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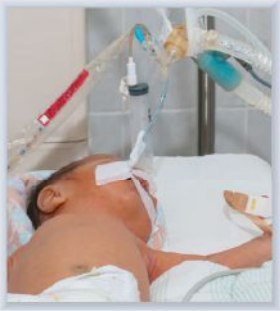


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References:

1. Frat JP, Thille AW, Mercat A, et al. High-Flow Oxygen through Nasal Cannula in Acute Hypoxemic Respiratory Failure. *The New England Journal of Medicine* 2015: DOI: 10.1056/NEJMoa1503326.
2. Dysart K, Miller TL, et al. Research in High Flow Therapy: Mechanisms of Action. *Respiratory Medicine* 2009 103, 1400 – 1405 Cited in support of HFNCT benefits not including CPAP as CPAP is off-label for Comfort Flo Humidification System.

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AARC Strategic Plan

The American Association for Respiratory Care has a Strategic Plan that includes its Mission and Vision Statements for 2015–2020.

Bookmark this page: http://www.aarc.org/member_services/mission/.

American Association for Respiratory Care

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American Association for Respiratory Care

What Litigating Has Taught Me About Honesty

by Anthony L. DeWitt, JD, RRT, FAARC

As a society, we value honesty. We make politicians take oaths of office. We ask people to take an oath to tell the truth in court. We enforce the oath through the crime of perjury. Honesty is important. Our laws are based upon it.

Lawyers are required to be truthful. We cannot knowingly spread false information about a party, or an expected party, in litigation. We are held to a high ethical standard in this regard. That is how it should be. We are officers of the court, and courts are about truth.

The first deposition I ever took was that of a pediatric intensivist. The case involved a two-year-old who had been given a huge dose of salt-poor intravenous solution, developed hyponatremia, and died. There was no question about the nurse's conduct, and the pathologist tied the infusion to the cause of death. Our experts testified that it was negligence — but the defense hires experts, too.

Incredibly, the pediatric intensivist testified the child had died not from the infusion, but from the syndrome of inappropriate anti-diuretic hormone (SIADH), which is really just a recent invention of the defense lawyers. SIADH tends to occur in people with heart failure or with a brain injury that affects the hypothalamus. It is rare in adults, with risk increasing with age, and it is extremely rare in children.[1] Excluding other causes almost always makes the diagnosis, and the idea that a full liter of salt-poor solution wouldn't cause a massive shift in sodium levels in a child weighing 25 pounds is laughable. But the pediatric intensivist, who testified he'd seen one case of SIADH in an adult and had never seen it in a child, testified that SIADH caused the death. There can be legitimate scientific dispute about his diagnosis, but I sat across from him in the deposition, and watched his body language and micro expressions. I knew he was lying.

Having worked with doctors, I was shocked to learn that a physician would simply lie about something as clinically unique as SIADH. But people lie. They lie often in litigation, and usually not very well. One deponent, when lying, turned scarlet in her face and neck, which was a tell she could not alter. Others fidget, or sit on their hands and look forward like a statue to keep themselves from fidgeting. They blink. They look away. They communicate their mendacity in a variety of ways.[2] Liars often try to tell us they aren't lying, but it is amazing how often jurors see through this.

Recently, I became embroiled in litigation with a major manufacturer. The lawyers on the other side came from multiple firms. One had a strong honesty culture; the other maybe not. The issue in the case involved a computer-operated part of the product. As a result, one of the things the plaintiffs sought in discovery was the source code for the software. The manufacturer produced several witnesses, all of whom swore affidavits and some of whom appeared in court to swear that the company had never let anyone look at their source code outside of a locked room in Michigan. Based on that testimony, the court ordered the plaintiffs to review only documents in the locked room, and only certain parts of the source code. Defense lawyers reiterated that the

about the author...

Anthony L. DeWitt, JD, RRT, FAARC, is an attorney and a partner in the firm Bartimus, Frickleton, and Robertson, PC, and resides in Opelika, AL. He has also published two books and numerous legal journal articles. This article is not a substitute for legal advice.

source code was a trade secret and couldn't be viewed. There was only one problem: those affidavits and testimony were false.

Before lawyers ever turn over things like emails for the other side to review, we review them ourselves to make sure there are no privilege issues. Conversations between lawyers and staff are generally not discoverable. This means that, before the company turned over literally millions of pages of documents and emails, its lawyers had an obligation to review them. They knew, or should have known, that the source code had been sent unencrypted around the world. Apparently, they did not review the attachments if the email went from Mr. X at the company to Mr. Y at another company. To our surprise, attached to those multiple emails was the source code plaintiffs were denied access to view outside the locked room.

The company lied. Its lawyers either lied knowingly or failed to perform due diligence. Like nearly all liars, they got caught, and they now face sanctions in federal court. In a case like this, the company takes a hit, and so do the lawyers, all of which could have been avoided with honesty.

I have never had a case where my client was without some level of fault or didn't have some skeleton buried deeply in his or her closet. In one sexual harassment case, the gentleman I defended made one very inappropriate statement, and quite honestly, did not understand why his comment was offensive to women. He was a case of "pure heart, empty head," and when asked about that, he told the truth. The plaintiffs' lawyer literally squealed with delight when that happened. But his case never made it to trial because we found that his client had lied to the bankruptcy court.

When you tell the truth, lawyers can explain it. When you lie, there is nothing we can do. In most cases, you've just destroyed your case, no matter which side you're on.

Early in my career, we had a client — I'll call him Carl — who came to us with a serious case of failure to diagnose melanoma. In working up his damages, we found he hadn't filed federal income taxes in the last seven years. We got him set up with a lawyer to fix that issue, and we quickly found out that the Social Security number he gave us was false, as was the rest of his identity. The Federal Bureau of Investigation was after him for interstate theft. His case had merit, but his repeated lies to us caused us to reject his case.

We often think that little lies ("No, honey, that dress does not make you look fat") do not matter. But all lies matter, particularly when they become a habit. When it's simply easier to lie than to tell the truth, you have a serious ethical problem.

You may get away with a lie. You might get away with it for many years. But the truth always wins out. That is important both in clinical practice and in dealing with conflict and attorneys. The truth really is the best defense. ■

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1. Upadhyay A, Jaber BL, Madias NE. Incidence and prevalence of hyponatremia. Am J Med 2006;119(7 Suppl 1):S30–S35.
2. Craig D. Detect Deceit: How to Become a Human Lie Detector in Under 60 Minutes. New York: Skyhorse Publishing; 2012:2–3.

Affirmation of a Job Well Done

by Debbie Bunch

Lisa Pope, BS, RRT, heard about the AARC's new Apex Award Recognition Program just two weeks before the application deadline. Given everything else on their plates, most managers would have just sighed and said, "Maybe next year." But Pope was determined to bring it home for the hard-working respiratory therapists in her department at LifeCare Hospitals of Chester County in West Chester, PA — and bring it home she did. "Yes, it was stressful," says the AARC member. "But highly worth it."

Staff at LifeCare Hospitals of Chester County are relishing their national award

Luckily, the RT department was already in good shape when it came to the Apex quality measures. "Not to say that meeting the requirements was easy, but when you have a high-caliber staff and work for a dynamite organization, it definitely gives you an upper hand with meeting the criteria for the award," says Pope.

Living the mission

LifeCare Hospitals of Chester County is a long-term acute care (LTAC) hospital with 39 beds devoted to the care and treatment of medically complex patients requiring extended lengths of stay. The goal of the facility — and its parent organization, LifeCare Health Partners — is to provide early and aggressive interventions to give patients the best possible opportunity for recovery from debilitating illnesses or injury.

Multidisciplinary teamwork is key to the facility's success, says Pope, and she emphasizes her department's receipt of the Apex Award would not have been possible without the colleagues in other disciplines who work so closely with RTs every day. "We have excellent working relationships across the multidisciplinary team at our facility, which is evident in our patient outcomes," says the RT manager.

She emphasizes that the overriding mission of the hospital is to accelerate healing, restore health, and improve lives, and she believes her staff live that mission with every patient encounter. "The personalized and compassionate care we give to our patients truly comes from the heart," says Pope. "The Apex Award is not only a testament to all of the great things we do in the RT department, but also to our co-workers, leaders, and the resources they provide us with, and the culture of teamwork that pervades the facility."

A place of excellence

Pope says executives in her hospital as well as the parent organization have been thrilled about the RT department's receipt of the Apex Award. LifeCare Health Partners' CEO Jim Murray even took time out of his busy

The Apex Recognition Award

The AARC developed the Apex Recognition Award to acknowledge the significant contributions of respiratory therapists and highlight best practices in respiratory care that are aligned with evidence-based medicine. The program can also help consumers choose health care facilities that promote patient safety by providing access to respiratory therapists to deliver their care.

Apex recognition is available for acute care hospitals, long-term care facilities, and home medical equipment companies. A complete set of resources is available on the AARC website for facilities that would like to apply for the recognition. Visit http://www.aarc.org/resources/programs-projects/apex-recognition-award/ to learn more about this great award program from the AARC to recognize excellence in respiratory care. Applications for the 2019–2020 Apex Award will open in October 2018. ■

schedule to visit the West Chester facility over the summer and offer his personal congratulations.

News of the award has been widely spread as well. "The business development team at our facility has been proud to promote this out in the community," says Pope, referring to providers and patients. "Our clinical liaisons in the field love sharing this recognition with prospective patients and their families who inquire about the award."

That's extremely important for a facility like LifeCare. "As an LTAC, you rely completely on your referral hospitals for patients," emphasizes Pope. "The Apex recognition has helped us stand out among competitors in our market and has labeled us as a place of excellence for the complicated respiratory patient."

LifeCare has also highlighted the award on its Facebook page and in an internal newsletter. Pope says she has personally received emails and congratulations from colleagues throughout the LifeCare system. Now she's fielding questions from other RT departments within the organization about applying for the award. "We hope to be a first mover and influence additional respiratory teams within the system to follow in our footsteps in 2018," she says. "I have no doubt that we have other teams throughout the system that are just as worthy of this praise."

One thing she hasn't needed to use the award for, though, is recruiting new staff. Pope notes that the majority of her team have been with her for many years and have no intentions of leaving anytime soon. However, she does believe the award is making an impact when it comes to generating interest in her facility from people seeking new employment. "I am always being asked if we are hiring, so maybe that can be attributed to this," she says of the Apex Award.

Pride in the profession

Lisa Pope says the staff members like to joke, "We always knew our respiratory therapists were great. We didn't need a certificate to tell us that!" But earning the Apex Award has brought a big sense of satisfaction to all. "It has been wonderful to feel the esteem and pride from our peers," says the RT manager. "It has been an absolute honor to be recognized by the AARC." ■

RTs at LifeCare pride themselves on delivering personalized, compassionate care.

IMPORTANT SAFETY INFORMATION

LONHALA MAGNAIR is contraindicated in patients with a hypersensitivity to glycopyrrolate or to any of the ingredients.

LONHALA MAGNAIR should not be initiated in patients with acutely deteriorating or potentially life-threatening episodes of COPD or used as rescue therapy for acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta$_2$-agonist.

As with other inhaled medicines, LONHALA MAGNAIR can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with LONHALA MAGNAIR, it should be treated immediately with an inhaled, short-acting bronchodilator; LONHALA MAGNAIR should be discontinued immediately and alternative therapy instituted.

Immediate hypersensitivity reactions have been reported with LONHALA MAGNAIR. If signs occur, discontinue LONHALA MAGNAIR immediately and institute alternative therapy.

LONHALA MAGNAIR should be used with caution in patients with narrow-angle glaucoma and in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema) and of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Patients should be instructed to consult a physician immediately should any of these signs or symptoms develop.

The most common adverse events reported in ≥2% of patients taking LONHALA MAGNAIR, and occurring more frequently than in patients taking placebo, were dyspnea (4.9% vs 3.0%) and urinary tract infection (2.1% vs 1.4%).

LONHALA solution is for oral inhalation only and should not be injected or swallowed. LONHALA vials should only be administered with MAGNAIR.

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Twice-daily dosing, morning and evening[1]

2-3 minute, virtually silent administration with tidal breathing[1,2*†]

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*Improper cleaning and maintenance may increase administration time.
†Patients breathe naturally through the mouthpiece when taking treatment.
‡When the administration cycle is completed, the user will hear 2 beeps, the green LED light will turn off, and the controller will automatically shut off.
§Handset is 2.4 x 4.7 inches. Controller is 1.6 x 4.6 inches. MAGNAIR™ Nebulizer System weighs 10.2 ounces (including batteries).
COPD=chronic obstructive pulmonary disease; LAMA=long-acting muscarinic antagonist.

INDICATION

LONHALA™ MAGNAIR™ (glycopyrrolate) is an anticholinergic indicated for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Assembly required.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

References: 1. LONHALA MAGNAIR [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; 2018. **2.** Data on file. PARI. Test report: loudness measurement eLete. November 30, 2017. **3.** LONHALA MAGNAIR [instructions for use]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; 2017.

For additional information, please see the Brief Summary of Prescribing Information on the following page. Please see full Prescribing Information and Patient Information for LONHALA MAGNAIR at www.sunovionprofile.com/lonhala-magnair.

Lonhala™ Magnair™
(glycopyrrolate) Inhalation Solution
25 mcg/1 mL

Lonhala™ Magnair™

(glycopyrrolate) Inhalation Solution

For oral inhalation use

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information, including Patient Information.

INDICATIONS AND USAGE

LONHALA™ MAGNAIR™ is an anticholinergic indicated for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

CONTRAINDICATIONS

LONHALA MAGNAIR is contraindicated in patients with a hypersensitivity to glycopyrrolate or any of the ingredients.

WARNINGS AND PRECAUTIONS

Deterioration of Disease and Acute Episodes

LONHALA MAGNAIR should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD. LONHALA MAGNAIR has not been studied in subjects with acutely deteriorating COPD. The initiation of LONHALA MAGNAIR in this setting is not appropriate.

LONHALA MAGNAIR should not be used as rescue therapy for the treatment of acute episodes of bronchospasm. LONHALA MAGNAIR has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting $beta_2$-agonist.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If LONHALA MAGNAIR no longer controls symptoms of bronchoconstriction the patient's inhaled, short-acting $beta_2$-agonist becomes less effective; or the patient needs more inhalations of a short-acting $beta_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of LONHALA MAGNAIR beyond the recommended dose is not appropriate in this situation.

Paradoxical Bronchospasm

As with other inhaled medicines, LONHALA MAGNAIR can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with LONHALA MAGNAIR, it should be treated immediately with an inhaled, short-acting bronchodilator; LONHALA MAGNAIR should be discontinued immediately, and alternative therapy instituted.

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of LONHALA MAGNAIR. If signs suggesting allergic reactions occur, in particular, angioedema (including difficulties in breathing or swallowing, swelling of the tongue, lips, and face), urticaria, or skin rash, LONHALA MAGNAIR should be discontinued immediately and alternative therapy instituted.

Worsening of Narrow-Angle Glaucoma

LONHALA MAGNAIR should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Worsening of Urinary Retention

LONHALA MAGNAIR should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The LONHALA MAGNAIR safety database included 2379 subjects with COPD in two 12-week efficacy studies and one 48-week long-term safety study. A total of 431 subjects received treatment with LONHALA MAGNAIR 25 mcg twice-daily (BID). The safety data described below are based on the two 12-week trials and the one 48-week trial.

12-Week Trials

LONHALA MAGNAIR was studied in two 12-week placebo-controlled trials in 431 subjects with COPD, treated with LONHALA MAGNAIR at the recommended dose of 25 mcg, twice daily. The population had a mean age of 63 years (ranging from 40 to 87 years), with 56% males, 90% Caucasian, and a mean post-bronchodilator forced expiratory volume in one second (FEV_1) percent predicted of 52% of predicted normal value (20%-80%) at study entry. The study population also included subjects with pre-existing cardiovascular disease as well as subjects with continued use of stable long-acting bronchodilator (LABA) +/- inhaled corticosteroid (ICS) and ipratropium bromide background therapy. Subjects with unstable cardiac disease, narrow-angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these studies.

The proportion of subjects who discontinued treatment due to adverse reactions was 5% for the LONHALA MAGNAIR-treated subjects and 9% for placebo-treated subjects.

Table 1: Adverse Reactions with LONHALA MAGNAIR ≥ 2.0% Incidence and Higher than Placebo

	Placebo (N=430) N (%)	LONHALA MAGNAIR 25 mcg BID (N=431) N (%)
Dyspnea	13 (3.0)	21 (4.9)
Urinary Tract Infection	6 (1.4)	9 (2.1)

Other adverse reactions defined as events with an incidence of ≥ 1.0% but less than 2.0% with LONHALA MAGNAIR but more common than with placebo included the following: wheezing, upper respiratory tract infection, nasopharyngitis, oedema peripheral, and fatigue.

48-Week Trial

In a long-term open-label safety trial, 1086 subjects were treated for up to 48 weeks with LONHALA MAGNAIR 50 mcg twice-daily (N=620) or tiotropium (N=466). The demographic and baseline characteristics of the long-term safety trial were similar to those of the placebo-controlled efficacy studies described above. The adverse reactions reported in the long-term safety trial were consistent with those observed in the placebo-controlled studies of 12 weeks. Adverse reactions that occurred at a frequency greater than that seen in either active treatment dose in the pooled 12-week placebo controlled studies and ≥ 2.0% were: diarrhea, edema peripheral, bronchitis, nasopharyngitis, pneumonia, sinusitis, upper respiratory tract infection, urinary tract infection, back pain, headache, Chronic Obstructive Pulmonary Disease, cough, dyspnea, oropharyngeal pain, and hypertension.

DRUG INTERACTIONS

Anticholinergics

There is a potential for an additive interaction with concomitantly used anticholinergic medications. Therefore, avoid unnecessary co-administration of LONHALA MAGNAIR with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic effects.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies in pregnant women. LONHALA MAGNAIR should only be used during pregnancy if the expected benefit to the patient outweighs the potential risk to the fetus. Women should be advised to contact their physician if they become pregnant while taking LONHALA MAGNAIR. In animal reproduction studies, there were no teratogenic effects in Wistar rats and New Zealand White rabbits at inhaled doses approximating 1521 and 580 times, respectively, the maximum recommended human daily inhalation dose (MRHDID) based on an AUC comparison.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Labor or Delivery

The potential effect of LONHALA MAGNAIR on labor and delivery is unknown. LONHALA MAGNAIR should be used during labor and delivery only if the potential benefit to the patient justifies the potential risk to the fetus.

Animal Data

Developmental studies in Wistar rats and New Zealand White rabbits in which glycopyrrolate was administered by inhalation during the period of organogenesis did not result in evidence of teratogenicity at exposures approximately 1521 and 580 times, respectively, the MRHDID of LONHALA MAGNAIR based on a comparison of plasma AUC levels (maternal doses up to 3.8 mg/kg/day in rats and 4.4 mg/kg/day in rabbits). Glycopyrrolate had no effects on peri-natal and post-natal development in rats following subcutaneous exposure of approximately 1137 times the MRHDID of LONHALA MAGNAIR based on an AUC comparison (at a maternal dose of up to 1.885 mg/kg/day).

Lactation

Risk Summary

There are no data on the presence of glycopyrrolate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. However, in a study of lactating rats, glycopyrrolate was present in the milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LONHALA MAGNAIR and any potential adverse effects on the breastfed infant from LONHALA MAGNAIR or from the underlying maternal condition.

Data

Glycopyrrolate (and its metabolites) was detected in the milk of lactating rats following a single intravenous injection of 4 mg/kg of radiolabeled glycopyrrolate.

Pediatric Use

LONHALA MAGNAIR is not indicated for use in children. The safety and efficacy of LONHALA MAGNAIR in pediatric patients have not been established.

Geriatric Use

Based on available data, no adjustment of the dosage of LONHALA MAGNAIR in geriatric patients is warranted. LONHALA MAGNAIR can be used at the recommended dose in elderly patients 75 years of age and older.

Of the total number of subjects in clinical studies of LONHALA MAGNAIR, 41% were aged 65 and older, while 8% were aged 75 and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

No dose adjustment is required for patients with mild and moderate renal impairment. The effects of renal impairment on the pharmacokinetics of glycopyrrolate have not been studied.

Hepatic Impairment

No dose adjustment is required for patients with hepatic impairment. The effects of hepatic impairment on the pharmacokinetics of glycopyrrolate have not been studied.

OVERDOSAGE

An overdose of glycopyrrolate may lead to anticholinergic signs and symptoms such as nausea, vomiting, dizziness, lightheadedness, blurred vision, increased intraocular pressure (causing pain, vision disturbances, or reddening of the eye), obstipation or difficulties in voiding.

In COPD patients, orally inhaled administration of LONHALA MAGNAIR at a total daily dose of 200 mcg for 28 consecutive days (maximum of 1 mg) was well tolerated.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

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Sunovion Respiratory Development Inc.,
a wholly-owned subsidiary of Sunovion Pharmaceuticals Inc.,
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Clinical Perspectives

Improving Patient Safety Through the Reporting of Adverse Events

by Thomas Lamphere, BS, RRT, RRT-ACCS, RPFT, FAARC

In 1999, the Institute of Medicine released a report called To Err is Human: Building a Safer Health System, in which experts estimated that as many as 98,000 people die in hospitals each year due to medical errors. The report put a spotlight directly on a problem that was silently continuing to occur year after year without any sustained effort to combat the problem.[1] A study in 2014 found that 1 in 20 adults (5%) in the United States are affected by an outpatient diagnostic error every year. Based on the U.S. population, this means that approximately 12 million people are affected by a diagnostic error every year. This is a sobering statistic, especially when one considers that it involves only outpatient diagnostics, which represent just a portion of all health care interactions.[2]

Clearly there is a need to reduce the number of medical errors and, ultimately, the number deaths caused by these types of avoidable events. There has been an ever-increasing focus on this goal due to the staggering costs associated with such errors. A 2010 study found that medical errors in 2008 cost the U.S. $19.5 billion.[3]

One method of reducing medical errors and improving patient safety in hospitals that has been receiving increased attention is to improve the reporting of adverse events. These events are defined as an injury related to medical management, as opposed to complications of the patient's disease or injury. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable, and they can include a "near miss," which is an event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. Other terms used to describe a near miss include a "narrow escape" or a "close call."

Another type of adverse event is a "sentinel event," which is a term used by the Joint Commission that is defined as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. A sentinel event is a patient safety event that reaches a patient and results in death, permanent harm, or severe temporary harm requiring intervention to sustain life. Any event that meets one or more of the above criteria must be thoroughly investigated and requires an action plan be submitted to the Joint Commission that mitigates the risks of future occurrences.[4]

A medical error is an adverse event or near miss that is preventable with the current state of medical knowledge. They can occur anywhere in the health care system, including hospitals, clinics, surgery centers, doctor offices, nursing homes, pharmacies, and patient homes. Medical errors can involve medications, surgery, diagnosis, equipment, or lab reports.

Since 2001, there has been a dramatic increase in the number of states that mandate reporting of adverse events. This has become a valuable tool in helping to raise awareness with the hope that this will lead to a meaningful reduction of such events. One example is in the state of Pennsylvania, which enacted a law in 2002 that established the "Patient Safety Authority" (PSA), a state-run agency that monitors adverse events in hospitals. This Pennsylvania law requires hospitals to report all "serious events" and "incidents" to the PSA within 24 hours of the event. The PSA then develops recommendations for either the reporting hospital or all hospitals that can be instituted to reduce these events and incidents. As

about the authors...

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another step further, this law requires licensed health care workers, including respiratory therapists, to report serious events and incidents to the hospital. Additionally, a hospital must report licensed personnel to their respective State Licensing Board if the organization discovers that the individual should have reported a serious event but did not do so. The licensing board then decides on disciplinary action for the individual, which could include a fine or suspension of license.

The PSA publishes an annual report, and there is some evidence that these and other changes have made a positive impact in certain areas related to medical errors. First, the total number of adverse event reports have increased fairly steadily. In 2005, approximately 160,000 reports were filed compared to nearly 250,000 filed in 2016. During that time, the number of events associated with patient deaths has decreased from approximately 450 in 2005 to 250 in 2016. While the reports do not specifically indicate why these improvements have been seen, it does show that there has been improvement.

Respiratory therapists are important members of the health care team. Unfortunately, there is a long history of medical errors involving the respiratory care profession. The unique equipment utilized by respiratory therapists play a role in these errors because some adverse events are caused by equipment, such as a mechanical ventilator physically malfunctioning. Other errors are caused by a respiratory therapist failing to utilize the equipment in a proper manner.

Sometimes an adverse event is caused by other, non-respiratory health care workers who utilize respiratory care equipment incorrectly. Most respiratory therapists who have worked in the profession for some time can tell you of a time when they have found a patient on a non-rebreather oxygen mask set at 5 or 6 L/min instead of the required 15 L/min, or a time when they have responded to a code and arrived to find the patient being ventilated with a resuscitation bag that was not attached to oxygen. These types of errors occur more often than they should, but the underlying problem is that we do not know how often they occur. The reason is that, all too often, health care workers who identify an error — whether it caused any identifiable problem with the patient or not — do not report the event to the hospital's administration.

Adverse events are not reported to administration for a variety of reasons. Some people struggle with the idea of reporting a friend's or co-worker's error or a near miss that resulted from their action (or lack of action). They fear a penalty from the employer to their friend or co-worker. In some cases, they may fear retribution from the friend or co-worker for reporting them. In other situations, a health care worker observes a situation that would lead to a medical error but takes action to prevent the error from occurring (i.e., a near miss). They then assume that, because the adverse event did not occur, there is no benefit to reporting it.

Cultural issues can also lead to a failure to report adverse events. These issues can include things such as:

- A generalized increase in work overload in health care, which reduces the available time for a worker to fill out and submit an adverse event report.
- Frustration with the health care organization, which can lead to a defeated or ambivalent mentality.
- A punitive perspective from within, which is often based on a health care worker's upbringing or religious beliefs and leads to a feeling of guilt when they submit an adverse event report related to a co-worker.

If medical errors and near misses are not reported, the root causes of these events will never be investigated because no one will know they are causing a problem or, perhaps worse, someone who makes mistakes in providing care is not held accountable for his or her dangerous errors. If the root causes continue to exist, the potential for another sentinel event remains in place. Many of the today's health care policies are a direct result of errors or near misses that have led to the discovery of an important root cause and thus to a policy or process change.

Respiratory therapists and other health care workers must overcome the human elements and cultural issues that prevent them from reporting adverse events. Failure to do so will allow medical errors to go on unrecognized, and it will allow more patients to experience medical errors that can lead to many unnecessary problems, up to and including death. ■

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1. Kohn LT, Corrigan J, Donaldson MS. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000.
2. Singh H, Meyer AN, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf 2014;23(9):727–731.
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For patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema

POWER

of a LABA/LAMA combination

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audiovisual feedback each time a dose is inhaled

INDICATION

UTIBRON™ NEOHALER® (indacaterol and glycopyrrolate) is a combination of indacaterol and glycopyrrolate indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Important limitations: UTIBRON NEOHALER is not indicated to treat acute deteriorations of COPD and is not indicated to treat asthma.

IMPORTANT SAFETY INFORMATION

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABAs) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another LABA (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including indacaterol, one of the active ingredients in UTIBRON NEOHALER.

The safety and efficacy of UTIBRON NEOHALER in patients with asthma have not been established. UTIBRON NEOHALER is not indicated for the treatment of asthma.

All LABAs, including indacaterol, are contraindicated in patients with asthma without the use of a long-term asthma-control medication; UTIBRON NEOHALER is also contraindicated in patients with a history of hypersensitivity to indacaterol, glycopyrrolate, or to any of the ingredients.

UTIBRON NEOHALER should not be initiated in patients with acutely deteriorating or potentially life-threatening episodes of COPD or used as rescue therapy for acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta$_2$-agonist.

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Powerful bronchodilation with UTIBRON™ NEOHALER® (indacaterol/glycopyrrolate)

- **>230 mL improvement in FEV_1 $AUC_{0\text{-}12hr}$ vs placebo at Week 12 in two trials (primary end point)**[1]
  - 262 mL improvement in FEV_1 $AUC_{0\text{-}12hr}$ vs placebo at Week 12 in Trial 1
  - 231 mL improvement in FEV_1 $AUC_{0\text{-}12hr}$ vs placebo at Week 12 in Trial 2
- **Reduction in rescue medication use all day and night with twice-daily UTIBRON NEOHALER vs placebo (secondary end point)**[1,2]
  - UTIBRON NEOHALER is not a rescue inhaler and is not indicated to treat episodes of acute bronchospasm
- **Whirring noise during inhalation confirms correct placement of the capsule in the chamber**[1]
- **Clear capsule design allows patients to visualize any medication left in the capsule and inhale all of the remaining dose**[1]
- **UTIBRON capsules are for oral inhalation only and should not be swallowed**[1]

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AUC, area under the curve; FEV_1, forced expiratory volume in 1 second; LABA, long-acting $beta_2$-adrenergic agonist; LAMA, long-acting muscarinic antagonist.

UTIBRON NEOHALER should not be used more often, at higher doses than recommended, or in conjunction with other medicines containing LABAs as an overdose may result. Patients who have been taking inhaled short-acting $beta_2$-agonists on a regular basis should be instructed to discontinue their regular use and to use them only for symptomatic relief of acute respiratory symptoms. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using UTIBRON NEOHALER should not use another medicine containing a LABA for any reason.

Immediate hypersensitivity reactions have been reported with UTIBRON NEOHALER. If signs occur, discontinue immediately and institute alternative therapy. UTIBRON NEOHALER should be used with caution in patients with severe hypersensitivity to milk proteins.

As with other inhaled medicines, UTIBRON NEOHALER can produce paradoxical bronchospasm that may be life threatening. If paradoxical bronchospasm occurs following dosing with UTIBRON NEOHALER, it should be treated immediately with an inhaled, short-acting bronchodilator; UTIBRON NEOHALER should be discontinued immediately and alternative therapy instituted.

STUDY DESIGN

The efficacy and safety of UTIBRON NEOHALER was established in two 12-week pivotal trials and one 52-week safety trial.[1,2]

For additional information, please see the Brief Summary of Prescribing Information, including BOXED WARNING, on the following pages.

Please visit www.SunovionProfile.com/UTIBRON for full Prescribing Information and Medication Guide.

References: 1. UTIBRON NEOHALER [prescribing information]. 2017. **2.** Data on file. FLIGHT2 and FLIGHT1 clinical study reports. Sunovion Pharmaceuticals Inc.

utibron™ neohaler®

(indacaterol/glycopyrrolate) inhalation powder 27.5 mcg/15.6 mcg

utibron™ neohaler®

(indacaterol/glycopyrrolate) inhalation powder

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

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INDICATIONS AND USAGE

UTIBRON™ NEOHALER® is a combination of indacaterol and glycopyrrolate indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Important Limitations of Use: UTIBRON NEOHALER is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

CONTRAINDICATIONS

UTIBRON NEOHALER is contraindicated in patients with asthma without use of a long-term asthma control medication.

UTIBRON NEOHALER is contraindicated in patients who have demonstrated hypersensitivity to indacaterol, glycopyrrolate, or to any of the ingredients.

WARNINGS AND PRECAUTIONS

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABAs) increase the risk of asthma-related death. Data from a large, placebo-controlled U.S. study that compared the safety of another LABA (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including indacaterol, one of the active ingredients in UTIBRON NEOHALER.

The safety and efficacy of UTIBRON NEOHALER in patients with asthma have not been established. UTIBRON NEOHALER is not indicated for the treatment of asthma.

Data from a large, placebo-controlled U.S. study in asthma patients showed that LABAs may increase the risk of asthma-related death. Data are not available to determine whether the rate of death in patients with COPD is increased by LABAs.

A 28-week, placebo-controlled U.S. study comparing the safety of another LABA (salmeterol) with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in patients receiving salmeterol (13/13,176 in patients treated with salmeterol versus 3/13,179 in patients treated with placebo; RR 4.37, 95% CI 1.25, 15.34). The increased risk of asthma-related death is considered a class effect of the LABAs, including indacaterol, one of the ingredients in UTIBRON NEOHALER.

No study adequate to determine whether the rate of asthma-related death is increased in patients treated with UTIBRON NEOHALER has been conducted. The safety and efficacy of UTIBRON NEOHALER in patients with asthma have not been established. UTIBRON NEOHALER is not indicated for the treatment of asthma.

Deterioration of Disease and Acute Episodes

UTIBRON NEOHALER should not be initiated in patients with acutely deteriorating or potentially life-threatening episodes of COPD. UTIBRON NEOHALER has not been studied in patients with acutely deteriorating COPD. The initiation of UTIBRON NEOHALER in this setting is not appropriate.

UTIBRON NEOHALER should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. UTIBRON NEOHALER has not been studied in the relief of acute symptoms, and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.

When beginning UTIBRON NEOHALER, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief of acute respiratory symptoms.

When prescribing UTIBRON NEOHALER, the healthcare provider should also prescribe an inhaled, short-acting beta$_2$-agonist and instruct the patient on how it should be used. Increasing inhaled beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If UTIBRON NEOHALER no longer controls the symptoms of bronchoconstriction; the patient's inhaled, short-acting beta$_2$-agonist becomes less effective; or the patient needs more inhalation of short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of UTIBRON NEOHALER beyond the recommended dose is not appropriate in this situation.

Excessive Use of UTIBRON NEOHALER and Use with Other Long-Acting Beta$_2$-Adrenergic Agonists

As with other inhaled drugs containing beta$_2$-adrenergics, UTIBRON NEOHALER should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing LABAs, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using UTIBRON NEOHALER should not use another medicine containing a LABA for any reason.

Paradoxical Bronchospasm

As with other inhaled medicines, UTIBRON NEOHALER can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with UTIBRON NEOHALER, it should be treated immediately with an inhaled, short-acting bronchodilator; UTIBRON NEOHALER should be discontinued immediately and alternative therapy instituted.

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions have been reported after administration of indacaterol or glycopyrrolate, the components of UTIBRON NEOHALER. If signs suggesting allergic reactions occur, in particular, angioedema (including difficulties in breathing or swallowing, swelling of tongue, lips and face), urticaria, or skin rash, UTIBRON NEOHALER should be discontinued immediately and alternative therapy instituted. UTIBRON NEOHALER should be used with caution in patients with severe hypersensitivity to milk proteins.

Cardiovascular Effects

Indacaterol, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms. If such effects occur, UTIBRON NEOHALER may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T-wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown.

Therefore, UTIBRON NEOHALER should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Coexisting Conditions

UTIBRON NEOHALER, like all medicines containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis, and in patients who are unusually responsive to sympathomimetic amines.

Worsening of Narrow-Angle Glaucoma

UTIBRON NEOHALER should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Worsening of Urinary Retention

UTIBRON NEOHALER should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Hypokalemia and Hyperglycemia

Beta$_2$-adrenergic agonists may produce significant hypokalemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Inhalation of high doses of beta$_2$-adrenergic agonists may produce increases in plasma glucose.

In patients with severe COPD, hypokalemia may be potentiated by hypoxia and concomitant treatment, which may increase the susceptibility for cardiac arrhythmias.

In 2 clinical trials of 12-weeks duration evaluating UTIBRON NEOHALER in subjects with COPD, there was no evidence of a treatment effect on serum glucose or potassium.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in clinical practice.

The UTIBRON NEOHALER safety database included 2654 subjects with COPD in two 12-week lung function trials and one 52-week long-term safety study. A total of 712 subjects received treatment with UTIBRON NEOHALER 27.5 mcg/15.6 mcg twice daily (BID). The safety data described below are based on the two 12-week trials and the one 52-week trial.

12-Week Trials

The incidence of adverse reactions associated with UTIBRON NEOHALER in Table 1 is based on two 12-week, placebo-controlled trials (Trials 1 and 2; N=1,001 and N=1,042 respectively). Of the 2040 subjects, 63% were male and 91% were Caucasian. They had a mean age of 63 years and an average smoking history of 47 pack-years, with 52% identified as current smokers. At screening, the mean post-bronchodilator percent predicted forced expiratory volume in 1 second (FEV_1) was 55% (range: 29% to 79%), the mean post-bronchodilator FEV_1/forced vital capacity (FVC) ratio was 50% (range: 19% to 71%), and the mean percent reversibility was 23% (range: 0% to 144%).

The proportion of patients who discontinued treatment due to adverse reactions was 2.95% for the UTIBRON NEOHALER treated patients and 4.13% for placebo-treated patients.

Table 1. Adverse reactions with UTIBRON NEOHALER (greater than or equal to 1% incidence and higher than placebo) in COPD patients

Adverse Reaction	UTIBRON NEOHALER 27.5/15.6 mcg BID (N=508) n (%)	Indacaterol 27.5 mcg BID (N=511) n (%)	Glycopyrrolate 15.6 mcg BID (N=513) n (%)	Placebo (N=508) n (%)
Naso-pharyngitis	21 (4.1)	13 (2.5)	12 (2.3)	9 (1.8)
Hypertension	10 (2.0)	5 (1.0)	3 (0.6)	7 (1.4)
Back pain	9 (1.8)	7 (1.4)	2 (0.4)	3 (0.6)
Oropharyngeal pain	8 (1.6)	4 (0.8)	8 (1.6)	6 (1.2)

Other adverse reactions occurring more frequently with UTIBRON NEOHALER than with placebo, but with an incidence of less than 1% include dyspepsia, gastroenteritis, chest pain, fatigue, peripheral edema, rash/pruritus, insomnia, dizziness, bladder obstruction/urinary retention, atrial fibrillation, palpitations, tachycardia.

52-Week Trial

In a long-term safety trial, 614 subjects were treated for up to 52 weeks with indacaterol/glycopyrrolate 27.5 mcg/15.6 mcg twice-daily, indacaterol/glycopyrrolate 27.5/31.2 mcg twice-daily or indacaterol 75 mcg once-daily. The demographic and baseline characteristics of the long-term safety trial were similar to those of the placebo-controlled efficacy trials described above. The adverse reactions reported in the long-term safety trial were consistent with those observed in the placebo-controlled trials of 12 weeks.
Additional adverse reactions that occurred with a frequency greater than or equal to 2% in the group receiving indacaterol/glycopyrrolate 27.5 mcg/15.6 mcg twice-daily that exceeded the frequency of indacaterol 75 mcg once-daily in this trial were upper and lower respiratory tract infection, pneumonia, diarrhea, headache, gastroesophageal reflux disease, hyperglycemia, rhinitis.

Postmarketing Experience
The following additional adverse reactions of angioedema and dysphonia have been identified during worldwide post-approval use of indacaterol/glycopyrrolate at higher than the recommended dose. Because this reaction is reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

DRUG INTERACTIONS

Adrenergic Drugs
If additional adrenergic drugs are to be administered by any route, they should be used with caution because the sympathetic effects of indacaterol, a component of UTIBRON NEOHALER, may be potentiated.

Xanthine Derivatives, Steroids, or Diuretics
Concomitant treatment with xanthine derivatives, steroids, or diuretics may potentiate any hypokalemic effect of $beta_2$-adrenergic agonists such as indacaterol, a component of UTIBRON NEOHALER.

Non-Potassium-Sparing Diuretics
The electrocardiographic (ECG) changes and/or hypokalemia that may result from the administration of non-potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, such as indacaterol, a component of UTIBRON NEOHALER, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical relevance of these effects is not known, caution is advised in the coadministration of UTIBRON NEOHALER with non-potassium-sparing diuretics.

Monoamine Oxidase Inhibitors, Tricyclic Antidepressants, QTc-Prolonging Drugs
Indacaterol, one of the components of UTIBRON NEOHALER, as with other $beta_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or other drugs known to prolong the QTc interval because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval may have an increased risk of ventricular arrhythmias.

Beta-Blockers
Beta-adrenergic receptor antagonists (beta-blockers) and UTIBRON NEOHALER may interfere with the effect of each other when administered concurrently. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in COPD patients. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-blockers in patients with COPD. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.

Anticholinergics
There is potential for an additive interaction with concomitantly used anticholinergic medicines. Therefore, avoid coadministration of UTIBRON NEOHALER with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects.

Inhibitors of Cytochrome P450 3A4 and P-gp Efflux Transporter
Drug interaction studies with indacaterol, a component of UTIBRON NEOHALER, were carried out using potent and specific inhibitors of CYP3A4 and P-gp (i.e., ketoconazole, erythromycin, verapamil, and ritonavir). The data suggest that systemic clearance of indacaterol is influenced by modulation of both P-gp and CYP3A4 activities and that the 2-fold area under the curve (AUC) increase caused by the strong dual inhibitor ketoconazole reflects the impact of maximal combined inhibition. Indacaterol was evaluated in clinical trials for up to 1 year at doses up to 600 mcg. Inhibition of the key contributors of indacaterol clearance, CYP3A4 and P-gp, has no impact on safety of therapeutic doses of indacaterol. Therefore, no dose adjustment is warranted at the recommended 27.5/15.6 mcg twice-daily dose for UTIBRON NEOHALER when administered concomitantly with inhibitors of CYP3A4 and P-gp.

USE IN SPECIFIC POPULATIONS

Pregnancy
Teratogenic Effects: Pregnancy Category C
There are no adequate and well-controlled studies with UTIBRON NEOHALER or its individual components, indacaterol and glycopyrrolate, in pregnant women. Animal reproduction studies were conducted with individual components, indacaterol and glycopyrrolate. Because animal reproduction studies are not always predictive of human response, UTIBRON NEOHALER should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women should be advised to contact their physician if they become pregnant while taking UTIBRON NEOHALER.

Indacaterol: Indacaterol was not teratogenic in Wistar rats and New Zealand rabbits at approximately 340 and 770 times, respectively, the MRHD in adults (on an AUC basis at maternal subcutaneous doses up to 1 mg/kg/day in rats and rabbits).

Glycopyrrolate: Glycopyrrolate was not teratogenic in Wistar rats or New Zealand White rabbits at approximately 1400 and 530 times, respectively, the MRHD in adults (on an AUC basis at maternal inhaled doses up to 3.83 mg/kg/day in rats and up to 4.4 mg/kg/day in rabbits).

Non-teratogenic Effects:
Indacaterol: There were no effects on perinatal and postnatal developments in rats at approximately 110 times the MRHD in adults (on an AUC basis at maternal subcutaneous doses up to 0.3 mg/kg/day).

Glycopyrrolate: There were no effects on perinatal and postnatal developments in rats at approximately 1100 times the MRHD in adults (on an AUC basis at maternal subcutaneous doses up to 1.88 mg/kg/day).

Labor and Delivery
There are no adequate and well-controlled human trials that have investigated the effects of UTIBRON NEOHALER during labor and delivery. Because beta-agonists may potentially interfere with uterine contractility, UTIBRON NEOHALER should be used during labor only if the potential benefit justifies the potential risk.

In human parturients undergoing Caesarean section, 86 minutes after a single intramuscular injection of 0.006 mg/kg glycopyrrolate, umbilical plasma concentrations were low.

Nursing Mothers
UTIBRON NEOHALER: It is not known whether UTIBRON NEOHALER is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when UTIBRON NEOHALER is administered to a nursing woman. Since there are no data from well-controlled human studies on the use of UTIBRON NEOHALER by nursing mothers, based on the data for the individual components, a decision should be made whether to discontinue nursing or to discontinue UTIBRON NEOHALER, taking into account the importance of UTIBRON NEOHALER to the mother.

Indacaterol: It is not known whether indacaterol is excreted in human breast milk. Indacaterol (including its metabolites) have been detected in the milk of lactating rats.

Glycopyrrolate: It is not known whether glycopyrrolate is excreted in human breast milk. Glycopyrrolate (including its metabolites) have been detected in the milk of lactating rats and reached up to 10-fold higher concentrations in the milk than in the blood of the dam.

Pediatric Use
UTIBRON NEOHALER is not indicated for use in children. The safety and efficacy of UTIBRON NEOHALER in pediatric patients have not been established.

Geriatric Use
Based on available data, no adjustment of UTIBRON NEOHALER dosage in geriatric patients is warranted. UTIBRON NEOHALER can be used at the recommended dose in elderly patients 75 years of age and older.

Of the total number of subjects in clinical studies of UTIBRON NEOHALER, 45% were aged 65 and older, while 11% were aged 75 and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment
Based on the pharmacokinetic characteristics of its monotherapy components, UTIBRON NEOHALER can be used at the recommended dose in patients with mild to moderate renal impairment. In patients with severe renal impairment (estimated GFR less than 30 mL/min/1.73 m^2) or end-stage renal disease requiring dialysis, UTIBRON NEOHALER should be used if the expected benefit outweighs the potential risk since the systemic exposure to glycopyrrolate may be increased in this population.

Hepatic Impairment
Based on the pharmacokinetic characteristics of its monotherapy components, UTIBRON NEOHALER can be used at the recommended dose in patients with mild to moderate hepatic impairment. Studies in subjects with severe hepatic impairment have not been performed.

OVERDOSAGE
In COPD patients, doses of up to 600/124.8 mcg UTIBRON NEOHALER were inhaled over 2 weeks and there were no relevant effects on heart rate, QTc interval, blood glucose or serum potassium. There was an increase in ventricular ectopies after 14 days of dosing with 300/124.8 mcg and 600/124.8 mcg UTIBRON NEOHALER, but low prevalence and small patient numbers (N=49 and N=51 for 600/124.8 mcg and 300/124.8 mcg UTIBRON NEOHALER, respectively) precluded accurate analysis. In a total of four patients, non-sustained ventricular tachycardia was recorded, with the longest episode recorded being 9 beats (4 seconds).

UTIBRON NEOHALER contains both indacaterol and glycopyrrolate; therefore, the risks associated with overdosage for the individual components described below apply to UTIBRON NEOHALER. Treatment of overdosage consists of discontinuation of UTIBRON NEOHALER together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medicine can produce bronchospasm. Cardiac monitoring is recommended in cases of overdosage.

Indacaterol
The potential signs and symptoms associated with overdosage of indacaterol are those of excessive beta-adrenergic stimulation and occurrence or exaggeration of any of the signs and symptoms, e.g., angina, hypertension or hypotension, tachycardia, with rates up to 200 bpm, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, muscle cramps, nausea, vomiting, drowsiness, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, metabolic acidosis and insomnia. As with all inhaled sympathomimetic medications, cardiac arrest and even death may be associated with an overdose of indacaterol.

In COPD patients, single doses of indacaterol 3000 mcg were associated with moderate increases in pulse rate, systolic blood pressure and QTc interval.

Glycopyrrolate
An overdose of glycopyrrolate may lead to anticholinergic signs and symptoms such as nausea, vomiting, dizziness, lightheadedness, blurred vision, increased intraocular pressure (causing pain, vision disturbances or reddening of the eye), obstipation or difficulties in voiding.

In COPD patients, repeated orally inhaled administration of glycopyrrolate at total doses of 124.8 mcg and 249.6 mcg once-daily for 28 days were well tolerated.

PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

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Ventilation for Life

Pediatric Mechanical Ventilation

by John Priest, BSRT, RRT, RRT-NPS, and Craig D. Smallwood, PhD(c), RRT

Mechanical ventilation in the pediatric population can be challenging. The population in a typical pediatric ICU is heterogeneous, covering an array of ages, sizes, diseases, and illness severity. Well-conducted, prospective, randomized, controlled trials addressing mechanical ventilation in this population are limited. As such, clinicians are forced not only to compile available pediatric data, but also to look at trials conducted in neonatal and adult populations. The Pediatric Acute Lung Injury Consensus Conference (PALICC) was formed to bring experts in pediatric mechanical ventilation together to make treatment recommendations and to set research priorities.

The PALICC group recently developed and voted on a total of 151 recommendations addressing the following topics related to pediatric acute respiratory distress syndrome (PARDS): 1) definition, prevalence, and epidemiology; 2) pathophysiology, comorbidities, and severity; 3) ventilatory support; 4) pulmonary-specific ancillary treatment; 5) non-pulmonary treatment; 6) monitoring; 7) noninvasive support and ventilation; 8) extracorporeal support; and 9) morbidity and long-term outcomes.[1] Some of the key PALICC recommendations (Figure 1[14]) included: 1) no age criteria for the definition of PARDS to better understand the pathophysiology of PARDS across the spectrum of age groups in future studies, although perinatal-related lung injury was excluded; 2) stratification of the severity of lung injury based on an oxygenation deficit, as defined by the oxygenation index (OI) or oxygen saturation index (OSI), if an arterial blood gas is not available; 3) inclusion of infants and children requiring noninvasive ventilation as well as those with congenital heart disease and chronic lung disease; and 4) inclusion of patients with unilateral lung disease.[2] Previous attempts at defining and making recommendations for the management of ARDS have not directly included the pediatric populations, and the majority of the prior recommendations have been formulated from adult data. The lack of pediatric-specific data is likely attributable to the challenges related to conducting randomized trials in children with ARDS, including a relatively low incidence of PARDS and the heterogeneity in pathophysiology and physiology across the spectrum of neonates up until adulthood.[3]

To classify PARDS severity, the PALICC group has moved toward using the OI or the OSI for invasively ventilated patients. The equations for OI and OSI are shown in Figure 2, where FiO_2 is the fraction of inspired oxygen expressed as a percentage. OSI should only be used when oxygen saturation is ≤97%, while still utilizing the traditional $PaO_2/FiO2$ (P/F) or SpO_2/FiO_2 (S/F) ratio for noninvasively ventilated patients without including a severity level. The S/F ratio and OSI are included in the PALICC recommendations when arterial blood gasses are not available; however, oxygen supplementation should be titrated to achieve a SpO_2 of 88–97%. Khemani et al demonstrated that, in children with acute hypoxemic respiratory failure, lung injury severity markers that

about the authors...

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Craig D. Smallwood, PhD(c), RRT, is a research associate at Boston Children's Hospital and Harvard Medical School.

Age	Exclude patients with peri-natal related lung disease			
Timing	Within 7 days of known clinical insult			
Origin of Edema	Respiratory failure not fully explained by cardiac failure or fluid overload			
Chest Imaging	Chest imaging findings of new infiltrate(s) consistent with acute pulmonary parenchymal disease			
Oxygenation	**Non Invasive mechanical ventilation**	**Invasive mechanical ventilation**		
	PARDS (No severity stratification)	Mild	Moderate	Severe
	Full face-mask bi-level ventilation or CPAP ≥5 cm H_20 [2] PF ratio ≤ 300 SF ratio ≤ 264 [1]	4 ≤ OI < 8 5 ≤ OSI < 7.5[1]	8 ≤ OI < 16 7.5 ≤ OSI < 12.3[1]	OI ≥ 16 OSI ≥ 12.3[1]
Special Populations				
Cyanotic Heart Disease	Standard Criteria above for age, timing, origin of edema and chest imaging with an acute deterioration in oxygenation not explained by underlying cardiac disease. [3]			
Chronic Lung Disease	Standard Criteria above for age, timing, and origin of edema with chest imaging consistent with new infiltrate and acute deterioration in oxygenation from baseline which meet oxygenation criteria above.[3]			
Left Ventricular dysfunction	Standard Criteria for age, timing and origin of edema with chest imaging changes consistent with new infiltrate and acute deterioration in oxygenation which meet criteria above not explained by left ventricular dysfunction.			

Figure 1. Key PALICC Recommendations

use SpO_2 are adequate surrogate markers for those that use PaO_2, as long as SpO_2 is between 80% and 97%.[4] In general, OI and OSI have the advantage of normalizing oxygenation to the level of ventilator support over P/F and S/F (both of which ignore mean airway pressure). Given the now routine use of pulse oximetry in nearly all ICUs, and the more infrequent use of arterial lines in children, noninvasive oxygenation criteria should be strongly considered to characterize patient risk and as enrollment criteria for clinical trials in children when PaO_2 is unavailable.[4]

Lung-protective ventilation (lower tidal volumes, permissive hypercapnia, and elevated positive end-expiratory pressure) is the strategy for mechanical ventilation during PARDS despite the limited availability of pediatric data. The National Institutes of Health/ National Heart Lung and Blood Institute ARDS Network (ARDSnet) guideline has been the ventilator strategy of choice in adult populations for many institutions, and it has been the basis of various pediatric protocols, but these strategies can vary across and within individual institutions. The PALICC group determined that there is no recommendation on a specific ventilator mode for this patient population. Instead, PALICC recommends using patient-specific tidal volumes (Vt) according to disease severity: Vt = 3–6 mL/kg ideal body weight (IBW) for patients with poor respiratory system compliance, and Vt = 5–8 mL/kg IBW for patients with better respiratory system compliance.[1] Overall, low Vt is underutilized in children with PARDS in the first 24 hours of illness.[5] Ward et al observed that when the definition of low Vt was expanded to include Vt up to 8 mL/kg IBW, the frequency of low Vt use increased to only 58–60%, which suggests a large proportion of patients receiving Vt higher than the cutoff recommended by ARDSNet.[5] Admittedly, there are no randomized, controlled trials to support the notion that 8 mL/kg is worse for a child than 6 mL/kg, but given the impact of a low Vt strategy in adults (i.e., 6 mL/kg), such targets should be considered.[5] A systematic review and meta-analysis of observational studies did not identify a relationship between Vt and mortality in mechanically ventilated children, regardless of the severity of disease.[6] Because of this uncertainty in pediatric mechanical ventilation strategies, future studies are needed to help guide

$$OI = \frac{FiO_2 \times P_{mean}}{PaO_2}$$

$$OSI = \frac{FiO_2 \times P_{mean}}{SpO_2}$$

Figure 2.
Equations for Oxygenation Index and Oxygen Saturation Index

practitioners in proper Vt selection. Overall, we need more data, but until that happens, it is prudent to target low Vt in children with PARDS. Indeed, many centers shoot for 5–7 mL/kg IBW.

Other questions regarding pediatric mechanical ventilation management during PARDS involve the parameters for positive end-expiratory pressure (PEEP) and ΔP (the difference between plateau pressure and PEEP). The PALICC group recommends moderately elevated levels of PEEP (10–15 cm H_2O) titrated to the observed oxygenation and hemodynamic response in patients with severe PARDS, while closely monitoring plateau pressure.[1] An important difference between PARDS and ARDS in adults is the association between oxygenation and mortality. In patients with PARDS, improved oxygenation has been shown to be associated with decreased risk of mortality.[7] On the other hand, adult ARDS mortality risk appears to be independent of oxygenation and may be more associated with pulmonary mechanics. For example, in adult trials of mechanical ventilation involving patients with ARDS, when VT and PEEP were included as independent variables, the dependent quantity ΔP was the variable that was most strongly associated with survival.[8] PEEP increments might be protective only when the increased PEEP values result in a change in lung mechanics so that the same VT can be delivered with a lower ΔP.[8]

High-frequency oscillatory ventilation (HFOV) has been shown to be less favorable in the management of ARDS. Two adult trials, OSCAR and OSILLATE, reported negative results. The PALICC demonstrated a weak agreement for recommending HFOV as an alternative ventilatory mode in hypoxic respiratory failure in patients with plateau airway pressures exceeding 28 cm H_2O in the absence of clinical evidence of reduced chest wall compliance.[1] Cools et al did not support selection of pre-term infants for HFOV on the basis of gestational age, birthweight for gestation, initial lung disease severity, or exposure to antenatal corticosteroids.[9] There is little evidence about the efficacy of using HFOV in PARDS, yet, despite the lack of data to support it, bedside decisions for pediatric patients have been made with adult and neonatal trials in mind. The RESTORE (Randomized Evaluation of Sedation Titration for Respiratory Failure) study published reports from prospectively collected data and showed inferior clinical outcomes including higher mortality, longer length of hospital stay, and more ventilator days in the HFOV group.[10] This study did not dictate a standardized approach to conventional ventilator management before or after HFOV, which may have skewed the interpretation of the results. Despite these studies, more pediatric-specific data are still needed. An important HFOV study is in the planning stages and awaiting funding and patient enrollment.[11]

The addition of noninvasive positive-pressure ventilation can improve gas exchange and potentially prevent intubation and mechanical ventilation in some children with mild PARDS.[12] The PALICC group recommends that noninvasive positive-pressure ventilation should be delivered in a setting with trained and experienced staff, where close monitoring is available to rapidly identify and treat deterioration.1 Monitoring may be the single most important intervention in the treatment of PARDS. FiO_2, SpO_2 and/or PaO_2, airway pressure, and PEEP monitoring are recommended to diagnose PARDS, assess its severity, and provide a guide to the management of oxygen failure.[1] These recommendations for monitoring are intended to promote optimization and consistency of care for children and identify areas of uncertainty requiring further investigation.[13] ■

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She Touched My Heart

by Sharon Tucker, BA, RRT

I work in a rehabilitation hospital and have had many memorable patients over the last 20 years. We get patients on our acute rehab unit (ARU) who sometimes don't seem quite ready to be there.

One patient who not only touched my heart, but the hearts of everyone who worked with her, came to our long-term acute care hospital with the diagnosis of hemorrhagic stroke and the possibility of living out the rest of her life in a vegetative state due to the severity of the damage.

When she arrived in the ARU, she was ventilated around the clock and she was not tolerating her speaking valve. Weaning trials had not been successful, but she had improved more than expected in cognition.

I got goosebumps

Over time, we were able to wean her to a noninvasive BiPAP with a rate to control her central apneas. She also had her tracheostomy removed. For me, the best moment in her care came the morning I walked into her room to do her respiratory treatment and she said, "Hi, Sharon." I literally got goosebumps!

After that, it was soon time for our patient to transition to a lower level of care, with the very real hope that she would ultimately be able to return to her own home. As we were looking to place her at the next level of care she would need prior to being discharged home, we learned that the durable medical equipment company for the facility only provided BiPAPs "without a rate."

For a while, it looked like the facility would not accept our patient due to concerns that a BiPAP "with a rate" would be too difficult for the facility staff to manage. I held a conference call with the facility on her behalf, explaining that if I were to bring in two tabletop BiPAPs — one with a rate and one without — they would not be able to tell the difference. The staff's management of the mask and humidity are the same for both.

A gentleman in the conference call said, "Are you serious, that's it?" After that, the facility accepted her, and their new understanding of the management of these devices has opened doors for others with a need for a BiPAP with a rate as well.

Glad to be an RT

As for the patient who led to this change, she has continually improved, and her determination to recover has inspired many. A nurse from the facility recently told me that everyone loves her.

This patient shows that not only do RTs get a chance to touch the lives of our patients, but we are often on the receiving end, too. It makes me glad that I am a respiratory therapist! ■

about the author...

Sharon Tucker is a respiratory therapist at Madonna Rehabilitation Hospital in Lincoln, NE.

For patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema

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INDICATION

SEEBRI™ NEOHALER® (glycopyrrolate) is an anticholinergic indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

IMPORTANT SAFETY INFORMATION

SEEBRI NEOHALER is contraindicated in patients with a hypersensitivity to glycopyrrolate or to any of the ingredients.

SEEBRI NEOHALER should not be initiated in patients with acutely deteriorating or potentially life-threatening episodes of COPD or used as rescue therapy for acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta$_2$-agonist.

As with other inhaled medicines, SEEBRI NEOHALER can produce paradoxical bronchospasm that may be life threatening. If paradoxical bronchospasm occurs following dosing with SEEBRI NEOHALER, it should be treated immediately with an inhaled, short-acting bronchodilator; SEEBRI NEOHALER should be discontinued immediately and alternative therapy instituted.

Immediate hypersensitivity reactions have been reported with SEEBRI NEOHALER. If signs occur, discontinue immediately and institute alternative therapy. SEEBRI NEOHALER should be used with caution in patients with severe hypersensitivity to milk proteins.

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- **>120 mL improvement in FEV_1 $AUC_{0\text{-}12hr}$ vs placebo at Week 12 in two trials (primary end point)**[1]
  - 139 mL improvement in FEV_1 $AUC_{0\text{-}12hr}$ vs placebo at Week 12 in Trial 1
  - 123 mL improvement in FEV_1 $AUC_{0\text{-}12hr}$ vs placebo at Week 12 in Trial 2
- **Reduction in rescue medication use all day and night with twice-daily SEEBRI NEOHALER vs placebo (secondary end point)**[1,2]
  - SEEBRI NEOHALER is not a rescue inhaler and is not indicated to treat episodes of acute bronchospasm
- **Whirring noise during inhalation confirms correct placement of the capsule in the chamber**[1]
- **Clear capsule design allows patients to visualize any medication left in the capsule and inhale all of the remaining dose**[1]
- **SEEBRI capsules are for oral inhalation only and should not be swallowed**[1]

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AUC, area under the curve; FEV_1, forced expiratory volume in 1 second; LAMA, long-acting muscarinic antagonist.

SEEBRI NEOHALER should be used with caution in patients with narrow-angle glaucoma and in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema) and of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Patients should be instructed to consult a physician immediately should any of these signs or symptoms develop.

STUDY DESIGN

The efficacy of SEEBRI NEOHALER was established in two 12-week, pivotal trials. The safety of SEEBRI NEOHALER was established in four 12-week lung-function trials and one 52-week, long-term study.[1,2]

For additional information, please see the Brief Summary of Prescribing Information on the following pages.

Please visit www.SunovionProfile.com/SEEBRI for full Prescribing Information and Patient Information.

References: 1. SEEBRI NEOHALER [prescribing information]. 2017. 2. Data on file. GEM1 and GEM2 clinical study reports. Sunovion Pharmaceuticals Inc.

seebri™ neohaler®

(glycopyrrolate) inhalation powder 15.6 mcg

seebri™ neohaler®

(glycopyrrolate) inhalation powder

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information, including Patient Information.

INDICATIONS AND USAGE

SEEBRI™ NEOHALER® is indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

CONTRAINDICATIONS

SEEBRI NEOHALER is contraindicated in patients who have demonstrated hypersensitivity to glycopyrrolate or to any of the ingredients.

WARNINGS AND PRECAUTIONS

Deterioration of Disease and Acute Episodes

SEEBRI NEOHALER should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD. SEEBRI NEOHALER has not been studied in subjects with acutely deteriorating COPD. The initiation of SEEBRI NEOHALER in this setting is not appropriate.

SEEBRI NEOHALER should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. SEEBRI NEOHALER has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting $beta_2$-agonist.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If SEEBRI NEOHALER no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting $beta_2$-agonist becomes less effective; or the patient needs more inhalation of a short-acting $beta_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of SEEBRI NEOHALER beyond the recommended dose is not appropriate in this situation.

Paradoxical Bronchospasm

As with other inhaled medicines, SEEBRI NEOHALER can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with SEEBRI NEOHALER, it should be treated immediately with an inhaled, short-acting bronchodilator; SEEBRI NEOHALER should be discontinued immediately, and alternative therapy instituted.

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions have been reported after administration of SEEBRI NEOHALER. If signs suggesting allergic reactions occur, in particular, angioedema (including difficulties in breathing or swallowing, swelling of the tongue, lips, and face), urticaria, or skin rash, SEEBRI NEOHALER should be discontinued immediately and alternative therapy instituted. SEEBRI NEOHALER should be used with caution in patients with severe hypersensitivity to milk proteins.

Worsening of Narrow-Angle Glaucoma

SEEBRI NEOHALER should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Worsening of Urinary Retention

SEEBRI NEOHALER should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in clinical practice.

The SEEBRI NEOHALER safety database included 3415 subjects with COPD in four 12-week lung function trials and one 52-week long-term safety study. A total of 1202 subjects received treatment with SEEBRI NEOHALER 15.6 mcg twice-daily (BID). The safety data described below are based on the four 12-week trials and the one 52-week trial.

12-Week Trials

The incidence of adverse reactions associated with SEEBRI NEOHALER in Table 1 is based on four 12-week, placebo-controlled trials in 2908 subjects with COPD. In the total population, 61.2% of patients had moderate COPD and 37.8% had severe COPD. Overall, 62% were males, 90% were Caucasian, and the mean age was 63 years (ranging from 41 to 89 years). In this population, 53% were identified as current smokers with an average smoking history of 48 pack-years.

The proportion of subjects who discontinued treatment due to adverse reactions was 2.4% for the SEEBRI NEOHALER-treated patients and 3.8% for placebo-treated patients.

Table 1. Adverse reactions with SEEBRI NEOHALER (greater than or equal to 1% incidence and higher than placebo) in COPD patients

Adverse Reaction	SEEBRI NEOHALER 15.6 mcg BID (N=951) n (%)	Placebo (N=938) n (%)
Upper respiratory tract infection	32 (3.4)	22 (2.3)
Nasopharyngitis	20 (2.1)	18 (1.9)
Urinary tract infection	13 (1.4)	12 (1.3)
Sinusitis	13 (1.4)	7 (0.7)
Oropharyngeal pain	17 (1.8)	11 (1.2)

Other adverse reactions occurring more frequently with SEEBRI NEOHALER than with placebo, but with an incidence of less than 1% include rash, pruritus, gastroenteritis, hypersensitivity, atrial fibrillation, insomnia, pain in extremity, dysuria, vomiting, productive cough, and diabetes mellitus/hyperglycemia.

52-Week Trial

In a long-term safety trial, 507 subjects were treated for up to 52 weeks with glycopyrrolate 15.6 mcg twice-daily or indacaterol 75 mcg once-daily. The demographic and baseline characteristics of the long-term safety trial were similar to those of the placebo-controlled efficacy trials described above. The adverse reactions reported in the long-term safety trial were consistent with those observed in the placebo-controlled trials of 12 weeks. Additional adverse reactions that occurred with a frequency greater than or equal to 2% in the group receiving glycopyrrolate 15.6 mcg twice-daily that exceeded the frequency of indacaterol 75 mcg once-daily in this trial were: diarrhea, nausea, upper abdominal pain, fatigue, bronchitis, pneumonia, rhinitis, back pain, arthralgia, dyspnea, and wheezing.

Postmarketing Experience

The following additional adverse reactions have been identified during worldwide post-approval use of glycopyrrolate, the active ingredient in SEEBRI NEOHALER, at higher than the recommended dose. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions are: angioedema, paradoxical bronchospasm and dysphonia.

DRUG INTERACTIONS

Anticholinergics

There is a potential for an additive interaction with concomitantly used anticholinergic medications. Therefore, avoid coadministration of SEEBRI NEOHALER with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic effects.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C

There are no adequate and well-controlled studies with SEEBRI NEOHALER in pregnant women. Because animal reproduction studies are not always predictive of human response, SEEBRI NEOHALER should only be used during pregnancy if the potential benefit to the patient justifies the potential risk to the fetus. Women should be advised to contact their physician if they become pregnant while taking SEEBRI NEOHALER.

Glycopyrrolate was not teratogenic in Wistar rats and New Zealand White rabbits at approximately 1400 and 530 times, respectively, the MRHD in adults (on an AUC basis at maternal inhaled doses up to 3.83 mg/kg/day in rats and up to 4.4 mg/kg/day in rabbits).

Non-teratogenic Effects:

Glycopyrrolate had no effects on peri-natal and post-natal developments in rats at approximately 1100 times the MRHD in adults (on an AUC basis at maternal subcutaneous doses up to 1.88 mg/kg/day).

Labor and Delivery

There are no adequate and well-controlled human trials that have investigated the effects of SEEBRI NEOHALER during labor and delivery. In human parturients undergoing Caesarean section, 86 minutes after a single intramuscular injection of 0.006 mg/kg glycopyrrolate, umbilical plasma concentrations were low.

Nursing Mothers

It is not known whether SEEBRI NEOHALER is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when SEEBRI NEOHALER is administered to a nursing woman. Since there are no data from well-controlled human studies on the use of SEEBRI NEOHALER by nursing mothers, a decision should be made whether to discontinue nursing or to discontinue SEEBRI NEOHALER, taking into account the importance of SEEBRI NEOHALER to the mother.

It is not known whether glycopyrrolate is excreted in human breast milk. Glycopyrrolate (including its metabolites) have been detected in the milk of lactating rats and reached up to 10-fold higher concentrations in the milk than in the blood of the dam.

Pediatric Use

SEEBRI NEOHALER is not indicated for use in children. The safety and efficacy of SEEBRI NEOHALER in pediatric patients have not been established.

Geriatric Use

Based on available data, no adjustment of the dosage of SEEBRI NEOHALER in geriatric patients is warranted. SEEBRI NEOHALER can be used at the recommended dose in elderly patients 75 years of age and older.

Of the total number of subjects in clinical studies of SEEBRI NEOHALER, 45% were aged 65 and older, while 10% were aged 75 and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

No dose adjustment is required for patients with mild and moderate renal impairment. SEEBRI NEOHALER should be used in patients with severe renal impairment (estimated GFR less than 30 mL/min/1.73m^2), including those with end-stage renal disease requiring dialysis, if the expected benefit outweighs the potential risk since the systemic exposure to glycopyrrolate may be increased in this population.

Hepatic Impairment

No dose adjustment is required for patients with hepatic impairment. The effects of hepatic impairment on the pharmacokinetics of glycopyrrolate have not been studied.

OVERDOSAGE

An overdose of glycopyrrolate may lead to anticholinergic signs and symptoms such as nausea, vomiting, dizziness, lightheadedness, blurred vision, increased intraocular pressure (causing pain, vision disturbances, or reddening of the eye), obstipation or difficulties in voiding.

In COPD patients, repeated orally inhaled administration of SEEBRI NEOHALER at total doses of 124.8 and 249.6 mcg once-daily for 28 days were well tolerated.

PATIENT COUNSELING INFORMATION

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Chronic Disease Manager

The A's, B's, C's, and D's of Personalities in Pulmonary Rehabilitation

by Aaron McColpin, DNP, RRT, RRT-NPS, FNP, CPFT

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death in the United States.[1] An estimated 15.7 million adults in the United States have been diagnosed with COPD, and an estimated 30 million people have abnormal spirometry test results.[2,3] COPD is one of the few chronic diseases that is increasing, with a worldwide prevalence in 2010 of 14.3% in men and 7.6% in women.[4]

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend that patients with high symptom burden and exacerbation risk (GOLD classes B, C, and D) attend pulmonary rehabilitation (PR), which emphasizes education, exercise, and psychosocial support.[4,5] Psychological treatment and support are often lacking in PR due to limited resources.[6] It is important for health care providers to understand the effects of personality types and disease acceptance to effectively improve patients' health-related quality of life (HRQoL). HRQoL is a multidimensional concept that includes domains related to physical, mental, emotional, and social functioning factors.[7] HRQoL goes beyond the direct measurements of physiological indicators of health and focuses on the impact of a patient's health status on their quality of life.

about the author...

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Personality

Personality characteristics or types are emerging as risk factors for chronic diseases, which can lead to a decreased quality of life. It is often said a person with a Type A personality is known as being outgoing or driven, whereas a person with a Type B personality is more laid back. With an increased understanding of the complexity of personalities, psychologists have added multiple dimensions to classify personality types, such as Type D, which is identified by neuroticism.

The Type D personality is based on the premise that emotional stress, anxiety, and depression, as a risk factor for negative health outcomes, is a reflection of a fairly stable psychological characteristic and involves the presence of a wide range of negative emotions in conjunction with the suppression of other emotions.[8] Patients with neuroticism often experience a lot of stress, anxiety, and mood shifts, and they can be easily upset. As with mental illness, the higher rates of smoking seen in patients with neuroticism could lead to a higher prevalence of COPD in this population.[9] This negative personality type was found to have a strong negative correlation with medication adherence and medical compliance.[10] Conversely, the personality types of Openness and Conscientiousness have been found to improve HRQoL and physical health. Openness, also identified as curiosity, is reflected by a person's willingness to try new experiences. Conscientiousness refers to a person's self-discipline and ability to plan.

The following section will review the three most commonly used personality-type instruments used in health care: the Big Five Inventory (BFI), the Myers-Briggs Type Indicator (MBTI), and the NEO Personality Inventory (NEO-PR-I), which are free to use by clinicians.

Big Five Inventory

The Big Five Inventory (BFI) was developed by John, Donahue, and Kently in 1991 as a short instrument to assess the five dimensions of personality from the Five-Factor Model, and it is often used to assess for neurosis.[11] The Big Five domains are often referred to as OCEAN: Openness, Conscientiousness, Extraversion, Agreeableness, and Neuroticism.

The BFI originally consisted of 44 short-phrase items that could be addressed in less than five minutes. The newest version of the BFI questionnaire consists of 10 short-phrase questions that can also be answered in less than five minutes. The BFI showed one of the highest reliabilities among personality-type assessments, with a mean alpha of .85.[12]

Myers-Brigg Personality Type Indicator

The Myers-Briggs Personality Type Indicator is one of the most common personality assessments used today. This assessment is based on Jung's theory of personality types.[13] The assessment has 16 types of personality traits composed of one element of each of the following four pairs of characteristics: Extraversion (E) or Introversion (I); Thinking (T) or Intuition (I); Thinking (T) or Feeling (F); and Judging (J) or Perceiving (P).[14] As an example, an ISTJ personality type would include traits of Introversion, Sensing, Thinking, and Judging. The ISTJ personality is known as the "The Logistician," and it is one of the most abundant personality types, making up approximately 13% of the population. The MBTI is commonly used in business and education, but it is less common in medicine as other assessments are thought to be more reliable with patients. One of the benefits of using the MBTI is that multiple free online assessments are available.

Neo-PR-I

The NEO Personality Inventory-Revised (NEO-PR-I) is a comprehensive detailed assessment of personality based on the Five-Factor Model that uses the domains of OCEAN.[15] The domain of Neuroticism contains the facets of anxiety, hostility, depression, and vulnerability to stress within the assessment. One of the problems with the instrument in the clinical setting is that it often takes 35–45 minutes to complete due to its in-depth questions. It is mostly commonly used in psychology, social work, research, etc., instead of in the clinical setting.[16]

Disease acceptance

The American College of Chest Physicians and the American Thoracic Society have recommended that all symptomatic COPD patients with an FEV^1 < 50% attend PR when their disease is stable.[17,18] However, multiple studies have shown that the completion rates of PR range from 42% to 58% for most programs.[19,20] Disease acceptance is defined as illness acceptance extensively discussed in the theoretical models of adaptation in chronic diseases. The thought is that when patients accept their disease, they will adjust their life toward more achievable goals by integrating this difficult medical diagnosis into their daily lives. By accepting their chronic disease, the patients are then expected to focus on managing its impact and, therefore, will change their routines, expectations, and goals, thus improving the chances of completing a PR program.

Disease acceptance instruments

Multiple disease acceptance instruments are available for clinicians to help determine whether a patients has come to accept his or her chronic illness. The most commonly used instruments are the Illness Cognition Questionnaire (ICQ), the Illness Perception Questionnaire (IPQ), the Implicit Models of Illness Questionnaire (IMIQ), and the Revised Illness Perception Questionnaire (IPQ-R). The ICQ and the IPQ are the most frequently used and are well validated. The ICQ is especially useful in the clinical setting due to being short and easy to use.

The ICQ is a generic survey to assess cognition across different chronic diseases, and it has been used to measure disease acceptance. The questionnaire consists of 18 questions on the factors of helplessness, acceptance, and perceived benefits. The questionnaire is scored on a 4-point Likert scale to determine the extent to which a patient agrees with a list of statements regarding the long-term illness. Acceptance of the disease has been shown to have a positive effect on psychological aspects of well-being and medication adherence.

Summary

Using HRQoL and disease acceptance questionnaires can help with individualizing treatment plans within PR programs. PR for those with COPD is often standardized and often does not consider personality characteristics or disease acceptance. Using personality-related disease-acceptance questionnaires may provide valuable insight to the respiratory therapist regarding when the patient should start a program and how to improve completion and follow-up rates within a program. Personality assessments and disease acceptance can be used with disease-specific measures of quality of life, such as the St. George Respiratory Questionnaire or the COPD Clinical Questionnaire, to help treat patients in a more holistic manner rather than with physiological measures alone. Examples of holistic treatments include meditation and mind/body practices for dealing with negativity, anxiety, and depression.[21]

Finally, RTs should identify personality types of patients in their PR programs to help tailor treatment. This would be especially helpful for patients who have negative personality types as they often need more counseling, medication, and implementation of holistic practices. ■

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Severe Asthma Tools and Shared Decision Making

by Tonya Winders, MBA

Asthma is a chronic disease of the respiratory system in which the airway becomes inflamed, constricted, and lined with excessive amounts of mucus, often in response to one or more triggers.[1]

Once considered a single but complex disease, asthma is now recognized as a syndrome or spectrum of diseases with environmental and genetic factors that cause airway inflammation. This inflammation results in airway hyper-responsiveness and reversible airway obstruction that may erupt in clinical symptoms such as coughing, wheezing, and shortness of breath. The body's ongoing attempts to correct the damage from inflammation can also lead to airway remodeling or permanent structural and functional changes.

Tonya Winders, MBA, is president and CEO of the Allergy & Asthma Network. She is also the current president of the Global Asthma & Allergy Patient Platform.

Asthma treatment guidelines say that most asthma can be controlled with a combination of allergen and irritant avoidance and medications.[1] However, studies show that 5–10% of people with asthma have severe asthma that does not respond to traditional anti-inflammatory or bronthchodilator medication.[2] Severe asthma is defined as asthma that, despite patient adherence, requires high-dose inhaled corticosteroids plus long-acting β2-agonists and/or additional controller medication, or requires oral corticosteroids to prevent the asthma from becoming controlled, or remains uncontrolled despite therapy.[3] While people with severe asthma make up a small percentage of the total asthma population, they represent a much higher percentage of the total health care costs related to asthma, i.e., 50–80%.[4]

However, not all uncontrolled asthma is severe, and not all severe asthma is uncontrolled.[3] Other factors to address before concluding therapeutic failure include the patient's inhaler technique, medication adherence, prescription fills and refills, allergen avoidance, comorbidities (e.g., allergic rhinitis, gastroesophageal reflux), medication side effects, access to treatment, and ability to pay the costs of treatment.

With this economic and quality-of-life burden, it is well worth distinguishing the underlying factors behind the disease. Multiple genetic and environmental links to asthma are now recognized; at least four phenotypes that respond to targeted treatments have been identified: allergic asthma, eosinophilic asthma, neutrophilic asthma, and airway smooth muscle hypertrophy.[5,6]

Management of severe asthma may involve stepping up current medications or adding new ones. To target treatment, an asthma specialist must first identify characteristics using skin and blood tests, FeNO (fractional exhaled nitric oxide) measurements, sputum analysis, and/or bronchoscopy. For some patients, high serum IgE levels and/or high eosinophil counts and high FeNO levels are associated with increased symptoms and acute exacerbations; for others, thickening of airway smooth muscle may be the major contributor. All may be targets for treatment with biologics or other newly developed therapies (Table 1).[5]

Table 1. Asthma phenotypes and targeted treatment options

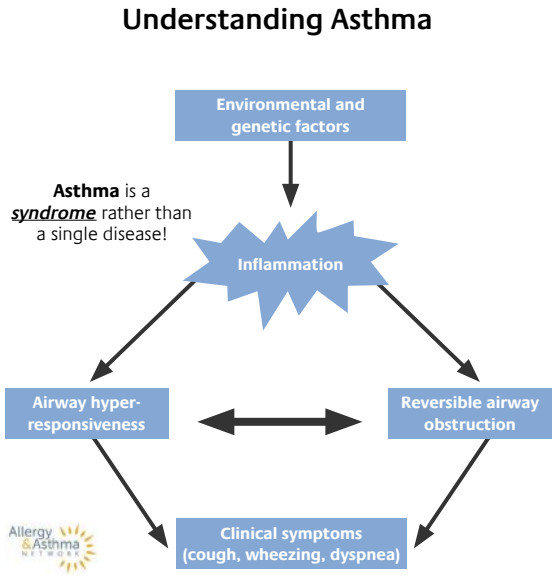
Asthma Phenotype	Characterized by difficult-to-treat asthma plus:	Targeted Treatment
Allergic IgE	Total serum IgE = 30–700 IU/mL *and* demonstrated IgE-mediated hypersensitivity to a perennial allergen	Add anti-IgE • omalizumab
Eosinophilic	Blood eosinophils >300 cells/uL and ≥2 exacerbations requiring oral corticosteroids in the past year *or* blood eosinophils ≥150 cells/uL and ≥3 exacerbations requiring oral corticosteroids in the past year	Add anti-interleukin-5 • mepolizumab • reslizumab • benralizumab
Neutrophilic	Sputum neutrophils in patients who do not respond to high-dose corticosteroids *and* do not have other type 2 markers	Consider adding a macrolide antibiotic
Airway smooth muscle hypertrophy	Patients who don't qualify for other targeted therapies *and/or* has tried and failed targeted therapies for which they might be eligible *and* demonstration of variable airflow obstruction by bronchodilator reversibility	Consider bronchial thermoplasty in addition to regular treatment

Partnering with patients

Developing a treatment plan for severe asthma requires more than an accurate diagnosis and evidence-based treatment guidelines. It is imperative for health care professionals and patients to work together to set up a management plan that is more than just clinically effective, but one that patients can and will follow.

To better understand health care provider and patient attitudes and beliefs regarding asthma — and identify areas for improvement — Allergy & Asthma Network recently commissioned the OPEN Asthma Survey.[7]

The survey involved 2,900 adult asthma patients and 859 health care professionals. The study design and methodology included a 20-minute, online, computer-assisted survey with health care providers and adult patients who self-identified as being diagnosed with asthma. Results exposed three main disconnects:



Patients' perception of control: The vast majority of patients believed their asthma was well or mostly controlled. However, their self-assessments did not correlate with their symptoms. Results showed that a significant number of self-reported "well controlled" and "mostly controlled" patients experienced symptoms once or twice a week.

The impact of asthma: While saying their lives were not strongly affected by asthma, 70% reported regularly experiencing limits to performing everyday activities such as walking, getting enough sleep, and completing household chores.

Health care provider and patient communication: When asked about their physician office visits, fewer than half of moderate and severe patients said they always discuss symptoms during routine visits; fewer than a third always discuss how asthma affects daily life; and even fewer discuss an action plan. In contrast, health care professionals said they address these issues regularly with their patients. This points out the need for shared decision making, which is a collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.

Allergy & Asthma Network has been listening to patients for more than 30 years, and it is clear is that patients face a wide range of financial, emotional, cultural, and personal barriers to care:

- Language difficulties, including people who do not speak English as a primary language, as well as those with limited education who do not understand medical terminology
- Cultural inhibitions about communicating that cause patients to refrain from asking questions, questioning authority, or talking about problems
- Inconvenience of carrying inhalers or holding chambers at school or work
- Household, work, or travel schedules that make daily medication schedules difficult to follow
- Inconsistent child care arrangements with multiple caregivers
- Difficulty getting to health care appointments during physician office hours due to school and work schedules as well as limited transportation options
- Cost of medications or health care appointments

When it comes to biologics and cutting-edge asthma therapies, even more questions and concerns arise, such as fear of needles, shots, or intravenous treatments; difficulty adhering to a treatment schedule; and fear of long-term side effects. All of these issues must be addressed. Shared decision making is more than just a buzzword — it is critical for a successful outcome.

Tools

Allergy & Asthma Network works with the American College of Allergy, Asthma & Immunology and the American College of Chest Physicians to develop tools that improve dialogue between health care professionals and patients. Some examples include the Asthma Control Quiz (http://asthma.chestnet.org/asthma-control-quiz), which helps patients correctly assess symptom control; the Asthma Severity Assessment Tool (http://asthma.chestnet.org/asthma-control-severity-assessment-tool), which helps patients and caregivers identify markers of severe asthma; and the soon-to-be-available Shared Decision Making Tool (http://asthma.chestnet.org), which clearly outlines treatment options and allows patients

to evaluate their own goals and limitations.

Bringing practitioners and patients together with meaningful tools can maximize health outcomes for patients who struggle with asthma. Working together can provide better care and, moving forward, save lives. ■

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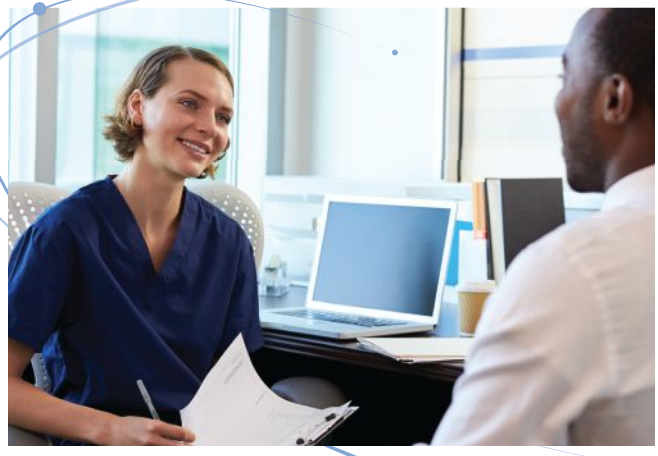

This Is What Fuels My Passion for the Profession

AARC members share the things that keep them engaged in respiratory care.

by Debbie Bunch

Respiratory therapists are among the heroes of health care, often working long hours with little recognition, helping patients who are struggling to breathe. What keeps them on the job? We asked five AARC members to tell us what fuels their passion for the profession.

How About a Round of Applause?

Nikki Barrett, BSRT, RRT, always thought she'd be a nurse. Her mom was a nurse and inspired her to want to help people just like she did. A long waiting list for the nursing program at her community college, coupled with a well-placed poster for the respiratory care program, however, changed her career direction, and she's glad it did.

"I can remember looking at a poster about respiratory therapy and asking someone who was standing beside me, 'What is a respiratory therapist?'" recalls the respiratory care manager at Wake Forest Baptist Medical Center in Winston-Salem, NC. The woman happened to be an RT student in her last semester and she filled Barrett in on the profession. "I was sold," says the AARC member.

Life-long learning

Barrett graduated from the Sandhills Community College program in 1999 and then earned her BSRT from the University of North Carolina–Charlotte in 2014. This spring she will complete the course work for her MBA in health care management at Liberty University. "Although I have been a therapist for 18 and a half years, there is always something new to learn," she says. "I know, because I continue to learn something new each and every day."

Her current job as manager at Wake Forest Baptist keeps her busy solving all the typical problems faced by RT departments, and she also works with the hospital's on-boarding program and software modifications for electronic health records. "As a manager, I have gone from practicing the art of respiratory care for the critically ill to ensuring quality respiratory care is provided by our therapists in an effective manner," says Barrett. "I have always been in love with

a new challenge, and that is what this position has allowed for me."

When it comes to fueling her passion for the profession, though, it was an experience she had while still working at the bedside that stands out in her mind.

Give it up for Nikki Barrett!

"A few years ago I took care of a patient who came in with marked shortness of breath and increased work of breathing," explains Barrett. "He was not yet intubated, but working so hard to breathe and ordered on Q4 Duonebs." The Duonebs helped, but the man was still being considered for intubation.

Nikki Barrett was honored with a Professional Excellence Award in 2015.

Barrett was working with a nurse practitioner on that shift and approached her about adding a Q4PRN albuterol order to the patient's plan of care. The nurse practitioner agreed, and Barrett spent the rest of the shift making sure he got what he needed when he needed it. "I set a timer at my station and stayed on top of administering the nebulizer therapies on a Q2 regimen," she says. "By morning, the patient was sleeping peacefully and breathing comfortably."

As she got ready to leave, she heard someone call her name. She turned to see the nurse practitioner giving handoff to one of the hospital's pulmonary physicians. Before she knew what was happening, the physician looked right at her and started clapping his hands. "Job well done," was all he said, but that was enough for Barrett.

"Talk about putting a smile on someone's face," she says. "It was unexpected and I will never forget it. I fell in love with respiratory care even more. I love what I do!" ■

▶ In Honor of Her Daughter

Having kids changes your life, and that was true on a big-time basis for Karla Provost, BSRT, RRT, AE-C. After her first child was born with respiratory complications, she quickly became acquainted with the profession of respiratory care and how to treat respiratory distress in a very small person.

"Those RTs taught me how recognize and treat her symptoms at home," says Provost, who serves as manager of pulmonary medicine and medical critical care at Essentia Health in Duluth, MN. "It was after that experience that I realized my passion and interest for treating respiratory illnesses and completed my degree."

Karla Provost poses with a pair of mega lungs set up for a Cancer Research in Your Community event.

Plethora of responsibilities

Her job comes with a long list of responsibilities, all of which keep her fully engaged with the profession and everything that goes with it. In addition to the day-in, day-out tasks involved in managing two departments, she has gotten involved in everything from ARDS research and grant writing to community health education. "What I like most about my job is the opportunity to work with the most talented team of providers, nurses, and therapists in the world," says Provost.

She thrives on all the changes taking place in health care as well and believes they keep her in a learning and creative mode. One role she particularly relishes is going out to local nursing homes to educate clinicians there on ways to help patients avoid inpatient admissions. "My goal with this is to empower the staff to recognize early signs and symptoms of respiratory illness so that treatment can be implemented quickly to avoid a hospital admission and/or readmission," says the AARC member.

Bringing new treatments to patients at her hospital is a top passion booster, too. That was in full view back in 2013

when she was asked by physician leadership to develop a bronchial thermoplasty program at Essentia Health. The first case was performed a year later, and she was proud to be a part of it.

Remarkable recovery

One particular patient continues to remind her why she does what she does. "She was diagnosed with asthma at age five, and when I met her at 21, her asthma had been severe and limiting her daily life for many years," says Provost. "After she completed bronchial thermoplasty treatments, she remains nearly symptom free, ran her first 5K, and always stops in to say hi to the treatment team."

Seeing that remarkable turnaround and others like it gives her the boost she needs to stay engaged. "She inspires me to keep learning and educating patients and the community on lung health," says Provost. ■

▶ A Go-To RT for PR Patients

Stacey Blank, BTPS, RRT, has worked with all kinds of patients over her nearly 35-year career in respiratory care, but she says her current role as pulmonary rehabilitation coordinator for Western Maryland Health System in Cumberland may be the best job she's ever had.

Stacey Blank loves helping her pulmonary rehabilitation patients breathe better.

She has their back

"I work with chronically ill, debilitated patients who need help with all aspects of their lives," says the AARC member. "We become their educators, therapists, resources, and friends." She says her patients look to her for acceptance, guidance, and trust, and she loves being the person they turn to when the going gets tough. "They need someone to listen — someone who has their back," says Blank.

For some of those patients, pulmonary rehab ends up being life-changing, allowing them to return to the activities they once thought they'd never be able to do again. For others, it eases the transition to come. Says Blank, "We are charged with making the life they have left more comfortable and tolerable, helping them to live the best quality of life they have. And when it comes time, we have those discussions with them that others are uncomfortable with because again, they've come to rely on us to be honest and caring with them, no matter what."

Her commitment to continuing her education has made a difference. A graduate of Allegany Community College, Blank got into respiratory care on the advice of her mother, who was a nurse but saw much promise in the relatively new profession of respiratory care back in the early 1980s. She went back to school to earn her bachelor's degree from Towson University in 2015, graduating with honors, and now she is taking classes at Jefferson University, with a focus on population health.

It all helps her make sure that her pulmonary rehab patients have access to the latest thinking on how to live with their chronic respiratory conditions. "A respiratory therapist is indeed a multidisciplinary team member whose contribution and knowledge cannot be replaced by any other clinical professional," Blank emphasizes. "That fact has fueled my goal of lifelong learning and service to my patients."

No regrets

Blank also shares her passion for respiratory care with her community at large, serving as president of the Maryland Association of Cardiovascular and Pulmonary Rehabilitation and as the key author for the COPD Foundation's Harmonicas for Health Pulmonary Education Program. She also gets a boost by attending both the annual American Association of Cardiovascular and Pulmonary Rehabilitation conference and AARC Congress whenever she can, and she says the educational opportunities she finds there are truly amazing.

Blank has witnessed a lot of change over her 35 years in the respiratory care profession, and it's all combined to convince her that there are so many more people out there who could benefit from her expertise. She says she loves what she does and the lives she gets to touch every day, noting, "My life has been touched by the career path I chose all those years ago. I wouldn't have changed a thing!" ■

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AARC
American Association for Respiratory Care

Eula Lewis, left, discusses a patient with fellow therapist Ingrid Barnoski, BS, RRT.

A Well-Lived Life

After being laid off from her job as a branch manager of a bank in 1992, Eula Lewis, BS, RRT, AE-C, CTTS, considered two paths: she was going to pursue a career in either law enforcement or health care. "As a single mother, I knew I needed a steady income and I did not want to encounter being laid off again," says the outpatient clinic coordinator for respiratory care services at Zuckerberg San Francisco General Hospital in San Francisco, CA. Her sister, a neonatal ICU nurse, suggested respiratory care.

Lewis enrolled in the program at Skyline College in San Bruno and is happy she did. Today, she holds the Certified Tobacco Treatment Specialist credential and is blazing new paths through her work in the Chest Clinic at her hospital and four others: Asthma/COPD, Allergy, RCS, and Sleep. She also serves as the program director of a grant-funded spirometry program that provides community clinics where she teaches people how to use spirometers. The program is called San Francisco Community Primary Care Spirometry, and training was provided by Spirometer 360, developed by the University of Washington. Lewis works with a medical director and nurse to train clinic staff and also reviews the tests for acceptability and reproducibility. It frees up the hospital pulmonary function lab so it can focus on more complex testing, and it's led to some exciting new opportunities for Lewis. "This program has allowed me to work on a couple of research projects, and I had the opportunity to travel to Uganda in January 2017 to train a research nurse in spirometry," says the AARC member.

Patients first

Lewis says her favorite parts of her job, though, are focused squarely on her patients. "The two things I love the most about my job are helping my patients with self-management skills and talking with them," says Lewis. "We are a county hospital, so many of our patients are from the underserved population. Many suffer from low literacy and low health literacy, and they find it difficult to use their inhalers properly." She notes that they often don't know when to seek medical attention or how to prevent exacerbations.

Lewis and her colleagues spend the time it takes to overcome these limitations and are always willing to lend an ear to the problems their patients are having with life in general as well. They often learn some interesting things along the way. "Some are just lonely and need someone to listen," says Lewis. "Many have very interesting stories to share."

One activity that is especially close to her heart is the monthly Better Breathers Club she co-facilitates, and she has also taken her expertise on a mission trip to Haiti to teach women about lung health. "For me, being a respiratory therapist is more than a job — it is a lifestyle and involves taking every opportunity to promote the field," says Lewis.

A new man

Lewis recalls one patient in particular whom she believes exemplifies that philosophy. "One of our many success stories is a patient with a diagnosis of bronchiectasis," she explains. "He was having recurring *Pseudomonas* infections with frequent hospitalizations."

After one hospitalization a few years ago, the Chinese-speaking gentleman spent about nine months in the hospital's skilled nursing facility ward before being discharged home with instructions to be seen in the clinic on a weekly basis. His care plan was complicated, to say the least. In addition to being on oxygen, he was taking inhaled antibiotics, was on a number of other inhalers, and was also prescribed mucus-clearance devices. The RTs on the team created a weekly individualized medication sticker plan for him that included pictures of all of his medications and when to take them. One of the therapists was able to translate instructions into Chinese.

"Each week, we would review the prior week's sticker plan and provide him with a new one," says Lewis. "We also would do mucus clearance with the MetaNeb device. It was a joint effort between the pulmonologist and the RCPs to assist this patient with improving his lung function and quality of life." Slowly but surely, improvements did indeed take place. The man was taken off the inhaled tobramycin, and the last time they saw him in the clinic he was off the oxygen as well.

"He looks like a different person than he was two years ago, when we first saw him," says Lewis. For her, patients like this one always bring to mind a song by legendary gospel singer Mahalia Jackson: "If I can help somebody, as I travel along… No, my living shall not be in vain." ■

Leap of Faith Pays Off

Denita Landsaw, BSCSM, RRT, RRT-NPS, AE-C, got into respiratory care after seven years of service in the U.S. Army. She knew she wanted to do something in the health care field, and she loved the fact that respiratory therapists are on the front lines. She soon joined the staff at Children's Health in Dallas, TX, and enjoyed working with patients and their families at the bedside.

A few years ago, she decided to take a leap of faith and help Children's Health launch a home medical equipment department within the home health division. "I started our HME/DME side from the ground up with absolutely zero home-care experience," says Landsaw. "My HME department is the most diverse department within the organization. I currently have three RRTs, one registered dietitian, two bio med techs, six equipment techs, and two HME schedulers. This has been an especially challenging but also very rewarding decision."

Denita Landsaw ensures children who go home on medical technology have the equipment and services they need to thrive.

Continuum of care

The job lets Landsaw make a huge impact on children going home on medical technology. In her position as HME manager, she assists with the planning, development, and direction of capital expenditures, developing and carrying out business objectives, and meeting departmental goals and strategies. She also works side by side with the operations/intake team to help build strong relationships with referral sources and physicians. As such, she collaborates with the supply chain to ensure the necessary inventory of equipment and supplies is on hand to meet patient needs and to ensure compliance with regulatory guidelines and requirements.

"What I like most about my position is being able to directly participate in our patient's continuum of care from the hospital to the home," she says. The company delivers equipment directly to the hospital so that families can "room in" and learn on the respiratory devices that are planned for home use.

HME respiratory therapists also assist the family with discharge planning and then go out to the patient's home to review set up and function of the equipment and home safety guidelines. Families are eligible to receive clinical respiratory services on a weekly basis, should they be in need of additional equipment or disease management services.

She found her niche

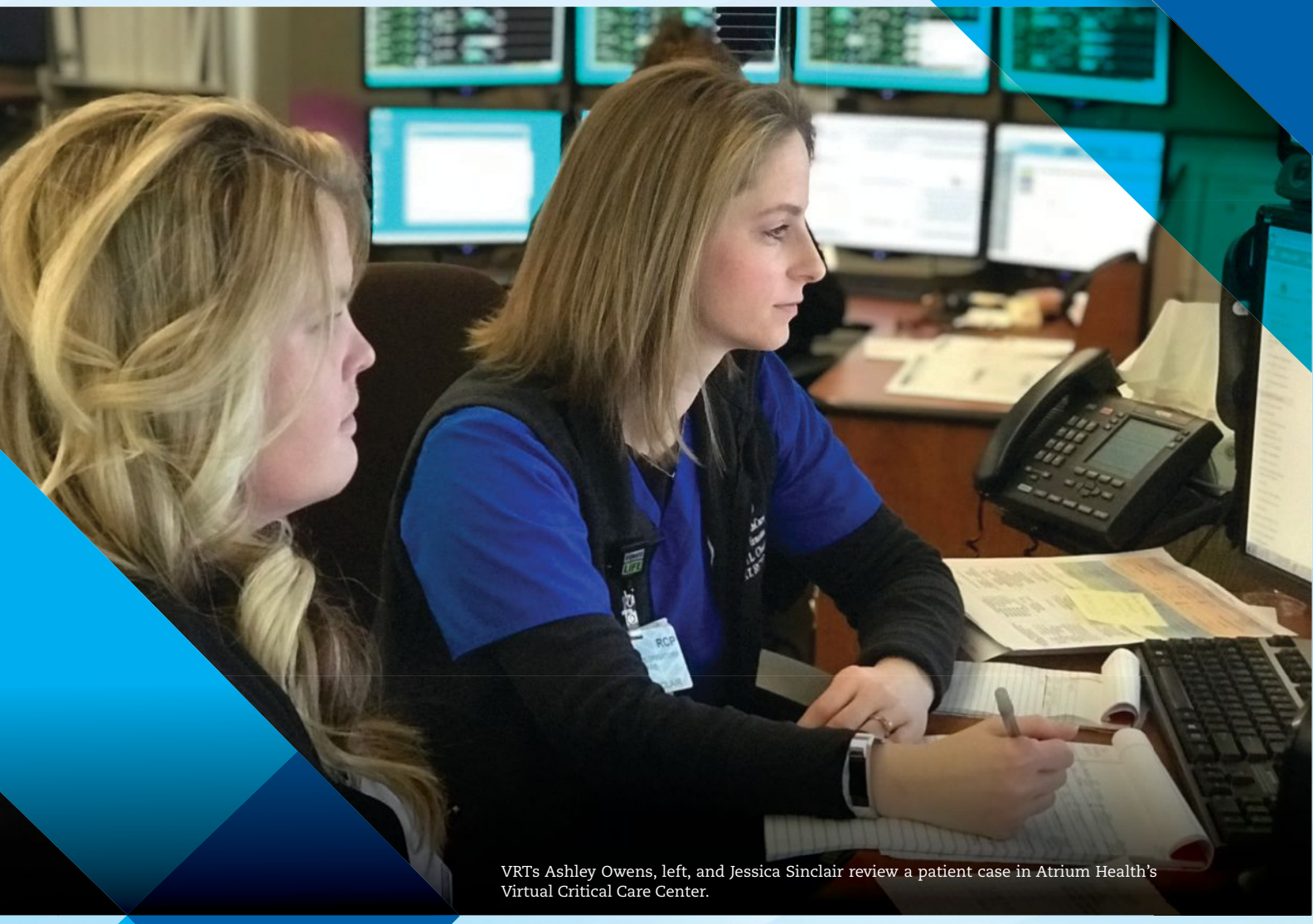
When Landsaw reflects back on the journey she took from inpatient care to the HME side, she is amazed at how little she and her colleagues really knew about home care, but finding out has been worth the effort. So many families — particularly those with children who require mechanical ventilation — are terrified of taking their kids home. The support and training they receive from the HME team helps relieve that burden.

The fact that the RTs whom the families see at home started out with them in the hospital is invaluable, too. "One of the most rewarding aspects of this role is that our RTs often get to provide services to families whom they have previously treated as inpatients," she says. She calls it a triple win because the organization, the clinician, and the patient all benefit from these prior relationships.

Landsaw has found her niche in the HME side of pediatric care, and she believes more therapists will be joining her in the future. "Due to all the recent cutbacks and the current 'uncertainty' in health care, we continue to see a greater need and emphasis placed on efficiency of care and keeping our patients out of the hospital," she says. "Many hospitals now depend on delivering a big portion of the patient's care at home."

She believes RTs have what it takes to act as each patient's advocate throughout the discharge planning and home-care process, saying, "RTs are in a perfect position to help patients and families adjust well in their home environment." ■

Editor's Note: This article came to fruition after author Debbie Bunch searched AARConnect for members who would be willing to talk about the things that keep them engaged in their profession. We thank the people who agreed to be interviewed and sent pictures to accompany the article. We are always looking for stories like this, so if you have ideas for such a story, please contact us at cathcart@aarc.org.



VRTs Ashley Owens, left, and Jessica Sinclair review a patient case in Atrium Health's Virtual Critical Care Center.

From RRT to VRT

Virtual respiratory therapists are blazing new trails in the Carolinas

by Debbie Bunch

Atrium Health — previously known as Carolinas HealthCare — is a multi-hospital system headquartered in Charlotte, NC. The system boasts more than 900 health care locations, including academic medical centers, hospitals, freestanding emergency departments, and nursing homes. All told, Atrium operates more than 7,600 licensed beds, employs nearly 60,000 people, and engages in approximately 12 million patient interactions every year.

Ensuring high-quality care throughout this diverse health care ecosystem requires a willingness to adapt to changing times and technology. One bold new initiative that got underway shortly after the first of the year is utilizing respiratory therapists to deliver critical care services through telehealth.

It started with the A-F bundle

The initiative grew out of Atrium's mission to implement the ABDCEF bundle (A-F bundle) in all of its facilities. "Atrium Health is committed to improving outcomes for critically ill patients and their families," explains AARC member Natasha Tyson, MHA, RRT, director of the company's Central Division. "A significant focus of this work has been around creating a multidisciplinary team approach to decreasing a patient's number of ventilator days and overall ICU length of stay."

The "ABCDEF" in the A-F bundle stands for "Assess, Prevent and Manage Pain; Both Spontaneous Awakening Trials and Spontaneous Breathing Trials; Choice of Analgesia and Sedation; Delirium: Assess, Prevent and Manage; Early Mobility and Exercise; and Family Engagement and Empowerment." The strategy has been studied extensively over the past 15 years as a method of eliminating the ICU delirium, cognitive dysfunction, and physical weakness that so often result from an ICU stay.

In partnership with the Society of Critical Care Medicine's ICU Liberation Campaign, respiratory leadership joined forces with Atrium's Critical Care Network, providers, nurses, and interdisciplinary colleagues to implement the bundle across primary enterprise facilities.

"The A-F bundle work underscored the need to standardize respiratory therapy's clinical practice as well as spread RT expertise in managing critically ill patients across the system," says Myra Stearns, MHA, RRT, RRT-RPFT, assistant vice president of respiratory services and also an AARC member.

Because the organization already had a Virtual Critical Care (VCC) team in place, it only seemed natural to put RTs to work in that setting, too.

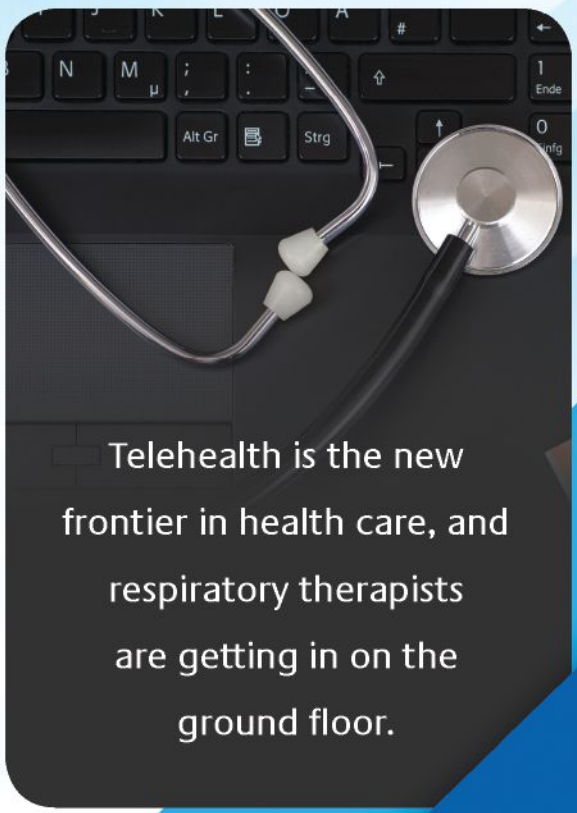
Two pilot programs set the stage

The project began in October 2016 when two respiratory therapists were dedicated to an eight-week pilot project to identify ways in which respiratory therapy could interface with the VCC team. Data collected by the group ranged from compliance with spontaneous breathing trials (SBT) to ideal body weight settings and overall standards of care. The group identified a number of opportunities to provide virtual support to bedside therapists at outlying hospitals who were charged with performing several high-risk, low-volume procedures.

"Findings from this initial pilot were presented to our system-level Critical Care Network leaders, respiratory therapy medical directors, and medical directors and operational leaders from the Virtual Critical Care team," says Tyson. The team wanted to know how a virtual respiratory therapist (VRT) could impact the care of critically ill patients in remote settings, so a second pilot was requested to find out. The second eight-week trial began in June 2017, and this time two RTs were placed in the VCC center and given full access to the VCC team and all of its tools.

The two RTs spent four weeks on the day shift and four weeks on the night shift, offering VCC services to a 30-bed ICU and an 18-bed ICU in two separate facilities within the Atrium system. "The RTs focused on providing support on A-F bundle elements, advanced ventilator modalities, and high-risk, low-volume procedures to the bedside critical care team," says Stearns. "The leadership team met weekly to review outcomes and overall progress of the pilot."

Following completion of the second pilot, respiratory leadership met with the VCC medical directors and operational leaders to hash out the effectiveness of the VRTs and come up with a way forward. The result was a formal proposal to place a VRT in the VCC for 12 hours a day, every day of the week. The proposal was approved, and the Virtual Respiratory Therapy program officially began in February of this year.



Close collaboration with RNs

Respiratory leadership selected Jessica Sinclair, BSRT, RRT, and Ashley Owens, BSRT, RRT, to help launch the VRT Program. The two AARC members were trained to work in the VCC by experienced staff nurses. Because there was no precedent for the training, the RTs and nurses worked together to ensure the therapists would be up to speed on workflow, provider and bedside communication, and the computer programs. The roles and responsibilities to be carried out by the VRTs were developed by respiratory leadership in partnership with the VCC medical directors and operational leaders, Program Coordinator Sandy Arneson, BSN, RN, CCRN, and Nurse Manager Marie Mercier, MSN, APRN, AGCNS-BC.

The VCC is funding the two new positions. Funding was accomplished by reassigning the RT clinical specialist positions to the VRT role. "The VRTs maintain a direct reporting relationship to respiratory therapy leaders but also have a 'dotted line' reporting structure to VCC nursing leadership," says Arneson. "This structure allows the VRTs to have multiple sources of support."

Mercier notes the VRTs also completed site visits to all of the ICUs in the health care system. The site visits gave them the chance to learn about the current practices and protocols in each unit, build relationships with the bedside teams, and become acquainted with the individual culture in each one.

"The workflows were initially trialed in a mock setting, revised, and then implemented during a 'soft go-live' phase," says Mercier. She explains that revisions to workflow and communication processes are continually assessed and improvements made as needed.

This is how it works

Training of the VRTs began in early January, with the soft go-live phase following two weeks later. The program officially launched on February 5 with seven facilities, with plans to add more facilities and additional VRTs to the service this spring.

How does all this play out in real time? Jessica Sinclair explains. "ICU patients are identified by the VCC RNs based on criteria outlined by VRTs and MDs," she says. "These patients are then placed on an electronic communication board for the VRT to review and suggest interventions when deemed appropriate."

She and Owens review the electronic health records for these patients, help to evaluate their needs, and suggest changes to their care plans. Their key objectives are to optimize ventilator management so patients will have successful SBTs, work through any barriers to SBTs, and ensure protocols are being followed. They also assist clinicians at the remote site in initiating new therapies and evaluating current therapies for their effectiveness.

They are called in during emergency situations as well. "During code events, VRTs serve as an additional resource for suggestions on initial mechanical ventilation settings as well as airway management during and after the event when needed," says Owens. "VRTs are also available to handle bedside staffs' requests via phone calls or the electronic alertbutton in the patient's room."

Patients assigned to care from the VRTs run the gamut from those with asthma and COPD to those suffering from sepsis, pneumonia, ARDS, and influenza. Postsurgical and trauma patients are included as well. Modalities vary widely. VRTs may care for patients with anything from a nasal cannula to advanced modes of ventilation such as extracorporeal membrane oxygenation. They are called in to assist with new ventilators, increasing ventilation needs, failed SBTs, continuous BiPAP, advanced ventilator modes, or issues with managing heliox, nitric oxide, proning, and high-frequency oscillatory ventilation.

These therapists serve as mentors for newly graduated RTs working in the critical care setting in these remote hospitals as well. "This is very important to our team," says Sinclair. "It is a great way to augment traditional educational opportunities offered within specific facilities throughout Atrium Health."

Paving the way

Tyson notes "it took a village" for RTs at Atrium to implement this VRT program. "Support from the bedside caregivers, administration, physicians, respiratory, and nursing is crucial to the success of an initiative like this," she says. Getting everyone on board took time and effort, but now that the program is up and running she believes all the hard work that went into it is paying off.

"VCC MDs and RNs have found the VRTs to be a welcome addition to the team and significant contributors in the management of ventilated and non-ventilated patients," she says. "Respiratory leaders throughout the system have fully embraced the program and are working closely with VRTs to set up the program for success."

Stearns agrees. "The interactions between VRTs and bedside RTs have been positive, with comments of thankfulness for the added layer of support and knowledge."

Can other RT departments do, it too? Sure, say these RT leaders, but they warn roadblocks may occur. The elephant in the room for most will be cost. "Atrium Health used the technology and support from its five-year-old Virtual Critical Care Unit as a platform for this initiative," notes Tyson. Many hospitals aren't that far along in the world of telehealth — though certainly that will change as time goes by — so for many RT departments this type of a program is a few years away.

Tyson and Stearns emphasize departments that do want to pursue the idea should make sure the foundations for acceptance are in place, clearly identify areas where the addition of a VRT can improve care, address staffing concerns, ensure metrics will be followed, and have a solid understanding of the financial impact. They will also need highly motivated, highly adaptable, and highly knowledgeable RTs to take on the VRT role.

Those are some big hurdles to jump, but as telehealth gains momentum throughout the health care arena, it is nice to know there are folks such as those at Atrium Health who are paving the way. Says Stearns, "Our team believes that telehealth is a great opportunity for the respiratory therapist." ■

Respiratory Therapists as Telehealth Practitioners: It's in Your Future

by Anne Marie Hummel, AARC Associate Executive Director of Government Affairs

You've read the encouraging news of respiratory therapists being part of a virtual respiratory therapy program focused on management of ventilated patients in the ICU. As we at the AARC hear more about RTs involved in telehealth programs, we hope to focus on success stories in *AARC Times* as part of our advocacy for RTs becoming telehealth practitioners.

Gaining support for RTs to become telehealth practitioners as part of the Medicare program has been a goal of the AARC for the past few years. For our Advocacy Day on Capitol Hill, we are excited about a new opportunity to gain pilot telehealth legislation that would focus solely on RTs.

At the end of last year, there were three telehealth bills that included RTs in addition to outpatient therapists, audiologists, and diabetes educators as telehealth practitioners. They are H.R. 2550, the Medicare Telehealth Parity Act; H.R. 2291, the HEART (Helping Expand Access to Rural Telemedicine) Act; and H.R. 766, Telehealth for Individuals Residing in Public Housing. Although we continue to support these bills, we have learned in our talks with key telehealth proponents on Capitol Hill that the committees of jurisdiction are focusing on telehealth provisions that are narrow in scope with a lower price tag. If the Congressional Budget Office scores a bill with a high cost, it usually means it will not advance through the legislative process.

We are proposing a three-year pilot that would provide information on both the health impact and the costs associated with allowing respiratory therapists to provide disease management services via telehealth to Medicare beneficiaries with COPD. The services would include self-management education and training, demonstration and evaluation of inhaler techniques, smoking cessation counseling, and remote patient monitoring.

Because Medicare tracks COPD hospital readmissions, we are limiting a patient's diagnosis to COPD based on the latest GOLD (Gold Initiative for Chronic Obstructive Lung Disease) Guidelines. Consistent with AARC's goal of moving the profession forward, RTs who are RRTs with a BS degree or higher would be qualified to furnish the services. As for billing, the physician would still be the one to bill Medicare, but we expect the Centers for Medicare and Medicaid Services to create a modifier that would be appended to the claim to identify the respiratory therapist as the professional providing the service. We are trying to keep the pilot as narrowly focused as possible to gain support while at the same time offering a bill that highlights the strengths and skills of respiratory therapists.

Studies show that telehealth services and other interventions for patients with chronic lung disease are beneficial and can reduce costly acute care interventions. Studies involving RTs also show that patients can improve their health status through self-management education and early detection and treatment of exacerbations. Obtaining Medicare data through our pilot will be the icing on the cake!

This is an exciting time, as the recognition of RTs by congressional leaders continues to gain momentum. It is especially encouraging to seek support for a bill that focuses solely on RTs. ■

— 2018 —

Since 1947, the AARC has been leading the effort to advance the science and practices of the respiratory care profession while promoting the highest quality of care for our patients. Collaborating with the respiratory communities at-large, we have successfully advocated at the federal, state and local level for patients, their families, the community, the profession and the respiratory therapist.

The AARC'S CORPORATE PARTNERS

The collaborative efforts between the respiratory care profession and manufacturers in pursuing unique and innovative ways to improve both the quality and outcomes of our patients makes us natural partners in today's ever changing health care continuum.

As health care finances become more strained and patient care becomes increasingly more complex, the mutual challenges become greater for the profession and its industry partners. The inherent synergies of the corporate partner concept are to provide an effective and efficient way to address those needs utilizing our combined skills and resources.

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Industry Watch

Positive results for chronic care management program

The Center for Medicare and Medicaid Innovation (CMMI) has released a new study showing that its chronic care management (CCM) program is associated with lower growth in Medicare costs, an enhanced ability to connect patients with community-based resources, and a greater chance of keeping patients out of the hospital. CCM was launched by the Center for Medicare and Medicaid in 2015. The initiative created a new Medicare benefit to support beneficiaries with two or more chronic conditions by providing new "in-between visit" revenue to participating providers, stimulating practices to enhance their focus on goal-directed, person-centered care planning, and provide aging-in-place resources, such as proactive care management.

InDevR expands influenza test kit capabilities for pandemics

InDevR has expanded its VaxArray® product portfolio with a new reagent kit to address the need for speed in combating flu viruses with pandemic potential. The VaxArray Influenza Pandemic Hemagglutinin potency test kit is now available for flu vaccines containing H5, H7, and H9 flu subtypes, including new H7 vaccines against the deadly avian H7N9 virus. This new potency assay enables rapid determination of immunogenic hemagglutinin in low-dose and adjuvanted flu vaccines. The work was sponsored as part of the U.S. Department of Health and Human Services' inter-agency influenza vaccine improvement initiative.

VoCare launches mobile multi-diagnostic device

VoCare, Inc., has developed a professional-grade mobile medical diagnostic device capable of collecting blood glucose, blood pressure, pulse, oximetry, temperature, and electrocardiography measurements. The Vitals360 device is equipped with WiFi, Bluetooth, and 4G LTE for data transmission, without the need for separate peripherals or an external hub. The size of a cell phone, the device can be used for both point-of-care and remote patient monitoring of patients with multiple chronic conditions such as diabetes, congestive heart failure, chronic obstructive pulmonary disease, and hypertension.

GSK presents flu vaccine data to CDC

In a presentation made at the U.S. Centers for Disease Control's Advisory Committee on Immunization Practices meeting earlier this year, GlaxoSmithKline reported that FLUARIX® QUADRIVALENT demonstrated 63.2% efficacy against moderate to severe influenza and 49.8% efficacy against influenza of any severity in children 6–35 months of age. The results are based on a randomized, observer-blind, non-influenza vaccine-controlled trial that enrolled 12,018 children in five independent cohorts in 13 countries.

FLUARIX® QUADRIVALENT was first approved in 2012 in the United States for the prevention of influenza disease in people three years of age and older. In 2018, the indication was expanded to children six months and older.

Langone Health adds lung transplant program

The Transplant Institute at NYU Langone Health has launched a new lung transplant program, the third specialized care program in the greater New York City area. The program will provide individualized treatment for patients in need of a transplant with a multidisciplinary team of transplant pulmonologists and surgeons, along with nurse coordinators, social workers, dietitians, pulmonary rehabilitation staff, and other specialists to provide comprehensive care and support.

Theravance submits study data on Trelegy Ellipta

Theravance Biopharma, Inc., has submitted IMPACT study data to the European Medicines Agency as part of a type II variation to support an expanded label for Trelegy Ellipta in Europe for the maintenance treatment of moderate to severe COPD. Trelegy

Ellipta is a triple-combination therapy of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA® inhaler to be taken once a day. The latest filing in Europe follows submission of a supplemental New Drug Application to the U.S. Food and Drug Administration, which is currently under review. In the IMPACT study, Trelegy Ellipta showed superiority to several other treatments for COPD on a range of clinically important endpoints, including reducing the number of exacerbations and improving lung function and quality of life.

FDA approval for lung cancer drug IMFINZI

According to AstraZeneca and MedImmune, the FDA has approved IMFINZI® (durvalumab) for the treatment of patients with unresectable stage III non-small cell lung cancer whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. The approval is based on the positive progression-free survival (PFS) data from the phase III PACIFIC trial in which IMFINZI demonstrated an improvement in median PFS of 11.2 months compared to placebo, representing a 48% reduction in relative risk of progression or death versus placebo in all patients, regardless of PD-L1 status. Detailed interim results of the PACIFIC trial were recently published online in the *New England Journal of Medicine.*

Single-dose escalation phase begins for Pulmazole study

Pulmatrix, Inc., has begun the single-dose escalation phase of the first-in-human study for Pulmazole, an inhaled iSPERSE™ formulation of the anti-fungal drug itraconazole for the treatment of allergic bronchopulmonary aspergillosis in patients with asthma. Chief Medical Officer Jim Roach, MD, noted this represents a major milestone for the program.

Propeller Health receives ISO certification

Propeller Health has received the International Organization for Standardization (ISO) 13485:2016 certification for medical device quality-management systems. Its FDA-cleared medical devices include sensors that attach to inhalers, along with mobile apps powered by an analytics platform, aimed at helping patients better manage their asthma and COPD symptoms. Providers use the platform's clinician tools to help improve care and treatment, as well as strengthen their relationship with patients.

Study finds good results for Hill-Rom's MetaNeb® System

Researchers presenting at the recent Society of Critical Care Medicine Annual Congress report that aggressive treatment after surgery using the Hill-Rom MetaNeb® System may reduce the incidence of postoperative pulmonary complications (PPCs) in high-risk surgical patients. According to the company, the MetaNeb System combines lung expansion, secretion clearance, and aerosol delivery into a single, efficient therapy. The study found that use of the MetaNeb System helps reduce PPCs, as well as reduces the time a patient has to spend on a ventilator. They also note that it promotes a decreased length of stay in the hospital.

Getinge receives FDA 510(k) clearance for its monitoring system

According to Getinge, the FDA has granted 510(k) clearance to its PulsioFlex Monitoring System and PiCCO Module. The PulsioFlex Monitoring System, from Getinge's Maquet brand, is a diagnostic aid used to measure and monitor blood pressure and cardiopulmonary, circulatory, and organ function variables in ICU patients. The accompanying PiCCO Module is used for hemodynamic management of critically ill patients and provides cardiac output measurement continuously based on pulse contour analysis, and intermittently through the transpulmonary thermodilution technique.

Prometic Life Sciences zeros in on IPF

Prometic Life Sciences, Inc., is making idiopathic pulmonary fibrosis (IPF) the top priority for its PBI-4050 clinical development program. "IPF remains to this day a significant unmet medical need affecting hundreds of thousands of patients," explained Prometic President and CEO Pierre Laurin. "The clinical efficacy demonstrated so far in multiple phase II clinical trials combined with an impressive safety and tolerability profile gives us great confidence in PBI-4050's ability to efficiently address fibrotic diseases." ■

Brief submissions and photos for this column may be sent to *AARC Times* Editor Marsha Cathcart at cathcart@aarc.org.

Industry Update

Featuring information on products and equipment from manufacturers

RC Currents

IN THE NEWS

Plant the Seed for Future Growth — Time To Volunteer!

by AARC President-Elect Karen Schell

In preparing for my first term as AARC president next year, I realize it is important to receive assistance from my colleagues to achieve everything the AARC and the patients we care for expect. I am asking you as AARC members to volunteer your time and expertise to our professional organization.

Having respiratory therapist volunteers not only facilitates our growth as a profession and association but also presents you with the opportunity to develop and advance leadership skills, increase professional contacts, give back to the profession and the patients we serve. Volunteers have always been the heart of the AARC and its leadership. Our strength and advancement comes from the countless hours of support volunteers provide through their time and knowledge.

Many members like you need and use the professional tools the AARC provides. Why not get in on the ground floor and collaborate with your fellow RTs to develop new tools?

For the important work of the AARC to be accomplished, we need you to volunteer your expertise, skills, and time to work on various committees and projects. Although our Association has a staff to do a lot of the work, it really is members like you who volunteer that are the backbone of this profession.

There is enormous momentum and potential for our profession right now. No one individual can accomplish everything we need to do, but I know that dedicated RTs supporting the AARC's efforts can make vast strides in assuring quality patient care and securing the RT's rightful place in our changing health care system.

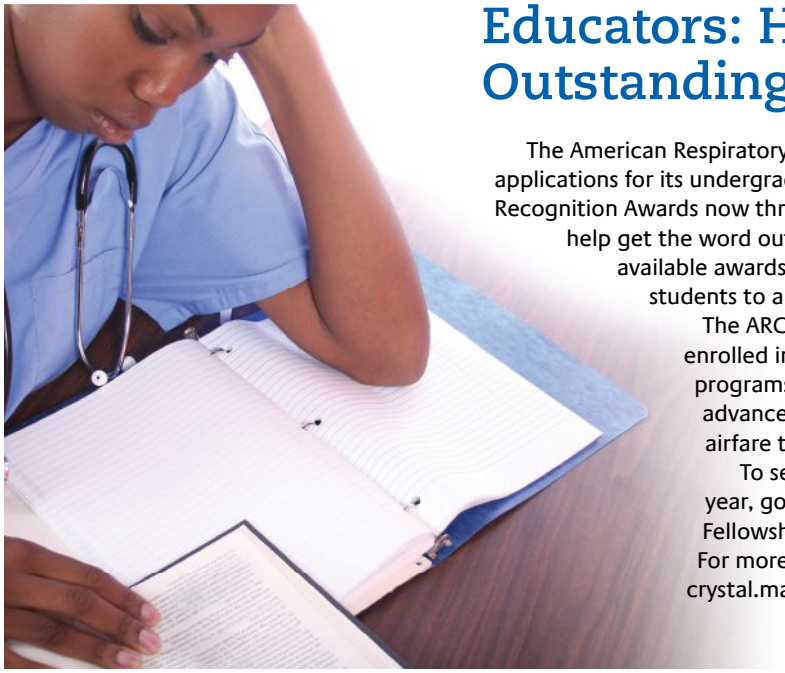
We need everyone's input to work together with purpose. With the increasing responsibilities RTs have, we count on you to help us identify and meet the educational and informational needs of our members.

This is your Association, and now is the time to volunteer. We are looking for a balance of experienced and new members to sustain the AARC as the vital professional organization it always has been. By mentoring new talent, we can ensure the future of the respiratory therapist in the changing health care environment.

Please consider this a friendly challenge. Think about how you can help your association, the profession, and the patients we serve. Take time now to network with your fellow AARC members whom you believe could contribute special talents or services to the AARC. Encourage them to volunteer.

You can write to me at the AARC Executive Office: 9425 N. MacArthur Blvd., Suite 100, Irving, TX 75063; or send an email to kuykendall@aarc.org. Tell me how you would like to serve, and provide a copy of your résumé so I can consider how to best put your talents to work for our Association.

I am confident we will continue to reach milestones in the profession if we all work together. Thank you for supporting the AARC. I look forward to working with you and seeing the profession grow together! ■



Educators: Help Recognize Outstanding Students

The American Respiratory Care Foundation (ARCF) is accepting applications for its undergraduate and postgraduate Education Recognition Awards now through **June 1** and is asking RC educators to help get the word out to their students. So check out the list of available awards and then encourage your best and brightest students to apply.

The ARCF offers awards to students who are currently enrolled in accredited respiratory care educational programs and to respiratory therapists pursuing advanced degrees. Awards include registration and airfare to attend the AARC Congress in 2018.

To see all the awards bestowed by the ARCF every year, go to the Foundation's Grants, Awards, and Fellowships page at www.arcfoundation.org/awards. For more information, contact Crystal Maldonado at crystal.maldonado@aarc.org. ■

Transitions

In the lives of AARC members

William "Rick" Sells, MBA, RRT, passed away earlier this year after a long battle with cancer. He entered the profession in 1969 and joined the AARC a year later. He spent the majority of his career at Wake Forest Baptist Health, in Winston-Salem, NC, where he served as director of the RT department from 1976 to 2011. During his tenure he developed the cardiopulmonary rehabilitation program, the ECMO program, and the shared governance model. He was an active member of the North Carolina Society for Respiratory Care (NCSRC) and served in multiple capacities, including as president in 1995–1996. He received a Life Membership in the NCSRC in 2009. ■

Contribute to Our "Transitions" Column

The AARC "Transitions" column is devoted to sharing news about AARC members who have recently passed away. You can submit news about a colleague's recent passing by going to http:c.AARC.org/transitions. Please provide any information about the member's obituary so that we can share it with the membership and pay tribute. ■

Tough Smoking Laws Lower E-Cigarette Use

New research from investigators at New York University suggests strict public policies on smoking translate not only to fewer smokers but also fewer users of e-cigarettes.

In a study published in *Nicotine & Tobacco Research*, the authors examined the association between e-cigarette and cigarette use and existing state-level tobacco control measures using 2012–2013 and 2013–2014 data from National Adult Tobacco Survey and the American Lung Association's State of Tobacco Control reports. States with stronger implementation of tobacco-control measures, including state-level funding for tobacco prevention and control programs recommended by the Centers for Disease Control and Prevention had lower rates of current cigarette and e-cigarette use. ■

Students and Seniors Get Price Breaks on Member Dues

Association members who are just starting out in their careers and those who are getting ready to wrap things up can benefit from exclusive membership offers the AARC has developed just for them.

The transitional student membership is available to student members who are preparing to graduate. AARC student members who renew their membership at least 91 days prior to graduation will save the most on dues, but savings are available up to 150 days past graduation. Those nearing graduation should look for an email with specific instructions on how to claim this special membership price break or call AARC Customer Service at (972) 243-2272 to participate.

Members age 65 and older who have been AARC members for at least 20 years are eligible to maintain their membership in the Association for just $25 per year. Alternatively, they can pay $200 and become members for life. This digital membership gives these loyal members the chance to stay in touch with everything going on in the respiratory care profession while they're planning for or entering retirement. Members eligible for this senior status can call AARC Customer Service at (972) 243-2272 to learn more about signing up. ■

Subset of T Cells May Predict Asthma Risk

Can a subset of T cells serve as an early childhood immune signature capable of predicting the risk of developing asthma? Yes, report researchers from the La Jolla Institute for Allergy and Immunology. Specifically, children who, at age one, had a higher frequency of a type of T cell called the MAIT cell were less likely to develop asthma by age seven than those who did not.

"In humans, MAIT cells are unique in that they are born to make gamma interferon, which could help skew the immune system toward an asthma-protective Th1 immune response," explains study author Shilip Chandra, PhD.

The study involved 110 children from four disadvantaged urban areas. All of the children gave blood samples at age one, which were analyzed for the frequency of different types of immune cells. The research appeared in a recent edition of the *Journal of Immunology*. ■

Share Your Wisdom

Our "Reflections" column is geared especially toward AARC members who have recently retired from the profession. Please consider looking back at your career or some aspect of it, then tell us what it meant to you and why. So start brainstorming, then submit your story or story idea to *AARC Times* Editor Marsha Cathcart at cathcart@aarc.org. ■

Motor Vehicles Aren't the Only Problem

You can't blame motor vehicles for the lion's share of air pollution anymore, according to researchers from the University of California Berkeley. In a study that focused on volatile organic compounds (VOCs) emitted by products such household cleaners, pesticides, paints, and perfumes made from petroleum, they found these products contributed about as much to air pollution in urban areas as the transportation sector — even though people use a lot more fuel to run their vehicles than they do the petroleum-based compounds found in these products.

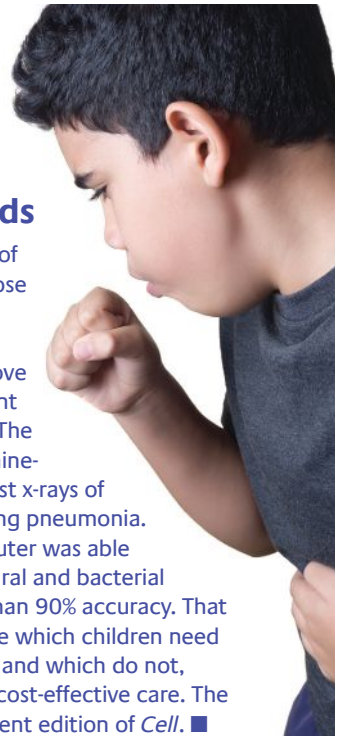
The investigators say it's all about the way these products are used. "Gasoline is stored in closed, hopefully airtight, containers and the VOCs in gasoline are burned for energy," study author Jessica Gilman was quoted as saying. "But volatile chemical products used in common solvents and personal care products are literally designed to evaporate. You wear perfume or use scented products so that you or your neighbor can enjoy the aroma. You don't do this with gasoline."

The research was published in a recent edition of *Science*. ■

Flu Vaccination Rates Fall Short

A recent report in the *American Journal of Public Health* suggests that influenza vaccination rates are not on track to meet goals. While "Healthy People 2020" calls for 70% of all adults in the United States to be vaccinated every year by the year 2020, influenza vaccine coverage in the 2015–2016 flu season was only 42%. Ethnicity and other factors played a role in who obtained the vaccine, according to the report. It notes that non-Hispanic blacks were more likely to be vaccinated when they had higher confidence or trust in their physician. The report notes that Hispanics who reported less acculturation were actually more likely to be vaccinated than were Hispanics who were more acculturated (41% vs 27%). ■

Artificial Intelligence Tool May Help Diagnose and Treat Pneumonia in Kids



An international group of investigators, including those from the United States, has found that an artificial intelligence tool can improve the diagnosis and treatment of pneumonia in children. The researchers used the machine-based tool to examine chest x-rays of children suspected of having pneumonia. They found that the computer was able to differentiate between viral and bacterial pneumonia with greater than 90% accuracy. That could help clinicians decide which children need treatment with antibiotics and which do not, ensuring more timely and cost-effective care. The research appeared in a recent edition of *Cell*. ■

More Work Needed To Prepare Bystanders To Give CPR

A recent survey conducted by investigators from the Cleveland Clinic sheds some light on bystander cardiopulmonary resuscitation (CPR) capabilities, and the picture is not encouraging. According to the survey, which was released by the Cleveland Clinic earlier this year:

- 54% of Americans say they know how to perform CPR, but only one in six know that the recommended technique for bystander CPR consists of chest compressions only in adults.
- Only 11% know that the correct pace for performing these compressions is 100 to 120 beats per minute.
- Only 27% report that an automated external defibrillator, considered critical in the event of a cardiac arrest, is available at their workplaces. ■

Why Healthy Kids Die of the Flu

Media reports about the number of children who died of the influenza this flu season were all too common earlier this year. Especially troubling were those reports of otherwise healthy kids succumbing to it. Researchers from the Ann & Robert Lurie Children's Hospital of Chicago attempted to find out how the flu turns deadly in these children in a study that examined specific immune pathways known to be activated during flu infections in both humans and mice.

The investigators focused on the initial immune response to the flu using healthy adult mice and healthy young mice that had not had previous exposures to the virus. They discovered that in the young mice, more immune cells called monocytes were recruited to the lungs and the gene expression profiles of these cells had more inflammatory features, causing greater inflammation and more severe lung injury.

"Our findings provide new targets for developing effective medicines to treat the flu in children," explained study author Bria Coates, MD. "We can seek ways to prevent monocytes from coming to the lungs, or we can target monocyte behavior in the lungs to reduce dangerous inflammation." The study was published in a recent edition of the *Journal of Immunology*. ■

Researchers Study How Asthma Meds Can Affect Fertility

Women with asthma who are seeking to become pregnant will be interested in a new study out of the University of Adelaide: results showed those who only used short-acting asthma relievers to treat their asthma had a harder time conceiving. Those who used long-acting asthma medications got pregnant just as easily as women who did not have asthma.

The study was conducted among more than 5,600 women in Australia, New Zealand, the United Kingdom, and Ireland who participated in the screening for pregnancy endpoints study. Ten percent of the women had asthma, and, overall, they took longer to get pregnant. When the investigators differentiated the women on the basis of the type of asthma medications they used, they found women using β-agonists took, on average, 20% longer to conceive and were 30% more likely to have taken more than a year to get pregnant, which was defined by the researchers as the threshold for infertility. The difference remained even after researchers took other factors known to influence fertility into account.

The investigators aren't sure how asthma meds come into play, but they speculate that asthma may be causing inflammation in other parts of the body in addition to the lungs, such as the uterus and ovaries. Whereas inhaled corticosteroids suppress the immune system, β-agonists do not, and this could be part of the explanation for better fertility in women on controller meds. The investigators are planning additional studies to find out how asthma medications affect women undergoing fertility treatments to further scientific understanding in this area. The study was published in a recent edition of the *European Respiratory Journal*. ■

Prior Flu Infections Shape Vaccine Response

U.S. researchers publishing in a recent edition of *Clinical Infectious Disease* have found that a person's immune history influences his response to the influenza vaccine. That may help explain why the vaccine works in some people and not in others.

The study counters the accepted theory that egg adaptations explain the variance in vaccine effectiveness, suggesting a phenomenon known as "original antigenic sin" may be at play instead. Specifically, once the immune system already has antibodies to target a given site on the virus, it preferentially reactivates the same immune cells the next time it encounters the virus. Antibodies produced from a person's first encounters with the flu, either from vaccines or infection, tend to take precedence over ones generated by later inoculations. So even when the vaccine is a good match for a given year, if someone has a history with the flu, the immune response to a new vaccine could be less protective. ■

E-Cigarettes Contain Harmful Metals

In a study that looked for the presence of 15 metals in various parts of e-cigarette devices used by 56 daily e-cigarette users, researchers at John Hopkins Bloomberg School of Public Health found much larger amounts of some metals in the e-liquids that had been exposed to the heating coils within e-cigarette tanks than in other parts of the devices. What's more, the investigators were able to show the metal contamination carried over to the aerosols produced by heating the e-liquids.

Among the metals found in the aerosols, lead, chromium, nickel, and manganese were most concerning because all four are toxic when inhaled. Nearly 50% of the aerosol samples had lead concentrations higher than health-based limits defined by the Environmental Protection Agency, and median aerosol concentrations of nickel, chromium, and manganese also approached or exceeded safe limits. The study was published online by *Environmental Health Perspectives* earlier this year. ■

Super-Enhancers May Hold the Key to New Asthma Treatment

Researchers from Houston Methodist Hospital believe they have uncovered the cellular factors that cause the airways in the lungs to close during an asthma attack. They have also found a way to stop it from happening, which may lead to new treatments for people with the condition.

The work began with the knowledge that in people with asthma, T helper cells produce large quantities of the protein interleukin 9 (IL-9), which then leads to the production of mucin in the lungs. The investigators discovered that a molecule called OX40 spurs that hyperactivity.

"In essence, OX40 activates the *IL-9* gene in T helper cells, leading to the overproduction of IL-9 protein through a powerful molecular machinery of super-enhancers that regulate gene expression," explains study author Xian C. Li, MD, PhD. Using chemical inhibitors, the team found a new way to stop this assembly of *IL-9* gene super-enhancers and prevent the production of IL-9. They believe targeting and blocking these super-enhancers may provide a new means of treatment.

The study was published in a recent edition of the *Journal of Experimental Medicine*. ■

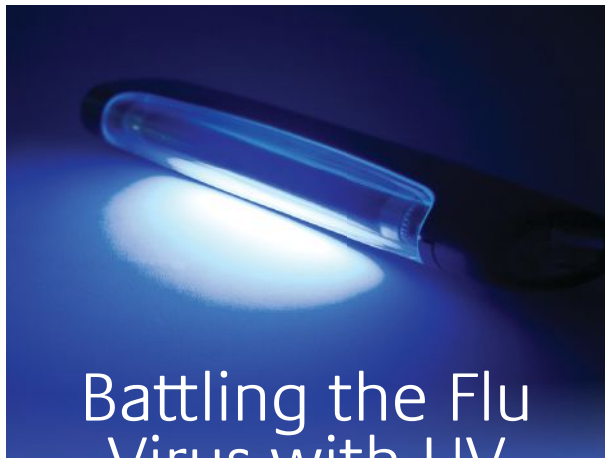
Good News
on Pediatric Asthma

According to a new *Vital Signs* report from the CDC, asthma is taking less of a toll on America's children. The report finds kids are having fewer asthma attacks, missed school days, and visits to the hospital. Among the key findings:

- The percentage of children with asthma who experienced one or more asthma attacks in the preceding 12 months declined from 61.7% in 2001 to 53.7% in 2016.
- Asthma hospitalizations for children with asthma declined from 9.6% in 2003 to 4.7% in 2013.
- The percentage of children who reported asthma-related missed school days was lower in 2013 than it was in 2003.

Better patient/family education may be playing a significant role in these declines. The report also notes that more children with asthma are getting asthma action plans and being taught how to recognize the signs and symptoms of an asthma attack and how to respond quickly.

Despite these positive findings, however, the CDC emphasizes there is still more work to do to bring pediatric asthma under good control. Statistics suggest that one in six children with asthma will still end up in the emergency department, and about one in 20 will be hospitalized each year. ■



Battling the Flu Virus with UV Light

Could overhead lights in hospitals, doctor's offices, and other public places minimize the circulation of the flu virus? According to researchers from Columbia University, the answer may be yes. They found that continuous low doses of far ultraviolet C (far-UVC) light can kill airborne flu viruses without harming human tissues.

The authors note this kind of light is different from the broad-spectrum UVC light used to decontaminate surgical equipment. That light has been shown to pose hazards to human health. The far-UVC light is a narrow spectrum of ultraviolet light with a very limited range that cannot penetrate the outer dead-cell layer of the skin or the tear layer in the eye, making it a safe alternative.

To test the virus killing capabilities of far-UVC light, the investigators released aerosolized H1N1 virus into a test chamber and exposed it to very low doses of 222-nm far-UVC light. A control group of aerosolized virus was not exposed to the light. The far-UVC light efficiently inactivated the flu viruses, with about the same efficiency as conventional germicidal UV light.

"If our results are confirmed in other settings, it follows that the use of overhead low-level far-UVC light in public locations would be a safe and efficient method for limiting the transmission and spread of airborne-mediated microbial diseases, such as influenza and tuberculosis," notes study author David J. Brenner, PhD. "And unlike flu vaccines, far-UVC is likely to be effective against all airborne microbes, even newly emerging strains."

The study was published by *Scientific Reports* earlier this year. ■

Bacterial Infections May Start Earlier than Thought in Kids with CF

In an effort to shed more light on how and when inflammation, bacterial infections, and lung damage begin in children with cystic fibrosis, researchers from the University of North Carolina analyzed bacterial DNA in samples of lung-lining fluid gathered from young children as part of an ongoing Australian project called AREST CF. The authors note that these kinds of samples are hard to come by in the United States, where bronchoscopies are rarely performed on children with CF who are too young to have presented with many significant clinical symptoms.

The researchers found little or no signs of bacteria in the samples of children who were under the age of one. However, in children between one and two years old, many samples contained a significant amount of bacterial DNA from the same bacterial species that usually populates the mouth and throat, not the lungs. In kids three to five years old, increasing evidence of the types of potentially deadly bacteria that are common in older children and adults with CF appeared, including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Haemophilus influenza*.

Since many of the bacterial species in these young children were anaerobic, and the dehydrated, thickened CF lung mucus creates pockets of low oxygen in lung tissues, the authors believe therapies aimed at breaking up mucus very early in life may make a difference in prognosis for kids with CF.

The study appeared in a recent edition of *PLoS Pathogens*. ■

Histamine Levels Higher in Bed Bug-Infested Homes

Researchers who looked at histamine levels in homes with and without bed bugs found higher levels in the bed bug-infested homes. They also observed that these higher histamine levels persisted for months after the bed bug infestation was eliminated.

"Histamine levels in bed bug-infested homes were at least 20 times higher than histamine levels in homes without bed bugs," says study author Zachary DeVries, from North Carolina State University. "And these levels didn't decrease much three months after treating the infested homes with heat and insecticides."

The study, which was conducted in homes in a Raleigh apartment complex, analyzed dust samples for evidence of histamine. *PLoS One* recently published the study. ■

Strange But True…

Neurons have help: Conventional wisdom says breathing is controlled by neurons in the brain. NIH researchers say not so fast. Their study finds star-shaped brain cells called astrocytes come into play, too, by sensing changes in blood carbon dioxide levels. When they silenced the astrocytes in the brains of rats, the animals breathed at a lower rate and could only run half the distance on a treadmill as they normally could. ■

Just breathe: The flu is spread by coughing and sneezing, right? U.S. researchers say simply breathing will do the trick, too. They tested the exhaled breath of people confirmed to have the flu over a five-year period, finding traces of the virus in the samples. ■

Light me up: Physicians from India who performed a bronchoscopy on a toddler who presented with coughing and a fever were surprised at what they found: a 2-cm LED light bulb. Thankfully, the little girl was okay. ■

Another good fat: Researchers from the National Institute of Allergy and Infectious Diseases (NIAID) believe the white fat that serves as the scaffold under our skin, muscles, and organs may have another purpose as well. Their study shows it is a warehouse for immune cells called memory T cells, which fight infections. ■

Double duty: RTs know montelukast as a drug that's used to treat asthma. Now the maker of the drug is repurposing it in an oral film-based product to target another disease: Alzheimer's. The company is launching a study to evaluate the safety, feasibility, tolerability, and efficacy of the drug in patients with the disease. ■

Calendar of Events

AARC & State Society Programs

May 17, 2018 – May 18, 2018
Boothbay Harbor, ME
The Maine Event
Contact: whitts@mmc.org or www.mesrc.org

May 30, 2018 – June 1, 2018
Oakbrook Terrace, IL
ISRC Annual Conference and Exhibition 2018-Celebrating 50 years/Back to the Future
Contact: mcqu612@aol.com or www.isrc.org

July 17 – 19, 2018
Texas Hill Country (near San Antonio)
AARC Summer Forum
Contact: https://www.aarc.org/aarc-meetings/summer-forum-2018/

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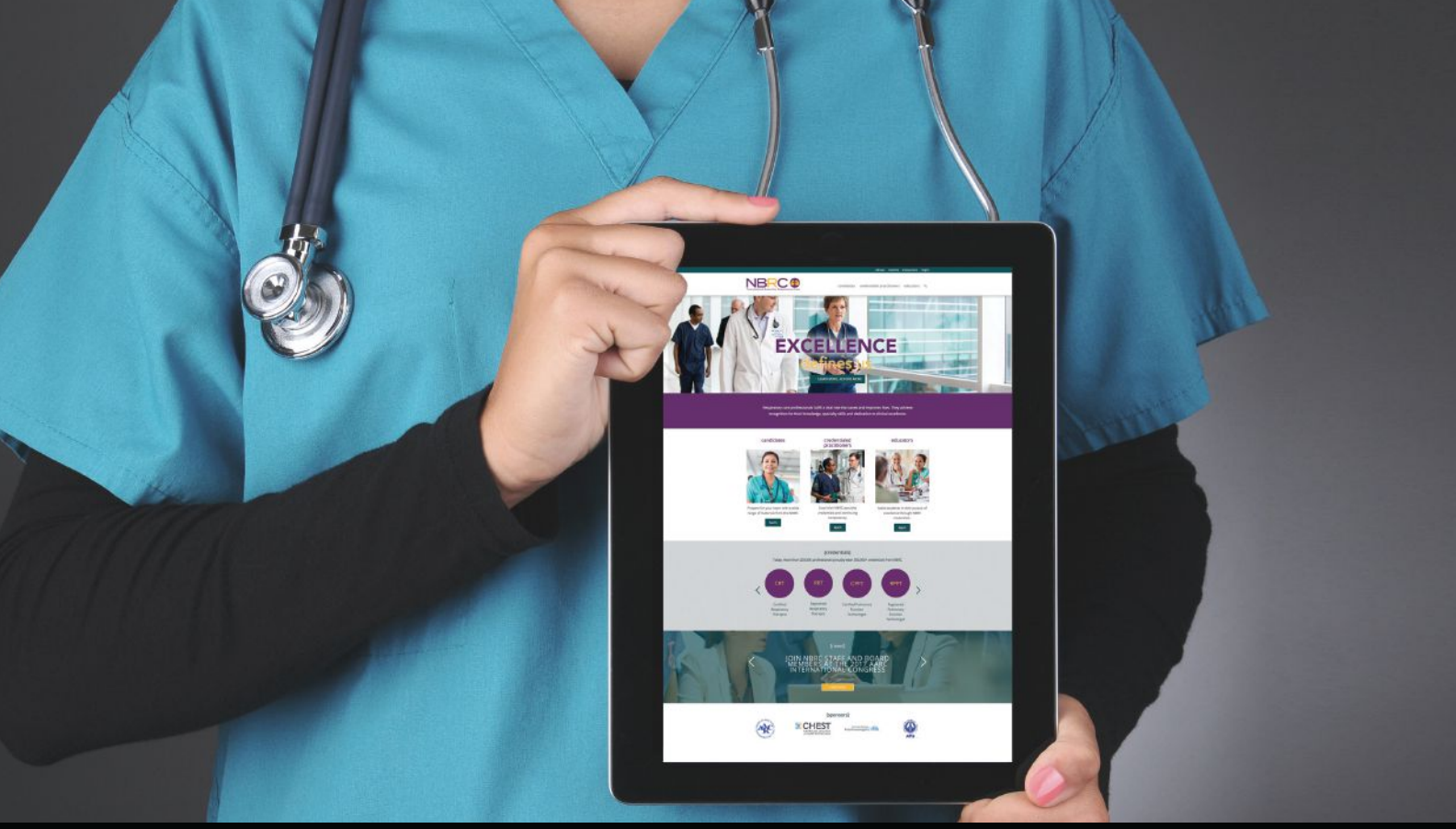

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[1] For complete specifications, including measurements, see Operator's Manual.

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