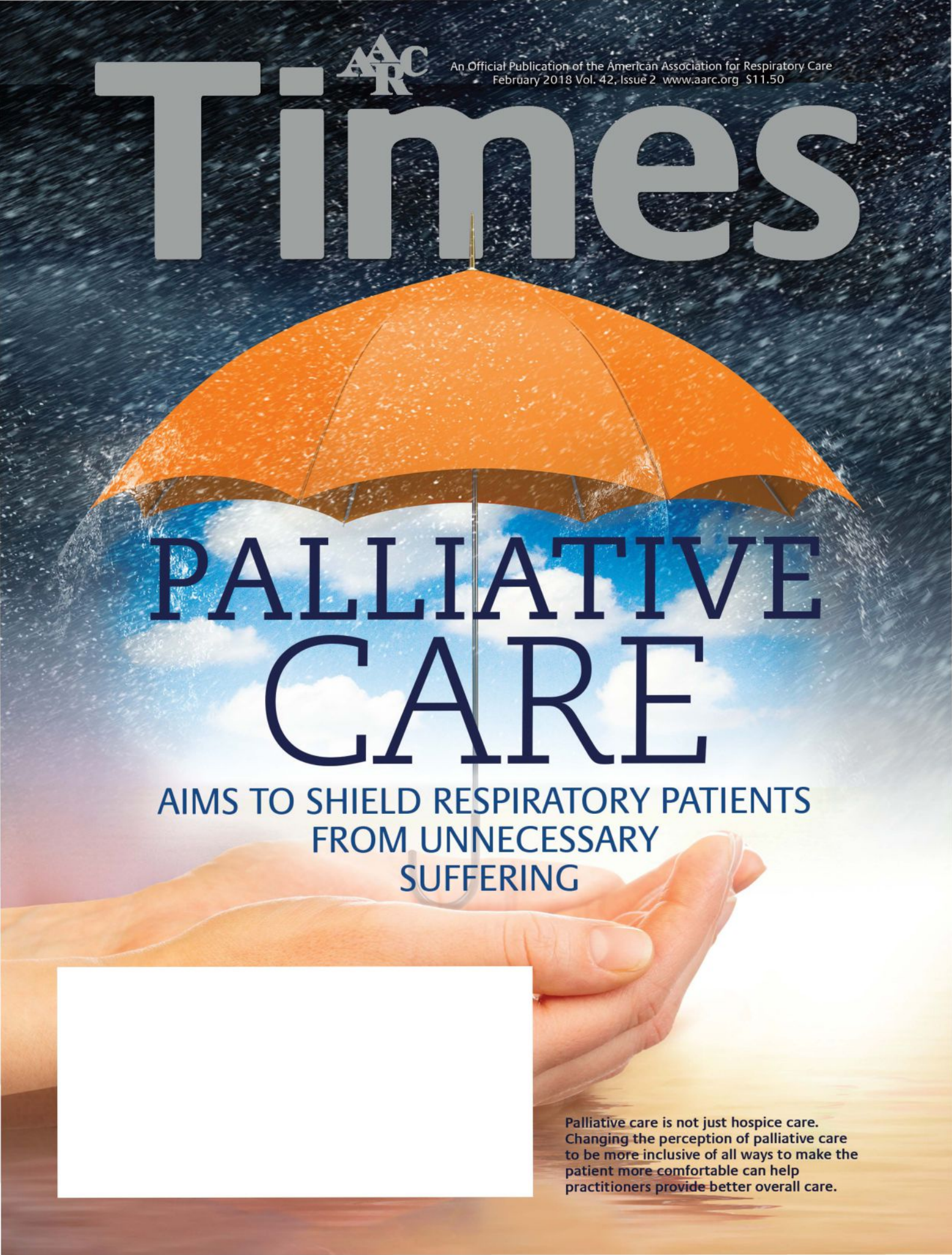




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Times



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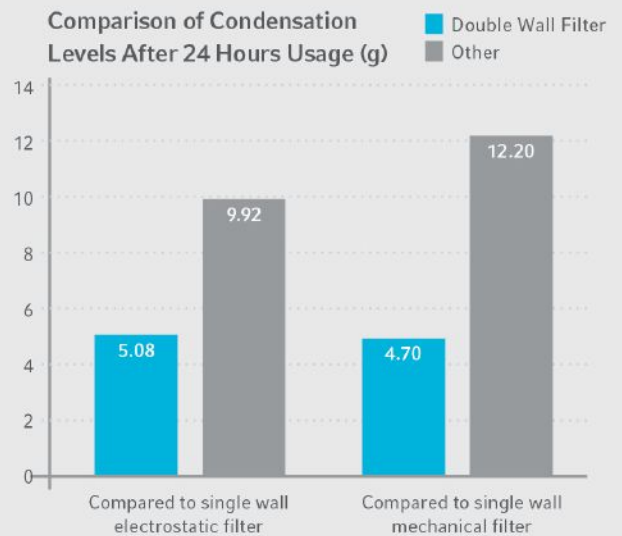
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AARC Strategic Plan

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/.



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The Other Side of Midnight: A Personal Journey into Palliative and Hospice Care

by Kim Bennion, MsHS, BSRT, RRT, CHC

On October 27, 2015, watching her labored breathing all night, I suddenly realized that I was experiencing “the other side of midnight” with my mom. I had crossed over from being her daughter to being her respiratory therapist and health care agent, a role I had prepared for but dreaded all my life. After years of advanced care planning (ACP) discussions due to her COPD, the time had come for me to ensure the honoring of her end-of-life goals. Our journey to identify, document, and honor her wishes had been a challenging one. Meeting with her physicians for a hospice order resulted in confusion and anxiety. Statements included “You still have nine lives.” “I hate to see it come to that because we love your mom!” All I could say to each was, “Are you kidding me? We all know my mother will probably be gone by Christmas. We are exhausted caring for her in our home. None of us gets out of here alive. I’m begging you to help me help her die without gasping for breath.” After pleading, we received the hospice order. While patients can enter hospice when death would not be a surprise within six months, too many patients are never offered the service. It provided medications delivered to our home, a nurse/nursing assistant for daily care as well as access to a social worker and a chaplain. Having coached the hospice physician to order what my mother needed for breathing ease, my question for this qualified team was, “...but where is the respiratory therapist?”

Why we avoid advanced care planning discussions

What causes such hesitation in talking about end-of-life care? Studies report key obstacles include lack of experience, avoidance of emotion, insensitivity, sense of guilt, assumptions of what might be best for a patient or what the patient really wants, leaving the impression of

no hope or giving up, fear of being sued, disagreement with decisions, lack of understanding of culture or goals of care, personal grief issues, ethical concerns, and many consulting teams with limited communication or coordinated care planning.¹⁻⁶ In health care, we have been taught to treat and save. It is reactive medicine where a patient presents with illness, and we assume the patient wants to be cured. Without honest, informative communication in both directions, we cannot uncover patient goals, fears, and concerns. Comfort care or answers to what happens “in the end” are often all the patient really wants.

about the authors...



Kim Bennion, MsHS, BSRT, RRT, CHC, is Corporate Respiratory Care Service’s quality assurance and program manager at Intermountain Healthcare in Salt Lake City, UT.

The COPD disease trajectory

While some pulmonary diseases such as lung cancer have a predictable disease trajectory, COPD does not (Figure 1). Approaching the medical director of our corporation’s advanced care planning (ACP) strategic team, I drew the COPD disease trajectory on his whiteboard and asked him where he felt RTs would fit. He put a mark just ahead of the patient’s death (red, vertical mark on Figure 1). I took the marker and placed a green vertical line at the time of diagnosis and wrote a list of things that RTs do or could do at that point, as pulmonary function tests for diagnosis, patient education, tobacco cessation support, disease care management, pulmonary rehab, care for every exacerbation, and early and frequent ACP discussions, just to name a few. He literally shook my hand at that moment and officially welcomed me as the newest member of Intermountain Healthcare’s ACP Team. Due to the RESPIRATORY CARE journal’s recent publications on the organization’s care of COPD patients, the team selected Respiratory Care Clinical Services to lead the charge in changing the gen-

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(glycopyrrolate) Inhalation Solution

25 mcg/1 mL

The **first and only**
nebulized LAMA for COPD
including chronic bronchitis and/or emphysema



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.

COPD=chronic obstructive pulmonary disease; LAMA=long-acting muscarinic antagonist.

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 beta₂-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,

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



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Learn more about a new nebulized COPD therapy at
sunovionprofile.com/lonhala-magnair

Handset is 2.4 x 4.7 inches. Controller is 1.6 x 4.6 inches. Assembly required.

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 $\geq 2\%$ 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.

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.

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(glycopyrrolate) Inhalation Solution

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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 beta₂-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 beta₂-agonist becomes less effective; or the patient needs more inhalations of a short-acting beta₂-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 (FEV₁) 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.

	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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Figure 1. COPD Disease Trajectory.

eral culture regarding early and frequent ACP discussions. Three years later, we have completed preparations to pilot early and frequent ACP discussions in our COPD population.^{1,2,4,6} Studying early prognostication criteria for death in this subset of patients, we are more aware of the signs of COPD end-stage disease as predictors of timeliness for various steps of discussions. Health care includes recognizing the need to shift when palliative and hospice care integration should ideally occur (Figure 2).⁴

Creating and training ACP teams for a standardized approach

We created a core team of interdisciplinary professionals including physicians, nurses, social workers, and respiratory therapists. Five members were sent to Gunderson Health to become certified Respecting Choices® discussion facilitator instructors.⁴ The course utilizes three “steps” to facilitate discussions with patients and their caregivers: identify the patient’s key health care goals, document and store patient preferences, and assure goals for care are honored. Discussion facilitators are taught the art of communicating without personal bias to assist with the identification of patient care goals. Patients, health care agents, and family members receive education regarding chronic disease(s), general care options, and information regarding CPR, breathing assist devices, and feeding tubes.

Setting respiratory therapists apart as the experts

Because we have uniquely positioned ourselves with proactive training and study goals, the team received a National Committee on Quality Assurance grant to create a pilot program in our Schmidt Pulmonary Clinic.⁷ By physician request, clinic RTs and RT Pulmonary Disease Navigators will be leading the scheduled ACP discussions. Discussions and health care goals will be documented and stored in the electronic medical record. A patient and family advisory panel will provide input regarding program structure, content, and feedback regarding what they feel would be more helpful.

Key goals of the NCQA project have been identified.⁶ Our approach includes the Respecting Choices training.⁴ The first step includes assisting all citizens 18 years of age and older in designating a health care agent who could express their health care wishes in the event they could not speak for themselves. The second step includes palliative care discussions at the time a chronic disease diagnosis is made to educate patients and their family about the disease, and to introduce them to care options congruent with the patient’s goals for care. The third step occurs when death would not be a surprise within a year and includes discussions around the completion of a Physician’s Order for Life-Sustaining Treatment (POLST) to ensure patient goals are identified, documented, and honored. ACP

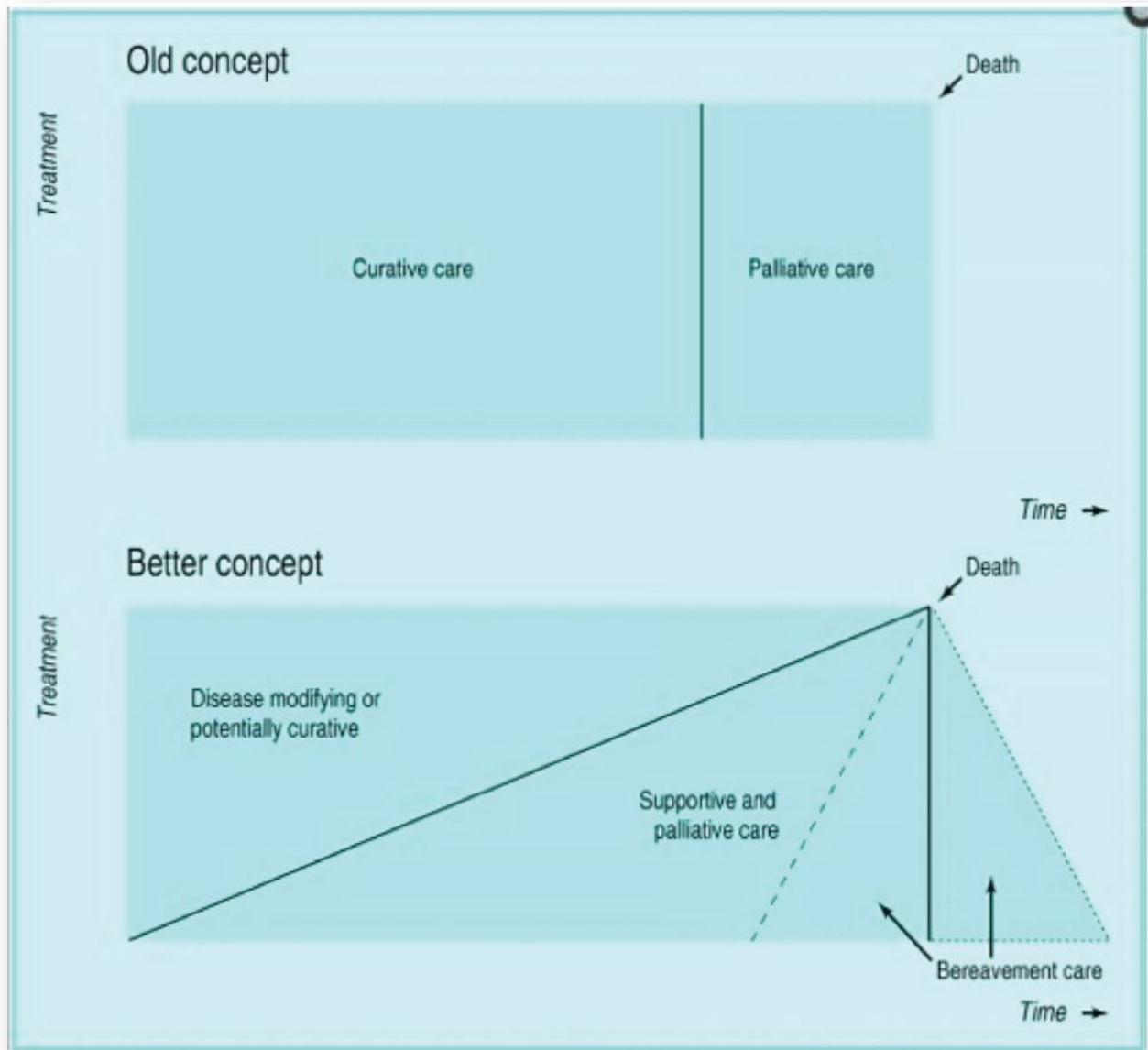
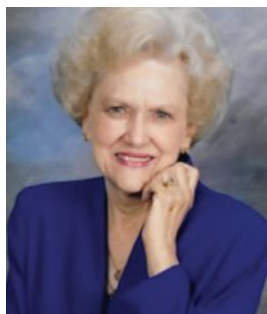


Figure 2. Timeliness of Palliative Care and Hospice Care Integration (Adapted from Lynn and Adamson, 2003). With permission from RAND Corporation, Santa Monica, California, USA.

discussions are not a “one and done” form-completion event; instead they should be integrated into the everyday clinical care of the patient.

Until we took the initiative to meet with the ACP team’s medical director and explained the unique qualifications of RTs, completed the initial on-line certification course, and became certified ACP discussion facilitator instructors, RTs were simply overlooked as key members



My mom, Betty J. Lawson

of the team. Now we are leading the NCQA collaborative.⁶

A tribute to respiratory therapists: a patient’s perspective

Should RTs be involved in ACP discussions? I believe my mother said it best during those last weeks: “I lived to be 88 years old because of respiratory therapists. I thank them with every fiber of my being. In my eyes, RTs are the

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with high-quality CPR has been shown in clinical studies to improve survival by 25% or more¹. In addition, pre-clinical studies have shown:

- Increased blood flow to the brain by 50%²
- Doubled blood flow to the heart³
- Doubled EtCO₂⁴

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¹ Idris et al. *Circulation* 2012; AHA Res abstract #LBRS-352.

² Lurie KG et al. *Chest* 1998;113(4):1084-1090.

³ Langhelle A et al. *Resuscitation* 2002;52:39-48.

⁴ Yannopoulos D, et al. *Critical Care Med.* 2006;34(5):1444-1449.

Studies available upon request. The generally cleared indication for the ResQPOD ITD available for sale in the United States (US) is for a temporary increase in blood circulation during emergency care, hospital, clinic, and home use. The studies referenced here are not intended to imply specific outcomes-based claims not yet cleared by the US FDA.

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ROCK STARS!" I believe she would now add, "...and RTs assured I could die where and how I wanted, with my family around me, 1940s music playing, and sunlight streaming through my window." Who among us would not want such a precious end-of-life goal honored? Don't our patients deserve to be heard? ■

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When To Implement Palliative Care in Chronic Illness

by Stephanie Williams, BS, RRT

Imagine yourself, a recent RT grad, and you are busy at work giving morning treatments on a medical/surgical floor when you happen to see the wife of one of the hospital's frequent COPD patients wandering the hallway. We'll call them the Smiths. She confirms what you already suspect: Her husband was admitted again, and this time he is in the ICU. Your pager beeps (yes, pager) and summons you to the ICU. As you enter, you notice that in one of the pods, they are working feverishly on a patient, and things are not going well. Your colleague calls to you to bring another cricothyrotomy kit. Your fears are confirmed as you see they are working on Mr. Smith.

After leaving the unit, Mrs. Smith sees you and says she is so excited that they are doing this procedure to help him breathe better. Then she asks, "Do you think this will help him enough that we can go dancing again?"

This story really happened, and I know my expression must have been one of total disbelief when she asked me about dancing. I thought, "Oh, my! She has no idea what is happening or what this means!" As a young person, I knew that something had failed this family, but it wasn't until much later that I realized this was a much larger problem.

It is likely that you have a story like this one, a patient or family who stands out in your mind because they seemed to lack information and knowledge that they needed to make informed decisions about their lives.

Over the past few years, there has been a real push to improve patient education, and that has been evident as hospitals have created positions for Respiratory Navigators/Coordinators. Much emphasis is put on educating people about their disease to help reduce hospitalizations and utilization, but there is an additional layer of

education, often overlooked, that would help: palliative care and hospice.

It may be helpful to make clear the distinction between palliative care and hospice before we go on. Palliative care is a branch of medicine that takes a whole-patient approach to providing relief for symptoms of a disease, regardless of whether a cure is available or possible. Hospice is a type of palliative care that is designed to maximize the quality of life for a person who has about six months or less to live. The statement can be made that hospice care is always palliative, but palliative care doesn't necessarily mean hospice.

If we think about this in very broad terms, as health care providers we are providing informal palliative care for our patients every day. We help them when they feel short of breath, need adjustments to their equipment, and even when they just need to be repositioned to feel more comfortable; the idea of palliative care shouldn't be too foreign to us. Palliative care, as a discipline, is a service that should be initiated when someone is first diagnosed with a chronic illness — it doesn't need to wait until there is nothing else that

medical science can do for the patient. There is often a misunderstanding that if you are receiving palliative care, you can no longer receive treatment or go to the hospital if needed. Very simply, that is inaccurate. Palliative care includes a component of curative medicine.

If someone is diagnosed with a chronic disease, they can begin seeing a palliative care team right away. This is beneficial because palliative care teams can assist with coordination of treatment, communication, education, and emotional support for the patient and their family. The goal is to improve the quality of care the patient gets, while ensuring that they have all necessary information

about the author...



Stephanie Williams, BS, RRT, is the director of community programs at the COPD Foundation, with locations in Washington, DC, and Miami, FL.



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neohaler®**
(indacaterol/glycopyrrolate)
inhalation powder

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

POWER
of a LABA/LAMA combination

FULL
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 beta₂-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 beta₂-agonist.



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 - 262 mL improvement in FEV₁ AUC_{0-12hr} vs placebo at Week 12 in Trial 1
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- **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 chamber¹**
- **Clear capsule design allows patients to visualize any medication left in the capsule and inhale all of the remaining dose¹**
- **UTIBRON capsules are for oral inhalation only and should not be swallowed¹**

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AUC, area under the curve; FEV₁, forced expiratory volume in 1 second; LABA, long-acting beta₂-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 beta₂-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.



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27.5 mcg/15.6 mcg



(indacaterol/glycopyrrolate) inhalation powder

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

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

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 beta₂-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 beta₂-agonist.

When beginning UTIBRON NEOHALER, patients who have been taking oral or inhaled, short-acting beta₂-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 beta₂-agonist and instruct the patient on how it should be used. Increasing inhaled beta₂-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 beta₂-agonist becomes less effective; or the patient needs more inhalation of short-acting beta₂-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 Beta₂-Adrenergic Agonists

As with other inhaled drugs containing beta₂-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 beta₂-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

Beta₂-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 beta₂-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 (FEV₁) was 55% (range: 29% to 79%), the mean post-bronchodilator FEV₁/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 (%)
Nasopharyngitis	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 beta₂-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 beta₂-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 m²) 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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to make informed decisions about their health care. The idea that a person “isn’t sick enough yet” to have palliative care should be forgotten. We should be empowering our patients with these new programs and helping them feel more informed and as in control as possible.

So, how can we help?

As RTs, we know many of our patients quite well because they can be admitted frequently. Our patients depend on our expertise to help them navigate their needs from a respiratory perspective. If we can share information about palliative care with them and help them understand the benefits it holds for them, we can contribute to the improved quality of life they so desire. Here are some real-world ways we can promote palliative care:

- Asking for consideration of palliative care consults on appropriate patients
- Encouraging patients to attend pulmonary rehabilitation
- Change in habits (smoking, diet, use of oxygen, etc.)
- Assessing the need for post-discharge care (home health, other durable medical equipment, social work)
- Helping the patient define wishes/goals for the future
- Asking the “What if” question

We can probably manage the first four items on this list without any hesitation, but the last two bear some explanation.

Helping the patient define wishes/goals for the future is not something we instinctively do. We can get caught up in the hectic workflow of trying to make sure everything on our list gets done, but we never stop to consider how understanding the goals of the patient might impact the care they need. After a conversation an RT had with one patient, it was discovered that he really wanted to be able to build up enough strength to take his wife to see the ocean before he died. When the doctor was told about this conversation, he made a referral for the patient to attend pulmonary rehab to build his stamina. It worked for him, and he took his wife to Myrtle Beach. Without that conversation, would that dream have ever been realized?

Helping someone define their goals and wishes might lead you to a conversation that some find uncomfortable: Asking the “What if” question. We usually find it difficult because we feel ill-prepared to have the discussion of how the effects of their illness will progress and affect their day-to-day activities. At some point, the

question must be asked: What are your wishes if you get to the point that you are struggling for breath? If you are brought into the ER? If you need intubation?

When I asked a group of patients who they wanted to have this type of conversation with, they said they want it to be someone they trust, who isn’t “giving up on them,” and who keeps their wishes in mind. I think that should describe us a group of providers, and we should be at the forefront of helping people have this very necessary conversation.

As RTs, we are trained to save lives. We fight alongside our patients to help them survive and thrive. It may feel counterintuitive for us to ask end-of-life questions, but by somehow asking these types of questions, and by engaging in this kind of conversation, we can learn so much about the people we are caring for and how to help them preserve their independence and dignity — and isn’t that what we want for them? ■

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Taking It to the Next Level

by Debbie Bunch

Editor's Note: In the November 2017 edition of *AARC Times*, we introduced AARC members to the Association's new APEX Recognition Program in which Piedmont Healthcare-Atlanta Hospital was profiled. In the coming issues, the AARC will celebrate all current APEX recipients with a brief profile on their hospital department and the efforts it took to achieve excellence in respiratory care.

Respiratory therapists at the Hospital of the University of Pennsylvania (HUP) are now wearing their pride in the profession on their sleeves. After receiving Apex recognition from the AARC last August, the Philadelphia hospital presented each staff member with a new scrub top with the embroidered Apex logo.

Department Director Margie Pierce, MS, RRT, CPFT, says the recognition has done wonders for staff morale. "The Apex award demonstrates we are being acknowledged in a similar fashion to other health care professionals who receive recognition from their organizations," says the AARC member. "It was highly rewarding for our staff to see the excitement and congratulatory remarks from our senior leadership, nursing, and physician colleagues."

Making it official

Pierce says her department has always operated at a high level and already had the respect of colleagues

Hospital of the University of Pennsylvania among the first to receive AARC APEX Recognition

throughout the hospital, but the Apex award made it official. "Receiving the award took it to the next level, and the support to spread this message throughout the organization was outstanding," says the manager.

The recognition was promoted internally during committee meetings and several staff celebrations. Externally, the accomplishment was blasted to the community at large through Pennsylvania Society for Respiratory Care (PSRC) postings on Facebook,

LinkedIn, and Twitter. "I believe the recognition enhanced our professional perception internally by validating the work of the RT team," says Pierce. "Externally, the executive director of the PSRC said we have raised the bar for the profession."

What did it take to get there? Pierce says the biggest challenge faced by her department was collecting and organizing the supporting evidence needed for the application. "We put together over 1,000 pages of documentation," she says.

Processes in place

The good news for HUP was that the department already met all of the criteria required to earn Apex recognition. "We did not need to take any action to meet the requirements because all of the processes were in place prior to the Apex Award criteria being published," says Pierce. But that doesn't mean the department didn't put in a lot of hard work to get to that place.

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. ■

“Two years ago we revised job descriptions, requiring all new hires to be registered and have a bachelor’s degree,” says Pierce. “We strengthened the clinical ladder, with all employees on the ladder required to be AARC members, and all Level IV’s are required to have a specialty credential.” These moves were in keeping with the culture at the hospital, which values clinical excellence, quality, and patient safety.

Pierce acknowledges the fact that other departments may have some work to do to meet the Apex requirements, but she encourages her fellow managers to go for it. “The advice I would give other department managers is to start making small changes that advance our profession because they add value,” she says. “Stay up to date with advancements in our field and be networked with other respiratory department leaders so you can share new ideas and keep up to date with regulatory requirements, process improvement initiatives, etc.”

Great opportunity

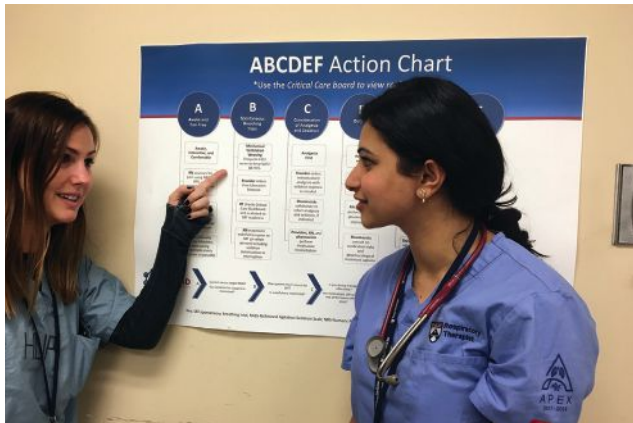
Apex recognition has paid off for the HUP department in so many ways, not least of which is the ability to recruit the best therapists out there for open positions. “We interviewed a potential recruit last week who stated, ‘This

must be a great place to work, I saw the department received the Apex Award,’” says Pierce.

For Pierce and her colleagues at HUP, applying for APEX recognition was a no brainer. “We were excited to hear that that the AARC created an award to recognize RC departments that strive for excellence and that specific criteria were established,” says the manager. “What a great opportunity for respiratory therapists to be recognized at a national level.” ■



RTs at the Hospital of the University of Pennsylvania are proud of their APEX recognition.



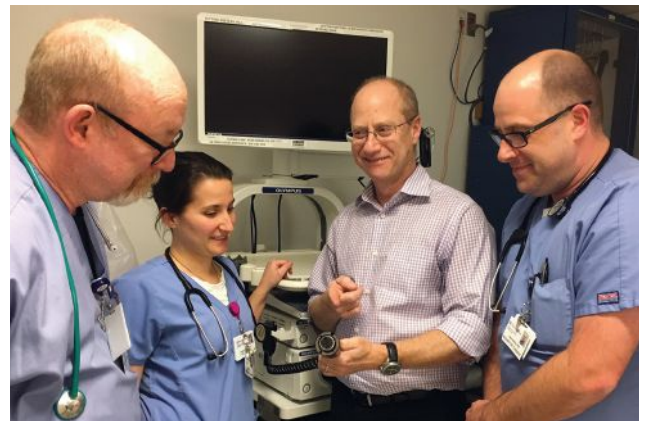
Jana Valentic, RRT, left, and Dimple Ceasar, BS, RRT, go over points on the department’s ABCDEF poster.



RTs join nurses for a photo op during COPD Awareness Month in November.



Night-shift therapists got together for a photo of their own.



Medical Director Barry Fuchs, MD, second from the right, discusses an equipment issue with a few staff members.

Dealing with the Police

by Anthony L. DeWitt, JD, RRT, FAARC

From an early age, most of us are told that police officers are our friends. By and large, over the last 62 years, I have found that to be true. I have blogged extensively about the perils faced by those who put on the badge. But just as you'll find at least one bad apple in every barrel, you'll find that not all police necessarily understand their place in society or the right way to do things.

By now the images are likely very clear to those of us in health care. Several months ago, a Utah nurse, doing her job as the patient's lawful protector, refused to let a police officer perform a drug test on a comatose patient. As a result, she was arrested, manhandled, and humiliated in front of patients and staff.

Let's be clear: Alex Wubbels, the arrested nurse, is a hero. Her job was to protect the patient. That is what she did. She did it by being arrested. She took abuse for her profession and for her patient. No one at the hospital intervened on her behalf. But she did something else, too, and it's this something else that stands out as the lesson in this matter.

Nurse Wubbels did not resist arrest other than to call for help and question what was being done to her. Her arrest was unlawful. She had a right to resist, and that right would have provided her with an affirmative defense had she been charged with resisting. But she didn't resist, and in so complying with her abductor, she kept the focus on the unlawful use of force rather than on any misconduct on her part. This is what happens often with innocent people: they get angry, and they get loud, and they lose their manners. All of that eventually gets played for a judge at the bond hearing. Not resisting and keeping quiet are key!

Police officers make honest mistakes. It happens all the time, usually without serious incident. In 1994, out-

side a convenience store, I was shoved up against a wall and frisked, handcuffed, detained, and then let go with an apology. My "crime?" I fit the description of an armed robber.

From my perspective, having a loaded handgun pointed at me, being the recipient of rather salty language, and being handcuffed seemed like a bit of overkill. So did the not-too-gentle probe of the parts of my

body where a gun might be concealed. But from the officer's perspective, I fit a description. The person they were looking for had a .357 Magnum handgun and had demonstrated a willingness to use it. The officer wanted to go home that night. When the officer explained it in that way, it made sense to me. I wasn't hurt; I let the matter go.

In Alex Wubbels' case, it is apparent that the police officer actually had the patient's interest at heart, although he had an odd way of showing it. A felony suspect had crashed head-on into the patient, and the police wanted drug-screen information to show that the patient was not impaired at the time of the crash, thus taking away a defense from the felony suspect. But they could not get a warrant (the patient was a victim, not a suspect), and the patient was unconscious and could not consent. Rules are rules for a reason. The hospital has a responsibility to protect the pa-

tient, and that duty was delegated to the nurse. Nurse Wubbels did her duty.

Instead of simply ignoring the nurse and doing the blood draw without permission, the officer retaliated against the nurse — someone who had done absolutely nothing wrong. The motivation for the arrest — the officer's wounded pride — would never have satisfied a judge, and it is worth noting that the officer's actions

about the author...



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got him fired and got his watch commander demoted from lieutenant to officer.

Sometimes police officers make mistakes that are not honest, and are not motivated by anything other than their desire to throw their weight around. A client of mine was arrested by the city police and had his face slammed into glass doors because he “looked ugly” at a police officer. He did nothing wrong and should never have been arrested, but he was. The charges against him were dropped only when I agreed to drop the internal affairs investigation into the officer. I advised the client to press forward, but he elected not to press the matter.

Alex Wubbels is a hero because she pressed the matter. She was not satisfied with having the bogus charges dropped. She took the police to task. She didn’t fight the officer at the time of the arrest; she fought him with a lawyer. A few weeks ago she settled out of court with the police for \$500,000.

The only way to stop bad behavior from those sworn to uphold the law is to challenge it in court. You will never win a fight on the street with a police officer, but you can win it in the courtroom. Make no mistake, the presence of body-camera footage was the

key factor in Nurse Wubbels’ case, but even without video, compelling testimony can lead to a just result.

If you’re ever in a situation where you have done nothing wrong yet you find yourself being arrested, do not resist the arrest. You can fight about that later in court with a lawyer. Be courteous to the officer, because everything you say will be played for the judge from the body cameras or from the dashboard camera. Do not answer any questions, and ask for a lawyer. Never give a statement. Do not talk to anyone other than your lawyer about what happened.

We all believe we won’t be thrown up against the wall like I was, or hauled off to jail for something we did not do. We believe this because we know 99% of police officers are good and decent people. But then again, Alex Wubbels never thought she’d finish her shift in jail that evening either. Forewarned is forearmed. ■

Editor’s Note: For more on this, you can view a video here: <http://www.npr.org/sections/thetwo-way/2017/11/01/561337106/utah-nurse-arrested-for-doing-her-job-reaches-500-000-settlement>

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PALLIATIVE CARE

by Shawna Strickland,
PhD, RRT, AE-C, FAARC

about the author...



Shawna Strickland, PhD, RRT, AE-C, FAARC, is associate executive director – member services at the American Association for Respiratory Care in Irving, TX.

Palliative care is a phrase commonly used in health care. Many people associate “palliative care” with chronic and end-of-life conditions. However, the definition of *palliate* from the Merriam-Webster dictionary is to “ease (symptoms) without curing the underlying disease” (<https://www.merriam-webster.com/dictionary/palliate>). The underlying disease does not have to be chronic or terminal; rather, patients with acute disease processes receive palliative care on a regular basis. For example, the patient with a broken arm is given analgesics to remove pain. Is the broken arm a chronic or terminal condition? No, but the patient still receives care designed to alleviate the symptoms while still receiving care to cure the disease—in this case, care to restore the arm to its previous function. Respiratory therapists provide care to a wide variety of patients in a wide variety of settings, and providing palliative care across this spectrum is vital.

The core concept of palliative care is to provide care focused on alleviating suffering.¹⁻³ Palliative care is provided regardless of expected lifespan or prognosis and can be provided concurrently with curative therapies.¹ The goal of palliative care is to improve quality of life. Nelson and Hope identify the core components of palliative care as the alleviation of symptoms, communication with patients and family about care goals, alignment of interventions with the patients' unique values and goals, transitional planning, and family support.⁴

Is palliative care the same as hospice?

Unfortunately, palliative care is often misunderstood to mean hospice care. Hospice care is also focused on alleviating suffering, but it is dependent on the prognosis. People admitted to hospice care have a life expectancy of six months or less.^{2,3} The care strategies have shifted to comfort measures only; curative therapies are discontinued during hospice care.

The overall goal for hospice care is to control suffering. While both palliative care and hospice care are very important strategies for the patient and family, they are not synonymous.

Stigma associated with palliative care

Separating the constructs of palliative care and hospice has proven to be problematic. Palliative care can lead to significant quality-of-life benefits and a decrease in psychological symptoms.⁵ However, the offer of palliative care is not always well received. Some of the barriers of integrating palliative care into the overall care strategy include the conflation of palliative care, end-of-life care, and hospice care. In addition, some have the perception that receiving palliative care results in a faster death.⁶

What's in a name?

Recent research has focused on whether the name "palliative care" is a factor in the perception of this type of care strategy. Zimmerman et al. interviewed patients with advanced cancer and their caregivers about their perceptions of palliative care.⁷ They discovered that the initial perceptions "were of death, hopelessness, dependency, and end-of-life comfort care for patients." These researchers then provided education to a subset of the participants to educate them about palliative care and, even though they reported that knowledge was increased, the participants still felt that the phrase carried a stigma.⁷

Another study asked patients with advanced cancer if calling the care strategy "supportive care" instead of "palliative care" would change their perception. The researchers found these participants viewed "supportive care" more favorably than "palliative care."⁸ Interestingly, other researchers discovered that clinicians have the same negative perception of the term "palliative care," and that care providers also responded more favorably

to the phrase "supportive care." These researchers found that clinicians would be more likely to refer patients to the "supportive care" service than the "palliative care" service.⁸⁻¹⁰

The role of the respiratory therapist

Several authors, guidance documents, and clinical practice guidelines have supported a multidisciplinary team approach to providing palliative care.^{2,11,12} This multidisciplinary approach emphasizes patient- and family-centered care, a focus on quality of life, early initiation of palliative care, and an appropriate level of competence for each of the team members.¹¹ As a respiratory therapist, member of the health care team, and patient advocate, each of us must be prepared to help the patient in all aspects of care.

The respiratory therapist can specifically contribute to palliative care through patient assessment, education, symptom control, communication, and collaboration. It is important that the respiratory therapist is aware of the potential stigma of palliative care and can provide the patient and family with vital information regarding the importance of symptom-control measures to improve quality of life. ■

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PALLIATIVE CARE RESEARCH POINTS THE WAY TO BETTER CARE

Recent studies delve into the issues surrounding the need for comfort care

By Debbie Bunch

Two COPD patients, admitted for recent emergency care, are nearing the end of their lives. Jane is discharged from the hospital with the usual instructions about calling her physician for a follow-up appointment. She goes home and struggles. Her family is beside themselves with worry. She makes three trips to the emergency room because they don't know what to do for her increasingly deteriorating condition and refractory breathlessness. After the third

trip, Jane is readmitted. Family members are faced with intubation or comfort care. Arguments ensue about the best course to take, but they finally decide against heroic measures. Jane passes away three days later surrounded by medical equipment and medical personnel.

Harvey and his loved ones leave the hospital armed with an advanced care directive and an end-of-life discharge plan that calls for hospice to begin visiting him at

home the next day. A home respiratory therapist will come by once a week to assess his dyspnea and recommend a course of action to his physician. The morphine he receives greatly reduces his struggles to breathe and keeps him comfortable. Family members receive the much-needed support to help Harvey in his final days, and he passes away peacefully at home with his loved ones around him.

Ensuring more patients have an experience like Harvey's rather than Jane's is important. What does scientific research have to say about the end-of-life process? A number of clinical trials over the past couple of years have shed some much-needed light on palliative care and the best strategies to implement special care for patients nearing the end of their lives.

Defining the need

A study conducted by investigators from Duke University School of Medicine is among the first to take a closer look at the need for palliative care in patients with serious, non-cancerous illnesses.¹ Noting that most palliative studies have involved cancer patients nearing the end of their lives, the researchers compare functionality, advanced care planning (ACP), hospital admissions, prognosis, quality of life, pain, dyspnea, fatigue, and depression between patients with cancer and those with end-stage renal disease, heart failure, and COPD to find out where the differences may lie.

Functionality as measured by the palliative performance scale served as the primary outcome measure in the study, and results showed patients with primary diagnoses other than cancer were less functional at the time of referral to palliative care. The researchers conclude, "One aim of palliative care for those with non-cancer severe illness should be directed toward improving and assisting with functionality and decreasing frequency of hospital admissions. These interventions could take place in the palliative care office, but could also be integrated into hospital discharge plans."

Clearly, respiratory patients have unique needs that should be met to ensure a better and more cost-effective end-of-life experience. Unfortunately, many of them are not even afforded the possibility of having those needs met. British researchers who conducted a meta-analysis of 21 studies on ACP among patients with respiratory conditions have found the practice was rarely carried out.² While health care providers acknowledged the need for ACP, a number of barriers stood in the way of its implementation, including the complex course of disease for those with chronic respiratory conditions, the concern that ACP would strip patients of hope, and the lack of continuity of care.

These researchers believe the key is to provide greater training for health care professionals around the ACP process. "Identification of trigger points, training and system-related changes can facilitate engagement," they write.

Spanish researchers examined the availability of palliative care for patients with interstitial lung diseases (ILD) by a questionnaire they sent to all members of the Spanish Society of Pulmonology and Thoracic Surgery.³ Among the 164 respondents, 98% said they were interested in palliative care, 46% had received training in the area, and 44% reported responsibility for palliative care in their ILD patients. However, while 78% said they had reached a consensual agreement with patients about the limitation of therapeutic efforts, only 35% had helped patients prepare end-of-life documents and just 22% agreed on a place of death. The authors conclude that formative and organizational gaps exist in their country regarding the implementation of palliative care for ILD patients.

Addressing breathlessness

If there's an elephant in the room when it comes to palliative care, it has to be breathlessness. Patients suffering from cancer and chronic respiratory disease alike are often most troubled by dyspnea as they near the end of life, and medical professionals have debated the best way to treat this.

A meta-analysis conducted by Austrian investigators looked at previous studies on patients with advanced cancer who were receiving opioids, benzodiazepines, corticosteroids, or oxygen and rated their breathlessness via a visual analog scale, a numerical rating scale, or the Borg scale.⁴ Thirteen studies met the criteria, with results showing that five of nine studies looking at the effectiveness of opioids versus placebo found significant benefit for opioids, three found no benefit, and two found a benefit for a combination of opioids and benzodiazepines.

Among three studies using benzodiazepines alone, no benefits were seen, and two studies on oxygen also showed no benefit. One study that examined the treatment of dyspnea with steroids did show a benefit compared to placebo.

An international group of investigators explored patient preference for morphine therapy versus placebo in the treatment of refractory breathlessness in patients with heart failure and COPD.⁵ The data came from three randomized, double-blind, crossover, placebo-controlled studies, with results indicating that 43% of the 65 participants preferred morphine, 32% preferred placebo, and 25% indicated they had no preference. Younger patients were more likely to come down on the side of morphine, and those who suffered sedation and nausea from morphine treatment were less likely to prefer it.

How can respiratory therapists and their fellow health care providers ensure more patients receive the palliative care services they need at the end of their lives?

The authors conclude, “Morphine offers clinically important improvement, but net benefit can be easily outweighed by side effects, reducing net benefits. Side effects require aggressive management to allow more patients to realize benefits.”

Another study from international investigators examined the effects of morphine for refractory breathlessness on sleep in 38 patients mostly suffering from COPD.⁶ Each patient received 20 mg oral sustained-release morphine daily or placebo for four days in the double-blind, randomized, placebo-controlled, crossover study.

Over the four-day period, sleep disruption due to breathlessness was seen in 13–32% of the patients when they were taking the placebo and in 13–26% when they were on morphine. However, breathlessness decreased each day the patients took morphine, and they were less likely to report sleep problems. Patients whose breathlessness decreased during morphine treatment were the most likely to report better sleep when on morphine. The authors believe these findings suggest morphine may not only help relieve dyspnea in those with refractory breathlessness, but may also help them get a better night’s sleep.

Identifying patients

How can respiratory therapists and their fellow health care providers ensure more patients receive the palliative care services they need at the end of their lives? Researchers have examined this issue as well.

In a Canadian study conducted among patients with idiopathic pulmonary fibrosis, a multidisciplinary approach that included a respiratory therapist on the care team resulted in reduced health care use in the final year of life and more deaths at home.⁷ In addition to a respiratory therapist, the multidisciplinary team included two pulmonologists, a nurse, a physiotherapist, and a dietician. Together they adopted an early integrated palliative care approach aimed at early management of

symptoms and ACP along with community-based care in the patients’ own homes.

Patients receiving care from the multidisciplinary team were 24.2 times less likely to go to the emergency department for respiratory issues in their last year of life, 2.32 times less likely to be hospitalized with a respiratory problem, and 9.2 times more likely to die at home or in a hospice facility.

A new tool called the Palliative Care Planner (PCplanner) developed at Duke University got good marks in a study involving ICU patients.⁸ The mobile web app system, which is integrated with the electronic health record (EHR) system, prototype was used to screen the EHR for ICU pa-



tients meeting five criteria considered triggers for palliative care. In a study involving 14 patients, 18 family members, and 10 clinicians, family members reported high acceptability of the PCplanner, and PCplanner patients had shorter mean hospital lengths of stay and more frequently received hospice care when compared to controls who received a palliative care consult.

“PCplanner represents an acceptable, usable, and clinically promising systems-based approach to delivering EHR-triggered, needs-targeted, ICU-based palliative care within a standard clinical workflow,” write the authors. They call for additional study in more patients to confirm the utility of the tool.

Of course, despite the best intentions of health care providers, some patients will still end their lives in the acute care hospital. Canadian researchers looked at the use of a comfort measures order set (CMOS) to assess imminently dying patients’ symptoms and needs in a tertiary care academic hospital.⁹ Patients cared for via CMOS were compared to those for whom the order set was not used.

Overall, 56 patients received the CMOS and 27 did not. Patients who received care through the CMOS were

significantly more likely to have spiritual care (66% vs. 19%), and they required only 1.7 adjustments to symptom management compared to 3.3 for patients not receiving CMOS care. No differences were noted, however, in significant distress around the time of death. Dyspnea was the most common reason for significant distress reported in the study. ■

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Industry Watch

Dräger donates ventilators to RT programs

To help foster a greater learning experience for respiratory therapy students, Dräger donated 12 V-Series ventilators to U.S. respiratory therapy schools during AARC Congress 2017 in Indianapolis. A Dräger spokesman said the company is honored to provide the latest mechanical ventilation technology to RT professionals, who are critical to the future of health care. A twelfth ventilator was donated to Lone Star College-Kingman after Hurricane Harvey destroyed the cardiopulmonary teaching lab in the Houston area. “As a corporate partner of AARC, and a company dedicated to life-saving technologies, Dräger takes pride in its corporate and social responsibilities,” said Ed Coombs, MA, RRT-NPS, RRT-ACCS, FAARC, director of marketing for intensive care, Dräger, Inc. “By providing leading innovations in respiratory care to the next generation of RT professionals, we hope to play a part in improving patient outcomes while maintaining cost effectiveness.”

Monaghan receives innovation award

Monaghan Medical Corporation received a 2017 Innovative Technology designation from Vizient, Inc., the largest member-driven health care performance-improvement company in the country, for its AEROBIKA® Oscillating Positive Expiratory Pressure (OPEP) device. The designation was based on direct feedback from hospital experts who interacted with the AEROBIKA OPEP device at the Vizient Innovative Technology Exchange in Denver last fall.

Dynavax begins dosing in inhaled lung cancer drug trial

Dynavax Technologies Corporation has begun dosing in a Phase 1B dose-escalation clinical trial of its investigational inhaled Toll-like receptor 9 (TLR9) agonist, DV281, in patients with non-small cell lung cancer. The multi-center, open-label trial is designed to evaluate safety and identify the optimal dose for a potential expansion phase of the study. Dynavax engineered DV281 specifically for inhalation to facilitate local administration of a TLR9 agonist to lung tu-

mors that are not easily accessible for intratumoral injection.

West Virginia University establishes inhalation facility

West Virginia University has launched a new inhalation facility to serve as the home for research and collaborations that measure, identify, and discover how the particles we breathe affect our health. The facility provides researchers with real-time monitoring capabilities and can accommodate many types of respirable particles during simultaneous experiments. It will also enable research into how nanomaterials and other inhalable particles from things like e-cigarettes and auto emissions may impact health.

Arch Biopartners drug advances

According to Arch Biopartners, Inc., the good manufacturing practice (GMP) production campaign for AB569 has advanced to the GMP glass vial-filling stage. AB569 is the company's inhalation drug candidate for treating antibiotic-resistant bacterial infections in the lungs of patients with

cystic fibrosis (CF) and COPD, as well as other indications. AB569 is a potential standalone or complementary treatment to existing and emerging standard of care therapies for patients with CF and COPD who have reduced lung function due to multi-drug-resistant bacterial infections.

Propeller Health launches free service for asthma patients

Propeller Health has released the first application programming interface aimed at allowing anyone in the country to share asthma conditions in their communities. Air by Propeller uses a trained machine-learning model on millions of days of anonymized data, including where and when people experience asthma symptoms and the environmental conditions at these times, to predict potential effects on people's breathing.

Pulmatrix receives QIDP for anti-fungal drug

According to Pulmatrix, Inc., the U.S. Food and Drug Administration has designated Pulmazole, its drug candidate for treating fungal infections

in the lungs, as a Qualified Infectious Disease Product (QIDP) in a second indication. Under the QIDP program, which is designed to speed the development of novel drugs against important pathogens, Pulmatrix will receive five years of additional market exclusivity for Pulmazole. “This second QIDP designation is a significant boost to our efforts to make this drug available as quickly as possible to severe asthma patients suffering from fungal lung infections,” Pulmatrix CEO Robert Clarke, PhD, was quoted as saying.

Theravance Biopharma drug outlined in new studies

Data from new studies of Theravance Biopharma’s VIBATIV® (telavancin) were presented at IDWeek™ 2017 last October. The studies included preliminary data on clinical response rates for patients enrolled in the ongoing Telavancin Observational Use Registry (TOUR™) study. TOUR is designed to report how telavancin is being used by health care practitioners to treat patients in real-world clinical settings. Additionally, findings from a study evaluating the in vitro potency of VIBATIV against several challenging *Staphylococcus aureus* pathogens as compared to other commercialized antibiotics were presented. This study examined difficult-to-treat methicillin-resistant and

methicillin-susceptible *S. aureus* (MRSA and MSSA) strains, including those considered to be multi-drug-resistant.

Tactio Health Group and MIR unite on telehealth

Tactio Health Group and Medical International Research (MIR) are teaming up to offer a telehealth solution specifically designed to remotely monitor COPD patients via the MIR SmartOne portable FEV₁ and peak flow meter. The joint solution adds MIR spirometers to a growing list of Bluetooth-enabled devices that seamlessly integrate with TactioRPM patient apps, enabling data collection without mandating third-party accounts. “With MIR SmartOne, COPD patients being monitored remotely with TactioRPM systems can benefit from an easy and simple way to self-test, report, and exchange with their pneumologist,” noted Michel Nadeau, PEng, CEO of Tactio Health Group.

Battling food allergy bullying

The Allergy & Asthma Network, Food Allergy & Anaphylaxis Connection Team, Food Allergy Research & Education, and Kids with Food Allergies have joined the pharmaceutical company kaléo in launching a new initiative to raise awareness about the prevalence and potential

dangers of food allergy bullying. Food allergy bullying occurs when children and teens living with life-threatening food allergies are teased, ridiculed, or even threatened or assaulted with food to which they are severely allergic. “No Appetite for Bullying” grew out of a survey commissioned by kaléo in which 82% of parents with kids with life-threatening allergies reported their own kids had been bullied.

United Therapeutics inhalation device approved

United Therapeutics Corporation has received FDA approval for its new inhalation device, the TD-300/A, for use with Tyvaso® (treprostinil) Inhalation Solution (Tyvaso). Tyvaso was originally approved by the FDA for the treatment of pulmonary arterial hypertension in 2009 under a New Drug Application covering a drug-device combination product consisting of the Tyvaso drug product and an ultrasonic nebulizer and accessories, referred to as the Tyvaso Inhalation System. United Therapeutics has been working on improvements to the system to aid patient compliance and enhance ease of use. The company believes the TD-300/A, with its single-button operation, an intuitive user interface for adjusting breath counts, a graphical display that leads patients through the inhalation

process and displays time since last treatment and an internal, rechargeable battery, is a significant step forward.

Spyryx Biosciences begins CF drug trial

According to Spyryx Biosciences, Inc., the first patient has been dosed in the HOPE-1 study, a multinational Phase II clinical trial for its lead compound, SPX-101, in CF. HOPE-1 is a 28-day study using an adaptive design testing two doses of SPX-101 against placebo in each of two serial cohorts of patients. In total, the study plans to enroll up to 78 subjects with CF and is being conducted in select clinics in Canada and Western Europe. The adaptive trial design allows for efficient testing of the efficacy, safety, and tolerability of SPX-101 across multiple dose levels. SPX-101 is an inhaled peptide with a novel cellular mechanism that durably reduces sodium absorption in the airway by internalizing epithelial sodium channels from the apical surface of the epithelium. The therapeutic effect of the drug is to enhance airway and mucus hydration and promote mucociliary clearance. ■

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



RC Currents

IN THE NEWS



Is There Gender Bias in Bystander CPR?

A new study from the Center for Resuscitation Science at Penn Medicine finds men are significantly more likely than women to receive CPR from a bystander.

Researchers evaluated 19,331 cardiac events using data from the Resuscitation Outcomes Consortium, a network of regional clinical centers in the United States and Canada that study out-of-hospital treatments of cardiac arrest and trauma. Their analysis showed that 45% of men received bystander CPR in public compared to 39% of women, making men 1.23 times more likely to receive it than women. Men

were also nearly two times more likely to survive a cardiac event after bystander CPR, and even without bystander CPR, they had 23% increased odds of survival when compared to women.

“By uncovering this disparity, we’ll be able to think about new ways to train and educate the public on when, why, and how to administer bystander CPR, in order to help save more lives — of both men and women,” lead author, Audrey Blewer, MPH, was quoted as saying. The study was presented at the American Heart Association Scientific Sessions 2017. ■



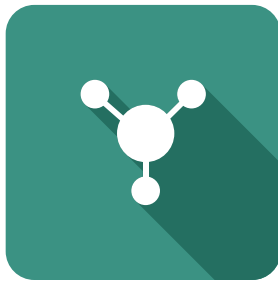
Become a Storyteller

Every therapist has a story to tell about a favorite or most memorable patient that would interest others in the profession. Maybe it was an “aha moment” when you knew you had made the right professional decision for that patient. Maybe it was when you first realized how much difference you were making in the lives of that patient and his family. Or maybe it was something the patient said or did that made you laugh or cry or just be inspired to be a better RT. Our “Storytellers” column is the place to share them. Send your story to *AARC Times* Editor Marsha Cathcart at cathcart@aacr.org. ■

Retirees: Share Your Wisdom

Have you recently retired from the profession? If so, we’d like you to look back at your career or some aspect of it and tell us what it meant to you and why for our Reflections column in *AARC Times*. Funny, sad, inspiring — the door is wide open! Start brainstorming some ideas and then submit your story to *AARC Times* Editor Marsha Cathcart at cathcart@aacr.org. ■





Protein Linked to Asthma Plays a Role in Food Allergies

Building on previous research showing that a small protein called histamine-releasing factor (HRF) plays a pro-inflammatory role in asthma, investigators from the La Jolla Institute for Allergy and Immunology have now found the protein is linked to food allergies as well.

The team reached that conclusion after engineering mice to become sensitized to egg protein and then treating them with an oral HRF inhibitor their lab had developed for use in asthma-related experiments. Then they re-exposed treated

and untreated mice to egg allergens. Untreated mice developed diarrhea and signs of gut inflammation, but these symptoms were delayed or much less severe in inhibitor-treated mice. Further study showed that the inhibitor reduced the allergen reactivity of mast cells isolated from the gut of allergic mice.

From there, the investigators looked at children with egg allergies and HRF-reactive IgE who were undergoing an anti-allergy procedure in which they were fed increasing amounts of egg to achieve desensitization. At the end of the therapy, children took a two-week break from eggs and then were retested after once again eating eggs. Children who met the final challenge maintained low blood levels of HRF while those who did not experienced a rise in HRF-reactive IgE.

The study was published in a recent edition of the *Journal of Clinical Investigation*. ■



Dan Grady, MEd, RRT, FAARC, passed away in November 2017. A well-known inventor of respiratory devices, Grady most recently served as director of research and development at Mission Health System in Asheville, NC. He held a number of offices in the North Carolina Society for Respiratory Care (NCSRC) over the years, including president in 1993–1994, and he was a nine-time NCSRC Sputum Bowl champion. Grady was on the winning Sputum Bowl team at the AARC Congress in 1991. He also served as a delegate to the AARC House of Delegates. ■

Contribute to Our “Transitions” Column

The AARC “Transitions” column is devoted to sharing news about the passing of AARC members. You can submit news about your colleagues’ recent passing by going to <http://c.AARC.org/transitions>. Please provide any information about the member’s recent obituary so that we can share it with the membership and pay tribute. ■

Gut-Brain Relationships May Impact Quitting

Could the differences seen in the ability of men and women to kick the smoking habit have their roots in the relationship between the brain and the gut? Investigators publishing in a recent edition of *Chemical Research in Toxicology* believe the answer could be yes.

They conducted a 13-week experiment in which they administered nicotine-infused water to mice. An analysis of the animals’ fecal samples showed major differences in the composition of the microbiomes in male and female mice. Specifically, levels of compounds and bacterial genes associated with the nervous system and body weight were altered in different ways.

For example, mice exposed to nicotine, especially the males, had lower fecal concentrations of glycine, serine, and aspartic acid, which could weaken the addictive effect of nicotine. Nicotine-treated female mice had reduced amounts of *Christensenellaceae* bacteria, while the treated male mice had increased levels, which are associated with a lower body mass index.

The team plans additional study to explore nicotine-gut-brain interactions on a molecular level to further understanding of the communication paths involved. ■



One Antibiotic Is Enough

Children with community-acquired pneumonia often receive both amoxicillin and azithromycin. Researchers from Vanderbilt University find that amoxicillin alone gets the job done just as well as the combination therapy.

The study was conducted among 1,418 children hospitalized for radiologically confirmed community-acquired pneumonia: 72% percent received amoxicillin alone, while 28% received both drugs. No significant differences in length of stay, intensive care admission, readmissions, or recovery at follow-up were seen between the groups. Nor were differences noted among subgroups of children most likely to benefit from the combination therapy, such as children with *Mycoplasma pneumoniae*, those with wheezing, and those admitted to intensive care.

“Pneumonia accounts for more antibiotic days in U.S. children’s hospitals than any other condition,” study author Derek Williams, MD, MPH, was quoted as saying. “Reducing unnecessary antibiotic use in pediatric pneumonia and other respiratory illnesses is one strategy to help slow the progression of antimicrobial resistance.”

The study appeared in a recent issue of *JAMA Pediatrics*. ■



Not Too Old

“Ideal donor” criteria generally call for an organ donor to be under the age of 50. A new study from investigators at the University of Louisville suggests it may be time to increase the age limit.

They looked at data on lung transplant patients age 18 and older from the United Network of Organ Sharing thoracic transplant database, finding there were 14,222 transplants performed between January 2005 and June 2014. Among that group, 26% were age 50 years or younger, and 2% received lungs from donors older than age 60. Five-year survival overall was about the same for these patients as for patients who received lungs from younger donors.

Further study, however, found the type of lung transplant performed made a difference. Specifically, younger patients who received a single lung transplant using an organ from an older donor had a five-year survival rate of 15% versus a survival rate of 50% among those receiving an organ from a younger donor. However, when a double-lung transplant was performed, the survival rates were 53% and 59%, respectively, which was not considered statistically different.

“This study demonstrated that reasonable outcomes are possible with the use of advanced age donors,” study author William Whited, MD, was quoted as saying. The research appeared in a recent issue of the *Annals of Thoracic Surgery*. ■

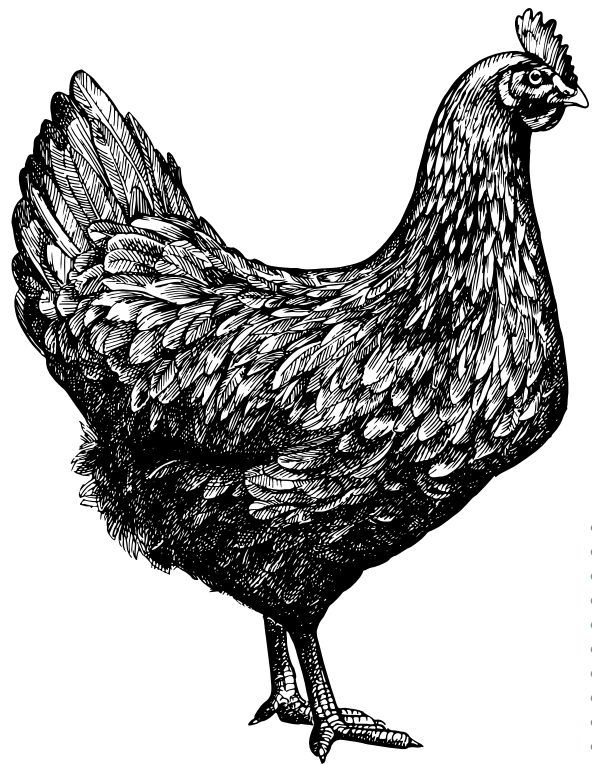


New Hope for an Old Vaccine?

A respiratory syncytial virus (RSV) vaccine that failed to protect children from the virus and instead caused severe respiratory illness and vaccine-enhanced respiratory disease (ERD) might work after all — under the right circumstances. In an animal study, Georgia State University researchers found immunizing mice with virus-like particles containing RSV fusion proteins before administering the formalin-inactivated (FI-RSV) vaccine prevented FI-RSV vaccine-enhanced lung inflammation and the invasion of disease-fighting eosinophils in mice infected with RSV.

They used control mice and two groups of mice that received one of two primers before receiving the FI-RSV boost vaccine. One group was primed with the FI-RSV vaccine and then given the FI-RSV boost. Another group was first primed with vaccine-like particles containing RSV fusion proteins and then given the FI-RSV boost. Blood samples were collected three weeks after these immunizations. After 15 weeks, the control mice and mice from the two immunization groups were infected with RSV to determine the efficacy of protection against RSV and assess ERD.

“This study provides insight into mechanisms responsible for ERD caused by FI-RSV vaccination and developing safe RSV vaccines,” study author Dr. Sang-Moo Kang, was quoted as saying. “We demonstrated that priming mice with virus-like particles that present RSV fusion proteins shifted immune response and resulted in preventing ERD.” The study appeared in a recent edition of *Virology*. ■



This May Be Why Recent Flu Vaccines Have Failed

The annual flu vaccine has been made by injecting influenza into chicken eggs for more than 70 years now. It might be time for a change.

According to researchers from the Scripps Research Institute, who published their findings in a recent edition of *PLoS Pathogens*, growing influenza vaccine components in chicken eggs disrupts the major antibody target site on the virus surface, rendering the flu vaccine less effective in humans.

In a study involving the H3N2 subtype of the influenza virus, the researchers used X-ray crystallography to show that, when grown in eggs, the H3N2 subtype mutates a key protein to better attach to receptors in bird cells. This mutation disrupts the region on the protein that is commonly recognized by the immune system, which means a vaccine containing the mutated version of the protein will not be able to trigger an effective immune response. The analysis found the current strain of H3N2 used in vaccines already contains this specific mutation and may be why recent flu vaccines have only been about 33% effective against H3N2 strains. ■



CF Drugs Found Effective

A two-drug therapy containing both tezacaftor and ivacaftor improved lung function by nearly 7% compared to placebo in cystic fibrosis (CF) patients with certain mutations in the *CFTR* gene in a study conducted by investigators from the University of Alabama at Birmingham. The combination therapy produced a nearly 2% improvement over ivacaftor alone. The study looked at 248 CF patients with one copy of the F508del mutation and a second mutation referred to as a residual function mutation.

Another study out of the University of Colorado found similar efficacy for the tezacaftor/ivacaftor combination in patients with two copies of the F508del mutation, which represents about half of all people with CF.

“The patient population in our study represents another 7–9% of patients, and the University of Colorado study represents about 50%,” UAB study author Steven Rowe, MD, was quoted as saying. “That still leaves a subset of patients without a good therapy for CF; but we are extremely excited about the next generation of medications currently under development, which could constitute a triple-combination therapy approach.”

Both studies were presented at the North American Cystic Fibrosis Conference, and the UAB study was also published recently in the *New England Journal of Medicine*. ■

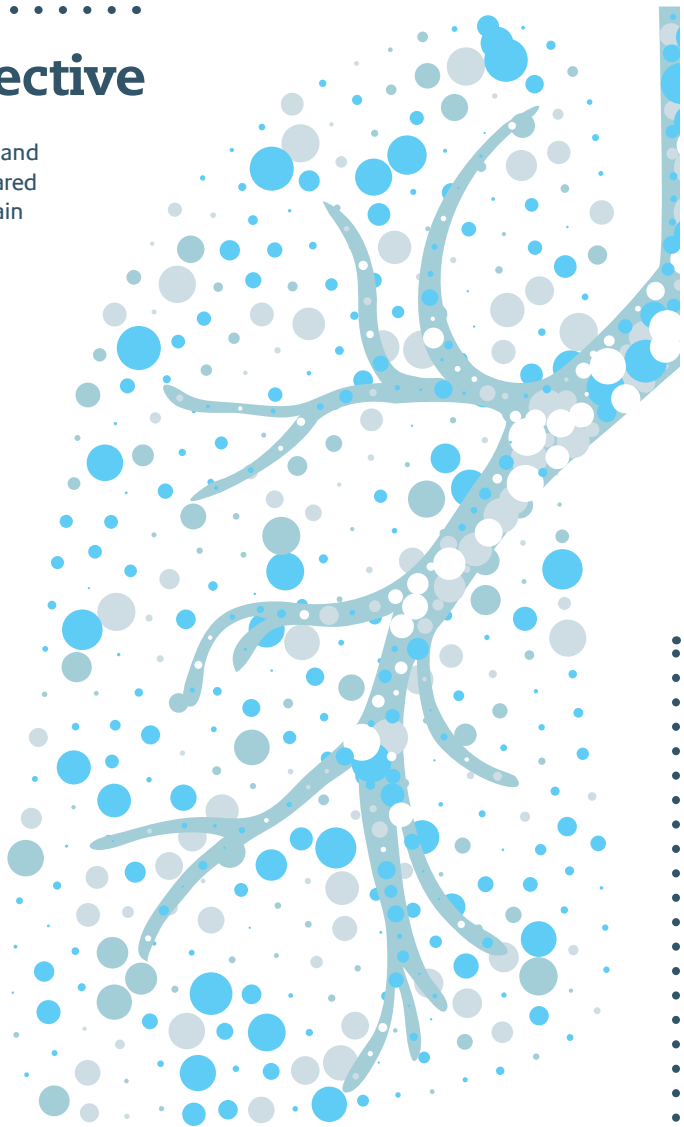
Lung Microbiome May Affect Asthma Severity

The causes of asthma severity have been explored in many studies, but new research from investigators at the University of Illinois at Chicago is adding something new to the mix. They find that the lung microbiome may be responsible for both asthma severity and response to treatment.

The study began with a group of clinically similar patients between the ages of 18 and 30 who were suffering from mild to moderate atopic asthma. From there, the investigators identified two asthma phenotypes, AP1 and AP2, by assessing the microbiome and

airway inflammation. AP1 showed decreased T helper cytokines and increased enterococcus bacteria, but pulmonary function tests were normal and AP1 was associated with less severe asthma. AP2 was associated with increased pro-inflammatory cytokines, increased oral taxa and strep pneumonia bacteria, decreased pulmonary function tests, and more severe asthma.

In both AP1 and AP2, the associations between the composition of the microbiome and specific inflammatory cytokines were decreased after treatment with an inhaled corticosteroid, suggesting inhaled corticosteroids may function by dampening responses to microbes. The study was published in *PLoS One*. ■



More Information Helps Explain SIDS

Australian researchers working with colleagues in the United States have discovered a developmental abnormality that could help explain many cases of sudden infant death syndrome (SIDS).

The investigators examined the cases of 55 U.S. infants who had died from SIDS, finding a key abnormality in part of the brainstem controlling breathing and movements of the head and neck. The abnormality occurs in the transmission of a neuro-peptide known as “substance P” and its binding with an associated neuroreceptor called neurokinin-1 (NK1R).

“An infant with this abnormality is likely to have impaired respiratory and motor responses to life-threatening challenges during sleep,” explains study author Dr. Fiona Bright. “While they may be otherwise healthy looking, there

is an inability for that child’s brain and body to respond appropriately to an event in which the child is deprived of oxygen in some way.”

The finding explains why it is so imperative for parents to put their infants to sleep on their backs, where they are significantly less likely to encounter a situation causing a deprivation of oxygen. Professor Roger Byard, who supervised the study, notes, “If a child has this underlying vulnerability in its brain chemistry, and its breathing becomes compromised by sleeping on its front, that child is at greater risk of death because its body simply can’t respond in the normal way. The baby can’t lift its head, and its breathing and heartbeat will be compromised.”

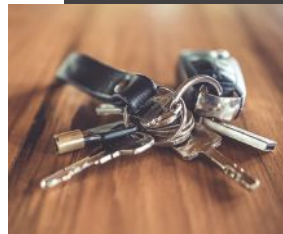
The study was published in a recent edition of *PLoS One*. ■

Strange But True...

+ **Remember this:** A new study funded by the National Institute on Aging will look at a novel use of the nicotine patch: improving memory loss seen in people with mild cognitive impairment. Small studies conducted among these patients have already seen positive results.



+ **Foodie alert:** It can be hard for people with food allergies to enjoy dining out, but that may soon change. Harvard researchers have developed a \$40 device that fits on a keychain and reportedly can accurately test for allergens like tree nuts or gluten in under ten minutes. It’s called the iEAT (which stands for “integrated exogenous antigen testing”).



+ **Blood type exposes risk:** Utah researchers who compared blood types with air-pollution levels in patients treated at their hospital between 1993 and 2007 have found that people with the A, B, or AB blood types have an elevated risk of having a heart attack during periods of significant air pollution, compared to those with the O blood type.



+ **You’re doing it wrong:** North Carolina researchers who used anatomy-based flow physics in the nasal cavities to determine the best route for nasal sprays aimed at treating allergies have found that current recommendations fall short of the mark. Their advice: if you want to reach the “magical fluid pathways,” insert the spray nozzle 10 mm into the nose and hold it at a 35-45 degree angle rather than the recommended 22.5 degrees. ■





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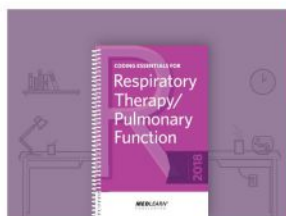
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Let the Adventure Begin

Terry J. Lirette, RRT, EMT, LPN

My adventure began in 1957 in the Navy. I served on a tank-landing ship and saw a volcano erupt in Hawaii. I was accepted into the Hospital Corps in California and transferred to the naval hospital in Corpus Christi, TX. My first “vent” patient was a fighter pilot in an iron lung. My last year at the hospital was in the dependent clinic delivery room. I had to play catch once in the delivery room; the mother said, “Not to worry, young man — after the fifth one the rest come easy.” I served five years active duty and five years in the reserves.

From LPN to RT

I took my LPN boards and was the only male nurse at Terrebonne General Hospital in Houma, LA. As such, they “let” me care for all the burn patients and the inhalation therapy needs. I then changed my major from nursing to inhalation therapy. Lucky me! I graduated with a degree in inhalation therapy in 1968 and was the first respiratory therapist southwest of New Orleans.

With the help of two classmates and nine on-the-job trainees, we opened the cardio-respiratory care department. Our medical directors, Dr. George Clauer and Dr. Jules Dupont, were so impressed that they wanted to help us start an educational program of our own. In cooperation with five hospital administrators, we recruited two students from each hospital with the intent to send them back to open their own departments. We graduated 19 in the first class. We sponsored many seminars to continue to educate our RTs. That was a great way to enhance the growth of the RT population. In 1967, we had fewer than 50 RT practitioners in the state of Louisiana. We now have 3,600. The credit belongs to all who got us here.

Honored to serve

We closed that program in 1977 and moved to a new associate degree program at Nicholls State University in Thibodaux in 1978. I directed the program until I retired from teaching in 1983. The new director was Kendrick Duet, MA, RRT. He improved the program and added a bachelor’s degree component. Now the associate degree program is at Fletcher Technical Community College in Schriever, under the direction of Errol Champagne, MEd, RRT.

I was honored to serve as president of the Louisiana Society for Respiratory Care in 1977 and again in 1985. When I was president-elect in 1984, we moved from three chapters to nine to give more voice to our new board of directors. We also wanted to improve communication between our society and our Louisiana legislators so that we could successfully lobby for our RT licensure bill in 1985. The law was signed that year.

I was honored to serve on the Louisiana State Board of Medical Examiners Advisory Committee on Respiratory Care for eight years with

Wayne Dixon, MS, RRT, RN, Sheila Guidry, CRT, and Ron Tucker, CRT. I thank them for their hard work on the board to regulate the law. I also have to give credit to James Liverett, BS, RRT, 1972 AARC president, and Wayne Dixon for their leadership.

Many of our great leaders no longer walk with us, but they are not forgotten — Ron Blevins, RRT; Rocco Tretola, BS, CRT; Richard Richard, BS, RRT; Able Ariza, RRT; Ricordo Leon, RRT; Dale Hutto, RRT; and too many others to list here.

Many who contributed time and treasure are still with us — Mike Nolan, BA, RRT, RN; Greg Pierce, RRT; Lester Murray, RRT; Dan Calahan, MBA, BSRT, RRT;

about the author...



Terry J. Lirette just celebrated 50 years as an AARC member in 2017.

Jackie Bush, BS, RRT; Doug McIntyre, MS, RRT, FAARC; Laurie Lynam, BS, RRT; Foster “Duke” Johns, and many more.

50 years and counting

I retired in 2004 to care for my wife, Alice. I thank her and my children, Mark, Eileen, and Angela, for their support in my adventures.

My 50-year membership in the AARC — and the education it has afforded me — have provided more opportunities than I can count. AARC membership has given me an identity, a feeling of belonging, and pride. I will continue to pay my membership dues out of respect to the profession that gave me so much.

I would like to give some advice to today’s RTs. All associate-degree CRTs: Take the RRT exam, then work toward a BS degree. You will need it!

The respiratory care profession got here due to the hard work of RTs across our country. I am humbled and proud to have worked with you. ■



Terry Lirette, right, enjoys a round of golf with one of his old Navy buddies, Ray Lovell.

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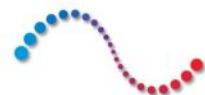
— 2018 —

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.

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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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1. Gailindo-Filho et al. 2015
2. AlQuaimi et al. 2017
3. Velasco et al. 2017

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