Ensuring the safety of vaccines in New Zealand

Harnessing Opportunities and Options
Vaccine Safety Monitoring - What do we want to do in the future

Dr Michael Tatley
Director: New Zealand Pharmacovigilance Centre
University of Otago Dunedin
Outline

• What we have
• What could be better
• Adding value
What we have

• Excellent Spontaneous reporting system
• Diligent committed & regular reporters
NZ Pharmacovigilance Support

Annual Total Reports Received by NZPhvC

Source of ADR/AEFI reports

Global Reporting Rates 2014

AEFI surveillance in the WPRO Region

Figure 2
Active ICSRs in the WHO global database per million inhabitants and year
Period covers 2008-03-03 to 2014-03-03

AEFI rate per 10,000

Source: JRF, 2015 data; denominator used is target population x DTP3 coverage
What we have

- Excellent Spontaneous reporting system
- Diligent committed & regular reporters
- Safety focused Regulator
- Well-established Immunization programme & NIR
- IMAC
- Diverse expertise in vaccinology & VSEAG
- Access to vaccine supply
- Distribution and cold chain
- Vaccinators
- Vaccine champions
- Communicate & coordinate as required
VSEAG

• Informal peer collaboration

• N Turner, H Petousis-Harris, E Wilson, G Reynolds, C Miller, S Kenyon, M Tatley

• Forum for
  ✓ discussion of individual cases,
  ✓ communication on emerging vaccine safety issues,
  ✓ opportunities for research
What we have

- Excellent Spontaneous reporting system
- Diligent committed & regular reporters
- Safety focused Regulator
- Well-established Immunization programme & NIR
- IMAC
- Diverse expertise in vaccinology & VSEAG
- Access to vaccine supply
- Distribution and cold chain
- Vaccinators
- Vaccine champions
- Communicate & coordinate as required
What could be better

- New Vaccines NZ safety profile – early insights
- Social media challenge and opportunity
- Widening the reporting base - Consumer reporting
- Centralizing NZAEFI data
- Common terminologies & approaches
- Routine & Exception report reviews to key bodies
- Capitalize on Inter-agency expertise
- Coordinating research projects & databases
- Accessing pooled AEFI data
Adding value

• Enhancing AEFI Surveillance mechanisms
• Improving analysis for patterns and signals
• Strengthening decision making & evaluation processes
• Optimising coordinated action
Enhancing AEFI Surveillance mechanisms

Passive Routine Voluntary Vaccine Vigilance Surveillance
  CARM – cornerstone of the NZAEFI/ADR reporting system
    enhanced by
      • SMS follow-up & report submission option/encouragement
      • Consumer-friendly reporting options
      • Improved follow-up mechanisms (and electronic feedback?)

Active surveillance
  ‘new’ NZ vaccines/emerging events of concern
    Near Real-time Vaccine Safety Monitoring
      • Prospective – Intensive Vaccine Monitoring Programme
Enhancing AEFI Surveillance mechanisms

Passive Routine Voluntary Vaccine Vigilance Surveillance
CARM – cornerstone of the NZAEFI/ADR reporting system
enhanced by
- SMS follow-up & report submission option/encouragement
- Consumer-friendly reporting options
- Improved follow-up mechanisms (and electronic feedback?)

Active surveillance
‘new’ NZ vaccines/emerging events of concern
Near Real-time Vaccine Safety Monitoring
- Prospective – Intensive Vaccine Monitoring Programme
- Near retrospective – CPRD / Vaccine Datalink approach

Data Linkage studies
**Improving analysis for patterns & signals**

- **21st Century national pharmacovigilance database** (AEFI/ADR)
  - Flexibility for changing requirements
  - Standardized dictionary with cross-linked matching (MedDRA/WHOART/ATC/SNOMED)
  - Interface with key NZ systems – NZHIS, NZULM, NIR, MWS, ‘EHR’
  - Integrated SMQ’s/report building/statistical analysis and data mining utility
  - (wider report assessing resources)

- **Data quality**
  - Consensus on key terminology and algorithms
    - Reporting
    - Assessment/evaluation

**Centralised Database**

- Accredited database access
- Networked analysis expertise
Strengthening the decision making & evaluation processes

Sharing vaccine surveillance findings beyond Medsafe & MARC

- Harness
  - Contextual perspectives
  - Specialized expertise and clinical insight on issues or cases
- Broader awareness of typical and emerging issues
- Linkage to other related developments
  - Inform other initiatives
  - Inform understanding of issue
- Identify further actions
Optimising coordinated action

Approach that enables
- Cross-sector network/working together
- Rapid responses
  - Proactive
  - Immediacy for emerging issues
- Source seen to be core cross-sector
- Integrated in the public sector vaccine messaging space
  - Health professionals
  - Public
- Consistent (consensus) messaging
- Exploit multiple channels
  - Health Sector – Intranet messaging
  - Public sector – the ‘social media’
Pulling it all together ....

- Network engagement
- Cross-sector
- Consensus messaging
- Multi-channel outputs

Enhancing AEFI Surveillance mechanisms

- Passive
- Active
- Data linkage

Improving analysis for patterns and signals

- Database
- Data quality
- Centralised data
- Distributed analysis

Optimising coordinated action

- Cross-sector
- Consensus messaging
- Multi-channel outputs

Strengthening decision making & evaluation processes

- Network engagement