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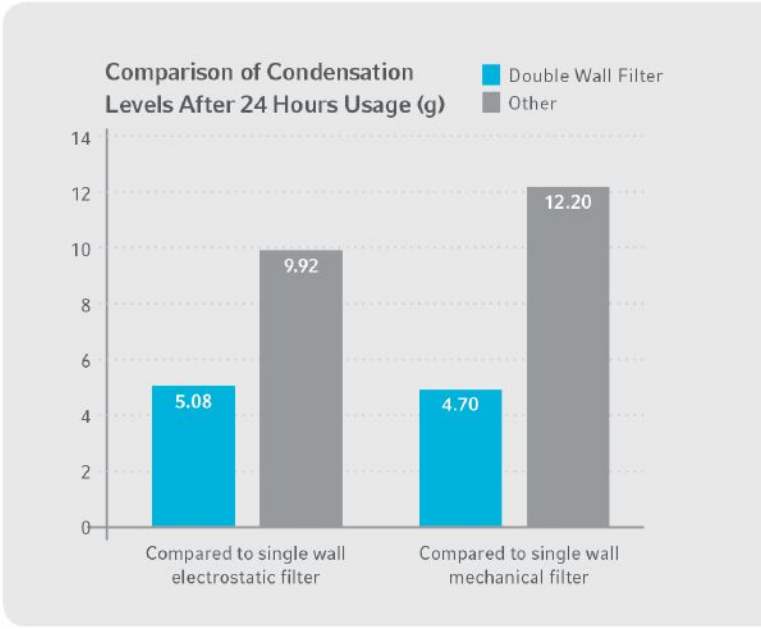

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AARC Strategic Plan

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

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American Association for Respiratory Care

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Safety Critical Software

by Anthony L. DeWitt, JD, RRT, FAARC

Have you considered recently how much of your job revolves around software? Your pulse oximeter uses software. Your mechanical ventilator likely does as well. ECG monitors have alarms that are software-based. Patient-controlled analgesia uses software. Your facility's billing, accounting, and auditing systems use software. Indeed, your secretarial staff use software to do their jobs.

But how much of that software is safety critical? In other words, if the software is defective, how many of these systems could potentially cause a failure that might cause a catastrophic result? And, more importantly, how can such catastrophes be prevented?

When equipment-deployed software was first introduced in the medical industry, it was not uncommon for little special attention to be given to safety. This changed by the early 1990s, in part as a result of the publication of a case study about the Therac-25 radiation therapy machine. Briefly, the Therac-25 was a radiation therapy medical device that was supposed to deliver controlled doses of radiation to cancer patients. This was a radiation-by-wire system where software replaced certain hardware safety mechanisms. Due to software defects (among other factors), it was involved in six known massive overdose accidents resulting in deaths and serious injuries.[1] Operators were taught that there were "so many safety mechanisms" that it was "virtually impossible to overdose a patient," leading to an overconfidence in fail-safes in routine operations.

After the first incident in 1985 at the Ontario Cancer Foundation, the manufacturer could not reproduce the reported problem. After analysis, it blamed a patient turntable position-measurement sensor. A sensor modification and a software fail-safe were added to mitigate the problem, and the manufacturer claimed a large safety improvement. Sadly, that did not turn out to be the case.

In 1986 two East Texas Cancer Center accidents proved the point. Two manufacturer engineers could not reproduce a malfunction indication reported by the local staff. The manufacturer explained after the first incident that it was not possible for the Therac-25 to overdose a patient. But this was found to be untrue after an investigation into a second overdose a month later at the same facility revealed the problem to be a software defect, although reproducing the software defect was difficult. The software was patched, but even then, an entirely different timing-dependent software problem emerged, causing a mishap in Washington state the following year.

That case study formulated fundamental principles that still hold today. One of those is that testing cannot ever be thorough enough to ensure safety, and randomly occurring software faults are difficult to reproduce and can kill. To combat this, a safety integrity-level (SIL) system was developed for the computing industry for safety-critical applications. This included creating software-specific system-safety standards that followed a SIL approach. SIL approaches are an accepted practice for managing risk in safety-critical software systems.

The general idea is to rank the level of software integrity required for a system on a scale from 0 (low integrity) to 4

(Continued on page 10)

about the author...

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

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

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

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

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

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

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

Sunovion Answers is there for your patients with support and answers. Call 1-844-276-8262 for more information.

Visit www.UTIBRON.com to learn more.

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

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

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

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

STUDY DESIGN

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

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

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

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

utibron™ neohaler®

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

utibron™ neohaler®

(indacaterol/glycopyrrolate) inhalation powder

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

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

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

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

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

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

Deterioration of Disease and Acute Episodes

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

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

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

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

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

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

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

Paradoxical Bronchospasm

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

Immediate Hypersensitivity Reactions

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

Cardiovascular Effects

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

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

Coexisting Conditions

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

Worsening of Narrow-Angle Glaucoma

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

Worsening of Urinary Retention

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

Hypokalemia and Hyperglycemia

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

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

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

ADVERSE REACTIONS

Clinical Trials Experience

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

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

12-Week Trials

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

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

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

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

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

52-Week Trial

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

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

DRUG INTERACTIONS

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

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

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

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

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

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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(Continued from page 5)

(high integrity). Software integrity is defined loosely as the degree of hazard/risk mitigation necessary to prevent software defects. On the SIL scale, if a software issue can cause a medical device to create a hazard that can produce serious problems, it is given a score of SIL 3. A score of SIL 4 is reserved for catastrophic failures like a complete ventilator shutdown or exhalation valve closure. In other words, designers evaluate the hazard, and how likely it is to occur, and take steps to mitigate those hazards. Not all hazards can be mitigated (eg, a combined failure of power, oxygen supply, and air supply is extremely unlikely and is doubtfully within the control of the programmer). The idea is to make software in medical systems as fail-safe as possible. A personal story helps explain this.

Many years ago (in a period my children refer to as "before broadband"), I wrote software simulation systems. They were written in a now-obsolete language called Turbo Pascal. Users entered values from the keyboard and moved through a clinical simulation in this way. The software was patterned on the NBRC Clinical Simulation Exam.

I believed the software to be error-free. Then one day a user called and complained that when he entered the number "1," the program crashed. I tried it on my computer and it worked fine. He had tried it on multiple computers, and it routinely failed. After a lot of hair pulling, we discovered the problem: the user had been taught to touch type on a typewriter. When he entered the number "1," he used the lowercase letter "L," which is what touch typists were told to use for the number "1." I had to patch the software to interpret an "L" as a "1" to solve the problem. It proved to me that you can never be certain of just how the users may misuse software.

What does all this mean in terms of the law? Every device you purchase for patient care, even if it is approved by the U.S. Food and Drug Administration, should certify that it meets the standards for safety-critical software systems if it contains a software element. Specifically, ask the manufacturer if the software complies with IEC 61508. That is an international standard published by the International Electrotechnical Commission, which sets standards for safety critical systems. Without certifying compliance with these standards, it is possible that even good programmers may have overlooked device faults or random errors that could trigger catastrophic results.

It's also important for a second reason. Whenever a lawsuit is brought, the manufacturer's first defense is that the operator made an error, claiming it is the operator, not the device, that was defective.

As with so many other things, buyer beware. Make sure that your electronic life support and monitoring systems comply with these international standards to ensure that your patients — and you — are safe. ■

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Asthma-COPD Overlap: A Diagnostic Dilemma

by Kathleen Ververeli, MD

Asthma-COPD overlap is a complex disease process incorporating facets of both individual diseases. Asthma and chronic obstructive pulmonary disease (COPD) have been extensively studied and defined by task force groups including the Global Initiative for Asthma (GINA) and Global Initiative for Chronic Obstructive Lung Disease (GOLD). Though their clinical presentations can vary, they each have criteria for diagnosis and treatment to aid health care providers in determining the best management plan for each patient. GINA defines this by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation."[1] The basis for asthma treatment is the use of anti-inflammatory medications such as inhaled corticosteroids and leukotriene antagonists. COPD is defined by GOLD as a "common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases."[1] The basis for its treatment is the use of bronchodilators such as a short- or long-acting beta-agonist and a long-acting anti-cholinergic. The use of inhaled corticosteroids does not play a role until the disease is more advanced.

Over the last decade, there has been a massive increase in research by pharmaceutical companies, national/international health organizations, and task force groups to better understand both asthma and COPD. In each of their study designs, they had specific inclusion and exclusion criteria to define the participants' diagnosis of either asthma or COPD. During this data collection, phenotypes of chronic lung disease emerged that did not fit into either the asthma or COPD category. Furthermore, the emergence of electronic medical records and standardized diagnostic codes revealed that patients would often be given a diagnosis of asthma as well as COPD by their clinicians. Because of this supporting data, task force organizations such as GINA and GOLD described a separate clinical classification for these patients in 2015: asthma-COPD overlap syndrome (ACOS). Since that time, both GINA and GOLD have partnered to promote better understanding of this clinical diagnosis. In 2017, the name was changed to asthma-COPD overlap. The reason for this change is that asthma-COPD overlap is not a single disease and can include several different phenotypes with variable underlying mechanisms. Therefore, the task force did not want to narrow the diagnosis and thereby limit patients who would fall into this classification.

about the authors...

Kathleen Ververeli, MD, is on faculty for the Lehigh Valley Hospital Pediatric Residency program and is the medical director of the Lehigh Valley Food Allergy Support Network.

Asthma-COPD overlap: description and rationale for investigation

"Asthma-COPD is characterized by persistent airflow limitation with several features usually associated with asthma and several features usually associated with COPD. Asthma-COPD overlap is therefore identified in clinical practice by the features that it shares with both asthma and COPD. This is not a definition, but a description for clinical use, as asthma-COPD overlap includes several different clinical phenotypes and there are likely to be several different underlying mechanisms."[1]

Epidemiologic review of asthma-COPD overlap showed various prevalence rates. Reported rates ranged from 15–55% of patients with chronic lung disease based on the definitions of asthma and COPD and the population studied. However, examining concurrent doctor-diagnosed

asthma and COPD, the prevalence is 15–20% of patients with chronic airway disease.[1] Therefore, the clinical classification of asthma-COPD overlap appears to be very common.

In addition to the prevalence rates, the review of the health-burden statistics for patients with asthma-COPD overlap revealed that these patients have higher exacerbation rates, more rapid decline in lung function, poorer quality of life, increased mortality, and increased healthcare utilization. Thus, the clinical spectrum of asthma-COPD overlap represents a significant impact on both patients and healthcare costs.

Because of the prevalence, clinical, and economic cost of asthma-COPD overlap, GINA and GOLD partnered to establish clinical diagnostic criteria and treatment recommendations to aid physicians in recognizing and treating these patients. Furthermore, the increased awareness of this diagnosis should lead to more research specifically focusing on asthma-COPD overlap diagnosis and treatment.

Asthma-COPD overlap: stepwise approach to diagnosis and treatment

GINA and GOLD partnered to create a set of steps to aid clinicians in the diagnosis and treatment of asthma-COPD overlap in patients who present with chronic lung disease. The five steps consist of the following categories (Fig. 1):

1) Does the patient have chronic lung disease?
2) Syndromic diagnosis of asthma, COPD, or overlap.
3) Spirometry.
4) Commence initial therapy.
5) Referral for specialized investigations (if needed).

Determining whether a patient with respiratory symptoms has chronic lung disease consists of a careful history that documents the presence of key symptoms, including chronic cough, chronic sputum, wheezing or dyspnea, and recurrent acute respiratory tract infections. The physical exam is often normal or may reveal evidence of wheezing and hyperinflation. Radiography including chest X-ray and computed tomography scans may reveal air-trapping, hyperinflation, or other diagnostic features.

Once a patient has been determined to have chronic lung disease, then his or her clinical features must be established to help delineate whether asthma, COPD, or asthma-COPD overlap should be diagnosed. The rule of 3's will help establish how to categorize the patients: if the patient has three or more features of one particular diagnosis, then that is the most likely diagnosis. There are certainly specific features that will suggest either asthma or COPD, but if a patient has multiple features of each, then the diagnosis of asthma-COPD overlap becomes more likely.

Spirometry is absolutely essential to differentiate the clinical presentations if chronic lung disease is suspected. Again, various measurements will suggest one of the diagnoses. For COPD and asthma-COPD overlap, a post-bronchodilator ratio of FEV_1/FVC must be <0.7, whereas a normal ratio excludes both the diagnosis of COPD and that of asthma-COPD overlap. The FEV_1 can vary in any of the diagnoses depending on the severity of the disease. Furthermore, while reversibility of 200 mL of the FEV_1 is often found in both COPD and asthma-COPD overlap, reversibility of 400 mL of the FEV_1 is frequently seen in asthma and is compatible with a diagnosis of asthma-COPD overlap while essentially ruling out COPD.

Initial treatment recommendations vary depending on the diagnosis. If the diagnosis is more consistent with asthma, then the initial treatment should consist of inhaled corticosteroids with later addition of a long-acting beta-agonist and a long-acting anti-cholinergic. If the diagnosis if more consistent with COPD, then the initial treatment is a short-acting bronchodilator followed by the addition of a long-acting beta-agonist, a long-acting anti-cholinergic, and then an inhaled corticosteroid. If the diagnosis is neither definitively asthma nor COPD and asthma-COPD overlap is considered, then the initial treatment should reflect that of asthma. The rationale for this recommendation is that a long-acting beta agonist is never considered to be a monotherapy for asthma. Other treatment considerations include cessation of smoking, treatment of comorbidities, pulmonary rehabilitation, vaccines, and other preventative care.

Referral for specialized investigations should occur if a patient continues to have exacerbations and poor control despite treatment measures. In cases where the diagnosis is uncertain because there are few criteria for either asthma or COPD and there are atypical symptoms such as hemoptysis, weight loss, or night sweats, then additional studies are needed. The presence of significant comorbidities that are difficult to control is another reason for referral.

Future directions for understanding asthma-COPD overlap

The partnership of GINA and GOLD and the resulting description of asthma-COPD overlap have greatly improved its recognition among clinicians. However, future research is greatly needed to further define the disease spectrum. Present studies are limited to either asthma or COPD and often exclude subjects with a combination disease. Therefore, research specifically

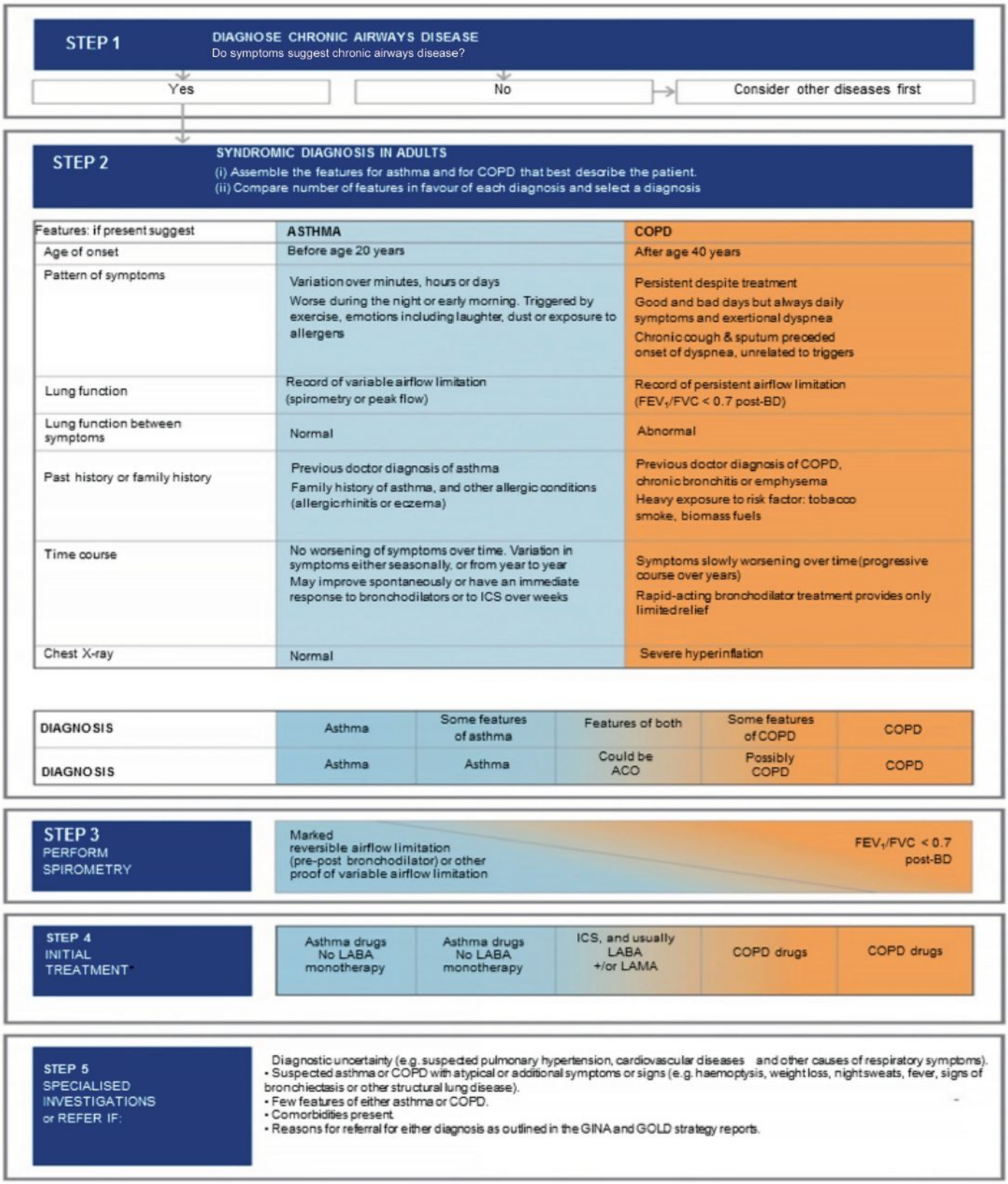

Figure 1. Asthma-COPD overlap stepwise diagnosis and treatment.

Reprinted from Global Initiative for Asthma web site, Diagnosis and initial treatment of asthma, COPD and asthma-COPD overlap: A joint project of GINA and GOLD.

STEP 2	SYNDROMIC DIAGNOSIS IN ADULTS (i) Assemble the features for asthma and for COPD that best describe the patient. (ii) Compare number of features in favour of each diagnosis and select a diagnosis	
Features: if present suggest -	**ASTHMA**	**COPD**
Age of onset	❑ Before age 20 years	❑ After age 40 years
Pattern of symptoms	❑ Variation over minutes, hours or days ❑ Worse during the night or early morning ❑ Triggered by exercise, emotions including laughter, dust or exposure to allergens	❑ Persistent despite treatment ❑ Good and bad days but always daily symptoms and exertional dyspnea ❑ Chronic cough & sputum preceded onset of dyspnea, unrelated to triggers
Lung function	❑ Record of variable airflow limitation (spirometry or peak flow)	❑ Record of persistent airflow limitation ($FEV_1/FVC < 0.7$ post-BD)
Lung function between symptoms	❑ Normal	❑ Abnormal
Past history or family history	❑ Previous doctor diagnosis of asthma ❑ Family history of asthma, and other allergic conditions (allergic rhinitis or eczema)	❑ Previous doctor diagnosis of COPD, chronic bronchitis or emphysema ❑ Heavy exposure to risk factor: tobacco smoke, biomass fuels
Time course	❑ No worsening of symptoms over time. Variation in symptoms either seasonally, or from year to year ❑ May improve spontaneously or have an immediate response to bronchodilators or to ICS over weeks	❑ Symptoms slowly worsening over time (progressive course over years) ❑ Rapid-acting bronchodilator treatment provides only limited relief
Chest X-ray	❑ Normal	❑ Severe hyperinflation

NOTE: • These features best distinguish between asthma and COPD. • Several positive features (3 or more) for either asthma or COPD suggest that diagnosis. • If there are a similar number for both asthma and COPD, consider diagnosis of ACO

DIAGNOSIS	Asthma	Some features of asthma	Features of both	Some features of COPD	COPD
CONFIDENCE IN DIAGNOSIS	Asthma	Asthma	Could be ACO	Possibly COPD	COPD

Details of Figure 1, Step 2. Syndromic classification of asthma and COPD.

Reprinted from Global Initiative for Asthma web site, Diagnosis and initial treatment of asthma, COPD and asthma-COPD overlap: A joint project of GINA and GOLD.

screening for asthma-COPD overlap needs to be conducted. Furthermore, clinicians must be educated to consider this combination diagnosis rather than limiting a patient's diagnosis to either asthma or COPD. Research into biomarkers, medication response, and outcomes with a specific focus on asthma-COPD overlap will allow for better understanding of the various phenotypes for asthma-COPD overlap and direct which treatment strategies should be utilized for specific patients. ■

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RT News from Around the World

by John D. Hiser, MEd, RRT, FAARC

The mission statement of the American Association for Respiratory Care includes the words *promote*, *advance*, and *advocate*, as well as the word *international*. The following news items from our friends and colleagues from around the world show that the AARC is promoting professional excellence, advancing the science and practice of respiratory care, and serving as an advocate for patients, their families, the public, and the respiratory therapist — and we are doing it at an international level. Here are some of this year's respiratory care activities around the world.

The editors thank John D. Hiser, MEd, RRT, FAARC, for his special contributions to this January international issue.

About the Author: John Hiser, MEd, RRT, FAARC, is chair of the AARC International Committee and was AARC president in 2005. He is the respiratory care program director at Tarrant County College in Fort Worth, TX.

International Council for Respiratory Care

International Council for Respiratory Care (ICRC) governors, organizational representatives, international fellows, and delegations representing more than 25 countries attended the recent AARC Congress in Indianapolis, IN. The ICRC convenes each year in a day-long session to consider action items and present annual reports and developments in respiratory care education, credentialing, and respiratory care clinical practice in their countries.

These ICRC meetings feature special reports such as "The Global Allergy Asthma Patient Platform: Best Practices To End Death and Suffering Due to Allergy and Asthma" and "Proposed New International Standards for Small-Bore RT and Oxygen Device and Accessory Connectors: Risk Identification and Potential Misconnections."

Everyone enjoys sharing information about respiratory care practices in their countries.

A collegial atmosphere at the ICRC meeting facilitates discussion between respiratory care professionals from around the world.

The ICRC met last October during the AARC Congress in Indianapolis.

International Respiratory Care Conference in China

By Xu Peifeng, 2015 AARC International Fellow

The 2017 West Lake International Respiratory Care conference and the founding meeting of the Respiratory Therapist Alliance of Zhejiang Province took place in Hangzhou China in August. Sir Run Run Shaw Hospital (SRRSH), which has the largest RT team in China, hosts this meeting. This international respiratory care forum includes ventilation management for critical care patients, pulmonary function testing, cardiopulmonary exercise testing, and pulmonary rehabilitation for chronic pulmonary diseases.

In 2017, more and more respiratory therapists joined the Pulmonary Rehabilitation Association in China. Pulmonary rehab for respiratory therapy is a very popular topic. SRRSH set up the first pulmonary rehabilitation clinic by a respiratory therapist this year on the mainland of China. Yuan Yuehua, a 2009 International Fellow, also translated the book titled *Pulmonary Rehabilitation Guidelines to Success* into Chinese to guide the respiratory therapists on how to perform pulmonary rehabilitation.

Report on the 10th Intercoastal Respiratory Therapy Assembly

By Xu Liang, MS, MD, Department of Respiratory Medicine, Wuhan Third Hospital, Wuhan, Hubei, People's Republic of China, and Chia-Chen Chu, MS, RRT, FAARC, Department of Respiratory Therapy, China Medical University & Hospital, Taichung City, Taiwan

The 10th Intercoastal Respiratory Therapy Assembly (ICRTA) and Wuhan Association of Critical Care Physicians Academic Conference was held Sept. 9–11 in Wuhan, Hubei Province, China. The assembly was co-sponsored by the Wuhan Association of Critical Care Physicians and the Taiwan Society for Respiratory Therapy, and was organized by Wuhan Third Hospital. More than 380 respiratory therapists, physicians, and nurses specializing in intensive care and respiratory medicine from the United States, South

A standing-room-only crowd of respiratory therapy practitioners attended a general session of the 10th Intercoastal Respiratory Therapy Assembly in Wuhan, China.

Korea, Taiwan, and mainland China participated in the forum featuring more than 30 poster presentations.

Twenty seminar faculty experts delivered excellent presentations covering the latest developments and contemporary topics in respiratory therapy. In addition to the plenary lectures, small-group breakout sessions and four workshops focused on critical care topics from the perspectives of ICU practitioners including respiratory therapists, physicians, and nurses. The forum enhanced communication among all disciplines involved in providing respiratory care.

Professor Jerome M. Sullivan, PhD, RRT, FAARC, president of the ICRC, discussed the Fundamental Respiratory Care Support Course, a new respiratory therapy training program being developed in the United States that has attracted great attention from Chinese participants. The conference has allowed respiratory care practitioners to present a series of training sessions on respiratory therapy technology standardization in many medical centers in Hubei Province.

The First Affiliated Hospital of Xi'an Medical College recently hosted the 11th Intercoastal Respiratory Therapy Assembly in Xi'an, Shaanxi, China.

Respiratory Care in Manipal, Karnataka, India

By Ramesh Unnikrishnan, 2015 AARC International Fellow

The department of respiratory therapy at Manipal University in Karnataka, India, trained 23 students and one postgraduate last year in the medical simulation center of Manipal University. Professor Brady Scott, from Rush University in the United States, gave an online lecture for the faculty of respiratory therapy as an introduction to planning and conducting clinical competency training. The postgraduate student then presented research posters at the Annual Congress of the Indian Society of Critical Care.

The RT department signed a memorandum of understanding with the University of Kansas in the United States. The department extended its RT education program by initiating the course in the Mangalore campus of Manipal University.

The Manipal University department faculty contributed articles related to mechanical ventilation to the educational newsletter initiated by Chest Research Foundation in Pune, India. The editorial team of this newsletter is headed by Madhura Gauri, who is an alumnus of Rush University Chicago. She visited Manipal in June 2017. The department faculty will also deliver lectures and participate as resource personnel for the Annual Congress of the Indian Association of Respiratory Care.

Sultanate of Oman Celebrates First Respiratory Care Week

By Khalsa Al Siyabi, Senior Respiratory Therapist, Royal Hospital, Head of Respiratory Services, Ministry of Health, Oman

After development and evolution spanning more than 20 years, the profession of respiratory therapy has matured and come of age in the Sultanate of Oman. The profession marked its state of development in the Sultanate by celebrating Respiratory Care Week on Oct. 23–25.

The Royal Hospital marked the inaugural recognition with events designed to raise awareness of the respiratory care profession and the need for improved lung health. Photo exhibits showed RTs in action, and RT stations

Khalsa Al Siyabi and RT colleagues at Royal Hospital celebrated Respiratory Care Week in Oman.

Royal Hospital celebrated Respiratory Care Week.

demonstrated equipment for airway management along with noninvasive ventilation and home care equipment, such as oxygen concentrators and transport ventilators.

Omani physicians were introduced to the RT profession and worked with respiratory therapists while studying in the United States and Canada during the early 1990s. The RT profession was introduced in the Royal Hospital in 1994, and it was the first site for RTs in Oman as it is the largest facility offering medical, surgical, renal, oncology, neurology, pediatric, and neonatal services.

Respiratory care services in Oman started from zero, with many challenges resulting from having only one respiratory therapist and one nurse. The RT department at Royal Hospital currently has a staff of 22 RTs who serve the facility and provide 24-hour coverage for patients. As of 2012, RTs have provided coverage in all regions of the Sultanate and are welcomed and accepted by their physician and nurse colleagues.

Since the establishment of RT in Oman, we have been following the policies and procedures of the AARC. We are very proud of our accomplishments and the goals we have reached as professional respiratory therapists, and there is interest in becoming members of the AARC. For all these reasons, we celebrated our first Respiratory Care Week in Oman. To encourage involvement and stimulate further development of the profession, all RTs in the various regions of the Sultanate were recognized with awards for their accomplishments.

In November 2017, the Ministry of Health in Oman held the first respiratory care workshop approved by the IERS, ICRC.

Saudi Arabia Holds Several Conferences

By Adil Alotaibi, PhD, RRT

We held our second Health Profession Conference at the King Saudi bin Abdulaziz University for Health Sciences Convention Center in April 2017. Many of the most prominent figures in the medical field were invited to be on the faculty. Time was also dedicated to research presentations and discussions. Our respiratory therapy program participated in the conference by presenting studies and conducting a workshop on advanced mechanical ventilation modes.

We participated in Asthma Awareness Day in May. The Ministry of National Guard — Health Affairs, Riyadh was represented by members of the Department of Medicine, the Respiratory Services Department, and the Nursing Services Department. With the theme "You Can Control Your Asthma," the event aimed to increase public awareness of asthma and its management.

The Saudi Critical Care Conference in May focused on improving all aspects of critical care in Saudi Arabia. The goals were to improve the standard of care and promote the best available knowledge among critical care staff for emergency medicine, trauma, burns, and infectious diseases.

We held our fourth Respiratory Care Student Symposium in April — an incredible scientific extravaganza of activities by students enrolled in a number of government and private universities and colleges in Saudi Arabia. It was a great opportunity for future respiratory care professionals to showcase their talents.

The Fourth Respiratory Care Student Symposium engaged students in activities to showcase their talents.

Institutional Profile: PLA General Hospital, Beijing, China

The Chinese PLA General Hospital is a large, modern, comprehensive teaching hospital providing high-quality health care and opportunities for postgraduate medical education and scientific research. The hospital was founded in 1953 and has 165 clinical medical departments, which accept 49,000 outpatients and emergency patients each year. We perform nearly 90,000 surgery cases per year. The medical-health care center is noted for providing high-end preventive care services.

Dr. Lu presented courses throughout the year to train ICU and emergency department doctors in China.

Using Simulations To Train Practitioners To Treat COPD and Asthma

By Liu Yang, MD, 2014 AARC International Fellow

From 2016 to 2017 we presented a course named Simulation for Intensive Mechanical Ventilation to simulate disease states such as pneumothorax, asthma, COPD, and ARDS as part of our national education curriculum at Shanghai, Urumchia, Xi'an, and Jiangxi provinces across China.

We have successfully trained more than 600 ICU and emergency department doctors, applying education funding provided by the Shanghai Health Bureau to support the course. We plan to apply for certification by the AARC and ICRC for this course.

Khalsa Al Siyabi from Oman visits Saudi Respiratory Care Departments

By Mohammed Al Ahmari, BSRC, MSc, RRT, Saudi Governor for Respiratory Care, ICRC and 2005 AARC International Fellow

The respiratory care department at Prince Sultan Military College of Health Sciences welcomed Khalsa Al Siyabi — the first head of a department of respiratory care services in Oman — for her exploratory visit to the respiratory care services department in the Kingdom of Saudi Arabia. During her visit to our respiratory care program, she met with the college officials and respiratory care faculty members, and she toured all of our college teaching facilities, including our advanced clinical simulation center. She learned about respiratory care curriculum development and its integration with clinical simulation.

Al Siyabi spent time at King Fahd Military Medical Complex, where she learned about respiratory care services in different settings. We also had a memorable visit organized by the respiratory care department at Johns Hopkins Aramco Hospital (JHAH). She had the chance to learn about respiratory care policies and procedures, educational materials, and clinical guidelines. There was

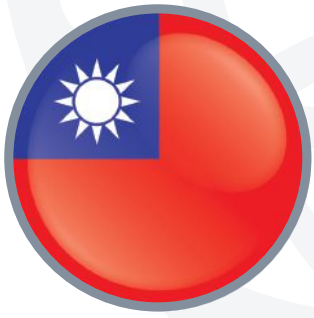
Khalsa Al Siyabi toured acute and non-acute settings at JHAH.

an additional tour of acute and non-acute settings, and Al Siyabi participated in a code blue situation while on tour. Her visit to JHAH was remarkable and a learning opportunity for all. She made an initial agreement to open opportunities for Omanis to study respiratory care at Prince Sultan Military College for Health Sciences. There was also an agreement to collaborate with us to improve respiratory care services in Oman.

Update on Respiratory Care in Turkey

2017 has been a great year for the development of respiratory care in Turkey, and the future of the respiratory care profession looks promising. Due to the ever-present challenge to provide optimum respiratory care to the patient, the Turkish Respiratory Society (TRS) foresaw the importance of developing a roadmap to improve the knowledge and practice of respiratory therapy. We met for an education program on respiratory care procedures during the Annual TRS Congress in October 2017.

Arzu Ari, PhD, RRT, PT, CPFT, FAARC, delivered a postgraduate course titled "The Mechanical Ventilation Education Program" that was offered in May 2017 at Mustafa Kemal University in Antakya, Turkey. Through the support of Dr. Hasan Hallaceli, program director of the School of Physical Therapy and Rehabilitation at Mustafa Kemal University, the program taught the basics of mechanical ventilation to Turkish physical therapists seeking clinical excellence and professional distinction. Participants received certifications approved by the International Education Recognition System that was developed by the International Council for Respiratory Care. Dr. Ari also gave various lectures to medical and physical therapy students at Sanko University in Gaziantep, Turkey.



Taiwan Respiratory Care Professionals Preparing for an Age Wave

By Chia-Chen Chu, PhD, RRT, FAARC, 2010–2016 Honorary Chairman of the Intercoastal Respiratory Therapy Assembly (ICRTA) and ICRC Governor for Taiwan

Taiwan has entered the aging society since 1993 (more than 7% of the elderly population) and will enter the elderly society in 2018 (more than 14% of the elderly population). We expect the elderly population to exceed 20% in 2026 and enter the super-aged society. The Taiwan government promotes long-term care. The Respiratory Therapists Society of the Republic of China is spreading awareness among the public on how respiratory therapists can help people in long-term care. Our RTs participated the 2017 Assistive Technology for Life Exhibition on Long-Term Care.

Taiwanese RTs at the 2017 Assistive Technology for Life Exhibition on Long-Term Care.

Respiratory care professionals in Taiwan informed the public about long-term care.

RT Profession in the Philippines Progresses

By Julita V. Toledo, RMT, RTRP, MPA, 2016 AARC International Fellow

There have been a lot of developments in the respiratory therapy profession in the Philippines over the past seven years. Recently, lifelong learning has become mandatory for all professionals through the implementation of the Continuous Professional Development Act of 2016. All professionals must obtain the required Continuous Professional Development (CPD) units per profession prior to the renewal of professional identification cards every three years. Hence, a respiratory therapist must obtain 45 CPD units every three years from accredited CPD providers or from self-directed learning activities as specified in the law.

Another important provision in this law is the establishment of career progression for all regulated professions, which now paves the way to institutionalize specializations in respiratory therapy. At present, the Professional Regulatory Board of Respiratory Therapy is gearing up to conduct focus-group discussions with stakeholders to establish the framework of this pertinent undertaking.

An international convention took place in December 2017 with topics focusing on specialty areas in respiratory therapy. Moreover, subsequent research in the practice of our profession in different countries is being conducted to determine commonalities in practice and to bridge differences to standardize professional competencies. We hope to obtain bilateral or multilateral agreements between the Philippines and other countries for mutual recognition of professional qualifications.

Challenging as these professional standard developments may seem, I believe these improvements will definitely be favorable to Filipino respiratory therapists as we all aim to upgrade our competencies toward specializations in our chosen field.

Filipinos are upgrading their educational and credentialing requirements.

Humanitarian Effort in Ghana Continues

By Lisa Trujillo, DHSc, RRT, Assistant Professor and Director of Clinical Education, Weber State University, Ogden, UT

Charity Beyond Borders, Weber State University, and the University of Kansas Medical Center have been providing medical and humanitarian education and assistance throughout Ghana for 11 years.

The University of Ghana RT program currently has nine respiratory students enrolled in their third semester, and a new cohort of students began in the fall of 2017. The students have the great opportunity to be taught by physicians from the University of Ghana and Korle Bu Teaching Hospital.

Ecobank Foundation of Ghana has partnered with Charity Beyond Borders, Weber State University, and the University of Kansas Medical Center to provide sponsorship and

Physicians from the University of Ghana and Korle Bu Teaching Hospital teach RT students.

resources in the development of the respiratory therapy program at the University of Ghana. Planning for a program is also underway at Kwame Nkrumah University of Science and Technology in Kumasi. Ecobank Foundation will provide $30,000 over five years to provide scholarships to respiratory therapy students. The CEO of Ecobank Foundation, Julie Essiam, notes that, through Ecobank's commitment, "lives will be saved and knowledge of respiratory therapy will be a national asset to be passed on to future generations."

Enhancing the Care of Pediatric Patients in Northern Haiti

By Natalie Napolitano, MPH, RRT-NPS, CTTS, AE-C, FAARC

Last June, pediatric intensive care doctors and nurses from four different hospitals in the United States joined me in teaching a basic pediatrics course at Hôpital Sacré Coeur (HSC) in Milot, Haiti. The physicians developed the course to standardize the teaching of advanced pediatric care in developing countries. The course was four days long and included pre- and post-testing, lecture, and simulation case scenarios.

HSC will be building a new pediatrics ward that will have dedicated intensive care beds formalizing pediatric critical care services and separating it from the adult ICU. The initiation of this training at HSC is the first step to building the groundwork and training for a formal pediatric critical service in northern Haiti, which will bring advanced skills and awareness to the pediatric clinicians.

The next steps are to continue clinical instruction with pediatric teams traveling to HSC three to four times each year and to initiate pediatric advanced life support training (PALS) and pediatric emergency assessment recognition (PEARS) courses. Respiratory therapists are essential members of these teams. Although it is a dedicated core team that travels each year, we are always looking for more qualified RTs to join the rotation! Contact Natalie Napolitano or Daniel Rowley (DDR8A@hscmail.mcc.virginia.edu) if interested in traveling with one of these teams to Haiti. ■

American physicians, nurses, and RTs travel to Haiti several times each year to enhance respiratory care there.

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Helping Kids No Matter Where They Live

AARC member Marcela Spraul is dedicated to bringing sick children from abroad to Shriners in St. Louis

by Debbie Bunch

A yearning for big city life led Marcela Spraul into a life of service instead.

Marcela Spraul has used her connections at Shriners in St. Louis to help kids in her native Colombia and elsewhere receive much-needed care.

Marcela Spraul, BSRT, RRT, was like a lot of 17-year-olds back in her hometown of Ibagué, Colombia, in the early 1990s — a small town girl who wanted to move to the big city. "I graduated from high school and I had big dreams of living in Bogotá, the capital of Colombia and a big cosmopolitan city," says the manager of respiratory therapy services at Shriners Hospitals for Children-St. Louis, in St. Louis, MO.

Getting there meant choosing a college and a major, and with little knowledge of what it was really all about, she settled on respiratory care at Fundación Universitaria del Area Andina. Her parents went for the idea — sort of. She says she had no idea what a respiratory therapy career was about but she was sure determined to convince her parents to pay for her education in Bogotá, and they did. But the big city lifestyle she had dreamed about was not to be. "Instead my parents sent me to live with nuns from Spain for five long years until I graduated," says the AARC member.

As it turns out, that experience taught her the value of community service, thus helping to set the stage for the humanitarian work she has been doing with children from Colombia and elsewhere for the past decade through her connections at Shriners. "I learned so much from the nuns about serving others," says Spraul.

It was a personal experience in 2009, however, that really put her plans in motion. Spraul worked as an RT at San José Hospital in Mariquitá during her thesis project and then took on a laboratory coordinator role for the health faculty at Fundación Universitaria del Area Andina. In 1995, she was asked to substitute for a professor teaching a pulmonary function testing course and ended up teaching that course until December of 1997.

Her journey to the United States began in 1996 when she met an American therapist named Richard Hamrick at a conference in Costa Rica. They married in March of 1997 and headed to the states in January of 1998. Unfortunately, he passed away in May of 2007, but by then Spraul considered herself an American and, indeed, became a U.S. citizen in Missouri in 2008. "I was 'born' in the 'Show Me' state," she says proudly.

She says the defining moment in her life came a year later. "In September 2009, my son Isaac was born at 28 weeks gestational age and 25 weeks development age," she explains. "It was an extremely hard experience." The outlook was not good, and on Isaac's second day of life she was called in to say her goodbyes. "I refused that it was the end, so I went on my knees and prayed to the Virgin of Guadalupe to make me the miracle to be a mother and I promised since that day that I will spend the rest of my life helping children."

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Today, Isaac is a thriving eight-year-old who saves up his pocket money to donate to his mother's cause, which is paving the way for children from other nations to travel to Shriners for life-altering care. Spraul has learned about most of them from spending time with her family during vacations in Colombia. If she believes Shriners may be able to help, she presents the child's medical records, x-rays, and some family history to the pediatric orthopedic physician specializing in the child's condition. If the physician agrees the child can benefit from treatment at Shriners, she takes the case to Natalia Rosales, director of patient referral at the World Pediatric Project, to acquire help finding free airline tickets, housing, transportation, and funds for food and other necessities the patient and family will require during their stay in St. Louis.

Her first patient

"My first patient was Maria Helena from Tegucigalpa, Honduras, Central America," says Spraul. "She had severe scoliosis." Maria was treated twice at Shriners but passed away from pneumonia after the recent birth of her second child through a C-section. "It is so sad as a respiratory therapist to know this," says Spraul.

Other children she has helped include Carlos Guillermo, the grandson of her mother's neighbor in Ibagué who suffers from idiopathic infantile scoliosis. He has been in treatment since he was two years old and Spraul says he's doing great. His Colombian doctors send his x-rays to Shriners every six months so physicians can evaluate his progress and plan for the additional care he will need when he becomes a teenager.

Maria del Carmen, also from Ibagué, came to Shriners with an undiagnosed case of severe rickets disease and ended up spending 17 months in the facility. "She was in our Research Center to strengthen the minerals in her bones, then she went through three surgeries to straighten her lower extremities," says Spraul.

Her involvement with Maria del Carmen's case led her to another child named Gabriele who was born with a congenital limb deformity called symbrachydactaly that affected her left arm. "Gabriela asked Santa Claus for a new arm on Christmas 2014, and Santa found her arm in our prosthesis and prosthetic department in March 2015," says Spraul. As of this writing in late 2017, she was set to receive a new arm before the end of the year. "She is growing beautifully," says the RT.

RT staff help out

There have been several more like these patients. Three Colombian kids with cerebral palsy have been treated at Shriners over the past few years, the first becoming the first child from abroad to come to the facility with that diagnosis. Another girl who is actually from the U.S. but has parents from Mexico is receiving care for spina bifida and scoliosis thanks, to Spraul. Another is getting treatment for a condition called genu valgus, a severe form of "knock-knee" in which the affected individual is unable to touch his feet together while simultaneously straightening his legs.

Spraul says her fellow RTs have been there for her with each of these kids, from helping to find them, to helping with the care application forms, to receiving them in St.

Spraul enjoys visiting respiratory students in Colombia.


The kids who Spraul has helped come to Shriners always leave with a new lease on life.


Spraul, left, spends some quality time with one of the kids she's helped.

The AARC Congress always gives Spraul a chance to network with other RTs who are interested in international respiratory care.

Louis, to translating from Spanish to English for family members, to caring for them at Ronald McDonald House.

Along the way she has also established ties to the AARC's International Council for Respiratory Care (ICRC).

Dr. Jerome Sullivan, president of the ICRC, invited her to the ICRC meeting while at the Las Vegas Convention Center at the AARC Congress in 2006, and since 2007, she has served as the ICRC governor for Colombia. She feels fortunate to have been able to bring Dr. Sullivan to Colombia in 2012 and to follow that up with a visit last September from current AARC President Brian Walsh, PhD, RRT, FAARC.

Spraul has also brought her Colombian colleagues to America to network with therapists. "In 2016, we were able to have for the first time a booth in the vendor hall in San Antonio at the 62nd AARC Congress to share what respiratory therapy is in Colombia through the Colombian Association of Respiratory Therapy Programs," says Spraul. "The directors of this association have been able to establish friendships and collaborative educational programs with hospitals and universities in the USA, like the University of Texas with Dr. Ruben Restrepo."

Her work will continue

As for her work helping sick kids from Colombia travel to Shriners for medical care, she says that is something she'll never stop. "I am committed to my promise," she says. "I love their smiling faces when they are done with treatments. I cry when they leave for home because I am happy to see the improved quality of life but sad because I know I will miss them!" ■

— 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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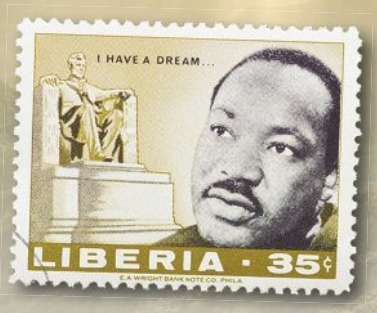
On the Ground in Liberia

Michael Davis is delivering much-needed respiratory care services as well as training RTs in Liberia

by Debbie Bunch



RTs are offering a shining ray of hope to a nation devastated by civil wars and a major medical crisis.

Nestled in Sierra Leone and the Ivory Coast in West Africa, Liberia is the oldest republic on the continent. Founded by freed slaves from the United States and the Caribbean in 1847, the country served as a base of operations for the Allies during World War II and was a founding member of the League of Nations, the United Nations, and the Organization of African Unity.

A military coup in 1980, however, led to years of political unrest. Civil wars eventually broke out, taking some 250,000 lives, destroying 95% of the nation's health care facilities, and leaving the country in economic shambles. A peace agreement in 2003 signaled better days to come and the nation was on the upward slope — until ebola struck in 2014. The deadly virus killed thousands during the height of the epidemic, leaving behind an even weaker health care system and a greater need for medical services.

None of that has deterred AARC member Michael Davis, PhD, RRT. Over the past decade, the assistant professor at Children's Hospital of Richmond at Virginia Commonwealth University (VCU) has worked tirelessly to improve health care in the country, often spending months at a time on the ground to deliver compassionate care and build the infrastructure needed to form a respiratory care profession there.

The idea is launched

Dr. Davis got involved in helping Liberia at the behest of his mentor at VCU, John Hunt, MD. "Dr. John Hunt, cofounder of Trusted Angels, went to Liberia and told me that I 'had to go,'" says Dr. Davis. After working with the organization stateside for a few years, he made his first trip to the country in 2011, working with Trusted Angels to deliver basic medical care to several orphanages, along with much-needed supplies donated by groups in the United States. It was during his second trip to the country in 2011 that the idea to begin a Liberian profession of respiratory care was launched. "On my second trip, I met Joseph Moore, the only RRT in Liberia. We immediately became friends," says Dr. Davis.

Joseph Moore, RRT, and Michael Davis, PhD, RRT, (right) have brought many improvements to health care in Liberia.

Moore, trained as an RT in America in the 1980s after he fled the violence in his home country, decided to take his 20 years of experience as an RT back to Liberia in 2007 and was working as the only therapist in the country when the two met. "He immediately recognized the need for improvements in respiratory care," says Dr. Davis. "However, while he was able to train medical and nursing students in the fundamentals of respiratory care, the

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lack of resources in the Liberian health care environment limited his options for furthering our profession in his country."

The need was great. Respiratory failure is a leading cause of death in Liberia, most often resulting from a lack of basic respiratory care treatments, such as oxygen therapy. "Patients who are unable to breathe adequately on their own will not survive," says Dr. Davis. Working closely with Moore, Dr. Davis took the initial steps to create an RT program at JFK Hospital, where Moore was working as an RT. The Liberian Respiratory Healthcare Institute (LRHI) was up and running with its first students only a year later, and the Liberian Medical and Dental Council subsequently created a licensure process for respiratory care practitioners.

Dr. Davis trains a new respiratory therapist.

Disaster strikes

Everything was moving along smoothly, until disaster struck in the form of the ebola virus. Dr. Davis' sixth trip to the country in the summer of 2014 didn't go as planned, as the epidemic severely limited his ability to move around the nation. Ebola effectively destroyed the country's already fragile health care system, not only leaving those affected by ebola with a lack of care but also those with all of the other medical conditions typically seen there.

Respiratory care education took a back seat to the growing medical crisis as students enrolled in the LRHI put their textbooks down and teamed up with the medical director of their clinic to provide basic care to patients. As the crisis deepened, they opened and operated the only PICU and NICU in the entire country and continued to staff those units even after the schools reopened.

Joseph Moore was the first respiratory therapist in Liberia.

Dr. Davis says he couldn't be prouder of the students and how they put their newfound medical skills to work to help their fellow citizens in their time of need. For his part, he pledged to continue his work with Moore and the LRHI as soon as he could get back into the country, and he has done that, and more, since the epidemic came under control in 2015.

The first nine RTs graduated from the program in 2016. All nine have now passed their Liberian RT board exams and are working as RTs. Another 11 students are now in their second year of the program, and a new class of 12 enrolled this fall.

The newly minted RTs are already having a big impact. "They are the first respiratory care practitioners in their country and are truly introducing both basic and advanced respiratory care there," says Dr. Davis, who spent most of this past spring in Liberia working with the program. "They are the primary caregivers to respiratory patients and the educators of other medical staff in these areas."

The profession is spreading beyond the LRHI as well. Six additional counties now have respiratory care programs of their own, more are on the drawing board, and Dr. Davis also has reached out to form a partnership with the TB and Leprosy Annexes in Liberia to introduce much-needed respiratory care to those centers.

Dedicated to a great cause

Dr. Davis and his friend, Scott Dwyer, also formed a new non-profit organization called Partner Liberia in 2013 to serve as an umbrella for all the work he wants to do in the country. In addition to supporting the LRHI, he and his colleague are working to improve childwelfare through a de-worming program for residents of an orphanage in Grand Basso County and to bring clean

The newly minted RTs are already having a big impact in Liberia.

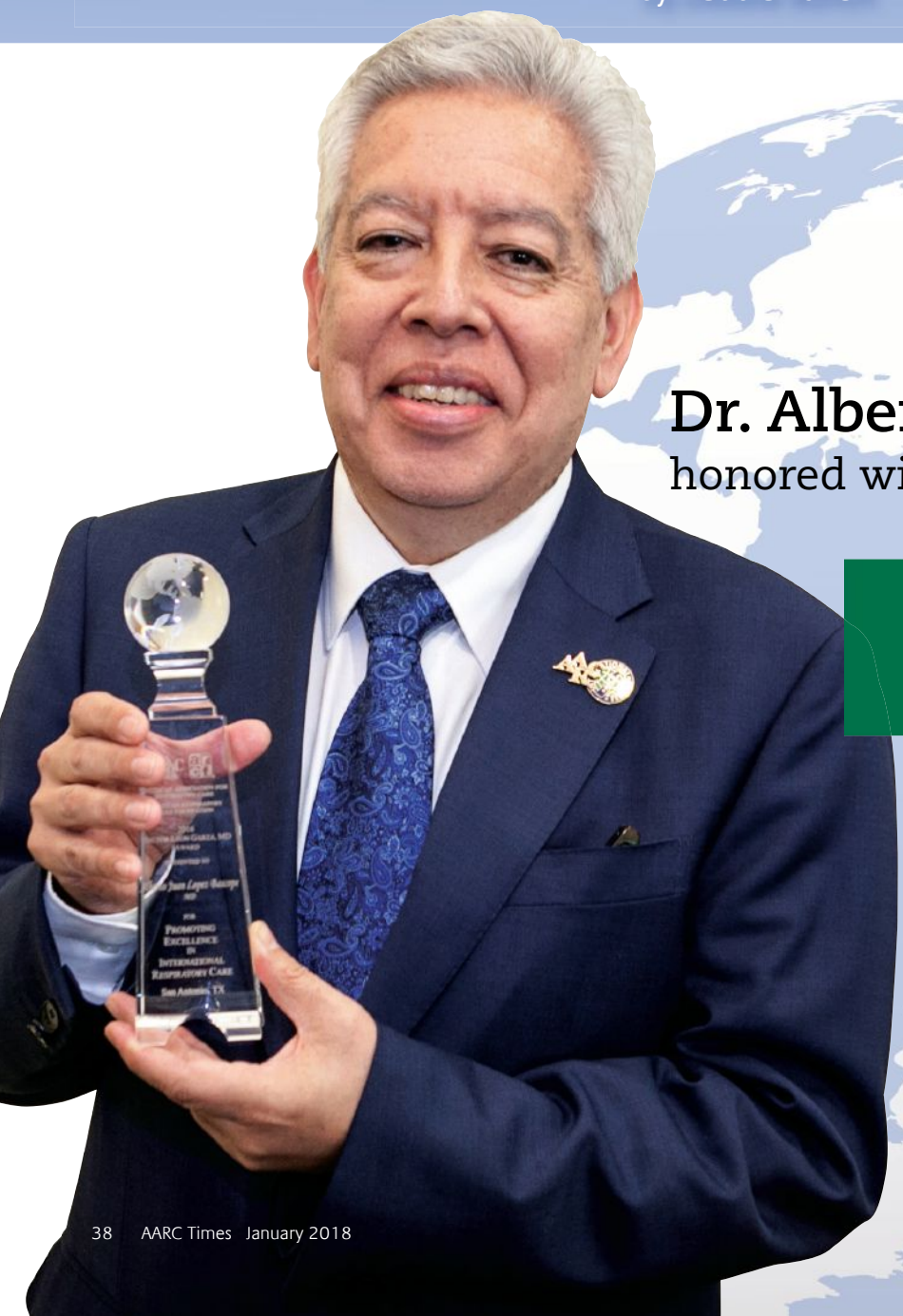
Solar power generators have been installed to bring clean energy to the country's orphanages and medical centers.

energy solutions to orphanages and medical centers throughout the country through the installation of solar power generators.

It all shows how a respiratory therapist can make a real difference in the face of overwhelming need. Says his longtime mentor, Dr. John Hunt, "Partner Liberia provides an example to the world showing what good people can do when they dedicate themselves to a great cause." ■

Spreading Respiratory Care's Reach into MEXICO and LATIN AMERICA

by Debbie Bunch



Dr. Alberto Lopez Bascope
honored with 2016 Garza Award

A number of countries south of the U.S. border now have respiratory care educational programs, respiratory care credentialing systems, and most importantly, respiratory therapists to serve patients in need. Alberto Lopez Bascope, MD, has played an instrumental role in bringing the profession to these nations, and he received the 2016 Héctor León Garza MD International Achievement Award at AARC Congress 2016 in recognition of that accomplishment. Dr. Bascope shares his thoughts on international respiratory care with us in this interview by *AARC Times* writer Debbie Bunch.

■ What led to your interest in respiratory care?

I was born in Bolivia, South America. To conclude my postgraduate training in medicine I immigrated to Mexico in the early 1980s. Around 1987, I got involved with respiratory areas. Traveling frequently to Latin American countries, I observed the high frequency of respiratory pathology and the lack of professional development in the area, so most of my conferences and workshops were oriented to those topics. Several countries have made great progress in the professionalization of respiratory therapy, others not, and even in the majority of them, outside of the big cities respiratory therapy is not yet adequately present. There is even less of a culture for respiratory health in the population.

■ You have played a big role in helping to foster the respiratory care profession in Mexico. Why did you decide to devote your time and energy to this area?

At the end of the last century, medicine in Mexico experienced a great development. But in respiratory therapy, development occurred only at the large hospital centers and university hospitals. A large part of the population — mainly the rural population — remained without respiratory care, and there was a large deficit of professionals in the field. For this reason, I devoted myself to teaching respiratory care. This void was an area of opportunity to provide teaching.

My goal was, and still is, to improve the academic level of those who dedicate themselves to respiratory care, encourage the participation of other professionals, and motivate young people to dedicate themselves to it. Possessing capable professionals in an adequate number to cover the demands of respiratory care in all the nations of Latin America is still a goal. Research is more epidemiological, to know how we should land our efforts.

■ Tell us how you've been involved in building the profession in Mexico.

I have been involved in respiratory areas for around 30 years and have been the head of the service at my hospital in Mexico City for around 20. At the same time I've been developing continuous medical teaching activity in the areas of anesthesiology and intensive care medicine but with an emphasis on respiratory areas.

Starting in 1998, I joined the team of Dr. Héctor León Garza in the Mexican Respiratory Therapy Association (AMTR), and from that time to the present, I have worked together with them and with Natividad Martínez, CRT, a pioneer in Mexico. Together we have jointly developed international congresses, symposia, workshops, conferences, etc. I have served two terms as president of the AMTR.

Latin America is making great strides in developing the profession of respiratory care, thanks in part to the efforts of the 2016 Garza Award recipient.

■ What's the status of respiratory care in Mexico today, and where do you see the profession heading?

In Mexico, respiratory care in general has been lagging behind, despite the fact that Mexico City is one of the most polluted cities worldwide. It is 2,250 meters above sea level, which means less barometric pressure. It is also far from seas and oceans where oxygen is produced, and it has a large population — automotive and industrial overcrowding, high levels of poverty, an aging population, and rural use of firewood in the homes. All these factors create an environment conducive to the development of respiratory pathology, and that is reflected in the health statistics.

Respiratory pathology in general is among the top causes of morbidity and mortality in Mexico. This backwardness was sadly shown to us by nature, when in 2009 the first case of H1N1 influenza appeared on Mexican soil, exceeded the country's sanitary capacity, and ended up as a global epidemic. However, it did allow the population, and above all the governmental health sector, to become aware of the importance of working on respiratory health. Since then things have improved a lot, although there is still a lot of work to be done.

■ How have you been involved with the AARC and its International Council for Respiratory Care, and why did you believe it was important to play a role there?

Always dedicated to medical education, I felt an obligation to keep up with the advances in our profession, and encouraged by Dr. Garza in 1998, I attended the AARC Congress for the first time. I was impressed by the academic, technological, and organizational aspects of the Congress, but above all by the human warmth with which everyone treated Dr. Garza and, of course, myself. I saw how teamwork by multiple professionals from different regions of the world paid off for the growth of respiratory therapy, I saw myself reflected in them, and I committed to someday contributing to that great commitment. And with the passing of the years, and after attending multiple Congresses, I am clear about the great work that the International Council is developing and the opportunity the Council gives me to contribute my work and my experience while I continue to learn from them.

■ Where do you think you've made the most impact on international respiratory care, and why?

In 2012, when I was president of the AMTR, we were getting ready to hold our eleventh International Congress of Respiratory Therapy. We decided to invite Latin American colleagues to jointly hold our congress, and it became the first Latin American Congress of Respiratory Therapy. From that the SOLACUR — Latin American Society of Respiratory Care — was born. So since March 2012, Latin American therapists have had a society where they can express themselves and disseminate knowledge. But above all, it has allowed the great Latin American community of professionals in respiratory health to come together.

I have also developed a Facebook page called Terapia Respiratoria LATAM to disseminate information on respiratory therapy aimed at all of Latin America. We have promoted a 10-month course on respiratory therapy on the Internet that has been replicated in several Latin American countries as well.

■ What have you gotten out of your involvement with international respiratory care?

Personally, in 2008 I applied to participate in the AARC's International Fellowship Program, and I was one of the chosen ones. During the program I had the opportunity to work in New York next to Felix Khusid, RRT-ACCS, RRT-NPS, FAARC, who provided me with a great experience. With him I learned to love this profession even more, and there in his unit and with his team of therapists, I sealed my commitment to work for the development of respiratory therapy in general. I redirected my long-term professional work plans to the respiratory area.

Now, years later, I think it was a wise decision. The program linked me with colleagues who work for respiratory health worldwide, and each makes responses to common problems according to the characteristics of their region. The power that comes from sharing that information during the meetings of the International Council is invaluable, because each of us can then take those solutions to our lands. Over the years, I have applied the fruits of this participation in our daily practice and used them to strengthen our profession in the present and with a view to the future.

■ Respiratory care continues to be delivered by a diverse group of providers around the world. How can they best come together to improve care for patients with respiratory conditions, and why is it important for them to do so?

In Latin America and Mexico, the development of respiratory therapy has been very different and is carried out by nurses, physiotherapists, respiratory technicians, and others. In recent years, the science and technology on which our profession is based has grown exponentially, which has forced the professional who is dedicated to it to sustain that dedication from the beginning of his academic training and devote all of his daily work entirely to respiratory pathology. That is the ideal. But in real practice, this transition will take some time, depending on the health policies of each country. Meanwhile, our work will be developed by a multi-professional team.

The work of the International Council, sowing professionals in different countries, and having the culture of respiratory health, will allow these professionals to lead the required change in their specific areas. It is important to promote this commitment to respiratory health because, given how the work of humans on Earth evolves, it is very likely that environmental conditions will be increasingly aggressive to our respiratory system. We must prepare our teams of professionals in respiratory health, so that they are adequately trained to face the challenge.

■ What did you think when you learned you would be the 2016 recipient of the Garza Award?

First, I felt incredulity. I already knew the importance of this recognition, and I felt some fear for the commitment it meant. Others who had received the award were professionals whom I admired, whose publications I read and applied to my practice. But if they believed in my ability, I would, too. It would be a challenge but one I would face with courage and capacity for the challenges that life presents to us. It also opens opportunities for me to more effectively influence the level of respiratory therapy available in Mexico and Latin America. I am sure that together we will be able to achieve the improvements needed.

■ How do you believe these diverse providers — including RTs in the United States — can best come together to improve care for patients with respiratory conditions?

The art and science of respiratory care has grown exponentially in the last several decades. Along with this has come the need for professionals who can truly be experts in the field. No longer can other professionals simply add these skills to their existing scope of practice — there is simply too much there. The U.S. recognized this early and the RT was born — the rest of the world is slowly catching on. As we in the U.S. continue to work with professionals throughout the world to develop quality respiratory care, we should also assist in the development of dedicated respiratory care professionals. ■

First Responders Save Lives in the Aftermath of Mexican Earthquake

Last September, a 7.1 earthquake hit Mexico, killing 370 people and injuring more than 6,000. Former president of the Mexican Respiratory Therapy Association and 2016 recipient of the AARC's Héctor León Garza MD International Achievement Award, Alberto Lopez Bascope, MD, shared these photos of first responders during the aftermath of the quake.

"This blow to Mexico has been hard. It was even worse against our children, but all of us are suffering more or less," says Dr. Bascope. "I lost what I have acquired with years of work, but Mexico, and the Mexicans, will move forward, and this will be where the human spirit on this Earth exists."

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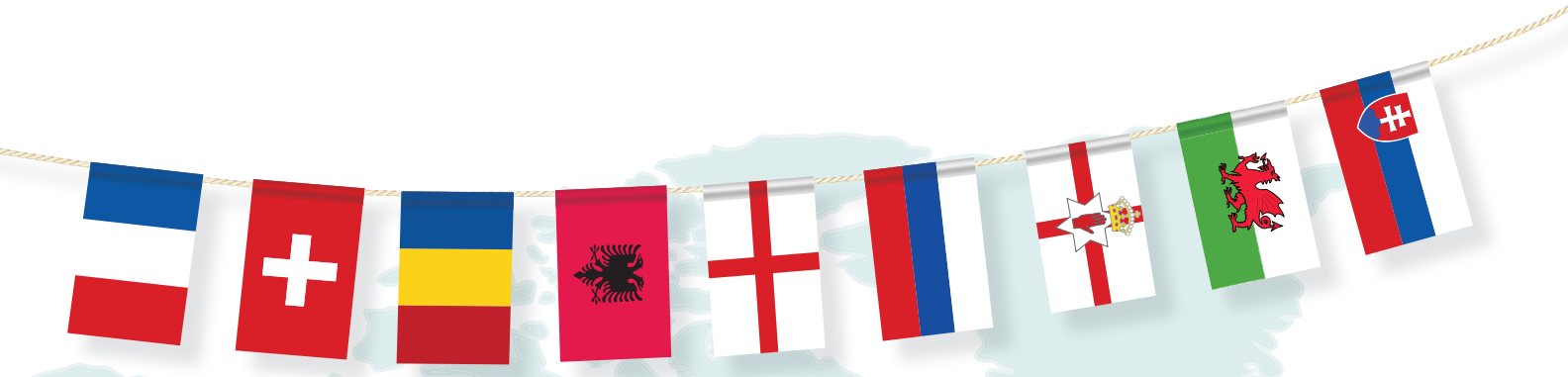


WORKING To Bring Quality Respiratory Care to the WORLD

Michael Amato (left) presented the 2017 Garza Award to Neil MacIntyre during the AARC Congress in Indianapolis last fall.

Dr. Neil MacIntyre receives 2017 Héctor León Garza MD International Achievement Award

International respiratory care has benefited from a number of thought leaders over the years. Few have been as influential as Neil MacIntyre, MD, FAARC, FCCP. The professor of medicine and medical director of respiratory care at Duke University Medical Center in Durham, NC, was honored for his years of service with the 2017 Héctor León Garza MD International Achievement Award at AARC Congress 2017 in Indianapolis, IN. He shares his perspective on international respiratory care in this interview.

▶ What has fed your passion for international respiratory care, and how do you believe fostering a greater sharing of research and information across borders enhances direct patient care for people with pulmonary disorders, both here in the United States and abroad?

I have a passion for respiratory care in general. It is a unique profession that combines engineering, physiology, and patient care. The application of respiratory care into patient management is appropriate for all regions of the globe. We in the United States need to take a leadership role in making sure state-of-the-art respiratory care is provided everywhere.

▶ You have graciously volunteered your time to lecture about respiratory care in many places around the world. Why did you decide to devote your time and energy to this effort?

I want to do my share in getting the benefits of good respiratory care to everyone in the world.

▶ You have also worked with international colleagues on research important to the profession. Tell me a little more about the key studies you've conducted with those colleagues and how you think they have impacted patient care.

I have been part of many research networks that have involved medical centers around the world. These have included drug trials, ventilator management strategies, and device evaluations. Those that come to mind are recent ventilator management surveys and COPD inhaler studies. Also important have been international guideline developments involving PFTs [pulmonary function tests], aerosols, pulmonary rehab, and vent management. What has been really striking in recent years has been the emergence of real thought leaders and clinical researchers in respiratory care in Europe, the Middle East, East Asia, and Australia and New Zealand.

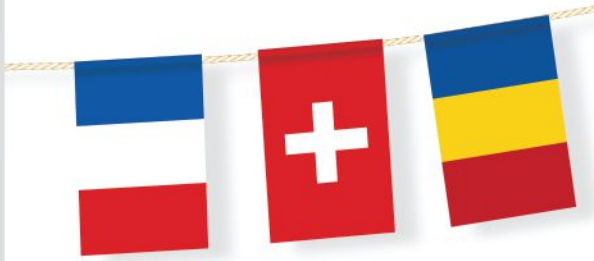
▶ Where do you believe you've made the most impact on international respiratory care and why?

Probably several areas. First, I have been involved with many studies that have enhanced the evidence base for respiratory care everywhere. Second, I have been an invited speaker at major symposiums in over 40 countries over the last 30 years. Third, I have written multiple original articles, reviews, and books that are published internationally. Fourth, I have been on a number of international guideline development committees that have addressed mechanical ventilation, PFTs, and pulmonary rehab.

▶ You've been actively involved with RESPIRATORY CARE for many years, during a time when international submissions to the Journal have grown. What do you think this says about the Journal, and how has it helped to elevate the stature of the U.S. form of RT around the world?

The Journal has been a major force in getting good respiratory care practiced around the world. Recent editors — Dave Pierson and Dean Hess — have been instrumental in attracting quality respiratory care papers from outside the U.S. Just as importantly, the Journal has grown in quality and prestige such that it is now widely recognized worldwide as a vital source for information regarding quality respiratory care. The Journal's annual Journal Conferences provide highly cited references utilized in publications from around the world.

America may have invented the respiratory care profession, but countries around the globe are now practicing it, too. The 2017 Garza Award winner believes that is a good thing for all.



▶ You've also played an integral role in the American Respiratory Care Foundation (ARCF). Please describe more about your work there and how it has figured into international respiratory care.

The ARCF plays a vital role in advancing respiratory care globally. As a nonprofit foundation, it can raise funds to support research and education everywhere. Current examples include supporting the International Fellows program, funding research fellows both from the U.S. and abroad, underwriting initial efforts for an international education program, and supporting Journal Conferences that are widely read around the world.

▶ What have you gained from your involvement with international respiratory care?

Interacting with international colleagues has been very rewarding both professionally as well as personally. We can all learn so much by listening to people from different backgrounds and experiences. We also need to recognize that the U.S. does not have a monopoly on respiratory care expertise — there are incredible research and educational programs in many places around the world.

▶ How do you believe these diverse providers — including RTs in the United States — can best come together to improve care for patients with respiratory conditions?

The art and science of respiratory care has grown exponentially in the last several decades. Along with this has come the need for professionals who can truly be experts in the field. No longer can other professionals simply add these skills to their existing scope of practice — there is simply too much there. The U.S. recognized this early and the RT was born — the rest of the world is slowly catching on. As we in the U.S. continue to work with professionals throughout the world to develop quality respiratory care, we should also assist in the development of dedicated respiratory care professionals.

▶ What did you think when you learned you would be the 2017 recipient of the Garza award?

Dr. Garza is a real giant in international respiratory care who has long emphasized the importance of research and education in advancing respiratory care globally. I was truly honored to receive the international award named for him. ■

Industry Update

Featuring information on products and equipment from manufacturers

RC Currents

IN THE NEWS

Gene Variant Linked to Nicotine Dependence, Lung Cancer

A study published in a recent edition of *Molecular Psychiatry* suggests a genetic factor in the development of nicotine dependence and lung cancer.

Researchers led by RTI International studied more than 38,600 current and former smokers from the United States, Iceland, Finland, and The Netherlands, looking for genetic markers associated with smoking. After testing nearly 18 million variants across the genome, they found the variant they were looking for in the DNMT3B gene.

"The variant that we identified is common, occurring in 44% of Europeans or European-Americans and 77% of African-Americans, and it exerts important effects on gene regulation in [the] human brain, specifically in the cerebellum, which has long been overlooked in the study of addiction," explained study author Dana Hancock, PhD. ■

RTs Go All Out for RC Week 2017

RESPIRATORY THERAPISTS

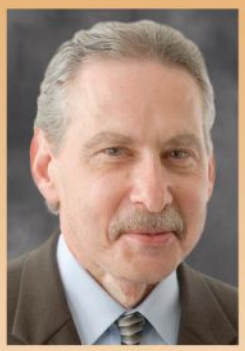
Working Together

SAVING LIVES

Laurel Technical Institute
Sharon, Pennsylvania

Transitions

In the lives of AARC members



Robert Cohn, MD, MBA, FAARC, passed away in October. A long-time supporter of respiratory therapists and the AARC, he served as medical director of the RT department at Dayton Children's Hospital in Dayton, OH. Known for maintaining a big picture view of medicine, he was a true believer in protocol-driven care and helped the department establish an asthma protocol years ahead of other hospitals. He spent 12 years on the Ohio Respiratory Care Board as well, where he led the Scope of Practice Committee and authored practice guidelines. Dr. Cohn was also a reviewer for the Joint Commission on Accreditation for Respiratory Care (the precursor to today's Commission on Accreditation of Respiratory Care) in the 1990s. He served as an instructor in the asthma course that the AARC held in cities across the nation. Dr. Cohn also published numerous papers on respiratory care topics and was a regular speaker at the AARC Congress.

David Gourley, MHA, RRT, FAARC, passed away last fall at age 61. A 40+ year member of the AARC, Gourley served as director of clinical operations and risk management for Millennium Respiratory Services in Whippany, NJ, and was an adjunct professor at Seton Hall University in South Orange. He formerly served as executive director of regulatory affairs at Chilton Hospital in Pequannock, NJ.

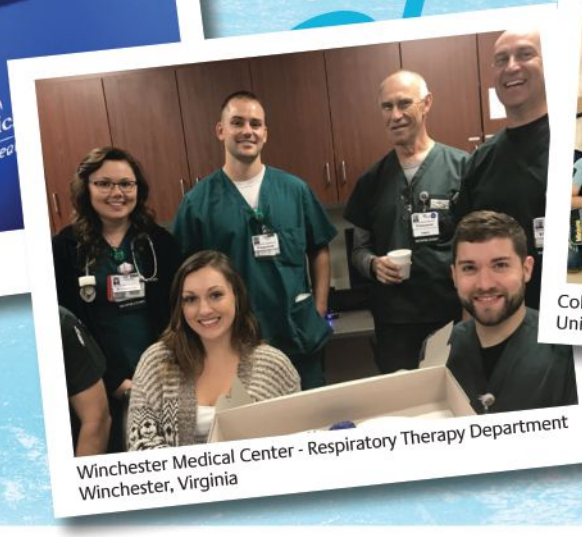
Gourley was a member of the AARC House of Delegates between 1990 and 1996 and played an active role in the Association's Home Care Section. ■

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. ■

Bradford Regional Medical Center
Bradford, Pennsylvania



Winchester Medical Center - Respiratory Therapy Department
Winchester, Virginia

College of Applied Medical Sciences, King Saud bin Abudulaziz University For Health Sciences, Jeddah-Saudi Arabia

Asthma-Eczema Connection May Predict Longer Hospitalizations

Children with a family history of asthma and those who suffer from both asthma and eczema may experience longer hospital stays when their asthma flares up. That's the take-home message from research presented at the American College of Allergy, Asthma and Immunology's Annual Scientific Meeting last fall.

In the study, investigators looked at 39 children between the ages of 1 year and 17 years who were admitted to a hospital for asthma. The number of allergies in these children did not affect hospital stay, but among those who required ICU care, 62% had a family history of asthma versus 14% of those who did not require ICU care. Children who had eczema had longer hospital stays and were more likely to require continuous albuterol. ■

Donor Organs Are Going Unused

Thousands of patients are waiting for a new set of lungs or other donor organs, but too many of them will never get them. Perhaps one reason why is the United States Public Health Service's "increased risk of infection" label.

In an analysis of data from the Organ Procurement and Transplantation Network, University of Michigan investigators found organs labeled as "increased risk" — most often because they came from drug users considered at high risk for hepatitis C or HIV — are 7% less likely to be used than organs without that label. This is despite the fact that, after rigorous screening, they carry a less than 1% chance of disease transmission. According to the study, an estimated 313 more transplants could be performed in the United States each year if those organs were used. The study appeared in a special issue of *Transplantation* dedicated to reducing organ discard while safely maximizing organ availability. ■

More Bad News for E-Cigarettes

Researchers from the University of North Carolina at Chapel Hill have found that e-cigarettes not only trigger some of the same immune responses leading to lung disease as traditional cigarettes but also some unique immune responses of their own.

The study compared sputum samples from 15 e-cigarette users, 14 current cigarette smokers, and 15 non-smokers. E-cigarette users uniquely exhibited significant increases in neutrophil granulocyte- and neutrophil-extracellular-trap-related proteins in their airways, which can contribute to lung disease if left unchecked. Both e-cigarette and cigarette users exhibited significant increases in biomarkers of oxidative stress and activation of innate defense mechanisms associated with lung disease.

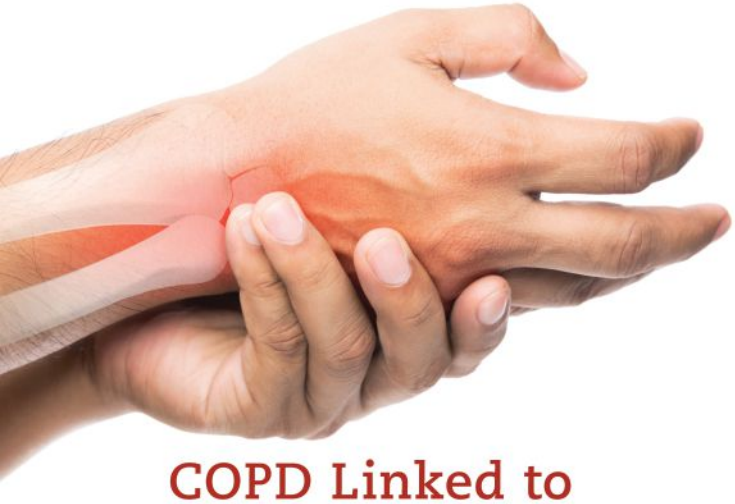
The data show that "e-cigarettes have a signature of harm in the lung that is both similar and unique, which challenges the concept that switching from cigarettes to e-cigarettes is a healthier alternative," said study author Mehmet Kesimer, PhD. The study appeared in a recent edition of the *American Journal of Respiratory and Critical Care Medicine*. ■

Long-Lasting Flu Vaccine May Be on the Horizon

The influenza vaccine is engineered every year based on the best estimate of which flu strains will predominate in the upcoming flu season. But there are components of the influenza virus that stay the same year after year. Now researchers from Cornell are taking one of those conserved proteins, Matrix-2, and packaging it in a nanoscale, controlled-release "capsule" in an attempt to create a quick-acting, long-lasting, multi-strain vaccine against pandemic influenza A. "Even if we have to give a booster shot every ten years, like tetanus, that's still very good," study author David Putman was quoted as saying. "Theoretically, it should last a long time." The study was published in a recent edition of *Vaccine*. ■

Respiratory Care Department in Royal Commission Hospital
Jubail Industrial City, Saudi Arabia

Rahe Bulverde Elementary School Costume Parade/Career Day
Bulverde, Texas



COPD Linked to Rheumatoid Arthritis

A new study out of Canada suggests people with rheumatoid arthritis may be at increased risk of developing COPD. The investigation grew out of previous research showing an association between COPD and inflammation.

The authors analyzed data on 24,625 patients with rheumatoid arthritis and 25,396 controls from the general population. Results showed the incidence of COPD hospitalization was greater in patients with rheumatoid arthritis than in the general population. After adjusting for potential confounding factors, individuals with rheumatoid arthritis had a 47% greater risk of needing to be hospitalized for COPD than controls. The increased risk remained significant after modelling for smoking and with varying COPD definitions. The study was published in *Arthritis Care & Research*.

No More Pneumonia?

Could pneumonia one day go the way of smallpox and polio? According to researchers from the University of Buffalo, the answer may be yes. They are developing a new pneumonia vaccine that provoked an immune response to 72 forms of S. pneumoniae in lab tests on animals, representing the most comprehensive coverage of pneumococcal disease to date.

How does it work? Unlike current pneumonia vaccines, which connect sugars in pneumonia strains to a protein, thus creating a covalent bond for each strain, this vaccine is engineered to use a liposome as a storage tank for the sugars, eliminating the need for a covalent bond and offering the potential for the tank to hold all of the sugars for all strains of pneumonia in one vaccine. When proteins are added at the surface of the liposome, immunotherapy is provoked. The study was published in a recent edition of *Science Advances*.

Cleveland Clinic PFT Lab
Cleveland, Ohio

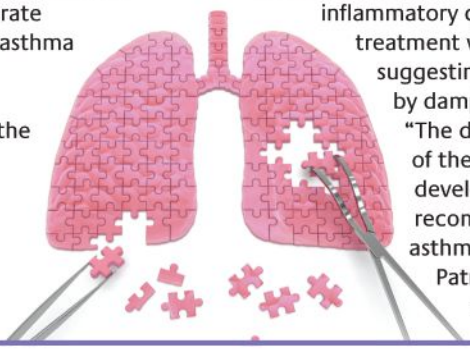
Pointe Coupee General Hospital
New Roads, Louisiana

El Camino Hospital
Mountain View, California

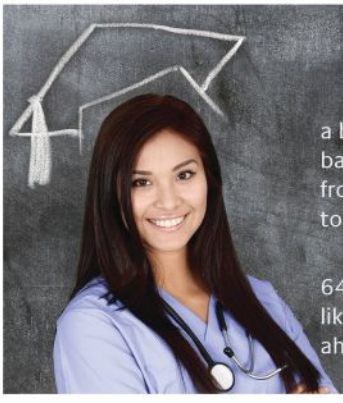
Studying the Lung Microbiome

Much has been written about the role of the gut microbiome. Researchers from the University of Illinois at Chicago believe that the lung microbiome is just as important.

In a study involving clinically similar patients 18–30 years old with mild or moderate atopic asthma, they identified two asthma phenotypes, AP1 and AP2, that are delineated by the prevalence and dominance of different bacteria in the lung. AP1 was associated with less severe asthma, decreased T helper cytokines, increased enterococcus bacteria, and normal pulmonary function tests. 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 that the drug may function by dampening responses to microbes. "The data suggest that further study of the microbiome may help to develop more personalized treatment recommendations for patients with asthma," noted study author Dr. Patricia Finn. The research appeared in a recent edition of *PLoS ONE*. ■



Goal for Nurses, Too

The AARC has set a goal calling for 80% of RTs to either hold or be working toward a bachelor's degree by the year 2020. Turns out, nurses are working toward an 80% bachelor's degree goal of their own. Will they make it? Probably not, say investigators from the NYU Rory Meyers College of Nursing, but that doesn't mean they aren't going to get there.

In a study published in the *Journal of Nursing Scholarship*, they predict 64% of hospital-based nurses will have a bachelor's degree by 2020, with the 80% goal likely to be reached in 2029. However, nurses on critical care units are projected to be ahead of the game. The investigators predict they'll reach the 80% goal by 2025. ■

Elliot Hospital Medical Explorers Program
Manchester, New Hampshire

Jacksonville State University Respiratory Therapy Program
Jacksonville, Alabama

As Seen on *AARConnect*

Have you looked at what your colleagues are talking about on the AARConnect discussion lists? You might find an interesting tidbit you can use in your area of respiratory care or maybe answer a question someone has asked. Here are some excerpts of a dialogue we found on AARConnect while preparing this edition of the magazine.

AARConnect...

I was wondering how many are doing a 3-minute walk test vs. a 6-minute walk test and which patients would be more likely to have this test done over the 6-minute [test]? Does anyone have any policy/procedure or guidelines they could share with me? My pulmonologist recently approached me about the possibility of performing this test.

Dawn Six, RRT, RPFT, AE-C
UPMC Pinnacle
Hanover, PA

As far as I know, there are no standardized guidelines published for the administration of this test for both the adult and/or pediatric population. Studies which have utilized this test have not indicated specifications under which it was performed but often mention following the guidelines described by the American Thoracic Society for the 6MWT as a reference.

This test has little-to-no evidence to support its use in the clinic; however, the shorter time frame may be more conducive for children who are severely limited in their ability to perform exercise for a longer period of time or children with significant physical impairments who are unable to ambulate further distances. Pan et al. (2009) reported utilization of this test in the emergency department with adults reporting acute dyspnea and significant cardiovascular history to predict poor outcomes after discharge.

Balamurugan Panneerselvam,
BS, RPSGT, RST, CPFT
Hamad Medical Corporation
Doha, Qatar

I routinely do this at my place of employment. We do them to determine an O_2 prescription upon discharge. Most of my patients are heart failure or COPD, so 6 minutes is way too hard for them. The problems that I have encountered are things like the oximeter readings are very difficult to get when they have to use assistive devices, likes canes and walkers. You better take a headband probe. Also, the amazing popularity of gel nails. There is no way to get that polish off! The nurses will have been checking sat on the patient's fingers, and if it is a red hue, they always look like they are fine. Then I come in with my forehead probe, and find out that the patient's real saturation is only 86, not 91. There is no real set way to do it. You just have to do whatever the patient can do. Many of them can't even walk further than the bathroom, if that.

Cathy Watts, RRT, RPFT
North Kansas City Hospital
Kansas City, MO

I work at a large clinic in Washington State with eight pulmonary providers. We also do the 3-minute walk routinely with our COPD patients. We are usually able to obtain SpO_2s with the gel nail polish issue, by either putting the oximeter on sideways on the finger, or using an overnight oximetry finger probe; their finger fits inside a rubber sheathing, and it works most of the time. We have used the forehead adapter as well.

Emilie Holder, RRT, CPFT, AE-C
The Vancouver Clinic
Vancouver, WA

We (Cleveland Clinic) used 3 minutes of the subject walking at their normal pace as a standard first step in a desaturation test. If tolerated (SpO_2 >88% and no symptoms preventing further walking) we would ask the subject to increase their pace, if possible, to represent the fastest they would walk, if required, for an additional 3 minutes. On our reports, we had a field for ACTIVITY and would make the entries, WALKING, USUAL PACE or WALKING, FASTEST PACE, when documenting the test results. We would record the distance, time walked, and duration of stops, if any. The entry screen (MS Access application) would use this to calculate and present data in another field, AVERAGE WALKING SPEED (MPH), on the report. Physicians seemed to like this, as they could use it to relate the subject's HR response to that speed and relate that to a normal walking speed (~3 MPH).

Kevin McCarthy, RPFT
eRT, Inc.
Matthews, NC

More Patients Seen in EDs than Inpatient or Outpatient Settings

It's easy to think most medical care in this country occurs in the primary care setting. Not so, report researchers from the University of Maryland School of Medicine. They found nearly half of care takes place in emergency departments (EDs).

The investigators examined publicly available data from several national health care databases covering all 50 states and the District of Columbia between the years of 1996 and 2010. Among the results were:

- There were nearly 130 million ED visits, compared with almost 101 million outpatient visits and nearly 39 million inpatient visits in 2010.
- Over the 14-year study, ED visits increased by nearly 44%.
- African-American patients were significantly more likely to have ED visits than patients in other racial groups.
- Patients in the "other" insurance category, which included those without any type of insurance, were significantly more likely to have ED visits than any other group.
- Patients living in the south were significantly more likely to have ED visits than patients living in other areas of the country.
- Overall, these groups accounted for increasing percentages of overall ED use: African-Americans, Medicare and Medicaid beneficiaries, residents of the south and west, and women.

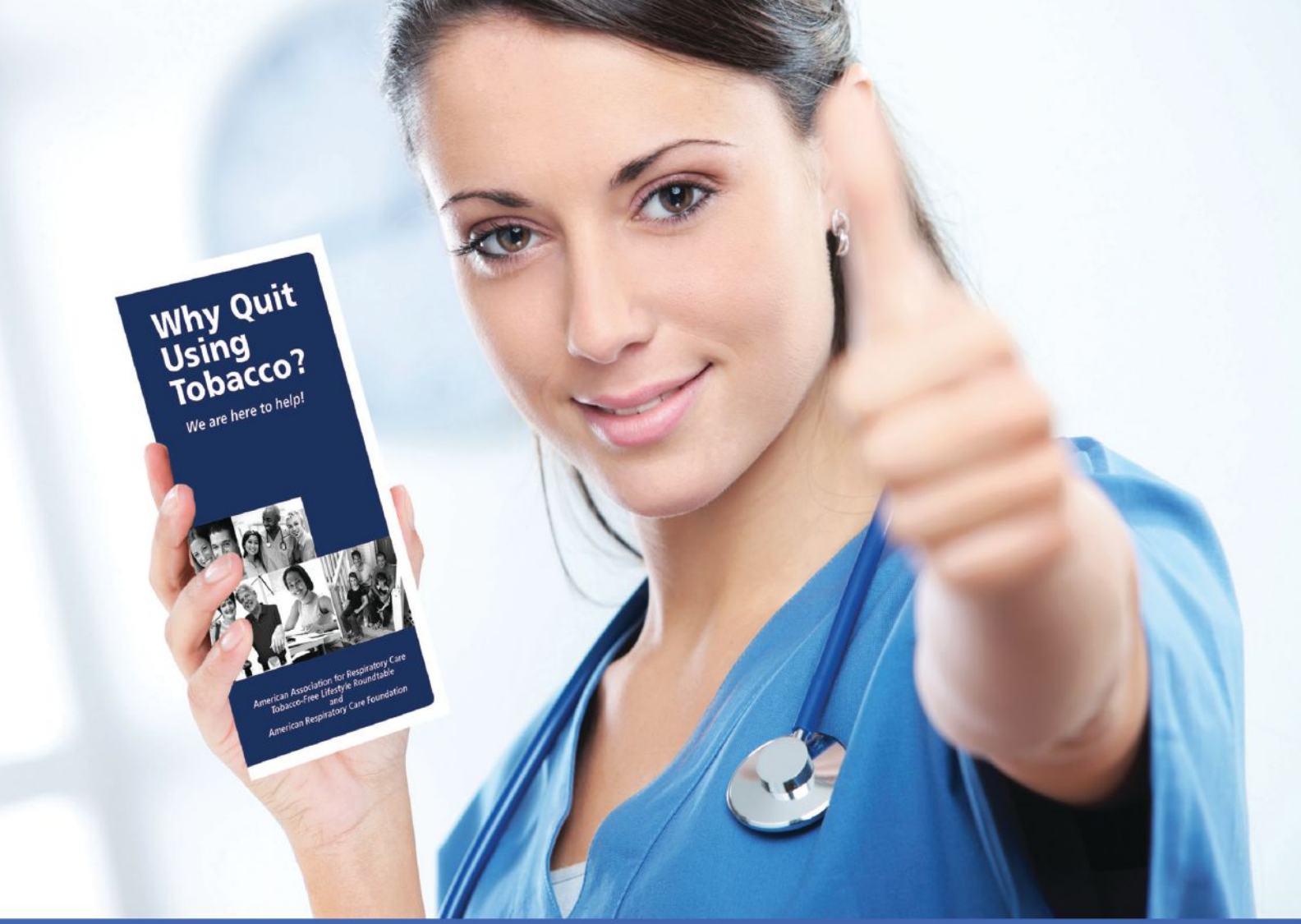
"I was stunned by the results," said author David Marcozzi. "The data might suggest that emergency care provides the type of care that individuals actually want or need, 24 hours a day." The study was published in a recent edition of the *International Journal of Health Services*. ■

Share Your Wisdom

AARC members who have recently retired from the profession have been writing about their careers in the *AARC Times* column called "Reflections." We invite submissions in which you would share special things that happened in your career, what they meant to you, and why. Funny, sad, inspiring — the door is wide open! So start brainstorming some ideas and then submit your story to *AARC Times* Editor Marsha Cathcart at cathcart@aarc.org. ■

Making a Real Difference

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@aarc.org. ■



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West Virginia Society for Respiratory Care Winter Health Care Conference

Contact: cynthia.keely@gmail.com or www.wvsrc.org

Other Meetings

February 2–3, 2018

Dallas, TX

4th International Tracheostomy Symposium GTC 2018
The Global Tracheostomy Collaborative

Contact: mjbrenner@gmail.com

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American Association for Respiratory Care

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