AusVaxSafety
Australia’s expanding nationwide active surveillance system
Overview

• History and role of AusVaxSafety’s active surveillance system

• Safety surveillance data
  – Influenza vaccine
  – Pertussis vaccine
  – Zoster vaccine

• Future directions
Lasting impact from vaccine safety scare

Parents attitude: Influenza vaccine is safe
Agree: 60% in 2008-2009 vs. 30% in 2010-2012
Disagree: 3% 2008-2009 vs. 14% in 2010-2012

Parents' faith in flu vaccinations for children was shattered by the fast-tracked rollout of a vaccine in 2010 that permanently brain damaged one WA child and gave 250 others serious reactions, a WA Health Department official says.

Blyth C et al. The impact of pandemic A(H1N1)pdm09 influenza and vaccine-associated adverse events on parental attitudes and influenza vaccine uptake in young children. Vaccine, 2014; 32,4075–81
2011: Australian Government Department of Health & Ageing review

Recommendation 7: The collection of vaccine usage & safety monitoring data should be a key priority for future e-health planning & development.

2011: Vaxtracker developed; piloted 2012 in Hunter New England, NSW

Nov 2011-June 2013: SmartVax piloted in WA
Need for coordinated active safety surveillance

- Influenza vaccines vary annually
- Paucity of brand head-to-head comparison data on safety
- Real time post-marketing surveillance
  - Timely signal detection
  - Detailed adverse event profile
National coordinated approach

NCIRS coordinating centre
Surveillance tools: SmartVax, Vaxtracker, STARSS
Commonwealth Department of Health
State/Territory Departments of Health
Vaccine safety experts

AusVaxSafety Consortium
AusVaxSafety components

**Component A**
Active SMS-based follow-up
(SmartVax, Vaxtracker and STARSS)

**Component B**
AEFI-CAN and State/Territory services follow-up serious AEFI

**Component C**
Analysis of NPS MedicineInsight data
(General Practice)
Active safety surveillance

- Over 200 GP practices, hospitals, Aboriginal Medical Service and community clinics

- 3 reporting platforms:
  - **SmartVax (Opt-out)** 96.5%
  - Vaxtracker (Opt-in)
  - STARSS (Opt-in RCT)

- Patient/parents report adverse events via SMS/email

- Follow-up medically attended cases

---

Number of state/territory surveillance sites
August 2017
Vaccinations captured by surveillance tool

SMS/email to participants: Any reactions after vaccination?
- Yes?
- No?
  - Yes: Flagged for follow-up
  - No: Improved vaccine safety monitoring, transparency, public confidence

Was medical attendance sought?
- No?
  - Yes: Flagged for follow-up

Safety signal detected? Bayesian/FIR CUSUM analyses
- Reports to Government & public (weekly/fortnightly/monthly)
SmartVax automated SMSs

97% of all participants
Medical attendance

• Used as a proxy for serious AEFI in safety signal detection analysis

• Can be used to identify individual cases requiring public health follow-up
History of vaccines monitored

1. **2014** Influenza vaccines – children

2. **2016** Pertussis vaccines – children (18 mo and 4 yr doses)
   - Zoster vaccine – 70-79 year olds

3. **2017** Influenza vaccines – all ages

4. **Future** All vaccines on National Immunisation Program
# Influenza vaccine safety surveillance

1 April – 20 August 2017

## Participants

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td>99,834</td>
</tr>
<tr>
<td>Participants (participation rate %)</td>
<td>71,476 (71.6%)</td>
</tr>
<tr>
<td>Female</td>
<td>41,436 (58.0%)</td>
</tr>
<tr>
<td>Pregnant</td>
<td>1,833 (2.6%)</td>
</tr>
<tr>
<td>Aboriginal/Torres Strait Islander</td>
<td>1,106 (2.0%)</td>
</tr>
<tr>
<td>Median age (range)</td>
<td>58 yrs (6mo-102yr)</td>
</tr>
<tr>
<td>Concomitant vaccine</td>
<td>9,847 (13.8%)</td>
</tr>
</tbody>
</table>
### Influenza vaccine surveillance, 2017: Adverse events reported

<table>
<thead>
<tr>
<th>Event</th>
<th>6 mo - 4 yrs N=5,811</th>
<th>5 yrs - 64 yrs N=36,058</th>
<th>≥65 yrs N=27,774</th>
<th>Pregnant N=1,833</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any event</td>
<td>8.4%</td>
<td>6.8%</td>
<td>6.0%</td>
<td>5.7%</td>
</tr>
<tr>
<td>Fever</td>
<td>2.3%</td>
<td>0.9%</td>
<td>0.8%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Rash</td>
<td>0.5%</td>
<td>0.2%</td>
<td>0.3%</td>
<td>0.06%</td>
</tr>
<tr>
<td>Seizure</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.01%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Injection site reaction</td>
<td>2.7%</td>
<td>2.3%</td>
<td>1.6%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Medical attention</td>
<td>0.9%</td>
<td>0.4%</td>
<td>0.3%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Rates are low & within expected ranges.
Pertussis vaccine (DTPa, DTPa-IPV)

31,054 children
Aged 12 months - 7 years
14 March 2016 - 13 August 2017

72% response rate

% of participants

Any reaction  Fever  ISR  Seizure  Medical attendance

1.6%
Zoster vaccine

13,049 adults
Aged 70 – 79 years
1 November 2016 – 20 August 2017

Influenza 71.6%
Pertussis 72%

Medical attention: 0.3%
Rash:
ISR: 67.5% response rate
Fever:
Any reaction:

% participants
LOTS OF PARTICIPANTS

TIMELY DATA
Real-time data communicated quickly

AusVaxSafety weekly influenza report
Data Mon-Sun each week reported Friday

Website updated with weekly data Friday
http://ausvaxsafety.org.au/
AusVaxSafety – why it’s important

• Well-communicated, timely vaccine safety surveillance can improve confidence & increase coverage

• Seasonal influenza vaccines require safety monitoring due to annual changes in composition

• AusVaxSafety is adaptable
  – Domestically – tailor for new vaccines
  – Internationally – provides template for others
Future direction

- Expand active surveillance to include ALL vaccines on National Immunisation Program
- Increase number of school students, pregnant women, health care worker participants
- Increase sentinel sites specifically schools, pharmacies and hospitals
- As new brands are introduced, future analysis of potential brand difference
Thanks to all participating GPs, clinic and hospital staff.
Thank you!

www.ncirs.edu.au
www.ausvaxsafety.org.au