# Zostavax update

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SAEFVIC

Clinical Vaccinology Update

Monday 7th December 2020



# Overview

- Disease and epidemiology
- Zostavax vaccine
- AEFI reporting (Power BI)
  - Error/Administration in immunocompromising condition
- Case studies
- Alerts
- What are we doing
  - Education
  - Melbourne Vaccine Education Centre (MVEC)
- Take home message

# SAEFVIC
## Surveillance of Adverse Events Following Vaccination in the Community

- Specialist service established in 2007
- Monitoring of adverse events (passive surveillance) in adults and children
- Individualised clinical assistance for patients and families affected by an AEFI
  - Paediatric & Adult Clinics
  - Referral to specialist allergy clinics as required
  - Supervised admissions
  - Telehealth
- Maintaining the confidence of general public and immunisation providers in the national immunisation program.
- Reports sent to ADRS who advise TGA
- Any trends are notified and investigated quickly, with close liaison with Victorian and National Health Authorities

# Herpes Zoster - Disease and epidemiology

- Herpes zoster (Shingles), is a reactivation of the varicella-zoster virus (VZV) in a person who has previously had varicella (chickenpox).

- The virus remains latent in the dorsal root ganglia and typically presents as a unilateral, painful self-limiting vesicular rash with a distinctive dermatomal distribution.

- Postherpetic neuralgia (PHN), a chronic neuropathic pain syndrome is the most common complication of herpes zoster. PHN can last for weeks or months, and occasionally, for years.

- The lifetime risk of reactivation of VZV is about 50% and this risk increases with age. Older people, particularly those aged over 70 years are also more likely to have shingles complicated by PHN.



- https://immunisationhandbook.health.gov.au/vaccine-preventable-diseases/zoster-herpes-zoster

# Zostavax - vaccine

- A live attenuated vaccine against herpes zoster (Zostavax®) was licensed in Australia in 2006.
- The vaccine contains live attenuated varicella-zoster virus. The amount of virus in the zoster vaccine is approximately 14 times greater than in varicella (chickenpox) vaccines.
- The dose of Zostavax is 0.65 mL given by subcutaneous injection.
- Mild injection site reactions such as pain, redness and swelling are likely to occur in approximately 50% of vaccine recipients
- Protection from vaccination tends to decline over time and with older age at vaccination. A booster dose is not currently recommended.
- Shingles cases should still be considered for treatment with antiviral therapy and analgesia, regardless of the patient's immunisation status.

# Zoster - Vaccination

## Who should be vaccinated

- Zostavax® (shingles vaccine) is registered for use in people aged 50 years and over as a single dose. Unless otherwise contraindicated, The Australian Immunisation Handbook recommends a zoster vaccine for all adults 60 years and older who have not previously received a dose.
- Since November 2016, Zostavax® has been funded under the National Immunisation Program for persons aged 70 years, with catch-up for those aged 71–79 years also funded until October 2021.
- Vaccination of people aged 70–79 years is estimated to prevent about 41% of the cases of shingles and two-thirds of post-herpetic neuralgia cases in that population. In vaccinated people in whom an episode of shingles occurs, the pain, severity and duration is reduced by 50%.



## Who should *not* be vaccinated

- People who are immunocompromised, pregnant women, and those who have previously had anaphylaxis to any VZV-containing vaccine or its components should *not* receive the zoster vaccine.

# Zoster

Latest Data Extract

11/29/2020 5:06:31 PM



272

Count of EventId

VaccineName, EventId

Zostavax

NOTES:

Zoster vaccine administered to older persons for prevention of shingles

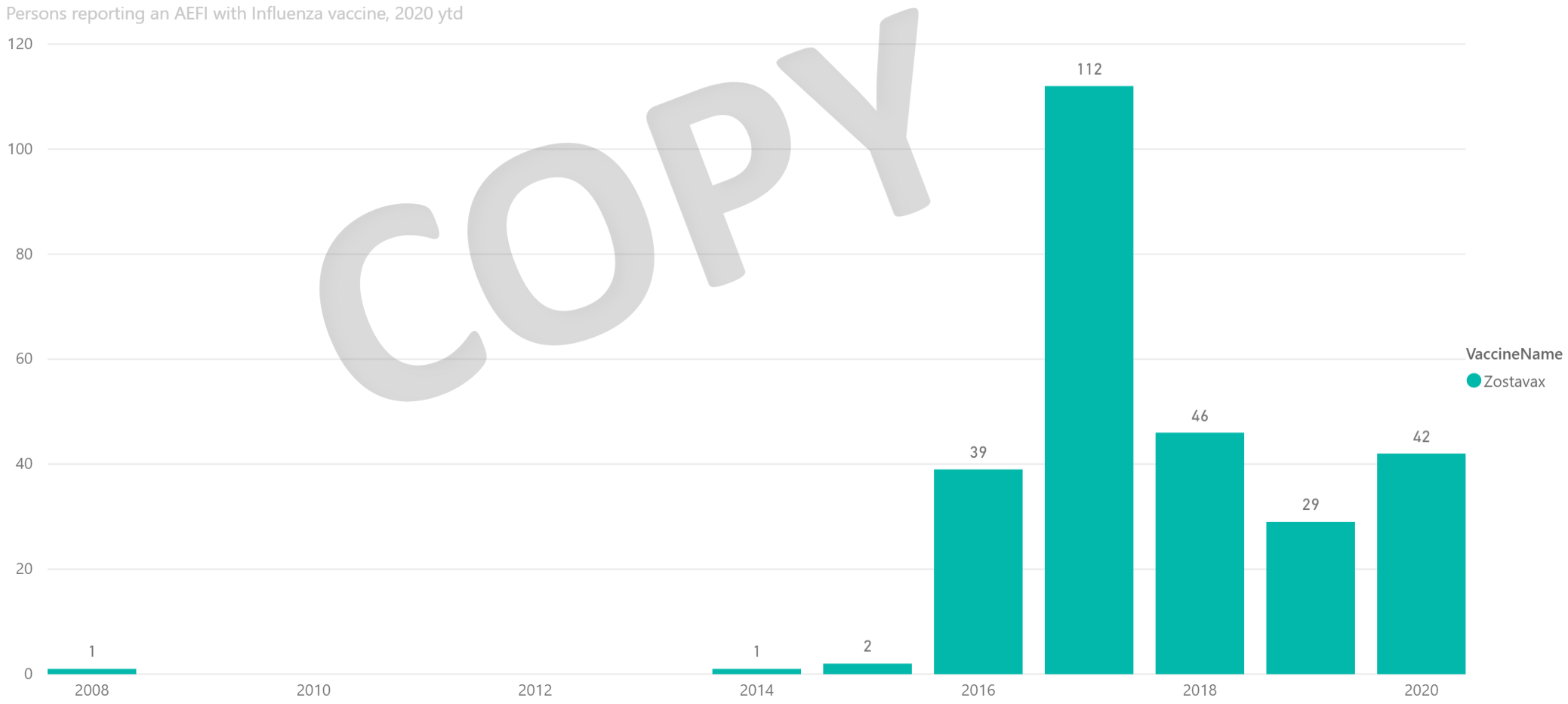
Commenced XXXX

Restricted to Victoria

# Zoster

Year, Quarter,...

- Select all
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017
- 2018
- 2019
- 2020
  - Qtr 1
  - Qtr 2
  - Qtr 3
  - Qtr 4



# Zoster

ReportedDate

2/9/2007 11/27/2020

| Year | Count of EventId |
|---|---|
| | 1 |
| 2007 | 544 |
| 2008 | 842 |
| 2009 | 1127 |
| 2010 | 1056 |
| 2011 | 1104 |
| 2012 | 902 |
| 2013 | 1182 |
| 2014 | 1320 |
| 2015 | 1377 |
| 2016 | 1434 |
| 2017 | 1808 |
| 2018 | 1732 |
| 2019 | 1962 |
| 2020 | 1845 |
| **Total** | **18236** |

| VaccineGroup | Count of EventId |
|---|---|
| Cholera | 3 |
| DTP | 8866 |
| Flu | 3201 |
| HepA | 179 |
| HepB | 4026 |
| Hib | 4893 |
| HPV | 1909 |
| immunoglobulin | 80 |
| JE | 3 |
| Meningococcal | 2030 |
| MMR | 4108 |
| NO VACCINE | 210 |
| Other | 359 |
| Panvax | 359 |
| Pneumococcal | 4729 |
| Polio | 6539 |
| Rotavirus | 3236 |
| TB | 254 |
| Typhoid | 134 |
| Unknown | 6 |
| Varicella | 1809 |
| Yellow Fever | 25 |
| Zoster | 272 |
| **Total** | **18236** |

## Zostavax

| Year | Quarter | Count of EventId |
|---|---|---|
| 2008 | Qtr 2 | 1 |
| 2014 | Qtr 3 | 1 |
| 2015 | Qtr 4 | 2 |
| 2016 | Qtr 2 | 1 |
| 2016 | Qtr 3 | 1 |
| 2016 | Qtr 4 | 37 |
| 2017 | Qtr 1 | 51 |
| 2017 | Qtr 2 | 28 |
| 2017 | Qtr 3 | 24 |
| 2017 | Qtr 4 | 9 |
| 2018 | Qtr 1 | 9 |
| 2018 | Qtr 2 | 14 |
| 2018 | Qtr 3 | 13 |
| 2018 | Qtr 4 | 10 |
| 2019 | Qtr 1 | 8 |
| 2019 | Qtr 2 | 12 |
| 2019 | Qtr 3 | 4 |
| 2019 | Qtr 4 | 5 |
| 2020 | Qtr 1 | 8 |
| 2020 | Qtr 2 | 13 |
| 2020 | Qtr 3 | 14 |
| 2020 | Qtr 4 | 7 |
| **Total** | | **272** |

| DoseNumber | Count of EventId |
|---|---|
| 1 | 202 |
| 2 | 69 |
| 99 | 2 |
| **Total** | **273** |

| BatchNumber | Count of EventId |
|---|---|
| | 76 |
| - | 1 |
| 10171 | 1 |
| 256092C1A | 1 |
| 5018176 | 1 |
| 5034167 | 1 |
| AO18176 | 1 |
| H043345 | 1 |
| M006056 | 2 |
| M029109 | 5 |
| m038137 | 1 |
| M038139 | 6 |
| M039225 | 12 |
| M039226 | 6 |
| M042524 | 1 |
| M042527 | 4 |
| M042528 | 3 |
| M04258 | 1 |
| M042707 | 1 |
| M043345 | 5 |
| M043345 04/18 | 1 |
| M043350 | 2 |
| M045442 | 1 |
| M046454 | 9 |
| m046454 (After 4 days) | 1 |
| M046455 | 5 |
| MO29109 | 1 |
| MO39225 | 1 |
| MO45442 | 1 |
| N001389 | 1 |
| N001402 | 9 |
| **Total** | **273** |

# Zoster

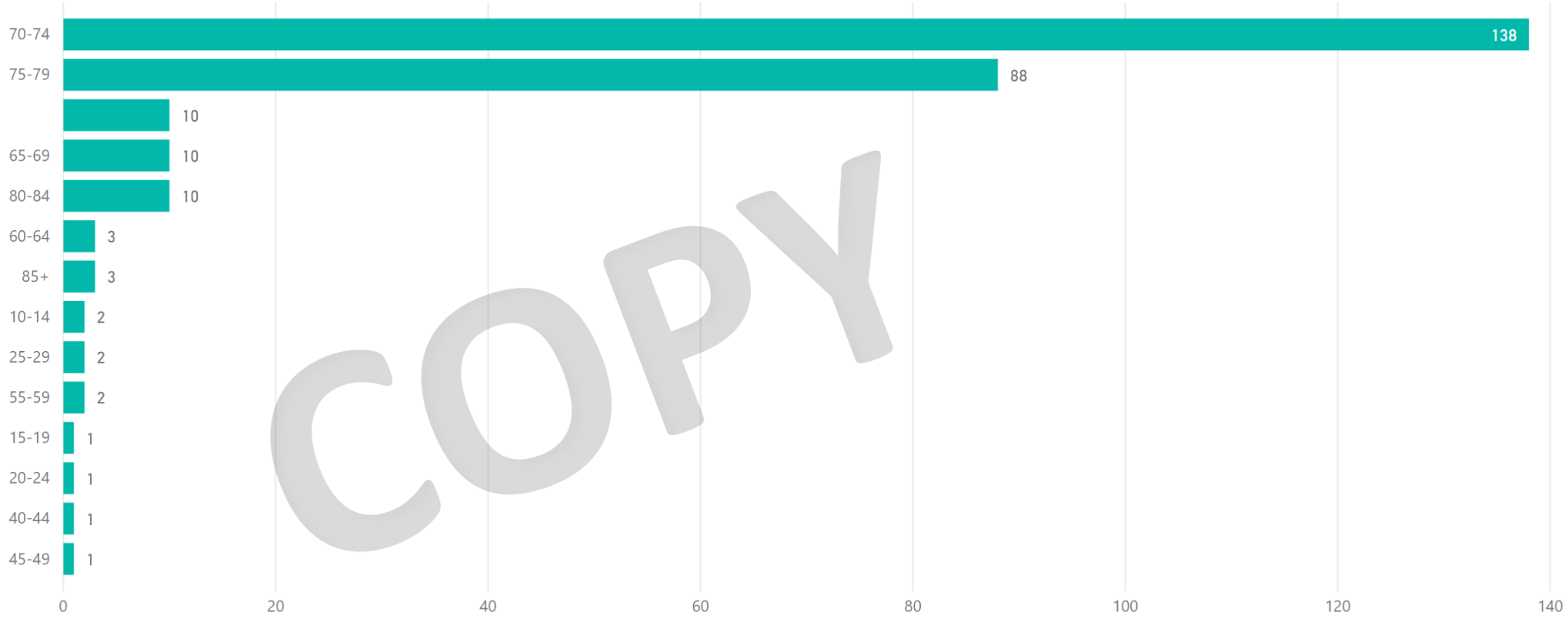
ReportedDate

1/1/2007 2/1/2021

AgeGroup

- [ ] Select all
- [ ]
- [ ] 10-14
- [ ] 15-19
- [ ] 20-24
- [ ] 25-29
- [ ] 40-44
- [ ] 45-49
- [ ] 55-59
- [ ] 60-64
- [ ] 65-69
- [ ] 70-74
- [ ] 75-79
- [ ] 80-84
- [ ] 85+

Count of EventId by AgeGroup






| AgeStage | 2008 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | Total |
|---|---|---|---|---|---|---|---|---|---|
| | | | 2 | 1 | 4 | 3 | | | **10** |
| School-Aged | | | | | 3 | | | | **3** |
| Adults | 1 | 1 | | 2 | 1 | | | 5 | **10** |
| Older Persons | | | | 36 | 104 | 44 | 29 | 37 | **250** |
| **Total** | **1** | **1** | **2** | **39** | **112** | **47** | **29** | **42** | **273** |

Count of EventId by AgeStage

# Zoster

ReportedDate

1/1/2007

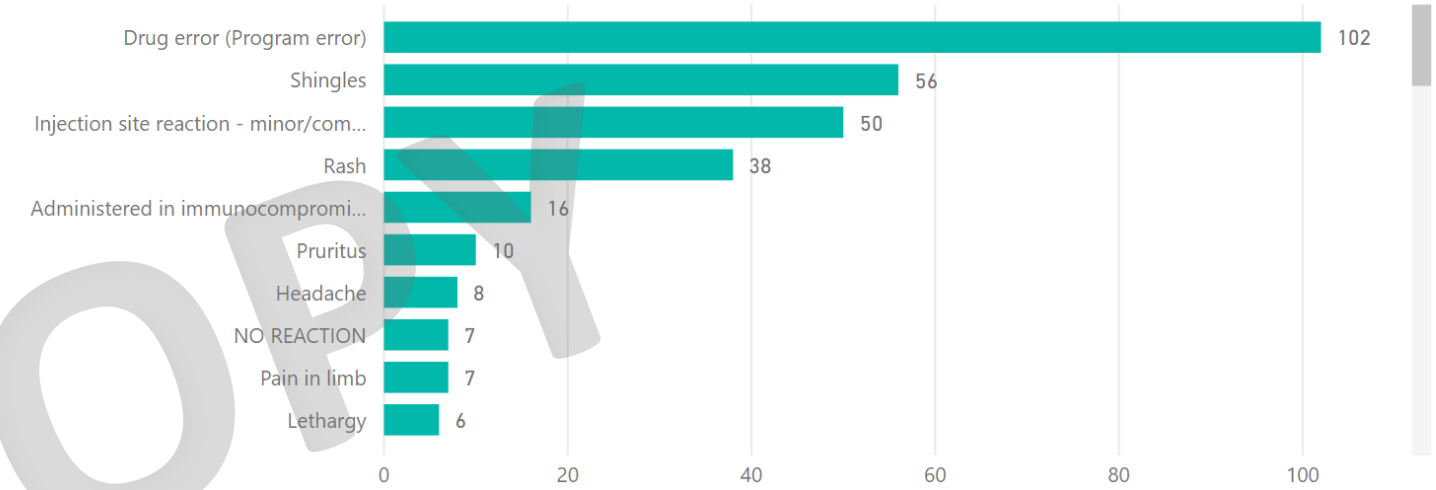
2/1/2021

ReactionName

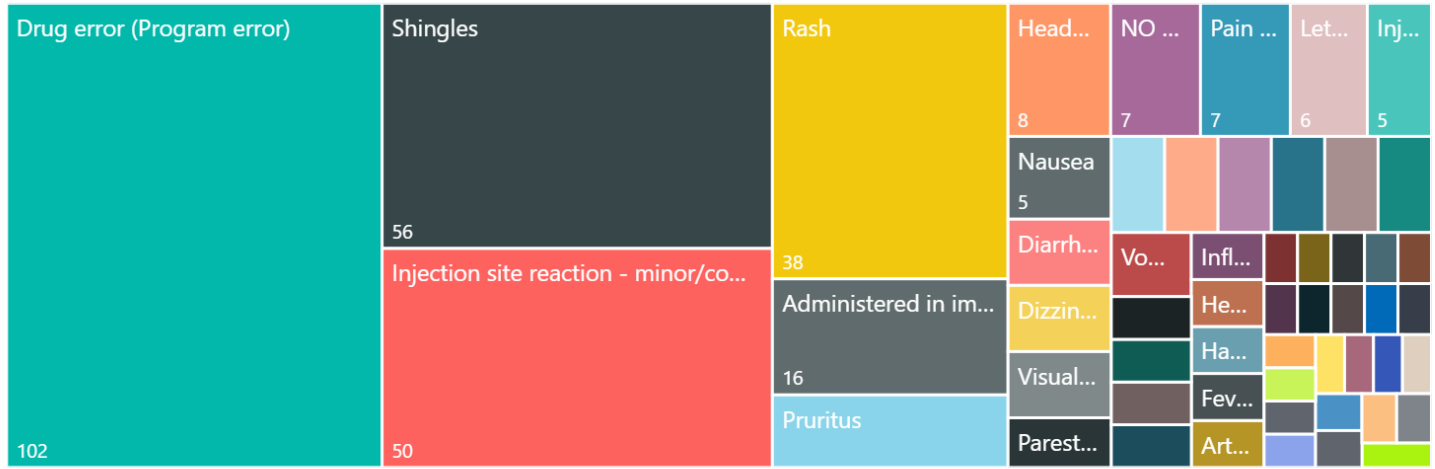
- [ ] Abdominal pain
- [ ] Administered in i...
- [ ] Allergic reaction ...
- [ ] Altered oral sens...
- [ ] Altered sensation
- [ ] Altered throat se...
- [ ] Angioedema
- [ ] Arthralgia
- [ ] Blistering
- [ ] Bursitis
- [ ] Cardiac symptoms
- [ ] Cellulitis at inject...
- [ ] Chickenpox
- [ ] Diarrhoea
- [ ] Dizziness
- [ ] Drug error (Prog...

| ReactionName | Count of EventId |
|---|---|
| Abdominal pain | 1 |
| Administered in immunocompromising condition | 16 |
| Allergic reaction (generalised) | 1 |
| Altered oral sensation | 1 |
| Altered sensation | 1 |
| Altered throat sensation | 1 |
| Angioedema | 3 |
| Arthralgia | 2 |
| Blistering | 3 |
| Bursitis | 1 |
| Cardiac symptoms | 3 |
| Cellulitis at injection site | 3 |
| Chickenpox | 1 |
| Diarrhoea | 4 |
| Dizziness | 4 |
| Drug error (Program error) | 103 |
| Eye discharge | 1 |
| Fever (unspecified) | 2 |
| Granuloma | 1 |
| Haematoma | 2 |
| Headache | 8 |
| Headache (severe) | 1 |
| Hearing loss | 2 |
| Herpes Simplex Virus | 1 |
| Herpes Zoster Ophthalmicus | 1 |
| Influenza-like-illness | 2 |
| Injection site reaction - minor/common/expected | 50 |
| Injection site reaction - severe | 5 |
| Lethargy | 6 |
| Lymphadenopathy | 3 |
| Lymphoma | 1 |
| **Total** | **273** |

Count of EventId by ReactionName




Count of EventId by ReactionName



# Zoster

Year, Quarter, Mo...

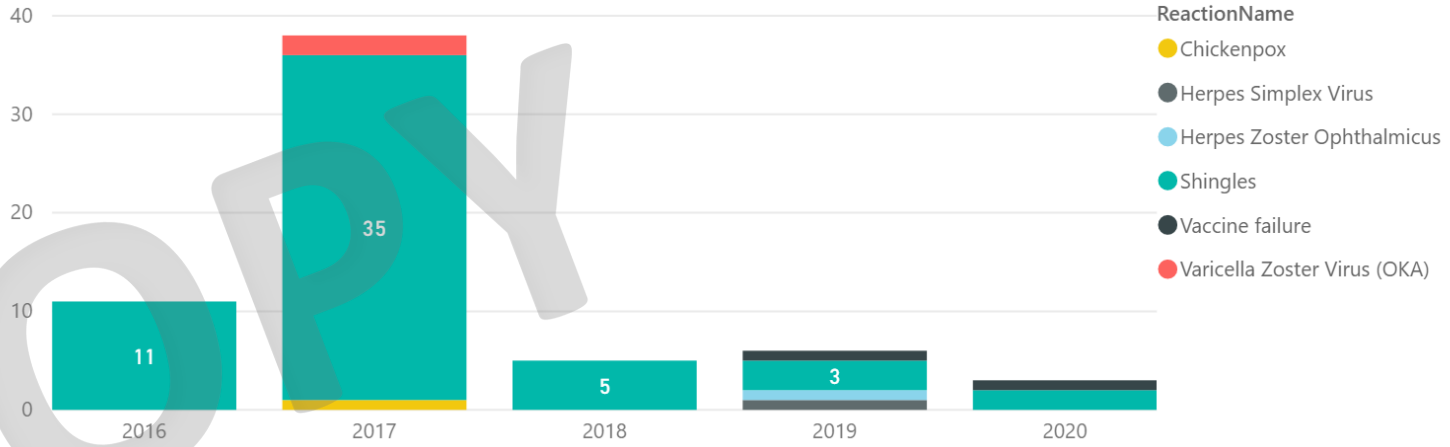
- Select all
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017
- 2018
- 2019
- 2020

**61**

Count of EventId

| ReactionName | 2016 | 2017 | 2018 | 2019 | 2020 | Total |
|---|---|---|---|---|---|---|
| Chickenpox | | 1 | | | | **1** |
| Herpes Simplex Virus | | | | 1 | | **1** |
| Herpes Zoster Ophthalmicus | | | | 1 | | **1** |
| Shingles | 11 | 35 | 5 | 3 | 2 | **56** |
| Vaccine failure | | | | 1 | 1 | **2** |
| Varicella Zoster Virus (OKA) | | 2 | | | | **2** |
| **Total** | **11** | **38** | **5** | **5** | **2** | **61** |

COUNT

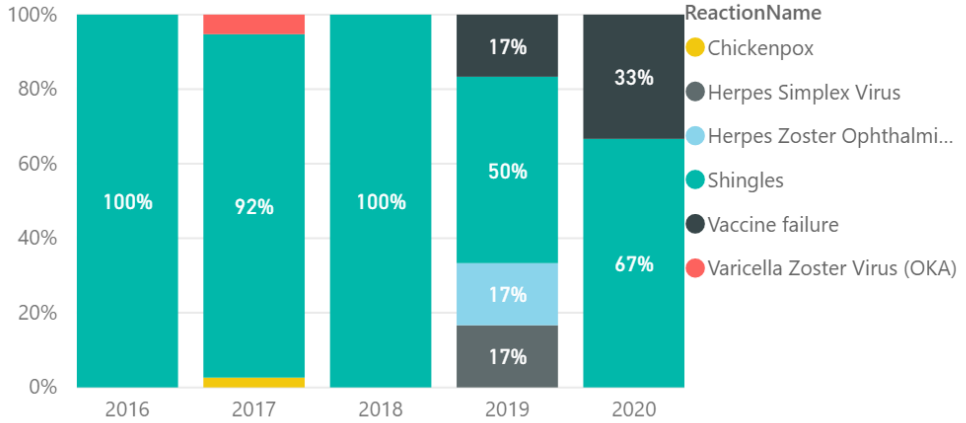



ReactionName

- Abdominal pain
- Administered in immunocompromi...
- Allergic reaction (generalised)
- Altered oral sensation
- Altered sensation
- Altered throat sensation
- Angioedema
- Arthralgia
- Blistering

Count of EventId by ReactionName


PERCENT



# VZV related AEFI

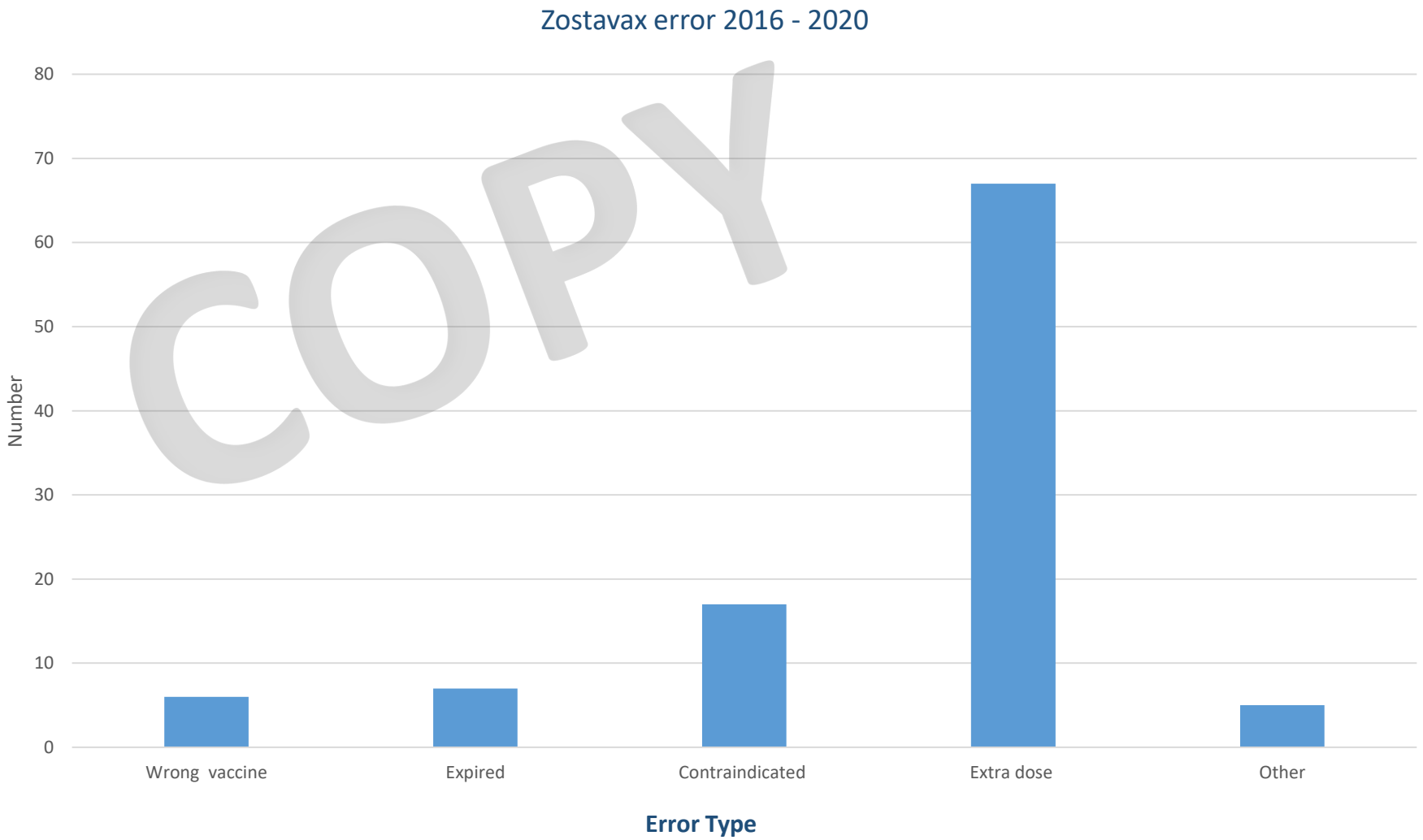
- 61/272  (22%) reports of Varicella virus related AEFI

- **Shingles**
- 56 reports of shingles following a Zostavax® vaccine
- 27/56 (48%) clinically diagnosed (no swab)
- 28/56 (50%) swabbed and 78% positive for varicella zoster virus

- **VZV (OKA)**
- 2 Varicella Zoster Virus (OKA) – vaccine strain
  - PHx CLL (quiescent) 2 weeks following zostavax
  - DHHS notification

# Drug errors related to Zostavax

- Extra dose = 67
- Contraindicated = 17
- Expired vaccine = 7
- Wrong vaccine = 6
- Other = 5




© 2017 Ted Goff
CONGRATULATIONS! YOU HAVE JUST DISCOVERED A COMPLETELY NEW ERROR!
GOFF

# Errors where Zostavax® is contraindicated

- People who are or have recently been immunocompromised due to a medical condition or medical treatment are contraindicated to receive the Varicella Zoster vaccine
- On rare occasions, disseminated varicella-zoster virus (Oka vaccine strain) infection can occur in patients and in severe cases this can lead to death

**Zostavax® administration in contraindicated individuals reported to SAEFVIC from 2016 include:**

- Individuals with Chronic Lymphocytic Leukaemia (CLL)
- Individuals with malignancies on active treatment
- Pregnancy
- Individuals with dermatological conditions on immunosuppressive therapies
- Individuals with rheumatoid arthritis on immunosuppressive therapies

# Why are these errors so concerning?




- Zostavax® administered in an immunocompromised patient with chronic lymphocytic leukemia (CLL)
- No evidence of primary varicella zoster virus (VZV) infection
- Presented to ED twice and treated for URTI
- 22 days after receiving Zostavax® the patient presented with a bilateral vesicular facial rash
- Managed as an outpatient with oral acyclovir
- Re-presented three days later and was diagnosed with disseminated VZV infection complicated by meningoencephalitis
- The patient died following cardiac arrest on day 10 of hospitalisation.

https://pubmed.ncbi.nlm.nih.gov/29807711/

# Zostavax GP decision aid

SAEFVIC

VICTORIA State Government | Health and Human Services

**LIVE SHINGLES VACCINE (Zostavax) SCREENING FOR CONTRAINDICATIONS**

Name:

Date of birth:

**Questions – This section can be completed by the Health Care Provider/Patient/Guardian**
*Note for Patient/Guardian: If you are unsure about an answer, please leave it blank and discuss with your Health Care Provider*

1. Have you ever had a shingles vaccine before? Y/N
*When:*

2. Do you feel unwell today? Y/N
*Details:*

3. Have you had shingles or post herpetic neuralgia (nerve pain following shingles) in the past year? Y/N
*Details:*



**Guide to safe doses of immunosuppressive therapy for Zostavax administration:**

| Mechanism of action | Examples* | Safe dose** | Comments |
|---|---|---|---|
| Anti-TNF | Etanercept<br>Infliximab<br>Adalimumab | NONE | Vaccinate 1 month before treatment initiation **OR** 12 months after treatment cessation |
| IL-1 inhibition | Anakinra | NONE | |
| Costimulation blockade | Abatacept | NONE | |
| B-cell depletion/inhibition | Rituximab | NONE | |
| Immunomodulators (antimetabolites) | Azathioprine<br>6-Mercaptopurine<br>Methotrexate | ≤3.0 mg/kg/day<br>≤1.5 mg/kg/day<br>≤0.4 mg/kg/week | Vaccinate 1 month before treatment initiation **OR** 3 months after treatment cessation |
| Corticosteroids | Prednisone | Any dose when duration <14 days OR <20 mg/day when duration ≥14 days | If ≥20mg/day for ≥14 days, vaccinate 1 month before treatment initiation **OR** 1 month after treatment cessation |
| T-cell activation/inhibition | Tacrolimus<br>Cyclosporine | NONE | Vaccinate 1 month before treatment initiation **OR** 3 months after treatment cessation |
| Others | Cyclophosphamide<br>Mycophenolate | NONE | |

* **NOTE:** This is not a complete list of all licensed biologics, or medications within each class, but serves as a guide only.
** Refer to *The Australian Immunisation Handbook* 10th edition, Chapters 3.3.3 and 4.24.

- https://mvec.mcri.edu.au/wp-content/uploads/2017/08/Zostavax-GP-Decision-Aid.pdf

# Case Study 1

- 72 year old male with history mesothelioma presented to GP and received Zostavax® vaccine
- 2 days later presented back to GP with vesicular rash to chest and back
- GP contacted SAEFVIC for advice and revealed patients medical history
- Patient had received chemotherapy 2 weeks prior to immunisation
- SAEFVIC advised GP to immediately recall patient and advise to present to ED
- ID consultant notified and recommend commencement of antivirals and swab of rash
- Patient admitted and treated with 4 days of IV acyclovir the discharged on oral acyclovir

## What went wrong???

- GP did not utilise GP decision aid prior to administration of Zostavax®
- Vaccine was documented in the software system **after** administration which then alerted GP that the vaccine was contraindication
- GP did not seek any advice until the patient represented with rash 2 days post administration

# Case Study 2

- 71 year old female with psoriasis presented to GP for Zostavax® on advice from dermatologist
- Patient receiving Infliximab (monoclonal antibody) infusions for treatment of psoriasis
- Post administration of Zostavax® vaccine GP realised this was contraindicated for this patient
- SAEFVIC called and advised to seek  urgent ID opinion
- Patient had rash appear 3 days later and Valtrex commenced and swab of rash sent
- Nil documented serology or hx varicella disease

## What went wrong?

- ?Dermatologist not aware of potential harm
- GP decision aid not used prior to administration

# How to avoid these errors

## Pre-immunisation checklist

**What to tell your doctor or nurse before immunisation**

**This checklist helps your doctor or nurse decide the best immunisation schedule for you or your child.**

### Please tell your doctor or nurse if the person about to be immunised:

- is unwell today
- has a disease which lowers immunity (for example, leukaemia, cancer, HIV, SCID) or is having treatment which lowers immunity (for example, oral steroid medicines such as cortisone and prednisone, disease-modifying anti-rheumatic drugs (DMARDs), radiotherapy, chemotherapy)
- is an infant of a mother who was receiving highly immunosuppressive therapy (for example, biological disease modifying anti-rheumatic drugs (bDMARDs) during pregnancy
- has had a severe reaction following any vaccine
- has *any* severe allergies (to anything)
- has had any vaccine in the past month
- has had an injection of immunoglobulin, or received any blood products, or a whole blood transfusion in the past year
- is pregnant
- is planning a pregnancy or anticipating parenthood
- is a parent, grandparent or carer of an infant aged up to six months
- has a past history of Guillian-Barré syndrome
- was a preterm baby born at less than 32 weeks gestation, or weighing less than 2000 g at birth
- is a baby who has had intussusception, or a congenital abnormality that may predispose to intussusception
- has a chronic illness
- has a bleeding disorder
- does not have a functioning spleen
- lives with someone who has a disease which lowers immunity (for example, leukaemia, cancer, HIV), or lives with someone who is having treatment which lowers immunity (for example, oral steroid medicines such as cortisone and prednisone, disease modifying anti-rheumatic drugs (DMARDs) radiotherapy, chemotherapy)
- identifies as an Aboriginal and/or Torres Strait Islander person
- is planning travel
- has an occupation or lifestyle factor/s for which vaccination may be needed.

**Before any immunisation takes place, your doctor or nurse will ask you:**

- Do you understand the information provided to you about the immunisation/s?
- Do you need more information to decide whether to proceed?
- Did you bring your / your child's immunisation record with you?

It is important for you to receive a personal record of your or your child's immunisation/s. If you don't have a record, ask your doctor or nurse to give you one. Bring this record with you for your doctor or nurse to complete every time you or your child visit for immunisation. Your child may need this record to enter childcare, preschool or school.

**For further information contact your doctor or local council.**

Material adapted from: Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au.

To receive this document in an accessible format email: immunisation@dhhs.vic.gov.au

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VICTORIA State Government | Health and Human Services

SAEFVIC

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## LIVE SHINGLES VACCINE (Zostavax) SCREENING FOR CONTRAINDICATIONS

Name:

Date of birth:

**Questions – This section can be completed by the Health Care Provider/Patient/Guardian**

*Note for Patient/Guardian: If you are unsure about an answer, please leave it blank and discuss with your Health Care Provider*

1. Have you ever had a shingles vaccine before? Y/N
*When:*

2. Do you feel unwell today? Y/N
*Details:*

3. Have you had shingles or post herpetic neuralgia (nerve pain following shingles) in the past year? Y/N
*Details:*

4. Have you had a serious allergic reaction (anaphylaxis) to a previous dose of shingles or varicella (chickenpox) vaccine or any vaccine components including neomycin or gelatin? Y/N
*Details:*

5. Have you ever had cancer, leukaemia, lymphoma, an organ, bone marrow transplant, stem cell therapy, or another health condition that weakens your immune system, including blood disorders, graft versus host disease or HIV/AIDS? Y/N
*Details:*

6. In the past 12 months, have you been on any treatment for rheumatoid arthritis, multiple sclerosis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease or other inflammatory conditions? Y/N
*Details:*

7. In the last 12 months have you taken medicine that weakens your immune system such as oral prednisolone, or other steroids, anti-cancer drugs, biological therapy, radiotherapy or chemotherapy? Y/N
*Details:*

8. Have you been treated recently with oral antiviral medication such as aciclovir for conditions such as herpes? Y/N
*Details:*

**Outcome – This section is to be completed by Health Care Providers ONLY (check relevant boxes)**

- ☐ There are no contraindications to Zostavax vaccination. Discussion of side effects of vaccination has occurred and informed consent for vaccination obtained
- ☐ **Zostavax is contraindicated**
- ☐ Zostavax should be delayed
  - until recovery from acute illness
  - until treatment is completed and for ____ months afterwards
  - until current episode of shingles has resolved and for a minimum of 1 year
- ☐ Specialist advice regarding immune status is required. Not for vaccination at this time.

Date: _____

Provider: _____

# TGA Alert

## Zostavax vaccine

### Safety advisory - not to be used in people with compromised immune function

6 July 2020

The Therapeutic Goods Administration (TGA) has previously advised that Zostavax should not be used in people with compromised immune function, as it is associated with a risk of mild to serious complications (including death) from infection with the vaccine virus.

Consumers and health professionals are advised that the TGA has received a report of a new case involving this adverse event in a patient on low doses of immunosuppressive medicine.

The patient, who at the time of vaccination was taking hydroxychloroquine and a low dose of prednisolone to treat arthritis, died 3 weeks after receiving Zostavax.

The TGA investigation found that Zostavax was used in line with existing recommendations. However, it is important for health professionals to be mindful of the potential for this very rare adverse event.

Zostavax is a live, attenuated varicella-zoster virus vaccine that is used to prevent shingles in patients aged 50 years and older and prevention/treatment of nerve pain associated with the virus in patients aged 60 years and older.

Zostavax is included on the National Immunisation Program for people aged 70 to 79 years.

# Vaccine side effects

**Please wait a minimum of 15 minutes after immunisation**

Vaccines given today ____/____ /20____ indicated below by tick in boxes. Time vaccine given _____.

| | | | |
|---|---|---|---|
| **Rotavirus vaccine**<br>Some babies will shed the rotavirus in their faeces.<br>By mouth | **Diphtheria-tetanus-whooping cough-polio-hepatitis B-Hib* vaccine**<br>**Haemophilus influenzae* type b*<br>RA LA RL LL | **Pneumococcal vaccine**<br>RA LA RL LL | **Meningococcal ACWY vaccine**<br>RA LA RL LL |
| ***Haemophilus influenzae* type b (Hib)**<br>RA LA RL LL | **Diphtheria-tetanus-whooping cough vaccine**<br>Some 18-month-olds have a large injection site reaction of redness and swelling from the shoulder to the elbow which parents should report to the immunisation provider or the Victorian vaccine safety service (contact details overleaf).<br>RA LA | **Measles-mumps-rubella-chickenpox vaccine**<br>About 7 to 10 days after vaccination:<br>• fever (can be >39 °C)<br>• faint red rash (not infectious)<br>• head cold symptoms<br>• swelling of salivary glands.<br>About 5 to 26 days after vaccination:<br>• mild chickenpox-like rash.<br>RA LA | **Measles-mumps-rubella vaccine**<br>About 7 to 10 days after vaccination:<br>• fever (can be >39 °C)<br>• faint red rash (not infectious)<br>• head cold symptoms<br>• swelling of salivary glands.<br>RA LA RL LL |
| **Diphtheria-tetanus-whooping cough-polio vaccine**<br>Some 4-year-olds have a large injection site reaction of redness and swelling from the shoulder to the elbow which parents should report to the immunisation provider or the Victorian vaccine safety service (contact details overleaf). | **Human papillomavirus (HPV) vaccine**<br>• mild headache<br>• mild nausea. | **Chickenpox vaccine**<br>About 7 to 10 days after vaccination:<br>• fever (can be >39 °C)<br>About 5 to 26 days after vaccination:<br>• fever<br>• mild chickenpox-like rash.<br>RA LA | **Meningococcal B**<br>• fever (can be >39 °C)<br>• Bexsero brand for children aged less than 4 years, give paracetamol in the 30 minutes before vaccination, or as soon as possible after vaccination. This should be followed by 2 more doses of paracetamol given 4 to 6 hours apart.<br>RA LA RL LL |
| | | **Polio vaccine**<br>• muscle aches.<br>RA LA | **Hepatitis B vaccine**<br>RA LA RL LL |

**Zoster (shingles) vaccine**

- redness, pain, swelling and/or itch at the injection site
- see over page for rare reportable events.

RA LA

VICTORIA State Government | Health and Human Services

## Common side effects occur soon after vaccination and last 1 to 2 days

**Vaccinations may cause the following reactions:**


Mild fever (>38.5 °C) that doesn't last long


Grizzly, unsettled, unhappy or sleepy


Where the needle was given: Sore, red, burning, itching or swelling for 1-2 days and/or small hard lump for a few weeks

**What to do at home:**

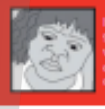

If baby/child has a fever do not have too many clothes or blankets on. Paracetamol can be given (check the label for correct use).


Breast feed more frequently and/or give extra fluids


Put a cold wet cloth on the injection site.

**When to seek medical advice:**


If pain and fever are not relieved by paracetamol (eg. Panadol).


If the reactions are not going away or getting worse or if you are worried at all, then see your doctor or go to hospital.

## Very rare vaccine side effects requiring immediate medical attention

- Febrile convulsion: caused by a high fever, generally occurs in children under 3 years of age.
- The baby suddenly becomes pale, limp and unresponsive from 1 to 48 hours after vaccination. Soon after the baby fully recovers.
- Bowel blockage (intussusception): occurs when a portion of the bowel slides into the next, like the pieces of a telescope. This can occur in a baby in the 7 days following the 1st and 2nd dose of rotavirus vaccine. Signs of bowel blockage include:
  - bouts of crying
  - pale appearance
  - pulling the legs up to the stomach.
- Inflammation of a nerve in the arm (Brachial neuritis): causes a feeling of weakness or numbness in the arm.
- A severe allergic reaction (anaphylaxis) occurring suddenly, usually within 15 minutes of vaccine administration but can occur within hours of administration. Early signs of anaphylaxis include:
  - redness and or itching of the skin
  - breathing problems

- After receiving a shingles (Zostavax) vaccine, the following reactions may occur:
  - Chickenpox-like rash within 3 to 4 weeks after vaccine administration
  - feeling unwell /fever.

**For further information:** Contact your doctor or your local council immunisation service.
**Or visit:** www.betterhealth.vic.gov.au

To receive this publication in an accessible format email: immunisation@dhhs.vic.gov.au

Material adapted from Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au.
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Available at: https://www2.health.vic.gov.au/about/publications/factsheets/vaccine-side-effects
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# Alerts




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Vaccination update 10 July 2020

**Zoster vaccination**

The TGA has issued a safety advisory following a Zostavax related death in a patient taking hydroxychloroquine and prednisone 'below the level expected to cause significant immunosuppression'.

https://www.tga.gov.au/alert/zostavax-vaccine-0







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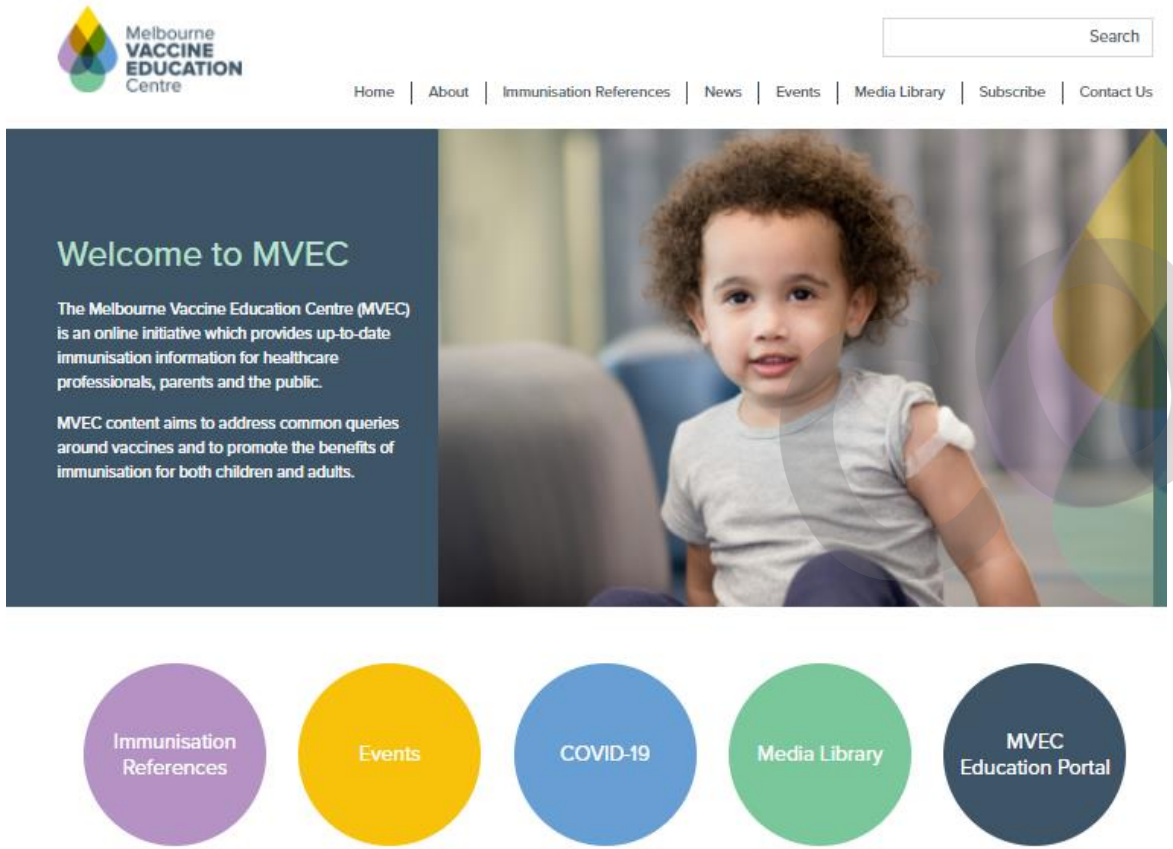
## VACCINATION SAFETY ALERT

### Warning issued after the death of an immuno-compromised patient following Zostavax administration

The Therapeutic Goods Administration has reiterated previous warnings about administering the Zostavax shingles vaccine to patients with immune systems deficiencies.

# Education




# Education

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## Zoster vaccine (Zostavax®) FAQs



MVEC's Zoster vaccine (Zostavax®) FAQ's have been designed for providers to use in conjunction with the MVEC: Zoster immunisation reference page as well as the Zostavax® GP Decision Aid. Where further clarification of circumstances or patient history is required, it is safest to delay vaccination until more information is available.

### General zoster vaccine questions

#### 1. Who should be immunised?

Zostavax® is registered for use in Australia as a single dose from 50 years of age for the prevention of zoster (shingles). It is recommended for immunocompetent adults aged over 60-years. Zostavax® is funded on the National Immunisation Program (NIP) for people aged 70-years, with a catch up program for people aged 71-79-years (ending October 2021). It is also available for private purchase for patients wishing to be immunised outside of this funded age group. There is currently no recommendations for booster doses when early vaccination is given.

#### 2. Can Zostavax® be recorded on the Australian Immunisation Register (AIR)?

Zostavax® should be recorded on the AIR to ensure that immunisation records are accurate and up to date. Patient recall should **never** be relied on for vaccine history and therefore accurate documentation will assist in avoiding any errors where multiple doses are administered.

#### 3. What are the side effects of Zostavax® vaccine?

Common side effects include pain, swelling and redness at the injection site.

# Summary- Take home message

- People who are or have recently been immunocompromised due to a medical condition or medical treatment are **contraindicated** to receive the varicella zoster vaccine


- Always use the pre immunisation checklist and GP decision aid **before** administering Zostavax® and consider the safety of giving zoster vaccine on a case-by-case basis

- If uncertain about the person's level of immunocompromise and whether vaccination is safe, **do not** vaccinate. Seek expert advice from the treating physician or an immunisation specialist

- If a recent Zostavax® recipient is suspected of having disseminated varicella-zoster virus infection know how to manage/treat

  - conduct appropriate diagnostic testing early
  - where appropriate, initiate antivirals empirically while awaiting test results
  - where feasible, cease immunosuppression.
  - **Notify** SAEFVIC -Victorian Vaccine Safety Service immediately: Telephone 1300 882 924 (option one)

murdoch children's research institute

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SAEFVIC

# Thank you