Why should we engage our patients in vaccine pharmacovigilance?

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Vaccine pharmacovigilance

“the science and activities related to the detection, assessment, understanding and communication of adverse events following immunisation and other vaccine- or immunisation-related issues, and to the prevention of untoward effects of the vaccine or immunisation.”

EMA, Guideline on good pharmacovigilance practices (GVP), 2013
Vaccine pharmacovigilance

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WA influenza vaccination program

Flu kills three young children

PETA RUIE and DEBBIE GUEST

Three children have been killed by the flu in Perth in the past few days, prompting experts to issue an urgent warning that parents should take their children to the doctor as soon as they show signs of the illness.

The three children were all under five and lived in the metropolitan area. It is understood each of them died within 24 hours of showing the first signs of the flu, which doctors say was a form of the common influenza A strain. They warned that high temperature, cough and fever were the key symptoms parents should look for and urged them to seek medical advice immediately.

“We do not want to create unnecessary panic, it is important for parents to be aware that the disease can cause serious illness within 24 hours,” Health Department director of communicable disease control Paul Van Heydersd said last night.

Two of the deaths were at Princess Margaret Hospital and at least two of the children had also contracted pneumonia as a result of the virus, which could have contributed to their deaths.

Doctors across the State have been warned that they may be inundated by worried parents, prompting the Health Department to advise them of the details of the deaths.

Australian Medical Association president Geoff Dobbs said influenza A strain was one of the most common during winter and that West Australians were particularly vulnerable because it had been several years since the last flu epidemic.

He said parents should not be worried if their children simply had a runny nose and headache, though they should look out for a fever above 38°C.

“The critical thing is the combination of a fever and a cough,” he said. “What we’re talking about here is not just having a runny nose and feeling unwell, often people refer to that loosely as having the flu. A true influenza will make you feel really unwell, more severe with cough fever and muscular aches and pains.”

He said that unlike the flu, people with a cold may have a sore throat and runny nose, followed by a cough, but without a significant fever.

Parents can call Health Direct on 1800 020 080 for advice and locations of their nearest after-hours clinic.

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West Australian Newspaper: 7th July 2007
The West Australian
Under-5s will get free vaccine to combat flu

WA influenza vaccination program

"WA is the only State taking this proactive approach to help make sure one of our most vulnerable groups has ready access to influenza vaccine"

Dr Paul Effler, Department of Health
2010: a problematic year

8th March 2010: Trivalent vaccine launched

13th April 2010: TGA notified

Reports of children requiring admission with ‘sepsis’ or fever following trivalent influenza vaccine

Reports of febrile convulsions presenting to ED follow TIV

22nd April 2010: Health Department suspends preschool influenza vaccination program
2010: later that year

“Children under 5 years of age can now be vaccinated against influenza using Vaxigrip® or Influvac® seasonal influenza vaccine.”
Impact of a safety signal

Virus in The System

Fevers, fits, brain damage... by the time the seasonal flu vaccine was banned for kids under five last year, its side-effects were being felt around the country. So what went wrong? Natasha Bita reports

WA: Influenza vaccine uptake < 5 years

- Fully vaccinated
- Partially vaccinated

2008: 50%  
2009: 40%  
2010: 30%  
2011: 20%  
2012: 10%  
2013: 0%
Finding solutions to 2010

Virus in The System

Fevers, fits, brain damage... by the time the seasonal flu vaccine was banned for kids under five last year, its side-effects were being felt around the country. So what went wrong? Natasha Bita reports

- What was the problem?
- Does TIV work in children?
- Is the current vaccine safe?
- Do we have a more robust surveillance system to enable earlier detection?
What was the problem?
Does TIV work in children?

Effectiveness of Trivalent Flu Vaccine in Healthy Young Children

**WHAT’S KNOWN ON THIS SUBJECT:** In the United States, given the high burden of disease, influenza vaccine is recommended for all children from age 6 months. The paucity of vaccine effectiveness data in children <2 years has led some to argue against routine vaccination in this age group.

**WHAT THIS STUDY ADDS:** This study reveals the effectiveness of trivalent influenza vaccine in young children and supports the current Advisory Committee on Immunization Practices recommendation. This study provides the strongest evidence to date confirming the effectiveness of trivalent influenza vaccine in children <2 years of age.

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Ensuring safety of the 2011 trivalent influenza vaccine in young children

Christopher C Blyth, Tracy Y Markus, Paul V Effler and Peter C Richmond

To the Editor: Young children are at increased risk of severe influenza compared with the general population. Routine vaccination of children using trivalent influenza vaccine (TIV) is recommended in the United States and Canada. The Western Australian government, with support from vaccine manufacturers, has been providing TIV free of charge to all children aged 6–59 months since 2008.¹

Enhanced Surveillance of Adverse Events Following Immunisation with Influenza Vaccine in Children <5 Years

“The AusVaxSafety Project”

†AusVaxSafety team members; NSW: Nicholas Wood, David Durrheim, Craig Dalton, Patrick Cashman, Jody Stevenson, Stephen Clarke, Mark Ferson, Deborah Thompson, Keira Glasgow, Lauren Dalton, Stephen Corbett, Salwa Gabriel, Michael Crampion, Katherine Veale, Marina Fulcher, Karen Orr, Kath Canning, Jennifer Murphy, Brendan McMullan, Geraldine Dunne Vie; Jim Buttery, Nigel Crawford, Gowri Selvaraj, Annette Alafaci, Greg Rowles, Peter Eizengburg WA: Christopher Blyth, Paul Effler, Peter Richmond, Tom Snelling, Peter Jacoby, Parveen Fathima, Annette Regan, Christine Robins

Thanks to all participating GPs, clinics and hospital staff
Do we have a more robust surveillance system?
Has this approach had an impact?

Vaccine uptake

Parental attitudes

Influenza is a mild disease

P < 0.01

NS

Influenza vaccine is safe

P < 0.01

NS

Fully vaccinated

Partially vaccinated

No

Unsure

Yes

0%

10%

20%

30%

40%

50%

60%

70%

80%

90%

100%

2008-2009 2010-2011 2012-2013

2008 2009 2010 2011 2012 2013
Impact of a safety signal

England & Wales: MMR uptake rate (2 years)

Why should we engage our patients in pharmacovigilance?

Safety “scares” are going to continue to occur.

Some may be real, many may not be.

Ensuring involvement of patients (and prescribers) in pharmacovigilance is the only way to ensure that a health care system is able to recover from these “scares” in a timely fashion, with minimal collateral damage.
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