

RESEARCH ARTICLE

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Assessing Asthma control in UK primary care: Use of routinely collected prospective observational consultation data to determine appropriateness of a variety of control assessment models

Gaylor Hoskins^{1*}, Brian Williams², Cathy Jackson³, Paul D Norman⁴ and Peter T Donnan¹

Abstract

Background: Assessing asthma control using standardised questionnaires is recommended as good clinical practice but there is little evidence validating their use within primary care. There is however, strong empirical evidence to indicate that age, weight, gender, smoking, symptom pattern, medication use, health service resource use, geographical location, deprivation, and organisational issues, are factors strongly associated with asthma control. A good control measure is therefore one whose variation is most explained by these factors.

Method: Eight binary (Yes = poor control, No = good control) models of asthma control were constructed from a large UK primary care dataset: the Royal College of Physicians 3-Questions (RCP-3Qs); the Jones Morbidity Index; three composite measures; three single component models. Accounting for practice clustering of patients, we investigated the effects of each model for assessing control. The binary models were assessed for goodness-of-fit statistics using Pseudo R-squared and Akaike's Information Criteria (AIC), and for performance using Area Under the Receiver Operator Characteristic (AUROC). In addition, an expanded RCP-3Q control scale (0-9) was derived and assessed with linear modelling. The analysis identified which model was best explained by the independent variables and thus could be considered a good model of control assessment.

Results: 1,205 practices provided information on 64,929 patients aged 13+ years. The RCP-3Q model provided the best fit statistically, with a Pseudo R-squared of 18%, and an AUROC of 0.79. By contrast, the composite model based on the GINA definition of controlled asthma had a higher AIC, an AUROC of 0.72, and only 10% variability explained. In addition, although the Peak Expiratory Flow Rate (PEFR) model had the lowest AIC, it had an AUROC of 71% and only 6% of variability explained. However, compared with the RCP-3Qs binary model, the linear RCP-3Q Total Score Model (Scale 0-9), was found to be a more robust 'tool' for assessing asthma control with a lower AIC (28,6163) and an R-squared of 33%.

Conclusion: In the absence of a gold standard for assessing asthma control in primary care, the results indicate that the RCP-3Qs is an effective control assessment tool but, for maximum effect, the expanded scoring model should be used.

Background

The ability to identify poor control is a pre-requisite for improving asthma. To achieve the guideline standards for asthma there is a necessity for primary health care professionals to efficiently assess and monitor symptom control. To do this they must utilise questions and tools

that are simple and brief to use, easy for the patient to understand, and have a scoring system meaningful to both practitioner and patient. Assessment of asthma control using a standardised tool is now considered good clinical practice [1,2]. There is, however, a lack of empirical evidence on the best tool to use in the primary care setting [3].

The complexity and variability of asthma makes prediction of treatment response difficult [4]. With such a complex disease, no single parameter can accurately

* Correspondence: g.hoskins@cpse.dundee.ac.uk

¹Population Health Sciences, School of Medicine, University of Dundee, Mackenzie Building, Kirsty Semple Way, Dundee, DD2 4BF, Scotland, UK
Full list of author information is available at the end of the article

classify and assess control in all individuals [5]. To build an accurate clinical picture, a range of criteria have to be assessed based on a patient's symptoms, sleep disturbance, use of rescue medication, daily activity limitation, patient and health professional overall assessment, and lung function. The concern is that patients, and indeed health professionals, often have a different understanding of the language used to describe control [6]. This creates a dilemma for those trying to improve the assessment and management of asthma.

In UK primary care, the tool most commonly used is the Royal College of Physicians 3 Questions (RCP-3Qs) [7]. Conceived as a practical clinical tool that 'makes sense to both clinician and patient' and 'improves standards of care' [7,8], its use has yet to be fully validated. Recently, Thomas et al. (2009) [9] indicated that when using the recommended Asthma Control Questionnaire (ACQ) threshold of 1.0 for 'well controlled' or 'not well-controlled' asthma, an RCP-3Q score of 0 was a good predictor of well controlled asthma but the study was small and the authors conceded that it could not be considered a validation study. There is also an argument that using standardised tools to assess and record relevant information may create a more physician-centred, or template-directed, consultation [10-12].

The UK Quality Outcomes Framework (QOF) rewards practices for use of screening questionnaires in other chronic conditions but not for asthma, despite the availability of recommended measurement instruments. Therefore, the absence of a gold standard screening tool for asthma is a barrier to its inclusion as a QOF outcome measure. This may in turn impact on the consistency of asthma review appointments in the community.

This paper adds to the limited knowledge available on asthma control screening tools by examining the appropriateness of a number of different models of asthma control assessment by:

- Creating models of control from an existing UK data set
- Using statistical modelling to identify the most appropriate model for assessing control.

Methods

Currently there is no recommended gold standard for assessing asthma control in primary care. Consequently, there is no gold standard against which a measure of asthma control can be assessed. There is, however, strong empirical evidence to indicate those factors which are strongly associated and predictive of asthma control. These include: patient characteristics such as age, weight, presence of symptoms and symptom pattern, as well as factors related to healthcare resource use and organisation and provision of care. As a result, we

would expect a good measure of control to be one whose variation was most explained by these factors, and a poor measure to be one which bears little relation to them. Therefore, utilising an extensive UK database, we used multiple regression techniques and statistical tests to examine a variety of current measures (assessing the derived models for fit and performance). We then identified which of them (e.g. GINA, RCP 3 questions) was best explained by the independent variables.

Recruitment and Data Collection

Between the beginning of January 2001 and the end of December 2005, over 1200 practices from throughout the UK participated in an electronic audit of asthma management. This provided cross-sectional observational review data for more than 78,000 patients from 0 to 99 years of age. The windows-based audit software was informed by the assessment recommendations of the British Thoracic Society (BTS) Guidelines for the management of Asthma and consisted of six data screens. Practice and patient personal details were completed prior to the consultation. The remaining screens, addressing symptoms, inhaler technique, use of self-management plans, compliance, health resource use, education, and therapeutic management, were completed during the consultation. The template acted as an aide memoir for conducting a thorough guideline-based asthma review. Based on previous audit experience [13,14], practices were encouraged to ask their patients about night-day-activity-related symptoms and medication use/compliance in the 4 weeks prior to the review; to observe and record peak expiratory flow rate and inhaler technique at the review; to record ownership and use of a self management plan, need for emergency medication, and health service resource use, since their last review.

For the purpose of the original audit, practice clinical systems were searched for patients > 4 years of age receiving preventative asthma medication BTS treatment step 2 within the previous 12 month period. Systems were also searched for patients who were over-using their β 2-agonist medication (more than 6 prescriptions for a short acting bronchodilator in the previous 12 months). Identified patients who met these inclusion criteria were then invited to the practice for a routine review of their asthma. The only exclusion criterion from the study was a co-morbidity of Chronic Obstructive Airways Disease (COPD). The review process was part of normal practice routine. Nurses were not expected to run special sessions in order to undertake the review but were instead required to fit it into their daily work schedule. Those patients who accepted the invitation for a review were asked for written consent for their consultation data to be downloaded

anonymously on a monthly basis to a central database at the research centre. Practices signed up to a 12 month audit service and over the course of the year were sent quarterly reports comparing their asthma management with current BTS guidelines. For the purpose of this study data analysis was confined to the information from the first review consultation. In addition, due to the differences in guideline management of children under 13 years of age to adults with asthma [1], only data on patients ≥ 13 years of age were included in the analysis.

Data Collection: Additional Data

Prior to analysis the quality of the data was reviewed. Whilst many of the variables were collected as a result of the routine asthma review some were added or enhanced for the purpose of the study. New patient variables were constructed from the existing data. This was then merged with the practice data which had been enlarged by the addition of information about the practice and its geographical area. The final dataset included a Body Mass Index score for each patient and a deprivation indicator for the local area ward in which each GP practice was located [15]. To investigate effects of urban or rural living on asthma control and management, a binary categorisation of rural/urban, [$< > 15$ persons per hectare (pph) [16]] was attributed to all practices in the dataset. Also added were: Quality Outcome Frameworks points for each practice; distance of the practice to the nearest district general hospital; and the availability of a respiratory specialist within that hospital. The variables used for the multi-level modelling process are itemised in Table 1.

Control Models

Figure 1 outlines the project process, the shaded area representing the methods and results described in this paper. The dependent binary outcome variable was poor control of asthma. Guided by two systematic reviews of the literature [17] eight binary (Yes = poor control, No = good control) models of asthma control were constructed (Figure 2) from the large UK database. The literature reviews were conducted according to strict methodological criteria (Figures 3 & 4) [18], and were designed to define 'poor' asthma control; and to identify the tools used in primary care to assess asthma control. The reviews identified a total of 26 asthma control assessment tools being used internationally in primary care. However, the range of control models constructed and analysed for this study were restricted by two things:

- The complexity of the scoring mechanism in some of the tools e.g. the Asthma Control Test (ACT) and

Table 1 Variables used for regression modelling.

Patient Variables	
Age	Rescue use inhaled steroid***
Gender	Rescue oral steroid***
Body Mass Index	Emergency Nebulisation***
Active Smoker	Scheduled Consult***
PEFR < 80% predicted/best*	Unscheduled Consult***
Symptoms**	Telephone Consult***
Days Off due to asthma**	Home Visit***
Regularly forget preventer*	Outpatient Visit***
Poor inhaler technique*	A&E visit***
No Self management plan	Admission to Hospital***
Overuse Short Acting Bronchodilator**	Asthma Symptoms** Night/Day/Activity
BTS Treatment Step	
Practice Variables	
Strategic Health Authority (SHA)	Number GPs in practice
SHA Deprivation	Full time (FT) Nurse in Practice
SHA Population	Number of FT Nurses
Primary Care Trust (PCT)	Part time (PT) Nurse in Practice
PCT Deprivation	Number of PT Nurses
PCT Population	Number of Nurses in practice
Ward Deprivation	Way Asthma Care Provided
Ward Population	Presence of Nurse Clinic
Rurality	Nurse with Diploma Level Asthma Training
Practice	Previous Asthma Audit
Practice Population	Previous use of Review Protocol
Full Time (FT) GP in Practice	Asthma UK QOF Points
Number FT GPs	Total UK QOF Points
Part time (PT) GP in Practice	Distance nearest District General Hospital
Number PT GPs	Respiratory Consultant at DGH

* Assessed at the review consultation

**In the 4 weeks prior to the review consultation

*** Since previous review

Note: Variables used in the construction of a control dependent variable were not used as an independent variable in the regression analysis for that particular control model

the Asthma Control Questionnaire (ACQ), made it impossible to model the asthma data to suit the score point for good and poor control.

- Many of the tools were based on the international criteria for good and poor control [2] thus reducing the necessity to model all the individual tools.

Thus, using the information from the literature reviews, the data were modelled to mirror two of the tools recommended by BTS/SIGN guidelines, the RCP-3Qs (Figure 5) and Jones Morbidity Index (JMI) (Figure 6), and three composite measures, one based on the

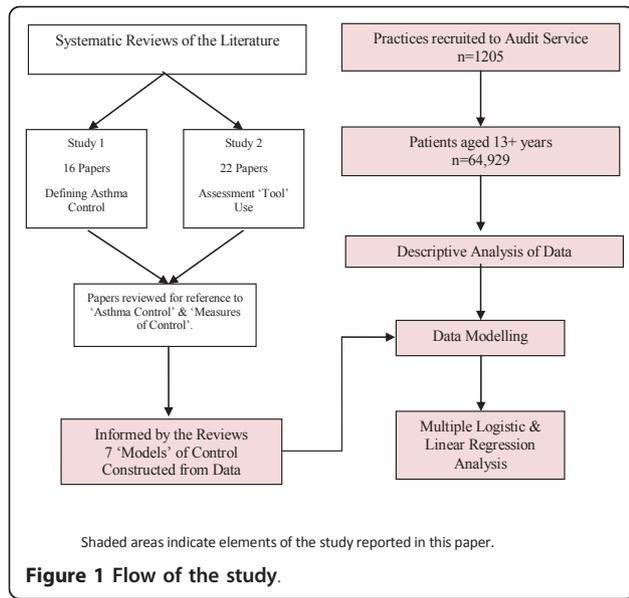


Figure 1 Flow of the study.

Global Initiative for Asthma(GINA) criteria [2] for controlled asthma, one on the GOAL study [19] criteria for total control, and another on the GOAL study [19] criteria for well/moderately controlled asthma. The GOAL

Systematic Review based Control Tool	Study Interpretation of Control Model
Specific Tool Control Assessment	
1 - RCP 3 Questions	
Poor Control = A positive answer to any question.	Poor Control = A positive answer to any question i.e. either day or night symptoms, or activity limitation.
Good Control = No to all questions	Good Control = No day or night symptoms and no activity limitation
2 - Jones Morbidity Index	
Low = 0 Yes answers Medium = 1 Yes answer High = 2-3 Yes answers	Poor Control = 'Yes' answer to any question i.e. night symptoms; symptom frequency; days off due to asthma. Good Control = No 'Yes' to any question
Composite Control Assessment	
3 - Controlled - GINA	
Daytime symptoms – ≤ 2 per week Nocturnal symptoms - None Activity limitation – None Reliever medication – Twice or less per week PEFR – Normal	Daytime symptoms = ≤ 2 APRS score Night-time symptoms = 0 APRS score Activity limitation = 0 APRS score Reliever medication = <1-2 per week All above in previous 4 weeks PEF ≥80% predicted on day of review.
4 - Moderately Controlled - GOAL study	
Daytime symptoms – 2-6 days/month Nocturnal symptoms - 3-4 nights/month Activity limitation – None Reliever medication – Minimal Days Off - None PEFR – Normal	Daytime symptoms = ≤ 2 APRS score Night-time symptoms = ≤1 APRS score Activity limitation = 0 APRS score Reliever medication = <1-2 per week Days Off = 0 All above in previous 4 weeks PEF ≥80% predicted on day of review.
5 - Totally Controlled - GOAL study	
Daytime symptoms – None/Minimal Night-time symptoms - None Activity limitation – None Reliever medication – None/Minimal Days Off - None PEFR – Normal	Daytime symptoms = 0 APRS score Night-time symptoms = 0 APRS score Activity limitation = 0 APRS score Reliever medication = <1-2 per week Days Off = 0 All above in previous 4 weeks PEF ≥80% predicted on day of review.
Single Item Control Assessment	
6 - Overuse of Short Acting Bronchodilator (SAB)	Poor Control = ≥ twice a day Good Control = ≤ once a day
7 - Peak Expiratory Flow Rate (PEFR)	Poor Control = <80% predicted/best Good Control = ≥80% predicted/best
8 - Severity by British Thoracic Society (BTS) treatment step	Severe = Steps 3, 4 or 5 Not Severe = Steps 0, 1 or 2

Figure 2 Asthma control assessment models constructed from the data.

Types of Study – Any of the following	
Review 1 & 2	
<ul style="list-style-type: none"> Randomised Controlled Trials Controlled trials Quasi-randomised trials Non-randomised trials Observational studies Systematic Reviews Meta-analysis Qualitative Studies 	
Types of Participant – All of the criteria must be met	
Review 1	Review 2
<ul style="list-style-type: none"> People >4 years of age with a diagnosis of asthma of any severity Health professionals in any setting 	<ul style="list-style-type: none"> People >4 years of age with a diagnosis of asthma of any severity being managed in primary care. Primary care based health professionals caring for people with asthma.
Types of Intervention – All of the criteria must be met	
Review 1	Review 2
<ul style="list-style-type: none"> Specifically defined asthma control. Took place in any setting, healthcare or otherwise. Discussed/compared results with usual practice or compared two (or more) interventions. 	<ul style="list-style-type: none"> Specifically defined the tool used for monitoring asthma control Utilised the monitoring tool within the review process. Took place in a primary care/general practice setting. Compared results with usual practice or compared two or more interventions.
Types of Outcome – All of the criteria must be met	
A priori identified outcomes or process measures of included studies	
Review 1	Review 2
<ul style="list-style-type: none"> Specifically quantified a definition of asthma control Described how the control definition was achieved 	<ul style="list-style-type: none"> Specified use of a tool for monitoring and managing asthma control Reported level of control Described how the tool was utilised in monitoring asthma control

Figure 3 Inclusion criteria for studies in the systematic review.

Types of Study	
Review 1	Review 2
<ul style="list-style-type: none"> Studies which focused on respiratory conditions other than asthma. Studies which combined asthma with other respiratory conditions but did not report asthma results separately. Control as a concept not defined, explained or discussed. Studies which focused on drug trials or were economic studies. 	<ul style="list-style-type: none"> Studies which focused on respiratory conditions other than asthma. Studies which combined asthma with other respiratory conditions but did not report asthma results separately. Control assessment as a concept not defined, explained or discussed. Studies which focused on drug trials or were economic studies.
Types of Participant	
Review 1 & 2	
<ul style="list-style-type: none"> Those with a respiratory condition other than asthma. 	
Types of Intervention	
Review 1	Review 2
<ul style="list-style-type: none"> Interventions which did not define asthma control. 	<ul style="list-style-type: none"> Interventions not related to the regular review and monitoring of symptoms and using a defined control assessment tool in a primary care setting.
Types of Outcome	
Review 1	Review 2
<ul style="list-style-type: none"> None given that relate to control definition. 	<ul style="list-style-type: none"> None given that relate to control measurement

Note: For the purpose of Study 2, a control assessment tool is that which has been designed to assess level of asthma control and is a written/electronic record of patient response to a number of questions

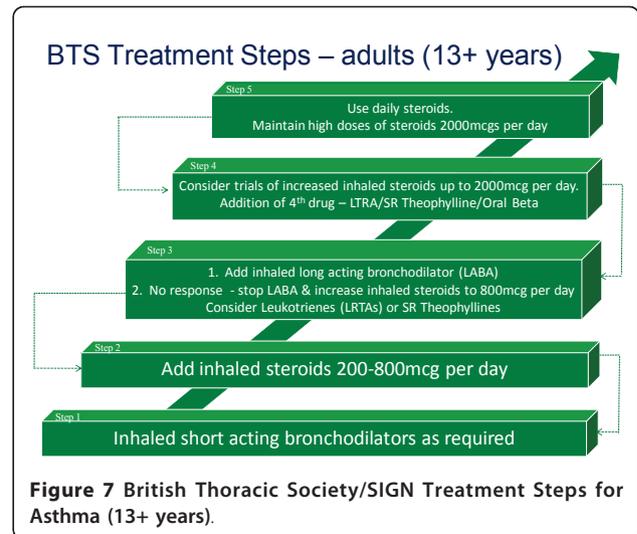
Figure 4 Exclusion criteria for studies in the systematic review.

Royal College of Physicians 3 Questions for Asthma
 No to all questions consistent with controlled asthma

In the last month	YES	NO
"Have you had difficulty sleeping because of your asthma symptoms (including cough)?"	<input type="checkbox"/>	<input type="checkbox"/>
"Have you had your usual asthma symptoms during the day (cough, wheeze, chest tightness or breathlessness)?"	<input type="checkbox"/>	<input type="checkbox"/>
"Has your asthma interfered with your usual activities (e.g. housework, work, school, etc)?"	<input type="checkbox"/>	<input type="checkbox"/>

Expanded Score for RCP-3Q's
 Each question scored by frequency of symptoms
 0 = no symptoms
 1 = once or twice per month
 2 = once or twice per week
 3 = daily symptoms
 Allocated score between 0 and 9

Figure 5 Royal College of Physicians 3 Questions for Asthma.



study criteria were based on the GINA definition of asthma control.

Three single component models were also analysed to assess their ability to predict poor control. Peak Expiratory Flow Rate (PEFR) and overuse of bronchodilator medication are important components of a composite assessment tool but have limited ability when used in isolation [3]. This was tested within the analysis. A severity model, based on BTS/SIGN treatment step (Figure 7), was also investigated. Variables

used in the construction of each dependent outcome were not used as independent variables in the regression analysis for that particular control model. Based on the findings from the logistic regression, linear regression was also carried out on an expanded score model of the RCP-3 Questions (Figure 5). Scored by question and frequency of symptoms [0(no symptoms) to 3(daily symptoms)], each patient was allocated a score between 0 and 9.

The Jones Morbidity Index

No to all questions consistent with controlled asthma

During the past four weeks:

- 1 Have you been in a wheezy or asthmatic condition at least once a week?
- 2 Have you had time off work or school because of your asthma?
- 3 Have you suffered from attacks of wheezing during the night?

0 or 1 Yes Answer	2 Yes Answer	3 Yes Answer
Low Morbidity	Medium Morbidity	High Morbidity

Figure 6 Jones Morbidity Index.

Statistical Analysis

Utilising the UK database descriptive statistics using Chi-squared tests for categorical data and t-tests for continuous data were carried out on the baseline data using SPSSv15(SPSS Inc., 2006). The Chi-squared statistic was reported for comparisons of categorical data and the Chi-Squared test for trend reported where significant.

Multiple regression modelling, accounting for practice clustering of patients, was undertaken to determine the strength of association of the independent variables (Table 1) within each model. Multiple logistic regression multi-level modelling was used to derive the eight simple binary (yes/no) models using STATAv9(Stata Corp LP, 2007). Linear regression analysis was used to analyse the RCP-3Q expanded score model. Model fit for all logistic regression models was assessed using three tests-Area Under the Receiver Operating Characteristic (AUROC) (c-statistic) which measured the ability of the model to predict control; Pseudo R-squared which was used to assess the amount of explained variance within the model; and Akaike's Information Criteria (AIC) used to assess fit and performance. The linear regression model was assessed using R-squared and AIC. Using these measures we ranked the performance of all eight models.

Ethical Approval

Ethical approval for the data collection was given by the Regional Medical Research Ethics Committee.

Results

From the 10,432 primary care practices in the UK (correct at time of data collection), 1,205 practices of all sizes and with a wide geographical spread, submitted usable practice data and data on 64,929 patients who attended for a routine asthma review. The study practices represented almost 12% of all UK practices. The proportion of practices from England, Scotland and Wales was similar (Table 2). Northern Ireland was considerably lower.

Study practices were spread over all 28 English Strategic Health Authorities (SHA); 11(73%) of the 15 Scottish Health Boards; 16(73%) of the 22 Health Authorities in

Wales; and all four in authorities in Northern Ireland (Figure 8). Practices were situated in 305(89%) of the 344 UK Primary Care Trusts (or equivalent e.g. Community Health Partnership (CHP) in Scotland).

The PCTs represented in the study had a higher mean population size than the average for all UK PCTs [Study Mean 220,940 (Upper Quartile(UQ) 247,996; Lower Quartile(LQ) 130,180) v National Mean 170,872(UQ 207,796; LQ 112,355)], indicating a slightly higher number of urban or semi urban practices in the study cohort. However, over 30% of the practices were situated in rural or semi-rural areas (Table 3).

Comparison of the mean local area deprivation score [15] for the study cohort [Mean 1.6508 (UQ 3.8750; LQ -1.1900)] with that for all UK practice wards [Mean 0.0009 (UQ 2.0848; LQ -2.6114)] confirmed that the study cohort was skewed slightly towards practices in more deprived areas, probably because of the higher number of urban practices in the study.

Practice size ranged from very small (367) to very large (32,000) (Table 3). Eight hundred and forty one (70%) of the practices had an asthma register of between 5 and 10% of their total patient population.

Table 2 Participating practices by UK country

	Total UK Practices	Study Practices	Proportion
England	8,551	1,014	11.9%
Scotland	1,014	116	11.4%
Wales	502	55	11.0%
Northern Ireland	365	20	5.5%
UK Total	10,432	1,205	11.6%

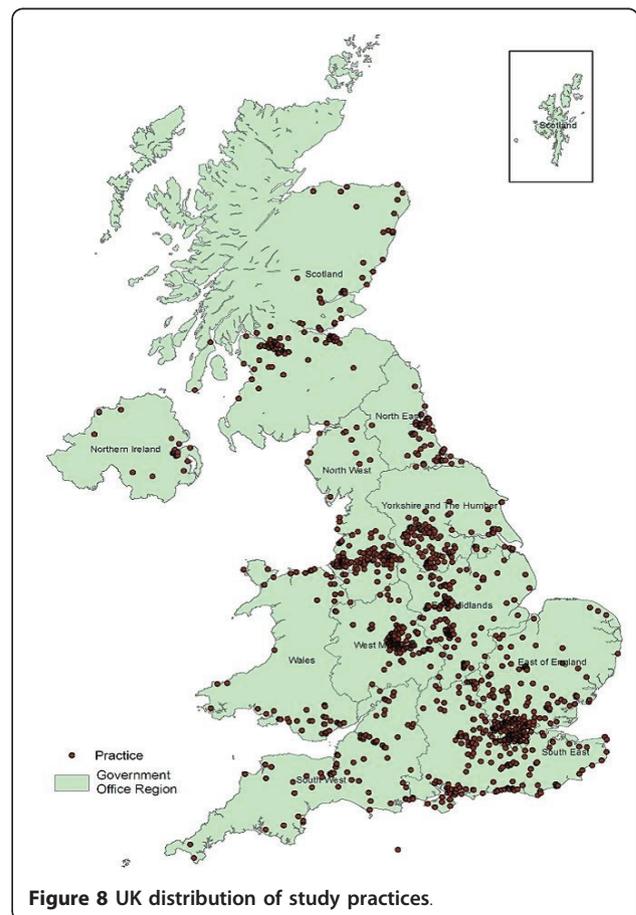


Figure 8 UK distribution of study practices.

Table 3 Practice Baseline Characteristics (n = 1205)

		Missing
Rurality: Urban practices	826 (68.5%)	0 (0.0%)
Practice population size	Mean 6,862 Lower Quartile 3,877.5 Upper Quartile 9,000 Range 367 to 32,000 Median 6,300	5 (0.4%)
Practices with a: Full time GP	1,090 (90.5%)	91 (7.5%)
Part time GP	381 (31.6%)	91 (7.5%)
Full time nurse	787 (65.3%)	105 (8.7%)
Part time nurse	478 (39.6%)	105 (8.7%)
Deprivation Score	Mean 1.65 (SD 3.62) Range -5.21 to 13.21 Median = 1.18	1 (0.08%)
Distance of practice from the nearest DGH	Mean 4.86 miles (SD 5.71) Range 0 to 96 Median = 3	1 (0.08%)
Respiratory Specialist in-situ in nearest DGH	1,150 (95%)	35 (2.9%)
Practices who had:		
Nurse run asthma clinic	830 (68.9%)	68 (5.6%)
Nurse with an accredited Asthma Diploma	897 (74.4%)	48 (4.0%)
Carried out asthma audit in the previous 3 years	723 (60.0%)	55 (4.6%)
Previous use of Asthma Stamp (Protocol)	561 (46.6%)	91 (7.5%)
Achieved ≥70% of Asthma QOF* Points 2004/5	617 (51.2%)	22 (1.8%)
Achieved ≥70% of Total QOF* Points 2004/5	1,152 (95.6%)	19 (1.6%)

QOF = Quality Outcome Framework

DGH = District General Hospital

Patient characteristics and asthma control status are summarised in Table 4. The mean Body Mass Index (BMI) of the study population was 26.16 (SD 5.79). Thirty nine percent of patients (25,537) were within normal BMI range (18 to 25). Nearly 54% were overweight or obese: 33% (21,546) were overweight (BMI 25 to 30); 21% (13,373) obese (BMI > 30). The proportion of current smokers [13,531(21%)] was slightly lower than the UK rate of approximately 1 in 4 adults [20].

At the time of the review 54,503 (83.9%) patients reported experiencing some degree of asthma related symptoms in the immediate 4 week period preceding the consultation: 13,438 (20.7%) on one or two days in the month; 17,451 (26.9%) patients one or two days a week; and 23,614 (36.4%) on a daily basis. Four out of five patients [52,178 (80%)] were on preventative asthma medication (BTS treatment steps 2-5) prior to the review. Although, as one would expect, level of treatment step was significantly associated to symptom reporting (Table 5), patients on all levels of treatment were experiencing frequent symptoms (Figure 9).

Prior to the review 30,360(47%) patients were reportedly overusing their reliever inhaler (more than 6 prescriptions for a short acting bronchodilator in the

previous 12 months), with males statistically more likely than females to be using it more than once every day [M 12,938(48%) v F 17,422(46%); $p < 0.0001$ (OR 0.93 (95%CI 0.91-0.96)]. Overuse increased with age, rising from 2,361(33.5%) of patients in the 13 to 19 year age band to 4,777(51%) of patients in the 70+ age range ($p < 0.0001$). It was also associated with weight being greatest in those with a BMI over 30 [6671(50%) of 13,373 patients] and lowest in those with a BMI of 18 to 25 [11,521(45%) of 25,537 patients] ($p < 0.0001$). Reported overuse of inhaled reliever medication was also linked to level of preventive medication treatment step with patients on low or no preventative medication more likely to overuse [Steps 0-2: 19,446(46%) v Steps 3-5: 10,914(36%); $p < 0.0001$ (OR 0.90(0.88-0.93)].

There was also a significant difference in the level of poor compliance between:

- Gender-males being more likely than females to forget their inhaler [M 8,672(32%) v F 10,197(27%); $p < 0.0001$ (OR 1.27(1.23-1.32)].
- Medication treatment step-patients on treatment step 0, 1 or 2 being more likely to forget to take their inhaler than patients on steps 3, 4 or 5 [Steps

Table 4 Baseline characteristics for patients aged 13 years and over (n = 64,929)

Issues assessed/discussed at consultation	Number	%
Age Mean (SD)	46.9 (SD 19.5)	
Patient numbers by age band: 13-19 years	7,047	11
20-29 years	7,258	11
30-39 years	10,616	16
40-49 years	10,029	15
50-59 years	10,298	16
60-69 years	10,259	16
70+ years	9,422	15
Female	37,826	58
Body Mass Index (BMI) Mean (SD)	26.16 (SD 5.79)	
Patient numbers by BMI band: ≤18	4,473	7
> 18-25	25,537	39
> 25-30	21,546	33
> 30	13,373	21
PEFR at consultation < 80% predicted	1,971	3
Days off in last 4 weeks due to asthma	8,382	13
Smoker	13,531	21
Symptoms in last 4 weeks	54,503	84
Inhaler Device(s) Technique observed as poor	6,789	10
Inhaler occasionally forgotten/not taken	18,869	29
Self management plan not in use prior to consultation	39,938	62
Temporary Increase in Inhaled Steroid since last review	3,157	5
Rescue Oral Steroid since last review	3,223	5
Emergency Nebulisation since last review	1,528	2
Over use of Inhaled Short Acting Bronchodilator*	30,360	47
Scheduled consult since last review	2,626	4
Unscheduled consult since last review	1,755	3
Telephone consult since last review	321	0.5
Home visit since last review	158	0.2
Outpatient visit since last review	95	0.1
A&E visit since last review	292	0.4
Admission to Hospital since last review	58	0.1
BTS Treatment Step prior to review: BTS Step 0	5,477	8
BTS Step 1	7,274	11
BTS Step 2	29,629	46
BTS Step 3	10,678	16
BTS Step 4	11,491	18
BTS Step 5	380	1

*Overuse of Short Acting Bronchodilator = SAB inhaler required more than once every day in the four weeks prior to the consultation
 BTS = British Thoracic Society

0-2: 14,495(34%) v Steps 3-5: 4,374(19%); $p < 0.0001$ (OR 2.16(2.08-2.25)).

- Age-teenagers and young adults being more likely to forget to take their preventer inhaler [13-19 yrs: 2,890(41%); 20-29 yrs: 2,905(40%); 30-39 yrs: 4,029 (38), 40-49 yrs: 3,271(33%), 50-59 yrs: 2,426(24%), 60-69 yrs: 1,888(18%); and patients aged 70+yrs: 1,460 (15.5%) ($p < 0.0001$)].
- BMI-the more overweight a patient the less likely they were to forget their preventer inhaler (BMI < 18: 1,501(34%); 18- < 25: 7,606(30%); 25-30: 6,108 (28%); 30+: 3,654(27%), ($p < 0.0001$).

Regression analysis of Asthma Control Models

Of the eight binary control models investigated, the RCP-3 Questions provided the best fit statistically. It had the second lowest AIC, highest pseudo R-squared (amount of explained variability) of 18% and an AUROC of 0.79 (Table 6). An AUROC of 0.79 is on a par with, for example, the Framingham predictors of Coronary Heart Disease [21]. By contrast, the composite model based on the GINA definition of controlled asthma had a higher AIC, an AUROC of 0.72, and only 10% variability explained. The PEFR model had the lowest AIC, an AUROC of 71% and only 6% of variability explained.

The Royal College of Physicians 3 Question model was interrogated further to investigate whether expansion to include a score for the various symptom frequency levels within each of the three questions contributed to a more robust assessment tool. Compared with the RCP-3Q binary model the RCP-3Q expanded score model provided the best fit with a lower AIC (28,6163) and an R-squared of 33% (Table 6).

Discussion

Statistical modelling found the Royal College of Physicians 3 Questions for asthma was the 'best fit' of the control models tested for determining asthma control in a routine review consultation. However, to be effective, a simple scoring system should be incorporated into the assessment process. The results may prove useful when determining future support strategies for UK Primary Care.

Strength of the Study

The difficulties observed in conducting randomised control trials in primary care means that the results from good quality observational data need to be used for planning and developing health care policy. Producing a

Table 5 Level of reported symptoms within each treatment step

BTS Treatment step	0 n = 5,477	1 n = 7,274	2 n = 29,629	3 n = 10,678	4 n = 11,491	5 n = 380
Symptoms	4,401 80%	6,065 83%	24,801 84%	8,754 82%	10,125 88%	357 94%

A Chi squared test for trend showed a statistically significant difference in distribution: λ^2 trend 146.811 df 1 p < 0.0001

predictive model requires data representative of the general asthma population. The practices that provided data mirrored the distribution pattern of practices throughout the UK and thus were representative of urban, semi-urban, semi-rural and rural area practices. They ranged in size and represented a wide range of social deprivation from highly deprived to highly affluent. With all levels of deprivation strongly represented the presence of slightly more deprived practice ward areas in the dataset was in actual fact a strength of the study as it ensured that any representation was in favour of those areas where there is potentially poorer control of asthma. This is preferable to over-representation of more affluent areas where control may be better [22,23].

The patients were representative of genders, all ages, and the full range of asthma severity. The number of patients on individual practice asthma registers was consistent with nationally expected numbers of asthmatic sufferers within a practice [24]. The greater number of women (F 58% v M 42%) in the study cohort is indicative of both the higher rate of asthma in adult females, particularly in the older age groups [25], and the tendency for women to be more likely to attend for a review [26]. The proportion of current smokers within the dataset was only slightly lower than the UK smoking rate and was most likely due to the fact that the patients in the study were all suffering from a respiratory disease.

The decision to create a categorical variable was a direct reflection of the structure of many of the control assessment tools in use. Although control is on a continuum from mild to very severe it is apparent that a desired feature from a clinical viewpoint should be a

distinct point at which poor control is considered a possibility. It should be emphasised that the assessment questionnaires are not meant to be used as stand-alone tools, but act as a guide to a more thorough review.

The data was from a very large representative cross section of the UK's primary care asthma community. In addition, the regression techniques and goodness-of-fit measures used to test the data ensured that the results could be considered at least internally valid. The use of AUROC, AIC, Pseudo R-squared, and R-squared, allowed comparison of model performance by ranking the outcome. The use of statistical testing to support the findings from cross-sectional observational data is an important step forward in finding the evidence required for supporting change [27].

Study Limitations

Use of a tool in the form of a questionnaire to aid assessment of asthma can provide clinicians with confidence that they will be able to identify patients with sub-optimal control [3]. The questionnaire must be simple, brief, easy to use, patient centred, and suitable for use in every consultation about asthma [7,28]. The British asthma guideline gives examples of a number of tools which may be appropriate, one of which is the Royal College of Physicians 'Three Key Questions' (RCP-3Q) [7]. The GINA guidelines [2] suggest several alternate control assessment tools such as the Asthma Control Test [29]; Asthma Control Questionnaire [30]; Asthma Therapy Assessment Questionnaire [31]; and the Asthma Control Scoring System [32]. Both guidelines stop short of recommending any one particular

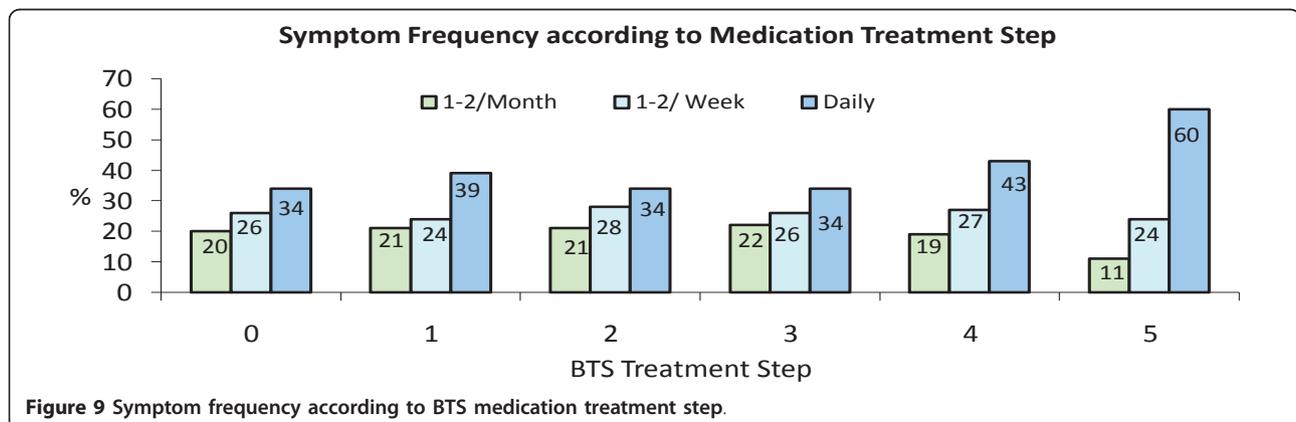


Figure 9 Symptom frequency according to BTS medication treatment step.

Table 6 Comparison of performance of multiple regression models

Control Model	Pseudo R-squared	Akaike's Information Criterion	Area Under ROC Curve
RCP-3 Q Model	0.1803	46,933	.7924 95% CI 0.7963, 0.7885
Jones Morbidity Index	0.1352	77,811	.7407 95% CI 0.7444, 0.7370
GINA Control	0.0977	61,868	.7135 95% CI 0.7180, 0.7090
GOAL Total Control	0.0843	51,660	.7028 95% CI 0.7079, 0.6969
GOAL Well Controlled	0.0845	65,481	.6970 95% CI 0.7015, 0.6925
PEFR	0.0615	16,602	.7085 95% CI 0.7183, 0.6985
Overuse of SAB	0.0833	82,299	.6942 95% CI 0.6983, 0.6901
BTS Treatment Step	0.0677	78,223	.6711 95% CI 0.6756, 0.6665
Linear Regression	R-squared	AIC	
RCP-3 Q Expanded Score Model	0.3258	28,616	N/A

tool for use in the primary care setting. The disparity in their 'recommendations' highlights the level of uncertainty that still exists on the best method for use in primary care [3].

Care must therefore be taken when making conclusions based on cross-sectional data from an observational study. This study was not designed to test the RCP-3Qs but to look at how poor control was being defined and operationalised in primary care and to test, where possible, the strength of each assessment model for predicting poor control of asthma. The data analysis was informed by the literature reviews and utilised all the control assessment sources possible for the available data. The number of control models tested was restricted by the structure of some of the other available tools e.g. the ACQ or the ACT, and by the confines of the existing data set. The ACQ and the ACT have more complex scoring systems not easily deconstructed and replicated for this analysis [30,33-35]. This limited the number of control models that could be tested. However, it was clear from the literature that many researchers were basing their control assessment measures on recommendations from published guidelines. It seemed appropriate therefore to construct a model based on the most commonly used criteria in the papers reviewed, the GINA criteria for control [2]. The two additional composite models of well/moderate control and total control, based on the study by Bateman et al. [19], were also constructed on this premise.

The simplicity of the RCP-3Qs meant that the model created for the study was a direct reflection of the tools properties (one yes answer being suggestive of poor

control). The Jones Morbidity Index on the other hand was less clear cut, the tool indicating three levels of morbidity (low, medium and high), and a decision was made to use the medium morbidity level (1 Yes answer) to define poor control [36]. A second model to capture only the patients who fell into the more stringent severity classification (2 or 3 Yes answers) may have resulted in a better performing model but the decision to use the less stringent measure was in line with the parameters for control in the RCP-3Q model. For both models, ability to measure control effectively may be dependent on the question to which the one 'Yes' answer refers.

The available evidence indicated that single component measures are not effective for identifying poor control [3,37]. The inclusion of two single item models in the analysis provided the opportunity to test this against both composite models of control measurement and morbidity question models.

As we were looking at models that predicted control it was necessary to include patients with both poor and good control. The search criterion given to practices to assist them with the procedure for identifying patients for review was a pragmatic solution to facilitate organisation of the invitation process. However, the consequence of this guidance could have resulted in the over-inclusion of patients at high risk of having poorly controlled asthma, thus compromising the generalisability of the study findings. The inclusion of patients on all medication steps, and with a range of frequency and type of control issue, indicates that the study cohort transcended the range of asthma patients managed in primary care. The number of patients who reported

control issues is, in fact, comparable with those reported by other studies [38-40].

Implications for practice

It is important for health professionals to accurately assess the level of asthma control experienced by their patients. Using a specific tool to aid this process not only increases their ability to identify sub-optimal control [3], but provides a platform for improving communication [41,42]. The ACT is used widely in the international primary care setting and has been tested against the GINA standards [43-45] however the lack of a recommended gold standard assessment tool for use in primary care has meant that the RCP-3Qs remains the most commonly used tool in the UK. Use of the RCP-3Qs on every occasion and by every health professional who sees the patient for their asthma not only has implications for the way control is assessed but has potential for increasing confidence in the management process.

This work, along with Thomas et al. [9], is a timely addition to the small amount of available evidence supporting the ability of the RCP-3Qs to assess asthma control. Health professionals are constantly asked to prove the care they provide is effective. The original concept of the RCP-3Qs was to develop a health outcome indicator for the assessment of asthma morbidity that could be used in both primary and secondary care. However, the lack of validated evidence of the 'tool's' ability to accurately measure asthma control has limited its use. This study provides additional evidence that, in the absence of a gold standard definition of control and assessment method, the RCP-3Q tool has the ability to identify poor control in patients with asthma.

Conclusion

Practical guidance on the best method to monitor and assess asthma control is required. The study underpinning this work was conducted on a large number of patients with a wide range of asthma severity and control, and from all levels of social strata across the UK. It supports the conclusions of Thomas et al. [9] that, along with other assessment tools such as the ACT, the RCP-3Qs can be used with confidence in UK primary care when reviewing people with asthma. It is quick and easy to complete and can be used with or without a scoring system, although the latter is more sensitive to poor control. The results may prove useful when determining future support strategies for UK Primary Care. Until there is evidence to negate its use in favour of another tool its use in UK primary care should be supported.

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Author details

¹Population Health Sciences, School of Medicine, University of Dundee, Mackenzie Building, Kirsty Semple Way, Dundee, DD2 4BF, Scotland, UK. ²Nursing, Midwifery & Allied Health Professional Research Unit, Iris Murdoch Building, University of Stirling, Stirling, FK9 4LA, Scotland, UK. ³School of Medicine, University of St Andrews, St Andrews, KY16 9TF, Scotland, UK. ⁴School of Geography, University of Leeds, Leeds LS2 9JT, England, UK.

Authors' contributions

GH managed the data collection, prepared the datasets, analysed the data, and wrote the first draft of the paper. PD, BW and CJ supervised and advised on the design of the project. In addition PD directed the statistical analysis; BW contributed to the focus of the analyses and interpretation of the data; and CJ advised on the clinical interpretation of the data. PN assisted with data preparation by geo-coding practice locations and linking them to primary care organisation geographies. He also obtained census data and adjusted these to Primary Care Organisation geographies and then calculated the deprivation scores and population densities which were used in analyses. All authors read and approved the final draft.

Conflict of interest

The authors declare that they have no competing interests.

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