DEVELOPING AN OUTCOME MEASURE FOR USE IN ECONOMIC EVALUATION SPANNING HEALTH AND SOCIAL CARE

EXTENDING THE QALY PROJECT (E-QALY PROJECT)

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Motivation for developing a new instrument

- Address limitations with standard HR-QALY
  - too narrow
  - misses important quality of life aspects for carers, social care users, & those with long-term conditions

- Multiple QALY measures used across sectors (EQ-5D, ASCOT, Carer-QoL) - comparability and aggregation problems
Focus of new instrument

1. Reflect impact of health and social care interventions on
   • physical and mental health
   • broader quality of life
   • judged to be important by service users and those impacted by interventions such as informal carers

2. Amenable to
   • generating a long-version of the measure & a preference-based index
   • being included in clinical trials and routine surveys
   • being used internationally

E-QALY project
Extending the QALY project partners

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Funders
- EuroQol Research Foundation
- NIHR CLAHRC
- UK Medical Research Council (MRC)

Governance & consultation groups
- EuroQol Research Foundation
- Advisory Group academics, wide range stakeholders
- Steering Group key stakeholders & academics
- Public Involvement Group N=7
- NICE Citizen’s Council

E-QALY project
Stage I: Identify Domains / Themes

Stage II: Generate long list of items (~100 items)

Stage III: Face validity interviews

Stage IV: Psychometrics

Stage V: Valuation
TTO (Time trade off), DCE and deliberative exercises

Stage VI: Impact
Possible mapping. Impact on existing cost effectiveness studies

Replicated in 5 countries:
- Argentina
- Australia
- China
- Germany
- USA

Consultations:
Items for long measure and classifier

Future work: Validity
E-QALY project
Stage 1: Qualitative literature review

- Aim: to identify potential domains for the new measure:
  - "Based on the voice of adult (aged 18 years and over) patients, social care users and carers what is the impact on **quality of life and wellbeing** of health conditions and interventions (health, social care and public health interventions)?"

- Best reflected in qualitative research
- Mostly from Europe, USA, Canada, Australia, New Zealand
Working conceptual model – a starting point for the review

**Conditions:**
- Biological and physiological variables
- Caring role
- Health or social care treatment or self-management

**Physical symptoms or impairment**
- Functioning & Activity
  - Mental symptoms or impairment
  - Social connections
  - Daily circumstances (caring hours, treatment regime e.g. time at hospital)

**Social judgements**
- Measure of Health, social care and carer-related quality of life

**Expectations, adaptation, response shift**

**Individual environment.**
- Social Environment.
- Personality.
Identification of evidence – systematic searching across four arms

1. Qualitative reviews of sample of 17 health conditions
2. Qualitative reviews of carers + measures
3. Qualitative reviews of social care users + measures
4. Qualitative work in development of generic measures

Analysis

Framework analysis using modified model of health and QoL (Wilson and Cleary)
Conceptual model used to develop extraction framework
Thematic analysis to develop themes and sub-themes

Consultation

Consultation at all stages with wider team and governance groups
Revised themes and sub-themes

E-QALY project
EXTENDING THE QALY INSTRUMENT DOMAINS & SUB-DOMAINS

Feelings and emotions:
- Sadness (depressed) / Happiness
- Hopeless / hope
- Worry (anxiety) / calm
- Vulnerable / safe
- Anger / frustration
- Self-care
- Enjoyable or Meaningful activity / roles
- Vision
- Hearing
- Communication / speech
- Mobility
- Treated with dignity / respect
- Self-worth / self-respect
- Autonomy & Control
- Coping
- Loneliness
- Support
- Stigma
- Belonging / connectedness
- Positive relationships & Friendship & social engagement
- Pain
- Discomfort
- Sleep problems
- Fatigue
- Memory
- Concentration
- Thinking clearly & Decision making

Activity:
- Autonomy & Control
- Coping
- Loneliness
- Support
- Stigma
- Belonging / connectedness
- Positive relationships & Friendship & social engagement
- Pain
- Discomfort
- Sleep problems
- Fatigue
- Memory
- Concentration
- Thinking clearly & Decision making

Self-identity:
- Autonomy & Control
- Coping
- Loneliness
- Support
- Stigma
- Belonging / connectedness
- Positive relationships & Friendship & social engagement
- Pain
- Discomfort
- Sleep problems
- Fatigue
- Memory
- Concentration
- Thinking clearly & Decision making

Self-care:
- Autonomy & Control
- Coping
- Loneliness
- Support
- Stigma
- Belonging / connectedness
- Positive relationships & Friendship & social engagement
- Pain
- Discomfort
- Sleep problems
- Fatigue
- Memory
- Concentration
- Thinking clearly & Decision making

Relationships:
- Autonomy & Control
- Coping
- Loneliness
- Support
- Stigma
- Belonging / connectedness
- Positive relationships & Friendship & social engagement
- Pain
- Discomfort
- Sleep problems
- Fatigue
- Memory
- Concentration
- Thinking clearly & Decision making

Physical sensations:
- Autonomy & Control
- Coping
- Loneliness
- Support
- Stigma
- Belonging / connectedness
- Positive relationships & Friendship & social engagement
- Pain
- Discomfort
- Sleep problems
- Fatigue
- Memory
- Concentration
- Thinking clearly & Decision making

Cognition:
- Autonomy & Control
- Coping
- Loneliness
- Support
- Stigma
- Belonging / connectedness
- Positive relationships & Friendship & social engagement
- Pain
- Discomfort
- Sleep problems
- Fatigue
- Memory
- Concentration
- Thinking clearly & Decision making

E-QALY project
Stage II: Item generation

- Drew on terminology from qualitative review
- Existing measures and item banks (n=687), plus new items where gaps
- Sifted through potential items using agreed criteria

Challenges:
- Identifying items that work in a generic context
- Identify items that convey construct without too much information (preference-elicitation in mind)

Result: over 90 items for face validation
Stage III: Face validation

- Test the content and face validity of the proposed domains and draft set of >90 items using a standardised protocol.
- Semi-structured cognitive interviews conducted with people reporting physical and mental health conditions, carers and social care users.
- Response options (frequency, severity, difficulty, agreement) were tested.
- Items were translated into Spanish, Chinese and German using forward and back translation (with input from international teams).
- Spreadsheet used to indicate item performance and any issues.

Resulted in some elimination, modifications and additional items leaving 62 items for the next stage.
Stage IV: Psychometric testing

- 62 item pool administered to patients, social care users, carers and general population from 6 countries
- Recruited in NHS in UK and (n=627) and online across all 6 countries (UK=2000; the rest 500-900)
- Factor analysis (EFA/CFA), Classical testing (missing data, distribution of responses, known group differences), and IRT

Generally difficult to identify poor performing items on the basis of classical psychometric results
Confirmatory factor analysis

Bifactor model separately accounting for positive and negative. Confirmed in most countries apart from China.

NB: Vision, hearing/communication, sleep and discomfort not included
Consultations on domains and item selection

Consultation used summary of face validity & psychometric evidence from the 6 countries

Participants: Advisory group, EuroQol group, international stakeholders, public involvement group in UK

Consultation 1) Long version: 25 items from 62 item pool, with at least one item for each sub-domain

Consultation 2) Classifier: 7-10 items from 25 item long version of measure
EQ-HWB Long form (25 items)

These questions are trying to measure how your life has been over the last 7 days:

**In the last 7 days:**

1. How difficult was it for you to see (using, for example, glasses or contact lenses if they are needed)?
2. How difficult was it for you to hear (using hearing aids if you usually wear them)?
3. How difficult was it for you to get around inside and outside (using any aids you usually use e.g. walking stick, frame or wheelchair)?
4. How difficult was it for you to do day-to-day activities (e.g. working, shopping, housework)?
5. How difficult was it for you to wash, toilet, get dressed, eat or care for your appearance?

**Vision**

**Hearing**

**Mobility**

**Daily activities**

**Self-Care**

**Enjoyable activities**

**In the last 7 days:**

19. I felt accepted by others e.g. feeling like you are able to be yourself and that you belong
20. I felt good about myself
21. I could do the things I wanted to do

**In the last 7 days:**

22. I had physical pain?
23. Please tick one box to describe your experience in the last 7 days:
   - I had no physical pain
   - I had mild physical pain
   - I had moderate physical pain
   - I had severe physical pain
   - I had very severe physical pain

**Control**

**Coping**

**Memory**

**Concentrating/thinking clearly**

**Frustrated**

**Sad/depressed**

**Anxious**

**Hopeless**

**Unsafe**

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EQ-HWB Short form 9-item descriptive system

These questions are trying to measure how your life has been over the last 7 days.

### In the last 7 days:

<table>
<thead>
<tr>
<th>Question</th>
<th>No difficulty</th>
<th>Slight difficulty</th>
<th>Some difficulty</th>
<th>A lot of difficulty</th>
<th>Unable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How difficult was it for you to get around inside and outside (using any aids you usually use e.g., walking stick, frame or wheelchair)?</td>
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</tr>
<tr>
<td>2. How difficult was it for you to do day-to-day activities (e.g., working, shopping, housework)?</td>
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</tbody>
</table>

### In the last 7 days:

<table>
<thead>
<tr>
<th>Question</th>
<th>None of the time</th>
<th>Only occasionally</th>
<th>Some of the time</th>
<th>Often</th>
<th>Most or all of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Felt unable to cope with my day-to-day life</td>
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<td>4. I had trouble concentrating/thinking clearly</td>
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<td>5. I felt anxious</td>
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<td>6. I felt sad/depressed</td>
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<td>7. I felt lonely</td>
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<td>8. I felt exhausted</td>
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</tbody>
</table>

9. Please tick one box to describe your experience in the last 7 days:
   - I had no physical pain
   - I had mild physical pain
   - I had moderate physical pain
   - I had severe physical pain
   - I had very severe physical pain

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Strengths and limitations

**Strengths**

• Rigorous methods to identify domains/sub-domains and items with valuation in mind from the start

• Extensive consultation with stakeholders at all stages (PHE, DHSC, NICE, service users)

• Pool of items, long measure and classifier (experimental measures) covering a broad range of domains for use across sectors

**Limitations**

• Further psychometric testing of items needed – e.g. responsiveness, recruited more beyond online (currently only n=627)

• Need to be understand how it compared to existing measures
Stage V: Valuation and next steps

- Pilot valuation using EQ-PVT v2 – qualitative (n=15) (resulted in some minor modifications)
- 25 items version and 9-item classifier agreed
- Name: EQ-HWB – agreed.

Next steps:
- Further pilot valuation – quantitative (n=50)
- Full valuation study in UK (n=460) with 7 TTO and 6 DCE or 12 (?) TTO only depending on results of pilot
- DCE with duration – mixed methods exploratory study (PhD)
Many thanks!

Project Website: https://scharr.dept.shef.ac.uk/e-qaly/project-updates/