**MEETING ABSTRACTS**

Abstracts from the 6th Respiratory Effectiveness Group Summit, 18–20 March, 2021

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**PP01**
Medication use and COPD control status based on clinical and CAT criteria
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**Rationale:** In a recent report (1) control status by clinical criteria (CC) was noted to be a better predictor of exacerbations compared to the COPD Assessment Test (CAT) criteria and that control was more likely to be achieved using clinical compared to CAT criteria. In the present report we describe medication use and COPD control based on clinical and CAT criteria.

**Methods:** This is a post-hoc cross-sectional analysis of data of the REG control prospective international study. A total of 307 patients were analysed (mean age 68.6 years and mean FEV1(%) = 52.5%).

**Results:** See attached results tables.

**Medication use and COPD control based on CAT Criteria**

| Medication                        | Controlled (n=116) | Uncontrolled (n=190) | P-value |
|----------------------------------|-------------------|----------------------|---------|
| SABA/SAMA alone or in combination| 4 (3.4%)          | 6 (3.2%)             | 0.890   |
| LABA alone                       | 11 (9.5%)         | 21 (1.1%)            | 0.663   |
| LAMA alone                       | 20 (17.2%)        | 20 (10.5%)           | 0.091   |
| ICS alone                        | 0 (0%)            | 1 (0.5%)             | 0.434   |
| LABA/LAMA                        | 36 (31%)          | 43 (22.6%)           | 0.103   |
| LABA/ICS                         | 15 (12.9%)        | 25 (13.2%)           | 0.285   |
| LAMA/ICS                         | 0 (0%)            | 6 (3.2%)             | 0.053   |
| LABA/LAMA/ICS                    | 29 (25%)          | 66 (34.7%)           | 0.074   |

**Conclusions:** Our findings show that there appears to be differences in COPD control based on CC and medication group warrants further study in larger primary care populations.

**Reference**
1. Soler-Cataluña JJ, Marzo M, Catalán P, Miralles C, Alcazar B, Miraviltes M. Validation of clinical control in COPD as a new tool for optimizing treatment. Int J Chron Obstruct Pulmon Dis 2018; 13: 3719-3731.

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The study was funded by an unrestricted grant from Novartis AG.

**Results:** Medication use and COPD control based on CAT Criteria*

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Chronic cough (>8 weeks) is a common reason for cough in adults seen in primary care? Multiple guidelines encompass the assessment of chronic cough by and has a significant impact on patient well-being and quality of life. Chronic cough is critical, because it can mask more serious conditions.

Research question: What are the essential and achievable elements required to support methodical assessment and referral of chronic cough patients within primary care who were successfully modified through the proposed algorithm.

We have developed a simplified algorithm for the assessment of chronic cough by primary care physicians who choose to use the algorithm in routine clinical care. The proposed modeling framework for RCC includes health states “on treatment” and “off treatment” for both treatment arms, defined by treatment on active therapy and active therapy discontinuation back to usual care. The model approach links changes in cough frequency as defined by early phase clinical trials (i.e., 24-hr cough frequency) with direct and indirect costs, and health-related quality of life (HRQoL) utility scores. RCC intervention costs were not available at the time of this analysis. In lieu of comprehensive trial evidence at the time of this abstract deadline, inputs were derived from early phase trials, expert opinion, and asthma proxies (controlled and uncontrolled) for both treatment arms.

Questions to discuss: The proposed study will help us identify assessment elements required for a successful diagnosis or referral of chronic cough in primary care patients. The use of the algorithm has the potential to improve the care of patients with chronic cough, by ensuring appropriate work-up/assessment of a patient is not delayed whilst referral to secondary care is being sought. Supporting a patient through what can be a long and complex disease management process, has the potential to improve patient quality of life and associated journey.

Declaration of interest: Dr. Kaplan is on advisory board or speakers bureau for Astra Zeneca, Behring, Boehringer Ingelheim, Covis, Grifols, GSK, Merck Frosst, Pfizer, Purdue, Novartis, NovoNordisk, Sanofi, Teva and Trudel.

References

1. Irwin RS et al. Chest 2018;153:196-209.
2. Morice AH et al. Eur Respir J 2020;55 pii: 1901136.

PP02
Improving the Assessment of Adults with Chronic Cough in Primary Care
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Respiratory Research 2021, 22(1) PP02

Research question: What are the essential and achievable elements required to support methodical assessment and referral of chronic cough in adults seen in primary care?

Background: Chronic cough (>8 weeks) is a common reason for patient visits to primary care physicians (PCPs). Careful assessment of chronic cough is critical, because it can mask more serious conditions and has a significant impact on patient well-being and quality of life. Multiple guidelines encompass the assessment of chronic cough by specialists, but there is less information available for the primary care setting. We have developed a simplified algorithm for the assessment of chronic cough in adult patients in Canadian primary care, modeled on the American College of Chest Physicians (ACCP) guidelines. The aim of our proposed study is to further refine and validate this algorithm.

Possible methodology: We propose to refine the algorithm through presentations at conferences and to other groups of primary care physicians and specialists. Feedback from these settings will be used to modify the algorithm, with the goal of emphasizing assessment elements that can be achieved by primary care physicians prior to referral to secondary care. We anticipate the development of related versions of this algorithm, tailored to reflect local or national practice patterns and testing/specialist access. Validation of the algorithm could be achieved by examining the proportion of chronic cough patients within primary care who were successfully evaluated or referred before, versus after implementation of the algorithm by primary care physicians who choose to use the algorithm in routine clinical care.

Questions to discuss: The proposed study will help us identify assessment elements required for a successful diagnosis or referral of chronic cough in primary care patients. The use of the algorithm has the potential to improve the care of patients with chronic cough, by ensuring appropriate work-up/assessment of a patient is not delayed whilst referral to secondary care is being sought. Supporting a patient through what can be a long and complex disease management process, has the potential to improve patient quality of life and associated journey.

Declaration of interest: Dr. Kaplan is on advisory board or speakers bureau for Astra Zeneca, Behring, Boehringer Ingelheim, Covis, Grifols, GSK, Merck Frosst, Pfizer, Purdue, Novartis, NovoNordisk, Sanofi, Teva and Trudel.

References

1. Irwin RS et al. Chest 2018;153:196-209.
2. Morice AH et al. Eur Respir J 2020;55 pii: 1901136.

PP03
Estimating the Economic Value of Pipeline Chronic Cough Therapies
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Respiratory Research 2021, 22(1) PP03

Introduction: Globally, more than $10 billion is spent annually on the treatment of chronic cough. Multiple pipeline therapies for the treatment of refractory chronic cough (RCC) are forthcoming and will need economic value evidence for coverage and reimbursement recommendations. Our objective was to build an economic modeling framework to identify a range of economic value scenarios using conservative and optimistic clinical benefits derived from early phase evidence on RCC pipeline therapies versus usual care (e.g., anti-tussive medications, corticosteroids, antibiotics, etc.).

Methods: The proposed modeling framework for RCC includes health states “on treatment” and “off treatment” for both treatment arms, defined by treatment on active therapy and active therapy discontinuation back to usual care (Figure). The model approach links changes in cough frequency as defined by early phase clinical trials (i.e., 24-hr cough frequency) with direct and indirect costs, and health-related quality of life (HRQoL) utility scores. RCC intervention costs were not available at the time of this analysis. In lieu of comprehensive trial evidence at the time of this abstract deadline, inputs were derived from early phase trials, expert opinion, and asthma proxies (controlled and partially controlled vs. uncontrolled) for changes in utility and direct and indirect cost offsets. Outcomes from the hypothetical model emphasize cost-offsets from the U.S. societal perspective and incremental quality-adjusted life years (QALYs) over a lifetime. Costs and outcomes were discounted at 3% per year.

Results: Simulated patient cohorts were similar to early phase trial populations with a mean age of 60, a mean (SD) 24-hr cough frequency of 27.5 (19.6), and discontinuation from active therapy of 20.6% within the first 3 months. On average, 9.8 years on active therapy was modeled over a lifetime. Assuming similar HRQoL utility and cost relationships to changes in asthma control, reducing 24-hr cough frequency by 45% (conservative clinical benefit), may result in an additional 0.26 QALYs with cost offsets of $16,000 over a lifetime compared to usual care alone. Whereas reducing 24-hr cough frequency by 60% (optimistic clinical benefit) may result in an additional 0.62 QALYs with cost offsets of $22,000 over a lifetime compared to usual care.

Conclusions: Future evidence generation should link cough frequency with improvements in day-to-day symptom management, work productivity, and HRQoL utility. Comprehensive economic assessments will also include the costs of RCC therapies alongside measures such as incremental QALYs and cost offsets.
There is increasing interest in patient-centered eco-

**Introduction.**

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PP04

Eliciting Patient-Informed Value Elements for Economic Evaluation of COPD Treatment

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Respiratory Research 2021, 22(1): PP04

**Introduction.** There is increasing interest in patient-centered economic evaluations and methods to incorporate the patient's perspective. Our previous work elicited 44 patient-informed value elements (i.e. factors related to healthcare that are important to patients) by directly engaging patients across a range of conditions. The objective of this study was to develop and test a discrete choice experiment (DCE) to quantify value elements specific to patients with chronic obstructive pulmonary disease (COPD).

**Methods:** Twenty-three study participants diagnosed with COPD completed four guided activities and a demographic questionnaire, administered through in-person, telephone or video interviews. Participants were asked to select specific elements that were important to them among three categories: treatment-, outcome- and care process-related factors. For the elements that emerged as most important, individual video interviews were conducted with seven participants to establish the attributes and wording for inclusion in a DCE instrument. A pre-test of the DCE instrument was conducted with ten participants.

**Results:** Interviews with 23 COPD patients resulted in eight value elements that emerged as most important, including four treatment-related, one care process-related, and three outcome-related attributes. Feedback from seven participants resulted in the addition of one care process-related attribute and consolidation and/or substitution of outcome- and treatment-related attributes. This resulted in the selection of six attributes for the instrument: two care process-related (Access to Care, Explanation of Benefits & Risks), three treatment-related (Side Effects, New Therapeutic Option, Willingness to Pay), and one outcome-related (Physical Endurance). A balanced orthogonal design with 100% D-efficiency was used to construct a DCE with nine experimentally derived choice tasks, each with three profiles displaying six attributes per profile. Two hold-out choice tasks were added as a reliability test.

**Disclosures:** RMB, MDW, and JDC received consulting fees from Merck & Co. to support this work. KS and JS are employees of Merck & Co.

**Conclusion:** A patient-informed economic evaluation begins with understanding elements of value from the patient perspective. Patient inclusion in the qualitative development of stated preference instruments authentically quantifies patient preferences. Resulting preference weights reflect the relative importance of patient-informed value elements. The next phase of this research will apply preference weights in a patient-informed economic evaluation.

PP05

Long-acting anti-muscarinic agents (LAMA) frequency of use and clinical features of patients with severe asthma in real-life setting: data from the Severe Asthma Network in Italy (SANI) registry

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**Introduction:** Patients with uncontrolled asthma despite high doses of inhaled corticosteroids plus another controller are defined as severe asthmatics. Tiotropium bromide Respimat is the only long acting muscarinic agonists (LAMA) approved for severe asthma.

**Aims:** To explore the frequency of severe asthmatics treated with LAMAs and characterize their clinical features in a real-life, registry-based setting.

**Methods:** Baseline data from the Severe Asthma Network in Italy (SANI) registry have been analyzed to study the use of LAMA and possible clinical features associated to it in severe asthmatics.

**Results:** Among a total of 698 enrolled patients, 35.9% were treated with LAMAs (23.3% Tiotropium bromide Respimat, 4.5% Tiotropium bromide Handihaler, 4.5% Aclidinium, 3.4% Glycopyrronium bromide 0.3% Umeclidinium bromide). Patients taking LAMAs had higher age of asthma onset and were more frequently former smokers. They had higher annual exacerbation rate, worst asthma control, worst disease-related quality of life and poorer lung function. Bronchiectasis were more frequently found in LAMA users (25.9% vs 13.1%).

**Conclusions:** Tiotropium bromide is still underused in severe asthma in a real-life setting, while a relevant proportion of patients are treated with other LAMAs not approved for severe asthma treatment. Patients taking LAMAs have features of the most severe asthmatics.

**Disclosures:** Personal fee and/or grants:

- Giorgio Walter CANONICA: Menarini, Alk-Abellô, Anallergo, Boehringer Ingelheim, Chiesi, Circassia, Genentech, Guidotti Malesci, GSK, Meda, Merck, Merck Sharp & Dome, Novartis, Recordati-InnuvaPharma, Roche, Sanoﬁ, Ställergeness, UCB Pharma, Uriach Pharma, Teva, AstraZeneca, ThermoFischer, Valea, Vibor Pharma
- Francesco Blasi: AstraZeneca, Bayer, Chiesi, Guidotti, GSK, Grifols, Insmed, Menarini, Novartis, Pfizer, Zambon
- Pierluigi Paggiano: AstraZeneca, Chiesi, Novartis, Alk-Abellô, GSK, Mundipharma, Guidotti, Menarini, Sanoﬁ
- Gianenrico Senna: AstraZeneca, GSK, Menarini, Novartis, Sanoﬁ, Mylan
- Enrico Heffler: AstraZeneca, Sanoﬁ, Novartis, GSK, Teva, Valea, Circassia, Nestlé Purina
Introduction. Allergic Rhinitis (AR) currently affects 40% of the world’s population posing a significant burden on individuals (QOL) and society. It has been established that 75% of patients with AR self-select their medication in Australian community pharmacy: 15% select optimally. This study tested the feasibility and impact of the Allergic Rhinitis Clinical Management Pathway (AR-CMaP), (ie a pharmacy AR management approach, based on an evidence-based clinical pathway and individualised for each pharmacy setting) on the AR medication selection of people with AR.

Methods: A mixed-methods, repeated measures study design was implemented. Baseline data collection using a researcher-administered questionnaire, enabling the evaluation of the appropriateness of the process and outcome of the patient medication selection. Pharmacists participated in the AR-CMaP training, which was supported by a modification of the pharmacy to address the particular needs of pharmacists (pharmacy workflow etc based on pre-identified pharmacist needs) and the patients in the pharmacy. Two weeks following training and pharmacy modification, the researcher-administered questionnaire (described above) was once again implemented. Pharmacists were interviewed to gain feedback on the implementation of the pathway in their pharmacy.

Results: Six pharmacies enrolled in the study; 241 and 240 eligible pharmacy customers participated at baseline and follow up respectively. The majority of AR patients experienced moderate-severe symptoms. The most common product purchased was an oral antihistamine. There were no significant changes in the pharmacist-patients interaction and medication selection process post-implementation of AR-CMaP. Forty-four percent of the AR patients reporting not seeing a doctor for follow-up, 26% reported it to be a doctor’s responsibility and 20% were satisfied with their self-management. Pharmacists reported that barriers to implementing AR management guidelines included not wanting to contradict a doctor’s recommendation and AR patients reluctance to change their treatment.

Conclusion: People with AR have pre-determined approaches to the management of their AR, neither seeking or wanting pharmacist involvement. Future research and strategies need to use a novel technique to address the self-management practices of patients who still continue to select sub-optimal medication to manage their AR.

Disclosures: Dr. Tan and Mrs Cvetkovski has nothing to disclose. Dr. Kritikos reports personal fees from AstraZeneca, personal fees from GlaxoSmithKline, personal fees from Pfizer, outside the submitted work.

Dr. Yan reports personal fees from AstraZeneca, personal fees from Boehringer Ingelheim, personal fees from GlaxoSmithKline, personal fees from Meda, personal fees from Mundipharma, personal fees from Pfizer, outside the submitted work.

Prof. Bosnic-Anticevich reports personal fees from Boehringer Ingelheim, personal fees from Boehringer Ingelheim, grants from MEDA, personal fees from TEVA, personal fees from TEVA, personal fees from AstraZeneca, personal fees from GSK, outside the submitted work.

PP08
Workflow Mapping of Nebulized COPD Therapy in In-hospital and Long-term Care (LTC) Settings in the US: a Precursor to an Observational Time and Motion (T&M) Study
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Respiratory Research 2021, 22(1); PP08

Introduction. The economic burden of COPD is substantial with medical costs projected to rise to $49 billion by 2020. Standard of care includes SABA, SAMA, or SABA+SAMA. Approximately 9% of US COPD patients use nebulizers for ongoing maintenance therapy. However, there is a lack of understanding of healthcare professional (HCP) time invested. This study tested the feasibility of developing a workflow mapping study in clinic and LTC settings in the US in order to achieve a better understanding of HCP time invested in COPD therapy. This study also measured the T&M of COPD therapy in LTC.

Methods: This was a cross-sectional study, considering the workflow mapping of different HCPs using nebulizers for COPD in an in-hospital and LTC setting and compared the T&M in these settings.

Results: A total of 29 HCPs were involved in the workflow mapping study, 17 in the in-hospital setting and 12 in the LTC setting. The average T&M for in-hospital setting was 237.74 min while in the LTC setting it was 127.25 min. The T&M for in-hospital setting was significantly higher than the T&M in the LTC setting (p < 0.001).

Conclusion: This study provides a first glimpse into the workflow mapping of nebulized COPD therapy in in-hospital and LTC settings in the US and provides an estimate of HCP time invested in COPD therapy. This study also provides a foundation for future observational T&M studies.

Disclosures: No disclosures.
Nebulization process

1. Collect nebulized drug (in-hospital automated dispensing cabinet vs. drug cart in LTC)
2. Collect materials (sometimes together with step 1)
3. Pre-nebulization assessment (may include patient education)
4. Add medication to reservoir and connect to nebulizer (may include patient education)
5. Start nebulization (may include pre-nebulization assessment)
6. Monitoring patient during nebulization
7. End nebulization (may include post-nebulization assessment; may be combined with step 8)
8. Store nebulizer/discard materials/clean nebulizer
9. Post-nebulization assessment
10. Record-keeping

Conclusion: Nebulization workflow is highly standardized and expected to be similar between in-hospital and LTC settings and also between nebulized drugs. Opinion-based time estimates suggest that HCPs dedicate substantial time to nebulization. This research confirmed the feasibility and suitability of T&M as a method to accurately quantify time dedicated by HCPs to perform nebulized COPD therapy in both settings. Data from this ongoing T&M study will be used to estimate potential efficiencies that could result from nebulized COPD therapies with less frequent dosing regimens.

Disclosures: Erwin De Cock is an employee of Syneos commissioned by TBPH to conduct this project. Grant Macaline is an employee of TBPH. Grace Leung is a consultant for Mylan Specialty L.P. Brooks Kuhn is a paid consultant for Syneos.
antagonists) using a pressurized metered dose inhaler (pMDI). In particular, we aim to: 1) determine an estimated recruitment time for a RCT, 2) assess patient and healthcare provider satisfaction with the smart spacer, 3) explore the distribution of medication adherence patterns (persistence and inhaler technique) and clinical outcomes and 4) obtain data to calculate the sample size for a definitive RCT.

Methods: The CE-marked smart spacer used in this study is based upon the Aerochamber Plus® with Flow Vu®. The smart spacer monitors both adherence and inhaler technique and can be used with multiple pMDI devices.

Randomized controlled feasibility trial of 2 months. Patients will be recruited from four general practices in the Netherlands. Patients (n=40) will use the spacer for 1 month (t=-1). At t=0, they will be randomized into two groups. The intervention group will receive tailored feedback and education on the basis of data from the smart spacer; the control group will receive usual care. After 1 month (t=1), the study ends and outcomes are assessed.

Results: At t=-1, t=0 and t=1, ACQ, WPAI, TAI and FeNO are measured. At t=0 and t=1, lung function will be tested. At t=1, device usability is evaluated by the SUS questionnaire as well as structured interviews with patients and healthcare providers. Finally, a scalp hair sample will be taken to compare electronically collected data with long-term inhaled drug exposure.

Conclusion: This study will provide insight in how healthcare providers can objectively monitor and manage patients’ adherence to inhalation medicines using a smart spacer. Furthermore, we will obtain data regarding optimal outcomes for a full RCT including medication adherence, inhaler technique and clinical outcomes. This RCT will provide evidence on the potential of personalized, smart spacer-data-informed inhaler education.

PP11
Are COPD prescription patterns aligned with guidelines?
A Canadian population-based study
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Respiratory Research 2021, 22(1), PP11

Background: In contemporary guidelines for the management of Chronic Obstructive Pulmonary Disease (COPD), the history of acute exacerbations plays an important role in the choice of long-term inhaled therapies. This study aimed at evaluating population-level trends of filled inhalation prescriptions over the time course of COPD and their relation to the history of exacerbations.

Method: We used administrative health databases in British Columbia, Canada (1997–2015) to create a retrospective incident cohort of individuals with diagnosed COPD. We quantified long-acting inhalation medication within each year of follow-up and documented its trend over the time course of COPD. Using generalized linear models, we investigated the association between the frequency exacerbator status (≥2 moderate or ≥1 severe exacerbation(s) in the previous 12 months) and filling a prescription after a physician visit.

Results: 132,004 COPD patients were included (mean age 68.6, 49.2% female). The most common medication class during the first year of diagnosis was inhaled corticosteroids (ICS, used by 49.9%), followed by long-acting beta-agonists (LABA, 31.8%). Long-acting muscarinic agents (LAMA) were used by 20.4%. 40.0% of patients received combination inhaled therapies in their first year of diagnosis, with ICS+LABA being the most common (30.7%). The association between exacerbation history was the most pronounced for triple therapy with an odds ratio (OR) of 2.68 for general practitioners (GPs) and 2.02 for specialists (internist and respirologists) (p<0.001 for both). Such associations were generally stronger among GPs compared with specialists, with the exception of monotherapy with LAMA or ICS as shown in the figure.

Conclusion: We documented low utilization of monotherapies (specifically LAMA) and high utilization of combination therapies (particularly ICS containing). Specialists were less likely to consider exacerbation history in the choice of inhaled therapies compared with GPs. Figure. Forest plot of Odds Ratio (OR) and 95% confidence interval between frequent-exacerbator status and filled prescriptions for each medication type, separately for GP and specialist.

Abbreviations: ICS, inhaled corticosteroids; LABA, long-acting beta-2 adrenoceptor agonists; LAMA, long-acting muscarinic agents; GP, General practitioner.

Disclosures:
Dr. Mohsen Sadatsafavi is the corresponding author and has received speaker fees and honoraria from Boehringer Ingelheim, GlaxoSmithKline, and AstraZeneca. He has received research funds directly into his research accounts within The University of British Columbia from Boehringer Ingelheim and AstraZeneca.

PP12
Development of a tool to measure the clinical response to biologic therapy in uncontrolled severe asthma: the FEOS score.
Luis Pérez De Llano1, Ignacio Dávila2, Eva Martínez Moragon3, Javier Dominguez Ortega4, Carlos Almonacid4, Carlos Colás5, Juan Luis García-Rivero6, Borja G Cosio7
1Pneumology Service. Lucus Augusti University Hospital, Lugo, Spain, 2Department of Allergy, University Hospital of Salamanca, Salamanca, 3Department of Pulmonology, University Hospital of Salamanca, Salamanca, 4Department of Pulmonology, University Hospital of Castilla La Mancha, Albacete, Spain, 5Department of Pulmonology, University Hospital of Castilla La Mancha, Albacete, Spain, 6Department of Pulmonology, University Hospital of Castilla La Mancha, Albacete, Spain, 7Department of Pulmonology, University Hospital of Castilla La Mancha, Albacete, Spain

Background: In contemporary guidelines for the management of Chronic Obstructive Pulmonary Disease (COPD), the history of acute exacerbations plays an important role in the choice of long-term inhaled therapies. This study aimed at evaluating population-level trends of filled inhalation prescriptions over the time course of COPD and their relation to the history of exacerbations.

Method: We used administrative health databases in British Columbia, Canada (1997–2015) to create a retrospective incident cohort of individuals with diagnosed COPD. We quantified long-acting inhalation medication within each year of follow-up and documented its trend over the time course of COPD. Using generalized linear models, we investigated the association between the frequency exacerbator status (≥2 moderate or ≥1 severe exacerbation(s) in the previous 12 months) and filling a prescription after a physician visit.

Results: 132,004 COPD patients were included (mean age 68.6, 49.2% female). The most common medication class during the first year of diagnosis was inhaled corticosteroids (ICS, used by 49.9%), followed by long-acting beta-agonists (LABA, 31.8%). Long-acting muscarinic agents (LAMA) were used by 20.4%. 40.0% of patients received combination inhaled therapies in their first year of diagnosis, with ICS+LABA being the most common (30.7%). The association between exacerbation history was the most pronounced for triple therapy with an odds ratio (OR) of 2.68 for general practitioners (GPs) and 2.02 for specialists (internist and respirologists) (p<0.001 for both). Such associations were generally stronger among GPs compared with specialists, with the exception of monotherapy with LAMA or ICS as shown in the figure.

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Background: In contemporary guidelines for the management of Chronic Obstructive Pulmonary Disease (COPD), the history of acute exacerbations plays an important role in the choice of long-term inhaled therapies. This study aimed at evaluating population-level trends of filled inhalation prescriptions over the time course of COPD and their relation to the history of exacerbations.

Method: We used administrative health databases in British Columbia, Canada (1997–2015) to create a retrospective incident cohort of individuals with diagnosed COPD. We quantified long-acting inhalation medication within each year of follow-up and documented its trend over the time course of COPD. Using generalized linear models, we investigated the association between the frequency exacerbator status (≥2 moderate or ≥1 severe exacerbation(s) in the previous 12 months) and filling a prescription after a physician visit.

Results: 132,004 COPD patients were included (mean age 68.6, 49.2% female). The most common medication class during the first year of diagnosis was inhaled corticosteroids (ICS, used by 49.9%), followed by long-acting beta-agonists (LABA, 31.8%). Long-acting muscarinic agents (LAMA) were used by 20.4%. 40.0% of patients received combination inhaled therapies in their first year of diagnosis, with ICS+LABA being the most common (30.7%). The association between exacerbation history was the most pronounced for triple therapy with an odds ratio (OR) of 2.68 for general practitioners (GPs) and 2.02 for specialists (internist and respirologists) (p<0.001 for both). Such associations were generally stronger among GPs compared with specialists, with the exception of monotherapy with LAMA or ICS as shown in the figure.

Conclusion: We documented low utilization of monotherapies (specifically LAMA) and high utilization of combination therapies (particularly ICS containing). Specialists were less likely to consider exacerbation history in the choice of inhaled therapies compared with GPs. Figure. Forest plot of Odds Ratio (OR) and 95% confidence interval between frequent-exacerbator status and filled prescriptions for each medication type, separately for GP and specialist.

Abbreviations: ICS, inhaled corticosteroids; LABA, long-acting beta-2 adrenoceptor agonists; LAMA, long-acting muscarinic agents; GP, General practitioner.

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Background: There is a lack of tools to holistically quantify the response to monoclonal antibodies (mAbs) in severe uncontrolled asthma (SUA) patients. The aim of this study was to develop a valid score to assist specialists in this clinical context.

Methods: The score was developed in 4 subsequent phases: (1) elaboration of the theoretical model of the construct intended to be measured (response to mAbs); (2) definition and selection of items and measurement instruments by Delphi survey; (3) weight assignment of the selected items by multicriteria decision analysis (MCDA) using the Potentially All Pairwise RanKings of all possible Alternatives (PAPRIKA) methodology via the 1000Minds software; and (4) face validity assessment of the obtained score.

Results: Four core items, with different levels of response for each of them, were selected: “severe exacerbations”, “oral corticosteroid use”, “symptoms” (evaluated by Asthma Control Test: ACT) and “bronchial obstruction” (assessed by FEV1 % theoretical). “Severe exacerbations” and “oral corticosteroid maintenance dose” were weighted most heavily (38% each), followed by “symptoms” (13%) and “FEV1” (11%). Higher scores in the weighted system indicate better response and the range of responses runs from 0 (worsening) to 100 (best possible response). Face validity was high (intrinsic correlation coefficient: 0.86).

Conclusions: The FEOS score (FEOS, Exacerbations, Oral corticosteroids, Symptoms) allows clinicians to quantify response in SUA patients who are being treated with mAbs.

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PP13

Biologic Utilization Patterns: Data from the International Severe Asthma Registry (ISAR)

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Table 1: Criteria, Select, Points

| Criteria | Select | Points |
|----------|--------|--------|
| Maintenance systemic corticosteroid dose: change with respect to baseline | Increase | 0 |
| No change | 14 |
| Reduction < 50% | 24 |
| Reduction between 50% and 100% | 29 |
| Complete withdrawal | 38 |
| Severe exacerbation: change with respect to the previous 12 months | Increase | 0 |
| No change | 11 |
| Reduction <50% | 22 |
| Reduction between 50% and 100% | 27 |
| 100% Reduction | 38 |
| ACT questionnaire: change with respect to baseline | ACT total score decrease | 0 |
| ≤ 3 points increase but total score <20 | 5 |
| ≥ 3 points increase, but total score <20 | 9 |
| ACT ≥ 20 | 13 |
| Pre-bronchodilator FEV1: change with respect to baseline | >100 ml decrease | 0 |
| No change or <100 ml and <10% increase | 5 |
| ≥100 ml increase and 10% but < 80% | 11 |
| FEV1 180% | 11 |

Total score
Methods: The International Severe Asthma Registry (ISAR; http://isaregistries.org) launched in 2017 includes patients aged ≥18 years on Global Initiative for Asthma (GINA) Step 5 or GINA Step 4 treatment with uncontrolled symptoms. Severe asthma patients recruited between January 2015 to August 2019 from Bulgaria, Canada, Greece, Italy, Japan, Kuwait, South Korea, Spain, and the United States (US) were included in the analysis (n=6,477). All countries had licences for ≥2 biologics. The following biologic utilization patterns were captured: 1) persistence on biologic for ≥6 months, 2) stopping (no record of biologic use for >3 months after the end of the last prescription), or 3) single switch/multiple switches (received a biologic, followed by a switch to another biologic). Both retrospective and prospective medication records were considered.

Results: Of the 6,477 patients with severe asthma, 1,727 were treated with biologics during 2017 to 2019. Of these patients, 73% (n=1,255) persisted with their biologic, 16% (n=280) stopped, and 9% (n=151) switched once or twice to a second or third biologic. Biologic persistence was most prevalent in Italy and least prevalent in Japan. More patients in the US (27%) stopped their biologic compared to other countries. South Korea had the most patients (33%) who switched biologics, although absolute numbers were low. Of those who switched once to a second biologic (n=122), 84% (n=103) continued on the second biologic. Only 11% (n=16) of 151 patients who switched once again to a third biologic, and of those 75% (n=12) persisted on the third biologic.

Conclusion: At the time of this data cut, three-quarters of patients with a biologic prescription were maintained on the first biologic therapy, with only a small percentage stopping or switching to another biologic. The majority of those who switched persisted with their second biologic, with only a very small percentage progressing to a third biologic. Patterns of use may be driven by multiple factors such as 1) biologic availability, 2) biologic prescription requirements, 3) country-specific health system issues, 4) patient preference and expectations, and 5) national stopping guidelines. These factors should be considered in future work analysing usage patterns.

Table. Proportion of patients treated with biologic (Bx) and treatment pattern by country

| Country     | All patients, n | Patients treated with a Bx, n (%) | Persisted with Bx, n (%) | Stopped Bx, n (%) | Switched Bx, n (%) |
|-------------|-----------------|----------------------------------|-------------------------|------------------|-------------------|
| Bulgaria    | 143             | 30 (21%)                         | 27 (90%)                | 1 (3%)           | 2 (17%)           |
| Canada      | 100             | 60 (60%)                         | 48 (80%)                | 3 (5%)           | 9 (13%)           |
| Greece      | 38              | 11 (29%)                         | 8 (73%)                 | 0 (0%)           | 3 (19%)           |
| Italy       | 563             | 363 (64%)                        | 351 (97%)               | 6 (2%)           | 6 (2%)            |
| Japan       | 89              | 19 (21%)                         | 16 (89%)                | 2 (11%)          | 1 (11%)           |
| Kuwait      | 131             | 100 (99%)                        | 108 (99%)               | 3 (2%)           | 18 (14%)          |
| S. Korea    | 39              | 6 (15%)                          | 4 (67%)                 | 0 (0%)           | 2 (33%)           |
| Spain       | 249             | 215 (86%)                        | 170 (79%)               | 23 (11%)         | 5 (2%)            |
| USA         | 5,145           | 3,823 (74%)                      | 3,422 (90%)             | 241 (7%)         | 34 (11%)          |
| Total       | 6,477           | 1,727 (27%)                      | 1,255 (73%)             | 280 (16%)        | 151 (9%)          |

*Percentage of all patients; **Percentage of patients treated with a biologic; ***Utilization pattern for 14 patients to be confirmed.

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Andrew N. Menzies-Gow has attended advisory boards for AstraZeneca, GlaxoSmithKline, Novartis, Sanofi and Teva, and has received speaker fees from AstraZeneca, Novartis, Roche, and Sanofi. He has participated in research with AstraZeneca for which his institution has been remunerated and has attended international conferences with Teva. He has had consultations agreements with AstraZeneca, Sanofi, and Vectura.

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Maria Anne Rowlands, Lakmini Bulathsinhala, Victoria Carter, Isha Chaudhry, Neva Eleangovan, Naeimeh Hosseini are employees of Optimum Patient Care and a co-founder of the International Severe Asthma Registry.

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PP14

Exacerbations Are Associated with Lung Function Decline in a Broad Asthma Population in England, Scotland, and Wales 1950–2019

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Introduction: Progressive lung function decline in patients with asthma may result in poorer control and worsening quality of life. Asthma exacerbations are thought to contribute to this decline. However, evidence is mixed and limited to a few mainly small, post-hoc studies. This longitudinal study aimed to assess the association between exacerbation burden and long-term lung function decline in a broad asthma patient population.

Methods: This was a historical cohort study of a broad asthma patient population covering the United Kingdom in the Optimum Patient Care Research Database. Patients were followed up from the first eligible post-18th birthday peak expiratory flow rate (PEF) record (primary analysis), or record of forced expiratory flow in 1 second (sensitivity analysis) until the last record of the same type. Linear growth models that adjusted for age, sex, follow-up length, height, and time-varying smoking status were used to test the impact of mean annual exacerbation rate (AER - averaged over follow-up) on lung function trajectory both overall and stratified by age (18-24, 25-39 and 40+ years) and by mean dosage of inhaled corticosteroids (ICS), categorized into terciles (lowest, middle and highest).

Results: We studied 109,182 patients with follow-up between 5 and 60 years. For each additional exacerbation per year an estimated additional 0.21% predicted PEF/year was lost (95% CI 0.18, 0.25). The effect was greatest in younger adults where those with AERs of 2+ and aged 18-24 years at baseline lost an additional 1.27% predicted PEF/year (95% CI 0.73, 1.81) compared to those with AER 0. These differences in the rate of LF decline between AER groups became progressively smaller as age at baseline increased. Apart from patients in the lowest ICS dosage tercile where there was no significant impact, there was a significant acceleration in lung function decline in patients with higher AERs compared to AER 0 for those in the middle and highest ICS terciles. The results using FEV1 were consistent with the above.

Conclusion: To our knowledge, this is the largest, population-based assessment of asthma exacerbation burden and lung function decline and addresses key evidence gaps. We show that exacerbations are associated with faster lung function decline, which is most accelerated in patients aged under 40 years and not entirely prevented by ICS. Earlier intervention with appropriate management in younger asthma patients could be of value to prevent excessive lung function decline.

Disclosure: Seyi Soremekun, Derek Skinner, Lakmini Bulathsinhala, Victoria Carter, Isha Chaudhry, Naimeh Hosseini, and Neva Eleangovan are employees of Optimum Patient Care, a co-founder of the International Severe Asthma Registry. Liam G. Hearney declares he has received grant funding, participated in advisory boards and given lectures at meetings supported by Amgen, AstraZeneca, Boehringer Ingelheim, Circassia, Evelo Biosciences, Hoffmann La Roche, GlaxoSmithKline, Novartis, Theravance and Teva; he has taken part in asthma clinical trials sponsored by Boehringer Ingelheim, Hoffmann La Roche, and GlaxoSmithKline for which his institution received remuneration; he is the Academic Lead for the Medical Research Council Stratified Medicine UK Consortium in Severe Asthma which involves industrial partnerships with a number of pharmaceutical companies including Amgen, AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Hoffmann La Roche, and Janssen. Ruth Murray declares no relevant conflicts of interest. Trung N. Tran, Benjamin Emmanuel, and Esther Garcia Gil are employees of AstraZeneca, a co-founder of the International Severe Asthma Registry. Andrew N. Menzies-Gow has attended advisory boards for AstraZeneca, GlaxoSmithKline, Novartis, Sanofi and Teva, and has received speaker fees from AstraZeneca, Novartis, Roche, Teva and Sanofi. He has participated in research with AstraZeneca for which his institution has been remunerated and has attended international conferences with Teva. He has had consultancy agreements with AstraZeneca, Sanofi, and Vectura. Matthew Peters declares personal fees and non-financial support from AstraZeneca and GlaxoSmithKline. Njira Lugogo consulted for AstraZeneca and GSK; on protocol committee with AstraZeneca; on advisory board with AstraZeneca, GSK, Sanofi, Novartis, Genentech and Teva.

David Price has board membership with AstraZeneca, Boehringer Ingelheim, Chiesi, Mylan, Novartis, Regeneron Pharmaceuticals, Sanofi Genzyme, Thermofisher; consultancy agreements with Airway Vista Secretariat, AstraZeneca, Boehringer Ingelheim, Chiesi, EPG Communication Holdings Ltd, FIECON Ltd, Fieldwork International, GlaxoSmithKline, Mylan, Mundipharma, Novartis, OM Pharma SA, PeerVoice, Phadia AB, Spirosure Inc, Strategic North Limited, Synapse Research Management Partners S.L., Talos Health Solutions, Theravance and WebMD Global LLC; grants and unrestricted funding for investigator-initiated studies (conducted through Observational and Pragmatic Research Institute Pte Ltd)
Research priorities in pediatric asthma: A global, multi-stakeholder survey by the Pediatric Asthma in Real Life (PeARL) Think Tank.

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Introduction: Pediatric asthma remains a public health challenge with enormous impact worldwide. There is a need of high-quality research and clinical recommendations to improve clinical outcomes. Pediatric Asthma in Real Life (PeARL), a think tank led by international clinical researchers in pediatric asthma initiated by the Respiratory Effectiveness Group (REG) aims to address this issue by developing consensus and recommendations that will improve patient care and limit disease burden, and also by crowdsourcing international expertise on pediatric asthma.

We present the results of a global, multi-stakeholder survey aiming to identify and prioritize unmet clinical needs in pediatric asthma that could be used to guide future research and policy activities.

Methods: Unmet needs were identified through an initial open-question survey that was administered to international experts in pediatric asthma. Prioritization of topics was then achieved through a second, extensive survey with global reach involving multiple stakeholders (leading experts, researchers, clinicians, patients, policy makers and the pharmaceutical industry).

Results: 57 unmet needs were identified by international experts and were prioritized by 412 survey respondents from 5 continents and 60 countries.

Conclusion: There is agreement among different stakeholder groups in the majority of research and strategic priorities for pediatric asthma. Stakeholder diversity is crucial for highlighting divergent issues that could be used to guide future research and policy activities.

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This study was supported by the Respiratory Effectiveness Group (REG).
None of the authors had any conflicts of interest directly related to this research.
Introduction: Allergic rhinitis (AR) affects 24% of young adults (≤ 26 years old) in Australia, making it the most common long-term chronic condition for this age group. When suboptimally managed, AR imposes a significant burden on people's quality of life (QOL), particularly their sleep quality and daytime productivity. Furthermore, 86% of people with asthma also experience AR, which has a direct impact on asthma control and, if poorly managed, it can increase the risk of asthma exacerbations. The nature of AR and the way it is managed has been well researched in both adult and paediatric populations. However, there is a gap in our understanding of the way AR is managed in young adults. Given the unique biopsychosocial developmental challenges faced by young adults, it is important that we investigate the management of AR in this population. This study aims to investigate the AR status of young adults. It also aims to investigate the way young adults manage their AR and the different sources of influence on their AR management.

Methods: This study was carried out online using cross-sectional observational study design. This survey included 20 items and investigated 3 domains: i) AR status, ii) AR medication management and iii) influences on AR management. The data were described descriptively, and logistic regression was used to determine the factors associated with optimal AR management.

Results: 145 participants were recruited in this study; 94% reported AR impacting on at least one domain of QOL. AR was significantly associated with depression, anxiety, and sleep disturbance. Only 11% of the participants were managing their AR with optimal treatment. As young adults transition to adult care, they require developmentally appropriate health care support to equip them with the health literacy skills needed to appropriately manage their AR.

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6. Walker et al (2007). J Allergy Clin Immunol 120: 381-387.

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