Perspectives of patients and professionals on the use of patient reported outcome measures in primary care
a systematic review of qualitative studies

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Abstracts for plenary sessions

P1
Using Patient Reported Outcome Measures (PROMs) in cancer care
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):P1

Monitoring of patients’ physical and psychological problems during and after cancer treatment is essential in modern oncology practice. Traditional clinical methods can be supplemented by Patient-Reported Outcomes Measures (PROMs) measures. The potential role of PROMs is recognised and endorsed by national and international practice guidelines. The introduction of formal measurement of PROMs in clinical practice is a complex healthcare innovation requiring careful planning, design and successful implementation of a number of essential components, such as choosing the patient questionnaire(s), a convenient affordable electronic method for reporting and display in hospital records and engaging clinicians to use and act on the reports. There is mounting research evidence that using PROMs in individual patient care in oncology is beneficial to patients, and the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

A66
Validation of the Long-Term Conditions Questionnaire (LTCQ) in a diverse sample of health and social care users in England
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A66

Background: Long-term conditions (LTCs) have emerged as a significant challenge to the sustainability of health systems. The rise of multi-morbidity has highlighted the need for joined-up services that can enhance people’s capacity for living well with LTCs.

Aims: The objective of this study was to validate a new generic well-being measure, the Long-Term Conditions Questionnaire (LTCQ).

Methods: Data were collected through two postal surveys (main and follow-up) from February 2016 to January 2017. The study sample included 1) a health care cohort of patients with at least one of 11 specified LTCs recruited through primary care practices and 2) a social care cohort receiving support for at least one LTC recruited through...
Local Authorities. The LTCQ's construct validity was tested with reference to the EQ-5D (5-level version), Self-efficacy for Managing Chronic Disease scale, an Activities of Daily Living scale, and the Bayliss multi-morbidity scale. The follow-up survey enabled assessment of test-retest reliability.

Results: The total sample (N = 1,211; 23% response rate; 24% confirmed social care users) exhibited high multi-morbidity, with 93% reporting two or more LTCs and 43% reporting a mental health condition. Low levels of missing data indicate acceptability of the LTCQ within this diverse sample. The LTCQ exhibits high internal consistency (Cronbach’s α = 0.95) across the scale’s 20 items and excellent test-retest reliability (ICC = 0.94, 95% CI 0.93 to 0.95). Associations between the LTCQ and all reference measures were moderate to strong and in the expected directions, indicating convergent construct validity.

Conclusions: This study provides evidence for the reliability and validity of the Long-Term Conditions Questionnaire, which has potential for use in a variety of health and social care settings. The LTCQ could meet a need for an outcome measure that goes beyond symptoms for use in a variety of health and social care settings. The LTCQ could meet a need for an outcome measure that goes beyond symptoms for use in a variety of health and social care settings.

A15

Developing preference based measures for diabetes for calculating QALYs: DHP-3D and DHP-5D

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Background: The cost per quality adjusted life year (QALY) of new interventions in long term conditions (LTCs) is assessed to inform resource allocation decisions. However, generic preference-based measures of health like EQ-5D may not be sufficiently sensitive for some LTCs. Condition specific PROMs like the Diabetes Health Profile (DHP) offer more relevant descriptions of how LTCs impact on people’s lives.

Aims: The aim was to develop two diabetes specific preference based measures (DHP-3D/DHP-5D) for use in the calculation of QALYs based on the non-preference based DHP (DHP-18/DHP-1).

Methods: For DHP-3D, Exploratory Factor Analysis and Rasch analyses were used to understand the dimensionality of the DHP-18, and select items to represent each in the classification system. The DHP-5D built on the DHP-3D adding two dimensions to extend the range of diabetes related impacts assessed. Each was valued by 150 members of the UK general public using the Time Trade Off (TTO) preference elicitation method. The valuation data was modelled using individual and mean level multivariate regression to produce utility values for every health state described.

Results: The DHP-3D classification system included three dimensions in line with the structure of the DHP-18 defined as mood, eating and physical function, providing a more holistic metric for living well with LTCs.

A62

Constructing and Validating the Short Recovering Quality of Life (ReQoL) Measure for Use in a Mental Health Population

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A62

Background: The concept of recovery for people experiencing mental health difficulties has received greater emphasis recently, prompting demands for new measures.

Aims: To assess the outcomes of mental health services in terms of recovering quality of life, we constructed and validated a 10-item version ReQoL measure.

Methods: After having established seven themes, we generated a long list of potential items which were tested for content validity. Psychometric analyses used confirmatory factor models and item response theory (IRT) analysis to focus on item fit and item information functions. A novel approach was developed to present qualitative and quantitative evidence to a group of service users, clinicians and researchers to make the final selection. Internal consistency was assessed using Cronbach’s alpha. Known group differences were calculated to test whether the scale was able to discriminate between groups with pre-specified hypotheses. Sensitivity to change was measured between baseline and follow-up for a group of people attending services. The ReQoL was compared with EQ-5D and SWEMWBS.

Results: Qualitative evidence from over 90 service users was used to reduce the number of items before field-trial quantitative data were collected from over 6200 service users. Factor analyses supported a unidimensional model. Evaluation of IRT test information functions suggested that a 10 item scale could cover as wide a measurement range as the pool of 40 items. A Cronbach alpha of 0.92 showed good internal reliability. The scale showed moderate responsiveness to change with a standardised response mean of 0.4 for those whose health improved and worsened. The ReQoL was able to detect known group differences and compared well with other measures.

Conclusion: This work provides a pragmatic yet rigorous approach to combining qualitative and quantitative evidence to develop the ReQoL to be both psychometrically robust and likely to have high face validity with service users and clinicians.

Session 1b. Qualitative evidence

A59

Development of a novel patient reported outcome measure for patients with haematological malignancy: a qualitative study

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A59
Aims: The impact of haematological malignancies (HM) and its treatment on patients’ health-related quality of life (HRQoL) is still not well understood. The aim of this study was to identify HRQoL issues and symptoms in patients with HM.

Methods: In a UK based multicentre cross-sectional prospective study, adult patients with various HM were recruited from six hospitals in England and Wales. The study employed semi-structured face-to-face interviews with open-ended questions related to the impact of HM and its treatment on HRQoL and symptoms. All the interviews were audio recorded, transcribed verbatim and content analysed using NVivo 11, a qualitative data analysis software.

Results: 129 patients (male = 76; mean age = 61.1 years; SD = 15.3; median age = 64.92 years; and age range = 18-88 years) with mean duration of the HM of 3.6 years (SD = 4.3; and range = 19 days-23 years) were interviewed. Diagnoses were: Acute Myeloid Leukemia (18); Acute Lymphoid Leukaemia (7); Chronic Myeloid Leukaemia (12); Chronic Lymphocytic Leukemia (11); Aggressive Non-Hodgkin’s Lymphoma (17); Indolent Non-Hodgkin’s Lymphoma (14); Hodgkin’s Lymphoma (11); Multiple Myeloma (21); Myeloproliferative Neoplasms (10); and Myelodysplastic Syndromes (8). The most prevalent QoL issues important to HM patients were: eating and drinking habits (117); impaired social life and participatory function (86); impaired physical ability or independency (70); disturbed sleep (66); and impaired psychological well-being (64). The most prevalent treatment side effects were: tiredness (74); feeling sick (36); lack of energy (21); and back pain (18). Most prevalent impact these may have. Dimensions of PROMs should be based on patients’ preferences of a patient with varicose veins (VV), and compare them to existing PROMs domains.

Methods: Eight electronic databases were searched to identify qualitative research published in English of the experiences of adults with VV. A thematic analysis was conducted and resulting themes were compared to existing VV PROMs domains to evaluate if they captured the impact the VV have on patients.

Results: A total of 1804 citations were identified; after screening only three studies met the inclusion criteria. Five overarching themes were described in the studies: physical impact, psychological impact, social impact, adapting to VV and reasons for seeking treatment.

Conclusion: The range and intensity of reported symptoms and the participant’s experience of VV was very varied. One key theme to emerge was adaptation, as there was evidence that patients attempted to adapt to the physical, psychological and social impact of VV. No PROM currently exists that would capture how VV patients adapt their lives.

Conclusion: The use of PROMs to gather information is well established in the NHS but those currently used may not capture the full impact. Qualitative research methods allow an in-depth understanding of the range and severity of symptoms experienced by patients, and the impact these may have. Dimensions of PROMs should be based on patient experiences, best generated by qualitative research methods.

A43

“Normal is redefined”; reflections on outcomes for women with breast cancer: an ethnographic study in London

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A43

Background: Prognosis for breast cancer is improving with 78% of women surviving >10 years. We conducted an ethnographic study of breast cancer care which focused on experience rather than outcomes, but revealed relevant themes.

Aim: To identify outcomes valued by women with breast cancer.

Methods: Secondary analysis of ethnographic data including 79 interviews (patients, staff, carers).

Results: Women referred to different concerns, preferences and aspirations. Desired outcomes were affected by the experience of treatment, changed over time, and influenced decisions about care. Three major themes emerged.

- Dependency: the dominant theme was a determination not to become dependent, and to continue to care for others. Women described children, partners and parents who they ‘took care of’. This priority affected how they hoped to balance quality and quantity of life; some chose less aggressive treatments in order to have a “decent quality of life to carry on”, others chose radical treatments to maximise their chance of staying around.

- Normality: some women looked forward to ‘getting back to normal’ but others recognised that they would never be the same again. One described how difficult it would be to resume her previous life, “you are changed, recalibrated, normal is redefined”. Specific aspirations included looking forward to your hair growing back, returning to work, attending a wedding, kayaking, a grandchild starting university. Some women worried about work, asking how they would cope financially, and how they could avoid pity.

- Reciprocity: In addition to some who planned new careers supporting people with cancer, several women aspired to ‘give back’ through volunteering, fund-raising and taking part in research.

A71

Perspectives of patients and professionals on the use of patient-reported outcome measures in primary care: a systematic review of qualitative studies

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A71

Background: Patient reported outcome measures (PROMs) allow measurement of outcomes elicited from patients; therefore PROMs should include domains that are relevant to patients. One source of this information may be existing qualitative research describing patient experiences and their impact on quality of life (QoL).

Aims: The aim of this qualitative evidence synthesis was to examine the symptoms and QoL domains that are important from the perspective of a patient with varicose veins (VV), and compare them to existing PROMs domains.

Methods: Eight electronic databases were searched to identify qualitative research published in English of the experiences of adults with VV. A thematic analysis was conducted and resulting themes were compared to existing VV PROMs domains to evaluate if they captured the impact the VV have on patients.

Results: A total of 1804 citations were identified; after screening only three studies met the inclusion criteria. Five overarching themes were described in the studies: physical impact, psychological impact, social impact, adapting to VV and reasons for seeking treatment.

Discussion: The range and intensity of reported symptoms and the participant’s experience of VV was very varied. One key theme to emerge was adaptation, as there was evidence that patients attempted to adapt to the physical, psychological and social impact of VV. No PROM currently exists that would capture how VV patients adapt their lives.

Conclusion: The use of PROMs to gather information is well established in the NHS but those currently used may not capture the full impact. Qualitative research methods allow an in-depth understanding of the range and severity of symptoms experienced by patients, and the impact these may have. Dimensions of PROMs should be based on patient experiences, best generated by qualitative research methods.
Session 1c. PROMs for specific patient groups

A53

Subjective Quality of Life (QOL) accounts. Essential for applied health research into long term conditions (LTCs)

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A53

Background: This study focuses on QOL measurement in Chronic Fatigue Syndrome (CFS/ME). A heterogeneous and complex illness with fluctuating and unpredictable symptoms.

Aims: To pilot a nationally recognised QOL Patient Reported Outcome Measure (PROM) to improve recording and analysis of patients’ personal accounts. To produce accessible data for clinical and research settings, with direct relevance to patient care and commissioning decisions.

Design and Methods: A scoping exercise appraised current practices and reviewed relevant measures. By CFS/ME specialist consensus, the World Health Organisation’s QOL PROM of 26 items (WHOQOLBREF-26) was completed with ten patient volunteers. Following a positive professional evaluation, the initiative was registered as a host trust Improvement, Quality and Efficiency project (IQC). A sample of one hundred patients completed the questionnaire in addition to the recommended PROM’s 1. before treatment and 2. after attending group sessions, at the start of individual therapy contact. Quantitative analysis compared longitudinally and to existing tools results.

Results: Standard practice, advocated by the British CFS/ME Association of Professionals (BACME) does not fully reflect patients’ self-reporting of CFS/ME. The literature emphasised QOL PROM’s but failed to reveal a universally agreed CFS specific measure. The popular Short Form 36 items (SF36) was regarded as more of a health status tool. Therapists observed ease of administration and interpretation. Change sufficient to endorse the NICE Guidelines for CFS/ME rehabilitation, enhance therapeutic encounters and commissioning decisions was demonstrated. The project outcomes are comparable to other research in this field.

Conclusions: Well validated PROM’s are applied in CFS practice and research but exhibit wide variation and lack sensitivity. Although the sample is modest, the WHOQOLBREF-26 provides a quantifiable perspective of the impact of CFS/ME for applied research and clinical application. It shows transferability to the research and evaluation of care in other LTCs.

A33

Effects of Out-of-Pocket (OOP) Payments and Financial Distress on Quality of Life (QoL) of People with Parkinson’s (PwP) and their Carers

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A33

Background: Parkinson’s, a neurodegenerative disorder largely affecting the older population, develops into gradual loss of both motor and non-motor functions, thus impacting their daily living activities. In the UK, over 127,000 people and families are affected by Parkinson's. Evidence shows an increased financial burden on families who are managing and caring for PwP.

Aims: To explore effects of OOP expenditure and loss of income on quality of life and wellbeing of PwP and their caregivers in the UK.

Methods: The on-line survey collected information from 853 PwP and caregivers across the UK on changes in their economic, social, health and living conditions due to Parkinson’s during 2015–16. Multivariate regression analyses were attempted, after adjusting for socio-demographic variables, to estimate the net effect of OOP expenditure and income loss on QALYs, VAS and wellbeing scores (on life-satisfaction, life worthwhile, happiness and anxiousness) of PwP and their main carers.

Results: QALY, VAS and wellbeing scores of PwP were negatively associated with how long they were diagnosed with Parkinson’s, i.e. disease progression. Mean OOP cost of treatment and care also increased with the duration of Parkinson’s. Significant negative relationships were found between OOP expenses and income loss on QoL of PwP as well as that of their carers. Magnitudes of coefficients were much higher in PwPs having the condition for >15 years. Similar effects but of smaller magnitudes were found on QoL and wellbeing of carers by duration of disease/ how long caring for. QoL was significantly lower in families having annual income < £20,000.

Conclusions: The management and care of Parkinson’s has resulted in considerable financial burden on PwP and their families, which further contributed in deterioration in their quality of life and wellbeing. There is a need to include financial distress indicators in PROMs for those having degenerative conditions including cancers.

A34

The Impact of Comorbidities on Outcomes of Hip and Knee Replacement: a meta-analysis

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A34

Background: Although the use of patient-reported outcome measures (PROMs) in healthcare settings has increased substantially over recent years, there is potential for them to play a greater role in primary care.

Aim: The underlying aim was to review and summarise studies exploring patients’ and health professionals’ perspectives on the use of PROMs in primary care, to identify positive and negative factors associated with their use, along with barriers and enablers.

Methods: A qualitative systematic review was conducted in Medline, Embase, PsychInfo and CINAHL from inception until 2016; further relevant references were retrieved through snowballing. Eligible studies were conducted in primary care settings, using qualitative methods, exploring patients and/or healthcare professional’s perspectives on the clinical utility of using PROMs in clinical practice.

Results: 19 studies met the inclusion criteria (4 after 2012), 11 of which were conducted in the UK, reporting on the views of professionals (8), patients (5), and both (7). The majority of studies (12) focused on mood disorders. Patients identified benefits associated with PROMs such as increased awareness, alertness, self-management, feeling validated, and being able to discuss problems they would not otherwise mention. Concerns were raised about PROMs replacing face-to-face consultations, restricting discussion, along with worries about stigma and being identified by illness(es). Professionals reported PROMs to be useful for aiding clinical decisions, monitoring and management options, aiding a better understanding of the longitudinal life of patients. Although PROMs were valued for facilitating communication it was also noted that they undermined the human element of consultations, along with professional intuition and judgement. Burden on GP time was also noted.

Conclusions: Patients and professionals highlighted a number of benefits of using PROMs in clinical practice, particularly in terms of supporting decision making, patient awareness and management/ self-management options. However, concerns were voiced about PROMs potentially undermining relational continuity of care.
### Session 2a. PROMs into practice

**A06**

**The Musculoskeletal Health Questionnaire (MSK-HQ): a partnership model of implementation to assess acceptability, feasibility and impact**  
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A06

**Background:** The Musculoskeletal Health Questionnaire (MSK-HQ) is a short self-completed questionnaire intended to be broadly applicable to assess the impact of musculoskeletal problems on patients’ daily life. This paper presents a case study of how to promote adoption of a PROM in the health service.

**Aim:** The aim of this study was to gain insights into how the MSK-HQ is used by early adopters as a resource to support organisational decision making about services and impact on individual patient care.

**Methods:** A partnership approach to implementation was adopted; a collaboration between a charity (ARUK), researchers and n = 10 partners providing a range of MSK services. Interim interviews were conducted over a one-year period to share emerging experiences, successes and challenges. Interviews were audio recorded and transcribed and framework analysis conducted using NVivo 10.

**Results:** Logistics and feasibility: Several partners experienced delays in implementation due to reconfiguration of services and installation of new clinical systems. Some experienced challenges with negotiating external processing for electronic capture and data governance. Capacity to process and analyse data was variable; some sites utilised external contractors whilst others relied on existing analytical support. Interpretability: The minimally important difference (MID) was considered fundamental to interpretation.

**Acceptability:** The MSK-HQ was acceptable to patients; easy to complete and relevant to their condition. A high level of staff engagement and confidence in the measure was evident with some staff reporting a more structured appointment resulting in more time for the delivery of treatment.

**Conclusion:** Despite some challenges, the MSK-HQ appears to be acceptable, feasible and useful for clinical decision making. Partnership between charities, academics and local NHS services is a promising mechanism to implement PROMs.

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**A56**

**When, how and why do PROMs feedback improve clinician-patient communication within the consultation? A realist synthesis**  
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A56

**Background:** It is suggested that the use of patient reported outcome measure (PROMs) in clinical practice can enhance patients’ consultations with clinicians and improve clinical management.

**Methods:** A realist synthesis to explore the contexts in which and processes through which PROMs enable patients to share concerns with clinicians and change clinicians’ communication practices. We identified the ideas and assumptions (theories) underlying how PROMs use was intended to work. Electronic databases were searched and backwards and forward citation tracking were carried out.

**Aim:** To understand how clinician-patient communication is detached from the patients’ routine NHS care pathway and how the use of PROM can enhance patient and clinician communication.

**Methods:** The Oxford hip and Knee PROMs collection is detached from the patients’ routine NHS care pathway and has a response rate of 60%.

**Aims:** The aim of this study is to examine whether embedding the use of electronic PROM score collection in the care pathway, creating value for patients, improves response rates.

**Results:** The Oxford hip and Knee scores were embedded into the clinical pathway. Using a cloud-based ePROM format was used to support decision making prior to surgery, to record the base line level of pre-operative symptoms, to monitor early outcomes and to offer long-term surveillance of outcomes. PROMs data was shared with patients at all stages, with the format guided by PPI development input. The response rate at 1-year follow-up was 39%. Comparison was made to standard NHS PROM collection as a control.

**Conclusions:** PROM scores can be used to enhance the patients’ pathway for Hip and Knee Replacement surgery in the NHS. Patients engagement in PROM use resulted in a significant increase in response rates at longer term follow-up.
out on key systematic reviews. We selected papers relevant to testing our theories and 36 papers were included.

Results: PROMs completion prompts patients to engage in self-reflection about their health. Whether PROMs supported or constrained patients in sharing issues with clinicians depended on the structure of the PROM and existing clinician-patient relationship. Clinicians perceived standardised PROMs constrained their relationship with patients and were difficult to incorporate into the flow of consultations. Clinicians avoided using them or adapted the PROM, which may compromise their validity. Individualised PROMs supported consultations by allowing patients to ‘tell their story’ but were less useful as an outcome measure. In oncology, PROMs did not substantially change clinicians’ communication practices; consultations focused largely on symptoms rather than psychosocial issues.

Conclusions: It is the process of PROMs completion which helps patients to reflect on their health and raise issues with clinicians. The structure of the PROMs was a key determinant of the extent to which the use of PROMs supported or constrained the clinician-patient relationship. Faster use of PROMs to disrupt the consultation process, and the relationship building function of the consultation, rather than just the information exchange and decision making functions.

A51 Converging and diverging views about PROMs: a qualitative study involving patients and clinicians
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A51

Background: Although the use of Patient Reported Outcome Measures (PROMs) is being advocated increasingly in clinical practice, there has been a lack of input from patients and clinicians into this process. The success of new initiatives rests on engagement from both of these groups.

Aims: To explore the views of patients and clinicians concerning the use of PROMs in musculoskeletal healthcare practice.

Method: A combination of focus groups and individual interviews were undertaken with patients and clinicians. A topic guide was used to support semi-structured interviews and focus groups which were audio-recorded. All transcripts were transcribed verbatim and analysed using the Framework approach. Themes and sub-themes were identified, and explanatory models were developed to describe the data.

Results: Interviews were held with patients (N = 18) and clinicians (N = 46) from around the United Kingdom. Clinicians and patients recognised how PROMs could facilitate communication between patients and healthcare professionals, and among healthcare professionals, demonstrate the effects of practice, provide the opportunity to contribute feedback about care, and the importance of having a clear statement on data use and security. Patients stressed their willingness to complete PROMs in an electronic format, and the importance of short questionnaires with a quick completion time. They emphasised their reluctance to use PROMs to disrupt the consultation process, and willingness to seek IT help if required. In contrast, clinicians expressed concerns about patient burden and patients’ IT capability, language accessibility, and suitability of PROMs for different settings. While reflection on practice was regarded as important by clinicians, dealing with patients’ feedback was regarded as challenging.

Conclusions: The clinicians’ concerns about patient burden and IT capability were not reflected by the patients who were willing to use PROMs. Patients welcomed the opportunity to provide feedback about their care.

A78 ACHIE - The Arthroplasty Candidacy Help Engine - Using PROMs data to identify thresholds for referral in hip and knee replacement surgery
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A78

Background: At present there is no evidence to support the use of the Oxford PROM scores to set pre-operative thresholds for referral for hip and knee replacement surgery. Despite this the practice has been widespread in the NHS.

Objectives/Research Questions: Can the Oxford Hip/Knee scores (OKS/OHS) be used to set referral thresholds for hip/knee replacement surgery? Does the choice of threshold affect the cost-effectiveness of the procedure?

Results: The absolute threshold for the OHS was 41 and 42 for the OKS. A model was created that used preoperative Oxford scores to estimate the probability of a good outcome allowed – e.g. an OHS of 35 or an OKS of 30 offers a patient a 70% probability of achieving a good outcome. The economic evaluation demonstrated that TKA and THA cost £20,000 per quality adjusted life-year (QALY) gained for >99.9% of patients who currently undergo surgery. It is cost-effective to conduct TKA on patients with OHS of 43 (95% credible interval, 42.4; 44.4) or less and on patients with OHS of 45 or less (95% CrI: 42, 44, 44).

Conclusion: Using the ACHE tool the Oxford Hip/Knee Scores can be used to assess an individual patients suitability for hip or knee replacement surgery. On a population level both interventions are highly cost-effective right up to the absolute threshold for intervention. The ACHE tool appears to be a useful evidence based clinical tool to aid referral from primary to secondary care.

Session 2b. Development and validation of measures – 2

A75 Collaborating with burn patients and their families to develop the CARe Burn Scales: a portfolio of burn-specific quality of life PROMs for use in paediatric and adult burn care
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A75

Background: 250,000 people in the UK each year suffer a burn injury. Those affected can experience life-long difficulties including pain, sleep disturbance, anxiety, depression and body image distress. Currently there is no standard practice for collecting PROM data in the NHS Burns Service. Few burn-specific PROMs exist and even less have been developed with burn patients themselves. In collaboration with adolescents and adults with a burn injury, family members and health professionals (HPs), we developed the CARe Burn scales: a portfolio of quality of life burn-specific PROMs for use in child, young people, and adult burn care.

Aim: To incorporate the opinions of patients and family members in the development of the CARe Burn Scales.
Method: Semi-structured interviews were carried out with patients \((n = 19)\), family members \((n = 25)\) and health professionals \((n = 8)\). Thematic analysis identified a number of issues experienced by individuals who are living, or supporting someone, with a burn-injury. The findings informed item generation and the conceptual framework for each PROM. Two systematic reviews of the PROMs currently used in paediatric and adult burn care were also conducted to inform the PROM development. Three age-specific PROMs for children (aged under 8), young people (aged 8–17) and adults (aged 18 and over) were developed. Twenty cognitive-debriefing interviews were then conducted with patients, family members and HPs who reviewed the PROMs in order to identify relevance and readability.

Results: The need for burn-specific PROMs to identify patient needs in burn care was reinforced, revisions to improve the PROMs were made and HPs suggested how they would utilise the PROMs within their practice. Psychometric analysis of the PROMs were then conducted using Rasch and classical test theory to further refine and validate the PROMs.

Conclusions: The CARE Burn Scales are now available for use in research and clinical practice.

A05
Testing the face validity and acceptability of the Primary Care Outcomes Questionnaires through cognitive interviews
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Health and Quality of Life Outcomes 2017, 15(Suppl 1): A05

Background: The Primary Care Outcomes Questionnaire (PCOQ) is a new patient-reported outcome measure designed specifically for primary care. It has two formats: the PCOQ-status (which has an adjectival scale) and the PCOQ-change (which has the same items as the PCOQ-status, but a transitional scale).

Aim: This paper describes the process of improving the face validity and acceptability of the PCOQ-status and PCOQ-change through cognitive interviews with primary care patients.

Methods: Three rounds of cognitive interviews were held with twenty patients from four health centres in Bristol. Tourangeau’s model of cognitive processing was adjusted for this research and used to identify problems. This contained four categories: general comprehension, temporal comprehension, decision process, and response process. The resultant pattern of problems was used to assess whether the items and scales were working as intended, and to make improvements to the questionnaires.

Results: The problems identified in the PCOQ-status reduced from 41 in round one to seven in round three. The PCOQ-status was both acceptable to patients and had face valid. As with previous studies, there were very few decision problems, and most comprehension problems. The new category of temporal comprehension helped improve the face validity. The PCOQ-change was less acceptable to patients and was misunderstood, resulting in it being completed incorrectly by 50% of patients. It was not taken forward after round one.

Conclusions: Overall the method of cognitive interviewing proved successful in reducing the number of problems for the PCOQ-status identified in each round. The PCOQ-change was poorly understood. Given that this corroborates existing research, this may call into question the use of transitional questionnaires for measurement of outcome in primary care, and the highlights need for cognitive testing of such questionnaires prior to quantitative psychometric testing.

A08
Validation and refinement of the HASMID questionnaire: a measure of health and self-management in diabetes
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Health and Quality of Life Outcomes 2017, 15(Suppl 1): A08

Aims: Last year we presented the processes undertaken to develop a new questionnaire to evaluate self-management in diabetes (HASMID questionnaire). This new study aims to assess the 1) mode of administration (online and paper-based) and 2) psychometric properties of HASMID to explore the relationships between some items and further refine the instrument.

Methods: Focus groups were held with people living with diabetes to further reflect on wording of the original 8-item HASMID questionnaire. Alternative phrasing was suggested for 5 items covering mood, daily routine, stress and hassle, and all 13 items were put forward for validation. The validation study consisted of two arms/groups - online or paper survey. Respondents were asked to complete 13 HASMID questions, EQ-SD and sociodemographic questions. Potential participants were recruited via a patient database and social media (email and Twitter), and asked to complete the survey at two time points, so that the responsiveness of the HASMID instrument could be assessed.

Results: Data collection for time point 1 is ongoing. Recruitment (up to 1st February 2017) included 1756 and 865 completions to the online and paper versions respectively. Completed responses from people with diabetes included those with type 1 = 792, type 2 = 1980 and other forms of diabetes = 49. Data collection for time point 2 will be complete in May 2017. Results will be presented to demonstrate the reliability (internal consistency) and validity (known-group differences) of the HASMID instrument. Item correlations, missing data, floor and ceiling effects, and comparison with EQ-SD scores will be reported. Reference will be made to the quality of data collected via paper vs. online completes. The refined HASMID questionnaire will be presented.

Conclusions: This study will demonstrate the benefits of further validation in the development of instruments. In addition, the consideration of differing modes of administration, and participant recruitment will be discussed.

Session 2c. Analytic issues

A61
What exactly is a good outcome for total knee replacement (TKR)? And what proportion of patients experience one?
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Health and Quality of Life Outcomes 2017, 15(Suppl 1): A61

Background: Patient reported outcome measures (PROMs) are used to assess total knee replacement (TKR). Variation exists in reported values for the proportion of patients achieving a “good outcome”, ranging from 53%–79%. The variation could reflect how a “good outcome” is calculated rather than true differences in study populations.

Aim: Using a large data set, the aim of this study is to determine the proportion of THR and TKR patients experiencing a “good outcome” using different criteria, and compare the results obtained via each method.

Methods: The TKR-PROMs dataset (2012–2013, \(n = 40,622\)), including 6-month Oxford Knee Scores (OKS) was investigated. Four common criteria (shown below) were used to calculate the proportion of patients achieving a good outcome:

1. ½ standard deviation (SD): For good outcome, the change pre- to post-operative OKS (\(\Delta\)OKS) must reach \(\frac{1}{2}\) SD of the average baseline OKS for the population
2. Minimally Important Change (MIC): For good outcome, \(\Delta\)OKS must reach the MIC.
3. Satisfaction Criteria: Good outcome defined by \(\Delta\)OKS or 6-month post-op OKS must reach the patient acceptable symptom state (PASS) score, which separates the satisfied from the unsatisfied.
4. Response: Good outcome defined by modified OMERACT-OARSI criteria, which categorizes patients as “responders” and “non-responders” based on change in pain and function.
Results: Good outcome was achieved in 88% (\(\pm\) SD), 74% (MIC), 71% (Satisfaction/PASS) and 83% (Response/OARSI) respectively.

Conclusions: In the same population, the proportion of patients achieving a good outcome can appear different depending on the metric used. Caution should be applied when viewing the outcome of data sets using different methods, particularly when using binary thresholding methods. A universal method of calculating and describing good outcome should be developed.

A04
Symptom clusters for revising scale membership in the analysis of Patient Reported Outcome Measures
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A04

Background: Summative scores (individual items pooled together usually using average) are used to extract and interpret information contained within PROMs. Tools such as University of California, Los Angeles Prostate-Cancer-Index (UCLA-PCI) arrange items in scales according to the underlying health concern. Those scales are used to create agglomerate scores. However, this generic approach may be less sensitive e.g. for varying side-effect profiles due to different treatments. An alternative method that offers a flexible and adaptive approach of grouping symptoms and summarising PROMs is to use symptom clusters (SC).

Aims: To compare SC with scales. To explore the value of SC in the analysis and interpretation of PROMs and in symptom management for patients.

Methods: A dataset of 843 prostate cancer patients from a randomised control trial called RT01 was used. PROMs were reported with the UCLA-PCI. SC were explored with hierarchical cluster analysis (HCA) and summarising PROMs is to use symptom clusters (SC).

Results: Two SC were identified (Urinary Cluster and Sexual Cluster). The grouping with SC was different than scales. Two items of the Urinary Function Scales ("Number of pads" and "Urinary leak interfering with sexual activity") were not included in the Urinary Cluster due to the low correlation which ranged from 0.20-0.21 and 0.31-0.39 respectively. Cronbach's Alpha also showed low correlation of those items with the scale (0.14-0.36 and 0.33-0.44 respectively). All Urinary Function Scale items were subject to a ceiling effect.

Conclusion: SC provide a study specific approach for adaptive modelling and interpretation of PROMs. Multiple-item scales should be evaluated with SC.

A22
Mapping between PROMS, and the Relative Responsiveness of PROMs: a meta-analytic approach
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A22

Background: There is often a need to synthesise treatment effects across trials which have reported similar but different outcomes. Standardised Mean Differences are used for this, but this introduces random error. There is also interest in the relative responsiveness of test instruments, and in the relationships between treatment effects on different - but similar - scales, sometimes for the purpose of health economic evaluation. The purpose of this research was to develop methods that achieve all these aims.

Methods: Statistical methods were developed to synthesise information on different measurement scales both within and between trials, from connected networks of trials. ("Connected" here means that each trial includes at least one test instrument that was used in at least one other trial). A key assumption was that the larger the treatment effect on one scale, the larger on the other scales. The models estimated coherent "mappings" between test instruments. If applied to standardised effects, the mappings reflect relative responsiveness. These models were applied to 3 datasets; first to 6 outcomes from 8 trials on biologic therapies in Ankylosing Spondylitis; second to 9 outcomes from 22 trials on treatments for Social Anxiety; and third to 6 outcomes on 19 trials of treatments of depression.

Results: The models fitted the data well, although the mappings varied slightly from trial to trial with a coefficient of variation approximately 13%. This may reflect non-linearity in the relationships between scales. Models based on standardised mean differences fitted less well, and estimated effects with less precision. It was possible to rank scales in responsiveness, and identify some scales as clearly more responsive than others.

Conclusions: Simultaneous synthesis and estimation of mappings is superior to standardisation while making fewer assumptions. It provides insights into the relative responsiveness of test instruments, and can efficiently estimate "mappings" between outcome scales.
Session 3a. Electronic delivery and CAT

A38

Patients, staff and relatives agree: electronic PROM reporting of adverse events is a feasible and acceptable adjunct to standard care in pelvic radiotherapy for cancer: eRAPID (Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice)

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A38

Background: PROMs are routinely used to report late effects of pelvic radiotherapy however recent reviews (Holch 2016 & Gilbert 2015) have shown they are under-utilised in the acute phase. We aimed to explore the acceptability and feasibility of an innovative online self-report and symptom management system (eRAPID) incorporating PROMs into the electronic patient records in routine cancer care. Currently eRAPID is proving acceptable and useful to patients undergoing systemic cancer treatment.

Aims: To explore whether radiotherapy patients and their relatives could see the benefits of online PROM reporting despite daily hospital attendance and if staff would find the electronically accessible PROM data a useful adjunct to clinical assessments.

Methods: N = 73 participants took part in audio-recorded semi-structured interviews at St James’s Institute of Oncology, Leeds and The Christie Hospital, Manchester. Patients (n = 37) undergoing radiotherapy/concurrent chemotherapy for prostate, colorectal and gynaecological cancer were interviewed during, on completion and 6 weeks post-treatment (age range 42–81 mean 62).

Additionally we interviewed key staff (nurses, oncologists and radiographers) (n = 26) and patient relatives (n = 9). Interviews were transcribed, coded thematically and managed in NVivo.

Results: Emergent themes revealed patients were positive about the online PROM system. They thought eRAPID could ‘enable the reporting of difficult or challenging symptoms’ and be a ‘source of out-of-hours information’. Staff felt the system would ‘enable support during follow up’ and ‘fill gaps in toxicity reporting’. Relatives highlighted that eRAPID would ‘forewarn of potential side effects’ and has the potential to ‘maintain patient independence’.

Conclusions: Findings suggest that despite daily hospital attendance both patients and their relatives stated an online PROM management system would be beneficial in the acute and late phases of treatment. Staff agree that eRAPID would be a valuable enhancement to current service provision. A feasibility study is currently underway at Leeds and The Christie NHS Trusts.

A24

The eSMART RCT: Comparing electronic Symptom Management using the Advanced Symptom Management System (ASyMS) with standard care for patients during adjuvant chemotherapy

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Background: ASyMS is a mobile-phone based remote-monitoring and alert system enabling real-time monitoring of patients’ chemotherapy-related symptoms. The eSMART RCT compares patient reported outcomes (PROs) and delivery of care for patients using ASyMS with those accessing the same Acute Oncology Service through the standard care pathway at each participating site.

Methods: Patients newly diagnosed with breast, haematological or colorectal cancer and scheduled to receive at least three cycles of chemotherapy are recruited into this multinational repeated measures, parallel-group stratified RCT. 1108 patients will be randomised to either ASyMS or standard care. Patient demographic and clinical data is collected at baseline and standardised PRO measures are completed at baseline, during each cycle of chemotherapy and every 3 months up to 12 months after chemotherapy. The primary outcome measure is the Memorial Symptom Assessment Scale. Secondary measures include: Functional Assessment of Cancer Therapy-General, Supportive Care Needs Survey-Short Form 34, State-Trait Anxiety Inventory, Communication and Attitudinal Self-Efficacy scale for cancer, WHOQOL Self-Reported Questionnaire, EuroQol and Client Services-Receipt Inventory.

Results: RCT data collection started in May 2016, and to date 432 patients have been recruited from 11 centres in 5 countries including participants from the UK.

Conclusion: Patients are willing to accept randomisation into the study and recruitment is ongoing. An overview of the trial aims and design and a reflection on the challenges faced in setting up the study and the solutions implemented to overcome them will be provided.

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A27

Quality of life assessment is more efficient precise when conducted using a computer adaptive testing protocol : an international study

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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A27

Background: We calibrated four item banks using the WHOQOL-100 quality of life assessment and deployed them online as computer adaptive tests using the Concerto assessment platform.

Methods: The WHQOL-CAT was developed using Concerto hosted online. Item selection and scoring was conducted using the partial credit ‘Rasch’ model with maximum likelihood estimation. The WHQOL-CAT provides four separate unidimensional assessments of quality of life in physical, psychological, social and environmental domains.

Results: 4886 patients from 115 countries, including 578 from the UK, completed the WHQOL-CAT. 1745 patients reported a long-term condition and 586 participants reported multiple long-term conditions (multimorbidity). Average age was 35 years (range 18 to 92) and 47% of the sample were female. Assessments were conducted with a mean reliability (Alpha Cronbach’s equivalent) of .83 (range .82-.88) using, on average, 4.8 items per domain. Average assessment time was 95 seconds (4.8 seconds per item). Participants who self reported long-term conditions reported significantly lower scores on the physical quality of life domain (t = -3.06, P < 0.01) but not on any of the other four domains.

Conclusions: When administered to a diverse international sample of participants, the WHQOL-CAT compares favourably to the WHOQOL-BREF and WHOQOL-100. The WHQOL-CAT is between 80% and 25% shorter than the paper-based measures and is slightly more reliable. Accurate QoL assessment across four domains can be made in under two minutes. Advantages of CAT which are typically demonstrated using simulated CAT administration ‘in the lab’ appear to be evident in studies using data collected ‘in the real world’ from a diverse international sample.
A23
The PROMIS Profile 29 allows valid comparisons of patient-reported health over France, and the UK
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A23

Background: Patient-Reported outcome measures are increasingly utilized. Comparability of such measures over different languages needs to be established to allow cross-national research. We investigate the comparability of the PROMIS Profile 29, a generic health-related quality of life measure, in general population samples in the UK, France and Germany.

Methods: A web based survey was simultaneously conducted in the UK (n = 1,509), France (1,501) and Germany (1,502). Along with the PROMIS profile 29, the participants answered sociodemographic questions as well as the EQ-5D. We tested measurement invariance by means of multi-group confirmatory factor analysis. Differences in the health-related quality of life between countries were modeled by linear regression. We present general population reference data for the included PROMIS domains utilizing plausible value imputation and quantile regression.

Results: Multi-group confirmatory factor analysis of the PROMIS Profile 29 revealed strong measurement invariance between different languages (CFI = 0.952, TLI = 0.950, RMSEA = 0.049, SRMR = 0.041). We observed significant differences in patient-reported health between countries, which could be partially explained by differences in overall ratings of health. The physical function and pain interference scales showed considerable floor effects in the normal population in all countries.

Conclusion: Scores derived from the PROMIS Profile 29 can be readily compared across the UK, France and Germany. Due to the use of plausible value imputation, the presented general population reference values can be compared to data collected with other PROMIS short forms or computer-adaptive tests.

Session 3b. Concepts and models

A12
The Development and Use of Conceptual Models
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A12

Background: Conceptual models (CMs) provide visual representation of disease related concepts and their causal linkages. CMs can aid the development and/or revision of patient reported outcome (PRO) instruments; guiding decisions around what and how to measure (e.g. identification of clinical trial endpoints and suitable PROs).

Aims: To undertake a targeted review of the use and development of CMs in published PRO research, using examples to make suggestions for best practice for developing and using effective CMs.

Methods: A targeted literature search was undertaken in PubMed (2007–2017) for publications associated with CM development associated with PROs. A separate hand search was conducted in relevant conference proceedings, such as ISPOR to identify CM guidelines and/or publications. Data was reviewed for CM development methods to guide best practice suggestions.

Results: Of 47 abstracts identified and reviewed, 12 were found to be potentially relevant for full text review; one didn’t include a CM and was therefore excluded. Of the included publications included patient research (qualitative interviews/focus groups) in their CM development; another five only included information extracted from a literature review (qualitative patient data), and one lacked development details. The majority of CMs included domains and sub-domains associated with symptoms, impact on health related quality of life, and associated treatment impacts. Only three studies reported including data from/review by clinical experts. No best practice guidelines for CM development were identified; although publications specific to PRO content validity were. These state that qualitative data should be included in research to confirm the conceptual framework of PROs used in trials.

Conclusions: CMs are important for identifying disease concepts from the patient perspective which is essential for identifying trial endpoints and confirming PRO content validity; a necessity for regulators. For a CM to fully explore patient perspective, the inclusion of patient data during the development appears to be essential.

A55
Chronobiology and PROMs: a systematic scoping review for patients with chronic health conditions
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A55

Background: Aggregate estimates of Patient Reported Outcome Measures (PROMs) are being increasingly used for measuring health care providers’ performance. There is also growing recognition of the potential of the individual use in enhancing patient centredness in the provision of clinical care. The impact of biological, environmental and social cyclical phenomena on intra-individual PROMs estimates has previously received little attention because of the implicit assumption that it may be negligible for group-level estimates. It may be however significant for individual use.

Aims: To map the key concepts that underpin research in the chronobiology of PROMs as well to identify and summarize available evidence for patients with chronic conditions.

Methods: We conducted a systematic search and review of the literature, following the PRISMA statement and a protocol in the PROSPERO database. Electronic databases (MEDLINE, Embase, PsycINFO, and CINHL) were searched using MeSH terms, free text and previously developed search strategies. All documents literature for chronobiology and PROMs focusing on chronic conditions were included, without any restriction. Two reviewers independently applied the criteria in the consecutive stages of title, abstract and full-text screening. A narrative synthesis of the data will be conducted.

Results: 2098 unique titles were identified, the majority of them (1460, 69.6%) were published in the last 10 years. The review is currently in progress and full results will be ready to report at the conference. Literature consists of quantitative analyses of observational data, and reports from experimental studies. Evidence have been identified for daily variations of patient reported outcomes as a result of biological rhythms for a range of chronic conditions, such as arthritis, asthma, migraines, depressive symptoms and cognitive status.

Conclusions: If chronobiology and its effects can be identified and therefore considered in a policy setting this will facilitate further use of PROMs in an individualised patient setting.

A76
Diversity in values across the life-course
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A76
**Background:** This paper considers the possibilities for the application of capability measures within a life course framework. Life course concepts focus on interlinking between generation and age. This may be a particularly useful way to think about values within a capability framework, given the importance of context within the approach and the potential for diversity in considering capability to different groups.

**Aims:** To explore the extent to which ‘what people have reason to value’ differs at different points in the life course.

**Methods:** (i) Examination of existing capability measures for adults, older people and end of life, generated using similar methods (in-depth interviews with the populations of interest and valuation using best-worst scaling/discrete choice techniques) to determine similarities and differences in values at different points of the life-course; (ii) Examination of issues that would arise in fully exploiting a life-course approach to capability measurement.

**Results:** Measures for adults and older people are broadly similar but there are important differences that may reflect life course issues, particularly in relation to differences between Achievement (adults) and Role (older people), and between Stability (adults) and Security (older people). The end of life measure has much greater variation within its attributes, appearing to reflect concerns with anticipated lack of capacity at end of life. Important issues in generating a comprehensive life-course approach include delineating points on the life course at which values changes, integrating measures across different stages of life, and generating appropriate measures for children that capture both well-being and well-becoming, and rapid changes in development and capacity.

**Conclusions:** Despite many challenges, a life-course approach to capability measurement may well offer an approach that accounts for much of the diversity in values without requiring new capability indices for every situation; pursuing this approach would be a worthwhile endeavour.
New methods for analysing the distribution of EQ-5D observations
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Health and Quality of Life Outcomes 2017, 15(Suppl 1):A45

Background: This paper proposes and tests new methods (Health State Density Index, Health State Density Curve and estimated Power Law functions) we have developed to characterise and summarise the distribution of health states in Patient Reported Outcome (PRO) data within a sample or population of patients. The purpose of these methods is to measure how diverse any given patient group is. These results are relevant to clinicians responsible for service delivery - for example, a homogenous population of patients can be managed by protocol based interventions whilst heterogeneity requires more complex service delivery. The methods also have applications in comparing the descriptive performance of alternative instruments (e.g. EQ-SD-5 L vs EQ-SD-3 L) and in understanding the underlying nature of changes in health states resulting from treatment in clinical settings or trials.

Methods: Using both the new methods and existing methods from information theory (e.g. Shannon’s Index), we compare the distribution of EQ-SD health profiles across three groups of patients in two data sets: Cambridgeshire Community Services NHS’s electronic patient records for the EQ-SD-5 L; and the Health Survey for England 2014 for the EQ-SD-3 L. To explore the link between changes in the distribution of self-reported health and health changes, we use data from the NHS PROMs programme which reports EQ-SD-3 L before and after four surgical procedures. The properties of the various methods are further examined using simulated data sets.

Conclusions: Our results show that each method has different properties and will give different insights into patients’ data. For example, the Shannon index (absolute and relative) is not sensitive to random variations but decreases slowly with “rare health states”. The HSDE decreases slowly with random variations and is strongly affected by “rare” health states with large decreases towards zero (total inequality). We discuss the implications for the interpretation and analysis of PRO data.