Drug Safety and Effectiveness Network

Canadian Association for Population Therapeutics
April 21, 2009

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Outline

- Genesis of the Drug Safety and Effectiveness Network (DSEN)
- Public Policy Objectives for the DSEN
- DSEN Design and Implementation (Diane Forbes)

Driving Force

- Large gaps in the evidence available about the safety and effectiveness of drugs based on their use in the “real world” by diverse patient groups, outside the controlled experimental environments of clinical trials
- Evolution of knowledge about medicines demands that governments and other decision-makers seek better evidence about the balance of benefit and risk throughout the product life cycle

Current Environment

- Post-market studies are largely *ad hoc* – predominantly driven by investigator interest
- Evidence generated does not always correspond to the needs of decision-makers (e.g., public payers, etc)
- Limited coordination and collaboration among researchers and decision makers to identify and address the most urgent evidence gaps
- Need for more rapid response to important policy concerns related to drug safety and/or effectiveness

A Public Policy Priority

- 2004 First Ministers Health Accord – the “10 year plan”
- Strengthening evaluation of real-world drug safety and effectiveness (RWSE) included as one of the five priority elements in the National Pharmaceuticals Strategy (NPS)
  - Recognition that RWSE knowledge gaps are a clear barrier to effective, evidence-based decision making
  - Need for greater coordination of efforts to generate and transfer information necessary to fill evidence gaps and support decision makers in a timely manner

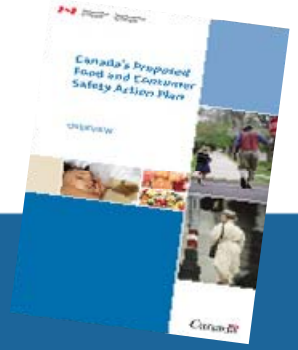
NPS

- Provided opportunity for collaborative development of options to improve our knowledge of RWSE
- *Medicines that Work for Canadians: Business Plan for a Drug Effectiveness and Safety Network* (2007)
    - Collaborative effort among NPS partners, Canadian Institutes of Health Research (CIHR), and the Canadian Drug Policy Development Coalition
    - *http://www.hc-sc.gc.ca/hcs-sss/pubs/pharma/2007-med-work_eff/index-eng.php*

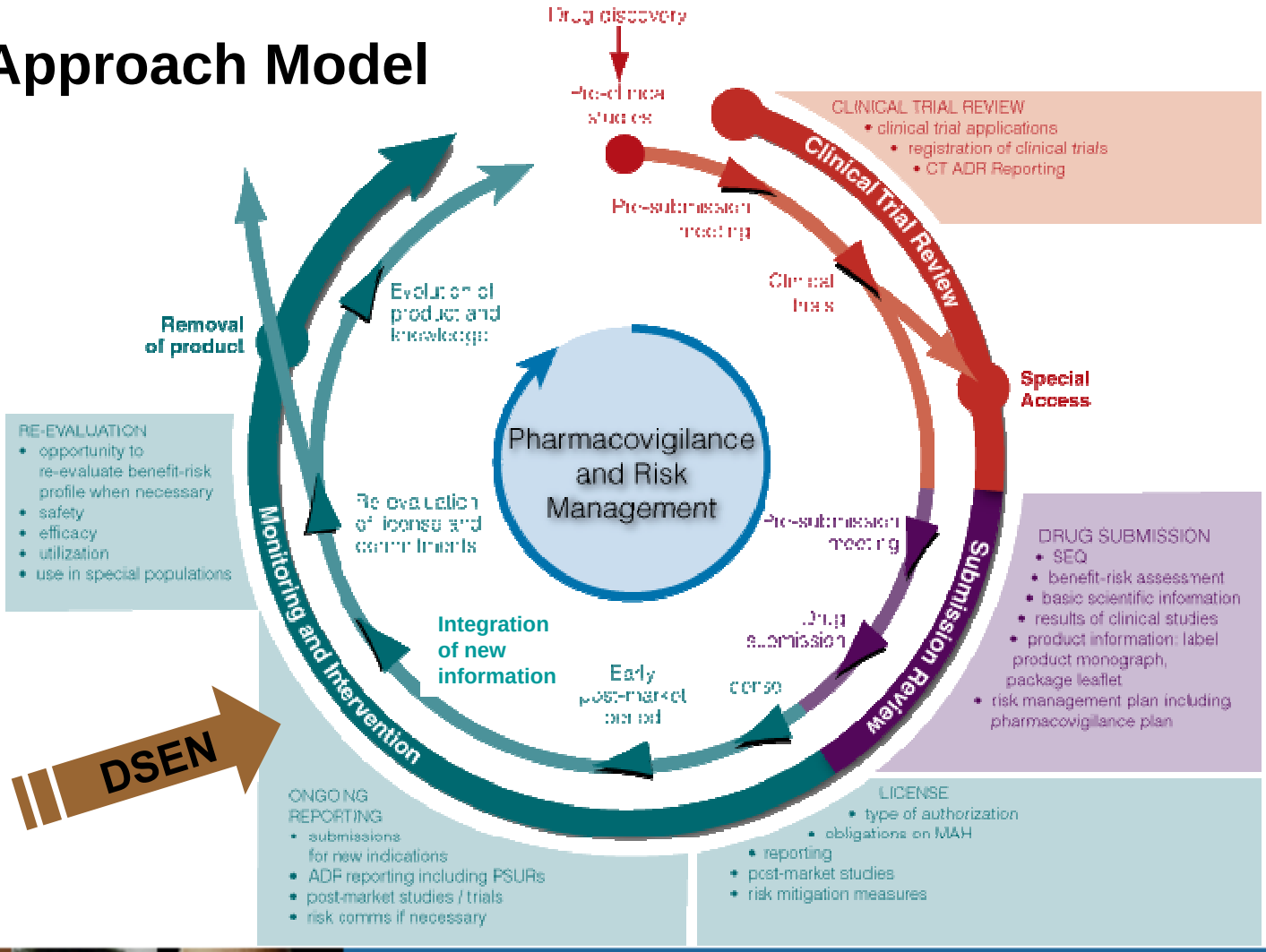
Post NPS

- DSEN included in the Government of Canada's ***Food and Consumer Safety Action Plan*** (December 2007)
    - Support product life-cycle approach to drug regulation by providing key evidence to Health Canada for use in ongoing risk-benefit assessment of drug products
    - Complement other pharmacosurveillance activities – provide additional tool

http://www.healthycanadians.gc.ca/pr-rp/action-plan_e.html



Life-Cycle Approach Model



News Release

Government of Canada Works to Improve Knowledge About the Safety and Effectiveness of Drugs

January 14, 2009

TORONTO – The Honourable Leona Aglukkaq, Minister of Health, today announced that the Government of Canada is continuing to support the Drug Safety and Effectiveness Network (DSEN), first announced in July 2008.

"Canadians can be confident that this Government is taking the steps necessary to ensure that our drug safety system remains one of the best in the world," said Minister Aglukkaq. "The Drug Safety and Effectiveness Network complements Canada's rigorous pre-testing of new drugs by studying how Canadians respond over time to already-approved drugs. The results will help in decision-making and enhance overall consumer safety."

Public Policy Objectives

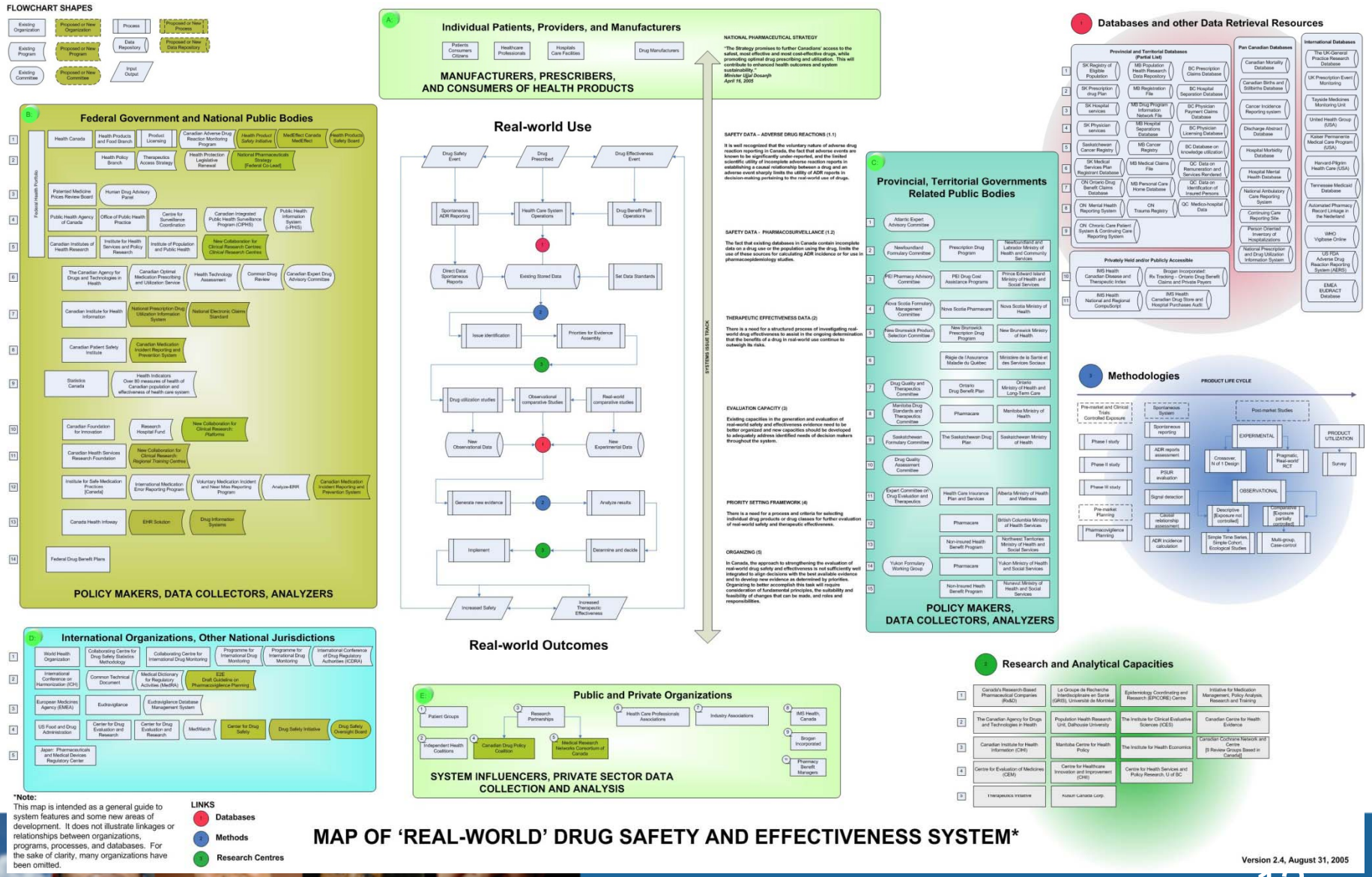
- Promote safe and effective use of pharmaceuticals by filling gaps in knowledge required to make effective evidence-based decisions about drugs
  - Decisions made at different points throughout the regulatory and health care system including post-market surveillance; reimbursement; prescribing, utilization

- Increase capacity within Canada to undertake high-quality post-market studies of RWSE
  - To support increased availability of needed evidence

Public Policy Objectives

- Leverage greater value from existing investments in post-market research within Canada by:
  - Building on what already exists
  - Improving coordination of research efforts, both nationally and internationally
  - Promoting greater collaboration

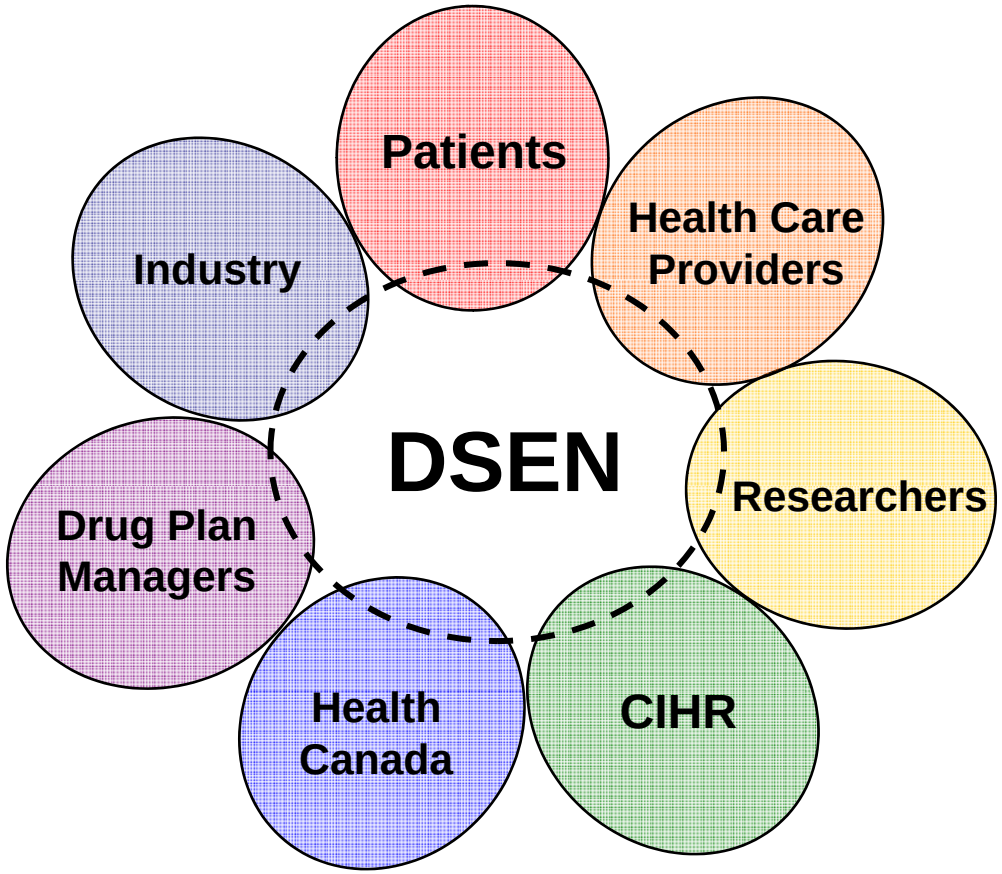
- Contribute to improved system efficiency to support accessible and sustainable health system responsive to the health needs of Canadians


FLOWCHART SHAPES
Existing Organization
Proposed or New Organization
Process
Proposed or New Process
Existing Program
Proposed or New Program
Data Repository
Proposed or New Data Repository
Existing Committee
Proposed or New Committee
Input Output
A.
Individual Patients, Providers, and Manufacturers
Patients Consumers Citizens
Healthcare Professionals
Hospitals Care Facilities
Drug Manufacturers
MANUFACTURERS, PRESCRIBERS, AND CONSUMERS OF HEALTH PRODUCTS
B.
Federal Government and National Public Bodies
Federal Health Portfolio
Health Canada
Health Products and Food Branch
Product Licensing
Canadian Adverse Drug Reaction Monitoring Program
Health Product Safety Initiative
MedEffect Canada MedEffect
Health Products Safety Board
Health Policy Branch
Therapeutics Access Strategy
Health Protection Legislative Renewal
National Pharmaceuticals Strategy [Federal Co-Lead]
Patented Medicine Prices Review Board
Human Drug Advisory Panel
Public Health Agency of Canada
Office of Public Health Practice
Centre for Surveillance Coordination
Canadian Integrated Public Health Surveillance Program (CIPHS)
Public Health Information System (i-PHIS)
Canadian Institutes of Health Research
Institute for Health Services and Policy Research
Institute of Population and Public Health
New Collaboration for Clinical Research Centres: Clinical Research Centres
The Canadian Agency for Drugs and Technologies in Health
Canadian Optimal Medication Prescribing and Utilization Service
Health Technology Assessment
Common Drug Review
Canadian Expert Drug Advisory Committee
Canadian Institute for Health Information
National Prescription Drug Utilization Information System
National Electronic Claims Standard
Canadian Patient Safety Institute
Canadian Medication Incident Reporting and Prevention System
Statistics Canada
Health Indicators Over 80 measures of health of Canadian population and effectiveness of health care system
Canadian Foundation for Innovation
Research Hospital Fund
New Collaboration for Clinical Research: Platforms
Canadian Health Services Research Foundation
New Collaboration for Clinical Research: Regional Training Centres
Institute for Safe Medication Practices [Canada]
International Medication Error Reporting Program
Voluntary Medication Incident and Near Miss Reporting Program
Analyze-ERR
Canadian Medication Incident Reporting and Prevention System
Canada Health Infoway
EHR Solution
Drug Information Systems
Federal Drug Benefit Plans
POLICY MAKERS, DATA COLLECTORS, ANALYZERS
Real-world Use
Drug Safety Event
Drug Prescribed
Drug Effectiveness Event
Spontaneous ADR Reporting
Health Care System Operations
Drug Benefit Plan Operations
Direct Data Spontaneous Reports
Existing Stored Data
Set Data Standards
Issue identification
Priorities for Evidence Assessment
Drug utilization studies
Observational comparative Studies
Real-world comparative studies
New Observational Data
New Experimental Data
Generate new evidence
Analyze results
Implement
Determine and decide
Increased Safety
Increased Therapeutic Effectiveness
Real-world Outcomes
SYSTEMS ISSUE TRACK
NATIONAL PHARMACEUTICAL STRATEGY
"The Strategy promises to further Canadians' access to the safest, most effective and most cost-effective drugs, while promoting optimal drug prescribing and utilization. This will contribute to enhanced health outcomes and system sustainability."
Minister Ujjal Dosanjh
April 16, 2005
SAFETY DATA – ADVERSE DRUG REACTIONS (1.1)
It is well recognized that the voluntary nature of adverse drug reaction reporting in Canada, the fact that adverse events are known to be significantly under-reported, and the limited scientific utility of incomplete adverse reaction reports in establishing a causal relationship between a drug and an adverse event sharply limits the utility of ADR reports in decision-making pertaining to the real-world use of drugs.
SAFETY DATA – PHARMACOSURVEILLANCE (1.2)
The fact that existing databases in Canada contain incomplete data on a drug use or its population using the drug, limits the use of these sources for calculating ADR incidence or for use in pharmacoepidemiology studies.
THERAPEUTIC EFFECTIVENESS DATA (2)
There is a need for a structured process of investigating real-world drug effectiveness to assist in the ongoing determination that the benefits of a drug in real-world use continue to outweigh its risks.
EVALUATION CAPACITY (3)
Existing capacities in the generation and evaluation of real-world safety and effectiveness evidence need to be better organized and new capacities should be developed to adequately address identified needs of decision makers throughout the system.
PRIORITY SETTING FRAMEWORK (4)
There is a need for a process and criteria for selecting individual drug products or drug classes for further evaluation of real-world safety and therapeutic effectiveness.
ORGANIZING (5)
In Canada, the approach to strengthening the evaluation of real-world drug safety and effectiveness is not sufficiently well integrated to align decisions with the best available evidence and to develop new evidence as determined by priorities. Organizing to better accomplish this task will require consideration of fundamental principles, the suitability and feasibility of changes that can be made, and roles and responsibilities.
C.
Provincial, Territorial Governments Related Public Bodies
Atlantic Expert Advisory Committee
Newfoundland Formulary Committee
Prescription Drug Program
Newfoundland and Labrador Ministry of Health and Community Services
PEI Pharmacy Advisory Committee
PEI Drug Cost Assistance Programs
Prince Edward Island Ministry of Health and Social Services
Nova Scotia Formulary Management Committee
Nova Scotia Pharmacare
Nova Scotia Ministry of Health
New Brunswick Product Selection Committee
New Brunswick Prescription Drug Program
New Brunswick Ministry of Health
Régie de l'Assurance Maladie du Québec
Ministère de la Santé et des Services Sociaux
Drug Quality and Therapeutics Committee
Ontario Drug Benefit Plan
Ontario Ministry of Health and Long-Term Care
Manitoba Drug Standards and Therapeutics Committee
Pharmacare
Manitoba Ministry of Health
Saskatchewan Formulary Committee
The Saskatchewan Drug Plan
Saskatchewan Ministry of Health
Drug Quality Assessment Committee
Expert Committee on Drug Evaluation and Therapeutics
Health Care Insurance Plan and Services
Alberta Ministry of Health and Wellness
Pharmacare
British Columbia Ministry of Health Services
Non-insured Health Benefit Program
Northwest Territories Ministry of Health and Social Services
Yukon Formulary Working Group
Pharmacare
Yukon Ministry of Health and Social Services
Non-Insured Heath Benefit Program
Nunavut Ministry of Health and Social Services
POLICY MAKERS, DATA COLLECTORS, ANALYZERS
1
Databases and other Data Retrieval Resources
Provincial and Territorial Databases (Partial List)
SK Registry of Eligible Population
MB Population Health Research Data Repository
BC Prescription Claims Database
SK Prescription drug Plan
MB Registration File
BC Hospital Separation Database
SK Hospital services
MB Drug Program Information Network File
BC Physician Payment Claims Database
SK Physician services
MB Hospital Separations Database
BC Physician Licensing Database
Saskatchewan Cancer Registry
MB Cancer Registry
BC Database on knowledge utilization
SK Medical Services Plan Registrant Database
MB Medical Claims File
QC: Data on Remuneration and Services Rendered
ON Ontario Drug Benefit Claims Database
MB Personal Care Home Database
QC: Data on Identification of Insured Persons
ON Mental Health Reporting System
ON Trauma Registry
QC: Medico-Hospital Data
ON Chronic Care Patient System & Continuing Care Reporting System
Privately Held and/or Publicly Accessible
IMS Health Canadian Disease and Therapeutic Index
Brogan Incorporated: Rx Tracking – Ontario Drug Benefit Claims and Private Payers
IMS Health: National and Regional CompuScript
IMS Health: Canadian Drug Store and Hospital Purchases Audit
Pan Canadian Databases
Canadian Mortality Database
Canadian Births and Stillbirths Database
Cancer Incidence Reporting system
Discharge Abstract Database
Hospital Morbidity Database
Hospital Mental Health Database
National Ambulatory Care Reporting System
Continuing Care Reporting Site
Person Oriented Inventory of Hospitalizations
National Prescription and Drug Utilization Information System
International Databases
The UK-General Practice Research Database
UK Prescription Event Monitoring
Tayside Medicines Monitoring Unit
United Health Group (USA)
Kaiser Permanente Medical Care Program (USA)
Harvard-Pilgrim Health Care (USA)
Tennessee Medicaid Database
Automated Pharmacy Record Linkage in the Nederland
WHO Vigibase Online
US FDA Adverse Drug Reaction Reporting System (AERS)
EMEA EUDRACT Database
3
Methodologies
PRODUCT LIFE CYCLE
Pre-market and Clinical Trials Controlled Exposure
Phase I study
Phase II study
Phase III study
Pre-market Planning
Pharmacovigilance Planning
Spontaneous System
Spontaneous reporting
ADR reports assessment
PSUR evaluation
Signal detection
Causal relationship assessment
ADR incidence calculation
Post-market Studies
EXPERIMENTAL
Crossover, N of 1 Design
Pragmatic, Real-world RCT
OBSERVATIONAL
Descriptive [Exposure not controlled]
Comparative [Exposure partially controlled]
Simple Time Series, Simple Cohort, Ecological Studies
Multi-group, Case-control
PRODUCT UTILIZATION
Survey
D.
International Organizations, Other National Jurisdictions
World Health Organization
Collaborating Centre for Drug Safety Statistics Methodology
Collaborating Centre for International Drug Monitoring
Programme for International Drug Monitoring
Programme for International Drug Monitoring
International Conference of Drug Regulatory Authorities (ICDRA)
International Conference on Harmonization (ICH)
Common Technical Document
Medical Dictionary for Regulatory Activities (MedRA)
E2E Draft Guideline on Pharmacovigilance Planning
European Medicines Agency (EMEA)
Eudravigilance
Eudravigilance Database Management System
US Food and Drug Administration
Center for Drug Evaluation and Research
Center for Drug Evaluation and Research
MedWatch
Center for Drug Safety
Drug Safety Initiative
Drug Safety Oversight Board
Japan: Pharmaceuticals and Medical Devices Regulatory Center
E.
Public and Private Organizations
Patient Groups
Research Partnerships
Health Care Professionals Associations
Industry Associations
IMS Health, Canada
Independent Health Coalitions
Canadian Drug Policy Coalition
Medical Research Networks Consortium of Canada
Brogan Incorporated
Pharmacy Benefit Managers
SYSTEM INFLUENCERS, PRIVATE SECTOR DATA COLLECTION AND ANALYSIS
2
Research and Analytical Capacities
Canada's Research-Based Pharmaceutical Companies (RxbD)
Le Groupe de Recherche Interdisciplinaire en Santé (GRIS), Université de Montréal
Epidemiology Coordinating and Research (EPICORE) Centre
Initiative for Medication Management, Policy Analysis, Research and Training
The Canadian Agency for Drugs and Technologies in Health
Population Health Research Unit, Dalhousie University
The Institute for Clinical Evaluative Sciences (ICES)
Canadian Centre for Health Evidence
Canadian Institute for Health Information (CIHI)
Manitoba Centre for Health Policy
The Institute for Health Economics
Canadian Cochrane Network and Centre [9 Review Groups Based in Canada]
Centre for Evaluation of Medicines (CEM)
Centre for Healthcare Innovation and Improvement (CHI)
Centre for Health Services and Policy Research, U of BC
Therapeutics Initiative
Roche Canada Corp.
*Note:
This map is intended as a general guide to system features and some new areas of development. It does not illustrate linkages or relationships between organizations, programs, processes, and databases. For the sake of clarity, many organizations have been omitted.
LINKS
1 Databases
2 Methods
3 Research Centres
MAP OF 'REAL-WORLD' DRUG SAFETY AND EFFECTIVENESS SYSTEM*
Version 2.4, August 31, 2005

DSEN – A Partnership Initiative

- Many players in Canada's "drug safety and effectiveness system"
  - from many sectors - governments, academia, industry, health care providers, patients
- Many different roles
  - regulatory, reimbursement, data holders, knowledge generators, treatment providers, prescribers, users

Intersect of RWSE Interests



DSEN Federal Partners

- CIHR and Health Canada, leading establishment of the DSEN, working with other partners and stakeholders:
  - **HC** providing policy leadership and coordination among DSEN program partners and integrating DSEN research findings into its existing drug regulatory and drug plan management activities
  - **CIHR** responsible for implementing, facilitating and coordinating DSEN operations and funding research

Thank you!

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