



## Surveillance of adverse events following immunisation in Australia, 2016

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## Introduction

### Background

Post-licensure vaccine safety surveillance is a vital component of an immunisation program

Adverse events following immunisation (AEFI)

• untoward medical occurrence which follows immunisation

- unfavourable or unintended sign e.g. pyrexia
- abnormal laboratory finding
- symptom or disease

Does not necessarily have a causal relationship

### Aim

To describe reporting of AEFI

- 2016
- Trends over 2000 to 2016



<http://www.health.gov.au/infocentre/immunisation/aei/Content/aei-aei-annual.htm>

## Methods



### Reporting and analysis

Australian surveillance AEFI data

Adverse Drug Reactions System (ADRS),  
Therapeutic Goods Administration (TGA)

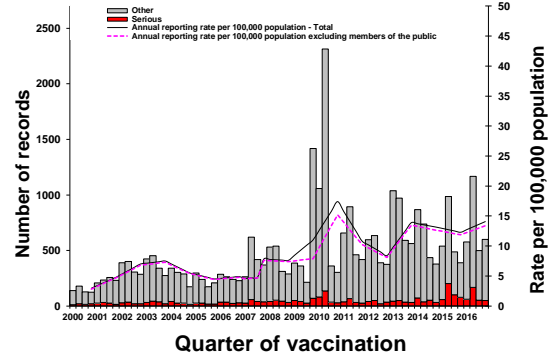


Numbers, reporting rates by vaccine type, age and jurisdiction

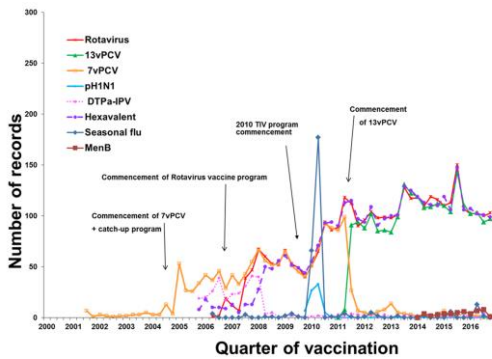


## Results

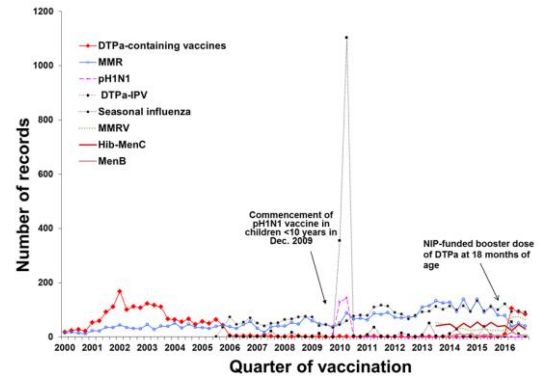
Adverse events following immunisation, 2000 to 2016, by quarter of vaccination



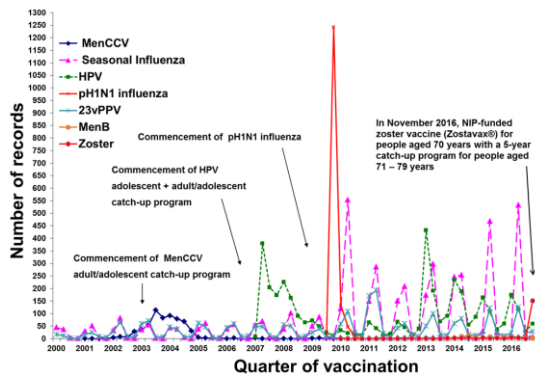
Adverse events following immunisation for children aged <1 year, 2000 to 2016



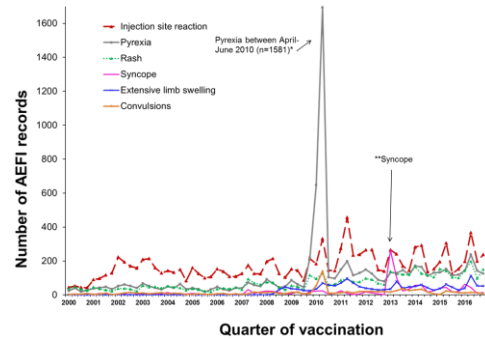
Adverse events following immunisation for children aged 1 to <7 years in frequently reported vaccines, 2000 to 2016



Adverse events following immunisation for people aged ≥7 years in frequently reported vaccines, 2000–2016



Selected frequently reported AEFI, 2000 to 2016, by quarter of vaccination





## Discussion

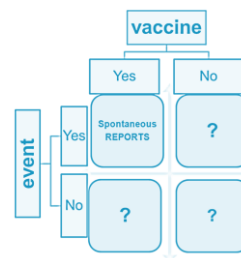
### “Spontaneous” Surveillance Systems

#### Weaknesses/limitations

- Reporting biases
- Under-reporting
- Stimulated reporting
- Inconsistent data quality/completeness
- Can't determine AEFI incidence
- Not designed to assess causality

#### Strengths

- Large population cover
- Simple to operate/inexpensive
- Signal detection
- Hypothesis generation
- Triggers further investigation



### Summary

- Increase in reporting rates over time – consistent with efforts to improve/promote reporting systems, including S/T based systems
- In 2016, increase in reports mainly attributable to introduction of the-
  - booster dose of DTPa at 18 months of age
  - zoster vaccine for those aged 70- 79 years
- Note that these results are from AEFI data (ADRS database) and not on comprehensive clinical notes or case reviews
- Important system for signal detection
- Active surveillance e.g. AusVaxSafety

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