The validation and use of patient-reported outcome and experience measures in older adult populations

Rick Sawatzky, PhD, RN
Principal Investigator

Canada Research Chair in Patient-Reported Outcomes
Associate Professor | School of Nursing | Trinity Western University
Research Scientist | Centre for Health Evaluation and Outcome Sciences
Objectives

- Introduction to PROMs and PREMs: Report on the results of a knowledge synthesis of PROM and PREM instruments for older adults in acute care

- Contextualize the use of PROM and PREM instruments in relation to modern perspectives of measurement validation

- Clinician and patient perspectives regarding the use of an electronic (tablet-based) quality of life assessment and practice support system (QPSS) in palliative home
Background on PROMs and PREMs
Quality of Life and Patient-Reported Outcomes in health services and research

- Increasing emphasis on understanding the impact of illness and healthcare services on people’s daily lives
- This includes individuals’ perspectives of their symptoms, functional status, and physical, social, and emotional wellbeing

World Health Organization definition of health

1946

1975

1989

2009

QOL as a Medical Subject Heading in Medline

WHO definition of QOL

US Medical Outcomes Study

Burgeoning PROMs activity:
- FDA guidance for industry
- UK NHS PROMs initiative
- PROMIS

US Medical Outcomes Study

US Medical Outcomes Study

WHO definition of QOL

WHO definition of QOL

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993

1993
Increasing emphasis in health research

March 2014 update

- 233,754 PubMed citations use QOL-related terms in the article title or abstract (2% of all PubMed citations in 2013)
- 3,637 PubMed citations use the term “patient-reported outcomes” (1,067 in 2013)

The imperative for person-centered care requires that the full range of healthcare needs relevant to the quality of life of palliative home care clients, and of their family caregivers, is routinely assessed.

“Our aim should be to find out what each patient wants, needs, and experiences in our health care system” M. Gerteis et al. (1993)
Self-report instruments that facilitate measurement of quality of life, including the health outcomes and healthcare experiences of patients and their family caregivers.

Patient- and family-centred outcomes and experiences

Essential building blocks for patient- and family-centered care

Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs), provide information about patients’ perspectives of their quality of life (QOL) and healthcare experiences without prior interpretation by a clinician or any other person.

- **PROMS**
  - used to assess patients’ and families’ perspectives of various domains of their health and QOL*

- **PREMS**
  - used to assess patients’ and families’ experiences with the care provided

* includes overall health, physical symptoms, mental health, social health and existential wellbeing
Patient-reported outcome measures (PROMs)

• **Self-report instruments** used to obtain healthcare recipients’ appraisals of their health status.

• Most PROMs are **multidimensional** in that they address various domains of human experience, including symptoms, functional status, and psychological and social and spiritual wellbeing.

• PROMs provide information about patients’ perspectives of their health and quality of life without interpretation by a clinician or any other person.
What do PROMs measure?

Explaining Patient-Reported Outcomes Measures

The complete PROMIS domain framework is available at: http://www.nihpromis.org/Documents/PROMIS_Full_Framework.pdf
What do PROMs measure?

Explaining Patient-Reported Outcomes Measures

Functional Assessment of Chronic Illness Therapy Measurement system

Quality of life

- Physical wellbeing
- Social/family wellbeing
- Emotional wellbeing
- Functional wellbeing

Life domains relevant to the QOL of people with chronic illness

www.facit.org
Domain coverage of generic PROMs*

*Refers to the representation of domains in the pool of items.
Example PROM for palliative care

The McGill Quality of Life Questionnaire (MQOL) Revised

Physical
- Physical symptoms
- Feeling physically well
- Physically unable to do things

Psychological
- Depressed
- Nervous or worried
- How often sad
- Fear of the future

Existential
- Meaning in life
- Achievement of life goals
- Control
- Self-esteem

Relationships
- Communication
- Relationships stressful
- Feel supported

Quality of Life

Patient-reported experience measures (PREMs)

- Assess various domains of patient-centred care (e.g., access to care, coordination of care, emotional support, information.)
- Provide information from patients’ perspectives without interpretation by a ‘middle man’.
## Common dimensions of patient experience

<table>
<thead>
<tr>
<th>Through the Patients’ Eyes (Picker Institute, 1986)</th>
<th>Model for Patient &amp; Family Centred Care (IPFCC, 1992)</th>
<th>Achieving an Exceptional Care Experience (IHI, 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for patient values &amp; preferences</td>
<td>Respect and Dignity</td>
<td>Respectful Partnerships</td>
</tr>
<tr>
<td>Information, Communication &amp; Education</td>
<td>Information Sharing</td>
<td>Evidence Based Care</td>
</tr>
<tr>
<td>Coordination of Care</td>
<td>Collaboration</td>
<td>Leadership</td>
</tr>
<tr>
<td>Involvement of Family</td>
<td>Participation</td>
<td></td>
</tr>
<tr>
<td>Emotional Support</td>
<td></td>
<td>Hearts &amp; Minds</td>
</tr>
<tr>
<td>Physical Comfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparation for Discharge / Continuity &amp; Transitions in Care</td>
<td></td>
<td>Reliable Care</td>
</tr>
<tr>
<td>Access</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Example PREM for palliative care

**Canadian Health Care Evaluation Project (CANHELP)**

<table>
<thead>
<tr>
<th>Domain</th>
<th># questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relationship with doctor</td>
<td>3</td>
</tr>
<tr>
<td>Illness management</td>
<td>9</td>
</tr>
<tr>
<td>Communication</td>
<td>3</td>
</tr>
<tr>
<td>Decision making</td>
<td>4</td>
</tr>
<tr>
<td>Feeling at peace</td>
<td>1</td>
</tr>
</tbody>
</table>

Each question is rated on (1) Importance, (2) Satisfaction


*Example questions:*

You were treated by doctors, nurses, and other members of the health care team in a manner that preserved your sense of dignity.

Your emotional problems (for example: depression, anxiety) were adequately assessed and controlled.
Reasons for using PROMs and PREMs

**Health professionals**

- At point of care, to inform treatment decisions, monitor patients’ conditions, promote patient-clinician communication, reveal health and quality of life concerns that may otherwise have not been noticed

**Health researchers**

- Examine the effectiveness of treatments and the impact of healthcare interventions
- Better understand the impacts of treatments and services on people’s health from their point of view

**Health service decision makers**

- Evaluate the efficacy, effectiveness and cost-effectiveness of healthcare services and programs

**Health care recipients**

- Monitor symptoms and concerns and communicate with health care professionals
Patient- and family-reported outcome and experience measures for elderly acute care patients

Knowledge synthesis
Knowledge Synthesis Team

**RESEARCHERS**

**Richard Sawatzky**  
Trinity Western University & Centre for Health Evaluation & Outcome Sciences, Providence Health Care

**Stirling Bryan** University of British Columbia

**Robin Cohen** McGill University & Investigator, Lady Davis Institute, Montreal

**Anne Gadermann** Centre for Health Evaluation & Outcome Sciences, Providence Health Care

**Kara Schick Makaroff** University of Alberta

**Kelli Stajduhar** University of Victoria

**LIBRARY SCIENCES**

**Duncan Dixon** Trinity Western University

**KNOWLEDGE USERS**

**Lena Cuthbertson** BC Ministry of Health

**Neil Hilliard** Fraser Health Authority

**Judy Lett** Fraser Health Authority

**Carolyn Tayler** Fraser Health Authority

**TRAINEES**

**Eric Chan** TVN Post-doctoral Interdisciplinary Fellow

**William Harding** Undergrad HQP

**Dorolen Wolfs** HQP

**RESEARCH ASSISTANTS**

**Glenda King** Graduate Research Assistant

**Kim Shearer** Graduate Research Assistant

**Sharon Wang** Graduate Research Assistant
Knowledge synthesis
Patient- and family-reported outcome and experience measures for elderly acute care patients

Motivation for the synthesis

• Although there are many PREM and PROM instruments, information about their reliability and validity, applicability, and administration in acute care settings for seriously ill older adults, and their families, has not been systematically reviewed and synthesized.

• Healthcare professionals, administrators, and decision makers require up-to-date information to direct the selection and utilization of appropriate PREM and PROM instruments.

AIM
The overarching aim of this knowledge synthesis project was to provide a comparative review of available PROMs and PREMs that would facilitate the selection and utilization appropriate measures for seriously ill elderly patients and their families in acute care settings.
<table>
<thead>
<tr>
<th>STAGE 1</th>
<th>Objective</th>
<th>Method</th>
<th>Selection criteria</th>
</tr>
</thead>
</table>
| To identify a comprehensive list of generically applicable PROM’s and PREM’s. | • Extensive searches of library databases, PROQOLID®, review articles, books, and websites.  
• Bibliometric analysis of instrument publications.  
• Data extraction of instrument characteristics. | • The instrument is applicable to elderly patients or their family caregivers.  
• There is evidence of use in a hospital setting.  
• The instrument has at least one publication during the past 5 years or has been developed during the past 5 years. |

<table>
<thead>
<tr>
<th>STAGE 2</th>
<th>Objective</th>
<th>Method</th>
<th>Selection criteria</th>
</tr>
</thead>
</table>
| To describe and compare characteristics of generic PROMs and PREMs. | • Systematic database searches of selected PROMs and PREMs.  
• Data extraction of information regarding their reliability, validity, applicability and use within the target population, as well as information regarding their administration. | • Exclude disease- or condition-specific instruments  
• PROMs must measure physical health and mental health domains  
• PREMs must measure more than one domain. |

<table>
<thead>
<tr>
<th>STAGE 3</th>
<th>Objective</th>
<th>Method</th>
<th>Selection criteria</th>
</tr>
</thead>
</table>
| To review the psychometric properties of the generic PROMs and PREMs. | • The COSMIN search strategy was used to identify psychometric validation studies.  
• The EMPRO criteria were used to evaluate the psychometric properties of the PROMs and PREMs. | • We only included PROM and PREM instruments with validation studies pertaining to elderly patients in acute care. |
### Stage 1 | Identification of relevant PROMs and PREMs

<table>
<thead>
<tr>
<th></th>
<th>PROMs</th>
<th>PREMs</th>
<th>PROMs/PREMs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient</td>
<td>FCG</td>
<td>Patient</td>
</tr>
<tr>
<td># of Instruments</td>
<td>136</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>Disease-/Condition-specific</td>
<td>67</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Generic</td>
<td>50</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Population-specific</td>
<td>19</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

**NOTE:** Short forms, revisions, and adaptations of original instruments are counted separately.
STAGE 1 | # of PROMs & PREMs per dimension

**PROMs**

- General/Overall QOL
- General/Overall Health
- Physical Function
- Physical Symptoms
- Mental Health
- Social Health
- Other PROM dimension

**PREMs**

- Information and education
- Coordination of care
- Physical comfort
- Emotional support
- Respect for patient...
- Involvement of family and...
- Continuity and transition
- Overall impression
- Access to care
- Global Rating
- Other PREM Dimensions

Legend:
- Patient PROMs
- Patient PREMs
- Patient PROMs and PREMs
- FCG PROMs
### STAGE 2

#### Selection criteria

<table>
<thead>
<tr>
<th>Selection criteria for PROMS</th>
<th>Data collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Exclude disease and condition specific instruments</td>
<td>• Scoring</td>
</tr>
<tr>
<td>2. Include multidimensional instruments that measure both physical health and mental health domains</td>
<td>• Scaling</td>
</tr>
<tr>
<td>3. Include all family caregiver PROMs</td>
<td>• Mode of Administration</td>
</tr>
<tr>
<td>4. Include all instruments developed for palliative or end-of-life care</td>
<td>• Response Burden</td>
</tr>
</tbody>
</table>

#### Selection criteria for PREMs:

1. Include only instruments that measure more than one domain (i.e., multidimensional)
2. Include all family caregiver PREMs
3. Include all instruments developed for palliative or end-of-life care
Measurement characteristics

### Scoring
- Total Scores
- Domain Scores
- Utility Scores
- Population Norms
- Canadian Norms

### Scaling
- Likert
- Guttman
- Binary
- Qualitative Responses
- Visual Analogue Scale
- Other (e.g., categorical)

### Mode of administration
- Self (paper)
- Interviewer
- Telephone
- Computer
- Clinician
- Proxy (caregiver)
- Proxy (clinician)
- Other

- Patient PREM
- Patient PROM
- Patient PROM & PREM
- FCG PREM
- FCG PROM
- FCG PROM & PREM
Most instruments consist of less than 20 items and take less than 10 minutes to complete.
• All 88 instruments are available in English
• Although instruments have been translated into different languages, validity evidence of the translated versions is limited
Instruments with a validation study pertaining to elderly patients in acute care:

**Canadian Health Care Evaluation Project Questionnaire (CANHELP and CANHELP LITE)**
- Designed to measure satisfaction with care for older patients with life threatening illnesses, and their family members.
- **CANHELP:**
  - 38 items (Patient version)
  - 40 items (Family version)
- **CANHELP LITE:**
  - 21 items (Patient version)
  - 23 items (Family version)


**Quality of Dying and Death Questionnaire (QODD)**
- Designed to measure the quality of dying and death using the perspective of family members
- 31 items

### Table 6: EMPRO Domain and Overall Scores

*NOTE: Dash denotes no information available; N/A denotes not applicable. Higher scores indicate better “quality”*

<table>
<thead>
<tr>
<th></th>
<th>QODD</th>
<th>CANHELP</th>
<th>CANHELP Lite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conceptual and Measurement Model</td>
<td>28.57</td>
<td>90.48</td>
<td>90.48</td>
</tr>
<tr>
<td>Reliability</td>
<td>0</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Validity</td>
<td>26.67</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Interpretability</td>
<td>0</td>
<td>88.89</td>
<td>88.89</td>
</tr>
<tr>
<td>Respondent Burden</td>
<td>11.11</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Administrative Burden</td>
<td>0</td>
<td>91.67</td>
<td>91.67</td>
</tr>
<tr>
<td>Alternative Modes of Administration</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Language Adaptations</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Overall</td>
<td>11.05</td>
<td>70.87</td>
<td>70.87</td>
</tr>
</tbody>
</table>
Summary of knowledge synthesis results

- There are many PROMs and PREMs that have been used in acute care settings for elderly patients. Several instruments were specifically developed for use in older adults, whereas others, such as the SF-36, were developed for general populations but are widely-used in older adults.

- Many of the identified PROMs and PREMs have not been validated for this population (i.e., elderly patients in acute care).
The Validation and Utilization of PROMs and PREMs for Health Services and Clinical Practice
An “explanatory” perspective of measurement validation

“an integrated evaluative judgment of the degree to which empirical evidence and theoretical rationales support the adequacy and appropriateness of interpretations and actions based on test scores or other modes of assessment”

An “explanatory” perspective of measurement validation

**OBJECTIVES**
- Comparison BETWEEN sampling units
- Comparison WITHIN sampling units

**PREMISES & METHODS**
- MEASUREMENT INVARIANCE
  - Differential item functioning (DIF)
  - Multi-group confirmatory factor analysis (MG-CFA)
  - Latent class mixture modeling

- RESPONSE SHIFT
  - Structural equation modeling
  - Growth curve modeling
  - Analysis of Residuals

**CONSEQUENCES**
- PERSONAL CONSEQUENCES
- SOCIETAL CONSEQUENCES
- VALUE IMPLICATIONS
- INTENDED CONSEQUENCES
- UNINTENDED SIDE EFFECTS

References:
Three foundational considerations

- **Comparisons of different people**
  - What evidence is needed to warrant comparisons between groups and individuals?
    - Comparisons between groups
    - Comparisons at the individual level

- **Comparisons over time**
  - What evidence is needed to warrant comparisons over time?
    - Comparisons before and after a treatment
    - Evaluation of trajectories over time

- **Consequences**
  - What are the value implications, including personal and societal consequences, of using PRO scores?

Validation of PROMs

**Population heterogeneity**
- Differences in how people interpret and respond to questions
- Threatens the comparability of scores across individuals or groups

**Response shift**
- An individual’s frame of reference may change in response to a health event or intervention
- Threatens the comparability of scores over time
Heterogeneity in the population

A conventional assumption underlying PROMs is that individuals interpret and respond to questions about their health in the same way, such that scores are equivalently applicable to all people in the population.
The challenge of heterogeneity

Is it reasonable to believe that people from different backgrounds and with different life experiences interpret and respond to questions about their health and quality of life in the same way?

People may respond to QOL and PROM questions in systematically unique ways because of:

- Cultural, developmental, or personality differences
- Contextual factors or life circumstances
- Different health experiences or events

In this situation, the PROMs will produce biased scores that are not comparable across different individuals or groups.
Examining the implications of heterogeneity

Latent variable mixture models: a promising approach for the validation of patient reported outcomes

Richard Sawatzky · Pamela A. Ratner · Jacek A. Kopec · Bruno D. Zumbo

Accepted: 7 July 2011
© Springer Science+Business Media B.V. 2011

Abstract

Purpose A fundamental assumption of patient-reported outcomes (PRO) measurement is that all individuals interpret questions about their health status in a consistent manner, such that a measurement model can be constructed that is equivalently applicable to all people in the target measurement model, (b) implications of sample heterogeneity with respect to model-predicted scores (theta), and (c) sources of sample heterogeneity. An example is provided using the 10 items of the Short-Form Health Status (SF-36®) physical functioning subscale with data from the Canadian Community Health Survey (2003) (N = 7,030

The Draper-Lindley-de Finetti (DLD) framework of measurement validation

Two conditions for general measurement inference

1) Item homogeneity / unidimensionality:
   - The items must be exchangeable so that the scores of different questions are comparable on the same scale.

2) Population homogeneity / parameter invariance:
   - The sampling units must be exchangeable (the items’ parameters must be invariant) so that the scores are comparable irrespective of any differences among individuals other than the characteristic being measured.
The validation of PROMs in heterogeneous populations

- The cumulative probability of an item response at or above category \( j \) within a latent class can be computed as follows:

\[
P_{ijk}(Y \geq j | \theta, C = k) = \frac{\exp(-\tau_{ijk} + \lambda_{ik}\theta)}{1 + \exp(-\tau_{ijk} + \lambda_{ik}\theta)}.\]

- Each class has a unique set of parameters that are estimated simultaneously in the latent variable mixture model:

\[
f(x) = \sum_{k=1}^{K} \pi_k f_k(x),\]

where \( f \) is the mixture of the class-specific distributions, and \( \pi_k \) is the mixing proportion.

- The cumulative probability of an item response at or above category \( j \) within a latent class can be computed as follows:

\[
P_{ijk}(Y \geq j | \theta, C = k) = \frac{\exp(-\tau_{ijk} + \lambda_{ik}\theta)}{1 + \exp(-\tau_{ijk} + \lambda_{ik}\theta)}.\]

- The cumulative probability of an item response at or above category \( j \) within a heterogeneous population is obtained by:

\[
P_{ij}(Y \geq j | \theta) = \sum_{k=1}^{K} (X_k \ast P_{ijk}(Y \geq j | \theta)),\]

where \( X_k \) is the posterior probability of an individual being in class \( k \).
Examining the implications of heterogeneity

- **Model specification and estimation**
  - For example: an IRT graded response model

- **Model fit and class enumeration**
  - Compare predicted and observed item responses and evaluate relative model fit

- **Implications of sample heterogeneity**
  - Compare predicted score of the LVMM to those of the one-class model

- **Explaining latent class membership**
  - Regression of latent classes on explanatory variables
Does your health limit you in any of the following activities:

- Walking one block
- Moderate activities, such as ...............  
- Vigorous activities, such as ...............
Measurement model that accommodates heterogeneity

Does your health limit you in any of the following activities:

- Walking one block
- Moderate activities, such as .................
- Vigorous activities, such as .................

The measurement model parameters are allowed to vary across two or more latent classes (subsamples):
- item thresholds (difficulty)
- factor loadings (discrimination)
## SF-36 physical function

<table>
<thead>
<tr>
<th>Physical function items</th>
<th>Response options</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFRC_03 Vigorous activities</td>
<td>0. No limitations</td>
</tr>
<tr>
<td>SFRC_04 Moderate activities</td>
<td>1. Limited a little</td>
</tr>
<tr>
<td>SFRC_05 Lifting or carrying groceries</td>
<td>2. Limited a lot</td>
</tr>
<tr>
<td>SFRC_06 Climbing several flights of stairs</td>
<td></td>
</tr>
<tr>
<td>SFRC_07 Climbing one flight of stairs</td>
<td></td>
</tr>
<tr>
<td>SFRC_08 Bending, kneeling, or stooping</td>
<td></td>
</tr>
<tr>
<td>SFRC_09 Walking more than one kilometer</td>
<td></td>
</tr>
<tr>
<td>SFRC_10 Walking several blocks</td>
<td></td>
</tr>
<tr>
<td>SFRC_11R Walking one block</td>
<td></td>
</tr>
<tr>
<td>SFRC_12R Bathing and dressing</td>
<td></td>
</tr>
</tbody>
</table>

### Conventional scoring method*

1. Add all items
2. - 20 (reverses the scale)
3. $x \times 5$ (scaled from 0 – 100)
Implications of ignoring heterogeneity on item response theory predicted scores

10% with difference scores ≥ 0.27
10% with difference scores ≤ -0.90

PROM score ignoring heterogeneity

Difference with PROM scores that accommodate heterogeneity
DO PEOPLE INTERPRET AND RESPOND TO QUESTIONS ABOUT THEIR PAIN IN A COMPARABLE MANNER?

Richard Sawatzky
Jacek A. Kopec
Eric C. Sayre
Pamela A. Ratner
Bruno D. Zumbo
We examined the fundamental assumption of sample homogeneity (exchangeable sampling units) by:

1. Identifying whether a sample is homogeneous with respect to a unidimensional IRT structure for the measurement of pain.

2. Evaluating the implications of sample heterogeneity with respect to:
   A. The invariance of measurement model parameters of the items measuring pain
   B. The IRT-predicted pain scores

3. Exploring potential sources of sample heterogeneity with respect to a unidimensional IRT model for the measurement of pain
Latent variable mixture model

Pain item bank of 36 items measuring severity, frequency, and impact of pain

- The thresholds and loadings are allowed to vary across two or more latent classes (subsamples).
The pain item bank

- Part of a previously developed Computerized Adaptive Test, the CAT-5D-QOL (Kopec et al., 2006).

- 36 items measuring the severity and frequency of pain or discomfort and the impact of pain on daily activities and leisure activities.

- Various ordinal formats:
  - not at all (1) ↔ extremely (5) (17 items)
  - never (1) ↔ always (5) (12 items)
  - none of the time (1) ↔ all of the time (5) (2 items)
  - Various item-specific response formats (5 items)

Sampling methods

Total sample: N = 1,666

- Adults from two rheumatology clinics in Vancouver (BC): N = 340
- Adults on a joint replacement surgery waiting list in BC: N = 331
- Stratified random community sample of adults in BC: N = 995
## Sample description

<table>
<thead>
<tr>
<th>Variables</th>
<th>Percent / mean(sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender = female</td>
<td>60.7%</td>
</tr>
<tr>
<td>Age (mean (SD))</td>
<td>56.7(15.9)</td>
</tr>
<tr>
<td>Has a medical problem</td>
<td>84.5%</td>
</tr>
<tr>
<td>Has osteoarthritis</td>
<td>36.6%</td>
</tr>
<tr>
<td>Has rheumatoid arthritis</td>
<td>28.0%</td>
</tr>
<tr>
<td>Uses one medication</td>
<td>23.5%</td>
</tr>
<tr>
<td>Uses two or more medications</td>
<td>54.2%</td>
</tr>
<tr>
<td>Has been hospitalized during the past year</td>
<td>20.5%</td>
</tr>
</tbody>
</table>
## Conclusions

- The sample is not homogeneous with respect to a unidimensional structure for the pain items.
- A relative improvement in model fit was obtained when 3 classes were specified.
There were considerable differences in the standardized IRT scores of the one-class model (ignoring sample heterogeneity) and the three-class model (adjusted for sample heterogeneity).
### Potential sources of sample heterogeneity

#### Bivariate associations with latent class membership

<table>
<thead>
<tr>
<th>Variables</th>
<th>Class 1</th>
<th>Class 2</th>
<th>Class 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (% male)</td>
<td>36.6</td>
<td>36.8</td>
<td>42.1</td>
</tr>
<tr>
<td>Age (means)</td>
<td>58.3</td>
<td>57.0</td>
<td>55.3</td>
</tr>
<tr>
<td>% has a medical problem (other than RA/OA)*</td>
<td>82.1</td>
<td>83.7</td>
<td>70.1</td>
</tr>
<tr>
<td>% has osteoarthritis (OA)*</td>
<td>40.1</td>
<td>45.6</td>
<td>27.7</td>
</tr>
<tr>
<td>% has rheumatoid arthritis (RA)*</td>
<td>37.6</td>
<td>27.9</td>
<td>21.9</td>
</tr>
<tr>
<td>% hospitalized during the past year*</td>
<td>27.2</td>
<td>16.3</td>
<td>17.2</td>
</tr>
<tr>
<td>% taking one or more medications*</td>
<td>85.9</td>
<td>84.3</td>
<td>67.8</td>
</tr>
<tr>
<td>Self-reported health status*</td>
<td>3.3</td>
<td>3.1</td>
<td>2.6</td>
</tr>
<tr>
<td>(1 = excellent; 5 = very poor) (mean)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:** Based on pseudoclass draws. *Statistically significant bivariate association ($p < 0.05$)
What we have learned to date

The challenge of heterogeneity in the population

People may not interpret and respond to questions about their health and quality of life in the same way.

Differences among people that may explain such inconsistencies include:

- Differences in health experiences
- Differences in age
- Cultural differences
- Gender differences

Application to PRO measurement

These and other sources of heterogeneity, if ignored, could result in substantial error (bias) in health and quality of life scores (PROMs).
The challenge of response shift

Is it reasonable to believe that people will be consistent over time in how they interpret and respond to questions about their health and quality of life?

Schwartz and Sprangers defined response shift as “a change in the meaning of one’s self-evaluation of a target construct as a result of change in”:

- **recalibration**: internal standards of measurement
- **reprioritization**: values (i.e. the importance of component domains constituting the target construct)
- **reconceptualization**: definition of the target construct

Fig. 1. A theoretical model of response shift and quality of life (QOL).
Why care about response shift?

• From a validation point of view, it is important to distinguish “true change” from RS change
  – Ignoring RS could lead to measurement bias:
    • Decreased sensitivity to detect change over time
    • Detecting change over time that does not exist

• Contributes to understanding regarding the meaning of scores
  – Unexpected health outcomes

• May want to promote response shift
  – Palliative care
  – Rehabilitation
  – Self-management
  – Other non-curative interventions
Understanding the consequences and utilization of PROMs and PREMNs in clinical practice
Integrating a quality of life assessment and practice support system in palliative home care

Barbara McLeod, RN, BSN, MSN, CHPCN (C)
Clinical Nurse Specialist, Hospice Palliative Care

Richard Sawatzky, PhD
Canada Research Chair in Patient-Reported Outcomes
Trinity Western University School of Nursing
Centre for Health Evaluation & Outcome Research
This presentation reports on a collaborative in-progress research initiative about the implementation and integration of an electronic innovation, the Quality of Life Assessment and Practice Support System (QPSS), into routine palliative home care for older adults who have and advancing life-limiting condition and their family caregivers.

Background

Research project

Emerging results
Research team

Principal Investigators
• Rick Sawatzky, Trinity Western University
• Robin Cohen, McGill University
• Kelli Stajduhar, University of Victoria

Co-Investigators
• Researchers from Trinity Western University, University of British Columbia, University of Victoria, McGill University, Ersta University College (Sweden), Manchester University (UK), Cambridge University (UK)

Fraser Health Knowledge Users
• Carolyn Tayler, Director of End of Life Care
• Barbara McLeod, Clinical Nurse Specialist Hospice Palliative Care
• Jean Warneboldt, Tri-Cities Palliative Physician

Highly Qualified Personnel
• Jennifer Haskins, Fraser Health Palliative-Focused Nurse
• Melissa Kundert, Fraser Health Palliative-Focused Nurse
• Kathleen Lounsbury, graduate student, Trinity Western University
• Esther Mercedes, doctoral student, McGill
• Sharon Wang, graduate student, Trinity Western University
Quality of life assessments
Routine use of PROMs and PREMs at point of care

Routine use of PROMs and PREMs can:

• Make patients' and family caregivers' concerns more visible
• Raise awareness of problems that would otherwise be unidentified
• Lead to improved clinician-patient communication
• Result in improved care plans
• Improve collaboration among healthcare professionals
Benefits of e-QOL

Assessment Instruments

1. Reduce patient burden
2. Reduced clinician burden
3. Enhanced visualization and monitoring of patient concerns through ongoing and immediate feedback
4. PROM & PREM information become part of administrative data for program evaluation and cost-effectiveness analysis
An innovative, integrated health care information system for patient- and family-centered care that facilitates:

- use of QOL assessment instruments (including PROMs and PREMs) at point of care
- instantaneous feedback with information about scores, score interpretation, change over time, and targets for improvement
- documentation of interventions planned to address areas of unmet need
- tracking and assessing whether an implemented intervention has achieved the desired result
- capacity to integrate with other health information systems
Examples of QOL Assessment Instruments:

- Edmonton Symptom Assessment System – Revised (ESAS-R)
- McGill Quality of Life Questionnaire -Revised (MQOL-R)
- Quality of Life in Life-Threatening Illness-Family caregiver version 2 (QOLLTI-F v2)
- Canadian Health Care Evaluation Project Lite Questionnaire (CANHELP Lite)
Research project

Integrating a quality of life assessment and practice support system in palliative homecare

The project involves working with clinicians, clients and family caregivers to answer the following research questions

1) How can we best facilitate the integration and routine use of electronically-administered quality of life (QOL) and healthcare experience assessment instruments as practice support tools in palliative homecare nursing for older adults who have chronic life-limiting illnesses and for their family care givers?

2) Does the routine use of these instruments improve quality of care, as indicated by patients’ and family caregivers' reports of enhanced QOL and experiences with the care provided?
The project involves working with clinicians, clients and family caregivers to answer the following research questions.

**Research Design**

Mixed-methods integrated knowledge translation study that involves 2 stages:

1. **Local adaptation**
   - Focus groups and interviews with clinicians’, patients’, and family caregivers to understand how to best adapt and integrate a QPSS into palliative homecare nursing
   - Collection of pre-intervention outcomes evaluation data

2. **Evaluation**
   - Qualitative evaluation of the process of QPSS integration
   - Quantitative evaluation of impact on the QOL and health care experiences of clients and FCGs

**Samples**

**Qualitative data**
- Entire homecare nursing team
- 10 clients who are registered with the palliative support program
- 10 family caregivers who are most involved in the client’s care

**Quantitative data**
- Comparator group: 40 clients and 40 family caregivers in stage 1
- Intervention group: 40 clients and 40 family caregivers in stage 2
QPSS design and implementation
An integrated knowledge translation approach*

A. Identify Problem
How can we best facilitate the integration and routine use of electronically-administered QOL and healthcare experience assessment instruments as practice support tools in palliative homecare for older adults who have chronic life-limiting illnesses and their FCGs?

B. Adapt knowledge to local context
Stage 1 - Objective 1
Understand clinicians’, patients’, and FCGs’ points of view about how to best adapt and integrate a QPSS into their practice.

C. Assess barriers to knowledge use
Stage 1 – Objective 1 (cont’d)
Identify strategies for overcoming barriers and building on facilitators regarding the routine integration of QOL assessments in practice.

D. Select, tailor & implement interventions
Stage 1 - Objective 2
Determine how a QPSS can be used to support practice by tracking interventions and practices of the palliative homecare team to address the needs of patients and their FCGs.

E. Monitor knowledge use
Stage 2 - Objective 3
Qualitatively evaluate the process of integrating a QPSS in palliative homecare.

F. Evaluate outcomes
Stage 2 - Objective 4
Quantitatively Evaluate the impact of use of a QPSS on the QOL and health care experiences of patients and their FCGs.

G. Sustain knowledge use
Stage 3 - Objective 5
KT activities aimed at sustainability, and building on the outcome evaluation. Disseminate project results regarding the integration of quality of life assessments into palliative home care practice.

Knowledge Creation
Regarding the use of PROMs & PREMs

Research design

Outcome evaluation

Before-and-after-design:
- Comparator group
- Intervention group

Time period for each group
- From enrollment until the end of each phase (6 months)

Frequency of outcome measures
- Every two weeks

Analysis
- Area under the curve
- Comparison of trajectories

Outcomes

Quality of life of patients and family caregivers

Satisfaction with care of patients and family caregivers
Emerging findings

Qualitative data from clients and family caregivers

**Advantages of using the tablet modality:** Simplicity and ease of use, increased speed of access to information, increased completion of tools at multiple time points, ability to see trends in items over time, and potential decrease in the amount of paper charting.

“I found the questions were very easy to understand. And it was easy for me to just read them on the tablet. And when I got used to not pressing too hard and using the light touch, I found it very easy to use. I'm very surprised… How did you feel?” (family caregiver)
Emerging findings
Focus groups with palliative home care clinicians

Use of QOL assessment instruments in routine care: Providing structure for holistic assessment, improvement in communication, opportunities for reflection, as well as the risk of assessment burden.

“As nurses we don’t use these tools enough, we will use them once, the pain scale, and then it won’t always be redone a second time, I think that if we have a tablet it will be easier, done more quickly, it’s analysed, we have all the results, it’s not just our words, there is something there to describe the situation. I think it’s super useful.” (Clinician)

“...as a nurse, I tend to focus quite a bit on physical symptoms. But it's a really, really nice tool to find out what the other symptoms are that we're not able to pick up on – psychological, emotional, existential. So I felt that's a great tool to use for patients. Then we get to focus on those.” (Clinician)
I have a client in his 90s – him and ... his wife said to me yesterday that she's finding it really helpful because it's ... like, reflecting on his care and his situation and that he's coming up with things that he hasn't made her aware of. So it's kind of enriching the level of care that he's going to get, from his feedback.

**Contradictory opinions about the tablet modality:** Potential interferences with communication and relationship building, patients’ physiological barriers to use, anxiety using technological mediums, damage and loss of the tablets.

“I find it’s so impersonal; it’s difficult for me to get a client to tell me, you know, do you feel your relationship with your doctor is very important and are you satisfied? In a way it’s a lot of juice to extract from a client, from the situation, so I go easy, but I see that it could be good for my practice to use it more.”
Next steps

Scaling up

Concurrent QPSS study at the tertiary palliative care unit in Abbotsford regional hospital

Funding applications in review for multi-site complex intervention studies:
- Home care
- Hospital-based care

Partnership with Intogrey and Cambian to operationalize integration with health information systems

Research on computerized adaptive testing to further increase efficiency and reduce response burden
Concluding comments

The importance of measurement validation
Our ultimate goal is to arrive at justifiable or “valid” inferences, judgements, and decisions based on the measurement of patient-reported outcomes and experiences, where measurement validation is defined as:

“an integrated evaluative judgment of the degree to which empirical evidence and theoretical rationales support the adequacy and appropriateness of interpretations and actions based on scores ...”

Framework for the selection and utilization of PROMs and PREMs

- Purposes for PROMs Data Collection
- Selection of PROMs
- Administration of PROMs
- Utilization of PROMs
“Our aim should be to find out what each patient wants, needs, and experiences in our health care system.”

*M. Gerteis et al. (1993)*