AusVaxSafety
An NCIRS led initiative

Profiles of adverse events across the infant National Immunisation Program schedule

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on behalf of the AusVaxSafety Consortium

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Aim

✓ Post-licensure safety surveillance

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✓ Vaccines are not usually given alone

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✓ Want to provide parents with relevant vaccination encounter safety data

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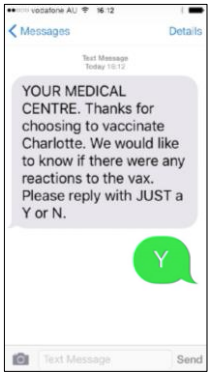
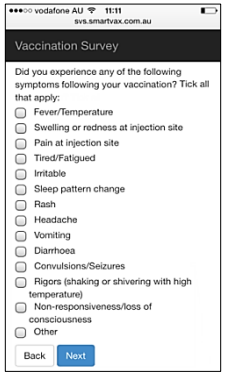
Analyse safety of infant NIP schedule points

Methods

3 days





Analysed responses for vaccination encounters meeting the following criteria:

Vaccines received:	**Schedule points:**	**Surveillance period:**
DTPa-hepB-IPV-Hib (Infanrix Hexa) **and** 13vPCV (Prevenar 13) **and** Rotavirus (Rotarix or Rotateq)*	2 months 4 months 6 months	14 months (November 2016-December 2017)

1. Determine adverse event rates reported at each schedule point
2. Compare adverse event rates between schedule points
3. Investigate responses from same participant across schedule points

* Not required for 6 month schedule point if given in NSW, TAS, ACT, or NT at any time, or in any state after 1 July 2017.

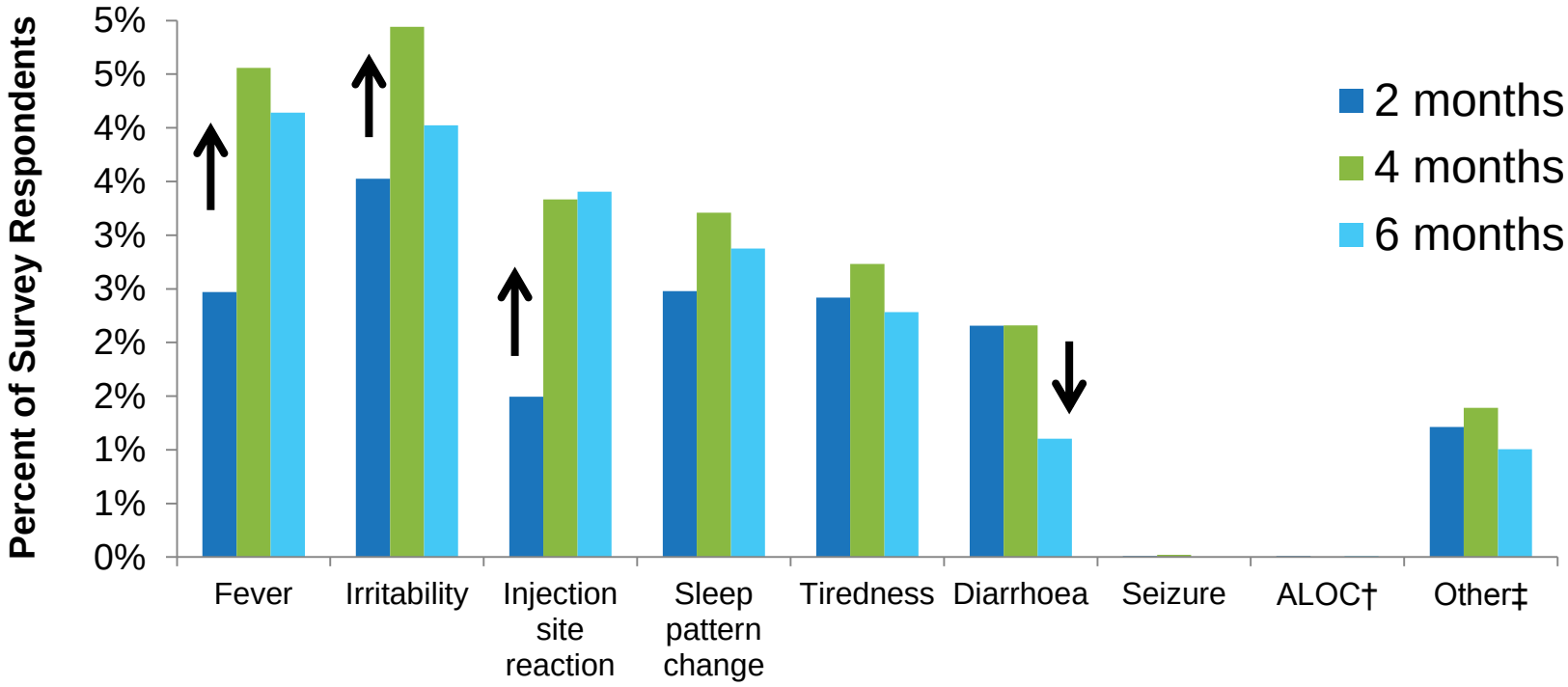
Results

Cross sectional analysis

Rates low and within expected ranges

Variable	2 months	4 months	6 months
Any adverse event	9.6%	12.8%	11.5%
Medically attended adverse event*	0.8%	1.0%	1.1%

~**10,000** participants per schedule point

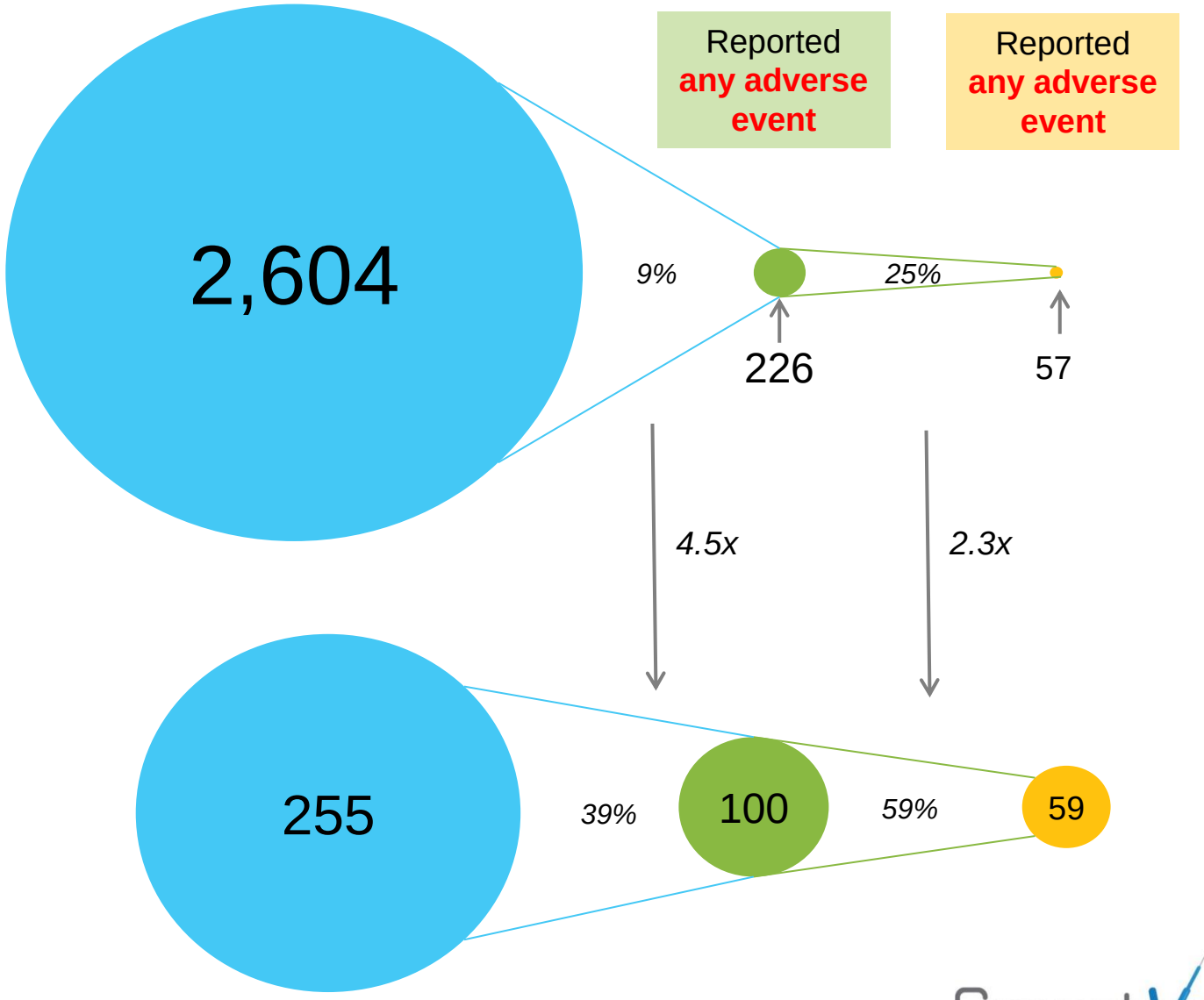


*A medically attended adverse event is defined as an adverse event requiring presentation to a health care provider, such as a GP or ED.
†ALOC: Altered Level of Consciousness (surveyed as "non-responsiveness/loss of consciousness")
‡Other includes the solicited events of rash, headache, and rigors, as well as unsolicited adverse events reported by free text.

Longitudinal analysis of responses (N=2,859)

(same parent/child over time)

2m → 4m → 6m



SmartVax

Conclusions

- Adverse event rates are **low and within expected ranges**
  - Maintain or improve **consumer confidence** in NIP schedule
- Parents may be more likely to report an adverse event after 4 and 6 month immunisations, if they reported an adverse event after 2 month immunisations
- Future opportunity to with 13vPCV NIP schedule change
  - Can compare safety of schedule points following change

Acknowledgements