

# ONTARIO PATIENT ORIENTED RESEARCH STRATEGY: Patient Reported Outcome-informed Innovation

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## BRIEFING DOCUMENT

**SUMMARY:** The following represents an initiative that has linked and implemented all of the tools, organizations, research strategies, and participatory research Knowledge User (KU)-End User (EU) Communities of Practice (CoP) to address needs around Self Management (SM) for Persons with Chronic Conditions (PCC) through implementation of Patient Reported Outcomes (PRO) for Comparative Effectiveness Research (CER). What is proposed leverages existing resources and combines them in a manner that is unprecedented.

**RATIONALE:** In support of Ontario's planning directions towards a shared vision for its Strategy for Patient Oriented Research (SPOR) Support for People and Patient-Oriented Research and Trials (SUPPORT) Unit in partnership with CIHR, the following brief directs itself to a generic approach to developing PRO for clinical decision support, and CER. The approach is informed by;

- a recent synthesis of existing literature (Ahmed et al, 2012),
- KU and EU identification of need for CER and PRO to inform clinical decision making and optimal use of resources,
- a proposed generic pilot demonstration within a national KU-EU participatory research learning and innovation Community of Practice (CoP) to address that need, based on learnings from an existing national exemplar (see Annexe 1), and
- the emergence of the nascent Canada PRO Network (Ahmed) that can be informed by SUPPORT.

The context will be Ontario's focus on implementation for their SPOR SUPPORT funding partnership with CIHR as per CIHR (2012) directions (sic); 'CIHR and jurisdictions will work together to develop a shared vision for their SPOR SUPPORT Units'.

The broader context for Ontario's directions is care standardization as the basis for monitoring, evaluation, and optimization of 1. patient outcomes, 2. quality improvement of provider/organization performance and 3. resource utilization, captured and managed in informatics platforms. This context is shaped by the following environmental scan;

1. Ontario's **Patient-Based Funding** directions;
2. Ontario's MOH&LTC Health System Research Funding (HSRF) Strategy;
3. Canada's CIHR Strategy for Patient-Oriented Research (SPOR);
4. Ontario's SPOR priority focus on **Implementation Science**;

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5. Strategy of Canada's Council of the Federation **Health Care Innovation Working Group** for national care standardization;
6. Health Council of Canada '**Which way to Quality?**' directions ([www.healthcouncilcanada.ca](http://www.healthcouncilcanada.ca)).

**Ultimate Deliverable:** Findings would be summarized in a PCC Self-Management Toolkit outlining the interventional components and existing resources within all levels of care relevant to the PCC of immediate interest to the KU and EU CoP. This innovation would also describe the methods and tools recommended for use in assessing PCC self-management interventions of immediate interest. The Center for Medical Technology Policy ([www.cmtpn.org](http://www.cmtpn.org)) has published a series of Effectiveness Guidance Documents (EGD) for incorporating PRO into CER; these EGD's represent an appropriate starting point for PCC Self-Management Toolkit development.

## **Anticipated Outcomes:**

1. A primary strength of this approach is that KU's and EU's are also the key developers, implementers, and conductors of self-management programming for PCC. KUs will be actively implementing secondary complication prevention and management education best practices in rehabilitation. In the context of the Levels of Management continuum, recognizing the need to extend this practice through self-management interventions (Supported Self-Management) for effective community reintegration of PCC will have great relevance for KUs and anticipated outcomes of this approach.
2. Another strength of the approach is to gain understanding of the importance of EU stakeholder engagement through PRO. As with any intervention, ongoing evaluation is a necessary requisite to sustainability through continuous quality improvement (CQI). Evaluation through engagement of EU through PRO provides an avenue for communication whereby the EU also act as knowledge producers. PRO also offer EU a method of purposely and clearly articulating, to themselves, the impact of the interventional components within their individual context.
3. A third strength of this approach is its immediate continued influence and extent of translation and mobilization. The results of this approach inform the self-management knowledge gap, 'in real time', identified by best practice implementation (BPI) activities. Moreover, identified effective self-management strategies can continue to be utilized by KU and EU in upcoming BPI for management of other secondary complications.
4. Depending on the size of the KU-EU CoP, broad cross-regional/cross-jurisdictional standardized uptake becomes feasible, and effectiveness can be captured through *a priori* evaluation to inform research agendas and funding strategies through CQI.
5. Finally, the approach has policy implications given its pertinence to funding trends highlighted in the environmental scan that are shifting, nationally and

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globally, from health system (provider)- focused to patient-based. The findings will be directly applicable to all stakeholders that design and deliver education, skill development, and support for PCC with the intent to support effective community integration and ongoing facilitation of health and wellness.

**BACKGROUND:** Patient-reported outcomes (PRO), defined as any outcome based on data provided by patients or patient proxies, provide a standardized method of measuring the patient perspective. To achieve such standardization, the following 'logic sequence' applies;

1. To inform decision making, patients' perspectives that reflect outcomes important to them and optimize their overall outcomes is needed and can be collected rigorously using appropriate PRO.
2. To the extent that PRO determination requires a basis in evidence, the goal of comprehensive CER within randomized clinical research trials, observational studies, clinical care settings, and population studies, is to explain the differential benefits and harms of alternate methods towards these ends. CER is defined as the generation and synthesis of evidence that compares the benefits and harms of alternate methods to prevent, diagnose, treat, and monitor a clinical condition (patient outcome) or to improve the delivery of care (provider/system performance) by shaping care delivery recommendations to patient preference,
3. PRO in CER are intended to provide a patient-focused evidence-informed guide to researchers, clinicians, and policy makers to ensure that information derived from PRO is applicable and interpretable for a given CER context.
4. In turn, CER will provide information that is necessary for clinicians, patients, and families to make informed care decisions, and in so doing overcome the challenge of limited application of PROs in research and even more so in clinical practice. As such, the **patient management portfolio** will evolve, on the basis of such evidence, to standardize **integration** of case management, patient reported outcomes, and individualized patient oriented recommendations (iPOR).

Based on this logic sequence, recommendations for selecting and incorporating PRO that can be applied to CER studies (and subsequently clinical practice, and population surveillance) have been proposed as follows (Ahmed et al);

### **Define the CER context**

1. CER goals: Frame the study question including the explicit reporting of the relevant PRO and whether it (they) is a primary or secondary outcome
2. Define and refine the patient population(s)
3. Define the intervention(s) being compared
4. Identify the mechanism for deriving CER data (randomized controlled trial, observational, clinical monitoring, PBE retrospective evaluation, population surveillance)
5. Timeline of intervention(s) and evaluation.

### **Measurement strategy for incorporating PRO in CER**

1. Identify relevant domains of PRO and CER

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2. Place domains within a conceptual framework (examples of existing biomedical and HRQL frameworks: WHO ICF, Wilson and Cleary, PRO classification systems)
3. Select the appropriate measure(s):
  - i. Consider the appropriateness of using a non-preference or preference-based measure(s)
  - ii. Consider the appropriateness of using a generic or disease-specific measure(s)
  - iii. Consider the measurement and psychometric properties
  - iv. Consider the interpretability of the scores: articulate *a priori* missing data rules or influence of missing data on results, clinical significance and minimal important difference, group vs. individual level estimates of change

As stated, such recommendations require the following *a priori* determination of patient-provider context as depicted in the Schema below;

1. For those with a lifelong chronic disorder, PRO would be expected to contribute most effectively to outcomes in the areas of Health Care Organization support for Personal Skills & Self- Management and Provider Decision performance and resource utilization.
2. PRO would be most effective in managing efficiency in risk for episodic secondary complications at 4 Levels of Management: 1. case management, 2. care management, 3. supported self-management and 4. wellness/health promotion/primary prevention. PRO for Levels 3 and 4 would be most effective for improved resource utilization cost.

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**APPROACH:** By considering;

- Patient perspective and its enhancement (including motivation, empowerment, resilience): influence on outcomes
- Provider perspective and its enhancement: influence on performance
- Level 3 Management and the patient-provider relationship translating to Knowledge Users (KU) – End Users (EU), PRO-iPOR development, ultimately embracing Level 4 Management

informed by initial consultation with KUs who have identified the following needs;

- Informing the development of approaches to facilitate self-management.
- Identifying outcome measurement tool selection, methods to best assess self-management programs, and examining PRO.
- Informing decision-making for selection of priority areas for funding or policy development.

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in the recognition that emerging changes will facilitate CER using PRO as an outcome to address the challenge of lack of information communication technology infrastructure to integrate PRO, clinical, best practice data to 'package' information in a manner that individuals and KU can use for clinical decision making;

- Electronic Personal Health Records (ePHRs)
- Registries
- Use of PRO in national monitoring initiatives
- Linking the information derived from PRO endpoints to decision making

**Objectives** of a generic participatory engaged scholarship **project and/or program description** within a Community of Practice (CoP) **with defined operational objectives** (see Annexe 1 as reflective of a national endeavour) can be advanced.

The **Overall Objective** is to identify interventional approaches targeting PCC that will facilitate self-management (EU focus) as well as inform their assessment (KU focus). A mixed methods approach incorporating both systematic synthesis review and scoping review methods are likely necessary to adequately address the research objectives for any PCC target group as follows;

1. **Specific Objective 1:** To identify interventional approaches aimed at facilitating self-management in PCC (PCC of immediate focus literature)
2. **Specific Objective 2:** To identify potential interventional approaches to facilitate self-management targeting PCC in general that might also prove effective if applied to the PCC of immediate focus (scoping review methods of the CC self-management literature) plus representative stakeholder consultation to assess relevance to the PCC of immediate focus.
3. **Specific Objective 3:** To identify the tools and methods used to assess these approaches, with a focus on examining PRO and their role in evaluation as well as in self-monitoring aspects of the intervention by combining methods of Specific Objectives 1 and 2.).

**Sub-Objectives:** Knowledge users (KUs) will continue to identify further specific sub-objectives throughout the process: Initial consultation has identified the following:

1. Each interventional component deemed to be relevant to PCC will be for evidence of effectiveness, sustainability and the context of previous application, with particular emphasis on those guided by existing theory-based constructs (e.g., health behaviour change, and coping/adaptation theories).
2. Notable gaps in the PCC-specific literature will be identified as made apparent by comparison with the general chronic disease literature.

***Respectfully submitted to the Health System Strategy Division, Ontario Ministry of Health and Long Term Care by S. Ahmed, K. Bassett-Spiers, J. Hsieh, R.J.Riopelle, D. Wolfe;  
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## ANNEXE 1

### **OPERATIONAL OBJECTIVES\* of a GENERIC COMMUNITY OF PRACTICE**

\*learnings of the national Spinal Cord Injury Knowledge Mobilization Network for participatory research in practice informing innovation



([www.sci-kmn.com](http://www.sci-kmn.com))

**OBJECTIVE 1** (relevance): **translate available evidence in chosen areas to practice**  
**(focus-knowledge ‘the thing’)**

integrated with

**OBJECTIVE 2** (delivery): **create efficient infrastructure and facilitating environments for implementation of best practices**  
**(focus-knowledge ‘the flow’)**

and with

**OBJECTIVE 3** (engaging): **practice informing policy**

represent the necessary and sufficient conditions for

**OBJECTIVE 4:** (value=effectiveness/efficiency):  
**optimize patient outcomes / services performance and resource utilization.**