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ORIGINAL RESEARCH

# Pragmatic 'real world' study of the effect of audit of asthma on clinical outcome

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## Summary

**Aims:** To test whether participation in clinical audit is associated with improved care of a long-term health condition.

**Methods:** 'Real world' study comparing 1339 patients of all ages and severity of asthma managed by 77 self-selected highly motivated general practices in Scotland with 9617 patients from 319 practices from a national sample.

**Results:** Patients managed by 'audit' practices had more structured clinical reviews by nurses [817 (61%) versus 4301 (45%) OR 0.52, 95% CI 0.46–0.58] and less acute GP contacts [440 (33%) v 4161 (43%) OR 1.56, CI 1.38–1.56]. Consequently they experienced more checking of inhaler technique, use of peak flow meters and self-management plans. 'Audit' patients had more symptom free days [365 (42%) v 2216 (23%) OR 0.80, CI 0.70–0.91], and fewer asthma attacks [217 (16%) v 1938 (20%) OR 1.30, CI 1.12–1.53]. They made less use of hospital services including A&E [30 (2%) v 326 (3%) OR 1.53, CI 1.03–2.28] and outpatients [42 (3%) v 459 (5%) OR 1.55, CI 1.11–2.16].

**Conclusions:** Patients with asthma benefit from being managed by a practice involved in a programme of audit.

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## Introduction

The care of many long-term health conditions, including asthma, is sub-optimal [1]. Local variations

in provision of care and discrepancies between best practice as recommended by guidelines and actual practice highlight the need to close the gap between theory and practice of modern quality care standards [2–4].

The public, media, and government expect those who work within and those who organise the health service to adopt best practice in accordance with

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Clinical Governance [5]. Evidence based Clinical Guidelines including those produced by the rigorous Scottish Intercollegiate Guideline Network (SIGN) method should form the 'gold standard' for clinicians to follow [3]. Unfortunately guidelines by their very nature are based around results of research studies rather than 'real world' clinical data. There is a pressing need to base clinical standards around realistic targets based on actual practice in order to support clinicians to improve care at a manageable pace.

The current evidence-based BTS/SIGN guideline recommendations highlight the importance of the use of regular audit to review practice management [6]. The importance of a structured tool for recording the review consultation, the presence of a trained asthma nurse, the importance of targeting care to 'at risk' groups and of monitoring outcome, have all been emphasised. A recent national audit of the care of people with asthma conducted across all regions of Scotland provided a unique opportunity to investigate the link between the structure, process and outcome of care based on 'real world' data. This paper reports on the link between how the care of people with asthma was organised within practices and their subsequent clinical outcome. Although not a randomised controlled trial, the paper utilises 'real world' clinical data to attempt to answer the question "does participation in audit improve patient outcome?"

## Method

All General Practices in Scotland were offered the chance to enrol in the Scottish Asthma Management Initiative (SAMI) supported by Health Boards, accredited for Post Graduate Educational Allowance, and recognised for Chronic Disease Management remuneration [7]. Practices could opt to use paper or electronic project materials (both formats contained identical information) and were asked to record details of how they organised the care of people with asthma, their commitment to training, and their experience of audit. Practices proceeded to complete a structured clinical review of 30 of their patients with asthma which included a review of medication, symptom scores, and health service utilisation. On enrolment practices were instructed on how to select the 30 patients from their practice asthma list using a pre-determined random number sequence which was provided. This figure of 30 was based on power calculations performed for previous work [8]. This target was also considered to be practical for the purposes of practice workload. On

completion of a 12 month retrospective recording of patient health service resource and medication use from medical records, patients were invited for a review of their current asthma status [7]. This assessment was based on the Royal College of Physicians 'Three Questions' for asthma and utilised the structure of the Tayside asthma assessment stamp [9]. The sampling process and recording materials were identical for all practices and throughout the life of the study. Practices were eligible to enrol and complete one or two annual audits. A full annual audit cycle consisted of a patient identification exercise, clinical assessment according to a structured format, issue of a set of current guidelines, and patient specific feedback on how their management compared to the then current British Asthma Guidelines. Practices were sent a personalised audit critique highlighting areas of concordance with the guideline and those areas where their current clinical practice was at variance. We requested a commitment from practices equivalent to two full days of clinical work and associated administrative time for each audit completed. Previous audit recruitment studies have suggested an expected completion rate of between 5% (UK postal survey) and 50% (local audit initiative) [8,10]. In order to examine whether participation in clinical audit was associated with favourable clinical outcome we opted to compare the second year of 'real life' clinical data from patients in practices that completed two consecutive years of the asthma audit cycle ('audit loop' group) with the data submitted by all the practices that participated in year one of the audit programme ('comparison' group).

We compared each patient-specific variable in both groups using two by two statistical tables. Our primary outcome variable was asthma attack rate. We emphasise as positive only those findings equivalent to  $p < 0.01$ .

## Results

### Practices and patients

Three hundred and nineteen (30%) of Scotland's 1049 practices voluntarily enrolled and completed at least one audit cycle. In year one the practices conducted a clinical review and reported data on 9617 patients with asthma. Data from this cohort was used to define the 'comparison' group. Seventy-seven of those practices opted to 'complete the audit cycle' by participating in two consecutive annual reviews submitting data on 1339 patients. These practices were classified as the

**Table 1** Comparison of practice characteristics at baseline for practices who completed the audit loop compared with practices who did not.

	One year audit only ( <i>n</i> = 242)	Two years of audit ( <i>n</i> = 77)	<i>p</i> values Odds Ratios and 95% Confidence Intervals
Number of partners			
1	28 (11.5%)	5 (6%)	<i>p</i> 0.29 1.88 (0.66–5.79)
2	50 (21%)	7 (9%)	<i>p</i> 0.33 2.60 (1.07–6.6)
3	43 (18%)	15 (19.5%)	<i>p</i> 0.87 0.89 (0.44–1.81)
4	39 (16%)	14 (18%)	<i>p</i> 0.80 0.86 (0.42–1.79)
5	40 (17%)	14 (18%)	<i>p</i> 0.87 0.89 (0.44–1.84)
6	21 (9%)	12 (15.5%)	<i>p</i> 0.13 0.51 (0.23–1.18)
7+	20 (8%)	10 (13%)	<i>p</i> 0.31 0.60 (0.25–1.46)
Unknown	1 (0.5%)		
Trained asthma nurse			
	174 (72%)	56 (73%)	<i>p</i> 0.99 0.68 (0.35–1.28)
Asthma clinic			
	179 (74%)	53 (69%)	<i>p</i> 0.46 0.87 (0.47–1.60)
Previous asthma audit in last 3 years			
	122 (50%)	56 (73%)	<i>p</i> 0.0009 0.38 (0.21–0.69)
Previous use of asthma stamp			
	116 (48%)	50 (65%)	<i>p</i> 0.0018 0.0.31 (0.16–0.60)

'audit loop' group. **Table 1** profiles the characteristics of the practices. At baseline there was no statistically significant difference in partner size, presence of an asthma trained nurse, or running of an asthma clinic between the practices that chose to complete a second year of audit and the practices who submitted only one year of data. Practices that completed the 'audit loop' were, however, statistically more likely to have completed a previous asthma audit in the 3 years prior to this study and to have used an assessment stamp for recording consultation data.

The patient age/gender profile was similar for both groups with 49% males and an age profile of 0–4 (3%), 5–15 (24%), 16–44 (39%), 45–74 (29%), 75 and above (5%) (**Table 2**). 16% of the people from all Scottish practices who submitted the first year of audit data ('comparison' group) were current smokers. In the 'audit loop' group the proportion

of smokers showed a non-significant difference of 16% compared to 14% (Odds Ratio 1.18, 95% Confidence Interval 0.95–1.46).

### Consultations and structured asthma reviews (**Table 3**)

In the 'comparison' group, unscheduled consultations with a GP for asthma related problems occurred in 4161 (43%) of patients, and with the practice nurse in 933 (10%) patients. There were fewer GP [440 (33%)] and nurse [88 (7%)] consultations for patients in year two of the 'audit loop' group (OR 1.56, 95%CI 1.38–1.76). By contrast a structured clinical review by a GP within a practice asthma clinic was recorded in 1705 (18%) and by a nurse in 4301 (45%) patients from the 'comparison' sample. For the 'audit loop' group in the second year of the audit, the equivalent figures were 215 (16%) GP (OR

**Table 2** Level of Prescribed Medication & Use of Emergency Medication.

	Comparison group (n = 9617) Number of patients (%)	Audit loop group (n = 1339) Number of patients (%)	Statistical comparison Odds Ratio and 95% Confidence Intervals
<b>Gender</b>			
Males	4705 (49)	652 (49)	
Females	4912 (51)	687 (51)	
<b>Age</b>			
0–4 years	286 (3)	64 (5)	
5–15 years	2327 (24)	346 (26)	
16–44 years	3754 (39)	446 (33)	
45–74 years	2810 (29)	424 (32)	
75+ years	440 (5)	59 (4)	
<b>British Asthma Guidelines Treatment Step</b>			
0	1434 (15)	199 (15)	1.00 (0.85–1.18)
1	1686 (18)	195 (15)	1.25 (1.06–1.47)
2	4375 (45)	613 (46)	0.99 (0.88–1.11)
3	1417 (15)	218 (16)	0.89 (0.76–1.04)
4	598 (6)	102 (7)	0.80 (0.64–1.01)
5	107 (1)	12 (1)	1.24 (0.66–2.38)
Emergency use of systemic steroids	1386 (14)	181 (14)	1.08 (0.91–1.28)
Emergency use of nebulised bronchodilators	517 (5)	55 (4)	1.33 (0.99–1.78)

1.13, 95% CI 0.96–1.32) and 817 (61%) nurse led review consultations (OR 0.52, 95% CI 0.46–0.58).

### Process of care

Inhaler technique was recorded as having been checked in 5262 (55%) of the 'comparison' sample but 892 (67%) of those patients in year two of the 'audit loop' group (OR 0.61, 95% CI 0.54–0.69). Peak flow was checked in only 62% of the 'comparison' group compared to 71% of the 'audit loop' group (OR 0.66, 95% CI 0.58–0.75). Equivalent figures for ownership of a self-management plan were 37% compared to 56% (OR 0.46, 95%CI 0.41–0.52), and ownership of a peak flow meter 38% compared to 54% (OR 0.48, 95%CI 0.48–0.60). Inhaler technique was deemed satisfactory in 87% of the 'comparison' group compared to 92% of the 'audit loop' group. A similar rate of recording of peak flow measurement in the notes (95%, 95%) and issue of a specific follow up date (76%, 78%) was seen in both groups.

### Symptoms

In the 'comparison' group only 23% of patients were reported as being free of asthma related symptoms

in the month prior to assessment compared to a 42% symptom-free rate in the 'audit loop' group patients (OR 0.80, 95% CI 0.70–0.91). A detailed breakdown of night time, day time and exercise symptoms for each age in each group is shown in [Table 3](#). Days lost (from normal activities such as play, school, work or leisure) due to asthma in the previous month were reported in 11.5% of the 'comparative' group compared to 8% in the 'audit loop' patients (OR 0.22, 95% CI 0.16–0.30). In the 'comparative' group 20% of patients reported one or more episodes of symptoms severe enough to be classified as an asthma attack prompting an urgent consultation and emergency treatment within the past year. Only 16% of patients in the 'audit loop' group experienced an attack or exacerbation (OR 1.30, 95% CI 1.12–1.53).

### Medication use

A similar proportion of patients in each group received one or more short courses of oral steroids (14%, 14%) and required emergency nebulised bronchodilators (5%, 4%). The proportion of patients from each group receiving British Asthma Guideline treatment Steps 0–5 is shown in [Table 2](#). There were no significant differences in the proportion of patients at each step.

**Table 3** Patient symptom levels, attack rate and use of health service resources.

	Comparison group ( <i>n</i> = 9617) Number of patients (%)	Audit loop group ( <i>n</i> = 1339) Number of patients (%)	Statistical comparison Odds Ratio and 95% Confidence Intervals
<b>Consultations</b>			
GP acute	4161 (43)	440 (33)	1.56 (1.38–1.76)
GP structured review	1705 (18)	215 (16)	1.13 (0.96–1.32)
Nurse acute	933 (10)	88 (7)	1.53 (1.21–1.93)
Nurse structured review	4301 (45)	817 (61)	0.52 (0.46–0.58)
<b>Process of care</b>			
Inhaler technique checked	5262 (55)	892 (67)	0.61 (0.54–0.69)
Peak flow measured	5945 (62)	951 (71)	0.66 (0.58–0.75)
Patient owns a SMP	3590 (37)	752 (56)	0.46 (0.41–0.52)
Patient owns a PFM	3689 (38)	719 (54)	0.54 (0.48–0.60)
<b>Primary care clinic attendance</b>			
Attended and assessed	6500 (68)	868 (65)	1.13 (1.00–1.28)
DNA	3117 (32)	471 (35)	0.88 (0.78–1.00)
<b>Symptoms and lifestyle impact</b>			
Symptom free	2216 (23)	365 (42)	0.80 (0.70–0.91)
Night time symptoms	2167 (23)	206 (24)	0.78 (0.68–0.89)
Day time symptoms	3529 (37)	364 (42)	1.55 (1.36–1.77)
Activity symptoms	2844 (30)	345 (40)	1.21 (1.06–1.38)
Days lost	115 (11.5)	71 (8)	0.22 (0.16–0.30)
<b>Primary care emergency management</b>			
Attacks and exacerbations	1938 (20)	217 (16)	1.30 (1.12–1.53)
<b>Secondary care service utilization</b>			
Accident and emergency attendance	326 (3)	30 (2)	1.53 (1.03–2.28)
Out patient attendance	459 (5)	42 (3)	1.55 (1.11–2.16)
Hospital admissions	240 (2.5)	23 (1.7)	1.46 (0.94–2.31)

### Hospital service utilisation

There were 326 (3%) patients who attended A&E due to their asthma in the 'comparison' group compared to 30 (2%) in the 'audit loop' group. Comparative figures for hospital admission were 240 (2.5%) versus 23 (1.7%), Outpatient attendance occurred in 5% of the 'comparative' sample but only 3% of the intervention sample (OR 1.46, 95% CI 0.94–2.31) (See Table 3).

### Discussion

'Real world' information on how practices actually manage people with asthma is important. Firstly, it serves as a benchmark for planning clinical services, assessing the impact of guidelines and clinical governance. Reform of the health service is critically dependent upon robust data

with a meaning and validity to working clinicians. The data presented here and displayed in Tables 2 and 3 can be used for comparison to measure change and progress. Long-term health conditions have an impact on individuals, their families and each tier of the health service. The results represent a national sample of one condition – asthma – and show the prevalence of symptoms, impact on lifestyle, primary and secondary care service utilisation, and medication use.

This 'real world' study is also important because it confirms that motivated medical teams can effect change. Patients registered with the practices that opted to complete two full audit cycles reported a reduction in symptoms, less disruption to lifestyle and greater concordance with the British Asthma Guidelines. Crucially these patients experienced less emergency health service utilisation in both primary and secondary care. The possible reasons for this favourable pattern of altered

disease control and reduced acute care need are interesting. The British Asthma Guideline Treatment Steps were similar for both groups but the structure and process of their care was different. Patients managed by practices that participated in two years of audit and thus completed the 'audit loop', were seen more frequently by the practice nurse for a review of their asthma management. They used self-management plans and home peak flow meters more frequently and most used their inhaler device in the correct manner. Enthusiasts will argue that this represents good evidence in favour of audit, guidelines, nurse led care and self-management plans.

The major limitation of this study is its reliance on routine clinical and audit data to infer causation. This was not a trial and the non-experimental, observational nature of the design means that care has to be taken when interpreting the results. If volunteering to participate in a study which required practices to spend a minimum total of 2 days to review their practice asthma management makes practices atypical then we can conclude that 30% of all Scottish practices are atypical. Comparison of the data between those groups interested enough in audit to enrol, and the sub-section of practices prepared to close the audit loop, merely highlights the association between interest, audit and improved patient care. Good recording of consultation data in notes and previous experience of the audit procedure may serve only to encourage practices to continue with the process. In the hierarchy of research methods pragmatic 'real world' studies are ranked well below meta-analyses and randomised controlled trials. We ask readers to judge for themselves whether a sample of one third of a nation's practices and a sample of over 9000 patients is a valid sample on which to base opinion. In a large and complex study one can debate how to group or classify participants. Comparison of practices that did or did not partake in one or two year's audit and regional variations may all be of some relevance. We think the most important message to highlight is the difference in patient outcomes seen when practices motivated to complete two audits are compared with those practices who were equally motivated to enrol initially but chose not to close the 'audit loop'. Inclusion in the 'audit loop' group in our study was based upon practice involvement but the results were derived from individual patients managed by those practices. In addition we could be accused of testing multiple outcome variables in search of positive results. For these reasons we report results at significance level  $p < 0.01$ .

One can speculate on whether the changes reported here are caused by or associated with participation in clinical audit. Asthma is a disease characterised by peaks and troughs. Patients will naturally improve and deteriorate over the course of a year. However, evidence in favour of cause and effect includes the consistent pattern of results across many variables. For example the changes in the structure of care given by the 'complete audit loop' practices (nurse reviews) is consistent with changes in process measures (peak flow usage, self-management plans), and clinical outcome (reduced symptom levels and asthma attack rates). Perhaps we should accept that the cause and effect debate should be consigned to academic archives and the real issue of what constitutes good care highlighted. High quality clinical audit is beneficial to practices and can contribute to improved patient care.

#### Conflicts of interest

None declared.

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