

Patient-Reported (PRO) and Focused Cancer Care Outcomes: A Core Set of Validated Measures

Dr. Doris Howell, RBC Chair,
Oncology Nursing Research,
Princess Margaret Hospital &
Scientist, Psychosocial
Oncology and Palliative
Care, Ontario Cancer
Institute & Lawrence
Bloomberg Faculty of
Nursing, University of
Toronto.



Research Team Members

- Doris Howell (PI): RBC Financial Group Chair, Oncology Nursing Research, Princess Margaret Hospital
- Esther Green: Provincial Head, Nursing and Psychosocial Oncology, CCO
- Diane Doran: Lawrence S. Bloomberg Professor in Patient Safety, University of Toronto
- Jonathan Sussman: Associate Professor, Division of Radiation Oncology, McMaster University
- Margaret Fitch: Director, Psychosocial & Behavioral Research Unit, Odette Cancer Centre
- Debra Bakker: Professor of Nursing, Laurentian University
- Tala Chulak, MSc: Study Coordinator
- Josie Chundamala: MA, Clinical Research Manager
- Survivor National Peer Support Representatives
- PhD students: Samantha Mayo, Shan Mohamed, Charlotte Lee

Introduction

- Growing consensus that patient-reported outcomes (PRO) conveys important information for assessing burden of cancer and effectiveness of clinical care.
 - ✓ Detecting unresolved levels of physical, emotional, and social distress or unmet needs, other adverse effects.
 - ✓ Guiding selection of or changes in the therapeutic plan and team communication.
 - ✓ Empower the patient to be actively involved in treatment decision-making and collaboration.
 - ✓ Monitoring quality of clinical care and stimulating improvement.
 - ✓ Can't improve what you don't measure

QUALITY GRAND ROUNDS

Series Editors: Robert M. Wachter, MD; Kaveh G. Shojania, MD;
Sanjay Saint, MD, MPH; Amy J. Markowitz, JD; and Mark Smith, MD, MBA

ACADEMIA AND CLINIC

A Hospitalization from Hell: A Patient's Perspective on Quality

Paul D. Cleary, PhD*

Patients usually cannot assess the technical quality of their care; however, examining a hospitalization through the patients' eyes can reveal important information about the quality of care. Patients are the best source of information about a hospital system's communication, education, and pain-management processes, and they are the only source of information about whether they were treated with dignity and respect. Their experiences often reveal how well a hospital system is operating and can stimulate important insights into the kinds of changes that are needed to close the chasm between the care provided and the care that should be provided.

This article examines the case of a patient admitted for ankle

arthrodesis due to severe hemophilia-related arthritis. The surgery was successful, but the hospital stay was marked by inefficiency and inconveniences, as well as events that reveal fundamental problems with the hospital's organization and teamwork. These problems could seriously compromise the quality of clinical care. Unfortunately, most of these events occur regularly in U.S. hospitals. Relatively easy and inexpensive ways to avoid many of these problems are discussed, such as reducing variability in non-urgent procedures and routinely asking patients about their experiences and suggestions for improvement.

Ann Intern Med. 2003;138:33-39.

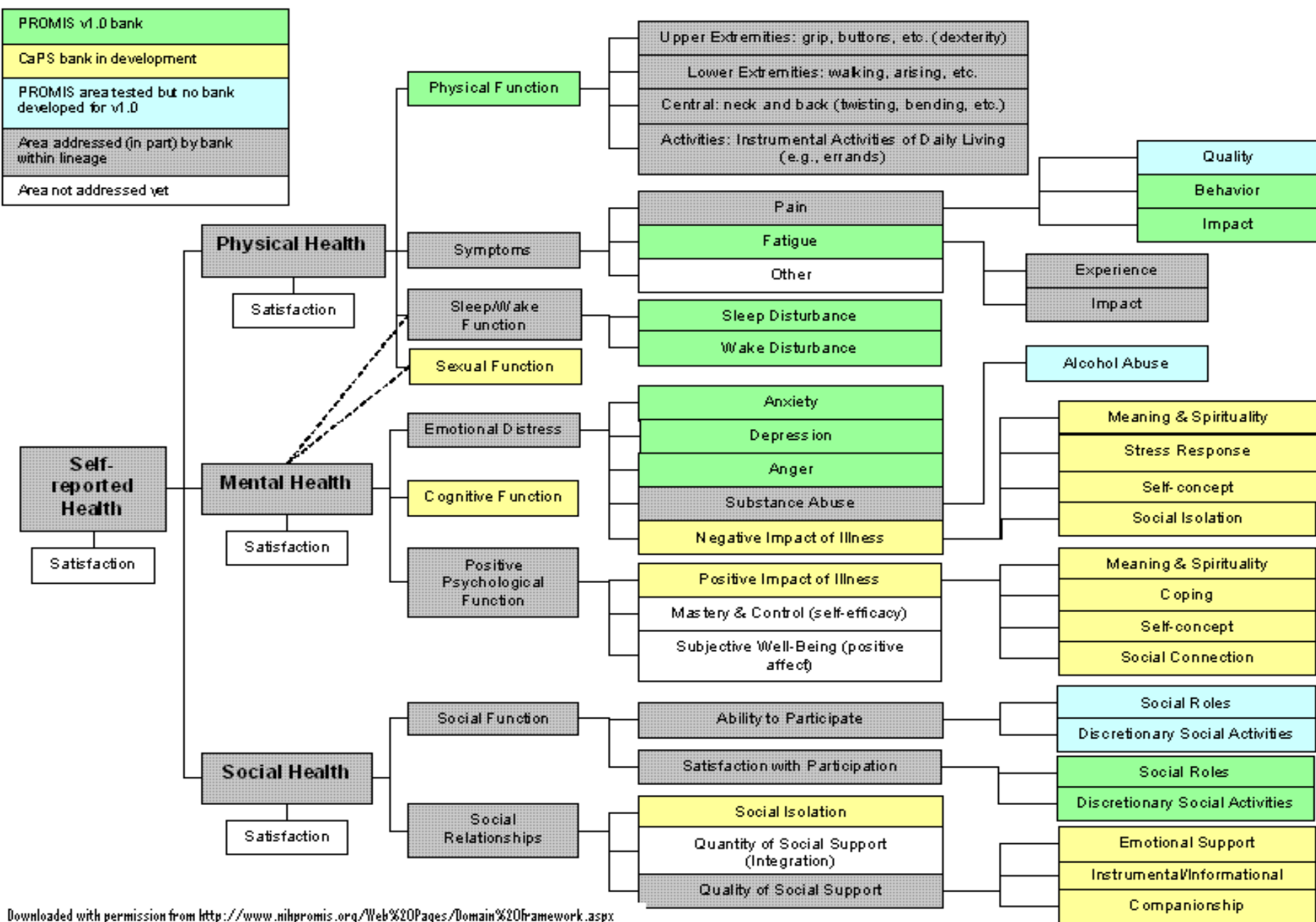
For author affiliation, see end of text.

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Study Objectives

- Reach national (cross-Canada) consensus on important patient-centered domains and dimensions for capturing patient experience of cancer.
 - Engage end-users as part of an integrated knowledge translation process with final consensus about a core set of outcomes and measures using a RAND appropriateness method (meaningful, actionable, feasible, valid).
- Identify PRO measures to capture domains with sound psychometric quality for use in a core outcome measurement system and/or identify areas where insufficient evidence exists.

Patient Reported Outcomes Measurement Information System (PROMIS) Domain Framework



Overview of Study: Core Outcome Measure Selection Process

Step 1

Initial review and endorsement of outcomes by panel members

Step 2

Scoping review of literature to identify conceptual definitions, instruments, and interventions

Step 3

1st Round Rating:
E-Delphi
(online survey)

Step 4

2nd Round Rating:
Expert Panel Meeting



Study Methodology - Scoping Review

- **Databases Searched:** Medline, HealthStar, PsychInfo, CINHALL, Web Of Science, Sociological Abstracts, Cochrane Databases of Systematic Reviews, Database of Abstracts of Reviews of Effects, Cochrane Controlled Trial Registry, and Health and Psychosocial Instruments.
- **Populations Studied:** sentinel cancer populations of breast, colon, lung, and prostate
- **Phases of Cancer:** diagnosis, treatment (chemotherapy, radiation, adjuvant therapy, or surgery), palliative care, and survivorship



Study Methodology - Consensus Process

- National expert panel members voted on the following four desirable characteristics suggested by Hermann and Palmer (2002) for selecting core outcome measures
 - Meaningful
 - Actionable
 - Feasible
 - Valid
- Panelists rated the outcomes and instruments on a scale from 1-9
 - 1 = definitely not meaningful, actionable, feasible, or valid
 - 9 = definitely meaningful, actionable, feasible, or valid.



Overview of Study: Delphi Process

- **Meaningful:** clinically important area, relevant to stakeholders, evidence-based and valid.
- **Actionable:** comprehensible, interpretable, and developed norms, benchmarks, and standards.
- **Feasible:** attributes measured are precisely specified, affordable, accurate, reliable, responsive, confidential, brevity of the measure, and generic
- **Valid:** sufficient evidence measures what it intended to measure based on conceptual definition, attributes of the outcome, and psychometric properties.

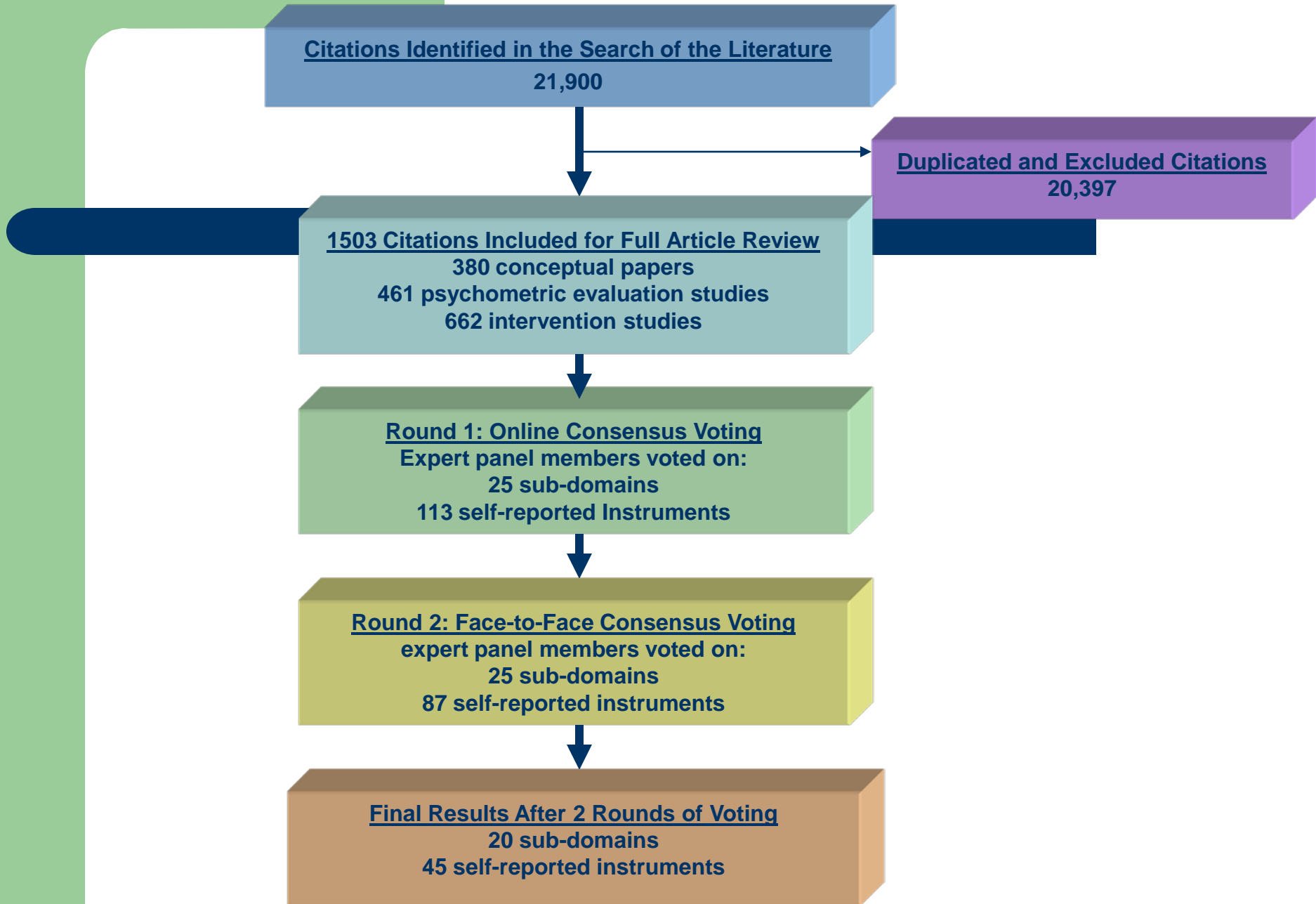
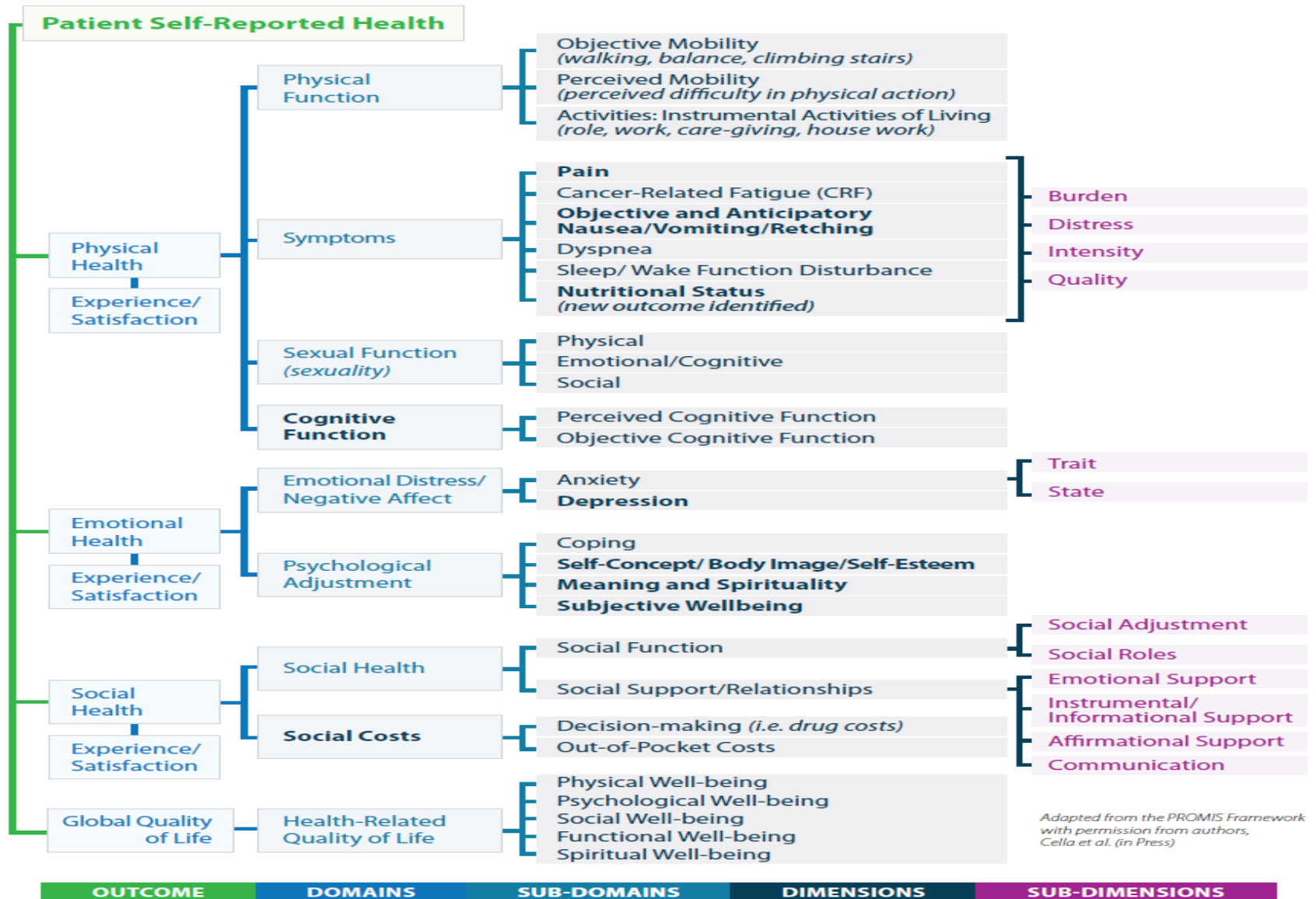


Figure 1.
 Patient-Focused Cancer Care Outcomes Study Findings:
 Patient-Reported Outcomes Measurement System in Cancer – Core for Canada
 (PROMS-Cancer Core).



Results: Physical Health Domain

- **Sub - domain:** Physical function
 - **Instruments:** Medical Outcomes Study- Physical Function Scale; Eastern Cooperative Oncology Group (ECOG) Performance Status; and the Sickness Impact Profile
- **Sub - domain:** Sexual Function
 - **Instruments:** Derogatis Interview for Sexual Functioning; Sexual Function Questionnaire; and the International Index of Erectile Dysfunction

Results: Physical Health Domain Continued

- **Sub-domain:** Overall Symptom experience
 - **Instruments:** Memorial Symptom Assessment Scale; M. D. Anderson Symptom Inventory;
 - Dimensions of Symptom Experience:
 - **Pain** (Instruments: Brief Pain Inventory; McGill Pain Question.; Numeric Rating Scales; Pain-O-Meter; Visual Analogue Scales)
 - **Fatigue** (Instruments: Cancer Fatigue Scale; Revised Piper Fatigue Scale; Multi-dimensional Fatigue Symptom Inventory; FACT-Fatigue; Brief Fatigue Inventory)
 - **Nausea and vomiting** (Instruments: Functional Living Index Emesis; Index of Nausea, Vomiting, and Retching)
 - **Dyspnea** (Instruments: Cancer Dyspnea Scale)
 - **Sleep and wake function** (Instruments: Pittsburgh Sleep Quality Index; Insomnia Severity Index)

Emotional Health Domain

- **Sub- Domain:** Emotional Distress/ Negative Affect
 - **Dimensions:**
 - **Anxiety** (Instruments: Hospital Anxiety and Depression Scale; Profile of Moods States-Short Form; Spielberger State Trait Anxiety Scale)
 - **Depression** (Instruments: Hospital Anxiety and Depression Scale; Centre for Epidemiological Study (CES)-Depression Scale; Profile of Mood States –SF)
 - **Anger and substance abuse** were removed from the framework of specific outcomes to measure
- **Sub-domain:** Cognitive Function
 - Instrument: FACT-Cog (Further investigation warranted)

Emotional Health Domain

- **Sub-domain:** Psychological Adjustment Dimension
 - **Dimensions:**
 - **Overall psychological adjustment** (instrument: Mental Adjustment to Cancer Scale (MACS); Mini MACS)
 - **Coping** (Instruments: Cancer Coping Questionnaire; Ways of Coping Questionnaire; COPE-SF)
 - **Self-concept/body image** (Instruments: Body Image Scale - * Further investigation warranted)
 - **Meaning and spirituality** (Instruments: No Instruments were selected - Further investigation warranted)
 - **Subjective well-being** (Instruments: Benefit Finding Scale; Post-traumatic growth inventory)
 - **Stress response and self-efficacy** were removed from the framework of specific outcomes to measure until further evidence is available

Social Health and Costs Domain

- Sub-domain: Social health
 - **Dimensions:**
 - **Social function** (Instruments: Psychosocial Adjustment to Illness - Further investigation warranted)
 - **Social support/relationships** (Medical Outcomes Study-Social Support Survey - Further investigation warranted)
 - **Social isolation and social costs** were removed from the framework until further evidence is available.

Quality of Life

- **Sub-domain:** Health-related Quality of Life
 - **Instruments:**
 - European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30)
 - FACT-General
 - McGill QOL Questionnaire
 - Functional Living Index Cancer and Quick- Functional Living Index Cancer
 - Cancer Care Monitor

Summary

- Many instruments not conceptually/content valid as miss important aspects of a domain
- We cannot embed all instruments into PRO measurement—move from classical test theory to item response paradigm.
- PPCIP shows we can collect PROs in clinical practice but requires a KT approach.

Next Steps

- National meeting in May 2010 of all key stakeholder groups.
- Completion of PROMS-Core for Cancer using tested PROMIS item banks.
- Research consortium (international potential) to be established.
 - Pilot test the PROMS-Core for Cancer-application for grant funding.
 - Build on existing provincial PRO measurement systems already implemented in Cancer Care Ontario and National Distress Screening Implementation

Need for a New Way of Acting

- “We might say that at this moment, as in the time of Galileo, what we most urgently need is much less new facts (there are enough and even embarrassingly more than enough of these in every quarter) than a new way of looking at the facts and accepting them. A new way of seeing, combined with a new way acting---that is what we need (Teilhard de Chardin).