Going National: AusVaxSafety 2014 and beyond

Dr Gulam Khandaker on behalf of the AusVaxSafety investigators*

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Outline of the presentation

- Background
- Surveillance Methods
- Results
- Conclusions/Next steps

**Funding:** AusVaxSafety surveillance 2014 has been funded by the Australian Government Department of Health (contract no HEALTH/082/1314)
In 2010, unexpected marked increase in fever and febrile convulsion
Associated with bioCSL seasonal influenza vaccine (Fluvax®)
All influenza vaccine use was suspended in children <5 yrs in 2010
bioCSL’s Fluvax® is no longer registered for use in children <5 yrs
Concern regarding influenza vaccine safety
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

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
## Existing/previous initiatives

<table>
<thead>
<tr>
<th>Year</th>
<th>Milestones</th>
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| 2011 | FAST ([Follow up and Active Surveillance of Trivalent influenza vaccine](#)) commenced in WA  
GP based AEFI reporting (SmartVax) in WA |
| 2012 | Vaxtracker (online parental survey) in HNE LDH and Children’s Hospital Westmead |
| 2013 | Pilot study funded by DoH  
NCIRS-led collaboration: >1,000 children <10 years from 6 tertiary paediatric hospitals in multiple states across Australia and several primary care practices in WA and NSW |
| 2014 | **AusVaxSafety** surveillance (combing FAST and Vaxtracker methods) coordinated by **NCIRS** in NSW, Vic and WA  
FASTmum and FASThealth in WA |
Objectives (to obtain):

- **Real-time information** on AEFI with influenza vaccine in children <5 yrs
- Rate of AEFI: **Fever, local & systemic reactions, SAE**
- Rate of **medical attendance/review** related to AEFI
- Real-time **safety signal** detection
- Evaluation of user friendly methods/technology

Methods: AusVaxSafety surveillance 2014
AusVaxSafety surveillance 2014 methods

AusVaxSafety – coordinated by NCIRS

Jurisdiction
System

NSW
System: Vaxtracker
Coordination: NCIRS & HNE

VIC
System: Vaxtracker
Coordination: SAEFVIC

WA
System: FAST
Coordination: Telethon Kids Institute

SMS/email to parents/carers and link to web-based survey

Data collation and analysis by NCIRS
Weekly reporting to HEALTH/TGA

Methodology

Sites

GP
HNE LHD - GPs
WS LDH & ML - GPs
SES LHD & ML-GPs

GP sites: Dr Eisenberg
Dr Rowles

Hospital
SCHN – CHW & Sydney CH
RCH
Monash Hospital

Central immunisation clinic

SMS to parents/carers CATI if ‘Yes’ or non-responder

Hospital
PMH
AuxVaxSafety surveillance: 2014 Recruitment

Between 10 March & 15 July 2014

948 offered participation

879 (92.7%) enrolled

782 survey completions for 715 (81.3%) children
AuxVaxSafety surveillance results 2014

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Survey completed</th>
<th>AEFI N (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSW</td>
<td>267</td>
<td>50</td>
<td>(18.7, 14.2-23.9)</td>
</tr>
<tr>
<td>Vic</td>
<td>250</td>
<td>61</td>
<td>(24.4, 19.2-30.2)</td>
</tr>
<tr>
<td>WA</td>
<td>265</td>
<td>33</td>
<td>(12.4, 8.7-17.0)</td>
</tr>
<tr>
<td>All</td>
<td>782</td>
<td>144</td>
<td>(18.4, 15.8-21.3)</td>
</tr>
</tbody>
</table>

- Median age 31.5 months
- No gender differences in the rate of AEFI
- Data on 4 vaccine brands (86% Vaxigrip, Fluarix 11%)
# Adverse events and serious adverse events (SAE)

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>Frequency of adverse events* (n)</th>
<th>Rate % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAE</td>
<td>3</td>
<td>0.4 (0.1-1.1)</td>
</tr>
<tr>
<td>Fever§</td>
<td>53</td>
<td>6.8 (5.1-8.8)</td>
</tr>
<tr>
<td>Seizure</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Injection site reaction</td>
<td>34</td>
<td>4.3 (3.0-6.0)</td>
</tr>
<tr>
<td>Rash</td>
<td>10</td>
<td>1.3 (0.6-2.3)</td>
</tr>
<tr>
<td>Chills and shakes</td>
<td>10</td>
<td>1.3 (0.6-2.3)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>14</td>
<td>1.8 (1.0-3.0)</td>
</tr>
<tr>
<td>Headache or irritability</td>
<td>65</td>
<td>8.3 (6.5-10.5)</td>
</tr>
<tr>
<td>Other</td>
<td>42</td>
<td>5.4 (3.9-7.2)</td>
</tr>
</tbody>
</table>

* Note: number of events does not necessarily equal number of participants or completed surveys (may have more than 1 event)

§ Fever is based on a parental report of fever and if a highest recorded temperature is reported, fever is considered when temperature is ≥37.5°C
# Medical Advice for AEFI

<table>
<thead>
<tr>
<th>Medical advice sought</th>
<th>Frequency (n)</th>
<th>Rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone advice</td>
<td>3</td>
<td>0.4 (0.1-1.1)</td>
</tr>
<tr>
<td>GP visit</td>
<td>6</td>
<td>0.8 (0.3-1.7)</td>
</tr>
<tr>
<td>Emergency department visit</td>
<td>2</td>
<td>0.2 (0.1-0.9)</td>
</tr>
<tr>
<td>Hospital inpatient</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0.1 (0-0.7)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>12</strong></td>
<td><strong>1.5 (0.8-2.7)</strong></td>
</tr>
</tbody>
</table>
Fast initial response cumulative summation (FIR CUSUM) real time signal detection

- Early detection in real time of an excess in AEFI (a ‘signal’)

The FIR CUSUM chart 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. If the event rate is truly closer to the threshold rate than the expected rate, the graph will trend upwards over time as the cumulative data increases.

The FIR CUSUM chart 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. If the event rate is truly closer to the threshold rate than the expected rate, the graph will trend upwards over time as the cumulative data increases.
Influenza vaccine safe for use in children

As of 22 June 2014, 735 children got 735 children got influenza vaccine.
- Fewer than 0.1% of children got a mild reaction such as redness.
- Fewer than 0.1% of children got a severe reaction.
- Reported reactions were mild.
- These findings were reported.

SOURCE
University of Sydney

An enhanced surveillance system used to monitor adverse events following immunisation has shown the 2014 seasonal influenza vaccine to be safe for use in children under five years of age.

The AusVaxSafety surveillance system collected information from the parents or guardians of 735 children. The study found that 18% of children vaccinated had a mild reaction at the point of injection such as redness, or a systematic reaction like a headache post vaccination. Less than 6.5% of children had fever after the vaccine.
Conclusions: 2014 surveillance

1. Confirmed good safety profile of 2014 seasonal influenza vaccine

2. Surveillance was based on common objectives and agreed protocol

3. AusVaxSafety provided near real-time data to HEALTH/TGA and investigators

4. AusVaxSafety provided greater transparency and better access to safety information
Next steps

- NCIRS vaccine safety seminar and AusVaxSafety investigators face to face meeting in **29-30**\textsuperscript{th} October

- Possible extension within existing and other states (QLD, SA and NT) in 2015 (subject to funding confirmation)

- Earlier publication and dissemination of findings
Acknowledgements

- **Funding:** AusVaxSafety surveillance 2014 has been funded by the Australian Government Department of Health (contract no HEALTH/082/1314)
- AusVaxSafety Investigators
  - A/Prof Kristine Macartney, Dr Nick Wood (NCIRS)
  - Prof Peter McIntyre, Dr Frank Beard and Clayton Chiu (NCIRS)
  - Karen Orr, Jennifer Murphy, Kath Cannings (NCIRS)
  - Nicole Jacobs, Donna Armstrong (NCIRS)
  - Dr Shopna Bag (WS PHU), Dr Kevin Yin & Dr Harunor Rashid (NCIRS)
  - Patrick Cashman (Vaxtracker, NHE PHU)
  - Stephen Clarke (Vaxtracker)
  - Dr Parveen Fathima (TKI)
  - Lauren Tracey (WA Health)
## Adverse Events by recruitment source

<table>
<thead>
<tr>
<th>Recruitment setting *</th>
<th>Local reactions N (%)</th>
<th>Fever N (%)</th>
<th>Headache/Irritability N (%)</th>
<th>Other Symptoms N (%)</th>
<th>Any adverse event N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSW Hospital (n=190)</td>
<td>7 (3.7)</td>
<td>16 (8.4)</td>
<td>13 (6.8)</td>
<td>10 (5.3)</td>
<td>36 (18.9)</td>
</tr>
<tr>
<td>NSW community (n=77)</td>
<td>6 (7.8)</td>
<td>4 (5.2)</td>
<td>7 (9.1)</td>
<td>6 (7.8)</td>
<td>14 (18.2)</td>
</tr>
<tr>
<td>Vic Hospital (n=204)</td>
<td>16 (7.8)</td>
<td>17 (8.3)</td>
<td>27 (13.2)</td>
<td>12 (5.9)</td>
<td>52 (25.5)</td>
</tr>
<tr>
<td>Vic community (n=46)</td>
<td>1 (2.2)</td>
<td>0</td>
<td>7 (15.2)</td>
<td>0</td>
<td>9 (19.6)</td>
</tr>
<tr>
<td>WA Hospital (n=188)</td>
<td>2 (1.1)</td>
<td>10 (5.3)</td>
<td>5 (2.6)</td>
<td>10 (5.3)</td>
<td>24 (12.8)</td>
</tr>
<tr>
<td>WA community (n=77)</td>
<td>2 (2.6)</td>
<td>6 (7.8)</td>
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<td>4 (5.2)</td>
<td>9 (11.7)</td>
</tr>
<tr>
<td>Total (n=782)</td>
<td>34 (4.3)</td>
<td>53 (6.8)</td>
<td>65 (8.3)</td>
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## AEFI by State and age group

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### Age group

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<th>Survey completed</th>
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<tbody>
<tr>
<td>6 months to 12 months</td>
<td>86</td>
<td>10 (11.6)</td>
</tr>
<tr>
<td>&gt;12 months - 24 months</td>
<td>198</td>
<td>32 (16.2)</td>
</tr>
<tr>
<td>&gt;24 months - &lt;60 months</td>
<td>498</td>
<td>102 (20.5)</td>
</tr>
</tbody>
</table>

* Significantly higher than WA rate