

# Pharmacovigilance Workshop Summary January 26, 2007

Institute of Population Health  
R. Samuel McLaughlin Centre for  
Population Health Risk Assessment

PAHO/WHO Collaborating Centre in  
Population Health Risk Assessment

Risk Sciences International (RSI)

Université d'Ottawa | University of Ottawa



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# Adverse Drug Reaction and Signal Detection in Canada

*Heather Sutcliffe, Health Canada*

- CADRMP: Canadian Adverse Reaction Monitoring Program (in place since 1965)
- 51% of approved drugs not detected before market approval
- 15,000 'spontaneous' ADR reports annually in Canada
- Canada participates in international ADR monitoring and harmonization programs
- 'Signal detection' a key objective of pharmacovigilance
- CADRMP can be searched on-line



# Future Directions in the Review of Postmarket Safety Data

*Lucye Galand, Health Canada*

- Progressive licensing: shift from passive to active surveillance
- ICH E2E: systematic approach to post-market surveillance
- EMEA: risk management plans
- FDA approach
- RiskMAPS: risk minimization
- Consultation with public and other stakeholders
- Database studies:
  - National: integration of provincial data
  - International
- Pharmacoepidemiology



# Risk Communication for Marketed Health Products

*Cindy Evans, Health Canada*

- Key message: 'All health products may pose some risk'
- Shared responsibility: Health Canada, industry, health care professionals, patients/consumers, provincial licensing authorities
- Notices to hospitals, public advisories, Dear Healthcare Professional Letters
- MedEffect website provides comprehensive information on drug safety
- MedEffect e-notices
- Challenges: clarify role of industry, tailoring the message (audience, communications medium), uptake and effectiveness



# The Future of Drug Safety

*David Corn, Institute of Medicine*

- Vulnerabilities: underfunding, organization, regulatory authority, inadequate data
- 25 specific recommendations ([www.nap.edu](http://www.nap.edu))
- Two key messages:
  - FDA needs more resources for its drug safety programs
  - Pre-market and post-market programs need to be better integrated (adopt a lifecycle approach to the evaluation of drug risks and benefits)
- Approval decision should not necessarily be final regulatory action
- New model for postmarket studies: public-private partnership for confirmatory studies
- Systematic evaluation of all postmarket results needed



# Knowledge Finding for Globally Important ADR Signals

*Ralph Edwards, World Health Organization*

- WHO Drug Monitoring Program in established in 1968 (located in Uppsala Sweden since 1978)
- ICSRs sent to National Centres, which report to the UMC
- Currently about 4 million reports from 82 countries
- Quantitative signal detection key to datamining (BCPNN)
- Challenge: how to link ADRs to genome



WHO Collaborating Centre for  
International Drug Monitoring

Maternal and Child Health Drug Safety  
*Mark Walker, Ottawa Health Research Institute*

- Thalidomide a critical event in maternal and child drug safety
- Pregnancy is an exclusion for virtually all Phase I, II and III clinical trials
- Pharmacosurveillance in pregnancy therefore essential
- OHRI and the McLaughlin Centre have initiated several studies in this area



Pharmacoepidemiology  
*Ineke Neutel, University of Ottawa*

- Pharmacovigilance: signal generation using individual case reports
- Pharmacoepidemiology used to test hypotheses in target populations
- Cox-2 inhibitors channeled to high risk groups, resulting in CVD and other complications, confirmed in case-control study based on health care records



# Spontaneous Adverse Drug Reaction Report Data

*Alex Ruggieri, Cerner Galt*

- Data quality issues in spontaneous ADR reports (ambiguity, consistency, concept representation) require attention
- Process issues (capture rate, temporal biases, nature of the event) also of concern
- Path forward
  - unburden the reporter (simplicity)
  - data standards (HL7, SNOMED CT)
  - harness datamining tools
  - uniform data definitions and practices



# Health Facts Datawarehouse and Active Surveillance

*Doug McNair, Cerner Life Sciences*

- Move from reactive to proactive pharmacovigilance
- HealthFacts datawarehouse based on data from 70+ U.S. hospitals and health care institutions
- Data can be used to describe dose response for ADRs, adjust for polypharmacy, and take co-morbidity into account



## Panel on 'Role of Academia in Pharmacovigilance'

*Colleen Metge, University of Manitoba (Chair)*

*David Clapin, Health Canada; Sam Kacew, McLaughlin Centre*

*Tony Krantis, University of Ottawa;*

*Mark Walker, Ottawa Health Research Institute*

- Canadian Drug Policy Development Coalition
- Undergraduate Biopharmaceutical Sciences Program and new Biopharmaceutical Sciences Institute at University of Ottawa
- Academia one important participant in drug safety
  - pharmacovigilance methodology
  - analysis of large databases
  - clinical data
  - basic research
  - pharmacogenomics
  - Training
- Public/private sector partnerships



# The Role of Risk Perception in Risk Management



## Some Thank You's!

- Sponsors: McLaughlin Centre, Risk Sciences International, Cerner Life Sciences
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- Arrangements: Suzanne Therien, Angela Brazeau
- Speakers
- Participants



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