- SABA Reliance Questionnaire (SRQ): identifying patient beliefs underpinning reliever over-reliance in
 asthma
- 3 Running title: SABA Reliance Questionnaire
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22	Funding: This study	y was supported by	y Spoonful of	Sugar Ltd, a UC	L Business s	pin-out com	pany, in

- 23 collaboration with IPCRG and Asthma Right Care, with funding from AstraZeneca. AstraZeneca had no
- 24 part in the design, data collection, analysis, or interpretation of the study data.

25 Conflicts of interest

- 26 Amy Chan: Director of AHYC Consultancy Ltd, providing freelance consultancy to UCL-business company
- 27 Spoonful of Sugar Ltd; grants from Innovate UK, A+ charitable trust (Auckland District Health Board), and
- 28 Maurice and Phyllis Paykel trust, outside the submitted work.
- 29 Caroline Katzer: Employee of a UCL-Business company (Spoonful of Sugar Ltd) providing consultancy on
- 30 supporting patients with medicines and treatment-related behaviours to healthcare policy makers,
- 31 providers and industry.
- 32 Alan Kaplan: Advisory Board or Speaker bureau: Astra Zeneca, Behring, Boehringer Ingelheim, Covis,
- 33 GSK, Merck Frosst, Griffols, Johnson and Johnson, Novartis, NovoNordisk, Paladin, Pfizer, Sanofi, Teva,
- 34 Trudell, Purdue
- 35 John Haughney: Grants/research support from AstraZeneca, Boehringer Ingelheim, Orion; Honoraria/
- 36 consultation fees from AstraZenexa, Boehringer Ingelheim, Cipla, Chiesi, Orion and Teva
- 37 Jaime Correia de Sousa: Grants/research support from GSK and AstraZeneca; Advisory board/ Speaker's
- 38 Bureau: AstraZeneca; Boehringer Ingelheim, GSK, Mundipharma
- 39 Siân Williams is CEO of the International Primary Care Respiratory Group which has received funding
- 40 from AstraZeneca to develop the IPCRG Asthma Right Care initiative.
- 41 Rob Horne: Grants/research support AstraZeneca; National Institute for Health Research (NIHR),
- 42 Collaboration for Leadership in Applied Health Research and Care (CLAHRC), North Thames at Bart's
- 43 Health NHS Trust and Asthma UK (AUKCAR); Honoraria/consultation fees: Abbvie, Amgen, Astellas,
- 44 AstraZeneca, Biogen, Erasmus, Idec, Gilead Sciences, GlaxoSmithKline, Janssen, Merck Sharp Dohme,
- 45 Norvartis, Pfizer, Roche, Shire Pharmaceuticals, TEVA. Founder and shareholder of a UCL-

- 46 Business company (Spoonful of Sugar Ltd) providing consultancy on supporting patients with medicines
- 47 and treatment-related behaviours to healthcare policy makers, providers and industry.

48

49 Highlights

- 50 What is already known about the topic?
- 51 There is a call to move away from the use of short-acting beta₂ agonists (SABA) alone to manage
- 52 asthma.
- 53 Many patients continue to be overly reliant on and overuse SABA.
- 54 No current assessment exists to evaluate the patient-related risk of SABA over-reliance.

55 What does this article add to our knowledge?

- 56 This paper presents a novel self-assessment tool the SABA Reliance Questionnaire (SRQ) to
- 57 assess perceptions of SABA that can drive over-reliance and overuse of SABA.
- 58 The paper reports on the psychometric properties of the SRQ, providing evidence of validity and
- 59 internal reliability.
- 60 How does this study impact current management guidelines?
- 61 Traditional assessments of asthma control and medication use do not shed any light on the
- 62 factors influencing asthma outcomes.
- 63 The SRQ can measure the patient beliefs that drive medication use and asthma control, thus
- 64 informing interventions to reduce inappropriate medication use and improve control.

- **Keywords:** asthma, reliever, short-acting beta₂ agonists, risk, questionnaire, measure, screening tool,
- 67 SRQ, reliance, control

69 Abbreviations

BMQ	Beliefs about Medicines Questionnaire
GINA	Global Initiative for Asthma
ICS	Inhaled corticosteroids
IPCRG	International Primary Care Respiratory Group
MARS	Medication Adherence Report Scale
mTurk	Amazon Mechanical Turk
NHS	National Health Service
SABA	Short-acting beta ₂ agonists
SD	Standard deviations
SRQ	SABA Reliance Questionnaire (SRQ)

71 Abstract (250 words)

Background Patient over-reliance on short-acting beta₂ agonists (SABA), with concomitant underuse of
 inhaled corticosteroids (ICS), is associated with poor asthma control and increased risk of asthma
 attacks.

75 **Objective** To develop and validate a brief questionnaire to elicit patients' perceptions of SABA (e.g. 76 belief that asthma is best managed by SABA alone) that could lead them to be overly reliant on SABA. 77 Methods The 5-item SABA Reliance Questionnaire (SRQ) was adapted from the well-validated Beliefs 78 about Medicines Questionnaire (BMQ) assessing patient perceptions of the importance of, and necessity 79 for, SABA in managing their asthma. The psychometric properties of the questionnaire were studied 80 using Amazon Mechanical Turk (mTurk), an online survey platform, in 446 people with self-reported 81 asthma. Internal reliability and criterion-related validity were assessed based on relationships between 82 SRQ scores and other variables, including self-reported adherence to ICS and perceived importance of 83 reliever inhalers. 84 **Results** Internal reliability was good with Cronbach's α = 0.74. Criterion-related validity was 85 demonstrated by inverse correlation between SRQ scores and self-reported adherence to ICS (r = 86 -0.291, p<0.0001), and significant correlation between SRQ scores and perceived reliever importance (r 87 = 0.216, p<0.0001), as well as by significant differences in SRQ scores between those with high vs. low

self-reported ICS adherence (adherence to ICS t = 4.825, p<0.0001).

Conclusions The SRQ demonstrated acceptable internal reliability, and criterion validity, supporting its
 potential utility as a pragmatic tool for identifying patients whose beliefs are indicative of over-reliance
 on SABA for asthma.

92

94 Introduction

95 Asthma is one of the most common long-term conditions worldwide, affecting over 339 million people 96 globally(1). Asthma has traditionally been managed pharmacologically using two strategies: 1) 97 bronchodilation providing symptom relief using short-acting beta₂ agonists (SABA), and 2) inhaled 98 corticosteroids (ICS) to reduce airway inflammation and prevent asthma attacks. Recently, asthma 99 management guidelines have taken a paradigm shift, whereby the importance of anti-inflammatory 100 treatment – in particular ICS – in the early stages of treatment has been reinforced, but crucially, the use 101 of SABA therapy alone is discouraged(2). The recent Lancet Commission on Asthma(3) and Global 102 Initiative for Asthma (GINA) report(4, 5) both advocate for a move away from the use of SABA alone for 103 asthma management. Although SABA provides short-term symptom relief, there is strong evidence that 104 SABA use alone does not protect against asthma attacks, and that regular or frequent use of SABA 105 increases the risk of asthma attacks(4) and mortality(6). The negative effects of SABA overuse can be 106 rapid – the odds of asthma-related admissions are increased by 1.45 in the three-month period 107 following SABA overuse – and overuse can increase asthma-related costs(7). 108 Despite the risks associated with inappropriate SABA use, SABA over-reliance remains common(8) and is 109 typically paralleled by underuse of ICS. Indeed, ICS adherence rates are typically only 25–35%, thus 110 reinforcing risks of SABA over-reliance(5, 9). This inappropriate SABA use may lead to delays in 111 necessary medical review, and increases the risk of subsequent hospitalisation and severe attacks of 112 asthma(6). However, reducing SABA over-reliance is challenging; it requires changes in the behaviour of 113 both clinicians (e.g. avoiding prescribing SABA monotherapy for asthma or supply of SABA monotherapy 114 over the counter in countries where SABA is available in pharmacies as non-prescription medicines) and 115 patients (e.g. avoiding over-reliance of SABA and engaging with anti-inflammatory treatments)(2-4). For 116 clinicians, this may represent a fundamental practice change from years of recommending SABA as the

mainstay of reliever treatment in milder forms of asthma, to recommending anti-inflammatory reliever
 treatment comprising ICS and beta₂ agonists, either in a single combination or two separate inhalers.

119 Motivating and enabling patients to reduce inappropriate SABA use also has its own challenges. Simply 120 providing information and informing patients about the change in guidelines and asthma management is 121 unlikely to be sufficient to change behaviour(10). Many patients are 'attached' to their SABA, believing 122 this to be the best way to control their asthma(11, 12), and thus need to be convinced of their personal 123 need to change treatments. Moreover, they may be unaware that their way of using SABA (e.g. more 124 than three times a week) is now considered to be excessive(4). Discussions between healthcare 125 professionals and patients that are designed to support patients to adjust their asthma self-126 management in accordance with guidelines are likely to be more effective if they take account of 127 underlying beliefs influencing how the patient uses their treatment and manages their asthma(10). 128 Patients' perceptions of asthma and treatment often differ from those of healthcare professionals(13). 129 For example, many patients see asthma as a short-term episodic, rather than long-term, condition, and 130 this perception reinforces an over-reliance on SABA (for rapid symptom relief) and underuse of ICS(14). 131 Qualitative studies of adults with asthma found that in patients with high SABA use, SABA overuse 132 'made sense' to them, as SABA gave them the quick symptom relief they desired. High SABA users 133 placed higher importance on rapid symptom relief than prevention(12, 15, 16).

Patients with such beliefs may be sceptical about switching from SABA to other asthma management
strategies, such as using ICS/formoterol combinations for both maintenance and reliever therapy(17),
even when such a switch is recommended by trusted clinicians acting on evidence-based guidelines.
When convincing patients to use less SABA and more anti-inflammatory treatment such as ICS, it may
first be necessary to identify and address potentially misplaced beliefs about the importance of
SABA(18, 19). However, the underlying beliefs influencing patient engagement with treatment are often
not revealed within time-limited consultations. Therefore, for busy clinicians, the first step towards

helping patients recognise the dangers of SABA overuse and change their behaviour accordingly is to
identify those whose perceptions of SABA place them at risk of SABA over-reliance, thus identifying
them for early review and intervention(20).

144 There are currently no validated methods available to systematically assess the beliefs that patients hold

about their SABA therapy. Existing measures available focus on either general beliefs about

treatment(21) or the illness(22), or on overall asthma inhaler use(23), rather than on beliefs about SABA

147 specifically. The SRQ was developed to fill this gap. This paper describes the development and validation

148 of this new questionnaire – the SRQ – which assesses and identifies patients' key beliefs that drive SABA

149 over-reliance.

150 Methods

151 Item development of the SABA Reliance Questionnaire (SRQ)

152 Statements assessing patients' perceptions of SABA use were adapted from the 5-item Necessity scale of 153 the Beliefs about Medicines Questionnaire (BMQ)(21). The BMQ is a widely used, well-validated 154 questionnaire that measures patients' beliefs about treatment(21), particularly their personal need or 155 concerns about treatment. The statements in the 5-item BMQ Necessity scale were adapted to generate 156 5 items that mapped onto the concept of personal need for SABA. The statements were chosen to 157 reflect the beliefs likely to be associated with SABA over-reliance, identified from previous research on 158 beliefs about SABA(12) and from consensus discussions with the International Primary Care Respiratory 159 Group (IPCRG). These statements were then reviewed by a multidisciplinary expert panel. The items 160 captured the key beliefs reported in the literature that are linked with SABA over-reliance(12, 16, 19). 161 Each of the statements describes a key concept relating to SABA over-reliance: symptom relief, anxiety, 162 reliever place in therapy, benefit vs. risk, and preference over controller therapy (for access to the actual 163 wording of the items, contact author Professor Rob Horne). The original 5-point Likert response options

164 (strongly disagree to strongly agree) were retained from the BMQ. This process resulted in the

165 development of the SRQ (see Online Repository Text A1).

166 A 5-item questionnaire was proposed with the potential to be used for two purposes: 1) as a *screening*

tool to identify patients who are a priority for intervention (e.g. discussions with clinician) to reduce

SABA over-reliance, and 2) to *identify* the key beliefs driving SABA over-reliance that could be targets for

169 modification within the intervention.

170 In accordance with the BMQ Necessity scale scoring, each of the 5 items of the SRQ was scored on a 5-

point Likert scale with 1 = strongly disagree and 5 = strongly agree. Total scores ranged from 5 to 25,

172 with higher scores indicating higher necessity beliefs for SABA (i.e. higher reliance on SABA).

173 Testing the reliability and validity of the SRQ

174 Participant population

175 Participants were recruited using the Amazon Mechanical Turk (mTurk) platform, an online participant 176 recruitment portal where participants are invited to complete tasks requiring human involvement and 177 are reimbursed with small monetary rewards. This method of conducting studies on mTurk has been 178 increasingly used in research due to its cost-effectiveness, efficiency, reliability, and ability to rapidly 179 recruit a diverse sample of participants whilst generating findings that appear comparable with those 180 collected via more traditional recruitment means(24). In this study, participants self-selected 181 questionnaire completion by responding to the online survey link posted on the mTurk platform and 182 completed a set of screening questionnaires to confirm study inclusion eligibility. The online 183 questionnaires hosted on mTurk (see below for questionnaire descriptions) were open to participants 184 who self-reported a diagnosis of asthma and were at least 18 years old. In accordance with the General 185 Data Protection Regulations, no additional demographics data were collected to ensure a de-identified 186 dataset could be used. Participants were reimbursed US\$3 for completion of the survey. According to an online review by the UK NHS Research Ethics Committee, no further ethical approval was deemednecessary for this study(25).

189 *Item analysis*

Descriptive analyses of each SRQ item was conducted to describe the means, standard deviations, and frequency distributions of participants' responses to each of the 5 items. This item analysis identified the percentage of respondents who responded agree/strongly agree to each of the 5 scale items. Frequency distributions for the whole 5-item scale were also calculated. This was based on the participants' mean SRQ scores, calculated by adding the response score for each item, then dividing by the number of items (5) to produce a mean overall score between 1 and 5.

196 Reliability testing

197 An internal reliability analysis assesses the consistency of results across items within a questionnaire and

is useful for determining the value that each respective scale item adds to the overall questionnaire. This

analysis produces Cronbach's α values for each scale item and for the whole questionnaire. Cronbach's α

values are the widely accepted measure of internal reliability (Cronbach's α >0.7 acceptable) and

indicate how closely related a set of scale items are as a group(26, 27). This enables researchers to

determine how necessary it is to include each specific item within the questionnaire.

To assess the internal reliability of the questionnaire, Cronbach's α for the 5 items combined was
calculated to assess the SRQ's overall internal reliability. This was also calculated for the remaining 4
items with each item deleted one at a time to evaluate each item's contribution to the internal
consistency reliability of the SRQ.

207 Validity testing

208	Validity relates to evaluating whether the questionnaire measures what it intends to measure, i.e. how
209	beliefs about SABA importance influence asthma inhaler use. As there is no 'gold standard' measure of
210	SABA beliefs, validity for the SRQ was judged based on the relationship between the SRQ and other
211	relevant constructs (i.e. criterion validity). Criterion validity assesses the extent to which a measure is
212	related to an outcome. Specifically, Pearson's correlation coefficients were calculated to explore
213	whether there were significant relationships between the SRQ composite score (based on total
214	participants' responses to the 5 scale items), and the following: perceived reliever importance, and a
215	self-report measure of adherence to ICS therapy.
216	Criterion validity
217	Criterion validity of the SRQ was assessed in terms of the following hypotheses:
218	- Perceived reliever importance
219	As the SRQ was developed to assess patient necessity beliefs driving SABA over-reliance, it was
220	hypothesised that higher SRQ scores would be related to higher perceived reliever importance. To
221	assess patients' perceptions of the importance of their reliever inhaler, a visual analogue scale (VAS) was
222	used. Participants rated importance on a scale from 0 (not important at all) to 10 (very important), in
223	response to the question 'how important is your reliever (SABA) medication?'.
224	Secondly, SRQ scores were compared between participants who rated their reliever as very important
225	(based on the VAS for perceived reliever importance scores of 8 and above) and those who rated their
226	reliever as low-moderate importance. A sensitivity analysis was conducted using VAS cut-offs of 9 and
227	above, instead of 8 and above, to see if this would impact findings.
228	- Self-reported adherence to ICS

SABA over-reliance is generally associated with poor adherence to ICS (underuse)(28). As such, it was
hypothesised that high SRQ scores would be associated with lower ICS adherence. The Medication
Adherence Report Scale for asthma (MARS, Online Repository Text A2)(29) was used to assess
medication-taking behaviours related to participants' use of ICS: this was adapted to produce a 9-item
MARS-ICS scale. Each of the 9 MARS-ICS items represent a medication-taking behaviour related to poor
adherence, e.g. '*I only use it when I need it*'. These items were rated on a scale from 1 (always) to 5
(never), with higher scores indicating better adherence.

236 To further demonstrate criterion validity, we conducted an independent-samples t-test was to 237 investigate whether there was a significant difference in SRQ composite scores between those with low 238 and those with high adherence scores on the MARS-ICS. The cut-off scores for low and high adherence 239 were determined by the sample responses to the MARS-ICS by calculating the maximum potential score 240 on the MARS-ICS (45), and identifying those participants scoring within the highest third (i.e. 31 and 241 above) and the lowest third (scoring 24 and below), respectively. Those in the top third were considered 242 to have high adherence; those in the lowest third had low adherence. To check whether using a 243 different definition of 'high' and 'low' adherence would impact on the analysis, a sensitivity analysis was 244 conducted using different MARS-ICS cut-off points; high and low adherence groups were defined as 245 those scoring in the top and bottom 30% of the sample (as opposed to top and bottom third).

246 Results

A total of 446 participants completed the Amazon mTurk survey. The final SRQ contained 5 items that
evaluated patients' beliefs about SABA.

249 Univariate analysis of scale items

250 Means and standard deviations

- 251 Table 1 reports on the means and standard deviations (SDs) of the participants' scores to each of the 5
- scale items on the SRQ. Higher scores are indicative of a stronger personal need for SABA.

253 Table 1 here

254

255 Frequency distributions

Figure 1 illustrates the percentage frequency distributions of participants' mean SRQ scores for the

257 whole 5-item scale. The mean for the sample population was 3.6 showing that participants' responses

trend slightly more towards agree/strongly agree, indicating a higher overall risk of SABA over-reliance

- in this sample when considering the overall SRQ score.
- 260 Figure 1 here
- 261

262 Item analysis of questionnaire items

263 Figure 2 illustrates the percentage of participants that responded either agree or strongly agree to each 264 of the 5 scale items of the SRQ. This figure shows that agreement was high (>50% of participants) for 265 each item. Overall, 92.6% of participants scored above the scale mid-point on the SRQ indicating strong 266 beliefs in their personal necessity for SABA. Item 1 (symptom relief) was the item that most participants 267 agreed or strongly agreed with (71.8%). In contrast, item 3 (reliever place in therapy) had lower 268 agree/strongly agree responses, but still over half of the sample agreed/strongly agreed with this. 269 Collectively, the participants' agreement with the statements of the SRQ showed that participants 270 overall held high necessity beliefs about their reliever medication, i.e. had high perceptions of personal 271 need for SABA treatment in managing asthma (Figure 2).

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273	Figure 2 here
274	
275	Internal reliability analysis
276	Overall, the SRQ demonstrated good internal reliability (Cronbach's α = 0.74), according to George and
277	Mallery's (2003) rule of thumb(27). Table 2 shows that the internal reliability of the SRQ was not
278	improved by removing any of the included scale items. This indicates that each of the 5 items was a
279	valuable addition to the scale's overall internal reliability, i.e. no items were redundant.
280	
281	Table 2 here
282	
283	Criterion validity analysis
284	In line with study hypotheses, SRQ scores were significantly positively correlated with the VAS item 'how
285	<i>important is your reliever (SABA) medication?</i> (r = 0.216, p<0.0001). Those who scored highly on the
286	SRQ, indicating higher over-reliance on SABA, also perceived their SABA medication to be important (see
287	Figure 3a).
288	There was a significant difference in SRQ scores in patients who rated their reliever as very important on
289	the VAS (\geq 8) vs. low–moderately important (\leq 7) (t = –5.006, p = 0.037). Those rating their reliever as
290	very important had higher mean (SD) SRQ scores of 18.9 (3.9) (N = 241) compared with those rating
291	their reliever as low–moderately important, whose mean (SD) score was 17.2 (3.4) (N = 205). The

sensitivity analysis conducted with 'very important' (defined as importance scores on the VAS ≥9 [as

293 opposed to ≥ 8]), and 'low-moderately important' (defined as scores of ≤ 8 [as opposed to ≤ 7]) gave 294 similar significant results.

There was a significant negative correlation between SRQ and MARS-ICS (adherence) scores (r = -0.291,

296 p<0.0001), indicating that patients with stronger beliefs in the personal necessity of SABA (high SRQ

scores) were significantly more likely to self-report low adherence to ICS (see Figure 3b).

298

299 Figures 3a and b.

300

301 The SRQ scores were different between patients reporting high vs. low adherence to ICS (t = 4.825,

302 p<0.0001). As predicted, those with low ICS adherence had significantly stronger beliefs in their personal

303 need for SABA than those reporting high ICS adherence: mean (SD) SRQ scores for the low ICS

adherence group (N = 156) = 19.7 (2.9) vs. 17.6 (4.4) for those reporting high adherence to ICS (N = 144).

305 The mean difference in SRQ scores between high and low ICS adherence groups was 2.05 (95%

306 Confidence Interval (CI), 1.21–2.88). The sensitivity analysis using the top and bottom 30% of the MARS-

307 ICS scores as cut-offs to define high and low adherence groups showed similar results.

308 Discussion

This is the first paper to report on the development and validation of a screening tool to assess patient perceptions of SABA reliever and risk of over-reliance. Inappropriate SABA use is associated with worse asthma outcomes(2, 4, 6) and is a key intervention target in current asthma management, as highlighted in the recent Lancet Commission on Asthma and GINA guidelines update(3, 4). However, tackling SABA over-reliance is challenging(18), as this requires changes in patients' behaviours, which are influenced by their beliefs about SABA(12, 16). An important first step towards tackling inappropriate SABA use is identifying patients who are at risk of overusing SABA. This SRQ is the first tool to systematically and pragmatically assess and identify beliefs that put patients at risk of SABA over-reliance. It captures the key findings from current literature on SABA and insights from practice about the patient beliefs that seem to drive SABA over-reliance(12, 16, 23, 30, 31). The resulting questionnaire is a summary of the literature findings and is based on the structure of the BMQ – a well-validated and widely used measure of treatment beliefs. This brief 5-item questionnaire can be used pragmatically to systematically assess and identify patients' beliefs associated with SABA use in practice.

322 Currently, evaluation of SABA use is limited to using prescribing and/or dispensing data, yet these data 323 are not always easily available and may not be accurate, particularly if patients use more than one 324 pharmacy, share SABA inhalers, or obtain SABA without a prescription, for example in countries where 325 SABA are available over the counter(16). Moreover, although SABA prescribing and dispensing data may 326 provide an indication of how patients are using SABA, they do not reveal why patients are using SABA in 327 the way they do. This study provides the first evidence to support the use of the SRQ as a potential tool 328 to identify key beliefs about SABA that may need to be addressed if patients are to be persuaded to 329 reduce their SABA over-reliance. The SRQ provides clinicians a brief, pragmatic way to systematically 330 assess the beliefs that underpin SABA over-reliance, thus facilitating clinician-patient discussions on 331 what could be targets for intervention in a way that is tailored to the patient. The SRQ can be used with 332 other tools, such as medication possession ratios or other information about patterns of SABA use, to 333 provide insights into the reasons behind SABA overuse, thus informing interventions to modify 334 inappropriate SABA use. For example, the IPCRG has developed a 'SABA slide rule' as a practical tool to 335 stimulate conversations about SABA use(32). The SRQ can be used with the slide rule by taking the 336 conversations initiated with the slide rule further, by exploring the reasons why the individual is over-337 relying on their SABA.

338 This study found that the SRQ may be used to differentiate between those with high and low ICS 339 adherence. In patients with high SRQ scores, indicative of higher personal need for SABA and risk of 340 over-reliance, the risk of poorer ICS adherence may be higher. This is in line with the hypothesis that 341 patients who have a high reliance on SABA do so because of a high perceived personal need for rapid 342 symptom relief, and potentially fears of using their ICS due to adverse effects with steroids; in this case, 343 using SABA rather than ICS makes more sense, leading to SABA over-reliance and ICS underuse(2, 12, 16, 344 19). The potential use of the SRQ in practice is three-fold: 1) as a screening tool, to identify patients at 345 risk of SABA over-reliance based on overall SRQ scores; 2) as an assessment tool, to identify the key 346 beliefs unique to the individual that drive SABA over-reliance, based on responses to the individual SRQ 347 items; and 3) as a proxy measure of ICS adherence, which can be confirmed using validated measures of 348 adherence such as the MARS-ICS.

As the SRQ provides both quantitative (numerical measure of SABA over-reliance risk) and qualitative information (about the beliefs driving over-reliance), it can potentially be used to monitor and measure changes over time in patient beliefs. However, as this present study was cross-sectional, as is common with questionnaire validation studies(33, 34), further research using the SRQ longitudinally is needed to determine test-retest reliability, how SRQ changes over time, and the predictive validity of the SRQ in relation to SABA use and outcomes.

Initial findings suggest good internal reliability and criterion validity , however, the correlations in the criterion validity analyses were low. This is potentially due to the finding that most respondents scored higher than the mid-point on the SRQ, and the self-reporting nature of the questionnaires used to establish criterion validity. In the absence of a more specific measure of SABA over-reliance, our measures of criterion validity were limited to two constructs that we hypothesised would be associated with SABA over-reliance (i.e. adherence to ICS as measured by MARS-ICS and perceived importance of SABA). Whilst there is a well-documented relationship between adherence to ICS and SABA use, the 362 relationship between these two measures are not consistently in the same direction in the literature. 363 Some patients may still have a high general reliance on SABA but maintain high ICS adherence; for these 364 patients any relationship between the two variables would act to counter the hypothesised relationship 365 in the opposite direction. Similarly, we used a visual analogue sale as a self-reported measure of 366 perceived SABA importance. Again, we did not expect a high correlation as the item is potentially 367 confounded by some patients who may rate their SABA as very important and rely on it too much, but 368 others may rate it as important but use it judiciously – these people within the sample would pull the 369 findings in the opposite direction of the hypothesised relationship. Additionally, as the MARS-ICS and 370 visual analogue scale relies on self-report, there is a risk of bias. This may have led to the small r values 371 observed. Whilst these r values would not usually be considered acceptable for proving criterion related 372 validity, as a preliminary test, we have accepted a smaller r value as an indicator of validity in the 373 absence of a more specific measure of SABA over-reliance. Further measures of criterion validity are 374 now warranted. . More detailed evaluations of the SRQ using objective estimates of actual SABA inhaler 375 use are needed to confirm these initial findings.

376 Further work is also needed to establish cut-off points with the SRQ to identify the threshold above 377 which the patient is identified as 'over-reliant'. However, these findings provide encouraging early 378 evidence that the SRQ does what it sets out to measure (as shown by its validity) and does so in an 379 internally consistent way (reliability). As with any survey, there is the limitation that the asthma 380 diagnosis could not be confirmed using objective measures as the diagnosis was self-reported. 381 Demographic information about the sample, such as asthma severity, treatment information, and 382 duration of diagnosis, was also not known. As treatment information was not included in the eligibility 383 screening, it is possible that some respondents may not have received controller treatment before. 384 There may also be differences in SABA over-reliance risk between patients on a fixed-dose, combination 385 controller inhalers and patients on ICS only. Further evaluation of the SRQ in clinical samples and

exploration of SRQ scores in patients on different treatment regimens are needed to confirm its validity
and reliability in other asthma populations. As the SRQ was developed in English and SABA over-reliance
is a global problem, the SRQ will need testing and adapting for use in other countries and cultural
settings to consider local variations, such as differences in availability of SABA, what SABA is referred to
as locally (e.g. reliever vs. rescue medication), and different cultural responses to risk.

Future research assessing these parameters are needed to provide more information on the reliability, validity and potential applications of the SRQ. Nevertheless, our data from this online sample provides preliminary evidence on the potential utility of this tool in assessing the beliefs that underpin SABA overreliance. The SRQ enables direct capture of the patient's voice, as it is patient self-reported, and allows clinicians to address the beliefs self-identified through the SRQ beyond a simple numerical measure of SABA over-reliance risk.

397 Conclusions

398 The SRQ is a novel measure that assesses patients' beliefs underpinning SABA over-reliance. The SRQ 399 demonstrated acceptable internal reliability, and criterion validity. This supports its potential usefulness 400 as a tool in asthma care that can help identify beliefs that may put patients at risk of SABA over-reliance, 401 and flag those individuals who would benefit from an asthma medication review and behaviour change 402 intervention to shift their beliefs about SABA. This questionnaire could be used as part of asthma 403 consultations, where healthcare professionals can screen patients for SABA over-reliance, and target 404 behaviour change interventions to those at highest risk, in a way that is individualised to the patient's 405 unique treatment beliefs about SABA. It represents an important first step towards addressing the 406 global issue of inappropriate SABA use.

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506 Figure legends

- 507 *Figure 1*: Percentage frequency distributions of participants' mean scores to the overall SABA Reliance
- 508 Questionnaire (SRQ) on a 5-point Likert scale (N = 446)
- 509 *Figure 2*: Item analysis of the 5 items of the SABA Reliance Questionnaire (SRQ)
- 510 Figure 3a and b. Scatterplots showing a. the association between perceived importance of SABA and
- reliance on SABA, b. the association between adherence to ICS and reliance on SABA. Higher adherence
- 512 (MARS), higher SABA over-reliance (SRQ) and higher perceived importance of SABA (VAS) are indicated

Table 1: Means and standard deviations (SDs) of each of the SABA Reliance Questionnaire's 5 scale items

Mean	SD
ne –	
v to keep 3.81	1.07
around 3.61	1.06
y rely on 3.50	1.13
outweigh 3.63	1.02
naler 3.57	1.10
	y to keep 3.81 r around 3.61 y rely on 3.50 outweigh 3.63

513 SABA = short-acting beta₂-agonist

Table 2: Cronbach's α of scale if scale item deleted

Scale item – SABA concept assessed*	
NB: item wording is copyrighted to Professor Rob Horne – please contact Professo	r deleted
Horne for permission to reuse	
1. Using my reliever to treat symptoms is the best way to keep on top of my	0.743
asthma	
2. I don't worry about asthma when I have my reliever around	0.760
3. My reliever is the only asthma treatment I can really rely on	0.738
4. The benefits of using my reliever inhaler massively outweigh any risks	0.751
5. I prefer to rely on my reliever than my preventer inhaler	0.732