

REPORT #2 FROM

# ERS International congress 2023

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## More from ERS!

**We have the pleasure** of serving you more highlights from the ERS congress in Milan, hoping it will tickle your interest. In this issue, you will find more on tele-health and mHealth, why ABE is the new GOLD standard, and how to (according to IRC) better prepare for the future. Happy reading!

Chiesi Nordics



### Innehåll

Update from the International Respiratory Coalition	. 3
Telehealth: remote monitoring of respiratory patients	. 6
GOLD guideline evolution: BC is out and Exacerbation prone is in	. 7
Longitudinal cohorts in airway disease: What have they taught us about personalised treatment of our everyday patients?	. 9
Next generation evidence-based decision-making in respiratory medicine	. 11
HOT TOPICS: Burden of tobacco farming and use of electronic nicotine delivery system on the environment and occupational health	13



### Update from the International Respiratory Coalition

Wednesday morning, a much-changed Milan and ERS appeared: the temperature had dropped, there was light rain, the city smelled of flowers and green grass, and a scarcity of people in the huge conference convention. All the voices, faces, queues and noise of the hard-working ventilation - soon just a memory.

#### COVID-19 - a fading memory?

The International Respiratory Coalition (IRC) presented its work, and we were reminded that the world suffered from the COVID-19 pandemic just two years ago, but even that memory seems to be fading. *The political area lost the knowledge of the pandemia*, says Tobias Welte, Hannover, Germany. The next pandemic will, no doubt, come at some point in time, and we must not miss the chance to be better prepared. The IRC was initiated to develop ways to tackle hazards for health care in the respiratory field.



While during the COVID-19 pandemic an increased life expectancy in people living with chronic respiratory conditions was observed<sup>1</sup>, re-prioritisation of health care resources also reduced the chances of survival in case of hospital admissions<sup>2</sup>. Hospital mortality of an acute COPD exacerbation, Welte reminds the audience, is 5%, while 30% of persons experiencing an acute exacerbation of their COPD will be re-admitted to hospital. This comprises huge consequences for people and healthcare. Moreover, during the pandemic, more people died due to de-prioritised or delayed care of conditions like lung cancer, cardiovascular diseases or other comorbidities<sup>3</sup>. Exacerbation rates in COPD became higher than before<sup>4</sup>.

#### COPD: cheaper to stick to guidelines

Marc Miravitlles, Spain, showed numbers on the financial impact of low adherence to treatment guidelines in COPD<sup>5,6</sup>, underlining the societal costs related to exacerbations. One COPD exacerbation has been shown to be a prognosticator for the next exacerbation<sup>7</sup>. Susceptibility to exacerbations in defined groups of persons and prognostics risk factors are known, thus, Dr. Miravitlles concludes: *"We know whom we shall concentrate our efforts on in the first place"*.

#### Wildfires, a burning health topic

More threats to global lung health: Christine Jenkins, Sydney, Australia, shows scientific evidence of the devastating impacts of wildfires on health: wildfire smoke is recognised for its toxicity, partly caused by the immense amount of respirable particulate matter. The frequency of wildfires increases after periods of dryness, and as we remember from pictures in the newspapers during summer 2023, wildfires are not limited to Australia or America, but occur in Europe. This gives rise to short and long-term consequences for lung health<sup>8</sup>:



Again, persons living with respiratory conditions are extra vulnerable in such environments, as shown by the increased need for oral corticosteroids<sup>9</sup>. Wildfires release greenhouse gases also contributes to global warming.

## So, what can be done NOW to be better prepared for the future?

HEPA filters: For the threats caused by wildfires, use of HEPA filters as well as recommendations for vulnerable groups (children, pregnant women, elderly, and persons living with asthma and/or COPD) to wear face masks and assure valid rescue medication at home were discussed during the presentation.

*Vaccinate:* The importance of preventive **vaccinations** cannot be overemphasised, as it has been shown to both reduce morbidity and mortality<sup>10</sup>. Furthermore, there is still a need to improve diagnosis of COPD, primarily using spirometry, and with this, to identify persons with increased health risks.

*Communicate:* In the capacity as representative of GAAPP, an international coalition of 108 patient advocacy groups, Tonya Winders, Hendersonville, USA, emphasised the patient 's perspective: we were presented with a clear communication on what matters for patients with respiratory conditions.

#### We need to look at the person, not just the patient or the diseased organ, says Winders.

Moreover, mortality, morbidity, knowledge of risk factors, and **communication** matters to patients. She expands the point of the importance of communication and demands information in native languages, taking cultural adaptations into account, and the use of lay language. "Talk as if you were addressing a ten-year old." As parts of the world are challenged in literacy, reliable digital health information is important, eg. collaborations with YouTube Health or the use of chatbots to manage chronic disease.

#### What can YOU yourself do?

*Educate yourself:* More suggested actions can be found in the paper "Climate change and respiratory disease: clinical guidance for healthcare" (see recommended reading).

*Organize.* If existing channels/organizations can be used to create more impact, use your voice. The IRC is welcoming actions to prepare healthcare for future challenges, but the IRC does not (yet) have national committees in the Nordic region. However, the IRC offers help and support to form one. Go to <u>https://international-respiratory-coalition.org</u> and find the "Join us" form.

#### **Recommended reading:**

IRC manifesto: <u>https://international-respiratory-coalition.org/</u> wp-content/uploads/2023/06/IRC-Manifesto-Final.pdf

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### Telehealth: remote monitoring of respiratory patients

The ability to monitor certain aspects of patients' health from their home has become an increasingly popular telehealth option that have been accelerated by the COVID-19 pandemic<sup>1</sup>. Generally, telehealth spans from simple video calls between patients and doctors replacing routine visits to complex remote monitoring of general health or specific disease related parameters. Interestingly, telehealth as such have been shown to cut down on patients' travel costs<sup>2</sup> and infection risk at hospitals or in the GPs office<sup>3</sup>. But the overall health benefits are debated and a recent review of 29 studies utilizing remote monitoring in COPD care concluded that no important benefits for patients were obtained, neither looking at symptoms nor quality of life<sup>4</sup>. However, people who were monitored through telehealth technology and usual care had some reduction in risk of hospital re-admission<sup>4</sup>.

#### In COPD and asthma care, remote monitoring can largely be categorized based on the purpose of the monitoring:

- To predict or foresee flare ups by collecting health and disease parameters. This kind of monitoring is usually associated with simple monitoring such as QoL questionaries and health parameters as body temperature which is report digitally and monitored by nurses or potentially AI.
- 2. To improve patient awareness of changes in symptoms by recording in digital diaries or mobile applications and thus realize potential triggers, which may lead to improved self-management.
- **3.** To improve care by increasing treatment adherence and or compliance, which usually involves the use of smart inhalers or add-on modules in connection with a mobile application displaying the data for the patient.

Despite the development of various digital tools such as mobile applications, smart inhalers, and smart add-on modules, a general implementation of these remains a challenge due to complexities in the use and the relative high cost that patients are reluctant to pay<sup>5</sup>. The cost related to remote monitoring and associated increased workload of analysing reports need to be studied to show that the use of these is cost effective, providing better disease control and improved quality of life for patients<sup>5</sup>.

Thus, having the purpose in mind when trying to identify patients where remote monitoring can add value seems to be key –when it comes to remote monitoring of patients there is no one size fits all!

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### GOLD guideline evolution: BC is out and *Exacerbation prone* is in

**Reference to presentation:** *Current challenges in airways disease management - Evolution in GOLD: we cannot 'see' 'C' anymore and LABA/ICS are gone. Helpful or a hindrance?* 

#### Speaker: Antonio Anzueto, USA

When the first GOLD guideline document was released in 2001, the assumption was that poorer lung function led to poorer outcome. The best strategy was therefore thought to be a step-up approach where more pharmacotherapy was added depending on the severity of the lung function reduction.

By 2015, data had accumulated showing that there was no association between the severity by lung function and symptoms evolution, risk of exacerbations or even outcomes. Data also clearly showed that there were means to prevent exacerbations and reduce symptoms. The GOLD committee decided to divide patients into four groups, ABCD (2015 Global Initiative for Chronic Obstructive Lung Disease).



#### Exacerbations - not just about lungs

It was not fully understood until recent years that exacerbations changes disease progression. It is now recognized that exacerbations are bad and should be prevented. They trigger more inflammations, accelerate decline in lung function, increase worsening of comorbidities<sup>1</sup>. Patients who are hospitalised due to exacerbation are significantly at risk for cardiac events within the next 30 days. Exacerbations should be viewed in the light of the intimate interaction between lungs and the cardiovascular system.

There is strong data evidence to justify replacing the CD category with just E for Exacerbation prone patients, irrespective of symptoms. *Whatever interventions done, they must address exacerbation risk.* 

## State of the art COPD treatment - according to GOLD 2023

Based on the large amount of data gained in recent years to understand the role of bronchodilators, the committee decided to make following changes in GOLD 2023 guideline:

- "Initial therapy should consist of a LAMA+LABA combination..."
- "Consider LAMA+LABA+ICS combination if eos >300 cells/µL (practical recommendation..."
- "We do not encourage the use of LABA+ICS combination in COPD..."
- "If patients have COPD and concomitant asthma, they should be treated like patients with asthma..."

#### GOLD 2023:



\*single inhaler therapy may be more convenient and effective than multiple inhalers

There are several publications showing that fixed LAMA/LABAs are better than ICS/LABA in lung function and reducing exacerbations.<sup>2,3,4</sup>



#### Use of ICS

Safety issues: Patients on ICS based medications that are still not getting any clinical benefit, may have increased risk for pneumonia due to the change of the airway microbiome<sup>5</sup>. Eosinophils may serve as biomarkers to indicate risk of pneumonia: a very low eosinophil count (<100 cells/µL) marks an increased risk.<sup>6</sup>

*Place in therapy:* ICS, together with bronchodilators, are intended to give maximum bronchodilation and anti-inflammation. Programs including thousands of patients in registration studies have demonstrated that these medications decrease exacerbations<sup>7</sup>. Exacerbations are known to be key drivers for mortality in COPD<sup>8</sup>.

#### Take-home message

- 1. We live in the golden era of COPD. More treatments are available now, compared to 20 years ago. New molecules are being developed and there is also a potential for biologics. The prospects are huge.
- **2.** Exacerbations are bad independent of the patient's symptoms.
  - Dual bronchodilators are the pivotal therapy<sup>9</sup>
  - ICS should be used only in the context of triple therapy<sup>9</sup>
  - Therapies are shaped by biomarkers and treatable traits

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# **Longitudinal cohorts in airway disease:** What have they taught us about personalised treatment of our everyday patients?

The importance and relevance of learnings from longitudinal studies was a topic in our previous issue of ERS congress report, and you can read more about the COPDGene and U-BIOPRED cohorts there. But because of its importance we wish to stay just a little longer on the subject.

The ATLANTIS<sup>1</sup> study, aiming to assess the involvement of small airways in asthma, presented by Monika Kraft (NY, USA), collected data from mild to moderate asthmatics for 8 years. Already in 1996, Dr. Kraft demonstrated that inflammation exists throughout the whole branch of the lungs. The study shows that the distal lung can no longer be referred to as the silent zone. ATLANTIS was the first study to collect data in a bigger sample size (n=773 individuals). Over 90% of study subjects were shown to have at least one sign of small airway dysfunction amongst all different measures performed<sup>2</sup>. Physiological, but not CT measurements, are drivers for exacerbations, and oscillometry measurements are of value<sup>3</sup>. The ATLANTIS investigators hope to develop a single question-tool to be provided to clinicians that would allow identification of small airways dysfunction and with this. identifying who is at risk of exacerbations. Moreover, data from persons living with COPD is required.

A study cohort collecting real world evidence from asthma, COPD or combination of both, Alberto Papi (Cona, Ferrara, Italy) presented the 3 year long **NOVELTY** study<sup>4</sup>. The study starts from real life and physician's diagnosis of disease, to thereafter break down the learnings into disease mechanisms<sup>5</sup> and treatable traits.<sup>6</sup> They are now starting to dig deeper into the molecular and underlying pathways and are hoping to present more insights characterizing new clinical endotypes within asthma and/or COPD. It will be exciting to see the future results of the study.



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# Next generation evidence-based decision-making in respiratory medicine

A session exploring how real-life research may aid decision-making and guideline development and complement RCT for better assessment of interventions.

**Bias**, both in randomised controlled trials (RCT) and Real-world evidence (RWE) is important to minimize, as pointed out by Dr Giorgio Walter Canonica (Milan, Italy). RCTs, on one hand might target a very narrow treatment group to mitigate confounding factors, whereas in RWEs, subpopulation results might get lost in the heterogeneity of the real world. While evidence of efficacy is the strongest with RCT, the evidence of effectiveness, i.e. how well a treatment works in practice in a broader population, is better shown with RWE<sup>1</sup>. And thus, they complement each other, and both are needed.

#### Better use of real-world data

Aiming to raise the profile of real-life research, the Respiratory Effectiveness Group (REG) was formed. Together with EACCI (the European Academy of Allergy and Clinical Immunology), certain quality standards have been implemented. One point of action is to establish more registries for more systematic capture of real-world data<sup>2</sup>.

The REG and EAACI also organised a workshop in March this year to discuss integration of RWE and EBM (Evidence Based Medicine) into next generation guidelines, in which regulatory bodies such as the FDA and EMA participated, as well as patient organisations. A second workshop in October will finalise the outcomes of the first workshop.

## mHealth – getting more health data from mobile devices

The WHO (world health organisation) defines mHealth as medical and public health practice supported by mobile devices, (e.g. mobile phones or personal digital assistants)<sup>3</sup>. With the huge collection of data, big data processing and artificial



intelligence (AI) algorithms can be used for future evidence generation<sup>4</sup>, says Dr Hilary Pinnock (Edinburgh, UK). Still, only a minority of mHealth is embedded in routine healthcare<sup>5</sup>, although an increase has been seen from 2010 and accelerated by the COVID pandemic. While traditional healthcare data collects data at visits, mHealth has the potential to capture so much more data over the course of an illness and/or a lifetime. EAACI lists a number of areas, e.g. epidemiology, health economics, public health, where mHealth can be of help.

## Do mHealth data represent everyone in the real world?

There is a risk that patient tools might attract a specific "type" of patient. In a study to demonstrate pollen and wildfire impact on asthma symptoms, predominantly white, male colleague students with high income signed up – however women over 40 were more likely to keep reporting data. Out of 7593 enrolled, only 64 and 37 respectively, logged persistent data throughout the study period.<sup>6</sup> So what happens, if we use biased limited data to train Al?

Use of automated feedback, like wearable devices may provide data that is more generalizable. Integration of these systems into routine practice is also a task for policy makers and administrators. We have a long way to go, concludes Dr Pinnock, before we are generating data evidence well from mobile devices and mHealth tools.



#### Connect CRC

The Clinical Research Collaboration was funded and launched by the ERS this year, with the vision to enable knowledge exchange, promote standardised approaches to implementation research in digital healthcare and plan research that will inform, develop and evaluate the implementation of digital respiratory healthcare. Read more on <u>www.ersnet.org</u>.

#### Suggested reading:

- https://www.ema.europa.eu/en/documents/ presentation/presentation-efficacy-effectiveness-models\_en.pdf
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# **HOT TOPICS:** Burden of tobacco farming and use of electronic nicotine delivery system on the environment and occupational health

**Even the tobacco industry** acknowledges the harm in smoking and claims to make efforts to transform by reducing health impacts of its products. The solution - as proposed by tobacco companies is not to end nicotine use but switching users to e-cigarettes. The e-cigarette market is growing rapidly but more typically from attracting new users than switching old smokers. Vaping is also where the industry sees its future growth, especially if combined with cannabis. Several of the biggest tobacco companies are *investing* in the cannabis industry – both medical and recreational use.



Vaping is not harmless. Combustible cigarettes and e-cigarettes, with or without nicotine, increases the resistance of small airways and decreases small airway function<sup>1</sup>. Sven-Erik Jordt, USA, presented findings from Duke University, that most of the available e-liquid products contain synthetic cooling agents. Addition of menthol is regulated in many markets since its cooling and pleasant sensory effects facilitate smoking and tobacco product initiation. However, since these derivates are without flavour, these may bypass regulatory limits on menthol content in tobacco products as they may not qualify as "characterizing flavour". This is a potential regulatory loophole that should be considered, especially since health effects of inhaling these compounds are not fully known.

**Environmental burden** beyond the direct health impact cigarettes have on consumers, the lifecycle impacts on the environment are considerable: from deforestation for agriculture of the sensitive tobacco plant that requires heavy use of fertilizers and pesticides, and burning biomass for tobacco curing, to the post-consumer waste with cigarette butts ending up in the oceans, poisoning water.

Greenwashing the industry to counteract the bad PR and divert attention from the harm done both from manufacturing and consumption of cigarettes, several tobacco companies are establishing an ESG concept (environmental, social and governance for sustainable development) to appear "green" and ethical. They are playing the game to keep investors and succeeding at it. For instance, Philip Morris Industry managed to get a high score on the Dow Jones Sustainability index. The tobacco companies also portray themselves as socially conscious, making charitable contributions, especially in LMIC (low-middle income countries). Labelling tobacco companies as philanthropists: That's rich coming from an industry that sells a product that kills half of its long-time users, says Elif Dagly (Turkey).

**The prevalence of smoking** tobacco has unfortunately not been a positive development: The number of smokers globally increased from 0.99 billion in 1990 to 1.14 billion in 2019, most of them coming



from LMIC countries. Globally in 2019, smoking tobacco use accounted for 7.69 million deaths and 200 million disability adjusted life years.<sup>2</sup>

In the final comment on the global burden of tobacco use, Om Prakash Kurmi of the Coventry University, UK concluded that the smoking epidemic is far from over.

The good news, however, is that health benefits come quickly on smoking cessation and life expectancy is increased - *it is never too late to stop smoking*.

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