Definition of Patient-Oriented Research

Figure. “Blue Highways” on the NIH Roadmap

BENCH
Basic Science Research
  - Preclinical Studies
  - Animal Research

TRANSATION TO HUMANS
T1
  - Case Series
  - Phase 1 and 2 Clinical Trials

BEDSIDE
Human Clinical Research
  - Controlled Observational Studies
  - Phase 3 Clinical Trials

T2
  - Guideline Development
  - Meta-analyses
  - Systematic Reviews
  - Phase 3 and 4 Clinical Trials
  - Observational Studies
  - Survey Research

PRACTICE
Clinical Practice
  - Delivery of Recommended Care to the Right Patient at the Right Time
  - Identification of New Clinical Questions and Gaps in Care

T3
  - Dissemination Research
  - Implementation Research

TRANSLATION TO PRACTICE

Special features of the Canadian Strategy for Patient Oriented Research (SPOR)

- Essentially all programs require partnerships, and thus buy-in from the community. This is to help assure the alignment of all stakeholders, optimize coherence, and maximize impact.

- It is comprehensive and proposes to address the operational obstacles to clinical research (contracts, ethics, new methodologies, cost structures, etc...), human resources, funding for multi-site studies, infrastructure (SUPPORT Units, and Networks), etc.

- Proposes that a major focus of our clinical research efforts go towards improving the efficacy of our health system thus improving quality of care and reducing costs.
Partners:

- Patients and their advocates;
- Health charities (e.g. Heart & Stroke);
- Academic health organizations (e.g. AHSN);
- Universities and research institutes;
- Federal, provincial (NAPHRO), and territorial governments (includes public health, ministries of health and ministries of industry and development);
- Life sciences industries (e.g. Rx&D member companies);
- Other research funders such as private foundations or foreign entities which fund patient-oriented research;
- CIHR
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Four major components of the Strategy for Patient-Oriented Research

1. Improve the research environment and infrastructure.

2. Set up mechanisms to better train and mentor health professionals and non-clinicians in health research.

3. Strengthen organizational, regulatory and financial support for multi-site studies.

**Establish national infrastructure: Multi-disciplinary research networks**

**Mandate:** Research Networks bring together a unified group to build a critical mass of technical and scientific expertise on a national scale to provide research leadership in an effort to improve the delivery of care through the development or validation of a health intervention.

**Objectives**

- Act as one coordinated group to effectively direct resources in specialty areas (e.g. mental health, Community Based Primary Health Care).
- Ask central questions to direct pan-Canadian studies most relevant to Canadians.
- Generate evidence from previous work and disseminate best practices to the patient-care community.
- Mentor and support the training of emerging talent.
- Develop international partnering and leadership.
Establish local infrastructure: SUPPORT units

Research networks are underpinned by local SUPPORT units that provide the resources and personnel to conduct research day to day.

- Integrated within a local clinical/care setting.
- Provides communities with access to expertise and resources (i.e. core functions and specialized modules).
- Enhances attraction and retention of talent to communities.
- Creates linkages with health centres (from tertiary hospitals to primary care centres), and national and international health stakeholders.

SUGGESTED SUPPORT UNIT FUNCTIONS

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CORE FUNCTIONS
- Data Management
- Biostatistics and Methods Support
- Project Management
- Consultation and Education

SPECIALIZED MODULES
- Knowledge Translation
- Health Systems Research
- Biobanks, Cohorts, working with administrative databases
- Large International Trials
When combined, SUPPORT units provide the infrastructure and skills for highly specialized Research Networks to identify and tackle key clinical questions.
Four major components of the Strategy for Patient-Oriented Research

1) Improve the research environment and infrastructure.

2) Set up mechanisms to better train and mentor health professionals and non-clinicians.

3) Strengthen organizational, regulatory and financial support for multi-site studies.

4) Support best practices in health care.
Strengthen organizational, regulatory and financial support for clinical trials (1)

- **Streamline ethics review** for multicentre trials by developing and/or taking advantage of common Ethics Review Boards with reciprocal arrangements: multiple challenges that requires national leadership in order to assure coherence and reciprocity.

- Develop a **national template for contracts** and inter-institutional agreements, (personnel credentialing, such as GCP, ethics training and SOPs) ACAHO and RxD.

- Develop national standards for the **costing of procedures and services** associated with Multi-site studies, and a common repository for certifications etc...
• Simplify and focus clinical research reporting (adverse events), and develop more flexible and adaptive protocols.

• Develop **national standards of operation** for all clinical research activities.

• Common **national administrative data base**, and common electronic medical records (**EMR**).
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3) Strengthen organizational, regulatory and financial support for multi-site studies.

4) Support best practices in health care.
- Develop a National taskforce that would work under a steering committee that will bring together all of the stakeholders. This taskforce and steering committee would be responsible for identifying an action plan, and to execute it. The exact makeup and organization of this task force and steering committee is yours to determine, but perhaps this should be co-chaired by the director of the NIH, and a leader of the academic community.
SPOR Governance

CIHR Governing Council

Executive Management Committee

Scientific Council

SPOR Office

Canada’s Strategy for Patient-Oriented Research National Steering Committee

CIHR SPOR Working Group
Jean Rouleau, Chair and Strategic Lead
Joy Johnson
Bob Peterson, DSEN
Phil Sherman
Robyn Tamblyn

External Advisory Groups: Human capital, Training; Ethics; RCT’s; Data strategy; Rx&D, Commercialization; Metrics
Low Hanging Fruit

- **Regulatory:**
  - Strive to resolve some of your regulatory problems.

- **Training and education:**
  - Involve the millineum generation in determining the best solutions for developing pro-research health professionnals.
  - Strive to modify your health educational process to one that is pro-research.
  - Take advantage of AHSCs evolving to ASCNs to encourage research in the community.
  - Strive to take advantage of charities and patient advocacy groups to better engage patients as partners in research.
Low Hanging Fruit

- Technological advantages: conceptualizing new business models around new technologies: (strive to develop standards and integrate research and clinical eMR systems)

  - Develop unique or adaptive research products, ex eHR/personalized medicine, networks of high content centers, etc...

  - Lead and take advantage of newer research methodologies, such as adaptive protocols, bayesian protocols, cluster trials: research on research, etc... (involve regulatory agencies)

  - Take advantage of eHR to evaluate best practices and conduct research in health systems innovation.

  - Take advantage of eHR to perform research in innovative ways to perform patient-oriented KT.
Low Hanging Fruit

- International Collaboration:
  - The global environment is ripe for more partnering to resolve common issues whether they be the more traditional multisite clinical trials or innovative approaches to health care delivery, whether on a micro (collaborative practices), on a meso (innovations within a health care system to better take care of patients with chronic diseases), or on a macro scale.
Le mot de la fin

Les sceptiques seront confondus