

SUNDAY, OCTOBER 5TH 2008

## 46. Wider aspects of managing respiratory disease in primary care

E217

### The level of sexual hormones in postmenopausal women with COPD (stage I-II)

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**Objective:** to determine the level of the women sexual hormones in patients with COPD at the postmenopausal age.

**Methods and materials:** 41 patients with COPD (mean age 50.8±1.41 years old) and 40 healthy women (mean age 51.5±0.64 years old) have been tested. All women worked on the large industrial enterprise of heavy machine-building. COPD diagnosis was established in accordance with COPD standards. The level of the woman sexual hormones was determined in the blood serum with the immunofluorescent method. All women were performed spirometry. Nobody received hormone replacement therapy. The average age of menopause beginning in patients with COPD 47.6±0.73 years old, in healthy women – 52.8±1.06 years old (p<0.05). Among the patients with COPD was revealed hypoprogesteronemia in comparison with the healthy group. In our study was determined linear correlation between indices of FVC (r=0.65) and FEV1 (r=0.62) and level of the progesterone in blood serum (p<0.05).

**Conclusion:** The low levels of women sexual hormones in patients with COPD to promote more severe course of disease.

E218

### Health care professionals' (HCPs) experiences and attitudes toward asthma management in rural communities

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**Background:** Asthma management practices in rural areas are unique and challenging. To date, the many potential reasons for this in Australian rural communities has not been widely investigated.

**Aim:** To investigate the experiences, attitudes and role-perceptions of general practitioners (GPs), pharmacists and people with asthma with regards to asthma management in rural communities.

**Methods:** Qualitative interviews were conducted with GPs, pharmacists and people with asthma in a rural area of Australia, based on a semi-structure interview guide. Interviews were transcribed verbatim and analysed using a content analysis approach.

**Results:** GPs and pharmacists widely commented that the largest barrier to optimal asthma management was the patient with asthma and their perception that asthma is not a serious condition requiring regular review and HCP input. The GPs and the pharmacists were aware that each of them played a significant role in asthma management but were not aware of the precise details and felt that improved communication between them would optimise the asthma management advice delivered to the patient. The patients did not feel that there were any significant barriers to optimising their asthma management and contradicted predictions by the GPs and pharmacists that large geographical distance and access to primary health care may be of concern.

**Conclusion:** These results suggest that the perceptions of asthma management of HCP and people with asthma, in a rural community are inconsistent. HCP identified low levels of interprofessional communication as a barrier to optimal asthma management.

E219

### The effects of vocal effort on respiratory health status in teachers

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**Aim:** In a cross sectional study we proposed to assess the possible risk for respiratory health status of teachers and identify risk factors for developing voice pathology.

**Material and Method:** The study was performed in a group comprised 370 full-time teachers (most of them primary and secondary school), age ranging from 18 to 65 years, compared with an adequate control group whose jobs did not involve vocal effort. All participants were subjected to a survey using an extensive questionnaire, general clinical examination, spirometric investigations, psychological and audiological studies, phonatory system and environmental condition of the workplace.

**Results:** The overall lifetime vocal symptoms were more frequent at teachers than at non-teachers (72 vs. 38%), and most frequent were: diseases of vocal cords and

larynx, chronic and allergic rhinitis, sinusitis, and pharyngitis, or teachers accused only hoarseness (permanent or recurrent) and dryness in the throat. Mean number of the voice symptoms was 3.17 in teachers and 1.83 in controls (p <0.001). Chronic and allergic rhinitis, sinusitis, and pharyngitis, were also significantly more frequent of teachers (33.5%) versus control (10.0%). Correlation between abnormal (non-euphonic) voice and abnormal spirometry was founded.

**Conclusions:** The prevalence of clinical signs of voice disorders or only self-reported symptoms is more frequent in teachers than in non-teachers. Different measures for preserving and recuperating the teacher's voice in formative, such as professional stages are proposed, and of special note is that the teacher must be considered a voice professional.

E220

### Effectiveness of guideline implementation within the German competence network CAPNETZ

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**Background:** Due to a gap between the recommendations of the German national guideline for management of community-acquired pneumonia (CAP) and the routine care, we developed and evaluated an implementation strategy to improve the quality of care of patients with CAP.

**Method:** In four randomised local clinical centres (LCC) of the competence network CAPNETZ the guideline was disseminated in several ways (seminars, poster, short printed form, interactive CD). Intermittent, participating general practitioners received a report including a comparison of their medical care before (September 1, 2006 to February 28, 2007) and after the implementation (March 1, 2007 to January 31, 2008). Furthermore, they were compared with control groups consisting of four LCC's without active implementation.

**Results:** Active guideline implementation resulted in a higher proportion of patients treated according to the guideline regarding the place of treatment (+0.7%), the length of treatment in outpatients (+11.1%) and inpatients (+5.9%), and the use of antibiotics in inpatients (+1.1%, not statistically significant). In contrast, the proportion of patients in the control group decreased in the same period by 6.3%, 8.4%, 4.3%, and 2.3%, respectively. In the control group CAP-mortality increased from 1.0% to 1.9% and decreased (not statistically significant after adjusting for sex and CAP-severity) in the intervention group from 3.7% to 0.7%.

**Conclusion:** This study shows slight improvements in the treatment of CAP after active implementation of a guideline. Further studies concerning the reasons, why physicians follow or do not follow guidelines could complement the knowledge about effective implementation strategies.

E221

### High prevalence of poorly controlled asthma amongst patients visiting clinics in Pune City, India

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The Global Initiative of Asthma has recently emphasized the importance of achieving and maintaining long-term control of asthma and recommends treatment action based on the patient's level of control. The aim of this study was to investigate the level of asthma control in asthmatic patients living in Pune city, India using the Asthma Control Test (ACT<sup>TM</sup>) and identify factors that determine asthma control an identify factors that determine asthma control.

**Methods:** 241 known asthmatics on regular asthma treatment of at least one year attending the general and chest clinics were administered the ACT<sup>TM</sup> questionnaire. Information on the family history, environmental factors and treatment history of the asthmatic subjects was also obtained. ACT<sup>TM</sup> score of ≤ 19 was considered to be uncontrolled asthma and ACT<sup>TM</sup> score > 19 was considered as controlled asthma.

**Results:** The prevalence of uncontrolled asthma was 62%. Presence of dampness in the walls at home [OR: 3.2 (CI=1.45-6.89)], absence of family history of allergy [OR: 2.98 (1.68-5.26)], use of biomass fuel [OR: 2.57 (CI= 1.06-4.36)] and poor treatment compliance [OR: 2.12 (1.22-3.67)] was associated with an increase odds of uncontrolled asthma.

**Conclusion:** This study demonstrates, for the first time, an increased prevalence of uncontrolled asthma (62%) amongst the asthmatics in India, which is particularly associated with wall dampness at homes, absence of family history of allergy, use of biomass fuel and poor treatment compliance.

E222

### Diagnostic accuracy of lipopolysaccharide-binding protein (LBP), fibrinogen and C-reactive protein (CRP) in differentiating pneumonia from acute bronchitis in primary care

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What is the diagnostic accuracy of lipopolysaccharide-binding protein and fibrino-

SUNDAY, OCTOBER 5TH 2008

gen compared to C-reactive protein for pneumonia in primary care patients with lower respiratory tract infections?

We assessed the sensitivities, specificities, positive and negative predictive values of all possible cut-off points of lipopolysaccharide-binding protein, fibrinogen and C-reactive protein for pneumonia and constructed receiver operating characteristic curves. To compare the overall diagnostic power of the blood tests, the respective areas under the curve were calculated and, additionally, compared with that of body temperature, an acknowledged clinical sign to differentiate pneumonia from acute bronchitis in primary care.

11 of 95 patients had radiographically confirmed pneumonia (11.7%). The area under the receiver operating characteristic curve was 0.90 for C-reactive protein, 0.92 for lipopolysaccharide-binding protein and 0.86 for fibrinogen. Body temperature yielded an area under the curve of 0.63. Differences between the areas under the curves were not significant for the three blood tests, but highly significant when compared to body temperature ( $p < 0.001$ ).

Lipopolysaccharide-binding protein and fibrinogen are equally strong predictors of pneumonia in patients with lower respiratory tract infection in primary care, but they do not perform better than C-reactive protein.

#### E223

##### Novel intradermal influenza vaccine: phase 3 data in targeted adult populations

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**Background:** Annual trivalent inactivated influenza vaccines (TIV) provide protection for hundreds of millions of individuals worldwide. Yet there is need to improve vaccine efficacy for the elderly who are most affected by influenza, and to increase vaccine coverage in younger adults. An ID TIV was developed with a unique, convenient microdelivery system, and 2 dosage presentations specifically for elderly and younger adults (respectively 15µg or 9µg hemagglutinin/strain/dose).

**Methods:** We conducted 2 multicentre, randomised controlled phase 3 trials to evaluate the immunogenicity and safety of the 2 ID TIV presentations versus a licensed intramuscular TIV, Vaxigrip<sup>®</sup>. Assessment criteria were the serum hemagglutination inhibition titres.

**Results:** 3701 elderly (60–94 yrs) and 2249 young adults (18–60 yrs) were enrolled and vaccinated ID (2612 elderly, 1796 young) or IM (1089 elderly, 453 young). Based on medical history, 65% of elderly and 43% of young subjects were at risk for influenza complications. In the elderly, ID vaccination resulted in significantly superior immune responses versus IM, as judged by all serological endpoints seroprotection, seroconversion and geometric mean titres. Significantly higher immune responses to ID TIV versus IM were also seen in the subgroups of elderly with at risk conditions. In young adults immunogenicity of ID vaccination with a lower dose of antigen was equivalent to IM.

**Conclusion:** Using microinjection to deliver antigen via the less-invasive intradermal route, ID TIV was shown to elicit superior immune responses to conventional vaccine in elderly adults, and provides an alternative vaccine for adults that may encourage increased vaccine uptake.

#### E224

##### Comparability of Asthma Control Test<sup>™</sup> (ACT) scores between different administration forms

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**Objective:** To evaluate the comparability of ACT scores between telephone interview and self-administered paper format.

**Methods:** Randomized, crossover design. ACT was administered twice (2-4 weeks apart) via mail (Paper) and interview (Telephone) formats to a convenient panel sample of English speakers  $\geq 18$  years old with an asthma diagnosis and receiving treatment. Adjusted mean ACT scores were compared at both time points. Repeated measures ANOVA was conducted with interaction term of ACT score and mode group. The ability of ACT scores to discriminate between severity was compared using ANOVA and t-test.

**Results:** Similar baseline characteristics with almost half of the sample indicating not well controlled asthma.

Table 1. Baseline Characteristics

Cross-over Group	(N)	Female (%)	Mean Age (yrs)	ACT Scores $\leq 19$ (%)
Telephone-Telephone	261	60.0	50.7	43.68
Paper-Paper	300	59.3	50.3	42.00
Paper-Telephone	279	63.2	51.3	48.03
Telephone-Paper	245	61.3	50.5	47.76

Adjusted mean ACT scores were affected by  $< 1$  point by mode group (range, 18.67-19.51). The interaction term for ACT score in ANOVA was not significant ( $p=0.43$ ). Mean ACT scores did not differ significantly between modes within severity.

Table 2. Comparison of Mean ACT Scores (SD) Between Formats, Baseline (n=1090)

	How would you rate the severity of your asthma in the past 4 weeks?				
	Not Noticeable	Mild	Moderate	Severe	Very Severe
Paper	23.6 (1.7)	19.9 (2.5)	15.5 (3.2)	10.3 (3.3)	8.0 (-)
Telephone	23.2 (1.8)	20.1 (2.6)	15.7 (3.3)	10.8 (2.7)	9.3 (3.4)
p-value	p=0.071	p=0.537	p=0.624	p=0.575	p=0.764

**Conclusion:** ACT scores from telephone interview are comparable to those from paper and pencil format.

#### E225

##### Mind the gap. A qualitative study of planned respiratory service development

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**Introduction:** Healthcare systems globally are reconfiguring to provide care for people with long-term conditions. In the UK, Primary Care Organisations (PCOs) are considering new ways of providing cost-effective respiratory care.

**Aims:** To explore the planned respiratory service reconfigurations and drivers/barriers to change

**Methods:** We purposively sampled 30 PCOs in England and Wales planning a range of respiratory services and conducted a semi-structured telephone interview with the person responsible for service development. Recorded interviews were transcribed and key themes identified.

**Results:** Although the primary driver was consistently identified as central policy to shift care into the community, the design of services was subject to a broad range of local, and at times serendipitous influences. Some PCOs seemed able to develop innovative and sustainable services despite uncertainty and financial restrictions. Most interviewees, however, highlighted the many barriers to progress describing initiatives shelved for lack of money, progress impeded by reluctant clinicians, and plans thwarted by conflicting policies. Although a challenge, teamwork between managers and clinicians was valued and could result in fruitful alignment of objectives and a broader approach to clinical, educational and strategic aspects of respiratory service development.

**Conclusions:** For many of our interviewees, there was a large gap between policy directives and practical reality. Active involvement of both primary and secondary care clinicians with PCO management seemed to be associated with broader service provision.

**Funding:** NIHR Service Development and Organisation.

WITHDRAWN

SUNDAY, OCTOBER 5TH 2008

**E227****Predictive factors of asthma control in clinical practice in France**

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**Introduction:** Asthma Control Test™ (ACT) is an easy-to-use, validated tool to assess the level of asthma control.

**Objectives:** One of the objectives of ATHMOS study was to describe asthma control in clinical practice using the ACT.

**Methods:** This was an epidemiological longitudinal survey of a cohort of asthma patients ≥18 y.o. at the time of an asthma consultation & again about 3 months later. Data about socio-demographic characteristics, asthma status & control (ACT), current treatments & their modifications were collected. We report the factors predicting a change from poor to good control.

**Results:** 987 doctors enrolled 2165 patients. At baseline, 38% of patients were well controlled (ACT score ≥20) vs 63% at follow up (p<0.001). We present the significant predictive factors of control.

	OR	P
Age	0.984 [0.976-0.992]	<0.005
Ongoing treatments:		
oral steroids	0.417 [0.180-0.966]	<0.05
anti-leukotrienes	0.662 [0.479-0.915]	<0.05
anti-cholinergics	0.227 [0.098-0.530]	<0.005
Prescription of:		
fixed combination of ICS & LABA	1.689 [1.161-2.455]	<0.05
theophyllin	0.334 [0.141-0.790]	<0.05
ER visits	0.491 [0.343-0.705]	<0.005
History of asthma	0.989 [0.978-0.999]	<0.05

**Conclusion:** The predictive factors of improvement of control after 3 months were younger age, treatment with a fixed combination of ICS&LABA, lesser ER visits, & shorter history of asthma.

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**E228****Clinical implications of diagnosing underlying chronic bronchitis (CB) in at-risk patients (pts) with acute bronchitis (AB) visiting general practitioners (GPs)**

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AB episodes may be the occasion of diagnosing underlying CB in at-risk pts. To describe the clinical implications of such a diagnosis, a cross-sectional study was performed by 737 GPs who screened 14 030 adult pts with AB. 7552 were qualified as "at-risk": age>40 years and >10 pack-years smoking history. Each GP selected 5 at-risk pts (age: 56.3±10.3 years; men: 68.4%) for analysis using questionnaires assessing demographic characteristics, risk factors, medical history, baseline symptoms, quality of life (EuroQOL-5D questionnaire), health care resource utilization and work loss.

Complete datasets (GP and pt questionnaires) were available for 2298 pts. Three groups were defined: pts with no CB (n=683); pts with CB diagnosed during the visit (n=278); pts with already known CB (n=1337).

Compared with pts with no CB, those with previously undiagnosed CB had more dyspnea (MRC stage 2 or more: 54% vs 36%) and more AB episodes, antibiotic courses for ABs (at least 1 during the last 3 years: 74% vs 62%) and periods of AB-related decrease in daily activity (at least 1 during the last 3 years: 50% vs 26%) (all, p<0.05). All quality-of-life domains and overall EuroQOL-5D scores were also more impaired (mean VAS: 61 vs 69 mm). Pts with previously undiagnosed CB were heavier smokers than pts with no CB. A higher proportion was also exposed to occupational gases and fumes or passive smoking.

Thus, undiagnosed CB has a significant impact on pts morbidity and health care resource utilization. AB episodes should lead to actively assess at-risk pts for the presence of CB.

Sponsored by Abbott France.

**E229****Retrospective analysis of ambulance calls caused by severe asthma exacerbation**

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The local ambulance base of information of call caused by severe asthma exacerbations has been analyzed. Compare the enlargement of general quantity of ambulance calls in 2005 (122540) with the same in 1995 (102929) (p<0,05) the real reduction of ambulance calls caused by severe asthma exacerbations is watched. In 1995 it was 3873 calls, 3,7% of the general quantity, in 2005 it was 3190 calls, 2,6% of all calls (p<0,05). The reductions of the share of ambulance calls is watched at the same time with the growth of general quantity of population (p<0,05) in 2005 (358403) compare to 1995 (302900).It is closely connected with the special state document putting into operation in 1999, were the general principles of diagnostic and asthma treatment for the doctors.

We also analyzed repeated ambulance calls. The absolute quantity of persons, who called the ambulance more than twice, reduced from 220 in 1995 to 143 in 2005 (p<0, 05). Accordingly, in 1995 they made 72,5% of all calls, in 2000 – 92% and in 2005 – 82,5%. So, not taking to consideration that fact that share of the calls is reduced in 2005 to 4,8%, we can watch the general growth of the share of repeated calls during the period of the latest ten year. It could be explained by the group of patient's existence with severe asthma exacerbations, who are controlled worse and worse year by year. This group of patient takes the biggest amount of state money given to the urgent help in general. So, the conclusion could be made that the commission of the state document gave positive results with asthma patient control. From the other side it showed some problems, which need the further study.

**E230****A new model of training to make spirometry in primary health care services**

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**Objective:** To compare the efficacy of two models of training on the quality of the spirometry (SP) in Primary Health Centres (PHC).

**Design:** Observational, descriptive, cross-sectional study

**Setting:** 28 PHC of Madrid

**Participants:** all the SP made in 27 PHC, after a classic model of training (CMT) and made in San Martin Centre (SMC), after an intensive model of training (IMT) during 1 month

**Interventions:** In 27 PHC, nurses made a classic formative activity of 6 hours. In SMC, nurses received the same training but with real patients in a short period of time and an extra support activity 15 days later. To evaluate the quality of SP 3 criteria were measured: forced expiratory time ≥ 6 seconds (C1), the forced expiratory maneuver is started instantaneously with a 'blast' leading to a rapid rise to peak flow, and the effort is sustained until the end (C2), and a concavity will be drawn up soft without rectifications and the finalization will be asintotic (C3).

**Results:** 241 SP were made after the CMT in 27 PHC and 249 after the IMT in SMC. 36,9% of SP in the 27 centres agree the 3 criteria of quality and 65,1 in SMC (p=0,000); the proportion ratio was 0,57 (IC 0,47-0,68). This difference between the two models maintained in every 3 criteria.

% of good quality criteria

	27 PHC (%)	SMC (%)	p
C1	58.1	92.4	0.000
C2	66.8	76.7	0.015
C3	68.0	79.9	0.008
Complete maneuver	36.9	65.1	0.000

**Conclusions:** An IMT to make SP is better than CMT to achieve an adequate quality of SP in PHC. The characteristics of this intensive model would be practices with real patients, to make a lot of SP in a short period of time, and extra support formative activity few weeks later.

**E231****Prevalence of asthma symptoms in athletes in the region of Tricity (Poland)**

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The aim of the study was to evaluate the prevalence of asthma symptoms in athletes in region of Tricity (Poland).

Young sportsmen from the Centre of Sport Medicine in Gdansk were included in the study. Data were collected during routine prophylactic visits. International Union Against Tuberculosis and Lung Disease (IUATLD) Asthma Questionnaire

SUNDAY, OCTOBER 5TH 2008

was used to evaluate the prevalence of asthma symptoms. Questionnaire was enriched by questions concerning age, gender, sports practiced, training experience, influence of physical activity, smoking, coexistence of other allergic diseases. 376 athletes (128 females-34% and 248 males-66%, aged 14-27 years -mean age 17 years) were examined. At least one exercise-related asthma symptom was observed in 38 athletes (10.1%). The most common symptoms were: chest tightness (31.9%), dyspnoea after exercise (29.8%), cough (21.3%), wheezing (17%). Co-existence of other allergic diseases (allergic rhinitis, conjunctivitis) was revealed in 46 patients (12.2%). Smoking was reported by 38 athletes (10.1%, 33 males, 5 females) including 31 daily smokers (8.2%) and 7 occasional smokers (1.9%). All daily smokers reported symptoms of asthma. Symptoms were significantly more common in subjects under age of 18 (23 subjects – 6.1%) than older ones (15 subjects – 4.0%) ( $p < 0.001$ ,  $\chi^2$  Pearson test=14.04) and in females compared to males ( $p < 0.05$ ,  $\chi^2$  Pearson test = 4.79).

Symptoms of asthma are frequent among the athletes in the Northern region of Poland, particularly in subject under 18. Smoking and other coexisting allergic factors might be associated with symptoms of asthma in athletes of Tricity. Questionnaire studies are helpful in detection of asthma symptoms.

**E232****The COPD dietician: food for thought**

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**Introduction:** BreathingSpace is a centre for the assessment and management of patients with COPD in Rotherham UK. Approximately 80 new patients are assessed each month. Approximately 50% of assessments at BreathingSpace meet referral criteria for dietician review, 12% requiring assessment for nutritional support (BMI <20) and 32% for weight reduction (BMI >30).

BreathingSpace has a 0.8 wte cardio-thoracic dietician who is responsible for patient management, administration, patient and staff education and home visits.

**Methods:** In the light of our BMI data collection we have calculated the dietician hours required to manage the above referrals. Initial audit of dietician activity suggests the following:

- 1.5 hour for nutritional support (30 min new appointment and 4 15 min follow up assessments)
- 18.5 hrs for 10 patients requiring weight reduction
  - 10 × 30 mins for each new patient appointment (5 hours)
  - 11 × 1 hr weight reduction sessions (assuming 10 patients each session)
  - 10 × 15 min follow up assessment (2.5 hours).

**Results:** 475 patients assessed May 2007 – Jan 2008. 75 dietician referrals during this period.

## Referrals to dietician

Nutritional Support		Weight reduction	
BMI <20	No. referred (%)	BMI >30	No. referred (%)
55 (11.6)	35 (7.3)	152 (32)	40 (8.4)

## Dietician workload broken down into hours per month:

- 52 hrs on weight reduction
- 21 hrs on nutritional support
- 10 hrs home visits
- 30 hrs administration and patient education
- 4 hrs staff education
- 8 hrs personal development (CPD)

Total = 120 hrs per month

**Conclusions:** 1) Referrals to the dietician are less than expected by BMI for underweight and obese patients.

2) Referral patterns are worse for weight reduction programmes.

3) BreathingSpace can support a 0.8wte dietician if adequate referrals are made.

**E233**

**Should guidelines be revised for add-on therapy in asthma? A 2 year randomized pragmatic equivalence trial of leukotriene antagonists (LTRAs) and long-acting beta agonists (LABAs) with inhaled corticosteroids (ICS) in primary care**

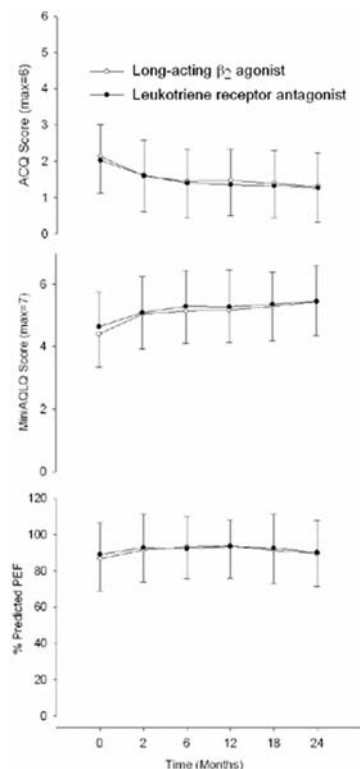
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**Background:** The relative effectiveness of LTRAs and LABAs as add-on therapy to ICS is unclear.

**Aim:** To test if LTRA provides equivalent improvements in asthma quality of life and control, at least equal to adding a LABA in uncontrolled asthmatic patients receiving ICS aged >11 years in primary care.

**Study Design and Methods:** Pragmatic, single-blind (to study staff), randomised controlled trial comparing LTRA and LABA as add-on to ICS with drug/device choices according to normal practice. Outcomes (Juniper Mini Asthma Quality of Life Questionnaire (mAQLQ), Asthma Control Questionnaire, % predicted PEF (%PEF), asthma exacerbations, respiratory tract infections (RTIs) and consultations for RTIs) were measured at baseline (time 0), 2, 6, 12, 18 and 24 months post-randomisation. Study was powered for equivalence based on mAQLQ difference of <0.3. Analysis of covariance (fixed effect: treatment; covariates: baseline value and time to follow-up) was used to compare all outcomes except %PEF, where Mann-Whitney test was used.

**Results:** 340 of 352 patients recruited (mean (SD) %PEF 88.01(17.69)) completed (164 LTRA, 176 LABA). No differences in outcomes at 2 months or 24 months were found.



**Conclusions:** Guidelines merit review to reflect equivalence of LTRA to LABA as add-on to ICS in primary care.

**E234**

**Non-inferiority comparison of budesonide HFA (BUD-HFA) pMDI with budesonide CFC (BUD-CFC) pMDI in patients with persistent moderate asthma**

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**Background:** CFC propellants in pMDIs are being replaced with HFA. Budesonide, a well known inhaled steroid has been developed by Cipla Ltd, India containing the HFA propellant.

**Aim:** To compare the clinical effect of BUD-HFA pMDI (Cipla Ltd, India) with the aim of proving non-inferiority to BUD-CFC pMDI (Pulmicort, UK) in achieving asthma control in symptomatic patients.

**Methods:** This was a randomized, double-blind, parallel group, multicentric study. Patients aged 12-65 years who were on a stable dose of inhaled steroids (< 800 mcg BDP equivalent) for the past 4 weeks; FEV1% predicted ≥60% and ≤80% were included. During the run-in period the patients underwent a dose reduction and were on a dose of 400 mcg of budesonide daily. Those who were symptomatic at the end of a 3 weeks open run-in period were randomized to a 12-week treatment with either BUD-HFA (n=146) or BUD-CFC (n=140) (200 mcg per actuation-2 puffs b.i.d). The primary efficacy variable was the change from baseline in pre-dose FEV1 over 12 weeks.

**Results:** For both the ITT (n = 286) and PP (n = 242) population, BUD HFA was not inferior to BDP CFC since the lower limit of two sided 95% CI for the change in pre dose FEV1 was greater than -200 ml (pre defined non-inferiority limit).

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[ITT population: 95% CI (-0.084, 0.052); PP population 95% CI (-0.098, 0.047)]. These findings were further supported by secondary efficacy parameters which were also comparable between two groups. The number of adverse events (AEs) was similar in both the groups.

**Conclusion:** It is concluded that BUD-HFA pMDI is clinically non-inferior to the BUD-CFC pMDI.