

Drug Safety and Effectiveness Network

2009 Annual CAHSPR Conference

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Canadian Institutes of Health Research

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 a priority element in the National Pharmaceuticals Strategy (NPS)
- *Medicines that Work for Canadians: Business Plan for a Drug Effectiveness and Safety Network (2007)*
 - ✓ Collaborative effort among NPS partners, 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

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 additional evidence about the balance of benefit and risk throughout a product’s life cycle

Driving Force

Fractured hips tied to heartburn remedies

The Globe
and Mail

BY CARLA K. JOHNSON, CHICAGO

Dec 27, 2006

THE GLOBE AND MAIL
THURSDAY, MARCH 2, 2006

Research links antibiotic to lethal blood-sugar levels

WINNIPEG FREE PRESS, SATURDAY, MAY 12, 2007

YOUR HEALTH

winnipegfreepress.com

A13

Cancer patients run a risk of addiction

DSEN Policy Objectives

- Increase the available evidence on drug safety and effectiveness available to regulators, policy-makers, health care providers and patients
 - ✓ Fill gaps in knowledge required to make evidence-based decisions about drugs
- Increase capacity within Canada to undertake high-quality post-market studies of RWSE
 - ✓ Leverage greater value from existing investments in post-market research within Canada

The Food And Consumer Safety Action Plan

- 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 additional evidence to Health Canada for use in ongoing risk-benefit assessment of drug products
 - ✓ Complement other pharmacosurveillance activities – provide additional tool

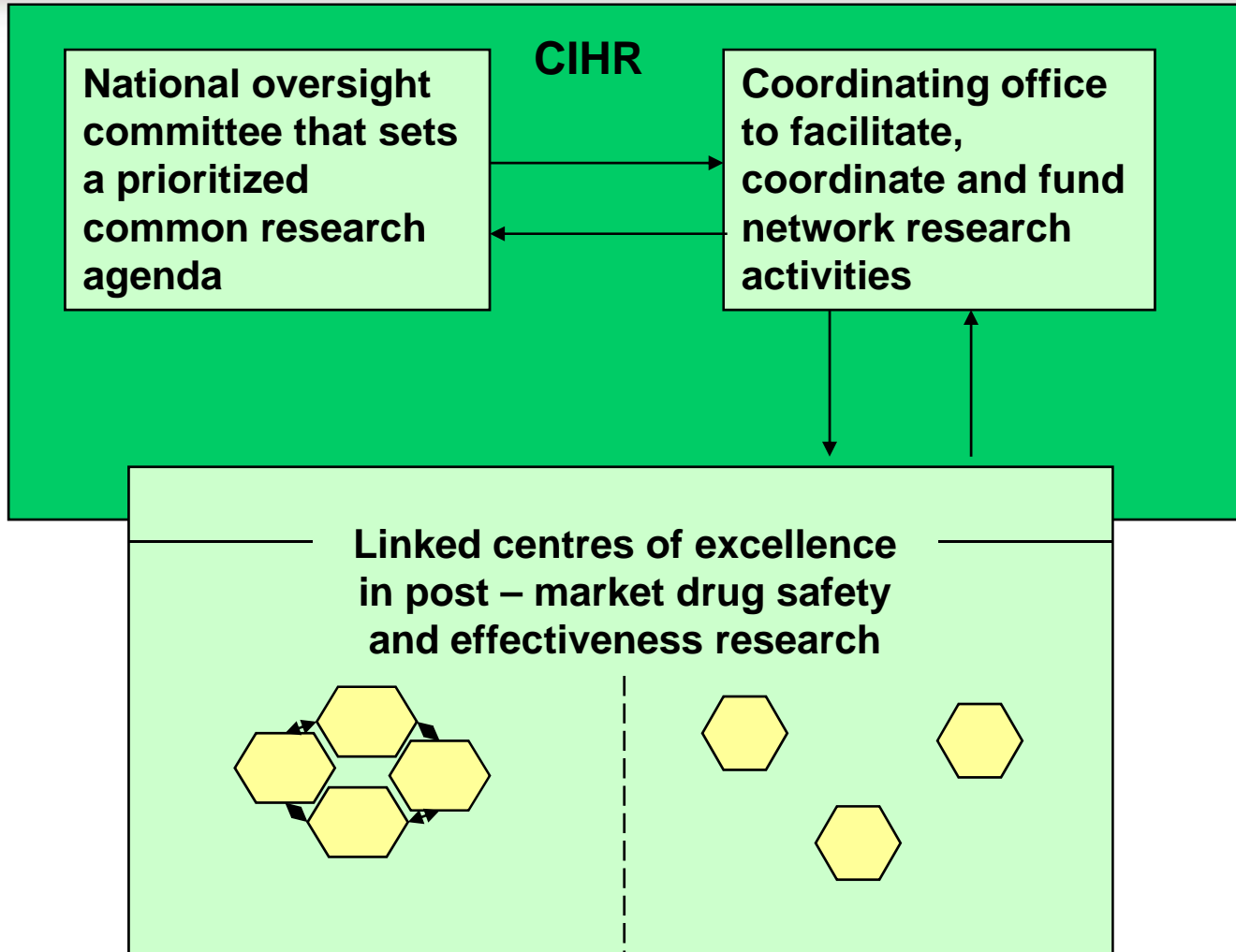
<http://www.healthycanadians.gc.ca/pr-rp/action-plan>



DSEN - A Partnership Initiative

- As Federal Partners, CIHR and Health Canada, are leading establishment of the DSEN Program
- Many players in Canada's "drug safety and effectiveness system"
 - ✓ From many different sectors - governments, academia, industry, health care providers, patients
 - ✓ With many any different roles - regulatory, reimbursement, data holders, knowledge generators, treatment providers, prescribers, users

DSEN Components



National oversight committee

- Represents broad stakeholder groups (e.g., regulators, drug plan managers, health professionals, patients)
- Develops a DSEN common prioritized research agenda by identifying gaps in information needed to make decisions regarding safety and effectiveness of pharmaceuticals
- Identifies stakeholder priorities for consideration in creating the common prioritized research agenda
- Supports and promotes translation of research knowledge into actions aimed at improving the health and safety of Canadians
- Respects principles for addressing conflicts of interest

Office of the Executive Director

- Supports and enhances linkages among researchers, research organizations and data sources located across Canada
- Administers DSEN funding program to support conduct of research projects responding to the prioritize research agenda
 - ✓ Facilitates collaboration among network “nodes” to achieve DSEN program objectives
- Supports the national oversight committee in maintaining the prioritized research agenda
- Supports knowledge translation
- Facilitates existing and develops new national and international partnerships for both research and data

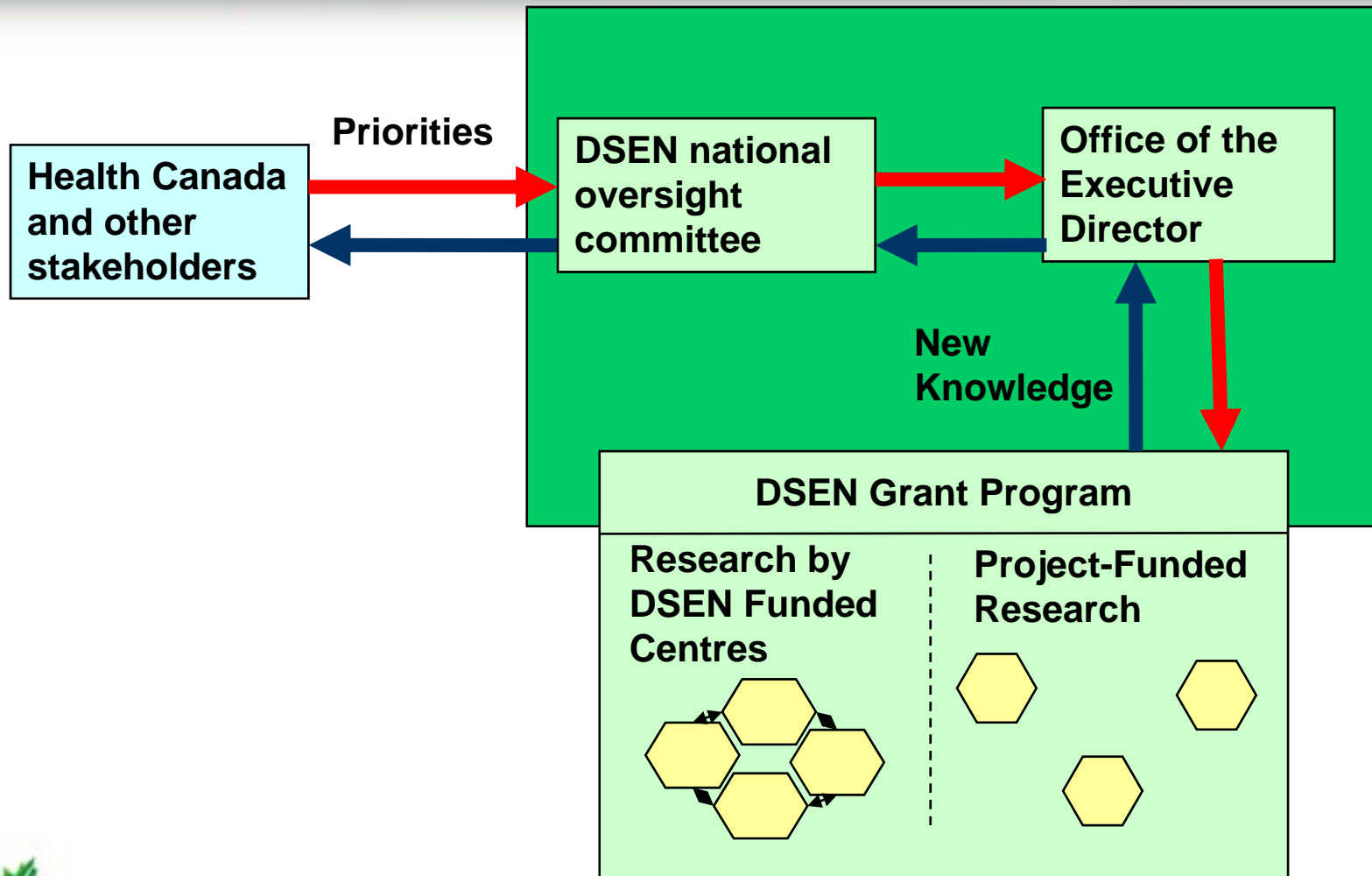
DSEN Funding

- Centre Funding:
 - ✓ Allocated to research centres to support capacity building and research activities allowing more rapid response to research questions.
- Project Funding:
 - ✓ Allocated more widely to support the conduct of studies addressing research questions which cannot be undertaken by dedicated centres alone (e.g., RCTs).

The Operational Process

- Identify and Prioritize Research
 - ✓ Oversight committee prioritizes research questions identified by stakeholders in a research agenda with support of the Office of the Executive Director
- Conduct Research
 - ✓ DSEN researchers will propose research protocols responding to the prioritized research agenda
- Use Results
 - ✓ Decision makers will use new additional source of information in combination with existing evidence to make decisions within their responsibility areas

DSEN Program

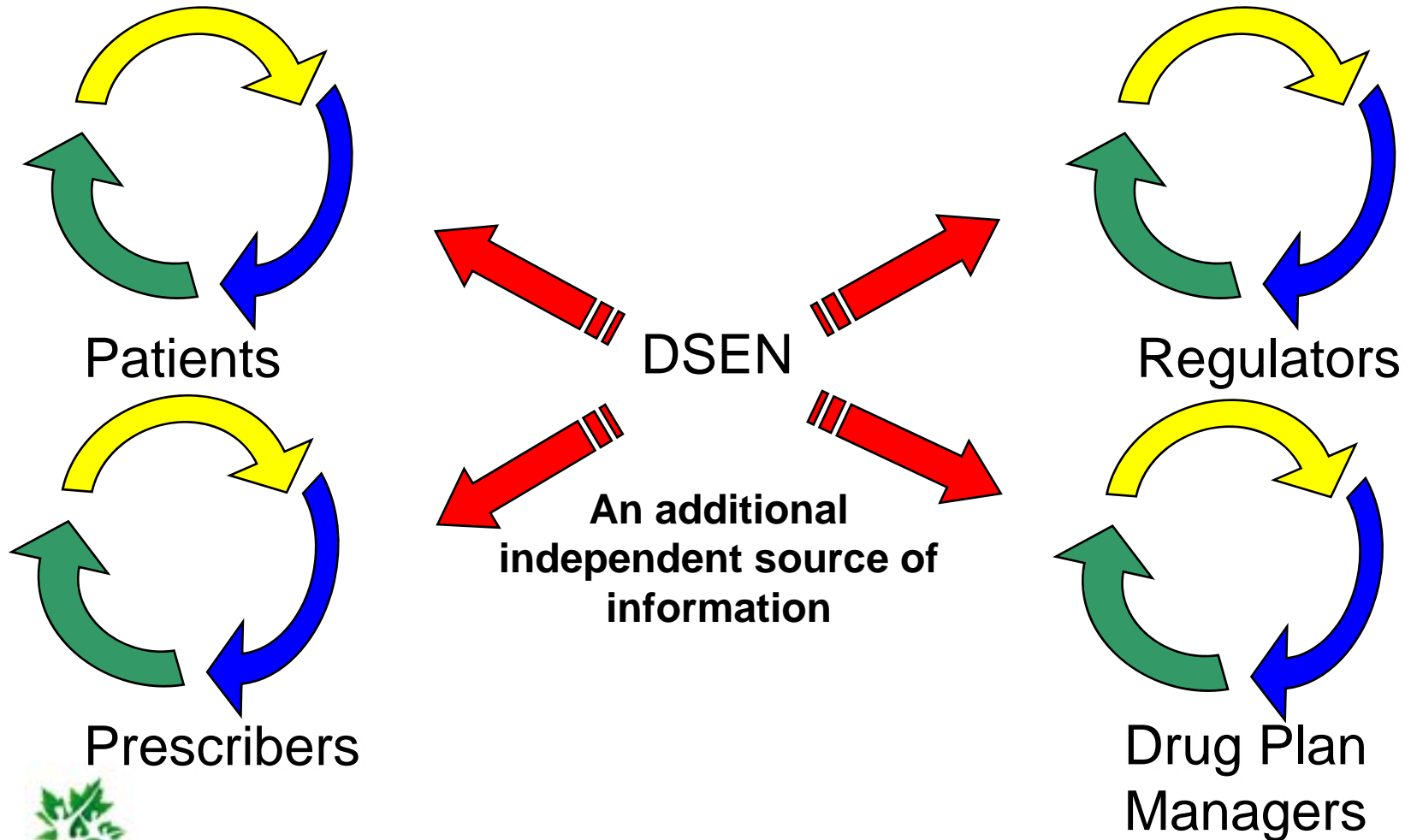


Goals for the DSEN Program

- Support collaboration and networking among researchers, research organizations and data holders located across Canada
 - ✓ Generate new evidence to address a prioritized agenda of questions on the safety and effectiveness of drugs
 - ✓ Utilize existing and develop new national and international partnerships for both research and data
 - ✓ Maintain and grow research capacity across Canada dedicated to DSEN priorities

- Facilitate Knowledge Transfer between decision makers and researchers
 - ✓ Prioritization of research agenda
 - ✓ Utility of new knowledge generated

Supports Decision Making



Current Status - Development in Parallel

- Planning and implementation are advancing together
 - ✓ Staffing the DSEN central coordinating office
 - ✓ Preparing grant opportunities for DSEN funding
 - ✓ Developing the operational framework

Working with DSEN partners

- Interim Network Advisory Committee
 - ✓ Provides advice, as needed, on the further development of and the first stages of implementation of the network until such time as the Executive Director and DSEN governance structure are established.

Colleen Flood, IHSPR Diane Forbes, DSEN (Chair)	CIHR
Cynthia Sunstrum, SPB Bob Liteplo, HPFB	Health Canada
Olaf Koester, MB Suzanne Taylor, BC	P/T Ministry of Health
Robyn Tamblyn Steve Morgan Muhammad Mamdani	Researchers
Judy Birdsell	Patients
Lisa Dolovich Anne Holbrook	Providers
Barb Shea	CADTH
Francine Anne Roy	CIHI
Vratislav Hadrava	Industry
John Santa	International

Future Funding Opportunities

- Working toward first launch for project
 - ✓ Drug safety and effectiveness research that will resonate with decision makers
 - ✓ Atypical of long term project funding opportunities
 - governance structure not established
 - no prioritized research agenda
 - ✓ Potential Off-cycle launch - August 2009

Consultations

- Linked centres of excellence to be established via a competitive RFA process
- Consultations to develop RFA beginning summer 2009
 - ✓ Networking
 - ✓ Pan-Canadian representation
 - ✓ Data access and sharing
 - ✓ Application requirements and process
- Research community, international expertise, existing networks
- Earliest possible launch December 2009

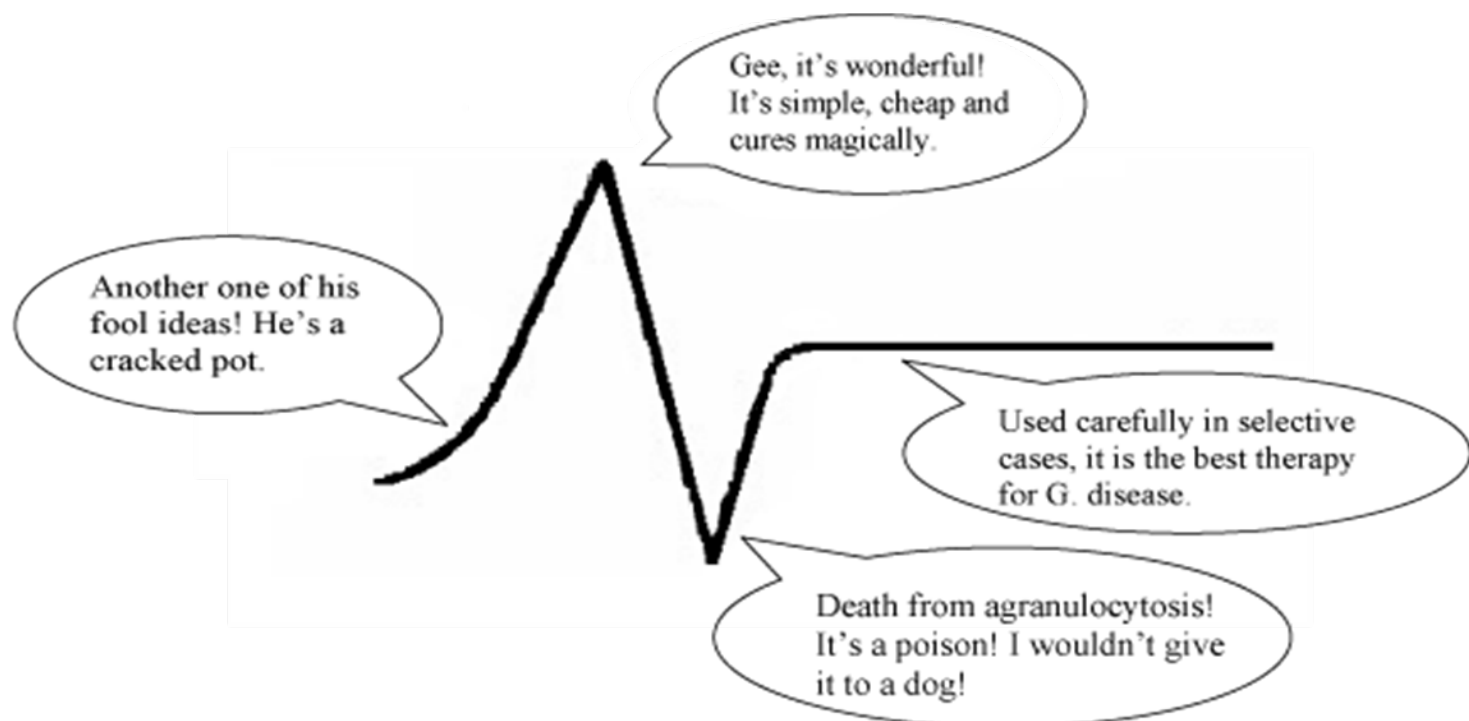


Figure 8-4 Oscillations in the development of a drug. (From Williams, R.H.: The clinical investigator and his role in teaching, administering, and the care of the patient. J.A.M.A., 156:131,1954.

Thank you:

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