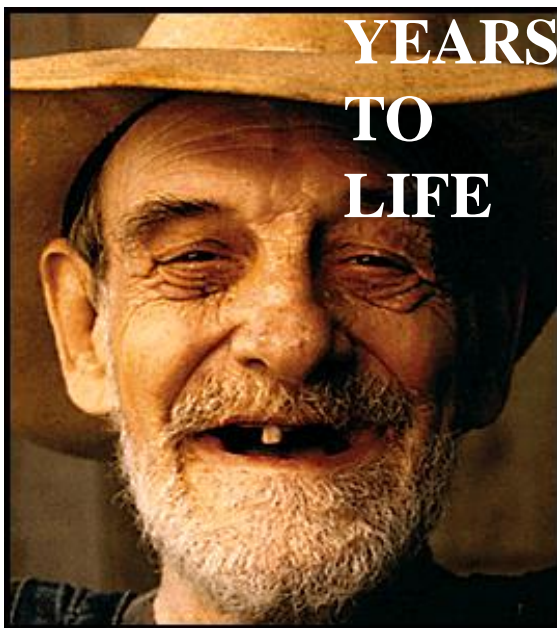
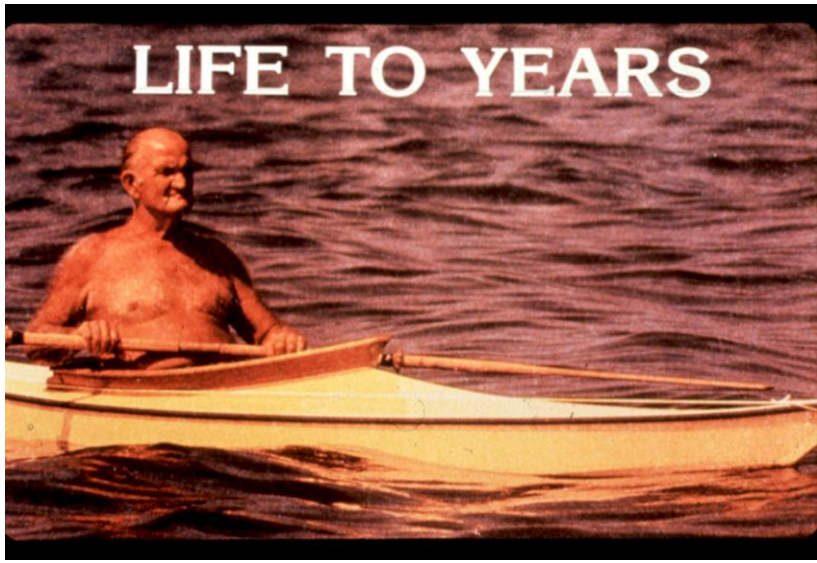


Today's health care ...



**With improved survival,
patients are living longer
but**





HeartQoL Project

**An international project to develop a
core specific HRQL questionnaire for patients
with ischaemic heart disease**

**European Association for Cardiovascular
Prevention and Rehabilitation**

European Society of Cardiology

European Health Psychology Society

PI: N. Oldridge, PhD, USA

Co-PI: H. Saner, MD, Switzerland; H. McGee, PhD, Ireland

Psychometricians: S. Höfer, PhD, Austria; R. Conroy, DSc & F. Doyle, PhD, Ireland

Ischemic heart disease & patient-reported outcomes

NHLBI & EMEA & FDA

PRO need to be considered in both clinical care and in relevant studies when evaluating treatment effectiveness

Krumholz H, et al. Circulation. 2005

Therapeutic objectives of treatment include

- **Maintain and**
- **Improve health-related quality of life [HRQL]**

Generic HRQL instruments

- **Across diseases; Broad; Items not always relevant**

Specific HRQL instruments

- ***Disease-specific; Focussed: Items relevant***

Specific IHD HRQL questionnaires

Major weakness

Cross-diagnosis HRQL comparisons within a condition is not possible using any one condition-specific questionnaire

Core IHD-specific questionnaire

Sufficiently generalizable, with adequate specificity, would permit within-IHD, across-diagnosis comparisons

Core HRQL questionnaires

Oncology

EORTC

1993

Aaronson NK, et al.. J Natl Cancer Inst.

FACT

Cella DF, et al. J Clin Oncol. 1993

Rheumatology

OMERACT

Bellamy N, et al.. J Rheum, 1997

The HeartQoL Questionnaire ?

Introducing a common core health-related quality of life instrument

Neil Oldridge, PhD;
Clinical Professor of Medicine
School of Medicine & Public Health,
University of Wisconsin, Madison; &
Director, Cardiology Fellowship Research and
Research Scientist
Aurora Cardiovascular Services,
Aurora Medical Group, Milwaukee, Wisconsin



**If at first you don't succeed,
Try and try again**

HeartQoL Project Plan

HRQL: at least physical, emotional and social domains

Seattle Angina Questionnaire **n= 9**

Minnesota Heart Failure Questionnaire **n= 13**

MacNew Heart Disease Questionnaire **n= 27**

Item reduction from 49 items to a smaller number

- **Clinical impact method**
- **Mokken Scaling**

Clinical impact method: “clinical sensibility”

Feinstein A, Clinimetrics, 1982

The following symptoms, activity limitations, and feelings may be associated with your heart disease.

First, in the last 3 months, have you been **bothered** by .. ?

	Yes	No
1. Being frustrated		
2. Feeling worthless or inadequate		
3. Not being confident about your heart problem		

If yes, check how much:

little					very
1	2	3	4	5	

frequency x **bothersomeness**
= **Clinical Impact Score**

Juniper E, et al. J Clin Epi, 1997

Final Candidate Item Pool

Using a clinical impact score ≥ 1.00

3 domains Physical

Emotional

Social

49 candidate items for Mokken analysis

Seattle Angina Questionnaire n= 9

Minnesota Heart Failure Questionnaire n= 13

MacNew Heart Disease Questionnaire n= 27

Seattle Angina Q items [n=5/13]; Clinical impact score ≥ 1.00

Impact score [0 – 5]	Indicate how much limitation you have had:
2.55	Participate in strenuous sports? Not common
2.53	Running or jogging
2.22	Lifting or moving heavy objects?
1.72	Walking more than 100 metres/yards at a brisk pace?
1.60	Climbing a hill or a flight of stairs without stopping ?
1.40	Gardening, vacuuming, carrying groceries?

Added 1 SAQ physical performance item with low impact score:

0.27 Walking indoors on the level



Minnesota Living with Heart Failure Q items [n=9/13]; Clinical impact score ≥ 1.00

Impact score [0 – 5]	Preventing you from living as you wanted by:
1.93	Feeling tired, fatigued, low on energy?
1.56	Feeling short of breath?
1.45	Climbing a flight of stair? In SAQ
1.45	Having to sit or lie down during the day?
1.40	Making sleeping at night difficult?
1.33	Feeling worried?
1.18	Making work around the house or yard difficult?
1.09	Making concentrating or remembering difficult?
1.04	Feeling depressed?

MacNew Q items [n=15/27]; Clinical impact score ≥ 1.00

Impact score [0 – 5]	Questions about how you have been feeling
2.03	Limited in doing sports or exercise?
1.70	Worn out? In MHLF
1.63	Physically restricted?
1.40	Restricted or limited?
1.63	Short of breath? In MHLF
1.40	Problems with sexual life?
1.38	Unsure about how much to exercise?
1.38	Have aching legs?
1.29	Relaxed and free of tension?
1.23	Confident and sure?
1.23	Have chest pain?
1.22	Frustrated, impatient, angry?
1.13	Discouraged and down in the dumps In MHLF
1.07	Pleased with personal life?
1.00	Dizzy or lightheaded?

Mokken scale analysis

A stepwise, nonparametric scale building method

Meijer RR, Baneke JJ. *Psych Methods*, 2004

- Clusters sets of items from a candidate item pool **[n=25]**

Seattle Angina Questionnaire	n= 5 /9
Minnesota Heart Failure Questionnaire	n= 8 /13
MacNew Heart Disease Questionnaire	n= 12 /27

- Identifies items which best form a scale conforming to Guttman's internal consistency criteria
- Items and scales with H value ≥ 0.50 are considered strong

HeartQoL Mokken analysis results [1]

Have you been bothered by ?

Impact score	Physical domain items in HeartQoL Seattle Minnesota MacNew	H value ≥ 0.50
0.26	Walking indoors on the level	0.52
1.10	Working around house or yard difficult	0.57
1.39	Gardening, vacuuming, or carrying groceries	0.61
1.56	Feeling short of breath	0.53
1.59	Climbing a hill or a flight of stairs not stopping	0.57
1.63	Being physically restricted	0.52
1.71	Walking more than 100 m at a brisk pace	0.59
1.94	Feeling tired, fatigued, low on energy	0.55
2.03	Being limited in doing sports or exercise	0.50
2.25	Lifting or moving heavy objects	0.54

Scale H = 0.55

HeartQoL Mokken analysis results [1]

Have you been bothered by ?

Impact score	Emotional domain items in HeartQoL Seattle Minnesota MacNew	H value ≥ 0.50
1.05	Feeling depressed	0.57
1.26	Being frustrated, impatient, angry	0.51
1.31	Not feeling relaxed and free of tension	0.51
1.35	Being worried	0.56

Scale H = 0.54

HeartQoL Questionnaire in Patients with Ischaemic Heart Disease

14-item HeartQoL heart disease-specific HRQL questionnaire with a **Global score:**

10 physical function items [H = 0.55]

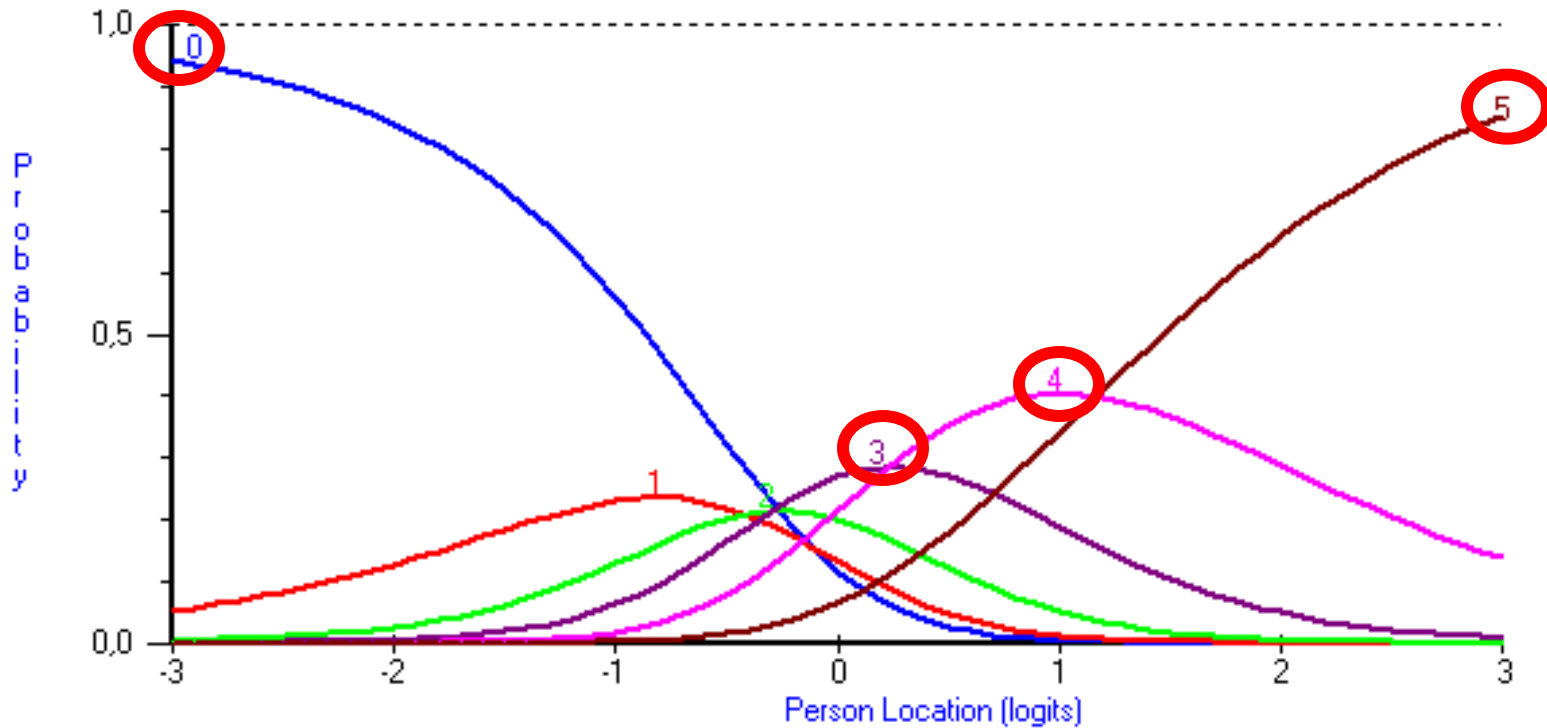
4 emotional function items [H = 0.54]

Propose 2 SF-36 items [not included in HeartQoL score]

In general, would you say your health is ... ?

Compared to one year ago, how would you rate your health in general now?

Answer options based on IRT



4 option scale

HeartQoL Questionnaire in Patients with Ischaemic Heart Disease

14-item HeartQoL heart disease-specific HRQL
questionnaire with a **Global score:**

10 physical function items

4 emotional function items

All H \geq 0.50

Interim psychometrics:

Test-retest reliability [Cronbach's α]

r= 0.88

Discriminative validity

Anxiety & depression: yes vs no

p<0.001

SF-36: health improve vs worse

p<0.001



HeartQoL

Thank you for addressing these questions that will give us an understanding of how your heart problem has affected you.

2 domains

Physical

Items 1 – 10

Emotional

Items 11 - 14

HeartQoL Project: final step

**Do not have responsiveness data in
HeartQoL Project**

Test **reliability, validity and responsiveness of the
prototype HeartQoL
in an international setting with**

- ***Revascularization***
- ***Rehabilitation***