QORU | quality and outcomes of person-centred care policy research unit

The development of the long-term conditions questionnaire (LTCQ)

Interim report

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March 2015

University of Kent

LSE THE LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

UNIVERSITY OF OXFORD

The Policy Research Unit in Quality and Outcomes of person-centred care (QORU) is a collaboration involving researchers in health and social care from the Universities of Kent, Oxford and the London School of Economics (LSE) funded by the Department of Health.

Our aim is to improve the quality of health and social care of people with long-term conditions through generating high-quality evidence about need, quality and outcomes of person-centred care.

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This is an independent report commissioned and funded by the Policy Research Programme in the Department of Health. The research for this report was also funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Oxford at Oxford Health NHS Foundation Trust. The views expressed are not necessarily those of the Department of Health or the NIHR.

Introduction and background

It is a key government priority to assess and improve outcomes in long-term conditions (LTCs) and recent policies have highlighted the importance of moving from a process-focused system of determining service quality, to a system that focuses on outcomes, particularly those outcomes identified by patients as important (Department of Health, 2013a,b). Traditional clinical outcomes indicators such as mortality or improvements in physical health may not be informative enough to monitor outcomes in LTCs. Disease-specific outcome measures may not capture outcomes that are relevant across conditions.

Patient-reported outcome measures (PROMs) aim to capture the patients' view on outcomes in relation to their LTC. There are important arguments in favour of using existing generic measures, such as the EQ-5D, due to the considerable effort needed to develop and validate such a measure. Our analyses have suggested that although the EQ-5D allows the derivation of a weighted index for monitoring quality of life in LTCs, it is highly focused on personal functioning, being sensitive to measuring the impact of interventions that *restore* functioning or alleviate impairment, but is less sensitive for interventions that help people manage the ongoing consequences of their LTC(s). Also, the EQ-5D is limited in the dimensions it assesses (mobility, self-care, usual activities, pain/discomfort and depression/anxiety) and other dimensions (for example, ability to self-manage, stigma or burden of treatment) are also crucial to quality of life in LTC(s). The case for a new measure is further strengthened by the need for outcome measures to reflect the full range of impact of services (not just on health status) and the consequences of service use for the service recipient rather than direct measures of the inputs, process or outputs of services.

On a practical level, there are problems using the EQ-5D together with other already existing disease-specific measures as these all assess different outcomes and it would be challenging to interpret and use the findings. These PROMs were not developed principally to facilitate communication in individual patient care and few have been tested for that application. Few have been developed in the context of the emerging agenda of change for services for LTCs, such as self- management or to capture 'higher order' dimensions such as social participation, stigma, or dignity. Furthermore, many issues and service needs for people with LTCs overlap and therefore a measure that assesses these commonalities would be beneficial.

Aims

The primary aim of this work was to develop a questionnaire for LTCs that captures both traditional and non-traditional outcomes. The intention for this questionnaire is to be complementary to the EQ-5D; hence not covering the EQ-5D dimensions but focusing on other dimensions of importance in LTCs. The aim was also to develop a measure that was applicable in both physical and mental health conditions, as well as single and multiple

morbidities. Additionally, it is intended that this questionnaire will be useful across health and social care services.

Progress to date

To develop the LTC questionnaire (LTCQ), a multi-phase study is underway. This consists of 1) literature reviews, 2) consultations with professionals, 3) qualitative interviews with people with LTC(s), 4) drafting potential items, 5) consultation with the Department of Health (DH) and NHS England (NHSE), 6) cognitive interviews with people with LTC(s), 7) translatability assessment, 8) professional stakeholders' review of the draft LTCQ, 8) further rounds of cognitive interviews, and 9) a validation survey. Phases 7 and 8 are currently underway.

1) Literature reviews

To develop the foundations for the LTCQ, a series of scoping reviews were conducted. The aim was to conduct reviews that focused both on traditional PROMs and measures that assessed dimensions not usually covered in traditional PROMs. For the former, we reviewed generic and disease-specific PROMs and social care measures across a range of LTCs. For the latter, we reviewed self-management tools, priorities of care from the views of patients and professional stakeholders, PROMs in clinical practice, patient empowerment, health literacy, burden of treatment and disease burden.

A conceptual framework was developed on the basis of the findings from the scoping reviews. Domains within this framework included 'ability to achieve personal goals', 'being involved and in control of health decisions', 'social aspects', 'coping well/badly with LTC', 'feeling informed', 'safety', 'stigma', 'burden'. These domains informed the consultation with professional stakeholders, as well as the development of the interview guide for people with LTC(s). All of these dimensions included sub-themes and these are shown in Table 1. This was intended as a flexible framework to be refined as the research progressed.

Table 1: Dimensions and sub-themes identified from the literature as important in LTC

Dimension	Sub-theme
Ability to achieve personal goals	• Disruption to life • Hope/ staying positive • Activity • Plans and goals/ purpose in life
Being involved and in control in relation to health decisions	• Care planning • Empowerment • Patient involvement • Choice • Patient preferences or priorities • Control • Mastery
Social aspects	• Social participation • Social support
Coping well or badly with LTCs	• (Process of) adjustment to LTCs • Distress • In(dependence) • Psychological well-being • Coping • Autonomy
Feeling informed in the way you want	• Health literacy • Health education • Empowerment/ information
Safety	• Feeling safe • Accommodation/ housing
Stigma	• Internalised stigma • External stigma
Burden	• Burden of treatment • Burden of care/ services received

2) Consultation with professional stakeholders

This consultation phase involved qualitative interviews with 31 professional stakeholders (commissioners, policy makers, service providers, health and social care services managers, front-line clinicians and charities). The interviews' main aim was to ascertain if there was support for developing a PROM for LTCs. The interview guide focused on the value, uses

(including settings), and content of a PROM for LTC. The majority of these interviews were conducted by telephone although two were conducted face to face. Interviews typically lasted on average 40 minutes. All participants signed an informed consent form. The interviews were digitally recorded and transcribed verbatim by a professional transcriber. A thematic analysis was under-taken.

The participants highlighted a range of challenges in the development of such a measure but broadly supported the development for a PROM specific to LTCs. Participants agreed that the PROM should be relevant to service users and front-line practitioners, work for individual patient care and work across multiple conditions. Uses for the PROMs included the improvement of services as it may allow the re-design of services or inform practitioner-patient interaction; increased involvement of patients in their care; and capturing outcomes for interventions. Front line clinicians mainly advocated a PROM for individual use, but participants with a commissioning or policy role also advocated using it an aggregated population level. Concerns included engaging patients and practitioners, implementation of the PROM across health and social care services, and the interpretability and usability of the PROM. The interviews highlighted the need for a PROM that includes both traditional PROM items and other non-traditional dimensions such as social participant, empowerment and experiences of services.

Ethics approval was obtained from the Medical Sciences Inter-Divisional Research Ethics Committee (MSD IDREC), University of Oxford (MSD-IDREC-C1-2013-206).

3) Qualitative interviews with people with at least one LTC

Participants for the qualitative interviews were recruited through primary care practices (n=42) within Oxfordshire and London. People with one of ten LTCs were invited for an interview by the practice. The ten LTCs were selected by the research team together with a panel of 5 researchers and three PPI advisors knowledgeable about LTCs. The PPI advisors were recruited through the QORU Public Involvement and Implementation Group (PIIG). The LTCs were selected on the basis of body systems, the WHO Global Burden of disease) [1], a recent primary care study on multi-morbidity [2], and the Quality and Outcomes Framework (QOF; http://www.nice.org.uk/aboutnice/qof/qof.jsp). The aim of the selection was to maximise diversity of LTCs in terms of symptoms, disease trajectory, prevalence, mean age of onset, likelihood of comorbidities, burden of disease, type of health and/or social care needed, level of self-management and burden of care. The specified LTCs are cancer, chronic obstructive pulmonary disease (COPD), ischaemic heart disease (IHD), diabetes, depression, inflammatory bowel disease (IBD), multiple sclerosis (MS), osteoarthritis (OA), schizophrenia, and stroke. Over half of the panel of experts selected 7 of these LTCs, apart from IBD, MS and schizophrenia. The latter 3 had been selected by at least one panel member and were included to maximally contrast the 7 LTCs selected by the majority. It was expected that at least some of the participants recruited would be affected

by multi-morbidity, and that the eventual sample would also include LTCs other than the 10 selected.

Inclusion criteria for the qualitative interviews were that the participant needed to be 18 years of age or above; the participant needed to have been diagnosed with an LTC at least 12 months ago. For LTCs that have lifelong implications (COPD, diabetes, IBD, IHD, MS, OA, stroke), eligibility is defined as the presence of the LTC. However where full prolonged remission or cure is possible (cancer, depression and schizophrenia) additional criteria in relation to duration of disease and/or current treatment were determined (i.e. patient needed to have taken relevant medication in the last 12 months).

Interviews were mostly conducted face to face in participants' homes although a small number selected to be interviewed at the University of Oxford. All 42 participants signed a consent form. Interviews lasted between 35-97 minutes (average = 60.1) and interviewing continued until category saturation was reached [3]. Three participants reported having COPD, 14 diabetes, 6 IHD, 5 cancer, 4 depression, 5 stroke/TIA, 4 IBD, 10 MS, and 10 OA. A further 21 health conditions were self-reported across the sample, covering the entire range of bodily systems. No participants with schizophrenia were recruited through the primary care route, but 6 interviews from a separate study on outcomes in schizophrenia were included in the analysis. The sample included 22 men, 20 women with an age range of 30-97 years (average 62.8). Most were from the Thames Valley area (n=26) and the majority (n=37) were White British/Irish/European. Seventeen participants had a single morbidity and 25 had multi-morbidity.

All interviews were transcribed verbatim by a professional transcriber. All transcripts were verified by the researchers by cross-checking transcripts with the recordings. The interviews were analysed by thematic analysis, using a framework based on the reviews and stakeholder consultations. The framework was further developed as new themes were identified. Early interviews were used to inform the first draft of the development of the PROM and later interviews were used to cross-check whether all the relevant dimensions and items were covered in the PROM. The interview guide had been adapted accordingly and participants were asked to reflect on the dimensions that the PROM was going to cover.

Participants valued a range of dimensions, including the impact of LTCs on their self-perception, social participation, mental wellbeing, and safety; their ability to be physically active, self-manage, cope with their illnesses, be in control of their daily lives, and maintain their independence. They talked about the importance of social support, the impact of stigma, and the importance of support from services as well. Burden of treatment and services was also considered important.

The idea of a questionnaire capturing issues of importance in LTCs was valued by the participants. They felt that such a questionnaire could prompt self-reflection on their health, enable more open and collaborative dialogue with practitioners, and aid their problem-solving in collaboration with practitioners. They also saw the value of the data for improving

practitioners' comprehension of their needs and the need of people with different LTCs. Participants felt that a questionnaire could enable them to manage their health more effectively and make care more collaborative, but were concerned with whether and how a questionnaire would be used, mentioning issues such as time constraints on consultations and budget cuts to services.

Ethics approval had been obtained through the National Research Ethics (NRES) Committee London-Bromley in May 2014 (REC reference 14/LO/0834), and R&D approval from the two participating former Primary Care Trusts (PCTs). The study was registered on the National Institute for Health Research (NIHR) portfolio (UKCRN ID: 16750).

4) Drafting potential items

The conceptual framework initially developed from the literature reviews was adapted following the consultation with stakeholders and early interviews. These refined dimensions included 'empowerment / sense of control', 'self-management', 'impact of illness and treatment' 'health status', 'ability to achieve personal goals', 'involvement in health decisions', 'social participation', 'coping well (or badly)', 'stigma', 'sense of being supported by services', 'information', 'dependency and being a burden', 'safe environment', 'worries about health in the future', 'loneliness', 'physical activity' and 'housing issues'.

The drafting of items was an iterative process which led to a first draft list of 23 items. These were based on reviews, consultation with professionals and qualitative interviews and were cross-checked against later qualitative interviews. When possible, the items were phrased positively, as this was important to people who had participated in a qualitative interview. It was acknowledged that there was overlap between some of the 23 items. This was a deliberate decision to give the participants of the cognitive interviews the possibility to identify their preferred items and preferred wording of items. No item covered 'health status'. Although this is an important dimension, it was felt that this was already covered by the EQ-5D.

5) Consultation with DH and NHSE

The first draft of the LTCQ was presented to the DH and NHS England for their expert advice. Suggestions were made in particular about the response options and to lengthen the time frame of the questionnaire. The choice of using frequency response options was queried and it was suggested that agreement/disagreement statements or response options linked to the construct could be used. The type of response options was further explored in the cognitive interviews. Items that covered less traditional outcomes, such as burden of treatment and services, were discussed in more detail to gain a deeper understanding for choosing to include these items.

The second part of the discussion focused on the further testing of the LTCQ, in particular the survey. If the LTCQ is to be complementary to the EQ-5D, the relationship between the two measures would need to be explored. Assessing outcomes across LTCs was seen as

challenging and the survey analysis should evaluate how the LTCQ works in people with different morbidities as well as single vs. multiple morbidities. It was also recommended that future work should focus on the implementation of the LTCQ within the NHS as well as how health and social care professionals and policy decision-makers can use the LTCQ data to respond to patients' needs and to improve care.

6) Cognitive interviews with people with at least one LTC

Participants for the first round of cognitive interviews were recruited from the participants from the qualitative interviews. Further rounds will recruit new participants through primary care, using the same selection process as for the qualitative interviews. An interviewing guide was developed to probe participants on the clarity and comprehensibility of the items. Additionally, participants were asked which items were particularly important to them and which items they believed could be deleted. All cognitive interviews were recorded and notes kept during the interviews were complemented with additional information from the recordings. Comments about each item, as well as the introduction to the PROM and the response categories, were summarised in a table with a specific focus on problems raised by the participants.

A first round of cognitive interviews was conducted with 13 participants (6 men and 7 women, 4 with single and 9 with multiple morbidities) from the qualitative interviews. Participants had the following LTCs: diabetes (5), cancer (1), OA (3), MS (3), IHD (1), COPD (1), stroke/TIA (1), IBD (1), other long-term physical health (8) or mental health conditions (1). These interviews lasted on average 79 minutes (range 19-123 minutes). The summary of the comments was discussed between the research team and the PROM was amended as appropriate.

Additionally feedback was given from 5 members of the QORU PIIG. The PIIG advisors were asked to comment on the questionnaire as public and patient representatives of people with LTCs. They were asked to comment on the completeness, comprehensibility, appropriateness for use in health and social care services, presentation and length of the questionnaire.

The comments made by the cognitive interview participants and the PIIG advisors broadly overlapped. The changes made to the LTCQ reflect both the participants and PIIG advisors comments. The initial timeframe of the LTCQ was two weeks, but participants preferred a longer time frame. The timeframe was therefore amended to four weeks. The participants felt the questionnaire was a reasonable length (completion time was between 3 and 10 minutes), and that most of the items were relevant and appropriate for LTCs. The interviews suggested that respondents were satisfied with the frequency response options. With regards to the items, the comments indicated that 2 items were difficult to understand and 4 items overlapped too much with other items. Hence these 6 items were deleted. It was advised to split the item on the burden of treatment/services into two more specific items. This resulted in a new version of the LTCQ of 18 items. The remaining 10 questions were

reworded, either to clarify their meaning or simplify the phrasing used. The order of the items was also amended, as participant suggested that the questionnaire should not change repeatedly between positively and negatively worded items. The new version starts and finishes with positive items (items 1-7 and items 14-18) with the negative items nested in between (items 8 – 13).

Ethics approval had been obtained through the National Research Ethics (NRES) Committee London-Bromley in January 2015, through an amendment of the NRES application for the qualitative interviews (REC reference 14/LO/0834), and R&D approval from the participating sites (the former Primary Care Trusts of Oxfordshire, Brent, Berkshire East, Berkshire West, Buckinghamshire, Ealing, Hammersmith and Fulham, Harrow, Hillingdon, Hounslow, Kensington, Milton Keynes, Oxfordshire and Westminster). The study was registered on the National Institute for Health Research (NIHR) portfolio (UKCRN ID: 16750).

Current and future plans

7) Translatability assessment

The re-drafted LTCQ has been submitted for a translatability assessment. This is conducted by PharmaQuest Ltd and consists of developing a concept elaboration document which define each item and translators reviewing each item of the questionnaire and elaborating how and whether this can be translated into a selected number of languages. Five languages were chosen on the basis of their frequency as a second language in the UK and to represent diverse language. The languages are Arabic (Egyp), French (France), Polish (Poland), Punjabi (India), simplified Chinese (China), and Urdu (Pakistan).

Amendments to the LTC PROM will be made as necessary.

8) Consultation with professionals to review the draft PROM

As well as conducting the translatability assessment, professional stakeholders have been invited to comment on the current version of the LTCQ. We invited the professional stakeholders who participated in the initial stakeholder consultation on the PROM. This phase of the work aims to evaluate if the items in the PROM are considered appropriate and meaningful from a professional perspective, with a particular focus on whether any items are missing. Professional stakeholders are also asked to consider the usefulness of the questionnaire for their purposes and for people with LTCs.

9) Further rounds of cognitive interviews

The LTCQ will be amended as appropriate following the translatability assessment and the consultation with the professional stakeholders. This new version will be pretested in at least one further round of cognitive interviews. It is expected that no more than two further rounds of cognitive interviews are needed until no further substantial amendments will be necessary.

For the second round of cognitive interviews, participants will be recruited through primary care using the same strategy as for the recruitment of the qualitative participants. The aim is to obtain feedback on the LTCQ from people with LTCs who have not previously been involved in the study. Each round of cognitive interviews will include between 10-15 people with at least one LTC. We may supplement the sample with participants from the qualitative interviews, in particular participants with mental health conditions as they are currently under-represented. It is expected that these steps will lead to a final version of the LTCQ.

10) Survey to validate the PROM in a larger sample

The final phase will involve testing the LTCQ in a larger sample of people with LTCs (a minimum of 1000 participants). Participants for the survey will be recruited through both health and social care services. The EQ-5D, SF-36 and a self-efficacy scale will be administered alongside the LTCQ to assess construct validity. The survey will also include some other key questions, such as demographics, comorbidities. A sub-sample will be invited to repeat the LTCQ to provide an assessment of reproducibility. Ethical approval will be obtained through NRES. The aim is to conduct the survey in the second half of 2015.

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