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The Long-Term Conditions Questionnaire (LTCQ): initial validation survey among primary care patients and social care recipients in England

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Abstract

Objective: The aim of this study was to validate a new generic patient-reported outcome measure, the Long-Term Conditions Questionnaire (LTCQ), among a diverse sample of health and social care users in England.

Design: Cross-sectional validation survey. Data were collected through postal surveys (February 2016 - January 2017). The sample included a health care cohort of patients recruited through primary care practices, and a social care cohort recruited through local government bodies that provide social care services.

Participants: 1,211 participants (24% confirmed social care recipients) took part in the study. Health care participants were recruited on the basis of having one of eleven specified LTCs, and social care participants were recruited on the basis of receiving social care support for at least one LTC. The sample exhibited high multi-morbidity, with 93% reporting two or more LTCs and 43% reporting a mental health condition.

Outcome measures: The LTCQ's construct validity was tested with reference to the EQ-5D (5-level version), the Self-efficacy for Managing Chronic Disease scale, an Activities of Daily Living scale, and the Bayliss burden of morbidity scale.

Results: Low levels of missing data for each item indicate acceptability of the LTCQ across the 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 both health and social care settings. The LTCQ could meet a need for holistic outcome measurement that goes beyond symptoms and physical function, complementing existing measures to capture fully what it means to live well with LTCs.

Key words: long-term conditions, chronic illness, patient-reported outcome measure, multi-morbidity, person-centred care

Strengths and limitations of this study

- This study is the first psychometric evaluation of the Long-Term Conditions Questionnaire, a new generic patient-reported outcome measure.
- The study included a large survey validation sample of 1,211 health and social care users in England.
- The sample was highly diverse in terms of illness burden and care needs, with 93% reporting multi-morbidity and 43% reporting a mental health condition.
- A limitation was the low response rate achieved among social care users, although this was consistent with previous studies.
- Further validation work among other ethnic groups and in non-English contexts is required since the vast majority of participants were white British.

INTRODUCTION

Long-term chronic conditions have emerged as a significant challenge to the sustainability of health systems worldwide. Considering the high global burden of long-term conditions (LTCs), their management is a top priority in policy terms.[1,2] In England, around one-quarter of the population lives with at least one LTC, accounting for nearly three-quarters of the cost of health and social care services.[3] In particular the rise of multi-morbidity has highlighted the need for integrated services that can address a person's overall health status and enhance their capacity for living well with their conditions.

Patient-reported outcome measures (PROMs) are essential tools for capturing the impact of illness as experienced by those living with LTCs, and the potential of PROMs for facilitating person-centred care has been recognized for more than a decade.[4] However, there is currently no agreed patient-reported measure for evaluating the intended outcome of person-centred care, which could broadly be described as 'living well' within the overall context of one's health condition(s). 'Living well with LTCs' is a complex construct that encompasses both traditional health-related quality of life (HRQoL) domains (e.g. symptom severity, physical and social functioning, emotional well-being) and more recently recognized domains of importance (e.g. treatment burden, empowerment, confidence in self-management).[5,6] A comprehensive measure for assessing the impacts of LTCs should thus move beyond traditional health-status domains of PROMs to capture a more holistic notion of living well.[7]

While a plethora of condition-specific and generic PROMs exist, both types of measure have shortcomings for capturing what it means to live well with LTCs. In focusing on a single disease category, condition-specific PROMs cannot adequately address the phenomenon of multi-morbidity, where impacts may be cumulative or inter-dependent across all conditions.[8] Standardised generic PROMs such as the EQ-5D[9] and SF-36,[10] while valuable for comparative population-level analyses, are unlikely to capture all issues of importance for people living with LTCs.[11,12] Furthermore, these measures may not be appropriate for long-term monitoring of LTCs, where the objectives of health and social care services may be to maintain well-being and/or to avoid deterioration rather than to achieve major health gains.[13] A further complication arises with the distinction between health-related and social care-related measures,[14] as people with complex needs will potentially draw on both types of services. A measure that is appropriate for both contexts could facilitate the development of person-centred care pathways, which are increasingly recognised as preferable to disease-specific care pathways in the context of multi-morbidity.[15]

The aim of this study was to test and validate a new PROM, the Long-Term Conditions Questionnaire (LTCQ). The LTCQ is intended to be relevant and acceptable for people with single or multiple LTCs (physical and/or mental health conditions), and meaningful for health and social care providers in their capacities for monitoring and improving outcomes in LTCs. Additionally, the LTCQ is intended to be short, easy to interpret, and feasible for use in different clinical settings. It is intended for use both as a tool for monitoring and enhancing individual care, and as a population-level tool for measuring health and social care performance, quality and outcomes. The scope of the LTCQ goes well beyond symptoms and physical function; its content development has been described previously and involved interviews with professional stakeholders,[16] qualitative in-depth interviews with people living with LTCs,[17] and pre-testing (e.g. cognitive interviews, translatability assessment) to refine questionnaire items.[18]

METHODS

This study was reviewed by England's National Research Ethics Service (NRES) Committee East Midlands – Derby (reference 15/EM/0414). Approvals for the study were granted by the Health Research Authority of England's National Health Service (NHS), and local health and social care organisations linked to participant recruitment sites. Data were collected through two postal surveys (a main survey and a follow-up survey) administered to two cohorts: a health care sample recruited through primary care practices (data collected February 2016 – July 2016), and a social care sample recruited through Local Authorities (LAs) that provide funding for social care services (data collected July 2016 – January 2017). Methods and findings presented below follow STROBE reporting guidelines for cross-sectional studies[19] and COSMIN criteria for reporting measurement properties of health status questionnaires.[20] The latter indicates a minimum sample size of 10 subjects per questionnaire item (i.e. 200 participants for this survey validation study), which exceeds the minimum of 100 subjects required for factor analysis within Classical Test Theory. Owing to the complexity of the construct being measured and the diversity of the target population, the study authors aimed to achieve a minimum sample size of 1000 participants.

Participant recruitment

For the health care cohort, participants were recruited by fifteen General Practitioner (GP) practices from three regions of England (South East, North West, Yorkshire & Humber). In an effort to recruit a maximally diverse sample, the research team selected practices that served both rural and urban areas, and areas of high and low deprivation. For a participant to be invited into the study, the GP practice confirmed diagnosis of one of eleven specified LTCs: cancer within the last 5 years, chronic back pain, chronic obstructive pulmonary disease (COPD), diabetes, depression, irritable bowel syndrome (IBS), ischaemic heart disease (IHD), multiple sclerosis (MS), osteoarthritis (OA), severe mental health (as defined under the UK Quality and Outcomes Framework,[21] including psychoses, bipolar disorder and schizophrenia), and stroke. The eleven selected conditions were chosen by a panel of PROMs researchers and lay advisors, with the aim of maximising diversity in terms of symptoms, disease trajectory, prevalence, mean age of onset, likelihood of comorbidities, burden of disease, type of health and social care needed, level of self-management and burden of care. Each practice recruited from patient groups representing at least five of the eleven conditions, with some practices asked to prioritise certain conditions that were otherwise under-represented. Recruitment was restricted to those diagnosed more than 12 months previously to ensure that participants had adjusted to their diagnosis and had experienced a range of services and strategies for the management of their LTC(s). Only adults (i.e. 18 years of age and above) able to consent who were able to communicate in English were included, with no upper age limit. A total of 2,983 eligible patients were invited to participate for the health care cohort (approximately 200 study packs mailed out by each participating GP practice).

For the social care cohort, participants were recruited by four Local Authorities of different types (unitary, metropolitan, county and London borough) in geographically diverse regions (North West, East of England, South West and Greater London) representing a mix of urban and rural communities. Individuals were eligible for the study if they received fully or partially funded long-term social care support, provided that the primary reason for support was a physical disability, sensory impairment, or a mental health condition as listed in table LTS001b on the Short and Long

Term (SALT) mandatory data returns for social care.[22] Potential participants were eligible if they received community-based services, were at least 18 years old, and were able to communicate in English. Individuals who received nursing or residential care, whose primary reason of support was a learning disability or cognitive impairment (as listed on Table LTS001b of SALT), or whose records indicated that they lacked mental capacity to consent to research were excluded. The research team provided each Local Authority with study packs, which were mailed directly by the LAs to 2,294 eligible participants. This was to ensure that no personal data of individuals were disclosed to the research team without consent.

The surveys

The study packs contained an invitation letter from the GP / LA, a participant information sheet, and the main survey (Survey 1). Survey 1 included the Long-Term Conditions Questionnaire (LTCQ – see Table 2 for description of items) and other measures for testing the LTCQ's construct validity: EQ-5D (5-level version including the EQ-VAS),[23] the Self-efficacy for Managing Chronic Disease 6-item scale,[24] an Activities of Daily Living scale,[25] and the Bayliss burden of morbidity scale (adapted with permission from the developers to include all conditions for which participants in this study had been recruited).[26] These were selected because they measure different domains that were hypothesized to underpin the LTCQ's broad construct of 'living well with LTCs': physical functioning, symptom burden and emotional well-being (EQ-5D); confidence to self-manage (Self-efficacy scale), functioning and independence (ADLs), cumulative impact of LTCs (Bayliss scale). Survey 1 also included demographic questions, questions on service use, a question about help needed to complete the questionnaire, and a box for free-text comments. Additionally for the social care cohort, Survey 1 included a measure of social care-related quality of life, the Adult Social Care Outcomes Toolkit (ASCOT),[27] but this measure is not included in the initial validation analysis for the total sample. A pre-paid, addressed return envelope was provided in all study packs. After approximately two weeks participants were sent a thank you / reminder letter from the GP / LA in order to encourage further responses.

Survey 1 contained an address slip through which respondents could express willingness to receive the follow-up survey (Survey 2). Among those who provided contact details (n = 980, 81%), a sub-sample of 693 respondents (57%) were sent Survey 2 approximately two weeks after returning Survey 1. The sub-sample included 54% of the health care cohort (n = 499) and 66% of the social care cohort (n = 194). Survey 2 contained only the LTCQ, a reduced number of demographics questions, and a health transition question asking about changes in health status during the period between completing Survey 1 and Survey 2. A pre-paid, addressed return envelope was provided with all questionnaires. Participants who had not returned Survey 2 within approximately two weeks were sent a reminder letter.

Analysis

All data were entered into SPSS (version 24), a statistical software package. A coding framework was specified in advance and used by all research team members for consistency in data entry. Data cleaning was undertaken via analysis of frequencies for all items in Survey 1, with any anomalies checked against the original questionnaires and corrected as necessary. Particular attention was given to the 20 items of the LTCQ, for which any missing or multiple responses prompted visual inspection and verification/correction of data for the entire Survey 1 questionnaire. The same procedure for data entry, checking and cleaning was followed for Survey 2 among the health cohort, and for both Survey 1 and Survey 2 among the social care cohort, to ensure data quality across the full dataset.

Exploratory factor analysis of the 20 LTCQ items was undertaken (see Results), from which it was concluded that the LTCQ could be scored as a single composite measure. The appropriateness of scoring items as a single scale was further evaluated through examination of inter-item correlations (acceptable if 0.8 or less) and item-total correlations (acceptable if 0.3 or more).[28] LTCQ items were scored on a scale from 0 (most negative response) to 4 (most positive response). Items 9-15 are negatively phrased and were therefore reverse-scored. Taking a conservative approach and following best practice guidelines,[29] only responses for which all 20 LTCQ items had been answered were included in the initial validation analysis. A sum of the 20 item scores was calculated and recalibrated to give an overall LTCQ score ranging from 0 to 100, with higher scores indicating a better level of 'living well with LTCs'. Cronbach's alpha (α) was calculated as a measure of internal consistency of the scale. Test-retest reliability was assessed via calculation of the Intraclass Correlation Coefficient (ICC) type 2 (two-way random effects, absolute agreement) among respondents who reported no change in health status between Survey 1 and Survey 2. ANOVA was employed to compare LTCQ scores among sub-groups within the sample (i.e. by gender, age, health versus social care cohort, mental versus physical health conditions, number of conditions reported).

Scores for all existing measures were calculated according to developers' instructions. For the EQ-5D-5L, value sets recently reported for a population in England were used to calculate a single index value for each participant's reported health state;[30] scores are only calculated if all five items have been completed, with a theoretical range of -0.28 (a state worse than death) to 1 (best possible health state). The EQ-VAS score, a measure of overall health on that day, ranges from 0 (the worst health you can imagine) to 100 (the best health you can imagine). For the Self-efficacy measure, six items asked about confidence in doing certain health-related activities on a scale from 1 (not at all confident) to 10 (totally confident); the overall score is calculated as the mean of item scores, provided that participants had completed at least four of the six items. The ADL score is calculated as the sum of all items for which difficulty in managing daily activities was reported, ranging from 0 (no difficulty with any listed activities) to 13 (at least some difficulty with all listed activities). The Bayliss burden of morbidity measure lists 25 LTCs and asks respondents to indicate the impact of each condition on their lives; a score of 0 indicates that the respondent does not have that condition, while scores for individual items ranging from 1 (has the condition but it does not limit daily activities at all) to 5 (has the condition and it limits daily activities a lot) indicates the impact of any reported condition. The total morbidity score was calculated as the sum of impact scores for all conditions reported, including up to three LTCs that respondents could list as 'other long-term conditions not mentioned above'. A count function was applied to the morbidity measure to calculate the number and type (physical or mental health) of LTCs reported by each respondent. For assessment of construct validity, correlations (Spearman's rho) were calculated for the LTCQ score in relation to all other measures.

RESULTS

Sample characteristics

A total of 917 participants were recruited through primary care (31% response rate), and 294 participants were recruited through social care (13% response rate), giving a total sample of 1,211 participants (23% overall response rate). Demographic information is shown in Table 1. The age range was 18 to 102 years, with a mean age of 67 (SD 15.3 years). Fifty-four percent (n = 656) were female, just over half were married or in a civil partnership (n = 648, 54%), and just under half were fully retired from work (n = 554, 46%). The sample was mainly white British (n = 1,097, 91%), with limited representation from non-white groups. Although participants were recruited on the basis of having one LTC, the sample exhibited a high degree of multi-morbidity; 1,124 participants (93%) reported having two or more conditions, with a mean of 6.2 LTCs (SD 3.8 LTCs) reported across the sample. 522 participants (43%) reported at least one mental health condition, with the majority of these also reporting at least one physical LTC.

Acceptability

The LTCQ was completed in full by 1,082 participants, which enabled calculation of an LTCQ score for 89% of the sample. Table 2 summarises the content and Survey 1 response rates for individual items. Levels of missing data were low and broadly uniform across items, ranging from 1.0% (item 10, dependence; item 11, loneliness; item 20, living life as you want) to 2.2% (item 13, services difficult to cope with). The low levels of missing data for all individual items indicate acceptability of the LTCQ within this diverse sample.

Floor / ceiling effects

For the total sample responses were generally skewed towards positive answers, with ceiling effects (i.e. less than 5% and more than 40% of respondents endorsing the most negative and positive response options, respectively)[28] observed in five items of the LTCQ (items 6, 7, 13, 14, and 18 – see Table 2). Ceiling effects were most pronounced for item 6 (home suitability) and item 7 (safety at home). These items convey content that was identified during previous qualitative phases of research as especially important for social care users, who represent a smaller portion of the sample. Whilst it is worth noting these item-level ceiling effects for their potential implications in population-level analyses, they are not in themselves problematic given the LTCQ's potential use for individual-level monitoring, where a key aim would be to identify and support the relatively smaller proportion of respondents who selected negative response options. No ceiling effect was observed for the measure as a whole (i.e. 15% or more of respondents achieving the highest possible score),[20] as less than 4% of respondents scored 100 on the LTCQ.

Factor analysis

The dataset's suitability for factor analysis was assessed via Bartlett's test of sphericity (highly significant, $p < 0.001$), the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy (0.96), and measures of sampling adequacy (MSA) (above 0.9 for each item). Exploratory factor analysis was undertaken using principal axis factoring (PAF). Three factors were extracted via the Kaiser criterion (eigenvalue > 1), which explained 66% of variance: factor 1 (eigenvalue 10.9, explaining 55% of variance), factor 2 (eigenvalue 1.2, explaining 6.0% of variance), factor 3 (eigenvalue 1.1, explaining

5.6% of variance). Over-extraction of factors is a recognised problem using this method,[31,32] and examination of the scree plot suggested that only the first factor should be retained. This was confirmed by Parallel Analysis,[31] which showed only the first factor with an eigenvalue exceeding the corresponding value generated for a random data matrix of the same size (20 items x 1082 respondents). For the one-factor solution, 19 LTCQ items loaded onto the general factor at levels ranging from 0.58 (good) to 0.86 (excellent),[33] with item 16 (knowledge about health conditions) loading less strongly (0.35). This evidence supports the LTCQ being scored as a single scale.

To check against under-extraction of factors, three-factor solutions (indicated by the Kaiser criterion) were also examined. With orthogonal (Varimax) rotation, all 20 items loaded onto one of the three factors with a minimum loading of 0.35 (item 16; all other items loaded at 0.49 or higher), and fourteen items cross-loaded onto additional factor(s). When oblique rotation (Direct Oblimin) was applied, the same pattern of primary loadings was observed across the three factors, with two items (item 10, dependence; item 19, confidence to manage illness) also loading weakly onto another factor. In this analysis the three factors correlated substantially with each other ($r > 0.6$ for all factor combinations), suggesting difficulty with interpreting and labelling the factors as distinct subscales. An examination of items within factors indicated that each factor contained multiple concepts; for example whilst factor 3 appeared to broadly group social and environmental influences on the management of LTCs, it contained conceptually distinct items on safety, suitability of the home, and social support. This observation is consistent with the conceptual framework from which items were developed,[17] in which 15 distinct concepts underpinned the 20 items tested in the initial validation survey. The items within each factor were summed and calibrated to yield dimension scores ranging from 0-100, which were suitable for factor analysis (Bartlett's test highly significant, KMO and MSA values all above 0.6). Higher-order factor analysis was undertaken using PAF and the Kaiser criterion; one factor was extracted with an eigenvalue of 2.3 that explained 75% of variance, with factor loadings of 0.93, 0.84, and 0.82. Thus the appropriateness of scoring the LTCQ as a single composite measure that captures the broad construct of 'living well with LTCs' was confirmed.

Internal consistency

The LTCQ exhibits high internal consistency across its 20 items (Cronbach's $\alpha = 0.95$). Corrected item-total correlations ranged from 0.35 (item 16, knowledge about health conditions) to 0.83 (item 4, felt in control of daily life), with negligible improvement in α if responses to item 16 were deleted. An examination of inter-item correlations showed that with one exception (item 3, able to be physically active and item 5, able to take part in enjoyable activities, $r = 0.83$), associations between items were moderate rather than strong. No items were considered duplicates of other items and all items contributed substantially to the single scale; thus no items were deleted following initial analysis.

Test-retest reliability

Of 693 participants sent the follow-up questionnaire, 544 (78%) completed and returned Survey 2. LTCQ scores for the 383 participants (70%) who reported their health as 'about the same' as two weeks ago were analysed for test-retest reliability. The ICC (type 2: two-way random effects, absolute agreement) for overall LTCQ scores between Survey 1 and Survey 2 was 0.94 (95% CI, 0.93 to 0.95). Correlations for individual item responses between Survey 1 and Survey 2 were examined and found to be moderate or strong and significant for all items, ranging from 0.50 (item 16, knowledge about health conditions) to 0.83 (item 2, able to fulfil responsibilities). Frequencies of Survey 2 responses were examined and found to follow the same pattern of skewing towards the most positive response options as for Survey 1. Levels of missing data were similarly low (less than 2% missing for each item) for Survey 2 as for Survey 1, and high internal consistency of the scale (α = 0.96) was again observed for Survey 2 responses with complete LTCQ data (N=492).

Sub-sample comparisons

The size and diversity of the sample enabled the comparison of LTCQ scores among different groups. Tables 3a and 3b present LTCQ score parameters and internal consistency measures for groups compared by cohort (health or social care), gender, age, number of conditions reported, and presence or absence of a mental health condition. ANOVA confirmed statistically significant differences in mean scores in a predictable pattern: LTCQ scores were lower for the social care cohort, women, the youngest (under 50) and oldest (over 85) age groups, high multi-morbidity (8 or more conditions reported), and the presence of at least one mental health condition. Internal consistency was high ($\alpha > 0.9$) for all groups. The analysis was repeated for responses to the follow-up survey (N=492), with the same pattern observed. Distributions of LTCQ scores by cohort and mental health are shown in Figure 1.

Convergent construct validity

The sample's mean scores for the LTCQ, EQ-5D-5L, EQ-VAS, Self-efficacy scale, Activities of Daily Living (ADL) scale, and Bayliss burden of morbidity scale are shown in Table 4, alongside correlations (Spearman's rho) of the LTCQ score with all other measures. Associations between the LTCQ and all reference measures were moderate to strong and in the expected directions, i.e. positive for measures where higher scores indicated better outcomes (EQ-5D-5L, EQ-VAS, Self-efficacy scale), and negative for measures where higher scores indicated poorer outcomes (ADLs, Bayliss burden of morbidity). The collective strengths of association are notable given the different domains being captured across the measures (e.g. physical and emotional functioning, confidence to self-manage, impact of LTCs on daily activities). Further item-level analyses are ongoing, but initial results suggest that while some LTCQ items correlate with specific items from reference measures, other LTCQ items seem to be tapping into distinct domains that underpin the broader construct of 'living well with LTCs'. For example responses to LTCQ items reflecting personal autonomy (e.g. items 1-5) are associated with responses to mobility, self-care and usual activities items from the EQ-5D; and LTCQ items reflecting illness burden (items 9-15) are associated with the EQ-5D depression/anxiety item; but LTCQ items reflecting social and environmental influences on the impact of LTCs (e.g. social support, suitability of the home) are not strongly associated with items from existing measures. Taken together this evidence indicates that the LTCQ score represents a more complex construct of 'living well with LTCs' that draws together domains from multiple existing measures.

DISCUSSION

The LTCQ is a new generic PROM for capturing what it means to live well with long-term conditions. In this study the LTCQ was found to be acceptable to a large and diverse sample of health and social care users (N=1,211), with low levels of missing data across all items. For initial analysis an LTCQ score was only computed if all items were completed; but given that 98% of the sample completed 18 items (90%) or more of the LTCQ, further work will explore the feasibility of imputing scores when one or two LTCQ items are missing. Internal consistency of the LTCQ is high, but analysis has not indicated direct repetition of content between items; this is consistent with the conceptual framework from which it was developed,[17] in which 15 distinct concepts underpinned the 20 items. Correlations with all reference measures (EQ-5D-5L, EQ-VAS, Self-efficacy scale, ADLs, Bayliss burden of morbidity) were strong and in the expected directions, supporting construct validity. Among this sample the LTCQ exhibited excellent test-retest reliability.

A strength of the study was the sample's diversity in the number, type and severity of health conditions reported, which indicates that the LTCQ is relevant for use across different types of LTCs. The potentially wide applicability of the LTCQ suggests that it could play a role in operationalising integrated person-centred care, with particular relevance for people with multi-morbidity. That social care users have been specifically included in the sample is a further strength, suggesting that the LTCQ may be relevant for use in both health and social care settings. The range of reference measures used to validate the LTCQ is a third strength, demonstrating the complexity of 'living well with LTCs' that the LTCQ aims to measure, which is not fully captured by other existing measures.

Weaknesses of the study include the lower response rate achieved among the social care cohort and the relative homogeneity of the sample in terms of ethnicity. The response rate for the health care cohort (31%) was broadly in line with that of a previous pilot study[13] and other national health surveys.[8,34] The lower response rate for the social care cohort (13%), who reported lower levels of 'living well' in comparison to the health care cohort, may indicate less willingness or ability to engage with PROMs in comparison to other groups. These findings are not entirely unexpected given the similarity of this response rate to those of other projects assessing social care recipients.[35] Because the vast majority of participants in this study were white British, further testing is recommended to assess the relevance and acceptability of the LTCQ in other ethnic groups.

The LTCQ provides a more holistic approach to outcome measurement, encompassing but moving beyond the focus on symptoms and functioning seen in existing generic health status measures such as the EQ-5D. The strong correlations of LTCQ scores with both the EQ-5D and the Self-efficacy scale suggest that the broad construct measured by the LTCQ captures both functional abilities and self-confidence to manage illness, among other domains. The availability of a valid, generic measure for monitoring the cumulative impacts of LTCs could play a key role in facilitating the shift to new models of person-centred care. Crucial to emerging goals for redesigned services is individuals' capabilities for managing the many demands of living with LTCs. Equally important is the extent to which people have positive self-worth and are able to participate in society through meaningful and rewarding activities, including employment. In line with current policy,[36,37] a generic PROM for LTCs should also assess key aspects of relevance to social care including safety, control over life and quality of support – concepts that are included in the LTCQ. In drawing together a unique range of health- and social care-related items, the LTCQ fills a distinct gap in the availability of measures that are appropriate for evaluating integrated services in the context of multi-morbidity.

A focus of future research will be to test the responsiveness of the LTCQ, which will be crucial for its potential use in routine monitoring. Furthermore, whilst this initial validation study has demonstrated the LTCQ's relevance for people with a diverse range of LTCs (including multi-morbidity), further validation work is needed in populations not represented here, for example those with dementia or learning difficulties, and those for whom English is not their first language. Translatability assessment of the LTCQ was undertaken during an earlier phase of its development[18] and concluded that it could be translated into multiple languages (e.g. French, Polish, Arabic, Urdu, simplified Chinese). Following translation, the acceptability, validity and reliability of the LTCQ would need to be tested through further studies in non-English contexts. Further structural validation work, for example employing Rasch analysis or bifactor models, would also contribute to the evidence base for this new measure.

CONCLUSIONS

This paper provides encouraging evidence for the reliability and validity of the Long-Term Conditions Questionnaire (LTCQ), a new instrument for measuring 'living well' in the context of chronic illness. As a generic PROM that taps into a broad range of domains relevant for both health and social care settings, the LTCQ could meet a distinct need for holistic outcome measurement that facilitates integrated service provision. The measure's reliability among all sub-groups within this diverse validation sample, coupled with previously reported evidence of content validity,[18] indicates that the LTCQ is relevant and acceptable for people with single or multiple LTCs, encompassing both physical and mental health conditions. In the context of increasing multi-morbidity, a generic PROM that comprehensively captures what it means to live well with LTCs from the individual's perspective could support the implementation of person-centred care.

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COMPETING INTERESTS

All authors declare: some authors had financial (salary) support from the two funding bodies listed below for the submitted work; no financial relationships with any other organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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AUTHOR CONTRIBUTIONS

RF, JF, AC, CJ and MP conceived the study. RF and JF secured its funding and managed its overall direction. JB and MB contributed to study design, ethics considerations and interpretation of study results as patient/pubic members of the research team. MP, LB and KJ led on securing ethics and other approvals for the study. AC, EG and CJ advised on data collection and data interpretation throughout the study. MP, CP, LB, LG, CA, LK, DF and KJ were jointly responsible for participant recruitment (including working with participating organisations and developing the database search protocol) and for all aspects of data management (collection, entry, checking). CP and MP led the analysis with direction from RF and CJ. CP drafted the paper, which was critically reviewed by all authors. All authors contributed to revisions and approved the final version of the manuscript.

DATA SHARING STATEMENT

As stated in the approved study protocol, only members of the research team (i.e. study authors) have access to the study data. The full anonymised data set was shared between all team members (University of Oxford and University of Kent). Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

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Table 1. Participant characteristics (N=1,211)

	Response option	N (%)
Recruitment	Health care (via GP practice)	917 (76%)
	Social care (via Local Authority)	294 (24%)
Age	18-49 years	162 (13%)
	50-64 years	277 (23%)
	65-74 years	331 (27%)
	75-84 years	259 (21%)
	85+ years	128 (11%)
	(missing)	*54 (5%)*
Gender	Female	656 (54%)
	Male	528 (44%)
	(missing)	*27 (2%)*
Condition* reported	Depression / anxiety	508 (42%)
	Chronic back pain	450 (37%)
	Diabetes	313 (26%)
	Osteoarthritis	308 (25%)
	Colon problems (e.g. IBS)	290 (24%)
	Heart disease	284 (24%)
	COPD	188 (16%)
	Stroke	185 (15%)
	Cancer within the last 5 years	166 (14%)
	Bipolar / psychosis / schizophrenia	88 (7%)
	Multiple Sclerosis	75 (6%)

	Response option	N (%)
Employment	Retired from work	554 (46%)
	Permanently sick or disabled	218 (18%)
	Employed / full-time education	211 (17%)
	Doing something else (e.g. volunteering)	85 (7%)
	Unemployed	31 (3%)
	(missing)	*112 (9%)*
Marital status	Married / civil partnership	648 (54%)
	Widowed	224 (19%)
	Divorced / separated	168 (14%)
	Single / never married	144 (12%)
	(missing)	*27 (2%)*
Ethnicity	White British	1097 (91%)
	Other White (e.g. Irish, European)	38 (3%)
	Black / Black British (e.g. African, Caribbean)	18 (2%)
	Asian / Asian British (e.g. Indian, Pakistani)	17 (1%)
	Mixed	8 (0.6%)
	(missing)	*33 (3%)*
Help needed completing questionnaire	No help	896 (74%)
	Had help, but answers are my own	227 (19%)
	Someone answered for me (proxy)	74 (6%)
	(missing)	*14 (1%)*

*Percentages for Condition reported exceed 100% because most participants reported multiple conditions.

Table 2. LTCQ item responses (N = 1,211)

Item	Never	Rarely	Sometimes	Often	Always	*Missing*	Not applicable**
1. Able to cope well with health conditions	3%	10%	29%	26%	31%	*1.5%*	
2. Able to fulfil responsibilities	12%	15%	20%	18%	32%	*1.9%*	
3. Able to be as physically active as you wanted	21%	20%	21%	17%	20%	*1.2%*	
4. Felt in control of daily life	8%	13%	22%	21%	35%	*1.3%*	
5. Able to take part in activities you enjoy	16%	22%	22%	17%	21%	*1.4%*	
6. Felt that your home is suitable for your needs	**4%**	5%	15%	18%	**56%**	*1.5%*	
7. Felt safe at home	**2%**	4%	10%	19%	**64%**	*1.2%*	
8. Felt safe outside the home	9%	10%	23%	18%	38%	*2.0%*	
9. Felt bothered by symptoms*	9%	12%	33%	26%	19%	*1.5%*	
10. Felt more dependent on others than you wanted*	19%	13%	20%	21%	27%	*1.0%*	
11. Felt lonely due to health conditions*	34%	15%	24%	15%	11%	*1.0%*	
12. Worried about being treated differently*	39%	17%	25%	10%	7%	*1.5%*	
13. Found health/other services difficult to cope with*	**20%**	13%	19%	6%	**3%**	*2.2%*	**36%**
14. Found treatments difficult to cope with*	**31%**	21%	19%	8%	**4%**	*1.4%*	**17%**
15. Felt that your health conditions made you unhappy*	20%	16%	31%	18%	13%	*1.3%*	
16. Felt you knew enough about your health conditions	5%	11%	24%	26%	32%	*2.1%*	
17. Had enough social contact with people	5%	13%	21%	21%	38%	*2.1%*	
18. Had enough support to cope well with health conditions	**4%**	9%	21%	25%	**40%**	*1.4%*	
19. Felt confident in managing health conditions	6%	8%	23%	22%	40%	*1.2%*	
20. Able to live your life as you want	16%	17%	20%	18%	28%	*1.0%*	

* Questions 9-15 are reverse-scored, i.e. 'Never' is the most positive response option
**Questions 13 and 14 have an additional response option: 'have not received any health-related services / treatments in the past four weeks'. For analysis these responses were coded as 'Never'.

Table 3a. Comparison of LTCQ scores among sub-samples (main survey)

LTCQ - main survey

		N	Mean	SD	SE	95% CI	α	ANOVA
	Total sample	**1082**	**65.1**	**23.0**	**0.70**	**63.7 - 66.5**	**0.95**	
cohort	Health care sample	838	70.0	21.7	0.75	68.6 - 71.5	0.95	F (1, 1080) = 201.8, P < 0.001
	Social care sample	244	48.2	19.1	1.22	45.8 - 50.8	0.92	
gender	male	482	68.5	22.6	1.03	66.4 - 70.5	0.96	F (1, 1057) = 19.8, p < 0.001
	female	577	62.2	23.0	0.96	60.3 - 64.1	0.95	
age[a]	18-64 years	413	59.7	23.3	1.15	57.5 - 62.0	0.95	F (2, 1032) = 27.4, p < 0.001
	65-84 years	525	70.2	21.7	0.95	68.3 - 72.0	0.95	
	85+ years	97	60.2	22.6	2.30	55.7 - 64.8	0.95	
morbidity[b]	1 LTC	60	76.5	21.3	2.74	71.0 - 82.0	0.94	F (3, 1057) = 75.3, p < 0.001
	2-4 LTCs	320	73.9	21.3	1.19	71.5 - 76.2	0.95	
	5-7 LTCs	351	67.9	21.5	1.15	65.7 - 70.2	0.95	
	8+ LTCs	330	51.1	20.1	1.11	49.0 - 53.3	0.93	
mental health	no mental health condition reported	624	74.2	20.2	0.81	72.6 - 75.8	0.94	F (1, 1080) = 291.2, P < 0.001
	at least one mental health condition reported	458	52.7	20.8	0.97	50.8 - 54.6	0.94	

N = sample size   Mean = mean LTCQ score for sub-sample   SD = standard deviation   SE = standard error of the mean   95% CI = 95% confidence interval

α = Cronbach's alpha (internal consistency) for 20 LTCQ items among sub-group   ANOVA = one-way between-groups analysis of variance of LTCQ scores

a. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly higher for the 65-84 years age group compared to both other age groups ($p < 0.001$).

b. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly lower for those with 5-7 LTCs compared to those with one LTC ($p < 0.05$) and compared to those with 2-4 LTCs ($p < 0.01$). LTCQ scores were significantly lower for those with 8+ LTCs compared to all other groups ($p < 0.001$).

Table 3b. Comparison of LTCQ scores among sub-samples (follow-up survey)

LTCQ - follow-up survey

		N	Mean	SD	SE	95% CI	α	ANOVA
	Total sample	**492**	**65.5**	**23.4**	**1.05**	**63.4 - 67.5**	**0.96**	
cohort	Health care sample	379	70.3	22.3	1.15	68.0 - 72.6	0.96	F (1, 490) = 82.4, p < 0.001
	Social care sample	113	49.2	19.3	1.82	45.6 - 52.8	0.92	
gender	male	229	68.7	22.8	1.5	65.8 - 71.7	0.96	F (1, 480) = 8.0, p < 0.01
	female	253	62.8	23.4	1.47	59.9 - 65.7	0.96	
age^{a}	18-64 years	184	58.8	23.8	1.76	55.3 - 62.3	0.96	F (2, 469) = 14.4, p < 0.001
	65-84 years	250	70.6	22.1	1.39	67.9 - 73.4	0.96	
	85+ years	38	65.6	20.7	3.35	58.8 - 72.4	0.94	
morbidity^{b}	1 LTC	22	78.2	18.3	3.89	70.1 - 86.3	0.93	F (3, 482) = 43.9, p < 0.001
	2-4 LTCs	157	76.2	19.9	1.59	73.1 - 79.4	0.95	
	5-7 LTCs	143	67.7	23.6	1.97	63.8 - 71.6	0.97	
	8+ LTCs	164	50.9	19.4	1.51	47.9 - 53.9	0.93	
mental health	no mental health condition reported	290	74.6	20.1	1.18	72.4 - 77.1	0.95	F (1, 490) = 144.2, p < 0.001
	at least one mental health condition reported	202	52.1	21.3	1.5	49.1 - 55.0	0.95	

N = sample size Mean = mean LTCQ score for sub-sample SD = standard deviation SE = standard error of the mean 95% CI = 95% confidence interval

α = Cronbach's alpha (internal consistency) for 20 LTCQ items among sub-group ANOVA = one-way between-groups analysis of variance of LTCQ scores

a. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly higher for the 65-84 years age group compared to the 18-64 years age group ($p < 0.001$).

b. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly lower for those with 5-7 LTCs compared to those with 2-4 LTCs ($p < 0.01$). LTCQ scores were significantly lower for those with 8+ LTCs compared to all other groups ($p < 0.001$).

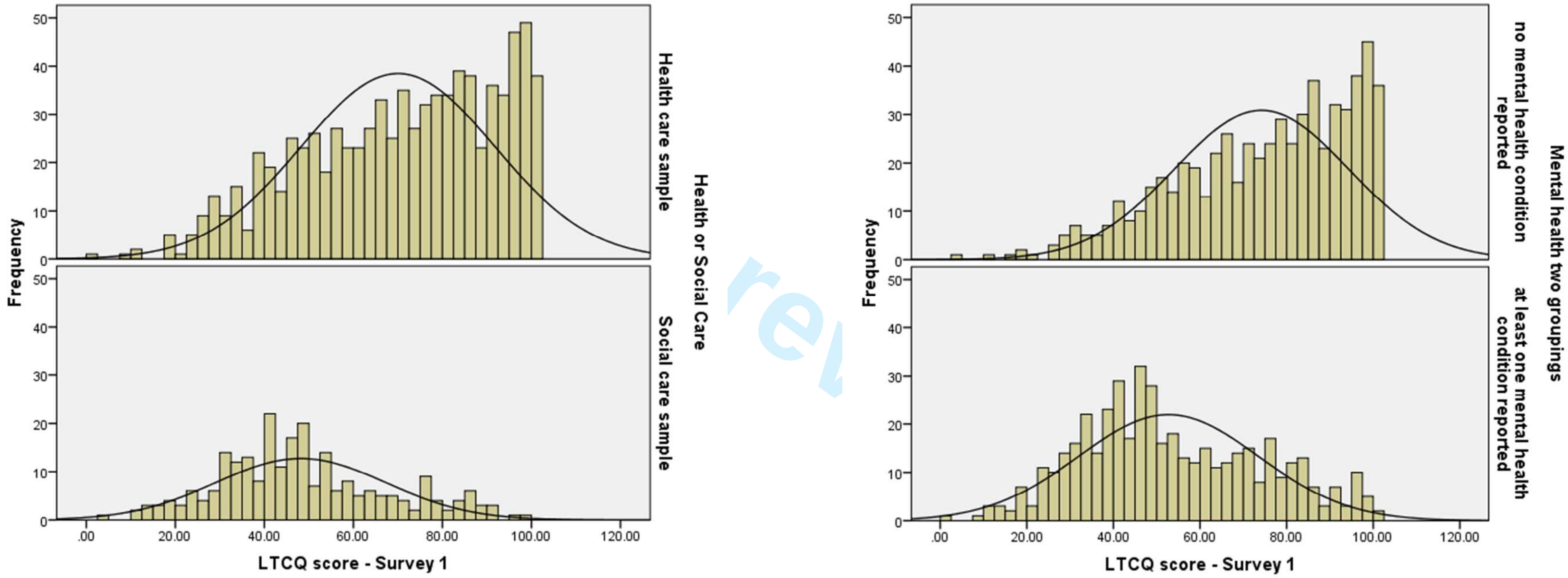
Table 4. Construct validity

Measure	Mean score (SD, SE, 95% CI)	Score range	Interpretation of higher score	Correlation with LTCQ score (Spearman's rho)
LTCQ	65.1 (23.0, 0.70, 63.7 – 66.5)	0 to 100	living better with long-term conditions	-
EQ-5D-5L	0.62 (0.33, 0.01, 0.60 – 0.63)	-0.28 to 1	better health-related quality of life	0.82***
EQ-VAS	62.4 (24.6, 0.72, 61.0 – 63.8)	0 to 100	better health-related quality of life	0.79***
Self-efficacy scale	6.2 (2.7, 0.08, 6.1 – 6.4)	1 to 10	greater confidence for managing chronic disease	0.87***
Activities of Daily Living	5.0 (4.8, 0.14, 4.7 – 5.3)	0 to 13	more problems with activities of daily living	- 0.79***
Bayliss burden of morbidity	16.4 (13.1, 0.38, 15.7 – 17.2)	0 to 150	more limits on daily activities from LTCs	-0.64***

***Correlation is significant at p < 0.001 (2-tailed).

SD = standard deviation SE = standard error of the mean 95% CI = 95% confidence interval

Figure 1. Comparison of LTCQ score distributions: health versus social care; mental versus physical health condition(s)



STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Location in paper
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title – p.1 Abstract – p.2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract – p.2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	p.3
Objectives	3	State specific objectives, including any prespecified hypotheses	p.3
Methods			
Study design	4	Present key elements of study design early in the paper	Abstract – p.2, Methods – p.4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods – p.4-5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Methods (Participant recruitment) – p.4-5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods (The Surveys) – p.5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods (Analysis) – p.5-6
Bias	9	Describe any efforts to address potential sources of bias	Methods (Participant recruitment) – p.4-5
Study size	10	Explain how the study size was arrived at	Methods – p.4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods (Analysis) – p.5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Methods (Analysis) – p.5-6
		(*b*) Describe any methods used to examine subgroups and interactions	Methods (Analysis) – p.6, Results (Sub-sample comparisons) – p.9
		(*c*) Explain how missing data were addressed	Methods (Analysis) – p.6
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of	Methods (Participant

		study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	recruitment) – p.4-5 , Results (Sample characteristics, Test-retest reliability) – p.7, p.8-9
		(b) Give reasons for non-participation at each stage	Cannot comment as no contact with non-responders
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results (Sample characteristics) – p.7 Table 1 – p.15
		(b) Indicate number of participants with missing data for each variable of interest	Table 2 – p.16
Outcome data	15*	Report numbers of outcome events or summary measures	Table 3 – p.17-18, Table 4 – p.19, Figure 1 – p.20
Main results Please note that these do not easily apply to a survey validation study. Quality criteria for reporting measurement properties of health questionnaires were followed instead.	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A as regression not performed for a survey validation study.
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Results (factor analysis, internal consistency, test-retest reliability, sub-sample comparisons, convergent construct validity) – p.7-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion – p.9-10 (paragraph 1)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion – p.10 (paragraph 3)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion – p.10-11 (paragraphs 4-5)
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion – p.10-11 (paragraph 5)
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study	Funding – p.11

on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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The Long-Term Conditions Questionnaire (LTCQ): initial validation survey among primary care patients and social care recipients in England

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The Long-Term Conditions Questionnaire (LTCQ): initial validation survey among primary care patients and social care recipients in England

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Abstract

Objective: The aim of this study was to validate a new generic patient-reported outcome measure, the Long-Term Conditions Questionnaire (LTCQ), among a diverse sample of health and social care users in England.

Design: Cross-sectional validation survey. Data were collected through postal surveys (February 2016 - January 2017). The sample included a health care cohort of patients recruited through primary care practices, and a social care cohort recruited through local government bodies that provide social care services.

Participants: 1,211 participants (24% confirmed social care recipients) took part in the study. Health care participants were recruited on the basis of having one of eleven specified LTCs, and social care participants were recruited on the basis of receiving social care support for at least one LTC. The sample exhibited high multi-morbidity, with 93% reporting two or more LTCs and 43% reporting a mental health condition.

Outcome measures: The LTCQ's construct validity was tested with reference to the EQ-5D (5-level version), the Self-efficacy for Managing Chronic Disease scale, an Activities of Daily Living scale, and the Bayliss burden of morbidity scale.

*Results***:** Low levels of missing data for each item indicate acceptability of the LTCQ across the 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 both health and social care settings. The LTCQ could meet a need for holistic outcome measurement that goes beyond symptoms and physical function, complementing existing measures to capture fully what it means to live well with LTCs.

Key words: long-term conditions, chronic illness, patient-reported outcome measure, multi-morbidity, person-centred care

Strengths and limitations of this study

- This study is the first psychometric evaluation of the Long-Term Conditions Questionnaire, a new generic patient-reported outcome measure.
- The study included a large survey validation sample of 1,211 health and social care users in England.
- The sample was highly diverse in terms of illness burden and care needs, with 93% reporting multi-morbidity and 43% reporting a mental health condition.
- A limitation was the low response rate achieved among social care users, although this was consistent with previous studies.
- Further validation work among other ethnic groups and in non-English contexts is required since the vast majority of participants were white British.

INTRODUCTION

Long-term chronic conditions have emerged as a significant challenge to the sustainability of health systems worldwide. Considering the high global burden of long-term conditions (LTCs), their management is a top priority in policy terms.[1,2] In England, around one-quarter of the population lives with at least one LTC, accounting for nearly three-quarters of the cost of health and social care services.[3] In particular the rise of multi-morbidity has highlighted the need for integrated services that can address a person's overall health status and enhance their capacity for living well with their conditions.

Patient-reported outcome measures (PROMs) are essential tools for capturing the impact of illness as experienced by those living with LTCs, and the potential of PROMs for facilitating person-centred care has been recognized for more than a decade.[4] However, there is currently no agreed patient-reported measure for evaluating the intended outcome of person-centred care, which could broadly be described as 'living well' within the overall context of one's health condition(s). 'Living well with LTCs' is a complex construct that encompasses both traditional health-related quality of life (HRQoL) domains (e.g. symptom severity, physical and social functioning, emotional well-being) and more recently recognized domains of importance (e.g. treatment burden, empowerment, confidence in self-management).[5,6] A comprehensive measure for assessing the impacts of LTCs should thus move beyond traditional health-status domains of PROMs to capture a more holistic notion of living well.[7]

While a plethora of condition-specific and generic PROMs exist, both types of measure have shortcomings for capturing what it means to live well with LTCs. In focusing on a single disease category, condition-specific PROMs cannot adequately address the phenomenon of multi-morbidity, where impacts may be cumulative or inter-dependent across all conditions.[8] Standardised generic PROMs such as the EQ-5D[9] and SF-36,[10] while valuable for comparative population-level analyses, are unlikely to capture all issues of importance for people living with LTCs.[11,12] Furthermore, these measures may not be appropriate for long-term monitoring of LTCs, where the objectives of health and social care services may be to maintain well-being and/or to avoid deterioration rather than to achieve major health gains.[13] A further complication arises with the distinction between health-related and social care-related measures,[14] as people with complex needs will potentially draw on both types of services. A measure that is appropriate for both contexts could facilitate the development of person-centred care pathways, which are increasingly recognised as preferable to disease-specific care pathways in the context of multi-morbidity.[15]

The aim of this study was to test and validate a new PROM, the Long-Term Conditions Questionnaire (LTCQ). The LTCQ is intended to be relevant and acceptable for people with single or multiple LTCs (physical and/or mental health conditions), and meaningful for health and social care providers in their capacities for monitoring and improving outcomes in LTCs. Additionally, the LTCQ is intended to be short, easy to interpret, and feasible for use in different clinical settings. It is intended for use both as a tool for monitoring and enhancing individual care, and as a population-level tool for measuring health and social care performance, quality and outcomes. The scope of the LTCQ goes well beyond symptoms and physical function; its content development has been described previously and involved interviews with professional stakeholders,[16] qualitative in-depth interviews with people living with LTCs,[17] and pre-testing (e.g. cognitive interviews, translatability assessment) to refine questionnaire items.[18]

METHODS

This study was reviewed by England’s National Research Ethics Service (NRES) Committee East Midlands – Derby (reference 15/EM/0414). Approvals for the study were granted by the Health Research Authority of England’s National Health Service (NHS), and local health and social care organisations linked to participant recruitment sites. Data were collected through two postal surveys (a main survey and a follow-up survey) administered to two cohorts: a health care sample recruited through primary care practices (data collected February 2016 – July 2016), and a social care sample recruited through Local Authorities (LAs) that provide funding for social care services (data collected July 2016 – January 2017). Methods and findings presented below follow STROBE reporting guidelines for cross-sectional studies[19] and COSMIN criteria for reporting measurement properties of health status questionnaires.[20] The latter indicates a minimum sample size of 10 subjects per questionnaire item (i.e. 200 participants for this survey validation study), which exceeds the minimum of 100 subjects required for factor analysis within Classical Test Theory. Owing to the complexity of the construct being measured and the diversity of the target population, the study authors aimed to achieve a minimum sample size of 1000 participants.

Participant recruitment

For the health care cohort, participants were recruited by fifteen General Practitioner (GP) practices from three regions of England (South East, North West, Yorkshire & Humber). In an effort to recruit a maximally diverse sample, the research team selected practices that served both rural and urban areas, and areas of high and low deprivation. For a participant to be invited into the study, the GP practice confirmed diagnosis of one of eleven specified LTCs: cancer within the last 5 years, chronic back pain, chronic obstructive pulmonary disease (COPD), diabetes, depression, irritable bowel syndrome (IBS), ischaemic heart disease (IHD), multiple sclerosis (MS), osteoarthritis (OA), severe mental health (as defined under the UK Quality and Outcomes Framework,[21] including psychoses, bipolar disorder and schizophrenia), and stroke. The eleven selected conditions were chosen by a panel of PROMs researchers and lay advisors, with the aim of maximising diversity in terms of symptoms, disease trajectory, prevalence, mean age of onset, likelihood of comorbidities, burden of disease, type of health and social care needed, level of self-management and burden of care. Each practice recruited from patient groups representing at least five of the eleven conditions, with some practices asked to prioritise certain conditions that were otherwise under-represented. Recruitment was restricted to those diagnosed more than 12 months previously to ensure that participants had adjusted to their diagnosis and had experienced a range of services and strategies for the management of their LTC(s). Only adults (i.e. 18 years of age and above) able to consent who were able to communicate in English were included, with no upper age limit. A total of 2,983 eligible patients were invited to participate for the health care cohort (approximately 200 study packs mailed out by each participating GP practice).

For the social care cohort, participants were recruited by four Local Authorities of different types (unitary, metropolitan, county and London borough) in geographically diverse regions (North West, East of England, South West and Greater London) representing a mix of urban and rural communities. Individuals were eligible for the study if they received fully or partially funded long-term social care support, provided that the primary reason for support was a physical disability, sensory impairment, or a mental health condition as listed in table LTS001b on the Short and Long

Term (SALT) mandatory data returns for social care.[22] Potential participants were eligible if they received community-based services, were at least 18 years old, and were able to communicate in English. Individuals who received nursing or residential care, whose primary reason of support was a learning disability or cognitive impairment (as listed on Table LTS001b of SALT), or whose records indicated that they lacked mental capacity to consent to research were excluded. The research team provided each Local Authority with study packs, which were mailed directly by the LAs to 2,294 eligible participants. This was to ensure that no personal data of individuals were disclosed to the research team without consent.

The surveys

The study packs contained an invitation letter from the GP / LA, a participant information sheet, and the main survey (Survey 1). Survey 1 included the Long-Term Conditions Questionnaire (LTCQ) and other measures for testing the LTCQ's construct validity: EQ-5D (5-level version including the EQ-VAS),[23] the Self-efficacy for Managing Chronic Disease 6-item scale,[24] an Activities of Daily Living scale,[25] and the Bayliss burden of morbidity scale (adapted with permission from the developers to include all conditions for which participants in this study had been recruited).[26] These were selected because they measure different domains that were hypothesized to underpin the LTCQ's broad construct of 'living well with LTCs': physical functioning, symptom burden and emotional well-being (EQ-5D); confidence to self-manage (Self-efficacy scale), functioning and independence (ADLs), cumulative impact of LTCs (Bayliss scale). Survey 1 also included demographic questions, questions on service use, a question about help needed to complete the questionnaire, and a box for free-text comments. Additionally for the social care cohort, Survey 1 included a measure of social care-related quality of life, the Adult Social Care Outcomes Toolkit (ASCOT),[27] but this measure is not included in the initial validation analysis for the total sample. A pre-paid, addressed return envelope was provided in all study packs. After approximately two weeks participants were sent a thank you / reminder letter from the GP / LA in order to encourage further responses.

Survey 1 contained an address slip through which respondents could express willingness to receive the follow-up survey (Survey 2). Among those who provided contact details (n = 980, 81%), a sub-sample of 693 respondents (57%) were sent Survey 2 approximately two weeks after returning Survey 1. The sub-sample included 54% of the health care cohort (n = 499) and 66% of the social care cohort (n = 194). Survey 2 contained only the LTCQ, a reduced number of demographics questions, and a health transition question asking about changes in health status during the period between completing Survey 1 and Survey 2. A pre-paid, addressed return envelope was provided with all questionnaires. Participants who had not returned Survey 2 within approximately two weeks were sent a reminder letter.

Analysis

All data were entered into SPSS (version 24), a statistical software package. A coding framework was specified in advance and used by all research team members for consistency in data entry. Data cleaning was undertaken via analysis of frequencies for all items in Survey 1, with any anomalies checked against the original questionnaires and corrected as necessary. Particular attention was given to the 20 items of the LTCQ, for which any missing or multiple responses prompted visual inspection and verification/correction of data for the entire Survey 1 questionnaire. The same procedure for data entry, checking and cleaning was followed for Survey 2 among the health cohort, and for both Survey 1 and Survey 2 among the social care cohort, to ensure data quality across the full dataset.

Exploratory factor analysis of the 20 LTCQ items was undertaken (see Results), from which it was concluded that the LTCQ could be scored as a single composite measure. The appropriateness of scoring items as a single scale was further evaluated through examination of inter-item correlations (acceptable if 0.8 or less) and item-total correlations (acceptable if 0.3 or more).[28] LTCQ items were scored on a scale from 0 (most negative response) to 4 (most positive response). Items 9-15 are negatively phrased and were therefore reverse-scored. Taking a conservative approach and following best practice guidelines,[29] only responses for which all 20 LTCQ items had been answered were included in the initial validation analysis. A sum of the 20 item scores was calculated and recalibrated to give an overall LTCQ score ranging from 0 to 100, with higher scores indicating a better level of 'living well with LTCs'. Cronbach's alpha (α) was calculated as a measure of internal consistency of the scale. Test-retest reliability was assessed via calculation of the Intraclass Correlation Coefficient (ICC) type 2 (two-way random effects, absolute agreement) among respondents who reported no change in health status between Survey 1 and Survey 2. ANOVA was employed to compare LTCQ scores among sub-groups within the sample (i.e. by gender, age, health versus social care cohort, mental versus physical health conditions, number of conditions reported). Owing to the clustered study design (i.e. participants recruited through selected GP practices and Local Authorities), Intra-Cluster Correlation Coefficients (ICCCs)[30] were calculated for each item to assess the extent to which variance in responses was associated with recruitment site.

Scores for all existing measures were calculated according to developers' instructions. For the EQ-5D-5L, value sets recently reported for a population in England were used to calculate a single index value for each participant's reported health state;[31] scores are only calculated if all five items have been completed, with a theoretical range of -0.28 (a state worse than death) to 1 (best possible health state). The EQ-VAS score, a measure of overall health on that day, ranges from 0 (the worst health you can imagine) to 100 (the best health you can imagine). For the Self-efficacy measure, six items asked about confidence in doing certain health-related activities on a scale from 1 (not at all confident) to 10 (totally confident); the overall score is calculated as the mean of item scores, provided that participants had completed at least four of the six items. The ADL score is calculated as the sum of all items for which difficulty in managing daily activities was reported, ranging from 0 (no difficulty with any listed activities) to 13 (at least some difficulty with all listed activities). The Bayliss burden of morbidity measure lists 25 LTCs and asks respondents to indicate the impact of each condition on their lives; a score of 0 indicates that the respondent does not have that condition, while scores for individual items ranging from 1 (has the condition but it does not limit daily activities at all) to 5 (has the condition and it limits daily activities a lot) indicates the impact of any reported condition. The total morbidity score was calculated as the sum of impact scores for all conditions reported, including up to three LTCs that respondents could list as 'other long-term conditions not mentioned above'. A count function was applied to the morbidity measure to calculate the number and type (physical or mental health) of LTCs reported by each respondent. For assessment of construct validity, correlations (Spearman's rho) were calculated for the LTCQ score in relation to all other measures.

RESULTS

Sample characteristics

A total of 917 participants were recruited through primary care (31% response rate), and 294 participants were recruited through social care (13% response rate), giving a total sample of 1,211 participants (23% overall response rate). Demographic information is shown in Table 1. The age range was 18 to 102 years, with a mean age of 67 (SD 15.3 years). Fifty-four percent (n = 656) were female, just over half were married or in a civil partnership (n = 648, 54%), and just under half were fully retired from work (n = 554, 46%). The sample was mainly white British (n = 1,097, 91%), with limited representation from non-white groups. Although participants were recruited on the basis of having one LTC, the sample exhibited a high degree of multi-morbidity; 1,124 participants (93%) reported having two or more conditions, with a mean of 6.2 LTCs (SD 3.8 LTCs) reported across the sample. 522 participants (43%) reported at least one mental health condition, with the majority of these also reporting at least one physical LTC.

Acceptability

The LTCQ was completed in full by 1,082 participants, which enabled calculation of an LTCQ score for 89% of the sample. Table 2 summarises the content and Survey 1 response rates for individual items. Levels of missing data were low and broadly uniform across items, ranging from 1.0% (item 10, dependence; item 11, loneliness; item 20, living life as you want) to 2.2% (item 13, services difficult to cope with). The low levels of missing data for all individual items indicate acceptability of the LTCQ within this diverse sample.

Floor / ceiling effects

For the total sample responses were generally skewed towards positive answers, with ceiling effects (i.e. less than 5% and more than 40% of respondents endorsing the most negative and positive response options, respectively)[28] observed in five items of the LTCQ (items 6, 7, 13, 14, and 18 – see Table 2). Ceiling effects were most pronounced for item 6 (home suitability) and item 7 (safety at home). These items convey content that was identified during previous qualitative phases of research as especially important for social care users, who represent a smaller portion of the sample. Whilst it is worth noting these item-level ceiling effects for their potential implications in population-level analyses, they are not in themselves problematic given the LTCQ's potential use for individual-level monitoring, where a key aim would be to identify and support the relatively smaller proportion of respondents who selected negative response options. No ceiling effect was observed for the measure as a whole (i.e. 15% or more of respondents achieving the highest possible score),[20] as less than 4% of respondents scored 100 on the LTCQ.

Factor analysis

The dataset's suitability for factor analysis was assessed via Bartlett's test of sphericity (highly significant, $p < 0.001$), the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy (0.96), and measures of sampling adequacy (MSA) (above 0.9 for each item). As indicated by the Intra-Cluster Correlation Coefficients reported for each item in Table 2, clustering effects by practice were very low (i.e. ICCC values below 0.10 for all items); thus the results of factor analysis reported below were interpreted as reasonably free from potential bias that could theoretically occur due to clustering of responses by recruitment site.

Exploratory factor analysis was undertaken using principal axis factoring (PAF). Three factors were extracted via the Kaiser criterion (eigenvalue > 1), which explained 66% of variance: factor 1 (eigenvalue 10.9, explaining 55% of variance), factor 2 (eigenvalue 1.2, explaining 6.0% of variance), factor 3 (eigenvalue 1.1, explaining 5.6% of variance). Over-extraction of factors is a recognised problem using this method,[32,33] and examination of the scree plot suggested that only the first factor should be retained. This was confirmed by Parallel Analysis,[32] which showed only the first factor with an eigenvalue exceeding the corresponding value generated for a random data matrix of the same size (20 items x 1082 respondents). For the one-factor solution, 19 LTCQ items loaded onto the general factor at levels ranging from 0.58 (good) to 0.86 (excellent),[34] with item 16 (knowledge about health conditions) loading less strongly (0.35). This evidence supports the LTCQ being scored as a single scale.

To check against under-extraction of factors, three-factor solutions (indicated by the Kaiser criterion) were also examined. With orthogonal (Varimax) rotation, all 20 items loaded onto one of the three factors with a minimum loading of 0.35 (item 16; all other items loaded at 0.49 or higher), and fourteen items cross-loaded onto additional factor(s). When oblique rotation (Direct Oblimin) was applied, the same pattern of primary loadings was observed across the three factors, with two items (item 10, dependence; item 19, confidence to manage illness) also loading weakly onto another factor. In this analysis the three factors correlated substantially with each other (r > 0.6 for all factor combinations), suggesting difficulty with interpreting and labelling the factors as distinct subscales. An examination of items within factors indicated that each factor contained multiple concepts; for example whilst factor 3 appeared to broadly group social and environmental influences on the management of LTCs, it contained conceptually distinct items on safety, suitability of the home, and social support. This observation is consistent with the conceptual framework from which items were developed,[17] in which 15 distinct concepts underpinned the 20 items tested in the initial validation survey. The items within each factor were summed and calibrated to yield dimension scores ranging from 0-100, which were suitable for factor analysis (Bartlett's test highly significant, KMO and MSA values all above 0.6). Higher-order factor analysis was undertaken using PAF and the Kaiser criterion; one factor was extracted with an eigenvalue of 2.3 that explained 75% of variance, with factor loadings of 0.93, 0.84, and 0.82. Thus the appropriateness of scoring the LTCQ as a single composite measure that captures the broad construct of 'living well with LTCs' was confirmed.

Internal consistency

The LTCQ exhibits high internal consistency across its 20 items (Cronbach's $\alpha = 0.95$). Corrected item-total correlations ranged from 0.35 (item 16, knowledge about health conditions) to 0.83 (item 4, felt in control of daily life), with negligible improvement in α if responses to item 16 were deleted. An examination of inter-item correlations showed that with one exception (item 3, able to be physically active and item 5, able to take part in enjoyable activities, r = 0.83), associations between items were moderate rather than strong. No items were considered duplicates of other items and all items contributed substantially to the single scale; thus no items were deleted following initial analysis.

Test-retest reliability

Of 693 participants sent the follow-up questionnaire, 544 (78%) completed and returned Survey 2. LTCQ scores for the 383 participants (70%) who reported their health as 'about the same' as two weeks ago were analysed for test-retest reliability. The ICC (type 2: two-way random effects, absolute agreement) for overall LTCQ scores between Survey 1 and Survey 2 was 0.94 (95% CI, 0.93 to 0.95). Correlations for individual item responses between Survey 1 and Survey 2 were examined and found to be moderate or strong and significant for all items, ranging from 0.50 (item 16, knowledge about health conditions) to 0.83 (item 2, able to fulfil responsibilities). Frequencies of Survey 2 responses were examined and found to follow the same pattern of skewing towards the most positive response options as for Survey 1. Levels of missing data were similarly low (less than 2% missing for each item) for Survey 2 as for Survey 1, and high internal consistency of the scale ($\alpha = 0.96$) was again observed for Survey 2 responses with complete LTCQ data (N=492).

Sub-sample comparisons

The size and diversity of the sample enabled the comparison of LTCQ scores among different groups. Table 3a presents LTCQ score parameters and internal consistency measures for groups compared by cohort (health or social care), gender, age, number of conditions reported, and presence or absence of a mental health condition. ANOVA confirmed statistically significant differences in mean scores in a predictable pattern: LTCQ scores were lower for the social care cohort, women, the youngest (under 50) and oldest (over 85) age groups, high multi-morbidity (8 or more conditions reported), and the presence of at least one mental health condition. Internal consistency was high ($\alpha > 0.9$) for all groups. The analysis was repeated for responses to the follow-up survey (N=492), with the same pattern observed (see Table 3b). Distributions of LTCQ scores by cohort (Figure 1) and mental health (Figure 2) are shown.

Convergent construct validity

The sample's mean scores for the LTCQ, EQ-5D-5L, EQ-VAS, Self-efficacy scale, Activities of Daily Living (ADL) scale, and Bayliss burden of morbidity scale are shown in Table 4, alongside correlations (Spearman's rho) of the LTCQ score with all other measures. Associations between the LTCQ and all reference measures were moderate to strong and in the expected directions, i.e. positive for measures where higher scores indicated better outcomes (EQ-5D-5L, EQ-VAS, Self-efficacy scale), and negative for measures where higher scores indicated poorer outcomes (ADLs, Bayliss burden of morbidity). The collective strengths of association are notable given the different domains being captured across the measures (e.g. physical and emotional functioning, confidence to self-manage, impact of LTCs on daily activities). Further item-level analyses are ongoing, but initial results suggest that while some LTCQ items correlate with specific items from reference measures, other LTCQ items seem to be tapping into distinct domains that underpin the broader construct of 'living well with LTCs'. For example responses to LTCQ items reflecting personal autonomy (e.g. items 1-5) are associated with responses to mobility, self-care and usual activities items from the EQ-5D; and LTCQ items reflecting illness burden (items 9-15) are associated with the EQ-5D depression/anxiety item; but LTCQ items reflecting social and environmental influences on the impact of LTCs (e.g. social support, suitability of the home) are not strongly associated with items from existing measures.

Taken together this evidence indicates that the LTCQ score represents a more complex construct of 'living well with LTCs' that draws together domains from multiple existing measures.

DISCUSSION

The LTCQ is a new generic PROM for capturing what it means to live well with long-term conditions. In this study the LTCQ was found to be acceptable to a large and diverse sample of health and social care users (N=1,211), with low levels of missing data across all items. For initial analysis an LTCQ score was only computed if all items were completed; but given that 98% of the sample completed 18 items (90%) or more of the LTCQ, further work will explore the feasibility of imputing scores when one or two LTCQ items are missing. Internal consistency of the LTCQ is high, but analysis has not indicated direct repetition of content between items; this is consistent with the conceptual framework from which it was developed,[17] in which 15 distinct concepts underpinned the 20 items. Correlations with all reference measures (EQ-5D-5L, EQ-VAS, Self-efficacy scale, ADLs, Bayliss burden of morbidity) were strong and in the expected directions, supporting construct validity. Among this sample the LTCQ exhibited excellent test-retest reliability.

A strength of the study was the sample's diversity in the number, type and severity of health conditions reported, which indicates that the LTCQ is relevant for use across different types of LTCs. The potentially wide applicability of the LTCQ suggests that it could play a role in operationalising integrated person-centred care, with particular relevance for people with multi-morbidity. That social care users have been specifically included in the sample is a further strength, suggesting that the LTCQ may be relevant for use in both health and social care settings. The range of reference measures used to validate the LTCQ is a third strength, demonstrating the complexity of 'living well with LTCs' that the LTCQ aims to measure, which is not fully captured by other existing measures.

Weaknesses of the study include the lower response rate achieved among the social care cohort and the relative homogeneity of the sample in terms of ethnicity. The response rate for the health care cohort (31%) was broadly in line with that of a previous pilot study[13] and other national health surveys.[8,35] The lower response rate for the social care cohort (13%), who reported lower levels of 'living well' in comparison to the health care cohort, may indicate less willingness or ability to engage with PROMs in comparison to other groups. These findings are not entirely unexpected given the similarity of this response rate to those of other projects assessing social care recipients.[36] Because the vast majority of participants in this study were white British, further testing is recommended to assess the relevance and acceptability of the LTCQ in other ethnic groups.

The LTCQ provides a more holistic approach to outcome measurement, encompassing but moving beyond the focus on symptoms and functioning seen in existing generic health status measures such as the EQ-5D. The strong correlations of LTCQ scores with both the EQ-5D and the Self-efficacy scale suggest that the broad construct measured by the LTCQ captures both functional abilities and self-confidence to manage illness, among other domains. The availability of a valid, generic measure for monitoring the cumulative impacts of LTCs could play a key role in facilitating the shift to new models of person-centred care. Crucial to emerging goals for redesigned services is individuals' capabilities for managing the many demands of living with LTCs. Equally important is the extent to which people have positive self-worth and are able to participate in society through meaningful and rewarding activities, including employment. In line with current policy,[37,38] a generic PROM for LTCs should also assess key aspects of relevance to social care including safety, control over life and quality of support – concepts that are included in the LTCQ. In drawing together a unique range of health- and social care-related items, the LTCQ fills a distinct gap in the availability of measures that are appropriate for evaluating integrated services in the context of multi-morbidity.

A focus of future research will be to test the responsiveness of the LTCQ, which will be crucial for its potential use in routine monitoring. Furthermore, whilst this initial validation study has demonstrated the LTCQ's relevance for people with a diverse range of LTCs (including multi-morbidity), further validation work is needed in populations not represented here, for example those with dementia or learning difficulties, and those for whom English is not their first language. Translatability assessment of the LTCQ was undertaken during an earlier phase of its development[18] and concluded that it could be translated into multiple languages (e.g. French, Polish, Arabic, Urdu, simplified Chinese). Following translation, the acceptability, validity and reliability of the LTCQ would need to be tested through further studies in non-English contexts. Further structural validation work, for example employing Rasch analysis or bifactor models, would also contribute to the evidence base for this new measure.

CONCLUSIONS

This paper provides encouraging evidence for the reliability and validity of the Long-Term Conditions Questionnaire (LTCQ), a new instrument for measuring 'living well' in the context of chronic illness. As a generic PROM that taps into a broad range of domains relevant for both health and social care settings, the LTCQ could meet a distinct need for holistic outcome measurement that facilitates integrated service provision. The measure's reliability among all sub-groups within this diverse validation sample, coupled with previously reported evidence of content validity,[18] indicates that the LTCQ is relevant and acceptable for people with single or multiple LTCs, encompassing both physical and mental health conditions. In the context of increasing multi-morbidity, a generic PROM that comprehensively captures what it means to live well with LTCs from the individual's perspective could support the implementation of person-centred care.

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COMPETING INTERESTS

All authors declare: some authors had financial (salary) support from the two funding bodies listed below for the submitted work; no financial relationships with any other organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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AUTHOR CONTRIBUTIONS

RF, JF, AC, CJ and MP conceived the study. RF and JF secured its funding and managed its overall direction. JB and MB contributed to study design, ethics considerations and interpretation of study results as patient/pubic members of the research team. MP, LB and KJ led on securing ethics and other approvals for the study. AC, EG and CJ advised on data collection and data interpretation throughout the study. MP, CP, LB, LG, CA, LK, DF and KJ were jointly responsible for participant recruitment (including working with participating organisations and developing the database search protocol) and for all aspects of data management (collection, entry, checking). CP and MP led the analysis with direction from RF and CJ. CP drafted the paper, which was critically reviewed by all authors. All authors contributed to revisions and approved the final version of the manuscript.

DATA SHARING STATEMENT

As stated in the approved study protocol, only members of the research team (i.e. study authors) have access to the study data. The full anonymised data set was shared between all team members (University of Oxford and University of Kent). Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

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Table 1. Participant characteristics (N=1,211)

	Response option	N (%)
Recruitment	Health care (via GP practice)	917 (76%)
	Social care (via Local Authority)	294 (24%)
Age	18-49 years	162 (13%)
	50-64 years	277 (23%)
	65-74 years	331 (27%)
	75-84 years	259 (21%)
	85+ years	128 (11%)
	(missing)	*54 (5%)*
Gender	Female	656 (54%)
	Male	528 (44%)
	(missing)	*27 (2%)*
Condition* reported	Depression / anxiety	508 (42%)
	Chronic back pain	450 (37%)
	Diabetes	313 (26%)
	Osteoarthritis	308 (25%)
	Colon problems (e.g. IBS)	290 (24%)
	Heart disease	284 (24%)
	COPD	188 (16%)
	Stroke	185 (15%)
	Cancer within the last 5 years	166 (14%)
	Bipolar / psychosis / schizophrenia	88 (7%)
	Multiple Sclerosis	75 (6%)

	Response option	N (%)
Employment	Retired from work	554 (46%)
	Permanently sick or disabled	218 (18%)
	Employed / full-time education	211 (17%)
	Doing something else (e.g. volunteering)	85 (7%)
	Unemployed	31 (3%)
	(missing)	*112 (9%)*
Marital status	Married / civil partnership	648 (54%)
	Widowed	224 (19%)
	Divorced / separated	168 (14%)
	Single / never married	144 (12%)
	(missing)	*27 (2%)*
Ethnicity	White British	1097 (91%)
	Other White (e.g. Irish, European)	38 (3%)
	Black / Black British (e.g. African, Caribbean)	18 (2%)
	Asian / Asian British (e.g. Indian, Pakistani)	17 (1%)
	Mixed	8 (0.6%)
	(missing)	*33 (3%)*
Help needed completing questionnaire	No help	896 (74%)
	Had help, but answers are my own	227 (19%)
	Someone answered for me (proxy)	74 (6%)
	(missing)	*14 (1%)*

*Percentages for Condition reported exceed 100% because most participants reported multiple conditions.

Table 2. LTCQ item responses (N = 1,211)

Item	Never	Rarely	Sometimes	Often	Always	*Missing*	Not applicable**	ICCC
1. Able to cope well with health conditions	3%	10%	29%	26%	31%	*1.50%*		0.059
2. Able to fulfil responsibilities	12%	15%	20%	18%	32%	*1.90%*		0.037
3. Able to be as physically active as you wanted	21%	20%	21%	17%	20%	*1.20%*		0.023
4. Felt in control of daily life	8%	13%	22%	21%	35%	*1.30%*		0.064
5. Able to take part in activities you enjoy	16%	22%	22%	17%	21%	*1.40%*		0.035
6. Felt that your home is suitable for your needs	**4%**	5%	15%	18%	**56%**	*1.50%*		0.040
7. Felt safe at home	**2%**	4%	10%	19%	**64%**	*1.20%*		0.028
8. Felt safe outside the home	9%	10%	23%	18%	38%	*2.00%*		0.060
9. Felt bothered by symptoms*	9%	12%	33%	26%	19%	*1.50%*		0.039
10. Felt more dependent on others than you wanted*	19%	13%	20%	21%	27%	*1.00%*		0.027
11. Felt lonely due to health conditions*	34%	15%	24%	15%	11%	*1.00%*		0.036
12. Worried about being treated differently*	39%	17%	25%	10%	7%	*1.50%*		0.053
13. Found health/other services difficult to cope with*	**20%**	13%	19%	6%	**3%**	*2.20%*	**36%**	0.037
14. Found treatments difficult to cope with*	**31%**	21%	19%	8%	**4%**	*1.40%*	**17%**	0.033
15. Felt that your health conditions made you unhappy*	20%	16%	31%	18%	13%	*1.30%*		0.068
16. Felt you knew enough about your health conditions	5%	11%	24%	26%	32%	*2.10%*		0.005
17. Had enough social contact with people	5%	13%	21%	21%	38%	*2.10%*		0.052
18. Had enough support to cope well with health conditions	**4%**	9%	21%	25%	**40%**	*1.40%*		0.060
19. Felt confident in managing health conditions	6%	8%	23%	22%	40%	*1.20%*		0.052
20. Able to live your life as you want	16%	17%	20%	18%	28%	*1.00%*		0.043

* Questions 9-15 are reverse-scored, i.e. 'Never' is the most positive response option

**Questions 13 and 14 have an additional response option: 'have not received any health-related services / treatments in the past four weeks'. For analysis these responses were coded as 'Never'.

ICCC = Intra-Cluster Correlation Coefficient, for item responses across recruiting GP practices. Coefficients approaching zero indicate negligible variance in responses across clusters (practices); a coefficient of 1 would indicate that all responses within a given cluster (practice) were identical i.e. all variance in responses is explained by cluster.

Table 3a. Comparison of LTCQ scores among sub-samples (main survey)

LTCQ - main survey		N	Mean	SD	SE	95% CI	α	ANOVA
	Total sample	**1082**	**65.1**	**23.0**	**0.70**	**63.7 - 66.5**	**0.95**	
cohort	Health care sample	838	70.0	21.7	0.75	68.6 - 71.5	0.95	F (1, 1080) = 201.8, $p < 0.001$
	Social care sample	244	48.2	19.1	1.22	45.8 - 50.8	0.92	
gender	male	482	68.5	22.6	1.03	66.4 - 70.5	0.96	F (1, 1057) = 19.8, $p < 0.001$
	female	577	62.2	23.0	0.96	60.3 - 64.1	0.95	
age[a]	18-64 years	413	59.7	23.3	1.15	57.5 - 62.0	0.95	F (2, 1032) = 27.4, $p < 0.001$
	65-84 years	525	70.2	21.7	0.95	68.3 - 72.0	0.95	
	85+ years	97	60.2	22.6	2.30	55.7 - 64.8	0.95	
morbidity[b]	1 LTC	60	76.5	21.3	2.74	71.0 - 82.0	0.94	
	2-4 LTCs	320	73.9	21.3	1.19	71.5 - 76.2	0.95	F (3, 1057) = 75.3, $p < 0.001$
	5-7 LTCs	351	67.9	21.5	1.15	65.7 - 70.2	0.95	
	8+ LTCs	330	51.1	20.1	1.11	49.0 - 53.3	0.93	
mental health	no mental health condition reported	624	74.2	20.2	0.81	72.6 - 75.8	0.94	F (1, 1080) = 291.2, $p < 0.001$
	at least one mental health condition reported	458	52.7	20.8	0.97	50.8 - 54.6	0.94	

N = sample size Mean = mean LTCQ score for sub-sample SD = standard deviation SE = standard error of the mean 95% CI = 95% confidence interval

α = Cronbach's alpha (internal consistency) for 20 LTCQ items among sub-group ANOVA = one-way between-groups analysis of variance of LTCQ scores

a. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly higher for the 65-84 years age group compared to both other age groups ($p < 0.001$).

b. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly lower for those with 5-7 LTCs compared to those with one LTC ($p < 0.05$) and compared to those with 2-4 LTCs ($p < 0.01$). LTCQ scores were significantly lower for those with 8+ LTCs compared to all other groups ($p < 0.001$).

Table 3b. Comparison of LTCQ scores among sub-samples (follow-up survey)

LTCQ - follow-up survey		N	Mean	SD	SE	95% CI	α	ANOVA
	Total sample	**492**	**65.5**	**23.4**	**1.05**	**63.4 - 67.5**	**0.96**	
cohort	Health care sample	379	70.3	22.3	1.15	68.0 - 72.6	0.96	F (1, 490) = 82.4
	Social care sample	113	49.2	19.3	1.82	45.6 - 52.8	0.92	p < 0.001
gender	male	229	68.7	22.8	1.50	65.8 - 71.7	0.96	F (1, 480) = 8.0,
	female	253	62.8	23.4	1.47	59.9 - 65.7	0.96	p < 0.01
age[a]	18-64 years	184	58.8	23.8	1.76	55.3 - 62.3	0.96	F (2, 469) = 14.4,
	65-84 years	250	70.6	22.1	1.39	67.9 - 73.4	0.96	p < 0.001
	85+ years	38	65.6	20.7	3.35	58.8 - 72.4	0.94	
morbidity[b]	1 LTC	22	78.2	18.3	3.89	70.1 - 86.3	0.93	
	2-4 LTCs	157	76.2	19.9	1.59	73.1 - 79.4	0.95	F (3, 482) = 43.9,
	5-7 LTCs	143	67.7	23.6	1.97	63.8 - 71.6	0.97	p < 0.001
	8+ LTCs	164	50.9	19.4	1.51	47.9 - 53.9	0.93	
mental health	no mental health condition reported	290	74.6	20.1	1.18	72.4 - 77.1	0.95	F (1, 490) = 144.2,
	at least one mental health condition reported	202	52.1	21.3	1.50	49.1 - 55.0	0.95	p < 0.001

N = sample size Mean = mean LTCQ score for sub-sample SD = standard deviation SE = standard error of the mean 95% CI = 95% confidence interval

α = Cronbach's alpha (internal consistency) for 20 LTCQ items among sub-group ANOVA = one-way between-groups analysis of variance of LTCQ scores

a. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly higher for the 65-84 years age group compared to the 18-64 years age group (p < 0.001).

b. Post-hoc analysis (Tukey HSD) indicated that LTCQ scores were significantly lower for those with 5-7 LTCs compared to those with 2-4 LTCs (p < 0.01). LTCQ scores were significantly lower for those with 8+ LTCs compared to all other groups (p < 0.001).

Table 4. Construct validity

Measure	Mean score (SD, SE, 95% CI)	Score range	Interpretation of higher score	Correlation with LTCQ score (Spearman's rho)
LTCQ	65.1 (23.0, 0.70, 63.7 – 66.5)	0 to 100	living better with long-term conditions	-
EQ-5D-5L	0.62 (0.33, 0.01, 0.60 – 0.63)	-0.28 to 1	better health-related quality of life	0.82***
EQ-VAS	62.4 (24.6, 0.72, 61.0 – 63.8)	0 to 100	better health-related quality of life	0.79***
Self-efficacy scale	6.2 (2.7, 0.08, 6.1 – 6.4)	1 to 10	greater confidence for managing chronic disease	0.87***
Activities of Daily Living	5.0 (4.8, 0.14, 4.7 – 5.3)	0 to 13	more problems with activities of daily living	- 0.79***
Bayliss burden of morbidity	16.4 (13.1, 0.38, 15.7 – 17.2)	0 to 150	more limits on daily activities from LTCs	-0.64***

***Correlation is significant at $p < 0.001$ (2-tailed).

SD = standard deviation SE = standard error of the mean 95% CI = 95% confidence interval

Figure legend

Figure 1. Comparison of LTCQ score distributions: health care versus social care cohorts

Figure 2. Comparison of LTCQ score distributions: mental versus physical health condition(s)

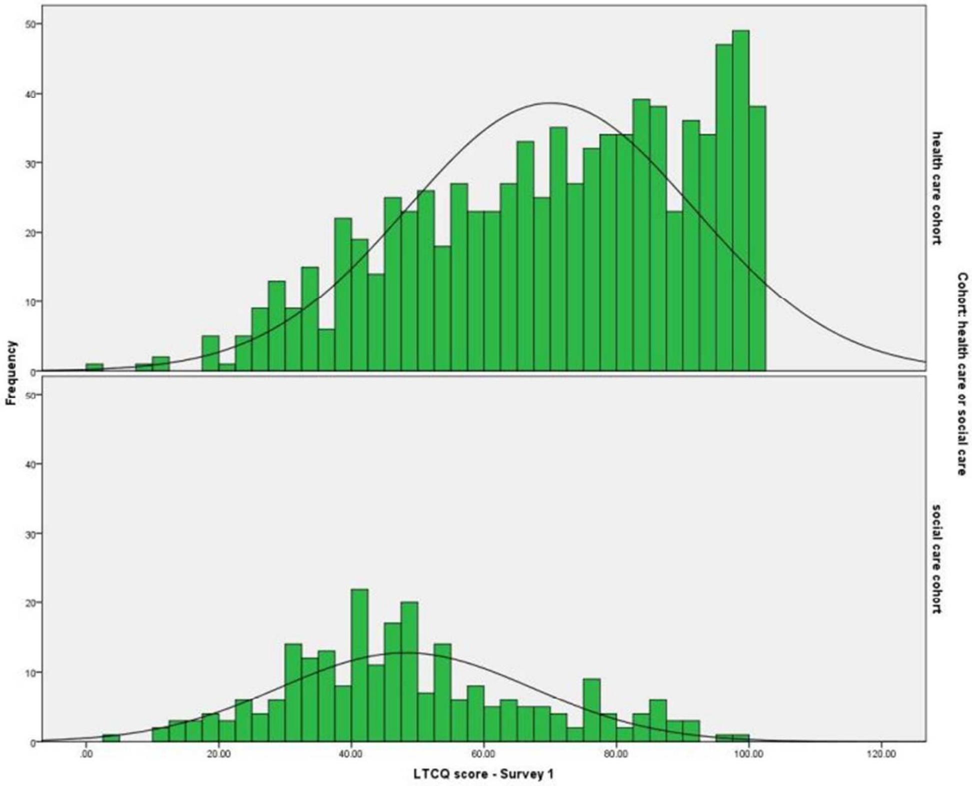

Figure 1. Comparison of LTCQ score distributions: health care versus social care cohorts

67x54mm (300 x 300 DPI)

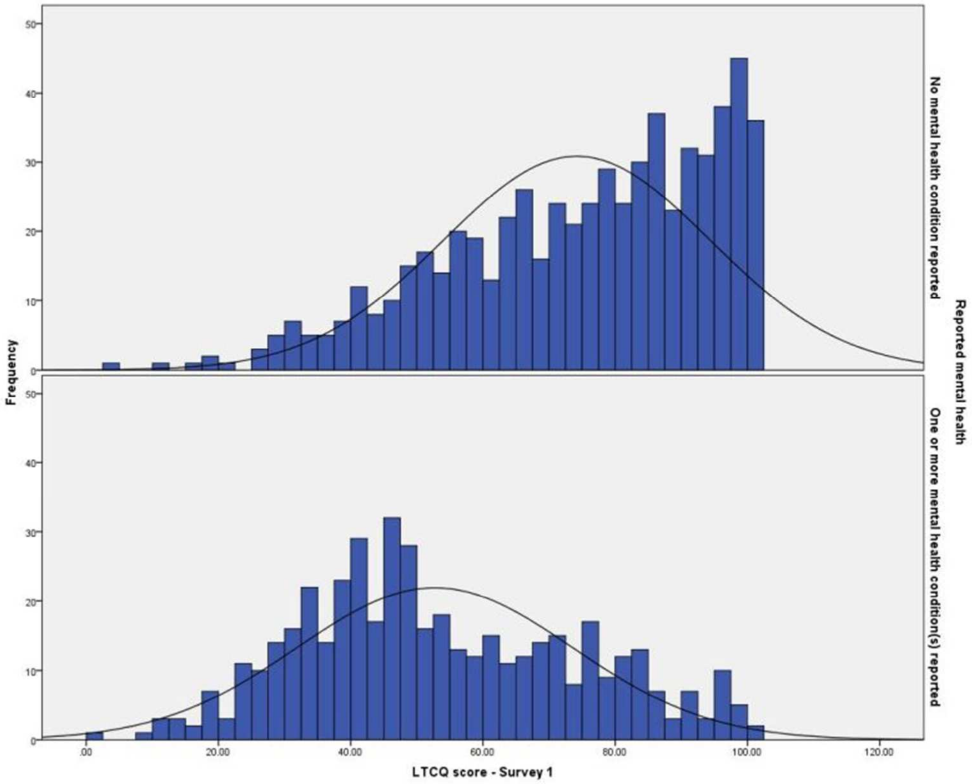

Figure 2. Comparison of LTCQ score distributions: mental versus physical health condition(s)

67x54mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Location in paper
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title – p.1 Abstract – p.2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract – p.2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	p.3
Objectives	3	State specific objectives, including any prespecified hypotheses	p.3
Methods			
Study design	4	Present key elements of study design early in the paper	Abstract – p.2, Methods – p.4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods – p.4-5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Methods (Participant recruitment) – p.4-5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods (The Surveys) – p.5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods (Analysis) – p.5-6
Bias	9	Describe any efforts to address potential sources of bias	Methods (Participant recruitment) – p.4-5
Study size	10	Explain how the study size was arrived at	Methods – p.4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods (Analysis) – p.5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Methods (Analysis) – p.5-6
		(*b*) Describe any methods used to examine subgroups and interactions	Methods (Analysis) – p.6, Results (Sub-sample comparisons) – p.9
		(*c*) Explain how missing data were addressed	Methods (Analysis) – p.6
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of	Methods (Participant

		study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	recruitment) – p.4-5 , Results (Sample characteristics, Test-retest reliability) – p.7, p.8-9
		(b) Give reasons for non-participation at each stage	Cannot comment as no contact with non-responders
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results (Sample characteristics) – p.7 Table 1 – p.15
		(b) Indicate number of participants with missing data for each variable of interest	Table 2 – p.16
Outcome data	15*	Report numbers of outcome events or summary measures	Table 3 – p.17-18, Table 4 – p.19, Figure 1 – p.20
Main results Please note that these do not easily apply to a survey validation study. Quality criteria for reporting measurement properties of health questionnaires were followed instead.	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A as regression not performed for a survey validation study.
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Results (factor analysis, internal consistency, test-retest reliability, sub-sample comparisons, convergent construct validity) – p.7-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion – p.9-10 (paragraph 1)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion – p.10 (paragraph 3)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion – p.10-11 (paragraphs 4-5)
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion – p.10-11 (paragraph 5)
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study	Funding – p.11

on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.