AusVaxSafety
An NCIRS led collaboration

AusVaxSafety annual report 2022

March 2023

Contents

s22

s22

List of tables

s22

List of figures

s22

Glossary

s22 [redacted]

ACCHO	Aboriginal Community Controlled Health Organisations
AEFI	adverse event following immunisation
AEFI-CAN	Adverse Event Following Immunisation-Clinical Assessment Network
AESI	adverse event of special interest
AIHW	Australian Institute of Health and Welfare
COVID	Coronavirus
CUSUM	cumulative sum
CVMS	COVID-19 Vaccine Management System
DHAC	Australian Government Department of Health and Aged Care

s22 [redacted]

FIR CUSUM	Fast Initial Response Cumulative Summation
GP	general practice
HCW	Health care worker

s22 [redacted]

MA	medical attendance
MedDRA	Medical Dictionary for Regulatory Activities

s22 [redacted]

s22

NCIRS	National Centre for Immunisation Research and Surveillance
NIP	National Immunisation Program
PPA	posterior predictive analysis
PT	preferred term
TGA	Therapeutic Goods Administration
TTS	thrombosis with thrombocytopenia syndrome

Introduction

The AusVaxSafety Annual Report 2022 covers data for the period 1 January 2022 to 31 December 2022. This report is a deliverable under contract with the Australian Government Department of Health and Aged Care (DHAC) in relation to services for the AusVaxSafety National Surveillance System.

The report provides a detailed summary of the AusVaxSafety modules, including analysis of all data collected under this program:

- Module 1: Active Follow-up of Vaccine Recipients
- Module 2: Adverse Events Following Immunisation-Clinical Assessment Network
- Module 3: Adverse Events of Special Interest Surveillance Program
- Module 4: Population-based Studies Using Linked Data

The AusVaxSafety Annual Report 2022 has been prepared by the AusVaxSafety team s22 at the National Centre for Immunisation Research and Surveillance (NCIRS) in consultation with the AusVaxSafety Advisory Group.

1. Executive summary

1.1 Background

AusVaxSafety was established in 2014 as Australia's national sentinel active vaccine safety surveillance system to monitor vaccine safety using participant reports of adverse events occurring within days of vaccination. Since 2016, AusVaxSafety has also been coordinating the Adverse Event Following Immunisation Clinical Assessment Network (AEFI-CAN), a complementary network that focuses on management of serious adverse events. In 2021, AusVaxSafety expanded to include two additional modules, Adverse Event of Special Interest (AESI) Program of Research and Population-based Linked Data, to further enhance the active surveillance system to monitor AEFI, including after COVID-19 vaccines.

AusVaxSafety complements the existing national system of passive AEFI surveillance conducted by the Therapeutic Goods Administration (TGA) and through individual state and territory programs.

1.2 Overview

1.2.1 Module 1: Active follow up of vaccine recipients

Analysis of de-identified response data and signal detection occurred s22 fortnightly for COVID-19 s22 vaccines over the surveillance period. Analyses reports were shared with Health and the TGA. Key vaccine safety results were made available publicly on the AusVaxSafety website.

1.2.2 Module 2: Adverse Event Following Immunisation - Clinical Assessment Network

The national AEFI-CAN continued to provide comprehensive expert clinical evaluation of individuals who experienced serious and/or unexpected AEFI, with 21 COVID-19 AEFI cases s22 discussed. Education sessions with guest speakers were introduced as the monthly videoconferences. The network maintained over 65 active members, representing specialist immunisation services as well as federal, state and territory health departments.

1.2.3 Module 3: Adverse Event of Special Interest Program of Research

AusVaxSafety continued the follow up of thrombosis with thrombocytopenia syndrome (TTS) and myocarditis cases following COVID-19 vaccinations under a national program of research. Data on the clinical management, progression and long-term morbidity and mortality outcomes of these two

AESI have been collected using standardised case report forms. Reports on initial and follow up outcomes are submitted to DHAC separately.

1.2.4 Module 4: Population-based studies using linked data

AusVaxSafety contributed to the establishment of internationally agreed on analysis protocols to assess the magnitude of association of AESIs with COVID-19 vaccines, under the Global Vaccine Data Network. Linkage process using these protocols is underway in New South Wales with preliminary analysis outputs planned for 2023.

1.3 Conclusion

AusVaxSafety built on the successes of 2021 by continued provision of reliable, ongoing and timely vaccine safety surveillance and vaccine safety clinical support nationwide through the four modules of work and was awarded Data Innovation Aware by Research Australia at the 19th Health and Medical Research Awards here for our contribution to Australia's pharmacovigilance.

2. Module 1: Active follow-up of vaccine recipients

2.1 Overview

This module involves monitoring of vaccine safety using data reported directly by vaccine recipients (or their carer) via an automated SMS or email sent using AusVaxSafety surveillance tools (SmartVax, Vaxtracker and COVID-19 Vaccine Management System [CVMS]). In 2022, AusVaxSafety conducted active surveillance for vaccines as outlined in Table 1.

Table 1. Summary of routine reporting for Module 1

Vaccine	Reporting period in 2022	Reporting frequency	Reporting detail
COVID-19	17 January to 16 December	Weekly to fortnightly	• Detailed reports on solicited AEFI, medical attendance rates by brand and dose • Signal detection
s22			

2.2 COVID-19 vaccine safety surveillance

2.2.1 Overview

AusVaxSafety continued COVID-19 vaccine safety surveillance in 2022 across all eligible age groups, populations and doses for the following vaccines:

- Comirnaty 30 µg (Pfizer)
- Comirnaty 5-11 years 10 µg (Pfizer)
- Vaxzevria (AstraZeneca)
- Spikevax 100 µg (Moderna)
- Spikevax 6-11 years 50 µg (Moderna)
- Spikevax 6 months-5 years 25 µg (Moderna)
- Spikevax Bivalent (Moderna)
- Nuvaxovid (Novavax)

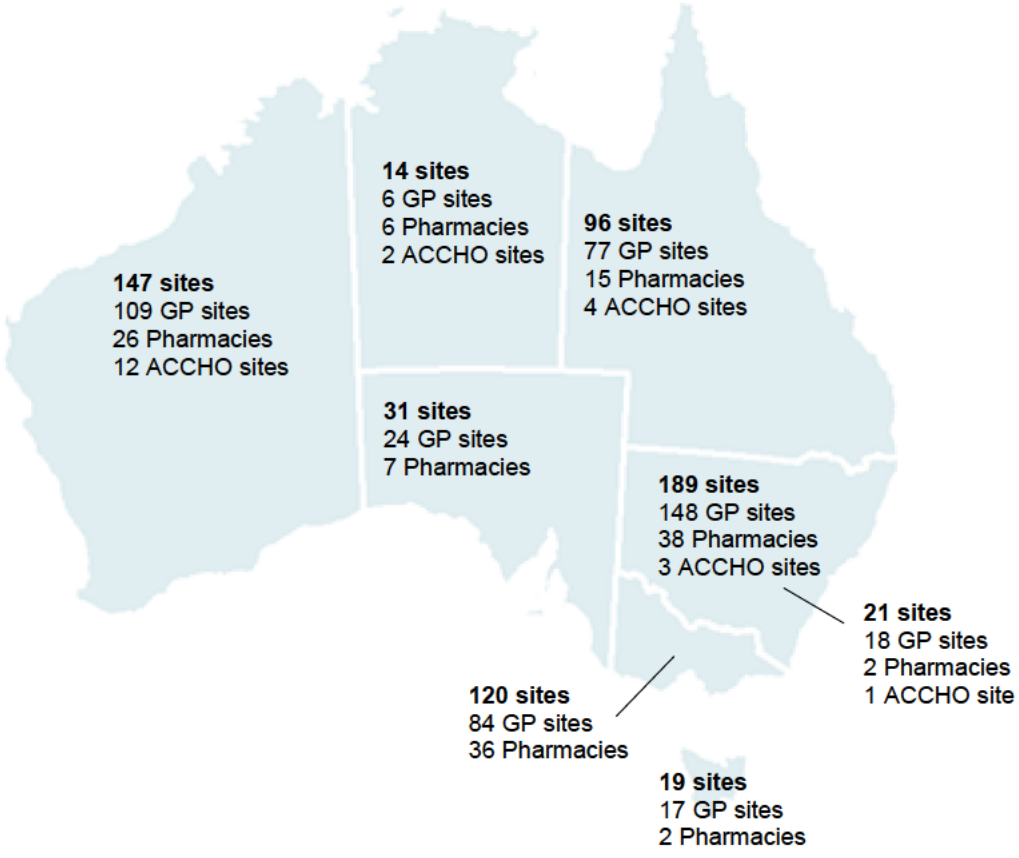
2.2.2 Surveillance sites

As COVID-19 vaccinations shifted from state/territory health vaccination hubs to general practice, AusVaxSafety increased the number of sentinel general practice surveillance sites to ensure ongoing representation of the general population receiving COVID-19 vaccines. Changes in surveillance sites from 2021 to 2022 are outlined in Table 2.

Table 2. Summary sentinel surveillance sites for 2021 and 2022*

Vaccination site type	2021	2022
GP	380	483
Pharmacy	136	132
ACCHO	31	22

Figure 1. AusVaxSafety vaccine safety surveillance sites (excluding state/territory health vaccination hubs)



*Excludes state/territory health vaccination hubs

2.2.3 Methods

De-identified data were exported from the surveillance tools and cleaned and analysed in Qlik Sense (Qlik Software). Qlik-generated data exports were used to generate signal detection reports in R (version 4.1) and R Markdown (version 2.1). Multiple methods of signal detection were used in 2022: cumulative sum (CUSUM) and posterior predictive analysis (PPA).

CUSUM analyses compare the relative likelihood that an underlying event rate is at a set threshold rate versus the liklihood that it is at an expected rate for the accumulated data. The CUSUM method compared observed medical attendance rates against the data accumulated by AusVaxSafety.

The PPA method estimates the distribution of predicted medical attendance for the previous week of data, adjusting for age, sex, jurisdiction, Indigenous status and chronic medical conditions of the surveyed population.

2.2.4 Reporting summary

In 2022, COVID-19 vaccine safety surveillance reports were produced weekly from 20 January to 3 May (reports 80 to 95). For the remainder of 2022, reports were generated once a fortnight (reports 96 to 111) (refer to Appendix 1). Aside from report 80 (20 January 2022), reports contained signal detection analysis only, with additional analyses presented in the AusVaxSafety Qlik application from January 2022.

2.2.5 Signal detection

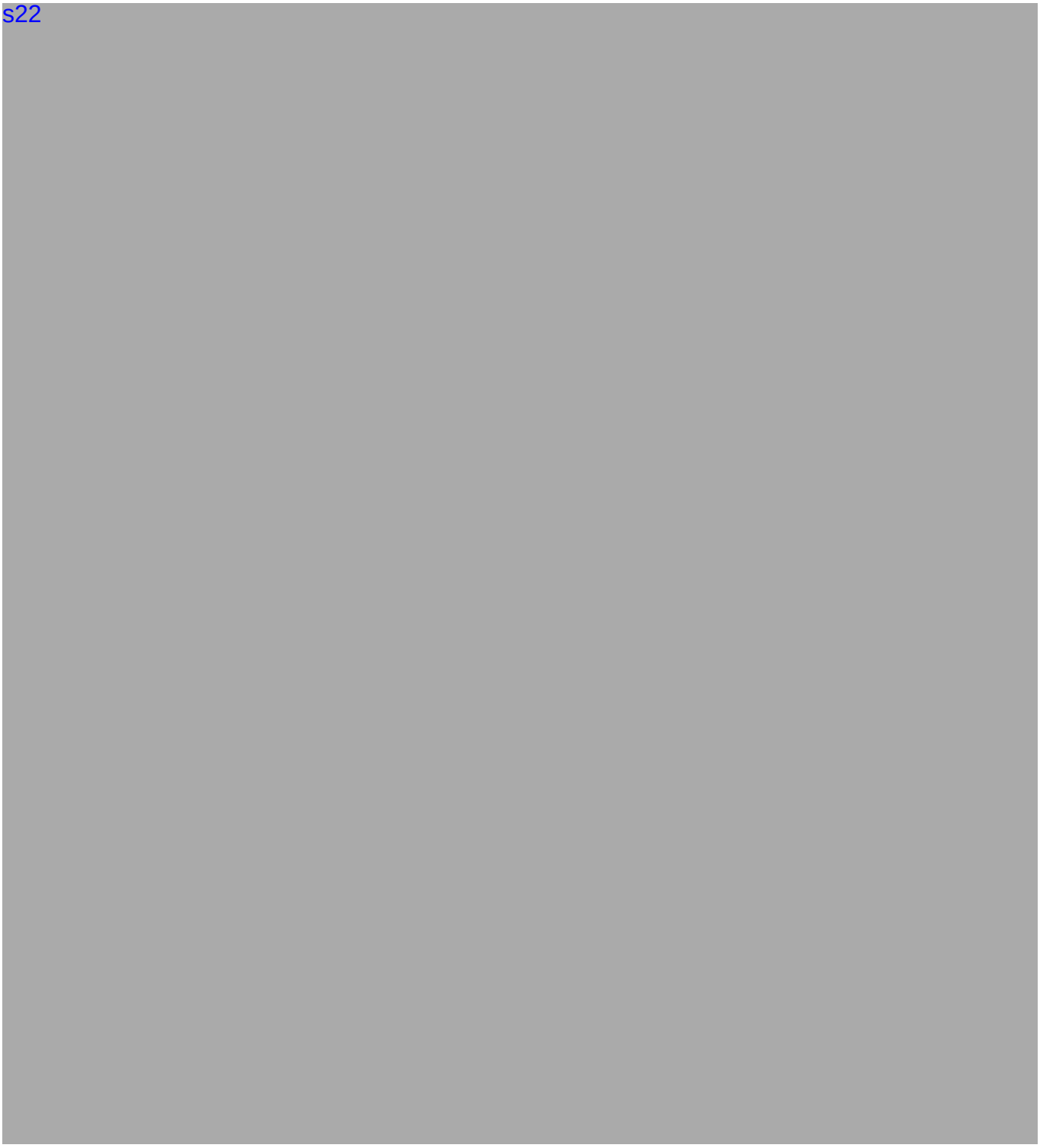
From January to September, intermittent safety signals were detected for Comirnaty dose 1 vaccine (<50 years and ≥ 50 years; PPA and CUSUM; reports 80-96,, 104). Safety signals were detected in January and February for Vaxzevia dose 1 (<50 years; PPA; reports 80-81) and Spikevax dose 1 and dose 2 vaccines (<50 years and ≥ 50 years; CUSUM; reports 80-82). Intermittent signals for Comirnaty and Vaxzevria vaccines were also ongoing from September to December 2021, and were notified to and discussed with the Department of Health Immunisation Branch, TGA Pharmacovigilance Branch and AusVaxSafety Advisory Group. Further analysis of these signals indicated they likely reflected a changing population of vaccine recipients who may have been more vaccine hesitant or more suscpetible to adverse events. It is hypothesised that signals detected for Spikevax dose 1 and dose 2 vaccines in 2022 also resulted from the changing vaccine recipient population. Notably these signals commenced as the rollout for these brands was ending, and following several months and thousands of responses with no safety signals.

In March, safety signals for Comirnaty 5-11 dose 1 (PPA; report 86) and Spikevax dose 3/booster (12 to <50 years; PPA; report 88) were detected, yet were resolved within a fortnight and not

observed again. Each new signal was observed only at one event above threshold by the PPA method, and not detected by the CUSUM method. Similarly, a safety signal was detected for Comirnaty 3/booster dose from March to April (12 to <50 years and ≥ 50 years; PPA; reports 90 - 91) resolved within four weeks and was conisdered to reflect changes in the recipient cohort.

Due to low response numbers in 2022, signal detection ceased for Vaxzevria dose 1 and dose 2 vaccines and Spikevax dose 1 and dose 2 vaccines in February, and for Comirnaty dose 1 and dose 2 vaccines in October.

s22



s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

s22

Document 1

3. Module 2: AEFI-Clinical Assessment Network

3.1 Overview

AEFI-CAN is a formal collaboration between state- and territory-based immunisation specialist services, jurisdictional health departments, Health (Immunisation Branch) and the TGA. As a national network, AEFI-CAN aims to:

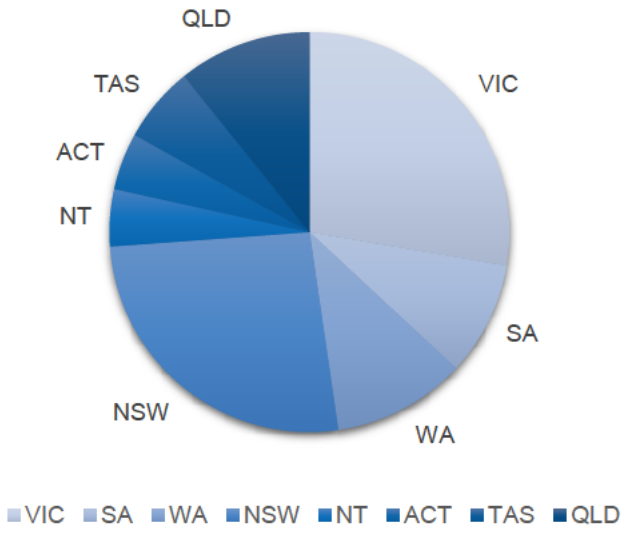
- discuss management of serious and/or severe AEFIs and work towards a harmonised, nationally consistent management approach
- provide education to AEFI-CAN members on vaccine safety
- provide advice, as group of vaccine safety experts, to clinicians and/or jurisdictional representatives on management of individual AEFI cases or clusters of AEFIs
- discuss knowledge gaps in vaccine safety that may lead to development of research questions and projects
- develop clinical guidance on revaccination management based on the national experience collated within the group.

In 2022, Associate Professor Nicholas Wood continued as the chair of AEFI-CAN, with AusVaxSafety continuing to provide coordination and secretariat support for the network.

3.2 AEFI-CAN membership

AEFI-CAN membership includes vaccinologists, infectious disease specialists, immunologists, paediatricians, nurses, immunisation providers, researchers and Health and TGA representatives. In 2022, AEFI-CAN had over 65 active members across Australia (refer to Figure 11).

Figure 11. Representation by state/territory in AEFI-CAN, 2022



3.3 Case discussions

A total of 10 AEFI-CAN teleconferences were in 2022, with an average of 30 members attending each teleconference. Table 18 lists the cases discussed in 2022.

Table 18. AEFI-CAN case discussions

Meeting	Case description	Vaccines	Case type	Revaccination outcome
January	Bullous pemphigoid	Comirnaty – Dose 1	Dermatological	Patient chose not to revaccinate
	Henoch-Schonlein Purpura	Comirnaty – Dose 1	Vasculitis	Patient chose not to revaccinate
	Atypical chest pain, arthralgia, subcutaneous nodules & ocular inflammation	SpikeVax – Dose 1	Cardiovascular	Unknown
	Delayed anaphylaxis	Comirnaty – Dose 1	Immunological	Positive intradermal testing, did not proceed with graded challenge
March	Vaccination advice for Freidrich's Ataxia patient post COVID-19 infection	N/A		Vaccinated with 2 Comirnaty doses with no AEFI.
	Transverse myelitis	Comirnaty – Dose 1	Neurological	Patient chose not to revaccinate as no platform switch available for age
	Possible acute interstitial lung disease	Vaxzevria – Dose 1 & 2 Comirnaty – Dose 3	Respiratory	Patient declined any further medical appointments
	Wide spread face, neck and scalp erythema with desquamation and exudate	Comirnaty – Dose 2	Dermatological	Proceed with catch up vaccines 1-month interval HPV, Flu, Boostrix & MenACY. No further COVID-19 vaccines given.
April	s22			
May	MIS-C post COVID vaccination and group A streptococcus sepsis	Comirnaty – Dose 1	Immunological/ Infectious	Patient chose not to revaccinate

Meeting	Case description	Vaccines	Case type	Revaccination outcome
	s22			
	Cutaneous leucocytoclastic vasculitis	Comirnaty – Dose 1	Vasculitis	Unknown
June	Kawasaki Disease-like PIMS-TS	Comirnaty – Dose 1	Immunological	Family chose not to revaccinate
July	Guillain-Barre Syndrome	Vaxzevria – Dose 1 Comirnaty – Dose 2	Neurological	Unknown
	Vaccination advice for influenza and COVID-19 in patient with seizures post H1N1 & COVID infections	N/A		Family chose not to vaccinate
	Vaccination advice for live vaccines on dupilumab therapy	N/A		Advised to proceed with live vaccinations without ceasing dupilumab
August	Intermediate uveitis	Comirnaty – Dose 3	Ophthalmology	Unknown
	Chronic inflammatory demyelinating polyneuropathy	FluadQuad – Dose 1 Comirnaty – Dose 4	Neurological	Unknown
	Myopericarditis	Comirnaty – Dose 3	Cardiovascular	Unknown
	Addison's disease	Comirnaty – Dose 1 & 2	Endocrine	Patient chose not to revaccinate
	Non-specific neurological syndrome	Comirnaty – Dose 2	Neurological	Unknown
October	s22			
	Vasoactive phenomenon	Comirnaty – Dose 1 & 2	Dermatological	Nil further COVID-19 vaccines but has received influenza, HPV and PCV113 with no AEFIs.
	Dermatological condition flare	Nuvaxovid – Dose 1 & 2	Dermatological	Unknown

Meeting	Case description	Vaccines	Case type	Revaccination outcome
November	s22			
	Prolonged urticarial reaction (10 months)	Comirnaty – Dose 1	Dermatological	Unknown
	Eosinophilic pneumonia	Comirnaty – Dose 4	Respiratory	Unknown
	s22			

4. Module 3: AESI Surveillance Program

4.1 Overview

AusVaxSafety established the AESI Surveillance Program in September 2021 to coordinate and harmonise the collection of high-quality data on the clinical management, progression and long-term morbidity and mortality outcomes of serious AESIs. Two conditions were monitored under this surveillance program – thrombosis with thrombocytopenia syndrome and myocarditis.

4.2 Thrombosis with thrombocytopenia syndrome

A report on the initial clinicopathological features of the 170 TTS cases in Australia as identified by the TGA was submitted to Health in June 2022 (Appendix 5). The case series has also been submitted as a manuscript for consideration for publication in a peer-reviewed journal.

Appendix 6 is a report detailing the follow-up outcomes in 99 of 170 TTS cases (58%) who consented for follow up nationally.

4.3 Myocarditis

A report on the initial clinicopathological features of myocarditis cases in Australia as identified by the TGA and a subset who consented for follow up will be submitted as a separate report in April 2023.

5. Module 4: Linked data

5.1 Overview

AusVaxSafety proposed a fourth module of work using linked data to enhance and complement the vaccine safety surveillance data provided through the other three modules and to support the detection and investigation of vaccine safety signals.

Stakeholder consultation with a range of Commonwealth and jurisdictional representatives and the Australian Institute of Health and Welfare (AIHW) staff was conducted in 2021 to determine interest and feasibility of various data linkage options. All jurisdictions agreed that vaccine safety analysis using linked data is an important component of a comprehensive vaccine surveillance system and committed to participating in and contributing to a national approach.

A project proposal was submitted to Health in October 2021, which was approved in January 2022, with the first deliverable under this module on a mycaroditis association study analysis to be delivered in January 2023.

6. Communication

6.1 AusVaxSafety website engagement

Traffic to the AusVaxSafety website dipped in 2022, driven by a declining number of COVID-19 vaccinations administered compared to 2021. Website traffic still remains well above pre-pandemic levels, with 176,398 users responsible for 435,188 page views in 2022. Key updates include:

- Introduction of mpox vaccine safety data
- Updated influenza safety data pages

6.2 Media / stakeholder engagement

AusVaxSafety maintained media engagement throughout 2022 through a sustained proactive and reactive media strategy. AusVaxSafety media engagement increased awareness of the AusVaxSafety program to journalists across Australia, with published pieces promoting vaccine safety and increasing public confidence in vaccines used in Australia. AusVaxSafety had 434 media mentions in 2022 – both organic and earned. Key highlights include:

- Do COVID boosters cause more or fewer side effects? How quickly does protection wane? Your questions answered (reach 7.38 million)
- First safety data on Novavax released (reach 821 thousand)
- How many Australians have had short-term reactions to COVID-19 vaccines? (reach 6.37 million)
- COVID vaccine side effects for children found to occur at lower rates than in trials (reach 7.39 million)

AusVaxSafety experts also authored and published numerous articles promoting vaccine safety in *The Conversation,* many of which were subsequently republished in media outlets across Australia. The articles provided the public and immunisation providers with access to timely and reputable information in a rapidly evolving vaccine safety landscape. Key highlights include:

- Dr Lucy Deng and Professor Nick Wood: *Do COVID boosters cause more or fewer side effects? How quickly does protection wane? Your questions answered*
- Professor Nick Wood: *The Moderna vaccine is now available for 6 to 11 year olds. Here's what parents need to know*
- Professor Nick Wood: *Should my child have a COVID vaccine? Here's what can happen when parents disagree*
- Professor Nick Wood: *16-17 year olds can now get their COVID boosters. Why not younger children?*

- Professor Nick Wood: *Respiratory infections like whooping cough and flu have plummeted amid COVID. But 'bounce back' is a worry*
- Professor Nick Wood: *COVID vaccination recommendations evolve over time. Who is due for which dose now?*
- Professor Nick Wood: *More than 100 Australian kids have had multisystem inflammatory syndrome after COVID. What should parents watch for?*
- Professor Nick Wood: *Previous COVID infection may not protect you from the new subvariant wave. Are you due for a booster?*

6.3 Research Australia Data Innovation Award winners

The AusVaxSafety team was recognised at Research Australia's 19th Health and Medical Research Awards, winning the Data Innovation Award for our work in delivering nationally consistent vaccine safety surveillance in near-real time from the first day of the COVID-19 vaccine rollout, the largest and most complex immunisation program ever delivered in Australia.

The Data Innovation Award recognises innovative data collection, processing and analysis that advances health and medical research and is a testament to AusVaxSafety's contribution to Australia's robust vaccine safety monitoring system.

7. Evaluation

7.1 Immunisation provider knowledge, attitudes and practices towards Australia's vaccine safety surveillance systems

In 2022, AusVaxSafety continued the evaluation of the impact of the AusVaxSafety active surveillance system on provider confidence in vaccines. The evaluation aims to examine immunisation providers' use of the active surveillance data and how it affects their immunisation practice.

Over five hundred survey responses from Health Care Workers (HCW) on their knowledge, attitudes and practices in regards to vaccine safety surveillance were analysed and a manuscript is currently being drafted for publication in a peer-reviewed journal. Preliminary data was presented at the 2022 Communicable Diseases and Immunisation Conference and to the AusVaxSafety Advisory Committee.

Twenty semi-structured telephone interviews were conducted with HCW for insights into their experiences and understanding of vaccine safety surveillance systems. Interviews were conducted between August and November 2022. Analysis of the interviews is currently underway with a manuscript planned for quarter 4 of 2023.

AusVaxSafety will use the information from this evaluation to improve surveillance methods and information dissemination.

8. Regular meetings

Table 19. Regular meetings held by AusVaxSafety

Module	Meeting description	Frequency
Overall	AusVaxSafety Advisory Group	6 – 8 weeks
Module 1	State/territory health departments	Monthly
	SmartVax	6 weekly
	Vaxtracker	6 weekly
	Signal detection	Monthly
Module 2	AEFI-CAN	Monthly
Module 3	Program operations group	As needed
	Program recruitment nurse	Monthly
Module 4	Stakeholder meetings with states, territories, data custodians, data linkage units	As needed

9. Publications

Deng L, Glover C, Dymock M, Pillsbury A, Marsh JA, Quinn HE, Leeb A, Cashman P, Snelling TL, Wood N, Macartney K. The short term safety of COVID-19 vaccines in Australia: AusVaxSafety active surveillance, February - August 2021. Med J Aust. 2022;217:195-202. doi:10.5694/mja2.51619. Epub 2022 Jul 4.

Salter SM, Li D, Trentino K, Nissen L, Lee K, Orlemann K, Peters I, Murray K, Leeb A, Deng L. Safety of four COVID-19 vaccines across primary doses 1, 2, 3 and booster: a prospective cohort study of Australian community pharmacy vaccinations. Vaccines (Basel). 2022;10:2017. doi:10.3390/vaccines10122017

Yap N, Buttery J, Crawford NW, Omer S, Heininger U; AEFI CAN Group. The impact of Australian childhood vaccination mandates on immunization specialists and their interactions with families. Pediatric Infectious Disease Journal. 2022;41:e188-e193. doi:10.1097/INF.0000000000003490.

10. Appendices

Appendix 1. AusVaxSafety National COVID-19 vaccine safety report 2022-12-12

s22

National COVID-19 vaccine safety surveillance

Report No. 111 • 12 December 2022
Surveillance of COVID-19 vaccinations from 22 February 2021
Data provided by Vaxtracker, SmartVax, VIC CVMS and QLD CVMS (data up to 12 December 2022 at 12 AM AEDT)

Signal Detection and Effect Estimates

CUSUM Analysis

As of Report No. 43, the FIR CUSUM analysis performed for Report No. 1-42, which benchmarked observed medical attendance rates against expectations from clinical trial data, has been superseded by a new CUSUM analysis, which benchmarks observed event (fever or medical attendance) rates against AusVaxSafety COVID-19 vaccine safety surveillance data to date and tracks the stability of these rates over time.

The cumulative sum (CUSUM) tracks the relative likelihood that the underlying event rate is at the threshold rate versus the likelihood it is at the expected rate given the accumulated data. Expected rates have been set at the observed event rates to 25 April 2021 for each brand, dose, and age subgroup, and threshold rates have been set at three times the expected rates. The table below is updated fortnightly, and analysis is performed subject to a minimum of new 100 responses per subgroup (superseded the original threshold of 5,000 responses per subgroup as of Report No. 103).

AusVaxSafety
An NCIRS led collaboration

Table 1. CUSUM Control chart results – Medical Attendance reported in Day 0-3

Event Type	Vaccine	Dose	Age Group	Analysis Date[a]	No. New Participants[b]	CUSUM Status[c]
Fever	Spikevax 6m-5y (Moderna)	1	6m-5 years	-	48	Insufficient Data
		2	6m-5 years	-	21	Insufficient Data
MA	Comirnaty 5-11 (Pfizer)	1	5-11 years	12 December 2022	0	No Signal Detected
		2	5-11 years	28 November 2022	26	No Signal Detected
		3 & Booster	5-11 years	14 November 2022	9	No Signal Detected
	Comirnaty (Pfizer)	1	CUSUM analysis ceased as of 17 October 2022 due to small numbers of responses			
		2				
		3 & Booster	12-<50 years	12 December 2022	0	No Signal Detected
			≥50 years	12 December 2022	0	No Signal Detected
	Vaxzevria (AstraZeneca)	1	CUSUM analysis ceased as of 7 February 2022 due to small numbers of responses			
		2				
		3 & Booster				
	Spikevax 6m-5y (Moderna)	1	6m-5 years	-	48	Insufficient Data
		2	6m-5 years	-	21	Insufficient Data
	Spikevax 6-11 (Moderna)	1	6-11 years	-	58	Insufficient Data
		2	6-11 years	-	40	Insufficient Data
	Spikevax (Moderna)	1	CUSUM analysis ceased as of 7 February 2022 due to small numbers of responses			
		2				
		3 & Booster	CUSUM analysis ceased as of 14 November 2022 due to small numbers of responses			
	Spikevax Bivalent (Moderna)	3 & Booster	12-<50 years	12 December 2022	0	No Signal Detected
			≥50 years	12 December 2022	0	No Signal Detected
	Nuvaxovid (Novavax)	1	18-<50 years	05 September 2022	50	No Signal Detected
			≥50 years	31 October 2022	17	No Signal Detected
		2	18-<50 years	13 June 2022	90	No Signal Detected
			≥50 years	30 May 2022	74	No Signal Detected
		3 & Booster	18-<50 years	05 September 2022	98	No Signal Detected
			≥50 years	14 November 2022	37	No Signal Detected

[a]Date of most recent analysis; [b]Cumulative number of participants contributing data to analysis (including the most recent analysis); [c]Number of new participants accumulated since the most recent analysis was performed (0 if analysis performed on day of report)

AusVaxSafety
An NCIRS led collaboration

Posterior Predictive Analysis

The posterior predictive analysis estimates the distribution of predicted events (fever or medical attendance) for the past week of data. This predicted distribution adjusts for the age, sex, jurisdiction, Indigenous status and chronic medical condition distributions of the population providing responses for the previous week. A signal is detected if the actual observed number of events exceeds the 99th percentile of the predicted distribution. This analysis is computed for the same subgroups as the CUSUM analysis.

Table 2. Posterior Predictive Analysis Results – Medical Attendance reported in Day 0-3

Event Type	Vaccine	Dose	Age Group	Rate (to date)[a]	Rate (past week)[b]	Responses[c]	Observed events (%)[d]	Signal threshold[e]	Status
MA	Comirnaty 5-11 (Pfizer)	1	5-11 years	0.4%	0%	23	0 (0%)	1	No Signal
		2	5-11 years	0.5%	0%	27	0 (0%)	1	No Signal
	Comirnaty (Pfizer)	1	PPA analysis ceased as of 17 October 2022 due to small numbers of responses						
		2							
		3 & Booster	12-<50 years	1.3%	0.6%	173	1 (8%)	8	No Signal
			≥50 years	0.5%	0.4%	245	1 (19%)	5	No Signal
	Vaxzevria (AstraZeneca)	1	PPA analysis ceased as of 7 February 2022 due to small numbers of responses						
		2							
		3 & Booster							
	Spikevax (Moderna)	1	PPA analysis ceased as of 7 February 2022 due to small numbers of responses						
		2							
		3 & Booster	PPA analysis ceased as of 14 November 2022 due to small numbers of responses						
	Spikevax Bivalent (Moderna)	3 & Booster	12-<50 years	0.5%	1%	305	3 (84%)	5	No Signal
			≥50 years	0.2%	0.3%	389	1 (28%)	5	No Signal
	Nuvaxovid (Novavax)	1	18-<50 years	3.1%	0%	2	0 (0%)	1	No Signal
			≥50 years	1.2%	0%	3	0 (0%)	1	No Signal
		2	18-<50 years	4.0%	0%	0	0 (0%)	0	No Signal
			≥50 years	1.2%	0%	0	0 (0%)	0	No Signal
		3 & Booster	18-<50 years	2.6%	0%	1	0 (0%)	1	No Signal
			≥50 years	0.7%	0%	5	0 (0%)	1	No Signal

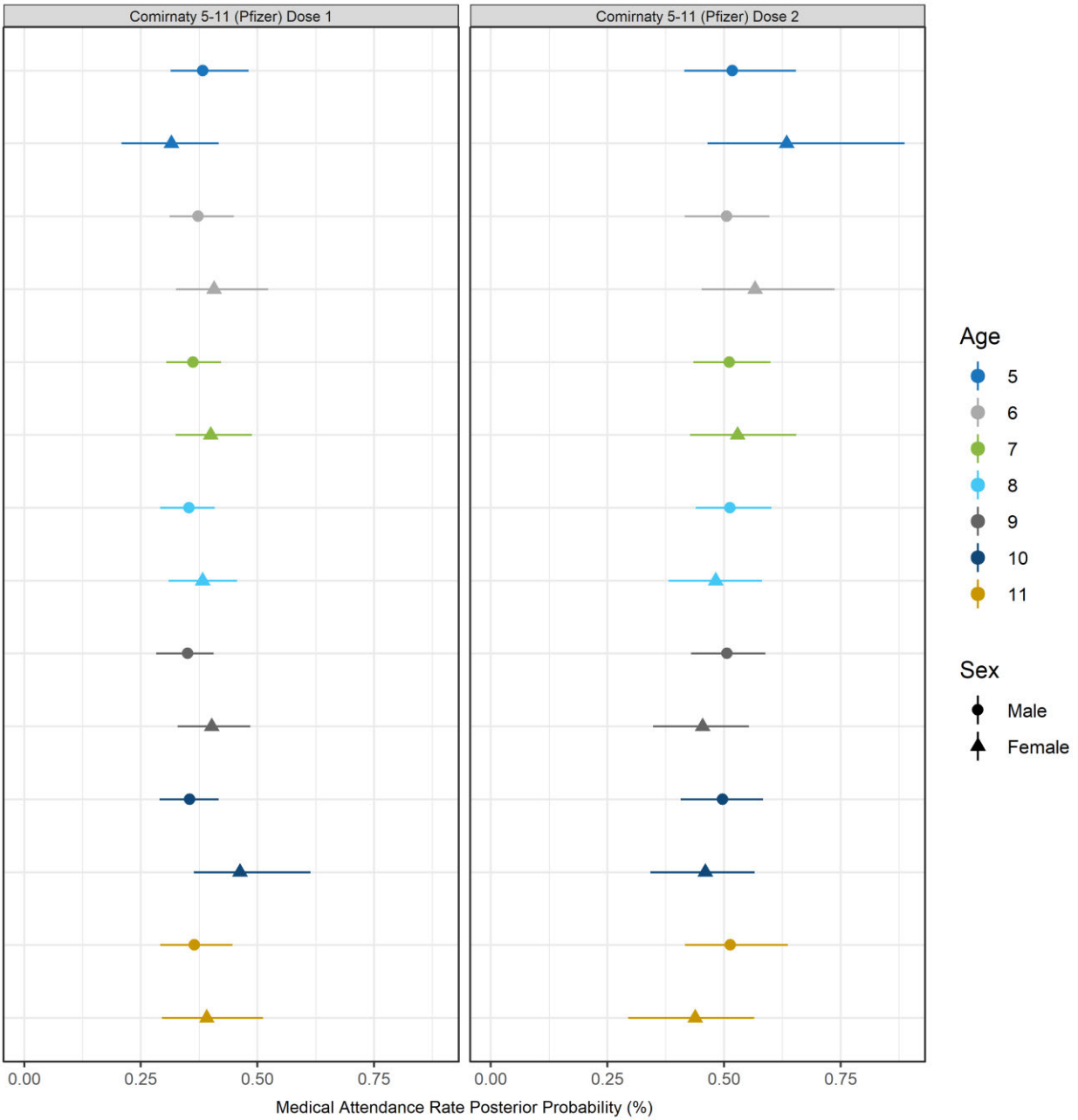
[a]Crude event rate to date; [b]Crude event for past week; [c]Number of participants responding to Day 3 survey in the past week; [d]Number of participants reporting event in the past week (percentile of the posterior distribution); [e]Number of events predicted at the 99th percentile of the posterior distribution

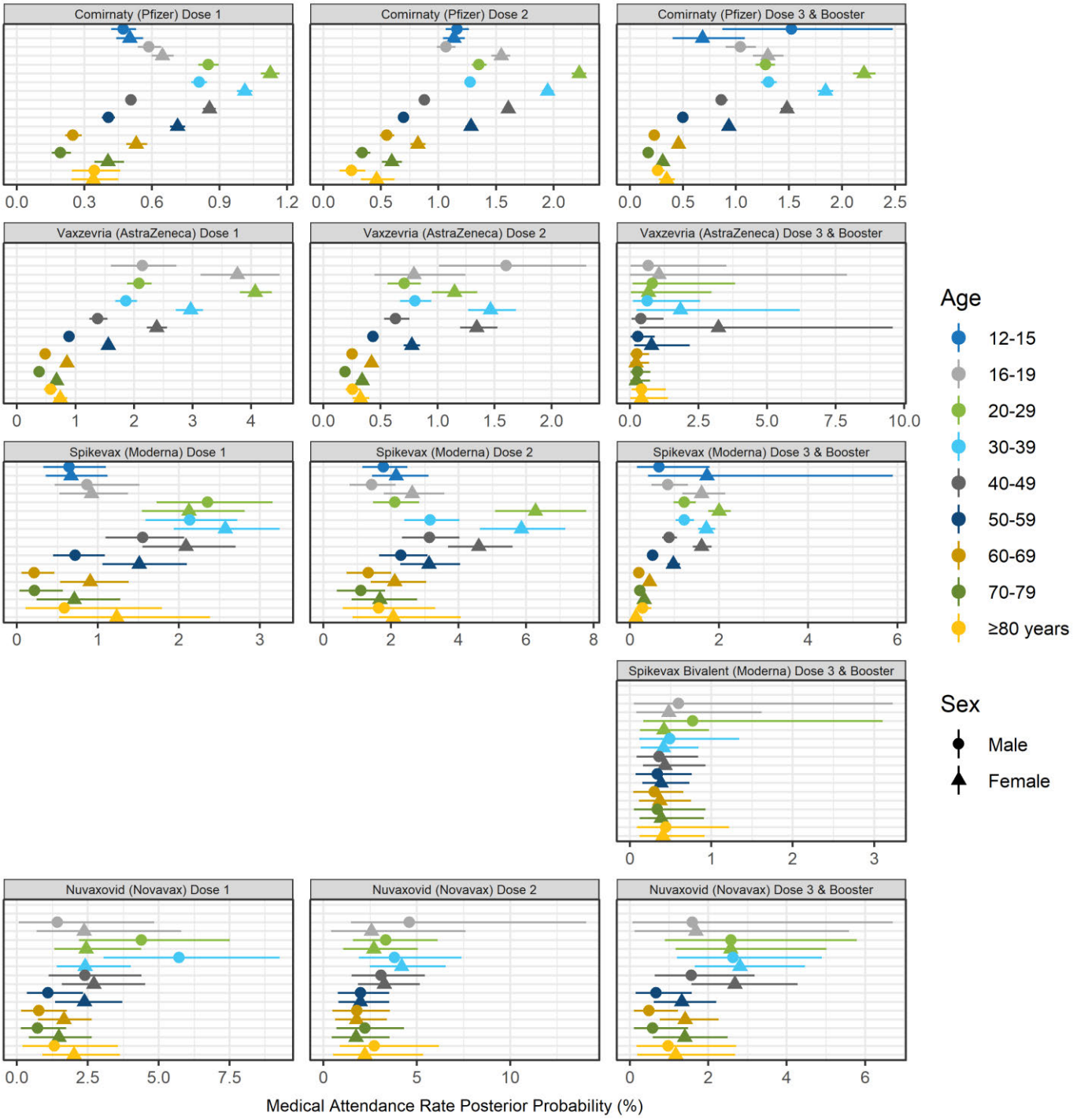
Bayesian Posterior Distributions

Point estimates with 95% credible intervals for the event (fever or medical attendance) rates in Day 0-3 are presented by brand and dose. The estimates are adjusted for participant age, sex, jurisdiction, Indigenous status and chronic medical condition. The model assumes independence between observations and a linear relationship between the variables used for adjustment and the log odds of the event. Note that as of 7 February 2022, the Bayesian effect estimates are no longer being updated for Vaxzevria (AstraZeneca) [Dose 1, Dose 2 and Dose 3 & Booster] and Spikevax (Moderna) [Dose 1 and Dose 2]. Similarly, as of 17 October, the Bayesian effect estimates are no longer being updated for Comirnaty (Pfizer) [Dose 1 and 2] and as of 14 November 2022, the Bayesian effect estimates are no longer being updated for Spikevax (Moderna) [Dose 3 & Booster].

Probability by Age Group and Sex

Medical Attendance

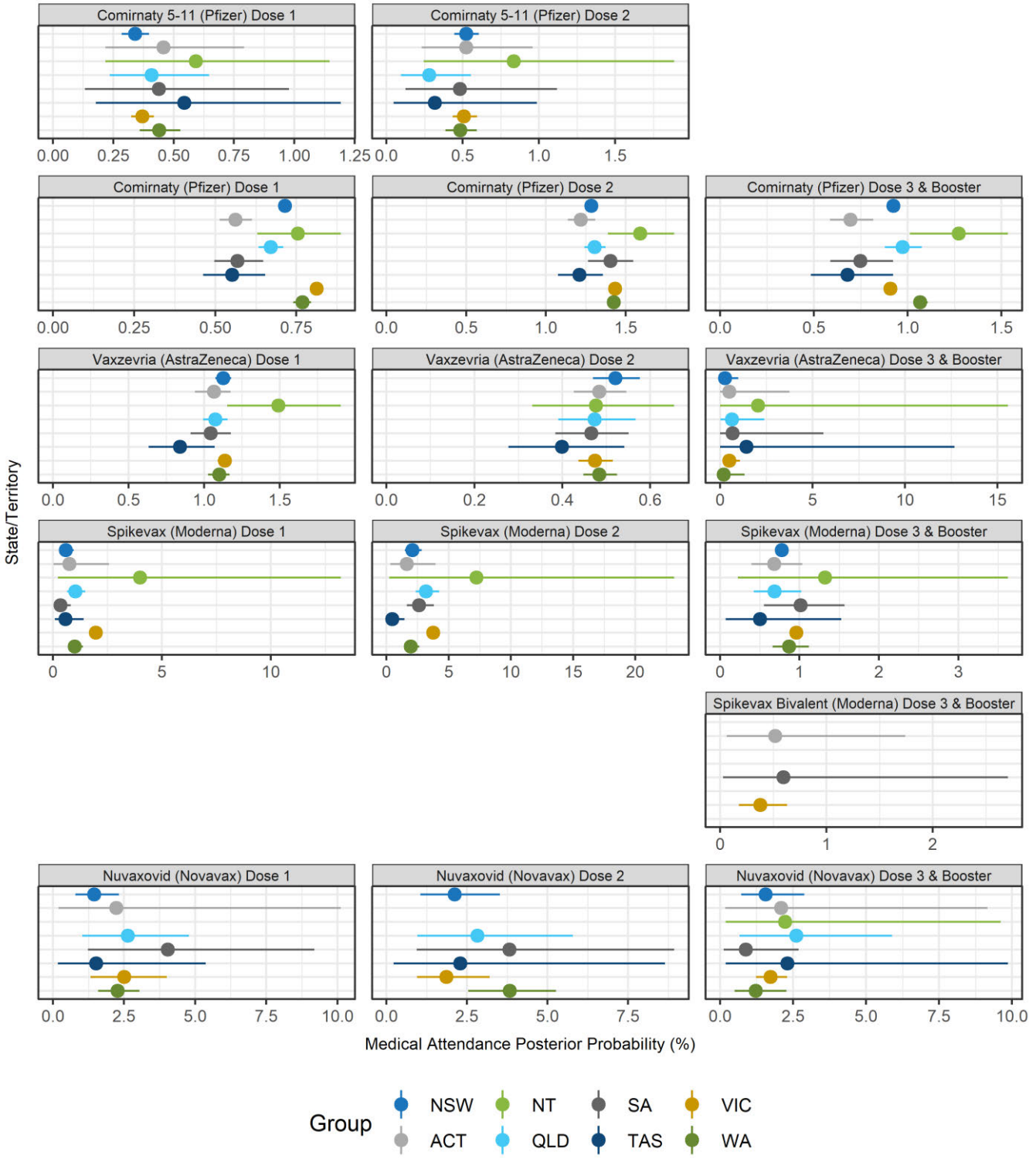



Comirnaty (Pfizer) Dose 1
Comirnaty (Pfizer) Dose 2
Comirnaty (Pfizer) Dose 3 & Booster
Vaxzevria (AstraZeneca) Dose 1
Vaxzevria (AstraZeneca) Dose 2
Vaxzevria (AstraZeneca) Dose 3 & Booster
Spikevax (Moderna) Dose 1
Spikevax (Moderna) Dose 2
Spikevax (Moderna) Dose 3 & Booster
Spikevax Bivalent (Moderna) Dose 3 & Booster
Nuvaxovid (Novavax) Dose 1
Nuvaxovid (Novavax) Dose 2
Nuvaxovid (Novavax) Dose 3 & Booster
Medical Attendance Rate Posterior Probability (%)
Age
12-15
16-19
20-29
30-39
40-49
50-59
60-69
70-79
≥80 years
Sex
Male
Female

AusVaxSafety
An NCIRS led collaboration

Probability by State/Territory

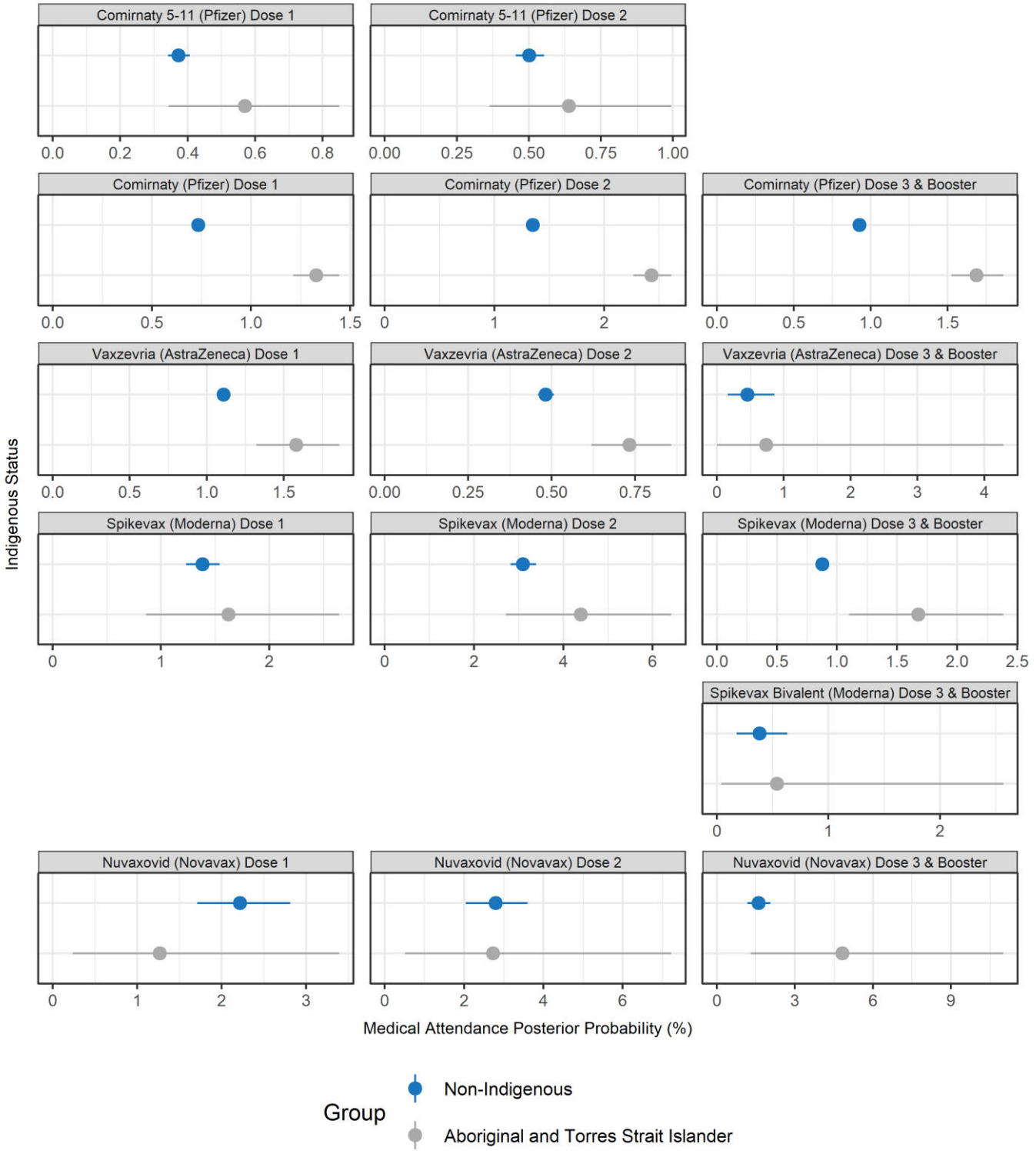
Medical Attendance



AusVaxSafety
An NCIRS led collaboration

Probability by Indigenous Status

Medical Attendance

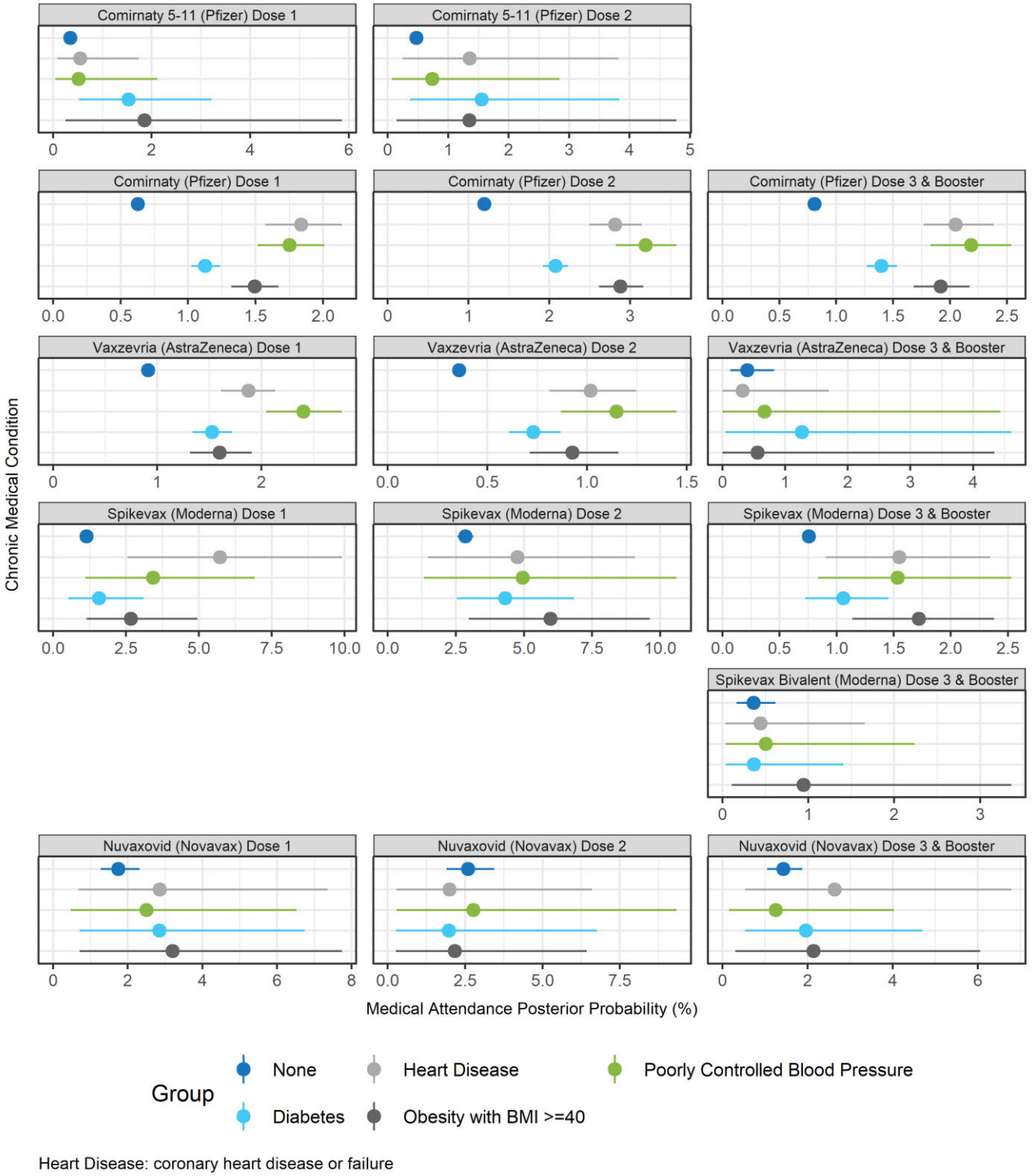


AusVaxSafety
An NCIRS led collaboration

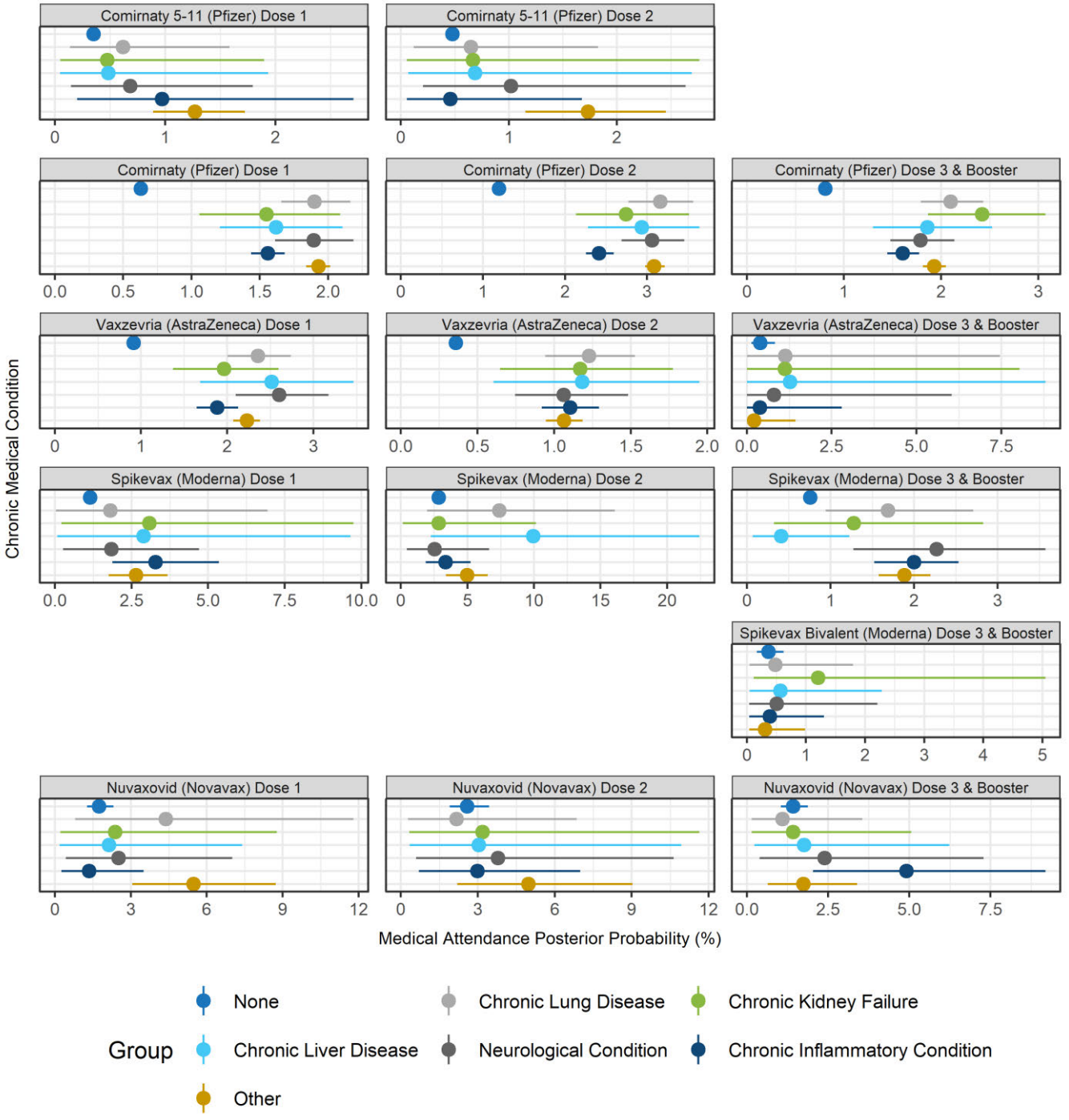
Probability by Chronic Medical Condition

Chronic medical conditions are solicited in the survey only, and are not sourced from medical records or verified. Chronic medical conditions are self-reported by answering 'Yes' to the question 'Do you have any chronic medical conditions?' and ticking one or more of the pre-defined conditions. Participants may be represented in multiple condition groups if they reported multiple conditions. Participants in the 'None' group for each of the below figures answered 'No' to the question 'Do you have any chronic medical conditions?'.

Medical Attendance

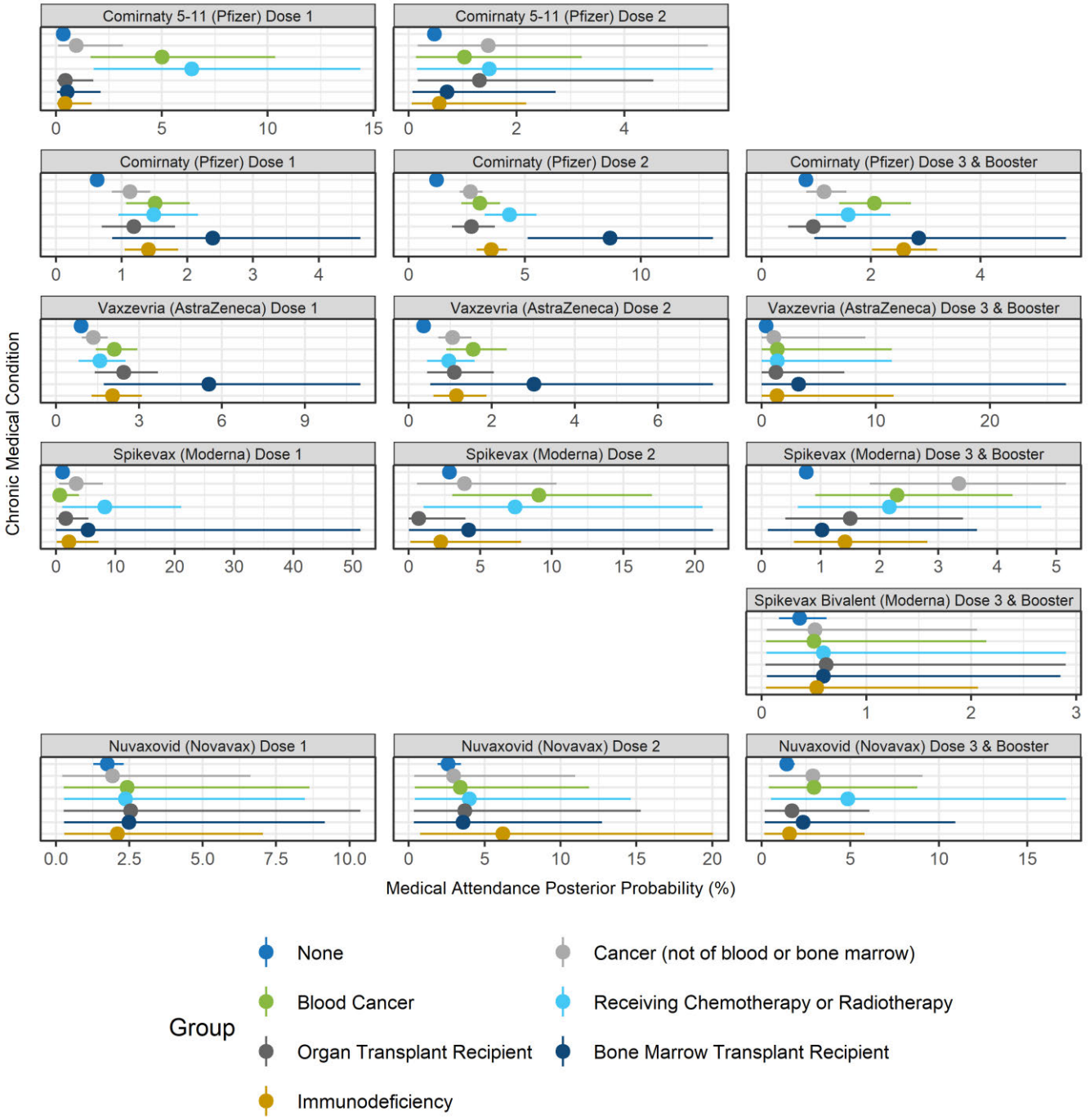


Heart Disease: coronary heart disease or failure



Chronic Lung Disease: not including mild/moderate asthma
Neurological Condition: e.g. stroke, dementia
Chronic Inflammatory Condition: e.g. rheumatoid arthritis, lupus
Other: conditions reported in free text

AusVaxSafety
An NCIRS led collaboration



Cancer (not of blood or bone marrow): diagnosed in the last 12 months
Blood Cancer: e.g. leukaemia, lymphoma or myelodysplastic syndrome, diagnosed within the last 5 years
Organ Transplant Recipient: on immune suppressive therapy
Bone Marrow Transplant Recipient: in the last 2 years
Immunodeficiency: primary or acquired immunodeficiency, including HIV

Note on methods

Data in this report include responses to an online vaccine safety survey sent via SMS message or email on Day 3 post vaccination with Comirnaty® (Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine, 10 and 30 microgram formulations), Vaxzevria (AstraZeneca Pty Ltd ChAdOx1-S COVID-19 vaccine [COVID-19 Vaccine AstraZeneca]), Spikevax (Moderna mRNA-1273 [Elasomeran] COVID-19 vaccine, 25, 50 and 100 microgram formulations), Spikevax Bivalent Original/Omicron (Moderna elasomeran/imelasomeran COVID-19 vaccine), or Nuvaxovid (Novavax NVX-CoV2373 COVID-19 vaccine). Responses to the Day 3 survey were included if received by Day 7 post vaccination. Participants are defined by completing the survey(s) following each vaccination encounter (dose), and are not defined as unique individuals.

Acknowledgements

Led by the National Centre for Immunisation Research and Surveillance (NCIRS) and funded by the Australian Government Department of Health and Aged Care, AusVaxSafety is a world-leading national vaccine safety system. For more information on AusVaxSafety's COVID-19 vaccine safety surveillance, please visit the AusVaxSafety website at www.ausvaxsafety.org.au.

We would like to acknowledge our collaborators at Vaxtracker (https://www.vaxtracker.net/) and SmartVax (https://www.smartvax.com.au/) for providing data, and collaborators at the Telethon Kids Institute and University of Sydney for developing signal detection and effect estimates.

Thanks to all participating vaccine recipients, clinic staff and jurisdictions.