Canadian Drug Policy Development Coalition and the National Pharmaceuticals Strategy

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Drug Safety & Effectiveness

- Pre-market(ing)
  - Trials focus on safety, efficacy, and intermediate outcomes
  - Limited populations
  - Limited comparators
  - Short time frames
- Post-market(ing)
  - Haphazard ADR (under-) reporting
  - 'Off-label' use – different indications, different populations, different doses, different durations

The farther backward you can look, the farther forward you are likely to see.

Winston Churchill

Previous Attempts

Health & Welfare Canada. 1991. A Blueprint for Developing a National Post-marketing Pharmaceutical Surveillance Program (JN Hlynka, Chair**). Ottawa, Bureau of Pharmaceutical Surveillance**

- A blueprint for the development of a PPSP including, list of participants/stakeholders that should be involved.
- Program components
  1. Monitoring ADRs (signals from an ADR reporting system)
  2. Drug use review (appropriate use)
  3. Drug post-approval evaluation (for safety & effectiveness)

  Research centres (public & private) to support these components

Wide Support for Post-Marketing Surveillance

…MacLeod says that instead of mandatory ADR reporting, **Canada needs targeted investigations of certain drug classes so that it can conduct prospective epidemiologic studies, and it needs to monitor all new drugs**.

***CMAJ* has endorsed the creation of a new regulatory agency that would work at arm's length from Health Canada officials** (*CMAJ* 2001; 165[10]:1293).

National Pharmaceuticals Strategy

- **Catastrophic coverage**
- **Common national drug formulary**
- **Accelerated access to breakthrough drugs for unmet health needs**
- **Accelerate access to non-patented drugs**
- **Purchasing strategies**
- Strengthen evaluation of real-world drug safety and effectiveness
- **Prescribing behaviour**
- **Develop e-prescribing and electronic health records**
- **Enhance analysis of cost-drivers, cost-effectiveness, best practices for drug plan policies**

Collapsed to:

-Access to Expensive Drugs Coverage

-Pricing & Purchasing

-Evaluation of 'real world' drug safety and effectiveness

Working Together:

- Canadian Drug Policy Development Coalition
  - Researchers and research centres across the country
  - Decision-makers representing orgs with funding, or drug approval, responsibilities
  - Consumer groups
  - Reps of interested agencies such as Cancer Care Ontario
- In collaboration with
  - NPS, HC, CIHR, CPSI, CADTH, CIHI, SC, CHSRF, CHI

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Dolovich, Lisa (exec) Chair of Research Group, Canadian Pharmacists' Association.
Gray, Jean Professor Emeritus, Medicine, and Pharmacology, Dalhousie University.
Hassen, Phil, CEO Canadian Patient Safety Institute
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Hux, Jan Senior Scientist, Institute for Clinical Evaluative Sciences (ICES)
Laupacis, Andreas (exec), Director, Li Ka Shing Knowledge Institute, U of T
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Maclure, Malcolm, School of Health Information Science, University of Victoria.
Metge, Colleen, Associate Professor Faculty of Pharmacy. University of Manitoba
Morgan, Steve, Health economist, University of British Columbia.
MacGibbon, Brenda (exec), Patient representative. McGill Centre Board of Directors
Paterson, Mike, Institute for Clinical Evaluative Sciences.
Peterson, Bob, Pediatric Clinical Pharmacologist UBC; former Director General TPD.
Roos, Noralou (exec) Founding Director, Manitoba Centre for Health Policy
Sketris, Ingrid (exec), Professor, College of Pharmacy, Dalhousie University
Sullivan, Terrence (exec), President and CEO of Cancer Care Ontario
Tamblyn, Robyn (exec), Professor, Faculty of Medicine, McGill University
Wright, Jim, Managing Director of the Therapeutics Initiative, UBC
Wiktorowicz, Mary, School of Health Policy and Management, York University

Canadian Pharmacosurveillance Initiative

- Proposed: A research network to produce new evidence on the *"safety and effectiveness"* of prescription drugs as they are used in the real world

Proposed Approach

- Three key elements
  - Systematized and comprehensive adverse drug reaction reporting
  - Longitudinal 'observational' monitoring using enhanced administrative and other databases
  - 'Real World' RCT involving head-to-head comparisons of competing alternatives

Proposed approach – benefits

- To inform decisions about:
  - **Federal**: product "labels" re: safety and continued market approval
  - **Provincial/Territorial**: drug coverage, for whom and under what conditions;
  - **Industry**: which populations have the most favourable benefit/risk profiles
  - **Providers**: prescribing and dispensing decisions
  - **Patients**: what are drug benefits and harms

Different than Current Research Programs

- Focused on post market safety & effectiveness of medicines
- Includes capacity building
- Not about curiosity driven research. Rather a *formal* program to coordinate & direct *prioritized* research to fill pressing *gaps* in evidence
- Resources & capacity are available for rapid response
- Focused *collaboration* among research centres
  - Strength of evidence will be greater with participation of multiple jurisdictions & / or centres (more data / different populations)
  - Able to assess different provincial policies related to drugs: what works & what does not

Partnership Approach to Business Plan Development

- National Pharmaceuticals Strategy (NPS)
- Canadian Institutes of Health Research (CIHR)
- Canadian Drug Policy Development Coalition (CDPDC)
- *Overseen by a Project Authority Advisory Committee (PAAC)*

Business Plan Advisory Committee (PAAC)

- Andreas Laupacis - *Coalition - researcher*
- Noralou Roos - CIHR - *researcher*
- Robyn Tamblyn - *Coalition - researcher*
- Paul Armstrong - *practitioner / physician*
- Stephanie Young - *practitioner / pharmacist*
- Denis Morrice - *patient*
- Susan Paetkau - *provincial S&E co-lead*
- David Clapin - *federal S&E co-lead*
- Bill Leslie - *federal S&E co-lead*
- Donna Cona - *Contract team: Gary Fox + Nick Otten*

Proposed Model – organization

Three key elements:

- **Oversight, direction, and accountability**
  - policy advisory board or committee channeling research efforts to areas of priority
  - scientific leadership
- **Network of Research Centres**
  - using observational data, registries, and clinical trials
  - respond to specific requests
  - operate at arms length from industry and government
  - research results made public
- **Comprehensive knowledge exchange/translation strategy**

Components of the Program

Stakeholders

- Health Canada
- PHAC
- CADTH
- F/P/T Drug Plans
- Patients
- Researchers
- Health Practitioners
- Industry
- International Partners
- Etc.

- Project requestors
- Users of results

Priority Setting

Oversight Committee

- Establish Priority Research Areas
- Project ranking & selection for funding
- Vets criteria for network membership

Network Management

Scientific Director

- Review research project suggestions, rank & make recommendations
- Review Research Results
- Maintain a Clinical Advisory Committee

Secretariat

- Co-ordinate Committee Meetings
- Monitor National & International research & Signal Events
- Knowledge Transfer (KT)

Network

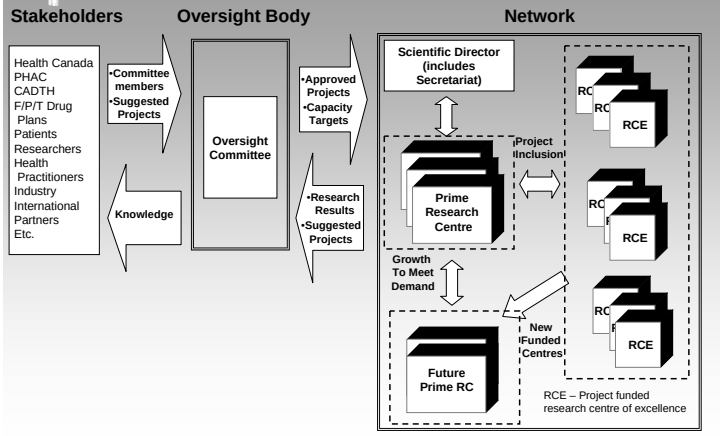
Prime Research Centre (PRC) (Funded)

- Lead research
- Capacity development
- Knowledge Transfer (Receives Infrastructure Funding)

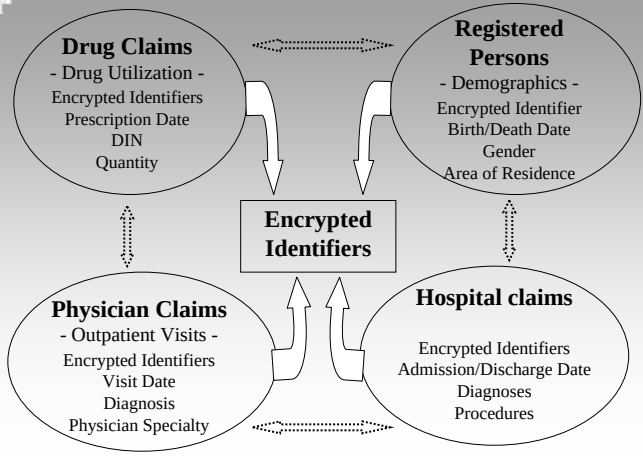
Project Funded Research Centres

- Participate in research
- May become PFC

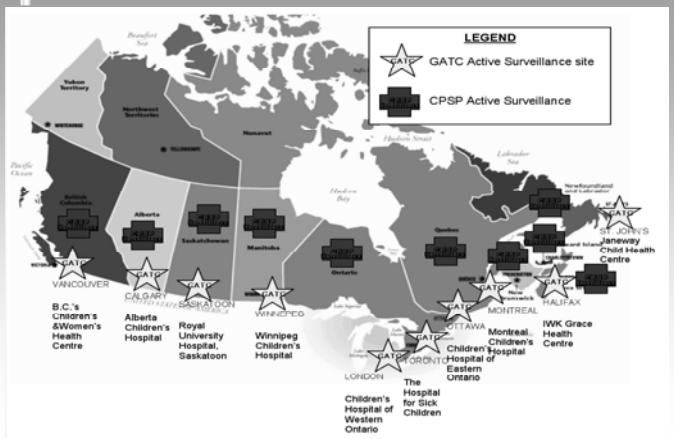
Operational Model



Canada's Data Capabilities



Canada-wide surveillance networks for ADRs in children



Canada's Data Capabilities Continued: (cont'd)

Hospital / Electronic Health Records

- **Potential for understanding why patients stop drug or change**
- **Variable progress geographically**
- **Spotty in terms of completeness of data provision**
- **Linkability subject to privacy concerns**

Canada's Data Capabilities Continued:

Patient Registries

- e.g. disease- , or drug(s)-based
- limited scope (patients; data elements)

Real world Randomized Clinical Trials

High Priority Proposed Network Research Projects

1- Second Generation Antipsychotics
2- Biologic Response Modifiers
3- Cholinesterase Inhibitors
4- Thiazolidinediones (TZD)
5- Cancer drugs
6- Drugs for chronic disease management

Assessing International Pharmacosurveillance Strategies: Lessons for Canada

- US: FDA, CERTS
- EU: EMEA
- ICH (International Conference on Harmonization)
- UK: Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Clinical Excellence (NICE), The National Patient Safety Agency (NPSA), Drug Safety Research Unit (DSRU), UK Clinical Research Collaboration; Medicines Monitoring Unit (MEMO) and World Health Organization (WHO)
- Australia: Therapeutic Goods Administration (TGA), a division within the Australian Government Department of Health and Ageing responsible for the assessment, monitoring, registration, and approval of all therapeutic products, NPS
- New Zealand: Medsafe
- France
- Norway
- Canada

Ethical Considerations for Post-marketing Evaluations of Pharmaceuticals

- Criteria for determining what research needs doing
- How the research will be conducted
- Where the burden of research will fall and fairness of the process
- Transparency of the goals and process

- The rationale for the proposed network *is itself profoundly ethical:* when there is scientific uncertainty, there is a strong public interest justification to more fully understand the harm and benefit of marketed drugs.

Second potential area for Drug Research Network: Pre-market assessment

- Re-think the drug development process
  - Raise the bar on drug safety considerations
  - Allow earlier access to new medicines
  - Create an involved, informed consumer
  - Create an environment for preferred R&D investment
  - Acquire enhanced safety data prior to general product approval

RG Peterson

Provisional Licensing

- Start cautiously, select suitable candidates
- Move selected products which meet public health objectives rapidly into clinical use after completion of strong Phase 2 clinical trials
  - Serious illness with unmet needs
  - Gov't's participate in decisions, share risks and costs in further drug evaluation
  - Access to new medicines improves
  - Better data obtained in public domain
  - Greater transparency

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What's in it for Canada?

- Innovation not just in drug development, but in drug regulation
- Healthcare System participates in drug development
  - Choices based upon need, not profit margin
  - Supports research and innovation in Canada
- Better access to better data
  - Structured entry of new drugs in Canada
  - Public funding leads to public data
  - Creates unique "post-approval" environment
- Decisions for NOC based upon experience in Canadian health delivery system

RG Peterson

What's in it for Canadian Industry?

- Industry wants better drug evaluation
  - Limited presently based by cost, working intellectual property, marketing decisions
- New scheme shares cost/risk of drug development
  - Generates data for use in other jurisdictions
  - Attracts global R&D to Canada

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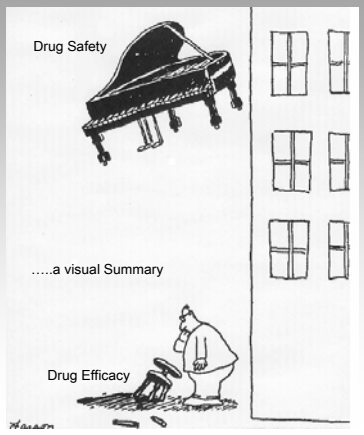
There are compelling reasons to re-focus our attention……



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