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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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Zombie Alert

by Anthony L. DeWitt, JD, RRT, FAARC

Those who like sausage and legislation should never watch either being made.

— Otto von Bismarck

When Congress passes a bill and the President signs it into law, it is sent to the Office of the Law Revision Counsel of the House of Representatives, where it is "codified." Medicare, for example, was passed in 1965 in the 89th Congress. It was then codified into the United States Code in Title 42, section 1395. Within the United States code, there are 52 titles and thousands of separate statutes governing everything from federal crimes (Title 18), banking and finance (Title 31), and social services (Title 42). While the United States code tries to organize statutes by subject matter, the nature of how laws get passed, changed, and reorganized means that finding any particular statute requires a computer search. It also means these statutes are constantly changing.

Making matters worse, when Congress passes a statute, like the Patient Protection and Affordable Care Act (PPACA, or Obamacare), it passes more than one statute. As has been widely reported, the statute was more than 2,000 pages long, and it is doubtful that any congressman or senator read the entire thing. But this also means that you won't be able to go to the United States code and find in one place all the statutes that were part of the PPACA.

The Trump Administration has said in recent interviews that it would be repealing and replacing the PPACA, but that in doing so it would keep certain portions that it believed were valuable, like coverage for pre-existing conditions and the ability for young people to stay on their parents' insurance plans. In addition, many of the provisions of the PPACA contained statutory segments that had nothing to do with providing health insurance. For example, inside the PPACA were revisions to the False Claims Act that changed certain standards for whistleblowers. This is a process that legislators call "log-rolling." A bill that "must pass" like the PPACA is saddled with hundreds of amendments. Some of those amendments name post offices, some provide funding for highway improvements, and some change other laws in ways that benefit legislators. Some of these amendments are stripped out during the legislative process, but most are not. Because the PPACA was large and unwieldy, it is likely to require painstaking work to repeal and replace it.

Imagine, if you will, a bowl of spaghetti. One strand represents the pre-existing condition language, another the ability to stay on a parental insurance plan up to a certain age. Each strand crosses other strands, and in pulling them free, you must avoid disturbing the rest of the bowl. Sound easy? In repealing and replacing PPACA, Congress will need to sort through the morass of code sections — the bowl of spaghetti — so as to ensure that the unrelated sections of code are not unnecessarily affected.

A wholesale repeal of the public law wipes out all of these statutes, and in the case of naming a post office, it is too little, too late. So Congress must painstakingly go through the whole code, isolate the code sections that need to be repealed, and then repeal them. In terms of the core concept of the PPACA, this pertains to the insurance exchanges and their federal subsidies, which are the sections most likely to get the axe.

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.

Replacement of the act is another tale altogether. President Trump has stated that he favors removing the restraints that previously prevented insurers from offering plans in more than one state and that he favors the use of health savings accounts (HSAs) to set aside money tax-free to pay medical expenses.

A law that permitted insurers to compete in offering health care plans across state lines might lower costs due to increased competition in much the same way that having multiple cell phone carriers reduced the cost of cell phones. Of course, it might not provide the same level of health promotion and disease prevention benefits currently required in the federal health care plans. HSAs might work for disciplined investors but might fail miserably for persons with chronic conditions. Even HSAs would need to be backed up with catastrophic care coverage.

President Trump's promise to repeal and replace the PPACA on the same day is likely to encounter serious roadblocks from trade and industry groups. Lobbyists and others will want to have their say, and some are suggesting that Medicare be revised with a "payor support" provision that allows Medicare to contract with private insurance plans, pushing the risk of fraud and abuse onto private entities. In other words, do not look for the "repeal and replace" to occur before the end of 2017.

At this point, it is almost anyone's guess what will eventually be repealed, but, generally speaking, I believe that provisions that do not cost the federal government money (for example, the requirement that employers provide nursing rooms for nursing mothers) or provisions that increase costs only slightly (allowing those over 18 to remain on their parents' insurance) are likely to be retained. Provisions that cost the federal government money (health care subsidies, insurance exchanges, etc.) will likely be removed. Federal funds earmarked for certain health promotion activities may be cut, and this could impact therapists.

The replacement is also anyone's guess, but most likely it will focus on HSAs for young and healthy citizens and will result in a markedly diminished level of benefits for older and sicker patients.

Health insurance, as we have known it in this country, is about to undergo a significant change. Initially, for therapists, the key is not to panic just because change is coming. Not all change is bad. No matter who is paying for health care, that health care is going to be needed for patients with heart and lung conditions.

Smart providers who can offer disease management for debilitating conditions like lung disease will still have a place in the health care system. But this place in the system won't come about magically — it will have to be carved out. The AARC and individual therapists will have to make their voices heard by policymakers in Washington. This is one reason why AARC membership (and its accompanying lobbying efforts in Washington) is so important. Without a commanding voice telling policymakers the value of respiratory care provided by respiratory therapists, RTs could easily be overlooked.

It is common in the United States to sell everything as if it were a panacea. Every vitamin supplement will make you Superman. Every car on the road will let you drive like James Bond. But, at the end of the day, we know that marketing just isn't real life. Although President Trump may well believe he can provide a better health care insurance system at a lower cost and retain the same level of benefits, there are no free lunches. Only so much can be saved from fraud and abuse. Somewhere, someone is going to have to pay more. The real questions are: who will pay, how much will they pay, and what will they get for it? ■

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Positioning the RT for Post-Discharge Oxygen Management

by Thomas J. Kallstrom, MBA, RRT, FAARC

According to the last AARC Human Resource Survey, approximately 75% of practicing respiratory therapists are employed by acute care hospitals. The remainder of respiratory therapists work as educators and in industry, sales, home care, or clinical care post discharge. To maintain clinical relevancy, we need to evolve beyond the walls of the hospital in this rapidly changing health care terrain. Fortunately, we are seeing this happen now.

Case in point is that respiratory therapists are now actively involved in hospital-based chronic pulmonary disease programs with the goal of reducing readmissions to the hospital. Whether it is for COPD, pneumonia, or congestive heart failure (CHF) — each has been deemed by the Centers for Medicare and Medicaid Services (CMS) as a measureable outcome if readmission occurs within 30 days — the hospital is held liable and is penalized by reduced Medicare reimbursement. As a result, this penalty process has brought about some unique programs that have been successful in reducing these readmissions.

Many RTs have been successful in chronic pulmonary disease programs that have positively impacted the readmission problem. RTs who manage some of these COPD programs have shared their protocols and experiences online at AARConnect in the COPD Best Practices Community. Currently there are approximately 400 members of this community. I encourage you to visit and engage with like-minded professionals if this is something that you find of interest.

There is one common denominator for CHF, pneumonia, and COPD — patients with these diseases are likely to be hospitalized and on oxygen or discharged on oxygen. Our challenge as RTs is to be sure they are assessed properly before discharge, that the correct delivery device is in place, that the patient and caregivers understand how to operate and troubleshoot the device, and that the patient is assessed post-discharge for the continued need for oxygen or changes in settings.

The Long-term Oxygen Treatment Trial (LOTT study) was recently released.[1] This long-awaited trial has highlighted the need for a more engaged clinician who can make an assessment for the right oxygen prescription and delivery device. It has also shown that there needs to be a shift in the paradigm of prescribing oxygen. According to the study, long-term oxygen should not be routinely prescribed in patients with mild to moderate hypoxemia at rest or during exercise. In fact, the study notes that patients with stable COPD on oxygen did not see a significant effect on time to death, time to first hospitalization, time to first exacerbation of COPD, or measures in quality of life, depression, anxiety, or functional status. This certainly is a change in thinking and will likely make a difference in how the discharged patient's need for oxygen will be assessed and prescribed. Who better than a respiratory therapist?

The AARC, Rush University, and the University of Illinois have recently completed a survey of the respiratory therapist's practices in pre- and post-discharge oxygen usage. This survey again demonstrates a void that needs to be filled. For example, the decision of which oxygen device a patient goes home on is determined by a variety of players: respiratory therapist (17%), social worker (18%), physician (28%), and durable medical equipment (DME) company (16%). Only

about the author...

Thomas J. Kallstrom, MBA, RRT, FAARC, is executive director of the AARC.

10% of patients receive a home visit to determine appropriate oxygen therapy post-discharge.

I recently had a personal communication with Dr. Jerry Krishnan, a lead author on another study (still in review) called the DORIC study. This study looked at oxygen use and showed that fewer than 20% of 350 patients with COPD in the study who were hospitalized at two health centers had an evaluation for supplemental oxygen needs at home before they were discharged from the hospital. Again, this shows a void that should be filled by respiratory therapists who can perform the evaluations.

This same need has caught the attention of the COPD Foundation, which prepared the Second Readmission Summit Report in August 2016 (with AARC leadership participation). The report noted that RTs should be included as central members of the health care team for people with COPD while hospitalized and post-discharge. The report goes on to say that organizations that have not yet included respiratory therapists in their COPD care teams, as well as those that have integrated them into their care processes, should make every effort to clearly elucidate the role of respiratory therapy and therapists at every stage of care.[2]

Finally, *The Lancet* published an in-depth analysis of the state of COPD management in the United States last year.[3] This issue included articles by a multidisciplinary group of authors, including RTs and several other disciplines, and it included articles giving the patient's perspective. The analysis recommended that nurses, respiratory therapists, and pharmacists be involved in multidisciplinary care coordination for both inpatient and outpatient care. Seems logical, doesn't it?

There needs to be more research in post-discharge processes regarding the utility of an RT for discharge oxygen needs and ongoing assessment. With decreasing numbers of RTs in the DME field today, hospital-based RTs should take a more prominent role in the post-discharge arena. With the wide variety of devices on the market today, it is essential that the respiratory therapist be the expert. ■

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Sleep and the Neurorespiratory Patient

by Garner Faulkner II, BSRC, RRT, AE-C

To sleep, perchance to breathe…. Maybe that is not exactly what Shakespeare wrote, but for many patients with a neurorespiratory disease, sleep-disordered breathing (SDB) is often a common complexity of their disease state. Diseases that affect the cortex, brainstem/basal ganglia, spinal cord, motor nerves, neuromuscular junction, and muscles have the potential to cause dysfunction of the respiratory system.[1, 2] These neurological diseases have been often referred to with the term neuromuscular disease (NMD) in literature.[2–4] NMDs are often notable for progressive muscle impairment, which can lead to respiratory muscle weakness and possibly death (likely from respiratory compromise).[4] NMD in particular has been associated with a higher incidence of SDB, the most common form being nocturnal hypoventilation.[1–3,5]

Why is this problematic during sleep?

Normally during sleep, there is a natural loss in muscle tone (atonia) of the skeletal muscles (excluding the diaphragm), specifically during rapid eye movement (REM) sleep.[6] During normal sleep, the tidal volume is reduced, the respiratory rate decreases, there is a reduction in the chemosensitivity of the central control of breathing, a loss of basal drive to breathe, and an increase in upper airway resistance.[5,7] During REM and atonia, the rib cage contribution to the tidal volume decreases to about 19% from 40% while awake.[7] Atonia during REM is the body's natural defense mechanism to prevent physical harm (to self or others) from involuntary dream-induced muscle movement.[6] During REM sleep, which is the restorative type of sleep, ventilation occurs almost solely through diaphragmatic operation.[8] In many NMDs, diaphragm dysfunction is reported to occur.[5–7] Hypoventilation, particularly in NMDs with respiratory muscle weakness, often first presents at night during REM due to decreased respiratory drive, excess effort needed by the diaphragm or associated weakness, and increased upper airway resistance during sleep atonia.[5, 8]

about the author…

Garner Faulkner II, BSRC, RRT, AE-C, is a respiratory care practitioner for the department of respiratory care/pulmonary function lab and serves as the clinic liaison for the ALS and Airway Education Clinics at UC San Diego Health System in San Diego, CA.

Symptoms of SDB

The symptoms that are the first indicators of possible SDB can be subtle or may be difficult to correlate with poor sleep quality and ventilation.[6] Due to these subtleties, it is very important to identify nocturnal symptoms because SDB can lead to significant morbidity and may precede daytime ventilatory failure.[1] The respiratory care practitioner (RCP) may play a huge role in this step. Orthopnea, daytime fatigue, daytime sleepiness, frequent nightmares, night sweats, excessive nighttime urination, morning headaches, poor concentration, short-term memory loss, irritability, depression, high blood pressure, and anxiety are some of many symptoms that may be encountered.[8,9] A questionnaire may be beneficial to the RCP/healthcare provider in screening those with SDB to determine whether further testing or intervention is needed. This may be as simple as asking a patient in the clinic what symptoms they have during the day or at night. The Epworth Sleepiness Scale (ESS) is a quick, easy, self-administered, validated questionnaire that can be

used to assess sleepiness in patients for whom SDB may be a concern.[8] Such questionnaires are commonly used in sleep clinics and labs to help identify those with obstructive sleep apnea; however, it may not be specific enough to detect those with NMD-induced SDB.[8,10] Steier et al showed the accuracy of using a more specifically derived questionnaire based on symptoms to identify patients with NMD at risk for SDB.[10] In this study, patients answered questions in a brief questionnaire, which included the following questions:[10]

- Do you feel breathless if:
  - You lie down?
  - You bend forward?
  - You swim in water or lie in a bath?
- Have you changed your position in bed?
- Have you noticed a change in your sleep (e.g., waking more, getting up, poor sleep quality)?

Most of these questions were rated with a "yes (2 points), sometimes (1 point), or no (0 points).[10]

Diagnostic testing for SDB

Pulmonary function testing (PFT) is often use as a screening tool in the clinical setting (e.g., outpatient clinics or a setting such as a PFT lab), specifically when concerned for diaphragmatic weakness. A PFT can be performed while sitting and while lying down (supine) when concerns of SDB are present.[11] Studies have shown that the decrease in the supine vital capacity (from sitting) is about 90% sensitive and 79% specific for diaphragm weakness.[11] In general, the greater the fall in vital capacity when the patient is in the supine position, the more likely of the patient is to have an associated SDB.[10] Identifying a decline in the supine forced vital capacity may be extremely helpful in early identification of NMD patients with diaphragmatic weakness and accompanied nocturnal hypoventilation.[11]

Overnight oximetry testing, done at home or in a hospital setting, may help determine SDB because frequent desaturations can imply nocturnal hypoventilation.[12] These tests are generally easier and less expensive to obtain, although they are less extensive, and they can be used to screen when concerned for SDB. Nocturnal oximetry desaturations of ≤88% for >5 minutes (a minimum 2-hour reading time) with a NMD will qualify a patient for Medicare coverage of NIV.[8,12]

Polysomnography (PSG) is considered the most objective diagnostic method of assessing nocturnal respiratory insufficiency in the NMD patient.[8] The routine use of PSG, however, in the NMD patient to identify the need to start NIV appears to be controversial.[12] This is perhaps due to its cost, its inconsistent availability in many demographic areas,[10] difficulties participating at a sleep center due to generalized weakness and decreased mobility, and potential long wait time for appointments.[8] Some NMD patients report symptoms of SDB without having objective measurements of muscle decline; it is difficult to assess sleep hygiene in general, and these could be directly qualified with PSG.[7,8] Patients with NMD and associated respiratory muscle weakness commonly have reduced total sleep time, frequent arousals, and a reduction in REM sleep.[5] The distinction between "obstructive" and "central" events is often difficult in NMD patients because obstructive apnea may be classified as central when muscle are too weak to move the chest wall.[5]

Noninvasive mechanical ventilation

NIV has become an integral part of management and care of patients with NMDs and of those who have SDB associated with it.[6] The NPPV task force of the American Academy of Sleep Medicine (AASM) states that the goal of effective treatment with NIV is to improve/reduce work of breathing by delivering appropriate tidal volumes, decreasing respiratory rate, and improving gas exchange.[13] Many studies have shown that there is improved survival in some patients with some types and an improvement in quality of life and daytime symptoms in most patients with NMD.[4–6,12] For many cases of NMD, it is recommended to initiate NIV at night for patients as soon as symptoms of hypoventilation start to present themselves.[8,12]

NIV devices in NMD usually are recommended to have a backup rate incorporated because central apneas can occur or, more commonly, as the disease progresses patients are unable to generate sufficient pressure/flow to initiate a breath from the device.[6,12] The consensus for care and titration of NMD patients with chronic alveolar hypoventilation on NIV should be individualized and based on specific goals in an individual patient.[13] These patients will often need to be reassessed and treatment may need to be modified often.[13] In general, continuous positive airway pressure (CPAP) treatment alone is not indicated for NMD patients with SDB because hypoventilation is the predominant concern due to muscle weakness.[6]

The AASM task force recommends attended NIV titration with PSG in NMD patients to be able to provide a true understanding of the adequate level of sup-

port needed.[13] With some NMDs, such as amyotrophic lateral sclerosis (ALS), evidence is lacking to support the routine use of PSG for the assessment and treatment of hypoventilation-driven SDB problems.[14] The American Academy of Neurology recommends treatment and titration of NIV empirically, initiated and frequently followed up in a clinic or homecare setting by RCP's or physicians who are experienced with the ALS population.[14]

Who ya gonna call, still?

The RCP's role has been growing and ever expanding. Over the years we have seen a shift away from quantitative types of therapies (how many nebs have been given) and toward a focus on roles where the RCP adds value in the care of the pulmonary patient. The fact that patients with NMD are often at higher risk of SDB along with respiratory failure and even death[4] is a huge implication for the value of the role of the RCP. It is paramount that the RCP is able to identify NMD patients at risk of SDB early on. Thorough assessment, follow-up, and treatment of respiratory concerns by the RCP and other health care providers can improve both quality and length of life for the patient suffering from neurorespiratory complications.[2]

The RCP plays a vital role in the detection, evaluation, respiratory monitoring, and therapeutic support of the NMD patient with SDB. Whether it is performing PFTs, performing and scoring PSG testing, performing and scoring nocturnal oximetry testing, providing detailed assessment of history and symptoms, performing ABG draws, measuring EtCO2 readings, or educating, setting up, maintaining, and titrating NIV, the RCP will likely be in the thick of it all and will be an integral part of ensuring appropriate diagnosis and care of the neurorespiratory SDB patient. ■

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Ventilation for Life

Making Sense of CMS Regulations Regarding Home Ventilation

By Joseph Lewarski, BS, RRT, FAARC

To set the stage for a discussion about some of the regulatory issues surrounding home mechanical ventilation, it may be helpful to share some thoughts and observations regarding clinical practice, technology, coverage policy and reimbursement…all variables that have influenced the current regulatory environment.

- The art and science of medicine. Despite the growth of evidenced-based care, there is still much art in the delivery of care, especially when treating medically complex, co-morbid patients, such as those with COPD. Changing health policy and payment models often accelerate changes in clinical practice, and a result, clinical practice often evolves without the high-level evidence we all hope for. This is true for much of home mechanical ventilation.
- Technology is moving faster than both the evidence and practice. Novel devices and approaches to care sometimes enter the market quickly, often without an abundance of randomized controlled clinical trials, which may not be the most practical or appropriate method of evaluating every new technology.
- Coverage policy and reimbursement models don't keep pace. With clinical practice and technology moving so quickly, it is difficult for policymakers and administrators to keep up. This is especially true in federal and state programs, where home care regulations are often rooted in statute and policy developed in the 1960s and 1970s.

about the author…

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Home mechanical ventilation

The movement for home ventilation can be traced to the 1980s, as the combination of technology and changing health care economics provided the catalyst to discharge certain technology-dependent individuals to be cared for at home.[1] The same catalysts of technology and economics are still driving forces behind home ventilation today, with the technology being much more advanced and the economic drivers much more complex, including readmission reduction programs/penalties, post-acute bundled payments, Accountable Care Organizations (ACO), and full risk payment models, where all of the financial risk is shifted to the health care provider or organization.

Home ventilation technology

Until the early 2000s, home mechanical ventilation was pretty straight forward; there was essentially one Healthcare Common Procedure Code (HCPCS), E0450, and no national or local coverage determination. The coverage criterion was respiratory failure, which could be the result of various diseases and disorders. The majority of applications were invasive, via tracheostomy, although there were pockets of noninvasive volume ventilation being used around country. Noninvasive applications (mask and mouth) were disproportionally used with post-polio patients, other neuromuscular disorders, and sometimes with obesity hypoventilation.[1]

Early home mechanical ventilators were primarily volume-control, life-support ventilators that offered basic ventilation modes (control, assist-control, synchronized intermittent mandatory ventilation) and minimal features. Over the last 15 years, there have been significant advances in portable ventilators. Modern portable ventilators incorporate turbines and other pressure/flow generators, allowing for more sophisticated modes of ventilation, including pressure support, pressure control, flow-by, and flow triggering.[2] In addition, some portable ventilator models offer spontaneous breathing support modes, including continuous positive pressure (CPAP) and bi-level, with and without a back-up rate setting. It is likely these spontaneous modes, which are available on various models of bi-level devices, referred to as respiratory assist devices (RAD) by Medicare, play a role in the current controversy and confusion surrounding home mechanical ventilation.

In 2005, Centers for Medicare & Medicaid Services (CMS) introduced four HCPCS codes to recognize the changes in ventilator technology and care:

- E0450: volume-control ventilator, without pressure support mode, may include pressure-control mode, used with invasive interface (e.g., tracheostomy tube)
- E0461: volume-control ventilator, without pressure-support mode, may include pressure-control mode, used with noninvasive interface (e.g., mask)
- E0463: pressure-support ventilator with volume control, used with invasive interface (e.g., tracheostomy tube)
- E0464: pressure-support ventilator with volume control, used with noninvasive interface (e.g., mask)

The codes were intended to recognize the "basic" versus "advanced" home ventilator technologies for both invasive and noninvasive applications. There was also an increased payment allowable for the advanced pressure-support ventilators, intended to compensate for the higher costs associated with the newer and more advanced devices and accessories. The Medicare 2015 DME fee schedule allowed for monthly rental amounts for all four codes as noted below:[3]

- E0450 and E0461: $1,020/month (average)
- E0463 and E0464: $1,561/month

In this context, ventilators are classified as frequent and substantial serving, which is an uncapped monthly rental as long as medical necessity exists.

Why the major focus on home mechanical ventilation?

As often happens after the introduction of new technologies, especially ones with improved features and benefits, the market moves in that direction. In the case of home ventilators, utilization shifted away from the older ventilators and moved to the newer devices. These technology advances and integrations often allow providers to use one type of device to meet the needs of a broader scope of patients. However, the technology shift alone is not what appears to have triggered concern among the regulators; it was the rapid increase in the use of noninvasive ventilation (NIV) in COPD (HCPCS code E0464) and the costs associated with it. According to the Office of the Inspector General (OIG), "Medicare paid 85 times more claims for noninvasive pressure-support ventilators in 2015 than it did in 2009, leading to a rapid increase in expenditures."[4] The OIG also noted that diagnoses for E0464 claims have dramatically shifted away from neuromuscular conditions to respiratory conditions. In 2009, neuromuscular disorders were 56% of claims, with chronic respiratory failure representing 29% of claims. In 2015, 85% of the E0464 claims were for chronic respiratory failure and only 7% for neuromuscular disease."[4]

The regulatory focus is on the significant growth in home NIV using the more sophisticated ventilator (E0464), which grew from about 500 home NIV patients in 2009 to 33,000 patients in 2015 (Figure 1). This represented an increase in Medicare payments from $3.8 million in 2009 to nearly $343 million in 2015 (Figure 2).

This raised concerns within CMS that perhaps there was a shift away from using the RADs (bi-level with or without a backup rate) to provide NIV in the home, to the more sophisticated E0464 ventilation devices. However, this theory is not supported by any data, and as noted by the OIG, only a very small percentage of patients used a RAD or CPAP device prior to using an E0464 device.[5]

So what happened? In my opinion, there are a number of factors in play, but the primary drivers are:

- Acceptance and increase of NIV use in acute care to manage respiratory failure in COPD
- Growing evidence of the benefit of NIV in certain populations of patients with chronic respiratory failure or insufficiency (the less defined condition) with COPD
- A very complex and restrictive RAD coverage policy, which is especially limiting for patients with COPD
- The negative affect of the RAD capped rental on long-term home RT follow-up and management of NIV patients
- More appealing features and benefits of new portable home ventilator technologies
- Blurred lines around ventilation options created by various existing, coded devices that are capable some of the same or similar modes of non-invasive pressure support (i.e., a bi-level device with or without backup rate)
- Changing health care payment models that measure and reward or penalize various outcomes, such as the readmission prevention program, post-acute bundled payments, ACOs, and other various value-based care initiatives.

Regardless of the causes, all of the aforementioned data have had CMS and its contractors very focused on home ventilation over the last few years.

Changing policy language

Because there is no national or local coverage determination for ventilation and the sole medical necessity criterion

for a ventilator is respiratory failure, Medicare used a 2001 CMS non-binding decision memo in 2014 to limit the use of NIV. The memo included some very concerning language that stated NIV is to be "distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of respiratory support leads to death."[5] This language was highly problematic and was opposed by nearly every clinical and professional organization. Despite that opposition, this statement was used by CMS to guide claims reviews and coverage decisions for use of E0464 devices for nearly two years.

In May 2016, Medicare updated the guidance on coding and coverage of ventilators. The new guidance was likely in response to myriad communications with the medical and clinical community and offered more rational and pragmatic coverage language. The new ventilator guidance eliminated the stipulation that ventilators and RADs are "covered for different disease groups, and that ventilators are not eligible for reimbursement for any of the non-life-threatening conditions described in RAD coverage policy." This clarified that, while the disease categories described in the coverage determinations for ventilators and RADs may overlap, the "choice of an appropriate treatment plan, including the determination to use a ventilator vs. a RAD, is made based upon the specifics of each individual beneficiary's medical condition." This appropriately shifted the treatment and device decisions back to the physician/prescriber.[6] The new rule also requires prescribers and home care providers to have all appropriate documentation supporting the specific prescribed treatment and technology. Recommended documentation includes:

- Valid physician's order with all appropriate ventilator specific settings, hours of use per day, etc.
- Diagnosis consistent with the language in the guidance documents
- Medical necessity justifying the type of ventilator support that is well documented in the medical record for the initial set-up, as well continued documentation to support the ongoing medical need (chart notes) from follow-up care visits
- Documentation of the ventilator provider's emergency plan and protocol
- Proof of delivery, training, etc.

Changing codes and reimbursement

In January 2016, CMS made significant changes to the coding, coverage, and allowed amounts for ventilators. In a Joint DME MAC publication, it was stated that "ventilator technology has evolved to the point where it is possible to have a single device capable of operating in numerous modes, from basic continuous positive pressure (CPAP and bi-level) to traditional pressure and volume ventilator modes. This creates the possibility that one piece of equipment may be able to replace numerous and different pieces of equipment. Equipment with multifunction capability creates the possibility of errors in claims submitted for these items."[7] The article provides additional guidance regarding the medical necessity, documentation, coding, and coverage of ventilators. It also introduces the new HCPCS codes for ventilators.

Effective for claims with dates of service on or after January 1, 2016, all products classified as ventilators must be billed using one of the following HCPCS codes:

- E0465: home ventilator, any type, used with invasive interface (e.g., tracheostomy tube)
- E0466: home ventilator, any type, used with noninvasive interface (e.g., mask, chest shell)

The 2016 Medicare fee schedule allowed amounts for E0465 and E0466 range from the ceiling (highest) of $1055.23 to the floor (lowest) of $896.95. This represents a payment reduction from the prior E0463 and E0464 allowable of approximately $506 to $664, depending on the state.

Summary

There are a lot of factors that have complicated home mechanical ventilation, and to discuss such in detail is beyond the scope of this article. As noted earlier, technology and practice are moving at a quick pace, and these developments have resulted in blurred lines regarding the types of devices both capable of and used to provide various levels of ventilator support, particularly NIV. New models of care, which bring various new incentives (or dis-incentives), have also influenced ventilation practices and prescribing patterns. The home is going to continue to become the focus of the care and treatment of patients with chronic disorders, as it provides a better economic alternative, and, if given a choice, most people would prefer to be at home. This means regulations and policy need to be speedy, dynamic, and relevant—as Bruce Lee said, "Be like water." ■

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Chronic Disease Manager

A Discussion on Home Ventilation

by Angela King, BS, RRT-NPS, RPFT

A recent report from the U.S. Department of Health and Human Services Office of Inspector General (OIG) has created quite a stir in the home care respiratory community. The Centers for Medicare and Medicaid Services (CMS) and its contractors have expressed concerns about the recent substantial increase in Medicare billing for noninvasive pressure support ventilators. The number of Medicare beneficiaries using noninvasive ventilators increased from 415 in 2009 to 32,848 in 2014.[1] (See Figure 1.)

While claims for noninvasive ventilators (NIV) have skyrocketed, the claims for all other types of mechanical ventilators have increased at much lower rates or even decreased during the same period of time. (See Figure 2.)

What is driving the increase in home ventilation?

There are several drivers for the transition of long-term ventilator-dependent patients from the hospital to the home:

1. The rising costs of hospital care.
2. The need to decrease the use of critical care resources for medically stable long-term ventilator-dependent patients who do not need critical care services.
3. The need to ensure availability of critical care beds for critically ill patients.
4. The desire to decrease the risk of long-term ventilator-dependent patients acquiring nosocomial infections.
5. The increased availability of mechanical ventilators suitable for the home plus a wide variety of noninvasive patient interfaces.
6. Patient desire to improve quality of life by transitioning to where they want to live.[2] (See Figure 3.)

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These reasons may explain the increase in invasive ventilator patients moving to the home, but it doesn't provide an explanation for the dramatic increase specific to noninvasive domiciliary ventilator patients. Additional drivers for the increase in home noninvasive ventilation may include:

1. An increased awareness that many neuromuscular diseases leading to chronic respiratory failure, such as Duchenne muscular dystrophy, may be optimally managed by avoiding the tracheostomy. Even patients who are completely ventilator-dependent may be successfully managed with NIV, which avoids many of the complications of the tracheostomy, including increased secretions, impaired swallowing and oral communication, increased risk of aspiration, and the bypassing of airway defenses.[3]
2. An increased use of NIV in the acute care setting for managing COPD patient exacerbations. When inpatient NIV ameliorates the patient's condition, physicians want to extend the therapy into the outpatient setting as well. This may be particularly relevant because hospitals are now penalized for COPD patient readmissions that occur within 30 days post-discharge.[4]
3. An increase in DME suppliers billing Medicare for a ventilator when a lower cost CPAP or RAD device is indicated per the patient's medical condition. The OIG report notes that in 2009, the primary diagnosis for an EO464 device was neuromuscular disease; by 2015, the primary diagnosis shifted to chronic respiratory failure.[1] This shift may be

noteworthy because chronic respiratory failure diagnoses may be treatable with a RAD. (See Figure 4.)

NIV coverage for home care patients

The CMS Medical National Coverage Determinations Manual lists clinical conditions that may be treated with a ventilator versus a RAD. (See Table 1.) A ventilator is appropriate for patients who have a severe condition in which the interruption of respiratory support could lead to serious harm.[5]

Ventilators differ from RADs in that they have internal batteries and therefore can still be useful during a power outage. Ventilators were designed to be able to withstand continuous usage, and include a full complement of alarms that may be individually adjusted to maximize patient safety. Additionally, ventilators typically have more robust flow capabilities and additional modes and features that may be useful for the more seriously compromised patient.

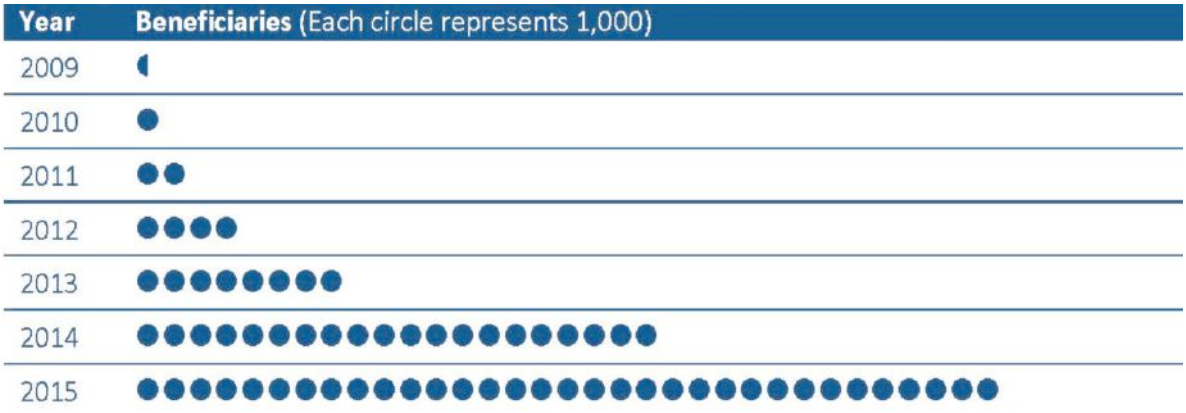
The RT's role in home ventilation

The home care respiratory therapist functions both as a therapist and as a case manager when preparing a ventilator patient to transition from the hospital to the home. A wide variety of tasks must be accomplished, generally within a very limited timeframe, before the patient can go home on a ventilator safely. Generally, invasive ventilation requires significantly more equipment and more training than NIV. (See Figure 5.)

The hospital discharge planner calls or faxes the potential home ventilator patient's information to the selected DME company. Typically, the hospital discharge planner already has a target date in mind for the patient's discharge to the home. The DME company's customer service personnel verify the patient's insurance and obtain insurance authorization for the required home medical equipment. As soon as possible, the home care therapist visits the prospective home care patient at the hospital to:

- Establish rapport with the patient and family caregiver(s).
- Review the current ventilator mode, settings, and accessories (such as heated humidifier, noninvasive mask type and size, nebulizer adapter, etc.) Determine if the patient's ventilatory needs can be met at home.
- Ascertain what DME may already be in the home and what new equipment will be needed.
- Begin the process of obtaining all required prescriptions.

Figure 1: Escalating Number of Beneficiaries Receiving EO464 (Noninvasive) Ventilators.



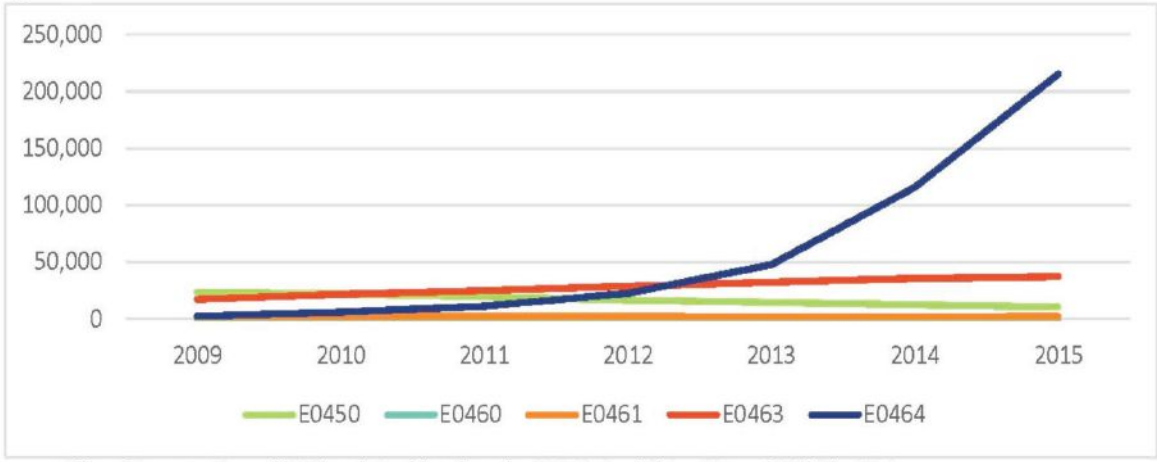
Source: OIG analysis of data from the CMS NCH File, 2016.

1U.S. Department of Health and Human Services Office of Inspector General, HHS OIG Data Brief, September 2016. OEI-12-15-00380. Escalating Medicare Billing for Ventilators Raises Concerns.

Table 1. Comparison of Medicare Requirements for Home Respiratory Devices

Device	Conditions Treated	Reasonable and Necessary
Ventilator	Neuromuscular disease, thoracic restrictive disease, or chronic respiratory failure secondary to COPD	Beneficiary has a severe condition in which the interruption of respiratory support could lead to serious harm.
RAD	Restrictive thoracic disorders, severe COPD, central sleep apnea, complex sleep apnea, or hypoventilation syndrome	Beneficiary has a less severe, non-life-threatening condition that requires only intermittent and relatively short durations of respiratory support.

Figure 2: Claims for EO464 Ventilators Grow Faster Than Those for Other Ventilators.



Source: Office of Inspector General (OIG) analysis of data from the CMS National Claims History (NCH) File, 2016.

1U.S. Department of Health and Human Services Office of Inspector General, HHS OIG Data Brief, September 2016. OEI-12-15-00380. Escalating Medicare Billing for Ventilators Raises Concerns.

- Determine whether a second ventilator may be required for mobility or therapeutic purposes.[6]
- Explain the importance of the home safety evaluation and to schedule the evaluation promptly.
- Learn who the family caregiver(s) will be and arrange their training.
- Provide a general overview of the discharge process and answer any questions the patient and family may have.

After meeting with the patient and family and completing the home evaluation, the therapist communicates back to the hospital discharge planner to:

- Update on whether the patient is appropriate for home ventilation.
- Update on whether the patient's home is suitable for home ventilation or if any modifications are required.
- Review the progress on the family education plan.
- Discuss whether home health nursing will be utilized and ascertain whether the home nursing staff require training on the selected home ventilator.
- Establish a tentative date for the family caregiver(s) to perform all care for 12–24 hours independently while in the hospital (often referred to as "rooming-in").
- Discuss whether the patient will be transported home by family vehicle or by ambulance.
- Review the anticipated discharge date and time.

Patient and family education

In addition to coordinating with the hospital discharge planner, the home care therapist also works with the hospital respiratory therapists and nurses to determine which portion of the family caregiver training each health care discipline will perform (See Table 2). Ideally, a multidisciplinary education plan, along with checklists and return demonstrations for each content area, are used to ensure adequate training.[7] (See Tables 2 and 3.)

During training, family caregivers are often taught a skill (and may even perform a successful return demonstration) but then don't perform the skill again until the rooming-in day. Patients and families may be better served by repetitively performing all the care they have been trained for, from the initial training date until discharge. This ensures that the caregivers will be confident and skilled on the rooming-in day and thereafter. It may be helpful to obtain permission to post a sign at the head of the patient's bed, reminding staff to encourage the family caregivers to keep practicing their skills.

Home ventilator in the hospital?

Ideally, the home care respiratory therapist brings the home ventilator to the hospital several days before the planned discharge date. If necessary, the home care RT will need to train the hospital RT staff on the home ventilator. The hospital representative will typically perform an electrical safety check on the home ventilator, and may elect to verify whether the home ventilator can interface with the nurse-call system or remote alarm system. Finally, the hospital RT and the home care RT work together to place the patient on the home ventilator and verify that the patient is tolerating the home ventilator. This also allows the family time to become more familiar with the home ventilator. Unfortunately, not all inpatient facilities allow the use of home care equipment due to patient safety and liability concerns.[8] Many hospitals will allow the use of an approved home ventilator if staff have been properly trained and if the family caregiver(s) are in attendance.

Patient monitoring

Regardless of whether the patient is invasively or noninvasively ventilated, Medicare does not cover the

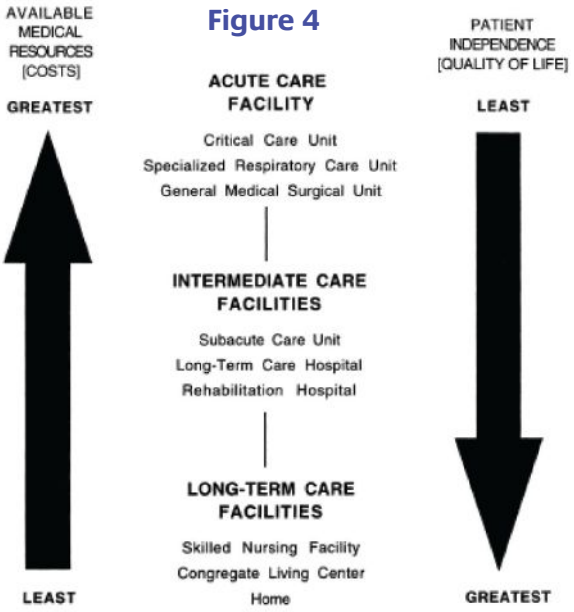


Figure 4

Make BJ, Hill NS, Goldberg AI, Bach JR, Dunne PE, Heffner JE, Keens TG, Donohue WJ, Oppenheimer EA, Robert D. Chest/113/5/May, 1998 SUPPLEMENT

Figure 5

Tips For Smooth Transitions

- Invasive patient gets 2-3 bins
- NIV patient gets 1-2 bins
- Resuscitation bag, spare trach tube and cuff syringe in top drawer

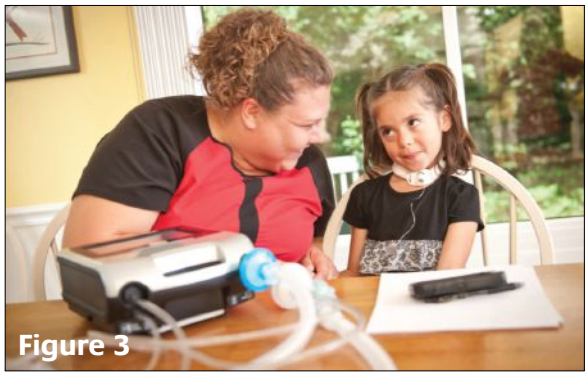


Figure 3

use of a home oximeter. Many insurance companies follow Medicare guidelines, but fortunately, Medicaid does allow oximeters when medically necessary and ordered by the physician. It is important to stress that, when prescribed, oximeters should be used on pediatric patients continuously, or at the very least, when the child is not visually monitored. Some advanced home care companies offer capnography, generally on a spot-check basis; this is rarely covered by insurance. Additionally, many newer home ventilators allow information to be downloaded to memory card or USB drive, or even transmitted via modem, although none of the devices transmit data in real-time as yet. There is some controversy regarding the extensive data now captured by some of the newer ventilators because there is no reimbursement for the data to be reviewed.

Gaps in patient and family education

A retrospective observational study of 228 children enrolled in a home mechanical ventilation program over 22 years was performed. Of the cohort, 47 children died, with almost half the deaths being unexpected. There was evidence of notable risk from tracheostomy-related events, with tracheal bleeding, tracheal obstruction from a mucus plug, and incorrect placement of the tracheostomy tube

Table 2. Suggested Educational Topics by Health Care Discipline

Hospital RN	Hospital RT	Home care Technician	Home care RT
All aspects of enteral nutrition program, including g-tube care	Trach care and suctioning	Home oxygen safety	All aspects of home ventilator(s), including troubleshooting
Medications (purpose, dose, route, frequency)	Emergency procedures for mucus plug and accidental decannulation	Verify home safety, including functional smoke detector	Verify that the caregiver can hear the vent alarms over ambient noise throughout home
When to call the doctor (temperature >100°F, increase in mucus, mucus thickening, change in color of mucus, bleeding from trach)	Use of resuscitation bag to the trach and with mask	Verify electrical safety including adequate grounded outlets	Emergency plans: • oxygen failure • power failure • vent failure • trach emergency • caregiver illness

Table 3. Family Caregiver Check-Off, Handling a Mucus Plug

	Reviewed and Demonstrated Procedure	Family Caregiver Performed Return Demonstration	RT Initials
1. Quickly check suction pressure and then suction the child.			
2. Give breaths with resuscitation bag after suctioning while listening to the child's lungs.			
3. If the suction catheter won't pass, quickly change the tracheostomy tube. When in doubt, ALWAYS change the trach tube!			
4. After trach tube change, give breaths with resuscitation bag until the child is back to normal.			
5. Place the child back on the monitoring equipment.			
6. Call the physician or respiratory therapist to report incident.			

Adapted from the Ventilator and Children's Home Program, Pennsylvania Department of Health, Children's Hospital of Philadelphia.

into a false tract accounting for almost 20% of the deaths.[9] These data encourage home care therapists to ensure that the family education includes managing tracheal emergencies (Table 3).

A Final Note on Safety

One study estimates the accidental death rate for children receiving home mechanical ventilation at 27.5%.[7] Another study examined the cause of death for eight patients who died while receiving home mechanical ventilation; two of the eight deaths were due to accidental disconnection of the ventilator circuit. One of the patients had been home on ventilation for 10 years, the other for 15 years, so presumably the families were well trained on proper ventilator management.[10] These data should encourage the home care therapist to ensure that the family can hear the ventilator alarm throughout the home. The therapist should also assess whether the patient has a means to summon assistance. Finally, the respiratory therapist should serve as a resource for appropriate assistive technology to facilitate patient communication.

A review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database also reveals patient deaths attributed to accidental ventilator disconnection and to mucus plugs occluding the airway. Some of these deaths reportedly did not trigger a ventilator alarm. It is good practice for the home care therapist to verify that a low-pressure alarm will sound if the patient decannulates with the trach tube or inner cannula remaining affixed to the end of the ventilator circuit. It is also good practice to verify that the ventilator will alarm in some fashion if there is an obstruction. Both of these alarm tests can be performed using the patient's emergency tracheostomy tube.

Home RT has the primary responsibility

Home ventilation is growing, especially noninvasive ventilation for chronic respiratory failure patients. There is some early evidence that home NIV may reduce hospital readmissions for these patients.[11] Regardless of whether the home ventilation is performed noninvasively or invasively, the home respiratory therapist has the primary responsibility to ensure that the home environment is suitable, that the patient and family have been adequately trained, and that the home equipment is clinically appropriate and efficacious. ■

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Time of Death: 0821

by D. Robert Handy, BSRT, RRT

"Time of death: 0821." Monitors are turned off; carts and equipment are pulled from the room. I turn off the oxygen and hang the bag on the wall. The doctor is in the hall with the social worker, consoling a grieving family.

I put all my equipment away and then walk down the hall to breakfast in a somber mood. As I pass others in the hallway, I pick my head up and keep moving. It is as if nothing has happened — I have moved on.

Am I heartless? Do I have no soul? Some may agree with that sentiment, but, truthfully, I have to move forward. There is a Russian proverb that says, "The shark that does not swim drowns."

I have been in health care for over 15 years, and every day that I go to work I meet someone who is having the worst day of their life. You empathize with their loss, and you empathize with their pain — but it is not your own.

It is not a matter of having become jaded or callous. You simply have to move forward. Other people still need your expertise and care. Other people still depend on you to save or sustain another's life. You have to find a way to shut out the sadness, the heartache, and the agony, and you must continue to care for others. Over the years, I have met people who can do this and others who cannot.

You learn to live parallel to the world in which your patients and their loved ones reside. Some of them find hope, relief, and even miracles. Others only find loss, regret, and pain. You pass along your condolences, and you allow them a shoulder to cry on, even if only for a brief moment.

But inevitably, the pager buzzes, or the phone rings, or the overhead system calls for your expertise. You take a breath, you slow down the world around you, and then you pick up the call and get moving. Not jaded, not callous. You found your calling in this life. Now someone else is about to have their worst day ever, and they need you to have your best — to BE your best. There is no bonus, no reward. No one will sing your praises, and they probably won't even know your name — but you found your calling, and the battle cannot rage on without you. Pick up your head and keep moving. ■

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Jovante's Legacy Lives On

Football great Ickey Woods is making sure his son's death was not in vain

By Debbie Bunch

Former Cincinnati Bengals star running back Ickey Woods and his family are no strangers to asthma. Both Ickey and his ex-wife Chandra suffer symptoms of the disease, and Chandra's dad had a severe case. So when their first-born son, Jovante, was diagnosed at age two, no one was all that surprised. Severe episodes struck throughout his childhood, nearly claiming his life when he was seven and putting him in the hospital when he was nine.

Ickey and Chandra always felt like they were doing everything they could to manage Jovante's condition. His physicians had him on preventative treatment, and as a responsible young man, Jovante was careful to adhere to the doctor's orders. Trips to the emergency department put them in touch with respiratory therapists, who educated them on the disease and how to get it under control. "They helped us out by giving us tools we could use in order to monitor the attacks of asthma," says Ickey. "We wouldn't know any information about the preventative methods and emergency methods without them, so having their help was always a gift and a blessing."

So when Jovante came home from football practice complaining of shortness of breath one afternoon in August of 2010, no one in his family really saw what was coming. When that shortness of breath escalated, however, into a severe asthma attack that left him unresponsive, it was clear something was very, very wrong.

Last act of giving

Jovante's younger brother Aubry was the one to find him, collapsed on the floor. He immediately called his dad and told him what had happened. Ickey was 15 minutes away. Call 911, he told his son. Then he hopped in the car and raced home, only to find Jovante being loaded into an ambulance.

Ickey and Chandra rushed to the hospital to be with their son, but in the end, it was already too late. "They got his heart pumping, but he had gone 30 minutes without any oxygen to the brain," says Ickey. "That was what actually killed my baby."

The Woods family was shocked, and their sorrow was overwhelming. At age 16, Jovante Woods was an outstanding young man, and they never saw anything but a bright future ahead of him. Like his dad, he loved sports, and that fall he was to be a starting cornerback on his high school team at Princeton High School in Sharonville, OH. With a 3.8 grade point average, he also had a keen mind and was especially interested in helping others. "Spreading goodness, motivation, and imploring others to stand up for themselves are traits of his that seemed to always stand out," says his dad. "This clever soul was aspiring to be a lawyer."

The Jovante Woods Foundation is funding important research into better treatments and possibly even a cure for asthma.

Jovante was also something else most kids his age are not: an organ donor. "Most teen drivers are not organ donors, but my son checked 'yes' on the organ donor box," says Ickey. So after three days of hope and prayer in the hospital that ended on August 14, when doctors told them their son was brain dead, Ickey and his family

Ickey Woods, at Glance

Football fans will remember Ickey Woods as one of the great players whose career was cut short way too soon. During his rookie year with the Cincinnati Bengals, Ickey scored 15 touchdowns and helped the team make its way to the Super Bowl. His unique touchdown dance — dubbed "the Ickey Shuffle" — captivated audiences around the world. An injury to his left anterior cruciate ligament in the second game of his second season, however, put him on the bench for 13 months, and combined with other injuries, ultimately ended his career after just four seasons.

Ickey went on to develop several successful businesses, and in 2003 began coaching the all-female football team, the Cincinnati Sizzle, which he now coaches and owns. Much of his time and energy, however, goes directly into the Jovante Woods Foundation and the fundraisers it holds throughout the year to raise money for the Asthma Research Division at Cincinnati Children's Hospital. The foundation also supports organ donation and student athletes through two annual scholarships. ■

Father and son had a close relationship.

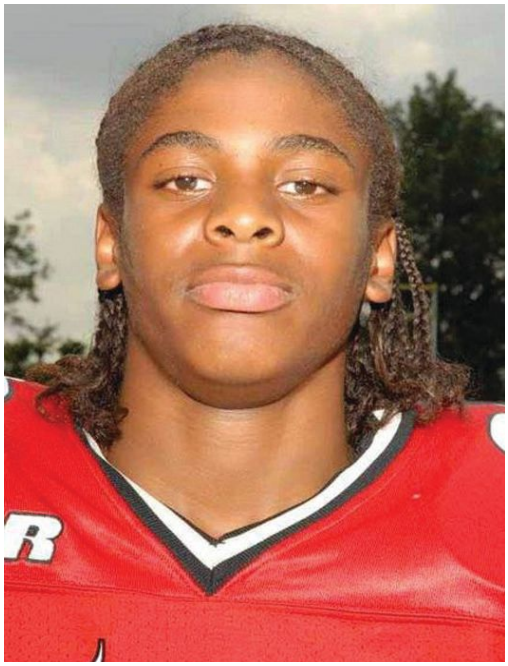
decided to take their son off life support and donate his organs. This young man's last act of caring and giving saved four lives through those donations, and he touched countless other lives through the donation of his tissue as well.

The Jovante Woods Foundation

Ickey and his family are making sure Jovante's legacy lives on. The Jovante Woods Foundation was established to keep his memory alive and helps ensure other children with asthma have a better chance to survive through the development of new and better treatments. Since its inception in 2010, the Foundation has donated $100,000 to the Asthma Research Division at Cincinnati Children's Hospital, and Ickey and his family plan to continue to support the division through an ongoing endowment in Jovante's name.

The foundation also works closely with the LifeCenter Organ Donor Network to educate the public about the importance of the "gift of life" that organ donation is to thousands of people every year, and it supports education through two annual "3.8 To Be Great" scholarships given to a male and female student athlete with a 3.8 grade point average or greater.

The scholarships emphasize Ickey's stance on sports for kids — with or without asthma. "Even certain severities of a disease don't keep a kid from being a kid," he says. With proper monitoring and preventative treatments, he believes children with asthma and many other chronic conditions can play sports or do anything else they want to do. "Let the children do what makes them happy."



Jovante was looking forward to being a starting cornerback on his high school team.

The journey continues

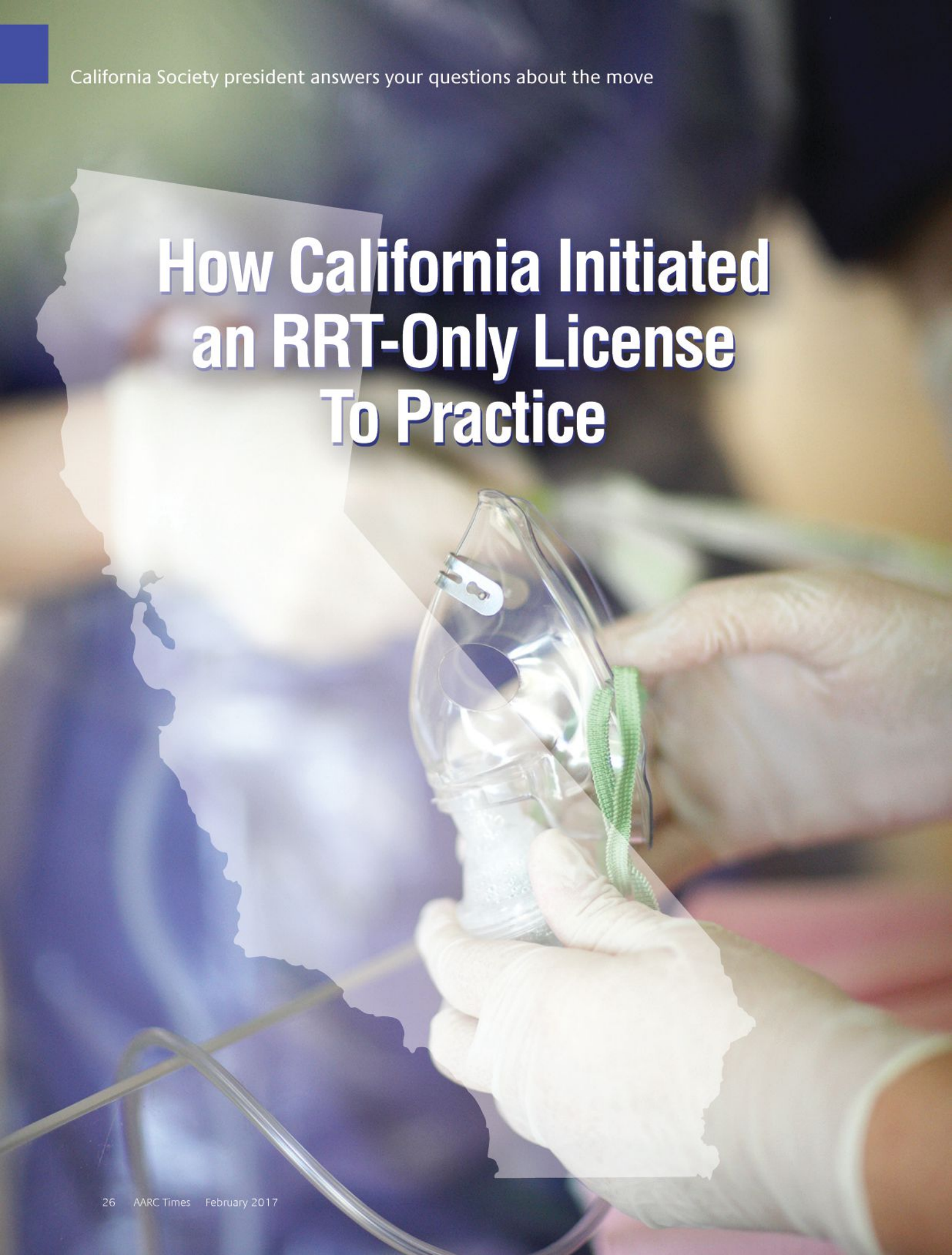
Ickey Woods firmly believes Jovante's untimely death could not have been prevented. "In our eyes, we were doing all that could be done. This path was unforeseen; therefore, no amount of medicine or assistance would have changed this," he says. "Our angel was being called home."

He also believes his son's ultimate fate was to make sure more people understand the severe turn asthma can take and to help the medical community come up with the kind of treatments — and possibly even a cure — that could have saved Jovante's life and could save millions of other children's lives in the future. "Just knowing that 11 kids a day die from this disease — it seems so unnecessary," says Ickey. "The Lord has a plan for all of us. It has been an honor to come into the opportunity to speak out about asthma and have a better understanding of a situation like this. We are thankful to be used as a vessel in this journey to help save lives."

What would Ickey like respiratory therapists to know about their role in treating patients like Jovante? "We know that this disease kills. Education as a society is key. We need to all continue working to bridge the gaps," he says. "Just to know that the medical team is involved helps build onto that bridge of educating all who suffer." ■

California Society president answers your questions about the move

How California Initiated an RRT-Only License To Practice



California Society for Respiratory Care President Mike Madison talks with *AARC Times* about how his state society was one of the first to lead the way.

If you've been keeping up with the professional planning going on at the AARC, you know the top priorities are to move to a baccalaureate entry level, promote advanced practice, and support continuing education for the respiratory therapist. These objectives were carefully developed after a series of groundbreaking conferences identified the knowledge, skills, and attributes respiratory therapists would need to thrive in the 21st century.

The conferences brought together not only key stakeholders in the respiratory care profession, but also representatives from employers and employee groups, foundations, professional associations, state and federal government agencies, educational institutions, and health care delivery systems so that a consensus on the best path forward could be reached among all of those with an interest in the future of the respiratory care profession.

Now those efforts are beginning to come to fruition, as California, Ohio, and Arizona have passed laws mandating an RRT credential as the entry into practice for all newly licensed respiratory therapists in the state. In the following interview, California Society for Respiratory Care (CSRC) President Mike Madison, MBA, RRT, explains how his state became one of the first to lead the way.

Please describe the process by which you went about enacting this change. How long did the process take?

The CSRC formed an Advanced Practice Commission (APC) on September 10, 2005. The APC researched the issue and formulated recommendations for the CSRC Board of Directors. On December 11, 2006, the board voted unanimously to accept the recommendations and submit a statement requesting a move to an RRT license minimum to the California Respiratory Care Board (CA RCB). The legislation was introduced in February of 2014 and signed into law by Governor Jerry Brown on July 23 of that same year.

Could you elaborate on what research was gathered? Why did it take 8 years before the change in legislation?

The commission gathered data on other states' activities, continuing education requirements, status of schools, quantity of candidates produced annually, etc., to see what was possible. Our Education Committee also gathered input from the majority of the 38 programs in California. Once the CSRC decided to submit our request, it all had to be presented to the CA RCB. The RCB then commissioned a workforce study, which was conducted in 2007. When the RCB had all the information it needed, it became a process of getting buy-in among RCB members, which took significant time. When a consensus was reached, the formal public comment processes and legislative language development began. Once the language was drafted, approved and a legislative sponsor was identified, things began moving quite quickly. The Commission on Accreditation for Respiratory Care's (CoARC) timing on concluding CRT programs on December 31, 2012, also suggested to us that the "market had changed," and we escalated our legislative advocacy efforts.

What impact do you believe the National Board of Respiratory Care (NBRC) testing matrix had on making it easier for new therapists to secure the RRT credential?

In reality, the NBRC adjustment to the testing matrix had very little effect on California's decision to move forward with an RRT license minimum. What had a larger impact, in our opinion, was that CoARC mandated that all accredited educational programs in the U.S. produce only RRT-eligible candidates. In a similar time frame, the California RCB commissioned a workforce study showing that 54% of educators and 45% of employers supported the additional requirement of an RRT license minimum. After reviewing those factors, it became evident that the market was evolving in favor of a higher entry-level credential.

How did you come to the conclusion to grandfather CRTs vs. requiring them to secure the RRT credential, and how will currently licensed CRTs working outside the state be addressed should they wish to relocate to California to work?

We were *very* careful to propose ample "grandfather" language in our amendment to the California License Practice Act in our legislative initiative, Assembly Bill 1972. Any RCP who is a CRT or who was licensed in California or held an active license in any other state prior to January 1, 2015, is eligible to apply for a license and practice in California. We felt — and still feel — that the letter of the law should provide for grandfathering for existing licensed RCPs while raising the standard through new entrants into the field.

How did you come to this conclusion? Is anything being done to enhance the perceived knowledge gap of existing CRTs?

California has such language in many of its regulations. The legislature is fairly protective of jobs and there are strong union influences in California. So there is always an eye toward what effect proposed legislation would have on our work force. In addition, the CA RCB's number one charge is to protect the public. If we elected NOT to grandfather existing CRTs into the legislation, there would have been a huge deficit of qualified caregivers, which might put our patients at greater risk. Therefore, the RCB likely would not have supported that approach. We believe RRTs possess a more comprehensive level of training and critical thinking that will make them ideal for roles enumerated in Senate Bill 525, such as ECMO support, cardio-respiratory education, and conscious/deep sedation.

As for closing any knowledge gaps, the CA RCB has doubled our bi-annual continuing education requirements from 15 to 30 CEUs. In addition, the CSRC has also entered into an agreement with Grand Canyon University to provide active members with a 10% tuition discount on any course or program (including doctoral programs). All in all, the CSRC is focusing on keeping CRTs current in their education and on providing safe, quality care while opening the ceiling on greater opportunities for those who want them.

According to the agenda for the CA RCB meeting held on March 11, 2016, there were exactly 300 FEWER licenses issued in 2015 compared to 2014. In turn, it also appeared that there were nearly 300 MORE people who sat for the written portion of the exam than in 2014. Could you speculate as to why this has taken place?

There are a number of factors at play here. According to CoARC, our student capacity is 1,700+ students per year. So a drop of 300 new licenses annually is only a ~17% swing in a workforce of 24,000+ RCPs. Yes, the new law has had an impact on the job market. However, I can't help but feel that we are ending up with a work force whose baseline knowledge and skill sets are rising. I think much of this falls on the schools to implement more rigorous admission screening programs and to improve the quality of their curricula. The current CA RCB Workforce Study is due to be completed in the first half of 2017, so we will hopefully have a better data set and a more comprehensive analysis of today's California job market for RCPs.

Is it your belief that ALL states should make this change? In a state like Maine, for example, with only 2 RT programs, a 25% reduction in graduates unable to secure the RRT credential could have a devastating impact on the work force.

California only saw a ~17% decrease, which is not significant (relatively speaking). However, it could be for other states, which is why I think that we need to do a better job as a profession in distributing our human resources and should support recruitment efforts among states with a surplus of RTs to states that may be at a job candidate deficit.

What advice would you offer to other states wanting to make a similar jump to the RRT credential requirement?

Do not wait! As was true with California, much of this work requires lengthy legislative action. The sooner a state affiliate starts the process, the sooner the required steps can be completed. The good news is, today all new RT graduates are already RRT eligible. Changing state licensure to require the RRT credential for new graduates will not preclude new graduates from entering the profession. If we have confidence in the quality of our schools and the ability of CoARC to ensure that all students receive a quality education, then any impact should be minimal. ■

— 2017 —

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

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

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IN THE NEWS

Are You Interested in an Education Career Pathway?

By Ellen A. Becker, PhD, RRT-NPS, RPFT, AE-C, FAARC

Several recent AARC initiatives promote bachelor's degrees for respiratory therapists. The AARC Position Statement on Respiratory Therapist Education calls for new respiratory therapy programs to award a minimum of a bachelor's degree.[1] This same position statement continues to support existing respiratory therapy programs at the associate degree level as part of a career ladder. Additionally, the AARC has set a goal for 80% of all therapists to hold or be working toward a bachelor's degree by 2020.[2] Thus, respiratory therapists with associate degrees should move to the next step on the career ladder and complete a bachelor's degree.

The issue: Program directors and directors of clinical education (DCE) for bachelor's and master's degree programs must hold a minimum of a master's degree to meet the Commission on Accreditation for Respiratory Care accreditation standards.[3] Across the country, there is a shortage of RT educators with the appropriate academic credentials to fill the vacancies for program directors and DCEs in bachelor's and master's degree programs.

The solution: Respiratory therapists with an interest in teaching should advance their education, whether their teaching goals are to serve in a clinical department or academic setting. In addition to gaining further content expertise, an advanced degree qualifies you for more career options. As a graduate of an associate of applied science degree program, it was clear to me that people who advanced in respiratory therapy careers had bachelor's degrees at a minimum. Thus, I pursued a bachelor's degree upon graduation.

Budding educators also need to gain teaching experience. The easiest way to gain this experience initially is through volunteerism. It is hard to reject a volunteer offer, and a willingness to volunteer demonstrates your commitment to teaching. Begin locally. Offer to provide an inservice to RT colleagues, nurses, or physicians. Also consider community-based education initiatives offered by local health fairs and local advocacy groups such as the American Lung Association. These initiatives may position you to fill a role such as a pulmonary disease educator or tobacco cessation counselor in your clinical setting.

If you want to work in an academic setting, it is critical to have some classroom teaching experience. The best way to start is to assist in teaching labs, as laboratory teaching is most similar to clinical practice. Next, move on to some guest lectures in the classroom. Co-teaching a class is another option to pursue. Here you gain exposure to classroom management skills such as assisting students who struggle with learning, providing feedback on academic performance and professional behaviors, and testing and evaluation. Build a solid teaching section in your resume to be competitive for academic positions.

The resources: The AARC website has a resource page for RTs who want to seek advanced degrees.[4] It describes the issues to consider when selecting a degree program. Your current employer may provide you with some tuition assistance. Give back by sharing information you learn while demonstrating your teaching skills. Join the Education Section of the AARC and participate in the Education Section Book Club.[5] Several times each year we

read a book that relates to teaching and learning applicable to clinical and academic educators. The Education Section also discusses education research so that we can better integrate it into our teaching practice. You might also enroll in the education track of the AARC's Leadership Institute[6] or participate in the Pulmonary Disease Educator[7] course. Lastly, ask an RC educator if you need further advice or mentorship. ■

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Ellen A. Becker is a professor at Rush University in Chicago, IL, and chair of the AARC's Education Section. This article previously appeared in the Nov.-Dec. issue of *The Respiratory Tract 2016*, published by the Illinois Society for Respiratory Care, and is reprinted here with permission.

Tell Your Story

Every therapist has a story to tell about a favorite or most memorable patient that may 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 family. Or maybe it was just something the patient said or did that made you laugh or cry or just be inspired to be a better respiratory therapist. Our "Storytellers" column is the place to share these experiences. Send your story to *AARC Times* Editor Marsha Cathcart at cathcart@aarc.org. ■

Columbia State Students Go All Out for the Great American Smokeout

The Great American Smokeout is held every year on the third Thursday in November to encourage smokers to kick the habit, and last year RT students from Columbia State Community College in Columbia, TN, decided to use the day to educate everyone on their campus about the dangers of smoking. The students set up a display table on campus highlighting what is in a cigarette and how those ingredients harm the lungs and other parts of the body. They also provided great information on how to quit and what quitting can do for a person's health.

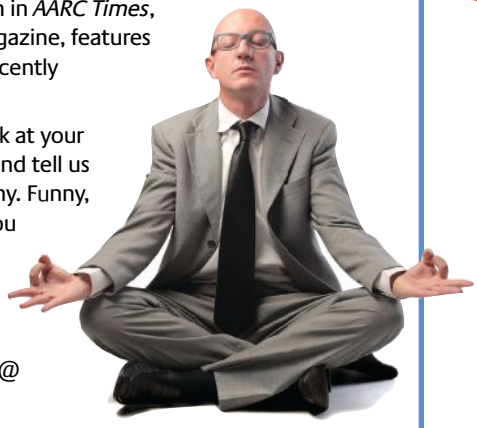
The Great American Smokeout is only one way students on this campus get involved in lung health. They also go out to local schools to educate kids about smoking awareness. "The students reach out to area schools each year to discuss the effects of smoking using pictures, crossword puzzles, pig lungs, etc., to promote lung health," says program director R. David Johnson, RRT. "It is common for teachers to call and ask that they come back to meet with more classes and to come back next year." ■

Hurst, Colin Iniesta, and Autumn Goltz display one of their posters (top).
Kaylee Jones, Lezlee Thursby, and Scarlet Hutchinson enjoy raising smoking awareness (middle).
Breanna Tankersley joins Lisa Gray and Lydia Herrick at the display table (bottom).

Share Your Wisdom with Your Colleagues

Our "Reflections" column in *AARC Times*, found at the back of the magazine, features AARC members who have recently retired from the profession.

We'd like you to look back at your career or some aspect of it and tell us what it meant to you and why. Funny, sad, inspiring — whatever you feel like writing! So start brainstorming some ideas and then submit your "Reflections" story to Editor Marsha Cathcart at cathcart@aarc.org.



Check Out the AARC New Members List Online

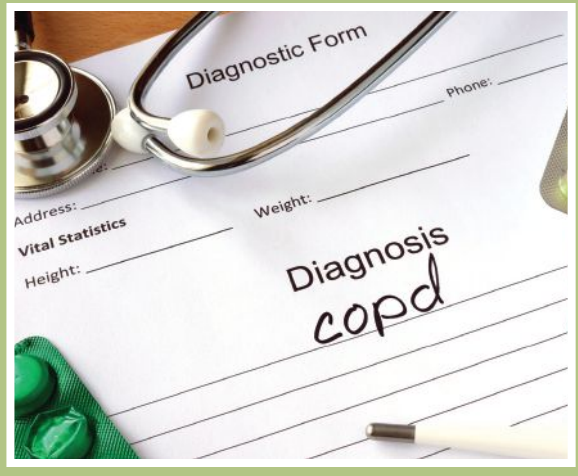
You can find the names of new members each month at http://c.AARC.org/new_members. Current AARC members are encouraged to check this site on the first of each month to view the names of individuals who have been approved as "Active Members" of the Association.

Diagnosing COPD in the Primary Care Setting

An innovative approach to identifying people with COPD in the primary care setting has received positive results in a new study led by investigators from Weill Cornell Medical College. Funded by the National Heart, Lung and Blood Institute, the approach first asks patients to complete a survey called the COPD Assessment in Primary Care To Identify Undiagnosed Respiratory Disease and Exacerbation Risk, which consists of these five questions:

1. Have you ever lived or worked in a place with dirty or polluted air, smoke, secondhand smoke, or dust?
2. Does your breathing change with seasons, weather, or air quality?
3. Does your breathing make it difficult to do things such as carry heavy loads, shovel dirt or snow, jog, play tennis, or swim?
4. Compared to others your age, do you tire easily?
5. In the past 12 months, how many times did you miss work, school, or other activities due to a cold, bronchitis, or pneumonia?

Those deemed at high risk for COPD are referred for definitive diagnostic tests. Those deemed at minimal risk need no further testing. Patients who fall in the middle perform a simple peak expiratory flow (PEF) test during their visit; men who exhale less than 350 L/min and women who exhale less than 250 L/min are referred for definitive testing. In their case-control study of 346 men and women with an average age of 63, the researchers found 52% required PEF to determine if further diagnostic testing was required. The *American Journal of Respiratory and Critical Care Medicine* published the study.



Cancer-Causing Chemicals Found in Flavored E-cigarettes

According to a new study in *Environmental Science & Technology*, the aerosols produced by flavored e-cigarette liquids contain dangerous levels of hazardous chemicals known to cause cancer in humans. These toxic aldehydes, such as formaldehyde, are formed not by evaporation, but rather during the chemical breakdown of the flavored e-liquid during the rapid heating process that occurs inside e-cigarettes or electronic nicotine delivery systems.

Desert Research Institute investigators reached those conclusions after measuring concentrations of 12 aldehydes in aerosols produced by three common e-cigarette devices. To determine whether the flavoring additives affected aldehyde production during vaping, five flavored e-liquids were tested in each device. Two unflavored e-liquids were also tested. In all experiments, the amount of aldehydes produced by the flavored e-cigarette liquids exceeded the American Conference of Governmental Industrial Hygienists Threshold Limit Values for hazardous chemical exposure.

"One puff of any of the flavored e-liquids that we tested exposes the smoker to unacceptably dangerous levels of these aldehydes, most of which originate from thermal decomposition of the flavoring compounds," study author Andrey Khylstov, PhD, was quoted as saying. "These results demonstrate the need for further, thorough investigations of the effects of flavoring additives on the formation of aldehydes and other toxic compounds in e-cigarette vapors." ■

E-cigarettes Also Raise Respiratory Risks in Kids

Teens who use e-cigarettes often think they're doing their lungs a favor by not smoking regular cigarettes. New research from California investigators finds that's just not true. When they analyzed results from the Southern California Children's Health Study, they found an 85% higher risk of respiratory symptoms among teens who had tried e-cigarettes in the past vs. those who had never tried them. The risk was double for current users. The study was published in a recent edition of the *American Journal of Respiratory and Critical Care Medicine.* ■

Aerosolized TB Drug Circumvents Resistance Issues

Oral pyrazinamide (PZA) has long been a first-line medication for the treatment of tuberculosis, but problems with drug resistance have limited its use in recent years. New research out of RTI International in Raleigh-Durham, NC, suggests an inhaled form of the drug delivered at only a fraction of the oral dose could work around the resistance issues.

Given locally to the lung at doses up to ten times lower than the oral dose, the active component of the drug, known as pyrazinoic acid (POA), bypassed the microbial enzymatic action needed when the drug was taken orally. PZA resistance is thought to lie in a mutation of the enzyme associated with the conversion to POA.

"What we've done in our research is to use a derivative of a drug that has been around for many years — pyrazinoic acid — and repurposed the drug to deliver it to the lungs, with some very promising results," according to study author Phillip Durham. Since oral PZA may have toxic side effects, he and his colleagues believe reducing the dose while providing the same level of efficacy has tremendous potential to benefit patients worldwide.

The study was presented at the recent American Association of Pharmaceutical Scientists meeting. ■

Bystander CPR Saves Kids' Lives

Teaching more members of the public how to perform cardiopulmonary resuscitation (CRP) could improve outcomes for children who suffer an out-of-hospital cardiac arrest, say researchers from Children's Hospital of Philadelphia, who analyzed 3,900 cases of out-of-hospital cardiac arrest (OHCA) in children up to age 18.

Bystander CPR was performed in 46% of the cases, most often by a family member, and 13.2% of those children survived vs. just 9.5% of those who did not receive bystander CPR. Neurologically favorable survival was also greater in these children — 10.3% compared to 7.6% — and it was also more likely in children who had received conventional CPR vs. compression-only CPR. In infants, overall survival was higher with conventional CPR as well, with compression-only CPR showing no advantage over no bystander CPR.

White children were significantly more likely to receive bystander CPR than black or Hispanic children, suggesting a particularly great need to train more people in bystander CPR in minority communities. The study was published in a recent edition of *JAMA Pediatrics*. ■

How Maternal Allergies May Cause ADHD, Autism in Offspring

Studies have shown a link between exposure to allergens in pregnancy and a greater likelihood of attention deficit/hyperactivity disorder (ADHD) and autism in offspring. A new study from investigators at Ohio State University is helping to explain why.

Researchers began by sensitizing female rats to ovalbumin before pregnancy, then exposed them to the allergen 15 days into their pregnancies, prompting an immune response. Rats born to allergic mothers were hyperactive and had lower levels of anxiety-like behavior. They were less mentally flexible on a test to measure their ability to find a treat as well, and males were more affected than females. Males in the allergen group were also less likely to roughhouse with their peers. The investigators linked these behaviors to changes in the brain that occurred in the offspring of allergic mothers. The study was presented at the Society for Neuroscience meeting last fall. ■

Vitamin D Linked to Fewer Severe Asthma Exacerbations

Vitamin D may help patients avoid severe asthma exacerbations, find researchers from the United Kingdom who looked at seven trials involving 435 children and two studies conducted among 658 adults, most of them with mild to moderate asthma. Results showed giving an oral vitamin D supplement reduced the risk of severe asthma attacks requiring hospital admission or an emergency department visit from 6% to around 3%. Vitamin D supplementation also reduced the rate of asthma attacks needing treatment with oral steroids, although that finding mostly pertained to studies involving adults.

No side effects of vitamin D were noted, but vitamin D did not improve lung function or day-to-day asthma symptoms. The investigators note most of the studies involving severe asthma exacerbations were conducted among adults with mild to moderate asthma.

They therefore believe more study is needed to see whether vitamin D has similar benefits for children or adults with severe asthma. The researchers also call for more study to determine whether vitamin D is effective in all asthma patients or only those with low blood levels of vitamin D. The study was published in a recent edition of *The Cochrane Review*. ■

Don't Blame the Hospital

Most of the focus on hospital readmissions has been placed on what hospitals are or are not doing to keep patients out of the revolving door. A new study out of the University of Michigan suggests certain patient characteristics are just as important and, what's more, those characteristics vary between the types of patient in question. For example:

- Pneumonia patients who were readmitted within 30 days were more likely than other pneumonia patients to already be having trouble with multiple tasks, like getting dressed, cooking food, or needing paid help at home, before their hospital stay.
- For patients with heart failure, family and race mattered the most. Wealthier patients and those with adult children were less likely to be readmitted, while being African-American somehow increased the risk.
- Among patients who had survived a heart attack, readmission was most likely among those who were in a nursing home prior to the attack, as well as those treated in hospitals with a higher percentage of minority patients.

The authors believe these findings suggest a need to refine the penalty system currently in place for excessive readmissions. "In many ways, hospitals these days are being held accountable for the failures of the social safety net," says study author Jennifer Meddings, MD, MSc. "As these programs are refined, understanding the impact of social determinants of health will be crucial."

The study was funded by the Agency for Healthcare Research and Quality and published in a recent edition of the *Journal of General Internal Medicine*.

How Calcium Triggers Deadly Infection

Pseudomonas aeruginosa is a frequent cause of hospital infections that is difficult to treat due to its multi-resistance to antibiotics. Swiss researchers now find chronic virulence of the bacteria is triggered by calcium. Specifically, a receptor located in the bacterial cell envelope monitors the calcium concentration in the environment and transmits this signal into the cell. Elevated calcium levels trigger the switch to a chronic program.

Patients with cystic fibrosis are particularly affected by calcium because one of the characteristics of the disease is deregulated calcium homeostasis. "We assume that elevated calcium levels in patients promote the switch from an acute to a chronic state of infection," explains study author Urs Jenal, from the University of Basel. "This is of advantage for the pathogen, as it may ensure its long-term survival in the respiratory tract." That would explain the lifelong chronic *P. aeruginosa* infections suffered by many with cystic fibrosis. The study was published in *Nature Microbiology*.

Asthmatic Teens Twice as Likely to Smoke

The last thing teens with asthma need is to smoke cigarettes, but new research presented at the American College of Allergy, Asthma and Immunology Annual Scientific Meeting finds these kids are actually about twice as likely to take up the habit as their healthy peers.

The study examined more than 3,300 questionnaires from adolescents 13–19 years old. Overall, 22% percent of kids with asthma reported being smokers vs. just 12% of kids without asthma. Teens with asthma who began smoking before age 11 said they continue to smoke because they believe the habit lessens their anxiety and stress.

What leads kids with asthma to light up that first cigarette? The survey found curiosity about smoking was the number one reason. Knowing that cigarettes were bad for their lungs wasn't a deterrent either, with most kids acknowledging the health hazards while still believing smoking wasn't a problem.

Strange But True...

Lab-grown lungs: University of Michigan scientists have successfully transplanted lab-grown mini lungs created from human stem cells into immunosuppressed mice. The lungs not only survived but matured and grew, too, in the end becoming indistinguishable from adult human tissue. The researchers hope to use the approach to better study human respiratory disease and the treatments developed for it.

Study tip: Listen up, RT students: Swedish researchers find test subjects who go for a run immediately following a period of intense learning retain more information than those who play video games after the educational session or just spend some time outdoors. The worst performance was seen in the video game group.

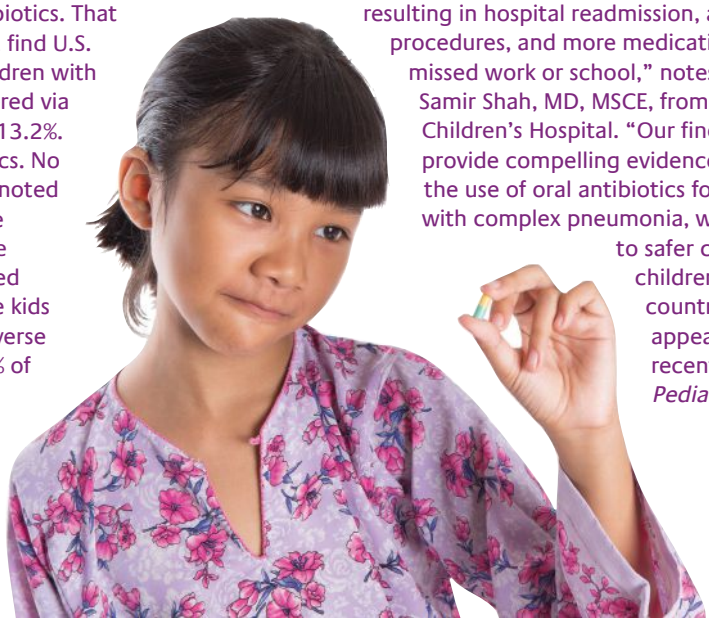
Patient performance: Theater arts grads usually dream of making it big on the stage or screen—but there's another option out there, too: become a "standardized patient." Health science centers are increasingly hiring theater majors to play the part of patients in scenarios to teach health professionals how to deal with the real thing.

One picture: Researchers from Hong Kong who tested the use of pictograms showing patients how to use their prescription drugs found these simple images improved adherence to drugs among older patients. The pictograms depicted concepts like "take with meals," "take in the morning," and "do not drink alcohol while taking this medicine." ■

Pediatrics Study:

Oral Antibiotics Best for Kids with Complex Pneumonia

Children recovering from complex pneumonia are often sent home on intravenous antibiotics. That may not be the best course of action, find U.S. researchers who looked at 2,123 children with the condition. Antibiotics were delivered via a PICC line in 281 of the children, or 13.2%. The remainder received oral antibiotics. No differences in treatment failure were noted between the two groups, but adverse events were significantly higher in the PICC line patients. Overall, PICC-related complications occurred in 7.1% of the kids being treated intravenously while adverse drug reactions were seen in only 0.6% of children taking oral medication.



"PICC line complications can be serious, resulting in hospital readmission, additional procedures, and more medications, as well as missed work or school," notes lead author Samir Shah, MD, MSCE, from Cincinnati Children's Hospital. "Our findings, which provide compelling evidence to support the use of oral antibiotics for children with complex pneumonia, will contribute to safer care for children across the country." The study appeared in a recent edition of *Pediatrics*. ■

Industry Watch

Illinois researchers launch spirometry study

Researchers at the University of Illinois at Chicago have been awarded a $1.5 million grant from the Agency for Healthcare Research and Quality to conduct a study for reducing diagnostic errors to improve patient safety in COPD and asthma (REDEFINE) in 400 adults who have a diagnosis of asthma or COPD but have not had spirometry testing. Patients who receive spirometry testing will be compared to a control group of patients who do not receive spirometry testing. The research team will follow both groups for one year, at which time the control group will have a spirometry test to confirm their initial diagnosis. To evaluate the effectiveness of the REDEFINE program, researchers will collect data on the prevalence of diagnostic errors, the efficiency of the program's intervention on patient-centered outcomes, and the cost of the program.

FDA approves new respiratory panel

The FDA has approved the FilmArray® Respiratory Panel EZ detection and diagnosis device for use in non-laboratory environments. Co-funded by the Defense Threat Reduction Agency's Joint Science and Technology Office and BioFire Diagnostics, the diagnostic test can be administered in minutes and can detect 14 viral and bacterial pathogens associated with respiratory infections within an hour. The device was granted a waiver from the FDA's Clinical Laboratory Improvement Amendments, allowing testing of the device by everyday users such as doctor's offices and clinics to provide the Department of Defense and health practitioners with real-time force protection capabilities to detect and diagnose diseases that cause public health concerns such as influenza, the common cold, or whooping cough. About 3,000 FilmArray RP EZ® units are in service globally.

Celtaxsys, Inc., announces publication of CF drug study

A second paper detailing the results from Phase 1 clinical trials for Celtaxys's flagship drug acebilustat has been published in *Clinical and Translational Science*. Acebilustat is a novel once-daily oral anti-inflammatory drug in development for the treatment of cystic fibrosis and other rare inflammatory diseases. The new paper details the effect of acebilustat on lung and systemic inflammatory biomarkers in adult CF patients. Acebilustat doses of 50 mg and 100 mg demonstrated reductions in markers of lung and systemic inflammation after 15 days of treatment. Sputum neutrophil count was reduced by 65% from baseline values in patients treated with 100 mg acebilustat. Investigators believe the acebilustat treatment enhances airway clearance.

The Joint Commission notes safety and quality are on the rise

America's hospitals continue to make strides toward improving patient safety and quality for common conditions that put people in the hospital, says The Joint Commission's 2016 Annual Report, "America's Hospitals: Improving Quality and Safety." The report presents information on how well 3,300 Joint Commission-accredited hospitals performed on individual measures of patient care during 2015. Topics covered in the report relate to children's asthma, tobacco use treatment, inpatient psychiatric services, venous thromboembolism care, perinatal care, and immunization.

ALS study gets underway at Cedars-Sinai

Regenerative medicine investigators at the Cedars-Sinai Board of Governors Regenerative Medicine Institute have received FDA approval to test a combination stem cell gene therapy developed to stall the progression of amyotrophic lateral sclerosis, or Lou Gehrig's disease. The approval allows 18 ALS patients to receive a new investigational drug and will be the first clinical trial to test the safety of this type of therapy. Investigators are working to improve leg mobility in patients with ALS.

Cuban therapy for lung cancer to be tested in United States

A New York State trade mission to Cuba in 2015 has resulted

in the launch of a U.S. clinical trial of a Cuban immunotherapy for lung cancer developed by the Center of Molecular Immunology. The Roswell Park Cancer Institute in Buffalo, NY, has received FDA authorization to begin offering the lung cancer treatment vaccine CIMAvax-EGF® to a limited number of patients through a clinical trial.

Wayne State receives grant to study asthma in African-Americans

Wayne State University researchers have received a $2.66 million award from the National Heart, Lung, and Blood Institute to test an intervention for asthma with 192 African-American adults with moderate-to-severe persistent asthma and low controller medication adherence recruited from clinic and emergency room settings. "We will use a technology-based intervention specifically targeting adherence to asthma controller medications to determine if it improves adherence to asthma medications," explains study leader Karen MacDonell, PhD.

Corbus Pharmaceuticals granted Orphan Designation for CF drug in Europe

The European Commission has granted Orphan Designation in the European Union for Corbus Pharmaceuticals Holdings' novel synthetic oral endocannabinoid-mimetic drug, Resunab. Corbus is currently testing Resunab in both the United States and Europe in a Phase 2, double-blinded, randomized, placebo-controlled trial that is evaluating Resunab's safety, tolerability, and potential clinical benefit, as measured by FEV1 and the Cystic Fibrosis Questionnaire-Revised Respiratory Symptom scale. The trial also will test the impact of the drug on bacterial load in the lungs and biomarkers of inflammation in the sputum and blood.

Researchers receive NHLBI grant to study lung regeneration

Researchers from Penn Medicine, Cincinnati Children's Hospital, and Boston University have received a $5.2 million, seven-year grant from the National Heart, Lung, and Blood Institute to study the cellular and molecular mechanisms that promote lung cell regeneration. The aim of the grant is to develop treatments for children with congenital lung diseases and adults whose lungs have been damaged from smoking, genetic defects, and acute injury. One of the major progenitor cell types that investigators will target is the alveolar type 2 cell. They will work to characterize AT2 cells at multiple levels from mouse and human lungs, seeking to better understand their role in lung function and repair. This information will be used to determine whether AT2 cells can be targeted using gene-editing techniques to alter their regenerative potential or correct disease-causing mutations.

GSK seeks FDA approval for COPD treatment

GlaxoSmithKline plc (GSK) has filed a regulatory submission with the FDA for the once-daily, closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) for patients with COPD. The closed triple combination therapy is delivered once-daily in GSK's Ellipta® dry powder inhaler. The U.S. regulatory submission is based on data from the closed triple combination therapy development program, as well as data from studies with FF, UMEC, and VI either alone or in combination. "This first regulatory submission of our closed triple therapy brings us a step closer to providing a once-daily treatment in a single Ellipta inhaler as an alternative option for those patients who require multiple therapies," GSK Head of Respiratory R&D Dave Allen was quoted as saying.

Fetal Health Foundation funds study on CDH

The Fetal Health Foundation has allocated $50,000 for a study to prevent congenital diaphragmatic hernia (CDH), an anomaly that disturbs lung development during fetal life. As many newborns die due to respiratory insufficiency and pulmonary hypertension, many others suffer significant pulmonary disease, according to a grant recipient spokesman representing the Katholieke Universiteit of Leuven in Belgium and the University College of London Institute for Women's Health. The scientists plan to investigate the efficacy of maternally administered sildenafil, a drug that selectively vasodilates the pulmonary arteries, to prevent pulmonary hypertension in newborns with CDH.

AllerGuarder announces support for Food Allergy Team

AllerGuarder, maker of a Bluetooth-powered bracelet and app defense system for kids with food allergies, has joined forces with the Food Allergy & Anaphylaxis Connection Team (FAACT). FAACT's mission is to educate, advocate, and raise awareness for all individuals and families affected by food allergies and life-threatening anaphylaxis. AllerGuarder is donating $1 to FAACT for each bracelet sold to help further the team's mission to bring greater awareness to the allergy community. ■

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

Special Advertising Section

Industry Update

Featuring information on products and equipment from manufacturers

Calendar of Events

AARC & State Society Programs

February 9–10
Daytona Beach, FL
Sunshine Seminar & Annual State Meeting
Contact: fsrc@fsrc.org, or (866)-534-6172

April 9–11
Auburn, WA
44th Annual Pacific Northwest Regional Respiratory Care Conference and Scientific Assembly
Contact: jon.jahns@virginiamason.org, or (206) 583-6458

April 13–14
Cedar Rapids, IA
Annual IaSRC Respiratory Care Conference
Contact: scarmody-menzer@scciowa.edu

April 20–21
Cocoa Beach, FL
Space Coast Cardiopulmonary Conference
Contact: fsrc@fsrc.org or (866) 534-6172

Submissions for the next available issue are due January 22.

For information on submitting calendar events, contact: Sarah Vaughn, *AARC Times*, 9425 N. MacArthur Blvd, Suite 100, Irving, TX 75063-4706 (972) 243-2272 Fax (972) 484-2720 E-mail Sarah.Vaughn@aarc.org.

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