REG

Respiratory Effectiveness Group

ADVANCES

in Real-life Respiratory Research

The Respiratory Effectiveness Group Newsletter
ISSUE SEPTEMBER 2023

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THE RESPIRATORY EFFECTIVENESS GROUP NEWSLETTER

ISSUE SEPTEMBER 2023

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EDITORIAL

Giorgio Walter Canonica
REG President

DEAR FRIENDS AND COLLEAGUES,

I hope this newsletter finds you well and you are having a successful 2023.

The major REG initiatives, which I have previously outlined, is a focus on how to integrate the value of RWE in the current Guideline procedure. We are well aware of the growing attention that has been paid to the credibility of the RWE impact. I am pleased to report that a workshop was held on Wednesday 15th March 2023 with other scientific organisations from around the world, representatives from FDA, EMA, PEI, NICE UK, as well as RWE researchers and patient organisation representatives and finally, methodology experts who helped to drive the discussion in three sessions. Firstly, the workshop discussed the value of real-world evidence, followed by an exploration of the methodological issues with guideline development and the pitfalls to avoid. Lastly, there was a review of registry-based studies and quality requirements that should ensure such data are acceptable for guideline inclusion. Publication of this workshop is in development, as well as the planning for a second workshop, which will take place in October 2023.

Another important activity regarding RWE and Guidelines was the recent joint session held with ERS during their congress in Milan this month. The Mini Symposium was entitled Next Generation Evidence-Based Decision-Making In Respiratory Medicine and discussed the differences between real world data and randomised controlled trials, their respective merits, as well as a deep dive into registries and how they can help provide evidence to support clinical decision making. We are extremely grateful for the support from ERS on this issue.

Participation in our various working groups and their projects is a fundamental part of REG's mission to promote high quality real-life research and I therefore would like to encourage everyone, especially colleagues in your department and those in early career training to join and contribute. The real-life research research in which our collaborators participate in bring new and better understanding of how to manage the challenges in respiratory diseases.

The work has begun for the next REG summit on 14 – 16 March 2024. Please Save The Date and more information will be shared with you as the planning progresses for the event. It will also be REG's 10 year anniversary, which is another reason to participate in the meeting and celebrate REG's achievements over the last decade.

I look forward to seeing you in Vienna at next year's REG Summit and please join us for our 10-year celebrations.

Giorgio Walter Canonica
Professor Respiratory Medicine - Humanitas University
Head Personalized Medicine Asthma & Allergy Clinic - Humanitas Clinical & Research Hospital-IRCCS
Milano-Italy

REG TEAM UPDATE

Michael Walker
REG CEO

The very successful REG Summit was held in Lisbon from 16th to 18th March. The stimulating scientific programme provided participants with opportunities for in-depth discussions about the many issues and controversies that challenge everyday care of patients.

On the day prior to the Summit meeting, REG Working Groups met to discuss and continue to develop their respective research projects. The Working Group meetings are an important opportunity for our Working Group members to connect and continue our active projects or discuss new projects in development.

The last few months have also been focused on the various REG research projects that are in development and an update can be read in this edition. Just two examples of our recent progress:

- The ILD patient diagnostic pathway: Comparing referral patterns, caseload and availability of diagnostic tools, resources and treatment between ILD specialist centres and non-ILD centres in; as well as implementation of virtual MDTs in the post-COVID era.
- Missed severe asthma in children: to determine the annual incidence and prevalence of severe asthma in children in the UK community using primary care data and applying different criteria for defining severe asthma.

REG has long advocated for the full integration of real-world evidence in guidelines. To this end, a first workshop was held in Lisbon in March 2023 and a second workshop is planned for October 2023. In addition, REG held a joint session with ERS at their recent congress in Milan. The mini symposium was entitled Next Generation Evidence-Based Decision-Making In Respiratory Medicine. More reporting on this topic will soon be available in the peer-reviewed literature.

An important Save The Date Announcement to note: the next REG Summit will be held in Vienna, Austria from 14 – 16 March 2024. This will be a special milestone event as REG celebrates in 10-year anniversary. We hope everyone can join us for this special event.

Lastly, I would like to acknowledge the support from our long-term supporters. Without their ongoing collaboration a lot of the work of REG would not be possible. I hope others are encouraged by the activities of REG and the REG Working Group meetings and will collaborate with us later this year or plan to in 2024. We will continue to support and reach out to our partners as we work together in real-life research.

REG SUMMIT 2023

The REG Summit 2023 was a tremendous success and attracted a wide audience from around the world.

The event took place as a live in-person event from 16th to 18th March. Close to 100 participants from 20 countries travelled to Lisbon for the meeting. The Summit included 10 Working Group meetings, 12 exciting sessions on a wide and diverse range of key issues and topics in respiratory health, featuring talks and debates from esteemed speakers and guests. The Summit was accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with 14 European CME credits (ECMEC®s) and received accreditation by European Board of Accreditation in Pulmonology (EBAP) for 14 CME credits covering the whole program.

The Scientific Programme included sessions on:

- Chronic cough
- Respiratory Infectious Challenges – RSV and bronchiectasis
- COPD - PIF and outcomes in COPD, EARCO registry for Alpha-1 antitrypsin deficiency and European registries on COPD, Will biologics ever have a role in COPD?
- Childhood Respiratory Challenges – Diagnosis, Monitoring, Treatment.
- Rhinitis: United Airways Diseases
- The Environment and Inhaler Choice
- PRO/CONs discussing "In COPD, Triple therapy should be used earlier than current guidelines recommend" and "In asthma, Biologics should be used earlier than current guidelines recommend"
- Definition and management of Long COVID
- Management of ILD/IPF and vMDTs – Improved patient management?
- Update from the ISAR Registry and research findings.
- Vaccination in Respiratory Diseases
- RWE & Guidelines Consensus Meeting Report

All sessions are available to watch on demand. For more information, go to **www.regsummit2023.org**

Thanks to all the speakers, session chairs and meeting participants for making it such a great meeting.

Thank you also for the support from our sponsors: Platinum: Sanofi-Regeneron and Teva, Gold: Menarini, Silver: Novartis, Pfizer, Roche and Contributor: Prospection.

The REG Summit will return next year in Vienna, Austria from 14 – 16 March 2024.

We look forward to seeing you there!

REG SUMMIT 2023 ABSTRACTS

The meeting attracted 10 abstract submissions which were presented as posters with authors from Canada, Spain, Netherlands, United Kingdom and Brazil.

PP01 ALGORITHM FOR CHRONIC COUGH ASSESSMENT IN PRIMARY CARE

Dr. Alan Kaplan[1]
[1]*Family Physician Airways Group of Canada, Stouffville, Canada*

TITLE: Algorithm to approach Chronic Cough in Primary Care

RATIONALE: Patients present to their Primary Care Practitioner (PCP) with Symptoms, requiring a diagnosis to be made. Only with an accurate diagnosis can the correct treatment be instituted. As such, an easy to follow algorithm to approach patients with chronic cough can lead to assessing the appropriate testing allowing the correct diagnosis and/or appropriate referral

METHODS: A clinical algorithm was created to assist in proper diagnosis and tested in multiple CMEs on this topic and found to be a potential valuable resource.

RESULTS: This algorithm was found to be understandable in 90% of participants, useful in 85% of participants and potentially practice changing. Frustration at knowing what to do with UCC (unexplained chronic cough) or RCC (refractory chronic cough) indicated a knowledge gap for this clinical issue.

CONCLUSIONS: This algorithm can support PCPs in their approach to an undifferentiated patient with Chronic Cough.

PP02 ALGORITHM TO APPROACH DYSPNEA IN CLINICAL CARE

Dr. Alan Kaplan[1]
[1]*Family Physician Airways Group of Canada, Stouffville, Canada*

RATIONALE: Patients present to their Primary Care Practitioner (PCP) with Symptoms, requiring a diagnosis to be made. Only with an accurate diagnosis can the correct treatment be instituted. As such, an easy to follow algorithm to approach patients with dyspnea can lead to making the correct diagnosis, even when it is a more unusual diagnosis.

METHODS: A clinical algorithm was created to assist in proper diagnosis and tested in multiple CMEs on this topic and found to be a potential valuable resource.

RESULTS: This algorithm was found to be understandable in 95% of participants, useful in 90% of participants and potentially practice changing.

CONCLUSIONS: This algorithm can support PCPs in their approach to an undifferentiated patient with Dyspnea.

PP03 ABO BLOOD GROUP AS A DETERMINANT OF COVID-19 AND LONG COVID: AN OBSERVATIONAL, LONGITUDINAL, LARGE STUDY

Prof. Joan B Soriano[1]
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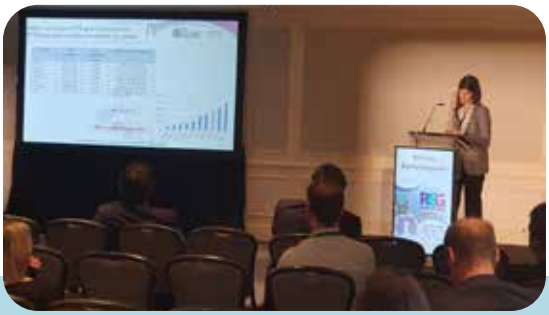
An association of AB0 blood group and COVID-19 remains controversial. Following STROBE guidance for observational research, we explored the distribution of AB0 blood group in patients hospitalized for acute COVID-19 and in those with Long COVID. Contingency tables were made and risk factors were explored using crude and adjusted Mantle-Haentzel odds ratios (OR and 95% CI). Up to September 2022, there were a total of 5,832 acute COVID-19 hospitalizations in our hospital, corresponding to 5,503 individual patients, of whom blood group determination was available for 1,513 (27.5%).

Their distribution by AB0 was: 653 (43.2%) group 0, 690 (45.6%) A, 113 (7.5%) B, and 57 (3.8%) AB, which corresponds to the expected frequencies in the general population. In parallel, of 676 patients with Long COVID, blood group determination was available for 135 (20.0%). Their distribution was: 60 (44.4%) from group 0, 61 (45.2%) A, 9 (6.7%) B, and 5 (3.7%) AB.

The distribution of the AB0 system of Long COVID patients did not show significant differences with respect to that of the total group ($p \geq 0.843$). In a multivariate analysis adjusting for age, sex, ethnicity, and severity of acute COVID-19 infection, subgroups A, AB, and B were not significantly associated with developing Long COVID with an OR of 1.015 [0.669-1.541], 1.327 [0.490-3.594] and 0.965 [0.453-2.058], respectively. The effect of the Rh+ factor was also not significant 1,423 [0.772-2,622] regarding Long COVID. No association of any AB0 blood subgroup with COVID-19 or developing Long COVID was identified.



REG SUMMIT 2023 ABSTRACTS

PP04

EFFECTIVENESS OF A MAINTENANCE AND RELIEVER DIGITAL SYSTEM TO IMPROVE ASTHMA CONTROL

Dr. Giselle Mosnaim[1], Dr. Flavia Hoyte[2,3], Dr. Guilherme Safioti[4], Dr. Randall Brown[5], Thomas Li[5], Dr. Michael DePietro[5], Dr. Tanisha Hill[5], Dr. Michael Wechsler[2]

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INTRODUCTION: In the Maintenance and Reliever Digital System (MRDS), Digihaler integrated inhalers (fluticasone propionate/salmeterol and albuterol Digihalers) transmit data wirelessly to a mobile application, which synchronizes with a Digital Health Platform to store and transfer data to a web-based Dashboard. This allows patients and clinicians to track and review inhaler usage and inhalation quality as part of clinical decision making. The CONNECT2 study (NCT04677959) evaluated asthma control as measured by the Asthma Control Test (ACT) in participants using the MRDS versus participants using the standard of care (SoC) maintenance and reliever inhalers.

METHODS: Eligible participants (≥13 years old with suboptimal asthma control [ACT score <19]) were randomized 4:3 to MRDS or SoC for 6 months. Primary outcome: the probability of greater odds for participants to achieve meaningful improvement in asthma control (ACT score ≥20, or increase ≥3 units from baseline at Month 6) with the MRDS versus SoC. Bayesian statistical analysis provided a posterior probability distribution for odds ratios with corresponding credible intervals (CrI).

RESULTS: Participants using the MRDS (n=210) had an 88.7% probability of greater odds of achieving improvements in asthma control vs those using SoC (n=181) after 6 months (Figure). The mean odds ratio (95% CrI) for MRDS/SoC was 1.35 (0.846, 2.038), demonstrating that, on average, participants in the MRDS group had 35% higher odds of achieving meaningful improvement in asthma control than those in the SoC group (Figure).

CONCLUSION: After 6 months, participants using the MRDS had greater odds of clinically meaningful improvements in asthma control versus SoC.

Originally presented during the ACAAI 2022 Annual Scientific Meeting.

PP05

OBJECTIVE MEASUREMENT OF ADHERENCE TO ASTHMA TREATMENT WITH A MAINTENANCE AND RELIEVER DIGITAL SYSTEM

Dr. Giselle Mosnaim[1], Dr. Flavia Hoyte[2,3], Dr. Guilherme Safioti[4], Dr. Randall Brown[5], Thomas Li[5], Dr. Michael DePietro[5], Dr. Tanisha Hill[5], Dr. Michael Wechsler[2]

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INTRODUCTION: Suboptimal adherence to inhaled maintenance therapy is common among patients with asthma. In the Maintenance and Reliever Digital System (MRDS), the Digihaler integrated inhalers (fluticasone propionate/salmeterol [FS] and albuterol Digihalers) transmit data wirelessly to a mobile application, which synchronizes with a Digital Health Platform to store and transfer data to a web-based Dashboard. The 6-month CONNECT2 study (NCT04677959) evaluated the MRDS in comparison with the standard of care (SoC) maintenance and reliever inhalers in participants with asthma aged ≥13 years with suboptimal asthma control (Asthma Control Test score <19). This analysis explored patients' adherence to their maintenance treatment while using the MRDS, based on data from the CONNECT2 study.

METHODS: 427 eligible participants were randomized 4:3 to the MRDS group or the SoC group. Participants' adherence to maintenance treatment in the MRDS group was assessed throughout the 6-month study period and calculated as percentages of FS doses taken daily, i.e., 0 dose = 0%, 1 dose = 50%, and 2 or more doses = 100%.

RESULTS: The mean monthly adherence to maintenance treatment in participants in the MRDS (n=210) started at 79.2% at Month 1, changed to 70.0% at Month 3, and thereafter remained relatively stable at 68.6% by Month 6 (Figure).

CONCLUSION: Study participants using the MRDS maintained good adherence throughout the 6-month study period, despite the pragmatic nature of this study without pre-determined adherence thresholds for action.

Originally presented during the ACAAI 2022 Annual Scientific Meeting.

REG SUMMIT 2023 ABSTRACTS

PP06

DATA FROM A MAINTENANCE AND RELIEVER DIGITAL SYSTEM SUPPORT PATIENT–CLINICIAN INTERACTIONS IN ASTHMA

Dr. Giselle Mosnaim[1], Dr. Flavia Hoyte[2,3], Dr. Guilherme Safioti[4], Dr. Randall Brown[5], Thomas Li[5], Dr. Michael DePietro[5], Dr. Tanisha Hill[5], Dr. Michael Wechsler[2]

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INTRODUCTION: In the Maintenance and Reliever Digital System (MRDS), the Digihaler integrated inhalers (fluticasone propionate/salmeterol and albuterol Digihalers) transmit data wirelessly to a mobile application, which transfers data to a web-based Dashboard. The 6-month CONNECT2 study (NCT04677959) evaluated the MRDS in participants aged ≥13 years with suboptimal asthma control (Asthma Control Test score <19). This analysis explored differences in frequency/types of participant–clinician interactions undertaken for asthma management of participants using the MRDS versus those using the standard of care (SoC) maintenance and reliever inhalers.

METHODS: 427 eligible participants were randomized 4:3 to the MRDS or SoC. For the MRDS group, clinicians obtained inhaler usage and inhalation quality data via the Dashboard, recorded reasons for participant contact outside of scheduled visits, and answered asthma management questions at each visit. Adjusted between-group differences (MRDS vs SoC) are reported with 95% credible intervals (CrI).

RESULTS: More participant–clinician interactions occurred in the MRDS group (n=210) versus the SoC group (n=181) (989 vs 473; mean difference [95% CrI]: 2.06 [1.691, 2.437]) (Figure). Compared with SoC, the MRDS was associated with substantially more technique-related participant–clinician interactions (277 vs 2; mean difference [95% CrI]: 0.94 [0.787, 1.098]), fewer planned follow-up interactions (168 vs 276; mean difference [95% CrI]: −0.66 [−0.881, −0.456]), and more frequent inhaler technique/adherence discussions (735 vs 150; mean difference [95% CrI]: 2.60 [2.301, 2.894]) (Figure).

CONCLUSIONS: A correlation was observed between use of the MRDS and interactions prompted by and leading to discussions on inhaler technique/adherence. These results suggest that the MRDS provides relevant information for asthma management.

Originally presented during the ACAAI 2022 Annual Scientific Meeting.

PP07

CLINICAL, FUNCTIONAL, RADIOLOGICAL, AND SURVIVAL CHARACTERISTICS IN PATIENTS WITH PROGRESSIVE FIBROSING INTERSTITIAL LUNG DISEASE (PFILD) TREATED WITH NINTEDANIB: 3-YEAR DATA FROM A SINGLE ILD SPECIALIST CENTRE IN THE UNITED KINGDOM

Dr. Janet marie Johnston[1], Dr Lachlan Stranks[1], Kate Newman[1], Theresa Garfoot[1], Dr Laurence Pearmain[1], Dr Stefan Stanel[1], Dr Conal Hayton[1], Professor Colm Leonard[1], Dr Melanie Greaves[2], Dr Pilar Rivera-Ortega[1]

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INTRODUCTION: In 2019, the INBUILD trial found that patients with fibrosing interstitial lung diseases treated Nintedanib demonstrated a slower rate of progression than those treated with placebo[1]. Access to Nintedanib was previously limited to those with Idiopathic Pulmonary fibrosis (IPF). Following on from this trial, access to Nintedanib for patients with non-IPF progressive fibrosis interstitial lung disease (PFILD) was granted by NICE in October 2019. This study aims to analyse key clinical, functional, radiological, and survivability characteristics of patients with PFILD treated with Nintedanib.

METHODS: Retrospective data was collected from 138 electronic patient records of our ILD specialist centre over a 3-year period (from November 2019 to November 2022). All 138 patients were diagnosed with PFILD after multidisciplinary team (MDT) consensus according to criteria used in INBUILD trial. The 138 records analysed included 47 samples from the Named Individual Patient Supply (NIPS from Boehringer UK) scheme and 91 samples from a service evaluation of patients on Nintedanib, taken from our ILD specialist centre.

RESULTS: Of the 138 PFILD patients, 31 (22%) had unfortunately passed away by December 2022. Ninety-eight PFILD patients (71%) started Nintedanib before December 2022. There was no statistically significant difference when considering age at diagnosis or sex. The most frequent diagnoses were connective tissue disease-associated ILD (30%) and hypersensitivity pneumonitis (26%); however, there was no statistically significant difference between diagnosis and survivability. There was no significant difference associated with oral steroids or concomitant immunosuppression. Severity of functional disease progression was found to have a statistically significant impact on survival, with the majority (35.5%) of deceased patients demonstrating ≥10% decline in forced vital capacity (FVC) at the time of diagnosis. As to be expected a lower baseline FVC (notably <70%), at time of diagnosis, showed a statistically significant difference between the surviving and deceased patients. Several studies have suggested that those with a usual interstitial pneumonia (UIP) pattern progress more rapidly than those with other radiological patterns[1]. Interestingly, our data showed a statistically significant trend towards an indeterminate UIP pattern as predictor of mortality, however, further studies are necessary to confirm this.

CONCLUSION: From our PFILD cohort lower baseline FVC and an indeterminate UIP pattern on CT-scan were all associated with an increased mortality risk.

REFERENCES: [1].Flaherty KR, et al. Nintedanib in Progressive Fibrosing Interstitial Lung Diseases. N Engl J Med. 2019 Oct 31:381(18):1718-1727

REG SUMMIT 2023 ABSTRACTS

PP08

PROVIDING EVIDENCE BASED ANSWERS TO FIRST HAND COVID AND RESPIRATORY QUESTIONS FROM THE IPCRG SENTINEL NETWORK OF PRACTISING PRIMARY CARE CLINICIANS: A NOVEL SERVICE REPORT.

Mr. Neil Fitch[1], Prof Alan Kaplan[2], Dr Fiona Mosgrove[3], Prof Janwillem Kocks[4], Prof Jaime Correia de Sousa[5], Prof Ee-Ming Khoo[6], Dr Karin Lisspers[7], Dr Tiago Maricoto[8], Prof Ioanna Tsiligianni[9], Dr Tracey Lonergan[1], Mrs Siân Williams[1]

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INTRODUCTION: The IPCRG iQ&A service was set up to help primary care practitioners dealing with a fast changing, high pressure environment during the COVID pandemic. COVID advice focused mainly on hospital care. Therefore, we created a real world, real time method for evidence-based answers to questions sourced from a global primary care Sentinel Network.

AIMS: To understand the right questions to answer, based on front line input, and to develop and produce usable answers to help primary care practitioners make decisions on their immediate priorities in their daily work.

METHODS: A novel process created by the working group defined an algorithm for the information flow from question identification, research, review by an Answer Review Group to publishing. This was refined in a pilot project which ran in 2020. In 2021 the iQ&A service launched. The IPCRG Sentinel Network was set up simultaneously to listen and respond to over 120 primary care clinicians representing every continent.

RESULTS: By January 2023, 190 questions were raised, prioritised and 51 answers provided. Over 15,000 views of the iQ&A webpages have been recorded to January 2022. Half of these were for the top 10 answers, which saw 1,800 downloads, 47% European and 30% Asian views. Vaccine efficacy and COVID Comorbidities were the most popular themes.

CONCLUSIONS: Providing up to date evidence based information to answer specific important questions about new issues helps primary practitioners do their work. Our initial focus is on managing COVID-19 in primary care settings. We will also include more respiratory conditions in the near future.

PP09

SPECTRAL AND INTRA-BREATH OSCILLOMETRY BUT NOT SPIROMETRY PREDICT ASTHMA CONTROL IN COMMUNITY PRACTICE NON-SEVERE ASTHMA

Dr. Ronald Dandurand[1,2,3], Mr. Paolo Medina[1,2], Ms. Carol Artico[2], Dr. Zoltan Hantos[4]

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INTRODUCTION: Spirometry is a poor estimate of asthma control yet continues to be the most popular measure of lung function for asthma management. We wished to explore the performance of oscillometry and spirometry in the evaluation of asthma control in community practice.

METHODS: Data were abstracted from charts of adults attending a single community respirology practice and included if the subjects had available an Asthma Control Questionnaire (ACQ), spirometry and oscillometry, both conventional spectral and intra-breath tracking at 10 Hz, and divided into Uncontrolled and Controlled Asthma using an ACQ threshold of above or below 1.5, respectively. Healthy control subjects (normal clinical evaluation, imaging, conventional lung function testing) were similarly identified and included. Data are presented as median and IRQ both as absolute and % predicted values using published normative data (Quanjer for spirometry, Berger for oscillometry). Between group differences were determined using Kruskal-Wallis and post hoc Dunn tests or X^2, and deemed significant if $p<0.05$ after Holm correction for multiple measures.

RESULTS: 59 subjects were included, 23 Healthy, 26 Controlled Asthma and 10 Uncontrolled Asthma. Groups were similar in terms of age, sex distribution and BMI (p=0.24-0.86). Of spirometry parameters, the FEV_1/FVC and MMEF were lower in Uncontrolled and Controlled Asthma compared to Healthy (p<0.01-p=0.01), but no spirometry parameter differed between Uncontrolled and Controlled Asthma (p=0.07-0.33). All spectral oscillometry parameters differed between Asthma and Healthy (p<0.01-p=0.03), and of these, R_{5-20} and AX were higher in Uncontrolled compared to Controlled Asthma (1.65 [1.13, 3.18] $cmH_2O/L/s$ vs 0.81 [0.57, 1.66], p=0.03 and 24 {19, 79] cmH_2O/L vs 14 [5, 28], p=0.04, respectively). Of intra-breath oscillometry parameters, end-expiratory resistance (ReE), end-inspiratory resistance (Rel), end-expiratory reactance (XeE), end-inspiratory reactance (Xel), reactance-volume area (AXV) and reactance-flow area (AXV) differed between Healthy and Asthma (p=0.01-0.05) and of these, XeE, Xel and AXV were lower in Uncontrolled compared to Controlled Asthma (p=0.02 for each).

CONCLUSIONS: While both spirometry and oscillometry distinguish between Asthma and Healthy subjects only oscillometry separates Uncontrolled from Controlled Asthma. Intra-breath oscillometry may make this distinction better than conventional spectral oscillometry. Our findings agree with the single published study using intra-breath oscillometry to evaluate adult asthma symptom control in severe asthma and extends this observation to non-severe asthma. Oscillometry may be a useful technique to aid management of community practice asthma regardless of severity, with a potential to reflect loss of disease control.

REG SUMMIT 2023 ABSTRACTS

PP10

IDENTIFYING OPPORTUNITIES FOR OPTIMISING THE MANAGEMENT OF HIGH-RISK COPD PATIENTS IN AUSTRALIA: AN OBSERVATIONAL STUDY

Mr. Alexander Evans[1], Kerry Hancock[2], Andrew P Dickens[1], Christine Jenkins[3], Anita Sharma[4], Belinda Cochrane[5,6], Paul Leong[7,8], Brian Ko[9], Florian Heraud[1], Porsche Le Cheng[1], Alexander Roussos[1], Sinthia Bosnic-Anticevich[10,11,12], Fabio Botini[1], Victoria Carter[1], Angelina Catanzariti[13], Clare Ghisla[13], Thao Le[14], Chantal Le Lievre[1], Ruth Murray[15], Kanchanamla Ranasinghe16,17, Deb Stewart[4], Marije van Melle[18,19], Rebecca Vella[1], Russell Wiseman[20], David Price[1,15,18,21]

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INTRODUCTION: Prior exacerbation history and current management opportunities are associated with future exacerbation risk. UK and US studies undertaken as part of the CONQUEST program have identified opportunities to optimise COPD management. It is unknown the extent of similar opportunities in other healthcare systems, such as Australia.

AIMS AND OBJECTIVES: To review management opportunities for high-risk COPD patients in Australia, with reference to national and international guidelines, and CONQUEST quality standards1 (identification, assessment, treatment and follow-up for high-risk COPD).

METHODS: We utilised the Optimum Patient Care Research Database Australia (OPCRDA), a primary care database of electronic health record (EHR) data containing 900,000 ever-active patients, to identify patients with a COPD diagnosis at high-risk of future exacerbations (≥2 exacerbations in the previous 12 months, based on clinical data and prescribed antibiotics or oral corticosteroids). EHR coded and free text data were analysed to examine COPD maintenance therapy, smoking cessation support and formal COPD reviews (defined as a recorded COPD review/advice/education or lung function assessment). Cross-sectional analyses were conducted on annual patient cohorts between 2015-2019 to exclude confounding by COVID-19.

RESULTS: The proportion of diagnosed COPD patients defined as high-risk ranged from 30.3% (1620/5340) in 2016 to 24.9% (1476/5992) in 2019 (Table 1). Across the 5-year period, approximately 40% of high-risk patients were not prescribed any COPD maintenance therapy, while the most common therapies were LABA/ICS (~18%) and LAMA/LABA/ICS (~25%). In this population, the proportion of smokers with recorded smoking cessation support reduced from 36% in 2015 to 30% in 2019. Less than 20% of high-risk patients received a COPD review in each study year (Table 1).

CONCLUSIONS: There is substantial opportunity to improve the assessment and treatment of patients with diagnosed COPD by reviewing and managing high-risk patients systematically in line with guidelines and CONQUEST quality standards.

REFERENCES: 1 Pullen et al. CONQUEST Quality Standards: For the Collaboration on Quality Improvement Initiative for Achieving Excellence in Standards of COPD Care. Int J Chron Obstruct Pulmon Dis. 2021 Aug 12;16:2301-2322. doi: 10.2147/COPD.S313498

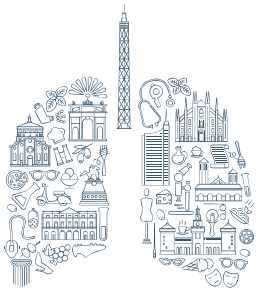
REG SUMMIT 2023 ABSTRACTS

Table 1: High-risk COPD patient populations and COPD management outcomes

	2015	2016	2017	2018	2019
Eligible COPD patients†	N=5,594	N=5,340	N=5,729	N=5,955	N=5,922
High-risk patients‡	1,534 (27.4%)	1,620 (30.3%)	1,665 (29.1%)	1,586 (26.6%)	1,476 (24.9%)
COPD therapy; n (%*)					
No therapy	567 (37.0)	681 (42.0)	720 (43.2)	661 (41.7)	632 (42.8)
Reliever only	81 (5.3)	19 (1.2)	19 (1.1)	30 (1.9)	23 (1.6)
ICS	27 (1.8)	32 (2.0)	37 (2.2)	25 (1.6)	20 (1.4)
LABA	20 (1.3)	6 (0.4)	11 (0.7)	12 (0.8)	6 (0.4)
LAMA	76 (5.0)	73 (4.5)	107 (6.4)	112 (7.1)	105 (7.1)
LABA/ICS	316 (20.6)	305 (18.8)	291 (17.5)	266 (16.8)	221 (15.0)
LABA/LAMA	32 (2.1)	57 (3.5)	74 (4.4)	95 (6.0)	86 (5.8)
LAMA/ICS	16 (1.0)	15 (0.9)	6 (0.4)	7 (0.4)	12 (0.8)
LAMA/LAMA/ICS	399 (26.0)	432 (26.7)	400 (24.0)	378 (23.8)	371 (25.1)
Smoking cessation; n (%**)	72 (35.6)	69 (32.1)	84 (31.7)	91 (35.1)	70 (30.2)
Annual COPD review; n (%*)	226 (14.7)	242 (14.9)	238 (14.3)	254 (16.0)	242 (16.4)

†COPD diagnosis, aged ≥40yrs, evidence of primary care consultation or prescription in last 24 months, no other significant lung disease, no active cancer (except non-invasive skin cancer)
‡≥2 exacerbations in last 12 months
*reported as a proportion of the high-risk COPD patients in each year cohort
**reported as a proportion of the high-risk COPD patients who were current smokers in each year cohort

REG @ ERS 2023, MILAN, ITALY



INTERNATIONAL CONGRESS 2023
MILAN Italy, 9-13 September

Session program:

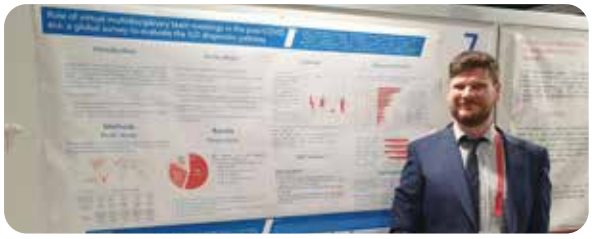
Chairs: S. Bosnic-Anticevich, Sydney (NSW) (Australia) & N. Beydon, Paris (France)

15:30 "Real-world" evidence vs randomized controlled trials: friends or foes?
G. Canonica (Milano (MI), Italy)

15:45 The future of evidence generation using mHealth tools
H. Pinnock (Edinburgh (Edinburgh), United Kingdom)

16:00 Building registries to inform decision-making: potential and challenges
D. Price (Singapore, Singapore)

16:15 Discussion and Q&A



Congratulations to Graham Lough, REG Researcher, for presenting the poster on the REG project "Role of virtual multidisciplinary team meetings in the post-COVID era: a global survey to evaluate the ILD diagnostic pathway

A joint ERS/REG session took place on Tuesday 12th September from 15:30 - 17:00 during the ERS congress in Milan. The Mini Symposium was entitled **"Next Generation Evidence-Based Decision-Making In Respiratory Medicine"**

SESSION REPORT

NEXT-GENERATION EVIDENCE-BASED DECISION-MAKING IN RESPIRATORY MEDICINE

During this joint session between ERS and The Respiratory Effectiveness Group, chaired by Sinthia Bosnic-Anticevich and Nicole Beydon, the faculty discussed the contributions of real-world data to decision-making processes, how it can complement intervention assessments, and the use of mobile health. Giorgio Walter Canonica began the symposium by describing the differences between RCT and RWE and the problems associated with RWE. Data from several studies highlighted the underrepresentation of real-world populations in RCTs as a result of selection bias. Risk of bias is therefore a critical issue when performing studies. Professor Canonica explored the next generation health guideline workshops, developed by the Respiratory Effectiveness Group, comprising representatives from respiratory societies, patient advocacy groups, healthcare agencies, and medical membership societies. These workshops have been designed to establish recommendations on how RWE can be integrated into decision-making processes.

Hilary Pinnock followed by providing an overview of mobile health and its potential research benefits in epidemiology, surveillance, health economics, clinical diagnosis, and patient status monitoring. Professor Pinnock referenced data from a study home-monitoring programme for COVID-19, in which 94% of patients remained compliant for 10 days. She then highlighted the challenges of compliance for long-term conditions, with the Asthma Mobile Health Study showing that of the 40,683 patients who downloaded the Apple ResearchKit app, only 6,470 (16%) used it. She suggested that virtual assistants, AI, and smart-watches could provide solutions to the limitations of mobile health. David Price closed the symposium by summarising the barriers to building data registries including funding, GDPR, data quality and utility, and data source diversity. Professor Price stated that incorporation of a QI model, streamlining of data entry, clinical trials, and regulatory work are needed to overcome the challenges of registry implementation. He concluded by presenting EMBARC and ISAR as examples of successful data registries.

This ERS/REG joint session summary is reprinted with the permission of teva

CLINICAL MANAGEMENT PERSPECTIVES

CLINICAL REMISSION IN SEVERE ASTHMA

The concept of Clinical Remission is a hot topic, currently discussed in Severe Asthma but I predict next in several other respiratory diseases. As indicated in our recent publication in the JACI, it is clear that over the years, there has been a noticeable evolution in the criteria and outcomes associated with asthma treatments. Indeed, previous outcomes focused on FEV1 and exacerbation rates, but now, as seen in various other fields of medicine, a "multicriteria approach" is being suggested. This conceptual step is promoted by the effects of biologics, defined as Disease Modifying Anti-Asthmatic Drug. Several definitions of Clinical Remission have been proposed, and in effect several publications and events have been spent on this topic. Since we are convinced a practical clinical application of this Multicriteria Outcome will be a real improvement in asthma management with additional value for our patients, the scientific community should reach an agreement about an official/ unified definition of Clinical remission to be used in clinical practice.

REG welcomes further discussion on this exciting development.

PROF. GIORGIO WALTER CANONICA
Senior Consultant | Personalized Medicine
Asthma & Allergy Clinic | Humanitas Research Hospital | Milano, Italy

Advancing precision medicine in asthma: Evolution of treatment outcomes

Giorgio Walter Canonica, MD,[a,b] Gilda Varricchi, MD, PhD,[c,d,e,f] Giovanni Paoletti, MD,[a,b] Enrico Heffler, MD, PhD,[a,b] and Johann Christian Virchow, MD[g] *Milan and Naples, Italy; and Rostock, Germany*

The article discusses the historical evolution of asthma treatment and highlights recent advancements in personalized medicine, specifically the use of biologics in severe asthma therapy and its potential combination with allergen immunotherapy (AIT). One of the major breakthroughs of biologics is their potential effect on airway remodeling, a crucial aspect of asthma chronicity. The article introduces the concept of disease-modifying antiasthmatic drugs, which aim to modify the course of asthma and possibly modulate or prevent airway remodeling. Furthermore, the critical importance of patient-centered outcome measures to evaluate the efficacy and effectiveness of asthma treatments is emphasized, with the innovative concept of asthma remission introduced as a potential outcome. Recent studies suggest that AIT can be used as an additional therapy to biologic agents for the treatment of allergic asthma. The combination of these treatments has been shown to induce improved clinical outcomes. However, AIT is actually not recommended for use in patients with severe asthma, but encouraging results from studies investigating the combined use of AIT and biologics indicate a novel approach to exploring these treatment modalities. In conclu[illegible] reduction of bi[illegible]

Abbreviations used
AIT: Allergen immunotherapy
DMAAD: Disease-modifying antiasthmatic drug
RCT: Randomized controlled trial
SCIT: Subcutaneous immunotherapy
SLIT: Sublingual immunotherapy

In the last decade, the availability of mAbs targeting cytokines or their receptors involved in the pathobiology of different asthma phenoendotypes opened a new dawn on asthma treatment, particularly for severe asthma.

This new era in the treatment of respiratory allergy, mainly severe asthma, through the use of biologics, has been comprehensively reviewed by Brusselle and Koppelman.[2] The advent of biologics has opened up a new horizon for precision or personalized medicine, allowing for the precise targeting of different and specific immunopathological mechanisms underlying asthma.[3,4] Before [illegible] biological treatments, allergen immuno-[illegible]

J Allergy Clin Immunol. 2023 Jul 31;S0091-6749(23)00929-6.

FIG1

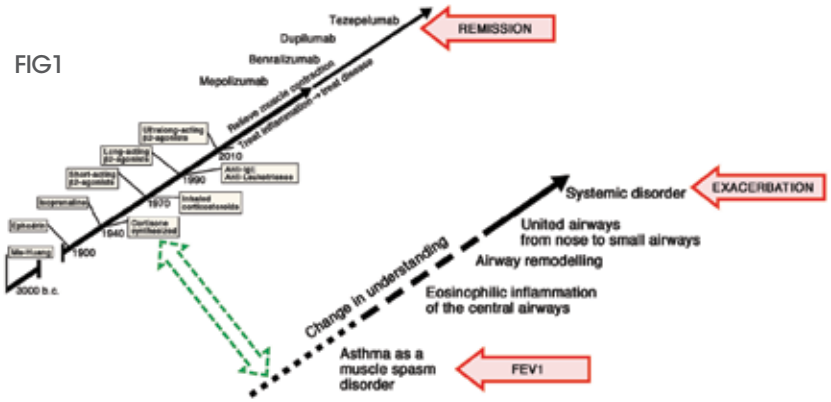


FIG 1. Evolution of asthma treatment and evaluation outcomes. Bjermer[19] described the trajectory of asthma treatment over the last century, paralleling the advancing understanding of asthma pathobiology with corresponding treatment approaches. In addition, this figure highlights the inclusion of new biologics approved for asthma treatment, indicating the continuous advancement in therapeutic options. The primary outcome measure of both trials and clinical practice in the last century was FEV_1. With the introduction of omalizumab at the beginning of this century, a new outcome has been introduced: exacerbation. Recently, clinical remission has been proposed as a novel outcome measure to evaluate treatment efficacy and effectiveness. Clinical remission involves a comprehensive multicriteria evaluation of treatment, as described in the text.

J Allergy Clin Immunol. 2023 Jul 31;S0091-6749(23)00929-6.

- A valuable and easy-to-use definition of clinical remission in severe asthma on biologics treatment is still needed. It will be useful for evaluating the clinical outcome of treatments.
- More data are needed on the effects of biologics on airways remodeling to further define the disease-modifying effects of these treatments.
- Data are needed to explore the effects of biologics in moderate asthma (eligible endotypes to be defined) to prevent airways remodeling.
- More data are needed to define the effective combination of biologics and AIT.

TABLE II
Specific research questions important for practicing clinicians

SEPTEMBER 2023

WORKING GROUP UPDATE

ALLERGY WORKING GROUP

The group is currently developing a new prospective study on secondary prevention in moderate allergic asthma with AIT. A manuscript is in preparation for a study on the impact of allergic rhinitis on health-related quality of life in Australia.

TECHNOLOGY WORKING GROUP

Potential new project ideas will be discussed at the working group meeting at REG Summit 2024.

ENVIRONMENT, EPIDEMIOLOGY & AIRWAYS WORKING GROUP

The manuscript for the Inhaler Choice & Environment (ICE) project has been submitted and under peer review. The project used surveys to identify the priorities of HCPs and asthma / COPD patients in inhaler device choice and planetary health. The REG opinion piece on the subject is currently being prepared. Visit the study website for more details: https://www.regresearchnetwork.org/research-2/inhaler-choice-the-environment/.

ILD WORKING GROUP

The manuscript for the ILD vMDT project is being prepared. The project aimed to characterise ILD diagnosis across 64 countries. An abstract "The Role of virtual multidisciplinary team meetings in the post-COVID era: a global survey to evaluate the ILD diagnostic pathway" was accepted for poster presentation at ERS Congress 2023. For more information on the study, please visit the study website: https://www.regresearchnetwork.org/research-2/global-evaluation-of-the-interstitial-lung-disease-ild-diagnostic-pathway-in-the-post-covid-era/

Additionally, a research proposal to develop a risk assessment tool for development of pulmonary hypertension in ILD patients. The project will use retrospective tertiary patient data of common diagnostic tests in ILD and pulmonary hypertension diagnosis.

COST EFFECTIVENESS WORKING GROUP

The group is currently discussing potential research projects.

ADHERENCE WORKING GROUP

The group has been working on two manuscripts for a scoping review project consisting of two phases. In Phase I, they aim to identify the main components of successful adherence in chronic respiratory disease management using novel technologies. In Phase II, they will evaluate current methods for measuring and monitoring adherence, as well as common barriers to adherence for respiratory diseases and how they are addressed in guidelines.

CHILD HEALTH WORKING GROUP

Paediatric Asthma in Real Life (PeARL) is an ongoing project that aims to identify and prioritise research questions in paediatric asthma using the Delphi methodology, followed by systematic reviews, meta-analyses, and Delphi exercises to evaluate the available evidence and reach a consensus. The WG has collected interesting results that were published in three scientific journals with a good impact factor. They have also utilised findings to finalise a monitoring survey paper, recently published in JAMA Netw Open. - 2023;6(5): e2313120, and two systemic reviews (1 on biomaterials and 1 on treatments) that are near completion.

Also, the WG has secured funding for a new retrospective epidemiological database - Determining the prevalence of severe asthma in children in UK primary care. The study aims to determine the annual incidence of children with severe asthma in UK primary care and the prevalence of asthmatic children referred to a specialist and/or eligible for biological treatments. Different criteria will be applied to define severe asthma. The WG has recently received a dataset from OPCRD and will soon commence data analysis.

COPD WORKING GROUP

The group has been conducting research on the Peak Inspiratory Flow (PIF) in COPD patients. The goal of this prospective observational study is to determine the prevalence of suboptimal PIF in COPD patients and to investigate the predictive value of PIF for exacerbations and symptom burden. In August of 2022, the group successfully enrolled 416 patients from 18 different study centres around the world and used the data collected during the patients' baseline visits to draft their first manuscript. Currently, they are hard at work collecting the final information from follow-up visits, which will take place in the coming weeks in conjunction with the planned completion of the study.

The WG is developing a risk prediction model for the first severe exacerbation in patients with COPD as part of the PRECISE-X project. Data analysis will begin once access to CPRD data is granted, which is expected to be by next month.

Also, the WG recently finalised a proposal and budget for a new COPD retrospective study to assess the effects of triple pharmacological therapy on post-discharge outcomes in patients with COPD. They plan to seek financial support from pharmaceutical companies.

SEVERE ASTHMA AND BIOMARKERS WORKING GROUP

At the REG Summit in 2023, the group explored potential ideas for upcoming projects.

DATABASES AND CODING WORKING GROUP

The WG has obtained funding for STANDOUT, a project to standardise respiratory definitions and outcomes with real-world data, and the study setup is now underway.

WHAT REG MEANS TO ME

My name is Brett McQueen and I am an Associate Professor at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences (CU-SSPPS) and Chair of the REG cost-effectiveness working group. As a contrast to many Respiratory Effectiveness Group (REG) members, my research is focused on value and affordability of health interventions. In my experience, many clinical societies have trouble integrating non-clinical researchers to professional society activities. REG has been nothing but welcoming since the beginning of my career. I started my involvement in REG approximately 10 years ago when I began my career at the Observational and Pragmatic Research Institute (OPRI). I was able to work directly with global experts through REG to bring context to our research. When I left OPRI for academia, I was welcomed as a collaborator and participant in the annual REG meetings. Through the years what remains is a close-knit but welcoming community of global respiratory experts with incredibly creative and impactful research that helps patients every day. From helping patients understand basic inhaler techniques to understanding appropriate use of biologics, REG covers a wide range of topics important to real-world respiratory care. I am honored to serve as Chair of the cost-effectiveness working group and I hope to continue contributing to the great research done through REG.

BRETT MCQUEEN
Associate Professor at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences (CU-SSPPS)

Respiratory health is a global concern that affects individuals irrespective of geographical boundaries. The Respiratory Effectiveness Group (REG) strives to improve the standards of respiratory care worldwide through promoting research and developing comprehensive respiratory care guidelines.

REG plays a vital role in facilitating research collaboration even among small countries, where resources and expertise may be limited, by addressing the unique challenges they face in respiratory healthcare as well as research difficulties encountered, especially when it comes to conduct significant research and publications independently. Working as a respiratory physician in Malta, a small Mediterranean island with a small population size and a single main hospital, REG has provided me with several ongoing opportunities to connect and collaborate with various healthcare professionals, scientists, and researchers across the globe. It has allowed me to participate in several international multicentre studies in various respiratory fields and conditions, while providing me with ample opportunities to voice my opinion, bring forward my ideas and share my experiences. REG has enabled me to participate in studies, which I would otherwise not have been able to perform due to a limited study population size.

In addition, REG provides valuable information about various respiratory conditions which plays a large role to optimise the respiratory health of patients locally. REG's initiatives positively impact the lives of individuals and contribute to improving respiratory effectiveness in small countries.

The constant support, efforts and enthusiasm they provide are a continual source of inspiration and motivation to me particularly when it comes to contributing to global research efforts through real world evidence studies. Sharing of knowledge and experiences has definitely helped to improve respiratory care outcomes and promote the overall well-being of patients in Malta. I am grateful for the invaluable contributions of REG and remain committed to supporting their mission of promoting respiratory effectiveness for all.

CAROLINE GOUDER
Consultant Respiratory Physician, Mater Dei Hospital, Malta

WHAT REG MEANS TO ME

No one can live outside a community (humans are social beasts, first declared by Aristotle!). However, choice is beyond necessity. So, for me, REG is a community I feel comfortably within. It has the right amount of intellectual stimulation (a lot!), high level discussions, minimum formalities and no pretense (despite the fact some of the most achieved and distinguished people in the field are part of the group!). And of course many dear friends - in fact several of these friendships have sprouted within REG, during the annual meetings and within the working group activities.

It's now several years, I'm part of the group - almost from the beginning and have even served as the President (who, according to Douglas Adams is the person who distracts everybody from the people who really run the show ;-). But it's not only about enjoyment. I believe that all of the activities that take place within REG are really helpful and get translated into patient benefit. REG has been a pioneer for real-life research, that is now getting into fashion, but used to be the black sheep of research methodology for many years! Some important milestones on the understanding and the standardization of real world methodologies stem from REG work, our manifesto to say the least!

I hope REG remains loose in structure and dense in ideas, also in the future. It would be great to see some more young minds coming in and upsetting everyone with their disrupting ideas. For many - me included - this is the recipe for making the world a better place - now that it desperately needs it!

NIKOS PAPADOPOULOS
Professor of Allergy and Pediatric Allergy
at the University of Athens (NKUA)
Head, Pediatric Allergy Department
Universit y of Athens
Athens, Greece

INTERNATIONAL SEVERE ISAR ASTHMA REGISTRY

ISAR Updates

The **International Severe Asthma Registry** (ISAR) enters its 7th year, with data from 19,759 severe asthma patients (including 14,953 patients with prospective data) from 26 collaborating countries. During ATS 2023, ISAR received approval in principle for a three-year extension (2024-2026) from original co-funders AstraZeneca and OPC Global. This funding extension will support ISAR's vision, as outlined at ERS 2022:

Every patient with severe asthma should have the right to:

- eliminate or reduce their OCS use
- shorten time to receive biologic therapy
- achieve clinical response or remission faster

ISAR believes these goals can be achieved by supporting consistent care through provision of organised data collection tools globally, which forms a central component of ISAR's 3-year funding extension.

ISAR in 2023: Publications

We are pleased to share 3 new published articles from ISAR in 2023. To view ISAR's publications, abstracts and slide sets, please access the **ISAR website**.

ISAR Publications

Pfeffer P, et al.
"Comparative effectiveness of Anti-IL5 and Anti-IgE biologic classes in patients with severe asthma eligible for both"
Allergy, 2023

Aim: To describe severe asthma patients eligible for both Anti-IL5/5R and Anti-IgE, and to compare the effectiveness of both biologic classes in real life.
Conclusions: In real life, both Anti-IL5/5R and Anti-IgE improve asthma outcomes; Anti-IL5/5R was more effective than Anti-IgE in reducing asthma exacerbations and long-term OCS use in patients eligible for both.
Click **here** to read the full article.

Chen W, et al.
"Impact of Initiating Biologics In Patients with severe asthma and on Long-Term OCS Or Frequent Rescue Steroids"
JACI:IP, 2023

Aim: To examine the effectiveness of initiating biologics in a large, real-world cohort of adult patients with severe asthma and high oral corticosteroid exposure.
Conclusions: In a real-world setting, including patients with severe asthma and high oral corticosteroid exposure from 19 countries, and within an environment of clinical improvement, initiation of biologics was associated with further improvements across multiple asthma outcomes, including exacerbation rate, OCS exposure, and health care resource utilization.
Click **here** to read the full article.

Scelo G, et al.
"Analysis of comorbidities and multimorbidity in adult patients in the International Severe Asthma Registry" *Ann Allergy Asthma Immunol, 2023*
In Press

Aim: To understand the prevalence and pattern of comorbidities and multimorbidity in adults with severe asthma and their association with asthma-related outcomes.
Conclusions: In a global study, comorbidity or multimorbidity is reported in most adults with severe asthma and is associated with poorer asthma-related outcomes.

ISAR in 2023: Conference Abstracts

We are pleased to share 2 new posters presented at the ATS conference, in Washington DC from the ISAR group, and 4 posters to be presented at the ERS conference, in Milan, Italy. To view ISAR's publications, abstracts, and slide sets, please access the **ISAR website**.

ATS 2023 | **Location:** Washington, DC
Date: 19-24 May 2023

Abstracts and Posters

Biologic responders and super-responders in the International Severe Asthma Registry (LUMINANT)
Denton E, et al.

Aim: To describe an international, real-world population who initiate biologic medications and to explore response and super-response across four individual asthma outcomes. Patients not initiating biologics were also examined for comparison.
Conclusions:

- Patients with severe asthma who initiated biologics had greater disease severity at baseline than those who did not initiate biologics, but biomarker levels were similar.
- Only 5.3% of study participants met even basic criteria for clinical trials
- Clinical response and super-response to biologics was observed in all four domains
- Super-response was more frequent amongst biologic initiators than non-initiators
- In the context of differing baseline impairment, response to biologics may differ by biologic class

Click **here** to read the full abstract, and **here** for the e-Poster.

Association between T2-related comorbidities and effectiveness of biologics in adult patients from the ISAR (PRISM Objective 3)
Scelo G, et al.

Aim: To determine the association between T2-related comorbidities and effectiveness of biologics in adult patients with severe asthma.
Conclusions: Patients with severe asthma with a Type 2 (T2), upper airway-related comorbidity might benefit from biologic therapy to a greater extent than patients without, likely as these comorbidities are proxies for T2-asthma, the target of anti-T2 biologics. The study highlights the importance of systemic evaluation for comorbidities and a multidisciplinary approach to their management.

Click **here** to read the full abstract, and **here** for the e-Poster.

ERS European Respiratory Society International Congress 2023

Location: Milan, Italy
Date: 9–13 September 2023

Abstracts and Posters

Real-world associations between outcomes and biomarkers in severe asthma patients treated with biologics (IGNITE), Townend J, et al.

Aim: To determine if pre-biologic measurements of biomarkers (blood eosinophil count [BEC], fractional exhaled nitric oxide [FeNO] and total immunoglobulin-E [IgE]) were associated with clinical outcomes in severe asthma patients following treatment with anti–IL-5/5R, anti–IL-4Ra or anti-IgE biologics in real-world settings.
Conclusions: These results from ISAR support the use of BEC and FeNO to help identify patients who will benefit most from biologics in real-world clinical practice. Combinations of biomarkers (such as BEC and FeNO) may also be useful when selecting the best treatment for patients.

Click **here** to read the full poster.

Clinical remission following biologic initiation in severe asthma: results of the International Severe Asthma Registry (FULL BEAM 1), Scelo G, et al.

Aim: To explore different definitions of remission using multiple asthma outcome domains, and to quantify the prevalence of remission when treated with biologics using these definitions in adults with severe asthma.
Conclusions: These results may be useful in informing physicians of the likelihood of remission 1-year post biologic, specific to domains of interest to patients. Identification of a continuum of remission according to type and number of domains highlights the need for a universal approach to assess remission.

Click **here** to read the full poster.

Real world biologic treatment response in severe asthma: an analysis of the International Severe Asthma Registry (FULL BEAM 2), Scelo G, et al.

Aim: To investigate single- and multiple-domain biologic responder definitions in adults with severe asthma and quantify responders ~1 year post-biologic according to these definitions.
Conclusions: These results provide realistic post-biologic expectations for both physicians and patients in real-life, considering multiple domains and level of pre-biologic impairment. These findings highlight the need for a common language and definition of response to facilitate cross-study comparisons and inform guidelines.

Click **here** to read the full poster.

Characteristics associated with clinical remission in patients with severe asthma who initiate biologics (FULL BEAM 3), Pérez De Llano L, et al.

Aim: To explore factors associated with different definitions of asthma remission at ~1 year post biologic initiation in adults with severe asthma.
Conclusions: These findings highlight the need to consider earlier intervention with biologics for patients with severe asthma prior to significant impairment and long-term OCS treatment.

Click **here** to read the full poster.

ISAR in 2023: Events

Respiratory Effectiveness Group (REG) Summit

Lisbon, Portugal

16-18 March 2023

ISAR Events at REG

ISC Closed Meeting 2023

• 41 attendees total (including in-person and remote)

ISAR Open Research Meeting 2023

• 50 attendees total (including in-person and remote)

ISAR Plenary Session

• 6 presentations on "ISAR BEYOND 2023"

Presentation at REG Workshop (18 March 2023)

• **"Developing sustainable disease registries in clinical practice". Presenter: Professor David Price**

This workshop (Next generation health guidelines: how to integrate Real-World Evidence & Evidence-Based Medicine) was attended by representatives of organisations such as the ATS, ERS, GOLD, FDA, GINA, and EAACI.

Sustainable registries such as ISAR answer critical research questions and support the next generation of healthcare guidelines. Through quality improvement initiatives and development into standardization and integration with clinical care, registries improve the lives of patients and ease the workflow for clinicians.

Upcoming ISAR Events 2023

European Respiratory Society (ERS)

Milan, Italy

9–13 September 2023

ISAR Research Working Group Meeting (9 September 2023)

• Discussions will be held on research questions that can impact and drive the field of severe asthma research forward.

• The discussion group, comprising ISAR Steering Committee Members from 26 countries, will contribute their valuable expertise during this event.

Joint ERS/REG session on Building Sustainable Registries (12 September 2023)

• To be presented by Professor David Price

Join ISAR today!

To register interest in joining the registry as a collaborating country, or to submit a research request or proposal for using ISAR data, please contact us **here**.

ACKNOWLEDGEMENTS

The work of REG would not be possible without the contributions from our invaluable supporters to fund innovative research projects developed by our expert Collaborators.

REG is looking to launch a number of ambitious research initiatives which offer the opportunity to impact clinical management guidelines and patient care.

We welcome any suggestions from Supporters and would be happy to discuss your ideas in more detail.

You can always get in contact with the REG team by email at
enquiries@regresearchnetwork.org,

or write to Michael Walker, REG CEO at
michael@regresearchnetwork.org

GOLD SUPPORTER

AstraZeneca

We would also acknowledge the support of the following companies:

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People and ideas for innovation in healthcare

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Pfizer

REG Respiratory Effectiveness Group

CELEBRATING 10 YEARS OF REG & RESPIRATORY REAL-LIFE RESEARCH

THE RESPIRATORY EFFECTIVENESS GROUP

REG SUMMIT 2024

www.regsummit2024.org

14 -16 March 2024

Vienna • AUSTRIA

NH Danube City Hotel

SAVE THE DATE