

DRUG SAFETY AND EFFECTIVENESS NETWORK (DSEN) NEWSLETTER

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Message from the DSEN Executive Director, Dr. Robert Peterson:

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Visit the Drug Safety and Effectiveness Network website to learn more:

www.cihr-irsc.gc.ca/e/40269.html

CIHR Funding News:

www.cihr-irsc.gc.ca/e/26626.html

CIHR Home Page:

www.cihr-irsc.gc.ca/e/193.html

Contact Us:

dsen-riem@cihr-irsc.gc.ca

The past several months have been highly productive for DSEN with both internal and external initiatives. This places us closer to the operational level that is needed, but we recognize that there remains a great deal of work leading up to that moment.



First, the accomplishments of the dedicated staff in the DSEN Coordinating Office:

A series of webinars were held in June 2010 to present the DSEN network architecture and the anticipated collaborating centre's funding announcements. More than 100 investigators and interested parties joined the two sessions and all were presented with material and questions and answers were subsequently posted on the DSEN website for general information. CIHR/DSEN finalized the first Collaborating Centre on Observational Studies (CCOS) Funding Opportunity announcement with posting on the CIHR's ResearchNet on September 22, 2010. This was an announcement of a single "directed" grant and was followed by DSEN funding support of an investigators' organizational meeting in Montreal on September 1, 2010. The deadline for the grant application was November 1, 2010 after which it is undergoing a review by a panel of international experts.

The DSEN Steering Committee was appointed following a nationwide nomination process and met for the first time on September 17, 2010. The agenda and minutes from the meeting will be made available on the DSEN website.

Recognizing the need for DSEN to support a multitude of research methodology platforms for the Network to be responsive to queries from decision makers, DSEN enlisted the collaboration of Health Canada, CADTH, Rx&D, and BIOTECanada Canada to participate in planning a Forum where a series of methods that are amenable to "real world" drug safety and effectiveness studies could be presented and discussed.

The Forum followed a strategy to have three parallel tracks with co-leaders, having a mix from both industry and academics, discuss and debate the strengths, limitations, methodology research needs, and to provide advice to DSEN based upon these discussions. We received a wealth of constructive advice that will be used in planning future funding announcements. Further details of this Forum, held on November 19, 2010 with more than 75 participants from academics, the pharmaceutical and biotech industries, government and CADTH is discussed later in this newsletter.

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News to Share?

We welcome your news, events and announcements related to research on post-market "real world" drugs in Canada. If you are organizing an event, or have interesting research findings or developments to share, we may feature it in this newsletter. Please send your news to:

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Message from the DSEN Executive Director: Dr. Robert Peterson: (continued)

Meetings with Health Canada have helped to refine the process by which queries will be vetted and transmitted through to the Network. The DSEN Coordinating Office is in the process of developing procedures for the management of these queries and those received from other interested parties.

These efforts, collaborations and accomplishments have helped position DSEN on a path to be able to respond to queries for the generation of evidence on "real world" drug safety and effectiveness issues that are of relevance and importance to decision makers throughout the healthcare system.



Robert Peterson MD, PhD, MPH
Executive Director, Drug Safety and Effectiveness Network

DSEN FUNDING OPPORTUNITIES:

DSEN Launches the Funding Opportunity for the Creation of the *Collaborating Centre for Observational Studies* (September 2010)

During a series of webinars in June 2010, the DSEN Coordinating Office invited the scientific community to form a single Canada-wide team to apply to a directed grant supporting the establishment of the DSEN *Collaborating Centre for Observational Studies (CCOS)*. The application deadline for this funding opportunity was on November 1, 2010 in order for the Collaborating Centre to be operational in January 2011. CIHR has allocated over \$17.5 million over five years for the CCOS.

It is expected that the CCOS will engage in a program of research creation and dissemination within the thematic area of Observational Studies for the DSEN initiative. The objectives of the CCOS are to work with the DSEN Coordinating Office and data partners to respond to specific queries identified on the prioritized research agenda as ratified by the DSEN Steering Committee.

DSEN has made significant progress towards the launching of competitive funding opportunities in February 2011 to establish two other CCs in the thematic areas of *Prospective Studies* and of *Network Meta-Analysis and Innovative Randomized Controlled Trial (RCT) Designs*. We encourage interested parties to continue to visit the DSEN website in order to stay informed on the latest programs and funding.

INAUGURAL DSEN STEERING COMMITTEE MEETING

Drug Safety and Effectiveness Network Steering Committee Meeting (September 17th, 2010)

The DSEN Coordinating Office held the inaugural meeting of its Steering Committee on September 17, 2010 at CIHR's offices in Ottawa. The DSEN SC is comprised of representatives from the federal and provincial governments and from the research, health care provider and patient communities who are able to significantly contribute to the achievement of DSEN's objectives in the overall interests of Canadians.

DID YOU KNOW?

« Overall, drugs are the fastest-growing expenditure item in health care, having increased by about 136% since 1998. Some factors that influence the growth in spending include the replacement of older, cheaper drugs with newer and more expensive drugs, as well as increased use of certain categories of drugs—notably, cardiovascular drugs.

Canadian drug-spending patterns and policies are notable in several respects. First, the publicly financed proportion of drug expenditures is comparatively low. Canada ranked 21st of 24 OECD countries in 2007. Second, drug coverage is uneven across populations. Some Canadians have relatively good public coverage—for example, seniors in some provinces but not others—while others have good private coverage through employer-based benefit plans. But many have only catastrophic drug coverage with high deductibles. Third, drug spending varies by 55% between the lowest-cost province (British Columbia) and the highest (Quebec). »

Canadian Institute for Health Information, *Health Care in Canada 2009: A Decade in Review* (Ottawa, Ont.: CIHI, 2009, p. 52.)

This Steering Committee acts in an advisory capacity providing strategic direction and will be establishing the prioritized research agenda for the DSEN taking into consideration the needs of decision makers in the health system.

During this first meeting, an overview of DSEN, its objectives and approaches to integrated Knowledge Translation were presented. An update on progress made by DSEN was also provided highlighting advances relating to the creation of the various DSEN Collaborating Centres (CCs). The DSEN SC provided strategic advice on the expectations and goals for the DSEN in terms of clarity, feasibility, timeliness, and usefulness of the knowledge to be generated through DSEN that will guide the direction of the initiative and inform evidence-based decisions. Copies of the agenda and minutes for this and subsequent DSEN SC meetings will be available on the DSEN website.

DSEN EVENTS:

Collaborative Innovation Forum: Research Methodologies in Real World Drug Safety and Comparative Effectiveness (November 19th, 2010)

DSEN organized the first key collaborative innovation forum on *Research Methodologies in Real World Drug Safety and Comparative Effectiveness* held on November 19, 2010 in Ottawa. The Forum was well attended by more than 75 participants from the Public (e.g., CIHR, Health Canada), Research, Information-Provider, Medical and Industry sectors from Canada and internationally who actively engaged in discussions regarding high quality research methodologies for the study of post-marketed drugs safety and effectiveness and to examine examples of successes, challenges, and best strategies in responding to “real world” drug safety and comparative effectiveness issues.

Opening remarks were given by [Ian Graham](#), Vice-President, Knowledge Translation and Public Outreach, CIHR followed by a presentation of the Forum’s objectives and an Overview of the Drug Safety and Effective Network by [Robert Peterson](#), DSEN Executive Director. The first portion of the morning session was dedicated to keynote presentations by [Paul C. Hébert](#), CMAJ Editor-in-Chief and [David K. Lee](#), Director, Office of Legislative and Regulatory Modernization, Health Canada.

Three parallel tracks were run simultaneously during the remainder of the morning and the early afternoon sessions along the methodological themes of:

- Track 1: *Network Meta-analysis / Systematic Reviews* led by [George Wells](#) (University of Ottawa Heart Institute) and [Heather Bennett](#) (I3 Innovus) with additional presentations by [Christopher Cameron](#) (CADTH);
- Track 2: *Innovating Randomized Controlled Trials (RCTs)* led by [Robert Noble](#) (GlaxoSmithKline) and [José Pinheiro](#) (Johnson & Johnson) with additional presentations by [Robert Li](#) (Health Canada), [Jeff Maca](#) (Novartis), and [Michael Krams](#) (Johnson & Johnson);
- Track 3: *Observational Studies* led by [David Henry](#) (ICES) and [Jesse Berlin](#) (Johnson & Johnson) with additional presentations by [Jeff Brown](#) (Harvard Medical School) and [Muhammad Mamdani](#) (St. Michael’s Hospital).

Following the afternoon break, participants reconvened in a final plenary session where Rapporteurs from each track provided a Track Report with highlights of the discussions, including recommendations for DSEN strategic investments.

The DSEN Coordinating Office is preparing a Forum Report that will be posted to our website, together with copies of the presentations.

Appreciation is extended to the Program Planning Committee, Chairs, Rapporteurs, Speakers and Facilitators for a successful event in support of increasing evidence on drug safety and comparative effectiveness in a “real world” context.

OTHER NEWS:

DSEN Coordinating Office Participates in the 9th Annual *Health Canada Science Forum* (November 1-2, 2010)

On November 1-2, 2010 Health Canada hosted its 9th annual Science Forum. The overall theme of the Forum was *Science in the Service of Health* and was inspired by the 2007 Food and Consumer Safety Action Plan and its three pillars of Active Prevention, Targeted Oversight and Rapid Response.

DSEN participated in this event with a presentation by Gary Condran, Associate Director, Strategic Operations on an overview of the DSEN initiative. The DSEN Coordinating Office was also provided with a booth and answered numerous DSEN-related questions from the Forum participants.



Pictured (left to right): Joane Delage, Siham Yasari, Christian Brochu, and Gary Condran.

COMING UP:

Key events and activities planned for Winter 2011:

- Science Advisory Committee meeting
- 2nd DSEN Steering Committee meeting
- Launch of the Funding Opportunities for additional DSEN Collaborating Centres

