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The asthma Symptom Free Days Questionnaire: how reliable are patient responses?

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ABSTRACT

Objective: Symptom free days are a widely used patient-reported outcome (PRO) in asthma clinical trials. We assessed the internal consistency of one instrument for this PRO, the *Symptom Free Days Questionnaire (SFDQ)*, in a population of Black adults with asthma enrolled in the Blacks and Exacerbations on Long-acting beta agonists and Tiotropium (BELT) trial. **Methods:** We assessed responses to the *SFDQ* collected at baseline, 6 and 12 months as part of the BELT trial. The internal consistency of responses, specifically number of patient-reported days with symptoms in 14 days were compared to the number of patient-reported days with no symptoms in the same 14 days. Lin concordance correlation coefficients (Lin ccc) were calculated over time to assess “learning” and by age, sex, geographic location, and annual family income. **Results:** The internal consistency of the responses of the 1070 enrolled patients was consistently low over the 12 months of the study; varying from 43.8% at baseline to 52.1% at 12 months. This corresponded to Lin cccs of 0.33–0.32 over the study period. Internal consistency and the Lin ccc did not vary by age group, sex, geographic location or percent poverty. Concordance was slightly but not significantly higher at all time points in those with family annual income of $\geq \$50,000$ compared to those with lower annual incomes. **Conclusions:** The *SFDQ* did not work well in the BELT population of Black adults with asthma. Further validation is required before the *SFDQ* is used in other large clinical trials with any population.

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Introduction

Asthma symptom-free days are a widely used outcome for asthma studies. For many years “symptom free days” or the number of day or nights that a patient did not report having any asthma symptoms was assessed with the use of daily diaries which are labor intensive and seldom feasible over long periods of time [1,2]. To address this barrier to use of the metric, The Health Resources and Services Administration (HRSA) Disparities Collaborative developed the asthma *Symptom Free Day Questionnaire (SFDQ)* [3]. Since that time the *SFDQ* has been employed in several large asthma clinical trials despite not being formally validated [4–6]. In 2012, the National Institutes of Health (NIH) convened a workgroup to establish standard definitions and evaluate data collection

methodologies for validated outcome measures in asthma clinical research. As part of the report, the workgroup identified the *SFDQ* an “emerging outcome metric [tool]” requiring further development and validation. We could find no further validation of the *SFDQ* tool reported in the literature since that time [1].

The purpose of this report is to present an assessment of the validity of the *SFDQ* tool based on data from a large asthma clinical trial [7]. This work should be considered as a first step in the standardization and validation process recommended by the NIH workgroup.

The *SFDQ* was one of the patients reported outcomes in the Blacks and Exacerbations on Long-acting beta agonists and Tiotropium (BELT) trial [7]. During

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Table 1. Symptom free days questionnaire [3].

1. In the past 14 days, how many days did you have wheezing, chest tightness, cough or shortness of breath?
2. In the past 14 days, how many days did you have to slow down or stop activities because of asthma, wheezing, chest tightness, cough or shortness of breath?
3. In the past 14 days, how many nights did you wake up because of asthma, wheezing, chest tightness, cough or shortness of breath?
4. Think about all three asthma signs or symptoms (wheezing, chest tightness, cough, or shortness of breath: slowing down or stopping activities: nights awakened), in the past 14 days, how many days did you have any of the daytime or nighttime symptoms?
5. In the past 14 days, how many days did you experience any day with NO daytime or nighttime symptoms of asthma (including no wheezing, no cough, no chest tightness or not shortness of breath)?

The SFD Questionnaire was developed by the HRSA Disparities Collaborative and include in the AHRQ quality metrics database. (<http://www.qualitymeasures.ahrq.gov/content.aspx?id=27596>)

review of baseline data, internal inconsistencies in patients' responses to the *SFDQ* were noted. We undertook this sub-study of the BELT trial to further assess the internal consistency of the patient responses to the *SFD Questionnaire*. Patients completed the *SFDQ* at enrollment (baseline) and at 1, 6 and 12 months' post-enrollment allowing us to assess internal consistency at initial use of the questionnaire and to assess the possibility of changes in internal consistency of the patient responses over time, e.g. "learning" effects. Such learning effects might be related to repeated exposure to the specific tool, allowing repeated opportunities to better understand the questions asked. We also assessed the external validity of a subset of the *SFDQ* responses to selected responses to the Asthma Symptom Utility Index (ASUI), a well-validated tool [1,8,9] which was also collected as a patient-reported outcome in BELT. The results of this sub-study were useful for determining how to report symptom data from the *SFD* for our study and may also be useful to other investigators deciding if the *SFDQ* is the best tool for reporting a measure of "symptom free days".

Methods

We analyzed data from the BELT trial [7], a parallel-group, randomized, pragmatic trial that enrolled 1070 self-identified Black adults aged 18–75 years with physician-diagnosed asthma and receiving combination LABA + ICS or taking ICS alone and having an Asthma Control Questionnaire (ACQ) [10,11] score >1.25. Patients were enrolled from 20 primary care or specialty practices. Each practice enrolled 25–180 patients. Patients continued to take their baseline ICS dose and were centrally randomized to either tiotropium (tiotropium once daily + ICS twice daily) or LABA (LABA + ICS twice daily). Subjects completed the *SFDQ*, ASUI and other asthma-related questionnaires and spirometry at baseline, and at 1, 6 and 12 months. We analyzed data from all patients who had completed the *SFDQ* and ASUI at least once at baseline, 1, 6 or 12 months. All patients provided

informed consent. The parent BELT study and this sub-study were approved by the central site institutional review boards (IRBs) at Brigham and Women's Hospital, the Olmsted Medical Center, and the American Academy of Family Physicians, as well as IRBs of local practice sites.

The *SFDQ* consists of five questions [3,12] (Table 1). The first three questions ask about the number of days in the prior 14 days in which the patient had 1) experienced asthma symptoms – wheezing, coughing, chest tightness or shortness of breath, 2) modified activities due to those symptoms or 3) was awakened with asthma symptoms. Question 4 requires the patient to combine all three types of symptoms to yield the total number of days with asthma symptoms or modified activity due to symptoms in the prior 14 days. The final question (number 5) then asks the number of days in the prior 14 with no symptoms. The responses to questions 4 and 5 (Q4 and Q5) should always add to 14. We assessed this internal consistency of the response to Q4 and Q5 by calculating the % of questionnaire in which the sum of Q4 + Q5 was greater or less than 14 as well as Lin's concordance correlation coefficient (Lin ccc). Lin ccc assesses the degree of agreement between two continuous variables [13–16]. We also assessed whether the response to Q#4 – the number of days with any symptoms was at least as large as the largest number of days listed in response to questions 1, 2 and 3 (Q#1, Q#2 and Q#3) which query the number of days/nights with specific symptoms.

To assess external validity, that is validity compared with another instrument, we used selected questions from the ASUI (Table 2) which we considered the "gold standard" to compare with responses on the same date to *SFDQ* items. The ASUI was reviewed by the NIH panel on outcome metrics and felt to be well validated and appropriate for use in asthma research studies [1]. Because the ASUI uses ranges of days of either daytime or nighttime symptoms except for the 0 category, we chose our primary comparison to be in patients who reported 0 d and 0 nights of symptoms on the ASUI compared to those reporting 0 days and

Table 2. ASUI Questionnaire (Questions 1, 3, 5 and 7) [8, 9] I would like to ask you some questions about different symptoms of asthma and how often you were bothered by these symptoms in the past 2 weeks.

1. How many days were you bothered by coughing during the past 2 weeks?
Not at all
1–3 days
4–7 days
8–14 days
3. How many days were you bothered by wheezing during the past 2 weeks?
Not at all
1–3 days
4–7 days
8–14 days
5. How many days were you bothered by shortness of breath during the past 2 weeks?
Not at all
1–3 days
4–7 days
8–14 days
7. How many days were you awakened at night during the past 2 weeks?
Not at all
1–3 days
4–7 days
8–14 days

0 nights of symptoms on the *SFDQ*. The first three questions of the ASUI ask about the number of days of three specific asthma symptoms over the prior 14 days: cough, wheeze and shortness of breath. Individuals reporting no days of symptoms on the ASUI questions 1, 2 and 3 should also report no days of symptoms on *SFDQ* question 1 (Q#1). Our secondary comparison was for night time symptoms. Individuals reporting 0 nighttime symptoms in the prior 14 days on the ASUI question 7 for which patients should also report zero on the *SFDQ* question 3 (Q#3) regarding awakenings due to symptoms.

Data analysis

Simple descriptive statistics were used to report the demographics of the group completing the baseline *SFDQ* and ASUI. Information on the internal consistency of the *SFDQ* is presented by comparing answers to question 4 (the total number of days with any symptoms) with question 5 (the total number of days without any symptoms or the symptom free days) of the *SFDQ*. To simplify graphic display, our calculations for the primary analysis used 14 days minus the sum of the responses to Q#4 and Q#5. The answer to this calculation should be 0 whenever the responses are internally consistent. Inconsistent responses are any answer to the calculation other than 0. We calculated the number and percent of consistent response (answer = 0) as well as number and percent of inconsistent responses (answer anything other than 0).

To further quantify the level of agreement or internal consistency between responses to Q#4 and Q#5, we calculated Lin ccc [13]. The Lin ccc quantifies the agreement between two measures of the same variable, in this case 14 minus the number of days without symptoms in 2 weeks with the number of days of symptoms in 2 weeks [13–17]. Similar to other correlation coefficients, r_c ranges from -1 to 1 , a value of $r_c = +1$ corresponds to perfect agreement, a value of $r_c = -1$ corresponds to perfect negative agreement and a value of $r_c = 0$ corresponds to no agreement. The interpretation of the r_c values are described by Landis and Koch [18] as; <0 as indicating no agreement and $0-0.20$ as slight, $0.21-0.40$ as fair, $0.41-0.60$ as moderate, $0.61-0.80$ as substantial and $0.81-1$ as almost perfect agreement. The exact cutoffs are considered arbitrary but with lower values associated with lesser levels of concordance.

To assess potential improvement or variability of internal consistency over time, e.g. “learning effects” and potential associations with patient factors such as sex, age, socio-economic status (SES) and geographic region of the USA. We calculated Lin ccc (r_c) stratified by each of these variables. Because we did not have individual patient data on SES markers, we used the % poverty of the block in which they reside as a proxy of SES.

For our secondary comparison, we calculated the number and percent of *SFDQ* in which the largest response to questions about the number of days with symptoms, Q#1, Q#2 and Q#3 was greater than the reported total number of days with any of these symptoms (response to Q#4). The calculation was done for survey data completed at baseline (randomization visit), 1, 6 and 12 months (Table 3).

To assess external validity of the *SFDQ* using a well validated “gold” standard, we compared the percent of time that patients reported no days of any asthma symptoms (Q#1 in the *SFDQ*) and reported no days of any of the asthma symptoms (Q#1, #2 and #3 in the ASUI). Similarly, we compared the number of nights reported with no asthma-related awakenings (Q#3 in the *SFDQ*) to reports of having no nights with asthma-related awakenings (Q#4 in the ASUI).

Results

Of the 1070 enrolled patients, 1018 (95.1% of total enrolled) completed all questions on the *SFDQ* and the ASUI Questionnaires at the baseline visit and could be included in baseline calculations for this study. Smaller numbers were available for analysis of

Table 3. Comparisons for internal consistency and criterion validity.

Internal consistency – questions within the <i>SFDQ</i>
<i>SFDQ</i> #4 – Days or nights with symptoms or activity limitations
<i>SFDQ</i> #5 – Days or nights with no symptoms and no activity limitations
Comparisons for <i>SFDQ</i> :
a. <i>SFDQ</i> #5 = 14–#4
b. <i>SFDQ</i> #4 $\geq$ any of #3, #2 and #1
External criterion validity across questionnaires, comparing same day answers for <i>SFD</i> and <i>ASUI</i>
a. Daytime symptoms:
<i>ASUI</i> #1 (coughing)
<i>ASUI</i> #3 (wheezing)
<i>ASUI</i> #5 (SOB)
<i>SFDQ</i> #1 (0) = <i>ASUI</i> #1 (0)
<i>SFDQ</i> #1 (0) = <i>ASUI</i> #3(0)
<i>SFDQ</i> #1 (0) = <i>ASUI</i> #5 (0)
b. Night time symptoms:
<i>ASUI</i> #7 – awakenings in last 14 days
Comparisons
<i>SFDQ</i> #3 (0) = <i>ASUI</i> (not at all)

subsequent time periods; 929 for 1 month, 783 at 6 months and 499 at 12 months. The demographics of the population answering the baseline questionnaire are shown in Table 4. The BELT enrollees were Black or African American adults with asthma with middle-aged women being the most commonly enrolled patients. All patients were on moderate to high dose inhaled corticosteroids with 69.9% also taking a long-acting beta agonist bronchodilator (combination therapy) at the time of enrollment. The ACQ [10,11] demonstrated that 53% of the patients met the BELT criteria for controlled asthma ($ACQ \leq 1.25$) at baseline.

Figure 1 is a histogram illustrating the concordance between the response to Q#4 (number of days with any asthma symptoms) and Q#5 (days with no symptoms) of the *SFDQ* at baseline. Only 43.8% of patients ($n=446$ of 1018 who completed the baseline questionnaire) had responses that were internally consistent (calculation result was zero). At baseline, 29.9% of the patients (304 of 1018) reported differences of 7 or more days. The baseline Lin's ccc was 0.33, considered to be indicative of “fair” agreement [18].

To assess whether internal consistency of the *SFDQ* varied over time, e.g. improvement with experience or “learning” we also calculated Lin ccc at 1, 6 and 12 months post-enrollment. The results are in Table 5. There were no statistically significant improvements over time and therefore no indication of “learning” with repeated completion of the *SFD*. We also assessed whether learning, e.g. improvement in Lin's ccc might vary across time by patient's sex, age group, socio economic status (SES) or region of the country of residence. No improvements were seen over time within any of the groups assessed. Those in the highest SES group (yearly family income $> \$50,000$) had

Table 4. Baseline demographics.

Patient characteristics	Overall (N = 1070 Subjects)
Age (years)	
Mean $\pm$ SD (N)	45.1 $\pm$ 12.6 (1070)
Gender	
Male	24.0% (257/1070)
Ethnicity	
Hispanic/Latino	6.3% (67/1070)
BMI	
Mean $\pm$ SD (N)	34.3 $\pm$ 9.3 (1070)
Smoking environment	
Yes	15.8% (169/1070)
Smoke in the past	35.1% (375/1069)
FEV1 (%predicted)	
<60%	15.0% (142/945)
60–79%	36.9% (349/945)
$\geq 80\%$	48.0% (454/945)
Years from first asthma diagnosis (years)	
Mean $\pm$ SD (N)	24.4 $\pm$ 15.9 (1002)
Asthma exacerbation past 12 months	
Past experience of asthma episodes in the past twelve months requiring an unscheduled office visit/emergency room visit/hospitalized	59.5% (636/1069)
Baseline medications	
Any ICS alone	27.8% (297/1070)
Combination therapy with one deliver system (one device)	69.6% (745/1070)
Other	
Combination therapy with two deliver systems (two devices)	0.5% (5/1070)
ICS plus combination therapy	1.1 % (12/1070)
Combination LABA, non-combination LABA and inhaled steroid	0.1% (1/1070)
None	0.8% (9/1070)
Combination LABA & non-combination LABA	0.1% (1/1070)

higher but not statistically significantly different scores at all times compared to the other income groups but did not demonstrate “learning” or improved Lin ccc from baseline to 12 months. Most values of the Lin ccc for the time periods assessed were between 0.20 and 0.40 which is generally considered to denote only fair concordance.

The secondary assessment of internal consistency: comparison of the highest number of days with any symptom to the total number of days with any symptom (highest of Q#1, Q#2 and Q#3 with response to Q#4) is illustrated in Figure 2. At baseline, 29.1% ($n=311$) of the patients responded to the *SFDQ* Q#1, Q#2 or Q#3 that they had day time symptoms or awakenings for more days than the total number of days that they reported having any asthma symptoms (Q#4) – indicating internal inconsistency. The rates of internal consistency did improve by this metric over time with the rate of discrepancy being 25.4% at 1 month, 21.1% at 6 months and 16.6% at 12 months ($p < 0.01$ for trend).

When comparing the *SFDQ* to the *ASUI*, only two sets of questions are directly comparable: the number of days with asthma-related symptoms and the number of nights with asthma-related awakenings. Patients

reporting no days of coughing, wheezing, chest tightness or shortness of breath on the *SFDQ* (Q#1) (26.7% of 1081) reported no coughing (Q#1 ASUI), no wheezing (ASUI Q#2) and no shortness of breath (ASUI Q#3) 68.7, 95.3, and 85.1% of the time, respectively. Those reporting no nights with asthma-related awakenings agreed 91.9% of the time between the two questionnaires.

Discussion

The *Symptom Free Days Questionnaire* (*SFDQ*) is one tool that has been developed to assess and report days that patients consider themselves to be without asthma symptoms – one important metric of asthma burden. However, in our large population of Black adults with asthma, the *SFDQ* is not internally consistent. The Lin concordance correlation coefficient for the metric of internal consistency was 0.33 at baseline and <0.41 at all time points measured, meaning internal consistency never improved to more than “fair” [13–18]. Quantitative assessment of the level of internal consistency using Lin ccc did not improve significantly over time or by sex, age group, geographic region of the U.S. or by income.

Comparisons with the ASUI which the NIH asthma outcomes panel recommended as a valid metric [1] may provide some insight into the internal consistency problems with the *SFDQ*. The similarity of responses related to the number of nights with asthma-related awakenings between the *SFDQ* and ASUI was very high suggesting that questions about night time awakenings were understood similarly between the two tools. The variability in the concordance of responses to individual daytime symptom questions varied with lesser agreement when the ASUI asked about only cough compared to the *SFDQ* question that combined all day time symptoms together. Agreement was high with ASUI questions asking about only wheezing or about only shortness of breath and the *SFDQ* question combining all symptoms together. This may suggest that respondents placed less emphasis on “cough” in the *SFDQ* question combining all symptoms since this was the question with the least agreement between the *SFDQ* and the ASUI.

The *SFDQ* demonstrated only “fair” internal consistency. There was good agreement among patients reporting no symptoms on both the *SFDQ* and ASUI but this was only a small percent of the total population (26.7%) and due to the structure of the response it was not possible to assess agreement between the

SFDQ and ASUI for patients reporting any frequency of symptoms other than 0.

Conceptually, using symptom free days as an outcome has advantages. It is very patient-centered and is likely to be important to patients and their families [1]. Additional asthma outcome metrics are also commonly used in asthma trials including asthma control, health care utilization, and exacerbation rates [1,19–21]. Health care utilization and exacerbations cover only limited impact of patient’s daily lives usually requiring an unknown and potentially variable “burden” threshold to be met before a patient considers seeking health care for symptoms or an exacerbation [20]. Asthma control combines symptoms frequency and symptoms impact into a composite outcome [19,21]. Conversely, symptom free days and the *SFDQ* tool focuses on a single outcome – symptom frequency.

However, the internal consistency of the specific *SFDQ* we assessed in our study results in only fair internal concordance. There are several possible reasons for this. Patients may not approach this as a mathematical issue and simply record the number of days of no symptoms rather than as 14 days minus the number of days with any symptom. Further, the *SFDQ* reading level is high and several questions include long, complex, and compound sentences. The reading level of the instrument is 12th grade per the Flesch–Kincaid reading level assessment [22]. This is significantly above the 5th to 6th-grade reading level commonly recommended for information given to the general public or for public surveys [23] (Table 1). The complexity of the questions is illustrated by questions 3 and 4. Question 3 asks “In the past 14 days how many nights did you wake up/” The juxtaposition of day and night could be confusing. Similarly, question 4 begins with a 43-word sentence that includes one parenthetical phrase and a colon and asks the patient to think about all three asthma signs or symptoms and then lists six categories of problems. The final question also may be confusing when asking “How many days did you experience any day with NO daytime or nighttime symptoms.” These examples suggest the *SFDQ* also has low face validity and could benefit from careful question re-construction and testing.

The difference in the assessment of days and nights with symptoms and symptom free days may also be impacted by the patient’s conceptualization of symptoms and having no symptoms. As highlighted in Leventhal’s Common-Sense Model [24], the patient’s response may be affected by perceptions related to

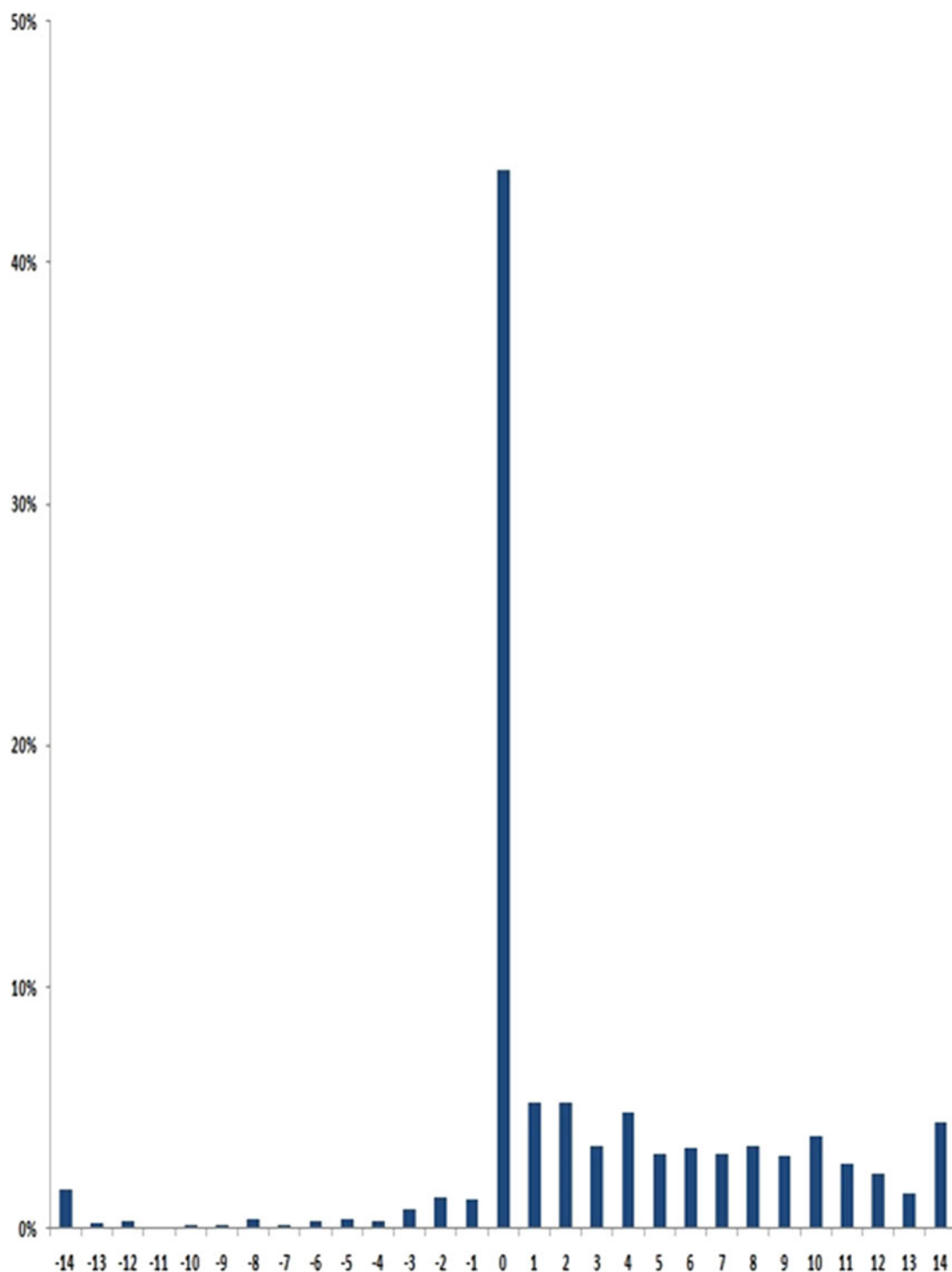


Figure 1. Lin ccc of the SFD regarding the number of days with and without symptoms. The calculation is the sum of the number of days with symptoms and the number of days without symptoms subtracted from 14. Perfect internal consistency would result in 100% of results being zero.

somatic and functional changes and personal expectations of the severity, changes, impact perceived cause and consequences of any asthma-related “burden”. Recent exacerbations, changes in treatment, asthma education or family experience with asthma might impact what is considered a symptom free day

without modifying the reporting of frequency of wheezing, coughing or shortness of breath [25–27]. Future validation or redesign efforts for the SFDQ should consider including a better understanding of patient’s conceptualization of both specific symptoms, such as shortness of breath but also the patient’s view

Table 5. Lin concordance correlation coefficient for SFD internal consistency.

Group	Time of survey administration			
	Baseline <i>N</i> = 1018	1 month <i>N</i> = 929	6 months <i>N</i> = 783	12 months <i>N</i> = 499
All	0.33 (0.28–0.38)	0.25 (0.21–0.30)	0.32 (0.27–0.38)	0.31 (0.25–0.38)
Sex				
Male	0.27 (0.18–0.37)	0.28 (0.18–0.37)	0.37 (0.30–0.47)	0.28 (0.14–0.43)
Female	0.35 (0.29–0.40)	0.25 (0.19–0.30)	0.31 (0.25–0.37)	0.33 (0.25–0.40)
Age				
<45 years	0.35 (0.28–0.42)	0.24 (0.17–0.31)	0.31 (0.22–0.39)	0.32 (0.22–0.42)
≥45 years	0.31 (0.25–0.38)	0.26 (0.20–0.33)	0.34 (0.27–0.41)	0.31 (0.22–0.40)
Region				
Florida	0.32 (0.22–0.41)	0.41 (0.32–0.50)	0.57 (0.48–0.66)	0.37 (0.22–0.51)
New England	0.43 (0.35–0.51)	0.30 (0.21–0.40)	0.41 (0.31–0.51)	0.29 (0.17–0.40)
Midwest/South	0.23 (0.16–0.30)	0.14 (0.07–0.21)	0.18 (0.11–0.26)	0.31 (0.22–0.41)
Income				
Income <\$20,000	0.31 (0.20–0.41)	0.18 (0.08–0.29)	0.35 (0.24–0.40)	0.34 (0.20–0.48)
\$20–50,000	0.29 (0.23–0.35)	0.23 (0.17–0.29)	0.30 (0.24–0.37)	0.26 (0.17–0.34)
>\$50,000	0.45 (0.34–0.56)	0.41 (0.30–0.54)	0.40 (0.27–0.53)	0.47 (0.33–0.60)
Rates at or below level of poverty for patient's community				
>50%	0.40 (0.25–0.55)	0.22 (0.06–0.38)	0.32 (0.15–0.49)	0.36 (0.17–0.55)
20–50%	0.30 (0.23–0.36)	0.22 (0.16–0.28)	0.37 (0.30–0.44)	0.26 (0.17–0.35)
<20%	0.36 (0.27–0.44)	0.33 (0.24–0.41)	0.26 (0.17–0.36)	0.38 (0.27–0.49)

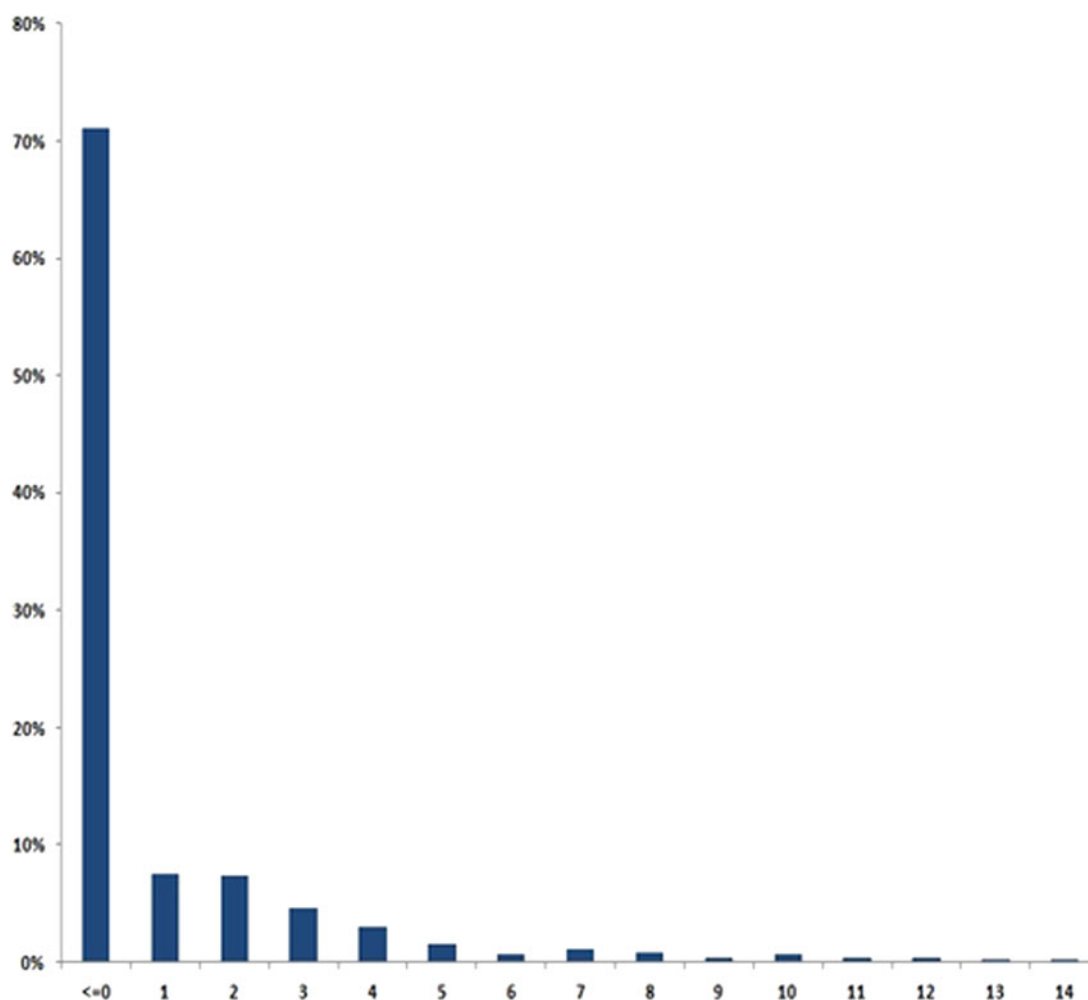


Figure 2. Display of the internal consistency of the SFD by comparing the largest of the number of days or nights with one or more symptom (Q#1, Q#2 or Q#3) and the total number of days or nights with any symptom (Q#4). Internal consistent requires that the response to Q#4 (how many days or nights with symptoms) be at least as large as the largest of the responses to Q#1, Q#2 or Q#3. Therefore, [(Q#1, Q#2 or Q#3) – Q#4] should always be <0.

of how they conceptualize a “symptom free day” [27]. Symptom free days are often reported as days free of symptoms per year which requires extrapolating from the two-week period assessed in the *SFDQ* to 52 weeks. The extrapolation from the reporting period of two weeks for the *SFDQ* to day free of symptoms per year greatly magnifies the problems with the internal inconsistency of the specific *SFDQ* as a PRO tool. Results reported over 2 weeks must be multiplied by 26 to obtain the number of days in the 52 weeks of a year. For example if the inconsistency of the *SFDQ* reported over 2 weeks is one day, it becomes a 26-d difference when reported over 1 year. Our data suggest that reported days free of symptoms per year could differ by 26 or more days per year or more in 57.2% of patients at baseline (Figure 1) and 47.5% at 12 months (data not shown) simply due to instrument-related internal inconsistencies making it difficult to know whether or not the number of days free of symptom actually improved over the year. We found no evidence of patient “learning” over the study period suggesting that simply exposing the patients to the questionnaire before gathering data is unlikely to improve the problem of internal consistency.

The NIH asthma outcomes workgroup report from 2012 did not recommend the *SFDQ* we studied as a “core” asthma outcome measure even though it has been used in several large trials [12,20,21]. The report states that there is lack of consensus of how to measure or define symptom free days and the psychometric properties of the *SFDQ* are unclear. Therefore, it is listed as an emerging measure or tool [1,2].

The widespread use of the *SFDQ* in large asthma trials has led many investigators to continue to use the questionnaire. However, we found no studies in the peer-reviewed literature formally assessing the psychometric properties of this instrument, including the level of basic literacy, health literacy or numerical literacy required to complete this questionnaire. Our data suggest that the *SFDQ* did not work well in our Black adult patients enrolled in the BELT study. Further validation work must be completed before the *SFD* is used in any other large trials.

The generalizability of our study results is limited by the inclusion of only Black adults in our large study population. Furthermore, those adults were required to have inadequately controlled asthma on ICS mono-therapy, thereby limiting our study population to those requiring combination therapies. Indeed, over half of the patients reported uncontrolled asthma at enrollment. It is possible that the internal consistency and criterion validity would be different in other

populations of different ages, races, socio-economic mixtures or differing levels of asthma control. However, it is also a strength that we report results from a large population of Black or African American adults highlighting the need to assess validity of PRO tools in racial, ethnic and possibly, specific age groups. We do report the data at several time points over a year demonstrating no improvement in internal consistency or concordance with time.

Conclusions/key findings

Based on the results from this population of Black adults with high rates of inadequately controlled asthma, the *SFDQ* does not appear to be internally consistent with a Lin ccc considered to represent only fair concordance. While results might be different in other racial, ethnic or younger age groups, the scope of the problems identified in using the *SFDQ* suggests that the tool requires further evaluation and validation before continued use and that alternative tools may need to be developed.

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

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