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ABSTRACTS

Selected abstracts from the PCRS-UK conference, Telford, UK, 7th-8th October 2011

1. Using consensus methodology to identify 'events' that could trigger holistic assessment of people with severe COPD

Cawley DC¹, Pinnock H, Oliver D, Billings J ¹University of Kent, Canterbury

Background: Current policy purports that 'quality' end of life care should be universally available irrespective of illness but evidence on how this should be done in non-malignant disease lacking. The 'lack of biographical disruption' and uncertainty of the COPD disease trajectory makes this difficult within a service model predicated on identifying 'transitions' to palliative care.

Aims: To identify 'events' within the life-long disease trajectory of COPD, that can trigger an assessment of the holistic (supportive and palliative care) needs of patients with severe disease and their carers.

Method: 1. Secondary analysis of transcripts from the 'Breath of Fresh Air' study (Pinnock *et al.*, *BMJ* 2011;**342**:d142) to identify candidate 'events' for consideration as triggers. 2. Consensus meeting of health and social care professionals to characterise a 'trigger' and prioritise candidate 'events' using a nominal group technique.

Results: Eight candidate 'events' were identified: requesting a 'Blue badge', home adaptations, hospital admissions, increasing burden of disease, housebound, failure to attend an appointment, shifting priorities of care, increasing carer burden. The consensus meeting affirmed that a successful 'trigger' should be visible to patient/carer/health or social care professional, meaningful to all stakeholders involved, actionable (i.e amenable to an intervention). The candidate 'events' that reached consensus (>75% agreement) were: requesting home adaptations, hospital admissions and being housebound.

Conclusion: The multi-disciplinary group agreed the key characteristics required for an effective 'triggers', and prioritised three candidate events. These need to be explored with COPD patients and their carers, to understand their acceptability, attributability, reliability, feasibility, and relevance of triggers in delivering quality care for people with severe COPD and carers.

Conflict of interest and funding: None

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2. Perspectives of patients and healthcare professionals on telemetrically supported patient self management for chronic obstructive pulmonary disease (COPD)

Fairbrother P, Pinnock H, Hanley J, McCloughan L, Todd A, McKinstry B

University of Edinburgh

Background: Tele-monitoring for chronic obstructive pulmonary disease (COPD) is promoted as a means of supporting patient self-management, though concerns have been raised about the risk of engendering dependence.

Aim: To explore the perceptions of patients and healthcare professionals on the role of COPD tele-monitoring in supporting (or otherwise) patient self management.

Method: Semi structured interviews were undertaken with patients and healthcare professionals participating in a tele-monitoring service for patients with COPD in Lothian, Scotland. Data were recorded, transcribed, coded and analysed thematically. Interpretation was supported by multidisciplinary discussion.

Results: 38 patients (47% male, mean age 67.5 years) and 32 healthcare professionals provided 70 interviews. Patients did not identify with the concept of 'self management'. Most appreciated being 'watched over' by the tele-monitoring, but rather than engendering dependence it seemed to give them confidence to manage their own condition. They credited tele-monitoring with improving their understanding of COPD and in reinforcing their decisions to adjust treatment or seek professional advice. Professionals discussed telemetry in terms of supporting attitudes and self-management behaviours related to medical compliance. They encouraged patients to exercise personal responsibility within these parameters.

Conclusion: Patients are willing to embrace greater responsibility for their health when supported and permitted to do so by healthcare professionals. Tele-monitoring can enable patients and professionals to realise the potential of telemetry to facilitate self management.

Conflict of interest and funding: None

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3. Reduction in exception rates from Respiratory QOF Gaduzo S, Ritchie B, Sullivan N Cheadle Medical Practice

Brief outline of context: Our suburban practice serving 11,800 patients has historically attained full QOF points for Asthma and COPD but with high exception rates.

Brief outline of problem: Comparison for 2009/2010 exception rates: COPD Asthma Practice 18.5% 2.6% PCT 10.9% 2.9% England 12.6% 5.2%

Assessment of problem and analysis of its causes: Commonest reasons for exemptions were "housebound, DNA, declined review, unable to perform spirometry."

Strategy for change: For the QOF year 2010/11 we adopted a structured, pro-active approach. BR (nurse) SCG (GP) and NS (HCA) formed the practice's respiratory team. Using the clinical software's disease registers we identified, early in the year, those patients who may be difficult to reach and who had previously been exempted. NS contacted them by telephone or letter, often on several occasions, explaining reasons for and importance of review, providing PILs where appropriate. Housebound patients were visited at home by BR and COPD/Asthma review was carried out. Those unable or

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unwilling to perform full spirometry were tested with a hand-held FEV_1 meter. Full medication and co-morbidity review was carried out to encourage holistic approach and to discourage further DNAs.

Measurement of improvement: Data for 2010/11 show no exceptions for asthma and 1.7% for COPD. Home visits, phone calls and printed matter were all well received and appreciated by patients

Effects of changes: For 2011/12 we plan to use this as an opportunity to extend the team approach to other clinical areas, and to involve social services, district nurses and voluntary organisations like Age UK.

Lessons learnt: A pro-active approach and near "zero tolerance" attitude to QOF exceptions have ensured almost all our respiratory patients are reviewed.

Message for others: Patient focussed "Zero tolerance" on exceptions is possible

Conflict of interest and funding: None

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4. Pulmonary Rehabilitation Services in the South West of England

Halpin DMG, Calvert J, Tanner K, Blackaby C, Holmes S NHS SW, UK

Aim: Pulmonary rehabilitation (PR) is one of the most effective interventions for people with COPD yet provision, capacity and uptake of PR is very variable.

Method: The Regional Clinical Respiratory Leads for NHS SW, surveyed all Primary Care Trusts and Hospitals in the SW to establish details of PR provision.

Results: 15 out of 17 hospitals and 8/14 PCTs replied. 10 Hospitals ran & 14 had access (3 partial depending on patients address) to PR programmes. 6 ran programmes in the community. 6 PCTs had access to PR (1 partial).

There was considerable variation in the staff running programmes: all included physiotherapists and most included nurses, some also had fitness instructors.

For those programmes providing data (n=15) the average maximum places/yr was 139 (range 60-300). The average waiting time was 21 weeks (range 6-52). The average ratio of referrals to places was 1.34 (range 0.88-2.13).

A variety of outcome measures were used by programmes: most had a measure of exercise capacity (12), some measured health status (7) and psychological parameters (6). Some used other measures, including locally developed questionnaires.

Only 3 programmes produced an annual report, only 1 PCT knew what it spent on PR and there were variations in the way programmes funded.

Conclusion: This survey demonstrates the heterogeneity in organisation and funding of pulmonary rehabilitation - this has the potential for creating inequities in access and outcomes from pulmonary rehabilitation that should be reviewed nationally

Conflict of interest and funding: None

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5. Coping strategies for young people with severe asthma Humphreys E Asthma UK

Aim: Up to 250,000 people in the UK have severe asthma, which is associated with poor quality of life. Coping with this can be particularly challenging for young people, although there is only limited understanding of their coping strategies. This project sought to identify how young people approach the management of severe asthma and the problems it causes in their lives.

Method: Two focus groups were held in early 2010 with eight people aged 16-24 with severe asthma, recruited via specialist centres in London and Belfast. A grounded theory approach was taken to data collection and analysis. These focus groups were a subset of a larger study investigating coping strategies across all age groups.

Results: Coping strategies aligned with the revised health belief model, which suggests that decisions about health behaviours are influenced by perceptions in four areas: the threat or severity of illness, the costs and benefits of taking action, the value of the change in threat or severity and self-efficacy. However, perceived costs and benefits of particular behaviours were often finely balanced in terms of health outcomes. This meant that social factors such as asthma's impact on young people's relationships and aspirations often substantially affected how they felt about asthma and approached its management. Coping strategies were therefore not always focused on improving asthma control, but on mitigating the consequences of asthma symptoms and treatment side effects on quality of life.

Conclusion: There may be scope to improve health outcomes among young people with severe asthma through developing support services which enable them to deal with severe disease effectively. Development of initiatives which complement existing provision would be valuable.

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6. Trends in respiratory symptoms in children Linehan MF, Niven RM, Baxter D, Frank TL University of Manchester

Aim: To investigate changes in respiratory symptoms over seven years **Method**: MANCAS and MANCAS2 investigated the relationship between BCG vaccination and risk of asthma. Participants were born in a Manchester maternity unit between 01.07.93 and 31.03.97 although the first MANCAS study excluded children born between 01.01.94 and 17.11.94. The cohort was aged 6-11 yrs for the MANCAS study and 13-17 yrs when MANCAS2 was carried out. Response rates were 47.5% (2414/5086) and 25.4% (1608/6338) respectively. Data were collected on prevalence of respiratory symptoms. Table 1 compares differences in prevalence between MANCAS and MANCAS2 for the 801 respondents to both studies

Results: Table 1

| 12-month | Wheeze | Night | Asthma | Hayfever/ |
|----------|--|--|--|--|
| wheeze | with exercise | cough | medication | eczema |
| 17.7% | 11.7% | 29.5% | 14.8% | 41.6% |
| 15.7% | 12.5% | 18.3% | 14.7% | 46.9% |
| 0.15 | 0.60 | <0.01 | 1.00 | <0.01 |
| | 12-month wheeze 17.7% 15.7% 0.15 | 12-month Wheeze wheeze with exercise 17.7% 11.7% 15.7% 12.5% 0.15 0.60 | 12-month Wheeze Night wheeze with exercise cough 17.7% 11.7% 29.5% 15.7% 12.5% 18.3% 0.15 0.60 <0.01 | 12-month Wheeze Night Asthma wheeze with exercise cough medication 17.7% 11.7% 29.5% 14.8% 15.7% 12.5% 18.3% 14.7% 0.15 0.60 <0.01 |

Conclusion: There was no change in prevalence of wheeze, wheeze with exercise or asthma medication suggesting that children with respiratory symptoms at age six will continue to show evidence of respiratory disease in adolescence. Wheezing patterns are shown to be established by age six with

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no change up to age 16 yrs for children with respiratory symptoms in the preschool years.¹ The significant decrease in night cough might signal maturation of the cough reflex pathway.² The increased lifetime prevalence of hayfever/eczema might reflect the additional time available for these disorders to manifest in adolescence.

- 1. Morgan *et al*. Outcome of asthma and wheezing in the first 6 years of life: followup through adolescence. *Am J Respir Crit Care Med* 2005;**172**(10):1253-8.
- Varechova et al. Role of gender and pubertal stage on cough sensitivity in childhood and adolescence. J Physiol Pharmacol 2008;59(suppl6):719-26.

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7. Telehealthcare for COPD McLean S, Nurmatov U, Pagliari C, Car J, Sheikh A Allergy and Respiratory Group, University of Edinburgh

Aim: To systematically review the effectiveness of telehealthcare for COPD. Method: We searched the Cochrane Airways Group Specialised Register of Trials. We searched registers of ongoing and unpublished trials. We selected randomised controlled trials comparing telehealthcare with control in those with a diagnosis of COPD. Our outcomes of interest were quality of life, emergency department visits, hospitalisations and death. Two authors independently selected trials for inclusion. Study quality was assessed using Cochrane collaboration's risk of bias method. Meta-analysis was undertaken using fixed effect or random effects modelling.

Results: Our searches identified 220 potentially relevant articles, from which 10 randomised controlled trials were included. Telehealthcare was not associated with a change in quality of life. Telehealthcare resulted in a significant reduction in the number of patients with one or more emergency department attendances: OR=0.27 (95% CI 0.11 to 0.66) and with one or more hospitalisations: OR=0.46 (95% CI 0.33 to 0.65) over 12 months. There was no significant difference in the risk of death: OR=1.05 (95% CI 0.63 to 1.75).

Conclusion: Telehealthcare can substantially reduce the risk of emergency department attendance and hospitalisation, but is unlikely to reduce the risk of mortality in people with COPD.

Conflict of interest and funding: SM received an honorarium for speaking on telehealthcare.

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8. The prevalence of asymptomatic viral infection of the respiratory tract in susceptible patients with asthma and chronic obstructive pulmonary disease Morjaria A

Barts and the London Medical School, London, UK

Aim: We sought to determine the prevalence of asymptomatic respiratory viral infection in patients with asthma and COPD. Also to identify the impact positive results would have on exacerbation rate and respiratory function in asymptomatic patients.

Method: Respiratory specimens were collected by induced sputum and nasopharyngeal and throat swabs from patients with asthma (n=50), COPD (n=50) and control individuals (n=84), when asymptomatic. The samples

were analysed by RT-PCR for: influenza A and B, respiratory syncytial virus, parainfluenza 1, 2 and 3, adenovirus, enterovirus, rhinovirus, metapneumovirus and the H1N1 influenza virus. We also measured the number of exacerbations suffered in the previous year, lung function, disease severity and disease control in asthma and COPD patients.

Results: From all respiratory samples taken 9/314 (2.9%) were positive for a virus. For the asthma group 5/100 (5.0%) of nasopharyngeal and throat swab and induced sputum samples were virus positive. In the COPD group, 2/83 (2.4%) of samples were positive and for control patients 2/131 (1.5%) of nasopharyngeal and throat swab samples were positive. However, we did not find an association between having a lower lung function, increased severity of disease, poor disease control and a higher number of exacerbations between individuals who were virus positive and negative.

Conclusion: Positive virology samples were only found in a small number of asymptomatic patients and no association was found for clinical characteristics between virus positive and negative subjects. However, an asymptomatic respiratory viral infection should be considered as a possible cause of frequent exacerbations and worsening lung function, as sample sizes in this study were too small to detect a difference.

Conflict of interest and funding: None

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9. HELPing older people with very severe chronic obstructive pulmonary disease (COPD) towards the end of their lives: developing a practical intervention (HELP-COPD) Pinnock H, Kendall M, Murray S, Worth A, Levack P, MacNee W, Sheikh A, White P, Rabinovich R, Drost E, Stewart J University of Edinburgh

Aim: Our recently published qualitative study (Pinnock H, *et al. BMJ* 2011;**342**:d142), and on-going work on intractable breathlessness offer new approaches to providing effective palliative and supportive care for the increasing number of elderly people with very severe COPD.

Method: Our prototype intervention (HELP-COPD) was first discussed at a multi-disciplinary discussion group. We propose to use qualitative methodology iteratively to develop and refine a novel holistic assessment, undertaken during or immediately after a hospital admission, which addresses the supportive care needs of people with severe COPD. We will then pilot the intervention in a randomised trial.

Results: A trial specialist nurse trained in palliative aspects of respiratory care will meet patients admitted with an exacerbation if COPD and work through the HELP-COPD tool with the patient (and carer if the patient wishes), and any areas of concern identified. Based on the findings of the assessment, a range of actions points may be generated, and any referrals made through the usual channels. The completed HELP-COPD tool will be sent to agencies and individuals receiving referrals as a result of the assessment, with copies for the patient, their GP, and hospital records. The tool will be reviewed by the trial nurse who will contact the patient at 1, 3 and 6 months to check progress with action points.

Conclusion: It would be helpful to have the opportunity to discuss our prototype HELP-COPD tool and proposed research with delegates at the PCRS-UK conference.

 $\mbox{Conflict of interest and funding:}$ None. This is a research idea for discussion

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10. Prioritising International Primary Care Respiratory Group (IPCRG) research needs: an e-Delphi exercise

Pinnock H, Yusuf O, Ostrem A, Tsiligianni I, Stallberg B, Román Rodríguez M, Ryan D, Thomas M, Williams S University of Edinburgh

Aim: The IPCRG Research Need Statement (RNS) identified 145 primary care research needs in five domains: asthma, allergic rhinitis, chronic obstructive pulmonary disease, tobacco dependence, respiratory infections.[Pinnock *et al. Prim Care Resp J* 2010;**19**(Suppl 1): S1-S21]. We aimed to identify the priority research questions in each disease domain.

Method: An expert panel (we invited 63 international clinicians: RNS authors, members of IPCRG research and education sub-groups, and associate/member country representatives) scored the clinical importance, feasibility, and international relevance of each research question on a scale of 1 (low) to 5. Subsequent rounds asked participants for an overall priority score informed by the groups' median scores. Consensus was defined as 80% agreement for the priority score of 4 or 5.

Results: 23 experts from 21 countries participated: 100% completed all three rounds. 62 (43%) of the questions were prioritised, evenly distributed across the five domains. 19% of the priority questions concerned identification/diagnosis, and 27% related to assessment of disease severity/control. A recurring theme was for simple tools (e.g. questionnaires) to enable diagnosis and assessment in the primary care setting. Seven questions recorded 100% agreement: identification of COPD, diagnosis of COPD and rhinitis, assessment of asthma and respiratory infections, management strategies for rhinitis, and implementing asthma self-management.

Conclusion: The five disease areas all included priorities for the IPCRG. Overarching priorities were the need for 'simple tools' for assessing diagnosis and severity, broad management strategies and implementing self-management. This will inform IPCRG research policy, and may influence funders and researchers prioritising real -life primary care respiratory research.

Conflict of interest and funding: None. The IPCRG provided administrative support.

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11. Patterns of Fostair[®] prescribing in the UK Price D, Small I, Haughney J, Ryan D, Gruffydd-Jones K, Papi A, Lavorini F, Huang S

Research in Real Life Ltd (RIRL), Norfolk, UK

Aim: A combination of extrafine inhaled corticosteroid (ICS) and long-acting beta-agonist, beclometasone/formoterol (BDP/FOR), Fostair 100/6 (Chiesi), is indicated in asthma patients ?18 years at British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) Asthma Guideline Step 3. Data are lacking on the nature of real-world BDP/FOR prescribing. This study characterises prescribing patterns (1) prior to; (2) at the time of BDP/FOR initiation.

Method: A pooled retrospective observational study using the UK's Optimum Patient Care and General Practice Research Databases (OPCRD and GPRD). Patients were characterised by therapy – using BTS/SIGN Steps – over a 12-month baseline period prior to BDP/FOR initiation (i.e. prior to the index

date) and by ICS dose change at the index date.

Results: Breakdown of patients by baseline therapy and ICS dose change at index date.

| ICS dose | BTS/SIGN therapy step during baseline | | | | | | | | |
|----------------|---------------------------------------|---------|-----------|------------|---------|---------|---------|-------------|--|
| change at | | | | | | | | | |
| index date | Step 0* | Step 1 | Step 2** | Step 3 | Step 4 | Step 5 | UA | Totals | |
| Initiated n(%) | 213(7.4) | 60(2.1) | 3(0.1) | 0(0.0) | 0(0.0) | 2(0.1) | 18(0.6) | 296(10.2) | |
| Increased n(%) | 0(0.0) | 0(0.0) | 489(16.9) | 371(12.8) | 7(0.2) | 15(0.5) | 0(0.0) | 882(30.5) | |
| No change n(%) | 0(0.0) | 0(0.0) | 356(12.3) | 377(13.1) | 14(0.5) | 8(0.3) | 0(0.0) | 755(26.1) | |
| Decreased n(%) | 0(0.0) | 0(0.0) | 94(3.3) | 835(28.9) | 9(0.3) | 17(0.6) | 0(0.0) | 955(33.1) | |
| Totals | 213(7.4) | 60(2.1) | 942(32.6) | 1583(54.8) | 30(1.0) | 42(1.5) | 18(0.6) | 2888(100.0) | |

*No asthma drugs; **includes patients prescribed LTRA only; UA=Unable to Assign step.

Conclusion: Fostair[®] was initiated in multiple clinical scenarios, predominately from BTS/SIGN Steps 2 (32.6%) and 3 (54.8%), where the change in ICS dose at initiation was: (1) initiating therapy (10.2%); (2) increasing ICS (30.5%); (3) decreasing ICS (33.1%); (4) switching within dose (26.1%).

Conflict of interest and funding: This analysis was co-funded by Chiesi and RIRL.

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12. Fluticasone/formoterol combination therapy has comparable efficacy to budesonide/formoterol in terms of pre-dose FEV1

Bodzenta-Lukaszyk A, Buhl R, Balint B, Lomax M, Spooner K, Dissanayake S

Clinical Department of Allergology and Internal Diseases, Uniwersytet Medyczny w Bialymstoku, Bialystok, Poland

Aim: A new combination asthma therapy containing fluticasone propionate (FLUT) and formoterol fumarate (FORM) in a single aerosol inhaler (FLUT/FORM; flutiform[®]) has been developed. This trial aimed to determine the non-inferiority of FLUT/FORM to budesonide/formoterol (BUD/FORM; single inhaler) with regards to efficacy, and to assess tolerability.

Method: This 12-week, double-blind, parallel-group trial involved adolescents and adults with moderate-to-severe persistent reversible asthma. Eligible patients had an FEV₁ of \geq 50% to \leq 80% for predicted normal values and \geq 15% reversibility in FEV₁ following salbutamol (400µg). A total of 279 patients were randomised to FLUT/FORM 250/10µg b.i.d. (N=140) or BUD/FORM 400/12µg b.i.d. (N=139). The primary efficacy endpoint was change in morning pre-dose FEV₁ from baseline to Week 12.

Results: A total of 261 patients completed the study; 133 in the FLUT/FORM group and 128 in the BUD/FORM group. Both treatment groups showed improvements in morning pre-dose FEV₁ from baseline to Week 12. FLUT/FORM was shown to be non-inferior to BUD/FORM: the lower limit of the 95% CI of the treatment difference (FLUT/FORM - BUD/FORM) was greater than the pre-defined threshold value of -0.2L (95% CI:0.130,0.043L; P<0.001). One patient in the FLUT/FORM group discontinued due to adverse events (asthma exacerbation: not related) vs. three patients in the BUD/FORM group (asthma exacerbation, acute sinusitis: not related; asthma exacerbation: possibly related).

Conclusion: Over 12 weeks, fluticasone/formoterol improved morning predose FEV₁ and demonstrated comparable efficacy to budesonide/formoterol with regards to asthma control. Fluticasone/formoterol and budesonide/formoterol also had similar tolerability profiles.

Conflict of interest and funding: Study funded by Mundipharma Research Limited. Fiona Millard (Napp Pharmaceuticals Limited) provided medical

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13. Fluticasone/formoterol combination therapy has comparable efficacy to its individual components administered concurrently

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Aim: A new combination asthma therapy containing fluticasone propionate (FLUT) and formoterol fumarate (FORM) in a single aerosol inhaler (FLUT/FORM; flutiform[®]) has been developed. This study investigated the efficacy and tolerability of the combination compared with its individual components administered concurrently (FLUT+FORM).

Method: This was a 12-week, open-label, parallel group, multicentre study in adults and adolescents (\geq 12 years) with mild to moderate-severe persistent asthma (N=210). Patients were randomised in a 1:1 ratio to treatment with one of two doses of FLUT/FORM (100/10µg or 250/10µg, b.i.d.) or FLUT+FORM (100 + 12µg or 250 + 12µg, b.i.d.). The primary endpoint was non inferiority of FLUT/FORM compared with FLUT+FORM based on post dose FEV₁ on Day 84.

Results: FLUT/FORM had comparable efficacy to FLUT+FORM, with a mean FEV₁ of 2.6L in both groups, 30 to 60 minutes post-dose on Day 84 (per protocol; least squares mean difference: -0.03 L; 95% CI: -0.148, 0.081). Non-inferiority was concluded as the lower limit of the 95% CI was above the pre defined threshold of 0.2L (P=0.004).

Analysis of other pulmonary function tests, patient reported outcomes, rescue medication use, asthma exacerbations and quality of life questionnaires were also comparable. The tolerability profiles of the two study groups were similar overall.

Conclusion: The efficacy and tolerability of fluticasone/formoterol combination therapy is comparable to its individual components administered concurrently.

Conflict of interest and funding: Study funded by Mundipharma Research Limited. Fiona Millard (Napp Pharmaceuticals Limited) provided medical writing assistance.

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14. Fluticasone/formoterol combination therapy has superior efficacy to both fluticasone and formoterol alone Pearlman DS, LaForce CF, Kaiser K

Colorado Allergy and Asthma Centers, Denver, CO, US

Aim: A new combination asthma therapy containing fluticasone propionate (FLUT) and formoterol fumarate (FORM) in a single aerosol inhaler (FLUT/FORM; flutiform[®]) has been developed. This study investigated the efficacy and tolerability of a low dose of FLUT/FORM compared with its individual components administered alone.

Method: This was a 12-week, double-blind, parallel group, multicentre study, in which adults and adolescents (\geq 12 years) with mild to moderate asthma (N=357) were randomised in a 1:1:1 ratio to treatment with FLUT/FORM (100/10 µg b.i.d.), FLUT (100 µg b.i.d.) or FORM (10 µg b.i.d.).

The co-primary endpoints were the change in FEV₁ from morning pre-dose at baseline to morning pre-dose at Week 12 compared with FORM and the change in FEV_1 from morning pre-dose at baseline to 2 hours post-dose at Week 12 compared with FLUT.

Results: Statistically significant differences in the co-primary endpoints were recorded for FLUT/FORM compared with FLUT or FORM administered alone. There were significantly greater improvements in the FLUT/FORM group with respect to change in pre-dose FEV₁ compared with FORM (full analysis set; least squares (LS) mean difference: 0.118 L; 95% confidence interval (CI): 0.034, 0.201; P=0.006) and post-dose FEV₁ compared with FLUT (LS mean difference: 0.122 L; 95% CI: 0.040, 0.204; P=0.004). Sensitivity analyses supported the co primary analyses. The tolerability profiles of FLUT/FORM, FLUT and FORM were comparable.

Conclusion: In adolescents and adults with mild to moderate asthma, fluticasone/formoterol was well-tolerated and showed statistically superior efficacy for the co primary endpoints compared with fluticasone and formoterol administered alone.

Conflict of interest and funding: Study funded by Skye Pharma. Fiona Millard (Napp Pharmaceuticals Limited) provided medical writing assistance. Corresponding author: Ms Kathleen Rosewarne Email: Kathleen.rosewarne@napp.co.uk Phone: +44 1223 424444 Institution: Napp Pharmaceuticals Cambridge Science Park, Milton Road Cambridge United Kingdom CB4 0AB

15. Developing a Respiratory Quality Award for Primary Care in the UK

Gruffydd-Jones K, Bryant T, Jennings I University of Aberdeen

Aim: To develop an award that reflects a quality service for patients being managed in Primary Care, that is universally applicable across Primary Care, reflects an accepted quality standard of patient care, assesses key areas across the patient journey, and is relevant for common respiratory conditions. **Method:** We used a multi-layered consultation and development process, overseen by a multi-disciplinary steering group, involving key stakeholders from the respiratory community, refining the final standards against a number of parameters. The process can be described as follows High level multi-agency group(HLMG) appoints steering group(SG) and development director(DD), SG/DD consults and accumulates content. SG/DD assesses content v evidence base, guidelines, deliverability comprehensiveness and assess-ability. Further consultation with HLMG and draft standards written, SG/DD concept tests and final edit of standards, standards and self assessment developed and beta tested in volunteer practices

Results: We present the Standards developed using this process, which cover the important areas of Prevention, Diagnosis, Chronic and Acute Care, Equipment and Teamwork

Conclusion: We believe that we have defined and described the essential components of a quality respiratory service in Primary Care, and set out a mechanism by which it can be delivered in practice, in such a way that it can be measured and acknowledged. The process used is robust, and could be used in future to develop quality standards across the NHS in other areas.

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