

**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

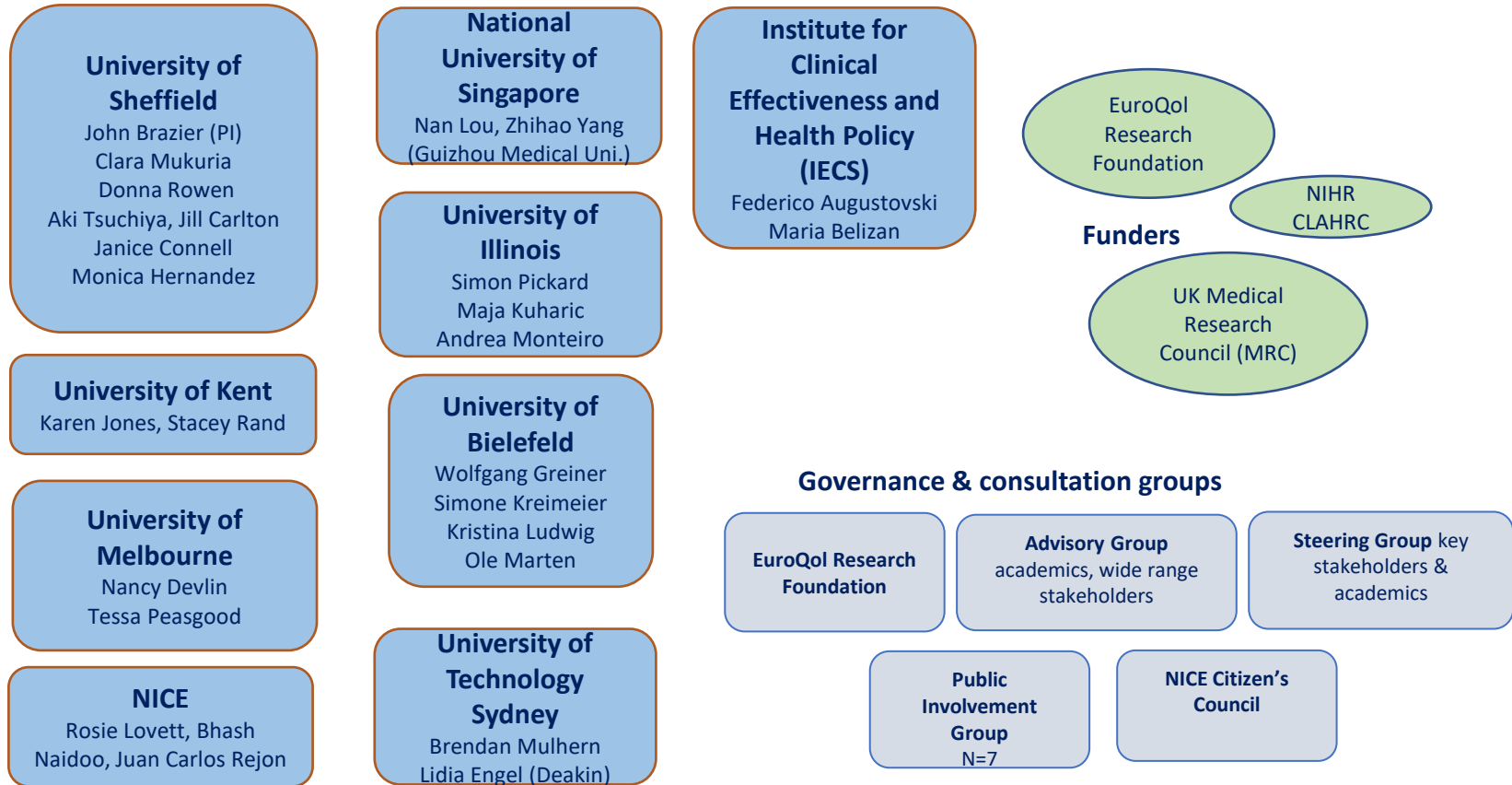
1. Reflect impact of health and social care interventions on

- **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

Extending the QALY project partners



Project timetable – completed stages in green

Stage I: Identify Domains / Themes

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

Stage III: Face validity interviews

Replicated in 5
countries

Stage IV: Psychometrics

Argentina
Australia
China
Germany
USA

Stage V: Valuation

TTO (Time trade off), DCE and deliberative exercises

Consultations:
Items for long
measure and
classifier

Stage VI: Impact

Possible mapping. Impact on existing cost effectiveness studies

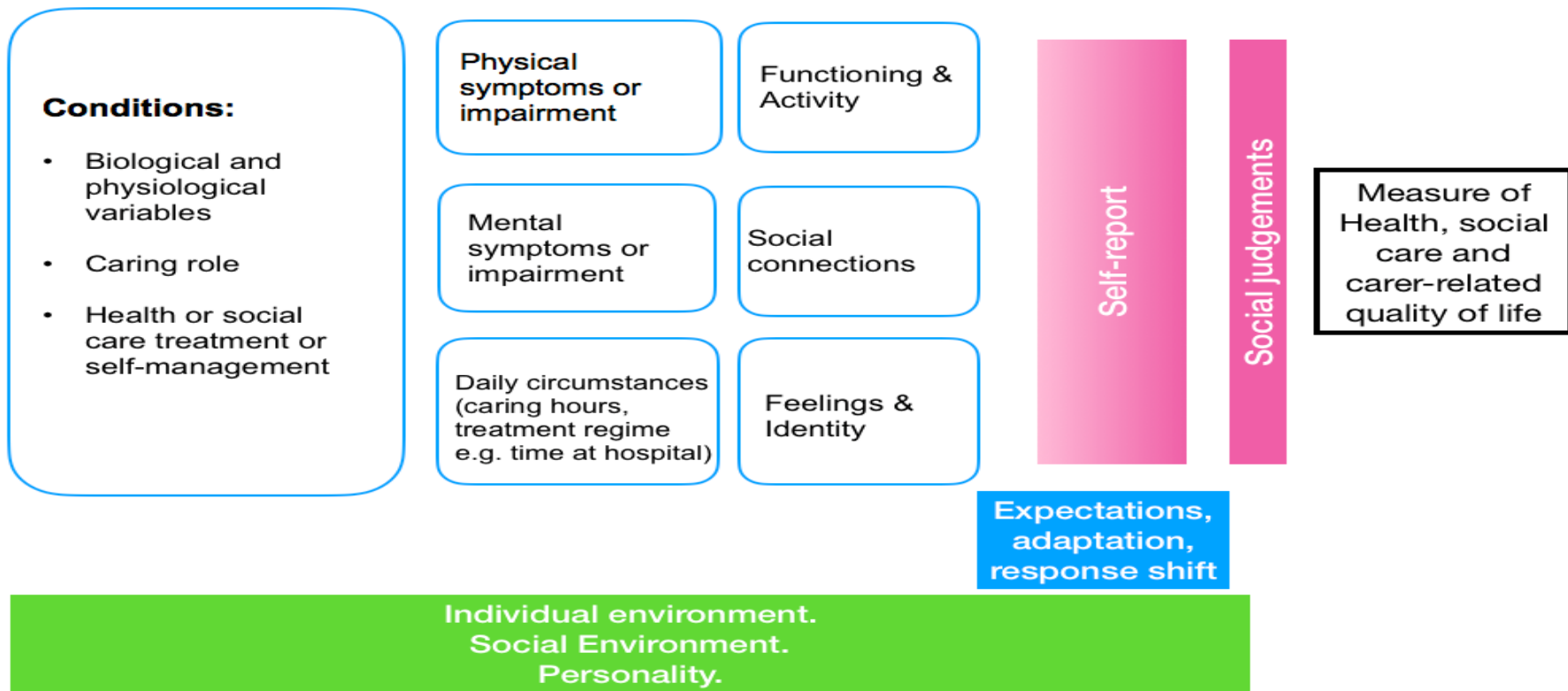
Future work: Validity

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



Identification of evidence – systematic searching across four arms

1. Qualitative reviews of sample of 17 health conditions

2. Qualitative reviews carers + measures

3. Qualitative reviews 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

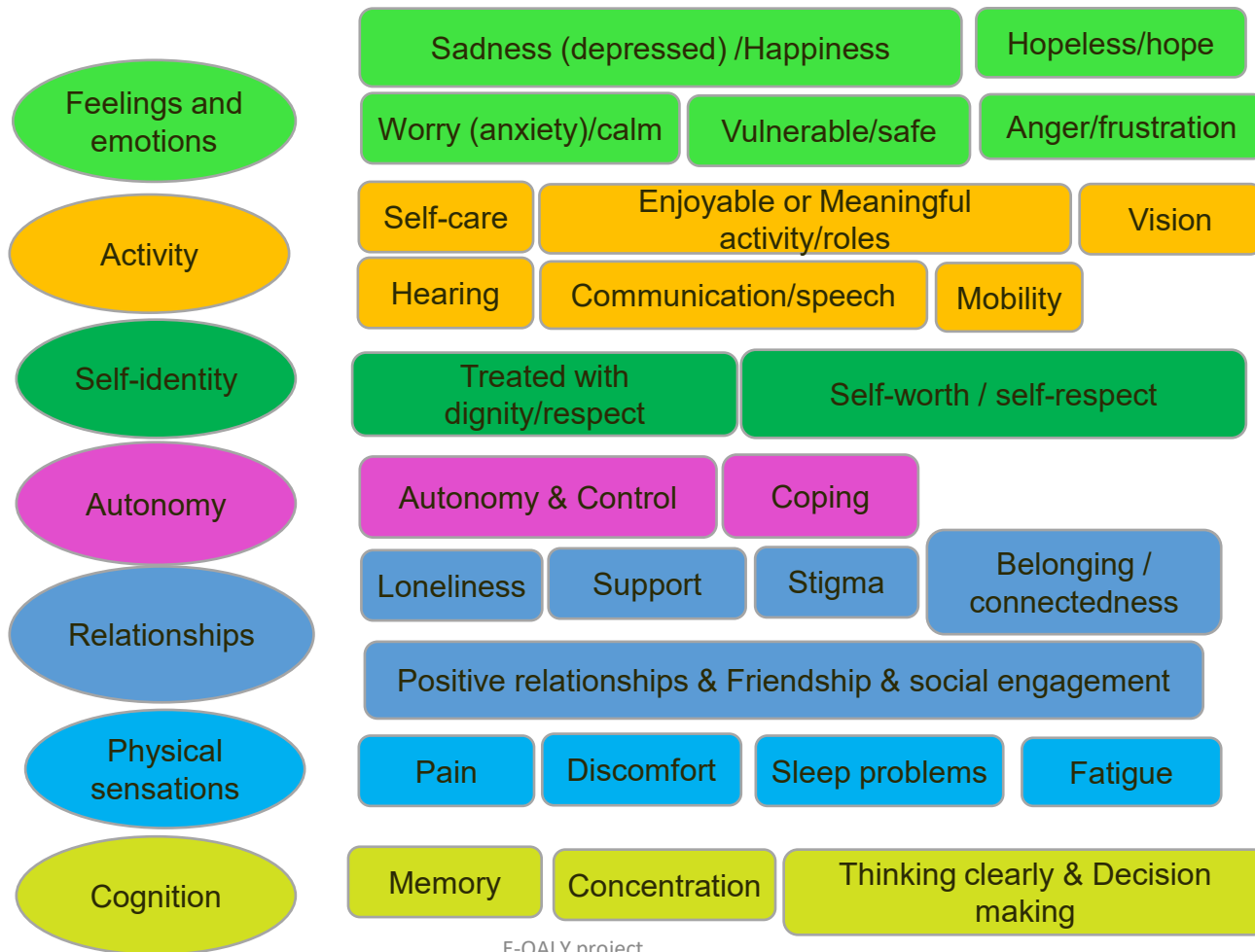
Thematic analysis to develop themes and sub-themes

Consultation

Consultation at all stages with wider team and governance groups

Revised themes and sub-themes

Extending the QALY instrument domains & sub-domains



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

Extending the QALY instrument sub-domains - profile

Sadness (depressed) / Happiness

Hopeless/hope

Worry (anxiety)/calm

Vulnerable/safe

Anger/frustration

Self-care

Enjoyable or Meaningful
activity/roles

Mobility

Self-worth / self-respect

Autonomy/Control

Coping

Relationships – loneliness,
support, stigma, belonging,
positive relationships

Pain

Fatigue

Cognition – concentration,
thinking clearly, memory

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**:

	No difficulty	Slight difficulty	Medium difficulty	Some difficulty	Very difficult
1. How difficult was it for you to see (using, for example, glasses or contact lenses if they are needed)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. How difficult was it for you to hear (using hearing aids if you usually wear them)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. How difficult was it for you to do day-to-day activities (e.g. working, shopping, housework)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How difficult was it for you to wash, toilet, get dressed, eat or care for your appearance?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Vision
Hearing
Mobility
Daily activities
Self-Care
Enjoyable activities

In the **last 7 days**:

	None of the time	Only occasionally	Some of the time	Often	Most or all of the time
19. I felt accepted by others e.g. feeling like you are able to be yourself and that you belong	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I felt good about myself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. I could do the things I wanted to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Self-worth

In the **last 7 days**:

	None of the time	Only occasionally	Some of the time	Often	Most or all of the time
22. I had physical pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Please tick one box to describe your experience in the last 7 days:					
I had no physical pain		<input type="checkbox"/>			
I had mild physical pain		<input type="checkbox"/>			
I had moderate physical pain		<input type="checkbox"/>			
I had severe physical pain		<input type="checkbox"/>			
I had very severe physical pain		<input type="checkbox"/>			

	None of the time	Only occasionally	Some of the time	Often	Most or all of the time
24. I had physical discomfort e.g. feeling sick, dizziness, or tiredness (not including pain)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Please tick one box to describe your experience in the last 7 days:					
I had no physical discomfort		<input type="checkbox"/>			
I had mild physical discomfort		<input type="checkbox"/>			
I had moderate physical discomfort		<input type="checkbox"/>			
I had severe physical discomfort		<input type="checkbox"/>			
I had very severe physical discomfort		<input type="checkbox"/>			

Control
Coping
Memory
Concentrating/ thinking clearly
Frustrated
Sad/depressed
Anxious
Hopeless
Unsafe

Loneliness
Support
Stigma/belonging
Pain
Discomfort
Sleep
Fatigue

EQ-HWB Short form 9-item descriptive system

Domains/ sub-domains

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

*In the **last 7 days**:*

	No difficulty	Slight difficulty	Some difficulty	A lot of difficulty	Unable
1. How difficult was it for you to get around inside and outside (<i>using any aids you usually use e.g. walking stick, frame or wheelchair</i>)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. How difficult was it for you to do day-to-day activities (<i>e.g. working, shopping, housework</i>)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*In the **last 7 days**:*

	None of the time	Only occasionally	Some of the time	Often	Most or all of the time
3. felt unable to cope with my day to day life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I had trouble concentrating/thinking clearly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I felt anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I felt sad/depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I felt lonely	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I felt exhausted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Mobility

Daily activities

Coping

Concentration & thinking clearly

Anxiety

Depression

Loneliness

Fatigue

Pain

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)



The
University
Of
Sheffield.

25 | School of
Health and
Related
Research
YEARS OF EXCELLENCE
1994 - 2019

Many thanks!

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