MENQOL
The Menopause-specific Quality of Life Questionnaire

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On the Road to a PRO

Dr. J.E.Lewis and Dr. Ben Rogers

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Developers of MENQOL & Derivatives

- **Initial questionnaire development:**
  — Primary Care Research Unit, Sunnybrook Health Science Centre
  — Supported by CIBA-Geigy Canada Ltd.

- **Psychometric Refinements and derivatives:**
  J.R. Hilditch, J.E. Lewis, C.J. Wong
  — Supported by Janssen-Ortho Inc., Canada.

......with sincere thanks to many women who participated in this work
The State of QOL research in 1989

Condition-specific quality of life is defined as “the extent that the physical, emotional, social aspects of an individual’s life are intact and not adversely affected by that condition or treatment”.

Fletcher AE & Bulpitt CJ, Cardiology, 1987

Our Goal when we began............

to develop a valid, reliable, responsive QOL questionnaire specific to the early postmenopausal years

based on women’s reported experience
**STEP 1: Content Identification Methods**

### CONTENT SOURCES
- Literature scan
- Other menopause questionnaires
- 8 in-depth interviews with women 2-7 years post-menopause until content saturation
- 8 content specialists
- 2 QOL specialists
- Write-in option during pretest

### DIMENSIONS
- Emotional
- Intellectual
- Social
- Sexual
- Physical
- Sleep
- Spiritual
- Work life
STEP 2: Item Reduction Study

- 106 items generated
- Recruited to develop a questionnaire, not for an intervention
- n= 88 women, 2-7 yr.(24-84 mon.) post-menopause, no HT for 6 mon.

**REDUCTION METHOD:** after Gordon Guyatt et all, McMaster U.
- Impact Scores reduction method
- not a factor analysis reduction

**ITEM FORMAT:**

- NIGHT
  - Not at all bothered
  - Extremely bothered
  - □No □Yes ➔ □0 □1 □2 □3 □4 □5 □6

- SWEATS

**FREQUENCY SCORE**

**BOTHERED SCORE**
STEP 3: DIMENSIONS TO DOMAINS

- 2 clinicians & 1 social scientist independently assigned all items to dimensions until consensus reached

- A priori decisions re domains:
  - Combine emotional, intellectual, social, spiritual dimensions into Psychosocial Domain
  - Combined sleep items into Physical Domain
  - Removed vasomotor items from the Physical Dimension to a Vasomotor Domain
  - Sexual Domain
  - Work life Domain
Domain Assignment by Impact Score

- A priori decision for final Questionnaire to be ~ 30 items with no domain fewer than 3 items

- Item Impact Scores (Frequency-importance (FI) scores) calculated

- IMPACT SCORE= %yes X mean bothered score /each item /all women

- Items with Impact scores < 1.5 removed from further consideration. This included all items in the Work Domain

- Items clustered in predetermined domains

- Correlation Coefficients calculated for all items by domain. For highly correlated, redundant items, only the highest impact scoring item remained on the domain list which was then sequenced from high to low impact scores.

- Top 3 ranking items by domain were left in domain, then all remaining items were ranked sequentially from high to low Impact score and sequentially distributed to their predetermined domains until the resulting questionnaire had 29 items.
Menopause-specific Quality of Life Questionnaire

- Physical Domain  16 items
- Vasomotor Domain  3 items
- Psychosocial Domain  7 items
- Sexual Domain  3 items

- On to STEP 4: Psychometric Property Assessment
NOTE difference between scaling for Impact Score in questionnaire development and scaling for study analysis

<table>
<thead>
<tr>
<th>Impact Score</th>
<th>Not at all bothered</th>
<th>Extremely bothered</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIGHT</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>SWEATS</td>
<td>□ No □ Yes □ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Analysis Score</th>
<th>1 2 3 4 5 6 7 8</th>
</tr>
</thead>
</table>
Psychometric properties: Validity

- **Face validity:** n=20, score 4.7/5.0
- **Content validity:** acceptable to experts
- **Construct validity:**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Comparator</th>
<th>Pearson CC</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td><strong>Somatic/Psychosomatic</strong></td>
<td>0.69</td>
<td>86</td>
</tr>
<tr>
<td></td>
<td><strong>Somatic</strong></td>
<td>0.4</td>
<td>86</td>
</tr>
<tr>
<td>Vasomotor</td>
<td>Flash Intensity</td>
<td>0.66</td>
<td>102</td>
</tr>
<tr>
<td></td>
<td><strong>Somatic</strong></td>
<td>0.4</td>
<td>86</td>
</tr>
<tr>
<td>Sexual</td>
<td>#Vaginal symptom score</td>
<td>0.38</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>#Libido Index</td>
<td>0.48</td>
<td>60</td>
</tr>
<tr>
<td>Psychosocial</td>
<td>General Well-Being Schedule</td>
<td>-0.70</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td><strong>Psychologic</strong></td>
<td>0.65</td>
<td>84</td>
</tr>
</tbody>
</table>

*All Pearson’s Correlation Coefficients <0.001
**Neugarten & Kraine, Menopausal Symptom Checklist Subscales (based on Blatt Kupperman Index)
#Channon & Ballinger
Psychometric properties: Responsiveness

- Measures how small a difference could be detected given the instrument’s variability in a stable situation - based on reproducibility analysis.

- Minimum Clinically Important Difference (MCID) = 0.5-1.0 change based on expert opinion. We chose a MCID of 1 for the MENQOL.

- Responsiveness Index = \( \frac{\text{Mean change score}}{\text{SD change score}} \times \text{MCID} \)
  
  - Physical: \( 0.21 \times 0.75 \times 0.5 = 1.33 \)
  - VM: \( 0.18 \times 1.1 \times 0.5 = 0.91 \)
  - PS: \( 0.28 \times 0.91 \times 0.5 = 1.10 \)
  - Sexual: \( 0.24 \times 1.28 \times 0.5 = 0.78 \)
Issues with reproducibility and other development questions

Reproducibility unexpectedly weak for VM (0.37) and moderately weak for Sexual (0.7) over a 28 day interval.

1. MENQOL asked women to assess their quality of life over the previous month. How would the reproducibility properties be improved by a 1 week recall?

2. Some researchers wanted to use a 1 week recall period.

3. How could the questionnaire reflect treatment side effects? ie HT could produce breast tenderness and bleeding which could negatively affect QOL. Another group wanted to use MENQOL in a SERM trial and were concerned with medication side effects.

4. Participants in the RCT expressed difficulty to the research assistant with regard to answering “Vaginal dryness, during intercourse” if no partner, partner impotent but some were still aware of dryness
MENQOL-Intervention (MENQOL-I)

- Consistent 1st person pronouns, simplified 3 items, optimized response options in the sexual item
- Recall period 1 week
- Additions to physical domain
  - Vaginal bleeding, breast tenderness (for HT trials)
  - Leg cramps (for SERM trials)

Pretest and face validity: contributed by 9 women familiar with the MENQOL from a previous trial.

Content validity: contributed by 5 menopause experts.
Further Development for 2005 paper

Hilditch 1996 *Oral vs Transderm E2 non-inferiority*
Lewis 2006 ‘Muffin Study’
Gelfand 2003 *Oral E2 q3d alt E2+progestin  x12wk*

<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Hilditch et al</th>
<th>Lewis et al</th>
<th>Gelfand et al</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Questionnaire Used</strong></td>
<td>MENQOL</td>
<td>MENQOL</td>
<td>MENQOL-Intervention</td>
</tr>
<tr>
<td>Repeated interval</td>
<td>1 month</td>
<td>1 month</td>
<td>2 weeks</td>
</tr>
<tr>
<td>n of study</td>
<td>88</td>
<td>70</td>
<td>73</td>
</tr>
<tr>
<td>Recall period</td>
<td>1 month</td>
<td>1 month</td>
<td>1 week</td>
</tr>
<tr>
<td><strong>Age of participants</strong></td>
<td>47 – 62 years</td>
<td>45 – 57 years</td>
<td>41 – 61 years</td>
</tr>
<tr>
<td>Mean age at menopause</td>
<td>50.7 years</td>
<td>49.6 years</td>
<td>50.1 years</td>
</tr>
<tr>
<td>Time since menopause</td>
<td>2 – 7 years</td>
<td>1– 9 years</td>
<td>1 – 8 years</td>
</tr>
</tbody>
</table>
### Psychometric properties: Cronbach’s alpha

<table>
<thead>
<tr>
<th>Authors</th>
<th>Hilditch</th>
<th>Lewis</th>
<th>Gelfand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument</td>
<td>MENQOL</td>
<td>MENQOL</td>
<td>MENQOL-I</td>
</tr>
<tr>
<td>Vasomotor</td>
<td>0.82</td>
<td>0.88</td>
<td>0.77</td>
</tr>
<tr>
<td>Physical</td>
<td>0.87</td>
<td>0.89</td>
<td>0.88</td>
</tr>
<tr>
<td>Psycho-social</td>
<td>0.81</td>
<td>0.82</td>
<td>0.86</td>
</tr>
<tr>
<td>Sexual</td>
<td>0.89</td>
<td>0.86</td>
<td>0.72</td>
</tr>
</tbody>
</table>
## Test-retest: Intraclass Correlation Coefficients

<table>
<thead>
<tr>
<th>Authors</th>
<th>Instrument</th>
<th>Interval</th>
<th>Vasomotor</th>
<th>Physical</th>
<th>Psycho-social</th>
<th>Sexual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hilditch</td>
<td>MENQOL</td>
<td>28 days</td>
<td>0.37</td>
<td>0.81</td>
<td>0.79</td>
<td>0.70</td>
</tr>
<tr>
<td>Lewis</td>
<td>MENQOL</td>
<td>28 days</td>
<td>0.78</td>
<td>0.81</td>
<td>0.69</td>
<td>0.76</td>
</tr>
<tr>
<td>Gelfand</td>
<td>MENQOL-I</td>
<td>14 days</td>
<td>0.73</td>
<td>0.78</td>
<td>0.75</td>
<td>0.83</td>
</tr>
</tbody>
</table>
Other Further Development & Future Needs

- Reading Level-grade 6 English
- Missing data strategy 2005 paper
- Involvement in linguistic validation of translations

- More to follow in the Future?????
  - Normative data by item, domain, and subject status
  - clinic MENQOL use
  - strategies to improve reporting
  - ?????????
Translations with Linguistic Validation

Documented linguistic and cultural validation into:
- English for Canada, USA, UK, Australia, New Zealand
- Spanish for Spain, Mexico, Argentina, USA, Puerto Rico
- French for Canada, France, Belgium
- Portuguese for Brazil,
- Italian for Italy,
- German for Germany,
- Swedish for Sweden,
- Serbian for Serbia,
- Dutch for Netherlands
- Norwegian, Polish, Finnish, Danish

Literature suggests translations also done into many Asian and South Asian languages, Farsi, Arabic, Russian, Ukrainian, Switzerland, Czech republic, Greece Ukraine, Turkey, Nigeria, Spanish for Colombia, Ecuador & Chile,

These translations may all require additional formatting work to match the MENQOL official versions or to convert MENQOL to MENQOL-I or visa versa or to update an early version to be consistent with the Official 2005 MENQOL or MENQOL-I
Key Discussion Points

- 4 Official MENQOL questionnaires include 3 derivatives works

- Questionnaires differ only in the RECALL PERIOD and 3 items in the PHYSICAL DOMAIN

- Ensure you use the most helpful, appropriate questionnaire in your research

- The items in the questionnaire reflect the priority negative perceptions identified by women about their early postmenopausal experiences

- The Importance Score method should be considered for Quality of Life instrument development.

- Construct Validation by domain, although significantly correlated with the MENQOL scores, used available instruments in the early 90’s that frequently had less rigorous development than the MENQOL.

- Good Domain consistency and Reproducibility data exists from repeated data gathering and analysis over 3 separate trials for women aged 41-62 years who were 1-9 years post last menses
MENQOL: Conditions of Use

- Conditions of use available and detailed on PROQOLID (www.proqolid.org)

- Process:
  - Signature of a User Agreement for each study
  - Free access for Non-Funded Academic Users:
    - Easy and quick access to the MENQOL for Non-Funded Academic Users via Online Distribution process on PROQOLID
  - Payment of access fees if the MENQOL is used in:
    - Funded academic research
    - Commercial studies
  - When the process is completed, Mapi Research Trust delivers:
    - Needed language versions (if available)
    - Scoring instructions
The MENQOL is subject to copyright Copyright © 2005 Sunnybrook Health Sciences Centre. All rights reserved.

Sunnybrook Health Sciences Centre
- one of the largest hospitals in Canada
- Research and teaching hospital affiliated with the University of Toronto

Primary Care Research Unit (development of the MENQOL)
- Established in 1985
- Affiliated with the Department of Family & Community Medicine at U of T
- Research areas: wait times, cognitive function, intervention evaluation, family medicine practices
Ownership of the MENQOL

- Sunnybrook’s intellectual property policy requires that ownership of all intellectual property developed by hospital staff be assigned to the hospital
- Sunnybrook’s technology transfer office was not aware of the MENQOL until September 2011
- Confirmatory assignment of the MENQOL was made to Sunnybrook in December 2011
- In May, 2014 Sunnybrook’s right to license MENQOL for commercial purposes was confirmed by the journal Maturitas, where the MENQOL was first published
How to Access the MENQOL

- Centralization of information and language versions
- Licensing process
- Distribution
  handled by Mapi Research Trust on behalf of the MENQOL’s copyright holder
MENQOL: conditions of use

- For any questions on the MENQOL:
  - please visit on PROQOLID via our ePROVIDE platform (https://eprovide.mapi-trust.org)
Conclusion
Thank You!

Additional Questions? Ask our Webinar Hosts directly!

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