SmartVax Vaccine Safety - Our Journey

CDCD WA – Immunisation Day

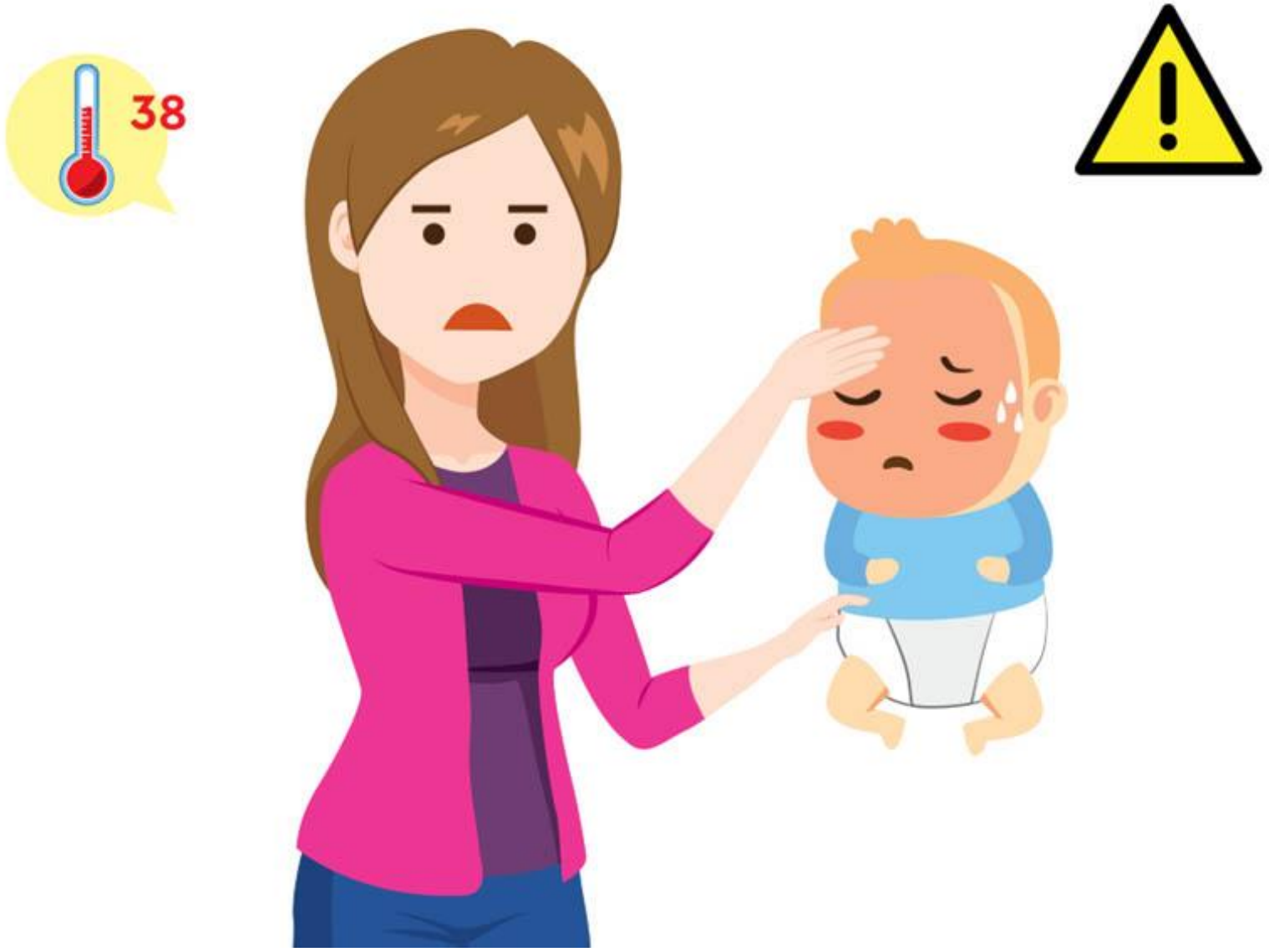
Dr Alan Leeb

Director - SmartVax

www.smartvax.com.au

Flu Vaccination Ban Goes National After Fever, Convulsions in Children

SmartVax



UNIVERSAL CHILHOOD INFLUENZA VACCINATIONS:WA

- Three child deaths in 2007 with confirmed Influenza
- In 2008 WA begins offering free flu vaccine to children 6 months to 5 years of age
- 2008 - 2009 - 60,000 doses of TIV given in WA
- 30%-40% of cohort vaccinated
- CSL – fluvax and Sanofi – vaxigrip

Flu kills three young children

PETA RULE and DEBBIE GUEST

Three children have been killed by the flu in Perth in the past few days, prompting experts to issue an urgent warning that parents should take their children to the doctor as soon as they show signs of the illness.

The three children were all under five and lived in the metropolitan area. It is understood each of them died within 24 hours of showing the first signs of the flu, which doctors say was a form of the common influenza A strain. They warned that listlessness, cough and fever were the key symptoms parents should look for and urged them to seek medical advice immediately.

"While we do not want to create

Doctors across the State have been warned that they may be inundated by worried parents, prompting the Health Department to advise them of the details of the deaths.

Australian Medical Association president Geoff Dobb said influenza A strain was one of the most common during winter and that West Australians were particularly vulnerable because it had been several years since the last flu epidemic.

He said parents should not be worried if their children simply had a runny nose and headache, though they should look out for a fever above 38C.

"The critical thing is the combination of a fever and a cough," he said. "What we're talking about here is not just having a runny nose and feeling

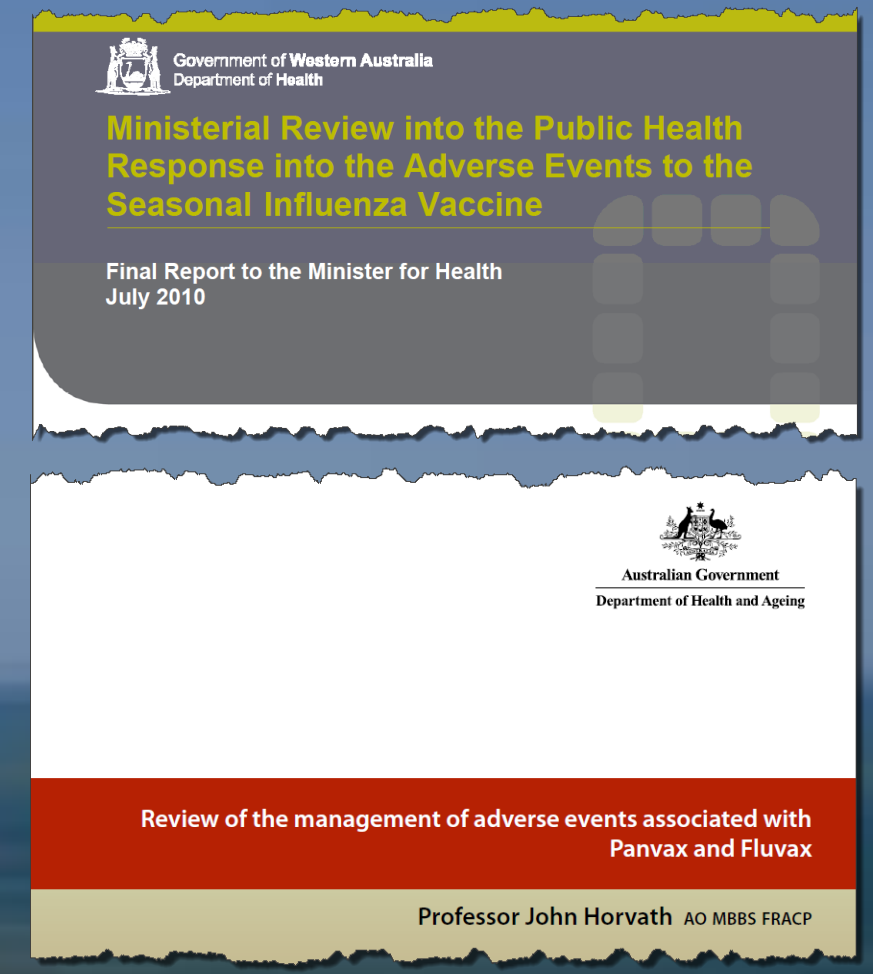
SmartVax®

Children Fully Immunised - TIV

45%

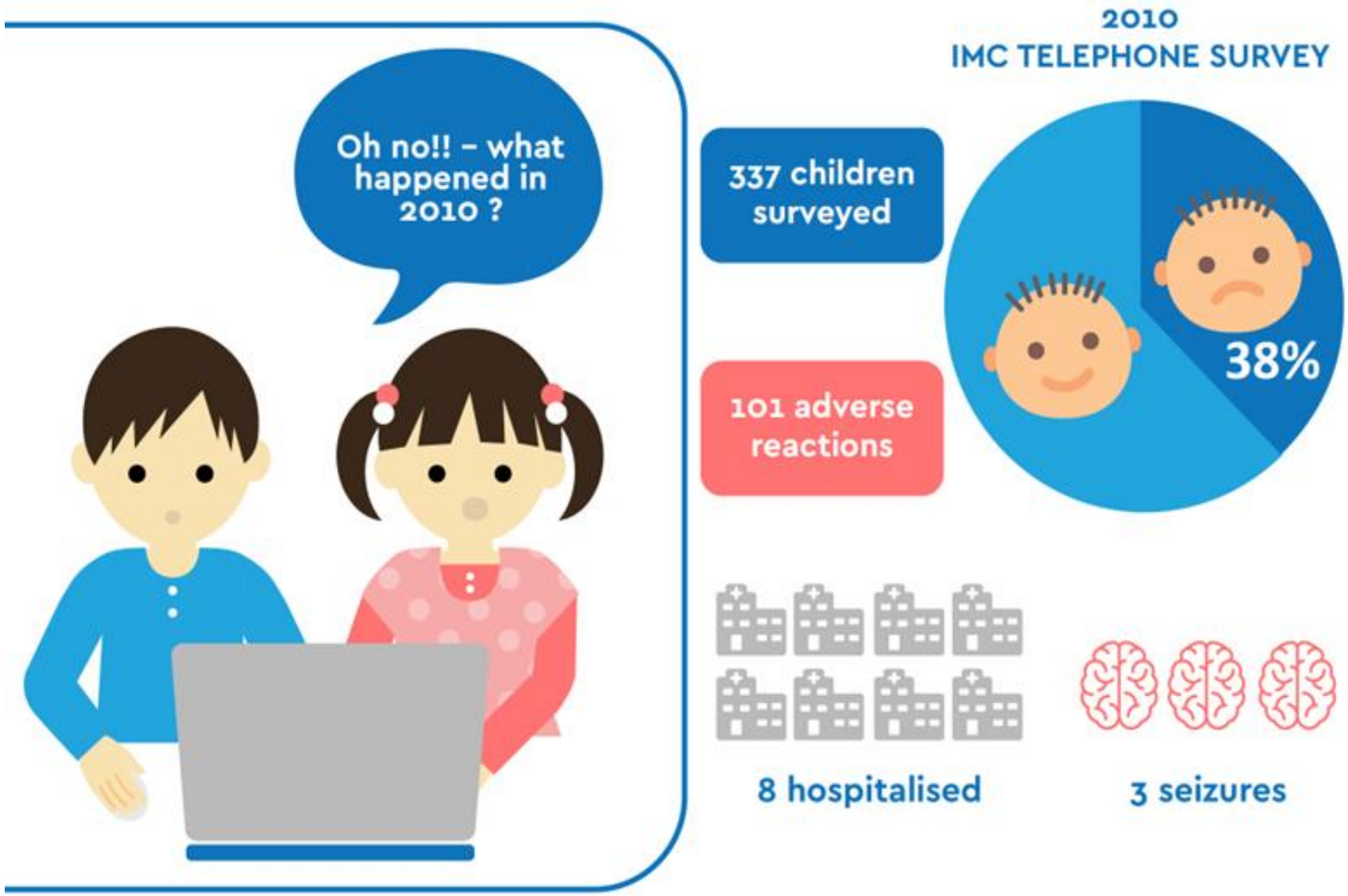
7%

2009 2011 2012




What took you so long?
AEFI
10 Days
Suspension of TIV program
Weeks
Aha!

Illawarra Med Ctr – TELEPHONE SURVEY 2010



2 Years to Uncover the likely cause

JUNE 21 2012 SAVE PRINT LICENSE ARTICLE

Virus traces in Fluvax cause of children's convulsions

Mark Metherell

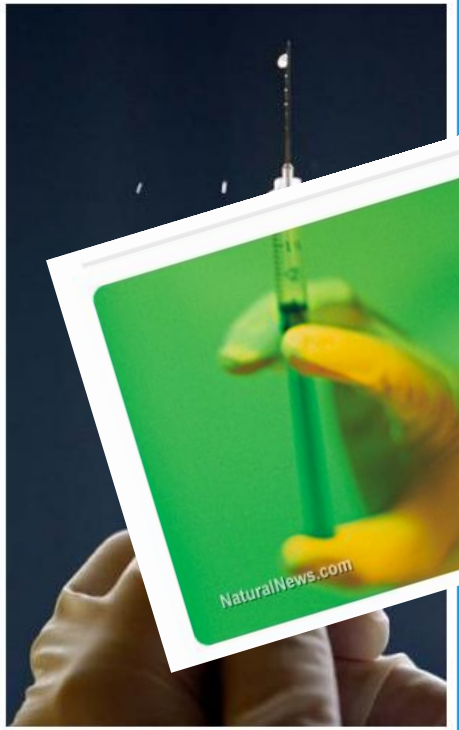
SHARE TWEET MORE

THE likely cause of convulsions that hit 101 Australian children given a CSL influenza vaccine has finally been uncovered, more than two years after the event.

The culprit appears to have been virus particles preserved in the CSL Fluvax vaccine, which had the effect of increasing the risk of febrile convulsions in children, CSL has said.

The impact of Fluvax on infants, particularly in Western Australia, prompted a ban on its use for the under-fives and triggered scrutiny, including from the US regulator, the Food and Drug Administration.

Asked whether the Fluvax saga indicated a flaw or oversight in manufacturing, CSL insisted yesterday its processes had stood it ''in good stead for many decades''.



Virus particles in the Fluvax vaccine increased the risk of convulsions in children, CSL has said. Photo: Reuters

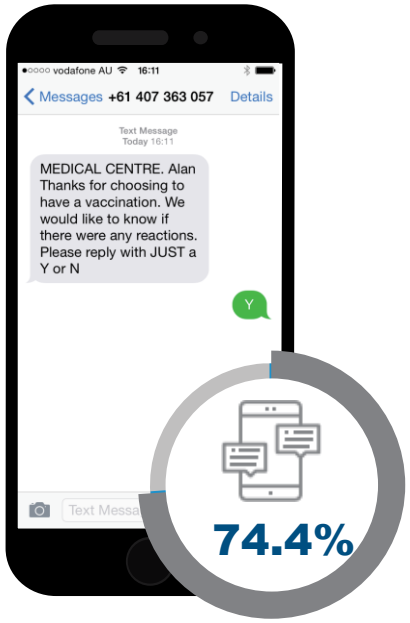
Adverse Event Surveillance – Australia 2010

- **Passive surveillance** only in Australia
- **Limitations** of passive surveillance – reliance on health providers and/or public recognition and reporting of AEFI to federal health authorities.
- TIV – **seasonal change** – assumed safety is not altered by the annual change in combination vaccine strains.
- **2010 – AEFI following ‘fluvax’ highlighted limitations of surveillance in WA**

What We Did!

SmartVax Patient Response Rate – Version 1

Reaction?

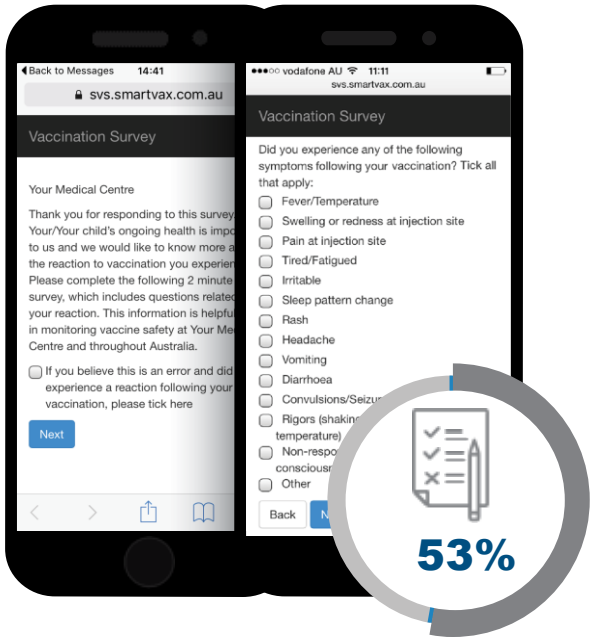


SMS 1:
Overall response rate

Medical Attendance?

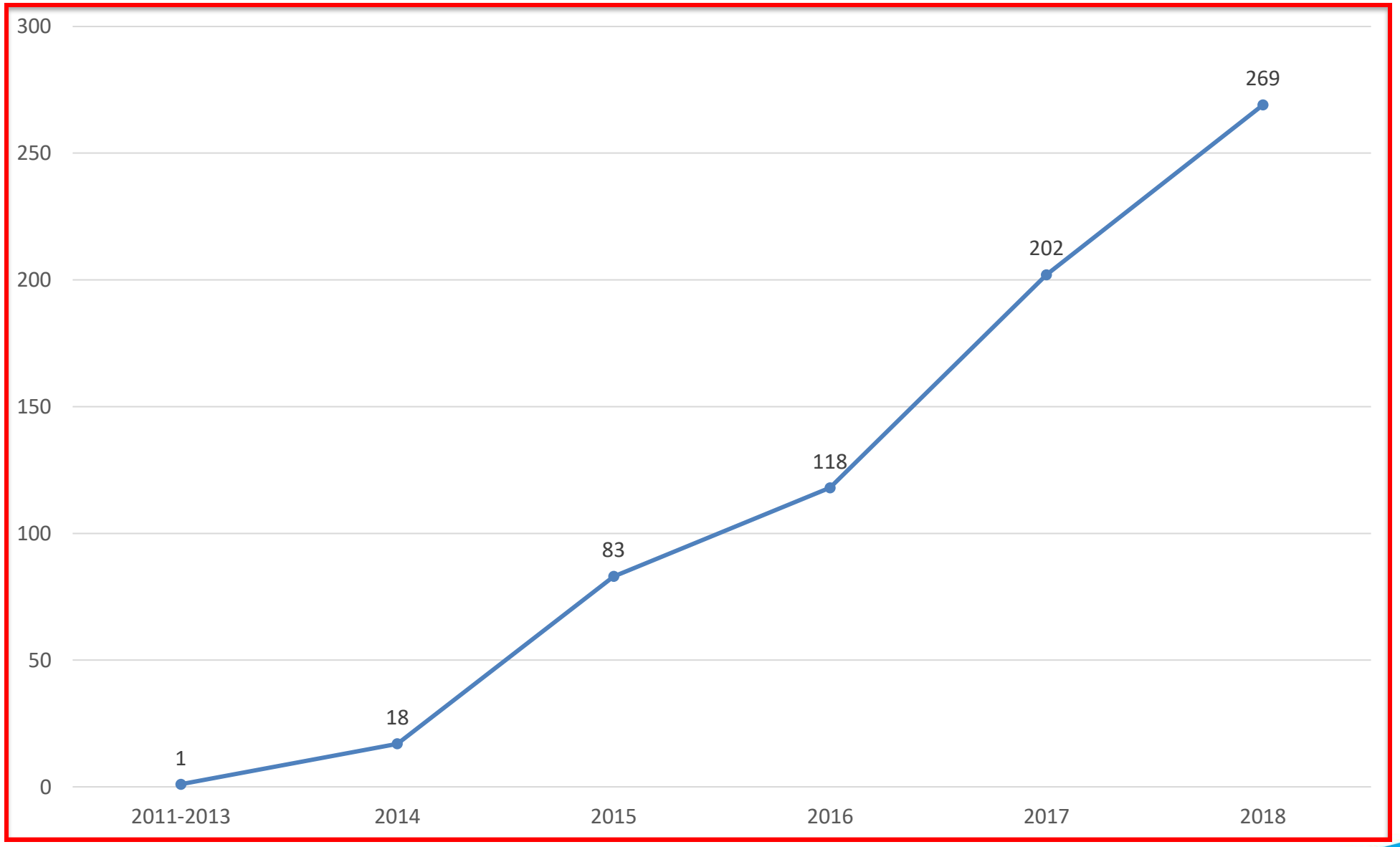
SMS 2:
Response rate

Survey



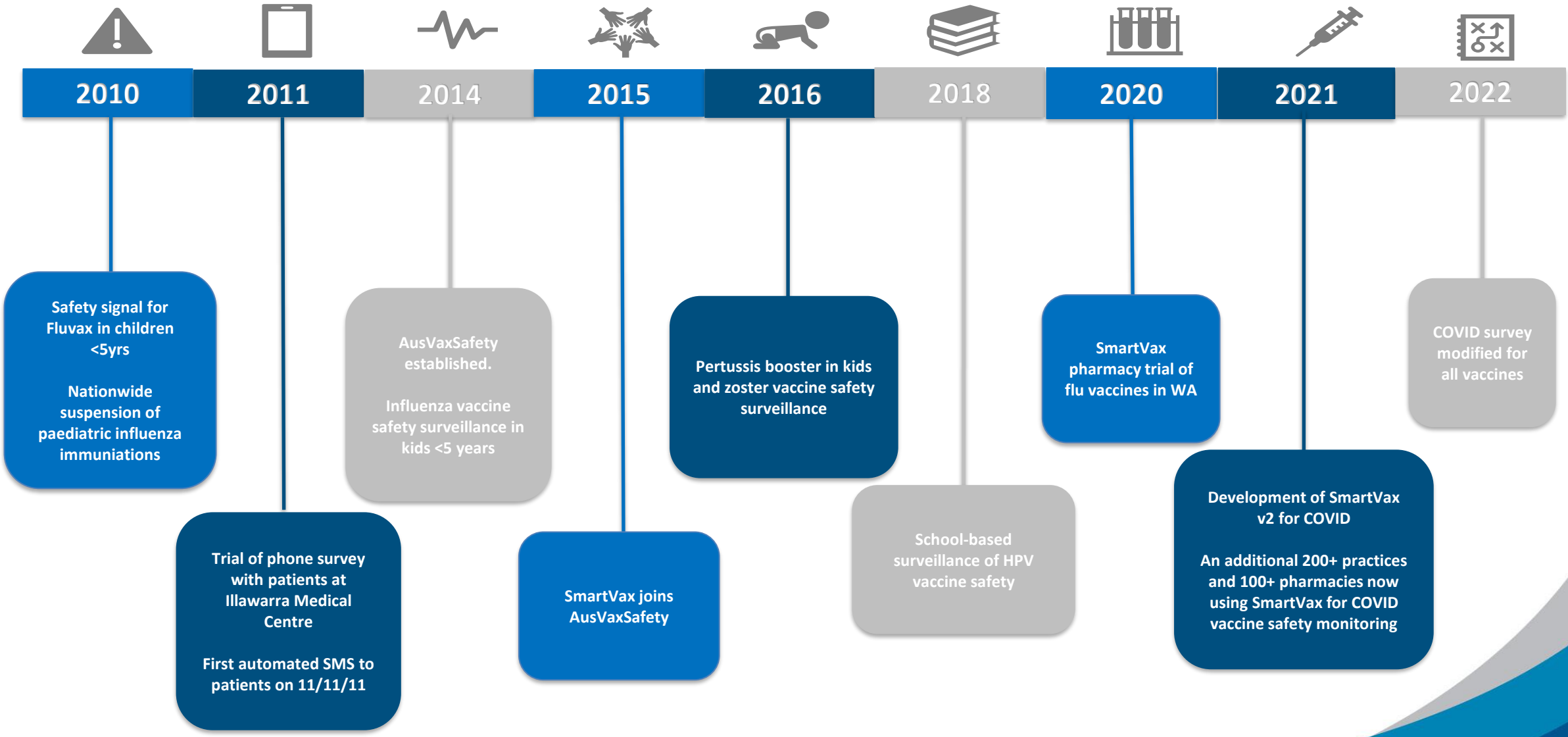
Survey:
Response rate

Growth of SmartVax Network (2011-2018)



AusVaxSafety

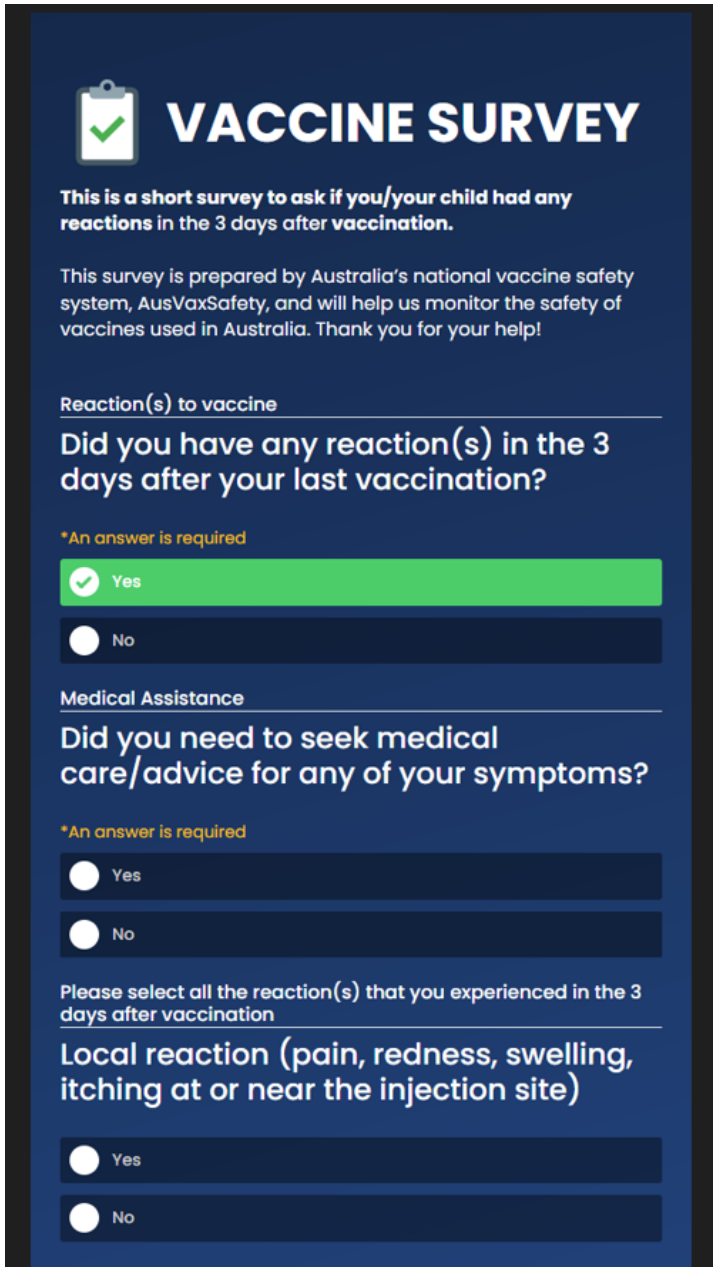
SmartVax – AusVaxSafety - Timeline

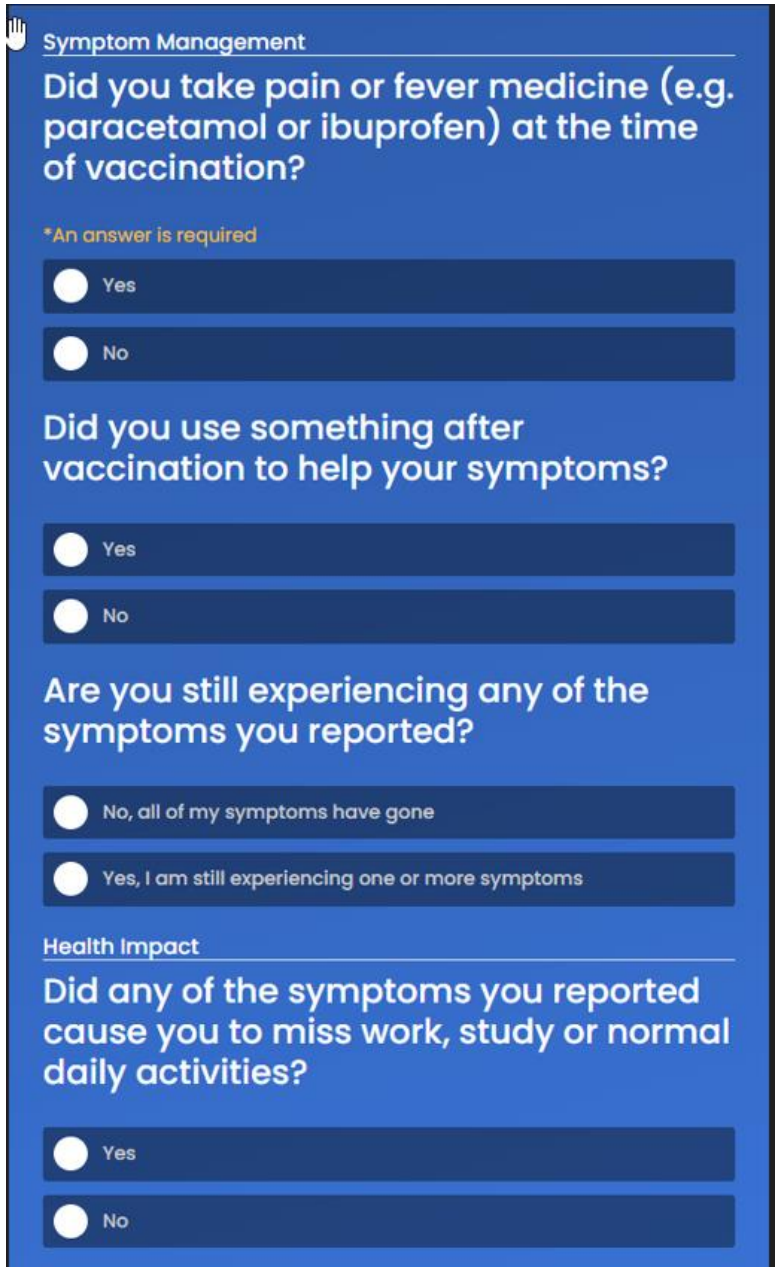


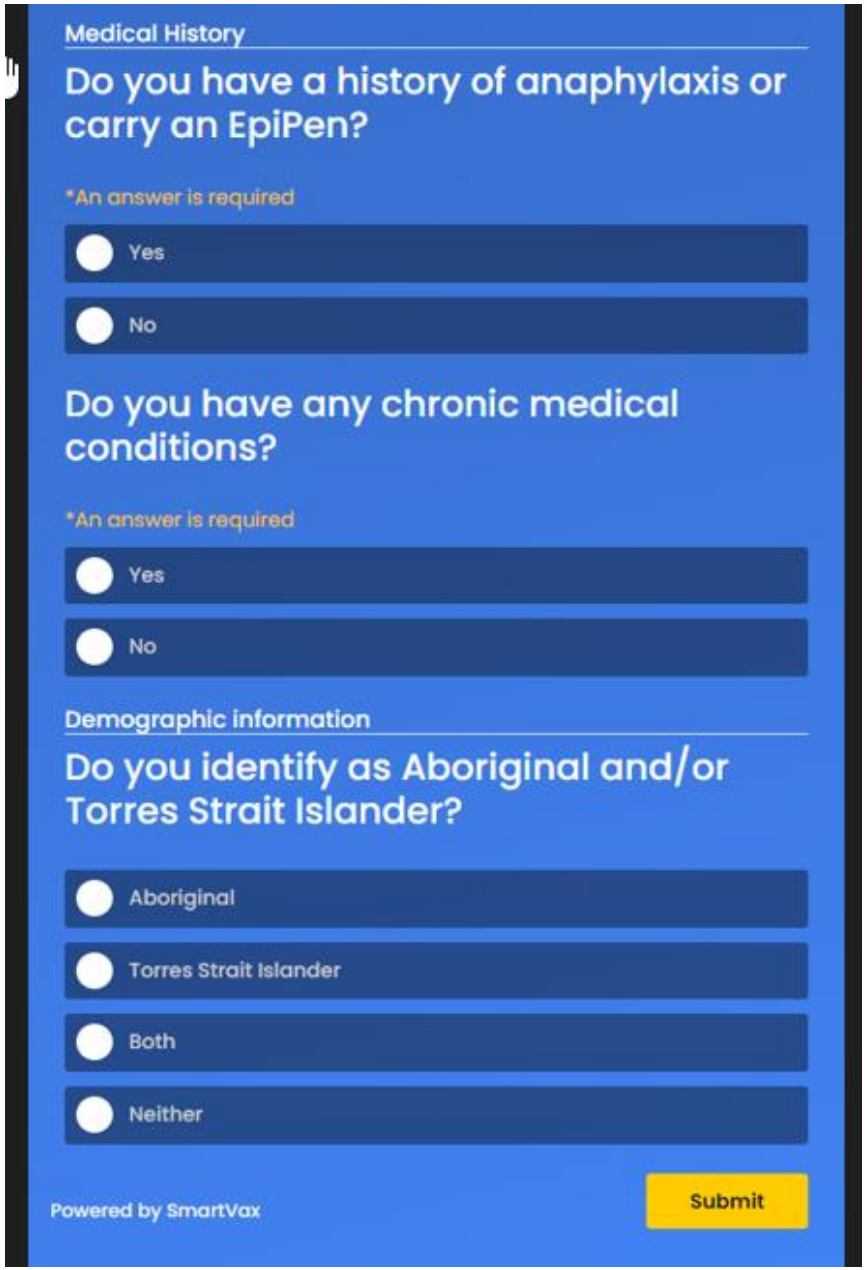
The Impact of COVID-19

COVID-19 Vaccine - The Great Unknown

- **COVID-19 vaccines** were different – novel vaccine technology - never been used before
- A number of vaccines with various technologies employed
- We had **no idea** of potential effects – short-term, medium-term, or long-term
- **Emergency Use Authorisation**


VACCINE SURVEY
This is a short survey to ask if you/your child had any reactions in the 3 days after vaccination.
This survey is prepared by Australia's national vaccine safety system, AusVaxSafety, and will help us monitor the safety of vaccines used in Australia. Thank you for your help!
Reaction(s) to vaccine
Did you have any reaction(s) in the 3 days after your last vaccination?
*An answer is required
Yes
No
Medical Assistance
Did you need to seek medical care/advice for any of your symptoms?
*An answer is required
Yes
No
Please select all the reaction(s) that you experienced in the 3 days after vaccination
Local reaction (pain, redness, swelling, itching at or near the injection site)
Yes
No

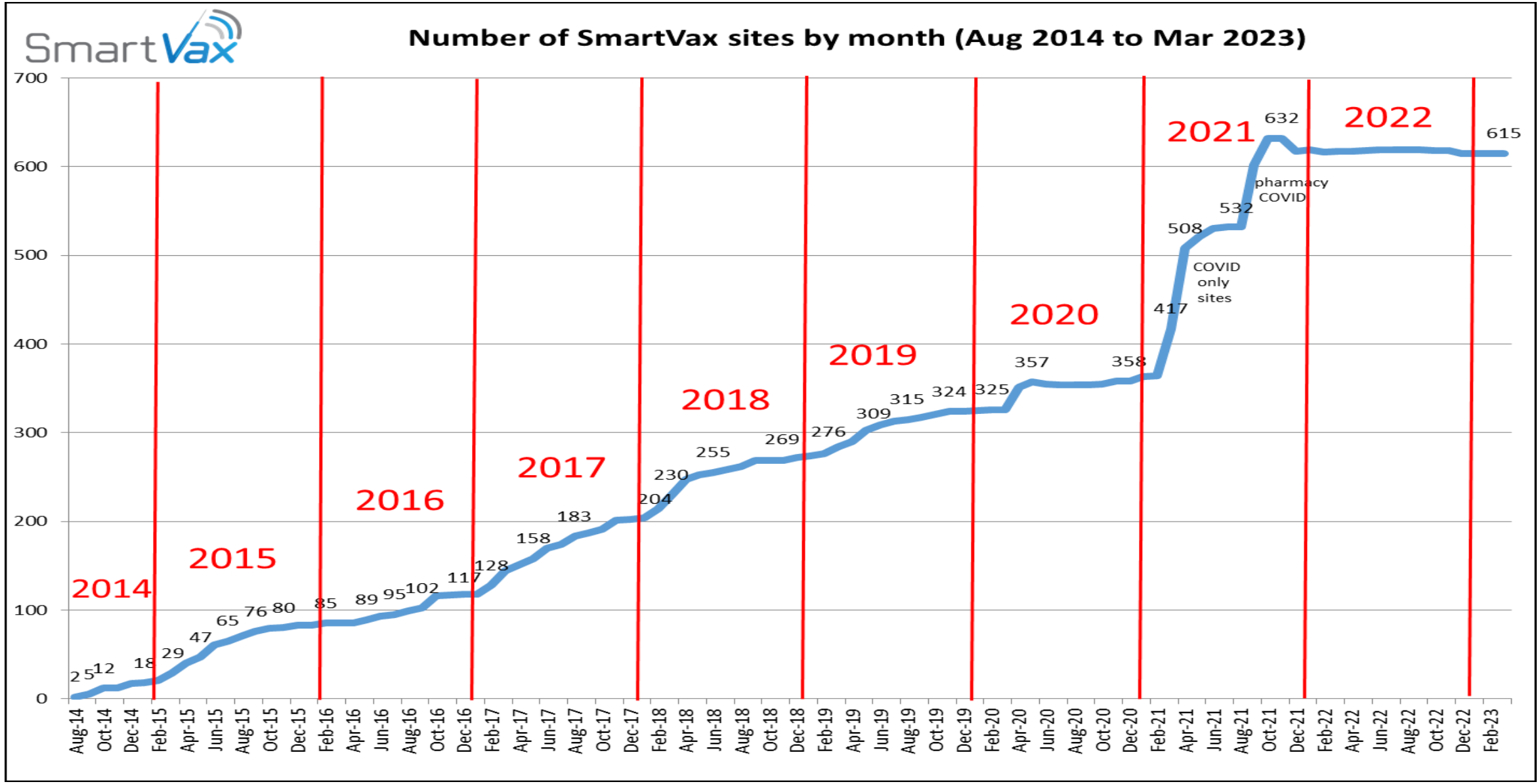

Symptom Management
Did you take pain or fever medicine (e.g. paracetamol or ibuprofen) at the time of vaccination?
*An answer is required
Yes
No
Did you use something after vaccination to help your symptoms?
Yes
No
Are you still experiencing any of the symptoms you reported?
No, all of my symptoms have gone
Yes, I am still experiencing one or more symptoms
Health Impact
Did any of the symptoms you reported cause you to miss work, study or normal daily activities?
Yes
No


Medical History
Do you have a history of anaphylaxis or carry an EpiPen?
*An answer is required
Yes
No
Do you have any chronic medical conditions?
*An answer is required
Yes
No
Demographic information
Do you identify as Aboriginal and/or Torres Strait Islander?
Aboriginal
Torres Strait Islander
Both
Neither
Powered by SmartVax
Submit

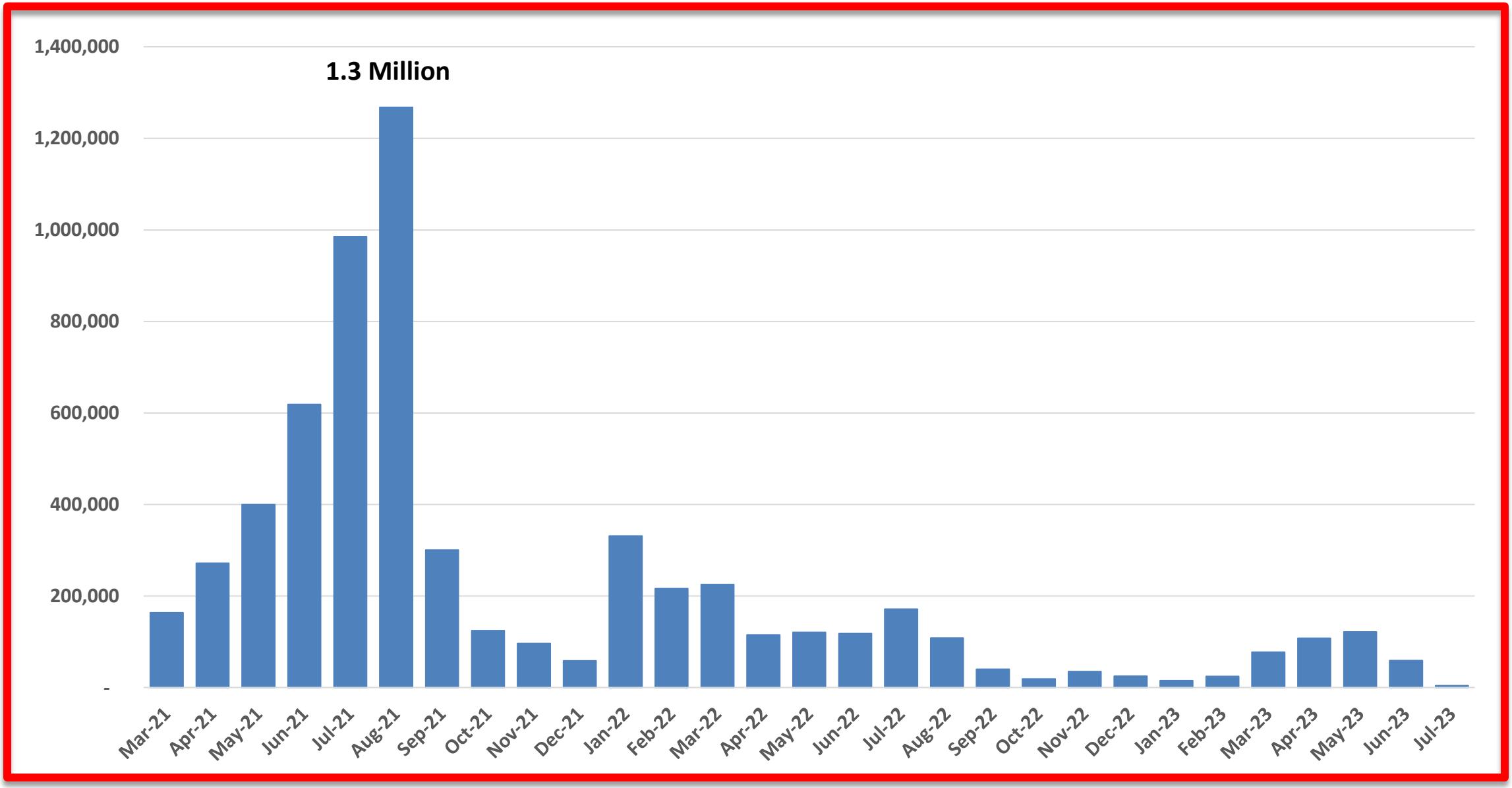
COVID-19 Version Development - Challenges

- 3-month development window – first vaccine due to be administered February 2021
- Our team worked 18 hour days for 14 weeks straight (including through Christmas & New Year)
- Unforeseen challenges:
  - FileMaker Developer left
  - Primary computer failed
- Little opportunity to pre-test; many functions could only be tested in a live system
- Working to a scale never before encountered

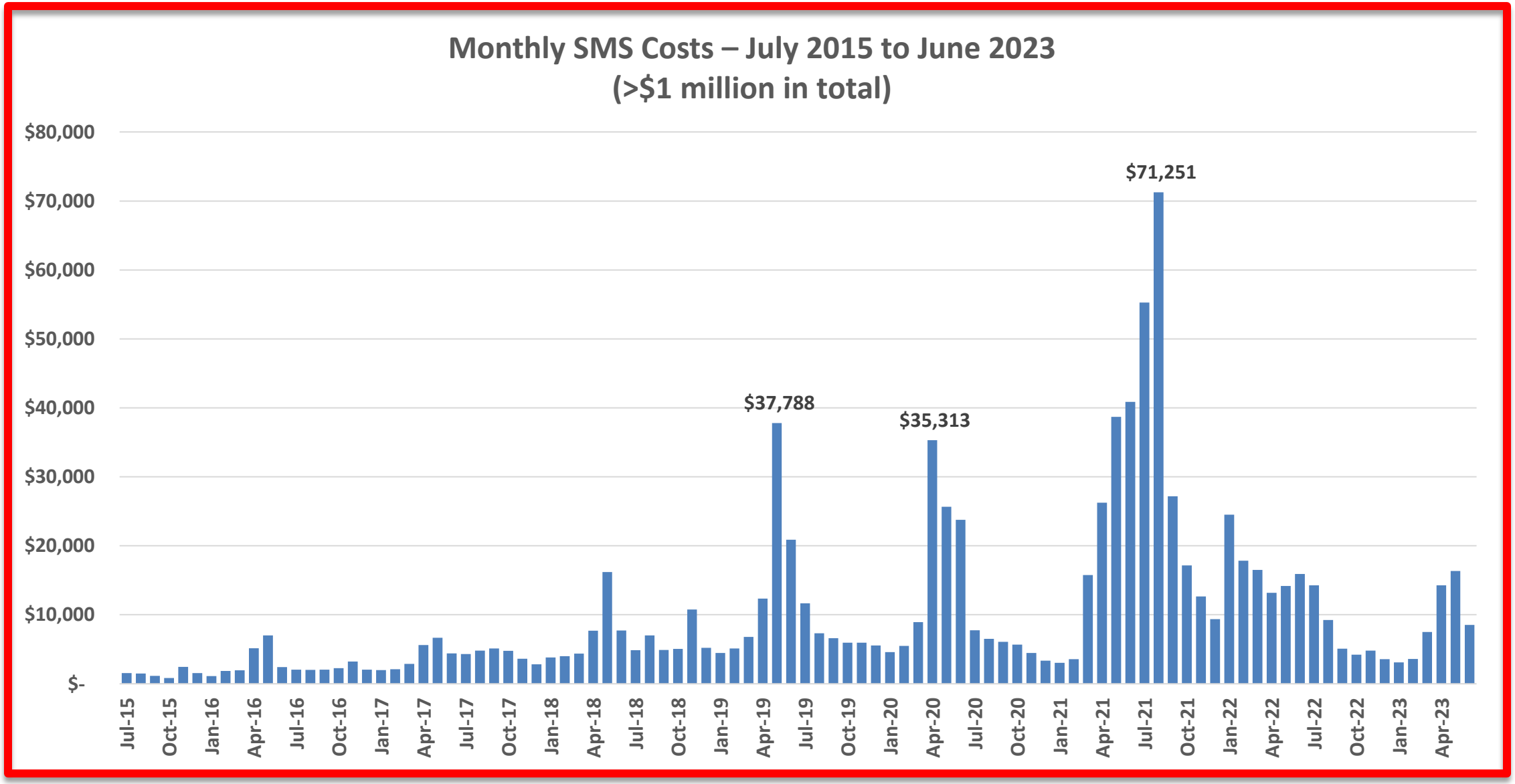
SmartVax COVID Network



COVID Messages Sent



SMS Costs


Monthly SMS Costs – July 2015 to June 2023
(>$1 million in total)
$80,000
$70,000
$60,000
$50,000
$40,000
$30,000
$20,000
$10,000
$-
$37,788
$35,313
$71,251
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
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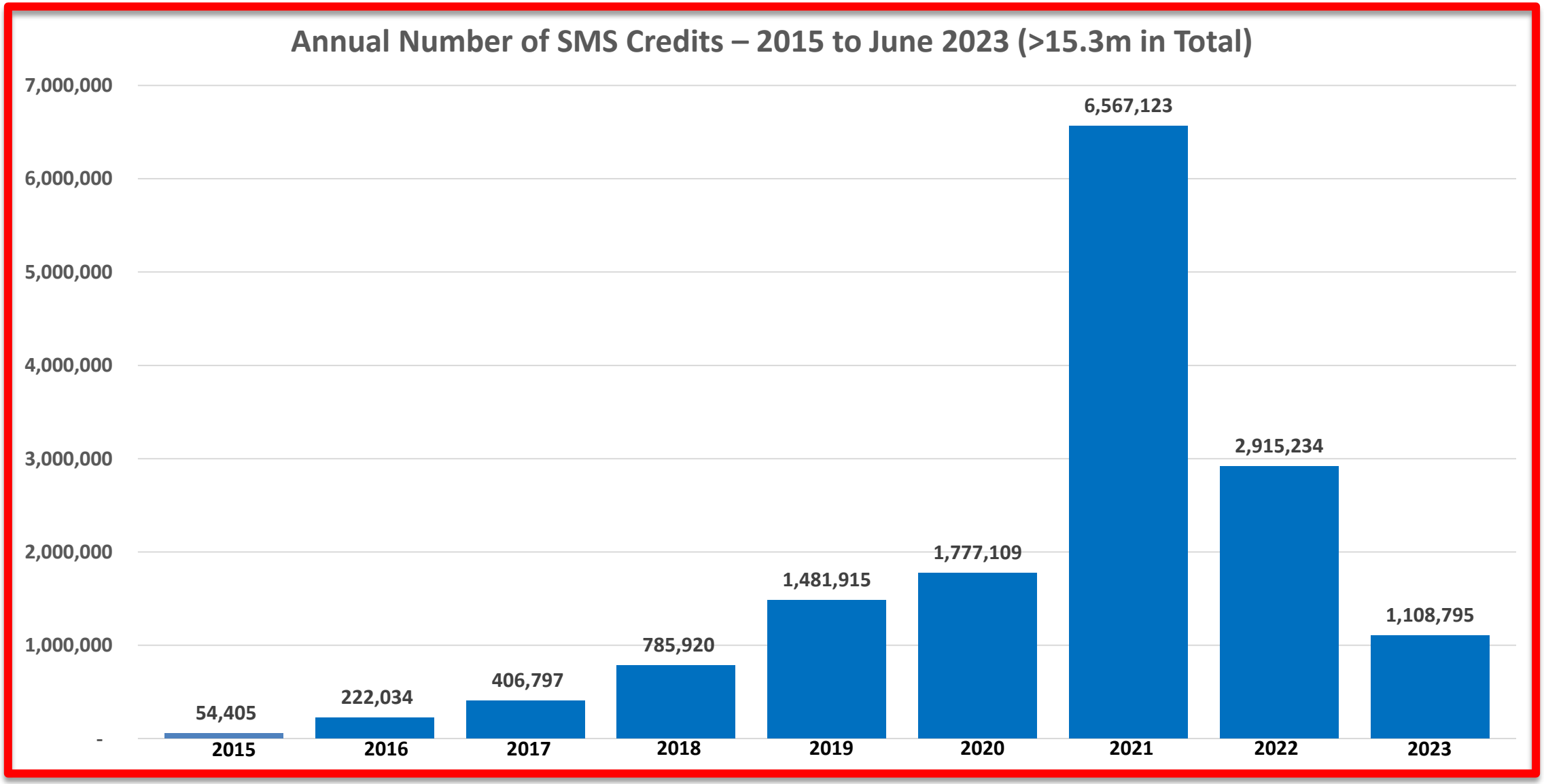
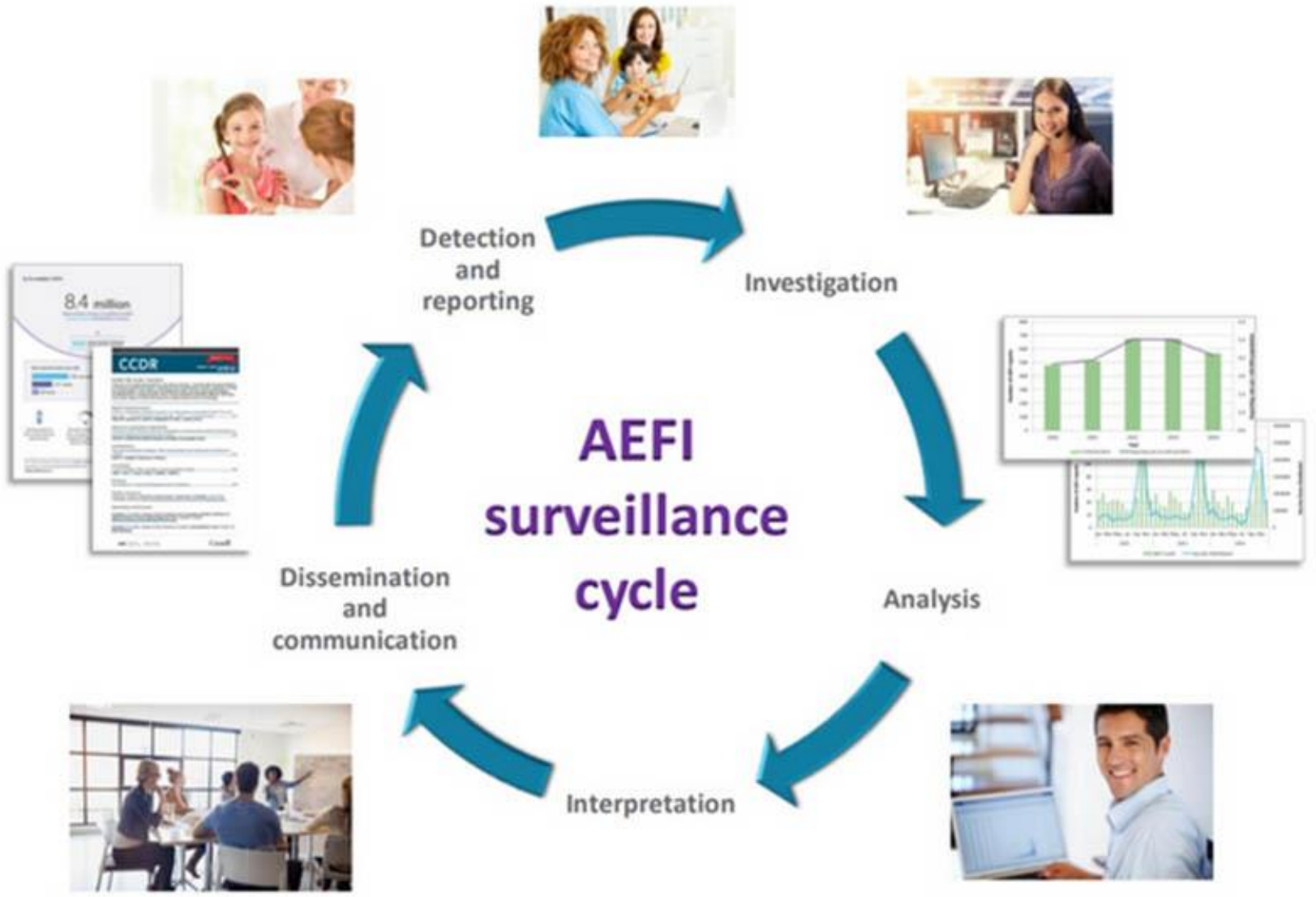
Jan-23
Apr-23

Annual Text Messages Sent



Importance of COVID Surveillance Data

AEFI Data


Detection and reporting
Investigation
Analysis
Interpretation
Dissemination and communication
AEFI surveillance cycle
8.4 million
CCDR

AusVaxSafety – Early Covid 19 Vaccine Safety Data

The short term safety of COVID-19 vaccines in Australia: AusVaxSafety active surveillance, February – August 2021

Lucy Deng[1,2,3], Catherine Glover[1], Michael Dymock[4,5], Alexis Pillsbury[1,2,3], Julie A Marsh[4,5], Helen E Quinn[1,2,3], Alan Leeb[6,7], Patrick Cashman[8], Thomas L Snelling[2,3], Nicholas Wood[1,2,3], Kristine Macartney[1,2,3]

The known: Clinical trials of the COVID-19 vaccines Comirnaty and Vaxzevria have found that mild to moderate local and systemic reactions are common, but serious events are few.

The new: In the largest published post-marketing analysis of the safety of Comirnaty and Vaxzevria, adverse events were more frequently reported by people with underlying medical conditions, including a history of anaphylaxis. Adverse event frequency was similar for Indigenous people and other Australians.

The implications: Our findings confirm the safety of Comirnaty and Vaxzevria in population use. AusVaxSafety continues to monitor COVID-19 vaccine safety in Australia, including that of third and future doses as our vaccination program evolves.

Abstract

Objective: To assess the short term safety of the COVID-19 vaccines Comirnaty (Pfizer–BioNTech BNT162b2) and Vaxzevria (AstraZeneca ChAdOx1) in Australia.

Design: Prospective observational cohort study; online surveys by AusVaxSafety, a national active vaccine safety surveillance system, three and eight days after vaccination.

Setting, participants: People aged 16 years or more who received COVID-19 vaccines at sentinel vaccination hubs, general practices, or Aboriginal Community Controlled Health Organisation clinics, 22 February – 30 August 2021.

Main outcome measures: Primary outcome: proportion of respondents who reported any adverse event following immunisation (AEFI) 0–3 days after vaccination. Secondary outcomes: proportions of respondents who reported specific adverse events or medical review for AEFI within seven days of vaccination; impact on usual daily activities; recovery.

Results: 4 851 480 people received COVID-19 vaccines at participating sentinel sites during the study period (25% of all COVID-19 vaccine doses administered in Australia to 30 August 2021). 3 035 983 people responded to both surveys (response rate, 62.6%); 35.9% of respondents reported one or more AEFI 0–3 days after Comirnaty dose 1, 54.7% after Comirnaty dose 2, 52.8% after Vaxzevria dose 1, and 22.0% after Vaxzevria dose 2. Local pain,

The Australian coronavirus disease 2019 (COVID-19) vaccination program began with Comirnaty (Pfizer–BioNTech BNT162b2) on 22 February 2021 and Vaxzevria (AstraZeneca ChAdOx1) on 9 March 2021. By 30 August 2021, more than 19 million doses of the two vaccines had been administered.[1] Most people who received the vaccines during this period were both COVID-19- and vaccine-naïve, and the

ELSEVIER

Vaccine

Volume 40, Issue 31, 29 July 2022, Pages 4065-4080

Review

A scoping review of active, participant-centred, digital adverse events following immunization (AEFI) surveillance: A Canadian immunization research network study

Athanasios Psihogios [a], A. Brianne Bota [a], Salima S. Mithani [a], Devon Greyson [b], David T. Zhu [a], Stephen G. Fung [c], Sarah E. Wilson [d e f], Deshayne B. Fell [c g], Karina A. Top [h], Julie A. Bettinger [i], Kumanan Wilson [a g j k]

Highlights

- Australia produces the most research on this topic.
- Smartvax is the most studied digital system.
- Email, SMS, and e-questionnaires are the most commonly used digital

Types of AEFI Surveillance Systems

1. **Passive Surveillance** – TGA – reports initiated by anyone and reports made online or on paper.

2. **Active Surveillance** –
    1. **Participant Centred, active surveillance AusVaxSafety, using SmartVax and VaxTracker** – active SMS and email based service used across 629 sites.

    2. **Enhanced Surveillance – AEFI-CAN** – collaboration between 55 state and territory based vaccine safety and immunisation services all reporting adverse events.

    3. **Data Linkage Programs – WAVSS** – expanded in 2021 to include AEFI reports identified through active surveillance via data linkage from ~50 datasets with over 100 million records. Links AIR vaccination data to ED attendance, hospitalisation and death databases to identify potential AEFI.

ALL OF THESE DATA SOURCES ARE COMBINED TO INFORM THE ANALYSIS AND INTERPRETATION OF VACCINE SAFETY

Government of **Western Australia**
Department of **Health**

Western Australian Vaccine Safety Surveillance – Annual Report 2021

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WAVSS Report – Data Linkage Data

Reaction	Number of data linkage cases identified
Bell's palsy	18
Chest pain	24
Deep vein thrombosis	11
Guillain Barré syndrome	3
Myocarditis/Myopericarditis	28
Pericarditis	25
Pulmonary embolism	35
Other AESI	46

Table 13. Adverse events following immunisation identified through data linkage active surveillance following COVID-19 vaccinations, 2021.

SmartVax

Total adverse event reports following immunisation to 1 October 2023

2.0	139,567	68,744,423
Reporting rate per 1,000 doses	Total adverse event reports	Total doses administered
48,855	81,886	7,618
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for Spikevax
1,024	781	
Total reports for Nuvaxovid	Total reports for brand not specified	

COVID Data Reporting – TGA, DoHAC, Public Health Units

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An NCIRS led collaboration

National COVID-19 vaccine safety surveillance

Report No. 124 • 26 June 2023
Surveillance of COVID-19 vaccinations from 22 February 2021
Data provided by Vaxtracker and SmartVax (data up to 26 June 2023); Data historically also provided by VIC CVMS and QLD CVMS

Report summary

This report summarises AusVaxSafety's COVID-19 vaccine safety signal detection and effect estimates for reports of Day 3 medical attendance, following:

- COVID-19 vaccines in children aged <12 years – all doses
  - Comirnaty 5-11 (Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine, 10 microgram formulation)
- Bivalent COVID-19 vaccines - Dose 3 & Booster
  - Spikevax Bivalent Original/Omicron BA.4-5 (Moderna elasomeran/davesomeran COVID-19 vaccine)
  - Comirnaty® Bivalent Original/Omicron BA.1 (Pfizer-BioNTech tozinameran and riltozinameran mRNA COVID-19 vaccine)
  - Comirnaty® Bivalent Original/Omicron BA.4-5 (Pfizer-BioNTech tozinameran and famtozinameran mRNA COVID-19 vaccine)
- Nuvaxovid (Novavax NVX-CoV2373 COVID-19 vaccine) – all doses

Public Facing All Vaccine Safety Data

www.ausvaxsafety.org.au

COVID Vaccine Safety Data

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COVID-19 vaccines

Vaccine safety data

COVID-19 vaccines
- Pfizer bivalent COVID-19 vaccine
- Moderna bivalent COVID-19 vaccine
- Pfizer COVID-19 vaccine adult formulation
- Pfizer COVID-19 vaccine paediatric formulation (5-11 years)
- Moderna COVID-19 vaccine
- Novavax COVID-19 vaccine
- AstraZeneca COVID-19 vaccine

Influenza vaccines

National Immunisation Program Schedule vaccines

Mpox (monkeypox) vaccine

AusVaxSafety is conducting active vaccine safety surveillance of the COVID-19 vaccines in use in Australia to ensure their ongoing safety. The COVID-19 vaccines currently being used are Comirnaty (Pfizer), Vaxzevria (AstraZeneca), Spikevax (Moderna) and Nuvaxovid (Novavax). AusVaxSafety is currently reporting safety data on Pfizer, AstraZeneca, Moderna and Novavax COVID-19 vaccines. Data on this page will be updated fortnightly.

COVID-19 vaccine safety data - at a glance

As at 6 February 2023

6,611,017
safety surveys completed*

103,116
safety surveys completed by Aboriginal and Torres Strait Islander people*

44.1%
reported at least one adverse event†

0.9%
reported visiting a GP or ED

Participants
0
500,000
1,000,000
1,500,000
2,000,000
2,500,000
3,000,000

*Surveys sent on Day 3 post vaccination.
†Adverse events are self-reported, have not been clinically verified, and do not necessarily have a causal relationship with the vaccine.

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Pfizer COVID-19 vaccine safety data - All participants

Pfizer COVID-19 vaccine adult formulation

COVID-19 vaccines

- Pfizer bivalent COVID-19 vaccine
- Moderna bivalent COVID-19 vaccine
- Pfizer COVID-19 vaccine adult formulation
  - All participants
  - Aboriginal and Torres Strait Islander participants
  - Adolescent participants
  - People affected by cancer and transplant recipients
  - Pregnant participants
- Pfizer COVID-19 vaccine paediatric formulation (5-11 years)
- Moderna COVID-19 vaccine
- Novavax COVID-19 vaccine
- AstraZeneca COVID-19 vaccine

Data on this page show the responses of all individuals aged 12 years and older who received the adult 30 microgram formulation of the Pfizer COVID-19 vaccine and completed an AusVaxSafety survey sent on day 3 after vaccination. Safety data for individuals aged 5-11 years who received the paediatric 10 microgram formulation of the Pfizer COVID-19 vaccine are available here. These data provide you with a profile of what to expect in the days following your Pfizer COVID-19 vaccination and can assist when planning for your COVID-19 vaccination.

AusVaxSafety has reaffirmed the safety of these vaccines. Data on this page will no longer be updated. Find out more here.

Data as at 23 January 2023

Safety surveys completed

2,121,357 Pfizer dose 1

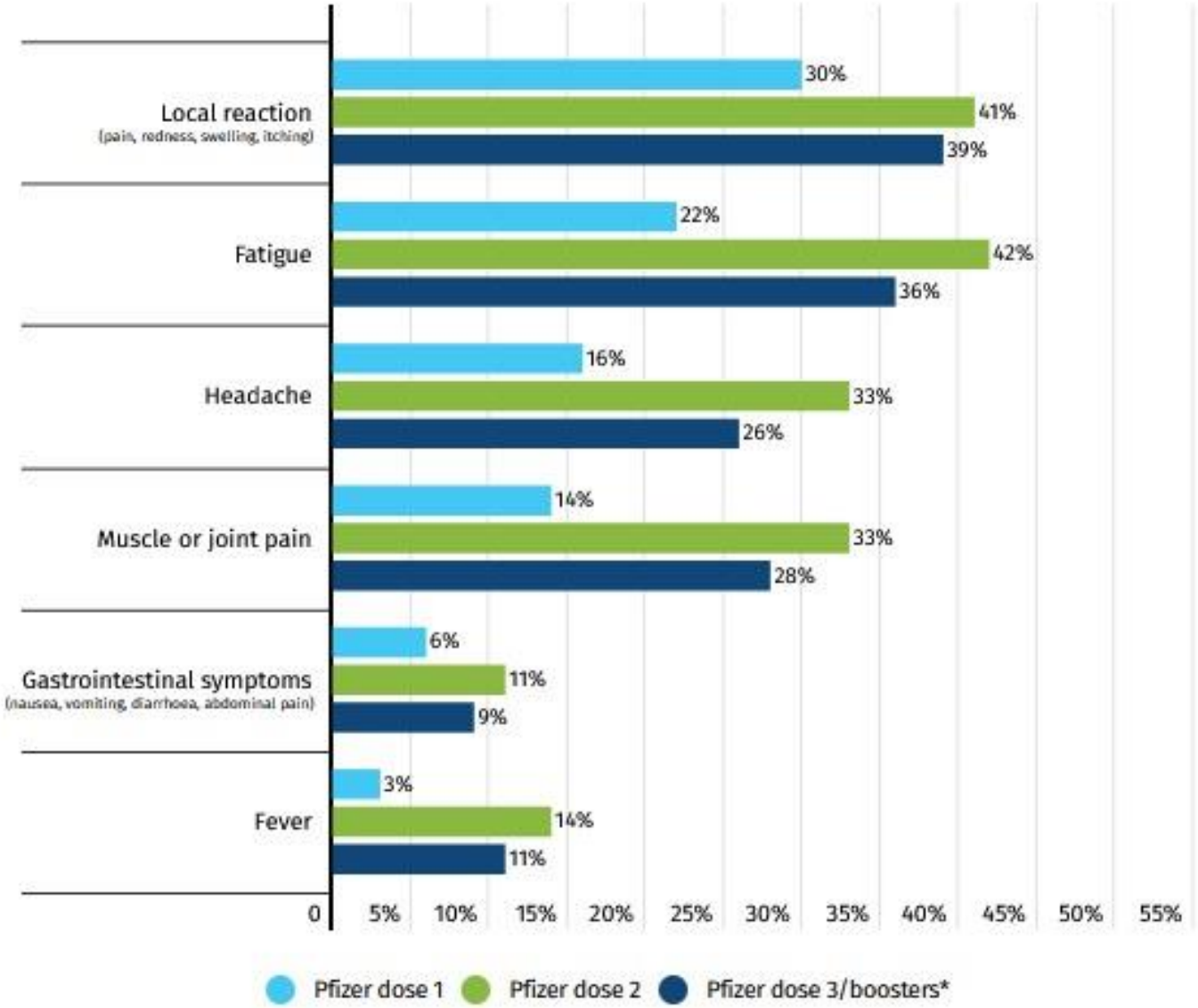
1,916,639 Pfizer dose 2

1,160,115 Pfizer dose 3/boosters*

Reported at least one adverse event

SmartVax

Commonly reported adverse events



These symptoms are known to occur after vaccination. They are generally mild and short-lived. **As with any adverse event reports, not all symptoms reported may be caused by the vaccine; they may be coincidental and due to other causes.**

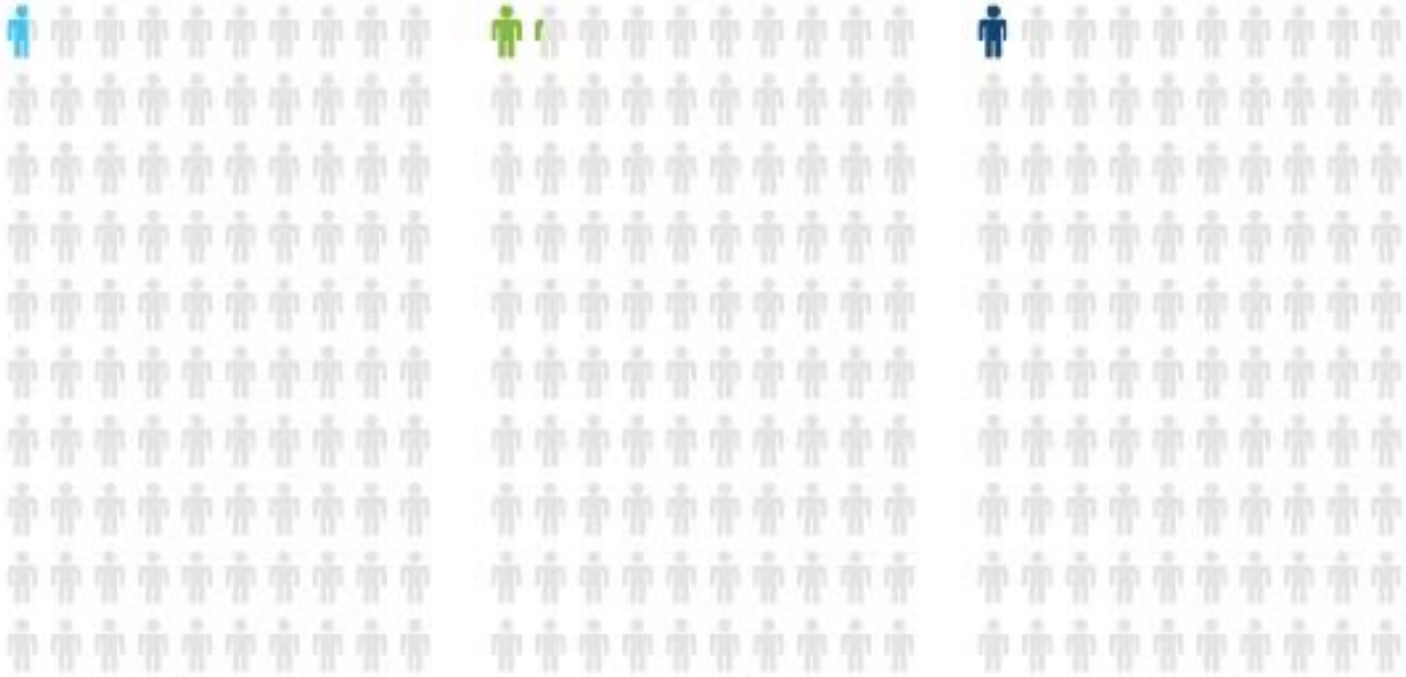
COVID Safety Data – Medical Attendance

Medical attendance

Less than 1 in 100 people reported seeing a doctor or going to the emergency department in the days after Pfizer dose 1

Just over 1 in 100 people reported seeing a doctor or going to the emergency department in the days after Pfizer dose 2

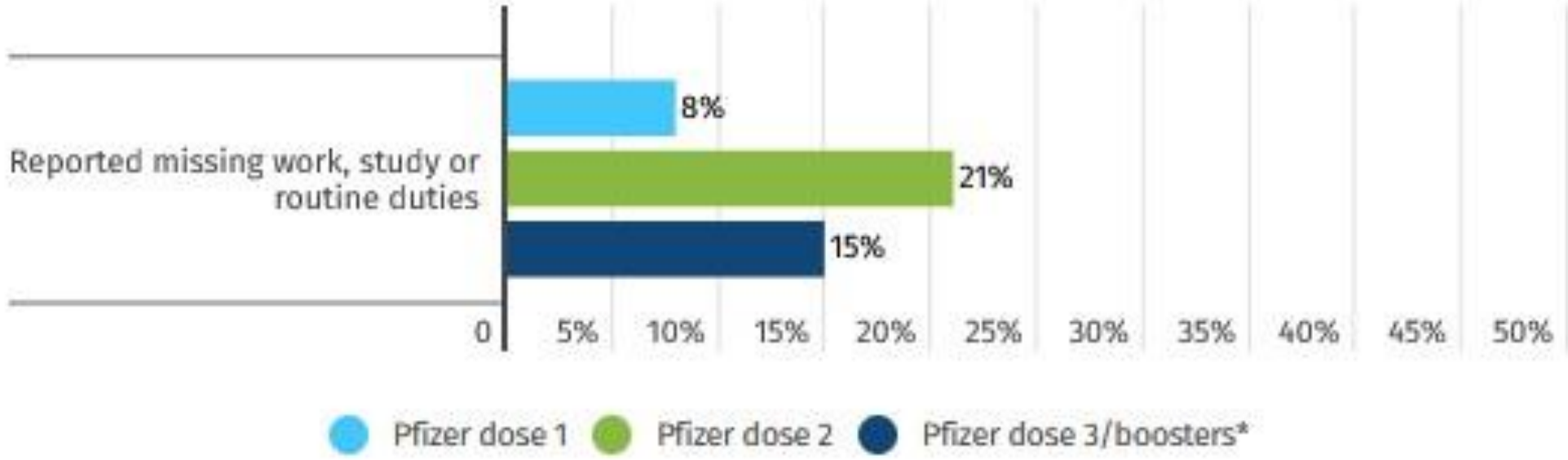
Less than 1 in 100 people reported seeing a doctor or going to the emergency department in the days after Pfizer dose 3/boosters*



Those who presented to GPs and emergency departments had similar adverse events to those who didn't. AusVaxSafety does not specifically ask participants the reason why they accessed medical care in the days following vaccination. Therefore medical attendance reported may or may not be related to any adverse events reported.

COVID Vaccine – Impact on Routine Activity

Impact on routine activities



The majority reported missing 1 day or less. Most participants who reported not being able to do work or routine duties had lethargy, headache and joint pain. These are common adverse events linked to the immune response following immunisation and understandably have meant some people have chosen to rest after vaccination.

Government of **Western Australia**
Department of **Health**

Western Australian Vaccine Safety Surveillance – Annual Report 2021

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WAVSS – Adverse events reported

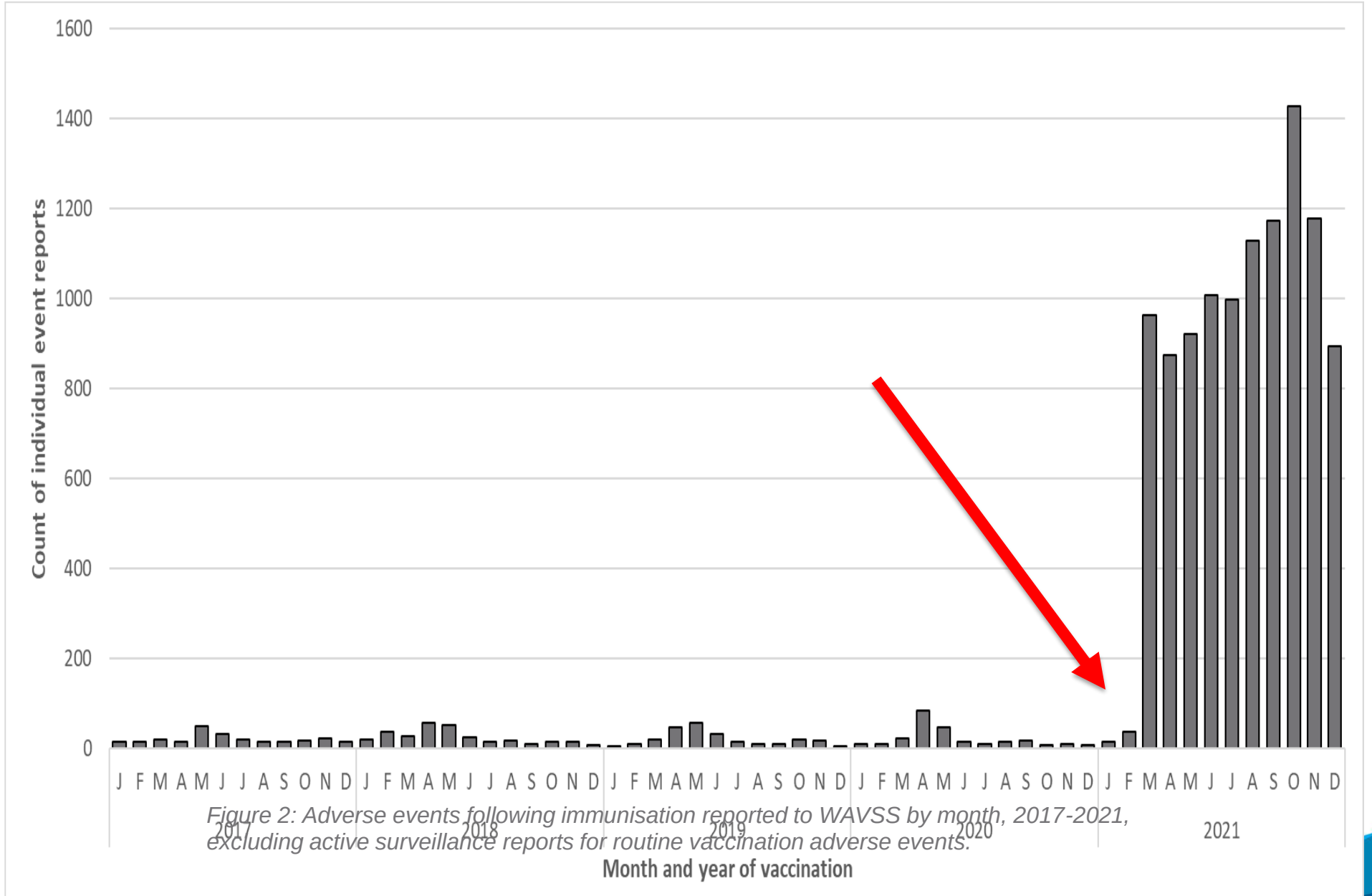


Figure 2: Adverse events following immunisation reported to WAVSS by month, 2017-2021, excluding active surveillance reports for routine vaccination adverse events.

WAVSS – Adverse events reported

Vaccine type	Number of vaccines administered in 2021	Number of adverse events reported to WAVSS	Rate of adverse events per 100,000 doses
Non COVID-19	1,808,050	200	11.1
COVID-19	3,948,673	10,428	264.1

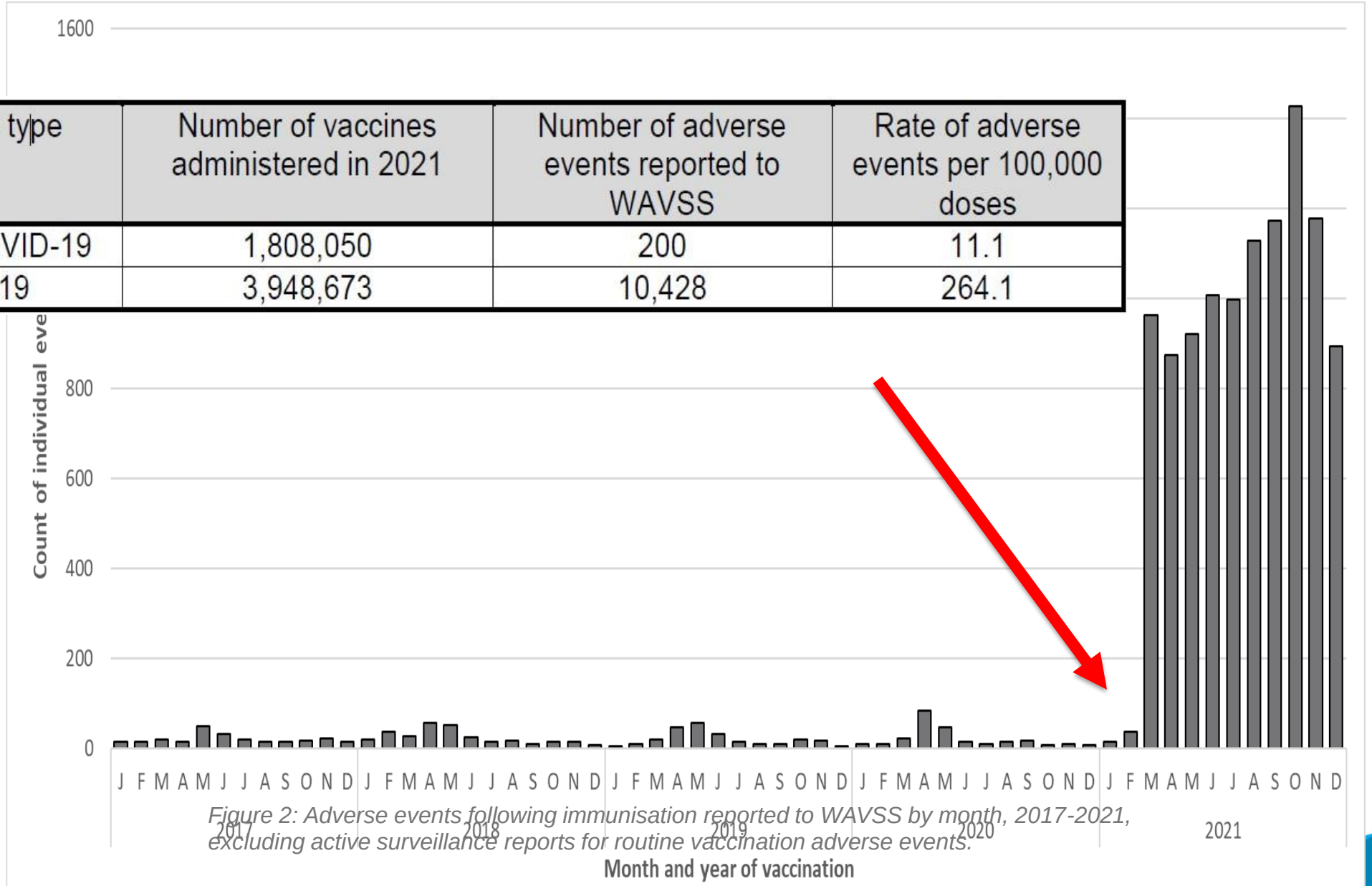


Figure 2: Adverse events following immunisation reported to WAVSS by month, 2017-2021, excluding active surveillance reports for routine vaccination adverse events.

SmartVax/AVS
– Where to From Here?

The Evolution of SmartVax

V1 (2011-2022)

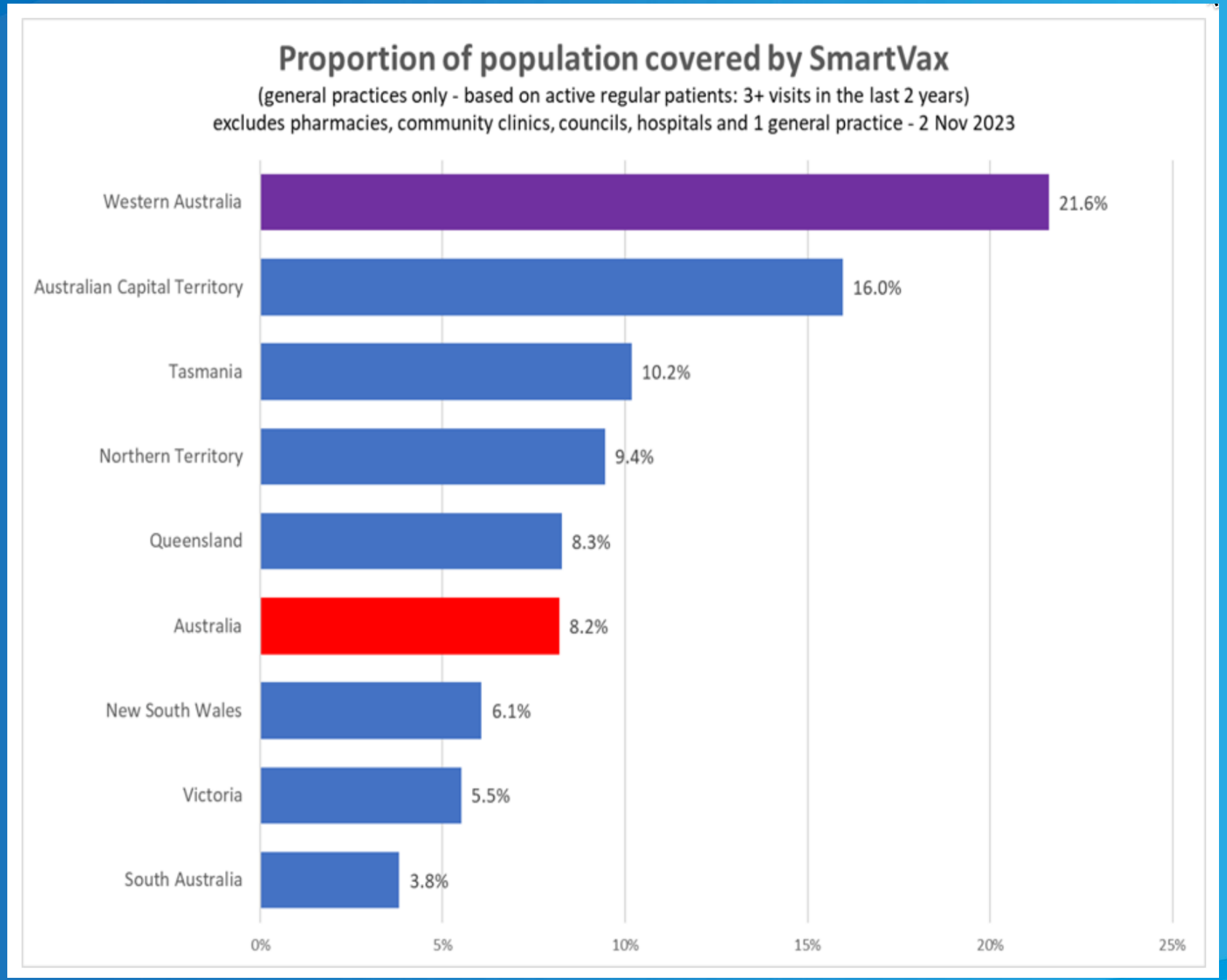
- All NIP & Travel Vaccines
- 3 SMS Process
- Survey link ONLY if reaction

V2 (2021-2022)

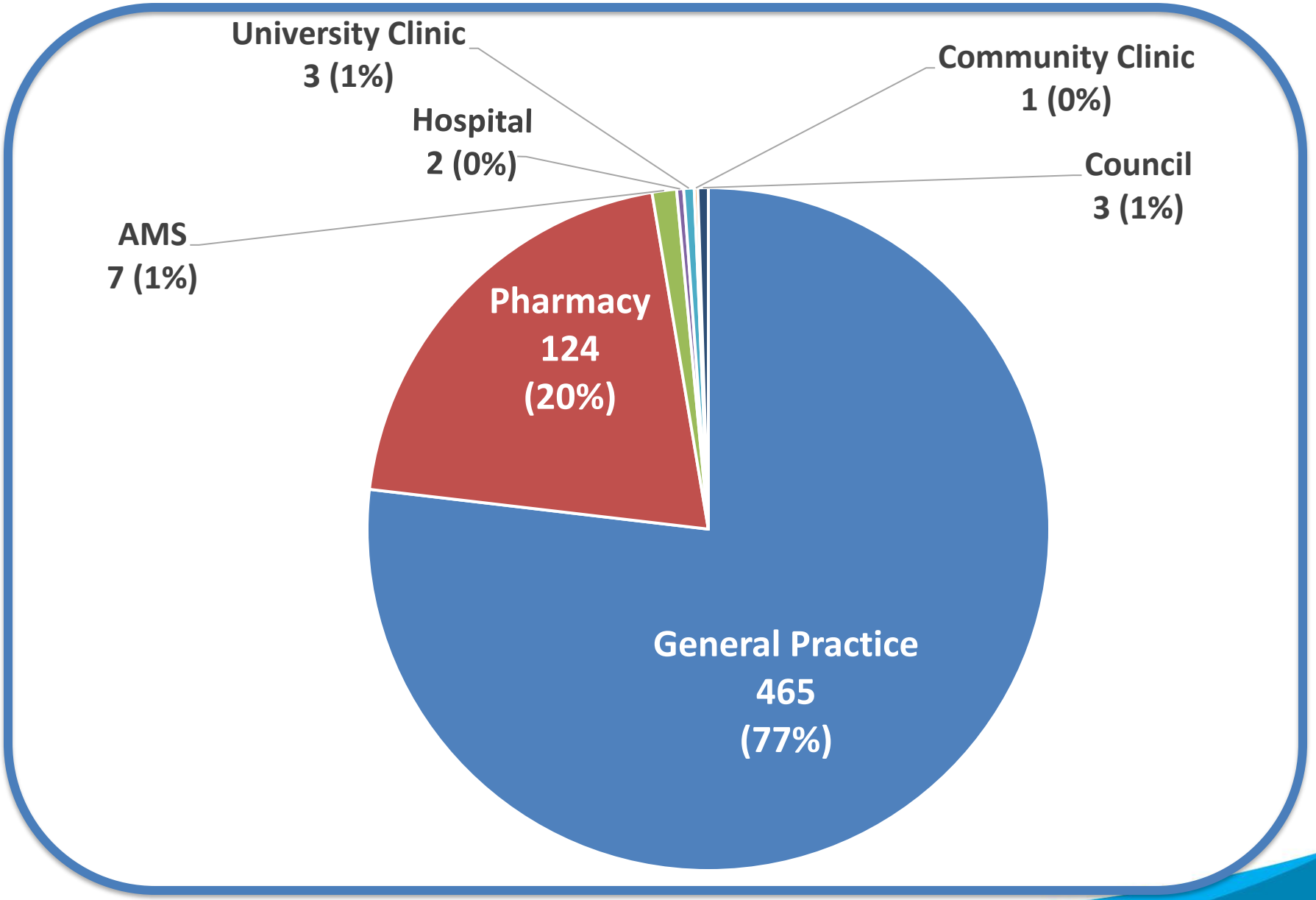
- COVID Vaccines ONLY
- Single SMS with survey link
- Day 3, 8 & 42
- Reminders for ALL if no response in 2 days

V3 (July 2023)

- ALL Vaccines – COVID, NIP & Travel
- Single SMS with survey
- Same survey for all vaccines
- Day 3 only – no reminder


Proportion of population covered by SmartVax
(general practices only - based on active regular patients: 3+ visits in the last 2 years)
excludes pharmacies, community clinics, councils, hospitals and 1 general practice - 2 Nov 2023
Western Australia
21.6%
Australian Capital Territory
16.0%
Tasmania
10.2%
Northern Territory
9.4%
Queensland
8.3%
Australia
8.2%
New South Wales
6.1%
Victoria
5.5%
South Australia
3.8%
0%
5%
10%
15%
20%
25%

SmartVax Sites (26 July 2023)



Research Australia - 19th Annual Health & Medical Research Awards

Data Innovation Award - Winner AusVaxSafety

info@smartvax.com.au

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