Fifty Years of Adverse Drug Reaction Reporting in New Zealand.
Primary care involvement and the developing use of e-health

Drs Ruth Savage, Michael Tatley & Desiree Kunac
Adverse Drug Reactions
a public health concern

**International:**
Account for 3 - 6 % of hospital admissions

**New Zealand:**
Accident Compensation Commission
~16% of claims for medication
~ $6 million (2013/14)
44% ADRs causing hospital admission are preventable

**Australia:**
5-fold increase in hospitalisations due to ADR’s in >65yr olds 1995-2002.

**Sweden:**
3% of deaths in general population due to ADRs
New Zealand Pharmacovigilance Centre

• National monitoring centre established in 1965
• WHO monitoring programme founding member in 1968
• Monitoring programmes
  – spontaneous reports
    medicines, vaccines, NHP’s
  – selected medicines
  – selected vaccines
  – medication error

New Zealand Pharmacovigilance Centre in 2003
NZ Pharmacovigilance components

Welcome to NZPhVC

The New Zealand Pharmacovigilance Centre consists of synergistic monitoring programs that contribute to and support the safety of medicines and related products in New Zealand through voluntary reporting of adverse events.

Centre for Adverse Reactions Monitoring
CARM
Report an Adverse Reaction

Medication Error Reporting Programme
MERP
Report a Medication Error

Psychoactive Substances, Recreational Substances & Legal Highs
Report a Reaction

News
IMMP
The IMMP closed in December 2013. Visit the archived site.

Available on the App Store
Report Sources

- https://nzphvc.otago.ac.nz
- PMS ADR tool(s)
Annual Total Reports Received by NZPhvC
Serious Reports for Medicines by Reporter Type 2000-2016

Chart Title

- Comm Pharm
- GP
- Hosp Dr
- Hosp Pharm
- Nurse

reports - non-serious
reports - serious
Seriousness Categories by Reporter Type 2000-2016

[Diagram showing the distribution of serious categories by reporter type, with bars for Congenital effect, Died, Hospitalisation, Intervention, Life-threatening, and Persisting disability, each with subcategories (Nurse, Hosp Phm, Hosp Dr, GP, Comm Phm).]
Report Processing

EACH EVENT or REACTION IS:
• coded according to WHO criteria using WHOART
  • reaction terms applied
  • assessed for severity & seriousness
  • assessed for relationship/causality

FOR ALL SPONTANEOUS REPORTS
• tailored response is sent to every reporter
  • causality
  • number of similar reports in N.Z. /WHO/literature
  • relevant additional information
    ... at risk groups
    ... prevention issues
  - cautions warnings or danger alert / advisories
  - follow-up information if required
The value of spontaneous monitoring

1. Patterns of reactions
   • Reinforce established knowledge
   • Local context
   • Changing patterns of use
   • Monitoring for patient safety
   • Product quality issues

   Clinician Queries ...

   Impetus for prescriber reminders
The value of spontaneous monitoring

1. Patterns of AEFI/Reactions
   • Re-inforce established knowledge
   • Local context
   • Impetus for prescriber reminders

2. Signal new AEFI/Reactions

3. Contribute to *individual* patient safety
   • medical warning system
   • NZ specific
National Medical Warning Register

• Patient-unique health Identifier links to core health information with national health-intranet access

• NZPhvC records Drug/Vaccine-Specific AEFI/ADR alerts as
  • Warning (precaution)
    (potentially) significant morbidity for patient
    > caution for future use
    > impact on daily living
  • Danger (contraindication/life threatening)
    Life-threatening event or other contraindication to future use

• Purpose to prevent re-exposure through alert
Hospital-side MWS alert
Medical Warnings and Dangers for Medicines by Reporter Type 2000 - 2016
... but

- National MWS currently only accessible by DHB’s (except South Island)
  - Primary Care access critical
- Low value entry format by some DHB’s
  - ‘Diclofenac’
- Critical carers cautious of entries
- CARM records valued - ‘6001’

- New EHR proposals include wide access
  - View records ✓
  - Enter alerts ±
- Need for:
  - clear operating guidelines so that quality alerts are entered.
  - ensuring alerts are clearly visible in DHB and other HCP software

... and prescription visibility will complement the safer use of medicines
Welcome to NZPhvC

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The Medication Error iceberg?

- Administration
- Formulation
- Preparation
- Route
- Device
- Drug interactions
- Drug omission
- Monitoring in chronic Rx
- Dose adjustments
- Under dosing
- Underlying disease
- Wrong – dose / drug / patient
CARM origin reports forwarded to MERP

Integration of CARM & MERP a unique model
Medication Error Harms

Figure 4: Number of reports by medication error type

Figure 5: Number of reports by patient outcome

opportunities for arranging PHO-specific feedback
Interactive Pharmacovigilance

• Support and Communication
  • Online/Telephone on-demand access by clinicians for ADR/AEFI discussion
  • Supporting clinical decision-making through ADR/AEFI data
  • Interaction with Health Care Providers & Patients
  • Media

? opportunities for more suitable PHO communication
Interactive Pharmacovigilance

• Support and Communication

• Reporter and Patient-Centred Focus
  • Ease of reporting to suit all
  • Tailored feedback on each report
    Highlighting relevant risks related to Drug/Vaccine-ADR/AEFI and comorbidity
  • Follow-up for clarity or Outcome

? Opportunity for integration into the EHR
Interactive Pharmacovigilance

• Support and Communication
• Reporter and Patient-Centered Focus
• Supporting Medsafe and Immunisation programmes
  • Weekly teleconference with Medsafe on current developments
  • Weekly and *adhoc* summary reports on specific vaccines or medicines
  • Quarterly reports to the Medicines Adverse Reactions Committee (MARC)
Interactive Pharmacovigilance

• Support and Communication
• Reporter and Patient-Centered Focus
• Supporting Medsafe and Immunisation programs

• Medicines monitoring .. $M^2$
  • Highlight potential safety issues from reports of suspected ADR’s/AEFI’s
  • Stimulate further reports & information about these issues
M² Medicines Monitoring

? Opportunity for integration into the EHR
Interactive Pharmacovigilance

• Support and Communication
• Reporter and Patient-Centered Focus
• Supporting Medsafe and Immunisation programs
• Medicines monitoring .. $M^2$

• Publically accessible database of Adverse Events
  • Suspected Medicine Adverse Reaction Search (SMARS)

### Detail for Human papillomavirus vaccine

Number of reports for Human papillomavirus vaccine: 558

Number reports where death was reported: 0

Number of reactions: 1381

<table>
<thead>
<tr>
<th>Report</th>
<th>Date</th>
<th>Gender</th>
<th>Age</th>
<th>Medicine(s)</th>
<th>Reaction(s)</th>
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<tbody>
<tr>
<td>75140</td>
<td>May 2007</td>
<td>Female</td>
<td>25</td>
<td>Gardasil vaccine injection (Suspect)</td>
<td>Injection site bruising, Injection site inflammation, Injection site pain,</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lymphadenopathy</td>
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<td>75309</td>
<td>May 2007</td>
<td>Female</td>
<td>16</td>
<td>Gardasil vaccine injection (Suspect)</td>
<td>Diarrhoea, Fatigue, Feeling of body temperature change, Somnolence, Vomiting</td>
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<td>75623</td>
<td>Jul 2007</td>
<td>Female</td>
<td>16</td>
<td>Gardasil vaccine injection (Suspect)</td>
<td>Injection site inflammation</td>
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<td>75999</td>
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<td>Female</td>
<td>16</td>
<td>Gardasil vaccine injection (Suspect)</td>
<td>Pain in extremity</td>
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<td>77157</td>
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<td>Female</td>
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<td>Influenza like illness, Injection site pain, Pain in extremity, Pyrexia</td>
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<td>77676</td>
<td>Feb 2008</td>
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<td>Gardasil vaccine injection (Suspect)</td>
<td>Lethargy, Periorbital oedema, Somnolence</td>
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<td>78148</td>
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<td>Female</td>
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<td>Arthralgia, Headache, Nausea, Pyrexia, Rash</td>
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<td>Anxiety, Chills, Fatigue, Insomnia</td>
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<td>Injection site abscess</td>
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<td>Sep 2006</td>
<td>Female</td>
<td>16</td>
<td>Gardasil vaccine injection (Suspect)</td>
<td>Angioedema, Dizziness, Hypotonia, Nausea</td>
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<td>81051</td>
<td>Sep 2006</td>
<td>Female</td>
<td>17</td>
<td>Gardasil vaccine injection (Suspect)</td>
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<td>Oct 2008</td>
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<td>17</td>
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<td>Abdominal pain, Injection site pain</td>
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<td>81602</td>
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<td>17</td>
<td>Gardasil vaccine injection (Suspect)</td>
<td>Injection site pain, Muscle oedema</td>
</tr>
</tbody>
</table>
The Future
themes and possibilities

• Improvement of Medical Warning System
  • Increased visibility of Medical Warnings

• Extended Health Intranet communications
  • CARM feedback
  • M² monitoring
  • Tailored PHO MERP feedback
  • Critical Medicine Safety messages

• Increasing HCP reporting
  • PMS integration has not greatly increased reporting
  • How do we motivate?

• Automatic transfer of ADR data from Practice Management Systems
  • General practice --- DHB’s
    • quality?, filtering?

• Patient reporting
  • Direct
  • Via HCP ("Take and Tell")
  • Patient feedback?
Acknowledgement

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