**An enhanced care package to improve asthma management in Malawian children: a randomised controlled trial**

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**Key messages:**

**What is the key question?**

Can an enhanced asthma care package, including optimisation of inhaler treatment and task-shifting of asthma education roles to non-physicians, improve asthma outcomes for children in a resource-limited setting, such as Malawi?

**What is the bottom line?**

Children receiving a pragmatic enhanced asthma care package reported significantly fewer symptoms and decreased exacerbations resulting in emergency health care attendance or school absence after 3-months, compared to those receiving standard care in a government hospital outpatient clinic in Blantyre, Malawi.

**Why read on?**

Asthma is an increasing concern in low- and middle-income countries but evidence to guide long-term management in these settings is lacking – it is essential to develop, evaluate and scale-up strategies specifically tailored to resource-limited settings to improve asthma care for the world’s poorest populations.

**ABSTRACT**

**Background**

Shortages of clinical staff make chronic asthma care challenging in low-income countries. We evaluated an outpatient asthma care package for children, including task-shifting of asthma management roles.

**Methods**

We conducted a non-blinded individually randomised controlled trial at a tertiary-level government hospital in Blantyre, Malawi. Children aged 6-15 years, diagnosed with asthma were recruited from outpatient clinic, stratified by Childhood Asthma Control Test (cACT) score, and allocated 1:1 from a concealed file, accessed during electronic questionnaire completion. The intervention, delivered by non-physicians, comprised; clinical assessment, optimisation of inhaled treatment, individualised asthma education. The control group received standard care from outpatient physicians. Primary outcome for intention-to-treat analysis was change in cACT score at 3-months. Secondary outcomes included asthma exacerbations requiring emergency health care and school absence.

Registration: Pan African Clinical Trials Registry: PACTR201807211617031

**Findings**

Between September 2018 to December 2019, 120 children (59 intervention; 61 control) were recruited; 65.8% males, with mean (SD) age 9.8 (2.8) years, mean (SD) baseline cACT 20.3 (2.6). At 3-months: intervention children (n=56) had a greater mean (SD) change in cACT score from baseline (2.7 (2.8) vs 0.6 (2.8)) compared to standard care participants (n=59); a difference of 2.1 points (95% CI: 1.1-3.1, p<0.001). Fewer intervention children attended emergency health care (7.3% vs 25.4%, p=0.02) and missed school (20.0% vs 62.7%, p<0.001), compared to standard care children.

**Interpretation**

The intervention resulted in decreased asthma symptoms and exacerbations. Wider scale-up could present substantial benefits for asthmatic patients in resource-limited settings.

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**INTRODUCTION**

Asthma is the most common chronic condition in childhood and is a growing concern in Africa.1 Asthma causes an estimated 1000 deaths worldwide every day, and is a major cause of morbidity in children, ranking in the top ten causes of disability adjusted life years.1 2 Asthmatic adults in sub-Saharan Africa (sSA) suffer frequent acute exacerbations, and have symptoms which are poorly controlled.3 4 Limited data from asthmatic children living in sSA suggest higher rates of severe symptoms compared to high-income settings, likely due to challenges with diagnosis and quality of asthma care.5

The Malawi Standard Treatment Guidelines for asthma management are extrapolated from global guidelines, adopting a step-wise approach centred on inhaled corticosteroid (ICS) therapy.6,7 These guidelines are appropriate where steroid-responsive, allergen-driven, eosinophilic asthma predominates: it is unknown whether this is true for Malawi. Limited evaluation of asthma guideline implementation in selected low- and middle-income countries (LMICs), found that physicians often underutilise ICS treatment, and that patient adherence to treatment is a challenge.8 Reasons for poor adherence are likely to be multifactorial, including unreliable supplies of affordable medication, and misconceptions regarding effective asthma treatments.9 10

Asthma education and the use of an Asthma Action Plan (AAP) are considered important elements of chronic asthma management in high-income countries (HIC) and are recommended in international guidelines.7 Studies demonstrating a beneficial impact of asthma education in HIC include a wide range of interventions, with variable content, duration and delivery methods.11 AAPs facilitate the early detection and treatment of an exacerbation, and have been shown to improve asthma health outcomes in HIC.12 However, the provision of asthma education can be time consuming and human resources constraints in Malawi limit the quality of care available. Task-shifting, defined as “the transfer of a task normally performed by a more highly trained health care worker to another with a different, usually lower level of training,” is a possible solution, but research exploring this approach to asthma management in LIC is lacking.13,14

We implemented a package of enhanced asthma care, appropriate for a LIC, delivered by non-physicians, which included a standardised clinical assessment, optimisation of locally available inhaled asthma treatment, and personalised asthma education.

We did a non-blinded, individually randomised controlled trial (RCT) comparing the effects of the enhanced asthma care package with standard outpatient care, on asthma outcomes over a 3-month period.

METHODS

Setting

Queen Elizabeth Central Hospital (QECH) is a government-run, tertiary hospital, located in Blantyre, Malawi’s second largest city, receiving referrals from the Southern Region. Children attending the general paediatric clinic are referred from primary health centres, and from within QECH following emergency department attendance or admission. The study was approved by the College of Medicine, Malawi (reference P.04/18/2384) and Liverpool School of Tropical Medicine, UK (reference 18-018) Research Ethics Committees.

Participants

All children aged 6-15 years attending the general paediatric outpatient clinic at QECH with a doctor-diagnosis of asthma recorded in their health passport were invited to participate. Children with symptoms suggestive of tuberculosis; productive cough, haemoptysis, weight loss, recurrent fevers or night sweats, were excluded.

Consent and randomisation

Study information was provided in the local language (Chichewa). Following written informed consent from the parent or guardian and assent from the child, a baseline electronic questionnaire was completed; children were stratified by their level of asthma control, as assessed by the childhood Asthma Control Test (cACT), into two groups (cACT≥20 or cACT≤19).15 Within each group, individuals were allocated 1:1 to intervention or standard care arms using pre-generated variable length, permuted block randomisation codes. Allocation information was not accessible to any staff prior to electronic questionnaire completion.

Procedures

The intervention comprised 3 components delivered by non-physicians; clinical assessment, optimisation of locally available inhaled asthma treatment, and asthma education. The components address the common challenges we have observed in Malawi and reallocate tasks usually performed by doctors to nursing staff and lay educators (Table 1).

**Table 1.** Components of enhanced care intervention; rationale for inclusion and member of staff performing each task

|  |  |  |  |
| --- | --- | --- | --- |
| **Factors contributing to suboptimal care** | **Component of intervention** | **Rationale** | **Staff\*** |
|  | ASSESSMENT |
| Assessment may be rushed or not systematic: symptoms often underreported or underrecognised | Administration of cACT | Objective and repeatable measurement of symptoms | L |
| Measurement of FeNO | Identify airway inflammation phenotype in this population  | L |
| Spirometry measurement | Objective measurement of airway obstruction | L |
| Spirometry QC/interpretation | N |
| Physical examination (auscultate chest, look for clubbing/lymph nodes) | Exclude co-morbidity or misdiagnosis (congenital /rheumatic heart disease, TB) | N |
|  | TREATMENT OPTIMISATION |
| Clinicians reluctant to prescribe ICS and escalate dose if needed | Treatment increased according to protocol based on cACT and FEV1/FVC ratio | Encourage appropriate use of ICS | L/N |
|  | ASTHMA EDUCATION |
| Fears and misconceptions, poor understanding of asthma and inhalers | 1-hour individualised asthma education session | Increase knowledge levels, improve inhaler technique and compliance | L |
| 6-week review: revision of asthma education | L |

\*Staff responsible for performing each intervention task: L, lay educator (non-clinical); N, nurse

Abbreviations: cACT, Childhood Asthma Control Test; FeNO, exhaled nitric oxide; FEV1, Forced Expiratory Volume in 1 second; FVC, Forced Vital Capacity; ICS, inhaled corticosteroid; QC, quality control; TB, tuberculosis.

Intervention: Clinical assessment

Participants in the intervention arm attended the hospital shortly after recruitment for an assessment visit which included clinical examination, anthropometry, exhaled nitric oxide (FeNO) measurement, and pre-and post-bronchodilator spirometry. All procedures were performed according to standardised operating procedures, with regular quality control monitoring by the study clinician. Asthma symptoms were assessed using Global Initiative for Asthma (GINA) and International Study of Asthma and Allergies in Childhood (ISAAC) questionnaires.5 7 Spirometry was conducted by experienced technicians, using an Easy On-PC spirometer (ndd Medical Technologies), according to American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines.16 Lung function was measured before and after 400µg salbutamol administered by metered-dose inhaler via a Volumatic spacer. Lung function parameters; forced expiratory volume in one second (FEV1), forced vital capacity (FVC), and FEV1/FVC ratio were interpreted with reference to the African American Global Lung Initiative 2012 equations.17 FeNO was measured using an NObreath machine (Bedford Scientific Ltd.), following ATS/ERS guidelines.18

Intervention: Optimisation of inhaled asthma treatment

Following clinical assessment, ICS treatment was started or escalated to a maximum daily dose of 400µg of beclometasone dipropionate, for children with poor control or obstructive spirometry (defined as cACT≤19 or FEV1/FVC ratio below the lower limit of normal (LLN) respectively). These participants were reviewed after 6-weeks to assess their response and encourage treatment adherence. Participants with cACT≥20 and FEV1/FVC above the LLN continued their previous medication.

Intervention: Asthma education delivered lay educators

Non-clinical “lay educators” delivered a 1-hour asthma education session to the child and carer, including discussion of a personalised AAP, with clinical support available if required. Educators were secondary school graduates, with no previous experience in medical education. Before study initiation, educators completed a structured training programme, and were required to pass a formal assessment of their knowledge and skills. Each asthma education session followed a structured approach, with checklist, to ensure consistency within and between educators. Details of the educators’ background, training programme and education session checklist are included in the online supplementary text S1 and tables S1 and S2.

Standard care

Participants in standard care continued with their asthma treatment and follow-up schedule prescribed by the QECH clinic staff (paediatric specialist of registrar or consultant level).

All participants received their medication from QECH pharmacy: salbutamol and beclometasone dipropionate inhalers are included in the Malawi Standard Treatment Guidelines, and usually available, free of charge. When inhalers were out of stock, children received their inhalers from a private supply, purchased by the Paediatric department.

Outcomes

All participants were invited for review at 3-months to assess primary and secondary outcomes. The primary outcome, asthma symptom control, was measured by the cACT, a 7-item questionnaire, translated into Chichewa according to linguistic validation guidelines, with forward and back translation and local piloting. Secondary outcomes were; asthma exacerbations requiring hospitalization, emergency health care use or treatment with oral corticosteroid; school absence; lung function; FeNO. Serious adverse events were reported within 72-hours to a Data Safety and Monitoring Board, which also met at regular intervals.

Follow-on care

At the end of the 3-month RCT period, participants receiving standard care were offered the intervention package. At the end of the intervention, all participants returned to QECH general clinic for ongoing care, with review after 3-months, or sooner if clinically indicated.

Statistical analysis

We planned to enrol 120 participants, aiming for at least 90 children with complete data, after loss-to-follow-up and technical difficulty with clinical procedures. Using two-tailed Student’s t-test, 45 children in each arm will detect a 3-point difference in cACT; an effect size of 0.6, given standard deviation 5, with 80% power at a 5% significance level.

Intention-to-treat analysis compared primary and secondary outcomes between the two arms using two-tailed Student’s t-test and Wilcoxon Signed-Rank test for normally distributed and skewed continuous data, respectively, with the primary outcome sub-analysed, stratified by baseline cACT . Pearson’s Chi-squared tests were used to compare proportions. Analyses were conducted using R v3.4.1 statistical software.

The trial was registered with the Pan African Clinical Trials Registry (reference PACTR201807211617031); the trial protocol is publicly available.19

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of this report. The corresponding author had full access to all the data in the study and final responsibility for the decision to submit for publication.

RESULTS

We recruited 120 children between September 12, 2018 to December 11, 2019; 59 and 61 were randomised to receive the intervention and standard care, respectively. Mean age (SD) of participants was 9.8 (2.8) years with 65.8% males. 115 participants were reviewed at 3-months (Figure 1): 114 children attempted spirometry, of these 86.8% (99/114) and 80.7% (92/114) produced acceptable FEV1 and FEV1/FVC measurements, respectively. Primary outcome questionnaire data was missing for one participant, and FeNO results for three participants due to technical issues. Mean (SD) duration of follow-up was 96.6 (12.0) days and 91.0 (10.1) days for intervention and standard care participants, respectively.

Eighty percent of participants reported previous hospital admission with asthma symptoms. In the preceding 3-months, 28/120 (23.3%) were admitted to hospital, 39/120 (32.5%) attended a health facility, but did not require admission, and 79/120 (65.8%) missed school due to asthma symptoms. Median (IQR) school absence was 3 (2-5) days, with 58.2% (46/79) of absentees seeking medical review. Baseline clinical characteristics were similar for both study arms (Table 2).

**Table 2.** Baseline characteristics of study population (n=120)

|  |  |  |
| --- | --- | --- |
|  | Interventionn=59 | Standard caren=61 |
| Age, mean (SD) years  | 10.1 (2.8) | 9.4 (2.9) |
| Sex: female, n (%) | 18 (30.5) | 23 (37.7) |
| Hospital admission ever, n (%) | 47 (79.7) | 49 (80.3) |
| Hospital admission in past 3 months, n (%) | 14 (23.7) | 14 (23.0) |
| Health facility attendance in past 3 months, n (%) | 18 (30.5) | 21 (34.4) |
| School absence in past 3 months, n (%) | 40 (67.8) | 39 (63.9) |
| School absence in past 3 months, median days (IQR) | 3 (2-5) | 3 (2-5) |
| Reported using salbutamol inhaler | 45 (76.3) | 51 (83.6) |
| Reported using steroid inhaler regularly | 21 (35.6) | 28 (45.9) |
| Daily dose beclometasone | 238 µg (n=21) | 273 µg (n=28) |
| GINA: Well controlled (score\* 0) | 12 (20.3) | 7 (11.5) |
| GINA: Partly controlled (score\* 1-2) | 20 (33.9) | 21 (34.4) |
| GINA: Uncontrolled (score\* 3-4) | 27 (45.8) | 33 (54.1) |
| cACT, mean (SD) | 20.4 (2.9) | 20.3 (2.3) |
| cACT ≥20 (well controlled) | 37 (62.7) | 40 (65.6) |
| cACT ≤19 (poor control) | 22 (37.3) | 21 (34.4) |

\* Score 1 for each positive response to: In the past 4-weeks, has the patient had: a) Daytime asthma symptoms more than twice/week? b) Any night waking due to asthma? c) Reliever needed for symptoms more than twice/week? d) Any activity limitation due to asthma?

Most children (106/120, 88.3%) reported wheezing in the past year; overall 68.3% (82/120) experienced ISAAC-defined severe asthma symptoms, with at least one of; ≥4 attacks (64/106, 60.4%), wheeze-related sleep disturbance more than once per week (34/106, 32.1%), or wheeze affecting speech (38/106, 35.8%), in the past year. By GINA criteria, asthma symptoms were well controlled in 19 (15.8%), partly controlled in one third (41/120) and uncontrolled in half (60/120) of participants. The baseline mean (SD) cACT score was 20.3 (2.6), with 43 (35.8%) participants stratified as having poor control (cACT≤19) and 77 (64.2%) with good control (cACT≥20) (online supplementary table S3).

At enrolment 96/120 (80.0%) participants reported using a salbutamol inhaler, with 67/96 (69.8%) using a spacer; 41/120 (34.1%) participants reported using a beclometasone inhaler (plus spacer) regularly, with a mean daily dose of 258µg and self-reported adherence of 89.6%.

None of the participants had been previously treated for tuberculosis. Of 105/120 participants who had been tested for HIV, all were HIV-negative. Half of participants (62/120, 51.7%) reported a family history of asthma, including 47/120 (39.2%) with asthma in a first-degree relative. The majority of participants experienced wheezing in early childhood; 52/120 (43.3%) reported wheeze onset before age 3 years, 41/120 (34.2%) aged 3-6 years, and 27/120 (22.5%) after age 6 years. Atopic symptoms were common; with self-reported rhinitis, hay fever, and eczema in 72/120 (60.0%), 37/120 (30.8%) and 31/120 (25.8%), respectively.

At 3-months, children in the intervention arm had a mean (SD) cACT of 22.9 (2.3), compared to 20.8 (3.0) in standard care (p<0.001). Children receiving the intervention had a greater mean (SD) change in cACT score from baseline; 2.7 (2.8), compared to 0.6 (2.8) for standard care participants, a difference of 2.1 points (95% CI: 1.1-3.1, p<0.001) (Table 3). On stratified analysis, overall those with baseline ACT≤19 showed greater change in mean (SD) cACT than those with baseline ACT≥20 (2.9 (3.3) vs. 0.9 (2.5), p<0.001): this was true for both intervention and standard care groups (Table 3). Participants receiving the intervention reported improvement in symptoms and GINA score, with little change for those receiving standard care (Figure 2).

Hospital admission and health facility attendance fell in both arms, compared to baseline. Compared with standard care, the intervention arm reported lower rates of admission (3.6% vs 10.2%, p=0.32), overall emergency health facility attendance (7.3% vs 25.4%, p=0.02), and school absence (20.0% vs 62.7%, p<0.001) (Table 3). Oral prednisolone was given during 8/30 (26.7%) exacerbations requiring emergency health care use.

FeNO levels and spirometry results were similar for both study arms at 3-months (Table 3). There were no significant differences in age, sex, study arm and baseline cACT between those with and without spirometry results (online supplementary table S4).

**Table 3.** Asthma outcomes at 3-months for 114 participants.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Interventionn=55 | Standard caren=59 | Comparison |
| **Primary outcome: cACT score** |  |  |  |
| cACT score, mean (SD) | 22.9 (2.3) | 20.8 (3.0) | P<0.001 |
| Change in cACT score from baseline, mean (SD) | 2.7 (2.8) | 0.6 (2.8) | P<0.001 |
| Stratified: baseline cACT ≤19 | 4.7 (2.6) *n=21* | 1.1 (3.0)*n=21* | P<0.001 |
| Stratified: baseline cACT ≥20 | 1.5 (2.2)*n=34* | 0.3 (2.7)*n=38* | P=0.046 |
| **Secondary outcomes** |  |  |  |
| ***Health care use*** |  |  |  |
| Exacerbations with hospitalization, no. children (%) | 2 (3.6) | 6 (10.2) | P=0.32 |
| Exacerbations with health facility attendance but not admission, no. children (%) | 3 (5.5) | 11 (18.6) | P=0.06 |
| Exacerbations with any emergency health care use, no. children (%) | 4 (7.3) | 15 (25.4) | P=0.019 |
| ***School absence*** |  |  |  |
| School absence, no. children (%) | 11 (20.0) | 37 (62.7) | P<0.001 |
| ***Pre-bronchodilator lung function*** |  |  |  |
| Mean (SD) % predicted FEV1 † | 86.9 (18.0) | 92.0 (17.5) | P=0.15 |
| Mean (SD) % predicted FEV1/FVC ratio‡ | 90.9 (12.5) | 92.8 (10.3) | P=0.42 |
| FEV1/FVC ratio below LLN, no. children (%)‡ | 15/47 (31.9) | 13/45 (28.9) | P=0.93 |
| ***Fractional concentration of exhaled nitric oxide (FeNO)*** |
| Median (IQR) FeNO, ppb \* | 41.8 (23.4-68.0) | 39.8 (22.9-57.9) | P=0.64 |
| High (>35 ppb), no. children (%) | 33 (58.9) | 31 (55.4) | P=0.85 |
| Intermediate (20-35 ppb), no. children (%) | 11 (19.6) | 15 (26.8) | P=0.50 |
| Low (<20 ppb), no. children (%) | 12 (21.4) | 10 (17.9) | P=0.81 |

†Technically acceptable FEV1 data available for 99 participants

‡Technically acceptable FEV1/FVC data available for 92 participants

\* FeNO data available for 112 participants

At 3-months, 98.1% (54/55) children in the intervention group were using a salbutamol inhaler with a spacer compared to 83.1% (49/59) receiving standard care (p=0.02). Daily ICS use was more common in the intervention group (47/55, 85.5% participants) compared to standard care (41/59, 69.5% participants) (p=0.07), with intervention participants prescribed a higher mean (SD) daily beclometasone dose: 331µg (121) vs 266 µg (99) (p=0.007). Self-reported adherence was 85.4% and 85.5% among intervention and standard care participants, respectively. Four carers (3 from intervention, 1 from standard care) reported non-availability of inhalers at QECH during the trial period.

Overall mean percentage predicted (SD) FEV1 was 89.4 (17.8) and mean percentage predicted FEV1/FVC ratio 91.9 (11.5), with one-third (28/92, 30.4%) of participants having a FEV1/FVC ratio below the lower limit of normal (Figure 3). Ten participants had a FEV1/FVC ratio below 0.7; of these, seven reported “good control” with a cACT≥20.

FeNO levels were generally high with a median (IQR) value of 41.5 (23.0-66.3) ppb and over half of participants (64/112, 57.1%) recording a FeNO level greater than 35 ppb (Figure 4).

No adverse events were reported except for asthma-related hospital admissions, which were not attributed to study procedures.

After RCT completion, 58 children in standard care received the intervention; 48 were reviewed again after 3-months (the remaining reviews were cancelled due to COVID-19). FeNO levels and lung function were similar, before and after the intervention (Table 4).

**Table 4.** Pre- and post-intervention FeNO levels and lung function, split by initial allocation groups\*

|  |  |  |  |
| --- | --- | --- | --- |
| **Initial allocation** | **Pre-intervention** | **Post-intervention** | **Pre-post comparison†** |
|  | **Median (IQR) FeNO, ppb** |
| Enhanced care | 44.5 (27.5-66.5)*n=57* | 41.8 (23.4-68.0)*n=56* | P=0.98 |
| Standard care | 39.8 (22.9-57.9)*n=56* | 35.0 (22.8-58.4)*n=48* | P=0.11 |
|  | **Mean (SD) % predicted FEV1** |
| Enhanced care | 88.5 (17.8)*n=48* | 86.9 (18.0)*n=50* | P=0.47 |
| Standard care | 92.0 (17.5)*n=49* | 88.1 (14.3)*n=44* | P=0.12 |
|  | **Mean (SD) % predicted FEV1/FVC ratio** |
| Enhanced care | 88.9 (9.8)*n=43* | 90.9 (12.5)*n=47* | P=0.29 |
| Standard care | 92.8 (10.3)*n=45* | 89.9 (9.1)*n=39* | P=0.30 |

\*A total of 117 children received the intervention (initial allocations: 59 enhanced care, 58 standard care), with 104 children reviewed 3-months post-intervention (56 enhanced, 48 standard).

†Pre- and post-intervention results compared using Wilcoxon-signed rank tests for paired data (for FeNO) and paired t-tests (for spirometry).

DISCUSSION

To our knowledge, this is the first RCT of a task-shifting intervention using nurses and lay educators to deliver asthma management in sSA. The key finding was a clinically and statistically significant improvement in asthma control in the intervention vs standard care group, with a difference in mean cACT change from baseline of 2.1 points (95% CI: 1.1-3.1) between groups. Greatest benefit was seen in those with poorer asthma control at baseline.

We found a high burden of symptoms among asthmatic children attending an outpatient clinic at baseline; in the preceding 3-months, one-quarter of participants had been admitted to hospital, a further one-third had attended a health facility, without overnight admission, and two-thirds had missed school due to acute asthma symptoms. The overall mean (SD) cACT was 20.3 (2.6), with 85% of participants reporting sub optimal asthma control, by GINA criteria. Despite a high burden of symptoms and previous engagement with the health care system, one-fifth had no salbutamol inhaler, and less than half had received ICS treatment, with relatively low daily doses.

In addition to improved asthma control, significantly fewer children in the intervention group experienced asthma exacerbations requiring emergency health facility attendance and school absence.

Participants demonstrated raised FeNO levels, confirming that ICS treatment is highly appropriate in this population. Self-reported ICS use was greater in the intervention group, with more children taking daily beclometasone, and participants prescribed a significantly higher daily dose. However, pre- and post-intervention FeNO levels were similar, suggesting unchanged levels of airway inflammation, possibly due to non-compliance with ICS treatment or lack of response in this population. Self-reported adherence rates were high (>85%), however there are often discrepancies when objective measures of adherence are compared to self-reports.20 Improved outcomes maybe due to increased confidence to intervene early in an attack, with self-management of symptoms at home, through effective use of inhaled salbutamol.

Current GINA guidance (for those ≥12 years) advises against salbutamol monotherapy, recommending using ICS either regularly or whenever salbutamol is taken.7 Compliance with daily ICS is a challenge in countries across the world; further research is required in LMICs to explore the clinical and cost-effectiveness of combination inhalers, which are becoming widely used in HICs.7 This is particularly important in children, where detrimental effects of airway inflammation during lung growth and development may have longer-term impact.

Participants were generally able to collect inhalers, free of charge, from our tertiary-level hospital pharmacy, however this does not reflect availability of inhalers more widely in Malawi: a recent survey reported <5% of health facilities, including district hospitals, have resources to treat chronic asthma.21 The reliable and affordable supply of inhaled medication, across all levels of health facilities, is a major challenge which must be addressed in many LICs.2

We found relatively high levels of reported asthma control (64.2%), defined by cACT≥20, compared to other studies in sSA, although most published data relate to adult patients. 3 4 Among paediatric patients attending a tertiary clinic in South Africa, 55.7% had controlled asthma (ACT/cACT >19) with mean (SD) cACT score 19.9 (5.5).22 However, despite the baseline cACT for our participants suggesting reasonable symptom control, the burden of exacerbations requiring health facility attendance and school absence was high.

Without a locally validated assessment tool, the choice of outcome measurement for this study was challenging; neither ACT nor cACT have been validated within sSA. The cACT is designed for children aged 4-11 years with four questions for the child, using a pictorial scale of Western children’s faces to rate symptoms, and three questions for their accompanying adult (total score: 0-27).15 23 The ACT is for those aged ≥12 years, with five questions (total score: 5-25).23 We chose to use the cACT for all participants, given the younger ages of most children attending clinic, rather than two separate tools, to avoid confusion for the study team and to avoid combining different scoring systems. However, obtaining responses which truly reflect the child’s clinical condition is difficult; younger children may struggle to recognise and articulate symptoms and have a poor perception of time, and children may be reluctant to answer, deferring to their elders in a culture which promotes hierarchical respect. Changing caregivers, meant that adults were sometimes unsure of the child’s symptoms over the preceding month, particularly at night or during the school day. To date, a clinically meaningful difference in cACT has not been established; in adults the minimally important difference in ACT is 3 points.23

We identified several children with severe airway obstruction but normal cACT scores; symptom perception may be impaired in children with chronic airflow obstruction and the poor correlation between self-reported symptoms and spirometry is well-recognised.24 Additionally, we recognise a cultural tendency among Malawians to underreport symptoms. Spirometry has limited availability outside of the research setting in most LICs, but peak flow meters can provide a useful alternative and may be a more appropriate component of future interventions, to provide an objective assessment of airway obstruction.7

Given the lack of other studies using non-clinical staff for task-shifting, we deliberately set a short follow-up period for this study, to minimise loss to follow up and maximise the chances of identifying a benefit or harm from this novel approach. Overall completeness of data collection was good, including acceptable and repeatable spirometry data for over 80% of participants.

We relied upon self-report of symptoms, exacerbations and inhaler use: recall bias is a potential limitation. We tried to quantify medication use by weighing inhalers but abandoned this as very few participants brought their inhaler cannisters despite reminders. Our study recruited patients attending outpatient follow-up at a tertiary hospital – we would expect a high rate of previous hospital admissions and attendances, since many patients are referred to this clinic from paediatric wards and the emergency department: this may explain why both groups to showed clinical improvement during the study and means our findings represent more severely affected asthmatic children in Malawi. Despite these limitations, our findings suggest that optimisation of inhaled treatment, supported by asthma education delivered by non-physicians, can have a beneficial effect on asthma outcomes.

Malawi suffers from a shortage of trained medical staff with 2 physicians and 28 nurses per 100,000 population, well below the WHO “critical shortage” threshold of 2.5 health professionals (including doctors, nurses and midwives) per 1000 population.25 This huge deficit in workforce requires an alternative approach to health care delivery: task-shifting has been successfully employed in the community case management of childhood illnesses and to improve access to HIV services in Malawi.26 27 Considering asthma management specifically, a study from Cameroon reported decreased asthma attacks among mostly adult patients attending a nurse-led asthma clinic, although loss to follow-up was high.14 Task-shifting asthma education to non-medical cadres has been explored in high-income settings, with comparable outcomes reported for asthma education delivered by lay people and nurses to adult patients.28 The use of lay educators has not previously been evaluated in LMICs: we propose that the potential impact may be greater than in HICs, due to lower baseline education and health literacy levels among poorer populations.

These promising data require further exploration of task-shifting in low-income settings. Scale-up of similar interventions across a wider range of health care settings, including both children and adults, could present substantial benefits to asthmatic patients and their families; assessment of health economic and longer-term clinical outcomes are required.

Together we can, and must, do better: building networks of clinicians and researchers from across sSA is essential to raise asthma awareness among local communities, health care providers and policy makers, to deliver LMIC-relevant research to inform clinical guidelines, and address the deplorable global disparities in access to inhaled medication.29 Effective asthma treatment should be available to all who need it, regardless of where they live.30

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**COMPETING INTERESTS**

None declared

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**FIGURE LEGENDS**

**Figure 1.** CONSORT flow diagram

**Figure 2.** Comparison of GINA categories at baseline (n=120) *(left)* and at 3-month follow-up (n=114) *(right)*

Standard care is shown in dark grey and intervention in light grey.

**Figure 3.** Distribution of percentage predicted FEV1 measurements at 3-months (n=99)

**Figure 4.** Distribution of FeNO levels measured at 3-months (n=112)

Dashed line shows threshold for high FeNO (>35ppb)

**ONLINE SUPPLEMENTARY MATERIALS**

**Text S1.** Asthma education intervention

**Table S1.** Pre-study asthma training for lay educators

**Table S2.** Asthma education checklist

**Table S3.** Baseline responses to cACT questionnaire from participants and carers.

**Table S4.** Comparison of those with and without spirometry data at 3-month follow-up

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