A UK developed NHS suitable brief patient reported outcome measure for cataract: 
**Cat-PROM5**

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The NHIR Funded Cataract Research Programme Team

• Bristol
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  – Mariusz Grzeda
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  – Ketan Kapoor
  – Jason Searle
  – Steve Chaffey
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  – Lara Edwards
  – Claire Buckland
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  – Robert Elvin
  – Elinor Griffiths
  – Liz Wilkinson
  – CTEU David Hutton & Chas Saw
  – Jenny Ward & Theatre Nurses
  – Martina Jones & POA Nurses

• Cheltenham
  – Rob Johnston
  – Peter Scanlon
  – Karen Townsend

• Torbay
  – Andy Frost
  – Barbara Finson
  – Sharon Criddle

• Brighton
  – Christopher Liu
  – Debbie Horney
  – And many others in the background!

5 Year NHIR Programme Grant for Applied Research £2M
Cataract
Opacification of the lens of the eye
Cataract

- **Surgery** is the only effective treatment

- **Most frequent** NHS Surgical Procedure
  - Around **400,000** Cataract Operations **Annually**

- **Visual Acuity** (letter chart) a **poor indicator** of
  - Visual difficulty
  - **Benefit** from surgery
Cataract Patient Reported Outcome Measure (Cat-PROM)

- Cataract is a **symptomatic condition**
- **Patients are the best judge** of their vision
- Cataract **surgery should improve** patients’ **self-reported visual difficulty**
Cataract Patient Reported Outcome Measure (Cat-PROM)

• Every day ophthalmologists informally
  – Ask their patients how much their vision is affected by Cataracts
  – Ask their patients how much better their vision is after Cataract Surgery
Cataract Patient Reported Outcome Measure (Cat-PROM)

- **Concept:** A few key questions can help us to better understand patient’s **visual disability from cataract and its relief from surgery**
  - A cataract PROM
  - **Structured, repeatable and psychometrically valid** instrument which is **responsive** to surgical intervention

(DH spent a couple of £100k and could not find an NHS suitable Cataract PROM)
Cataract Patient Reported Outcome Measure (Cat-PROM)

Aim

To develop a brief NHS suitable UK relevant cataract surgery patient reported outcome measure capable of reliably measuring visual difficulty from cataract and its relief from surgery.
Vision-related Issues

Expectations for age
Food and drink preparation
Indoor and outdoor sports and games
Freedom of choice
Eating and Drinking
Hobbies and pastimes
Safety in the home
Personal hygiene
Social activities
Safety outside the home
Use of medicines, contact lenses and Voluntary, or social work
eye-drops
Caring for another person
Maintenance of personal appearance
Family activities
Dressing and undressing
Religious activity
Care of clothes
Holidays
Cleaning, tidying and maintaining a
Indoor and outdoor mobility
home

Embarrassment, Self-conscience
Orientation in space and time
Overall quality of vision
Confidence
Use of transport, driving
Rate of deterioration of vision
Satisfaction
Shopping, Use of money
Blur, mistiness
Overall life interference
Reading
Distortion
Fear of deterioration in vision
Writing
Glare
Mistreatment by others
Face recognition
Vision in dim light
Depression
Dealing with strangers
Colour perception and recognition
Depression
Making friends
Adaptation to dim light
Meeting people
Adaptation to bright light
Care of clothes
Distance vision
Cleaning, tidying and maintaining a
Near vision
home
Judging distances

Independence
Indoor and outdoor mobility
Movement perception

Anger
Orientation in space and time

Anxiety
Use of transport, driving

Loneliness
Shopping, Use of money

Independence
Reading

Indoor and outdoor sports and games
Writing

Mistreatment by others
Face recognition

Depression
Dealing with strangers

Vulnerability
Making friends

General health and well-being
Meeting people

Concern about coping
Use of the telephone

Confidence
Employment

Embarrassment, Self-consciousness
Money income

Self-esteem
Obtaining information

Confidence

Use of the telephone

Satisfaction
Employment

Overall life interference

Near vision

Fear of deterioration in vision

Distance vision

Mistreatment by others

Judging distances

Depression

Movement perception

Dealing with strangers

Vulnerability

General health and well-being
Questionnaire Development

- **Initial work in the 1990’s**
  - Define construct being measured
  - Generation of relevant issues
  - Consultation with visually impaired adults
  - Consultation with professionals and support workers
  - Literature review
  - Operationalisation
  - Pre-testing
  - Selection of items
  - Studies
    - Construct validity
    - Reliability
    - Responsiveness
  - Refine as necessary (iterative process)
Building on Existing Work

• **Construct**
  – Visual difficulty due to cataract

• **2 UK developed Parent VR-QoL Questionnaires**
  – **VSQ** developed for 2\textsuperscript{nd} eye cataract RCT
    
    Donovan et al. Ophthalmic Epidemiology 2003

  – **VCM1** developed for Somerset and Avon Eye Study
    
    Frost et al. Ophthalmic Epidemiology 1998

• **21 Initial items (= questions) harvested**

• **Iterative Cycles** of testing and **item reduction**
Questionnaire Development

• **Iterative item reduction**
  - Face validity
  - Content validity
  - Construct validity
  - Multidimensionality
    • Rasch
    • Factor analysis
  - Rasch modelling
    • Choice of model
    • Fit statistics
    • Disordering
    • Differential item functioning
    • Reliability indices

• **Evaluation**
  - Test-retest Repeatability
  - Ceiling and floor effects
  - Missing values
  - Effect size (responsiveness to intervention)
  - Compare performance against existing measures
Cataract Patient Reported Outcome Measure (Cat-PROM)

- **4 Centres**
  - Bristol (John Sparrow), Torbay (Andy Frost), Cheltenham (Rob Johnston), Brighton (Christopher Liu)

- **Cycle 0: Pilot** (21 Items, 200 patients, pre-op only)

- **Cycle 1: Development** (11 Items, 316 patients, pre- & post-op)

- **Cycle 2: Confirmation** (5 Items, 306 patients, pre- & post-op)

- **Three Cycles Combined**
  - **822 Patients**
  - **1266 Questionnaires** for final analysis and calibration
Scales

• Nominal or Categorical
  – Sighted / Blind

• Rank ordered or ordinal
  – Street numbers (order & direction)
  – Questionnaire items about visual disability

• Continuous (i.e. Parametric Statistics)
  – Meters or kilometres of distance
  – Underlying latent visual disability scale
How would you describe your vision **overall in the past month** - with both eyes open, wearing glasses or contact lenses if you usually do?

<table>
<thead>
<tr>
<th>Vision Level</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>0</td>
</tr>
<tr>
<td>Very good</td>
<td>1</td>
</tr>
<tr>
<td>Quite good</td>
<td>2</td>
</tr>
<tr>
<td>Average</td>
<td>3</td>
</tr>
<tr>
<td>Quite poor</td>
<td>4</td>
</tr>
<tr>
<td>Very poor</td>
<td>5</td>
</tr>
<tr>
<td>Appalling</td>
<td>6</td>
</tr>
</tbody>
</table>
Translating Questionnaire Scales

Rank ordered or ordinal question responses

Rasch

Continuous underlying latent scale
How does Rasch help?

- Identifies the **Underlying Latent Trait** being measured by the questionnaire
- Assesses **Dimensionality** (questions measure the same thing)
- Establishes a **Continuous Scale** for the Latent Trait
- **Positions items and rank ordered item category levels** along the Continuous Latent Scale
- **Positions Respondents** on the same **Continuous Latent Scale**
  - Very powerful feature as this allows **parametric statistical analysis** of data collected as rank ordered data
Sample Question 1 - Vision Overall

How would you describe your vision **overall in the past month** - with both eyes open, wearing glasses or contact lenses if you usually do?

<table>
<thead>
<tr>
<th>Option</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>0</td>
</tr>
<tr>
<td>Very good</td>
<td>1</td>
</tr>
<tr>
<td>Quite good</td>
<td>2</td>
</tr>
<tr>
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</tr>
<tr>
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<td>6</td>
</tr>
</tbody>
</table>
Well functioning Sample Question
Vision Overall
Threshold Probability Curve

Underlying Latent Scale of visual disability in Logits
Have you felt **lonely** or **isolated** because of your eyesight?

<table>
<thead>
<tr>
<th>Option</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>0</td>
</tr>
<tr>
<td>Very rarely</td>
<td>1</td>
</tr>
<tr>
<td>A little of the time</td>
<td>2</td>
</tr>
<tr>
<td>A fair amount of the time</td>
<td>3</td>
</tr>
<tr>
<td>A lot of the time</td>
<td>4</td>
</tr>
<tr>
<td>All the time</td>
<td>5</td>
</tr>
</tbody>
</table>
Poorly Functioning Sample Question
Lonely
Threshold Probability Curve

Underlying Latent Scale of visual disability
Final Item Selection

• Choices based on
  – Statistical considerations
  – Patient views
  – Expert opinion
Cat-PROM5
Threshold Probability Curves

- Interference
- VSQ Overall
- VSQ Bad Eye
- VSQ Doing
- VSQ Reading
Cat-PROM5

Psychometric Performance

- Rasch Reliability = 0.90
- Person separation = 2.98
- Cronbach’s alpha = 0.89
- Unidimensional
  - 1st Residual eigenvalue = 1.5
- Item invariance
  - Minor Differential Item Functioning (DIF) only
- Good Targeting, Spread & no significant ceiling / floor
  - Pre-op cataract patient mean = 0.01 Logits
- Repeatable
  - Intra-class Correlation Coefficient = 0.89
- Standardised Effect Size
  - Cohen’s d: = -1.45
Cat-PROM5
Psychometric Performance

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Final Item Set of 5 Questions

Short
Reliable
Repeatable
Unidimensional
Responsive to Surgery
Cat-PROM5
Pre-op & Post-op distributions & Item Locations

Cat-PROM5 pre-operative patients

Cat-PROM5 post-operative patients

Cat-PROM5 item locations (Loc) and Rasch Andrich thresholds (Th)

Bad Eye

Overall

Reading

Interfer

Doing
Qualitative Elements

• Both original **Parent Questionnaires** involved extensive patient and eye health professional input
  – VSQ (40 interviews)
  – VCM1 (38 + 58 interviews in 2 rounds)

• Cataract Surgery **Patients assessing Cat-PROM5**
  – Co-researcher patient advisory group input
  – Pre-operative interviews with patients
  – Post-operative interviews with patients
  – Patients with and without ocular co-morbidities
  – Comparison against existing longer ‘best of class’ questionnaire

• Cat-PROM5 **favourably received** by interviewees
Cat-PROM5
Patient Reported Benefits from Surgery

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small or better (0.2SD or more)</td>
<td>83%</td>
</tr>
<tr>
<td>Medium or better (0.5SD or more)</td>
<td>72%</td>
</tr>
<tr>
<td>Large or very Large (0.8SD or more)</td>
<td>68%</td>
</tr>
</tbody>
</table>
How to use it?
Translating Questionnaire Scales

Rank ordered or ordinal question responses

‘Look up’
Table

Continuous underlying latent scale
‘Look-up’ Table

<table>
<thead>
<tr>
<th>Total score</th>
<th>Rasch measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-9.18</td>
</tr>
<tr>
<td>1</td>
<td>-6.80</td>
</tr>
<tr>
<td>2</td>
<td>-4.92</td>
</tr>
<tr>
<td>3</td>
<td>-4.03</td>
</tr>
<tr>
<td>4</td>
<td>-3.37</td>
</tr>
<tr>
<td>5</td>
<td>-2.81</td>
</tr>
<tr>
<td>6</td>
<td>-2.29</td>
</tr>
<tr>
<td>7</td>
<td>-1.80</td>
</tr>
<tr>
<td>8</td>
<td>-1.31</td>
</tr>
<tr>
<td>9</td>
<td>-0.82</td>
</tr>
<tr>
<td>10</td>
<td>-0.32</td>
</tr>
<tr>
<td>11</td>
<td>0.18</td>
</tr>
<tr>
<td>12</td>
<td>0.69</td>
</tr>
<tr>
<td>13</td>
<td>1.22</td>
</tr>
<tr>
<td>14</td>
<td>1.76</td>
</tr>
<tr>
<td>15</td>
<td>2.33</td>
</tr>
<tr>
<td>16</td>
<td>2.93</td>
</tr>
<tr>
<td>17</td>
<td>3.56</td>
</tr>
<tr>
<td>18</td>
<td>4.23</td>
</tr>
<tr>
<td>19</td>
<td>4.98</td>
</tr>
<tr>
<td>20</td>
<td>6.01</td>
</tr>
<tr>
<td>21</td>
<td>7.45</td>
</tr>
</tbody>
</table>

![Graph showing the relationship between Cat-PROM5 Total Score and Rasch Measure in logits](image-url)
Cat-PROM5 Implementation

• Specialty Specific Ophthalmology EMRs
  – **Medisoft EMR** in over half NHS cataract services
  – **OpenEyes EMR** gaining ground and used in one very large flagship eye hospital

• Both EMRs wish to implement **Cat-PROM5** for routine use in **NHS Cataract Surgery Services**
Cat-PROM5

- Psychometrically robust questions which work well and are highly responsive to cataract surgery

- Has the potential to empower patients to express their visual difficulty in a structured format

- Responses can be calibrated to a continuous underlying visual difficulty latent scale

- Provides opportunity for patients to express their benefit from surgery

- Avoids limitations of relying only on monocular visual acuity to assess surgery
The NHIR Funded Cataract Research Programme Team

- **Bristol**
  - Pippa Craggs
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5 Year NHIR Programme Grant for Applied Research £2M
Thank You