Evaluating the safety of South Australia's Meningococcal B Vaccination Program

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The research presented today was published earlier this year – thank you to my co-authors and former colleagues:

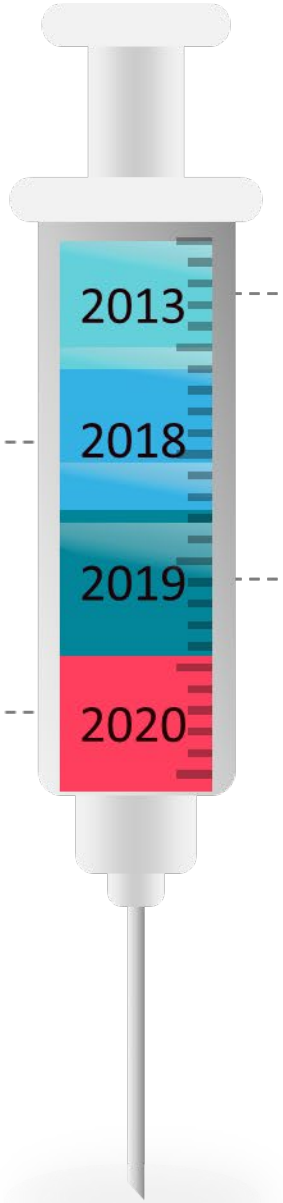
Wheldrake, K., Sisnowski, J., AHoure, M., Anagnostou, N., Almond, S., & Flood, L. (2025). Surveillance of adverse events following immunisation with meningococcal B vaccine (4CMenB), South Australia, 2018-2022. *Vaccine, 56.* https://doi.org/10.1016/j.vaccine.2025.127158

Government of South Australia
SA Health

Outline of presentation

- Bexsero vaccination in South Australia (SA)
- SA's Vaccine Safety Surveillance system
- Methodology
- Findings
- Discussion
- Reflections
  - Strengths and limitations

Bexsero vaccination in South Australia



Bexsero first licensed for use

European Medicine Agency – January 2013
Therapeutic Goods Administration – August 2013

SA infant vaccination program starts

3 dose regime at 6 weeks-2 months, 4 months and 12 months
Catch-up program for children aged 12 months to 4 years (ends 31/12/2019)

SA school-based program starts

Year 10 students
Catch-up program for Year 11 students and young people aged 17 to < 21 years
(ended Feb 2020, ongoing program up to 19 years)

Included in National Immunisation Program

Aboriginal and Torres Strait Islander children aged 6 weeks to < 2 years of age[2]

South Australia's Vaccine Safety Surveillance (SAVSS) system

- *Adverse event following immunisation (AEFI): any untoward medical occurrence that follows immunisation ≠ causal relationship with vaccine*
- SAVSS: passive surveillance system → managed by Immunisation Section of Communicable Disease Control Branch (CDCB) of SA Health
- Since 2021, all AEFI other than common or very common adverse events legally mandated to be notified by immunisation providers, including medical practitioners, pharmacists and registered nurses and midwives.[3]

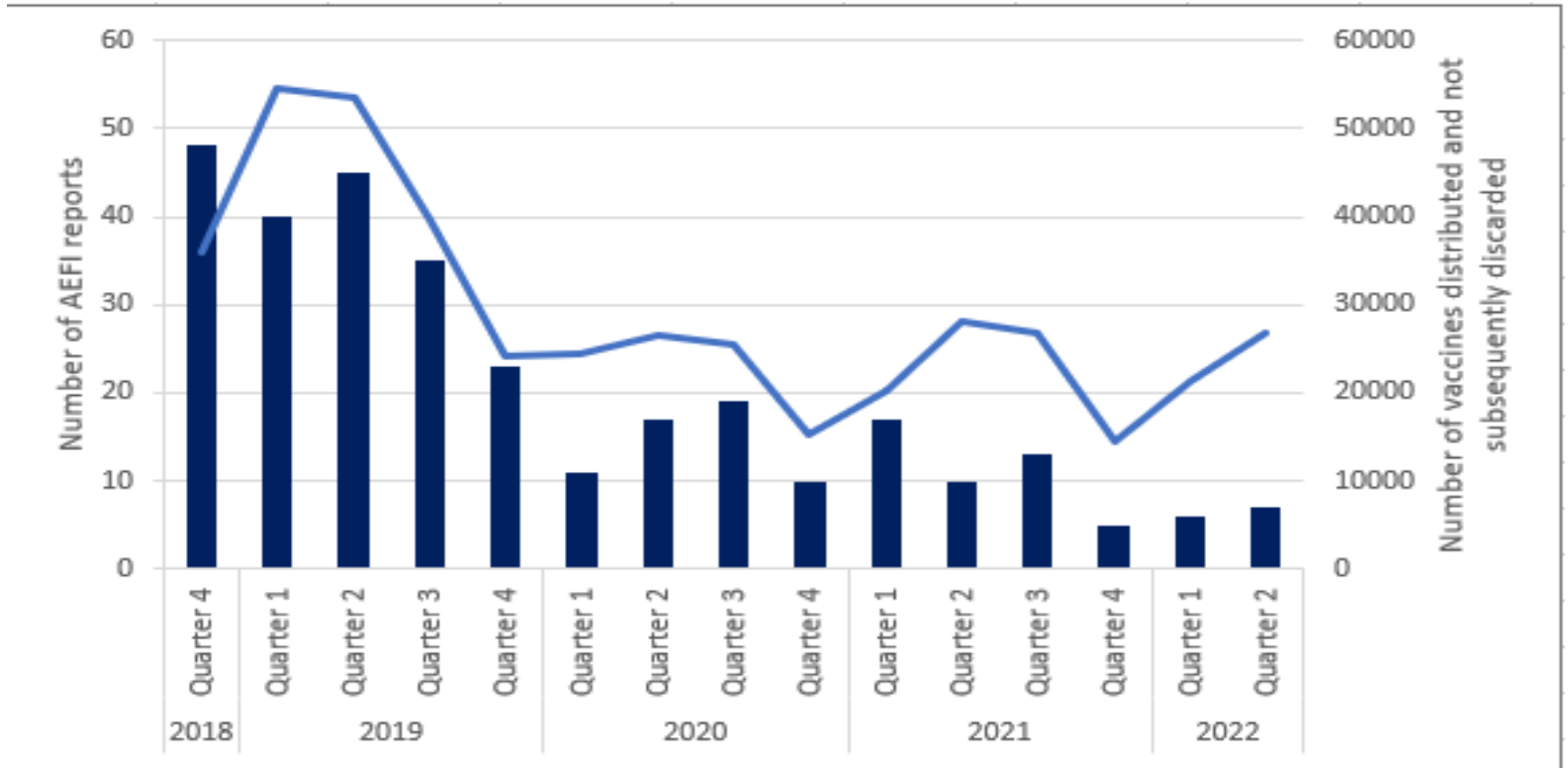
Methods

- Retrospective study; routinely collected data on AEFI held by CDCB.
- Extracted AEFI reports from CDCB database; coded free text reports into adverse event terms from Product Information (PI)[1] +/- commonly understood medical phenomena.
- Classified events as *serious* based on Safety Plan + as *suspected unexpected serious adverse reactions* (SUSAR) when unexpected → not listed in PI[4]

Results

From 1 October 2018 to 30 June 2022:

- 306 AEFI notifications for Bexsero vaccines given in the Program and NIP
- 437,462 vaccines distributed and not subsequently discarded due to cold chain breaches
- = AEFI reporting rate of 69.9 AEFI reports per 100,000 doses distributed



Non-serious adverse event clinical features

Non-serious AEFI (discrete symptoms)*	Number reported	Percentage of total symptoms reported
Rash	89	14%
Injection site reaction	87	14%
Fever	72	11%
Nausea/vomiting/diarrhoea	69	11%
Headache	50	8%
Lethargy	33	5%
Feeling of warmth	29	5%
	TOTAL	634 (100%) in 260 AEFI reports

**Non-serious AEFI symptoms comprising ≥ 5% of total reported*
See the paper for the full table/more details

Serious AEFI and SUSAR

Reports of serious AEFI (non-SUSAR)			
Hypotonic-hyporesponsive episodes		12	30%
Need for inpatient hospital admission	fever below 40°C (3); unusual crying (2); unresponsive episode; rash; diarrhoea and vomiting; malaise, diarrhoea and vomiting; fever, lethargy and hypotonia	10	25%
High fever 40°C or above		6	15%
Anaphylaxis or anaphylactoid		5	13%
Seizure		4	10%
Febrile convulsion		2	5%
Other	Details: hyporesponsive episode not requiring hospital admission	1	3%
		Total:40	

6 SUSAR – case details available in our paper

Discussion

- Reporting rate:
  - ↓ than AEFI reporting rates in pre-marketing and post-marketing research[5-8]
- Proportion of serious AEFIs
  - ↑ (15%) than proportion of serious AEFI for all vaccines: 2020 Australian AEFI surveillance report (7.6%)[9]
- Passive surveillance approach:
  - Associated with under-ascertainment of AEFI + alteration in serious-to-non-serious adverse reaction ratio, in favour of serious AEFI[10-12]

Reflections

> Strengths

- Comprehensive program, long time period
- Active detailed follow up in early years
- Mandatory reporting after 2021 may have improved completeness of selected AEFI
- Paracetamol administration data collected

> Limitations

- Denominator is a proxy – likely discrepancy to true denominator (vaccines administered)
- Selection bias
- Passive surveillance → under-ascertainment of AEFI, true rate likely higher[10-12]

Conclusion

- This study adds to the safety evidence for the Bexsero vaccine; contributing to a nuanced, evidence-based discussion about vaccine safety.
- The findings may also be of relevance/interest to other jurisdictions that are considering their own Bexsero vaccination programs.

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References

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Table 4: Symptoms reported for non-serious AEFI and reports of serious AEFI, 1 October 2018 - 30 June 2022, South Australia			
	Frequency grouping (cohort) *where available*	Number and percentage of cases	
		n	%
Non-serious AEFI (discrete symptoms)			
Rash	Very common (toddlers), common (infants and children)	89	14%
Injection site reaction	Very common (all age groups)	87	14%
Fever	Very common (infants, toddlers, children)	72	11%
Nausea/vomiting/diarrhoea	Very common (vomiting/diarrhoea - infants/toddlers; nausea - adolescents)	69	11%
Headache	Very common (all age groups)	50	8%
Lethargy	Very common (infants, toddlers, children)	33	5%
Feeling of warmth	*Not listed in PI*	29	5%
Myalgia	Very common (adolescents)	24	4%
Irritability	Very common (infants, toddlers, children)	23	4%
Urticaria	Rare (infants, toddlers, children)	20	3%
Dizziness	*Not listed in PI*	20	3%
Anorexia	Listed in PI as eating disorders - very common (infants-children)	15	2%
Malaise	Very common (adolescents)	12	2%
Pallor or cyanosis	Pallor: uncommon (infants and children)	11	2%
Unusual crying	Very common (infants and children)	10	2%
Vasovagal episode	*Not listed in PI*	10	2%
Other symptoms (reported by fewer than ten cases each)	oedema, tachycardia, dyspnoea, dysphagia, hypotonia, shaking, breath-holding, anaphylactoid, hoarseness, night terrors, other gastrointestinal symptoms, other neurological symptoms	55	9%
		Total: 634	