Quality of life of cardiac patients in Europe: HeartQoL Project
Stefan Höfer

The HeartQol Questionnaire: methodological and analytical approaches
Is quality of life important in cardiovascular care?

- Patients
- Treatment
- Survived
  - Good condition
  - HRQL
- Death
  - Worse condition
  - x% Mortality
  - Death

European Association for Cardiovascular Prevention & Rehabilitation (EACPR)
A Registered Branch of the ESC
Literature Consensus on HRQoL Instrument use?

• 10-year review of responsiveness of psychosocial instruments to cardiac rehabilitation interventions (1986-95)
  – 32 interventions; 21 ES calculable; 16 QoL instruments

  (McGee, Hevey & Horgan, 1999)

• Cochrane review of exercise rehabilitation
  – 11 RCTs; 18 QOL instruments

  (Jolliffe et al, 2001)

= not possible to draw useful QOL-related conclusions about instruments or findings
HeartQoL Project

“A single valid HRQL instrument will optimize between-diagnosis, within- or across-treatment comparisons & increase efficiency of clinical service providers and researchers when assessing patient-reported outcomes”

Oldridge N, et al. EJCPAR, 2005

Objective:

Using established and validated condition-specific HRQL instruments, develop a valid and reliable core HRQL instrument for use in patients with myocardial infarction, angina pectoris, or heart failure which often exist or evolve sequentially in the same patient over time
Criteria of HRQoL Instruments

• Conceptual and measurement model
• Reliability
• Validity
• Responsiveness
• Interpretability
• Alternative forms
• Respondent and administrative burden
• Objectivity
• Cultural and language adaptations
Conceptual & measurement model

QoL

HRQoL

Physical

Emotional

Social

Item 1
Item 2
Item 3

Item 1
Item 2
Item 3

Item 1
Item 2
Item 3

...
Reliability

• Is an instrument free from random error?
  – Internal consistency – the precision of a scale:
    • i.e.: Cronbach’s alpha
  – Reproducibility – stability over time:
    • i.e.: Test-retest reliability
Validity

• Does an instrument measure what it purports to measure?
  – Content-related:
    • Evidence that the domain of an instrument is appropriate relative to its intended use
  – Construct-related:
    • Evidence that supports a proposed interpretation of scores based on theoretical implications associated with the constructs being measured
  – Criterion-related:
    • Evidence that shows the extent to which scores of the instrument are related to a criterion measure
Criteria of HRQoL Instruments

✓ Conceptual and measurement model
✓ Reliability
✓ Validity
  • Responsiveness
  • Interpretability
  • Alternative forms
✓ Respondent and administrative burden
✓ Objectivity
✓ Cultural and language adaptations
Responsiveness

- Is an instrument able to detect change over time?
  - Evidence on the changes in scores of the instrument
  - Longitudinal data that compare a group that is expected to change with a group that is expected to remain stable
Interpretability

• Are the numbers produced easily understood?
  – Meaningful “benchmarks” to facilitate interpretation of the scores (“norms”)
  – ... Pre – post change ...
  – Clinical important difference
Valid disease-specific HRQL questionnaires used to develop a core IHD questionnaire

<table>
<thead>
<tr>
<th>MacNew MI Q</th>
<th>Seattle Angina Q</th>
<th>Minnesota Living with Heart Failure Q</th>
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<tr>
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<td>19 items</td>
<td>21 items</td>
</tr>
<tr>
<td>3 sub-scales:</td>
<td>5 sub-scales</td>
<td>2 sub-scales</td>
</tr>
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<td>Physical limitation</td>
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</tr>
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<td>Angina frequency</td>
<td>Sub-scale scores</td>
</tr>
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<td>Total score</td>
</tr>
<tr>
<td>Total Score</td>
<td>Disease perception</td>
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</tr>
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Sub-scale scores

Seattle Angina Q

Sub-scale scores

Minnesota Living with Heart Failure Q

Sub-scale scores

Total score
Valid disease-specific HRQL questionnaires used to develop a core IHD questionnaire

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49 items
What we did

• Item reduction from 49 item to as few as possible:
  – Clinical impact method
  – Mokken scaling
  – Item response theory
• Pre-testing the prototype instrument
• Decision about scoring method
• Determination of reliability
• Validation…
  – ...
  – ...
• Goal reached: one common metric in heart disease in Europe and the world
  – Primary analysis across the whole sample
Mokken Scaling

• Identifying items falling into a domain

• Ranking the items according to difficulty of endorsing

Easiest item to endorse

Most difficult item to endorse
Answer options
Eligibility

**PATIENT ELIGIBILITY**

______________________________ meets the eligibility criteria for this study.

*All 5 items need to be checked to be considered for clinical eligibility*

- More than 18 years of age
- No present substance abuse
- No serious psychotic disorder
- Able to complete the questionnaires in the appropriate language
- No hospitalization for MI or heart failure in last 6 weeks
Eligibility

Specifics of the PRIMARY current diagnosis

**MI**  [Must be between 4 weeks and 6 months post MI; meet at least 2 of the first 3 criteria]:

1. Chest discomfort  

2. ECG changes indicative of MI  
   [ST elevation ≥0.1mV in 2 or more limb leads  OR  
    ≥0.2mV in 2 or more contiguous precordial leads]

3. Positive CK-MB [≥ 2 X, or concentration >99% of reference group]  
   AND/OR  
   Troponin rise [concentration >99% of reference group]

4. Site:  
   - Anterior  
   - Posterior / Inferior  
   - Lateral
Eligibility

**Angina**
[Must meet each of the criteria]:

1. Current typical chest pain
2. Functional class [CCS or NYHA: see below]
3. Presence of CHD
   a. Positive non-invasive testing [exercise testing, stress echo, or nuclear imaging]
   b. Positive invasive testing [coronary angiography]

*New York Heart Association [NYHA] and Canadian Cardiovascular Society [CCS]*

- **II** Slight limitation of ordinary physical activity
- **III** Marked limitation of ordinary physical activity
- **IV** Inability to carry out any physical activity without discomfort; discomfort may be present at rest.
Eligibility

Heart failure  [Must meet each of the criteria]
1.  Dyspnea
   Major symptom if not dyspnea [describe]

2.  NYHA functional class [see page 1]
3.  LV ejection fraction <40%  [echo or left heart catheterization]
4.  Presence of CHD
   a.  Positive non-invasive testing
      [documented previous MI, exercise testing, stress echo, or nuclear imaging]
   b.  Positive invasive testing [coronary angiography]
HeartQoL Project: International

- **21 countries**
- **15 languages**
- **n= 6,249**

**EE:** Hungary, Poland, Russia, Ukraine
**NE:** Denmark, Norway, Sweden
**WE:** Austria, Belgium, France, Netherlands, Germany, Switzerland
**UK, Ireland**
**SE:** Portugal, Spain
**SE:** Italy

Australia; Canada; USA
Sample

- mi primary: 37.3%
- angina primary: 33.1%
- heartfailure primary: 29.6%

Age: 62.3±11.3

- mi primary: 59.7±11.4
- angina primary: 63.0±10.2
- heartfailure primary: 64.9±11.5
# HeartQoL patient profiles:
## International cohort summary

<table>
<thead>
<tr>
<th></th>
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<th>EuroAspire III</th>
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<tbody>
<tr>
<td>Age / % male</td>
<td>62.3 / 75%</td>
<td>61.9 / 73%</td>
</tr>
<tr>
<td>BMI</td>
<td>27.4</td>
<td>28.0</td>
</tr>
<tr>
<td>Smoking</td>
<td>15.1%</td>
<td>18%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>20.6%</td>
<td>28%</td>
</tr>
<tr>
<td><strong>Treated for</strong></td>
<td>90.1%</td>
<td><strong>35%</strong></td>
</tr>
<tr>
<td>Hypertension</td>
<td>55.4%</td>
<td>61%</td>
</tr>
<tr>
<td><strong>Treated for</strong></td>
<td>95.9%</td>
<td><strong>89%</strong></td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>59.6%</td>
<td>46%</td>
</tr>
<tr>
<td><strong>Treated for</strong></td>
<td>92.1%</td>
<td><strong>88%</strong></td>
</tr>
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</table>
2000 - 2010

- Data collection
- Item reduction
- Item analysis
- Item answering options

... the HeartQoL