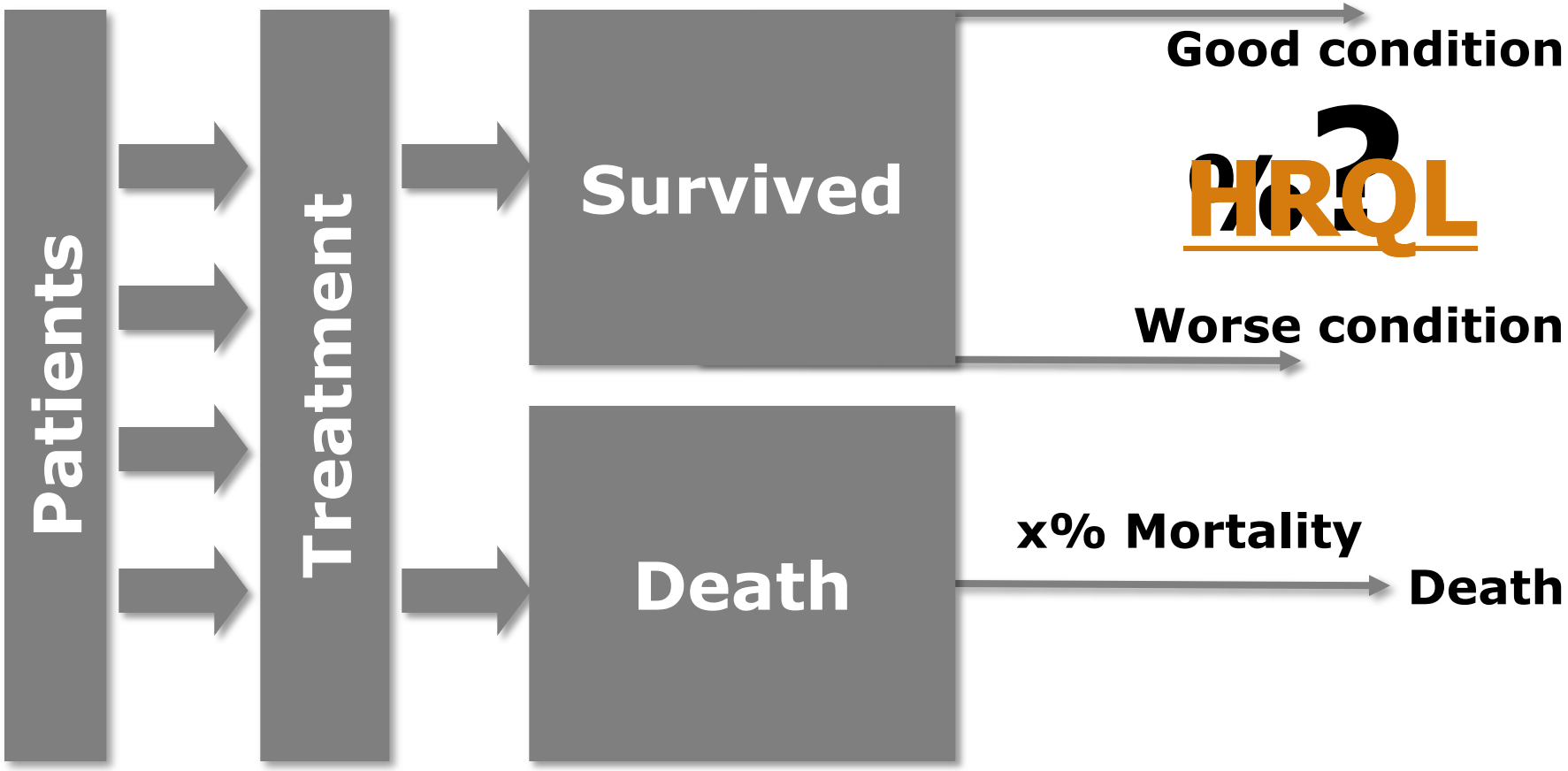
Quality of life of cardiac patients in Europe: HeartQoL Project

Stefan Höfer

The HeartQol Questionnaire:
methodological and analytical approaches

Is quality of life important in cardiovascular care?



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. EJCPR, 2005

Objective:

Using established and validated condition-specific HRQL instruments, develope a

valid and reliable core HRQL instrument

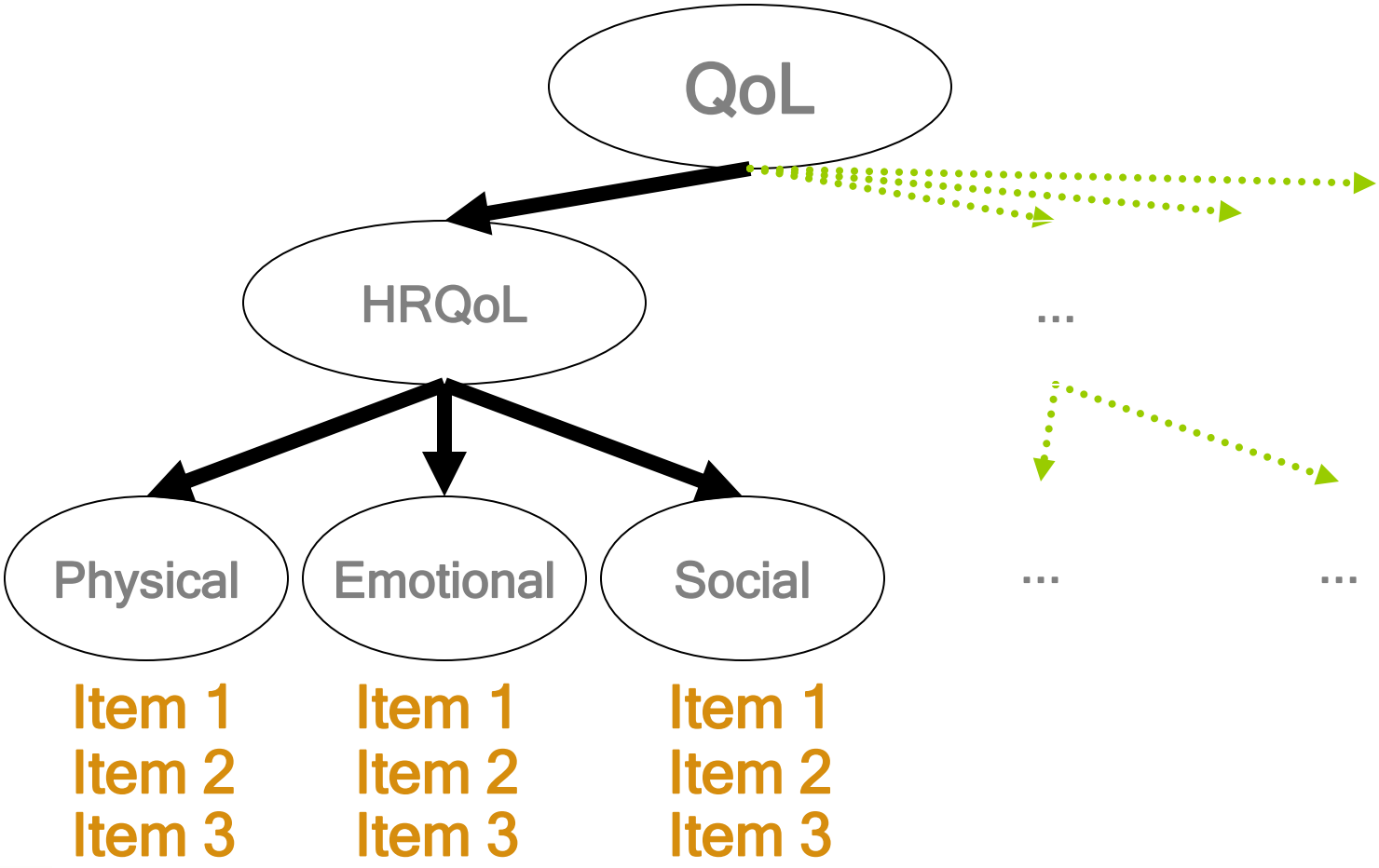
for use in patients with myocardial infarction, angina pectoris, or heart failure which often exist or evolve sequentially in the same patient over time

Criteria of HRQoL Instruments

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

Scientific Advisory Board, Quality of life Resaerch, 2002

Conceptual & measurement model



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

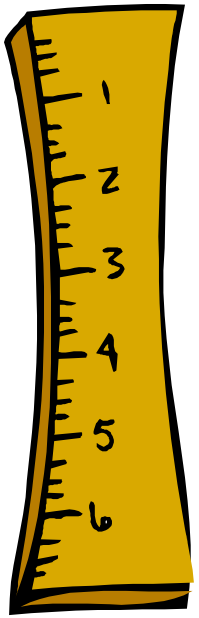
Scientific Advisory Board, Quality of life Resaerch, 2002

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

MacNew MI Q

27 items

3 sub-scales:

Physical

Social

Emotional

Sub-scale scores

Total Score

Seattle Angina Q

19 items

5 sub-scales

Physical limitation

Angina stability

Angina frequency

Treatment satisfaction

Disease perception

Sub-scale scores

Minnesota Living with Heart Failure Q

21 items

2 sub-scales

Physical

Emotional

Sub-scale scores

Total score

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Physical

Emotional

Sub-scale scores

Total score

49 items

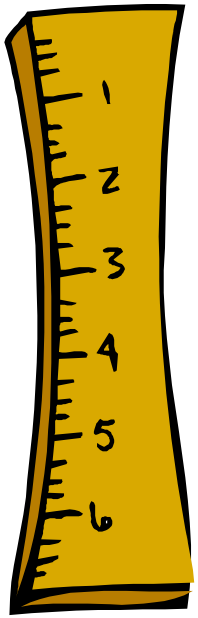
What we did

- 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

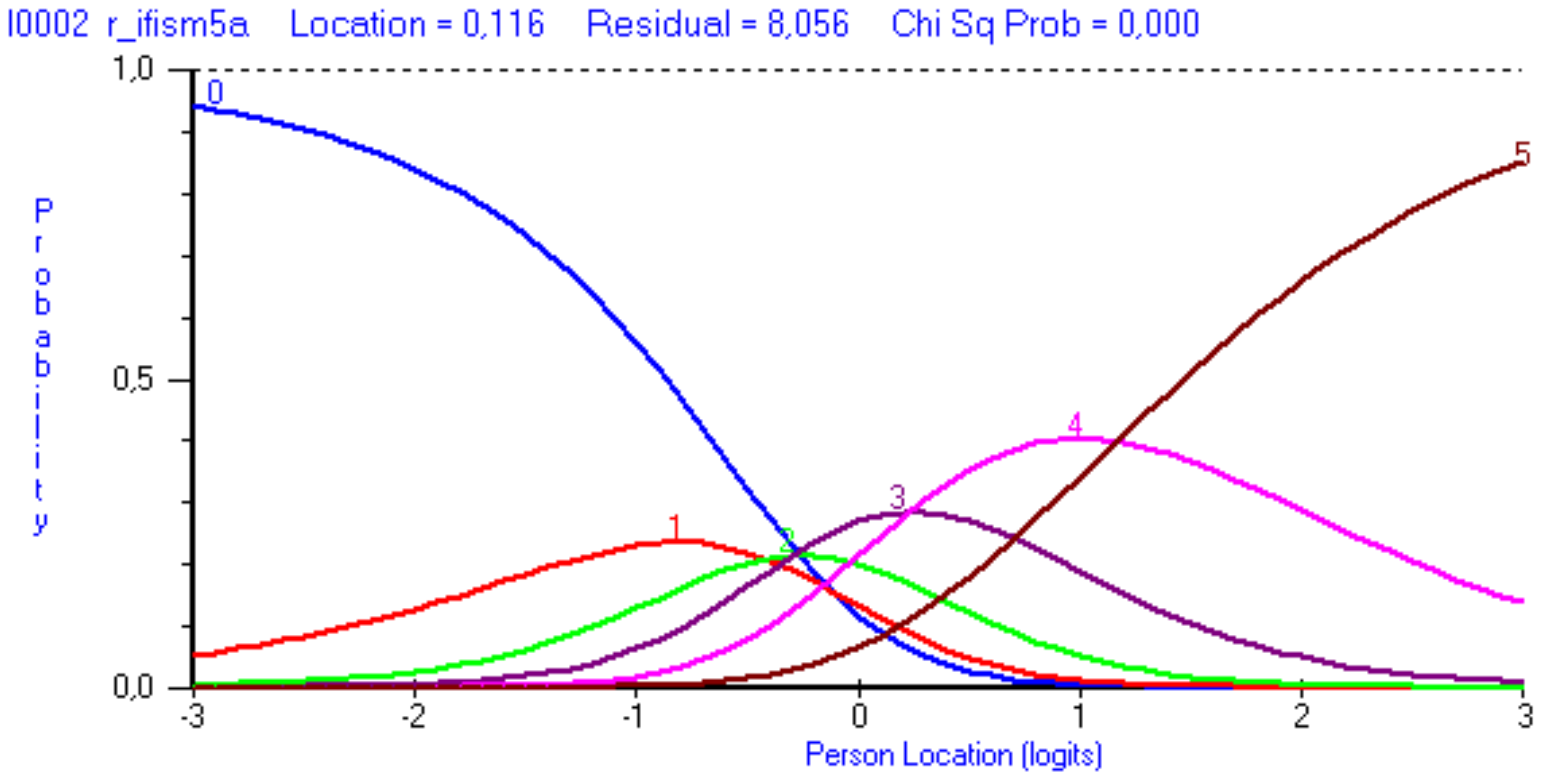
- Identifying items falling into a domain
- Ranking the items according to difficulty of endorsing

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] ❑ II ❑ III ❑ IV
3. Presence of CHD
   a. Positive non-invasive testing [exercise testing, stress echo, or nuclear imaging] ❑ AND/OR
   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.

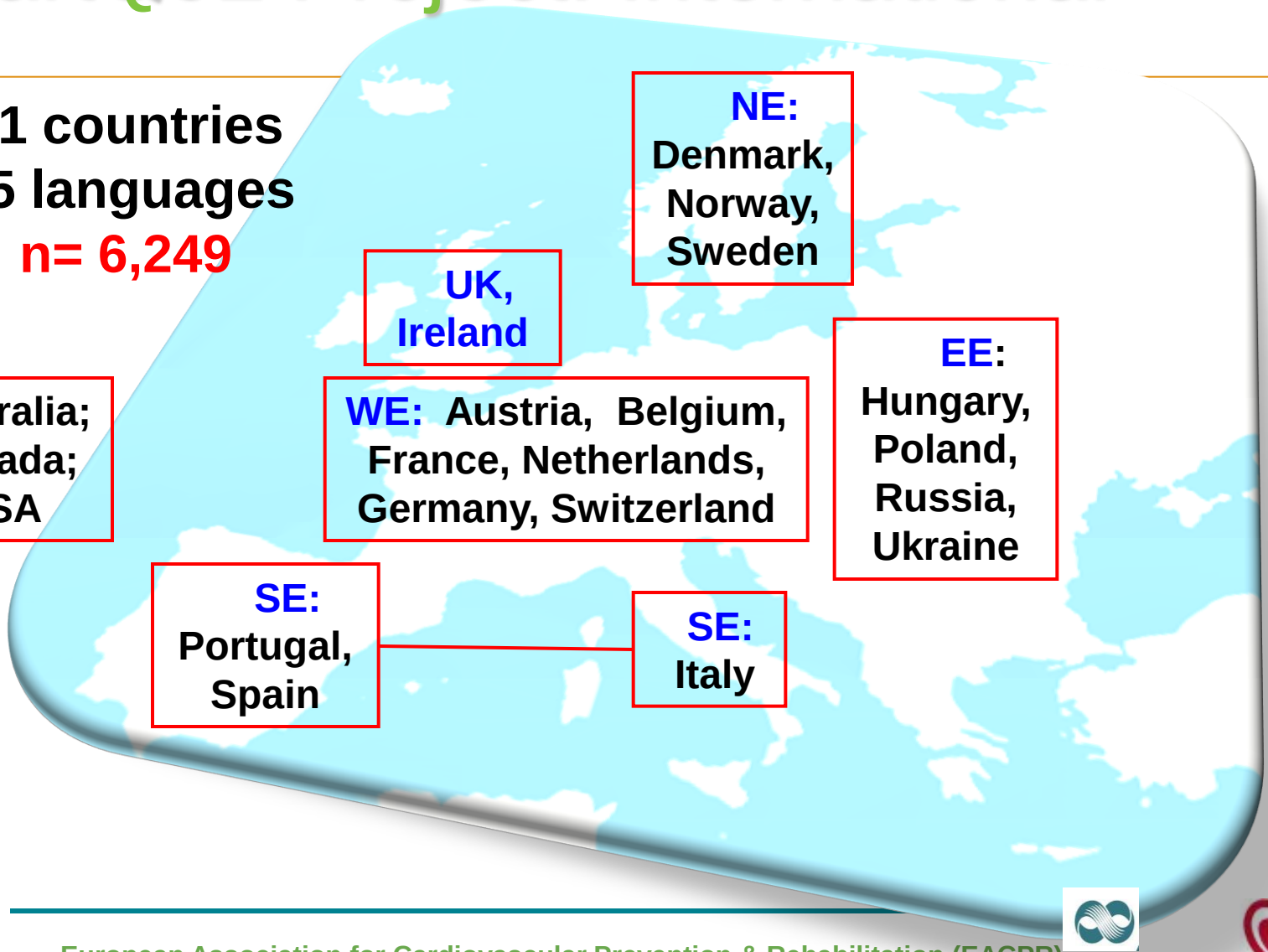
Eligibility

Heart failure [Must meet each of the criteria]

1. Dyspnea ❑
   Major symptom if not dyspnea [describe]_____
   _____
2. NYHA functional class [see page 1] ❑ II ❑ III ❑ IV
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] ❑ AND/OR
   b. Positive invasive testing [coronary angiography] ❑

HeartQoL Project: International

21 countries
15 languages
n= 6,249



NE: Denmark, Norway, Sweden

UK, Ireland

EE: Hungary, Poland, Russia, Ukraine

Australia; Canada; USA

WE: Austria, Belgium, France, Netherlands, Germany, Switzerland

SE: Portugal, Spain

SE: Italy

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

	HeartQoL	EuroAspire III
Age / % male	62.3 / 75%	61.9 / 73%
BMI	27.4	28.0
Smoking	15.1%	18%
Diabetes	20.6%	28%
Treated for	*90.1%*	*35%*
Hypertension	55.4%	61%
Treated for	*95.9%*	*89%*
Hypercholesterolemia	59.6%	46%
Treated for	*92.1%*	*88%*

2000 - 2010

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

- ... the HeartQoL