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# **The Long-Term Conditions Questionnaire (LTCQ): Conceptual framework and item development**

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## **Abstract**

### **Purpose**

To identify the main issues of importance when living with long-term conditions to refine a conceptual framework for informing the item development of a patient-reported outcome measure for long-term conditions.

### **Methods**

Semi-structured qualitative interviews (n=48) were conducted with people living with at least one long-term condition. Participants were recruited through primary care. The interviews were transcribed verbatim and analysed by thematic analysis. The analysis served to refine the conceptual framework, based on reviews of the literature and stakeholder consultations, for developing candidate items for a new measure for long-term conditions.

### **Results**

Three main organising concepts were identified 'Impact of long-term conditions', 'Experience of services and support' and 'Self-care'. The findings helped to refine a conceptual framework leading to the development of 23 items that represent issues of importance in long-term conditions. The 23 candidate items formed the first draft of the measure, currently named the Long-Term Conditions Questionnaire (LTCQ).

### **Conclusions**

The aim of this study was to refine the conceptual framework and develop items for a patient-reported outcome measure for long-term conditions, including single and multiple morbidities, and physical and mental health conditions. Qualitative interviews

identified the key themes for assessing outcomes in long-term conditions and these underpinned the development of the initial draft of the measure. These initial items will undergo cognitive testing to refine the items prior to further validation in a survey.

Abstract: 205 words

## Introduction

Patient-reported outcome measures (PROMs) have been proposed as a means to measure what matters to patients to strengthen patient involvement in their care, to enable individualisation of care,<sup>1</sup> and to evaluate the performance and quality of care.<sup>2</sup> It is generally agreed that a PROM should have a clear underlying conceptual framework,<sup>3-5</sup> which specifies the specific goal of the measure, its intended use and the target population.<sup>3,4</sup> Although these criteria have been highlighted in particular for PROMs used in clinical trials, it is equally important that PROMs developed for use in other contexts such as clinical practice or performance monitoring are also developed to a high standard. It is recommended that an initial hypothesised conceptual framework is based on a literature review and expert opinion, and this framework is further refined as domains and items are developed on the basis of in-depth qualitative and cognitive interviews.<sup>5</sup>

Long-term chronic conditions are the main challenge facing health and social care services today due to their increasing prevalence, complexity and impact on quality of life.<sup>6-10</sup> Multi-morbidity adds further to this challenge. Enhancing quality of life for people with long-term conditions (LTCs) by monitoring PROMs scores is a key goal of health and social care policy in England and in other countries.<sup>11-14</sup> The use of PROMs has been pilot tested for six LTCs in primary care.<sup>15</sup> This pilot study highlighted a number of challenges, including the reporting of PROMs data (for one generic and six disease-specific PROMs) in a meaningful and concise manner across multiple LTCs.<sup>16</sup> As no PROM exists to capture outcomes across all LTCs, the EQ-5D is used in England to assess LTC outcomes, for example as part of the GP Patient Survey.<sup>17</sup> However, the EQ-

5D may not capture all issues of importance to patients and clinicians. Hence, professional and lay stakeholders support the development of a new measure for LTCs.<sup>18</sup> The intention of this measure would be to capture issues of importance across LTCs and to offer a practical, easily interpretable and useful method to assess outcomes across a range of health and social care services.

The aim was to develop a short self-completed questionnaire about issues of importance when living with LTCs. The intention was to develop a measure for use by adults with single and multiple morbidities, including both physical and mental health conditions. We intend it to be used for individual care and for population monitoring across all health and social care settings. The domains and items are intended to be complementary to those of the EQ-5D and to reflect both traditional domains (i.e. aspects of quality of life) and less traditional domains of importance in LTCs (e.g. empowerment) that can be assessed by patient self-report. Following scoping reviews of the literature covering 12 key domains that can be assessed through patient reports and a stakeholder consultation,<sup>18</sup> an initial conceptual framework was developed (see Table 1 for the initial framework)<sup>3,4</sup> This article describes the refinement of the conceptual framework and the development of the thematic domains and initial items.

## **Methods**

### **Qualitative interviews**

#### *Recruitment*

Ethics approval was obtained through the National Research Ethics Service (NRES) Committee London – Bromley. Eight primary care practices in England (four in Oxfordshire and four in London) agreed to recruit people with at least one of ten

specified LTCs from their patient database. The ten LTCs were selected by a panel composed of the authors, PROMs experts, and lay advisors. The aim was to select maximally diverse LTCs (in terms of symptoms, bodily systems, disease trajectory, prevalence, likelihood of comorbidities, burden of disease and care, level of self-management). To aid this process, the panel was provided with information on bodily systems, the World Health Organization Global Burden of Disease study,<sup>20</sup> a study on multi-morbidity,<sup>7</sup> and the LTCs included in the Quality and Outcomes Framework (<http://www.nice.org.uk/aboutnice/qof/qof.jsp>). The following LTCs were selected: cancer, chronic obstructive pulmonary disease (COPD), ischaemic heart disease (IHD), diabetes, depression, inflammatory bowel disease (IBD), multiple sclerosis (MS), osteoarthritis (OA), schizophrenia and stroke. Seven of these were selected by over half the panel, and three (IBD, MS and schizophrenia) were selected by at least one panel member and were included to maximally contrast with the other seven LTCs.

Practice staff conducted a search on the database comprised of the electronic patient record of all individuals registered with the practice. Search criteria and instruction were of their patient database according to instructions developed and tested by one of the authors (CA). This search produced a list of patients with the relevant LTCs. Practices fed back the number of patients identified per LTC. The researchers used an online randomisation tool ([www.random.org](http://www.random.org)) to generate random patient numbers per LTC. Practice staff then selected patients according to the randomisation numbers from the list and were checked each patient against the inclusion and exclusion criteria. A total of 360 eligible patients were invited into the study. For LTCs with lifelong implications (COPD, diabetes, IBD, IHD, MS, OA, stroke), eligibility was defined as the presence of the LTC. 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, similar to the approach taken by Barnett et al.<sup>7</sup> Additionally, the diagnosis needed to have been confirmed more than 12 months ago, to ensure that patients had time to adjust to their diagnosis and had experienced a range of services and strategies for the management of their LTC(s). Only adult patients were included (i.e. 18 years of age and above). There was no upper age limit.

No participants with schizophrenia were recruited through primary care; therefore the data were supplemented with interviews from a study conducted in 2013/4 by RF and MP on outcomes valued by people with schizophrenia.<sup>21</sup> Participants had been recruited through an email invitation by Rethink Mental Health and snowball sampling. The exact number of people receiving the invitation is not known but 47 people made contact to participate. Of these 47, 13 were excluded due not reporting a diagnosis of schizophrenia or schizoaffective disorder, 5 people refused to be interviewed and 7 failed to respond to emails after their initial contact. For the purposes of the study presented here, six transcripts of diverse participants (in terms of age and gender) were selected for secondary analysis. Ethics approval for the schizophrenia study had been gained through the East of Scotland Research Ethics Service (EoSRES).

### *Data collection*

Eligible patients were sent a letter of invitation by the primary care practice and were asked to contact the researchers if they were interested in participating. Following initial contact that included confirmation of eligibility, the researchers arranged an interview time and location according to the preference of the participant; most interviews took place in participants' homes, their workplace, or the University of

Oxford. All participants gave written consent. The semi-structured interviews were conducted by CH, LK and CP. All interviews were digitally audio-recorded.

The topic guide for the primary care participants (Table 2) was informed by our previous scoping literature reviews on PROMs and the key domains (Table 1), health care policy documents (such as the National Health Service Outcomes Framework and the Social Care Outcomes Framework <sup>22,23</sup>), and the stakeholder interviews.<sup>18</sup> It focused on impacts and outcomes of LTCs, personal self-care strategies, help needed or received in managing LTCs (including experiences of health, social care, or community/voluntary services), and goals or problems regarding LTC management. In later interviews, participants were also invited to comment on emerging themes that were being considered as candidate items for a new PROM for LTCS.. The schizophrenia topic guide (Table 2) was developed on the basis of a stakeholder consensus meeting and the literature.

#### *Data analysis and development of items*

The interviews were transcribed verbatim by a professional transcription company. All transcripts were verified and anonymised by the interviewers before analysing the data in QSR NVivo 10, a qualitative software package. Iterative framework analysis was used.<sup>24</sup> According to this approach, eight interviews were analysed according to an initial coding framework drawing on the literature review and the stakeholder interviews.<sup>18</sup> After discussion among the authors the coding framework was expanded to take account of emerging themes, particularly those relating to social care; a further 18 interviews were analysed using the expanded framework. CH, CP and LK conducted the analysis, and MP and RF analysed ten interview transcripts (five each). These ten transcripts were selected to represent a range of LTCs. The analysis framework was

then discussed and further refined before the remaining 22 interview transcripts (including the six schizophrenia transcripts) were analysed. Once all transcripts had been coded the framework was reviewed again, with no further changes made. Earlier transcripts were then re-coded to incorporate the additional codes from the final framework.

A data saturation table was created to evaluate if thematic saturation had been achieved. Saturation was defined as “the point in the data collection process when no new concept-relevant information is being elicited from individual interviews or focus groups”.<sup>4</sup> The interview data were analysed systematically and subsequently, and concurrently with data collection, using a constant comparison method moving between the codebook, the saturation table, and full transcripts,<sup>25</sup> to determine if new themes emerged. Data collection was considered complete when no new relevant themes were emerging. As described above, the analysis framework was established following a review of the framework based on the analysis of 18 interviews. No further themes were added to the framework during the subsequent analysis. .

Individual team members (MP, CH, LK, RF, CJ and AT) drafted candidate items based on a number of dimensions. Each dimension represented either one theme or sub-theme from the qualitative analysis or two merged themes/sub-themes. All the dimensions represented the refined conceptual framework underpinning the new measure. The candidate items were discussed in team meetings to identify and reach consensus on individual candidate items. Criteria for retaining candidate items included that they represented issues identified as important in the interviews (either to all the participants or important sub-groups such as social care users) and that were deemed clear and easy to understand. Usually duplicate items, or those that significantly overlap

(i.e. represent similar underlying concepts) would also be removed in this process.

However the first draft of the questionnaire included a small number of items that were duplicates (as they were either worded positively and negatively) or that represented similar concepts. Whilst this meant some items were very similar, it allowed pre-testing differently worded items with people with LTCs in cognitive interviews.

## **Results**

### **Participants**

A total of 48 people with LTCs (42 recruited through primary care and 6 through the schizophrenia study) were interviewed (Table 3 and supplement 1 for details on participants). Participants reported a wide range of LTCs in addition to the index LTC. Information on co-morbidities and the use of social care was only available for the participants recruited through primary care, as the schizophrenia study did not directly ask about these.

### **The overarching concepts and themes**

Following the analysis, three overarching organising concepts were identified to focus thinking about the emerging patterns of data in relation to living with LTCs – ‘Impact of LTC(s)’, ‘Experiences of Services and Support’ and ‘Self-care’. The three overarching concepts contained 27 themes. Twenty-one themes were analysed at this level only, and six themes contained 15 sub-themes (Table 4). ‘Impact of LTC(s)’ encompassed the largest range of themes with 16 themes, ‘Experience of services and support’ included seven themes and ‘self-care’ was composed of 4 themes. The majority of the participants discussed aspects of each of the three overarching concepts.

### *Impact of LTC(s)*

Participants described how their lives had been affected by their LTCs (Table 4). This included issues such as impact on day-to-day activities and emotional or mental well-being, and social participation mentioned by more than 75% of participants, to themes such as impact on family or carers and loneliness discussed by fewer than 25% of participants (Table 5).

A 64-year old woman with COPD, stroke, arthritis, agoraphobia, depression, IHD, gout and stenosis of the spine described the impact of her LTC(s) on her physical health and daily activities.

‘...I can dress myself except for when it comes to my feet, because I can’t get that far on my back, and my knees don’t move properly... so I can’t do that... I’ll cook with a microwave, but I can’t prepare vegetables, but I can cook, but I can’t hold hot saucepans, and hot things so, if it’s just a matter of putting something in a microwave, I can do that. I just look to do the things I can do like I can dust, my husband hovers, I can’t manage the Hoover...’

The ability to achieve personal goals was discussed by over half of the participants.

Personal goals could relate to anything that participants valued, however mostly it centred on work and family, but could also focus on the ability to look after pets or keeping up with hobbies or physical activity. A 51 year-old man explained how schizophrenia impacts on his work:

‘...I have a degree in psychology, I am a qualified counsellor; I wanted to become an analyst. I mean my career, every time I had a breakdown, it falls apart...’

Maintenance of independence or becoming dependent formed a significant part of the impact of LTC(s). A 65-year old woman with multiple sclerosis (MS) explained how a parking permit for disabled drivers helps her keep mobile and independent

‘...I have a condition which is incurable and in general what happens is you just get worse until you end up in a wheelchair, so I mean obviously my priority is keeping mobile, keeping independent, so independence and mobility is what would be my aim ... I think I’m independent, but frankly my blue badge is important to me for independence...’

### *Experiences of services and support*

In this concept, participants described the types of health and/or social care services they had used, their various types of support, and the burden caused by the services and care needed to manage their LTC(s). Support included help given by people or organisations outside of health and social services, such as family members, friends or charities. The most frequently discussed themes (by over 75% of participants) were support either by services or others, and burden of treatment (Table 5). A 77-year old man with IHD explained how hospital appointments could be difficult to manage

‘... and it's also planning sort of like work around hospital... I seem to have so many hospital appointments these days, just seem to be... I get the impression that once they get hold of you they're never going to let you go...’

In contrast, a 69-year old man with cancer has found the input by health services helpful

‘... impressed with the health service. One of the things that's difficult I personally think is, like most other I suspect, it's difficult to get a GP appointment when you actually want one, but I think once you've been identified as having something

they have to treat, or believe that they will be able to help with treatment, I have to say I haven't looked back, the treatment and care and the response I get from even the GP I was transformed by that...'

Additionally to whether services provide adequate support, participants also talked about how they were treated by health care professionals. A 66-year old woman with cancer and IBD talked about contrasting experiences when consulting different doctors

'...there was only the 2 main doctors, the first one [DOCTOR] he seemed very abrupt, very doctorerfied if that makes sense, whereas the other one was very casual in his mannerisms, and you felt you could talk to him...'

However it is not only health services that provide support. The importance of social support is explained by a thirty-five year old male with IBD and chronic renal failure

'...we travel a lot, that's partly because actually my wife forces me to, or has forced me to, and now I do it a lot more, and I enjoy it and I get a lot out of it. One role of the partner I think is potentially quite interesting, you know I've had some amazing travel experiences over the last four years, partly because I'm with somebody I don't worry as much about what might happen if I were ill and I was away, and also she absorbs ... quite a lot of my angst, so that enables me to do those things...'

### *Self-care*

'Self-care' focused on actions or strategies that participants use to look after themselves and their LTC(s) or strategies to cope with their LTC(s). This included both active strategies, such as planning around the LTC(s) or passive strategies such as acceptance of their limitations and re-framing priorities. The most widely discussed theme (by over

75% of participants) was coping with LTC(s). 'Self-care' had the potential to positively or negatively influence the impact of LTC(s). Participants differed in the extent to which they felt able to take positive actions such as adopting healthier behaviours. There was also a time impact, with participants discussing variations in how well they could self-care during different time periods. When participants struggled with self-care, other problems could occur or the impact of LTC(s) could increase, or worsen the impact of the LTC(s) as explained by a 31 year old man with depression and medication induced psychosis.

'... I've still got depression, I fight every day, I do fight it every day, but before where I'd let it sort of overtake me... I could sit indoors for two weeks. I think there was about a time of 2-3 months where I was going to bed at 12 o'clock in the day and sleeping until 9 o'clock at night and then I'd wake up, and I'd sit the whole night like just watching TV, and all I'd eat was a bowl of Weetabix. I went down to 9 stone, I looked anorexic, and it just spiralled out of control...'

A certain degree of own judgement and flexibility was often needed to find the best way to deal with the LTC(s). A 68-year old woman described how she adapted to cope with the dietary changes needed to manage her diabetes:

'...Initially I had to re-educate myself diet-wise ... by nature I have a very bad sweet tooth, so I had to restrict my intake of sweets. But otherwise it wasn't... but I'm somebody once I know I have to do something, I condition my mind and just get on with it ...'

Acceptance of LTC(s), and the limitations this might impose, was explained by a 72-year old man with four different morbidities, including diabetes and arthritis.

‘...I’ve had these various problems starting with polio and asthma when I was very young, I’ve missed a fair bit of schooling through the polio, you just get sort of used to it, and you get one more thing to put up with and you get on with it, there’s no point in sitting around, you’ve got to make the best of things and you know, and fight back basically...’

## **Item development**

As it is the intention to develop a short measure for LTCs, it was not feasible to include items for each theme or sub-theme from the interviews, although the three organising concepts are represented in the items. Twenty themes or sub-themes were taken into account in item development. These twenty themes or sub-themes mostly ranked highly in terms of the number of interviews in which they were discussed. The lowest level of analysis was used for the ranking, meaning 21 themes and 15 sub-themes. The 20 themes/sub-themes selected for item development are highlighted in bold in Table 5 and they underpinned 17 dimensions (some themes collapsed for item development e.g. ‘Impact on day-to-day activities’ and ‘Impact on emotional or mental well-being’ were collapsed into ‘impact of LTCs’) that were used to develop items (Table 6). The dimensions, representing the refined conceptual framework on which item development was based, are defined in Table 6 together with further illustrative quotes from the interviews. Themes that ranked less highly either significantly overlapped (i.e. represented a similar underlying concept) with a more highly ranked theme (such as ‘loneliness’ overlapping with ‘social participation’) or they were considered important for less represented groups in the sample. In line with the aim to develop a short measure, a small number of items (1-3 items) were developed per dimension to give a

total of 23 initial items. These 23 items will undergo cognitive testing in further interviews with people with LTCs.

## **Discussion**

The aim of this study was to develop a measure for long-term conditions. The aim of this new PROM is to be relevant to adults with single or multiple LTCs (both physical and mental health conditions), is intended for use both at an individual and population-based level across all health and social care services. This qualitative study served to further refine the conceptual framework that was initially developed on the basis of literature reviews and stakeholder interviews. The use of in-depth qualitative interviews serves to enhance content validity of a newly developed measure.<sup>26</sup>

The in-depth interviews identified outcomes of importance to people with single and multiple morbidities. Due to the sampling strategies, the 10 pre-selected LTCs were more commonly represented, but 23 additional morbidities were reported by the participants. The 10 LTCs were chosen on the basis of their diversity and together with other reported morbidities; a good spread of LTCs was reported by the 48 participants. The interviews generated rich data on a wide range of issues of importance to outcomes in LTC(s). These themes and sub-themes formed three concepts 'Impact of LTC(s)', 'Experiences of services and support' and 'Self-care'.

Many of the themes, in particular those coded in 'Impact of LTC(s)', resonate with those that are often included in PROMs,<sup>27</sup> however some themes, such as self-management, empowerment, experiences of services, suitability of housing or safety, may be explored less frequently as part of a PROM. These latter outcomes represent outcomes of care rather than the more traditional outcomes of the condition or disease, but they are

nonetheless important in LTCs. Also, these are frequently assessed by patient self-report, for example self-management can be assessed by the Self-Management Ability (the SMAS-30) questionnaire.<sup>28</sup> Empowerment on the other hand is still considered ill-defined, and the need for a specific PROM to assess empowerment has been identified.<sup>29</sup> Some would argue that experiences of services is a process not an outcome, however recently is becoming more widely recognised that health care and treatment, in particular in multi-morbidity, can place a burden on people.<sup>30</sup> Therefore as the new measure intends to cover a broad range of issues of relevance in potentially very diverse LTCs, these issues have been included in the item development. The majority of themes/sub-themes that underpinned item development ranked highly in terms of the number of participants who discussed them. There were some exceptions for example loneliness, safety and suitability of housing were talked about by fewer participants. However, these are considered important either due to their impact on LTCs or due to their impact relevance to specific groups of people with LTCs. For example, issues such as suitability of housing and safety are of high importance for social care recipients as demonstrated by the fact that such items are included in the Outcomes Tool (ASCOT).<sup>31</sup> Therefore items based on these themes were also developed for the LTCQ.

Whilst some PROMs, such as the SMAS-30 or the ASCOT gives scope to assess specific outcomes (self-management and outcomes in social care respectively) in more depth, the ambition of the new measure is to be short and practical whilst assessing issues of importance in a wide range of LTCs. If outcomes in LTCs are to be assessed within clinical care or on a routine basis, it would not be practical if multiple different tools needed to be used with the same patient and across health and social care services. The items developed for the measure include less traditional, but important, outcomes. It is

hoped that this approach will result in making the LTCQ a measure that is practical for use in the context of clinical care and routine PROMs data collection. The candidate items for the new measure will be pre-tested in cognitive interviews before a large scale survey is conducted to test the psychometric properties of the measure.

Some limitations of the study need to be acknowledged. First, although the sample included participants with a wide range of LTCs, there were proportionally fewer participants with mental health problems and few participants with experience of social care. This was not unexpected as they represent smaller groups of people. In the process of selecting themes and refining the conceptual framework, it was ensured that themes that are valued by participants who were less represented were not excluded on the basis that they were not discussed by the majority of the participants. Also, the mental health sample was supplemented by interviews from a study on outcomes in schizophrenia as no patient with schizophrenia invited through primary care agreed to participate. Although the method of recruitment and interview topic guides differed between the two studies, many issues of importance (e.g. treatment burden) overlapped with those reported in the primary care sample as shown in Table 5. Also, plans for future testing will aim to include larger samples of people with mental health conditions and social care experience. A second limitation might be that a single method of data collection was used. Differences may have been found through using focus groups, although the extensive literature searches and stakeholder consultations give confidence that the main issues of importance for LTCs have been covered. A final limitation may be that LTCs were self-reported, even though participants were selected by GP practices on the basis of a formal diagnosis of a specific LTC. Participants may not have reported all their LTC(s), and issues of importance in relation to these would not

have been discussed. Nevertheless, a wide range of LTCs has been included and thematic saturation was achieved in the interviews. This gives confidence that the main issues of LTCs have been included and that the resulting measure will have wide relevance.

## Conclusions

This paper describes the development of items for a new PROM for long-term conditions. On the basis of previously published interviews with stakeholders, literature reviews and in-depth qualitative interviews, a conceptual framework was developed and refined. This framework served to develop 23 items to form the first draft of the new PROM. These items will be pre-tested in cognitive interviews to make any necessary amendments to ensure its relevance and validity before the new PROM currently term Long-Term Conditions Questionnaire (LTCQ). is administered to a larger sample of people with LTCs in a survey to test its psychometric properties.

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## **Conflicts of Interest**

None of the authors have any conflicts of interest.

## **Ethical approval**

For the primary care participants, ethics approval was obtained through the National Research Ethics Service (NRES) Committee London – Bromley. Ethics approval for the schizophrenia study had been gained through the East of Scotland Research Ethics Service (EoSRES). All participants signed an informed consent form.

## **Disclaimer**

The views expressed in this paper are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

## **Authors' contribution**

RF, MP, CJ, AC and JF conceived the study. CP, LK and CH conducted and analysed the qualitative interviews. CA developed and tested the search strategy for identifying eligible participants. MP, CP, LK, CH, EG, CJ, AC, JF, AT and RF were involved in developing and refining the conceptual framework and in developing the items. MP led the writing of the manuscript, with the contribution of all other authors.