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ORIGINAL RESEARCH

Validation of an instrument to measure patients' experiences of medicine use: the Living with Medicines Questionnaire

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Background: Medicine-related burden is an increasingly recognized concept, stemming from the rising tide of polypharmacy, which may impact on patient behaviors, including nonadherence. No instruments currently exist which specifically measure medicine-related burden. The Living with Medicines Questionnaire (LMQ) was developed for this purpose.

Objective: This study validated the LMQ in a sample of adults using regular prescription medicines in the UK.

Methods: Questionnaires were distributed in community pharmacies and public places in southeast England or online through UK health websites and social media. A total of 1,177 were returned: 507 (43.1%) from pharmacy distribution and 670 (56.9%) online. Construct validity was assessed by principal components analysis and item reduction undertaken on the original 60-item pool. Known-groups analysis assessed differences in mean total scores between participants using different numbers of medicines and between those who did or did not require assistance with medicine use. Internal consistency was assessed by Cronbach's alpha. Free-text comments were analyzed thematically to substantiate underlying dimensions.

Results: A 42-item, eight-factor structure comprising intercorrelated dimensions (patient–doctor relationships and communication about medicines, patient–pharmacist communication about medicines, interferences with daily life, practical difficulties, effectiveness, acceptance of medicine use, autonomy/control over medicines and concerns about medicine use) was derived, which explained 57.4% of the total variation. Six of the eight subscales had acceptable internal consistency ($\alpha > 0.7$). More positive experiences were observed among patients using eight or fewer medicines compared to nine or more, and those independent with managing/using their medicines versus those requiring assistance. Free-text comments, provided by almost a third of the respondents, supported the domains identified.

Conclusion: The resultant LMQ-2 is a valid and reliable multidimensional measure of prescription medicine use experiences, which covers more diverse domains than existing questionnaires. However, further validation work is necessary.

Keywords: medicines, polypharmacy, patient experience, questionnaire, validation

Introduction

Polypharmacy is increasing worldwide,[1–3] driven by disease-specific clinical guidelines and specialist care, and has been recognized by policy makers in England as a problem to be addressed.[4,5] This increasing tide of prescribing, frequently involving prophylactic drugs for secondary prevention, is clearly becoming burdensome to some patients.[6–8] The need to use long-term medicines engenders a mix of emotions, frequently combining gratitude for the potential benefits with anxiety about adverse effects and general

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skepticism about net gain.[9] Numerous studies in different countries show that most patients would prefer not to take medicines, particularly those with chronic conditions, that some patients are resistant toward using medicines[10] and that there is a desire among some to stop some or all of their medicines.[11] However, these perceptions and views may not always be taken into account during consultations about treatment, or incorporated into research studies, despite the increasing emphasis placed on patient perspectives of health outcomes both in practice and in research.

Recent policy documents in the UK seek to promote strategies for optimizing the growing problem of polypharmacy in individual patients,[4,5,12] but in order to determine which patients are most likely to benefit from interventions and to evaluate the interventions themselves, a patient-centered measure of experiences of multiple medicine use is needed.

A number of instruments exist which seek to measure satisfaction with medicines[13,14] and the overall impact of using medicines on quality of life.[15] The long-term use of medicines is, however, multidimensional and complex; any individual can experience both positive and negative aspects of medicine use.[16–18] No existing instrument covers all issues that patients describe in their varied experiences of using medicines.[19] A recently developed generic measure of treatment burden, defined as "the impact of health care on patients' functioning and well-being", exists,[20] which includes, but is not specific to, the burden of prescription medicine use. A number of disease-specific measures of treatment burden mostly assess the workload of self-managing diabetes and are not applicable to other long-term conditions.[21] Medicine-related burden is a relatively new concept, which a recent metasynthesis of qualitative studies suggests impacts on behaviors, including nonadherence.[18] In addition to side effects and potential adverse events, medicine burden includes practical difficulties (such as opening packaging), challenges with managing complex regimes, psychosocial issues, particularly social stigma, disruptions to daily living and health system burden associated with regular medicine use, the latter including both patient–provider communication and information burden.[18,22] Hence, any instrument purporting to measure medicine burden must cover these issues. Medicine characteristics and prescribing regimens may all affect burden, for example, number of medicines, formulations, route of administration, complex dosage regimens and generic brand switching.[18]

The Living with Medicines Questionnaire (LMQ; Supplementary material) was developed for the specific purpose of measuring overall medicines burden.[22] The instrument was based on the findings from interviews with 21 patients of different ages who were taking a diverse range of long-term multiple medicines,[23] and covered the range of issues outlined above. Both initial item generation and content validation involved patients, unlike many instruments purporting to represent patient views.[19] Preliminary testing of the LMQ involved patients taking long-term medicines recruited from an English primary care setting.[22] This instrument included 60 statements (items), accompanied by a five-point Likert-type scale (strongly agree to strongly disagree) plus a free-text open question. Results suggested that a larger sample was required to enable further psychometric testing and to reduce the number of items into a more manageable instrument. We describe here the results of psychometric testing and further development of this instrument.

Methods
Study population
Members of the general public were targeted for this study, as the proportion of people using long-term medicines in England is high ($>50\%$)[1] and it enabled us to reach a diverse population. Ethics approval was granted by Medway School of Pharmacy Research Ethics Committee.

The inclusion criteria were adults, using regular prescription medicines and living in the UK. All potential participants were provided with information about the study's purpose and informed that consent was implied by completion and return of the questionnaire. Those interested were required to answer screening questions to ensure they met the inclusion criteria before completing the instrument.

Questionnaire distribution
A mixed-methods approach was used to maximize both response rates and diversity of demographic characteristics. The two main methods of distribution were 1) paper questionnaires distributed to both the general public using street intercept and to community pharmacy users in southeast England and 2) an online survey available to the UK general public recruited through social media and health websites. Street surveys yield wide, representative, sociodemographic profiles, in terms of age, education or employment and are also a cost-effective distribution method for paper surveys,[24,25] while distribution to community pharmacy users increases the likelihood of reaching the people using long-term medicines. The online survey was utilized to reach people from a wider geographic distribution, including the housebound, but is more likely to reach those with higher education and socioeconomic status.

Recipients of paper questionnaires were given freepost envelopes for return. Online survey responses were downloaded from the provider website (Qualtrics®).

Data analysis

Data were managed and analyzed using IBM Statistical Package for the Social Sciences (version 22). Two databases were set up to handle paper and online surveys separately, then checked for errors and merged for analysis. Any significant differences in participant characteristics were examined using chi-squared tests. The 60-item pool had 34 positively phrased and 26 negatively phrased statements. Reverse scoring enabled uniformity in the direction of responses, such that higher scores depicted negative experiences with medicine use.

Principal components analysis (PCA)

The correlation matrix was examined for item intercorrelations, and Kaiser–Meyer–Olkin measure of sampling adequacy (acceptable values >0.6) and Bartlett's test of sphericity (acceptable if P-value <0.05) were computed to ensure the data were suitable for factor analysis.[26] PCA was conducted on the combined dataset using oblique rotation techniques (promax), assuming intercorrelations among underlying components (factors), to ascertain the dimensional structure of the instrument. Scree plots (of eigenvalues and their associated number of components), and Kaiser's rule (retain only factors with eigenvalue >1) were used to assess questionnaire dimensionality. In addition, parallel analysis with Monte Carlo PCA was used to confirm the number of appropriate factors.[27] We then reviewed the remaining items for potential floor or ceiling effects (ie, items with >50% of answers concentrated in the first or last answer category) and examined item skewness and kurtosis (acceptable values <1.0).

Reliability analysis

Internal consistency was evaluated using Cronbach's alpha (acceptable values >0.7), and changes in alpha following deletion of individual items from subscales were used to further inform decisions on item reduction/retention.

Known-groups validity

Known-groups analysis compared mean total LMQ-2 scores (for the 42-item version) between subsets of participants predicted to experience different degrees of burden, relating to the numbers of medicines used and whether assistance with managing medicines was required. Independent sample t-tests and one-way analysis of variance, involving only those

respondents who completed all the LMQ items, were used for this analysis as LMQ-2 scores were normally distributed.

Responses to open question

The free-text comments box allowed respondents to add any other views about how medicines affected their day-to-day life in order to determine whether any outstanding major issues arose not covered by the instrument. Responses were analyzed thematically using the eight themes identified in the patient interviews, from which the original item pool was derived[23] as an additional measure of the validity of the instrument.

Results

A total of 507 responses were obtained using paper questionnaires (45.6% of all those meeting the inclusion criteria), with more than half the respondents having been recruited from community pharmacies (60.5%, n=307). A total of 670 participants completed the online survey (68.4% of those accessing the survey link) through health websites (38.2%, n=374) and social media (30.2%, n=296). Overall, 544 questionnaires were fully completed on the original 60-item pool, and the overall item-level response rates were over 90%. Most items had skewness and kurtosis statistics <1.0, suggesting a tendency to univariate normality of the dataset. Raw mean scores on all items ranged from 2.13±1.02 to 4.60±0.71. Only 5 of 60 items had skewness and kurtosis statistics >1 in absolute value, and one item had 68.5% of responses at the ceiling.

Participant characteristics

More females completed both paper (62.1%) and online (81.6%) surveys than males (P<0.001), with the overall age of participants ranging from 18 to 90 years (Table 1). Younger respondents (<65 years) and those with college/further education mostly completed the online survey, whereas more people aged 65 and above returned the paper survey (P<0.001). Overall, most participants (80.4%, n=992) used up to and including eight prescription medicines, 113 (9.7%) needed assistance with using their medicines and 326 (27.9%) paid for their National Health Service prescription medicines.

Results of the PCA

A total of 544 fully completed responses (listwise deletion of missing data) were subjected to PCA. The Kaiser–Meyer–Olkin statistic (0.888) was satisfactory (>0.6) and the Bartlett's test of sphericity was significant (chi-square =9,788.903, degrees of freedom =861, P<0.001); thus, the data met the

Table I Characteristics of participants completing the survey

Characteristic	Paper survey (n=507), n (%)	Online survey, (n=670), n (%)	Total sample, (N=1,177), n (%)
Gender			
Female	306 (62.1)	542 (81.6)	848 (73.3)
Male	187 (37.9), n=493	122 (18.4), n=664	309 (26.7), n=1,157
Age, years			
18–29	48 (9.7)	93 (13.9)	141 (12.1)
30–49	98 (19.7)	258 (38.7)	356 (30.6)
50–64	143 (28.8)	254 (38.1)	397 (34.1)
65 or over	208 (41.8), n=497	62 (9.3), n=667	270 (23.2), n=1,164
Education level			
Bachelor degree or higher	148 (30.5)	301 (45.2)	449 (39.0)
College level	140 (28.8)	258 (38.7)	398 (34.5)
Secondary level	145 (29.8)	93 (14.0)	238 (20.6)
Up to primary	53 (10.9), n=486	14 (2.1), n=666	67 (5.8), n=1,152
Employment			
Employed	176 (35.8)	324 (49.0)	500 (43.4)
Unemployed	74 (15.1)	182 (27.5)	256 (22.2)
Retired	241 (49.1), n=491	155 (23.4), n=661	396 (34.4), n=1,152
Ethnicity			
White	408 (83.8)	613 (93.4)	1,021 (89.3)
Asian/Chinese	27 (5.5)	28 (4.3)	55 (4.8)
African/Caribbean	44 (9.0)	6 (0.9)	50 (4.4)
Mixed	8 (1.6), n=487	9 (1.4), n=656	17 (1.5), n=1,143
Number of medicines			
1–4	261 (53.2)	302 (45.2)	563 (48.6)
5–8	176 (35.8)	253 (37.9)	429 (37.0)
≥9	54 (11.0), n=491	113 (16.9), n=668	167 (14.4), n=1,159
Requires assistance with using medicines			
No	453 (91.5)	596 (89.4)	1,049 (90.3)
Yes*	42 (8.5), n=495	71 (10.6), n=667	113 (9.7), n=1,162
Pay for prescriptions			
No	349 (71.7)	494 (72.0)	843 (72.1)
Yes	138 (28.3), n=487	188 (27.4), n=682	326 (27.9), n=1,169

Note: *Carers included spouse/partner, relative, friends, nurse, support workers, support group.

necessary criteria for factor analysis. Moreover, interitem correlation coefficients showed no evidence of multicollinearity ($r<0.8$),[28] which also encouraged PCA. The initial solution resolved into 14 components with eigenvalues >1.0, explaining 61.1% of the total variation. Inspection of the scree plot revealed two breaks at the fifth and ninth components (Figure 1).

Parallel analysis (Monte Carlo PCA) confirmed eight components with observed eigenvalues exceeding the criterion values (Table 2). PCA was re-run and the number of components fixed to eight. The resulting eight-factor solution explained 57.4% of the total variation and was conceptually interpretable (Table 3).

Item reduction and factor structure

Items with factor loadings <0.4 and/or cross loadings of $≥0.32$ on at least two factors were deleted, based upon professional judgment that they did not fit well in underlying domains. This resulted in removal of 18 items (n=18) from the original item pool, leaving 42 items. Five items with ceiling effects were retained as their factor loadings exceeded the minimum threshold for item retention ($≥0.4$), and were also judged as conceptually relevant.

Table 3 shows the 42-item factor structure. Emerging factors were interpreted as: patient–doctor relationships and communication about medicines (9 items), interferences with daily life (8 items), practicalities (7 items), effectiveness (4 items), patient–pharmacist communication about medicines (3 items), acceptance of medicine use (4 items), autonomy/control over medicine use (4 items) and concerns about potential harm (3 items). Most subscales have acceptable internal consistency (Cronbach's alpha range, 0.592–0.887).

All factor intercorrelations were <0.8 (range 0.099–0.711), suggesting minimal redundancy among instrument subscales, and thus possible discriminant validity.[29]
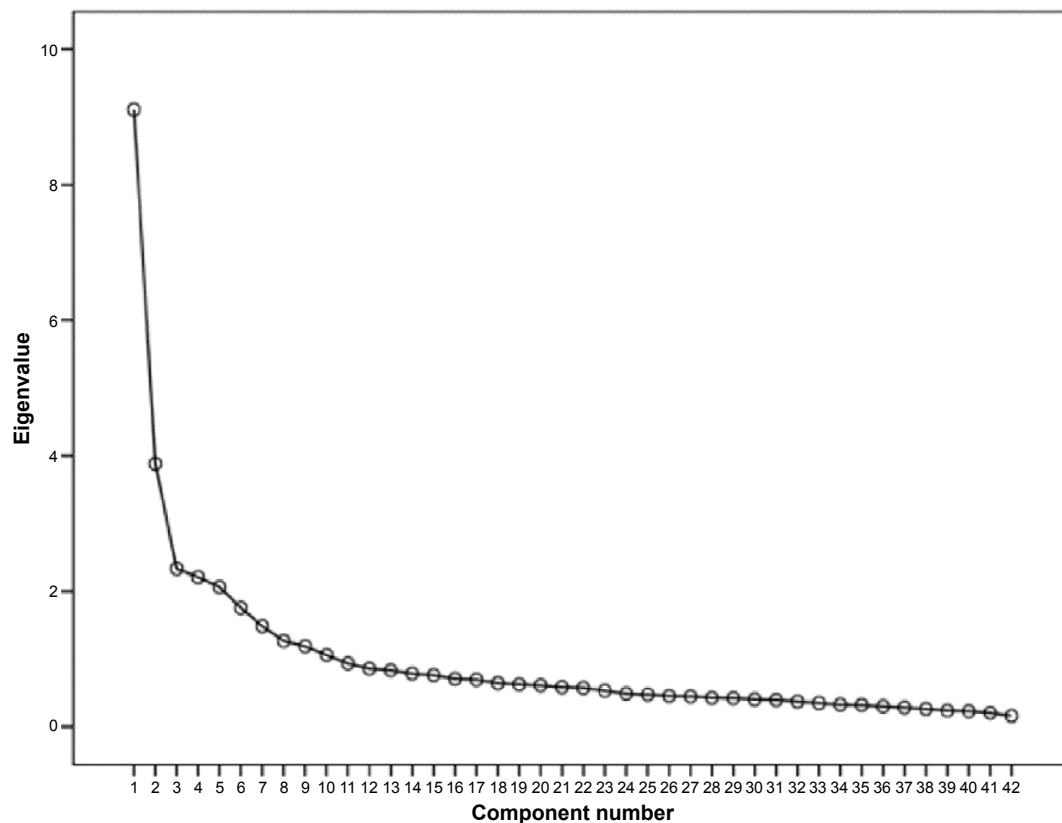
Figure 1 Scree plot of the number of components (factors) in the Living with Medicines Questionnaire, showing two breaks at components 5 and 9, suggesting a multidimensional factor solution.

The strongest correlation was between perceived effectiveness and patient–doctor relationships and communication about medicines ($r=0.711$, $P<0.001$; Table 4). Autonomy was negatively correlated with all other subscales, in particular, acceptance of medicine use (Table 4).

Known-groups validity

As hypothesized, the instrument was able to distinguish between participants using different numbers of medicines

Table 2 Comparison of observed and criterion eigenvalues from parallel analysis

Component	Observed eigenvalues	Criterion eigenvalues*	Decision
1	9.962	1.4519	Accept
2	4.036	1.4163	Accept
3	2.367	1.3878	Accept
4	2.076	1.3637	Accept
5	1.976	1.3412	Accept
6	1.724	1.3242	Accept
7	1.515	1.3055	Accept
8	1.389	1.2868	Accept
9	1.152	1.2686	Reject
10[a]	1.110	1.2526	Reject

Notes: *Generated randomly in 100 replications/simulations. [a]Only 10 of 60 components are shown in the table.

and between those who did or did not require assistance with medicine use. The mean LMQ-2 total score increased with the number of medicines used, and the medicine burden score for those requiring assistance was higher than for those who did not (Table 5).

Free-text comments

A total of 421 different comments were received, almost all of which supported the content domains. In particular, there were 76 comments describing the impact of using medicines, 71 describing medicine-related disruption to daily activities, 65 describing the impact of adverse effects on daily activities, personal life and socialization, 61 relating to efficacy or its lack and concerns about dependence on medicines for symptom relief, performance of daily activities and prolonging life, 79 covering practical issues including desire for more suitable packaging and labeling, and information and 58 describing relationships with health professionals.

Discussion

This study reports the validation of the LMQ, a generic multidimensional questionnaire designed to encompass issues experienced by patients using long-term medicines, into a potentially useful instrument, the LMQ-2. The original

Table 3 Pattern matrix of the 42-item, eight-factor structure of the LMQ-2

LMQ-2 subscale/items	Components							
	1	2	3	4	5	6	7	8
1. Patient–doctor relationships and communication about medicines (9 items, α=0.887)								
Q53. My doctor(s) listen to my opinions and concerns about my medicines	**0.887**	0.012	−0.123	0.062	−0.080	−0.030	0.094	−0.044
Q22. The information my doctor(s) gives me about my medicines is useful	**0.846**	−0.099	0.029	−0.043	0.116	−0.074	0.017	−0.003
Q42. My doctor(s) spends enough time discussing my medicines with me	**0.805**	0.057	0.034	−0.159	−0.075	0.087	−0.010	0.030
Q20. I am confident speaking to my doctor(s) about my medicines	**0.791**	0.012	0.062	−0.049	0.022	0.015	0.020	−0.176
Q57. My doctor(s) takes my concerns about side effects seriously	**0.728**	0.054	−0.155	0.183	−0.142	−0.037	−0.053	−0.091
Q21. I understand what my doctor(s) tell me about my medicines	**0.658**	0.037	0.044	−0.171	0.197	0.119	0.087	−0.082
Q50. The health professionals providing my care know enough about me and my medicines	**0.592**	−0.100	0.025	0.180	0.062	−0.059	−0.028	0.137
Q33. I trust the judgment of my doctor(s) in choosing medicines for me	**0.542**	−0.001	0.031	0.314	0.015	−0.159	−0.129	0.001
Q45. There is enough sharing of information about my medicines between the different health professionals providing my care	**0.542**	−0.028	0.004	0.058	0.062	−0.003	0.004	0.209
2. Interferences with daily life (8 items, α=0.838)								
Q32. Taking medicines interferes with my social life	−0.009	**0.849**	−0.039	0.064	0.015	0.067	0.008	−0.092
Q35. Taking medicines causes me problems with daily tasks (such as work, housework)	−0.048	**0.820**	−0.089	0.091	0.046	−0.037	0.035	−0.047
Q60. The medicines I use have an adverse effect on the holidays I can take	−0.052	**0.730**	−0.012	0.177	−0.005	0.006	−0.019	−0.150
Q29. My life revolves around using my medicines	−0.120	**0.698**	−0.052	0.181	−0.022	−0.317	0.100	−0.143
Q37. Taking medicines affects my driving ability	0.002	**0.686**	−0.110	0.029	0.040	0.026	−0.122	−0.077
Q34. I have to put a lot of planning and thought into taking my medicines	0.068	**0.618**	0.041	−0.192	−0.044	−0.180	−0.171	0.121
Q38. I worry that I have to take several medicines at the same time	0.140	**0.592**	0.087	−0.059	−0.073	0.046	0.047	0.135
Q56. Changes in daily routine cause problems with my medicines	0.024	**0.558**	0.105	−0.214	0.070	−0.009	−0.136	0.188
3. Practicalities (7 items, α=0.708)								
Q7. It is difficult to identify which medicine is which	−0.133	−0.037	**0.773**	−0.034	0.046	0.030	0.073	0.019
Q1. The instructions on my medicines are easy to follow	0.059	−0.163	**0.683**	0.139	−0.045	0.051	0.006	−0.066
Q5. I find opening the packaging of my medicines difficult	−0.048	0.002	**0.640**	0.017	−0.062	−0.052	0.109	−0.002
Q2. I find getting my prescriptions from the doctor difficult	0.244	−0.064	**0.635**	0.087	−0.163	−0.043	−0.192	−0.121
Q3. I find getting my medicines from the pharmacist difficult	−0.099	0.041	**0.628**	0.259	0.089	−0.165	−0.175	−0.146
Q17. I find using my medicines difficult	−0.027	0.295	**0.465**	−0.087	0.040	0.208	0.134	−0.019
Q8. It is easy to keep to my medicines routine	0.027	0.083	**0.400**	−0.049	0.009	0.221	0.011	0.116
4. Effectiveness (4 items, α=0.796)								
Q18. I am satisfied with the effectiveness of my medicines	−0.066	0.037	0.161	**0.698**	0.102	−0.051	0.041	0.129
Q30. My medicines live up to my expectations	0.073	0.088	−0.014	**0.694**	−0.008	0.084	0.054	0.092
Q51. My medicines are working	0.090	−0.007	0.060	**0.685**	0.019	0.008	0.181	0.137
Q31. My medicines prevent my condition getting worse	0.040	0.033	0.041	**0.650**	−0.070	0.168	−0.137	−0.049
5. Patient–pharmacist communication about medicines (3 items, α=0.877)								
Q25. The information my pharmacist gives me about my medicines is useful	0.030	0.000	−0.039	0.049	**0.911**	−0.026	−0.045	−0.036
Q23. I am confident speaking to my pharmacist about my medicines	0.034	0.030	−0.055	0.037	**0.879**	0.002	−0.041	0.027
Q24. I understand what my pharmacist tells me about my medicines	−0.012	0.014	0.008	−0.042	**0.936**	0.013	0.006	−0.035
6. Acceptance of medicine use (4 items, α=0.592)								
Q13. Taking medicines is routine for me	−0.019	0.010	0.060	−0.114	−0.030	**0.824**	0.001	0.008
Q27. I accept that I have to take medicines long term	−0.011	−0.088	−0.107	0.254	−0.049	**0.739**	−0.130	−0.006
Q4. My medicines are important to me	−0.084	−0.232	0.097	0.083	0.053	**0.494**	−0.068	−0.093
Q28. My medicines allow me to live my life as I want to	0.050	0.185	−0.045	0.278	0.098	**0.483**	0.102	0.037
7. Autonomy/control over medicine use (4 items, α=0.625)								
Q54. I can vary the dose of the medicines I take	−0.002	−0.245	−0.010	0.064	0.028	−0.092	**0.763**	−0.049
Q49. I can change the times I take my medicines if I want to	0.002	0.077	−0.061	−0.021	−0.128	0.086	**0.752**	−0.111
Q41. I can choose whether or not to take my medicines	0.034	−0.103	0.115	−0.106	0.035	−0.301	**0.592**	0.043
Q52. I can adapt my medicine-taking to my lifestyle	0.038	0.106	0.037	0.194	−0.004	0.050	**0.592**	0.029
8. Concerns about potential harm (3 items, α=0.751)								
Q11. I am concerned about experiencing side effects	−0.053	−0.041	−0.051	0.040	−0.003	−0.013	−0.021	**0.925**
Q12. I am concerned about possible damaging long-term effects of taking medicines	−0.055	−0.120	−0.099	0.205	−0.029	−0.019	−0.080	**0.902**
Q40. I worry that my medicines may interact with each other	0.053	0.329	0.163	0.011	−0.068	−0.061	0.048	**0.421**

Notes: Extraction method: principal component analysis. Rotation method: promax with Kaiser normalization. α=Cronbach's alpha. The numbers in bold represent substantive factor loadings (above 0.4) showing items that are adequately associated with a specific domain/subscale of the LMQ-2.
Abbreviations: LMQ, Living with Medicines Questionnaire; Q, question.

Table 4 Intercorrelations among the LMQ-2 subscales

Subscale	Doctor	Interfrnc	Practical	Effectiv	Pharm	Accept	Auto	Concern
Doctor		0.241**	0.506**	0.711*	0.616**	0.319*	−0.189*	0.201*
Interfrnc			0.502**	0.356**	0.254**	−0.032	−0.029	0.406*
Practical				0.511*	0.507**	0.256**	−0.242*	0.190*
Effectiv					0.574**	0.534*	−0.148	0.317**
Pharm						0.269*	−0.156*	0.099
Accept							−0.402**	0.127
Auto								0.100
Concern								

Notes: *$P<0.05$; **$P\leq0.001$.
Abbreviations: accept, acceptance of medicine use; auto, autonomy/control over medicine; concern, concerns about potential harm; doctor, patient–doctor relationships and communication about medicines; effectiv, effectiveness; Interfrnc, interferences with daily life; LMQ, Living with Medicines Questionnaire; pharm, patient–pharmacist communication about medicines; practical, practicalities.

LMQ was shown to cover more domains than most other instruments purporting to describe patient experiences of medicine use.[19] The instrument covers eight interrelated, yet distinct, dimensions of the medicine use experience: perceptions about effectiveness, concerns about medicine use, patient–provider relationships and communication about medicines, practical difficulties, interferences with daily life, autonomy/control over medicine and acceptance of medicine use, which have been cited by users of long-term medicines as burdensome.[18] These dimensions match well to both the domains identified from qualitative research on which the instrument was originally based and with subsequent literature.[18,19] Additional comments added by questionnaire respondents also support these domains. We believe they all relate to an overarching construct of medicine burden, for which no measure currently exists.

Perceptions of efficacy and concerns about the negative effects of medicines are widely reported in the literature, with most patients weighing benefits from medicines against any associated burden, perhaps enduring inconveniences associated with their use while reluctantly accepting the need for treatment.[18,30,31] Patients' perceptions concerning the desired therapeutic outcome influence both attitudes and behaviors toward medicine.[32,33] Concerns about potential harm from side effects, long-term use and/or dependency are common.[10] Relationships with health professionals supplying medicines and information sharing may influence both commitment to taking medicines and perceptions of effectiveness,[31] with poor relationships and communication becoming burdensome to some individuals due to consultation styles, amount of information provided, conflicting information and lack of continuity of care.[34,35] Observational research shows that overall treatment burden may be compounded by patients' experiences of medicine use being neglected during consultations.[36] Practical difficulties with the long-term use of medicines have been documented as burdensome,[37–39] while the burden of managing medicine routines has been reported as demanding of both time and resources.[8,18] There is also evidence that many patients manipulate their medicine regimens, especially when they experience unbearable burden, perceive their medicines as inappropriate or are dissatisfied with their medicine.[33,40–42] Conversely, regimens which are inconvenient may lead to perceived lack of control or autonomy. The autonomy subscale was highly negatively correlated with acceptance of medicine use, suggesting that such acceptance may be associated with perceived inability to modify regimens. This, together with experiences of adverse effects, may add to the overall burden through interfering with daily activities.[18] Indeed, our data support this, with the domain of practicalities being positively correlated with interference, but also negatively correlated with autonomy. Negative correlations were also found between autonomy and communication with both doctors and pharmacists, which may suggest a reluctance to go against the advice/directions of health care professionals.

The eight subscales of the LMQ-2 are valid and reliable. The generic nature of this questionnaire contributes to its potential usefulness in identifying a wide range of issues

Table 5 Known-groups validity of the LMQ-2

Category	Number of participants per subgroup	Total LMQ-2 score (mean ± standard deviation)
Number of medicines		
1–4	267	96.3±17.5
5–8	196	101.7±17.8
≥9	69	106.2±22.0 ($P<0.001$)
Assisted with medicine use		
No	490	99.0±18.2
Yes	44	105.5±20.2 ($P=0.026$)

Abbreviation: LMQ, Living with Medicines Questionnaire.

arising from medicine use either in single conditions or in patients with multimorbidity. Preliminary evidence of the measure's discriminant validity is promising, with the data showing that using a higher number of medicines and needing assistance with medicines were significantly associated with more medicine burden.

Strengths, limitations and future work

The LMQ looks promising as a patient-reported measure of the burden of using long-term medicines. Item-level response rates were generally high, potentially indicating interest in the medicine-related issues covered in the questionnaire. Unlike many instruments reported in the literature, the development and validation of the LMQ were founded on patient-generated data from representative patient populations.

Elimination of poorly performing items, using psychometrically sound criteria and an adequate sample size recruited from demographically diverse settings, resulted in a revised instrument, the LMQ-2. However, the item reduction process may have led to loss of potentially important items. Side effects did not emerge as a separate domain, instead merging with concerns about potential harm, but generated a significant number of free-text comments. No significant ceiling effects were apparent, in contrast to measures of treatment satisfaction.[13] The reliability of the LMQ-2 subscales may be strengthened by use of both negatively and positively phrased statements and the intermixed ordering of items across different content domains. Methodological studies suggest that grouping questionnaire items into their hypothetical domains, a common occurrence in existing medicine-related measures, may artificially inflate internal consistency.[43] Potential obsequiousness bias, a common methodological problem with self-report measures, was minimized by the use of different self-report methods (paper and online), encouraging completion outside of standard health facilities, in diverse public settings.

Further development work is necessary to assess criterion-related validity by comparison with existing measures of the medicine use experience. Our samples were insufficiently large to assess whether the different distribution methods resulted in any differences in the instrument's psychometric properties. Moreover, confirmatory factor analysis was not undertaken. Thus, further work is required with larger sample sizes to enable these analyses. Cross-cultural adaptations may be needed to support the instrument's usability in other populations. Future studies may also involve adaptations of the LMQ (or its subscales) for use in specific disease conditions or patient populations.

Conclusion

The LMQ-2 is a valid and reliable multidimensional measure of adult patients' experiences of prescription medicine use. Although further work on the instrument is desirable, the findings reported here are promising and suggest the instrument may be useful in measuring medicine-related burden, currently a neglected aspect of the assessment of health care interventions.

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Disclosure

The authors report no conflicts of interest in this work.

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