

Michael Tatley, Ruth Savage, Desiree Kunac, Janelle Ashton
New Zealand Pharmacovigilance Centre, Dunedin School of Medicine, University of Otago, New Zealand.

INTRODUCTION

The Centre for Adverse Reactions Monitoring (CARM) commenced operation as the New Zealand national ADR monitoring centre in April 1965 as one of the first few national centres established in the wake of the thalidomide tragedy of the early 1960s. CARM operates within a University setting delivering national ADR monitoring on contract to the NZ drug regulator (Medsafe) and is one of the very few national monitoring centres that are not within the Regulator

CARM has seen sustained and steady growth in reporting over its five decades of operations and has become entrenched as a respected service to its reporters and a source of quality ICSR case detail. For many years CARM sustained the highest rate of reporting per capita as measured by the Uppsala Monitoring Centre. CARM has often been host to training and orientation visits from other smaller national centres who have been keen to learn how a mature but relatively small and limited resourced facility has achieved its success including its contribution and integration in research.

AIM

To reflect and elaborate on the key factors contributing to the success of a mature national pharmacovigilance centre.

KEY SUCCESS FACTORS IN SUSTAINABILITY

SUPPORT AND COMMUNICATION

- Online/Telephone on-demand access to clinician for ADR discussion.
- Interaction with Health care providers, Patients & Media

SERVICE SYNERGY

- Complementary programs utilising common infrastructure and related methodologies



- Capitalises known credibility
- Cross programme awareness
- 'Vigilance in Drug Safety' concept
- Public Health Registrar training

INFORMING NATIONAL POLICY

- Medicines Adverse Reactions Committee



RESEARCH SUPPORT

- Academic**
Local context data
Signals generate further research
- Public**
Assistance with ADR data interpretation

NETWORKING

Establishing & maintaining linkages with bodies who operate in related fields.



REPORTER AND PATIENT-CENTERED FOCUS

Reporter

- Ease of reporting
- Hardcopy
- Online
- Practice software tool
- Smartphone
- Telephone
- Tailored ADR feedback - CME for clinician
- Follow-up for clarity or outcome

Patient

- Tailored response supports reporter discussion with patient
- Highlight relevant risks related to Drug/ADR or Co-Morbidity

National Medical Alert Register

- National Medical Alert Register
- Patient-unique health Identifier links to core health information with national access
- NZPhVC records Drug-specific ADR alerts as Warning (precaution) or Danger (contraindication)
- Purpose to prevent re-exposure



PROMOTION

- Hospital Grand Round presentations
- Primary care networks and Groupings
- Speciality group conferences & CME sessions
- Community and patient support groups
- Medical news publications

CONCLUSION

The combined effect of synergistic and complementary activities and operational approach has been instrumental in sustaining the credibility, utility and growth of support of the NZPhVC as a national resource which has seen its role extend into areas beyond monitoring of traditional medicine-related ADRs into a broader vigilance

and drug safety surveillance role. This model and its elements add value to the relevance of pharmacovigilance as a dynamic tool with value for clinical decision making, patient support and reassurance, providing richer data to inform research agendas and national drug safety initiatives.