I Do Clinical Research, What Can SPOR SUPPORT Do For Me?

Finlay McAlister, Ross Tsuyuki, and Dean Eurich on behalf of the AB SPOR Support Unit
Historical Perspective

- SPOR concept document released in 2011
- Visits started in 2010 (Paul Hebert à Jean Rouleau à multiple CIHR Visits {President, Institute Directors, etc}).
- SPOR Leadership Changes (Paul Hebert à Jean Rouleau à Penny Moody-Corbett à Jane Aubin).
- SPOR National Steering Committee
CIHR SPOR Concepts

• SPOR: Provincial SUPPORT Units and National Networks

• MAX of One SPOR SUPPORT Unit per province (some amalgamation – *Atlantic Canada SPOR*)

• Budget limits:
  – $2-6 million/year X 5 years with 1:1 matching;
  – Renewal: unclear (sustainability).

• Must link to other provincial initiatives
• Contents could be customized:
  – Directed by CIHR, SPOR Steering Committee, and provincial feedback.
The Focus for SPOR

Figure. “Blue Highways” on the NIH Roadmap

**BENCH**
- Basic Science Research
  - Preclinical Studies
  - Animal Research

**BEDSIDE**
- Human Clinical Research
  - Case Series
  - Phase 1 and 2 Clinical Trials
  - Controlled Observational Studies
  - Phase 3 Clinical Trials

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

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

**Translation to Patients**

**Translation to Practice**

What kind of Research was SPOR designed to support?

CIHR Pillar III (II, IV)
Our National Priorities for Research

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication & Dissemination Research
- Addressing Disparities
- Accelerating PCOR and Methodological Research
2015 CIHR SPOR Guiding Principles

• Patient Engagement
• Alberta/ NWT
• Align with provincial health system priorities and performance metrics.
• Impact (ROI, Health and Health System improvement)
• Long term Sustainability for the Unit.
• Supporting Academics, SCNs, National SPOR Networks
SPOR Nationally

SPOR Provincial Support Units

Community-Based Primary Healthcare Research Network
Mental Health Research Network

Chronic Disease Management Network in LOI stage
AB SPOR Support Unit = A Collaboration

- AIHS
- University of Alberta
- University of Calgary
- Patients
- University of Lethbridge
- Alberta Health Services
- Alberta Health Services
Timeline

2013
- CIHR call for proposals

2014
- AB’s SPOR Support Unit approved Nov 2013
- Recruit SPOR CEO = SPOR Executive Director

Sep 1, 2014
- Recruit Platform leads from Academia

Apr 28, 2015
- Release of Start-up Funds to Platform Leads
- AB SPOR Portal
Alberta’s Leadership

- Platform leads
- Steering Committee
Alberta SPOR SUPPORT Unit

**Key Messages:**

- **Not** operating grants – but rather enabling infrastructure – new capacities and approaches to research.
- Transformative, change focused.
- Sustainability and Impact.
- Core philosophies – the translation of knowledge into policy and practice.
Need for Intake Process

Limited resources to achieve

Impact

[Image: A graphic illustration of a planet or celestial body with aoshi light effect, perhaps symbolizing impact or a significant event.]
Process

- Request
- Case Manager
- Review
- Resource allocated

Questions
Letter of Support
Scholarship
Research Question Refinement
Project Support

Eligibility Criteria
Selection Criteria
Recommended Process Flow

1. Secretariat responds
   - possible
2. Secretariat drafts and signs
   - possible
   - Referral to other services

Location AB/NWT

If student project, evidence of supervisor Clarifies with Researcher - as needed

3. Requested Platform Support responds

4. Requested Platform Support responds

5. Requested Platform Support performs initial review

Criteria*
- Evidence of patient-centric research
- Evidence of end-user engagement
- Evidence of Resources

Reviewers:
- Steering (1-2)
- Management (1-2)
- Requested Platform (1)

Proof of Ethics
- Criteria*
- Evidence of patient-centric research
- Evidence of end-user engagement
- Evidence of Resources
- Likelihood of patient/system impact

Steering Committee Approves

*See attached

Target Timelines
- # 1-2 Review: 0.5 week
- # 3 Assess: 1.5 - 2 weeks
- # 5 Approve: 3 - 4 weeks
Alberta SPOR SUPPORT Unit

Intake
- Adequately resources
- Patient-oriented
- Feasible

Projects selected

Resources Assigned

Projects Supports

0% 50% 100%

1 2 3 4 5 6 7 8 9 10

Evaluation

Patients Benefit

System Change

Resources Reassigned

Data Platforms & Services

Methods support & development

Patient Engagement

Health systems research, Implementation research & Knowledge Translation

Pragmatic clinical trials

Consultation & research services

Career development in methods & health services research

Adequately resources
Patient-oriented
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Criteria

• Eligibility Criteria
  – AB/NWT PI, AB setting
  – Proof of ethics

• Selection Criteria
  – Patient-oriented or health system-oriented outcomes
  – End-user engagement
  – Feasibility
  – Likelihood of Significant Patient/System Impact
Research to Impact Process

- Research question
- Preliminary data Gathering
- SPOR SUPPORT request
- Research
- Results produced
- Results Disseminated
- Informing Decision Making

Alberta SPOR SUPPORT Unit
Alberta SPOR SUPPORT Unit Platforms

- Data Platforms (Dr. F. McAlister)
- Methods Development (Dr. H. Quan)
- Knowledge Translation (Dr. S. Majumdar, Dr. L. Hartling)
- Pragmatic Clinical Trials (Dr. M. Hill)
- Career Development/Training (Dr. D. Eurich, Dr. Marilynne Hebert)
- Consultation and Research Services (Dr. R. Tsuyuki)
- Patient Engagement (Dr. V. Vandall-Walker)
The AB Data Platform

• Support Services for Research Involving secondary analysis of existing Large Datasets *(especially, but not limited to, administrative data)*:
  – **Research Design**: methods, sample size, biostatistical plan, support letters for grants, assistance with Researcher Agreements
  – **Data Management**: data extraction, linkage, and cleaning
  – **Biostatistics**: consultations and/or analyses (if necessary, and in conjunction with Methods Support platform)
  – **Training** (in conjunction with Training and Methods Support platforms): emphasis on practicums, theses.
But Not

• Incubation/development of research questions and choice of study methods (primary vs. secondary data sources, RCT vs. cohort, etc)

• Support for primary data collection studies

• Consultation and Research Services Platform OR the Clinical Trials Platform
ED Visits (NACRS, EDIS, REDIS)

Outpatient Clinic

AHSDRR

Pharmaceutical Claims

Lab

Vital Statistics and Registry

SES (Census Data)

DAD

PHYSICIAN CLAIMS

EMS*

ED Visits (NACRS, EDIS, REDIS)

OR: Insite.albertahealthservices.ca/4773.asp
8 pages of info on datasets in the AHSDRR

- **Inpatient - Discharge Abstract Database (DAD)**
  - Available from: April 1, 2002 to February 28, 2015
  - **Data refresh** occurrence: Monthly

- **Laboratory (Lab R1 and R1.1)**
  - **Data refresh** occurrence: Daily (with up to 8 days latency)

- **Provincial Registry**
  - Available from: Fiscal Year End 1994 - 2013
  - **Data refresh** occurrence: Annually
The AHSDRR and where does AB SPOR Support Data Platform fit?

ALBERTA HEALTH SERVICES
- Mental Health & Addictions
- Cancer
- Seniors’ Health
- Primary Care
- Public Health
- Cardiology
- Emergency Care
- Critical Care
- Surgery
- Bone & Joint
- Zones
- Respiratory
- Research

AHSDRR
- Advanced Analytics
- Methods and Models
- Information Products/Studies

AHS RPI (specifically the Research Facilitation Group)

AB SPOR SUPPORT Data Platform

ALBERTA HEALTH
- Family & Population Health
- Primary Health Care
- Strategic Services
- Health Benefits and Compliance
- Health Work Force
- Senior Services & Continuing Care
- Research

EXTERNAL
- Academic Institutions
- Other Ministries
- HQCA

Strategy for Patient-Oriented Research
Putting Patients First

Alberta Innovates Health Solutions
Resources

• **Infrastructure support:**
  – DIMR: Dr. J. Bakal (biostatistician), Mr. M. Lin and B. Li (data managers/analysts)
  – Non-DIMR: Mr. E. Youngson, UofC tba (data managers/analysts)
  – Computers, stats software, CPE funds

• Pan-provincial meetings, international visitors (in collaboration with the Methods Support and Development Platform)
Activities thus far

• Research Design: 9 grants
  – ER, card, pulm, nephro, family med, surgery

• Data Management: 17 cohorts generated
  – ICU, pharmacy, CV surgery, community health, ER, geriatrics, surgery, card, GIM, bone and joint

• Statistical Analysis: 11 cohorts analyzed
  – GIM, card, ICU, bone and joint, community health, surgery
  – one collaborative project with Ontario ICES data (HOMR score)
Career Development in Methods & Health Services Research Platform

Dean T Eurich, PhD
Associate Professor, School of Public Health,
University of Alberta
Who We Are

Marilynne Hebert, PhD
U of C, Community Health Sciences

Dean Eurich, PhD
U of A, School of Public Health

Melanie Rosario
Platform Manager

University of Lethbridge – Coordinator.
AIM

• To help promote and build health research capacity in Alberta.
  – Undergraduates; Graduate; Health Researchers, Professionals/Practitioners
• To work with the other platforms to build capacity in their specific areas

Our Mandate

• Full spectrum – All POR researchers and areas
• Shared strategy/responsibility – including training costs and compensation;
• Longitudinal vision and relationship building – including pipelines, early and mid career support, mentorship;
• Integrated best practice training – including collaboration, multi-disciplinarity, alternate career paths.
Our Vision

<table>
<thead>
<tr>
<th>Academic Stream – Formal Learning Opportunities</th>
<th>Academic/Applied Stream– Informal Learning Opportunities</th>
<th>Applied Stream (Health Services/Patient Oriented Research Institute) – Formal Learning Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academically accredited degree</td>
<td>Not for credit</td>
<td>Employer credit; may contribute toward degree</td>
</tr>
<tr>
<td>-designated scholarships for incoming students who agree to complete a POR project preferably in conjunction with an SCN</td>
<td>Can respond quickly to emerging needs for skills and knowledge</td>
<td>(e.g. learners commit to completing the program);</td>
</tr>
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<td></td>
<td>e.g. New Investigator Forums; Health Research Methods On-line Course; Methods Journal Club; Method Workshops; Patient Workshops/ Engagement (e.g. PACER)</td>
<td>-Are supported by their employers;</td>
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<td></td>
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<td>-Receive recognition for completing the program and implementing change</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Modeled after existing programs</td>
</tr>
</tbody>
</table>

Laddering process (certificate-diploma-Master’s degree) to formally recognize advancing leadership preparation and demonstrated leadership in research, including knowledge translation and patient engagement activities.

Figure 1 – Capacity Building Framework (Draft)
Top Initiatives

1. Environmental Scan and Building Provincial Wide Network (Community of Practice)

- Key stakeholder groups (e.g. the universities, professional groups) as well as identified user groups who participate in the research and training process (e.g. researchers, research assistants, project managers, students and patients).
- Multiple opportunities for consultation
  - Key Banff June 11-13th!!
- The purpose of the meetings is to identify:
  - What we currently have;
  - What we need;
  - Can we build a framework to help move forward to fill the gaps;
  - What success and sustainability might look like.
Top Initiatives

2. MSc/PhD Recruitment Scholarships
   - Aimed at outstanding trainees conducting research in priority areas at an Alberta university.
   - Scholarships will:
     • foster the development in research methods and health services research to build provincial capacity in patient-oriented research;
     • Be targeted in thematic areas in alliance with the priorities of the SPOR Platforms and larger community (SCN’s; Universities, Private and Public Sectors).

• Training and Development Partnerships
   - building partnerships with key stakeholders in the province (e.g., universities, government, private enterprises) and existing funding organizations to expand the number of SPOR training and development Scholarships within the province.
Top 3 Services

3. Identify and catalogue all currently available resources in Alberta
   – Yes, a massive undertaking!
• Guide community at practice to available resources;
• Identify gaps and facilitate programs to address those gaps (or gently nudge existing programs!)
Consultation and Research Support Platform

Ross T. Tsuyuki, PharmD, MSc
Professor, Department of Medicine,
University of Alberta
Consultation and Research Services

• Purpose: to support the design, conduct and analysis of patient-oriented clinical and outcomes/health services research

• Mostly primary data collection (trials, registries, etc)

• Infrastructure:
  – EPICORE Centre, Platform lead Dr. R. Tsuyuki
  – CRU
  – WCHRI
  – others?
Consultation and Research Services

• Consultation on:
  – Study design
  – Study implementation
  – Sample size
  – Statistical analysis plans
Consultation and Research Services

• Research Services:
  – Case report form design
  – Database design and maintenance
  – Training for data collection
  – Randomization
  – Study coordination/management
  – Data quality assurance procedures
  – Statistical analyses
Other Platforms

• Methods Development (Dr. H. Quan)

• Knowledge Translation (Dr. S. Majumdar, Dr. L. Hartling)

• Pragmatic Clinical Trials (Dr. M. Hill)

• Patient Engagement (Dr. V. Vandall-Walker)
Key Messages: Alberta SPOR SUPPORT Unit

• A provincial initiative
• Not a funding body, but can facilitate
• Access to expertise and resources
• A “net gain” for clinical/outcomes/health services research
Questions?

“I think you should be more explicit here in step two.”

from *What’s so Funny about Science?* by Sidney Harris (1977)