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Large Care Gaps in Primary Care Management of Asthma: A Longitudinal Electronic Practice Audit

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DATA SHARING: All study data can be made available upon request to the corresponding author.

ABSTRACT

Objectives: Care gaps in asthma may be highly prevalent but are poorly characterized. We sought to prospectively measure adherence to key evidence-based adult asthma practices in primary care, and predictors of these behaviours.

Design: One year prospective cohort study employing an electronic chart audit.

Setting: Three family health teams (2 academic, 1 community-based) in Ontario, Canada.

Participants: A total of 884 patients (72.1% female; 46.0 ± 17.5 years old) (4199 total visits; 4.8 +/- 4.8 visits/patient) assigned to 23 physicians (65% female; in practice for 10.0 ± 8.6 years).

Main Outcome Measures: The primary outcome was the proportion of visits during which practitioners assessed asthma control according to symptom-based criteria. Secondary outcomes included the proportion of: patients who had asthma control assessed at least once; visits during which a controller medication was initiated or escalated; and patients who received a written asthma action plan. Behavioural predictors were established a priori and tested in a multivariable model.

Results: Providers assessed asthma control in 4.9% of visits and 15.4% of patients. Factors influencing control assessment included clinic site and presenting complaint. Assessment occurred more often during visits for asthma symptoms (35.0%) or any respiratory symptoms (18.8%) relative to other visits (1.6%) ($p<0.001$). Providers escalated controller therapy in 3.3% of visits and 15.4% of patients. Factors influencing escalation included clinic site, presenting complaint, and prior objective asthma diagnosis. Assessment occurred more often during visits for asthma symptoms (21.0%) or any respiratory symptoms (11.9%) relative to other visits (1.5%) ($p<0.001$) and in patients without a prior objective asthma diagnosis (3.5%) relative to those with this (1.3%) ($p=0.025$). No asthma action plans were delivered.

Conclusions: Major gaps in evidence-based asthma practice exist in primary care. Targeted knowledge translation interventions are required to address these gaps, and can be tailored by leveraging the identified behavioural predictors.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the largest practice-based audit of primary care adherence to three asthma management practices recommended across international guidelines: assessment of asthma control, initiation/escalation of asthma controller therapy, and provision of asthma action plans.
- The novel multivariable modelling in this study allowed for identification of behavioural predictors which complement those previously identified through surveys and qualitative studies.
- The study was carried out in real-world academic and community primary care settings with broad socio-demographic representation.
- Chart review methods are susceptible to underestimation of care due to poor clinician documentation.
- None of the included sites included allied health resources for asthma management, whereby findings are limited to settings without such resources.

INTRODUCTION

Asthma is one of the most common chronic diseases in the United Kingdom, increasing in prevalence, and carrying a direct annual healthcare expenditure of more than £1 billion.[1] Although effective therapies exist, up to 53% of patients remain poorly controlled.[2,3]

Poor health outcomes in patients with asthma have been attributed to gaps between evidence-based recommendations and practice, particularly in primary care, where the majority of asthma patients are seen.[4] A striking consequence of these gaps was presented in the United Kingdom (UK) National Review of Asthma Deaths, which found that 46% of asthma deaths could have been avoided if appropriate guidelines were followed.[5] Although asthma guidelines can be complex[6] and sometimes divergent,[7] certain recommendations are longstanding and common across guidelines. First, asthma control should be assessed at each visit.[8,9] "Good asthma control" is defined by a series of criteria, which correlate with improved quality of life and reduced health care utilization. Failure to meet any of these criteria defines the need for initiation or escalation of therapy. These criteria were first articulated in the original (1996) Canadian Asthma Guidelines[10] and the 2003 British Asthma Guidelines,[11] and have been re-iterated in successive guideline updates. Second, pharmacotherapy should be tailored to asthma control.[8] Early initiation of inhaled corticosteroids (ICSs) (a "controller" medication) in poorly controlled asthma improves quality of life and lung function while reducing symptoms, exacerbations, and mortality.[12-15] This has been recommended consistently since the 1990 British Asthma Guidelines[16] and the 1996 Canadian Asthma Guidelines.[10] Similarly, addition of a long-acting beta agonist (LABA) in patients with poor control on an ICS improves lung function and reduces rescue bronchodilator use and exacerbations,[17] and has been recommended since the 2003 British Asthma Guidelines[11] and the 2003 Canadian Asthma Guideline update.[18] Finally, a written asthma action plan (AAP) is an individualized self-management plan produced by a health care professional for a patient with asthma.[19] AAPs reduce hospitalizations, emergency department (ED) visits, unscheduled doctor visits, absenteeism, and nocturnal asthma symptoms, and improve quality of life.[19] A recommendation that all patients receive a written AAP has also been found in each British Asthma Guideline since 1990[16] and each Canadian Asthma Guideline since 1996.[10] All of these practices are equally recommended in the latest asthma guidance document from the National Institute for Health and Care Excellence (NICE).[20]

Estimates of care gaps across these three fundamental asthma management principles have been limited to patient and provider self-report[21,22] and extrapolation from population health databases.[23] Furthermore, little is known about factors that predict adherence to these recommendations. We measured these clinical behaviours and identified their predictors in Canadian community and academic primary care practices, with a view to targeting future knowledge translation initiatives.

METHODS

Study Design

This was a prospective cohort study employing an electronic audit of asthma care delivered by prescribers across 2 academic family health teams (primary health care teams including family physicians, nurses, and allied health members) in Hamilton, Ontario (population: 536,917)[24] and 1 community-based family health team in Brampton, Ontario (population: 593,638).[25] Clinics used the OSCAR electronic medical record (EMR) system (http://oscarcanada.org), were under a capitated funding model, and did not have asthma educators or respiratory therapists on site. Invitations were sent to all physicians and nurse practitioners (NPs). We identified asthma patients through a validated EMR search algorithm including: "asthma" in the cumulative patient profile (a standardized chart component which includes active and past medical history), use of the diagnostic billing code for asthma/allergic bronchitis (493) within the last 3 years [excluding patients in whom a chronic obstructive pulmonary disease (COPD)-related diagnostic billing code (491, 492, 496) had been used in the last 3 years]; and presence of "asthma" in any of the typed chart notes[26] (algorithm-generated lists were vetted/modified by clinicians). We included asthma patients belonging to all consenting clinicians, who were $\geq$ 16 years old, understood English, and had been on asthma medication in the prior 12 months, while excluding patients who had been on a COPD medication in the prior year.[26] Patients who were pregnant, or whom the physician deemed to have cognitive limitations or a life expectancy of < 1 year were excluded. We reviewed all outpatient visits and asthma-related telephone interactions by staff physicians, residents, NPs, NP students, or physician assistants (PAs) between August 1st, 2012 and July 31st, 2013. We excluded visits exclusively for administration of injection medication(s) (e.g. the flu shot).

Patient Involvement

A patient organization (the Asthma Society of Canada) was involved from project inception and its members helped to guide the choice of research questions and the research design, and will lead efforts to disseminate results to patients.

Data Collection

Four trained reviewers entered data in a standardized electronic form (in Excel®). Data elements were agreed upon by primary care (GA, DC, AK, SGo) and respirology experts (SG, LPB). The form was refined for clarity and usability through three cycles of testing, each involving 20 visit reviews by each reviewer. Reviewers then independently abstracted data from 40 randomly selected visits to ensure agreement. Abstracted data included visit time/date, presenting complaint, demographics, baseline asthma parameters, baseline and changes to respiratory medications, previous asthma diagnostic testing (spirometry and/or methacholine challenge), previous hospitalizations or emergency department (ED) visits for asthma, previous referrals/visits to respirologists or allergists (and their findings), clinician documentation of asthma control according to symptom-based guideline criteria (Table 1),[8,9,20] actual asthma control according to symptoms recorded in any place in the chart, and provision of a written AAP.

Outcomes

The primary outcome was the proportion of visits during which practitioners assessed asthma control according to symptom-based criteria. Patients were considered to have poor control if they met one or more criteria for uncontrolled asthma (based on review of the current and any prior visits within each corresponding timespan) (Table 1). Secondary outcomes included the proportion of: patients who had asthma control assessed at least once; visits during which a controller medication was either initiated or escalated (and the proportion of patients with this); and patients who received a written AAP.

A priori, we identified the following clinically-relevant parameters, which might predict these outcomes: clinic, practitioner type, objective diagnosis of asthma, asthma control status,

documented physician diagnosis of asthma, presenting complaint type, time of visit, billing physician (most responsible physician/other), and previous ED visits/hospitalizations for asthma. We also characterized the proportion of patients who had control assessed at least once, which control questions were being asked, and current medication use as a function of control status, prior objective diagnosis, and prior emergency department (ED) visit/hospitalization for asthma.

Analysis

Interrater reliability was calculated using percent agreement. We summarized baseline clinician and patient characteristics descriptively, using information from the first visit in patients with multiple visits. We compared patient variables between sites with Fisher's exact/chi square tests and ANOVAs, as appropriate, and compared patient subgroups using the Fisher's exact test. We used multivariable logistic regression to identify predictors of each outcome (covariates tested are listed above). In measuring AAP delivery, we eliminated patients who had not been on a controller medication at any time during the study period (controller medication changes in the the AAP are only recommended in patients on a baseline controller).[27] Analyses were performed using R Statistical Software (Version 3.2.4). Statistical significance was defined at a two-sided 0.05 level.

RESULTS

Chart Review

Agreement between reviewers in chart abstraction was 82.8–97.3% for control criteria, 97.5% for assessment of medication changes, and 100% for AAP delivery.

Population

We recruited 19/42 (45%) physicians and 1/3 (33%) nurse practitioners (NPs). The NP had patients from an additional 4 physicians under their care, enabling us to analyze data for 23/42 (55%) physicians. These physicians had been in practice for 10.0 ± 8.6 years (range 0–29) and 15/23 were female (65%). They were the most responsible physician (MRP) for 884 asthma patients (Table 2). These patients received care from 108 residents (66% female), 46 staff physicians [72% female, in practice for 9.8 ± 10.1 years (range <1-43)], 17 NPs, and 2 PAs. Each provider averaged 24.3 ± 39.4 patient visits (range 1 – 255) over the study period.

Fifty-five (6%) patients had been seen in the ED or hospitalized for asthma in the prior 10 years. These patients were more likely to be on a controller medication (32/55) (58.1%) than those without an ED visit or admission (243/829) (29.3%) ($p<0.01$). Ninety (10.2%) patients had an objective diagnosis of asthma (by spirometry or methacholine challenge).[14]

There were 4199 eligible visits over the study period (4.8 ± 4.8 visits/patient), among which 572 (13.6%) were for respiratory complaints, including 163 (3.9%) specifically for asthma. During the study period, 331 (37.4%) patients had at least one visit with a respiratory complaint and 28 (3.2%) were referred to see a respirologist or allergist. A further 159 (18.0%) patients had been seen by a specialist in the prior 10 years. Among these, 6 (3.8%) had received an AAP from that specialist.

Asthma Care

Asthma Control Assessment

Of 884 patients, 136 (15.4%) had their control status determined at least once in the study year, with 135 (15.3%) having poor control and 1 (0.01%) having good control. Among the patients with poor control, 61/135 (45.2%) were on a controller medication [31/61 (50.8%) ICS alone; 27/61 (44.3%) ICS/LABA; 3/61 (5.0%) ICS + leukotriene receptor antagonist (LTRA)], compared to 221/749 (29.5%) of the patients with unknown or good control ($p<0.01$) [104/221 (47.0%) ICS alone; 110/221 (49.8%) ICS/LABA; 7/221 (3.2%) ICS + LTRA)].

Practitioners determined asthma control in 202/4122 (4.9%) eligible visits. Among 261 (6.2%) visits where *any* control question was asked, an average of 1.6 questions were asked, as follows: daytime symptoms (60.5%); rescue puffer use (44.8%); nighttime symptoms (27.2%), physical activity limitations (23.0%); and school/work absenteeism (4.2%). All five questions were asked in 4 (1.5%) of these visits (Figure 1).

In the multivariable model, clinic site and nature of presenting complaint were significant predictors of asthma control assessment (Table 3).

Controller Medication Initiation or Escalation

Controller medications were initiated or escalated by prescribers in 138 (3.3%) eligible visits. Of 884 study patients, 136 (15.4%) had a controller medication initiated or escalated at least once in the study year. There was only 1 eligible visit (0.02%) in which a medication de-escalation was made.

In the multivariable model, clinic site and nature of presenting complaint were significant predictors of initiation or escalation. Patients with a prior objective diagnosis of asthma were also less likely have a medication initiation or escalation. However, these patients were more likely to already be on a controller medication (61/90) (67.8%) than those without an objective diagnosis (380/794) (47.9%) ($p<0.01$). Uncontrolled asthma predicted initiation or escalation in a univariate analysis, but could not be added to the multivariable model (Table 4).

Asthma Action Plan Delivery

There were no AAPs delivered by any prescriber over the one-year study period to patients on a controller medication.

DISCUSSION

We reviewed Canadian primary care asthma management and identified large gaps across three fundamental evidence-based practices.[28] To our knowledge, this is the largest report to objectively characterize these gaps and to measure their predictors in a primary care asthma population.

Asthma control assessment was seldom performed, but was more common at academic sites (Table 3). This may be due to practice variation, as seen in other care practices (Table 2), and/or to population differences (Table 1). Control was more often assessed if the presenting complaint was asthma- or respiratory-related. This may reflect formal control assessment or the effect of expected targeted questioning and/or patient symptom report. Although it might not be reasonable to expect clinicians to ascertain control at each visit, 85% of patients did not have control assessed despite an average of ~5 visits over the year and with 37% of patients having had at least one visit with a respiratory complaint. A lack of familiarity with control criteria may be a cause of this gap.[29] In a Canadian study, primary care physicians identified an average of 2.2

out of 8 control criteria.[30] Similarly, 26% of US primary care physicians were confident that they could assess asthma control.[31] Additional barriers include lack of time, forgetting to assess control, and patient preferences for consultation content.[30] A periodic physician prompt with embedded questions[30] or a patient questionnaire might address some of these barriers. Certain control criteria, such as absenteeism, were rarely ascertained and should be emphasized in future interventions.

Although we did not find a report of this gap in a Canadian setting, a US review of 430 primary care charts noted that *all* control criteria were assessed in 1% (0.1% of visits in our cohort), and at least one criterion was assessed in 59% of visits (6% of visits in our cohort).[31] In a 2014 UK review, among 135 patients who died of asthma and whose last asthma care visit had been in primary care, only 37 (27%) had asthma control assessed at that visit..[5] Considering that a majority of primary care patients are found to be uncontrolled when asked all five symptom-based criteria, and that our data and others'[32] suggest that practitioners are more likely to alter therapy in uncontrolled patients, our findings support a hypothesis that failure to recognize poor asthma control is a contributor to undermedication.

Correspondingly, therapy was infrequently augmented. Augmentation was more common in the non-academic site and during visits with asthma- or respiratory-related complaints (Table 4). A lack of objective diagnosis also predicted augmentation, likely because these patients were less commonly on a controller medication. Augmentation was more common during visits with poor asthma control, but occurred in only 6% of such visits, suggesting that other barriers play a role. Although clinicians seem to be aware of the importance of systematic therapeutic escalation and recognize its expected favorable impact on outcomes,[33] barriers include a lack of knowledge of specific guideline-recommended thresholds for initiating/escalating therapy,[34-36] poor implementability of guidelines[6,22], and patient factors such as medication affordability and ICS aversion.[22,37] Overall, only 16% of patients received augmentation, compared to an estimated poor asthma control prevalence of 59% in prior studies.[22,23,32,38] Whereas the British Asthma Guideline suggests reducing therapy after achieving control to minimize side-effects and cost,[9] medication *de-escalation* occurred only once during the study period. Accordingly, our data may also suggest an "overtreatment" care gap among the ~35% of patients who were on controller

medications. Future behavior change interventions might use methods to elicit respiratory complaints and/or focus on visits with respiratory complaints, which appear to be an enabler of medication optimization.

In a Canadian administrative database review, 37% of patients with poor control (defined based on short-acting bronchodilator prescriptions, ER/hospital visits, or asthma deaths) were not prescribed an ICS, compared with 54.8% in our study. The study also found that 74% of those with poor control on a high dose ICS were not prescribed an add-on LABA,[23] compared with 55.7% of patients with poor control on *any* ICS dose in our study. A similar administrative database review found that 47% of poorly controlled patients were not prescribed an ICS.[39] A practice audit of 15 Scottish primary care practices also suggested underuse of LABA therapy, with 180/547 (32.9%) patients on *high dose* ICS not on add-on LABAs.[33]

We did not record any AAP delivery over the study period. Previously, 12.8% of surveyed Scottish GPs reported providing their patients with AAPs[33] and 11% of surveyed Canadian patients reported receiving an AAP.[22] However, as is the case with other surveys[32], these data were likely affected by both reporting bias and selection bias. In contrast, both Canadian [40] and US [31] chart audits found results much closer to ours, with only 2% of patients having received an AAP. In a survey of Scottish patients who had an acute asthma attack requiring steroids or hospitalization in the previous six months, 58/254 (22.8%) reported possession of a written asthma action plan, however only 11 (3.9%) had received it from their GP.[33] Similarly, the UK National Review of Asthma Deaths revealed that only 23% of patients who died of asthma had ever received an AAP (from primary or secondary care).[5] Surveys and qualitative studies indicate that a majority of physicians are aware of guideline recommendations for AAPs and consider AAPs to be important,[33] but fail to provide them due to a lack of time,[22,41,42] experience and confidence,[33,43] and lacking availability at the point of care.[22,33,41,42,44-47] In a Canadian study, 30% of physicians attending an asthma skills workshop were unable to prepare an adequate AAP,[46] while in a Scottish survey, an identical 30% of respondents indicated that they were "not at all" confident in preparing AAPs for their patients.[33] In the same survey, 47.7% of respondents indicated that AAP templates were not available in their practice.[33] Practices with access to allied health care team members with specific asthma management skills and knowledge and effective

communication for delegation of tasks have been shown to have higher asthma guideline adherence.[48] Correspondingly, 46% of Scottish GPs indicated that a reorganization of care would enable them to improve implementation,[33] Accordingly, for this particular care gap, an organizational change may be required for increased uptake. Of interest, our data suggest that this problem is not limited to the primary care setting, given that less than 4% of patients seen by specialists received an AAP.

We believe that our sample may be reasonably representative of primary care academic and non-academic environments. We measured the behavior of 46 staff physicians,108 residents, 17 NPs and 2 PAs spanning a wide range of practice experience. No sites had access to allied health resources for asthma management. Accordingly, clinicians managed asthma individually, as would occur in smaller group or solo practices. The divergent socio-demographic compositions of the two involved cities (Hamilton and Brampton) also support generalizability. Hamilton is a large urban centre with an average age of 41.3 years[24], median income of $87,590,[49] 14.3% visible minorities,[50] and 6.3% unemployment[51]. In contrast, Brampton is a suburb within the Greater Toronto Area, has an average age of 36.5 years,[52] median income of $68,782,[53] 66.4% visible minorities,[54] and 9.5% unemployment.[55]

Our study has several of limitations. Our approach may have underestimated asthma control assessment and AAP delivery due to poor chart documentation. However, we believe that clinicians would be very likely to document poor asthma control if ascertained, given its clinical relevance and influence on treatment decisions. Furthermore, only 15.3% of patients had poor control documented, compared to the expected 59% prevalence of poor control,[22,23,32,38] supporting the presence of an assessment care gap. Although chart reviews were performed remotely and contact with clinicians was minimal, clinicians may have improved care as a result of observation. Participation bias may have favored those with an interest in asthma. Our sample may not be representative of jurisdictions with vastly different socio-demographic compositions and/or practice models than those studied. Finally, although we used a validated algorithm to identify patients with asthma[26] and physicians vetted algorithm-generated lists, some diagnostic misclassification likely occurred.

CONCLUSIONS

Large care gaps exist in primary care settings, across basic asthma care recommendations that have been found across international guidelines for over 15 years, and that are widely considered to be the standard of care. These care gaps are larger than previously found in self-report and survey-based studies. Complex implementation strategies will be required to overcome these gaps. Behavioural predictors identified quantitatively in this study complement those identified previously through surveys and qualitative studies. These factors should now be used to tailor and then test specific implementation strategies to effect behaviour change for each key care gap.

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TABLES

Table 1. Symptom-based criteria for assessing asthma control[8,9,20]

Criterion	Controlled	Uncontrolled
Daytime Symptoms *	<4 days/week	≥4 days/week
Night-time Symptoms*	<1 night/week	≥1 night/week
Physical Activity	Normal/No limitations	Restricted due to asthma in previous 3 months
Absenteeism	None	Missed work/school/other activities due to asthma in previous 3 months
Short-acting bronchodilator use*	<4 doses/week	≥ 4 doses/week

* Evaluated as an average of the prior 6 months

Table 2. Patient Characteristics

Characteristic	Overall n=884	Site 1 (Academic) n=429	Site 2 (Academic) n=245	Site 3 (Non-Academic) n=210	p-value
Mean age +/- SD (years)	46.0 ± 17.5	49.3 ± 17.9	43.9 ± 17.4	42.7 ± 15.9	<0.01
Sex, n (%)					0.604
Female	638 (72.1%)	307 (71.6%)	174 (71.0%)	157 (74.8%)	
Male	246 (27.9%)	123 (28.7%)	71 (29.0%)	53 (25.2%)	
Smoking status, n (%)					<0.01
Non-smoker	442 (49.8%)	226 (52.7%)	109 (44.5%)	107 (50.0%)	
Ex-smoker	132 (14.9%)	80 (18.6%)	32 (13.1%)	20 (9.5%)	
Smoker	168 (19.0%)	75 (17.5%)	47 (19.2%)	46 (21.9%)	
Not documented	142 (16.1%)	48 (11.2%)	57 (23.3%)	37 (17.6%)	
Comorbidities, n (%)					
Atopy	359 (40.6%)	192 (44.8%)	104 (42.4%)	63 (30.0%)	<0.01
COPD	68 (7.7%)	46 (10.7%)	13 (5.3%)	9 (4.3%)	<0.01
Other Resp. Diagnosis	16 (1.8%)	10 (2.3%)	5 (2.0%)	1 (0.5%)	0.243
Previous Diagnostic Testing, n (%)					
Spirometry	342 (38.7%)	198 (46.2%)	97 (39.6%)	47 (22.4%)	<0.01
Bronchodilator challenge (% of spirometries)	237 (69.3%)	137 (69.2%)	64 (66.0%)	36 (76.6%)	0.432
Methacholine challenge	88 (10.0%)	52 (12.1%)	30 (12.2%)	6 (2.9%)	<0.01
Baseline medications, n (%)					
Short-acting bronchodilator	564 (63.8%)	281 (65.5%)	149 (60.8%)	57 (27.1%)	<0.01
Inhaled corticosteroid alone*	150 (17.0%)	87 (20.3%)	45 (18.4%)	18 (8.6%)	<0.01
Inhaled corticosteroid with long-acting beta-agonist	132 (14.9%)	67 (15.6%)	30 (12.2%)	35 (16.7%)	0.359
Long-acting beta-agonist alone	6 (0.7%)	4 (0.9%)	1 (0.4%)	1 (0.5%)	0.669
Leukotriene receptor antagonist	21 (2.4%)	10 (2.3%)	9 (3.7%)	2 (1.0%)	0.515
Prednisone+	9 (1.0%)	6 (1.4%)	2 (0.8%)	1 (0.5%)	0.041

* without concurrent use of a long-acting beta-agonist in a combination inhaler or as a separate inhaler

+ includes only those patients using prednisone chronically

Table 3. Predictors of Asthma Control Assessment*

	Control Not Assessed (n=3920visits)	Control Assessed (n=202 visits)	p-value**
Primary care clinic			0.019[a]
Site 1	1727 (95.0%)	90 (5.0%)	
Site 2	801 (92.7%)	63 (7.3%)	
Site 3	1392 (96.6%)	49 (3.4%)	
Appointment provider type			0.11[b]
Physician	1847 (97.1%)	55 (2.9%)	
Nurse Practitioner	414 (95.4%)	20 (4.6%)	
Resident	1417 (92.6%)	114 (7.4%)	
Physician Assistant	242 (94.9%)	13 (5.1%)	
Clinical diagnosis of asthma			0.074
Yes	2296 (94.1%)	145 (5.9%)	
No	1624 (96.6%)	57 (3.4%)	
Objective diagnosis of asthma			0.79
Yes	357 (93.5%)	25 (6.5%)	
No	3563 (95.3%)	177 (4.7%)	
Presenting complaint			<0.001[c]
Asthma	101 (63.9%)	57 (36.1%)	
Other respiratory complaint	358 (80.6%)	86 (19.4%)	
Non-respiratory complaint	3461 (98.3%)	59 (1.7%)	
Time of visit			0.11
On hours	3478 (94.8%)	191 (5.2%)	
Weekend/After Hours	442 (97.6%)	11 (2.4%)	
Previous ED visit/Hospitalization for asthma			N/A[d]
Yes	63 (100%)	0 (0%)	
No	3857 (95.0%)	202 (5.0%)	
Patient seen by own MRP[d]			0.33
Yes	1269 (97.5%)	33 (2.5%)	
No	2707 (94.1%)	169 (5.9%)	

* In measuring asthma control assessment, we eliminated visits in which asthma control had been assessed within the prior 28 days (a standard look back period for symptom-based asthma control assessment)[28]
**p-value for each variable shown is from the multivariable model.
a although significant across all sites, differences were not significant in pairwise comparisons
b. although not significant across all provider types, in pairwise comparisons, residents were more likely to assess control compared to staff physicians [OR 1.8, 95% CI (1.1 – 3.0)]

c. in pairwise comparisons, control was assessed more often in asthma-related visits than in non-respiratory visits [OR 29.8, 95% CI (19.3-45.9)] and in any respiratory-related visits than in non-respiratory visits [OR 14.5, 95% CI (10.1-20.8)]

d this covariate was removed from the multivariable model due to no subjects having this variable among those who had their control assessed; the univariate p-value was 0.074.

MRP denotes most responsible physician

Table 4. Predictors of Controller Medication Initiation or Escalation*

	Controller not initiated or escalated (n=4021 visits)	Controller initiated or escalated (n=138 visits)	p-value**
Primary care clinic			<0.001
Site 1	1781 (97.8%)	40 (2.2%)	
Site 2	869 (98.3%)	15 (1.7%)	
Site 3	1371 (94.3%)	83 (5.7%)	
Appointment provider type			0.72
Physician	1845 (96.6%)	65 (3.4%)	
Nurse Practitioner	419 (95.0%)	22 (5.0%)	
Resident	1512 (97.5%)	39 (2.5%)	
Physician Assistant	245 (95.3%)	12 (4.7%)	
Clinical diagnosis of asthma			0.47
Yes	2369 (96.3%)	92 (3.7%)	
No	1652 (97.3%)	46 (2.7%)	
Objective diagnosis of asthma			0.025
Yes	383 (98.7%)	5 (1.3%)	
No	3638 (96.5%)	133 (3.5%)	
Presenting complaint			<0.001[a]
Asthma	124 (79.0%)	33 (21.0%)	
Other respiratory complaint	394 (88.1%)	53 (11.9%)	
Non-respiratory complaint	3503 (98.5%)	52 (1.5%)	
Time of visit			0.66
On hours	3586 (97.0%)	112 (3.0%)	
Weekend/After-Hours	435 (94.4%)	26 (5.6%)	
Previous ED visit/Hospitalization for asthma			0.86
Yes	60 (95.2%)	3 (4.8%)	
No	3961 (96.7%)	135 (3.3%)	
Patient seen by MRP			0.17
Yes	1273 (96.8%)	42 (3.2%)	
No	2748 (96.6%)	96 (3.4%)	
Asthma Control Level			N/A[b]
Uncontrolled	636 (93.9%)	41 (6.1%)	
Unknown or Controlled	3385 (97.2%)	97 (2.8%)	

* In measuring controller escalation/initiation, we eliminated visits in which patients had had a controller medication escalated within the last three months (the typical duration of a therapeutic trial).[56] Initiation included starting of any

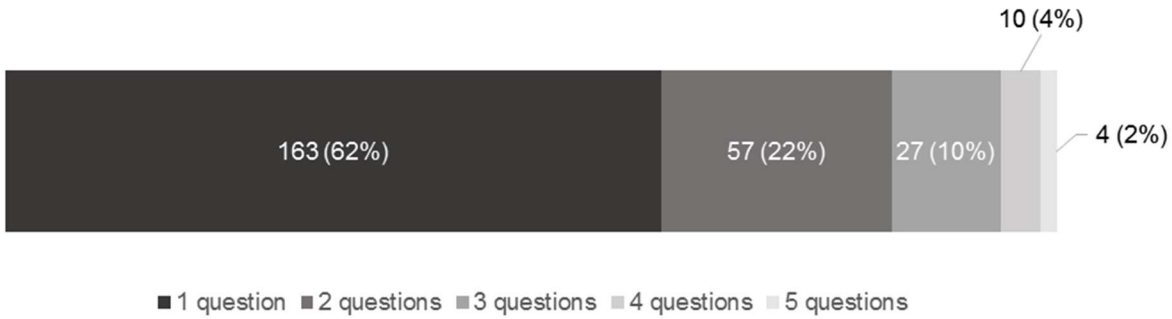
of the following medications: inhaled corticosteroid (ICS) alone, inhaled corticosteroid with long-acting beta-agonist (ICS/LABA), long-acting beta-agonist alone (LABA), leukotriene receptor antagonist, long-acting anticholinergic (LAAC). Escalation included an increase in the dose of an inhaled corticosteroid (ICS) or a combination ICS/LABA, addition of a LABA to an ICS, addition of a leukotriene receptor antagonist (LTRA) to an ICS or ICS/LABA, or addition of a LAAC to an ICS, ICS/LABA, or LTRA

**p-value for each variable shown is from the multivariable model

a. In pairwise comparisons, controller medications were initiated/escalated more often in asthma-related visits than in non-respiratory visits [OR 17.8, 95% CI (11.3-27.956)] and in any respiratory-related visits than in non-respiratory visits [OR 7.7, 95% CI (5.7-11.159)]

b. This covariate was removed from the multivariable model since there were no subjects that had controlled asthma who had a controller initiated or escalated; the univariate p-value was <0.001

Figure 1. Proportion of Visits* With Each Number of Symptom-Based Asthma Control Questions Asked



*Among the 261/4122 visits in which any control question was asked

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, explain how loss to follow-up was addressed
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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Large Care Gaps in Primary Care Management of Asthma: A Longitudinal Practice Audit

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Large Care Gaps in Primary Care Management of Asthma: A Longitudinal Practice Audit

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DATA SHARING: All study data can be made available upon request to the corresponding author.

ABSTRACT

Objectives: Care gaps in asthma may be highly prevalent but are poorly characterized. We sought to prospectively measure adherence to key evidence-based adult asthma practices in primary care, and predictors of these behaviours.

Design: One-year prospective cohort study employing an electronic chart audit.

Setting: Three family health teams (2 academic, 1 community-based) in Ontario, Canada.

Participants: 884 patients (72.1% female; 46.0 ± 17.5 years old) (4199 total visits; 4.8 +/- 4.8 visits/patient) assigned to 23 physicians (65% female; practicing for 10.0 ± 8.6 years).

Main Outcome Measures: The primary outcome was the proportion of visits during which practitioners assessed asthma control according to symptom-based criteria. Secondary outcomes included the proportion of: patients who had asthma control assessed at least once; visits during which a controller medication was initiated or escalated; and patients who received a written asthma action plan. Behavioural predictors were established a priori and tested in a multivariable model.

Results: Primary outcome. Providers assessed asthma control in 4.9% of visits and 15.4% of patients. Factors influencing assessment included clinic site (p=0.019) and presenting complaint, with providers assessing control more often during visits for asthma symptoms (35.0%) or any respiratory symptoms (18.8%) relative to other visits (1.6%) (p<0.01). Secondary outcomes. Providers escalated controller therapy in 3.3% of visits and 15.4% of patients. Factors influencing escalation included clinic site, presenting complaint, and prior objective asthma diagnosis. Escalation occurred more frequently during visits for asthma symptoms (21.0%) or any respiratory symptoms (11.9%) relative to other visits (1.5%) (p<0.01) and in patients without a prior objective asthma diagnosis (3.5%) relative to those with (1.3%) (p=0.025). No asthma action plans were delivered.

Conclusions: Major gaps in evidence-based asthma practice exist in primary care. Targeted knowledge translation interventions are required to address these gaps, and can be tailored by leveraging the identified behavioural predictors.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the largest prospective practice-based audit of primary care adherence to three asthma management practices recommended across international guidelines: assessment of asthma control, initiation/escalation of asthma controller therapy, and provision of asthma action plans.
- The multivariable modelling in this study allowed for identification of novel behavioural predictors which complement those previously identified through surveys and qualitative studies.
- The study was carried out in real-world academic and community primary care settings with broad socio-demographic representation.
- Chart review methods are susceptible to underestimation of care due to poor clinician documentation.
- None of the study sites included allied health resources for asthma management, whereby findings are limited to settings without such resources.

INTRODUCTION

Asthma is one of the most common chronic diseases in the United Kingdom, increasing in prevalence, and carrying a direct annual healthcare expenditure of more than £1 billion.[1] Although effective therapies exist, up to 53% of patients remain poorly controlled.[2,3] Poor health outcomes in patients with asthma have been attributed to gaps between evidence-based recommendations and practice, particularly in primary care, where the majority of asthma patients are seen.[4] A striking consequence of these gaps was presented in the United Kingdom (UK) National Review of Asthma Deaths, which found that 46% of asthma deaths could have been avoided if appropriate guidelines were followed.[5] Although asthma guidelines can be complex[6] and sometimes divergent,[7] certain recommendations are longstanding and common across guidelines.

First, asthma control should be assessed at each visit.[8,9] "Good asthma control" is defined by a series of criteria, which correlate with improved quality of life and reduced health care utilization. Failure to meet any of these criteria defines the need for initiation or escalation of therapy. These criteria were first articulated in the original (1996) Canadian Asthma Guidelines[10] and the 2003 British Asthma Guidelines,[11] and have been re-iterated in successive guideline updates.

Second, pharmacotherapy should be tailored to asthma control.[8] Early initiation of inhaled corticosteroids (ICSs) (a "controller" medication) in poorly controlled asthma improves quality of life and lung function while reducing symptoms, exacerbations, and mortality.[12-15] This has been recommended consistently since the 1990 British Asthma Guidelines[16] and the 1996 Canadian Asthma Guidelines.[10] Similarly, addition of a long-acting beta agonist (LABA) in patients with poor control on an ICS improves lung function and reduces rescue bronchodilator use and exacerbations,[17] and has been recommended since the 2003 British Asthma Guidelines[11] and the 2003 Canadian Asthma Guideline update.[18]

Finally, a written asthma action plan (AAP) is an individualized self-management plan produced by a health care professional for a patient with asthma.[19] AAPs reduce hospitalizations, emergency department (ED) visits, unscheduled doctor visits, absenteeism, and nocturnal asthma

symptoms, and improve quality of life.[19] A recommendation that all patients receive a written AAP has also been found in each British Asthma Guideline since 1990[16] and each Canadian Asthma Guideline since 1996.[10] All of these practices are equally recommended in the latest asthma guidance document from the National Institute for Health and Care Excellence (NICE).[20]

Estimates of care gaps across these three fundamental asthma management principles have been limited to patient and provider self-report[21,22] and extrapolation from population health databases.[23] Furthermore, little is known about factors that predict adherence to these recommendations. Accordingly, our objectives were both to measure adherence to these clinical behaviours and to identify their predictors in Canadian community and academic primary care practices, with a view to targeting future knowledge translation initiatives.

METHODS

This report adheres to STROBE reporting guidelines.[24]

Study Design

This was a prospective cohort study employing an electronic audit of asthma care delivered by prescribers across 2 academic family health teams (primary health care teams including family physicians, nurses, and allied health members) in Hamilton, Ontario (population: 536,917)[25] and 1 community-based family health team in Brampton, Ontario (population: 593,638).[26] Clinics used the OSCAR electronic medical record (EMR) system (http://oscarcanada.org), were under a capitated funding model, did not have asthma educators or respiratory therapists on site, and were not using any asthma-related decision support tools. The study was approved by hospital and university institutional review boards before commencement. Invitations were sent to all physicians and nurse practitioners (NPs). We identified asthma patients through a validated EMR search algorithm including: "asthma" in the cumulative patient profile (a standardized chart component which includes active and past medical history), use of the ICD-9 diagnostic billing code for asthma/allergic bronchitis (493) within the last 3 years [excluding patients in whom a chronic obstructive pulmonary disease (COPD)-related ICD-9 diagnostic billing code (491, 492, 496) had been used in the last 3 years]; and presence of "asthma" in any of the typed chart notes[27] (algorithm-generated lists were vetted/modified by clinicians). We included asthma

patients belonging to all consenting clinicians, who were ≥ 16 years old, understood English, and had been on asthma medication in the prior 12 months, while excluding patients who had been on a COPD medication in the prior year.[27] Patients who were pregnant, or whom the physician deemed to have cognitive limitations or a life expectancy of < 1 year were excluded. We reviewed all outpatient visits and asthma-related telephone interactions by staff physicians, residents, NPs, NP students, or physician assistants (PAs) between August 1st, 2012 and July 31st, 2013. We excluded visits exclusively for administration of injection medication(s) (e.g. the flu shot).

Patient Involvement

A patient organization (the Asthma Society of Canada) was involved from project inception and its members helped to guide the choice of research questions and the research design, and will lead efforts to disseminate results to patients.

Data Collection

Four trained reviewers entered data in a standardized electronic form (in Excel®). Data elements were agreed upon by primary care (GA, DC, AK, SGo) and respirology experts (SG, LPB). The form was refined for clarity and usability through three cycles of testing, each involving 20 visit reviews by each reviewer. Reviewers then independently abstracted data from 40 randomly selected visits to ensure agreement. Abstracted data included visit time/date, presenting complaint, demographics, baseline asthma parameters, baseline and changes to respiratory medications, previous asthma diagnostic testing (spirometry and/or methacholine challenge), previous hospitalizations or ED visits for asthma, previous referrals/visits to respirologists or allergists (and their findings), clinician documentation of asthma control according to symptom-based guideline criteria (Table 1),[8,9,20] actual asthma control according to symptoms recorded in any place in the chart, and provision of a written AAP.

Outcomes

The primary outcome was the proportion of visits during which practitioners assessed asthma control according to symptom-based criteria. Patients were considered to have poor control if they met one or more criteria for uncontrolled asthma (based on review of the current and any prior visits within each corresponding timespan) (Table 1). Secondary outcomes included the proportion of: patients who had asthma control assessed at least once; visits during which a controller medication was either initiated or escalated (and the proportion of patients with this); and patients who received a written AAP.

A priori, we identified a set of practically measurable, clinically-relevant, and plausibly explanatory parameters which might predict these outcomes, through a consensus of study co-investigators and knowledge-users, grounded in existing literature where possible. Parameters included: clinic, practitioner type, objective diagnosis of asthma, asthma control status, documented physician diagnosis of asthma, presenting complaint type, time of visit, billing physician (most responsible physician/other), and previous ED visits/hospitalizations for asthma.

We also characterized the proportion of patients who had control assessed at least once, which control questions were being asked, and current medication use as a function of control status, prior objective diagnosis, and prior ED visit/hospitalization for asthma.

Analysis

Interrater reliability was calculated using percent agreement. We summarized baseline clinician and patient characteristics descriptively, using information from the first visit in patients with multiple visits. We compared patient variables between sites with Fisher's exact/chi square tests and ANOVAs, as appropriate, and compared patient subgroups using the Fisher's exact test. We performed univariate analysis followed by multivariable logistic regression to calculate odds ratios and p-values for predictors of each outcome (covariates tested are listed above). In measuring control assessment, visits occurring within 1 month after a provider assessed control (a standard look-back period for symptom-based control questions) were excluded from the analysis. In measuring controller medication initiation/escalation, visits occurring within 3 months of a controller escalation or initiation were excluded (a standard period during which

further medication adjustments are discouraged, in order to allow for the prior medication changes to take effect). In measuring AAP delivery, we eliminated patients who had not been on a controller medication at any time during the study period (controller medication changes in the AAP are only recommended in patients on a baseline controller).[28] Analyses were performed using R Statistical Software (Version 3.2.4). Statistical significance was defined at a two-sided 0.05 level.

RESULTS

Chart Review

Agreement between reviewers in chart abstraction was 82.8–97.3% for control criteria, 97.5% for assessment of medication changes, and 100% for AAP delivery.

Model Assessment

The goodness of fit of the logistic regression models was assessed with the Hosmer-Lemeshow test, using a range of groupings. All were found to be non-significant, indicating the model was adequately fit. Additionally, we used bootstrap validation to assess the accuracy of the model. Based on the Somers' Dxy and the slope shrinkage factor, we identified very slight model overfitting.

Population

We recruited 19/42 (45%) physicians and 1/3 (33%) nurse practitioners (NPs). The NP had patients from an additional 4 physicians under their care, enabling us to analyze data for 23/42 (55%) physicians. These physicians had been in practice for 10.0 ± 8.6 years (range 0–29) and 15/23 were female (65%). They were the most responsible physician (MRP) for 884 asthma patients (Table 2). Given that patients could be seen by clinicians other than the MRP, these patients received care from 108 residents (66% female), 46 staff physicians [72% female, in practice for 9.8 ± 10.1 years (range <1-43)], 17 NPs, and 2 PAs. Each provider averaged 24.3 ± 39.4 patient visits (range 1 – 255) over the study period.

Fifty-five (6%) patients had been seen in the ED or hospitalized for asthma in the prior 10 years. These patients were more likely to be on a controller medication (32/55) (58.1%) than those without an ED visit or admission (243/829) (29.3%) ($p<0.01$). Ninety (10.2%) patients had an objective diagnosis of asthma (by spirometry or methacholine challenge).[14] Although patients receiving a COPD-specific medication and/or in whom a COPD billing code had been used were excluded through the EMR search algorithm, detailed chart review identified that 7.7% of asthma patients did have comorbid COPD (Table 2).

There were 4199 eligible visits over the study period (4.8 ± 4.8 visits/patient), among which 572 (13.6%) were for respiratory complaints, including 163 (3.9%) specifically for asthma. During the study period, 331 (37.4%) patients had at least one visit with a respiratory complaint and 28 (3.2%) were referred to see a respirologist or allergist. A further 159 (18.0%) patients had been seen by a specialist in the prior 10 years. Among these, 6 (3.8%) had received an AAP from that specialist.

Asthma Care

Primary Outcome: Asthma Control Assessment

Practitioners determined asthma control in 202/4122 (4.9%) eligible visits. Among 261 (6.2%) visits where *any* control question was asked, an average of 1.6 questions were asked, as follows: daytime symptoms (60.5%); rescue puffer use (44.8%); nighttime symptoms (27.2%), physical activity limitations (23.0%); and school/work absenteeism (4.2%). All five questions were asked in 4 (1.5%) of these visits (Figure 1).

In the multivariable model, clinic site ($p=0.019$) and nature of presenting complaint ($p<0.01$) were significant predictors of asthma control assessment (Table 3).

Of 884 patients, 136 (15.4%) had their control status determined at least once in the study year, with 135 (15.3%) having poor control and 1 (0.01%) having good control. Among the patients with poor control, 61/135 (45.2%) were on a controller medication [31/61 (50.8%) ICS alone; 27/61 (44.3%) ICS/LABA; 3/61 (5.0%) ICS + leukotriene receptor antagonist (LTRA)],

compared to 221/749 (29.5%) of the patients with unknown or good control (p<0.01) [104/221 (47.0%) ICS alone; 110/221 (49.8%) ICS/LABA; 7/221 (3.2%) ICS + LTRA)].

Secondary Outcomes

Controller Medication Initiation or Escalation

Controller medications were initiated or escalated by prescribers in 138/4159 (3.3%) eligible visits. Of 884 study patients, 136 (15.4%) had a controller medication initiated or escalated at least once in the study year. There was only 1 eligible visit (0.02%) in which a medication de-escalation was made.

In the multivariable model, clinic site (p<0.01) and nature of presenting complaint (p<0.01) were significant predictors of initiation or escalation (Table 4), as was the absence of a prior objective diagnosis of asthma (p=0.025). However, patients lacking prior objective diagnosis of asthma were less likely to already be on a controller medication (380/794) (47.9%) than those without an objective diagnosis (61/90) (67.8%) (OR 0.44, 95% CI [0.27, 0.69])(p<0.01). Uncontrolled asthma predicted initiation or escalation in a univariate analysis, but could not be added to the multivariable model (Table 4).

Asthma Action Plan Delivery

There were no AAPs delivered by any prescriber over the one-year study period to patients on a controller medication.

DISCUSSION

We reviewed Canadian primary care asthma management and identified large gaps across three fundamental evidence-based practices.[29] To our knowledge, this is the largest report to objectively characterize these gaps and to measure their predictors in a primary care asthma population.

Asthma control assessment was seldom performed, but was more common at academic sites (Table 3). This may be due to practice variation, as seen in other care practices (Table 2), and/or to population differences (Table 1). Control was more often assessed if the presenting complaint

was asthma- or respiratory-related. This may reflect formal control assessment or the effect of expected targeted questioning and/or patient symptom report. Although it might not be reasonable to expect clinicians to ascertain control at each visit, 85% of patients did not have control assessed despite an average of ~5 visits over the year and with 37% of patients having had at least one visit with a respiratory complaint. A lack of familiarity with control criteria may be a cause of this gap.[30] In a Canadian study, primary care physicians identified an average of 2.2 out of 8 control criteria.[31] Similarly, 26% of US primary care physicians were confident that they could assess asthma control.[32] This problem is compounded by the fact that patients also under-perceive their poor control and thus seldom volunteer poor control to their providers.[21] Additional barriers include lack of time, forgetting to assess control, and patient preferences for consultation content.[31]At least some of these barriers could be addressed by a periodic physician prompt with embedded questions[31] (paper or electronic), and/or a self-directed patient asthma control questionnaire which could be completed before the clinical visit. Certain control criteria, such as absenteeism, were rarely ascertained and their importance should be emphasized in future behavioural interventions.

Although we did not find a report of this gap in a Canadian setting, a US review of 430 primary care charts noted that *all* control criteria were assessed in 1% (0.1% of visits in our cohort), and at least one criterion was assessed in 59% of visits (6% of visits in our cohort).[32] In a 2014 UK review, among 135 patients who died of asthma and whose last asthma care visit had been in primary care, only 37 (27%) had asthma control assessed at that visit.[5] Considering that a majority of primary care patients are found to be uncontrolled when asked all five symptom-based criteria, and that our data and others'[33] suggest that practitioners are more likely to alter therapy in uncontrolled patients, our findings support a hypothesis that failure to recognize poor asthma control is a contributor to undermedication.

Correspondingly, therapy was infrequently augmented. Augmentation was more common in the non-academic site and during visits with asthma- or respiratory-related complaints (Table 4). A lack of objective diagnosis also predicted augmentation, likely because these patients were less commonly on a controller medication. Augmentation was more common during visits with poor asthma control, but occurred in only 6% of such visits, suggesting that other barriers play a role.

Although clinicians seem to be aware of the importance of systematic therapeutic escalation and recognize its expected favorable impact on outcomes,[34] barriers include a lack of knowledge of specific guideline-recommended thresholds for initiating/escalating therapy,[35-37] poor implementability of guidelines[6,22], and patient factors such as medication affordability and ICS aversion.[22,38] Overall, only 16% of patients received augmentation, compared to an estimated poor asthma control prevalence of 59% in prior studies.[22,23,33,39] Whereas the British Asthma Guideline suggests reducing therapy after achieving control to minimize side-effects and cost,[9] medication *de-escalation* occurred only once during the study period. Accordingly, our data may also suggest an "overtreatment" care gap among the ~35% of patients who were on controller medications. To address this gap, future behavior change interventions could use methods to elicit respiratory complaints from patients and alert physicians to these, and/or could exclusively target visits with respiratory complaints, which appear to be an enabler of medication optimization.

In a Canadian administrative database review, 37% of patients with poor control (defined based on short-acting bronchodilator prescriptions, ER/hospital visits, or asthma deaths) were not prescribed an ICS, compared with 54.8% in our study. The study also found that 74% of those with poor control on a high dose ICS were not prescribed an add-on LABA,[23] compared with 55.7% of patients with poor control on *any* ICS dose in our study. A similar administrative database review found that 47% of poorly controlled patients were not prescribed an ICS.[40] A practice audit of 15 Scottish primary care practices also suggested underuse of LABA therapy, with 180/547 (32.9%) patients on *high dose* ICS not on add-on LABAs.[34]

We did not record any AAP delivery over the study period. Previously, 12.8% of surveyed Scottish GPs reported providing their patients with AAPs[34] and 11% of surveyed Canadian patients reported receiving an AAP.[22] However, as is the case with other surveys[33], these data were likely affected by both reporting bias and selection bias. In contrast, both Canadian [41] and US [32] chart audits found results much closer to ours, with only 2% of patients having received an AAP. In a survey of Scottish patients who had an acute asthma attack requiring steroids or hospitalization in the previous six months, 58/254 (22.8%) reported possession of a written asthma action plan, however only 11 (3.9%) had received it from their GP.[34] Similarly, the UK

National Review of Asthma Deaths revealed that only 23% of patients who died of asthma had ever received an AAP (from primary or secondary care).[5] Surveys and qualitative studies indicate that a majority of physicians are aware of guideline recommendations for AAPs and consider AAPs to be important,[34] but fail to provide them due to a lack of time,[22,42,43] experience and confidence,[34,44] and lacking availability at the point of care.[22,34,42,43,45-48] In a Canadian study, 30% of physicians attending an asthma skills workshop were unable to prepare an adequate AAP,[47] while in a Scottish survey, an identical 30% of respondents indicated that they were "not at all" confident in preparing AAPs for their patients.[34] In the same survey, 47.7% of respondents indicated that AAP templates were not available in their practice.[34] Practices with access to allied health care team members with specific asthma management skills and knowledge and effective communication for delegation of tasks have been shown to have higher asthma guideline adherence.[49] Correspondingly, 46% of Scottish GPs indicated that a reorganization of care would enable them to improve implementation,[34] Accordingly, for this particular care gap, an organizational change may be required for increased uptake. Other complex interventions, such as a point-of-care computerized clinical decision support system which auto-generates an AAP might also be considered.[50] Of interest, our data suggest that this problem is not limited to the primary care setting, given that less than 4% of patients seen by specialists received an AAP.

We believe that our sample may be reasonably representative of primary care academic and non-academic environments. We measured the behavior of 46 staff physicians,108 residents, 17 NPs and 2 PAs spanning a wide range of practice experience. No sites had access to allied health resources for asthma management. Accordingly, clinicians managed asthma individually, as would occur in smaller group or solo practices. The divergent socio-demographic compositions of the two involved cities (Hamilton and Brampton) also support generalizability. Hamilton is a large urban centre with an average age of 41.3 years[25], median income of $87,590,[51] 14.3% visible minorities,[52] and 6.3% unemployment[53]. In contrast, Brampton is a suburb within the Greater Toronto Area, has an average age of 36.5 years,[54] median income of $68,782,[55] 66.4% visible minorities,[56] and 9.5% unemployment.[57]

Our study has several limitations. Our approach may have underestimated asthma control assessment and AAP delivery due to poor chart documentation. However, we believe that clinicians would be very likely to document poor asthma control if ascertained, given its clinical

relevance and influence on treatment decisions. Furthermore, only 15.3% of patients had poor control documented, compared to the expected 59% prevalence of poor control,[22,23,33,39] supporting the presence of an assessment care gap. Although chart reviews were performed remotely and contact with clinicians was minimal, clinicians may have improved care as a result of observation. Participation bias may have favored those with an interest in asthma. Our sample may not be representative of jurisdictions with vastly different socio-demographic compositions and/or practice models than those studied. Additionally, although we used a validated algorithm to identify patients with asthma[27] and physicians vetted algorithm-generated lists, some diagnostic misclassification likely occurred. Finally, our analysis was unable to account for repeated measures within subjects.

CONCLUSIONS

Large care gaps exist in primary care settings, across basic asthma care recommendations that have been found across international guidelines for over 15 years, and that are widely considered to be the standard of care. These care gaps are larger than previously found in self-report and survey-based studies. Complex implementation strategies will be required to overcome these gaps. Behavioural predictors identified quantitatively in this study complement those identified previously through surveys and qualitative studies. These factors should now be used to tailor and then test specific implementation strategies to effect behaviour change for each key care gap.

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TABLES

Table 1. Symptom-based criteria for assessing asthma control[8]

Criterion	Controlled	Uncontrolled
Daytime Symptoms *	<4 days/week	≥4 days/week
Night-time Symptoms*	<1 night/week	≥1 night/week
Physical Activity	Normal/No limitations	Restricted due to asthma in previous 3 months
Absenteeism	None	Missed work/school/other activities due to asthma in previous 3 months
Short-acting bronchodilator use*	<4 doses/week	≥ 4 doses/week

* Evaluated as an average of the prior 6 months

Table 2. Patient Characteristics

Characteristic	Overall n=884	Site 1 (Academic) n=429	Site 2 (Academic) n=245	Site 3 (Non-Academic) n=210	p-value
Mean age +/- SD (years)	46.0 ± 17.5	49.3 ± 17.9	43.9 ± 17.4	42.7 ± 15.9	<0.01
Sex, n (%)					0.604
Female	638 (72.1%)	307 (71.6%)	174 (71.0%)	157 (74.8%)	
Male	246 (27.9%)	123 (28.7%)	71 (29.0%)	53 (25.2%)	
Smoking status, n (%)					<0.01
Non-smoker	442 (49.8%)	226 (52.7%)	109 (44.5%)	107 (50.0%)	
Ex-smoker	132 (14.9%)	80 (18.6%)	32 (13.1%)	20 (9.5%)	
Smoker	168 (19.0%)	75 (17.5%)	47 (19.2%)	46 (21.9%)	
Not documented	142 (16.1%)	48 (11.2%)	57 (23.3%)	37 (17.6%)	
Comorbidities, n (%)					
Atopy	359 (40.6%)	192 (44.8%)	104 (42.4%)	63 (30.0%)	<0.01
COPD	68 (7.7%)	46 (10.7%)	13 (5.3%)	9 (4.3%)	<0.01
Other Resp. Diagnosis	16 (1.8%)	10 (2.3%)	5 (2.0%)	1 (0.5%)	0.243
Previous Diagnostic Testing, n (%)					
Spirometry	342 (38.7%)	198 (46.2%)	97 (39.6%)	47 (22.4%)	<0.01
Bronchodilator challenge (% of spirometries)	237 (69.3%)	137 (69.2%)	64 (66.0%)	36 (76.6%)	0.432
Methacholine challenge	88 (10.0%)	52 (12.1%)	30 (12.2%)	6 (2.9%)	<0.01
Baseline medications, n (%)					
Short-acting bronchodilator	564 (63.8%)	281 (65.5%)	149 (60.8%)	57 (27.1%)	<0.01
Inhaled corticosteroid alone*	150 (17.0%)	87 (20.3%)	45 (18.4%)	18 (8.6%)	<0.01
Inhaled corticosteroid with long-acting beta-agonist	132 (14.9%)	67 (15.6%)	30 (12.2%)	35 (16.7%)	0.359
Long-acting beta-agonist alone	6 (0.7%)	4 (0.9%)	1 (0.4%)	1 (0.5%)	0.669
Leukotriene receptor antagonist	21 (2.4%)	10 (2.3%)	9 (3.7%)	2 (1.0%)	0.515
Prednisone+	9 (1.0%)	6 (1.4%)	2 (0.8%)	1 (0.5%)	0.041

* without concurrent use of a long-acting beta-agonist in a combination inhaler or as a separate inhaler
+ includes only those patients using prednisone chronically

Table 3. Predictors of Asthma Control Assessment*

	Control Not Assessed (n=3920 visits)	Control Assessed (n=202 visits)	p-value**	Odds Ratio** (95% CI)
Primary care clinic			0.019[a]	
Site 1	1727 (95.0%)	90 (5.0%)		
Site 2	801 (92.7%)	63 (7.3%)		1.37 (0.93, 2.02)
Site 3	1392 (96.6%)	49 (3.4%)		0.72 (0.45, 1.14)
Appointment provider type			0.11[b]	
Physician	1847 (97.1%)	55 (2.9%)		
Nurse Practitioner	414 (95.4%)	20 (4.6%)		1.17 (0.60, 2.29)
Resident	1417 (92.6%)	114 (7.4%)		1.79 (1.07, 3.00)
Physician Assistant	242 (94.9%)	13 (5.1%)		1.26 (0.57, 2.77)
Clinical diagnosis of asthma			0.074	
Yes	2296 (94.1%)	145 (5.9%)		
No	1624 (96.6%)	57 (3.4%)		0.73 (0.51, 1.03)
Objective diagnosis of asthma			0.79	
Yes	357 (93.5%)	25 (6.5%)		
No	3563 (95.3%)	177 (4.7%)		0.93 (0.58 – 1.52)
Presenting complaint			<0.001[c]	
Non-respiratory complaint	3461 (98.3%)	59 (1.7%)		
Asthma	101 (63.9%)	57 (36.1%)		29.8 (19.3, 45.7)
Other respiratory complaint	358 (80.6%)	86 (19.4%)		14.5 (10.1, 20.8)
Time of visit			0.11	
On hours	3478 (94.8%)	191 (5.2%)		
Weekend/After Hours	442 (97.6%)	11 (2.4%)		0.57 (0.29, 1.13)
Previous ED visit/Hospitalization for asthma			N/A[d]	
Yes	63 (100%)	0 (0%)		
No	3857 (95.0%)	202 (5.0%)		
Patient seen by own MRP[d]			0.33	
Yes	1269 (97.5%)	33 (2.5%)		
No	2707 (94.1%)	169 (5.9%)		1.33 (0.75, 2.44)

CI denotes confidence interval

* In measuring asthma control assessment, we eliminated visits in which asthma control had been assessed within the prior 1 month (a standard look back period for symptom-based asthma control assessment)[29]

**p-values and odds ratios for each variable shown are from the multivariable model.

a although significant across all sites, differences were not significant in pairwise comparisons

b. although not significant across all provider types, in pairwise comparisons, residents were more likely to assess control compared to staff physicians [OR 1.8, 95% CI (1.1 – 3.0)]

c. in pairwise comparisons, control was assessed more often in asthma-related visits than in non-respiratory visits [OR 29.8, 95% CI (19.3-45.9)] and in any respiratory-related visits than in non-respiratory visits [OR 14.5, 95% CI (10.1-20.8)]
d this covariate was removed from the multivariable model due to no subjects having this variable among those who had their control assessed; the univariate p-value was 0.074.
MRP denotes most responsible physician

Table 4. Predictors of Controller Medication Initiation or Escalation*

	Controller not initiated or escalated (n=4021 visits)	Controller initiated or escalated (n=138 visits)	p-value**	Odds Ratio** (95% CI)
Primary care clinic			<0.01	
Site 1	1781 (97.8%)	40 (2.2%)		
Site 2	869 (98.3%)	15 (1.7%)		0.68 (0.41, 1.14)
Site 3	1371 (94.3%)	83 (5.7%)		1.61 (1.05, 2.48)
Appointment provider type			0.72	
Physician	1845 (96.6%)	65 (3.4%)		
Nurse Practitioner	419 (95.0%)	22 (5.0%)		0.92 (0.51, 1.65)
Resident	1512 (97.5%)	39 (2.5%)		0.81 (0.49, 1.35)
Physician Assistant	245 (95.3%)	12 (4.7%)		0.68 (0.33, 1.42)
Clinical diagnosis of asthma			0.47	
Yes	2369 (96.3%)	92 (3.7%)		
No	1652 (97.3%)	46 (2.7%)		0.88 (0.62,1.25)
Objective diagnosis of asthma			0.025	
Yes	383 (98.7%)	5 (1.3%)		
No	3638 (96.5%)	133 (3.5%)		2.44 (1.12, 5.26)
Presenting complaint			<0.01[a]	
Non-respiratory complaint	3503 (98.5%)	52 (1.5%)		
Asthma	124 (79.0%)	33 (21.0%)		17.8 (11.3, 28.0)
Other respiratory complaint	394 (88.1%)	53 (11.9%)		7.67 (5.73, 11.2)
Time of visit			0.66	
On hours	3586 (97.0%)	112 (3.0%)		
Weekend/After-Hours	435 (94.4%)	26 (5.6%)		1.11 (0.69, 1.80)
Previous ED visit/Hospitalization for asthma			0.86	
Yes	60 (95.2%)	3 (4.8%)		
No	3961 (96.7%)	135 (3.3%)		1.11 (0.37, 3.33)
Patient seen by MRP			0.17	
Yes	1273 (96.8%)	42 (3.2%)		
No	2748 (96.6%)	96 (3.4%)		1.43 (0.86, 2.38)
Asthma Control Level			N/A[b]	
Uncontrolled	636 (93.9%)	41 (6.1%)		
Unknown or Controlled	3385 (97.2%)	97 (2.8%)		

* In measuring controller escalation/initiation, we eliminated visits in which patients had had a controller medication escalated within the last three months (the typical duration of a therapeutic trial).[58] Initiation included starting of any

of the following medications: inhaled corticosteroid (ICS) alone, inhaled corticosteroid with long-acting beta-agonist (ICS/LABA), long-acting beta-agonist alone (LABA), leukotriene receptor antagonist, long-acting anticholinergic (LAAC). Escalation included an increase in the dose of an inhaled corticosteroid (ICS) or a combination ICS/LABA, addition of a LABA to an ICS, addition of a leukotriene receptor antagonist (LTRA) to an ICS or ICS/LABA, or addition of a LAAC to an ICS, ICS/LABA, or LTRA

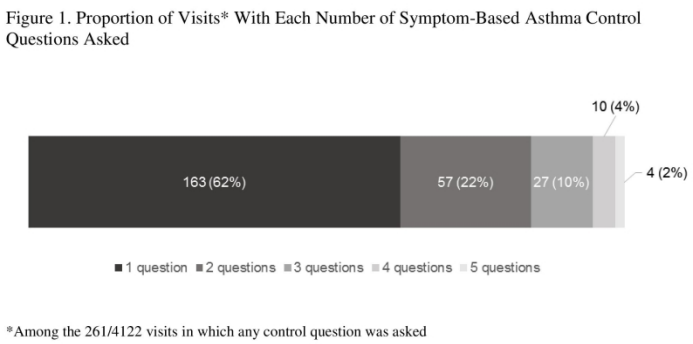
**p-values and odds ratios for each variable shown are from the multivariable model

a. In pairwise comparisons, controller medications were initiated/escalated more often in asthma-related visits than in non-respiratory visits [OR 17.8, 95% CI (11.3-27.956)] and in any respiratory-related visits than in non-respiratory visits [OR 7.7, 95% CI (5.7-11.159)]

b. This covariate was removed from the multivariable model since there were no subjects that had controlled asthma who had a controller initiated or escalated; the univariate p-value was <0.01

Figure Legends

Figure 1: Proportion of Visits With Each Number of Symptom-Based Asthma Control Questions Asked. The stacked bar graph provides the number and proportion of visits during which each of 1,2,3,4 or 5 symptom-based control questions were asked by the clinician (among the total visits across the study period where controlled was assessed).



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215x279mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

Note: Page numbers are shown based on the revised paper – all changes accepted

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract – **page 1, title**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found – **page 3**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported – **pages 5, 6**
Objectives	3	State specific objectives, including any prespecified hypotheses – **page 6**
Methods		
Study design	4	Present key elements of study design early in the paper – **page 6**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection – **page 6, 7**
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up – **page 6, 7**
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed – **N/A**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable – **page 8**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group – **page 7 (Data Collection), 8 (outcomes, analysis) / top of page 9**
Bias	9	Describe any efforts to address potential sources of bias **page 8 (outcomes, analysis) / top of page 9**
Study size	10	Explain how the study size was arrived at – **page 6, study design**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why – **page 8, analysis**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding – **page 8, analysis / page 9, model assessment**
		(*b*) Describe any methods used to examine subgroups and interactions – **page 8, analysis**
		(*c*) Explain how missing data were addressed – **N/A**
		(*d*) If applicable, explain how loss to follow-up was addressed – **N/A**
		(*e*) Describe any sensitivity analyses – **N/A**
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed – **page 9, population**
		(b) Give reasons for non-participation at each stage – **N/A**
		(c) Consider use of a flow diagram – **N/A**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders – **Table 2, patient characteristics**
		(b) Indicate number of participants with missing data for each variable of interest – **N/A**
		(c) Summarise follow-up time (eg, average and total amount) – **N/A**
Outcome data	15*	Report numbers of outcome events or summary measures over time – **page 10 (primary outcome), page 11 (secondary outcomes)**

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included – **Tables 3, 4**
		(*b*) Report category boundaries when continuous variables were categorized – **N/A**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period – **N/A**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses – **page 10 (primary outcome), page 11 (secondary outcomes)**
Discussion		
Key results	18	Summarise key results with reference to study objectives – **Page 11, paragraph 2 & page 12, paragraph 2**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias – **page 14, paragraph 3**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence – **page 15, paragraph 2 (conclusions)**
Generalisability	21	Discuss the generalisability (external validity) of the study results – **page 14, paragraph 2**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based – **page 1**

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.