Using PROMs in clinical practice: rational, evidence and implementation framework

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Disclosure

• Professor of Health Services & Policy (University of Exeter)
• President-elect of the International Society for Quality of Life Research (ISOQOL)
• Funding: NIHR, Cancer Research UK, European Commission, WHO
Plan

• What PROMs are
• Why use them in clinical practice
• What is the research evidence for their use (systematic review and realist synthesis)?
• Frameworks for implementation
• Exeter GP PROMS supported care planning and monitoring for people with multimorbidity
• A vision of the future
What are Patient Reported Outcomes (PROs)?

“a measurement of any aspect of a patient’s health status that comes directly from the patient (i.e., without the interpretation of the patient’s responses by a physician or anyone else)”

Food and Drug Administration (FDA). Federal Register 2006;71:5862–3
Valderas JM, Alonso J. Qual Life Res 2009;17(9):1125-35

Yeah, right. But then, what are Patient Reported Outcome Measures (PROMs)?
Patient Reported Outcome Measures (PROMs):

1. **UK/Ireland English for PROs**
2. **The application of PROs to the specific purpose of measuring performance of health care providers**
3. **The instruments used to measure PROs (which would be then a CONSTRUCT, not a measure)**
Valderas JM & Alonso J. *Qual Life Res* 2008
# Clinical use of PROMs

<table>
<thead>
<tr>
<th>Used at the clinician–patient interface</th>
<th>Level of aggregation of PRO data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Individual</td>
</tr>
<tr>
<td></td>
<td>Screening</td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
</tr>
<tr>
<td></td>
<td>Promoting patient-centred care</td>
</tr>
<tr>
<td>No</td>
<td>Decision aids</td>
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<tr>
<td></td>
<td>Facilitating communication within multidisciplinary teams</td>
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<tr>
<td></td>
<td>Population monitoring and assessing quality of care</td>
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Greenhalgh J. *Qual Life Res* 2009
Box 1. Potential clinical applications of patient-reported outcomes.

- Supporting decision-making in the diagnostic process:
  - Screening
  - Diagnosis
- Informing risk stratification and prognosis (identification of vulnerable patients and patients ‘at risk’)
- Supporting prioritization and goal setting
- Supporting decision-making in indication for treatment (medical/surgical)
- Facilitating monitoring of:
  - General health status
  - Response to treatment/management
- Facilitating communication:
  - Between patients and health professionals
  - Within teams and between professionals: consistent use along the care pathway

<table>
<thead>
<tr>
<th>Condition</th>
<th>PRO measures</th>
<th>Type of recommendation</th>
<th>Relevant guidance [source]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>Royal College of Physicians (RCP) 3 questions</td>
<td>Use of PRO measures recommended (assessment)</td>
<td>“An assessment of asthma control should use a recognised tool. The tool used should be appropriate for the age of the person with asthma. The available tools include the Royal College of Physicians (RCP) 3 questions, the Asthma Control Questionnaire, the asthma control test or children’s asthma control test and the Mini Asthma Quality of Life Questionnaire or Paediatric Asthma Quality of Life Questionnaire.” [NICE quality standard 25]</td>
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<tr>
<td></td>
<td>Asthma Control Questionnaire (ACQ)</td>
<td>Identification of interventions that can improve PROs</td>
<td>“Direct or passive exposure to cigarette smoke adversely affects quality of life, lung function, the need for rescue medications for acute episodes of asthma, and long-term control with inhaled steroid. Assessment of anxiety may help identify individuals who are at risk for poorer asthma specific quality of life. Breathing exercise programmes (including physiotherapist-taught methods) can be offered to people with asthma as an adjuvant to pharmacological treatment to improve quality of life and reduce symptoms.” [BTS, 2011]</td>
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<tr>
<td></td>
<td>Asthma Control Test (ACT)</td>
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<tr>
<td></td>
<td>Children’s Asthma Control Test</td>
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<td></td>
<td>Mini Asthma Quality of Life Questionnaire (Mini-AQLQ)</td>
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<td>Paediatric Asthma Quality of Life Questionnaire (PAQLQ)</td>
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<tr>
<td>COPD</td>
<td>Clinical COPD questionnaire (CCQ)</td>
<td>Use of PROs measures recommended (assessment)</td>
<td>“A tool such as the Clinical COPD Questionnaire (CCQ) could be used to assess current health status. Additionally there is evidence that inhaled therapies can improve the quality of life in some patients with COPD.” [Quality and Outcomes Framework 2014/2015, COPD-003]</td>
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<tr>
<td></td>
<td>The Medical Research Council (MRC) dyspnoea scale</td>
<td>Identification of interventions for improving PROs</td>
<td>“A comprehensive clinical and psychosocial assessment should include, but is not limited to, the following: health status measures (using for example, the COPD assessment tool [CAT] or St George’s respiratory questionnaire [SGRQ]).” [NICE quality standard 10]</td>
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<tr>
<td></td>
<td>COPD assessment tool (CAT)</td>
<td>PRO scores linked to clinical management options</td>
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<tr>
<td></td>
<td>St George’s respiratory questionnaire (SGRQ)</td>
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<tr>
<td>Depression</td>
<td>Patient Health Questionnaire (PHQ-9)</td>
<td>Use of PROs measures recommended (assessment, informing and evaluating treatment)</td>
<td>“When assessing a person with suspected depression, consider using a validated measure [for example, for symptoms, functions and/or disability] to inform and evaluate treatment.” [NICE CPG CG90]</td>
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<td></td>
<td>Hospital Anxiety and Depression Scale [HADS]</td>
<td></td>
<td>“Clinicians may wish to use formal assessment questionnaires such as PHQ9, HADS and BDII to monitor response to treatment.” [Quality and Outcomes Framework 2014/2015, DEP-003]</td>
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<td></td>
<td>Beck Depression Inventory [BDI]</td>
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<tr>
<td>Diabetes</td>
<td>None identified</td>
<td>Generic recommendations</td>
<td>“A specific focus when assessing the patient’s quality of life should be placed on the impact of diet, self-monitoring of plasma glucose and other efforts to maintain the individual target for HbA1C (including hypoglycaemia and frequency of injections).” [NICE CPG CG66]</td>
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<tr>
<td>Heart Failure</td>
<td>None identified</td>
<td>Identification of interventions for improving PROs</td>
<td>“Diuretics should be routinely used for the relief of congestive symptoms and fluid retention in patients with heart failure, and titrated (up and down) according to need following the initiation of subsequent heart failure therapies.” [NICE CPG CG108]</td>
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<td>“Specialist referral for transplantation should be considered in patients with severe refractory symptoms or refractory cardiogenic shock.” [NICE CPG CG108]</td>
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<td>Osteoarthritis</td>
<td>Oxford Hip Score (OHS)</td>
<td>Use of PROs measures recommended (assessment, informing and evaluating treatment)</td>
<td>“The effect of osteoarthritis on the person’s function, quality of life, occupation, mood, relationships and leisure activities should be assessed. Regular reviews should be offered to all people with symptomatic osteoarthritis. Reviews should include monitoring the person’s symptoms and the ongoing impact of the condition on their everyday activities and quality of life. Referral for joint surgery should be considered for people with osteoarthritis who experience joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life and are refractory to non-surgical treatment.” [NICE CPG CG177]</td>
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<tr>
<td>(hip/knee)</td>
<td>Oxford Knee Score (OKS)</td>
<td>Identification of interventions for improving PROs</td>
<td>“The use of orthopaedic scores and questionnaire-based assessments to identify people who are eligible for referral for consideration of joint surgery has become widespread. These usually assess pain, functional impairment and sometimes radiographic damage. The commonest are the New Zealand score and the Oxford Hip or Knee score. Many [such as the Oxford tools] were designed to measure population-based changes after surgery, and none have been validated for assessing appropriateness of referral.” [NICE quality standard 87]</td>
</tr>
<tr>
<td></td>
<td>New Zealand Score for Hip and Knee Surgery</td>
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Evidence for using PROMs in clinical practice

Systematic Review of RCTs

- Systematic review of RCT (2008): 28 studies
- Intervention: feedback of PROMs to health professionals (+/- additional interventions) compared to no feedback
- USA (21), UK (5), Canada (1), The Netherlands (1)
- Mental health (50%), generic health status, other
- 65% studies showed some impact on processes (diagnosis, advice/education/counselling)
- 47% studies showed some impact on outcomes (PROMs)
- Most clear benefit for screening/diagnosis of depression
- More recent additional studies are showing increased impact on outcomes

Routine provision of information on patient-reported outcome measures to healthcare providers and patients in clinical practice (Protocol)

Framework for implementing PROMs in clinical practice

• PRO instrument:
  • Valid
  • Responsive
  • Interpretable (actionable: explicit link to clinical activity/task)
  • Simple
  • Tailored to the particular setting and purpose

• Feedback system:
  • integrated in clinical information systems
  • Structured
  • Health care professionals AND patients
  • Frequent and timely

• Training on the interpretation of scores and outputs

Realist synthesis of individual use of PROMs

Function

• **Information exchange, supporting decision-making AND relationship-building**
• **Supporting patients in raising issues** with clinicians rather than changing clinicians’ communication practices with patients.
• **Shift in clinicians’ perceptions** of their remit:
  • to shift clinicians’ communication practices
  • focus discussion on psychosocial issues.

Type of measures

• **Patients value both standardised and individualised PROMs** (selective approach)
  • Standardized: Useful for patients who find it difficult to raise sensitive issues verbally for sharing information with clinicians.
  • Individualised PROMs:
    • Time consuming, feasibility in primary care or outpatient appointments?
    • Clinicians feel not useful for measuring change over time
    • ‘conversation opener’ rather than as an ‘outcome measure’

Greenhalgh J, et al. NIHR HS&DR 2017
Realist synthesis of individual use of PROMs

• Administration
  • Nurses!
  • PROMs completion may be an emotional experience for some patients (terminally ill), would require support

• Recipients
  • Accessible to multiple clinicians so that issues can be addressed by those with the appropriate remit (integration into the patients’ electronic record).
  • Clear division of labour/responsibility among professional groups

Greenhalgh J, et al. NIHR HS&DR 2017
Clinical management
Disease focus

Clinical management

Biomedical model

Measurement

Standardized PROMs
Patient centred care
Patient centred care

Whole person approach
Patient centred care

Whole person approach

Goal setting
Patient centred care

Whole person approach

Goal setting

Individualized PROMs
Patient centered care

Whole person approach

Goal setting

Individualized PROMs

Psychosocial model
asthma
COPD
depression
diabetes
heart failure
osteoarthritis
asthma
COPD
depression
diabetes
heart failure
osteoarthritis

Disease specific
EQ5D
PGI
asthma
COPD
depression
diabetes
heart failure
osteoarthritis

Disease specific

EQ5D

PGI
Annual review (Nurse Practitioner)

- Asthma
- COPD
- Depression
- Diabetes
- Heart failure
- Osteoarthritis

Disease specific

- EQ5D
- PGI
PROMs

Conditions specific

Asthma - Mini Quality of Life Questionnaire (mini-AQLQ) + RCP 3 asthma questions.

COPD - Clinical COPD questionnaire (CCQ) + MRC breathlessness scale.

Depression - Patient Health Questionnaire (PHQ-9)

Diabetes – Diabetes Health Profile (DHP)

Heart failure – Minnesota Living with Heart Failure Questionnaire (MLHFQ)

Osteoarthritis – Oxford Hip Score (OHS); Oxford Knee Score (OKS)

Generic: EuroQol (EQ-5D).

Individualised: Global Patient Generated Index (GPGI)
Mr Smith: Your health profile

<table>
<thead>
<tr>
<th>1. Your health conditions</th>
<th>2. Your health overall</th>
<th>3. Your health priorities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Worst</strong> COPD <strong>Best</strong></td>
<td><strong>Worst health</strong></td>
<td>1) Spending time with grandchildren</td>
</tr>
<tr>
<td><strong>Worst</strong> Osteoarthritis (knee) <strong>Best</strong></td>
<td><strong>Best health</strong></td>
<td>2) Walking</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3) Socialising</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4) Pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5) Work</td>
</tr>
</tbody>
</table>
COPD

2.5 Clinical COPD Questionnaire (CCQ)

How should these scores be interpreted?
Scores range from 0 (very good health status in relation to your COPD) to 6 (very poor health status in relation to your COPD).

What are average scores for patients in General Practice?
In a large scale study, the average score for patients diagnosed with COPD in General Practice in England was 2.6

MRC breathlessness score

How should these scores be interpreted?
1: not being troubled by breathlessness except on strenuous exercise
2: being short of breath when hurrying on the level or walking up a slight hill
3: walking slower than most people on the level, stops after a mile or so, or stop after 15 minutes walking at your own pace
4: stopping for breath after walking about 100 yards or after a few minutes on level ground
5: being too breathless to leave the house, or breathless when undressing

Implications for clinical management based on current clinical guidance in England

This score can be used to assess current health status. Inhaled therapies can improve the quality of life in some patients with COPD.

[QOF guidance 2014/2015, COPD-003]

Participation in a pulmonary rehabilitation programme should usually be offered to patients scoring 3 or above on the breathlessness scale. Such programmes should incorporate physical training, disease education, nutritional, psychological and behavioural intervention. Pulmonary rehabilitation is not suitable for patients who are unable to walk, have unstable angina, or who have had a recent myocardial infarction.

[NICE guideline CG10: Management of chronic obstructive
ISOQOL User’s Guide to Implementing PROs Assessment in Clinical Practice

• What are your goals for collecting PROs in your clinical practice and what resources are available?
• Which key barriers require attention?
• Which groups of patients will you assess?
• How do you select which questionnaire to use?
• How often should patients complete questionnaires?
  - Should it be tied to visits or a way to follow patients between visits?
• How will the PROs be administered and scored?
ISOQOL User’s Guide to Implementing PROs Assessment in Clinical Practice

• What tools are available to aid in score interpretation and how will scores requiring follow-up be determined?
• When will results be presented?
• Where will results be presented?
• How will results be presented?
• Who will receive score reports?
• What will be done to respond to issues identified through the PROs?
• How will the value of using PROs be evaluated?
Summary

• Mostly black box approach to evaluation in RCTs, progressive improvement in methods

• Increasingly solid evidence on the use of PROMs in clinical practice using a range of methodologies (systematic review, meta-ethnography, realist synthesis)

• PROMs use can improve processes AND outcomes of care

• Research is needed on effectiveness for specific clinical applications and more generally on interpretation, training of health professionals, role of individualized PROMs
What is coming next...

• Increased used of multiplatform electronic data collection
• Computerized adaptative testing based on IRT models
• Better evidence based on RCTs and implementation studies on how and when PROMs may best support health care
• Better uptake of PROMs based evidence in clinical practice guidelines
• Outcomes oriented models of care
I have seen things...

• Fully integrated real time electronic collection, interpretation and feedback supporting self-management
• Widespread use of construct oriented computerized adaptative testing based on IRT models
• Chronobiologically, environmentally and culturally sensitive methods of data collection
• Free text measurement based on calibration of large qualitative data
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- and eventually...

sustainable equitable health care driven by patients' needs and goals
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