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Validity of three asthma-specific quality of life questionnaires: the patients' perspective

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Abstract

Objectives

It is not known which of the many asthma-specific quality of life questionnaires best capture the lived experience of people with asthma. The objective of this study was to explore patients' views of three commonly used asthma-specific quality of life questionnaires.

Design

Qualitative study using semi-structured interviews.

Setting

Primary and secondary care in Brighton and Hove, UK.

Participants

Thirty adult people with a physician-diagnosis of asthma who were asked to complete the Juniper Asthma Quality of Life Questionnaire (AQLQ-J), the Sydney Asthma Quality of Life Questionnaire (AQLQ-S) and the Living with Asthma Questionnaire (LWAQ) to elicit their views on the content validity of these.

Results

Thematic content analysis revealed a lack of congruence between the concerns of people with asthma and the questionnaire content was found, both in terms of missing (e.g. allergies) and irrelevant (e.g. smoky restaurants) content. The AQLQ-J was perceived as a 'narrow', 'medical' questionnaire focussed on symptoms, the environment and functional ability. In contrast, the LWAQ and the AQLQ-S were perceived to be 'non-medical'. The LWAQ was described as a 'test', but also as a wide-ranging, embracing and holistic questionnaire. Its strong emotional focus was irritating to some. The AQLQ-S was described as a simple, quick and easy questionnaire, although there was a perception that it was lacking in depth.

Conclusion

Patient interviews highlighted both strengths and shortcomings in the content validity of these three asthma-specific questionnaires. For patients, the AQLQ-S content seemed to be the most pertinent in its adequacy of coverage of medical, social and emotional aspects of health-related quality of life in asthma.

Strengths and limitations of this study

- there is a body of research comparing the psychometric performance of asthma-specific quality of life measures, but the assessment of the validity of available measures requires an assessment of their content validity
- since no attempt has yet been made to assess the content validity of available measures from the patients' perspective, we used a qualitative interview technique to elicit how the experience of patients with asthma related to the content of available questionnaires
- patient involvement in comparing and contrasting the validity of asthma-specific quality of life measures has been limited to date, but is of key importance in guiding the choice of instrument in clinical and research settings
- we were able to recruit a diverse sample, there was a female preponderance and a lack of ethnic diversity
- data was analysed by a diverse research team
- data generated was rich, revealing the co-existence of missing, irritating, redundant and irrelevant content

INTRODUCTION

To capture patient's perception of the burden of disease on their functional status and wellbeing, the use of patient-reported outcome measures (PROMs) in clinical trials has been recommended by regulatory bodies such as the U.S. Food and Drug Administration [1]. PROMs are also used in clinical audit, patient registries, quality management and routine healthcare [2]. Health-related quality of life (HrQoL) is a widely used PROM. A structured literature review of six asthma-specific HrQoL questionnaires concluded that they differed in almost all the review criteria (conceptual and measurement model, reliability, validity, interpretability, burden, administration format and number of linguistic validations/translations) [3].

While head-to-head comparisons are often conducted to investigate the comparative psychometric performance of questionnaires, the patient's perspective of comparable content validity has not been explored. This study aimed to capture the views of people affected by asthma of three commonly used asthma-specific quality of life questionnaires, to understand how they perceived the relevance of the questionnaires in relationship to their own experience of living with asthma.

METHODS

Data collection

At the beginning of each encounter with participants, the reasons for conducting this research were explained. First, participants completed three different, commonly used asthma-specific quality of life questionnaires. In-depth interviews then explored individuals' subjective narratives of how the content of the questionnaires related to their experience of living with asthma. Using a topic guide, derived from the literature (3) and discussions within the research team (box 1), the two interviewers (CA & CJ) encouraged participants to talk freely about bothersome aspects of their asthma and whether the questionnaire items covered these aspects. CA & CJ both hold PhDs and had prior training in qualitative research methodology. Basic demographics (age, gender, duration of asthma, years in full time education) were noted. Repeat interviews were not carried out.

Interviews lasted between 20 and 90 minutes. They were audio-recorded and transcribed verbatim. Field notes were additionally taken. Transcripts were not returned to particpants for comment and/or correction.

Box 1: Topics covered in the interview topic guide

General impression of the questionnaires: What were your feelings/thoughts when completing the questionnaires?
Length of the questionnaires: How did you feel about the length of the questionnaires?
Layout/visual clarity: How did you feel about the looks/the layout of the questionnaires?
Format of the questions/response options: How did you feel about the options that were given to choose from when responding to each question?

Comprehensibility: How understandable were the questions to you?
Burden: How strenuous was it for you to answer the questions?
Redundancy of questions: are there any questions which are repeated or very similar?
Need for specification of question wordings: are there any questions which should be phrased in a more specific manner?
Adequacy/validity of questionnaires in relation to situation of living with asthma: How much did you feel the questions in the questionnaires covered the issues you are concerned with because of your asthma? Do important aspects of living with asthma lack in the questionnaires?
Suggestions for improvement: do you have any suggestions to improve the questionnaires?
Preference: Did you like one of the questionnaires better than the other/others? Could you tell a preference? If questionnaires should be judged as insufficient: which questionnaire is still the most adequate?
Preference: Would you recommend one of the questionnaires?
We are very interested in all of your views and impressions, so in this last section please feel free to add any other comments you feel are relevant to the ways asthma influences quality of life.

Recruitment

This qualitative study was conducted between August 2011 and November 2012. Patients were purposively sampled if they had a physician-diagnosis of asthma, good spoken and written English and no severe mental health difficulties. Particular efforts were made to sample male people with asthma. Posters describing the study in lay language and how to contact the research team were displayed in the out-patient departments of two local general hospitals and in the waiting rooms of general practices in Brighton and Hove, East Sussex, UK. A relationship was present with some of the participants, but otherwise relationships were not established prior to interviews.

Participants established contact via telephone and/or e-mail. Interviews took place in private at the medical school, hospital or participant's home. Besides the participants and researchers, nobody else was present at the interviews. Written informed consent was sought from each study participant.

Recruitment continued until enough data were obtained to formulate meaningful comparisons about the three questionnaires.

Questionnaires

The three questionnaires used were:

Sydney Asthma Quality of Life Questionnaire (AQLQ-S)

A 20-item self-administered questionnaire with a five-point Likert scale [4]. Responses are based on experiences in the preceding four weeks (four-week recall period). The AQLQ-S has four subscales: breathlessness, mood disturbance, social disruption and concerns for health.

Living with Asthma Questionnaire (LWAQ)

This comprises of 68 items in eleven domains (social/leisure, sport, holidays, sleep, work and other activities, colds, mobility, effects on others, medication usage, sex, dysphoric states, attitudes) and has no specified recall period [5]. It uses a three-point Likert scale. A mixture of positive and negative items compensate for acquiescence bias. Unlike the other two questionnaires, LWAC has a 'not applicable' response option.

Juniper Asthma Quality of Life Questionnaire (AQLQ-J)

AQLQ-J's idiographic component allows patients to choose from a list five activities important to them [6]. It has 32 items in four domains (activity limitation, symptoms, emotional functioning, exposure to environmental stimuli) and uses a seven-point Likert scale and a two-week recall period.

Data analysis

Thematic content analysis was performed by coding the data material and then grouping the codes into thematic categories [7]. Data were coded by CA using ATLAS.ti [8 9]. The emerging themes were discussed regularly within the research team and credibility of the findings was established by seeking agreement among co-researchers [10].

Ethical approval

Brighton East Research Ethics Committee (REC), reference number: 10/H1107/38.

RESULTS

Thirty individuals with asthma participated (table 1). Participants spoke about wide ranging issues, seven themes related specifically to content validity.

Missing content

Participants identified a number of areas that they considered missing from the questionnaires, such as the need to seek health care (medication, consultation or admission) for their asthma (Box 2). Participants commented on a lack of content relating to asthma control (such as peak flow measurement), and noted their responses to the items would vary reflecting how well their asthma was controlled.

"Well I have to say, like I said, the one thing that is missing, is the asthma management of an individual, because that will have a bearing on quality of life - if it is very badly managed." (P15)

Participants also lamented that allergies and asthma triggers were not reflected in the questionnaires' content, thereby almost missing the very nature of asthma as a fluctuating disease.

"(…) it was almost like it is for someone who has got asthma just all the time, you know … but my asthma mainly occurs when I come in contact with animals or with tree pollen or the things that set me off, you see what I mean?" (P11)

Box 2: Patients' perspective on content missing in the questionnaires

Questionnaire	Missing content	Illustrative quote
AQLQ-S	Cough	"(...) cough didn't come up in that questionnaire. (...) Yes, yes because certainly at the moment, err, my cough is the main area in which I feel my life is restricted." (P8)
	Sex life	"(...) the only one that it didn't have on there, which the other two did, was about sex life. I think maybe that should have been on there (…)" (P13)
	Medication needs	"Umm … there was one questionnaire that talked about it is a nuisance having to take tablets - it is a nuisance having to use your inhaler. I think that is maybe missing from the 'Marks' because your quality of life quite often is affected by how many times you have to stop, use an inhaler. (...) That, actually probably affects my quality of life more than anything else. Because I can get half way down the street, on my way to work, and then think … I haven't brought my orange inhaler! " (P15)
	Family impact	"And the 'Marks' and the 'Juniper' don't really talk about the family impact which can then affect guilt." (P15)
	Asthma triggers	"It doesn't touch on any other trigger of asthma, such as smoking, food, stress and things like that." (P20)
	Wheezing attacks	"The wheezing attacks: more about that. It was very, very brief." (P22)
AQLQ-J	Social life	"It didn't really cover much of the social things…(...) There is a lot of kind of social things that I find a bit difficult or, not embarrassing sometimes, I used to it; but things I don't like because of it. (...) And I am not too keen on that. And that for me is much more of a problem than not being able to walk up a hill." (P4)
	Hospitalisation due to asthma	"it doesn't really mention going to hospital, or like, time taken going to hospital appointments" (P5)
	Mental well-being	"If there was anything missing, it would be more about … err … how it affects your … your mental state, your mental wellbeing and … err … you know … it is not very personal I guess." (P11)
	Asthma management	"But again, missing … umm … was the rest of the management that goes with the asthma. It is not just about a concern for the need for medication or anything like that, it is still avoiding the …

		well actually it is quite time consuming to sit in the morning and do this-that-and-the-other and map your peak flow." (P15)
	Family impact	"And the 'Marks' and the 'Juniper' don't really talk about the family impact which can then affect guilt." (P15)
LWAQ	Hospitalisation due to asthma	"It didn't really talk about going into hospital with an asthma attack" (P5)
	Cough	"And again although the cough features here, it is - 'I tend to cough at night'. Well I don't. So it didn't come out, how asthma is affecting me with the cough; that didn't really get reflected. Umm …" (P8)
	Allergies	"Umm - well there isn't really a lot about allergies, and my asthma is affected a lot by my allergies. And it is not … it didn't really, sort of … it was almost like it is for someone who has got asthma just all the time, you know. I do take preventative medicine in the mornings and in the evenings and stuff, but my asthma mainly occurs when I come in contact with animals or with tree pollen or the things that set me off, you see what I mean?" (P11)
	Environment	"And they are all very culturally specific. It doesn't factor in, you know, where people live, if it is countryside or city, if there is more pollution or less pollution." (P22)

Redundant or similar content

All three questionnaires attracted comment about redundant content. For example the AQLQ-S asks about frustration (item 9), anger (item 10) and worry (item 19), which were perceived as being so similar as to be repetitive. Examples from all three questionnaires are shown in Box 3.

The use of positive and negative items in the LWAQ was also contextualised in a discourse of redundancy (e.g. item 3 "*Having asthma restricts the sort of holiday I can take*" and item 25 "*I can go on the same kind of holiday as everybody else*").

Box 3: Patients' perspective on redundant questionnaire content

Questionnaire	Redundant content	Illustrative quote
AQLQ-S	*Shortness of breath/ tightness of breath*	"Well I don't know what other people experience. Umm, but usually a shortness of breath is automatically accompanied by tightness. And it feels like it is the same question twice." (P15)
	Being limited in going to certain places because they are bad for one's asthma / being limited in going to certain places because one has been afraid of getting an asthma attack	"I think for example, in this questionnaire, there is a question about - 'being limited and going to certain places because they are bad for your asthma' - and then 'being limited in going because you are afraid of getting and asthma attack'. So they are both about socialising with asthma." (P21)

	Feeling angry/frustrated/worried about asthma	"There often seems to be questions about … umm … feeling angry and frustrated with your asthma, and worried and all that kind of thing. And for me they are quite easy questions and I will move on. But I don't know … they are often repeated quite a lot." (P21)
AQLQ-J	Asthma symptoms as a result of dust exposure / avoidance behaviour because of dust	"'Experience symptoms as a result of being exposed to dust' - 'to avoid a situation or environment because of dust' (P2)"
	Asthma symptoms as a result of cigarette smoke exposure / avoidance behaviour because of cigarette smoke	"'Have you experienced asthma symptoms as a result of being exposed to cigarette smoke?' - I suppose that they are good questions but, like I said, but then about avoiding a situation where there is cigarette smoke." (P13)
	Activities	"You see, 'doing regular social activities', I suppose yeah … yeah … and 'shopping'. 'Going for a walk' and 'playing sport' 'jogging or exercising'. (...)I would have thought they would … a lot of them seem to be, you know, all … all the same sort of things. 'Washing cars' 'doing home maintenance' 'doing your house work' 'gardening'. I would have thought they could have been more lumped into one. (...) 'Home maintenance' … err … doing home maintenance and doing housework, you know … they seem very similar, you know." (P19)
LWAQ	Being limited where one goes	"(...) there was a question about - 'am I limited on where I go?' (...) - and then - 'am I limited where I go on holiday?' But they were just in separate places in the questionnaire (...) And it is almost like …I have already answered this. And I kept thinking as I was answering - 'am I putting the same thing as I did for the last one?' 'Why are they asking me this twice?' (...) And if, obviously they are measuring consistency, then that is a good option. (...) But it is quite annoying." (P1)
	Walking up a hill / walking upstairs and downstairs	"But … (humming)… I think it was about going up and down stairs. Either walking up a hill or walking up and down stairs: the different formats in which the question is asked." (P8)
	Restriction in choice of holiday	"'Having asthma restricts the sort of holiday I can take' - and then later on in the questionnaire it says - 'I can go on the same kind of holiday as anybody else'." (P14)
	Engaging in sports	So they are kind of asking you - well it is not the same thing twice, but it is obviously similar thing and it is talking about (pause) umm… 'I feel frustrated at

		being unable to engage in a sport' - 'I feel I have missed out because there are some sporting activities I cannot join in with'. 'I can run like other people'." (P14)
	Colds	"I am trying to think. There were lots of questions about colds I think. 'I tend to be more conscious than other people of the early symptoms of a cold' 'colds don't bother me much'." (P21)

Irrelevant content (box 4)

No irrelevant content was identified in the AQLQ-S. In the AQLQ-J and LWAQ items relating to cigarette smoke (AQLQ-J item 9: *experiencing asthma symptoms as a result of being exposed to cigarette smoke*, item 11: *feeling having had to avoid a situation or environment because of cigarette smoke*) were considered irrelevant and outdated because the UK has had a smoking ban in all enclosed public space and work places since 2007.

In the AQLQ-J having to avoid situations because of exposure to, for instance perfume, was not thought to be pertinent. The items relating to having sexual intercourse (an activity option), air pollution, fighting for air, experiencing a feeling of chest heaviness as well as feeling bothered by heavy breathing were also highlighted as irrelevant.

"Umm, I feel bothered by breathing difficulties, you know. Or constricted breathing or something like that, you know, rather than heavy breathing. So yes, that was that." (P19)

The list of activity items from which to choose five items in the AQLQ-J was perceived as not offering the right choice.

"Yes, but they are not the choices that I would have (…) they are not the things that I would have put down as choices. So I wasn't really able to choose the right things, if that makes sense." (P22)

With respect to the LWAQ, carrying shopping, colds, taking tablets for asthma, the questions on holidays, walking up stairs and getting depressed about asthma were mentioned as examples of irrelevance. These views were frequently expressed but without people being able to offer alternative suggestions.

Box 4: Patients' perspective on irrelevant questionnaire content

Questionnaire	Irrelevant content	Illustrative quote
AQLQ-S		

AQLQ-J	Emotive wording	"I think such emotive words - although they don't really apply to me - I am not afraid of not having my medication or anything like that (...)"(P1)
	Smoking	"And of course it was out of date, because there is a great deal in here on cigarette smoke." (P3) "(...) but that might be because the age, well up until I was twenty when I left home, my dad smoked at home and my dad smoked forty-a-day, and we just sat in rooms that were just full of smoke and had layers of cloud and smoke hanging in the air. (...)So, yes, I don't really avoid anywhere because of cigarette smoke." (P12)
	Avoiding situations	"Do you have to avoid stuff … and it doesn't apply to me. I don't really go places with strong smells of perfume." (P10)
	Sexual intercourse	"(…) one thing did make me laugh though, about all these things on the … umm … on these questions and then having sexual intercourse - no one is going to put having sexual intercourse! People just won't do it! It is almost irrelevant how they get there" (P11)
	Air pollution	"- 'weather' 'air pollution': I have never noticed bothering me" (P12)
	Fighting for air	"'I have a feeling of fighting for air' - I think … umm, I don't know … I remember … I have gone to A&E before and I had a peak-flow of 90 at it was horrible. But I guess when you have had it a long time you … yes it is not nice but I have never been one of those people who needs a brown paper bag and is told to calm down. So that question I just think, well that doesn't say anything about me really, because I don't think I … I don't think it is relevant." (P21)
	Heavy chest	"Err … I never really get a heavy chest" (P18)
	Heavy breathing	"Umm, I feel bothered by breathing difficulties, you know. Or constricted breathing or something like that, you know, rather than heavy breathing. So yes, that was that." (P19)
	Activity items	"Yes, but they are not the choices that I would have … they are not the things that I would have put down as choices. So I wasn't really able to choose the right things, if that makes sense." (P22)
LWAQ	Smoky	"(...) when they asked about being in a smoke-y restaurant, that

	restaurants	doesn't apply anymore, because you are not allowed to smoke in restaurants in this country." (P1)
	Carrying shopping	"(...) carrying shopping doesn't really come into it very much!" (P8)
	Colds	"I wouldn't … as the 'Living with Asthma' questionnaire spoke a lot about colds … a few questions are about colds. I have never really been affected by colds." (P18) "And so … I don't … that is … I don't feel 'drained after a cold' … my cold just turns into a chest infection." (P19)
	Taking tablets for asthma	"No. I don't think so. I could relate to pretty much … I think there was one maybe … oh yes. I didn't … I don't ever take tablets for asthma, so I didn't … I put in 'not applicable'." (P18)
	Holiday	"There were a few questions on, on holiday, which I have never even … I have never even contemplated not going anywhere on holiday and not going somewhere because of my asthma." (P18)
	Walking up stairs	"I didn't like to sort of say, but that one … I have only ever had one case, number 42: 'I can walk up the stairs without stopping'. Well I put … umm … true because I can, I don't stop. Except this one particular case... (..)" (P19)
	Sad/depressed	"And I also don't see, again, how relevant … again it was number 60 - 'I often get depressed about my asthma'" (P22)

Confusing and challenging content

In the AQLQ-S, the items *"I have felt that asthma has prevented me from achieving what I want in life"* (item 11), *"I have felt asthma is controlling my life"* (item 17) and *"I have been restricted in walking up hills and doing heavy housework because of my asthma"* (item 5) were reported to be confusing or meaningless. One participant (P20) mentioned that frequent use of the word '*troubled*' in the AQLQ-S was confusing because it could relate to both emotional or physical problems.

In the AQLQ-J it was felt that item 23 *experiencing asthma symptoms as a result of the weather or air pollution outside* was a difficult item as most people are unaware of levels of air pollution.

The final two AQLQ-J questions, one asking whether one was *limited in the overall range of activities that one would have liked to have done* (item 31) the other *whether one was limited in all the activities that one has done* (item 32) were felt to be confusing. Asking these questions when questions about activities had already been asked at the very beginning fuelled the confusion. The item asking whether one *felt afraid of not having one's asthma medication available* (item 21) was problematic because it was unclear what type of medication was being referred to, be it reliever or preventer medication. The item *feeling afraid of getting out of breath* (item 27) was perceived as

difficult to understand. *Experiencing a wheeze in one's chest* (item 10) was perceived as confusing because not everyone with asthma experiences wheeze.

With respect to the LWAQ, *feeling angry with one's body* (item 9) lacks clarity of meaning. '*Getting emotionally upset when puffy*' (item 32) was described as 'not English' terminology and of limited meaningfulness. *Never feeling fed up because one has asthma* (item 20) was considered challenging because the precise reason for feeling fed up lacked definition (for example, someone wondered whether it related to activity limitation or medication regime). Patients were unsure about the item on *taking good care to avoid doing things which make one's asthma worse* (item 5) as well as the item on *having a good future ahead of oneself* (item 50). *Being able to walk up a flight of stairs without stopping* (item 42) was perceived as problematic because ability depended on the characteristics of the stairs.

"*Well I suppose when they ask you (…) if you can walk up a flight of stairs. And then you realise that you did have a situation where you couldn't walk up some stairs, but the reason was because they were extremely long and extremely high*." (P19)

Irritating content

Content could sometimes cause respondents to feel patronised, for instance questions on depression (AQLQ-S and LWAQ). The item asking whether one felt angry with one's body (item 9) was reported to have an irritating effect. The item on sexual frustration in the LWAQ (item 56) was described as irritating and invasive.

"*In the 'Living with Asthma' questionnaire is a really difficult one to … to … it is quite a … one could feel angry with one's body for many different reasons and again, I felt that was too limiting and wasn't quite the right … I was a bit put off by that. I found it a bit, you know, presumptuous*." (P22)

General perceptions

Generally the AQLQ-S was reported as quick and easy to complete, with unambiguous questions. Its focus on the social, attitudinal and emotional, rather than the medical, aspects of asthma was noted. Participants valued its broad questions relating to everyday life. One participant suggested one needed to be very emotive to relate to the AQLQ-S and it may only be relevant to people with extreme asthma. Feedback was not consistent. Some interviewees mentioned that the brevity of the questionnaire resulted in it being 'light', lacking breadth of coverage.

The AQLQ-J was considered a 'medical' questionnaire. Its foci on environmental triggers and activity restriction were perceived as too narrow by some, but pertinent to others. Choosing five relevant activities was viewed positively, individualising the questionnaire and making people think about areas of importance to themselves, but some participants found it difficult to choose five specific activities from the list provided. Some concern was expressed that people would not necessarily

choose the activities truly important to them in order to create a good impression with the clinician or researcher.

There was a strongly held view that the LWAQ was a 'holistic' and 'non-medical' questionnaire with a focus on the social and emotional. Some participants said that the content coverage of the questionnaire was wide ranging and that it was a thorough, in-depth questionnaire. On the other hand, the LWAQ was described as irritating because it was felt to generate problems with its emotional focus and its intrusive questioning.

When comparing the different questionnaires, interviewees described the AQLQ-S as being located between the AQLQ-J and LWAQ because it was partly a 'social' and partly a 'medical' questionnaire. They emphasised that the LWAQ dealt least well with symptomatology but also that it was the questionnaire which was most reflective of the impact of asthma on quality of life. The AQLQ-S was considered to be concise and "short and sweet". In comparison to the AQLQ-S and the LWAQ being able to choose activity items was seen as an advantage of the AQLQ-J.

DISCUSSION

Statement of principal findings

Participants expressed a wide variety of views about the content of the three questionnaires. The emotional focus of the LWAQ was perceived as irritating by some participants. Completion was described as burdensome and likened to a "test" or "quiz". A recurrent theme was that the LWAQ was a wide-ranging and holistic questionnaire. In contrast, the AQLQ-J was perceived as a 'narrow', 'medical' questionnaire with a focus on symptoms, environment and functional ability. The selection of relevant activities was perceived to be positive by some and difficult by others. The AQLQ-S was described as a simple, quick and easy questionnaire, but there was also a perception that it simultaneously lacked depth. Overall, the AQLQ-S was felt to be located 'between' the AQLQ-J and the LWAQ on the 'medical'-'emotional' spectrum.

Strengths and weaknesses of this research

This novel study elicits patients' views on the content validity of different questionnaires that purport to measure the same construct (HrQoL) for asthma. We interviewed adults with a wide age range of and range of disease duration. The interviewers were non-clinical which may have facilitated an open discussion that might have been impeded if the interviewers had been clinical. The research team included a male health services researcher and female psychologist both holding PhDs as well as a female academic GP and a male respiratory specialist, both holding MDs. A further strength of this study is that it built on a previous small-scale pilot study conducted in Germany[11]. Interestingly, all the themes that had emerged in the previous study were also found in this study, but our data was much richer and the thematic framework was expanded to include the new themes of 'confusing/difficult content' and 'irritating content'.

Interviews were our chosen method because they are more suitable for sensitive issues and, unlike focus groups, can be arranged for the convenience of each participant. However, group discussion may have further enriched the information generated [12-14]. The sample has a female preponderance and, with one exception, is of White British origin. Although common themes were identified in this

study and the preceding German study, caution must be exercised when generalising findings. Generalisability as conceptualised in empirical quantitative research is not usually sought in qualitative research which seeks theoretical generalisability [10]. Participant checking (participants providing feedback on the findings) was not undertaken in this study.

Similarity to other published work

Two previous studies have addressed the respondents' perspectives on self-reported health status questionnaires. The first study explored how older people with chronic health problems interpreted questions in the most widely used health status questionnaire, the Short-Form (SF)–36 [15]. Participants found some questions vague, e.g. "How about lifting or carrying groceries?" was unclear as there was no detail about the weight of the bag. Such findings were reflected by the participants in our study who found lack of specificity confusing and challenging.

A similar study assessed the validity of the Oxford hip score (OHS), a joint-specific measure to assess patients' disability following total hip replacement [16]. There is resonance in several areas between the OHS study findings and our study. Using the OHS, patients were unsure whether they should report their actual disabilities or their level of disability using aids (i.e. actual or relative disability). Similarly, patients with asthma were unclear whether they were being asked about impairments pre- or post-control. Patients with hip replacement found it difficult to report an average level of pain, as their pain was dynamic rather than static. Patients with asthma also spoke frequently about its dynamic, fluctuating nature. OHS study participants reported difficulties separating out the impact of their hip problems from other significant co-morbidities. In the context of asthma, allergies, coughs and infections were mentioned as co-morbidities influencing responses, but lacking in the questionnaires. Difficulties with activities not being important to all individuals and activities with changing importance over time have been noted with many validated patient-centred outcome measures [16]. This highlights the tension between the subjectivity of the PROMs and their apparent claim to be objective measures.

Implications of the findings

Improving content validity

All three questionnaires involved patients in the identification of important issues in their early development, but as the development process progresses, the need for robust objective measurement overrides attentiveness to the subjective lay perspective. Inevitably items are lost to achieve a practical questionnaire with an internally consistent dimensional structure from a large item pool. Our work highlights how the existing and conventional process can result in patient concerns about missing items as well as items considered as difficult or confusing. This suggests that it may be advantageous to check content validity after consideration of the metrics of the item set.

While patient involvement highlights shortcomings in the content validity of existing questionnaires, the patient's view needs to be balanced with a scientific perspective. The suggestion from respondents that asking about depression or sadness was irrelevant fails to recognise that for

others, these emotions can affect both asthma control and quality of life [17]. This example highlights that some tension between the lay perspective and the professional perspective is inevitable, but this should not stop us striving to minimise non-congruence.

Choice of questionnaire

Based our findings, the AQLQ-S seems to be the most partinent questionnaire for people with asthma. However, there was a diversity of views expressed and some participants also liked the focus on activities or the psychosocial domain in the AQLQ-J or LWAQ, respectively. Future research needs to explore patient responses in other cultural or linguistic contexts.

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Contributions

CA conceived and designed the study, conducted interviews, analysed and interpreted the data, wrote the manuscript and reviewed it for important intellectual content. CJ conducted interviews, interpreted the data, helped with writing the manuscript and reviewed it for important intellectual content. AF helped with patient recruitment and writing the manuscript and also reviewed it for important intellectual content. HS supervised the concept and design of the study, interpreted the data, wrote the manuscript and reviewed it for important intellectual content. All authors have read and approved the final version of manuscript.

Competing interest

None declared.

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Data sharing statement

The dataset is available from the authors upon request.

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group? CA & CJ	Methods, p.4
2. Credentials	What were the researcher's credentials? E.g. PhD, MD First and second author: PhD Third and last author: MD	Discussion, p.15
3. Occupation	What was their occupation at the time of the study? CA: health services researcher CJ: psychologist/research fellow TF: respiratory specialist HS: academic GP	Discussion, p.15
4. Gender	Was the researcher male or female? CA: male CJ: female TF: male HS: female	Discussion, p.15
5. Experience and training	What experience or training did the researcher have? CA and CJ had prior training in qualitative research methodology.	Methods, p.4
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement? Relationship was present with some of the participants, but otherwise relationship was not established prior to interviews.	Methods, p.5
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research Reasons for doing the research were described prior to interviews.	Methods, p.4
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias,	Methods, p.4

	assumptions, reasons and interests in the research topic The researcher's interest was clarified prior to the interviews.	
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis Thematic content analysis	Methods, p.6
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball Purposive sampling	Methods, p. 5
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email Posters, telephone, email	Methods, p.5
12. Sample size	How many participants were in the study? 30	Results, p.6
13. Non-participation	How many people refused to participate or dropped out? Reasons? Participants contacted researchers on a voluntary basis, so there is no drop out or non-participation rate	N/A
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace Medical school, hospital, participant's home	Methods, p.5
15. Presence of non-participants	Was anyone else present besides the participants and researchers? No	Methods, p.5
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date Age, gender, years in full time education, and age of asthma diagnosis are reported	Results, p.6/7
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested? All the questions/prompts are provided	Methods, p.4/5
18. Repeat interviews	Were repeat inter views carried out? If yes, how many? No.	Methods, p.4
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Methods, p.4

	Audio recording	
20. Field notes	Were field notes made during and/or after the inter view or focus group? Yes	Methods, p.4
21. Duration	What was the duration of the inter views or focus group? Variable. From 20 to 90 minutes.	Methods,p.
22. Data saturation	Was data saturation discussed? Yes	Methods, p.5
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Methods, p.4
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data? One	Methods, p.6
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data? Themes were derived from the data.	Methods, p.6
27. Software	What software, if applicable, was used to manage the data? Atlas.ti	Methods, p.6
28. Participant checking	Did participants provide feedback on the findings? No	Discussion, p.16
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number Quotations are presented and identified	Results, p.7-14
30. Data and findings consistent	Was there consistency between the data presented and the findings? Yes	Results and discussion, p.7-17
31. Clarity of major themes	Were major themes clearly presented in the findings? Yes	Results, p.7-15
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? Yes	Results, p.13 Discussion,p.17

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Validity of three asthma-specific quality of life questionnaires: the patients' perspective

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Validity of three asthma-specific quality of life questionnaires: the patients' perspective

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Keywords: quality of life, asthma, qualitative interviews, content validity

Abstract

Objectives

It is not known which of the many asthma-specific quality of life questionnaires best capture the lived experience of people with asthma. The objective of this study was to explore patients' views of three commonly used asthma-specific quality of life questionnaires.

Design

Qualitative study using semi-structured interviews.

Setting

Primary and secondary care in Brighton and Hove, UK.

Participants

Thirty adult people with a physician-diagnosis of asthma who were asked to complete the Juniper Asthma Quality of Life Questionnaire (AQLQ-J), the Sydney Asthma Quality of Life Questionnaire (AQLQ-S) and the Living with Asthma Questionnaire (LWAQ) to elicit their views on the content validity of these.

Results

Thematic content analysis revealed a lack of congruence between the concerns of people with asthma and the questionnaire content was found, both in terms of missing (e.g. allergies) and irrelevant (e.g. smoky restaurants) content. The AQLQ-J was perceived as a 'narrow', 'medical' questionnaire focussed on symptoms, the environment and functional ability. In contrast, the LWAQ and the AQLQ-S were perceived to be 'non-medical'. The LWAQ was described as a 'test', but also as a wide-ranging, embracing and holistic questionnaire. Its strong emotional focus was irritating to some. The AQLQ-S was described as a simple, quick and easy questionnaire, although there was a perception that it was lacking in depth.

Conclusion

Patient interviews highlighted both strengths and shortcomings in the content validity of these three asthma-specific questionnaires. For patients, the AQLQ-S content seemed to be the most pertinent in its adequacy of coverage of medical, social and emotional aspects of health-related quality of life in asthma.

Strengths and limitations of this study

- there is a body of research comparing the psychometric performance of asthma-specific quality of life measures, but the assessment of the validity of available measures requires an assessment of their content validity
- since no attempt has yet been made to assess the content validity of available measures from the patients' perspective, we used a qualitative interview technique to elicit how the experience of patients with asthma related to the content of available questionnaires
- patient involvement in comparing and contrasting the validity of asthma-specific quality of life measures has been limited to date, but is of key importance in guiding the choice of instrument in clinical and research settings
- we were able to recruit a diverse sample, there was a female preponderance and a lack of ethnic diversity
- data was analysed by a diverse research team
- data generated was rich, revealing the co-existence of missing, irritating, redundant and irrelevant content

INTRODUCTION

To capture patient's perception of the burden of disease on their functional status and wellbeing, the use of patient-reported outcome measures (PROMs) in clinical trials has been recommended by regulatory bodies such as the U.S. Food and Drug Administration [1]. PROMs are also used in clinical audit, patient registries, quality management and routine healthcare [2]. Health-related quality of life (HrQoL) is an outcome domain which is widely measured by PROMs in questionnaire form. A structured literature review of six asthma-specific HrQoL questionnaires concluded that they differed in almost all the review criteria (conceptual and measurement model, reliability, validity, interpretability, burden as measured by time required to complete the questionnaire, administration format and number of linguistic validations/translations) [3].

While head-to-head comparisons are often conducted to investigate the comparative psychometric performance of questionnaires, the patient's perspective of comparable content validity has not been explored. This study aimed to capture the views of people affected by asthma of three commonly used asthma-specific quality of life questionnaires, the Sydney Asthma Quality of Life Questionnaire (AQLQ-S), the Living with Asthma Questionnaire (LWAQ) and the Juniper Asthma Quality of Life Questionnaire (AQLQ-J), to understand how they perceived the relevance of the questionnaires in relationship to their own experience of living with asthma.

METHODS

Design and recruitment

This qualitative study was conducted between August 2011 and November 2012. Patients were purposively sampled if they had a physician-diagnosis of asthma, good spoken and written English and no severe mental health difficulties. Particular efforts were made to sample male people with asthma because in the first cycle of interviews (n=8) few males (n=2) had been included. Posters describing the study in lay language and how to contact the research team were displayed in the out-patient departments of two local general hospitals and in the waiting rooms of general practices in Brighton and Hove, East Sussex, UK. A relationship was present with some of the participants, but otherwise relationships were not established prior to interviews.

Participants established contact via telephone and/or e-mail. Interviews took place in private at the medical school, hospital or participant's home. Besides the participants and researchers, nobody else was present at the interviews. Written informed consent was sought from each study participant.

Recruitment continued until enough data were obtained to formulate meaningful comparisons about the three questionnaires and theoretical saturation was reached, i.e. when no new themes emerged in three consecutive interviews.

Questionnaires

The choice of questionnaires used for this study was based the structured literature review mentioned in the introduction. This review was informed by discussions with experts in the field who identified six QoL measures frequently used in asthma. From these, we chose the three that were

specifically developed and validated for patients with asthma (and not for instance for people with chronic respiratory illness in general or people with asthma and rhinitis).

The three questionnaires used were:

Sydney Asthma Quality of Life Questionnaire (AQLQ-S)

A 20-item self-administered questionnaire with a five-point Likert scale [4]. Responses are based on experiences in the preceding four weeks (four-week recall period). The AQLQ-S has four subscales: breathlessness, mood disturbance, social disruption and concerns for health.

Living with Asthma Questionnaire (LWAQ)

This comprises of 68 items in eleven domains (social/leisure, sport, holidays, sleep, work and other activities, colds, mobility, effects on others, medication usage, sex, dysphoric states, attitudes) and has no specified recall period [5]. It uses a three-point Likert scale. A mixture of positive and negative items compensate for acquiescence bias. Unlike the other two questionnaires, LWAC has a 'not applicable' response option.

Juniper Asthma Quality of Life Questionnaire (AQLQ-J)

AQLQ-J's idiographic component allows patients to choose from a list five activities important to them 6. It has 32 items in four domains (activity limitation, symptoms, emotional functioning, exposure to environmental stimuli) and uses a seven-point Likert scale and a two-week recall period.

Ethical approval

Ethical approval was obtained from Brighton East Research Ethics Committee (REC), reference number: 10/H1107/38.

Data collection

At the beginning of each encounter with participants, the reasons for conducting this research were explained. First, participants completed three different, commonly used asthma-specific quality of life questionnaires. In-depth interviews then explored individuals' subjective narratives of how the content of the questionnaires related to their experience of living with asthma. Using a topic guide, derived from the literature (3) and discussions within the research team (box 1), the two interviewers (CA & CJ) encouraged participants to talk freely about bothersome aspects of their asthma and whether the questionnaire items covered these aspects. CA & CJ both hold PhDs and had prior training in qualitative research methodology. Basic demographics (age, gender, duration of asthma, years in full time education) were noted. Repeat interviews were not carried out.

Interviews lasted between 20 and 90 minutes. They were audio-recorded and transcribed verbatim. Field notes were additionally taken. Transcripts were not returned to particpants for comment and/or correction.

Box 1: Topics covered in the interview topic guide

General impression of the questionnaires: What were your feelings/thoughts when completing the questionnaires?
Length of the questionnaires: How did you feel about the length of the questionnaires?
Layout/visual clarity: How did you feel about the looks/the layout of the questionnaires?
Format of the questions/response options: How did you feel about the options that were given to choose from when responding to each question?
Comprehensibility: How understandable were the questions to you?
Burden: How strenuous was it for you to answer the questions?
Redundancy of questions: are there any questions which are repeated or very similar?
Need for specification of question wordings: are there any questions which should be phrased in a more specific manner?
Adequacy/validity of questionnaires in relation to situation of living with asthma: How much did you feel the questions in the questionnaires covered the issues you are concerned with because of your asthma? Do important aspects of living with asthma lack in the questionnaires?
Suggestions for improvement: do you have any suggestions to improve the questionnaires?
Preference: Did you like one of the questionnaires better than the other/others? Could you tell a preference? If questionnaires should be judged as insufficient: which questionnaire is still the most adequate?
Preference: Would you recommend one of the questionnaires?
We are very interested in all of your views and impressions, so in this last section please feel free to add any other comments you feel are relevant to the ways asthma influences quality of life.

Data analysis

Thematic content analysis was performed by coding the verbatim transcripts and then grouping the codes into thematic categories [7]. Data were coded by CA using ATLAS.ti [8 9]. The emerging themes were discussed regularly within the research team and credibility of the findings was established by seeking agreement among co-researchers [10].

Here, we report on those themes that related to the content validity from the respondents' perspective.

RESULTS

Thirty individuals with asthma participated of which 12 were male. . Their age ranged from 20 to 68, with a median age of 39. 11 participants reported onset of asthma in infancy (0-2 years), 14 reported onset in childhood (2-14 years) and 5 participants reported adult onset of their asthma.

General perceptions

Generally the AQLQ-S was reported as quick and easy to complete, with unambiguous questions. Its focus on the social, attitudinal and emotional, rather than the medical, aspects of asthma was noted. Participants valued its broad questions relating to everyday life. One participant suggested one needed to be very emotive to relate to the AQLQ-S and it may only be relevant to people with extreme asthma. Feedback was not consistent. Some interviewees mentioned that the brevity of the questionnaire resulted in it being 'light', lacking breadth of coverage.

The AQLQ-J was considered a 'medical' questionnaire. Its foci on environmental triggers and activity restriction were perceived as too narrow by some, but pertinent to others. Choosing five relevant activities was viewed positively, individualising the questionnaire and making people think about areas of importance to themselves, but some participants found it difficult to choose five specific activities from the list provided. Some concern was expressed that people would not necessarily choose the activities truly important to them in order to create a good impression with the clinician or researcher.

There was a strongly held view that the LWAQ was a 'holistic' and 'non-medical' questionnaire with a focus on the social and emotional. Some participants said that the content coverage of the questionnaire was wide ranging and that it was a thorough, in-depth questionnaire. On the other hand, the LWAQ was described as irritating because it was felt to generate problems with its emotional focus and its intrusive questioning.

When comparing the different questionnaires, interviewees described the AQLQ-S as being located between the AQLQ-J and LWAQ because it was partly a 'social' and partly a 'medical' questionnaire. They emphasised that the LWAQ dealt least well with symptomatology but also that it was the questionnaire which was most reflective of the impact of asthma on quality of life. The AQLQ-S was considered to be concise and "short and sweet". In comparison to the AQLQ-S and the LWAQ being able to choose activity items was seen as an advantage of the AQLQ-J.

Missing content

Participants identified a number of areas that they considered missing from the questionnaires, such as the need to seek health care (medication, consultation or admission) for their asthma (Box 2). Participants commented on a lack of content relating to asthma control (such as peak flow

measurement), and noted their responses to the items would vary reflecting how well their asthma was controlled.

"Well I have to say, like I said, the one thing that is missing, is the asthma management of an individual, because that will have a bearing on quality of life - if it is very badly managed." (P15)

Participants also lamented that allergies and asthma triggers were not reflected in the questionnaires' content, thereby almost missing the very nature of asthma as a fluctuating disease.

"(…) it was almost like it is for someone who has got asthma just all the time, you know … but my asthma mainly occurs when I come in contact with animals or with tree pollen or the things that set me off, you see what I mean?" (P11)

Box 2: Patients' perspective on content missing in the questionnaires

Questionnaire	Missing content	Illustrative quote
AQLQ-S	Cough	"(...) cough didn't come up in that questionnaire. (...) Yes, yes because certainly at the moment, err, my cough is the main area in which I feel my life is restricted." (P8)
	Sex life	"(...) the only one that it didn't have on there, which the other two did, was about sex life. I think maybe that should have been on there (…)" (P13)
	Medication needs	"Umm … there was one questionnaire that talked about it is a nuisance having to take tablets - it is a nuisance having to use your inhaler. I think that is maybe missing from the 'Marks' because your quality of life quite often is affected by how many times you have to stop, use an inhaler. (...) That, actually probably affects my quality of life more than anything else. Because I can get half way down the street, on my way to work, and then think … I haven't brought my orange inhaler! " (P15)
	Family impact	"And the 'Marks' and the 'Juniper' don't really talk about the family impact which can then affect guilt." (P15)
	Asthma triggers	"It doesn't touch on any other trigger of asthma, such as smoking, food, stress and things like that." (P20)
	Wheezing attacks	"The wheezing attacks: more about that. It was very, very brief." (P22)
AQLQ-J	Social life	"It didn't really cover much of the social things…(...) There is a lot of kind of social things that I find a bit difficult or, not embarrassing sometimes, I used to it; but things I don't like because of it. (...) And I am not too keen on that. And that for me is much more of a problem than not being able to walk up a hill." (P4)
	Hospitalisation due to asthma	"it doesn't really mention going to hospital, or like, time taken going to hospital appointments" (P5)
	Mental well-being	"If there was anything missing, it would be more about … err … how it affects your … your mental state, your mental wellbeing and … err … you know … it is not very personal I guess." (P11)

	Asthma management	"But again, missing … umm … was the rest of the management that goes with the asthma. It is not just about a concern for the need for medication or anything like that, it is still avoiding the … well actually it is quite time consuming to sit in the morning and do this-that-and-the-other and map your peak flow." (P15)
	Family impact	"And the 'Marks' and the 'Juniper' don't really talk about the family impact which can then affect guilt." (P15)
LWAQ	Hospitalisation due to asthma	"It didn't really talk about going into hospital with an asthma attack" (P5)
	Cough	"And again although the cough features here, it is - 'I tend to cough at night'. Well I don't. So it didn't come out, how asthma is affecting me with the cough; that didn't really get reflected. Umm …" (P8)
	Allergies	"Umm - well there isn't really a lot about allergies, and my asthma is affected a lot by my allergies. And it is not … it didn't really, sort of … it was almost like it is for someone who has got asthma just all the time, you know. I do take preventative medicine in the mornings and in the evenings and stuff, but my asthma mainly occurs when I come in contact with animals or with tree pollen or the things that set me off, you see what I mean?" (P11)
	Environment	"And they are all very culturally specific. It doesn't factor in, you know, where people live, if it is countryside or city, if there is more pollution or less pollution." (P22)

Redundant or similar content

All three questionnaires attracted comment about redundant content. For example the AQLQ-S asks about frustration (item 9), anger (item 10) and worry (item 19), which were perceived as being so similar as to be repetitive. Examples from all three questionnaires are shown in Box 3.

The use of positive and negative items in the LWAQ was also contextualised in a discourse of redundancy (e.g. item 3 "*Having asthma restricts the sort of holiday I can take*" and item 25 "*I can go on the same kind of holiday as everybody else*").

Box 3: Patients' perspective on redundant questionnaire content

Questionnaire	Redundant content	Illustrative quote
AQLQ-S	*Shortness of breath/ tightness of breath*	"Well I don't know what other people experience. Umm, but usually a shortness of breath is automatically accompanied by tightness. And it feels like it is the same question twice." (P15)
	Being limited in going to certain places because they are bad for one's asthma /	"I think for example, in this questionnaire, there is a question about - 'being limited and going to certain

	being limited in going to certain places because one has been afraid of getting an asthma attack	places because they are bad for your asthma' - and then 'being limited in going because you are afraid of getting and asthma attack'. So they are both about socialising with asthma." (P21)
	Feeling angry/frustrated/worried about asthma	"There often seems to be questions about … umm … feeling angry and frustrated with your asthma, and worried and all that kind of thing. And for me they are quite easy questions and I will move on. But I don't know … they are often repeated quite a lot." (P21)
AQLQ-J	Asthma symptoms as a result of dust exposure / avoidance behaviour because of dust	"'Experience symptoms as a result of being exposed to dust' - 'to avoid a situation or environment because of dust' (P2)"
	Asthma symptoms as a result of cigarette smoke exposure / avoidance behaviour because of cigarette smoke	"'Have you experienced asthma symptoms as a result of being exposed to cigarette smoke?' - I suppose that they are good questions but, like I said, but then about avoiding a situation where there is cigarette smoke." (P13)
	Activities	"You see, 'doing regular social activities', I suppose yeah … yeah … and 'shopping'. 'Going for a walk' and 'playing sport' 'jogging or exercising'. (...)I would have thought they would … a lot of them seem to be, you know, all … all the same sort of things. 'Washing cars' 'doing home maintenance' 'doing your house work' 'gardening'. I would have thought they could have been more lumped into one. (...) 'Home maintenance' … err … doing home maintenance and doing housework, you know … they seem very similar, you know." (P19)
LWAQ	Being limited where one goes	"(...) there was a question about - 'am I limited on where I go?' (...) - and then - 'am I limited where I go on holiday?' But they were just in separate places in the questionnaire (...) And it is almost like …I have already answered this. And I kept thinking as I was answering - 'am I putting the same thing as I did for the last one?' 'Why are they asking me this twice?' (...) And if, obviously they are measuring consistency, then that is a good option. (...) But it is quite annoying." (P1)
	Walking up a hill / walking upstairs and downstairs	"But … (humming)… I think it was about going up and down stairs. Either walking up a hill or walking up and down stairs: the different formats in which the question is asked." (P8)
	Restriction in choice of holiday	"'Having asthma restricts the sort of holiday I can take' - and then later on in the questionnaire it says -

		'I can go on the same kind of holiday as anybody else'." (P14)
	Engaging in sports	So they are kind of asking you - well it is not the same thing twice, but it is obviously similar thing and it is talking about (pause) umm… 'I feel frustrated at being unable to engage in a sport' - 'I feel I have missed out because there are some sporting activities I cannot join in with'. 'I can run like other people'." (P14)
	Colds	"I am trying to think. There were lots of questions about colds I think. 'I tend to be more conscious than other people of the early symptoms of a cold' 'colds don't bother me much'." (P21)

Irrelevant content (box 4)

No irrelevant content was identified in the AQLQ-S. In the AQLQ-J and LWAQ items relating to cigarette smoke (AQLQ-J item 9: *experiencing asthma symptoms as a result of being exposed to cigarette smoke*, item 11: *feeling having had to avoid a situation or environment because of cigarette smoke*) were considered irrelevant and outdated because the UK has had a smoking ban in all enclosed public space and work places since 2007.

In the AQLQ-J having to avoid situations because of exposure to, for instance perfume, was not thought to be pertinent. The items relating to having sexual intercourse (an activity option), air pollution, fighting for air, experiencing a feeling of chest heaviness as well as feeling bothered by heavy breathing were also highlighted as irrelevant.

"Umm, I feel bothered by breathing difficulties, you know. Or constricted breathing or something like that, you know, rather than heavy breathing. So yes, that was that." (P19)

The list of activity items from which to choose five items in the AQLQ-J was perceived as not offering the right choice.

"Yes, but they are not the choices that I would have (…) they are not the things that I would have put down as choices. So I wasn't really able to choose the right things, if that makes sense." (P22)

With respect to the LWAQ, carrying shopping, colds, taking tablets for asthma, the questions on holidays, walking up stairs and getting depressed about asthma were mentioned as examples of irrelevance. These views were frequently expressed but without people being able to offer alternative suggestions.

Box 4: Patients' perspective on irrelevant questionnaire content

Questionnaire	Irrelevant content	Illustrative quote
AQLQ-S		
AQLQ-J	Emotive wording	"I think such emotive words - although they don't really apply to me - I am not afraid of not having my medication or anything like that (...)"(P1)
	Smoking	"And of course it was out of date, because there is a great deal in here on cigarette smoke." (P3) "(...) but that might be because the age, well up until I was twenty when I left home, my dad smoked at home and my dad smoked forty-a-day, and we just sat in rooms that were just full of smoke and had layers of cloud and smoke hanging in the air. (...)So, yes, I don't really avoid anywhere because of cigarette smoke." (P12)
	Avoiding situations	"Do you have to avoid stuff … and it doesn't apply to me. I don't really go places with strong smells of perfume." (P10)
	Sexual intercourse	"(…) one thing did make me laugh though, about all these things on the … umm … on these questions and then having sexual intercourse - no one is going to put having sexual intercourse! People just won't do it! It is almost irrelevant how they get there" (P11)
	Air pollution	"- 'weather' 'air pollution': I have never noticed bothering me" (P12)
	Fighting for air	"'I have a feeling of fighting for air' - I think … umm, I don't know … I remember … I have gone to A&E before and I had a peak-flow of 90 at it was horrible. But I guess when you have had it a long time you … yes it is not nice but I have never been one of those people who needs a brown paper bag and is told to calm down. So that question I just think, well that doesn't say anything about me really, because I don't think I … I don't think it is relevant." (P21)
	Heavy chest	"Err … I never really get a heavy chest" (P18)
	Heavy breathing	"Umm, I feel bothered by breathing difficulties, you know. Or constricted breathing or something like that, you know, rather than heavy breathing. So yes, that was that." (P19)
	Activity items	"Yes, but they are not the choices that I would have … they are not the things that I would have put down as choices. So I

		wasn't really able to choose the right things, if that makes sense." (P22)
LWAQ	Smoky restaurants	"(...) when they asked about being in a smoke-y restaurant, that doesn't apply anymore, because you are not allowed to smoke in restaurants in this country." (P1)
	Carrying shopping	"(...) carrying shopping doesn't really come into it very much!" (P8)
	Colds	"I wouldn't … as the 'Living with Asthma' questionnaire spoke a lot about colds … a few questions are about colds. I have never really been affected by colds." (P18) "And so … I don't … that is … I don't feel 'drained after a cold' … my cold just turns into a chest infection." (P19)
	Taking tablets for asthma	"No. I don't think so. I could relate to pretty much … I think there was one maybe … oh yes. I didn't … I don't ever take tablets for asthma, so I didn't … I put in 'not applicable'." (P18)
	Holiday	"There were a few questions on, on holiday, which I have never even … I have never even contemplated not going anywhere on holiday and not going somewhere because of my asthma." (P18)
	Walking up stairs	"I didn't like to sort of say, but that one … I have only ever had one case, number 42: 'I can walk up the stairs without stopping'. Well I put … umm … true because I can, I don't stop. Except this one particular case... (..)" (P19)
	Sad/depressed	"And I also don't see, again, how relevant … again it was number 60 - 'I often get depressed about my asthma'" (P22)

Confusing and challenging content

In the AQLQ-S, the items *"I have felt that asthma has prevented me from achieving what I want in life"* (item 11), *"I have felt asthma is controlling my life"* (item 17) and *"I have been restricted in walking up hills and doing heavy housework because of my asthma"* (item 5) were reported to be confusing or meaningless. One participant (P20) mentioned that frequent use of the word '*troubled*' in the AQLQ-S was confusing because it could relate to both emotional or physical problems.

In the AQLQ-J it was felt that item 23 *experiencing asthma symptoms as a result of the weather or air pollution outside* was a difficult item as most people are unaware of levels of air pollution.

The final two AQLQ-J questions, one asking whether one was *limited in the overall range of activities that one would have liked to have done* (item 31) the other *whether one was limited in all the activities that one has done* (item 32) were felt to be confusing. Asking these questions when

questions about activities had already been asked at the very beginning fuelled the confusion. The item asking whether one *felt afraid of not having one's asthma medication available* (item 21) was problematic because it was unclear what type of medication was being referred to, be it reliever or preventer medication. The item *feeling afraid of getting out of breath* (item 27) was perceived as difficult to understand. *Experiencing a wheeze in one's chest* (item 10) was perceived as confusing because not everyone with asthma experiences wheeze.

With respect to the LWAQ, *feeling angry with one's body* (item 9) lacks clarity of meaning. '*Getting emotionally upset when puffy*' (item 32) was described as 'not English' terminology and of limited meaningfulness. *Never feeling fed up because one has asthma* (item 20) was considered challenging because the precise reason for feeling fed up lacked definition (for example, someone wondered whether it related to activity limitation or medication regime). Patients were unsure about the item on *taking good care to avoid doing things which make one's asthma worse* (item 5) as well as the item on *having a good future ahead of oneself* (item 50). *Being able to walk up a flight of stairs without stopping* (item 42) was perceived as problematic because ability depended on the characteristics of the stairs.

"*Well I suppose when they ask you (…) if you can walk up a flight of stairs. And then you realise that you did have a situation where you couldn't walk up some stairs, but the reason was because they were extremely long and extremely high*." (P19)

Irritating content

Content could sometimes cause respondents to feel patronised, for instance questions on depression (AQLQ-S and LWAQ). The item asking whether one felt angry with one's body (item 9) was reported to have an irritating effect. The item on sexual frustration in the LWAQ (item 56) was described as irritating and invasive.

"*In the 'Living with Asthma' questionnaire is a really difficult one to … to … it is quite a … one could feel angry with one's body for many different reasons and again, I felt that was too limiting and wasn't quite the right … I was a bit put off by that. I found it a bit, you know, presumptuous*." (P22)

DISCUSSION

Statement of principal findings

It was the aim of this study to explore how people affected by asthma perceive the relevance of three commonly used asthma-specific quality of life questionnaires (the Sydney Asthma Quality of Life Questionnaire (AQLQ-S), the Living with Asthma Questionnaire (LWAQ) and the Juniper Asthma Quality of Life Questionnaire (AQLQ-J)) in relation to their own experience of living with asthma. Participants expressed a wide variety of views about the content of the three questionnaires. The emotional focus of the LWAQ was perceived as irritating by some participants. Completion was described as burdensome and likened to a "test" or "quiz". A recurrent theme was that the LWAQ was a wide-ranging and holistic questionnaire. In contrast, the AQLQ-J was perceived as a 'narrow',

'medical' questionnaire with a focus on symptoms, environment and functional ability. The selection of relevant activities was perceived to be positive by some and difficult by others. The AQLQ-S was described as a simple, quick and easy questionnaire, but there was also a perception that it simultaneously lacked depth. Overall, the AQLQ-S was felt to be located 'between' the AQLQ-J and the LWAQ on the 'medical'-'emotional' spectrum.

Strengths and weaknesses of this research

This novel study elicits patients' views on the content validity of different questionnaires that purport to measure the same construct (HrQoL) for asthma. We interviewed adults with a wide age range of and range of disease duration. The interviewers were non-clinical which may have facilitated an open discussion that might have been impeded if the interviewers had been clinical. The research team included a male health services researcher and female psychologist both holding PhDs as well as a female academic GP and a male respiratory specialist, both holding MDs. A further strength of this study is that it built on a previous small-scale pilot study conducted in Germany[11]. Interestingly, all the themes that had emerged in the previous study were also found in this study, but our data was much richer and the thematic framework was expanded to include the new themes of 'confusing/difficult content' and 'irritating content'.

Interviews were our chosen method because they are more suitable for sensitive issues and, unlike focus groups, can be arranged for the convenience of each participant. However, group discussion may have further enriched the information generated [12-14]. We had expected a certain degree of respondent fatigue, as completing three questionnaires may be perceived burdensome. However, in reality, participants appreciated completing the questionnaires and being able to talk at length about their experience. Recall bias (i.e. bias introduced by participants focusing on the last completed questionnaire) was dealt with by actively encouraging respondents to provide feedback on all questionnaires. The sample has a female preponderance and, with one exception, is of White British origin. Although common themes were identified in this study and the preceding German study, caution must be exercised when generalising findings. Generalisability as conceptualised in empirical quantitative research is not usually sought in qualitative research which seeks theoretical generalisability [10]. Participant checking (participants providing feedback on the findings) was not undertaken in this study.

Similarity to other published work

Two previous studies have addressed the respondents' perspectives on self-reported health status questionnaires. The first study explored how older people with chronic health problems interpreted questions in the most widely used health status questionnaire, the Short-Form (SF)–36 [15]. Participants found some questions vague, e.g. "How about lifting or carrying groceries?" was unclear as there was no detail about the weight of the bag. Such findings were reflected by the participants in our study who found lack of specificity confusing and challenging.

A similar study assessed the validity of the Oxford hip score (OHS), a joint-specific measure to assess patients' disability following total hip replacement [16]. There is resonance in several areas between the OHS study findings and our study. Using the OHS, patients were unsure whether they should report their actual disabilities or their level of disability using aids (i.e. actual or relative disability).

Similarly, patients with asthma were unclear whether they were being asked about impairments pre- or post-control. Patients with hip replacement found it difficult to report an average level of pain, as their pain was dynamic rather than static. Patients with asthma also spoke frequently about its dynamic, fluctuating nature. OHS study participants reported difficulties separating out the impact of their hip problems from other significant co-morbidities. In the context of asthma, allergies, coughs and infections were mentioned as co-morbidities influencing responses, but lacking in the questionnaires. Difficulties with activities not being important to all individuals and activities with changing importance over time have been noted with many validated patient-centred outcome measures [16]. This highlights the tension between the subjectivity of the PROMs and their apparent claim to be objective measures.

Implications of the findings

Improving content validity

All three questionnaires involved patients in the identification of important issues in their early development, but as the development process progresses, the need for robust objective measurement overrides attentiveness to the subjective lay perspective. Inevitably items are lost to achieve a practical questionnaire with an internally consistent dimensional structure from a large item pool. Our work highlights how the existing and conventional process can result in patient concerns about missing items as well as items considered as difficult or confusing. This suggests that it may be advantageous to check content validity after consideration of the metrics of the item set.

While patient involvement highlights shortcomings in the content validity of existing questionnaires, the patient's view needs to be balanced with a scientific perspective. The suggestion from respondents that asking about depression or sadness was irrelevant fails to recognise that for others, these emotions can affect both asthma control and quality of life [17]. This example highlights that some tension between the lay perspective and the professional perspective is inevitable, but this should not stop us striving to minimise non-congruence.

Choice of questionnaire

Based our findings, the AQLQ-S seems to be the most partinent questionnaire for people with asthma. However, there was a diversity of views expressed and some participants also liked the focus on activities or the psychosocial domain in the AQLQ-J or LWAQ, respectively. Future research needs to explore patient responses in other cultural or linguistic contexts.

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Contributions

CA conceived and designed the study, conducted interviews, analysed and interpreted the data, wrote the manuscript and reviewed it for important intellectual content. CJ conducted interviews, interpreted the data, helped with writing the manuscript and reviewed it for important intellectual content. AF helped with patient recruitment and writing the manuscript and also reviewed it for

important intellectual content. HS supervised the concept and design of the study, interpreted the data, wrote the manuscript and reviewed it for important intellectual content. All authors have read and approved the final version of manuscript.

Competing interest

None declared.

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Data sharing statement

The dataset is available from the authors upon request.

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group? CA & CJ	Methods, p.4
2. Credentials	What were the researcher's credentials? E.g. PhD, MD First and second author: PhD Third and last author: MD	Discussion, p.15
3. Occupation	What was their occupation at the time of the study? CA: health services researcher CJ: psychologist/research fellow TF: respiratory specialist HS: academic GP	Discussion, p.15
4. Gender	Was the researcher male or female? CA: male CJ: female TF: male HS: female	Discussion, p.15
5. Experience and training	What experience or training did the researcher have? CA and CJ had prior training in qualitative research methodology.	Methods, p.4
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement? Relationship was present with some of the participants, but otherwise relationship was not established prior to interviews.	Methods, p.5
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research Reasons for doing the research were described prior to interviews.	Methods, p.4
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias,	Methods, p.4

	assumptions, reasons and interests in the research topic The researcher's interest was clarified prior to the interviews.	
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis Thematic content analysis	Methods, p.6
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball Purposive sampling	Methods, p. 5
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email Posters, telephone, email	Methods, p.5
12. Sample size	How many participants were in the study? 30	Results, p.6
13. Non-participation	How many people refused to participate or dropped out? Reasons? Participants contacted researchers on a voluntary basis, so there is no drop out or non-participation rate	N/A
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace Medical school, hospital, participant's home	Methods, p.5
15. Presence of non-participants	Was anyone else present besides the participants and researchers? No	Methods, p.5
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date Age, gender, years in full time education, and age of asthma diagnosis are reported	Results, p.6/7
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested? All the questions/prompts are provided	Methods, p.4/5
18. Repeat interviews	Were repeat inter views carried out? If yes, how many? No.	Methods, p.4
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Methods, p.4

	Audio recording	
20. Field notes	Were field notes made during and/or after the inter view or focus group? Yes	Methods, p.4
21. Duration	What was the duration of the inter views or focus group? Variable. From 20 to 90 minutes.	Methods,p.
22. Data saturation	Was data saturation discussed? Yes	Methods, p.5
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Methods, p.4
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data? One	Methods, p.6
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data? Themes were derived from the data.	Methods, p.6
27. Software	What software, if applicable, was used to manage the data? Atlas.ti	Methods, p.6
28. Participant checking	Did participants provide feedback on the findings? No	Discussion, p.16
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number Quotations are presented and identified	Results, p.7-14
30. Data and findings consistent	Was there consistency between the data presented and the findings? Yes	Results and discussion, p.7-17
31. Clarity of major themes	Were major themes clearly presented in the findings? Yes	Results, p.7-15
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? Yes	Results, p.13 Discussion,p.17