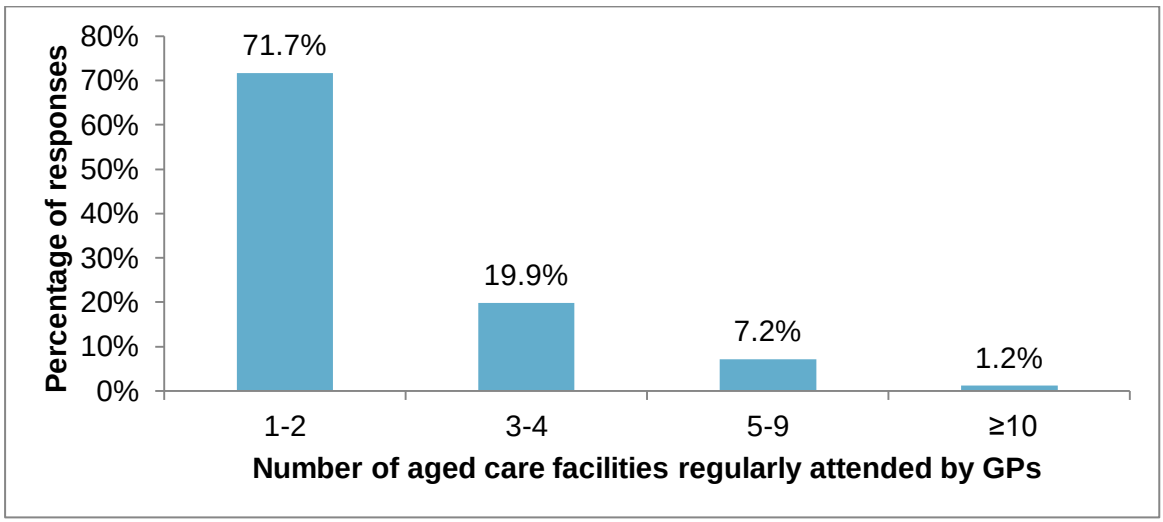
Table 2.2. Summary comments from GPs and other primary health staff N=1,567

Since the program rollout in November 2016, I have …..	Most days n (%)	Weekly n (%)	Rarely n (%)	Never n (%)
Administration of the vaccine				
Given zoster vaccine to eligible people	108 (9)	588 (51)	329 (29)	121 (11)
Advised zoster vaccine free for people aged 70 years	367 (32)	543 (48)	167 (14)	72 (6)
Advised zoster vaccine free as a catch up dose for those aged 71 to 79 years	339 (30)	525 (46)	192 (17)	92 (7)
Seen patients with shingles at my practice	25 (2)	121 (11)	917 (80)	80 (7)
Treated patients with post herpetic neuralgia (PHN)/chronic shingles pain	23 (2)	92 (8)	351 (74)	180 (16)
Referred people with shingles or PHN to a specialist for treatment	7 (0.5)	6 (0.5)	345 (30)	786 (69)
Received referral of a person from a specialist for zoster vaccine	6 (0.5)	10 (0.5)	226 (20)	903 (79)
Encountered a person who refused to be vaccinated with the zoster vaccine	12 (1)	80 (7)	689 (61)	360 (32)
Adverse events & safety concerns				
Observed a patient with a mild adverse event after zoster vaccination	4 (0.5)	9 (0.5)	357 (31)	776 (68)
Observed a person with a severe adverse event, such as anaphylaxis	2 (0.5)	1 (0.5)	27 (2)	1113 (97)
Had people express concerns about safety of the zoster vaccine	8 (1)	81 (8)	640 (55)	414 (36)
Procedural issues				
Reported my patients' zoster vaccination to Australian Immunisation Register (AIR)	202 (18)	361 (32)	231 (20)	344 (30)
Disposed of zoster vaccine due to cold chain breach	5 (1)	5 (1)	86 (7)	1042 (91)
Patient issues				
Patients Q: "Had chickenpox vaccine, am I protected against shingles?"	64 (6)	212 (18)	448 (39)	418 (37)
Encountered a person who refused to be vaccinated with the zoster vaccine	12 (1)	80 (7)	689 (61)	360 (32)

Aged-care facilities

A total of 640 practices (640/1,567) reported attending aged care facilities, with 583 reporting they attended facilities 'regularly' (**Figure 2.4**)

Figure 2.4. Number of aged care facilities regularly attended by GPs (n=583)



Of the 583 respondents who answered this question, the majority attended 1–2 aged care facilities (418, 72%), followed by 3–4 facilities (116, 20%) (**Figure 2.4**).

Administration of the shingles vaccine to aged care residents

About frequency of administration of the shingles vaccine (**Table 2.3**), 509 (32.5%) reported giving the vaccine at least once since the rollout in November 2016, with the majority (77%) giving it once or twice per month during that time.

The number of times the GP had given the vaccine in aged care facilities is given in **Table 2.3.**

Table 2.3. Number of times per month that the GP had given aged care residents the shingles vaccine since November 2016

Number of times per month GPs had given the shingles vaccine to aged care residents	Number (%)
1–2 times per month	393 (77)
3–4 times per month	54 (11)
5–9 times per month	34 (7)
≥10 times per month	28 (5)
Total	509 (100)

Satisfaction with aged care shingles vaccine

Of the 640 GPs attending aged care facilities, 268 (42%) stated they were satisfied that most of the eligible residents were receiving the vaccine. The majority of written comments (83%) identified ineligible age groups as the most significant issue, as residents were usually older than 79 years and unwilling to pay for the vaccine.

Approximately 5% of GPs were not satisfied with the uptake of shingles vaccine among their patients in aged care facilities, commenting that some patients or families had declined to receive it, particularly dementia patients.

Other barriers to aged care administration of the shingles vaccine included facilities unaware of the vaccine (4%); cold chain and supply difficulties (3%); unknown patient vaccination history and/or unknown contraindications (3%); and priority given to flu vaccine (2%).

Collaboration with others organisations/stakeholders

GPs and practice nurses/managers reported collaborating within usual partners, such as jurisdictional managers, PHUs, PHNs, NCIRS and Seqirus representatives.

One GP reported working with the vaccine distribution centre because of initial shortage of vaccine and 5 GPs collaborated with company representatives from practice software recall systems in training on identifying and recalling unimmunised patients

Questions GPs received from patients regarding the shingles vaccine

A summary of 1,233 comments from GPs and other primary healthcare staff regarding questions that their patients ask them regarding the shingles vaccine is listed below. The main questions from patients were about vaccine side effects, safety, efficacy, need for a booster dose and cost.

All written comments provided by GPs and practice nurses (n=1233) about the questions their patients ask were tallied, distributed into themes and ranked by total number of comments in descending order as below:

1. What are the side effects? (293)
2. Efficacy. Does the vaccine really work? Does it prevent shingles? (186)
3. Is the vaccine safe? (123)
4. Will I need a booster dose? What sort of protection does it offer? (119)
5. Do you recommend it for me? Do you think I should have it? What are the pros and cons for me? (108)
6. Do I need the vaccine if I’ve already had shingles? (88)

7. What is the cost? (83)
8. Will the vaccine give me shingles? Will it make me sick? (62)
9. Why is it limited by age group? (37)
10. Do I need the vaccine if I've already had chickenpox? (32)
11. Will I be contagious for shingles or chickenpox after I have the vaccine? Will I give my grandchildren chickenpox? Will it give me chickenpox? (25)
12. Am I eligible for the new shingles vaccine? (21)
13. Will it hurt? (10)
14. Do I need it if I've never had chickenpox? (9)
15. Can I have it with my next flu or pneumococcal vaccine? (7)
16. Does it prevent chickenpox? (6)
17. Can I get it on a private script? (5)
18. My partner has shingles now; do I need to get the vaccine? (3)
19. Do I need the vaccine at my age? (3)
20. Do I need it if I've already received the chickenpox vaccination? How is it different to the chickenpox vaccination? (3)
21. When is the best time to have it? (2)
22. Can I have it if I'm pregnant? (2)
23. Can I have it today? (1)
24. Does it contain preservatives? (1)
25. Will it interact with my medications? (1)
26. Why can't I get the more effective vaccine available from the USA? (1)
27. Can I do a blood test to see if I'm immune to shingles? (1)
28. Can I get shingles from someone who has chickenpox? (1)

The large number and nature of responses suggest considerable uncertainty and the need for ongoing consumer education as new cohorts become age-eligible for the vaccine.

Table 2.4.Knowledge of GPs and other primary healthcare staff about recommendations and eligibility

The shingles vaccine is registered for use in which adult age groups?	**Yes N (%)**	**No N (%)**	**Don't know N (%)**
50 to 59 years	662 (66)	176 (17)	177 (17)
60 to 69 years	840 (82)	92 (9)	97 (9)
70 to 79 years	1072 (97)	3 (1)	34 (3)
80 years and older	536 (54)	204 (21)	251 (25)
The shingles vaccine is recommended for use in which adult age groups?			
50 to 59 years	470 (49)	294 (32)	180 (19)
60 to 69 years	859 (83)	84 (8)	97 (9)
70 to 79 years	1078 (96)	5 (1)	24 (3)

80 years and older	429 (45)	260 (27)	271 (28)
The shingles vaccine is <u>funded</u> for use in which adult age groups?			
50 to 59 years	5 (1)	762 (93)	49 (6)
60 to 69 years	22 (3)	745 (91)	47 (6)
70 to 79 years	1097 (97)	4 (1)	27 (2)
80 years and older	61 (7)	681 (84)	76 (9)

Responses summarised in **Table 2.4** show that the vast majority of GPs and practice nurses/managers (97%) knew the vaccine was registered for use in 70–79-year- olds but were uncertain about other age groups. Most seemed to consider 'recommended' being an equivalent term to 'registered', with 96% responding that vaccine was recommended for use among patients aged 70–79 years. Some 19% stated vaccine was recommended for 50–59-year-olds and 28% for over 80 years.

Similarly, while the funding of the vaccine in 70–79-year-olds was known to 97% of GPs and practice nurses/managers, funding for other age groups was less well-known, with 6–9% believing vaccine was funded outside 70 to 79 years. It is unclear whether this resulted in leakage of funded vaccine outside the targeted age group.

GPs and other primary healthcare staff knowledge of who *should not* be given the live Zostavax® vaccine

The survey asked participants to answer the following open-ended question – 'In general terms, who should not be given the live shingles vaccine?'

A summary of all 1,853 written open-ended comments from GPs and practice nurses/managers, distributed into themes and ranked in descending order regarding who *<u>should not</u>* get the vaccine is listed below. The responses indicate a sound understanding of contraindications.

1. Immunocompromised or immunosuppressed/immunodeficient patients (820)
2. Patients who have had shingles in the past 12 months (250)
3. Patients with previous anaphylaxis or known allergies (180)
4. Patients on chemotherapy medications (122)
5. Those on certain medications such as steroids, DMARDS, rheumatoid arthritis medications (94)
6. Pregnant women (80)
7. Those who have been given a live vaccine in previous 4 weeks (48)
8. Those in an ineligible age group (33)
9. Patients who are febrile (28)
10. Patients with a temperature over 38.5 degrees (28)
11. Patients over 80 years (26)
12. Don't know/Unsure (22)

13. Patients who are currently unwell (20)
14. Patients with an autoimmune condition or HIV/AIDS (20)
15. Patients who have never had chickenpox (12)
16. Those aged under 60 years (10)
17. Those aged under 50 years (10)
18. Asplenic patients (8)
19. Organ transplants/bone marrow transplant (8)
20. Active tuberculosis (8)
21. Breastfeeding (8)
22. Those who don't want it (6)
23. Those with previous or recent varicella vaccination (6)
24. Patients on antivirals (2)
25. Those aged over 55 years (2)
26. Those aged over 60 years (2)

The results for knowledge of the shingles vaccine, eligibility, contraindications and patient awareness are given in **Table 2.5**.

Knowledge was generally sound, with a range of 67–90% answering correctly.

However, there was limited knowledge in some areas. For example, as shown in **Table 2.5**, 4–21% of respondents answered that they 'did not know' the answer to several questions about the shingles vaccine.

Table 2.5. GPs and other primary healthcare staff knowledge of the shingles vaccine

Please give your response to the following:	Yes N (%)	No N (%)	Don't know N (%)
Immunocompromised people should not receive the shingles vaccine	1021 (90)	74 (6)	37 (4)
The shingles vaccine is effective as a treatment at the onset of acute shingles	62 (5)	902 (80)	166 (15)
Eligible people could receive the shingles vaccine with their influenza or pneumococcal vaccine	836 (74)	180 (16)	117 (10)
People aged over 50 years should receive shingles vaccine annually	24 (2)	1020 (90)	88 (8)
The varicella (chickenpox) vaccine could also be used to prevent shingles in older people	138 (12)	796 (71)	193 (17)
A person with acute shingles should wait at least 12 months before receiving the shingles vaccine	758 (67)	130 (12)	241 (21)
Most of my patients are aware of free shingles vaccine	613 (55)	322 (29)	184 (16)

It was interesting that 16% of respondents 'did not know' if their patients were aware of the free shingles vaccine. This suggests a gap in communication among GPs and practice nurses/managers and their patients, which may be improved via education and training.

Table 2.6. Awareness and use of communication resources

Since the program rollout in November 2016, have you seen any 'Protect yourself against shingles' information and resources below:	Not seen n (%)	Seen n (%)	Displayed in my practice n (%)	Distributed to patients n (%)
Brochure	245 (22)	434 (38)	362 (32)	93 (8)
Brochure – Aboriginal and Torres Strait Islander	786 (71)	217 (20)	90 (7)	13 (2)
Brochure – non–English-speaking	942 (85)	129 (12)	26 (2)	7 (1)
Fact sheet for providers	245 (22)	769 (69)	96 (8)	7 (1)
Poster	235 (21)	440 (39)	442 (39)	7 (1)
Poster – Aboriginal and Torres Strait Islander	820 (75)	186 (16)	86 (8)	7 (1)

In light of the mixed results regarding knowledge of the shingles vaccine, GPs and other primary healthcare staff exposure to the communication and education materials was also limited in some instances. For example, in **Table 2.6**, 22% indicate not having seen the '*Protect yourself against shingles'* brochure or the fact sheet for providers, and 21% had not seen the poster.

In addition, a large number of GPs and other primary healthcare staff (75%) had not seen the Poster – Aboriginal and Torres Strait Islander, 71% had not seen the brochure for Aboriginal and Torres Strait Islander people and 85% had not seen the non-English brochures. This is likely because the non-English brochures are not distributed to GPs or primary healthcare services, but rather are made available on the Department of Health website (www.health.gov.au) and promoted to relevant groups.

Only 39% of GPs and other primary healthcare staff had displayed the poster in their practice and 32% had displayed the brochure, with only 8% having given the brochure to their patients.

These results suggest limited display and distribution of the resources by GPs and practice nurses/managers at the clinics, which could be related to lack of awareness

or wariness of promoting because of the vaccine shortages experienced. This can be improved through education and training or prioritisation in that practice.

Among those respondents who had seen the communication and education materials, comments were positive, with some typical comments below –

> *Good publicity on TV and in posters displayed in medical centres. Patients are seeing these posters and are asking questions*
>
> *A lot of information in the 70-79 age group spread directly from person to person..particularly evident straight after the roll out of the funded vaccine.*
>
> *The resources were very useful*

Other recommendations regarding the educational materials included the following –

> *Have a photo of person with truncal shingles rash on brochure and poster*
>
> *State that Zostavax® is a live vaccine*
>
> *Be more upfront about the efficacy (50%) of Zostavax® and that if you get shingles after vaccination still seek treatment within 72 hours of onset of rash*
>
> *Have a flowchart for decision making*
>
> *Social media campaign to encourage families to talk to older relatives?*
>
> *The poster doesn't shout "Vaccine available" - more obvious linking statement?*
>
> *It would be good to have another info sheet which answers some of the questions that we get asked*
>
> *It's more about the lack of space to display posters - we prefer to use our TV to advertise this information*
>
> *Have multi-lingual versions of the resources for patients*

Feedback about strengths of the National Shingles Vaccination Program

Strengths of the program as perceived by GPs and other primary healthcare staff were mostly related to having the vaccine available for free; raised public awareness; support for the vaccine among this elderly age group; and good awareness-raising before the rollout - as below.

The timing is appropriate. A lot of patients report knowing someone who has had shingles in the past year, and this encourages them to attend

Far reaching. Lots of interest.

Good that we were informed/educated prior to the rollout

Seems to have worked as many patients initiate the request for it

Feedback about challenges of the National Shingles Vaccination Program

Challenges were mostly related to supply problems for GPs and other primary healthcare staff:

Insufficient supply at the start of the program!!! Hard to get; had a long waiting list and then momentum fell off when stock became available.

We were not able to access enough vaccines in the early stages

We were also not made aware that private Zostavax® was going to become unavailable and not able to prepare for that by pre-ordering vaccine for those outside the funded age group that were requesting to purchase the vaccine

Other challenges included the difficulty of applying the age criteria in general practice and the lack of information about contraindications –

Shame we can't vaccinate >79-year olds in funded program especially when it is a partner of someone in their 70's

Hearts get broken if a couple are aged say 78 and 81. Would prefer that age restrictions be broadened both up and down

Better information about contraindication was needed earlier on

GPs and practice nurses/manager recommendations

The major focus of recommendations was eligibility, particularly to expand the age eligibility (younger and older) and to extend the time for catch-up.

Vaccinate older people also

Extend age groups funded?

Catch up program needs to continue for a longer time period as there are still many 75-79 year olds we haven't been able to approach and/or immunize yet

Another suggestion was to extend eligibility for other family members.

Consider subsidising Zostavax® for family members of shingles sufferers

Also noted that at present, GP clinic is the main focus of the rollout and education –

Primary care is the main method of informing patients

Additional recommendations included expanding the activities to raise awareness to include the general public, aged care facilities and non–English-speaking communities.

Improve awareness in aged care facilities.

Translate to multiple languages in the community

In addition, mass public immunisation was suggested –

The place of arranging mass vaccination

Suggestions regarding Medicare rebates were also made. A typical comment was:

Fix the Medicare rebates and allow item numbers for practice nurse time with patients, to allow e.g. public health initiatives whilst nurses have down time.

In general, GPs and other primary healthcare staff were well aware of the fact that age eligibility was important, but also very important to thoroughly investigate for history of immunocompromise and medication use. A GP commented on a patient who was on an antiviral medication (Famvir®):

The program should highlight a cautious check of the patient's history. Just giving them a checklist to read does not identify accurately if they are eligible. I had a patient read through, state they were all good, then noticed they were on Famvir, when asked why, it was for "a horrid rash I keep getting over the right side of my back". Yes, they had recurrent shingles.

As per the Australian Immunisation Handbook, patients on antiviral medication should cease treatment no less than 24 hours prior to vaccination and for at least 14 days after vaccination.[3]

Summary

Providers from GP practices representing every state and territory of Australia participated in the evaluation of this national vaccination program.

GPs and practice nurses/managers pleased to receive the new vaccine for the prevention of shingles reported that their patients were keen to receive it.

Providers reported being made aware of the vaccine availability well before the rollout and most received the communication resources and educational materials.

The main problem cited by GPs was the lack of supply of the vaccine, which created frustration and confusion for providers and consumers who had to be put on waiting lists. Despite the delay in supply, most GPs reported having offered and administered the vaccine to eligible patients in practice and in aged care facilities.

Very few GPs or practice nurses reported having observed any adverse events to the vaccine (13 reported mild events) or severe adverse events (3 reported severe events like anaphylaxis).The majority of providers expressed frustration that many of their patients and aged care residents were ineligible because of their age.

GPs and other primary healthcare staff reported they responded to many questions about the vaccine from their patients, with main focus being on side effects and the need for a booster dose.

Recommendations

Some providers recommended improved messaging in resources for this and other future immunisation programs. In relation to the zoster program there was an expressed need from some providers that educational materials emphasise that this is a live vaccine; provide more information on how to assess contraindications; and provide a picture of the typical shingles rash. They also suggested providing a flowchart for excluding individuals who had contraindications to Zostavax® vaccination for better decision making. Some GPs and other primary healthcare staff suggested that the materials should be available in more languages than currently available and promoting the vaccine via aged care facilities.

Other recommendations from GPs and other primary healthcare staff relating to making the vaccine more widely available to younger and older age groups would need to be progressed through appropriate pathways.

Module 3: Consumer survey using Computer Assisted Telephone Interviewing

Aims

To assess knowledge, attitudes and behaviours of consumers on the shingles immunisation program and related issues. As the shingles program is a large new program, this module aimed to generate a more comprehensive understanding of consumer perspectives on the rollout of the program, including knowledge, attitudes and behaviours.

Methods

Participants

A random sample of consumers aged 70 to 79 years was obtained using computer assisted telephone interviewing (CATI) by Sydney-based market research company (EKAS).

Instruments

The survey (**Appendix C**) was developed by NCIRS with input from NIC members, including a consumer representative from the Consumers Health Forum of Australia (CHF). The survey was approved by the SCHN ethics committee (**Appendix A).**

Procedure

EKAS accessed a random sample of home landlines Australia-wide, telephoning 2,178 numbers in September 2017, of which 1,146 answered the phone and of those, 403 eligible consumers completed the CATI survey (response rate 35%).

Reasons for non-response were as follows – 616 no answer; 609 refusal; 329 answering machine; 70 did not answer call back; 51 wrong number; 31 unable to speak English; 13 busy/engaged; 11 no one at home aged 70 to 79 years; and 2 business number.

The survey script was read verbatim by each interviewer and responses typed into the CATI database, including responses to open-ended questions.

Results

Table 3.1 provides demographics for the 403 consumers who participated.

A balanced mix of male and female consumers (47% versus 53%) participated, with a mean age of 73.9 years.

More than half (n=262) self-reported having a chronic medical condition, which, in descending order, were high blood pressure; heart disease; diabetes; cancer; and asthma (**Table 3.1**). Males reported underlying heart disease more frequently than females (29% versus 14%). Approximately 9% (n=35) were considered likely to be immunocompromised on the basis of their self-reported medical condition of cancer (27), immunosuppressive drugs (5), transplant, or rheumatoid arthritis (3), although these self-reports could not be clinically verified.

Table 3.1. Consumers who participated in the survey (n=403)

Age range (years)	**Number (%)**
70 – 71	102 (25)
72 – 73	75 (19)
74 – 75	80 (20)
76 – 77	58 (15)
78 – 79	58 (15)
80 +	24 (5)
Prefer not to say age	6 (1)
Mean (SD) age (years)	73.9 (2.8)
Aboriginal/Torres Strait Islander	5 (1.2)
Gender	
Male	190 (47)
Female	213 (53)
Highest educational level	
Completed primary school	9 (2)
Completed some high school	161 (40)
Completed Year 12	52 (13)
TAFE/trade college	52 (13)
Undergraduate degree	102 (25)
Postgraduate degree	27 (7)

State or territory	150 (37)
NSW	96 (24)
VIC	85 (21)
QLD	36 (9)
WA	18 (5)
SA	9 (2)
ACT	7 (1.5)
TAS	2 (0.5)
NT	
Self-reported chronic medical condition	255 (63)
High blood pressure	97 (38)
Heart disease	44 (17)
Diabetes	42 (16)
Cancer	27 (11)
Lung disease/asthma	20 (8)
Kidney/bladder disease	10(4)
Osteoarthritis	7 (3)
Immunosuppressive drugs/transplant	5 (2)
Rheumatoid arthritis	3 (1)

Shingles vaccination and intention to vaccinate

Of the 316 people who responded to this question, 237 (75%) reported that they had been vaccinated and 79 (25%) said that they had not been vaccinated. Of the 79 people who were not vaccinated, 68 stated they intended to be vaccinated in the near future, but were waiting to discuss it with their doctor, while 11 were unsure of their intention to get vaccinated. The main reason for delay in getting the vaccine was that some (68/79) had not been to their GP for a while and were waiting to ask their doctor's opinion. A few (4/79) were not yet 70 years old. There were 87 people who did not answer this question on shingles vaccination.

Consumer awareness, risk and diagnosis of shingles

Consumer awareness of shingles and the vaccine is summarised in **Table 3.2**.

Table 3.2. Consumer awareness of shingles and related issues

Consumer awareness	**Number responding Yes (%) (Adjusted for missing data)**
Have you heard about the medical condition shingles?	387 (96)
Before today, were you aware of the shingles vaccine?	265 (66)
Do you know of anyone who has had shingles?	274 (68)

Consumer risk and diagnosis of shingles	
Have you ever had chickenpox?	246 (68)
Have you ever had shingles?	83 (26)
If yes, was your shingles diagnosed by a doctor?	81(98)
Have you been recommended the shingles vaccine by your GP?	149 (47)
Communication resources	
Seen information about the shingles vaccine?	118 (37)
Seen 'Protect yourself against shingles' poster?	76 (24)
Seen 'Protect yourself against shingles' brochure?	47(15)

Note: Percentages have been adjusted where there are missing data

Consumer knowledge, beliefs and attitudes about shingles

The vast majority (387, 96%) of consumers, (93% males; 98% females) reported being aware of shingles.

Of the 83 people who reported previous shingles, 98% stated it was diagnosed by a doctor. Of the 316 consumers who responded to the question, approximately a quarter of male and female consumers respectively reported having had shingles (64 males and 89 females). The vast majority (274/316, 87%) reported knowing someone who had had shingles, with a female (155) preponderance (males 119).

Regarding consumer awareness of communication resources such as posters or brochures, approximately a third (118/316, 37%) reported having seen various sources of consumer information about the shingles vaccine.

Consumer knowledge about shingles and the vaccine (**Table 3.3**) was generally sound, but some consumers answered that they 'did not know' whether they were at risk of getting shingles (13%). The majority of consumers knew the following: shingles is a harmful disease (84%); shingles is caused by the same virus as chickenpox (82%); shingles causes a painful rash and the pain can continue after the rash is gone (90%); the risk of shingles increases with age (69%); and the shingles vaccine is free for people aged 70 to 79 years (74%).

While knowledge was generally good in some areas, **Table 3.3** shows that some consumers were unable to answer questions about shingles risk in their age group (31%); the harmfulness of the disease (8%); the relationship of shingles risk to chickenpox (16%); the availability of, and access to, the vaccine (25%); vaccine safety (18%); vaccine efficacy (24%); vaccine side effects (42%); and contraindications for the vaccine (31%).

Females tended to have better knowledge about the harmfulness of shingles (11% versus 3%); that shingles is caused by the same virus that causes chickenpox (90% versus 73%) and that the vaccine is free (79% versus 65%), given as a single dose through their GP (54% versus 40%) with people aged 70 to 79 years eligible (78% versus 66%).

Table 3.3. Consumer knowledge, beliefs and attitudes about shingles

	True	False	Don't know
	n (%)		
Beliefs			
I think I am at risk of getting shingles	97 (31)	166 (41)	53 (13)
I find it difficult to go to the doctor for vaccination	10 (2.5)	303 (75)	3 (1)
In general, I am opposed to vaccinations	6 (1)	309 (77)	1 (1)
Attitudes			
I do not think that shingles is a particularly harmful illness	25 (8)	267 (84)	26 (8)
I think that the shingles vaccination is not effective	3 (1)	237 (75)	76 (24)
I have concerns about the possible side effects of the vaccine	27 (9)	246 (78)	43 (13)
Knowledge			
Shingles causes a mild rash but is not a serious disease	68 (21)	217 (69)	31 (10)
Shingles is caused by the same virus that causes chickenpox	260 (82)	5 (2)	51(16)
People with shingles can get severe pain with their rash and sometimes the pain remains after the rash is gone	287 (90)	4 (1)	27 (9)
A person is less likely to get shingles as they get older	29 (9)	219 (69)	68 (22)
The shingles vaccine is free for people aged 70 years old	234 (74)	4 (1)	78 (25)
People aged 71-79 years can get the shingles vaccine for free	230 (73)	3 (1)	83 (26)
The shingles vaccine can be given by your GP	290 (73)	26 (7)	78 (20)
If a person has had chickenpox they are at risk of shingles	182 (58)	15 (5)	119 (37)
The shingles vaccine is safe for most people	255 (81)	3 (1)	58 (18)
People who have shingles do not need the shingles vaccine	36 (9)	114 (36)	166 (53)
People with weak immune systems should receive the vaccine	208 (66)	11 (4)	97 (30)
The shingles vaccine cannot be used to treat shingles; the shingles vaccine is only used to reduce your risk of getting shingles	245 (78)	9 (2)	62 (20)
A person only needs one dose of the shingles vaccine	149 (47)	16 (5)	151 (48)
Older people can receive the shingles vaccine with their flu vaccine	110 (35)	28 (9)	178 (56)
The shingles vaccine may cause side effects such as redness, swelling or pain at the injection site	148 (47)	34 (11)	134 (42)
The shingles vaccine is recommended for people under the age of 50 years	73 (23)	71 (23)	172 (54)

* Percentages in Table 3.3 are calculated on the basis of number of consumers who answered each question.

Open-ended responses

Consumers were asked to comment as to why they answered questions yes/no. Responses were transcribed verbatim by the telephone interviewer.

A very small number of consumers (n=7) reported having concerns about the shingles vaccine safety and side **effects**, with some indicative comments below –

It can be a concern as my immune system is low

I've known people who had side effects from those sorts of injections

Well for every action there is a reaction. I've been fine. Everyone I know has been fine

You can get side effects with anything you put in your body even if it is only mild

Reasons for consumers' beliefs about their risk of shingles

An interesting finding regarding consumer knowledge of shingles and the shingles vaccine became evident from verbatim consumer responses to the question 'I think I am at risk of getting shingles – Why?'

While 92 consumers agreed that they were at risk of getting shingles, their open-ended answers were not always factually accurate.

The reasons for consumers' beliefs about their susceptibility to shingles were tallied, categorised and the major themes are ranked in descending order as follows –

- **Susceptible because of past risk** – 24/92 consumers (26%) who considered themselves at risk of getting shingles reported they had had shingles already and that as shingles can recur they expect it will come back.

  Because I have had it 7 times from the age of 30

  I had before and I can get it again

  I've had 2 bouts so may get third one

  Once you have had it you can get it again

- **Susceptible because of age** – 23/92 consumers (25%) who considered themselves at risk of getting shingles identified increasing age as a risk factor.

I'm in that age bracket. ….it seems to me that more people get it when they are older

I'm over 65, so yeah…

There is more risk of getting them again as you get older

I think age is a factor / your system weakens as you get older

- **Susceptible because had chickenpox** – 15/92 consumers (17%) knew that having had chickenpox increases the risk of getting shingles –

  Because I've had chicken pox in the past……..

  Because I've had chicken pox and it's still there in my system

- **Susceptible because everyone is at risk** – 15/92 consumers (17%) believed all people were at risk of getting shingles, that is, general population risk –

  As far as I'm aware everyone is susceptible

  I think anybody is at risk anybody can get shingles

  It's in the air and if your resistance is weak you can pick it up

- **Susceptible because of family/heritable risk** – 4/92 consumers (4%) believed that the risk of shingles was increased with a family history

  Well my mother got it

  My mother had shingles so it may be passed on, and my sister had it

- **Susceptible because low immune system/chemotherapy** increases the risk – 4/92 consumers (4%) stated they were at an increased risk because their immune system was poor or compromised

  Because my immune system may be compromised due to my cancer treatment

  Because I have been having radio and chemo therapy my immune system must be shot

  Because of age & stress related to my MS

  Because my immune system may be compromised due to my cancer treatment.

- **Shingles is contagious** – 3/92 consumers (3%) believed shingles contagious
  Risk is like getting a cold. Virus like a cold

  My wife has it and there is every chance that I may get it

  Because I come in contact with people all the time
  Shingles is contagious

- **Stress can cause shingles** – 2/92 consumers (2%) identified stress
  I'm in a stressful situation in my personal life….. I could get shingles.

  I'm always at risk ……it affects your nervous system and as you get older you worry about more things….. you get more agitated.

- **Skin diseases increase the risk** – 2/92 consumers (2%) reported having skin diseases increases their risk

  I have a lot of skin problems and herpes (cold sores).

  I have dry skin disease so I think I would make me susceptible.

A summary of consumer comments about shingles is shown below in **Table 3.4.**

Table 3.4. Consumer comments about the shingles vaccine

Are any of these statements true for you?	Consumer comments ('If yes, why?')
I don't like going to the doctors.	• *I don't like going to the doctor unless I have to* • *Distance, I'm in the scrub* • *I am wheelchair-bound* • *I'm petrified of injections* • *I am 100km away from the doctor* • *I had an aversion to vaccinations, like a phobia*
In general, I am opposed to vaccinations.	• *Just concerned that it might have bad side effects. A lot of things do have, and I'm a little bit frightened that it might too* • *Because with any medical treatment there is a risk of side effects. No medical invention is risk free* • *I don't want any solution to go into my blood stream unless I really need it.*

I do not think that shingles is a particularly harmful illness.	• *A lot of people seem to get but they do get over it* • *I haven't seen people who have died from it* • *I think it's not harmful, I don't know why*
I think that the shingles vaccination is not effective.	• *I've been told by doctors* • *I've had the vaccine and it hasn't fully stopped my shingles* • *It hasn't stopped me from getting shingles even after I had vaccination*
I have concerns about the possible side effects of the vaccine.	• *We all should be concerned about vaccinations* • *It can be a concern as my immune system is low* • *I've known people who had side effects from those sort of injections* • *Well for every action there is a reaction* • *Not sure, logic says yes* • *You can get side effects with anything you put in your body even if it is only mild*
I have concerns about the shingles vaccine safety.	• *I am concerned about all vaccines safety* • *General side effects, sore arm, everyone is different, concerns about injections as a baby, general concern* • *Concerned for old people who get vaccination* • *Concerns about the ingredients of the vaccine and its effects* • *Because what you hear is its very dangerous having vaccines in general* • *I don't know how I would react to it* • *That I might get shingles from it*
I have concerns about the shingles vaccine effectiveness.	• *It's not 100% effective - no vaccine is* • *I've been told that they don't work very well* • *Query whether it actually works. No proof it is effective.* • *Most vaccines effectiveness are not high* • *Whether it's lasting or not. Like whether it lasts for a year or more or 20 or 30 years* • *It hasn't stopped me from getting shingles even after I had vaccination* • *Because of my condition rheumatoid arthritis* • *Because vaccine going into my blood stream might affect another part of my body or bring other illness on*
Do you intend to receive the	• *If required or told to do so by my GP*

shingles vaccine in the near future?	• *Because I am a candidate to get shingles. I also saw my neighbour with it as well* • *The GP mentioned it but he didn't have any supplies and I haven't been back since* • *I only have 18 months before I'm 80yrs old* • *I have never heard of it before and now speaking to you I will get more info about it - and I probably will get it* • *If the doctor recommends it, I wouldn't say no* • *Only if the doctor strongly recommends it*

Summary

Consumer awareness of shingles was high, with 96% having heard of shingles or reporting knowing someone who had had shingles, and about a third reporting having had shingles themselves. Survey responses suggested that the vaccine was very popular and desirable among the age group for which it is targeted, consistent with reports from healthcare providers.

During the period of interview in September 2017, more than half of all consumers surveyed reported receiving the vaccine, with almost all of the remainder reporting that they intend to get the vaccine when they next visit their doctor. Most information about and awareness of the vaccine was reported as coming from the consumer's own GP, with only a third of consumers reporting seeing the communication resources such as posters or brochures. The majority of consumers had been offered the vaccine by their GP. Almost all of those who had not received it indicated that they were waiting to discuss it with their doctor or were waiting to become age eligible when they turn 70 years old.

Consumer knowledge about the disease shingles was generally good, with a high proportion and knowing relevant facts about shingles such as being a harmful disease caused by the same virus as chickenpox; causing a painful rash with pain that can continue after the rash is gone; and risk increases with age. Consumers were aware of the age eligibility for the free vaccine (70 to 79 years). However, two thirds of respondents stated incorrectly that people with weak immune systems should get the vaccine and one third of the consumers correctly answered the question on their risk of getting shingles.

A few consumers were uncertain about the harmfulness of the disease; the relationship of shingles risk to chickenpox; the availability of, and access to, the vaccine; vaccine safety; vaccine efficacy; vaccine side effects; and contraindications for the vaccine. These are areas for potential consumer education and clarification of misinformation, particularly among males, whose knowledge tended to be lower than that of females.

Recommendations

Consumers clearly reported wanting to receive the vaccine, particularly if it was recommended by their doctor. Consumers want the vaccine to be more widely available to younger and older age groups. There appears to be scope for consumer education with respect to concerns about the vaccine side effects, safety, efficacy and that there is no requirement for an annual vaccination or booster dose. Given the high attendance of this age group at general practice, and reliance on their GP for advice, although there may be value in communication and educational messages delivered through community channels, delivery by healthcare providers is likely to be most efficient.

Discussion

The new shingles vaccine was very well received in Australia and was welcomed, promoted and provided by stakeholders, professional associations, PHUs, PHNs and GP providers alike, and happily received by consumers. Consumers were acutely aware of shingles and their risk of developing it, and the vast majority were very keen to receive the free vaccine. The reported uptake was about 50 % per year after the rollout, with all, but a very few, consumers expressing their intention to receive it.

Awareness of the disease of shingles was high among all stakeholders, including immunisation staff, consumers and GPs, with nearly all consumers having heard of shingles, reporting knowing someone who had had shingles and/or having had shingles themselves.

At the date of field data collection from August to October 2017, nearly two thirds of all consumers surveyed had received the vaccine. Of the ones who had not received the vaccine, most were waiting to be recommended the vaccine by their GP, with 68/79 indicating they intended to receive it in the near future. Most information and awareness about the vaccine had come from the consumers' own GP, with only a third of consumers reporting seeing the communication resources such as the television advertisement about shingles or the posters or brochures. Because of issues with vaccine supply at the commencement of the program, promotional materials may not have been widely distributed to consumers by providers to avoid creating demand for the vaccine when there was uncertainty about supply.

Consumer and primary healthcare staff knowledge was generally similar. Also, consumers and primary healthcare staff were generally aware of the age eligibility for the free vaccine. Less than a fifth of consumers were uncertain about their shingles risk. These may be areas for potential consumer education and/or patient education.

The common theme among stakeholders from all spheres of immunisation practice, primary healthcare staff and consumers alike was that they were pleased to be able to provide and receive such an important vaccine for the prevention of a well-known nasty illness among a demographic of older consumers who they know will traditionally support vaccination. In summary, the availability of the shingles vaccine was popular among all concerned.

Regarding awareness of shingles and the availability of the shingles vaccine, the vast majority of stakeholders and primary healthcare staff, and a third of consumers from all around Australia commonly reported being made aware of the vaccine availability well before the rollout and receiving communication resources and educational materials in a timely manner.

Collaboration between stakeholders was often cited as helpful, with providers especially receiving useful communication and education resources from the

Commonwealth, NCIRS and Seqirus. GP and aged care providers and specialists mentioned that they would have liked more timely information about the contraindications for the vaccine for use among immunocompromised patients and they would have been able to utilise a checklist and/or flashcard for this purpose.

Similar to the general consensus of all stakeholders, GPs and consumers on their welcoming of the shingles vaccine and their appreciation of receiving it for free was the consensus on the lack of supply of the vaccine, which created frustration and confusion for providers and consumers who had to be put on waiting lists.

Despite the delay in supply, most stakeholders, GPs and consumers reported having been able to successfully offer, administer or receive the vaccine.

While there was an expectation of adverse effects, very few GPs or practice nurses reported observing either minor or more severe adverse events to the vaccine.

The unfortunate death of a man in NSW in January 2017[19] is likely to have increased awareness of the risks associated with giving the live vaccine to immunocompromised individuals among healthcare professionals. Providers, professional colleges and specialists made similar and strong recommendations for more education and clear guidelines on contraindications to this live vaccine among various categories of immunocompromised patients. The case was reported in the medical press (Australian Doctor, 6minutes) and a TGA alert was issued.

Another common theme among all groups of participants was the frustration expressed by many consumers, GPs and providers that they knew of people who were ineligible to receive the shingles vaccine because of their age. This message was clearly conveyed by the majority of consumers, GPs and immunisation providers alike, with suggestions that the free vaccine be made more widely available to younger and older age groups.

Among stakeholders and representatives of Aboriginal and Torres Strait Islander groups, there were recommendations for availability of the free shingles vaccine to Aboriginal and Torres Strait Islander people at a younger age, but this issue was not raised by primary healthcare staff or consumers.

Primary healthcare staff reported receiving questions from their patients about the vaccine, with the main focus being on side effects; safety; efficacy; and the need for a booster dose. Professional clinical education and consumer education should work to further clarify these queries.

Delay in supplying this vaccine was cited by all stakeholders, GPs and consumers alike. Lack of supply in the first six months of the program was reported as causing frustration and confusion for providers, GPs and consumers. The rollout was well-

promoted in the early preparation stages, communication programs were well-established and educational materials were distributed, but stakeholders and providers generally expressed a concern that the vaccine had been over-promoted without adequate consideration of how the supply could be met. Consumers expressed some concern that they had to wait to receive the vaccine, but were also dissatisfied with the age eligibility restrictions. GPs pointed out that these created difficulties when couples had differing age eligibility.

Despite the unfortunate death of an immunocompromised patient in 2017[17], and the risk of the live vaccine being administered to immunocompromised patients, very few severe adverse events were reported via AusVaxSafety or the TGA. Most of the AEFI reports that were mentioned in this process evaluation were minor.

Recommendations

The following recommendations, covering how to improve the current shingles vaccination program and implementation of future adult vaccination programs, are provided for the consideration of the Department of Health and other key stakeholders, including states and territories.

- Early assessment of vaccine procurement, supply and marketing via greater communication between the Australian Government Department of Health, the pharmaceutical companies supplying the vaccine and jurisdictions and other stakeholders where relevant.
- Better and more timely management of vaccine supply and demand so that consumer demand does not exceed vaccine supply.
- More timely and comprehensive educational resources addressing clinical risk assessment of individual patients who should not receive the live vaccine.
- Greater clinical education for GPs, practice nurses, specialists and immunisation workers about risks of administering the live vaccine in this elderly age group who are likely to have comorbidities, be taking several medications and be at risk of immunocompromise.
- Tailored consumer education about risks of adverse events following immunisation.
- Consider extension of eligibility for the funded vaccine to younger and older age groups, and in particular to Aboriginal and Torres Strait Islander people aged <70 years (this is not an implementation issue and would need to be progressed separately through appropriate pathways).
- Educational activities should be more culturally suitable for CALD and Aboriginal and Torres Strait Islander people; suitability could be assessed in consultation with relevant communities.
- More webinars would be helpful for professional education, particularly in rural and remote regions.

- The Australian Immunisation Handbook needs to be simplified so that it is easier to read and includes plain English summaries.

Other more detailed recommendations are included in relevant sections (Module 1-3) above**.**

Conclusions

The National Shingles Vaccination Program was successfully rolled out in Australia from November 2016, and findings to date after nearly 12 months show that the shingles vaccine was well-promoted and well-received among stakeholders, consumers and providers, with very few adverse effects.

As expected among stakeholders and consumer groups, the vaccine was a very popular addition to the vaccination schedule for this age group of older consumers, who generally appreciate the benefits of vaccination and are used to receiving their annual free influenza and pneumococcal vaccines.

The delays in meeting supplies of this vaccine in the first few months of the rollout clearly caused frustration among stakeholders, GP providers and consumers, but the vaccine, when received, was appreciated by consumers and providers and produced fewer side effects or adverse events than were expected on the basis of clinical trial data and/or international experience.

The occurrence of adverse events related to inappropriate use of the vaccine in immunocompromised people reinforces the importance of continued communication and education about vaccine contraindications. This is particularly so in light of the unfortunate administration of the vaccine to a person who was contraindicated to receive it, in the second month of program rollout. Future administration of this and other national programs aimed at the elderly should focus on the clinical education of providers regarding patient risk assessment for contraindications because of immunocompromise from program onset. A pre-screening tool to assess for immunocompromising conditions and medication use to avoid adverse events resulting from the live vaccine virus has been promoted for use in general practice. Consideration of evaluating the use of this or other similar tools may be warranted.

This report's findings emphasise the need to examine the vaccine program's impact on herpes zoster and post-herpetic neuralgia which, to date, has not been done in Australia and may be challenging, given no disease impact/surveillance plan has yet been finalised.

Full program evaluation of impact on disease burden is also needed to understand the current epidemiology of herpes zoster and post-herpetic neuralgia to assess the potential impact of the non-live adjuvanted sub-unit herpes zoster vaccine (Shingrix®, GSK), which was registered in Australia on 2 July 2018. Shingrix® can be used in immunocompromised adults, in whom Zostavax® is contraindicated.

CHAPTER 2: VACCINATION COVERAGE

Aims

To evaluate early impact of the shingles vaccination program using coverage estimates of Zostavax® in adults aged 70 to 79 years in Australia using the Australian Immunisation Register (AIR).

Specific objectives

Coverage was assessed for the following elements of the program between 1 November 2016 and 31 March 2018:

- **Adults aged 70 years to less than 71 years**
  - Number of doses recorded
  - Percentage of 70 year olds recorded as vaccinated in the program
- **Adults aged 71 years to less than 80 years**
  - Number of doses recorded
  - Percentage of 71–79-year-olds recorded as vaccinated in the catch-up program

Methods

On 30 September 2016, the Australian Childhood Immunisation Register expanded to become the Australian Immunisation Register (AIR), collecting data on vaccinations given from birth to death. One of the factors underpinning the expansion of the register was the inclusion of Zostavax® on the NIP as the first new population-based program for older people using a live-attenuated vaccine. All people registered with Medicare are automatically added to the AIR. Participation in the AIR is 'opt-out' and so constitutes a nearly complete population register for Australian residents.

AIR data for adults aged ≥50 years (focussing on adults aged 70–79 years) were analysed to determine vaccination coverage and vaccine doses administered by age, gender, Aboriginal and Torres Strait Islander status and jurisdiction. Trend analysis of Zostavax® doses by month/year of vaccination was also undertaken. Aboriginal and Torres Strait Islander (Indigenous) status on the AIR is recorded as 'Indigenous', 'non-Indigenous' or 'unknown', as reported by Medicare or by the immunisation provider to the AIR. For this report we considered two categories: 'Indigenous' and 'Other' (non-Indigenous + unknown status). Coverage during the period 1 November 2016 to 31 March 2018 was assessed by age group using counts of doses as the numerator and relevant AIR age group as the denominator as of 31 March 2018.

Results

Coverage of Zostavax® in 70-year-olds, 1 November 2016 – 31 March 2018

Recorded coverage of 1 dose of Zostavax® for adults aged 70 years was 33.9%. The number of doses given to those aged 70 years is shown by month of administration in **Figure 1.** The number of doses recorded in October 2016, the month before the program commenced, was low at 197, presumably representing doses purchased in the private market. An average of around 4,500 doses per month was recorded as given nationally in the first five months of the program from November 2016 to March 2017. Uptake improved to 6,813 doses in April 2017, with a further increase in May 2017 (9,140 recorded doses). This increase is likely due to availability of shingles vaccine after a period of shortage and concomitant influenza vaccination. However, a decline was then seen, with the number of recorded doses fluctuating from around 3,500 to 5,500 between June 2017 and March 2018 (refer to **Figure 1**).

Catch-up dose of shingles vaccine for adults 71–79 years of age, 1 November 2016 – 31 March 2018

Recorded coverage of 1 dose of Zostavax® for adults aged 71–79 years was 25.8%. The number of doses given to those aged 71–79 years by month of administration is shown in **Figure 2**. Over 55,000 doses were given nationally in the first month of roll-out in November 2016, followed by an average of around 35,661 per month from December 2016 to May 2017. The number of doses then declined in June (23,271) and continued to trend downwards to around 11,000 in March 2018.

Shingles vaccine coverage by jurisdiction, 1 November 2016 – 31 March 2018

For adults aged 70 years, there was variation in Zostavax® coverage by jurisdiction, ranging from 20.6% in the Northern Territory to 42.6% in South Australia (**Table 1**).

For adults aged 71–79 years, there was also variation in Zostavax® coverage by jurisdiction, with coverage estimates ranging from 16.6% in the Northern Territory to 31.5% in South Australia (**Table 1**).

For adults aged 50–<70 and ≥80 years, that is, those not eligible for funded vaccine under the national program, shingles vaccination coverage was very low, at less than 1% and 2%, respectively (**Table 1**).

Shingles vaccination coverage by gender, 1 November 2016 – 31 March 2018

For adults aged 70 years in the funded program, recorded shingles vaccination coverage was 9.4 percentage points higher in females than in males (38.6% versus 29.2%).

For adults aged 71–79 years in the catch-up program, shingles vaccination coverage was 3.2 percentage points higher in females than in males (27.4% versus 24.2%) (**Table 2**).

Shingles vaccination coverage by Indigenous status, 1 November 2016 – 31 March 2018

For Indigenous people aged 70 years in the funded program, recorded shingles vaccination coverage was 43.3%, almost 10% higher than that for other Australians (33.8%) (**Table 3**).

For Indigenous people aged 71–79 years in the catch-up program, shingles vaccination coverage was also higher than that for other Australians (32.9% compared with 25.8%, respectively) (**Table 3**).

Differences in recorded shingles vaccination coverage between Indigenous people and other Australians varied by jurisdiction, with 71.1% of Indigenous people in Victoria aged 70 years recorded as vaccinated for shingles compared with 33.9% of same-age other Australians (**Table 3**).

Discussion

Our analyses show that recorded zoster vaccination coverage in the first 17 months of the funded program was low (33.9% for 70-year-olds and 25.8% for the catch-up program for adults aged 71–79 years) compared with coverage for childhood vaccines. For adults aged 50–<70 years and ≥80 years, zoster vaccination coverage was very low, at less than 1% and 2%, respectively. This suggests low rates of 'leakage' to non–NIP-eligible age cohorts, noting that it is not possible to determine if doses administered were privately purchased or used NIP-funded vaccine.

Recorded coverage was higher for Indigenous people than that for other Australians and higher in females than in males. Variations in uptake were seen across jurisdictions.

Our coverage estimates are similar to those reported from the United States of America, where shingles vaccine coverage among adults aged ≥60 years was 28% in 2014 (although available and recommended since 2006), with target set at 30%

for 2020.[22, 23] However, shingles vaccination coverage in England, where the publicly funded population-level program began in 2013, was 55% in 2015–2016 in the routine cohort (aged 70 years) and 56% for the catch-up cohort (aged 79 years).[11, 13]

The lower than anticipated coverage may have been contributed to by the shortage of vaccine in the first 6 months of the program. In 70-year-olds, an average of around 4,500 doses per month was recorded as given nationally in the first 5 months of the program, from November 2016 to March 2017. Uptake improved to 6,813 doses in April 2017, with a further increase in May 2017 (9,140 recorded doses). This increase is likely due to availability of shingles vaccine after a period of shortage along with concomitant GP visits for influenza vaccination.

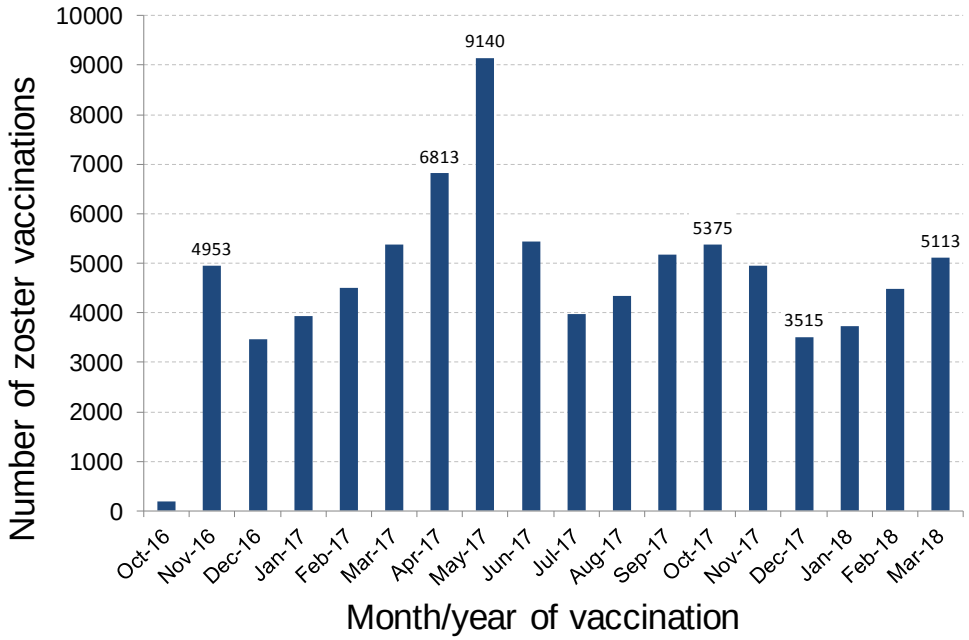
The reported coverage is also likely to underestimate the true level of coverage because of under-reporting to the AIR. There were 1,370,395 doses of Zostavax® distributed under the NIP during this period, as reported by the Department of Health, but our analysis shows that only 489,605 doses were recorded in the AIR. While not all vaccines distributed would have been administered, the large discrepancy suggests underreporting. In our national process evaluation, vaccine shortage, under-reporting and AIR data quality were identified by stakeholders as issues. The extent of underreporting was not possible to be assessed in this evaluation.

Conclusion

There was relatively low recorded coverage of the shingles vaccine, which may be attributable to a combination of under-reporting to the AIR and to the shortages of Zostavax® supply in the initial months of the program implementation. AIR zoster vaccination data completeness would be expected to improve over time as GP practice management software packages are updated, and initiatives to improve data entry and transfer are implemented.[24] However, recorded Zostavax® coverage was gratifyingly higher in Indigenous people than in non-Indigenous Australians. The recorded coverage among adults aged 70 years was higher compared with coverage for the catch-up program for those aged 71–79 years.

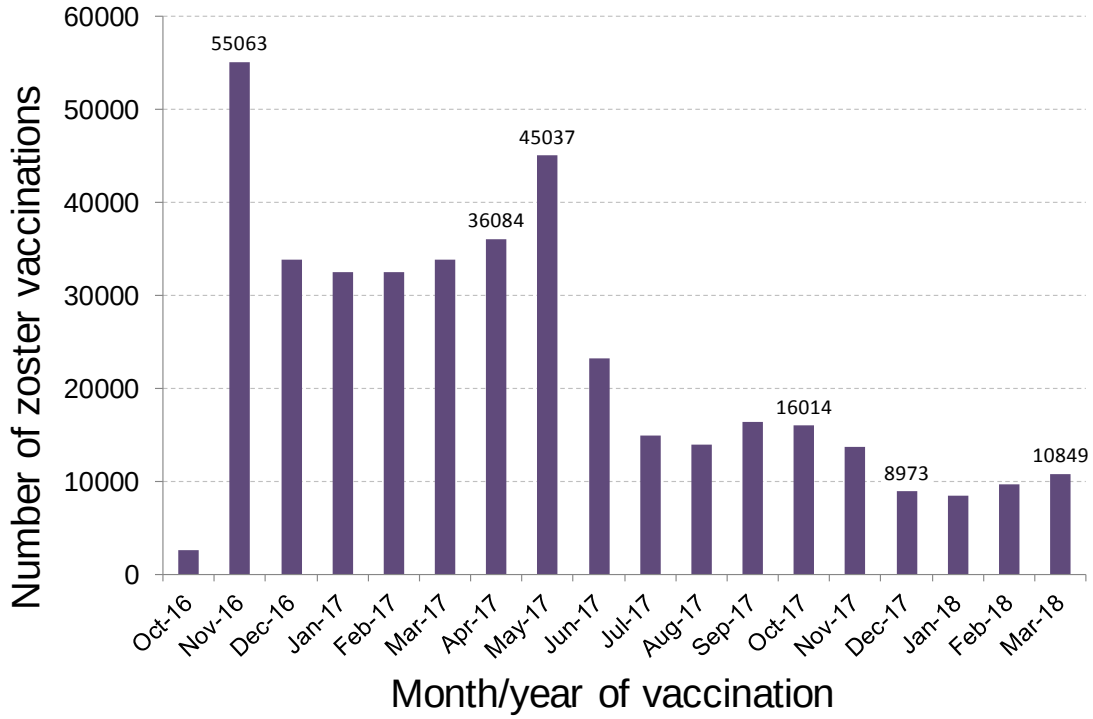
Figures and tables

Figure 1. Trends in number of shingles vaccine doses given to adults aged 70 years, Australia, October 2016 to March 2018*



*Source: Australian Immunisation Register

Figure 2. Trends in number of shingles vaccine doses given to adults aged 71 –79 years, Australia, October 2016 to March 2018*



*Source: Australian Immunisation Register

Table 1. Coverage of shingles vaccine by state/territory, November 2016 – March 2018

State or Territory	50 - < 60 years	60 - < 70 years	70 - < 71 years	71 - < 80 years	80+ years
ACT	0.2	0.9	38.1	27.4	2.0
NSW	0.1	0.6	26.1	21.3	2.0
Vic	0.1	0.8	34.2	25.1	2.1
Qld	0.1	0.7	40.5	30.5	2.0
SA	0.1	0.8	42.6	31.5	2.1
WA	0.1	0.7	38.3	28.6	2.2
Tas	0.2	0.8	38.5	28.6	2.5
NT	0.1	0.4	20.6	16.6	1.9
Australia	**0.1**	**0.7**	**33.9**	**25.8**	**2.0**

Table 2. Coverage of shingles vaccine by gender, November 2016 – March 2018

Gender	70 - < 71 years	71 - < 80 years	80+ years
Female	38.6	27.4	2.0
Male	29.2	24.2	2.1
Australia	**33.9**	**25.8**	**2.0**

Table 3. Coverage of shingles vaccine by Indigenous status and state/territory, November 2016 – March 2018

State/ territory	Indigenous status	Number of doses given 70 - < 71 years*	Number of doses given 71 - < 80 years**	Percentage vaccinated 70 - < 71 years*	Percentage vaccinated 71 - < 80 years **
ACT	Indigenous	4	16	44.0	27.6
	Other	1464	6249	38.1	27.4
	All	1468	6265	38.1	27.4
NSW	Indigenous	193	909	31.1	27.1
	Other	21,247	111,013	26.0	21.3
	All	21,440	111,922	26.1	21.3
Vic	Indigenous	337	1349	71.1	46.3
	Other	20,546	97,044	33.9	25.0
	All	20,883	98,393	34.2	25.1
Qld	Indigenous	204	913	41.7	33.6
	Other	20,006	94,790	40.5	30.5
	All	20,210	95,703	40.5	30.5
SA	Indigenous	32	121	37.2	25.4
	Other	8251	39,184	42.6	31.5
	All	8283	39,305	42.6	31.5
WA	Indigenous	51	197	27.9	20.5
	Other	9354	42,682	38.4	28.6
	All	9405	42,879	38.3	28.6
Tas	Indigenous	45	154	63.3	40.8
	Other	2460	11,655	38.3	28.5
	All	2505	11,809	38.5	28.6

CHAPTER 3: VACCINE SAFETY

Aims

To evaluate vaccine safety related issues of the shingles vaccination program using Zostavax® in adults aged 70 to 79 years in Australia.

Specific objectives

1. **Therapeutic Goods Administration (TGA) Adverse Events Management System (AEMS) data**

The AEMS is a spontaneous (passive) surveillance system for monitoring harmful occurrences associated with the use of a medicine, vaccine or medical device. Reports of AEFI received by TGA from providers and the public (typically provided via state and territory reporting systems for NIP vaccines, with the exception of Tasmania) are entered into the AEMS.[25] Information recorded in the database includes the adverse event(s), the vaccine(s) involved and other relevant information, such as relevant medical history, laboratory results and how the adverse event was treated.[25]

Zostavax® vaccine safety was assessed using AEMS data for the following:

- Number of adverse events following immunisation (AEFI)
- Overall AEFI reporting rate
- Types of AEFI
- Serious AEFI
- Number of AEFI by age group (< 70 years, 70 years, 71–79 years, ≥80 years)
- Number of AEFI by state and territory
- Number of AEFI by gender
    - Male
    - Female
- Number of AEFI by Indigenous status
    - Indigenous
    - Other

2. **AusVaxSafety[26]**

AusVaxSafety is an enhanced active surveillance system for AEFI coordinated by NCIRS and funded by the Australian Government Department of Health.[26]

AusVaxSafety monitors the safety of vaccines through sentinel active participant-based surveillance.[26] SmartVax and Vaxtracker are software programs run by GPs and immunisation clinics that send an SMS or email to patients (or parents of vaccinated patients for childhood vaccines) following a vaccination.[26]De-identified information from SmartVax and Vaxtracker is combined and monitored by

AusVaxSafety to detect possible safety signals for vaccines. SmartVax and Vaxtracker are used by more than 200 sentinel surveillance sites, including general practices, immunisation clinics, hospital- and community-based clinics and Aboriginal Medical Services spread across all Australian states and territories.[26] Surveillance for AEFI with Zostavax® using AusVaxSafety commenced on 1 November 2016, with monthly reports of data on all participants (those reporting 'yes' or 'no' to an AEFI) provided to key stakeholders since that time.

Methods

1. Vaccine safety data from AEMS were analysed and reported for the first 16 months of rollout of the program, that is, from 1 November 2016 to 28 February 2018.
   Data for adults aged 70–79 years were analysed to determine vaccine safety outcomes and related issues in both Indigenous and non-Indigenous Australians and in relevant age groups nationally and by jurisdiction.
   Trend analysis of Zostavax®-related AEFI by month of onset date was undertaken.
   Adverse events were analysed using Medical Dictionary for Regulatory Activities (MedDRA) preferred terms (PT).

2. AusVaxSafety data were reviewed for the first 19 months of the rollout of the program, that is, 1 November 2016 to 3 June 2018. Data from two data systems (SmartVax and Vaxtracker) that feed into AusVaxSafety were used in this review. The review focused on events including fever, injection site reaction, rash, tiredness, fatigue and headache; these were analysed by age, gender, Indigenous status and whether any concomitant vaccine/s were received. For rapid signal detection, fast initial response cumulative summation (FIR CUSUM) and Bayesian methods were employed weekly to estimate the probability that any potential safety signal was true or false.

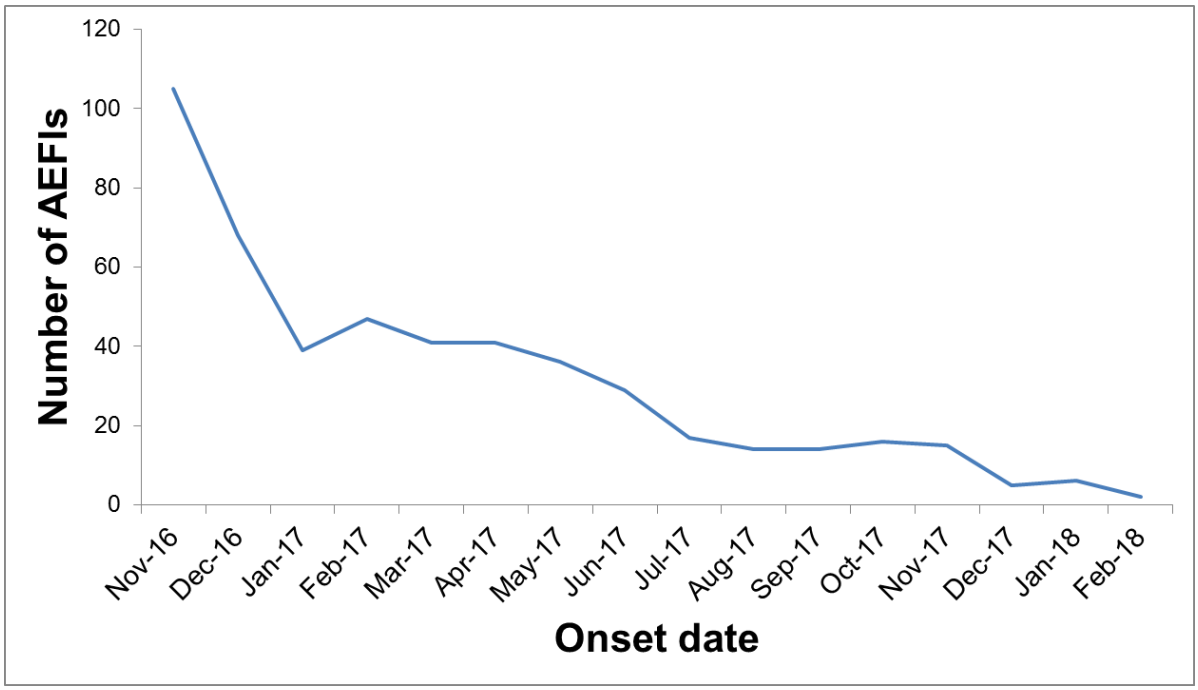
Results

1. Spontaneous surveillance system (AEMS)

Adverse events following Zostavax® vaccination, AEMS, 1 November 2016 – 28 February 2018

From the spontaneous/passive surveillance system (AEMS), there were 542 reported AEFI associated with the shingles vaccine from 1 November 2016 to 28 February 2018. The majority of AEFI were reported in the first 3 months of the program (refer to **Figure 1.1**).

Figure 1.1. Trend in number of AEFI reported for Zostavax®, AEMS, 1 November 2016 – 28 February 2018



Adverse events following Zostavax® vaccination by age group, AEMS, 1 November 2016 – 28 February 2018

Table 1.1 shows that the highest age-specific, shingles-related AEFI reporting rate per 100,000 population occurred in those aged 70 years (24.7 per 100,000 population) followed by those aged 71–79 years (22.7 per 100,000 population), although there were overlapping confidence intervals between the two age groups.

Table 1.1. Number and rate of AEFI reported following shingles vaccination by age group, AEMS, 1 November 2016 – 28 February 2018

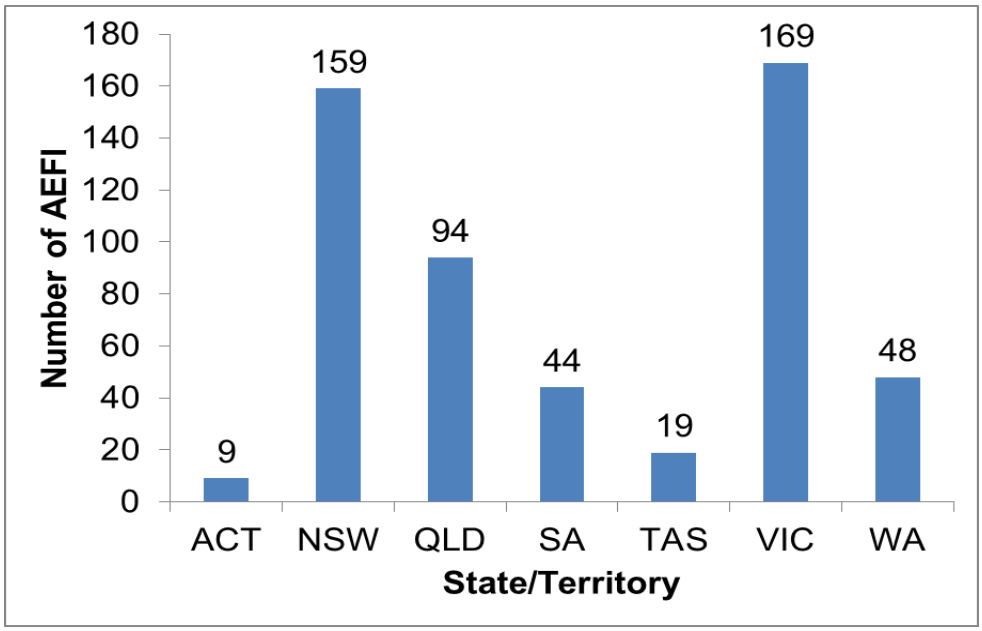
Age group	Number of events	Rate per 100,000 population	95% Confidence Interval
<60 years	15	0.06	(0.03 – 0.10)
60-69 years	18	0.54	(0.32 – 0.85)
70 years	66	24.67	(19.08 – 31.38)
71-79 years	405	22.66	(20.50 – 24.97)
80 years+	15	1.20	(0.67 – 1.98)
All ages*	542	1.68	(1.54 – 1.82)

* Missing age for 23 events

Adverse events following Zostavax® vaccination by jurisdiction, AEMS, 1 November 2016 – 28 February 2018

The number of AEFI reported by jurisdictions ranged from 9 (2%) in the Australian Capital Territory to 169 (31%) in Victoria (refer to **Figure 1.2**). AEFI reporting rates per 100,000 population ranged from 1.41 (in Western Australia) to 2.75 (in Tasmania) but were not significantly different (overlapping confidence intervals).

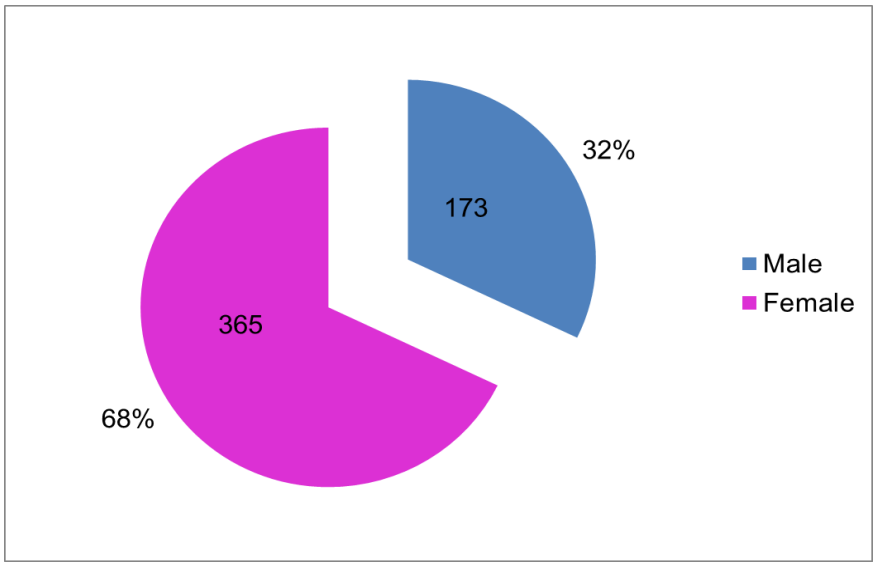
Figure 1.2. Number of AEFI reported following shingles vaccination by jurisdiction, AEMS, 1 November 2016 – 28 February 2018



Adverse events following Zostavax® vaccination by sex, AEMS, 1 November 2016 – 28 February 2018

Two thirds (365, 68%) of adverse events following Zostavax® immunisation were reported in females (refer to **Figure 1.3**). Although recorded shingles vaccination coverage was higher in females than in males (see Coverage chapter), the gender differential for reported adverse events was higher than that for coverage.

Figure 1.3. Number and percentage of AEFI reported following shingles vaccination by sex, AEMS, 1 November 2016 – 28 February 2018



Adverse events following Zostavax® vaccination by Indigenous status, AEMS, 1 November 2016 – 28 February 2018

Of all the shingles-related adverse events, there was only one Indigenous person (a 76-year-old from Victoria) with an adverse event following Zostavax® immunisation for this reporting period. The adverse events reported for this person were rash, injection site reaction and pain in extremity.

Adverse events following Zostavax® vaccination by AEFI type, AEMS, 1 November 2016 – 28 February 2018

Out of the 542 records of adverse events following Zostavax® immunisation, the most frequently reported adverse events were injection site reactions (90), herpes zoster (86), rash (55), vaccination error (35), varicella virus test positive (25) and headache (17) (**Table 1.2**). Other adverse events of interest were disseminated varicella zoster vaccine virus infection (2), angioedema (2), syncope (1) and seizure (1). Refer to **Table 1.2** for details.

Herpes zoster and varicella (varicella virus test positive) were reported to TGA as AEFI. Of note, it is possible that these may not be adverse events but could be attributed to the low (~40%) expected vaccine effectiveness of Zostavax® in this age group. Lack of vaccine effectiveness (or vaccine failure) could result in reactivation of latent varicella zoster virus (VZV). However, without isolation and genotyping of VZV from any varicella-like rashes, it is not possible to determine vaccine versus wild-type (reactivated) virus.

Table 1.2. Numbers of selected adverse events following Zostavax® vaccination, overall and by age group, AEMS, November 2016 – February 2018

Adverse event	Total events	Age missing	< 60 years	60-69 years	70 years	71-79 years	80+ years
Injection site reaction*	90	3	3	16	63	1	3
Herpes zoster	86	4	2	1	9	67	3
Rash†	55	4	0	5	6	38	2
Vaccination error	35	2	5	0	5	23	0
Varicella virus test positive	25	0	1	1	1	22	0
Headache	17	1	1	0	5	10	0
Pruritus	13	0	0	0	1	12	0
Fatigue	7	0	0	1	1	5	0
Pain	6	0	0	0	0	6	0
Arthralgia	6	0	0	0	1	5	0
Nausea	5	0	0	0	1	4	0
Chills	5	0	0	1	0	4	0
Blister	5	0	0	0	1	4	0
Vomiting	4	0	0	0	0	4	0
Urticaria	4	1	0	0	0	3	0
Myalgia	4	0	0	0	0	3	1
Pyrexia	4	0	0	1	0	3	0
Malaise	4	0	0	1	1	2	0
Extensive swelling of vaccinated limb	3	0	0	0	1	2	0
Erythema	3	0	1	0	0	2	0
Vertigo	3	0	0	0	1	2	0
Disseminated varicella zoster vaccine virus infection	2	0	0	0	0	2	0
Angioedema	2	0	0	0	0	1	1
Vertigo positional	1	0	0	0	0	1	0
Syncope	1	0	0	1	0	0	0
Seizure	1	0	0	0	0	1	0

* Injection site reaction includes the following MedDRA PTs: injection site reaction, injection site cellulitis, injection site vesicles, injection site swelling, injection site rash, injection site nodule, injection site haematoma, injection site granuloma, injection site pain, injection site erythema, injection site induration, injection site abscess, injection site bruising and injection site infection

† Rash includes the following MedDRA PTs: rash, rash erythematous, rash pruritic, rash maculo-papular, rash vesicular, rash papular, rash morbilliform

Zostavax®-associated death

There was 1 death reported in a 71-year-old male from NSW who died on 2 January 2017 following Zostavax® vaccination. This person developed disseminated varicella zoster vaccine virus infection.[20, 21] The person should not have received the vaccine as he was immunocompromised due to having chronic lymphocytic leukemia - a contraindication to Zostavax® vaccination. Other cases of vaccination error, not resulting in death, were also reported.

Another 78-year-old male from NSW who also developed disseminated varicella zoster vaccine virus infection following Zostavax® vaccination recovered without sequelae.

The majority of reported adverse events were defined as 'non-serious' (n=522, 96.3%).

2. AusVaxSafety

During the surveillance period of 1 November 2016 to 3 June 2018, a low rate of adverse events and medical attendance following shingles vaccine was reported by AusVaxSafety, which is consistent with the existing knowledge of the vaccine safety profile.[26] There were no vaccine-virus associated or other unusual events seen in patients who reported medical attendance within 3 days after vaccination, to the extent to which follow-up data were available on these cases.

No safety signals were detected by Fast Initial Response Cumulative Summation (FIR CUSUM) or Bayesian analysis during the surveillance period.

Table 2.1 shows cumulative participation in AusVaxSafety from 1 November 2016 to 3 June 2018. Because of differences in surveillance methodologies, SmartVax and Vaxtracker data were analysed separately.

SmartVax

Data for the majority of participants (97.6%) were collected by SmartVax. **Table 2.2** shows data from SmartVax shingles vaccine (Zostavax®) safety surveillance. The median age of SmartVax participants was 73 years, and 46.8% were males. The most common adverse events reported were injection site reaction, rash and fever.

Table 2.1. Cumulative participation from 1 November 2016 to 3 June 2018

	SmartVax	Vaxtracker	Total
Number enrolled	21,020	553	21,571
Number of participants (participation rate, %)	15,196 (72.3%)	367 (66.4%)	15,563 (72.1%)
Number reporting any adverse event following shingles vaccination (AEFI rate, %)	1,237 (8.1%)	55 (15.0%)	N/A*
Number reporting AEFI requiring medical attendance (medical attendance rate, %)	49 (0.3%)	6 (1.6%)	N/A*

* Note: SmartVax and Vaxtracker employ different reporting periods. SmartVax reports on events experienced within 3 days of vaccination; Vaxtracker reports on events experienced within 16 days post vaccination. For Vaxtracker, an additional survey is sent at 24 days post vaccination inquiring whether participants have experienced a chickenpox-like rash or influenza-like symptoms or been hospitalised in the 24 days following vaccination. Replying 'yes' to having a rash and influenza-like symptoms and/or requiring hospitalisation triggers an alert for follow-up. Because of these differences in reporting periods, SmartVax and Vaxtracker data are analysed separately in this report.

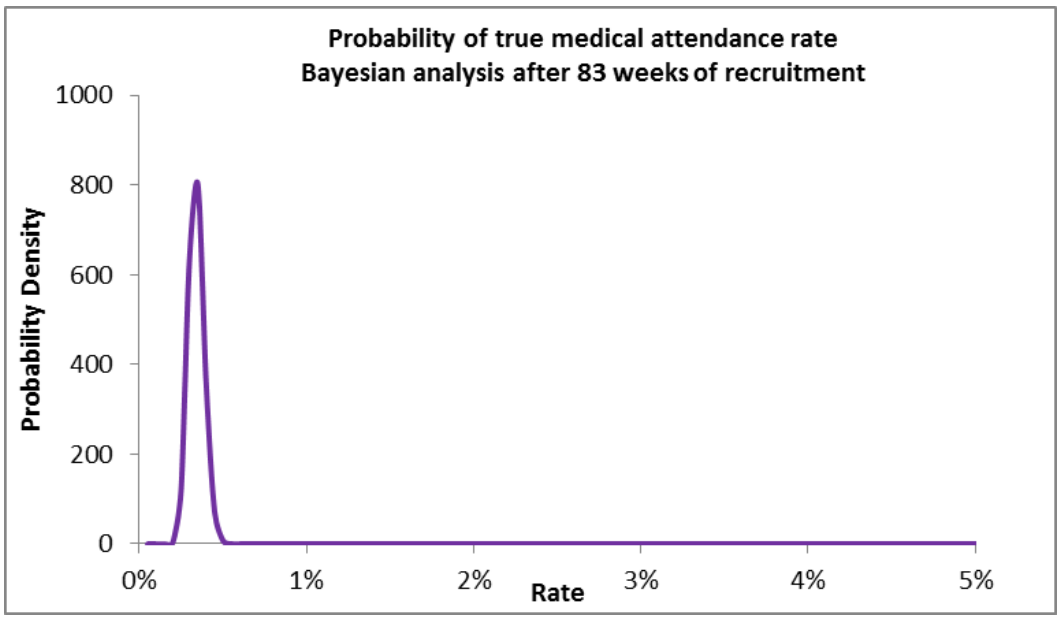
Table 2.2. Summary of key variables, AEFI and whether medical advice or attention sought, SmartVax participants, 1 November 2016 – 3 June 2018

	Variable	Number (%)*
Descriptive	Male	7,110/15,194 (46.8%)
	Median age (range)	73 years (70–79 years)
	Aboriginal or Torres Strait Islander	62/12,387 (0.5%)
	Concomitant vaccine received	3,551/15,196 (23.4%)
AEFI	Any event	1,237/15,196 (8.1%)
	Fever	91/14,543 (0.6%)
	Injection site reaction†	422/14,543 (2.9%)
	Rash	94/14,543 (0.7%)
	Other‡	346/14,543 (2.4%)
Medical advice or attendance	Medical advice sought for event	20/14,543 (0.1%)
	Medical attendance sought for event	49/14,935 (0.3%)

* Denominator is based on number of respondents.
† Includes pain, swelling or redness at the injection site.
‡ 'Other' events primarily included tiredness/fatigue/sleepiness and headache.
Note: Some respondents replied they had experienced an adverse event but did not provide further details describing the adverse event. Therefore, the denominator for 'any event' does not equal the denominator for fever, injection site reaction, rash and 'other' events.

Bayesian analysis of medical attendance rates reported by SmartVax participants following an adverse event, which incorporated published shingles vaccine safety data as prior information, showed that the 95% credible interval for the true medical attendance rate was between 0.25% and 0.44% (**Figure 2.1**).

Figure 2.1 Posterior probability of true medical attendance following an adverse event reported by SmartVax participants following Zostavax® vaccination, 1 November 2016 – 3 June 2018



FIR CUSUM analysis, which tracks the relative likelihood that the medical attendance rate is at a threshold rate versus the likelihood that the medical attendance rate is at an expected rate (with threshold and expected rates of medical attendance for an adverse event following shingles vaccination based on evidence from published literature), for SmartVax participants showed that the cumulative medical attendance rate of 0.3% between 1 November 2016 and 3 June 2018 was within the expected range.

Vaxtracker

Vaxtracker conducted shingles vaccine safety surveillance from December 2016 to April 2018, using opt-in participation. Data solicited using the Vaxtracker system typically provide higher participant-based reporting rates for non–medically attended AEFI than for the Smartvax, opt-out system**.**

Table 2.3 shows the key demographic variables, AEFI and medical advice sought within 16 days post vaccination by Vaxtracker participants.

Table 2.3. Summary of key demographic variables, AEFI and whether medical advice sought within 16 days post vaccination, Vaxtracker participants, December 2016 to April 2018

	Variable	Number (%)*
Descriptive	Male	170/367 (46.3%)
	Median age (range)	73 years (70–79 years)
	Aboriginal or Torres Strait Islander	2/367 (0.5%)
	Concomitant vaccine received	62/367 (16.9%)
	Underlying medical condition†	153/367 (41.7%)
AEFI	Any event	55/367 (15.0%)
	Fever‡	8/367 (2.2%)
	Injection site reaction§	25/367 (6.8%)
	Rash (generalised)	7/367 (1.9%)
	Other‖	36/367 (9.8%)
Medical advice or attendance	Medical advice sought for event	2/367 (0.5%)
	Medical attendance sought for event	6/367 (1.6%)

* Denominator is based on number of respondents.
† Including arthritis, heart disease, respiratory disease, cancer, blood/immune disease and diabetes.
‡ Fever is considered when temperature is ≥37.5°C.
§ Includes pain, swelling or redness at the injection site.
‖ 'Other' events primarily included tiredness/fatigue/sleepiness and headache.

Discussion

Analyses of data from AEMS and AusVaxSafety provide evidence that there is a low rate of adverse events following shingles vaccination, which is consistent with the existing knowledge of the vaccine safety profile.[12] These results are similar to those reported from post-licensure safety surveillance of Zostavax® in the United States of America from the Vaccine Adverse Event Reporting System (VAERS).[27] VAERS received 23,092 reports following Zostavax® vaccination from 2006 to 2015, and 96% of these reports were classified as non-serious.[27] Injection site erythema, herpes zoster, injection site swelling and rash were the most commonly reported symptoms among non-serious reports in the VAERS. [27]

While there is anecdotal evidence that some individuals received two doses of zoster vaccine, we were unable to assess the frequency of occurrence of double doses. However, we found a higher level of AEFI reporting in the initial months of the program than in later months, as shown by data from AEMS. An early increase in AEFI reporting has been previously shown to often occur when a new vaccine is introduced, as immunisation providers are more likely to report milder, less serious AEFI for vaccines with which they are less familiar. A reduction in and stabilisation of reporting rates over time occur thereafter.[28-38]

Both surveillance systems (AEMS and AusVaxSafety) reported similar profiles of milder events, for example, injection site reactions and rash. However, more serious events and vaccination errors, particularly vaccination of immunocompromised persons, were reported to both the systems as previously published.[20, 21] There was a death due to disseminated vaccine-derived varicella zoster virus infection following vaccination error (vaccine given to an immunocompromised person) reported to the TGA during this period.[20] This live vaccine (Zostavax®) is contraindicated in immunocompromised people. Our process evaluation recommended that there needs to be greater clinical education for GPs, practice nurses, specialists and other immunisation providers about risks of administering the live vaccine in this elderly age group, who will often have comorbidities, be taking several medications and be at risk of immunocompromise.

In response to the Zostavax®-related death and in conjunction with public health authorities as part of the safety signal investigation, a retrospective review of patient data from the Smartvax/AusVaxSafety system was undertaken. Data were used to identify patients with potentially immunocompromising conditions (noting that such data are not usually available to the system for analysis). Review found that administration of Zostavax® to immunocompromised patients was occurring at a greater rate than reported to the TGA AEMS; although in the small sample identified, no AEFI occurred.[21]

There are limitations with using AEMS and AusVaxSafety data. It is important to note that in the AEMS database, vaccine information and MedDRA preferred terms are not based on review of comprehensive clinical notes or case reviews. The reported symptoms, signs and diagnoses in each adverse event record in the AEMS database are temporally associated with vaccination but are not necessarily causally associated with a vaccine or vaccines. However, the use of AusVaxSafety data allows for active follow up of medically attended AEFI by immunisation providers and/or jurisdictional health departments. Nevertheless, AusVaxSafety data are reported for sentinel practices that agree to participate in surveillance, and further to notify medically attended AEFI to jurisdictional health departments. Hence, there could be selection bias using only AusVaxSafety data. This shorter period of post-vaccination follow-up for AusVaxSafety participants in the Smartvax (but not Vaxtracker) system may also not allow for AEFI potentially related to vaccine virus replication (~10–28 days) to be detected. Of note, data from another pilot analysis of Zostavax® vaccinated patients attending general practices enrolled in NPS Medicine Insight - not reported here but contained in the AusVaxSafety 2016–2017 annual report to the Department of Health – also showed no evidence of any safety signals or unusual or serious AEFI in the 28 days following vaccination.

Our review included both spontaneous (AEMS) and active surveillance (AusVaxSafety) data, which provide a more comprehensive view of vaccine safety.

Conclusion

The data reported here are consistent with an overall high level of safety for Zostavax® when used as indicated under the NIP schedule. However, evidence of inappropriate administration of the vaccine to immunocompromised individuals, including resulting in the death of one elderly man, has resulted in renewed efforts to ensure that patient screening before vaccination occurs and that provider information on vaccine contraindications is made widely available.

As elderly (as well as other aged) patients with significant immunocompromising conditions are at highest risk of developing herpes zoster and post-herpetic neuralgia, the inability to safely use a live vaccine in this age group results in an unmet need with regard to shingles disease prevention in this group in Australia.

References

1. Cohen JI. Herpes zoster. N Engl J Med. 2013;369:255-63.

2. Pan J, Hsu T-Y, Johnson KD, Xu R, Acosta CJ, Kawai K. Cost-effectiveness analysis of herpes zoster vaccine in adults above 50 in Singapore. Dermatologica Sinica. 2017 2017/12/01/;35(4):177-81.

3. Australian Technical Advisory Group on Immunisation (ATAGI). The Australian immunisation handbook 10th edition. Canberra: Australian Government Department of Health; Updated August 2016 [29 September 2016]; 10th:[Available from: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home~handbook10part4~handbook10-4-24.

4. Immunise Australia. Herpes-zoster (Shingles). [28 June 2018]; Available from: https://beta.health.gov.au/health-topics/shingles-herpes-zoster.

5. Karki S, Newall AT, MacIntyre CR, Heywood AE, McIntyre P, Banks E, et al. Healthcare Resource Utilisation Associated with Herpes Zoster in a Prospective Cohort of Older Australian Adults. PLoS ONE. 2016;11(8):e0160446.

6. Stein AN, Britt H, Harrison C, Conway L, Cunningham A, MacIntyre CR. Herpes zoster burden of illness and health care resource utilisation in the Australian population aged 50 years and older. Vaccine. 2009;27:520–9.

7. de Boer PT, Wilschut JC, Postma MJ. Cost-effectiveness of vaccination against herpes zoster. Human vaccines & immunotherapeutics. 2014;10(7):2048-61.

8. Insinga RP, Itzler RF, Pellissier JM. Acute/subacute herpes zoster: healthcare resource utilisation and costs in a group of US health plans. PharmacoEconomics. 2007;25(2):155-69.

9. Oxman MN, Levin MJ, Johnson GR, Schmader KE, Straus SE, Gelb LD, et al. A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. N Engl J Med. 2005;352(22):2271-84.

10. National Centre for Immunisation Research and Surveillance. Herpes zoster. [30 May 2018]; Available from: http://www.ncirs.edu.au/assets/provider_resources/fact-sheets/zoster-vaccine-fact-sheet.pdf.

11. Dooling K, Guo A, Leung J, Belongia E, Harpaz R. Performance of Zoster Vaccine Live (Zostavax): A Systematic Review of 12 years of Experimental and Observational Evidence. Open Forum Infectious Diseases. 2017 Fall

10/04;4(Suppl 1):S412-S3.

12. Willis ED, Woodward M, Brown E, Popmihajlov Z, Saddier P, Annunziato PW, et al. Herpes zoster vaccine live: A 10year review of post-marketing safety experience. Vaccine. 2017 Dec 19;35(52):7231-9.

13. Public Health England. Herpes zoster (shingles) immunisation programme 2015 to 2016: evaluation report. [6 December 2016]; Available from: https://www.gov.uk/government/publications/herpes-zoster-shingles-immunisation-programme-2015-to-2016-evaluation-report.

14. Amirthalingam G, Andrews N, Keel P, Mullett D, Correa A, de Lusignan S, et al. Evaluation of the effect of the herpes zoster vaccination programme 3 years after its introduction in England: a population-based study. The Lancet Public health. 2018 Feb;3(2):e82-e90.

15. Marin M, Yawn BP, Hales CM, Wollan PC, Bialek SR, Zhang J, et al. Herpes zoster vaccine effectiveness and manifestations of herpes zoster and associated pain by vaccination status. Human vaccines & immunotherapeutics. 2015;11(5):1157-64.

16. Tseng HF, Lewin B, Hales CM, Sy LS, Harpaz R, Bialek S, et al. Zoster Vaccine and the Risk of Postherpetic Neuralgia in Patients Who Developed Herpes Zoster Despite Having Received the Zoster Vaccine. The Journal of infectious diseases. 2015 Oct 15;212(8):1222-31.

17. Tseng HF, Smith N, Harpaz R, Bialek SR, Sy LS, Jacobsen SJ. Herpes zoster vaccine in older adults and the risk of subsequent herpes zoster disease. Jama. 2011 Jan 12;305(2):160-6.

18. Australian Technical Advisory Group on Immunisation (ATAGI). ATAGI bulletin for the 56th meeting 19-20 February 2015 [29 May 2018]; Available from: https://beta.health.gov.au/resources/publications/atagi-bulletin-for-the-56th-meeting-19-20-february-2015.

19. Therapeutic Goods Administration. Zostavax vaccine. Safety advisory – not to be used in patients with compromised immune function. [9 May 2018]; Available from: www.tga.gov.au/alert/zostavax-vaccine.

20. Alexander KE, Tong PL, Macartney K, Beresford R, Sheppeard V, Gupta M. Live zoster vaccination in an immunocompromised patient leading to death secondary to disseminated varicella zoster virus infection. Vaccine. 2018;36(27):3890-3.

21. Gowland A, Hiam R, Behm C, Phillips A, Macartney K. Live vaccine administration to immunocompromised patients: use of active surveillance data to enhance vaccine signal investigation. Poster presentation. Asian Conference on Pharmacoepidemiology (ACPE); Brisbane2017.

22. US Department of Health and Human Services. Healthy People 2020: Adults vaccinated against zoster (shingles) (percent, 60+ years). [23 November 2016]; Available from: https://www.healthypeople.gov/2020/data-search/Search-the-Data#srch=zoster;topic-area=3527;.

23. Williams WW, Lu P, O'Halloran A, Kim DK, Grohskopf LA, Pilishvili T, et al. Surveillance of Vaccination Coverage Among Adult Populations — United States, 2014. Morbidity and Mortality Weekly Report (MMWR), 2016. 65 (1):1-36. [24

November 2016]; Available from: http://www.cdc.gov/mmwr/volumes/65/ss/ss6501a1.htm.

24. Dalton L, Meder K, Beard F, Dey A, Hull B, McIntyre P, et al. Australian Immunisation Register Data Transfer Study. Stage 2 Final Report. August 2018. [10 January 2019]; Available from: http://www.ncirs.org.au/sites/default/files/2018-12/2018%20AIR%20data%20tranfer%20report_FINAL_0.pdf.

25. Therapeutic Goods Administration. Reporting adverse events. [21 June 2018]; Available from: https://www.tga.gov.au/reporting-adverse-events.

26. National Centre for Immunisation Research and Surveillance. AusVaxSafety. [21 June 2018]; Available from: http://www.ausvaxsafety.org.au/.

27. Miller ER, Lewis P, Shimabukuro TT, Su J, Moro P, Woo EJ, et al. Post-licensure safety surveillance of zoster vaccine live (Zostavax(R)) in the United States, Vaccine Adverse Event Reporting System (VAERS), 2006-2015. Human vaccines & immunotherapeutics. 2018 Mar 26:1-7.

28. Lawrence GL, Aratchige PE, Boyd I, McIntyre PB, Gold MS. Annual report on surveillance of adverse events following immunisation in Australia, 2006. Commun Dis Intell. 2007 09 /;31(3):269-82.

29. Lawrence G, Boyd I, McIntyre P, Isaacs D. Annual report: surveillance of adverse events following immunisation in Australia, 2005. Commun Dis Intell. 2006 09 /;30(3):319-33.

30. Lawrence G, Gold MS, Hill R, Deeks S, Glasswell A, McIntyre PB. Annual report: surveillance of adverse events following immunisation in Australia, 2007. Commun Dis Intell. 2008 12 /;32(4):371-87.

31. Menzies R, Mahajan D, Gold MS, Roomiani I, McIntyre P, Lawrence G. Annual report: surveillance of adverse events following immunisation in Australia, 2008. Commun Dis Intell. 2009 12 /;33(4):365-81.

32. Mahajan D, Roomiani I, Gold MS, Lawrence GL, McIntyre PB, Menzies RI. Annual report: surveillance of adverse events following immunisation in Australia, 2009. Commun Dis Intell. 2010 Sep;34(3):259-76.

33. Mahajan D, Cook J, McIntyre PB, Macartney K, Menzies RI. Annual report: surveillance of adverse events following immunisation in Australia, 2010. Commun Dis Intell. 2011 Dec;35(4):263-80.

34. Mahajan D, Cook J, Dey A, Macartney K, Menzies RI. Annual report: surveillance of adverse events following immunisation in Australia, 2011. Commun Dis Intell. 2012 Dec;36(4):E315-32.

35. Dey A, Wang H, Quinn H, Hill R, Macartney K. Surveillance of adverse events following immunisation in Australia annual report, 2014. Communicable Diseases Intelligence. 2016;40(3):E377–E90.

36. Mahajan D, Dey A, Cook J, Harvey B, Menzies R, Macartney K. Surveillance of adverse events following immunisation in Australia annual report, 2012. Commun Dis Intell. 2014;38(3):E232– E46.

37. Mahajan D, Dey A, Cook J, Harvey B, Menzies R, Macartney K. Surveillance of adverse events following immunisation in Australia annual report, 2013. Commun Dis Intell. 2015;39(3):E369–E86.

38. Dey A, Wang H, Quinn H, Cook J, Macartney K. Surveillance of adverse events following immunisation in Australia annual report, 2015. Communicable Diseases Intelligence In press. 2017.

39. Kerzner B, Murray AV, Cheng E, Ifle R, Harvey PR, Tomlinson M, et al. Safety and immunogenicity profile of the concomitant administration of ZOSTAVAX and inactivated influenza vaccine in adults aged 50 and older. J Am Geriatr Soc. 2007 10 /;55(10):1499-507.

40. Tseng HF, Smith N, Sy LS, Jacobsen SJ. Evaluation of the incidence of herpes zoster after concomitant administration of zoster vaccine and polysaccharide pneumococcal vaccine. Vaccine. 2011 May 9;29(20):3628-32.

41. Baylor NW. Perspective of the U.S. Food and Drug Administration on concomitant administration of Zostavax and Pneumovax [letter]. Vaccine. 2011 Nov 8;29(48):8771.

42. Centers for Disease Control and Prevention (CDC). Update on herpes zoster vaccine: licensure for persons aged 50 through 59 years. MMWR Morb Mortal Wkly Rep. 2011 Nov 11;60(44):1528.

43. Shingles (herpes zoster). In: Salisbury D, Ramsay M, editors. Immunisation against infectious disease: The green book. London: Public Health England, Department of Health; 2016.

44. Centers for Disease Control and Prevention (CDC), Kroger AT, Sumaya CV, Pickering LK, Atkinson WL. General recommendations on immunization – recommendations of the Advisory Committee on Immunization Practices (ACIP). [erratum appears in MMWR Recomm Rep. 2011 Jul 29;60:993]. MMWR Recomm Rep. 2011 Jan 28;60(RR-2):1-61.

45. Vafai A, Berger M. Zoster in patients infected with HIV: a review. Am J Med Sci. 2001 06 /;321(6):372-80.

46. Centers for Disease Control and Prevention (CDC), Harpaz R, Ortega-Sanchez IR, Seward JF. Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2008 06 06/;57(RR-5):1-30.

47. Gourishankar S, McDermid JC, Jhangri GS, Preiksaitis JK. Herpes zoster infection following solid organ transplantation: incidence, risk factors and outcomes in the current immunosuppressive era. American Journal of Transplantation. 2004 01 /;4(1):108-15.

48. Schmader KE, Levin MJ, Gnann JW, Jr., McNeil SA, Vesikari T, Betts RF, et al. Efficacy, safety, and tolerability of herpes zoster vaccine in persons aged 50–59 years. Clin Infect Dis. 2012 Apr;54(7):922-8.

49. Oxman MN, Levin MJ, Johnson GR, Schmader KE, Straus SE, Gelb LD, et al. A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. N Engl J Med. 2005 06 02/;352(22):2271-84.

50. Tseng HF, Liu A, Sy L, Marcy SM, Fireman B, Weintraub E, et al. Safety of zoster vaccine in adults from a large managed-care cohort: a Vaccine Safety Datalink study. J Intern Med. 2012 May;271(5):510-20.

Appendix A – Ethics Approval

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30 August 2017

Professor Jennifer O'Dea
National Centre for Immunisation Research and Surveillance (NCIRS)
The Children's Hospital at Westmead

Dear Professor O'Dea,

HREC reference number:	**LNR/17/SCHN/250**
Project title:	**Zoster Immunisation Program Evaluation**
Sites:	**The Children's Hospital at Westmead**

Thank you for submitting the above project for single ethical and scientific review. This project was first reviewed by the Executive Officer of SCHN HREC on the **10 July 2017** and was also ratified by the Sydney Children's Hospitals Network Human Research Ethics Committee's Executive Committee ("the Committee") at its meeting **19 July 2017**. The response to the request for further information was subsequently reviewed by the Executive Committee on the **3 August 2017** and the second response to the request for further information was reviewed out of session on the **30 August 2017.**

This HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review, and by the National Health and Medical Research Council as a certified committee in the review of multi-centre clinical research projects.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and *CPMP/ICH Note for Guidance on Good Clinical Practice.*

I am pleased to advise that the Committee has granted ethical approval of this research project. Your approval is valid for three (3) years, effective the date of this letter.

This application has been assessed in accordance with, and meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

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The documents reviewed and approved by the Committee are:

Document Reviewed	*Version*	*Date*
LNR Submission Code, AU/6/E00F215		29 June 2017
Consumer Survey	V2	21 Jul 2017
DoH Survey	V2	12 Jul 2017
Final GP and nurse survey	V2	21 Jul 2017
Jurisdictional program manager telephone survey	V1	29 June 2017
National Shingles PHN PHU Local Council for NIC	V1	29 June 2017
Professional peak body telephone survey	V1	29 June 2017
Specialist telephone and online survey	V2	21 Jul 2017
Zoster PIS - Consumers	V2	21 Jul 2017
Zoster process and early impact evaluation plan	V1	29 June 2017
Response to Committee		21 Jul 2017
PIS FOR DoH	V2	21 July 2017
PIS GPs and Nurses	V2	21 Jul 2017
PIS for professional peak body	V2	21 Jul 2017
PIS for Specialists	V2	21 Jul 2017
PIS jurisdictional Program Managers	V2	21 Jul 2017
PIS PHNs PHUs and Local Councils	V2	21 Jul 2017
Requested PHU contacts		Received 29 Aug 2017

Please note the following conditions of approval:

1. The Coordinating Investigator will immediately report anything which may warrant review of ethical approval of the project in accordance with the SCHN adverse event reporting policy.

2. All proposed changes to the research protocol, including the conduct of the research, changes to site or personnel, or an extension to HREC approval, are to be provided to the HREC or its delegate for review before those changes can take effect.

3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. The co-ordinating investigator will provide an annual report to the HREC on the anniversary of this approval letter, and a final report on completion of the study.

5. Your approval is valid for three (3) years from the date of the final approval letter. If your project extends beyond that three year period and you are still actively recruiting you will be required to resubmit your application incorporating any amendments within six (6) months of that approval expiry date. If your project is in follow up on, or analysis, please submit and application for amendment to extend the approval period. Ethics approval can be extended for a period of twelve (12) months at a time.

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6. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

Should you have any queries about the HREC's consideration of your project please contact the Research Ethics Administration Assistant on (02) 9845 1253.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The HREC wishes you every success in your research.

Yours faithfully

SGarnett

Associate Professor Sarah Garnett
Chair, Sydney Children's Hospitals Network Human Research Ethics Committee
Sydney Children's Hospitals Network Human Research Ethics Committee

cc Dr Mohamed Tashani

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Appendix B – Sampling Matrix

	Stakeholder	National	NSW	ACT	QLD	VIC	TAS	SA	NT	WA
Government and associated committees/ advisory groups	Australian Government Department of Health (Department of Health)	X								
	Jurisdictional Immunisation Coordinator (JIC)	X	X	X	X	X	X	X	X	X
	National Immunisation Committee (NIC)	X								
	Australian Technical Advisory Group on Immunisation (ATAGI)	X								
	Communicable Diseases Network Australia (CDNA)	X								
	Australian Government Department of Human Services	X								
	State and Territory Departments of Health	X	X	X	X	X	X	X	X	X
	Advisory Committee on Vaccines (ACV)	X								
	Therapeutic Goods Administration (TGA)	X								
Peak professional /practitioner groups	Australian Medical Association (AMA)	X								
	Royal Australian College of General Practitioners (RACGP)	X								
	Australian College of Rural & Remote Medicine (ACRRM)	X								
	Royal Australian College of Physicians (RACP)	X								
	Australian Primary Health Care Nurses Association (APNA)	X								
Providers/ services/ other relevant group/s	Primary Health Networks (PHNs)		X	X		X			X	
	Public Health Units (PHUs)		X		X		X	X	X	X
	Specialists (Geriatricians, neurologists, rehabilitation medicine, dermatologists)			X			X			

	AusVaxSafety	X								
	Key vaccination expert	X								
Pharmaceutical company	Seqirus	X								

Appendix C – Stakeholder surveys (Example – Jurisdictional program managers)

Evaluation of the National Shingles Vaccination Program

Jurisdictional Immunisation Program Managers

- The National Centre for Immunisation Research and Surveillance (NCIRS) is currently undertaking an evaluation of the National Shingles Vaccination Program.
- The results will be provided to the Australian Government and the National Immunisation Committee (NIC) to inform future national vaccination programs.
- The questions will be the basis for a telephone interview. They are being provided now to allow you time to reflect on them and collect any supporting information to inform your responses.
- All information you provide will be confidential and the final report to the Department of Health will contain de-identified, summarised information.

The telephone interview questions will cover the following-

- ✓ Your role during the National Shingles Vaccination Program
- ✓ Program implementation
- ✓ Communication strategies & resources
- ✓ Data
- ✓ Program strengths and challenges

Internal Use Only

Participant	Participant Affiliation	Interviewer	Interview Date	Recorded	Transcription complete

Version 1 (29th June 2017)

Page **1** of **4**

Telephone interview questions

1. Participant details
1.1 In which state are you located? ☐NSW ☐ACT ☐NT ☐QLD ☐ SA ☐TAS ☐VIC ☐WA
1.2 What is your current role in the National Shingles Vaccination Program?

2. Communication and resources
2.1 How and when were you advised about the National Shingles Vaccination Program?
2.2 Did your jurisdiction develop or amend state/territory policies/guidelines specifically for the National Shingles Vaccination Program? If so, please describe and indicate if/where available?
2.3 Who were your target groups/organisations to inform about the program?
2.4 How did you advise them about the program? (e.g. media, letters, workshops, brochures, use of Commonwealth resources).
2.5 Have you seen the "*Protect yourself about shingles*" brochure, posters or fact sheets? Yes/No 2.5.1 If yes, how have you utilised these resources in your jurisdiction? Any feedback? 2.5.2 Has your jurisdiction developed any program -specific resources for the program? Yes/No 2.5.3 If yes, please describe 2.5.4 What was developed? 2.5.5 Why? 2.5.6 When? (ie: pre/post program commencement) 2.5.7 Who was the target audience/s? 2.5.8 How were they distributed? 2.5.9 Key messages in these materials? 2.5.10 Evaluations/feedback obtained? 2.5.11 How would you rate the usefulness of these resources?

3. Service Delivery
3.1 Please comment on the initial rollout of the National Shingles Vaccination Program in your jurisdiction. 3.1.1 Funding arrangements 3.1.2 Sufficiency of lead time 3.1.3 Obtaining vaccines 3.1.4 Initial availability of information and resources
3.2 Which department/sections of your state/territory government have been involved in the planning and/or implementation of the program?
3.3 Who are the main immunisation providers for the National Shingles Vaccination Program in your jurisdiction?
3.4 Have you/your jurisdiction tailored the program for any of the following groups: 3.4.1 Aboriginal or Torres Strait Islander people? 3.4.1.1 If yes please describe 3.4.1.2 What was developed? 3.4.1.3 Who developed? 3.4.1.4 When? 3.4.1.5 Key messages/actions? 3.4.1.6 How was it implemented? 3.4.2 People from Culturally and Linguistically Diverse backgrounds 3.4.3 If yes please describe 3.4.4 What was developed? 3.4.5 Who developed? 3.4.6 When? 3.4.7 Key messages/actions? 3.4.8 How was it implemented?
3.5 Was/is there any location/group/population that were/are not well served by the National Shingles Vaccination Program in your jurisdiction? (e.g. access related factors)
3.6 Please describe any collaborations/partnerships

4 The vaccine
4.1How do providers order the zoster vaccine in your jurisdiction?
4.2 Please describe any issues with vaccine supply (i.e. vaccine shortage) and/or vaccine management which you have encountered in the National Shingles Vaccination Program.
4.3 Have you received any reports of issues with the administration of the National Shingles Vaccination Program? If yes, please describe.

5 Data
5.1 How do you collect and record: 5.1.1 Doses? 5.1.2 Wastage? 5.1.3 Coverage? 5.1.4 Leakage?
5.2 Were uptake/coverage targets set in your jurisdiction for the program in the first year of the program? If so, what were they?
5.3 How well is information on the Indigenous status of vaccination recipients collected and recorded in your program?
5.4 Are there any other data collected or available from your jurisdiction, which have not been previously mentioned?
5.5 Has your jurisdiction undertaken or planned any internal evaluation specific to National Shingles Vaccination Program? 5.5.1 If yes, are there any reports/information available on these?

6 Strengths and challenges
6.1 From your perspective and compared with other national immunisation programs;
6.1.1 What, if any, are the strengths of the implementation of the National Shingles Vaccination Program? 6.1.2 What, if any, are the challenges of the implementation of the National Shingles Vaccination Program? 6.1.3 What, if any are the issues/problems which you have encountered with implementing the National Shingles Vaccination Program? 6.1.3.1 Have they been resolved? If so, how? (e.g. vaccine supply, systems/processes, consent)
6.2 Based on your experiences with the National Shingles Vaccination Program, do you have any recommendations for planning/implementing future national immunisation programs? 6.2.1 If yes, please describe.
6.3 Any further comments?

THANK YOU FOR YOUR TIME AND CONTRIBUTION

Appendix D – Implementation Plan for the National Shingles Vaccination Program

Implementation Plan for the commencement of the National Shingles Vaccination Program

November 2015

This implementation plan is for internal use by the Immunisation Branch within the Office of Health Protection, to guide the successful delivery of the National Shingles Vaccination Program (the Program) from November 2016.

This document outlines:

- program background;
- program governance;
- key roles and responsibilities;
- key tasks and critical timeframes; and
- risk management.

The purpose of this plan is to provide high-level guidance on the implementation of the Program. Separate, more detailed project plans will be drafted for each component of the Program, with responsibility falling to the relevant sections within the Immunisation Branch. These project plans will outline activities relating to procurement, vaccine safety, communications and program evaluation.

This plan was endorsed by the NIP Implementation Steering Committee on 24 November 2015.

Table of Contents

Policy Background

The National Shingles Vaccination Program (the Program) will commence on 1 November 2016, and will provide shingles vaccination to 70 year olds, with a five-year catch-up program for 71-79 year olds. The five year catch-up program will cease in 2021-22.

The shingles vaccine (Zostavax®, manufactured by Seqirus, formerly bioCSL) will protect against shingles (herpes zoster) and associated post-herpetic neuralgia (PHN).

Shingles is a painful rash caused by the varicella-zoster virus, which is the same virus that causes chickenpox. The shingles rash occurs when the dormant chickenpox virus is reactivated in the nerve tissues and causes inflammation of the nerve. While most symptoms last up to three weeks, nerve injury can take longer to heal resulting in PHN, a debilitating, long lasting pain condition that has a large impact on older Australians.

The shingles vaccine can still be provided to persons with a history of shingles; however it is recommended that the vaccine be given at least one year after the shingles episode. The need for a booster dose has not yet been determined. Should data indicate need for a booster, vaccine recipients will be able to be recalled using data captured in the Australian Immunisation Register.

Approximately 240,000 people will be eligible each year under the ongoing program for 70 year olds. Approximately 1.4 million people will be eligible for the five-year catch-up program for 71-79 year olds. The Program will reduce cases of shingles and its complications. For every 1000 people who receive the shingles vaccine, compared to no vaccine, 38-57 people would avoid a case of herpes zoster, and between 6 and 11 of those would avoid a case of PHN.

The Program has the potential to benefit the whole Australian community, as a decrease in disease prevalence will have a positive impact not only on individuals, but also on carers and employers.

The shingles vaccine will be available through General Practice and other vaccination providers.

Pharmaceutical Benefits Advisory Committee (PBAC) Recommendation
Zostavax® was recommended by the PBAC for inclusion on the National Immunisation Program (NIP) in November 2014. Given the uncertainty of the duration of efficacy for the

vaccine, and the potential high cost to Government, the PBAC recommended that an adult vaccination register be established as a high priority, with capacity to notify individuals if a booster is required. This recommendation was agreed to by Government in May 2015.

Program Funds

As part of the 2015-2016 Federal Budget process, it was agreed that $132.8 million over four years will be provided to fund the Program through the NIP. This funding also includes the expansion of the Australian Childhood Immunisation Register to capture adult immunisation data. The table below provides a breakdown of this total.

	2015-16 ($m)	2016-17 ($m)	2017-18 ($m)	2018-19 ($m)	TOTAL ($m)
Health Departmental	+0.4	+0.4	+0.1	+0.03	+1.0
Health Administered	+0.5	+34.6	+35.8	+30.5	+101.4
Department of Human Services	+4.6	+11.0	+6.2	+5.3	+27.2
National Partnership - Treasury	0.0	+0.53	+1.3	+1.3	+3.2
TOTAL	+5.6	+46.5	+43.5	+37.2	+132.8

Key Tasks and Critical Timeframes

To ensure November 2016 rollout, the Branch will complete the following implementation activities. Refer to the Gantt Chart at Appendix 1 for more detailed information.

Implementation Activities	Section	Timeframes
Amendment to Legislation • Amend *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)* to list Zostavax from 1 July 2016, as agreed by Government.	Policy	March 2016 – June 2016
Vaccine Safety Surveillance Planning • Develop a Vaccine Safety Plan, which outlines mechanisms for active surveillance of adverse events following immunisation with shingles vaccine. • Consult with ATAGI, ACSOV and the TGA. • Develop a vaccine safety risk management plan. • Implement the actions from the agreed shingles Vaccine Safety Plan, including procurement of enhanced vaccine safety surveillance mechanisms as required.	Policy	August 2015 – August 2016
Development and Implementation of a Communication Strategy	Programs	December 2015 – August 2016

• Increase uptake by building awareness among vaccination providers and the target cohort, of the addition of the shingles vaccine to the NIP.		
Program Evaluation Planning • Consult with NCIRS to develop a program evaluation plan. The Department has a standing contract with NCIRS which includes post implementation reviews of new NIP vaccines as set out in the program evaluation framework.	Programs	July 2017 – October 2017
Register Capabilities • The *Australian Immunisation Register Bill 2015* passed through the House of Representatives on 12 October 2015 and the Senate on 15 October 2015. The Bill obtained Royal Assent on 12 November 2015. This Bill will form the legislative framework for the expansion of immunisation registers. • Have an agreed costing with the Department of Human Services (DHS) to expand the Australian Childhood Immunisation Register (ACIR) to collect all vaccinations from birth to death. • This expanded register will be known as the Australian Immunisation Register (AIR). • Work closely with DHS to ensure timeframes are met for the expansion of the ACIR to become the AIR from September 2016. • Work closely with DHS to ensure the AIR will collect shingles vaccine doses administered from November 2016. • Work closely with DHS to ensure the AIR has appropriate mechanisms in place to report on the shingles vaccine in order to support the program (i.e. vaccine coverage etc.).	Registers	November 2015 – August 2016

Vaccine Procurement Process and Contract Negotiations • Seek approval in principle to undertake procurement. • Seek CDNA JEG approval of procurement approach. • Seek AHPPC approval of procurement approach. • Develop RFT documentation and seek State and Territory agreement. • Seek approval to release RFT. • Undertake vaccine supply tender processes. • Undertake contract negotiations. • Seek State and Territory agreement to negotiated Vaccine Agreement. • All parties execute Vaccine Agreement.	Procurement and Contract Management	November 2015 – August 2016

Key Roles and Responsibilities

Figure 1 broadly outlines the roles and responsibilities of Steering Committee members and their relevant work streams.

NIP Steering Committee

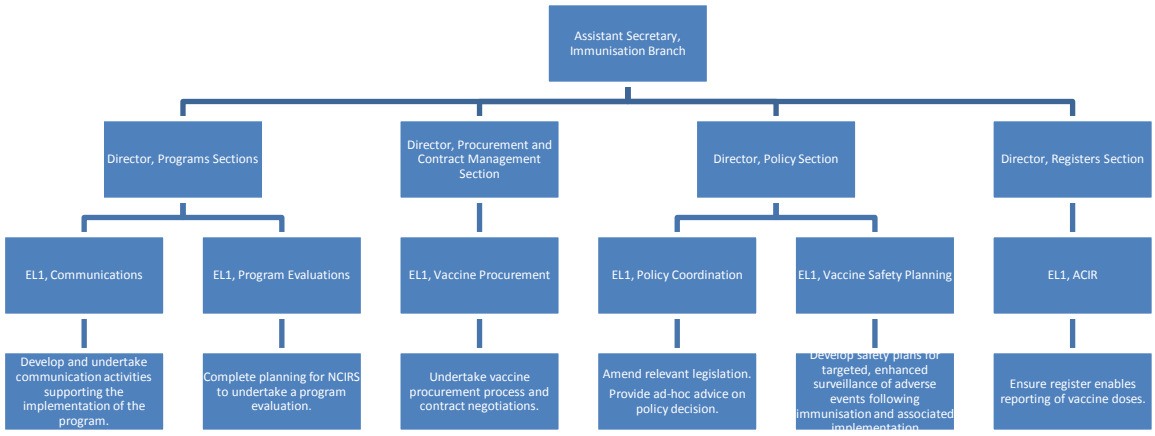

Figure 1: Steering Committee Roles and Responsibilities

Risk Management

Potential risks will be managed actively by the Steering Committee through regular communication at the monthly meetings. An assessment of potential risks and their proposed mitigation strategies are shown in the table below. Note risks will be considered in detail in separate project plans for procurement, vaccine safety and communications.

Risk	Risk Level	Management
Legislation Amendment The variation to the Determination is not finalised before the required vaccine listing date, causing delay to procurement processes and subsequent Program rollout delay.	**Low.** The timeframes and process of varying the Determination are clearly defined and well understood.	Immunisation Policy Section will liaise with Legal Services Branch in early-2016 to ensure timeframes to list Zostavax on the Determination from 1 July 2016 are met.
Vaccine Safety Plan Enhanced vaccine safety surveillance mechanisms are not in place for planned commencement of the Program.	**Low.** Vaccine Safety Planning processes are embedded in the work of the Branch for all new vaccines and/or cohorts to the NIP.	The Branch will consult with the TGA, ATAGI and ACSOV to identify safety surveillance requirements for shingles vaccine and the targeted cohort.
Communications Communication materials are not provided within the required timeframes causing delay to the commencement of Program due to a lack of awareness of the available vaccine.	**Low.** Mail out of communication materials are scheduled to be mailed out to immunisation providers prior to Program start date, subject to vaccine supply. A media release will also be issued prior to Program commencement, and the Immunise Australia website will be updated accordingly.	A carefully constructed communication campaign, underpinned by market research, will be conducted nationally, to inform and promote use of the vaccine for the target cohort to vaccination providers.
Program Evaluation Planning Timeframes in which the development of the evaluation plan and timeframes are not met.	**Low.** Evaluation is reported to be undertaken in the Program Evaluation Framework.	Immunisation Programs will work with NCIRS to develop evaluation plan and reporting timeframes.
Register Capabilities Timeframes for the establishment of the Australian Immunisation Register are not met.	**Low.** The Branch works closely with the responsible registers team at DHS. Program commencement date was agreed with DHS prior to Program announcement.	The Branch will continue to work closely with DHS to ensure timeframes are met.
Vaccine Supply Vaccine supply not available in time for Program rollout.	**Low.** Program commencement date was agreed with the vaccine company prior to announcement of Program rollout date.	Regular liaison with the supplier through the procurement process to ensure adequate supplies of

		the vaccine are available ahead of Program commencement.
Vaccine Procurement Process Timeframes for the procurement of vaccine are not met.	**Low.** Delays in finalising the tender due to internal processes, the RFT process and/or negotiation breakdown.	Active management and regular liaison with the suppliers and OHP Executives.

State and Territory Delivery State and territory governments do not have the capacity to rollout the Program at the planned commencement date.	**Low.** The proposed Program start date and the implementation timeframe has been developed in consultation with states and territories.	The Branch will continue to work closely with states and territories through Jurisdictional Immunisation Coordinators (JIC) and the National Immunisation Committee (NIC) to understand stakeholder concerns regarding any implementation barriers.

Governance

The NIP Implementation Steering Committee has been established to provide strategic oversight and coordinate delivery of the Program. The Steering Committee comprises of the Branch Head, Branch Directors and Assistant Directors of relevant work streams, and will meet monthly to discuss progress and emerging issues.

Managers within each work stream will be required to:

- Plan and lead delivery of implementation activities;
- Identify emerging risks and issues and work towards possible solutions;
- Consult with stakeholders where necessary and consider their views through key stakeholder groups such as the Australian Technical Advisory Group on Immunisation (ATAGI), Australian Health Protection Principal Committee (AHPPC), Jurisdictional Immunisation Coordinators (JIC) and the National Immunisation Committee (NIC);
- Manage team resources;
- Work collaboratively across the Immunisation Branch to minimise duplication and ensure coordinated Program rollout; and
- Monitor and review all activities against the Program Gantt Chart (Appendix 1), noting that the Gantt chart is a working document and will be updated over time.

Appendix E – Vaccine Safety Plan

Vaccine Safety Plan – National Shingles Vaccination Program

Contents

Abbreviations

ACSOV	Advisory Committee on the Safety of Vaccines
AEFI	Adverse event following immunisation
ATAGI	Australian Technical Advisory Group on Immunisation
Department of Health	The Commonwealth Department of Health, incorporating the Therapeutic Goods Administration
JIC	Jurisdictional Immunisation Coordinators
HZ	Herpes zoster
ISR	Injection Site Reaction
The Horvath Review	Review of the management of adverse events associated with Panvax and Fluvax
NCIRS	National Centre for Immunisation Research and Surveillance
NIC	National Immunisation Committee
NIP	National Immunisation Program
OHP	Office of Health Protection, incorporates Immunisation Branch
PHN	Post-hepatic Neuralgia
TGA	Therapeutic Goods Administration
VSP	Vaccine Safety Plan
VZV	Varicella-zoster Virus

Executive Summary

This Vaccine Safety Plan (VSP) recommends that, in addition to the routine surveillance of adverse events following immunisation (AEFI) undertaken by the Therapeutic Goods Administration (TGA), the Office of Health Protection (OHP) continue to actively monitor adverse events following immunisation (AEFI) following vaccination with Zostavax as a new vaccine added to the National Immunisation Program (NIP).

The OHP is committed to the effective and safe roll out of the National Shingles Vaccination Program (the Program). In addition to this VSP, the OHP is undertaking:

- the expansion of the Australian Childhood Immunisation Register (ACIR), which from September 2016 will expand to become the Australian Immunisation Register (AIR), capable of capturing all vaccines administered throughout a person's life, including Zostavax;
- the development of targeted communications materials to inform eligible cohorts, vaccination providers and key stakeholders about the Program; and
- disease surveillance activities to monitor and evaluate the impact of including Zostavax on the NIP.

This VSP includes two active components:

1. continuing monthly AEFI teleconferences between the Jurisdictional Immunisation Coordinators (JIC), TGA and OHP to monitor and discuss AEFI associated with Zostavax in the 70 year old cohort and the 71-79 year old catch up cohort; and
2. a funded active, enhanced surveillance project to monitor any AEFI following Zostavax. The proposed project will:
    - use technologies appropriate to the cohort, including accessing data from GP software / databases, telephone interviews, letters and/or email and SMS technology to follow up patients; and
    - recruit participants from a number of sentinel sites across all states and territories.

It is anticipated that the project will run for two years to monitor safety during the initial implementation of the Program.

Purpose

Implementation of this VSP will allow the OHP and the TGA to promptly review any concerns that may be outside what is anticipated for adverse events following the use of Zostavax, particularly given the lack of data on the use of this vaccine in a population-wide program. Enhanced surveillance activities also assist in ensuring continued public confidence in the NIP.

Background

The National Immunisation Strategy 2013-2018 features a focus on vaccine safety under Strategic Priority Four: Continue to enhance vaccine safety monitoring systems. A key action under this Strategic Priority is to assess the need for, and implement where required, a specific VSP for the release of each new vaccine or existing vaccine to a new cohort for the NIP.

Herpes zoster

Varicella-zoster virus (VZV) is a DNA virus that is a member of the herpesvirus family. Primary infection with VZV is known as varicella or 'chickenpox'; Herpes zoster (HZ), also known as shingles, is caused by reactivation of latent VZV. HZ is a localised, painful, vesicular skin rash that occurs in about 20-30% of people, most after the age of 50. People over 60 are more likely to develop post-herpetic neuralgia (PHN), a chronic neuropathic pain syndrome, as a complication of shingles.

Zostavax

The vaccine Zostavax, manufactured by Seqirus (formerly bioCSL) provides protection against HZ and PHN. At its November 2014 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended Zostavax be added to the NIP, with the vaccine provided as an ongoing program for 70 year olds, with a five-year catch-up program for 71-79 year olds. Given the uncertainty of the duration of efficacy for the vaccine, and the potential high cost to Government, the PBAC recommended that an adult vaccination register be established as a high priority, with capacity to notify individuals if a booster is required. The Government agreed to these recommendations in May 2015.

Australian Technical Advisory Group on Immunisation Advice / Safety of vaccine

ATAGI has advised there are currently no specific safety signals emerging from clinical trials or the post licensure studies for the zoster vaccine. However, approximately half of clinical trial participants experienced injection site reactions (ISR) including erythema, pain, swelling and/or itching. In addition, chicken pox-like rashes occurred rarely (0.1%) at the injection site.

An update to Chapter 4.24: zoster (herpes zoster) of the Australian Immunisation Handbook was endorsed by the National Health and Medical Research Council (NHMRC) on 1 August 2016. This update is now available on the Immunise Australia website (see page 12 for further information). Importantly this chapter provides information on the contraindications to vaccination and the co-administration of Zostavax with other vaccines, including a recommendation that allows for co-administration with 23-valent pneumococcal polysaccharide vaccine (23vPPV), a recommendation which differs from the manufacturer's product information document[1].

[1] **Variations from product information**
In some instances, the ATAGI recommendations in the *Handbook* may differ from information provided by the manufacturer in the vaccine product information document (PI); these differences may be recommendations that are in addition to or instead of those listed in the PI. Where indicated, variations from the PI are detailed in each

Program Implementation

In addition to these safety activities, the OHP is undertaking work to ensure the safe and successful rollout of the Program. Activities undertaken include:

- the expansion of the ACIR, which from September 2016 will expand to become the AIR, capable of capturing all vaccines administered throughout a person's life, including Zostavax. This expansion will allow vaccination providers to ascertain if individuals have received Zostavax and allow them to recall patients if at some point in the future, a booster dose is required;
- disease and program surveillance activities including:
    - monitoring the incidence and severity of herpes zoster in the Australian population post vaccine introduction;
    - monitoring the incidence of post herpetic neuralgia in the vaccine targeted age groups; and
    - monitoring vaccination coverage, vaccine effectiveness and vaccine failure.

Communications

OHP has developed a Communications Strategy (the Strategy) for the Program in order to increase awareness of Zostavax, provide information about the catch-up program, and encourage participation. The target audiences will include people aged 69 and 70 years, people aged 71-79 years for the catch-up program, and health professionals, including geriatricians and rheumatologists.

Key messages under the Strategy will include a focus on vaccine safety and efficacy, including contraindications, clinical study results regarding Zostavax, and co-administration of the vaccine.

As the target audience is heavily influenced by their GP, traditional communication channels will be the most effective. Therefore, communication materials will primarily focus on delivery of information to health professionals via key mail outs while other information will also be available online and electronically.

Materials will include a letter from the Chief Medical Officer, targeted posters and brochures for both mainstream consumers and Aboriginal and Torres Strait Islander consumers and fact sheets for health professionals. In addition, a social media approach, using the Department of Health's Twitter account, Pinterest board and a digital media kit (including electronic copies of materials, sharable graphics and web badges used to direct health professionals and consumers to the Immunise Australia webpage), will provide secondary support to extend key messages for the target audience via intermediaries such as their children and health professionals.

AEFI surveillance in Australia

The TGA has regulatory responsibility for ensuring that vaccines and medicines continue to have an acceptable safety profile once they are registered for use in

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relevant vaccine chapter under the heading 'Variations from product information'. ***Where a variation exists, the ATAGI recommendation should be considered best practice.***

Australia. The TGA operates the Australian adverse drug reaction reporting system, the surveillance system to which reports of adverse reactions to both medicines and vaccines are submitted nationally.

AEFI are notified to the TGA via different routes. In most jurisdictions (except Tasmania), AEFI should be reported directly to the relevant state or territory health authority who then forward all reports to the TGA. Reports are also provided directly to the TGA by vaccine sponsors, health professionals and consumers. The TGA provides state and territory health authorities with information about all AEFI reports directly received for the relevant jurisdiction. Each year, an analysis of AEFI data reported to the TGA is published by the National Centre for Immunisation Research and Surveillance (NCIRS) in conjunction with the TGA.

The TGA undertakes regular review of all AEFI reports and bimonthly statistical analysis using the Proportional Reporting Ratio (PRR) method. Any safety signal is investigated and may be referred to expert/s or expert committees for advice.

As a result of recommendations of the *Review of the management of adverse events associated with Panvax and Fluvax* (the Horvath Review), a new governance structure for vaccine safety was implemented, with the Advisory Committee on the Safety of Vaccines (ACSOV) holding its inaugural meeting in March 2013. ACSOV provides advice as required to the TGA and the OHP on all vaccine safety matters, including those related to NIP funded vaccines.

Strengths and limitations

The TGA AEFI surveillance system has a number of strengths and remains the core of the national surveillance system for vaccine safety. However, as described above, it is a surveillance system that relies on voluntary reporting. Rather than actively searching for adverse events, the TGA system relies on spontaneous reporting of adverse event(s) following receipt of a vaccine (or medicine), by health practitioners, vaccine sponsors, jurisdictional health authorities or members of the public.

This is similar to adverse event surveillance systems in comparable countries: the United Kingdom, the United States of America and Canada. While such surveillance systems are valuable because they allow population-wide post-market monitoring of potential adverse events at relatively low cost, it is acknowledged that they have limitations and may need to be supplemented by other activities in certain circumstances. The surveillance systems can identify potential safety signals; however, determining causality is often difficult and usually requires further evaluation using active surveillance and epidemiological studies.

Rationale for enhanced surveillance activities

Monitoring AEFI is important for maintaining a safe NIP and encourages public confidence in the program overall. As vaccine safety is an issue that continues to receive widespread media attention both nationally and internationally it is important to ensure that the implementation of a new program features a focus on monitoring of adverse events.

In the case of the National Shingles Vaccination Program while there are no specific safety signals associated with the Zostavax vaccine it is important to closely monitor for potential safety issues due to:

- The large cohort size (approximately 400,000, based on an estimated uptake in cohort population); and
- The prevalence of comorbidities, including the potential for patients receiving Zostavax to be immunocompromised or using immunosuppressive therapies, chronic medical conditions and use of multiple medications in the cohort.

In addition to monitoring reports from the TGA, vaccine-specific enhanced surveillance activities suggested in this VSP are designed to capture any AEFI following the administration of Zostavax.

Protocols for Program Action and Communication (Appendix B)

Based on recommendation five of the *Review of the management of adverse events associated with Panvax and Fluvax* (the Horvath Review), the Department developed, in conjunction with jurisdictions, a set of nationally agreed protocols for program action and communication, including informing health professionals, consumers and the media, in the event a possible safety signal is detected affecting a NIP vaccine. These protocols are included at **Appendix B**.

Governance of this Vaccine Safety Plan

Development of a Vaccine Safety Plan Template

Based on previous experience implementing enhanced surveillance activities for monitoring AEFI, the OHP have drafted a template VSP at **Appendix A**. This template is designed to be an internal document that is flexible, in order to be easily adapted for the requirements of future vaccines and/or new cohorts being added to the NIP.

As future vaccines added to the NIP may have differing safety profiles and both the size and requirements of new cohorts will vary, this template will be used by OHP as a basis to develop specific VSPs. For each new VSP, the OHP will seek input and advice from key stakeholders including the TGA, ACSOV, ATAGI and NIC as appropriate.

Development of the National Shingles Vaccination Program Vaccine Safety Plan

The VSP for the National Shingles Vaccination Program has been drafted with reference to:

- ATAGI pre- and post- submission advice to the PBAC;
- the Australian Immunisation Handbook 10th Edition;
- advice from key stakeholders; and
- Communication Strategy National Shingles Vaccine Program.

Stakeholder Roles and Responsibilities

All stakeholders have a responsibility to ensure the safety of new vaccines and cohorts added to the NIP. Specific roles and responsibilities will vary according to the cohort and/or the vaccine, and will be reviewed and articulated in each new VSP.

The roles and responsibilities specific for this VSP are outlined below:

1. The OHP is responsible for drafting and seeking appropriate input and feedback on this VSP.
2. The OHP is responsible for consulting with jurisdictions and other relevant stakeholders on proposed activities and implementation, and for providing this VSP to ACSOV.
3. The ACSOV are responsible for reviewing the VSP and commenting on its suitability for monitoring vaccine safety for the new program.
4. The OHP is responsible for the funding and contract management of any active surveillance component.
5. The TGA is responsible for the coordination and administration (including secretariat) of the monthly JIC-TGA-OHP AEFI teleconferences.
6. JICs are responsible for attending the monthly JIC-TGA-OHP AEFI teleconferences, or to provide an appropriate proxy if unavailable.
7. Should any safety or programmatic concerns arise regarding the National Shingles Vaccination Program outside of these monthly meetings, JICs are responsible for notifying the OHP and the TGA as soon as practicable.
8. Should a safety signal arise, the OHP is responsible for coordinating a national response to the issue, in close consultation with the TGA and jurisdictions, in line with the agreed *Protocols for Program Action and Communication* (the Protocols, **Appendix B**). The Protocols aim to ensure a nationally consistent program response to a possible or confirmed vaccine safety signal for a NIP vaccine.

Review of the Vaccine Safety Plan

This VSP is intended to be a living document and will be reviewed by the OHP and updated as required.

Overview of Vaccine

Benefits of vaccination

The implementation of the Program will provide benefit to the whole Australian community.

The introduction of Zostavax for 70 year olds, along with the catch up program for 71-79 year olds, will reduce the incidence of HZ and PHN. For every 1000 people who receive Zostavax, compared to no vaccine, 38 to 57 people would avoid a case of HZ, and between 6 and 11 of those would avoid a case of PHN. The PBAC considers this program will be cost effective and ATAGI considers that including Zostavax on the NIP is clinically appropriate.

Zostavax would help to avoid the limiting effects of HZ and its complications, which currently have a large impact on older Australians. An improvement in disease burden will also have a flow on effect for the carers and employers of patients suffering from HZ and its complications.

Vaccination uptake

Vaccination update and coverage will be monitored through the AIR from the commencement of the Program.

The AIR will allow:

- Vaccination providers secure access to a range of reports, which will allow them to monitor vaccine uptake in all of their patients;
- Vaccination providers access to records of all individuals to determine if any vaccines are overdue;
- Health professionals, state and territories, and Primary Health Networks (PHNs) to identify areas of low coverage; and
- All individuals to have access to their own vaccination records via history statements.

Reports available from the AIR include coverage rates at varying age ranges, geographic levels and reports of overdue individuals who require catch up vaccines.

TGA Product Information

The TGA prepares a 'Product Information' document and a 'Consumer Medicine Information' document to provide further information for the public. These documents can be accessed on the TGA's website:

https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=zostavax

Vaccine Sponsor responsibilities, including post-market surveillance and Risk Management Plans (if applicable)

All vaccine sponsors have a mandated responsibility to report adverse events and other significant safety issues to the TGA under the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations 1990 in accordance with the TGA *Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines*.

Regulatory approval of vaccines currently requires the submission of a Risk Management Plan (RMP). The role of an RMP is to describe important identified risks, important potential risks and important missing information and propose a pharmacovigilance plan and a risk minimisation plan. However, the regulatory approval of Zostavax predates the requirement for an RMP.

The TGA has noted that in some overseas countries the Sponsor has RMPs in place, and still produces Periodic Safety Update Reports (PSURs). The Sponsor has indicated to the TGA that it can provide recent copies of PSURs if required.

The TGA and OHP are satisfied that while there is no RMP in place for Australia, the safety profile of the vaccine is good and there is sufficient safety information and cooperation from the Sponsor should further information be required.

Safety of Vaccine

The following information on Zostavax is taken from the Australian Immunisation Handbook 10th Edition. This information was updated and approved by the NHMRC on 1 August 2016.

Co-administration with other vaccines

Zostavax can be given at the same time as influenza vaccine,[39] using separate syringes and injection sites.

Zostavax can be given at the same time as pneumococcal polysaccharide vaccine,[40-42] using separate syringes and injection sites (refer to 4.24.4 *Vaccine* above).

Zostavax can be administered at the same visit as, or at any time following receipt of, other inactivated vaccines (e.g. tetanus-containing vaccines), if required.

If administration of both Zostavax and another live parenteral vaccine (e.g. MMR or yellow fever) is indicated, the vaccines should be given either on the same day or at least 4 weeks apart. (Refer also to 4.22 *Varicella*.)

Contraindications

Anaphylaxis to vaccine components

Zoster vaccine is contraindicated in persons who have had:

anaphylaxis following a previous dose of any VZV-containing vaccine

anaphylaxis following any vaccine component.

Persons who are immunocompromised

Live attenuated zoster vaccine is contraindicated in persons with severe immunocompromise due to either a primary or acquired medical condition, or due to medical treatment. This includes persons receiving high-dose systemic immunosuppressive therapy, such as chemotherapy, radiation therapy, oral corticosteroids or disease modifying anti-rheumatic drugs (DMARDs); persons suffering from malignant conditions of the reticuloendothelial system (such as lymphoma, leukaemia, Hodgkin's disease); persons with AIDS or symptomatic HIV infection; and any person with similar immunocompromise due to a disease or treatment (refer to 3.3.3 *Vaccination of immunocompromised persons*).

Persons with less severe immunocompromise than described above (e.g. those on low-dose corticosteroids or DMARDS, or with asymptomatic HIV infection) may be considered for vaccination on a case-by-case basis after seeking appropriate specialist advice (refer to 4.24.10 *Precautions* below and 3.3 *Groups with special vaccination requirements*). For example, zoster vaccine can be given to patients receiving certain non-biological DMARDs in low doses (i.e. methotrexate <0.4 mg/kg per week, azathioprine ≤3.0 mg/kg per day or mercaptopurine ≤1.5 mg/kg per day), either on their own or in combination with low-dose corticosteroids.[43, 44] At these doses, it is likely that the level of immunocompromise is not severe. In addition, most adults >50 years of age have had previous wild-type VZV infection, and thus have immune memory to VZV, which also mitigates any risk of vaccine virus replication.

Persons who have been receiving high-dose systemic immunosuppressive therapy and have ceased therapy may be vaccinated if appropriate intervals have been met (refer to 3.3.3 *Vaccination of immunocompromised persons*).

If an immunocompromised person is inadvertently vaccinated with zoster vaccine, they should be promptly assessed to establish the degree of immunocompromise and extent of risk of vaccine-associated adverse effects in order to inform appropriate management (refer to 3.3.3 *Vaccination of immunocompromised persons)*.

Precautions

Persons with HIV infection

Vaccination with zoster vaccine is not recommended for persons with AIDS or symptomatic HIV infection (refer to 3.3 *Groups with special vaccination requirements*, Table 3.3.4 *Categories of immunocompromise in HIV-infected persons, based on age-specific CD4$^+$ counts and percentage of total lymphocytes*) or significant immunocompromise due to other diseases and/or treatment (refer to 4.24.9 *Contraindications* above).

Persons with asymptomatic HIV infection, low stable viral load and adequate CD4$^+$ counts may be considered for vaccination on a case-by-case basis after seeking appropriate specialist advice (refer to 3.3 *Groups with special vaccination requirements*). Serological confirmation of previous VZV infection is recommended prior to vaccination (refer to 4.24.7 *Recommendations*, 'Serological testing before and after zoster vaccination' above).

Although asymptomatic HIV-infected persons are likely to have a higher relative risk of developing HZ in the future,[45] it is possible that both the efficacy and the safety of zoster vaccination may be reduced in such recipients, as compared with uninfected persons.

Persons anticipating future significant immunocompromise

Immunocompetent persons who anticipate future alteration of their immune status because of an existing illness can be given zoster vaccine on a case-by-case basis after seeking appropriate specialist advice.[46] This may include persons with conditions such as chronic lymphocytic leukaemia, conditions requiring organ transplantation,[47] solid tumours that will require future chemotherapy or radiation therapy, and inflammatory diseases (e.g. rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease, psoriasis) who, at the time, may have minimal alteration to their immune system, but can anticipate significant immunocompromise in the future due to their disease and/or treatment. Since these persons are at high risk of developing zoster in the future, vaccination at least 1 month prior to the onset of immunocompromise may be appropriate (after seeking specialist advice).[46] Serological confirmation of previous VZV infection is recommended prior to vaccination (refer to 4.24.7 *Recommendations*, 'Serological testing before and after zoster vaccination' above).

Vaccination before or after immunoglobulin or blood product administration

Zoster vaccine can be given at any time before or after administration of immunoglobulin or any antibody-containing blood product. This is because zoster vaccine is indicated in persons who, because of their age, are assumed to have had a previous VZV infection and, therefore, already have serum antibody levels comparable to those found in blood products. (Refer also to 3.3.4 *Vaccination of recent recipients of normal human immunoglobulin and other blood products*.)

Persons receiving long-term aspirin or salicylate therapy

Persons receiving long-term salicylate therapy (aspirin) can be vaccinated if indicated. There have been no reports of an association between Reye syndrome and varicella vaccination, and it is unlikely that vaccination of a previously VZV-infected older person with zoster vaccine carries any risk of Reye syndrome.

Persons receiving antiviral medication

It is possible that the use of antivirals with anti-VZV activity, such as acyclovir, famciclovir or valaciclovir, may interfere with the replication of the Zostavax live attenuated virus. Persons on such antiviral medication should cease treatment no less than 24 hours prior to vaccination and for at least 14 days after vaccination.[44, 46]

4.24.11 Adverse events

Injection site reactions (including erythema, pain, swelling and/or itch at the injection site) occurred in approximately half of clinical trial participants given Zostavax, irrespective of a previous history of HZ (refer also to 4.24.4 *Vaccine* above).

Varicella-like rashes at the injection site occurred rarely, in 0.1% of recipients; however, they were more common than in placebo recipients. Varicella-like rashes that were not localised to the injection site were also rare, and did not occur more often in vaccine compared with placebo recipients (0.1% in both groups). In the clinical trials in which rashes were analysed by PCR for VZV, the majority were due to wild-type virus; only 2 subjects were found to have rashes due to the Oka/Merck VZV vaccine strain (refer also to 4.24.4 *Vaccine* above).

Fever >38.3°C was not seen more commonly in vaccine recipients, and occurred in <0.1% of subjects overall.

Systemic symptoms were reported in vaccine recipients more commonly than in placebo recipients (Zostavax 6.3% versus placebo 4.9%), with the most frequently reported systemic symptoms being headache[48] and fatigue.[49]

Post-marketing surveillance in the United States in a cohort of almost 200 000 adults who received the zoster vaccine found no increased risk for a number of potential adverse events occurring after vaccination (such as cerebrovascular events, encephalitis, etc.), but did find a 2-fold increased risk in the 1st week after vaccination for events coded as ‘allergic reactions’, of which the majority were injection site reactions.[50]

4.24.12 Variations from product information

The product information for Zostavax states that the vaccine can be administered concurrently with inactivated influenza vaccine but not with 23vPPV. The ATAGI instead recommends that Zostavax may be administered concurrently with other vaccines (including 23vPPV).

The product information for Zostavax states that the safety and efficacy of Zostavax have not been established in adults with known HIV infection, with or without evidence of immunocompromise. The ATAGI recommends instead that Zostavax may be administered to HIV-infected persons without immunocompromise on a case-by-case basis, after seeking appropriate specialist advice, and following confirmation of pre-existing immunity to VZV.

Proposal for enhanced surveillance of AEFI

Proposed activities

This VSP recommends that, in addition to the routine passive surveillance undertaken by the TGA, the OHP continue to actively monitor AEFI following vaccination with Zostavax.

The OHP will conduct an open tender process seeking a provider to conduct an active, enhanced surveillance project to monitor any AEFI following Zostavax. As with previous projects, based on advice from ACSOV, the tender will be designed to:

- Capture AEFI from across Australia with sufficient sample size to detect a safety signal;
- Capture a range of outcome measures, which could include alternate proxy(s) for serious events, such as visiting a GP or emergency department;
- Report of all identified AEFI to the OHP and the TGA, and to states and territories (as required under jurisdictional legislation); and
- Provide rapid reporting of data and analysis to allow early identification, and/or appropriate management of, any safety signal.

Requirements included in the Request for Tender (RFT) will reflect:

- The large cohort size (approximately 400,000);
- The prevalence of comorbidities, chronic medical conditions and use of multiple medications in the cohort;
- The administration of vaccinations is expected to occur largely in GP surgeries; and
- The need for follow up technologies appropriate to the cohort, including accessing data from GP software / databases, telephone interviews, letters and/or email and SMS technology to follow up patients.

Background data analysis will be important for considering historic age-specific rates of mortality and morbidity (e.g. stroke, acute myocardial infarction) in the 70-year old cohort and in the 71-79 year old catch-up population. This background information will allow the successful Tenderer to differentiate any effect of the vaccine on the cohort. The specific background data requirements will be discussed by OHP with the successful Tenderer as part of contract negotiations.

Given the absence of specific safety signals, it is anticipated that the project will run for two years during the initial implementation of the National Shingles Vaccination Program.

In addition to a funded project to monitor AEFI, monthly teleconferences between the JIC, TGA and OHP will continue, providing opportunities for discussion and identification of any potential safety issues.

Reporting requirements

Reporting requirements for this VSP are as follows:

- JIC-TGA-OHP AEFI teleconferences will continue to occur monthly and will include a focus on Zostavax. Minutes and agenda papers will continue to be circulated to participants prior to the meeting as per current practice. If required, these teleconferences can occur more regularly.

- The proposed enhanced surveillance project will be required to provide progress reports to the OHP and the TGA as appropriate across the surveillance period.
- The OHP will provide a verbal update on the progress and outcomes of this VSP to ACSOV, ATAGI and NIC as appropriate.

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Bibliography

Australian Technical Advisory Group on Immunisation, 2014. Pre - submission advice to the Pharmaceutical Benefits Advisory Committee.

Australian Technical Advisory Group on Immunisation, 2015. Post - submission advice to the Pharmaceutical Benefits Advisory Committee.

The Australian Government Department of Health, 2016. Communication Strategy National Shingles Vaccine Program.

The Australian Government Department of Health, 2015 Implementation Plan for the commencement of the National Shingles Vaccination Program.

The Australian Government Department of Health and Ageing 2013, *Australian Immunisation Handbook 10th Edition*, [ONLINE] available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home. [Accessed 1 August 2016].

The Australian Government Department of Health 2013, *National Immunisation Strategy 2013-2018*, [ONLINE] Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/immunisation-strategy-2013-18-cnt. [Accessed 4 April 2016].

Australian Government Department of Health and Ageing 2011, *Review of the management of adverse events associated with Panvax and Fluvax,* [ONLINE] available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/aefi.htm. [Accessed 4 April 2016].

Appendix 1: Template Vaccine Safety Plan

Vaccine Safety Plan – Addition of a New Vaccine to the NIP

Executive Summary

- A brief (half page to a page) summary of:
  - *Adverse Events of Special Interest (AESI) relevant to the specific vaccine and/or cohort (if applicable).*
  - *Proposal for AEFI/AESI detection.*

Background

- Background:
  - *Expert Advice (Benefits of vaccine; Safety of vaccine).*
- AEFI Surveillance in Australia:
  - *Strengths and limitations.*
  - *Rationale for enhanced surveillance activities (or rationale for not conducting enhanced surveillance, as appropriate).*

Governance of Vaccine Safety Plan

- Governance of Vaccine Safety Plan:
  - *Development of a Vaccine Safety Plan Template.*
  - *Development of [insert vaccine name] Vaccine Safety Plan.*
  - *Stakeholder Roles and Responsibilities.*
  - *Review of the Vaccine Safety Plan.*

Overview of Vaccine

- Overview of Vaccine:
  - *Benefits of [xx vaccine] vaccination.*
  - *TGA Registration and Product Information.*
  - *Vaccine Sponsor responsibilities, including post-market surveillance and Risk Management Plans.*
  - *Expected AEFI / rates (background rates if available).*

Safety of Vaccine, including Adverse Events of Special Interest (AESI) (if applicable)

- Safety of Vaccine:
  - *Any relevant information to the specific vaccine and/or cohort.*
  - *List of AESI, if applicable.*

Proposal for enhanced surveillance of AEFI

- Proposal for enhanced surveillance of AEFI:
  - *Proposed Activities (including rationale).*
  - *Reporting Requirements.*

Vaccine Safety Plan – Addition of a New Cohort to the NIP

Template Instructions

Depending on the safety profile of the vaccine; the size and characteristics of the cohort, the addition of a new cohort to the NIP may only warrant a short Vaccine Safety Plan and little or no additional activities.

If a Vaccine Safety Plan is developed, it would include similar information to that for a new vaccine

Communication Strategy National Shingles Vaccine Program 2016

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Introduction

The National Shingles Vaccination Program (the Program) will commence from November 2016, and aims to reduce the number of cases of, and complications from shingles in older Australians.

The Program will provide free shingles vaccinations to 70 year olds via the National Immunisation Program (NIP). The Government will also implement a five year catch-up program for people aged 71 – 79 years. The five year catch-up program will cease in 2021-22.

The shingles vaccine will protect against shingles (herpes zoster) and associated complications such as post-herpetic neuralgia (PHN).

This strategy outlines communication activity that will increase awareness among vaccination providers and patients of the new shingles vaccine as well as information about the catch-up program.

Background

Shingles is a painful rash caused by the varicella-zoster virus – the same virus that causes chickenpox. The shingles rash occurs when the dormant chickenpox virus is reactivated in the nerve tissues, causing inflammation of the nerves. The shingles rash develops into itchy blisters, which fill with a liquid and burst before the skin crusts over and heals. While most symptoms last up to three weeks, nerve injury can take longer to heal resulting in PHN, a debilitating, long- lasting condition that significantly impacts older Australians.

Approximately 240,000 people will be eligible each year under the programme for 70 year olds and about 1.4 million people will be eligible for the five-year catch-up programme for 71-79 year olds. For every 1000 people who receive the shingles vaccine, 38-57 people will avoid a case of herpes zoster, and between 6 and 11 of those will avoid a case of PHN, compared to those who have not been vaccinated.

The shingles vaccine can be provided to people with a history of shingles, however it is recommended that it be given at least one year after the last shingles episode. The need for a booster dose has not yet been determined, however it is not expected that a booster is required. Should surveillance data indicate one is needed in future, vaccine recipients will be able to be recalled using data captured in the Australian Immunisation Register.

The Program has the potential to benefit the whole Australian community, as a decrease in disease prevalence will have a positive impact not only on individuals, but also on carers and employers.

Program Aim

The aim of the shingles vaccine program is to reduce the number of shingles cases in this age group and its associated sequelae.

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Communication Aim

The overarching aim of communication activities is to inform people aged 70 or about to turn 70 years, people aged 71-79 years (catch-up program), family, carers and vaccination providers about provision of the shingles vaccine on the NIP.

Consultation and Collaboration

Consultations will be held with:

- National Immunisation Committee (NIC) and Jurisdictional Immunisation Committee (JIC).
- Advisory Committee on the Safety of Vaccine (ACSOV) and its members.
- National Centre for Immunisation Research and Surveillance (NCIRS).
- Australian Technical Advisory Group on Immunisation (ATAGI)
- National Aboriginal and Torres Strait Islander Immunisation Network (NATSIIN)
- Indigenous Health Division.
- Aged Care.
- General Practice Roundtable.
- Primary Health Networks.
- Vaccine manufacturer (Seqirus).

Research

Qualitative and quantitative research with patients and general practitioners (GPs) was conducted by Forethought Research from 2013-2015 to provide guidance on the communication approach required to encourage patients to seek a shingles vaccination from their doctor.

The research was commissioned by Seqirus, who manufacture Zostavax, and shared with the Department.

Overall, the research found that the inclusion of the shingles vaccine as part of the NIP was welcomed by patients aged 70-79, who were concerned about any illness that could impact their quality of life. The research also identified some apprehension about why the vaccine is only free for people aged 70-79 and what that meant for those over 80.

Other key insights and considerations taken from this research are:

Patient Target Audience

Patients aged 70-79 demonstrated attitudes and behaviours that differentiated them from younger patients. They:

- Understood that illness could have a big impact at their age.
- Were not in denial about the prospect of health issues.
- Liked a direct approach.
- Were heavily influenced by their GP.

Patient awareness of a shingles vaccination was low (1.4% unprompted), however a recommendation from their GP increased their likelihood of accepting a vaccination.

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Perceptions of Shingles

Patients aged over 70 had a high awareness of shingles however, there were some misconceptions about how likely they were to develop the disease. Patient perception about the severity of shingles was heavily influenced by having had shingles or knowing someone who had.

In addition:

- 27% believed shingles was contagious.
- 66% correctly identified that it related to previous exposure to chicken pox.
- 45% had discussed shingles with their GP.
- 40% believed that shingles was severe enough to warrant vaccination.

General Practitioners

The research found that GPs had a high awareness of the shingles vaccine (81% prompted awareness), however they would like to know more about it to have the confidence to recommend it to patients.

In order to be more confident GPs need:

- More information about the vaccine – particularly efficacy and safety.
- To know the vaccine is free.
- GP specific information materials on the vaccine and who is eligible.
- Information materials to provide to patients.
- Advice on appropriateness and logistics of co-administering with the flu and other vaccines.

Any misconceptions, including safety and efficacy concerns were addressed by the association with the NIP which is considered a trusted source.

Communication Recommendations

To better understand the communication needs of patients aged 70-79 the research explored messaging, images and secondary sources of information.

The research found that:

- Messages need to highlight the risk, severity and complications.
- Messages need to mention that the vaccine is *"free"* and *"funded by the Australian Government"*.
- Messages should include the eligible age range.
- Messages need to encourage people to speak to their GP.
- Overall, realistic images that portrayed the pain of shingles were the most impactful.
- Lifestyle images did not resonate with the group as they did not add anything to their understanding of the disease.
- Online and digital media was not mentioned in any of the research groups.

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Target Audiences

The target audiences for communication are:

- People aged 69 and 70 years, including people from Culturally and Linguistically Diverse and Aboriginal and Torres Strait Islander backgrounds.
- People aged 71-79 years, including people from Culturally and Linguistically Diverse and Aboriginal and Torres Strait Islander backgrounds – for the catch-up program.
- Health professionals, including aged care workers and carers.

Relevant health professionals:

- General practitioners.
- Vaccination providers.
- Specialist physicians eg geriatricians and rheumatologists.
- Aged care workers.
- Aboriginal and Torres Strait Islander community managed health organisations and Aboriginal Health Practitioners.
- Stakeholder groups, such as Primary Health Networks, Australian Medical Association, Community Health Nurses, Australian Practice Nurses Association, and the Royal Australian College of General Practitioners.

Previous Communication Activity

To date no specific communication activity has been undertaken to promote the availability of a shingles vaccine. However, the Department has undertaken a range of communication activities recently to promote other immunisation programs, including vaccines for:

- Seasonal influenza.
- Measles, Mumps Rubella, Varicella (MMRV).
- Pneumococcal .
- Pertussis (whooping cough).
- Human Papillomavirus.

Communication activities to support these programs include information materials such as fact sheets, posters and brochures, along with digital tools such as web badges and social media support.

Objectives

The overall objective is to encourage participation in the program and inform target audiences about the catch-up program.

Therefore, the objectives the communication activities are:

Awareness

- To increase awareness that the shingles vaccine will be available from November 2016 under the National Immunisation Program (NIP).
- To increase awareness that there will be a five year catch-up program for people aged 71 – 79 years.
- To increase awareness that the vaccine is free, safe and effective.

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Attitudes

- To increase confidence in the vaccine's safety and efficacy.
- To reinforce the importance receiving the appropriate vaccinations as people get older.

Intentions

- To generate an increased intention to participate in the program.

Health Professionals

- As a trusted source of information, to increase confidence in the program and encourage patients to be vaccinated.

Key Messages

Based on research findings, the following key messages should be used, as appropriate, in all information products including factsheets and posters.

Shingles

- Shingles can be painful and debilitating condition.
- It occurs more frequently and tends to be more severe in older people.
- Shingles is a painful skin rash, often with blisters. A shingles rash usually appears on one side of the face or body and lasts for two to four weeks.
- The main symptom of shingles is pain, which can be quite severe.
- Shingles is caused by the same virus that causes chickenpox. If you have had chickenpox, or received the chickenpox vaccine in the past, you are at risk for developing shingles.
- Shingles occurs when the chickenpox virus reactivates later in life. Pain from shingles lesions, called post-herpetic neuralgia, can be very severe and can last a year or more.
- Half of people who live until age 85 will develop shingles.

The Vaccine and the Program

- Free shingles vaccines will be available for 70 year olds from November 2016 under the NIP.
- There will also be a five year catch-up program for people aged 71 – 79 years which will cease in 2021-22.
- People aged 69 years can plan for the shingles vaccine with their doctor.
- The vaccine is safe and effective.
- Talk with your GP or vaccination provider to determine whether you should receive this vaccine.
- Vaccines will be available from GPs and other vaccination providers e.g. nurses at local councils and community based clinics.
- The shingles vaccine does not protect everyone, so some people who get the vaccine may still get shingles.
- The shingles vaccine is effective for at least six years but may last longer; research is being done in this area.
- You should not get the shingles vaccine if you are allergic to any of its ingredients, including gelatin or neomycin, have a severely weakened immune system or take high doses of steroids.

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Vaccination, Safety and Efficacy

- The need for vaccination does not end in childhood. Vaccines are recommended throughout our lives based on health conditions, age, lifestyle, occupation and locations of travel.
- Vaccines are thoroughly tested before licensing and carefully monitored even after they are licensed to ensure that they are very safe.
- Zostavax is recommended and safe for most people aged 70-80, including those people with chronic diseases. A few people may be unable to have Zostavax, please see your vaccination provider for advice.
- Like any medicine, this vaccine can cause side effects (usually minor and temporary), but their impact is less than having Shingles. The risk of serious side effects is extremely low.
- It is important that you report any adverse events or side effects.

Health Professionals

- You have a key role in increasing the uptake of the shingles vaccine by taking the opportunity to make your eligible patients aware of this important vaccine, including the catch-up program.
- Based on a large study (Shingles Prevention Study) among 38, 546 adults aged 60 years or older found that Zostavax® reduced the risk of shingles by 51.3 % and the risk of post-herpetic neuralgia by 66.6 %.
- Zostavax is safe for most older people with existing chronic disease (arthritis, hypertension, chronic renal failure, diabetes and other similar conditions) who may be taking medications.
- The shingles vaccine recommendations in the Immunisation Handbook 10th edition were updated in 2015. It is important you access the online version of the Handbook for the current information.
- Zostavax® is safe and generally well tolerated. The most common mild side effects include, redness, soreness, swelling, or itching at the site of the injection.
- Shingles vaccine can be administered at the same time when patients are called for the seasonal influenza vaccine and/or 23-valent pneumococcal polysaccharide vaccine (PPV).
- If given at the same time as influenza vaccinations, care should be taken to ensure that the appropriate route of injection is used for each vaccination.
- Please note that Zostavax® should be administered via the subcutaneous route only.
- Additionally, given that some individuals eligible for seasonal influenza vaccination may be immunosuppressed, it is important to check that there are no contraindications to administering the live Zostavax® vaccine to these clinical risk groups.
- The Australian Childhood Immunisation Register will be expanded to become the Australian Immunisation Register (AIR) by 1 September 2016, prior to the roll-out of the National Shingles Program. All vaccinations should be reported to the AIR. If you are not using the appropriate software please report the vaccination directly to the AIR.
- Adverse events following immunisation should be reported through the usual reporting mechanisms in your state/territory or to the TGA through the 'report a problem' link via its website at www.tga.gov.au
- Those who are not eligible to receive the vaccine as part of the program, can purchase it on the private market.

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Strategic Rationale

Research supports a strategic approach that focuses on information-based, below-the-line communication efforts. Patients in the target audience are heavily influenced by their GP when it comes to making decisions about their health, including vaccination. This reliance on a health professional's recommendation – a traditional source of health information - also suggests that more traditional communication channels will be the most effective. GPs have also clearly indicated a desire to receive information they can provide to their patients.

Therefore, it is proposed that the communication activity focus primarily on delivery of information to health professionals via key mail outs with other information residing online and being made available electronically through stakeholder networks. All materials will focus on promoting who is eligible for the free vaccine and the safety and benefits of the vaccine.

Although not heavily used by the target audience, social media also has a place in providing secondary support to promote messages to patients via intermediaries such as their children, media and health professionals. A social media strategy will engage media and consumers with some additional targeted messaging aimed at health professionals.

A suite of information materials will be developed to support this approach. These materials use a simple, clear and visual style which reflect research recommendations, include the appropriate key messages and can be adapted for target audiences. All materials will focus on promoting who is eligible for the free vaccine and the safety and benefits of the vaccine.

CALD and Aboriginal and Torres Strait Islander audiences
Specialist agencies should be engaged to assist in the design and delivery of materials suitable for Aboriginal and Torres Strait Islander people and people from Culturally and Linguistically Diverse backgrounds. Their role will be to assist in ensuring communication elements are appropriate, translated or adapted and provide some assistance in ensuring effective distribution methods are used to reach these audiences.

Adaptations and appropriate communication channels will be undertaken based on strategic advice from these organisations.

Communication Approach

The communication mix will combine traditional communication efforts, such as Public Relations, editorial and targeted information materials, with online and social media efforts.
Targeted resources will also be developed, where appropriate, for ATSI and CALD audiences.

A review of the images available in the immunisation photo library should be conducted to determine if additional images are required.

Immunise Australia Website
The Immunise Australia website will be the main source of information for consumers and health professionals, in line with the Australian Government's commitment to the provision of information and services online. The website aims to increase national awareness of the Program by providing information to the general public and health professionals on the free vaccination programmes and communicating information about immunisation.

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It is a trusted source for health professionals and consumers.

Information Materials

Printed Materials

Given the age of target audience (69-79) and their preference for traditional communication material and channels means that some printed material must be produced. Specifics of what should be produced can be found at **Attachment A**.

Research indicates that people aged 70-79 rely heavily on the recommendation of a health professional and actively seek information from them. This material should include:

- Brochure.
- Fact sheets.
- Poster.
- Updated NIP schedule card for health professionals.

Given the target audience's reliance on health professionals for medical information – and their willingness to receive this material from their doctor - these should be distributed to immunisation providers to assist with discussions about the shingles vaccine. Aged care providers will also receive this information.

Consideration should also be given to the production of information material such as a poster, flyer or abridged version of the NIP that brings together the vaccinations people aged over 65 are eligible for – seasonal flu, pneumococcal and shingles. The focus would be on the importance of vaccination as people get older.

Online Information Materials

The communication material will include posters and fact sheets for consumers. They will be printed, but also made available as an online information kit through the Immunise Australia website.

In addition to preparing online information materials, it is important to use key partners to ensure messages reach consumers. These include the NIC members, immunisation providers, and Public Health Networks and peak bodies (e.g.: Australian Practice Nurse Association, AMA, RACGP) through the GP Roundtable.

Online materials should include items health professionals and stakeholders can use on their digital platforms such as websites and social media. Communication tools such as web badges and infographics would be appropriate in this context.

Digital Marketing

A proactive social media approach will further extend the reach of key messages via intermediaries. We know from experience that social media is heavily used but the volume of traffic through these channels means competition to have messages heard is high. To cut through, content must be relevant, targeted, interesting, conversational and engaging.

Twitter

A series of tweets for the target audiences will be prepared for dissemination via the department's Twitter account. The content of tweets would be a mix of key messages, images, and infographics.

Note: The department's Twitter account is a broadcast-only medium. The department tweets health related information and links but does not engage with followers or participate in

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discussions, except where this activity has been agreed with the program area, Communication Branch Executive and the Media Unit.

If a user makes an enquiry via the department's Twitter account (by mentioning the department's account – @healthgovau – in their tweet) the Digital Marketing Unit will either respond with a request for the user to email enquiries@health.gov.au, or they will take no action. In either case, the Digital Marketing Unit will provide details of the enquiry to the relevant program area for information.

Digital Media Kit
To further focus attention on its online resources, the department will develop a digital media information kit. This kit will include:

- Shareable graphics for Twitter and Facebook.
- Twitter badges.
- Key information and messages.
- Suggested tweets or a request to share the department's tweets.
- A web badge which can be used by states and territories and stakeholders to drive consumers and health professionals from their sites to the Immunise Australia website for information.
- Electronic copies of information materials – poster, fact sheets.

Prezi Video
Prezi is interactive presentation software that brings ideas to life and is now being used across Australian Government departments to explain policy or programmes in a clear and entertaining format.

A Prezi video will be produced which highlights key messages and people who are eligible for the free vaccine. Prezi videos can be produced cheaply and quickly and uploaded to the Immunise Australia website, the department's YouTube channel and be offered to other websites (other Government accounts, states and territories and stakeholders) to host and could also be aired digitally in Centrelink/Medicare/local shopfront Service Centres.

The link to the Prezi could be made available from #healthau twitter account to raise awareness. The prezi should also be distributed through stakeholder networks, immunisation committees and state and territory government counterparts.

Media Strategy
A media release will be drafted and discussions will be held with the Minister's Office about potential announcements. Media releases are also tweeted via the department's twitter account.

A Question and Answers (Q&A) document will be drafted addressing any potential issues which may arise following announcement or communication about the start date.

Indigenous Audiences
To support effective communication in Aboriginal and Torres Strait Islander communities, materials and messages developed for mainstream communication will be adapted for Aboriginal and Torres Strait Islander audiences (outlined above).

Culturally appropriate resources will be developed to provide information on shingles vaccine including a poster, a consumer factsheet and a letter from the CMO. These materials can be distributed via Indigenous stakeholders and immunisation providers. Specialist expertise will be sought to ensure that materials are appropriate.

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An A3 poster (printable in either A3 or A4 for the web) aimed at increasing awareness of the free vaccine to will be distributed to Aboriginal and Torres Strait Islander communities through Aboriginal Medical Services, the Aboriginal and Torres Strait Islander coordinator at the National Centre for Immunisation Research and Surveillance, the National Aboriginal Torres Strait Islander Immunisation Network (NATSIIN) and other community providers working in or with Aboriginal and Torres Strait Islander communities.

Culturally and Linguistically Diverse Audiences
Expert advice will be sought to ensure that the materials produced are culturally appropriate. The Department will also seek advice on appropriate translations and distribution mechanisms.

Health Professionals
Research indicates that health professionals want more technical information about the shingles vaccine, particularly its safety, efficacy and how it should be administered. Therefore, the communication approach for health professionals will focus on provision of key information via direct mail.

Research also suggests that health professionals wish to receive consumer information to assist with discussions with patients. Therefore patient information will also be provided as outlined above.

A letter from the CMO and relevant information materials will be distributed in hard copy and include information emphasising the key messages. This correspondence will be distributed to GPs and other vaccination providers, using Medicare Benefits Division (GPs, geriatricians and rheumatologists), ACIR (other immunisation providers) and aged care provider mailing lists.

Key stakeholders and peak associations will also be approached to assist with distribution electronically via email networks and other digital platforms.

Roles and Responsibilities

This project will be led by the Immunisation Branch in the Office of Health Protection. The Communication Branch in the Chief Operating Officer Group within the department will be engaged to assist with the development and implementation of the communication strategy.

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Attachment A - Communication Materials

The following products will be developed for the 2016 National Shingles Vaccine Program. Note: all dates are subject to vaccine supply and negotiation with States and Territories.

Product	Rollout
A printed letter from the Chief Medical Officer Health professionals (GPs and other vaccination providers, relevant specialists, Aboriginal and Torres Strait Islander health services (approx. 40,000))., and residential aged care services (approx. 5,000) The letter will include two A3 printed posters targeting mainstream and Aboriginal and Torres Strait Islander consumers (see below), and the fact sheet for health professionals (see below). Immunisation Branch will provide content and source mailing lists.	End Sept 2016
An A3 poster targeted at mainstream consumers, available to download from the Immunise Australia website. Approx. 45,000 will be printed to include in the mail out to health professionals. **An A3 poster targeted at Aboriginal and Torres Strait Islander consumers**, available to download from the Immunise Australia website. Approx. 45,000 will be printed to include in the mail out to health professionals.	End Sept 2016
A fact sheet for health professionals, available to download from the Immunise Australia website. Approx. 45,000 will be printed to include in the mail out to health professionals.	End Sept 2016
A brochure for mainstream consumers, available to download from the Immunise Australia website. Approx. 45,000 will be printed to include in the mail out to health professionals. The consumers' **brochure (above) translated into 13 languages**, available to download from the Immunise Australia website.	End Sept 2016
A brochure for Aboriginal and Torres Strait Islander consumers, available to order online from the Immunise Australia website.	End Sept 2016
Twitter campaign using the department's twitter channel, and engagement with key websites and blogs	End Sept and throughout the rest of the year
Pinterest - pin board on the Health Pintrest board throughout the rest of the year **YouTube Prezi video**, through the Department of Health's YouTube channel, and available for other departments to use in public spaces. **Infographics**, available on request. **Web badge**, available on request. The social media elements, i.e. the twitter campaign and the Pintrest board, will comply with departmental social media guidelines and should have the support and participation of relevant department executives.	End Sept 2016 and

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Attachment B - Indicative Budget and Timeframes

The budget requirements for communication will include design, expert advice, translation, print and distribution of information materials (brochure, poster, fact sheets, letters to vaccination providers, aged care facilities and AMSs) for mainstream, Aboriginal and Torres Strait Islander and CALD audiences.

Element	Description and quantity	Timing	Estimate (inc GST)
EXPERT ADVICE	Engagement of expert Indigenous and CALD organisations to ensure appropriate design, translations and distribution mechanisms are considered	May/June2016	$45,000 CALD $45,000 ATSI
DESIGN AND TYPESETTING	**Poster-** Design of a mainstream poster	Communications Branch - mid June 2016. Immunisation Programs Section - send to NIC (out of session) in June. Advice to Communications Branch in end June Communications Branch - Chosen design implemented and remaining materials designed and approved early July 2016	$10,000
	Poster- Design of Indigenous poster		
	Brochures- Four similar brochures: mainstream consumers, translated mainstream, Indigenous consumers	Communications Branch –July 2016	
	Fact sheet- Design of health professionals factsheet	Communications Branch – July 2016	
	Digital resources - infographics, Twitter badge, and web badge	Communications Branch – July 2016	
	Design alternation- existing NIP schedule	Communications Branch – August 2016	
PRINTING (FULL COLOUR)	Consumer brochure (70 and 71-79 year olds) 100,000 PRINTED & ONLINE	Communications Branch - Completed by September 2016	$20,000
	Fact sheet for vaccination providers – 45,000 PRINTED & ONLINE		$6,000
	Poster- mainstream 45,000 PRINTED & ONLINE		$4,200
	Poster - Aboriginal and Torres Strait Islander audience 45,000 PRINTED & ONLINE		$4,200
NIP schedule 45,000 PRINTED & ONLINE			$5,100
Indigenous Brochure ONLINE			

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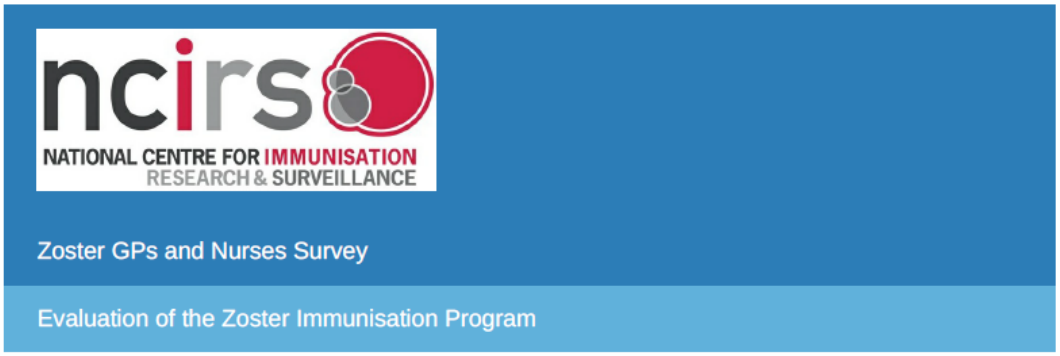
PRINTING AND MAILING	Letter from CMO to vaccination providers 40, 000 PRINTED	Immunisation Programs Section (National Mail and Marketing - NMM) – prior to commencement of the programme End Sept/early Oct 2016	$1,600
	Letter from CMO or CNO to aged care facilities- 5000 PRINTED	Immunisation Programmes Section (National Mail and Marketing - NMM) – prior to commencement of the programme End Sept/early Oct 2016	$800
	Pack for immunisation providers, including: • letter to vaccination providers • fact sheet vaccination providers • brochure mainstream x 2 (of same brochure) in each letter • mainstream poster (a3 size, to be folded) • Aboriginal and Torres Strait Island poster (a3 size, to be folded) • NIP schedule card • printed enveloped 40,000 PACKS	Immunisation Programmes Section (National Mail and Marketing - NMM) – prior to commencement of the programme End Sept/early Oct 2016	$70,000
	Pack for aged care providers, including: • covering letter to providers • fact sheet health professionals • brochure mainstream x 2 (of same brochure) in each letter • mainstream poster (A3 size, to be folded) • Aboriginal and Torres Strait Island poster (a3 size, to be folded) • printed enveloped 5000 PACKS SOURCE: AIHW RESIDENTIAL AGED CARE FACILITIES JUNE 2011)	Immunisation Programmes Section (National Mail and Marketing - NMM) – prior to commencement of the programme End Sept/early Oct 2016	$20,000
TRANSLATION	Translation of consumer mainstream brochure into 13 languages ONLINE	Communications Branch – July 2016	$6,000
BANNER	Banner for use at conferences- 2m tall 4 BANNERS	Communications Branch - July 2016	$1,500
PREZI VIDEO	Development and production of a Prezi video	Communications Branch - procurement July. 2015 - development July-Aug 2015 TOTAL$249,400	$10,00

Appendix G – GP and Nurses Survey



- The National Centre for Immunisation Research and Surveillance (NCIRS) is currently undertaking an evaluation of the National Shingles Vaccination Program
- We will be asking you questions to evaluate the National Shingles Vaccination Program and the results will be provided to the Australian Government and the National Immunisation Committee (NIC) to inform future national vaccination programs
- This survey is voluntary, anonymous and confidential.

* 1. Occupation

- ◯ GP
- ◯ Aged care nurse
- ◯ Practice Nurse
- ◯ Other (please specify)

* 2. Your age group

- ☐ 25-34
- ☐ 55-64
- ☐ ≥85
- ☐ 35-44
- ☐ 65-74
- ☐ 45-54
- ☐ 75-84

* 3. Gender

- ◯ M ◯ F

* 4. In which state is your practice located?

- ◯ NSW
- ◯ QLD
- ◯ VIC
- ◯ ACT
- ◯ SA
- ◯ WA
- ◯ NT
- ◯ TAS

5. The post code of your practice is

* 6. Type of practice?

- Private, independent solo practice
- Private, independent group practice (5-9 GPs)
- Hospital-based clinic
- Private, independent group practice (2-4 GPs)
- Private, independent group practice (≥10 GPs)
- Aboriginal Medical Service (AMS)
- Other (please specify)

* 7. Do you provide medical services to aged care facilities?

- Yes
- No

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Zoster GPs and Nurses Survey

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8. How many aged care facilities do you attend on a regular basis?

- 1-2
- 5-9
- 3-4
- ≥10

9. Approximately, how many times per month have you ordered/given the zoster vaccine to aged care residents since November 2016?

- ◯ 1-2
- ◯ 5-9
- ◯ 3-4
- ◯ ≥10

10. Are you satisfied that most residents in the aged care facilities that you attend are receiving the zoster vaccine?

- ◯ Yes
- ◯ No (please specify)

11. Since the program roll out in November 2016, I have ….

	Very Frequently (Most days)	Frequently (Weekly)	Rarely (Monthly or less)	Never
Administered the zoster vaccine to eligible people	◯	◯	◯	◯
Advised people that the zoster vaccine is free for people aged 70 years	◯	◯	◯	◯

	Very Frequently (Most days)	Frequently (Weekly)	Rarely (Monthly or less)	Never
Advised people that the zoster vaccine is offered free as a catch up dose for those aged 71 to 79 years	○	○	○	○
Seen patients with shingles at my practice	○	○	○	○
Treated patients with post herpetic neuralgia (PHN)/chronic shingles pain	○	○	○	○
Referred people with shingles or PHN to a specialist for treatment	○	○	○	○
Received referral of a person from a specialist for zoster vaccination	○	○	○	○
Encountered a person who refused to be vaccinated with the zoster vaccine	○	○	○	○
Observed a patient with a mild adverse event after zoster vaccination	○	○	○	○
Observed a person with a severe adverse reaction to the zoster vaccine, such as anaphylaxis	○	○	○	○
Had people express concerns about safety of the zoster vaccine	○	○	○	○
Reported my patients' zoster vaccination data to the Australian Immunisation Register (AIR)	○	○	○	○
Had to dispose of zoster vaccine stocks due to cold chain breach	○	○	○	○
Had my patients ask me: "If I had the chickenpox vaccine, am I protected against shingles?"	○	○	○	○

12. Did you collaborate with any other organisations/stakeholders in your implementation of the zoster immunisation program? (please comment)

13. In general terms who should not be given the live zoster vaccine?

14. What questions do your patients ask you regarding zoster vaccine?

15. The zoster vaccine is registered for use in which adult age groups?

	Yes	No	Don't know
50 to 59 years	◯	◯	◯
60 to 69 years	◯	◯	◯
70 to 79 years	◯	◯	◯
≥80	◯	◯	◯

16. The zoster vaccine is recommended for use in which adult age groups?

	Yes	No	Don't know
50 to 59 years	◯	◯	◯
60 to 69 years	◯	◯	◯
70 to 79 years	◯	◯	◯
≥80	◯	◯	◯

17. The zoster vaccine is funded for use in which adult age groups?

	Yes	No	Don't know
50 to 59 years	◯	◯	◯
60 to 69 years	◯	◯	◯
70 to 79 years	◯	◯	◯
≥80	◯	◯	◯

18. Please give your response to the following:

	Yes	**No**	**Don't know**
Immunocompromised people should not receive the zoster vaccine	◯	◯	◯
The zoster vaccine is effective as a treatment at the onset of acute shingles	◯	◯	◯
Eligible people could receive the zoster vaccine with their influenza or pneumococcal vaccine	◯	◯	◯
People aged over 50 years should receive the zoster vaccine annually	◯	◯	◯
The varicella (chickenpox) vaccine could also be used to prevent shingles in older people	◯	◯	◯
A person with acute shingles should wait at least 12 months before receiving the zoster vaccine	◯	◯	◯
Most of my patients are aware of the free shingles vaccine	◯	◯	◯

19. Since the program roll out in November 2016, have you seen any of the "Protect Yourself Against Shingles" information resources below:
(Click the link below)

	Not seen	Seen	Displayed in my practice	Distributed to patients
Brochure	○	○	○	○
Brochure-Aboriginal and Torres Strait Islander	○	○	○	○
Brochure-non-English	○	○	○	○
Fact Sheet for providers	○	○	○	○
Poster	○	○	○	○
Poster – Aboriginal and Torres Strait Islander	○	○	○	○

How could we improve these resources? (please specify)

20. Did you receive any information from other sources about the National Shingles Vaccination Program? (Please specify)

21. Do you have any feedback about strengths of the rollout of the National Shingles Vaccination Program

22. Do you have any feedback about challenges/barriers to the rollout of the National Shingles Vaccination program?

23. **Do you have any recommendations?**

24. **Please enter your mobile number to enter the prize draw (this is optional)**

Appendix H – Consumer CATI Survey

Consumer Survey

- The National Centre for Immunisation Research and Surveillance (NCIRS) is currently undertaking an evaluation of the National Shingles Vaccination Program.
- We will be asking you questions to evaluate the National Shingles Vaccination Program and the results will be provided to the Australian Government and the National Immunisation Committee (NIC) to inform future national vaccination programs.
- This survey is anonymous, voluntary and confidential.
- Your name will not be included in this survey.

- **Age Group** 50-60☐ 60-70☐ 70-75☐ 75-80☐ 80+☐
- **Gender**: Male ☐ Female ☐
- **Nationality/Cultural Background**:
- **Are you Aboriginal and/or Torres Strait Islander** Yes ☐ No☐
- **Are you on:** ☐Medicare ☐Private health insurance
- **What is the highest level of education you have achieved?**

☐Completed Primary school ☐Completed Year 10 ☐Completed Year 12
☐TAFE/Trade College ☐College Degree/ University ☐Postgraduate Degree

- **Are you:** ☐Retired ☐Working full Time ☐Working Part Time ☐Working Casually ☐Self-employed ☐Running own business
- **Do you have any chronic illnesses?** ☐Yes ☐No
- **If Yes, you may tick more than one answer below**

☐Diabetes ☐Heart Disease ☐High Blood Pressure ☐Lung Disease (e.g. asthma) ☐Cancer ☐Kidney/Bladder Disease ☐Immunosuppressive Conditions (e.g. transplant recipient) ☐Other (please specify)……

- **Do you take any prescribed medications?** ☐No ☐Yes (please specify)……
- **Have you heard about the medical condition shingles?** ☐No ☐Yes

Internal Use Only

Consumer	Participant Affiliation	Interviewer	Date	Record number

To what extent do you Agree or Disagree with the following:	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Shingles causes a mild rash but is not a serious disease	☐	☐	☐	☐	☐
Shingles is caused by the same virus that causes chickenpox	☐	☐	☐	☐	☐
People with shingles get severe pain with their rash and sometimes the pain remains after the rash is gone	☐	☐	☐	☐	☐
The risk of shingles reduces with age. Older people are less likely to get it.	☐	☐	☐	☐	☐
Shingles vaccine is free for people aged 70 years old	☐	☐	☐	☐	☐
People aged 71-79 years can also get the shingles vaccine for free	☐	☐	☐	☐	☐
Shingles vaccine can be given by my GP	☐	☐	☐	☐	☐
If you have ever had chickenpox you are at risk of getting shingles	☐	☐	☐	☐	☐
Shingles vaccine is safe for most people	☐	☐	☐	☐	☐
Shingles is contagious when a person has open blisters and can result in chickenpox	☐	☐	☐	☐	☐
People who have had shingles should wait at least a year before they get the shingles vaccine	☐	☐	☐	☐	☐
People with a weak immune system should not receive the shingles vaccine	☐	☐	☐	☐	☐
Shingles vaccine cannot be used to treat shingles; shingles vaccine is only used to reduce your risk of getting shingles	☐	☐	☐	☐	☐
Currently a person only needs one dose of shingles vaccine	☐	☐	☐	☐	☐
Older people can receive shingles vaccine with their flu or pneumococcal vaccine	☐	☐	☐	☐	☐
Shingles vaccine may cause some side effects such as redness, swelling or pain at the injection site	☐	☐	☐	☐	☐
Household members of a person with shingles should also be given the shingles vaccine	☐	☐	☐	☐	☐
Shingles vaccine is not recommended for people under the age of 50 years	☐	☐	☐	☐	☐

Could you please answer the following -	Yes	No
Before today, were you aware of the shingles vaccine?	☐	☐
Have you ever had chickenpox?	☐	☐
Have you ever had shingles?	☐	☐
Have you been recommended the shingles vaccine by your GP?	☐	☐
Have you received the shingles vaccine?	☐	☐
If you have not had the shingles vaccine, do you intend to	☐	☐

receive it in the near future?		
Are you aware of anyone in your family ever having shingles?	☐	☐
Have you seen any information about the shingles vaccine?	☐	☐
Have you seen the "Protect yourself against shingles" poster?	☐	☐
Have you seen the "Protect yourself against shingles" brochure?	☐	☐
Do you have any concerns about the shingles vaccine safety? If yes, please comment:	☐	☐
Do you have any concerns about the shingles vaccine effectiveness? If yes, please comment:	☐	☐
I had difficulty finding out about the shingles vaccine If yes, please comment:	☐	☐
I had difficulty receiving the vaccine from my GP If yes, please comment:	☐	☐
Please add your comment on the difficulties		

Are any of these statements true for you? *(you can choose more than one answer)*	
I do not think of myself being at risk of having shingles Comment:	☐
I find it difficult to go to the doctor for vaccinations Comment:	☐
In general, I am opposed to vaccinations Comment:	☐
I think that the shingles vaccination is not very effective Comment:	☐
I fear the possible side effects of the shingles vaccine Comment:	☐
I do not think that shingles is a particularly harmful illness Comment:	☐
My doctor has recommended the shingles vaccine for me	☐
I'm not sure if I can afford the shingles vaccine	☐

This is the end of the survey

Thank you for completing the survey