Canadian Medical Devices Sentinel Network

Presentation to the Product Vigilance Workshop
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Objective of the Presentation

To provide information about a new medical device event reporting program being initiated within select health care facilities
Overview

• Describe medical devices event reporting with Health Canada?
• Is there a need for new approach?
• What is a sentinel surveillance system?
• Describe the steps taken to initiate a sentinel program here in Canada.
• Describe the Canadian Medical Devices Sentinel Network pilot. (see Appendix 2)
Medical Device Program

Health Canada

Health Products and Food Branch

Marketed Health Products Directorate

Marketed Pharmaceutical and Medical Device Bureau

Medical Device Division

Therapeutic Products Directorate

Medical Devices Bureau

Device Evaluation Division, Device Surveillance Division

Health Product and Food Branch Inspectorate

Compliance and Enforcement Division

Medical Devices Compliance Unit [Device Surveillance]
Medical Devices Reporting Requirements

Manufacturers and importers are required to report incidents related to a medical device:

- Within 10 days: if an incident leads to death or a serious deterioration of health.
- Within 30 days: if an incident were to recur, could end in death or serious deterioration of health.

All other types of reports and reporters are voluntary.
Number of Medical Device Adverse Events Reported - 2008

- **327** Voluntary
- **320** Mandatory
- **2634** Recalls

* Source Medical Devices System (MDS)
Is There a Need for New Approach?

- Over 80,000 devices currently licensed for sale in Canada; increase complexity care/technology
- Adverse medical device events have found to occur 83.7 times per 1,000 hospital admissions (Samore et al. 2004).
- Under reporting from clinical community (under 15% all reports); passive approach to collection
- Reports are device focused, not patient centred
- Technology required updating
  - Need modernized/more accessible report form
  - Not able to query database for patient outcomes

Auditor General report of Medical Device Program (2004) recommended a pro-active approach to post market medical device surveillance
What is a Sentinel Approach to Surveillance?

Sentinel system approach:
• It is a group of dedicated, trained health care facilities that report high quality data of adverse events associated with medical devices.
• It will provide a mechanism for enhanced 2-way communication with the clinical community.

Goal:
• The safety of Canadians will be impacted by better quality risk assessments and earlier regulatory interventions.
• It will provide citizens with timely information to make informed health choices will help them maintain and improve their health.
What Makes it Different?

Voluntary system
- Passive approach
- Universal system
- All types of reporters
  - no training
  - report for work/personal purposes
- All types of reports- more serious types valued?
- Basic information about adverse event
- Manual system to receive reports and enter them Medical Device System.
- Communication with Inspectorate only
- Delays ability to search for signals

Sentinel system
- Pro-active approach
- Subset of reporters
- Reporters are:
  - professionals with training
  - who report for the facility
- Any type of incident- near misses types more valued?
- Detailed reports on problem characteristics
- Web page report form, electronic system-database
- Feedback loop within network
- Provides early warning system for signals
Initiating the Sentinel System Project in Canada

- March 2004- Auditor General’s recommendation
- May 2005- 2007- Review of other regulatory agencies, feasibility study
- Oct-Dec 2007- Project documents created
- Dec- Jan 2008- Stakeholder meetings
- July 2008- First sentinel health care facility recruited!! (St Joseph's in Hamilton)
- Sept 2008- Name chosen
  - Canadian Medical Devices Sentinel Network /Réseau sentinelle canadien pour les matériels médicaux.
    - Acronyms will be... CMDSNet & ResSCMM with the emphasis on networking!
- Dec 2008- Recruitment closed (12 centres)
- April, 2009- Go live with pilot
Others Using Sentinel Approaches?

Canada: IMPACT (Immunization Monitoring Program ACTive)
- Paediatric hospital-based national active surveillance network (12)
- Reports most serious adverse events following immunization, vaccine failures
- Designated nurse monitor and voluntary physician/centre
- IMPACT is administered by the Canadian Paediatric Society with funding from Public Health Agency of Canada.

United States: MedSun Approach
- Dedicated trained reporters- Voluntary
- Medical Devices specifically
- Providing feedback, sense of community
- Early warning of safety trends

Brazil: ANVISA
- Paid representatives in 100 hospitals
- All health products, disinfectants
- Network used to validate scope of problem
- Research/best practice focus
Feasibility Study of a Sentinel System

- Overview of Health Canada situation
- Interviews with 11 health care facilities - biomedical, risk management and nursing staff contacted
- Unaware of how to report to Health Canada
- Health Canada information used last; not timely
- No feedback from Health Canada
- Confidentiality and privacy not as big of a concern as in US
- Biggest concern: time required for reporting; <5-10 min
- Recommends Sentinel system; not a particular software tool
Business Requirements

• Electronic system, easily accessible
• Limited burden on reporter, <5-10 min
• Mix of mandatory fields & variety of data entry methods
• Compatible & linked with other Health Canada tables & databases
• Complies with Health Canada privacy and software requirements
• Auto generates acknowledgement and unique ID number to incident
• Able to archive, easy to query and generate reports
• Ready for pilot implementation in 2008-9
Stakeholder Discussions

• Internal- Medical Device Bureau, Inspectorate, Canada Vigilance Program, MedEffect Web Department, Information Technology
  – Need to coordinate & compliment efforts

• Associations- MEDEC, Canadian Heart Rhythm Society, Canadian Institute for Health Information, Canadian Patient Safety Institute, Institute for Safe Medication Practices Canada
  – Need for feedback, standardized process
  – Concern for biases reporting and interpretation

• Institutions- The Ottawa Hospital, Ottawa Heart Institute, London Health Science
  – Variety of reporting structures, needs coordination
  – Concern about who reports & lack of time to do so
Challenges in Health Canada Environment

- No mandatory requirement for health care facilities to report
- No consistent structure within institutions for reporting
- No universal adverse event coding for medical devices
- Facilities funded by province; this is federal initiative
- Other reporting projects being undertaken by hospitals
- Information management strategy to have one approach and electronic portal for all health products
- Need to be able to merge data into other Health Canada databases
- Resources within Health Canada and in hospitals
- Health Canada software requirements
Challenges= Need to Start with a Small Pilot

First…pilot:
- Use web page for on-line reporting and tracking mechanism
  - Similar approach with drugs - report form on MedEffect webpage.
  - Resource and time issue
  - Less risk and able to gather more information about challenges of reporting with small implementation

Then…comprehensive implementation:
- Need to explore other systems currently used for other Health Canada products (Canada Vigilance?)
  - Will have buy-in from institutions
  - Health Canada environment changed? I.e.: reporting structures and requirements
  - Reporting activity by health care reporters for other products?
What will be the “Sentinel Process”

- Report sent in by select reporters> acknowledged
- Triaged & entered into tracking mechanism
- Report transferred to manufacturer
- Signal verification- network/other
- Feedback to reporting health care facility
- Codes event for future queries
- Reporting- internally & externally
Reports…to Data…to Risk Assessments

- **Focusing on…**
  - patient outcomes
  - safety concerns
  - characteristics of the problem
- **Create two way communication with clinical community to understand environment better**
- **Trying to identify factors that can be impacted by risk mitigation activities**
  - awareness of hazards/conditions of use
  - improved labeling
  - improvements to safety standards
Benefits of the Sentinel Program

- Fulfill Auditor General’s recommendation for Medical Device Program program
- Increase in credibility of Health Canada as source for post market information
- Similar approach of other regulators- opportunity to share information
- Creates awareness of hospital staff to adverse event reporting
- Quality improvement transferable to other health care facilities
- May provide for safer product development and licensing in the future
Canadian Medical Devices Sentinel Network Pilot

- **Representative samplings of different types of facilities & reporting structures**
- **Run pilot long enough to have enough incidents to see safety trends**
- **Objectives**
  - Increase number of voluntary reports received
  - Validate data fields, reporting tool and database requirements
  - Determine best reporting structures and processes to target for program
  - Identify any reporting gaps
  - Validate business unit re-development
  - Test communication tools
Pilot thus far…

- Recruitment completed
- PDF/print bilingual forms developed
- External/Internal materials developed
- Hiring of analysts started
- Sample reports received
- Scope: All devices
- Quarterly evaluations planned with health care facilities/manufacturers
- Pilot launched: April 15th, 2009
  - For one year duration
Health Care Facility Representation
Project Schedule

- Business Case approval
- Engage Information Technology
- Project Charter/Plan approval

Investigate & recruit health care facilities

Develop training and support materials

Develop standardized processes

Train & support health care facilities

Launch

Pilot

Completion report

Ongoing Project Decisions

- Jun-Jul08
- Aug-Sep08
- Oct-Nov08
- Dec-Jan09
- Feb-Mar09
- Apr-May09
- Jun-Jul09
- Aug-Sep09
- Oct-Nov09
- Dec-April 10
- April-June 10
Next Steps

Pilot: Planned completion April 2010

- Will review outcomes of pilot and consider more fulsome implementation of project.
Questions?

Thank you!

Further information please contact:
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