MEETING ABSTRACTS

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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.

Based on Clinical and CAT Criteria, forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) in controlled patients was greater in individuals receiving LAMA alone compared to LABA/ LAMA/ICS, P<0.002. While no differences were noted in the uncontrolled CC group for FEV1 and FVC, FEV1 in the CAT group was higher in the LAMA vs LABA/LAMA/ICS group, p<0.02. Values for mMRC in both the CAT and CC groups were significantly higher in the LABA/ LAMA/ICS vs LAMA with the exception of those uncontrolled in the CC group where there was no difference.

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, Miravitlles 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*

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 (11.1%)	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

Medication use and COPD control based on Clinical Criteria*



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Medication	Controlled (n=197)	Uncontrolled (n=106)	P-value
SABA/SAMA alone or in combination	6 (3%)	4 (3.8%)	0.735
LABA alone	24 (12.2%)	8 (7.5%)	0.211
LAMA alone	32 (16.2%)	7 (6.6%)	0.017
ICS alone	1 (0.5%)	0 (0%)	0.462
LABA/LAMA	55 (27.9%)	23 (21.7%)	0.238
LABA/ICS	23 (11.7%)	17 (16%)	0.285
LAMA/ICS	4 (2%)	2 (2%)	0.932
LABA/LAMA/ICS	49 (24.9%)	45 (42.5%)	0.002

Disclosures:

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PP02

Improving the Assessment of Adults with Chronic Cough in Primary Care

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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,1,2 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) guide-lines1. 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 (and even during the process of) referral to specialty 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 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 assessment 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, Griffols, 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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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 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.





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

PP04

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

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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 guestionnaire. 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 processrelated 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 treatmentrelated, 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 treatmentrelated (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.

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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Respiratory Research 2021, 22(1): PP05

Introduction: Patients with uncontrolled asthma despite high doses of inhaled corticosteroid 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:

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- Enrico Heffler: AstraZeneca, Sanofi, Novartis, GSK, Teva, Valeas, Circassia, Nestlè Purina

PP06

Chronic rhinosinusitis with nasal polyps impacts in severe asthma patients: evidences from the Severe Asthma Network Italy (SANI) Registry

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Respiratory Research 2021, 22(1): PP06

Introduction: The clinical and laboratory features of patients enrolled in the Severe Asthma Network in Italy (SANI) registry, a web-based observatory collecting demographic, clinical, functional and inflammatory data of patients with severe asthma were evaluated, with a special emphasis to chronic rhinosinusitis with nasal polyposis (CRSwNP).

Methods: For each eligible patients the following information has been collected: demographic data, clinical features, asthma control in the previous month according to the GINA (Global INitiative for Asthma) Guidelines and standardized questionnaires, concomitant regular and on demand treatments and inflammatory markers.

Results. 695 patients with severe asthma enrolled in 66 SANI centers were analyzed. The prevalence of chronic rhinosinusitis with nasal polyposis was 40.6%. Atopic dermatitis and bronchiectasis was significantly more frequent in patients with CRSwNP than in subjects without nasal polyposis; similarly, FeNO values are significantly higher in subject with CRSwNP respect patients without nasal polyposis. Finally, patients with CRSwNP had a significantly higher number of asthma exacerbations per year, although on more days on oral corticosteroids (OCS) and a higher number OCS long term users.

Conclusion: OCS sparing is needed in patients with severe asthma, mainly in subjects with CRSwNP, adopting adequate strategies such as a better adherence to the treatment with inhaled therapy accordingly to the GINA recommendations, the use of biologic agents and a multi-disciplinary approach of the patient.

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- Luca Malvezzi: Sanofi-Genzyme, Novartis
- Francesco Blasi: AstraZenca, Bayer, Chiesi, Guidotti, GSK, Grifols, Insmed, Menarini, Novartis, Pfizer, Zambon
- Pierluigi Paggiaro: AstraZeneca, Chiesi, Novartis, Alk-Abellò, GSK, Mundipharma, Guidotti, Menarini, Sanofi
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PP07

Community management of allergic rhinitis: A real life community pharmacy study targeting the barriers to Allergic Rhinitis management

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¹Woolcock Institute of Medical Research, Glebe, Australia, ²University of Sydney, Camperdown, Australia, ³Royal Prince Alfred Hospital, Camperdown, Australia, ⁴Sydney Local Health District, Campsie, Australia **Correspondence:** Sinthia Bosnic-Anticevich **Respiratory Research** 2021, **22(1)**: PP07 **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 need for pharmacist 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 patient's 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 mediation to manage their AR.

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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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Correspondence: Grant Maclaine *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

dedicated to nebulized COPD therapy administration. Workflow mapping was performed as a precursor to an observational T&M study.

Methods: A survey was designed to understand (1) center characteristics and pharmacologic COPD therapy, (2) SABA (albuterol (ALB)) and SABA+SAMA (ipratropium bromide plus albuterol sulfate (IPR/ALB)) nebulization workflow, and (3) estimated time per nebulization. Two HCPs from in-hospital and two from LTC settings completed the survey and were subsequently interviewed.

Results: HCPs across both settings reported that the majority of COPD patients are prescribed IPR/ALB for short-term relief. No differences in workflow were reported between IPR/ALB and ALB. There appeared to be consensus on consecutive activities; minor deviations included the need or not for pre- and post-nebulization assessment, and the logistics around storing/discarding/cleaning materials (Table). The process is performed by respiratory therapists in the in-hospital setting and by (licensed vocational) nurses in LTC. Estimated time per nebulization was 13 and 27 minutes in in-hospital setting, and 21 and 37 minutes in LTC.

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.

Nebulization process

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

Disclosures:

Erwin De Cock is an employee of Syneos commissioned by TBPH to conduct this project. Grant Maclaine is an employee of TBPH. Grace Leung is a consultant for TBPH. Hemal Shah is a consultant for Mylan Specialty L.P. Brooks Kuhn is a paid consultant for Syneos.

PP09

Opinions of GPs regarding their role in preventive medicine and eHealth support

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Correspondence: Esther Metting Respiratory Research 2021, 22(1): PP09

Background: In 2019 the Dutch government started with reimbursing a "Combined Lifestyle Intervention-program (CLI)" for high risk patients with poor lifestyle. This is relevant for the COPD population because 88% suffers from ≥ 1 comorbidities which are mostly lifestyle related and these increase the risk of exacerbations1.

Aim. To evaluate opinions of GPs regarding their role in preventive medicine. Moreover, we evaluated the current status of the CLI in the north of the Netherlands and the possible role of eHealth in preventive medicine.

Methods: We performed semi structured interviews in 15 GPs (mean age= 54 ± 10 years, 87% male). The topics were: 1) opinions regarding the role of primary care, 2) views on the CLI and 3) opinions regarding eHealth. We triangulated the findings in an questionnaire with 94 GPs (mean age 52 ± 8 years, 59% male).

Results: There was no consensus about the role of GPs in primary prevention, however secondary prevention was considered to be a task for primary care. Some GPs were demotivated "the patients' attitude makes me give up." Only few GPs used the CLI, because the CLI is not available in all areas. eHealth is hardly used by GPs, but is considered to be possibly relevant in a limited group of patients.

Conclusion: GPs are divided about their role. COPD patients with poor lifestyle might benefit from the CLI but this is not available in certain regions. Better National organisation of preventive programs and possibly innovative eHealth tools might enhance lifestyle support in primary care.

Westerik JA, Metting El, van Boven JF, Tiersma W, Kocks JW, Schermer TR. Associations between chronic comorbidity and exacerbation risk in primary care patients with COPD. Respir Res. 2017;18(1):31. Published 2017 Feb 6. https://doi.org/10.1186/s12931-017-0512-2

PP10

Smart spacer supported medication adherence management in patients with asthma: study protocol for the randomized controlled OUTER SPACE trial

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Respiratory Research 2021, 22(1): PP10

Introduction: Adherence to inhalation medicines is still a topic of major concern. This study aims to assess overall feasibility of undertaking a definitive randomized controlled trial (RCT) of a smart spacer device in adults with asthma treated in primary care with inhaled corticosteroids/long-acting beta agonists (+/-long-acting muscarinic

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 smart 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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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 inhaled 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 inhaled 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 frequent exacerbator status $(\geq 2 \text{ moderate or } \geq 1 \text{ severe exacerbation(s) in the previous } 12 \text{ months})$ 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 the least commonly prescribed (10.4%). ICS remained the most common prescription throughout follow-up, being used by approximately 50% of patients during each year 39.0% 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

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.

Medication class	Odds Ratio		Lower limit	Upper limit	P Value
ICS-LABA					
GP	1.39	н	1.36	1.43	<.0001
Specialist	1.29	H	1.23	1.36	<.0001
ICS-LAMA					
GP	2.2	H	1.98	2.45	<.0001
Specialist	1.58	H	1.23	2.02	0.0004
LAMA-LABA					
GP	1.65	⊢ •−−1	1.42	1.91	<.0001
Specialist	0.81 H	• •	0.64	1.01	0.0658
ICS only					
GP	1.07	H	1.03	1.12	0.0004
Specialist	1.21	⊢ •-1	1.09	1.34	0.0002
LAMA only					
GP	1.7	H	1.65	1.76	<.0001
Specialist	1.14	H	1.07	1.21	<.0001
LABA only					
GP	0.97	H=-1	0.86	1.09	0.5818
Specialist	0.7		0.55	0.9	0.0046
Triple therapy					
GP	2.68	572-152	H=H 2.59	2.78	<.0001
Specialist	2.02	H=	1.9	2.14	<.0001

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PP12

Development of a tool to measure the clinical response to biologic therapy in uncontrolled severe asthma: the FEOS score.

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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 (intraclass correlation coefficient: 0.86).

Conclusions: The FEOS score (FEV1, Exacerbations, Oral corticosteroids, Symptoms) allows clinicians to quantify response in SUA patients who are being treated with mAbs.

Criteria	Select	Points
Maintenancesystemic corticosteroid dose: change	with respect to bas	seline
Increase [‡]		0
No change [£]		14
Reduction < 50%		24
Reduction between 50% and 100%		29
Complete with drawal		38
Severe exacerbations: change with respect to thep	revious 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		5
≥ 3 points increase, but total score <20		9
ACT ≥ 20		13
Pre-bronchodilator FEV1: change with respect to ba	aseline	
>100 ml decrease		0
No change or <100 ml and <10% increase		5
≥ 100 ml increase and 10%, but < 80%		9
FEV1≥80%		11
	Total	1
	score	

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PP13

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

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Introduction: Use of biologics in severe asthma has grown dramatically in the last decade. However, little is known about the patterns of biologic use in real-life. Our aim was to describe frequency and patterns of biologic use in an international severe asthma cohort.

Methods: The International Severe Asthma Registry (ISAR; http:// isaregistries.org) launched in 2017 includes patients aged \geq 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 \geq 2 biologics. The following biologic utilization patterns were captured: 1) persistence on biologic for \geq 6 months, 2) stopping (no record of biologic use for \geq 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 switched 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.

Country	All patients, n	Patients treated	Persisted with	Stopped Bx,	Switched Bx,
		with a Bx, n	Bx, n (% ^b)*	n (% ^b)*	n (% ^b)*
		(%ª)		5-14 C	
Bulgaria	143	30 (21%)	27 (90%)	1 (3%)	2 (7%)
Canada	100	60 (60%)	48 (80%)	3 (5%)	8 (13%)
Greece	38	11 (29%)	10 (91%)	0 (0%)	1 (9%)
Italy	563	363 (64%)	351 (97%)	6 (2%)	6 (2%)
Japan	69	19 (28%)	5 (26%)	2 (11%)	2 (11%)
Kuwait	131	130 (99%)	108 (83%)	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	893 (17%)	541 (61%)	242 (27%)	107 (12%)
Total	6,477	1,727 (27%)	1,255 (73%)	280 (16%)	151 (9%)

Disclosures:

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. Eileen Wang has received honoraria from AstraZeneca and Clinical Care Options. She has been an investigator on clinical trials sponsored by AstraZeneca, GlaxoSmithKline, Genentech, Novartis, Teva, and National Institute of Allergy and Infectious Diseases (NIAID) for which her institution has received funding.

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

Marianna Alacqua and Trung N. Tran are employees of AstraZeneca, a co-funder 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, posthoc 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), categorised 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. **Disclosures:**

Seyi Soremekun, Derek Skinner, Lakmini Bulathsinhala, Victoria Carter, Isha Chaudhry, Naeimeh Hosseini, and Neva Eleangovan are employees of Optimum Patient Care, a co-funder of the International Severe Asthma Registry.

Liam G. Heaney declares he has received grant funding, participated in advisory boards and given lectures at meetings supported by Amgen, AstraZeneca, Boehringer Ingelheim, Circassia, Evelo Biosceinces, 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.

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Research priorities in pediatric asthma: A global, multistakeholder 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 weer 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 responders 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 future guidelines should consider. The PeARL Think Tank will attempt to address prioritized issues by producing focused evidence updates and by developing clinical and research recommendations.

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How do young adults manage their hav fever?

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Introduction: Allergic rhinitis (AR) affects 24% of young adults (<26 years old1-3) in Australia, making it the most common long-term chronic condition for this age group4. When suboptimally managed, AR imposes a significant burden on people's quality of life (QOL), particularly their sleep quality and daytime productivity5,6. Furthermore, 86% people with asthma also experience AR. AR has a direct impact on asthma control and, if poorly managed, it can increase the risk of the asthma exacerbations4. 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 was burdened with general burden and study/work of most concerned and 32% have coexisting asthma. Only 11% of the participants were managing their AR with optimal treatment for the reported AR symptoms and their severity. General practitioners, pharmacists and parents had the strongest influence on participants' AR management.

Conclusion: This study indicates that the majority of the young adults with AR are experiencing high burden on their QOL and are not managing their AR with appropriate 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. References:

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