## ABSTRACTS OPEN Abstracts from the 2017 Respiratory Effectiveness Group Summit: what lies ahead? Translating the value and potential of real-life evidence

Sheraton Heathrow Hotel, London, UK, 31 March-1 April 2017

Scientific Committee: Walter G.Canonica, Omar S. Usmani, Nemr S. Eid, Joan B. Soriano, Demosthenes Bouros, George Christoff, Nicolas Roche, Bernardino Alcázar Navarrete

**Sponsorship:** Publication of this supplement was funded by the Respiratory Effectiveness Group. **Note:** Presenter names appear in bold type.

npj Primary Care Respiratory Medicine (2017) 27, 17009; doi:10.1038/ npjpcrm.2017.9; published online 14 December 2017

#### SESSION 1A: EPIDEMIOLOGY AND FUTURE RISK

### **REGABS17010:** Prevalence and comparability of asthmachronic obstructive pulmonary disease (COPD) overlap populations in routine primary care

Nicolas Roche<sup>1</sup>, David Price<sup>2</sup>, Anjan Nibber<sup>3</sup>, Alison Chisholm<sup>3</sup>, Jerry A. Krishnan<sup>4,5</sup>

<sup>1</sup>Respiratory and Intensive Care Medicine, Cochin Hospital Group, AP-HP, University of Paris Descartes, Paris, France; <sup>2</sup>Academic Primary Care, University of Aberdeen, UK; <sup>3</sup>Respiratory Effectiveness Group, Cambridge, UK; <sup>4</sup>Population Health Sciences Program, University of Illinois Hospital and Health Sciences System, Chicago, IL, USA; <sup>5</sup>Department of Medicine, University of Illinois at Chicago, Chicago, IL, USA

*Background:* Some adults present with characteristics of both asthma and chronic obstructive pulmonary disease (COPD). In such cases of asthma-COPD overlap (ACO), it can be difficult to establish a clear diagnosis. Unfortunately, there are no evidence-based studies to guide the evaluation or management of individuals of ACO. The criteria for a diagnosis of ACO also vary in different publications, which is a barrier to understanding the pathogenesis of ACO or defining the best practices for the evaluation and management of ACO.

*Aim:* To compare prevalence estimates using different ACO definitions in a large primary care registry in the United Kingdom.

Methods: This was a cross-sectional study using clinical data collected during a 24-month period (1 January 2013 to 31 December 2015) from the Optimum Patient Care Research Database (OPCRD) http://optimumpatientcare.org/ database-overview/. Patients age ≥40 years were divided into four 'series' based on the documented clinician diagnoses in the 24-month period: Series A—COPD diagnoses only (≥2 consultations with a COPD diagnosis plus 0 consultations with a asthma diagnosis); Series B-asthma and COPD diagnoses (≥1 consultations with asthma diagnosis at any time prior to the 24-month observation period plus  $\ge 1$  consultations with a COPD diagnosis in the 24month observation period OR  $\ge$  2 consultations with both asthma and COPD diagnoses at each consultation within the 24-month observation period); Series C—asthma diagnoses only (≥2 consultations with asthma diagnosis plus 0 consultations with COPD diagnosis); Series D-Reference population  $(\geq 2$  consultations, 0 with asthma diagnosis and 0 with COPD diagnosis). Within each series, we identified individuals with clinical documentation of ever smoking (current or past), post-bronchodilator airflow obstruction (postbronchodilator forced expiratory volume in 1 s (FEV<sub>1</sub>)/forced vital capacity (FVC) < 0.7), and individuals with post-bronchodilator airflow obstruction and airflow reversibility ( $\geq$ 12% and  $\geq$  200 ml increase in post-bronchodilator FEV<sub>1</sub> or FVC). Within each of the series (A–D), we compared demographics, smoking history, body mass index (BMI), and comorbidities. We also calculated the prevalence of ACO in each of the series using the following criteria: ever smokers (yes), post-bronchodilator airflow obstruction (FEV<sub>1</sub>/FVC < 0.7), and post-bronchodilator airflow reversibility (>200 ml). A two-tailed *P*-value < 0.05 defined a statistically significant difference.

*Results*: Patients age ≥40 years (n = 3,433) were classified as COPD diagnoses only (Series A; 1,015, 29.5%); Asthma and COPD diagnoses (Series B: 395, 11.5%); Asthma diagnoses only (Series C: 755, 22.0%); and Reference population (Series D: 1,268, 37.0%). The four populations varied significantly in demographics, smoking history, BMI and various comorbid conditions. ACO prevalence varied significantly across series A, B, C and D (20.5%, 32.1%, 14.4% and 8%, respectively; P < 0.001 ( $\chi^2$ ) across groups), and approached 1 in 3 individuals in Series B (see Table 1).

*Conclusion:* The prevalence of ACO varies significantly in individuals within a large primary care registry in the United Kingdom, and approaches 1 in 3 among those who carry a diagnosis of both asthma and COPD.

Disclosures: In the past 5 years, NR has received (i) fees for speaking, organising education, or consulting from Aerocrine, Almirall, Altana Pharma-Nycomed-Takeda, AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, MEDA, MSD-Chibret, Mundipharma, Novartis, Pfizer, Teva; (ii) research grants from Novartis, Nycomed, Boehringer Ingelheim and Pfizer. DP has board membership with Aerocrine, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, Mylan, Mundipharma, Napp, Novartis, and Teva Pharmaceuticals; consultancy agreements with Almirall, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Mylan, Mundipharma, Napp, Novartis, Pfizer, Teva Pharmaceuticals, and Theravance; grants and unrestricted funding for investigatorinitiated studies (conducted through Observational and Pragmatic Research Institute Pte Ltd) from Aerocrine, AKL Research and Development Ltd, AstraZeneca, Boehringer Ingelheim, British Lung Foundation, Chiesi, Mylan, Mundipharma, Napp, Novartis, Pfizer, Respiratory Effectiveness Group, Teva Pharmaceuticals, Theravance, UK National Health Service, Zentiva; payment for lectures/speaking engagements from Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Cipla, GlaxoSmithKline, Kyorin, Mylan, Merck, Mundipharma, Novartis, Pfizer, Skyepharma, and Teva Pharmaceuticals; payment for manuscript preparation from Mundipharma and Teva Pharmaceuticals; payment for the development of educational materials from Mundipharma and Novartis; payment for travel/accommodation/meeting expenses from Aerocrine, AstraZeneca, Boehringer Ingelheim, Mundipharma, Napp, Novartis, and Teva Pharmaceuticals; funding for patient enrolment or completion of research from Chiesi, Novartis, Teva Pharmaceuticals, and Zentiva; stock/stock options from AKL Research and Development Ltd which produces phytopharmaceuticals; owns 74% of the social enterprise Optimum Patient Care Ltd (Australia, Singapore, and UK) and 74% of Observational and Pragmatic Research Institute Pte Ltd (Singapore); and is peer reviewer for grant committees of the Efficacy and Mechanism Evaluation programme, and Health Technology Assessment. All other authors have no disclosures



Carles A D

	Whole eligible population; n = 3,435	A COPD only (n = 1,015, 29.5%)	B Asthma and COPD (n = 395, 11.5%)	C Asthma only (n = 755, 22.0%)	D Reference (n = 1,268, 37.0%)	P-value*
Age	Years, mean	71.1 (9.6)			70.0 (10.4)	
64.1 (12.2)	64.1 (12.4)	< 0.001				
Gender	Male, n (%)	561 (55.3)	170 (43.0)	294 (38.9)	583 (46.0)	< 0.001
	Female, <i>n</i> (%)	454 (44.7)	225 (57.0)	461 (61.1)	685 (54.0)	
Smoking history	Non-smoker, n (%)	75 (7.4)	65 (16.5)	326 (43.2)	451 (35.6)	< 0.001
	Current smoker, n (%)	296 (29.2)	107 (27.1)	108 (14.3)	287 (22.6)	
	Ex-smoker, n (%)	644 (63.4)	223 (56.5)	321 (42.5)	530 (41.8)	
BMI	Underweight, n (%)	48 (4.6)	13 (3.3)	9 (1.2)	21 (1.7)	< 0.001
	Healthy weight, n (%)	327 (32.2)	115 (29.1)	183 (24.2)	332 (26.2)	
	Overweight, n (%)	341 (33.6)	122 (30.9)	250 (33.1)	414 (32.7)	
	Obese, <i>n</i> (%)	296 (29.2)	144 (36.5)	312 (41.3)	490 (38.6)	
	Missing, n (%)	3 (0.3)	1 (0.3)	1 (0.13)	11 (0.9)	
Comorbidities	Cardiovascular, n (%)	458 (45.1)	148 (37.5)	234 (31.0)	428 (33.8)	< 0.001
	lschaemic heart disease, <i>n</i> (%)	235 (23.2)	82 (20.8)	107 (14.2)	200 (15.8)	< 0.001
	Heart failure, n (%)	55 (5.4)	22 (5.6)	17 (2.3)	38 (3.0)	0.001
	Hypertension, n (%)	303 (29.9)	98 (24.8)	214 (28.3)	260 (20.5)	< 0.001
	Myocardial infarction, n (%)	89 (8.8)	38 (9.6)	41 (5.4)	59 (4.7)	< 0.001
	Cerebrovascular disease, n (%)	114 (11.2)	24 (6.1)	48 (6.4)	108 (8.5)	0.001
	Rhinitis, <i>n</i> (%)	161 (15.9)	102 (25.8)	229 (30.3)	204 (16.1)	< 0.001
	Active rhinitis, n (%)	77 (7.6)	58 (14.7)	146 (19.3)	97 (7.7)	< 0.001
	Eczema, n (%)	245 (24.1)	102 (25.8)	188 (24.9)	258 (20.4)	0.029
	Bronchiectasis, n (%)	51 (5.0)	27 (6.8)	25 (3.3)	27 (2.1)	< 0.001
	Diabetes, n (%)	564 (55.6)	204 (51.7)	396 (52.5)	634 (50.0)	0.069
	GERD, n (%) Active GERD,	203 (20.0) 161 (15.9)	82 (20.8) 66 (16.7)	146 (19.3) 121 (16.0)	201 (15.9) 153 (12.1)	0.028 0.015
	n (%) Osteoporosis,	124 (12.2)	67 (16.7)	91 (12.1)	119 (9.4)	0.001
	n (%) Chronic Kidney	124 (12.2)	52 (13.2)	71 (9.4)	122 (9.6)	0.051
	uisease, <i>n</i> (%) Anxiety and depression,	110 (10.8)	44 (11.1)	78 (10.3)	120 (9.5)	0.665
	n (%)					

Table 1: [REGAB005317010] Characteristics in different patient

### **SESSION 1B: PATIENT CENTRICITY**

### REGABS17020: Does duration of antibiotic prescription affect treatment failure in asthma or chronic obstructive pulmonary disease (COPD) exacerbations or lower respiratory tract infections? protocol and preliminary results

**Marie Stolbrink**<sup>1</sup>, Dan Wootton<sup>2</sup>, Laura Bonnett<sup>3</sup>, David Price<sup>4</sup>, Victoria Carter<sup>5</sup>, Alison Chisholm<sup>6</sup>, John D Blakey<sup>7</sup>

<sup>1</sup>NIHR Academic Clinical Fellow, Arrowe Park Hospital and University of Liverpool, UK; <sup>2</sup>Clinical Lecturer, Institute of Infection and Global Health, University of Liverpool, UK; <sup>3</sup>NIHR Postdoctoral Fellow, University of Liverpool, UK; <sup>4</sup>David Price: Professor of Primary Care Respiratory Medicine, University of Aberdeen, Aberdeen, UK; Owner of Optimum Patient Care Ltd and Chairman of the Respiratory Effectiveness Group, Cambridge, UK; <sup>5</sup>General Manager of Optimum Patient Care, Cambridge, UK; <sup>6</sup>Chief Scientific Officer of the Respiratory Effectiveness Group, Cambridge, UK; <sup>7</sup>Senior Lecturer, Liverpool School of Tropical Medicine, Honorary Consultant, Royal Liverpool University Hospital, UK

*Background:* Lower respiratory tract infections (LRTI), asthma and chronic obstructive pulmonary disease (COPD) exacerbations cause significant morbidity and mortality and result in a large burden of antibiotic prescriptions in primary care. Evidence supporting their use is limited.

*Aim:* Characterise patterns of antibiotic prescribing for LRTIs, asthma and COPD exacerbations in UK primary care. Correlate these patterns with repeat antibiotic prescriptions and clinical outcomes.

Methods: A prospectively planned, cross-sectional database study drawing on retrospective, electronic medical records from the Optimum Patient Care Research Database (OPCRD) http://optimumpatientcare.org/database-overview/. OPCRD holds information on primary care encounters from over 525 UK general practices. Ethical approval was granted by Trent Multi-Centre Research Ethics Committee and the Anonymised Data Ethics & Protocol Transparency (ADEPT) committee. We included patients who received at least one antibiotic prescription for lower respiratory tract infection symptoms. Primary outcome was new antibiotic prescription for LRTI during the initial treatment course or within 14 days of its completion. Secondary outcomes included other antibiotic prescriptions during or within 14 days of the index course completion, healthcare consultations and hospital admissions. Statistical analysis was carried out using SPSS version 20 (IBM). Data were analysed according to variable type. Regression and sensitivity analysis will be carried out to investigate the associations between demographic and clinical characteristics on repeat prescription rates (e.g., age, co-morbidity, smoking status).

*Results:* The database included over 1.5 million cases of antibiotic prescription for lower respiratory tract symptoms from 1984 to 2017. There were 321,742 encounters by patients with asthma, 130,636 by patients with COPD and 753,885 encounters by patients without underlying lung disease. Primary analysis of those without underlying lung disease showed that the majority were current or ex-smokers (60.7%). The commonest duration for initial antibiotic prescription was 7 days (74.1%), followed by 5–6 days (22.7%). Amoxicillin, clarithromycin and erythromycin were the commonest used antibiotics (65.1%, 9.1% and 7.4% respectively). Doxycycline and clarithromycin were proportionally used more in longer initial antibiotic durations (see Figure 1). A total of 6.2% received a repeat antibiotic course for LRTI during the initial course or within 14 days of its completion. Non-smokers appeared to have a higher relative risk (RR) of repeat antibiotic prescription than current smokers (RR 1.23, P < 0.001).

*Conclusion:* Once completed this study will describe the current antibiotic prescribing practice in primary care for individuals with asthma, COPD and without underlying lung disease. It could form the basis for further interventional studies to establish optimal antibiotic durations for LRTI symptoms.

Disclosures: MS: National Institute of Health Research Academic Clincial Fellow at the University of Liverpool. The Eleanor Peel trust supplied funding for bespoke data extraction and database creation from Optimum Patient Care Service, Cambridge, UK. DP has board membership with Aerocrine, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, Mylan, Mundipharma, Napp, Novartis, and Teva Pharmaceuticals; consultancy agreements with Almirall, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Mylan, Mundipharma, Napp, Novartis, Pfizer, Teva Pharmaceuticals, and Theravance; grants and unrestricted funding for investigator-initiated studies (conducted through Observational and Pragmatic Research Institute Pte Ltd) from Aerocrine, AKL Research and Development Ltd, AstraZeneca, Boehringer Ingelheim, British Lung Foundation, Chiesi, Mylan, Mundipharma, Napp, Novartis, Pfizer, Respiratory Effectiveness Group, Teva Pharmaceuticals, Theravance, UK National Health Service, Zentiva; payment for lectures/speaking engagements from Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Cipla, GlaxoSmithKline, Kyorin, Mylan, Merck, Mundipharma, Novartis, Pfizer, Skyepharma, and Teva Pharmaceuticals; payment for manuscript preparation from Mundipharma and Teva Pharmaceuticals; payment for the development of educational materials from Mundipharma and Novartis; payment for travel/accommodation/meeting expenses from Aerocrine, AstraZeneca, Boehringer Ingelheim, Mundipharma, Napp, Novartis, and Teva Pharmaceuticals; funding for patient enrolment or completion of research from Chiesi, Novartis, Teva Pharmaceuticals, and Zentiva; stock/stock options from AKL Research and Development Ltd which produces phytopharmaceuticals; owns 74% of the social enterprise Optimum Patient Care Ltd (Australia, Singapore, and UK) and 74% of Observational and Pragmatic Research Institute Pte Ltd (Singapore); and is peer reviewer for grant committees of the Efficacy and Mechanism Evaluation programme, and Health Technology Assessment. VC: works for and is paid by Optimum Patient Care who own OPCRD. JDB has received personal fees from GlaxoSmithKline, AstraZeneca, and Novartis and has received personal fees and nonfinancial support from Napp. No other disclosures.

#### [REGABS17020]



Figure 1. Index antibiotic by commonest initial durations

#### SESSION 2B: DEVICES AND TECHNOLOGY

#### **REGABS17013: Real life experience of telemonitoring in a** remote and rural sleep medicine service

Phyllis Murphie<sup>1</sup>, Robin Paton<sup>1</sup>, Ross Paton<sup>1</sup>, Musa Ali<sup>1</sup>, Stuart Little<sup>1</sup> <sup>1</sup>NHS Dumfries and Galloway, Dumfries, Scotland

Background: Our service manages people with a diagnosis of obstructive sleep apnoea hypophoea syndrome (OSAHS), obesity hypoventilation syndrome (OHS) and neuromuscular disorders (ND). In 2015, we initiated telemonitoring with continuous positive airway preasure/automatic positive airway pressure (CPAP/APAP; Resmed, Abingdon, UK) and non-invasive ventilation (NIV; Resmed, Abingdon, UK) devices that facilitate efficacy data transfer via an inbuilt subscriber identity module (SIM) card to a secure website for those commenced on treatment for the first 30 days following initiation. There is also the option for long term telemonitoring where this is thought to be appropriate in individual cases.

Aim: Review the potential benefits of telemonitoring in our sleep medicine service

Methods: Assess the impact of telemonitoring on service delivery and review the telemetry data in terms of adherence to therapy, mask fit and efficacy of CPAP and NIV therapy.

Results: Telemonitoring data for 26 patients commenced on CPAP/APAP is available and for 22 commenced on NIV. Seven were using APAP devices with one non-adherent individual (machine has been recalled). The other six have an average adherence of 6.5 h per night and a residual Apnea-Hypopnea Index (AHI) of 0.1–22 with no mask-leak issues. The remaining 19 CPAP users had an average adherence of 6.55 h/night with a residual AHI of 0.5-41 (1 patient) and 4 had high mask leaks. Of those commenced on NIV, 2 have a diagnosis of neuromuscular disease with adherence of 8-11 h/ night with no mask-fit issues. The remaining 20 NIV users have an average adherence of 7 h/night on days used and a residual of AHI of 0.2-10 with 8 having unacceptable high mask leakage. One non adherent user (58 min per night) had a residual AHI of 51.8 (now discontinued therapy).

Conclusion: Where poor adherence with therapy/high mask leaks are seen via the telemonitoring platform this prompts a telephone review and/or a clinic follow-up. Our experience to date of those being telemonitored is positive (with no adverse outcomes reported) and allows us to monitor treatment adherence/efficacy data remotely and intervene where necessary. Data transmission has been unproblematic and adherence/efficacy data can be viewed on a daily basis or as needed. Machine pressure settings and other parameters can also be adjusted using this platform. We propose that it is advantageous for patients/clinicians and we are now planning to conduct a pilot randomised controlled trial in 2018 to research this further. Disclosure: None for all authors

### REGABS17021: A novel bluetooth enabled, smartphone compatible device for home monitoring of airways resistance.

Ronald J. Dandurand<sup>1,2</sup>, James Anglehart<sup>3</sup> and Oleg Grudin<sup>3</sup>

<sup>1</sup>Montreal Chest Institute, Meakins-Christie Laboratories, FOT Unit, Centre for Innovative Medicine, Montral, Canada and McGill University Health Centre and Research Institute, McGill University, Montreal, Canada, and <sup>3</sup> Spiro-Tech Medical Inc., Montreal, Canada

Background: Spirometry indirectly estimates airways resistance (Raw) and has long been the standard with which to monitor the health status of patients with asthma and chronic obstructive pulmonary disease (COPD). Forced oscillation technique (FOT) provides a direct measure of respiratory system resistance (R<sub>rs</sub>) and has become increasingly recognised as an easier to perform alternative to spirometry. Inexpensive spirometers have been used for home monitoring of such patients. We have developed a similarly inexpensive, easy to use device, which directly measures  $R_{aw}$ , the Relaxed Expiratory Occlusion Monitor (REOM) (pat # WO2015/066812).

Aim: We wished to compare the accuracy of the REOM to FOT. We hypothesise that the  $R_{aw}$  measured by means of the REOM would agree to within 10% of the  $R_{\rm rs}$  measured by FOT at 5 Hz.

Methods: The hand-held instrumentation unit of REOM prototype contains flow tube and electromechanical module and has wireless connection with Android-based tablet or smartphone. Software deployed on the tablet provides data processing, visualisation, calculation of airway resistance and other service functions. Two asthmatic and 5 healthy control subjects underwent 2-3 determinations of REOM and FOT. Subjects were instructed to exhale normally into the REOM or breath normally into the FOT device (tremoFlo C-100 software, Thorasys, Montreal, QC, Canada). Mean R<sub>aw</sub> by REOM and R<sub>rs</sub> by FOT at 5 Hz and coefficient of variation (CV) for three measurements from each device were calculated. BlandAltman analysis and interclass correlation coefficient (ICC) were used to compare REOM to FOT. Student ttests were used to determine differences between group means. Significance was set at P < 0.05 after Bonferroni correction.

*Results:* Subjects were  $47 \pm 12$  (mean  $\pm$  s.d.) years old with BMI of  $25 \pm 4$  kg/m<sup>2</sup>. REOM  $R_{aw}$  and FOT  $R_{rs}$  agreed to within 8% (REOM 2.63 ± 0.29 mean ± s.e.m. cmH\_2O/L/s vs. FOT 2.43  $\pm$  0.28, NS) with similar CVs (6  $\pm$  2% vs. 8  $\pm$  1, NS). The Pearson r was 0.92, P < 0.005 (Figure 1A), there was negligible slope to the bias (0.03) by Bland-Altman analysis, the bias confidence interval (CI) included 0 (Figure 1B), and ICC was 0.90.

Conclusion: In this small pilot study, the REOM Raw agrees to within 8% of FOT  $R_{rs}$  at 5 Hz. If these results are reproducible in a larger population comprising a broader spectrum of asthma and COPD subjects, the REOM would offer an inexpensive, portable and internet ready device for home monitoring of obstructive lung disease requiring minimal patient effort. This work received no external funding.

Disclosure: all authors are shareholders of the Spirotech Medical Inc., the company that owns the patent of the device.

[REGABS17020]



Figure 1. Bland-Altman analysis REOM vs. FOT, n=7.

### REGABS17022: Correlation of patient reported outcomes with forced oscillation technique (FOT) and spirometry based staging of chronic obstructive pulmonary disease (COPD) in community practice

**Ronald J. Dandurand**<sup>1,2</sup>, Myriam Dandurand, <sup>1,2</sup> Jean Bourbeau<sup>1,2</sup> and David H. Eidelman<sup>1,2</sup>

<sup>1</sup>Montreal Chest Institute, Meakins-Christie Laboratories, FOT Unit, Centre for Innovative Medicine, Respiratory Epidemiology, Montreal Canada and <sup>2</sup>Clinical Research Unit; McGill University Health Centre and Research Institute, McGill University, Montreal, Canada

*Background*: Spirometry based staging of chronic obstructive pulmonary disease (COPD) correlates weakly with patient reported outcomes (PRO).

Aim: We hypothesised that forced oscillation technique (FOT) based staging using integrated area of low-frequency reactance (Ax) as a marker of ventilatory inhomogeneity might correlate better with PRO than spirometry. Methods: Three hundred COPD subjects (>10 pack-year smoking and either forced expiratory volume in 1 s (FEV1)/forced vital capacity (FVC)>0.7, maximum mid-expiratory flow (MMEF) 130% predicted or residual volume (RV) >130% predicted) from a community respirology practice had COPD Assessment Tests (CAT), modified Medical Research Council (mMRC) dyspnea scale, acute exacerbation rates (AER), chronic bronchitis (CB) questionnaires, PFTs (Jaeger or Vmax22, Carefusion, Germany) and FOT (tremoFlo C-100, Thorasys, Canada) abstracted from charts. 21 healthy control subjects also underwent FOT and spirometry. The study had Institutional Review Board (IRB) approval. The upper limit of normal (ULN) of  $A_X$  was established by inspection of its frequency histogram (FH) from healthy control subjects, outlier rejection and calculating the mean+2DS on In transformed data. COPD subjects below the ULN were assigned FOT stage 0 and the remainder FOT stages I-IV delineated by doublings of the ULN. Subjects were grouped by both FOT stages and Global initiative for chronic obstructive lung disease (GOLD) stages (using fixed ratio for the FEV $_1$ /FVC < 0.7). Analysis of variance (ANOVA) was conducted on continuous variables. Dichotomous variables as a percentage of total were regressed against stage. Significance was set at P < 0.05 after Bonferroni correction.

*Results:* The InA<sub>X</sub> FH of healthy controls demonstrated 4 outliers. After outlier rejection, the mean+2 s.d. of InA<sub>X</sub> was 2.18 or  $\approx$ 9 cmH<sub>2</sub>O/L/s. Lower cut points for FOT stages were then set at A<sub>X</sub> of 9, 18, 36 and 72 cmH<sub>2</sub>O/L/s for I, II, III and

IV, respectively. COPD subject distribution by GOLD, and FOT Stages, and PRO results are shown in Table 1.

*Conclusion*: In this small group of COPD subjects, FOT staging results in a more even subject distribution than GOLD staging. CAT, mMRC and CB correlates better with FOT stages but not AER. We speculate that this better correlation of CAT, mMRC and CB with FOT stages may be, in part, due to the greater sensitivity of FOT to early airflow limitation, and the reduction of airflow limitation overestimation in older and underestimation in younger subjects, resulting from using the fixed ratio FEV<sub>1</sub>/FVC of 0.7. While both FOT and spirometry are complimentary in predicting the burden of COPD symptoms, the simplicity of FOT use for both subject and health care provider is a major advantage of this technique of pulmonary function assessment. Confirmation of these findings awaits larger, prospective studies employing both FOT and spirometry.

Disclosure: Supported by AstraZeneca, Boehringer-Ingelheim, Novartis.

#### SESSION 3A: VALIDATION AND QUALITY

#### REGABS17017: Quality of spirometry in primary care: a focus on clinical use—study protocol

Hendrik-Jan Baretta<sup>1</sup>, Bertine Flokstra-de Blok.<sup>1</sup>, Thys van der Molen<sup>1</sup>, Jan Willem H. Kocks<sup>1</sup>

<sup>1</sup>Department of General Practice, Groningen Research Institute for Asthma and COPD Primary Care (GRIAC-PC), University Medical Centre Groningen, Groningen, The Netherlands

*Background:* Spirometry is increasingly used in primary care for better diagnosis and better guidance of respiratory patients. Health insurances have debated raising the quantity minimum of 80 spirometries per year per general practitioner to 150. This gives a strong incentive to establish the quality of spirometry in primary care. Quality of spirometry is traditionally assessed using the criteria as formulated by the American Thoracic Society (ATS) and European Respiratory Society (ERS). According to these criteria the quality of spirometry is known to be lower in primary care than in secondary care. However, a different approach to assessing the quality is the patient outcome; whether the quality is sufficient to make clinical decisions.

	GOLD Stage				FOT Stage							
	non-GOLD	1	Ш	III	IV		0	1		ш	IV	
n (%)	33 (11)	49 (16)	150 (50)	54 (18)	14 (5)		41 (14)	39 (13)	74 (25)	94 (31)	52 (17)	
Continuous Variables						p value						p value
CAT (mean ± SE)	16±1	12±1	15±1	19±1	17±2	< 0.005	11±1	14±1	16±1	17±0.8	19±1	< 0.0001
mMRC	2.3±0.2	1.9±0.2	2.3±0.1	2.9±0.2	3.2±0.4	< 0.0001	1.5±0.1	2.4±0.2	2.4±0.1	2.5±0.1	2.7±0.2	< 0.0001
AER	0.8±0.2	0.6±0.1	1.1±0.1	1.6±0.2	2.0±0.4	< 0.0005	0.9±0.2	0.7±0.2	1.0±.2	1.3±0.2	1.4±0.2	NS
Dichotomous Variable						r, p value						r, p value
Chronic Bronchitis (%)	33	24	39	48	21	NS	24	26	42	41	40	0.84, <0.05

Table 1 [REGABS17022]. Patient Reported Outcomes by GOLD Stage and FOT Stage in COPD, n = 300

*Aim:* To investigate whether the quality of spirometry in primary care practices is high enough to make clinically relevant decisions.

*Methods*: Spirometry and medical history data will be collected from primary care practices from 150 patients. Both a general practitioner and two lung physicians make a diagnosis, a treatment advice and an evaluation of spirometry quality based on these data separately. Furthermore, the spirometries will be evaluated by two lung function analysts to determine whether they are performed according to the ATS/ERS criteria. Two consensus meetings will be organised, one for the lung physicians and another one for the two lung function analysts to resolve any conflicts.

*Results:* The primary outcome of this study is the correspondence of diagnosis and treatment advice of the general practitioners (GP) and the pulmonologists using the Cohen's Kappa. A coefficient of over > 0.81 will be considered good agreement. Secondary outcomes will include the difference of agreement between (1) ATS/ERS-fulfilled spirometries and (2) non-ATS/ERS-fulfilled spirometries assessed as the correlation between number of conducted spirometries per practice and ATS/ERS fulfilment and the correlation between number of conducted spirometries per practice and agreement between GP and lung physicians).

*Disclosure*: This investigator initiated study is funded by Chiesi Pharmaceuticals with an unrestricted grant.

#### SESSION 3B: TREATMENT PRACTICES AND TRENDS

#### REGABS17001: Are we closer to the global initiative for chronic obstructive lung disease (GOLD) standard? characterising the evolution of chronic obstructive pulmonary disease (COPD) treatment in primary care between 2010 and 2015 in the United Kingdom

**David Price**<sup>1, 2</sup>, Alice Durieux<sup>1</sup>, Simon Wan Yau Ming<sup>1</sup>, Derek Skinner<sup>3</sup>, Jessica Martin<sup>1</sup>, Shawna Tan<sup>1</sup>, Catherine Hutton<sup>1</sup>

<sup>1</sup>Observational and Pragmatic Research Institute, Singapore, Singapore; <sup>2</sup>Centre for Academic Primary Care, University of Aberdeen, Aberdeen, UK; <sup>3</sup>Optimum Patient Care, Cambridge, UK

*Background*: Chronic obstructive pulmonary disease (COPD) affects > 3 million people in the UK, and is responsible for significant morbidity and healthcare utilisation<sup>1</sup>. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommends initial treatment with long-acting muscarinic antagonists (LAMA) or long-acting b<sub>2</sub>-agonists (LABA). Inhaled corticosteroids (ICS), which reduce the risk of COPD exacerbations can be prescribed in addition to the maintenance therapy of LABA±LAMA in patients with severe airflow limitation (forced expiratory volume in 1 s (FEV<sub>1</sub>) < 50% of predicted) and/ or two or more exacerbations per year. Monotherapy of ICS is not recommended in less severe patients because of the risk of pneumonia<sup>2</sup>. Despite these guidelines, a study using UK data from 2013 showed GOLD recommendations are not followed; ICS are over-prescribed to mild and moderate patients<sup>3</sup>.

*Aim:* To compare COPD treatment in the UK between 2010 and 2015 to investigate whether prescription patterns are progressing to be closer to GOLD guidelines.

*Methods:* This was a historical cross-sectional database study conducted using the Optimum Patient Care Research Database (OPCRD) http://optimumpatient-care.org/database-overview/ a primary care database containing anonymous routine data from over 570 practices in the UK. We examined 1 year of continuous clinical records for COPD patients aged  $\geq$  40 years with at least one prescription for respiratory medication in the year examined. Patients with any chronic respiratory lung disease other than COPD were excluded. Data were extracted from practices in 2010 and in 2015, resulting in two cross-sections. The primary outcome was COPD treatment in the year prior to extraction.

*Results:* A total of 48,911 (2010) and 23,161 (2015) patients were included in the study, of which 51% had moderate airflow limitation (GOLD Stage 2). Approximately 69% of patients in both cohorts received inhaled corticosteroids (ICS), most frequently in combination with a LABA (30% in 2010; 25% in 2015) or a LABA and a LAMA (27% in 2010; 35% in 2015) (Table1). The combination of ICS+LAMA and ICS alone were less commonly prescribed in

2015 (9%) than 2010 (13%). Approximately 40% (2010) and 52% (2015) of mild and moderate patients (GOLD Groups A and B) were treated with ICS+LABA or ICS+LABA+LAMA. Approximately 63% (2010) and 59% (2015) of patients without comorbid asthma, and 66% (2010) and 64% (2015) of patients with  $\leq$  1 exacerbation in the previous year received ICS.

*Conclusions*: There was little to no progression towards COPD being treated according to GOLD recommendations in the UK primary-care setting between 2010 and 2015. Most patients still receive ICS irrespective of severity of airflow limitation, asthma diagnosis and exacerbation history.

Disclosure: This was an independent OPRI study funded by Zentiva. DP has board membership with Aerocrine, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, Mylan, Mundipharma, Napp, Novartis, and Teva Pharmaceuticals; consultancy agreements with Almirall, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Mylan, Mundipharma, Napp, Novartis, Pfizer, Teva Pharmaceuticals, and Theravance; grants and unrestricted funding for investigator-initiated studies (conducted through Observational and Pragmatic Research Institute Pte Ltd) from Aerocrine, AKL Research and Development Ltd, AstraZeneca, Boehringer Ingelheim, British Lung Foundation, Chiesi, Mylan, Mundipharma, Napp, Novartis, Pfizer, Respiratory Effectiveness Group, Teva Pharmaceuticals, Theravance, UK National Health Service, Zentiva; payment for lectures/speaking engagements from Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Cipla, GlaxoSmithKline, Kyorin, Mylan, Merck, Mundipharma, Novartis, Pfizer, Skyepharma, and Teva Pharmaceuticals; payment for manuscript preparation from Mundipharma and Teva Pharmaceuticals; payment for the development of educational materials from Mundipharma and Novartis; payment for travel/accommodation/meeting expenses from Aerocrine, AstraZeneca, Boehringer Ingelheim, Mundipharma, Napp, Novartis, and Teva Pharmaceuticals; funding for patient enrolment or completion of research from Chiesi, Novartis, Teva Pharmaceuticals, and Zentiva; stock/stock options from AKL Research and Development Ltd which produces phytopharmaceuticals; owns 74% of the social enterprise Optimum Patient Care Ltd (Australia, Singapore, and UK) and 74% of Observational and Pragmatic Research Institute Pte Ltd (Singapore); and is peer reviewer for grant committees of the Efficacy and Mechanism Evaluation programme, and Health Technology Assessment.

CH has received research support from Mundipharma Research Limited (fees paid to Observational and Pragmatic Research Institute for research and dissemination); has received consultancy fees from Almirall, Amgen, AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Meda, Mundipharma Research Limited, Napp, Novartis, Pfizer, Teva Pharmaceuticals, and Theravance; was employed by Observational and Pragmatic Research Institute Pte Ltd, which receives funding from UK National Health Service, British Lung Foundation, Aerocrine, AKL Ltd, Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Eli Lilly, GlaxoSmithKline, Meda, Merck, Mundipharma Research Limited, Napp, Novartis, Orion, Pfizer, Respiratory Effectiveness Group, Takeda, Teva Pharmaceuticals, and Zentiva; has received lecture fees from Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Cipla, GlaxoSmithKline, Kyorin, Meda, Merck, Mundipharma Research Limited, Novartis, Pfizer, Skyepharma, Takeda, and Teva Pharmaceuticals; has received payment for manuscript preparation from Mundipharma Research Limited and Teva Pharmaceuticals; has received payment for developing educational presentations from Novartis and Mundipharma Research Limited; has received travel support from Aerocrine, Boehringer Ingelheim, Mundipharma Research Limited, Napp, Novartis, Teva Pharmaceuticals, and AstraZeneca; has received funding for patient enrolment or completion of research from Chiesi, Teva Pharmaceuticals, Zentiva, and Novartis (fees paid to Observational and Pragmatic Research Institute); and was peer reviewer for grant committees of Medical Research Council (2014), Efficacy and Mechanism Evaluation programme (2012), and HTA (2014).

#### References:

1. NICE, "Chronic obstructive pulmonary disease," 2010 [Online]. Available at https://www.nice.org.uk/guidance/cg101.

2. GOLD, "Global Strategy for the Diagnosis, Management and Prevention of COPD," 2015 [Online]. Available at www.goldcopd.org. (accessed on 27 June 2015).

3. Price.Management of COPD in the UK primary care setting: an analysis of real-life prescribing patterns, *Int. J. COPD*, **9**. doi: https://doi.org/10.2147/COPD. S62750 (2014).

# Table 1 [REGABS17001]. Chronic obstructive pulmonary disease (COPD) therapies prescribed to patients in 2010 and 2015

COPD treatment	2010	2015
ICS+LABA+LAMA ± LTRA ± SAMA ± SABA	13001 (26.6)	8110 (35.1)
$ICS+LABA \pm LTRA \pm SAMA \pm SABA$	14684 (30.0)	5840 (25.2)
$ICS+LAMA \pm LTRA \pm SAMA \pm SABA$	1183 (2.4)	425 (1.8)
$ICS \pm LTRA \pm SAMA \pm SABA$	5243 (10.7)	1587 (6.8)
LABA+LAMA $\pm$ LTRA $\pm$ SAMA $\pm$ SABA	597 (1.2)	529 (2.3)
$LABA \pm LTRA \pm SAMA \pm SABA$	997 (2.0)	667 (2.9)
LAMA $\pm$ LTRA $\pm$ SAMA $\pm$ SABA	4657 (9.5)	2743 (11.8)
$LTRA \pm SAMA \pm SABA$	103 (0.2)	37 (0.2)
OTHER	27 (0.1)	7 (0.0)
SAMA	604 (1.2)	109 (0.5)
SAMA+SABA	1314 (2.7)	212 (0.9)
SABA	6501 (13.3)	2895 (12.5)

# REGABS17015: Trends in the pharmacological treatment of chronic obstructive pulmonary disease (COPD) in primary care (2007-2012)

Cristina Esquinas<sup>1</sup>, Monica Monteagudo<sup>2</sup>, Miriam Barrecheguren<sup>1</sup>, Esther Rodriguez<sup>1</sup>, Jaume Ferrer<sup>1</sup>, Eulalia Borrell<sup>3</sup>, Carl Llor<sup>4</sup>, Marc Miravitlles<sup>1</sup>

<sup>1</sup>Hospital General Universitari Vall d'Hebron, Barcelona; <sup>2</sup>IDIAP Jordi Gol, Barcelona Department of Pneumology; <sup>3</sup>Primary Care center Jaume I, Tarragona; <sup>4</sup>Primary Care center Badalona-5, Badalona, Spain

*Background:* Treatment for chronic obstructive pulmonary disease (COPD) is tailored based on severity and clinical characteristics but prescription treatment patterns in COPD might change over time.

*Aim:* To describe the changes in trends in the characteristics and treatment of COPD patients in Primary Care (PC) during a period of 6 years.

*Methods*: Epidemiological study with the data obtained from the Information System for Development in Research in Primary Care (SIDIAP) http://www. sidiap.org/, a population database that contains information of 5.8 million of habitants (80% of Catalonia's population). Newly diagnosed COPD patients in the years 2007–2012 were identified through a diagnostic algorithm. We applied jointpoint lineal regression to identify the changes in tendency for every variable over the study period and to calculate the annual percent change (APC) and the average annual percent change (AAPC).

Results: We identified 41,592 patients with a new diagnosis of COPD. The mean age and gender distribution were similar throughout the study. Up to two thirds of the patients were non exacerbators and the distribution remained stable during the study. The codification of smoking habits improved from 2007 to 2012 with less patients identified as 'unknow'. Less than half of the patients were diagnosed by spirometry, although there was a trend to increase its use. During the 6 years of the study there was a decrease in the number of untreated patients (AAPC of patients without any inhaled treatment -7.33% (-13.73, -0.42, P=0.042). On the contrary, there was a significant trend to increase the number of patients treated with a short-acting muscarinic antagonist (SAMA) in monotherapy (AAPC 6.15% (4.09, 8.25, P = 0.001) but also with Inhaled long-acting bronchodilators (LABD) alone or in combination (long-acting  $\beta_2$ -agonists (LABA) AAPC 19.86 (0.28,43.25), long-acting muscarinic antagonists (LAMA) 13.37 (10.26, 16.57), and LABA+LAMA 26.07 (-3.39, 64.51). Interestingly, there was a decreased trend to treat patients with inhaled corticosteroids (ICS) alone or in combination with a LABA (LABA+ICS -4.36 (-7.13, -1.52), ICS - 12.45 (-20.54, -3.54), although the number of patients treated with triple therapy remained unchanged. The use of mucolytics decreased drastically from 2010 (APC 2007-2010 0.97 (-0.94, 2.91); APC 2010-2012 -21.05 (-24.01, -17.99), AAPC -8.5 (-8.77, -8.23), P < 0.001).

*Conclusion:* Despite the guidelines recommendations there is still a high number of COPD patients that remain untreated after diagnosis, although there has been a trend to decrease the number of untreated patients. The use of ICS has decreased and, there was a trend to increase the use of LABD although it is still low. The number of spirometries performed in primary care has increased.

Disclosure: Study funded by Novartis Spain.

MM has received speaker fees from Boehringer Ingelheim, AstraZeneca, Chiesi, GlaxoSmithKline, Menarini, Teva, Grifols and Novartis, and consulting fees from Boehringer Ingelheim, GlaxoSmithKline, Gebro Pharma, CLS Behring, Cipla, Medilmmne, Mero Biopharma, Teva, Novartis and Grifols

#### Appendix

The following studies were presented at the Summit and have now been published:

1. Smith, P. et al., ASCIA-P56: BURDEN OF ALLERGIC RHINITS IN AUSTRALIA. Intern. Med. J., 46: 22. doi:10.1111/imj.56\_13197 (2016).

2. Belhassen, M., Demoly, P., Bloch-Morot, E., de Pouvourville, G., Ginoux, M., Chartier, A., Laforest, L., Serup-Hansen, N., Toussi, M., Van Ganse, E. Costs of perennial allergic rhinitis and allergic asthma increase with severity and poor disease control. *Allergy*; **72**: 948–958 (2017).

3. Monteagudo, M., Roset, M., Rodriguez-Blanco, T., Muñoz, L., Miravitlles, M. Characteristics of COPD patients initiating treatment with aclidinium or tiotropium in primary care in Catalonia: a population-based study. Dovepress, **2017**: 1145–1152, https://doi.org/10.2147/COPD.S131016

4. Smith, P. *et al.*, ASCIA-P57: impact of allergic rhinitis on health related quality of life: results from an Australian survey. *Intern. Med. J.*, **46**: 22. doi:10.1111/ imj.57\_13197 (2016).

5. Smith, P. *et al.* ASCIA-P58: treatment preferences in australian patients with allergic rhinitis: a discrete choice experiment. *Intern. Med. J.*, **46**: 22–23. doi:10.1111/imj.58\_13197 (2016).

6. Voorham, J. *et al.*, Does co-payment for inhaler devices affect therapy adherence and disease outcomes? A historical, matched cohort study, Dovepress, **2017**: 31–41, https://doi.org/10.2147/POR.S132658.

7. Laforest, L., Belhassen, M., Devouassoux, G., Didier, A., Ginoux, M., Van Ganse, E. Long-term inhaled corticosteroid adherence in asthma patients with short-term adherence. *J Allerg Clin Immunol Pract*, **4**, 890–899.e2, http://dx. doi.org/10.1016/j.jaip.2016.07.008.

8. Russell, R. Effect of ICS on glycaemic control in patients with COPD and comorbid type 2 diabetes: Historical case-matched cohort study. European Respiratory Journal, 48(Supplement 60), (PA867). DOI: 10.1183/13993003. congress-2016.PA867 (2016).

10. Price, D. *et al.* An innovative approach to study design: using electronic medical records to inform the feasibility and design of the novelty study (a novel observational longitudinal study on patients with asthma and/or copd) *Thorax.* **71:** A271. http://dx.doi.org/10.1136/thoraxjnl-2016-209333.468 (2016).

This work is licensed under a Creative Commons Attribution 4.0 International License. The images or other third party material in this article are included in the article's Creative Commons license, unless indicated otherwise in the credit line; if the material is not included under the Creative Commons license, users will need to obtain permission from the license holder to reproduce the material. To view a copy of this license, visit http://creativecommons.org/licenses/ by/4.0/

© The Author(s) 2017