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# AARC Times

## A Patient's Personal Experience with CF MEDICATIONS

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# A Patient's Personal Experience with CF Medications

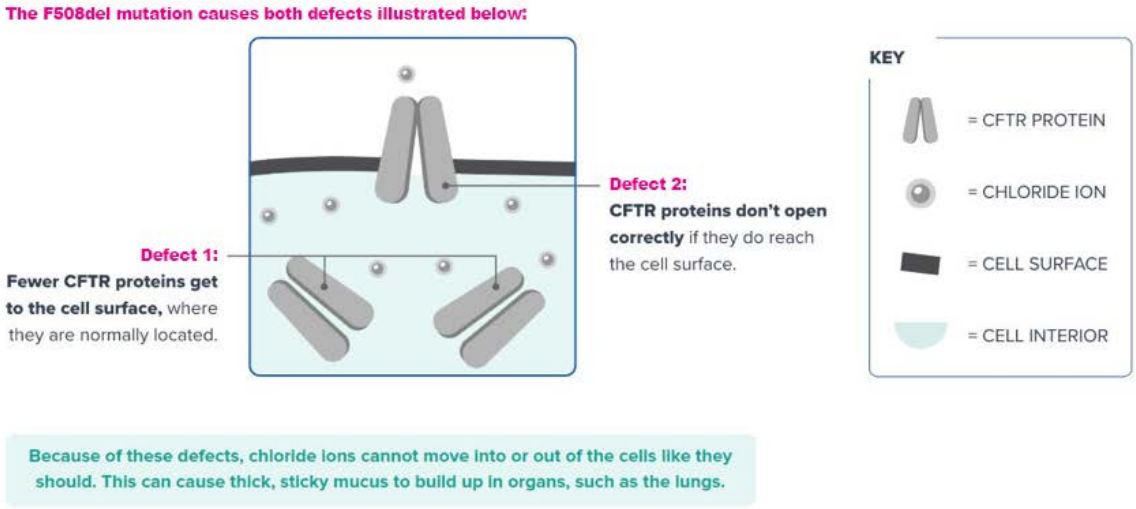
by Jeremy Parks, BS, RRT

The course of treatment for cystic fibrosis (CF) has changed drastically over the past decade. Thick secretions, chronic lung infections, pancreatic insufficiency, etc., are all byproducts of CF and the primary focus of treatments since the early 1990s. That all changed in January 2012 when the revolutionary new drug ivacaftor (Kalydeco, Vertex Pharmaceuticals, Boston, Massachusetts) received FDA approval.[1] That drug, along with its successors, no longer treat symptoms but the root cause of the disease. These drugs have completely changed the face of CF and the lives of those afflicted by it. The evolution of these medications has culminated most recently with elexacaftor /tezacaftor/ivacaftor in combination (Trikafta, Vertex Pharmaceuticals, Boston, Massachusetts).

After the release of Kalydeco, which treats only a small percentage of people with very specific genotypes (ie, 4% of individuals with CF), the Cystic Fibrosis Foundation set a goal to find a drug that would treat a larger percentage of people with CF.[1,2] There are five categories of mutations in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene, and drugs released since Kalydeco have targeted those people with one or two copies of the *deltaF508* gene mutation, which is the most common mutation in the *CFTR* gene and makes up approximately 88% of people with CF.[3] The Cystic Fibrosis Foundation along with Vertex Pharmaceuticals accomplished this with the release of lumacaftor/ivacaftor in combination (Orkambi) and tezacaftor/ivacaftor in combination (Symdeko, which is very similar to Orkambi but with fewer side effects and slightly better outcomes).

The release of both Orkambi and Symdeko were, at least from the perspective of those with CF (myself included), anti-climactic because, while these drugs were a step in the right direction, most of us in the CF community were hoping for far better outcomes. This hope came to fruition with the release of Trikafta on October 21, 2019.[4] My social media feeds exploded with people ecstatic over the news! Some could barely speak through tears of joy about the release. Many of us in the CF community had read or heard of the amazing results the drug showed in clinical trials. Knowing we would soon have the ability to take the drug and see for ourselves was something to be elated about. My experience with the drug has been nothing short of miraculous.

**Figure 1.**




Source: Vertex Pharmaceuticals (https://www.trikafta.com/how-trikafta-works).

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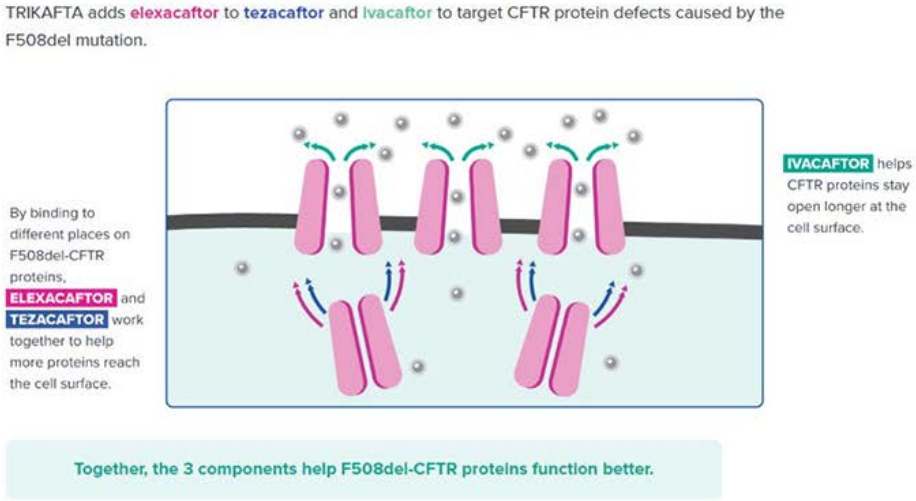
**Figure 2.**




Source: Vertex Pharmaceuticals (https://www.trikafta.com/how-trikafta-works).

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Before getting into that, let's first talk about how Trikafta works. All the problems and symptoms caused by CF can be traced back to the CFTR protein. The genetic defect found in CF patients causes this protein to malfunction. The CFTR protein controls the chloride ion channel in the mucus membranes, and the defect disrupts the chloride ion channel. Because the chloride ion is key to regulating hydration, the malfunctioning protein causes the thick, sticky mucus that in turn leads to all the problems associated with CF. There is a class of drugs called CFTR modulators that correct this genetic defect. Trikafta is in that drug class, along with Kalydeco, Orkambi, and Symdeko.[5] Essentially, if you treat the malfunctioning protein, you effectively treat the root cause of CF. That is exactly what these drugs do, and Trikafta does it best by far.[4] Figure 1 illustrates the malfunctioning CFTR protein in CF patients. Some of the proteins do not make it to the surface of the cell at all, while ones that do reach the surface don't open correctly. Figure 2 shows how Trikafta helps correct the CFTR protein and return it to near-normal function. The drug helps the protein reach the surface of the cell, open correctly, and stay open longer to allow for hydration of the mucus membranes. With the mucus membranes hydrated adequately, many of the

symptoms and problems caused by CF are alleviated, especially those in the lungs. This alleviation of symptoms is precisely what I experienced.

My personal journey with Trikafta began in late November 2019. The day I started the drug, I began to see the effects of what many refer to as the "clean-out" phase. Roughly six hours after the first dose, I experienced *a lot* of coughing and sputum production — emphasis on *a lot*! Had I not known it was coming, I would have sworn I was going into a full-fledged exacerbation requiring a hospital admission. I had been in a research study for another drug in development at the same time as Trikafta, and I experienced the same thing, so I had an idea it was coming. My awesome CF care team warned me as well. As the drug begins to rehydrate the lungs, it allows the secretions that were once thick, sticky, and stuck in the lungs to begin mobilizing. The clean-out phase involved roughly a week of excessive coughing and producing copious amounts of secretions, along with lots of headaches and feeling worn down. It was rough.

However, the phase ended almost as abruptly as it began, almost as if someone flipped an internal switch. Then the true miracle happened. I stopped coughing — almost completely. When doing my vest and treatments, I now rarely cough and usually produce only a small amount of secretions. I have dreamed my entire life about the day when I didn't cough anymore. For the day I could laugh without fear of a coughing fit and needing to spit out a bunch of disgusting mucus in front of people I may or may not know very well. For the day I could run around and play with my kids without the same coughing fit or needing to take a break because daddy has "cisty fibwosis," as my kids call it. For the day I could lie down at night and go to sleep without getting short of breath, then coughing because I was short of breath, and having to get back up to spit. Only to repeat the whole cycle after lying back down. That day has come, and it's amazing!

Another unexpected but welcome side effect has been weight gain. Before Trikafta, I struggled to keep my weight between 150 and 155 pounds, which is low for my 6-foot-tall stature. When my wife and I got married, I weighed 145 pounds. After starting Trikafta, my weight has increased to just shy of 190 pounds, which puts me at a healthy body mass index. I've never felt so fat in my life, but I'm loving every minute of it! It's still surreal to step on a scale and see numbers that high. I had to buy new clothes!
The most phenomenal side effect, and the goal of these modulators, has been the increase in lung function. Before I started Trikafta, my $FEV_1$ was 54% of predicted, which had been my baseline for a few years. Nine days after I started Trikafta, I had a clinic visit, and my $FEV_1$ had increased to 65% of predicted. That's an 11% increase in just over a week on the medicine! That's too high to be explained by normal variance. It's due to Trikafta! I've heard from friends who have been on the drug longer than I have (ie, they were in the research study and stayed on drug through the FDA approval process) that have continued to see lung function increases for close to a year. I have several friends who have current $FEV_1$ values (after Trikafta) that are equal to where they were 15 or more years ago.

The last "side effect" I'll mention, which has been hugely impactful to me personally, is the increase in mental fortitude I've experienced from seeing my life change so drastically. I deal with my CF in a very positive way and have a great outlook on life as a result of CF. Yet there are internal struggles that many of us with CF experience but may not show to others. Trikafta has helped me overcome some of those struggles. I now see my life through a completely different lens. It's not that I saw my life through a terrible lens before Trikafta, but trying to picture myself as an old man surrounded by grandkids seemed realistically unlikely without a lung transplant, and even then, seemed highly unlikely. It was especially difficult as I watched my lung function decline over the last decade and a half and I calculated the years if the decline were to continue. Thinking about advancing my career seemed a waste of time. It would be a significant commitment of time and money, and I didn't expect I would live long enough to reap the benefits. I chose to focus every bit of my time and energy on my wife and children because I had no idea how long I'd be around. This newfound health has got me thinking more about retirement and planning

for the future, and I relish the idea that I may actually live long enough to meet my grandkids. I've said it multiple times already, but it's amazing. In the months since I started using Trikafta, I've challenged myself to strive for more out of life rather than living my life to the fullest, enjoying every moment but always questioning when it will end. I'm now living my life to the fullest waiting to see what life has in store for my family and me. I've even enrolled in graduate school to pursue my master's degree. This may sound morbid or depressing, but what I mean is that I learned not to expect too much out of life or to wish for things that seemed too unrealistic. It's hard to explain in words, but before Trikafta there were certainties that I knew would be reality with CF, such as not living beyond 60, not living past my 50s without a lung transplant, and some day dying from end-stage CF and respiratory failure (which is not pretty). Those certainties may no longer be foregone conclusions with Trikafta. I, along with many others with CF, have a newfound zeal for life, one that only came to those blessed enough to receive a lung transplant and know what it means to breathe without the weight of CF in their lungs. I feel more normal, now, which is a feeling I never thought I'd feel. That being said, it's important for those with CF to understand that as normal as we may feel, we still have Cystic Fibrosis. The research of these drugs took place with patients continuing their normal treatment regimen. It's tempting I can assure you to want to cut back on treatments when you feel so tremendous. Especially with many of us spending close to or upwards of two hours a day on treatments. As a respiratory therapist, you can help CF patients to understand they must continue with their treatments with the same tenacity as they had before Trikafta. The CF Foundation has not recommended any changes to treatment regimens, yet. They are looking into the possibility of eliminating either Pulmozyme or Hypertonic Saline, while still performing airway clearance, since the lungs are better hydrated with Trikafta. But for now, we, as CF patients, need to continue to push forward with our therapies and wait for the experts to give their recommendations. A tough message to deliver at times, but a necessary one.

We in the CF community know Trikafta is not a cure, but it sure feels like it. That, I can assure you, has been liberating in more ways than one. I've shed many a tear over Trikafta and the blessing that it's been to me and to my family. It's given me and the CF community even more hope that the Cystic Fibrosis Foundation's motto of making CF stand for "Cure Found" may actually come true. It's so exciting to know that all the kids with CF will be able to start taking these at a young age and potentially have very little impact to their lives from CF, that maybe they'll live long lives free from the burdens of CF and never have to endure the struggles that adults with CF today have faced. While the impact of Trikafta to the CF community is tremendous, there is still work to do. Only 90% of people with CF can take Trikafta because of their genetic makeup. The Cystic Fibrosis Foundation is now searching for a modulator that can meet the needs of the other 10%. Trikafta is hope that some day, hopefully in the very near future, all people with CF will have access to a life-changing modulator.

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**Jeremy Parks BS, RRT is a 36 year old with Cystic Fibrosis. He is a Supervisor for the Respiratory Care Department at Barnes-Jewish Hospital in St. Louis, MO. He is passionate about Cystic Fibrosis Awareness and making CF stand for Cure Found!**

# Its Time for Journal Club

by Amanda Hopkins, RRT


What is Journal Club? It is a time for fellow respiratory therapists within our hospital system to gather together to review the studies that the AARC publishes in the monthly journal, Respiratory Care. The Journal Club focuses on articles that go along with that month's Continuing Respiratory Care Education (CRCE), which is available through the AARC (https://www.aarc.org/education/online-courses/crce-through-the-journal, *Accessed April 22, 2020.*)

I had worked as a respiratory therapist for seven years before I ever heard of Journal Club. Around this point in my career, I was looking for a job closer to home. A co-worker who had worked for the hospital where I was applying shared that they had a journal club and explained what it was all about. A couple months after I had started at this facility, I decided to be brave and attend a meeting. It can be a little scary to attend something new, where you don't really know the people, and I wondered if I knew enough to contribute. It ended up being very laid back, and they have helped me grow as a respiratory therapist. Listening to the facilitator's questions and the responses of my fellow coworkers helped me learn what to look for in an article and how to read it. I learned some important questions to ask as I read any article. What kind of study was it? How many subjects were involved in the study? Did their outcomes answer what they were investigating? The group also discussed how the article's results could impact practices at our hospital.

Our Journal Club meets at a different location every month. The facilitator calls ahead to the restaurant to try to reserve a room or a quiet location inside the restaurant. When the weather is nice, we have meeting places with outdoor seating. Usually the group will give suggestions of restaurants to meet for the next month's meeting.

I reached out to Ashley Stabley, BS, RRT, who started our Journal Club, to see how she went about it. She shared, "I thought Journal Club would be a fun way to meet up (off the clock) and discuss journal articles that could help improve or influence the way we practice and maybe even inspire research within our hospital system. When I initially approached the Operations Manager about starting Journal Club, I was told it had been done and it wasn't successful. We trialed a bunch of different times and places for Journal Club; we've done morning, afternoon, and evening. We've had it on-site at the hospital and off-site. We submitted a survey on how to improve attendance, which was good at first but then started to dwindle after a few months. Before the survey went out, I knew that having Journal Club off-site was definitely

preferred to having it at the hospital. Ultimately, we discovered the biggest key to successful attendance was having plenty of notice, at least two weeks. After we made sure to get the articles out to the staff members in addition to informing them of the time and place, attendance picked back up. Most people who answered the survey preferred a time in the evening, and we discussed the option of selecting journal articles that would be more pertinent to our hospital system; we therefore had to forego the CEU (continuing education unit), but we realized a lot of people really do come because of the ability to obtain one free CEU."

Journal Club meeting at Wyndridge Farm

Participating in a Journal Club is a great way to get to know your team and to learn together. If you are starting one up or trying to get new people involved, it is important to talk about it, let them know what goes on! Our group is fortunate to have leadership attend regularly, such as the director of pulmonary services and the previous operations manager of pulmonary rehab and pulmonary physiology lab).

Stabley also stated, "It helps to have an educator or someone who is into literature present. I facilitate the Journal Club but certainly don't know it all . . . we've been fortunate that our department educator or our department's Research Representative is present to help answer questions, simplify things, pick out important points, etc. We used to have the Director of our RT school attend but haven't had attendance since he retired; when he was present, he was very good at discussing the model of the study, if it was a good study, the methods, etc."

It's also fun to get creative. "One December we had an Ugly Sweater Journal Club, the winner received a gift card to a local restaurant," Stabley shared.

I have been with WellSpan York Hospital for almost two years. I started with in-patient care at the hospital and then transitioned to pulmonary rehab in April 2019. This world was new, and I was learning a lot. One of our monthly meetings centered articles that talked about things related to pulmonary rehab. I was able to bring some papers to show the other respiratory therapist what the journal article was talking about. The point I'm getting at is this: Invite everyone to journal club! Include staff who work in the hospital, pulmonary function, pulmonary rehab, sleep . . . . We can help each other learn!

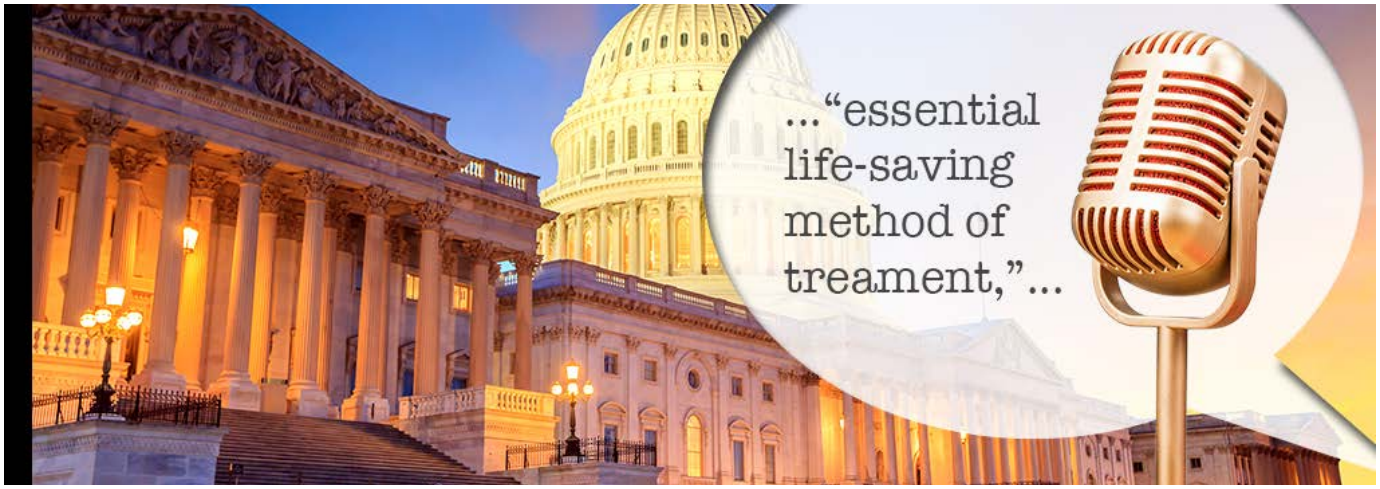
**about the author...**

**Amanda Hopkins received her license in June 2011 and worked in the hospital setting until April 2019, when she moved to pulmonary rehabilitation. She is currently pursuing a bachelor's degree in respiratory therapy.**

# 40+ Years in the Halls of Congress and Beyond

## The history of government advocacy in the AARC

by Debbie Bunch




Advocating for the profession and its patients has been a key mission at the AARC since the Association was founded in 1947. For the first few decades, though, that advocacy was mainly focused on growing the profession in hospitals and schools and on establishing solid bonds with physician organizations. No one really saw much of a need to get actively involved in government representation.

But you know what they say about things changing. Enter the 1970s. Health care costs were becoming a major issue in Washington, DC, with legislators and government officials alike increasingly pointing the finger at the fee-for-service Medicare law passed in the prior decade as the problem. Health care professionals, they said, were taking advantage of the system to provide covered, but not always necessary, services to too many patients.

In 1977, it got personal for respiratory therapists. During Congressional hearings on costs, Department of Health, Education, and Welfare (DHEW) Secretary Joseph Califano specifically challenged the need for services being provided by unlicensed providers known as respiratory therapists. According to Secretary Califano, there was little scientific evidence supporting the provision of these services to patients. While he was basing that statement mainly on one modality delivered by RTs — intermittent positive pressure ventilation — and therapists had moved far beyond that simple therapy, it was true that RTs were not licensed, and some in the medical community did not view therapists as true professionals.

With no organization on the ground in Washington, DC, the AARC was blindsided by the Secretary's testimony and had to scramble to formulate a response. Thankfully, the Association was able to rally its forces quickly, and letters went out to a range of government officials to explain the vital role respiratory therapists played in the nation's health care system. Leading physicians jumped on board, too, offering corroboration for the AARC's statements.

The massive undertaking paid off, and the government backtracked its testimony. A reply received from DHEW on behalf of Secretary Califano stated, "It is a well-documented fact that respiratory therapy is an essential life-saving method of treatment," and "respiratory therapists are dedicated, responsible professionals."

But the incident served as a cautionary tale, and the Association was bound and determined nothing like it would ever again have the element of surprise on its side. Sam Giordano, MBA, RRT, FAARC, who served as AARC president in 1980 and came on board for what would end up being a 30-year tenure as executive director in 1982, recalls the sentiment among the leadership at the time.

“Reacting to these challenges was not enough. We had to engage, to educate, and get the record straight while addressing our shortcomings,” Giordano said. “We needed a robust and sustainable advocacy system so the profession could be at the table, at both national and state levels.”

**Setting up the infrastructure**

The next few years were spent building the infrastructure, and by the time long-time AARC Director of Government Affairs Cheryl West, who retired from the position in 2017 after more than 30 years of service, came on board in the early 1980s, the Association had staff in place in Washington, DC, to keep up with developing legislation and regulations that had the ability to affect the profession.

“There was an increasing recognition that federal health policy, be it through Congress and legislation, or equally importantly through federal government regulations, would have a direct impact on how RTs functioned in their jobs,” she said. “Impacting Medicare, and to an extent, Medicaid laws and regulations was the primary vehicle available to help advance the RT profession.”

Fundraising was an important part of the equation, and the AARC formed its own Political Action Committee (PAC) to raise money to support legislators friendly to the AARC cause. West explained why it was necessary.

“PACs provide an opportunity to assist a supportive member of Congress while educating the member and their staff on a key issue for a particular profession or industry,” she said. “In most cases, the issue might be small and easily overlooked by a member crafting legislation, but that same issue might be monumental to the community of interest at hand. That is certainly true for the RTs and the pulmonary patients they serve.”

The AARC PAC formed by the Board of Director in the 1980s has time and again provided the momentum the Association needed to get a member of Congress on board with legislation important to the profession.

**Paving the way for licensure**

AARC government advocacy may have been kick-started by the Califano incident back in 1977, but as Giordano alluded to earlier, other factors certainly came into play as well, not the least of which was state licensure for respiratory therapists. The concept had been kicked around for years, but leaders in the Association had always concluded that it would impede the ability of the fledgling profession to grow and develop. The time came, however, when the value of holding a state license became clear, and with its government affairs infrastructure in place, the AARC was ready to lead the way for its state affiliates.

“The national AARC staff was committed to assisting its state societies by developing a model state RT licensure legislation that could be used as a template as each state undertook the considerable task of advocating for licensure at their own state legislature,” West said. “The AARC national office also directed its government affairs staff to act as a clearinghouse for state affiliates wanting to know the ‘best practices’ other states used in gaining not only licensure but other state-based legislation that impacted the profession.”

Giordano emphasized that it was a team effort across the board.

“AARC persuaded major physician and hospital organizations to change their long-standing opposition to licensure to that of support or at least neutrality by systematically addressing the reasons to oppose,” he said. “We then provided guidance, grants, and public policy professionals to assist our state societies in getting legislation passed and subsequently writing regulations.”

The first modern licensure law took effect in California in 1982, and slowly but surely other states followed suit. By 1993, 38 states had passed legal credentialing laws for respiratory therapists, and this number steadily increased over the next 17 years until Hawaii became the 49th state to pass a law in 2010. Alaska, the only remaining state without licensure, is in the early stages of pursuing that goal now.

This decades-long process left the AARC and its state societies with a wealth of knowledge and expertise in dealing with our system of government, and this knowledge has been put to good use in recent years as licensure laws have been challenged.

Current Associate Executive Director of Government Affairs Anne Marie Hummel summed it up like this: “By providing our state societies with comprehensive materials, support, and arguments about why licensing RTs is essential to protecting the public’s general health and welfare, the states and AARC Government Affairs have been successful over time through our combined advocacy efforts in defeating every attempt by state legislatures to de-license the profession, Montana and Texas being two examples.”


**The PACT is born**

In addition to helping states with licensure, the Association formed a political action network early on that was aimed at issuing a quick response to any challenge or issue on the state or national level that could affect the profession or its patients. This “cascade network,” as Giordano terms it, was made up of volunteers who used call and fax lists to communicate with members in their states and ask them to contact their members of Congress or state legislators.

“Within a couple of years, we were able to generate thousands of responses and comments to lawmakers and regulators relating to our professional recognition and issues impacting our patients,” he said. “We leveraged the power of constituency and still do.”

In 1999, the Association decided to take that concept up a notch. A new and improved political action network, now called the AARC Political Advocacy Contact Team (PACT), was formed. Consisting of two members from each state, the team was charged with marshalling the forces in their states to respond to issues of concern. They spent a couple of years being trained in government representation at the AARC.

Then, in March 2002, they packed their bags and made their way to DC to lobby members of Congress during what was our first Capitol Hill Lobby Day.

Frank Salvatore, MBA, RRT, FAARC, our AARC president in 2015–2016, began representing his home state of Connecticut on the PACT in 2000, and he's been to every Capitol Hill Lobby Day in DC except for two in the years since.

"I've always enjoyed politics and thought it would be a great way to get involved," says Salvatore. "In 2004, President-Elect John Hiser asked me if I'd chair the Government Affairs Committee. Since I was already hooked, I said yes."

Salvatore has headed up that committee — now known as the Advocacy & Government Affairs Committee — for much of the last two decades, and as such has helped establish the AARC as a key player on Capitol Hill.

"The AARC Advocacy & Government Affairs Committee and our associate executive director of government affairs have worked tirelessly over the years to document for elected officials the value of respiratory therapy to their constituents who are our patients," Salvatore said. "We've partnered with many like-minded organizations to get some legislation passed."

**Successful efforts**

One the earliest legislative victories for the Association, though, came even before much of the current system was in place. It was the mid-1980s and the AARC had joined a wide range of groups and organizations in lobbying Congress for passage of a ban on smoking on commercial airliners. But the Association took an extra step as well — one that many believe is why we have smoke-free airplanes today.

"AARC led an effort partnering with its state societies to conduct the only national survey among the flying public in airports throughout the country demonstrating that a large majority of the flying public supported such a ban," Giordano said.

Congress took notice, and the first law limiting smoking on airplanes went into effect in 1988. The initial ban applied only to domestic flights of two hours or more, but subsequent legislation beefed up the original provisions, and by the year 2000 smoking was effectively banned on all domestic and foreign flights originating or ending in the United States.

"We now have enjoyed 30 years of smoke-free flying," Giordano said. "I believe the survey results were the tipping point, and if it wasn't for AARC, our state societies, and our individual member volunteers stationing themselves at approximately 90 airports, it would not have happened. That's the epitome of advocacy."

Another key piece of legislation that the AARC fought hard for involved the inclusion of respiratory therapists as named health professionals in the Medicare law covering Comprehensive Outpatient Rehabilitation Facilities (CORFs). West notes this was the first time RTs had been named as covered providers under any part of Medicare, so even though the CORF benefit is only a small part of Medicare, the change was significant for the profession.

"It was a toe in the door to continue to justify why RT professionals must be included in further Medicare changes such as telehealth legislation," she said.

Similarly, the AARC's successful efforts to include qualified RTs as part of the U.S. Commissioned Health Service Corp brought greater recognition of the value RTs add to care.

West said, "It was another step in establishing the critical role the respiratory therapist plays in delivering health care services through federal government programs."

A seemingly small thing that was really a great big thing to RTs working in the pulmonary function laboratory was addressed by the AARC back in 1990 — this made a huge difference in the ability of these RTs to continue to do their jobs.

West said, "When the Clinical Laboratory Improvement Act, or CLIA, was issued way back in the late 1980s, the list of professionals who could administer a PFT [pulmonary function test] did not include RTs, meaning any RT giving a PFT would place themselves and the lab in violation of a federal regulation and could be cited."

When the discrepancy was noted, the AARC government affairs staff and the communication system it set up to bombard the federal agency with a rapid response from thousands of RTs across the country convinced the agency to change the regulation to include respiratory therapists as covered providers.

One of the biggest victories for the AARC and the patients it serves, however, came in 2008 when legislation adding a Medicare benefit for pulmonary rehabilitation was enacted by Congress. John Campbell, MA, MBA, RRT-NPS, RPFT, FACHE, who serves on the Advocacy & Government Affairs Committee with Salvatore, is proud of the role he and his colleagues in his home state of Arkansas played in bringing it to fruition.

"In the late 1990s, I met with Senator Blanche Lincoln in her Little Rock office and she soon introduced a bill," he recalled. "A little later, I talked to my Congressman in Washington, Representative Mike Ross, and he introduced the bill in the House."

Like most legislation in Congress, time and perseverance were needed to bring the bill to fruition. But with continued lobbying on the part of the AARC and others, Campbell says Sen. Lincoln and Rep. Ross kept reintroducing the bill in each new session of Congress, and, slowly but surely, it garnered the co-sponsors it needed to succeed.

"Twelve years after that first meeting with Sen. Lincoln, the bill made it through the committees, came up for a vote, and today pulmonary rehabilitation is included in the Medicare regulations," he said.

Giordano says the benefit still needs work, but just having it on the books has made a difference for patients with chronic lung disease.

"It is far from perfect, but it was a new benefit specifically aimed at our chronic lung community," he said. "I know current leadership is working to expand access to all who can benefit."

**Trickle-down effect**

AARC advocacy efforts on the national level have spilled over to the states in ways that transcend licensure for respiratory therapists, too. Frank Salvatore saw that trickle-down effect play out in Connecticut in 2018 when members of the Connecticut Society were able to push a change to their respiratory care practice act through the legislature, allowing RTs with sufficient training to perform extracorporeal membrane oxygenation.

"The leadership and their lobbyists worked with members of the public health committee, and when all was said and done, SB403 was moved into a larger Public Health Appropriations bill and became law," he said. "This is one example of how the chartered affiliates have become proficient advocates through their work, federally and statewide."

Other members of the Advocacy & Government Affairs Committee have similar stories to tell. Kim Bennion, MsHS, RRT, CHC, has been working on respiratory-related issues in Utah since 2008 and believes the biggest accomplishments she's seen so far are in the areas of tobacco control and the dangers of opioid use.

"Two key initiatives come to mind," Bennion said. "The first is tobacco legislation, where we worked to increase the tobacco purchase age to 21 and for the regulation of e-cigarettes in terms of manufacture, marketing, and distribution; both passed after four years of lobbying on behalf of each. The second is Utah's SCR004, which passed in 2018."

SCR004 is essentially aimed at promoting awareness of home monitoring for patients who are prescribed opioids. The legislation grew directly out of conversations Bennion had with legislators on other topics and was co-authored by RTs from two organizations in the state. The resolution led to a grant that now allows Bennion and her colleagues to study home monitoring for high-risk opioid patients undergoing orthopedic surgeries.

"It is a feasibility study of side-by-side monitoring of end-tidal $CO_2$ and pulse oximetry, where four days of recorded data are being analyzed," she explained. "We plan to report our outcomes to Utah legislators once the study is completed. Our desire is to keep the topic front and center in the minds of health care professionals and legislators, as well as to spotlight the significant contributions that RTs make in health care research."

Joseph Goss, MSJ, RRT, RRT-NPS, FAARC, who has been actively involved with government representation in New Jersey ever since he started attending licensure board meetings about 20 years ago, believes the states' efforts to keep their licensure acts current are vital to patients and providers alike.

"Twice, I have been directly involved with amending the New Jersey licensure act," he said. "While I hear that amending is a scary thing, how could we move the profession forward without the amendment process?"

He believes remaining engaged makes the difference, and he appreciates the support the AARC provides the states in matters large and small. "The AARC gives the local therapist the knowledge and tools to advocate both locally and nationally, so when it is time to move forward, we are prepared."

For California member Michael Madison, MBA, RRT, involvement in government advocacy dates all the way back to high school, when he was inspired by a teacher who impressed upon her students that "with freedom goes responsibility." The AARC and the California Society have provided Madison with the means to live out that decree for his profession. When he was president of the California Society for Respiratory Care, Madison started a Legislative Day in the state capital to educate lawmakers about issues important to the profession, and he says the day is still going strong seven years later. But he believes individual participation by RTs in California and around the country counts for a lot, too.

"What we do here in California affects the AARC and adjoining states, as do other states' and AARC's activities," he said. "Sending advocacy letters to legislators and sharing the AARC PACT plan with colleagues is just as important as knocking on doors in Washington, DC, or Sacramento. It's a

participatory form of government, and consistently paying attention to the AARC's initiatives, reading the information, and sharing the information with our colleagues is one of the simplest yet most effective ways to move our profession forward."

**Back to DC**

These state-based efforts have helped build important connections with legislators and other health care groups and organizations alike, and it all feeds back into the AARC's ongoing advocacy process on the federal level. In fact, in recent years, AARC government advocacy has channeled much of its effort into working with like-minded stakeholders and public policy coalitions to support legislation. Together they've targeted everything from reversing the youth tobacco epidemic and improving coverage of remote patient monitoring to ensuring access to liquid oxygen, protecting patients who need ventilatory support in the home, and acquiring funding for the COPD National Action Plan.

At the same time, staff have kept a close eye on any and all regulatory developments that could impact the profession and its patients, and they regularly issue comments to the appropriate agencies when necessary.

As Giordano said, "We share a vision that all patients who need the expertise and services of a respiratory therapist have access to them regardless of care setting. We still pursue the realization of this vision as a team."

Advocacy & Government Affairs Committee member Natalie Napolitano, MPH, RRT, RRT-NPS, FAARC, believes this persistence pays.

"We have had some years when we have not had our legislation move through," she noted. "However, by being constantly present and reminding the elected officials, their staff members, and other organizations who we are and what we do best, we have been included in legislation that other organizations have spearheaded . . . they see the importance of what we do and want us involved."

Hummel says our annual Lobby Day and other ongoing lobby events designed to garner face time with members of Congress and their staffs have made the whole process a lot easier.

"Years ago, when we visited the Hill during our advocacy day each spring, many staff and Congressional leaders were unfamiliar with respiratory therapists and the type of care they provided," she noted. "Over the years, we have raised the profile in numerous ways through our virtual lobby campaigns and meetings both in DC and in state district offices. Although it is always difficult to get a bill enacted, the efforts and time spent on our advocacy have raised the bar for future inroads as the health care system continues to advance, especially in the area of telehealth."

Hummel credits the AARC PACT and the state societies with making it happen.

"A huge thank you goes to our Political Advocacy Contact Team members and our state societies and their members whose advocacy and leadership at the grassroots level has elevated our level of success," she said

**The mission continues**

In Cheryl West's view, protecting the right of RTs to provide the care only they can provide best is an essential role for the government affairs operation at the AARC, and one that she believes has more than justified its 40-plus years of existence.

“Bluntly put, if you want a seat at the table where the fate of a profession can be advanced or diminished, you darn well better pull a chair up to the table,” she said.

Giordano echoes those sentiments. “A friend once told me that if you weren’t at the table you may be on the menu,” he said. “I am forever grateful that our profession stepped up and continues to do so. It and all of you deserve all the credit. Keep it going!”

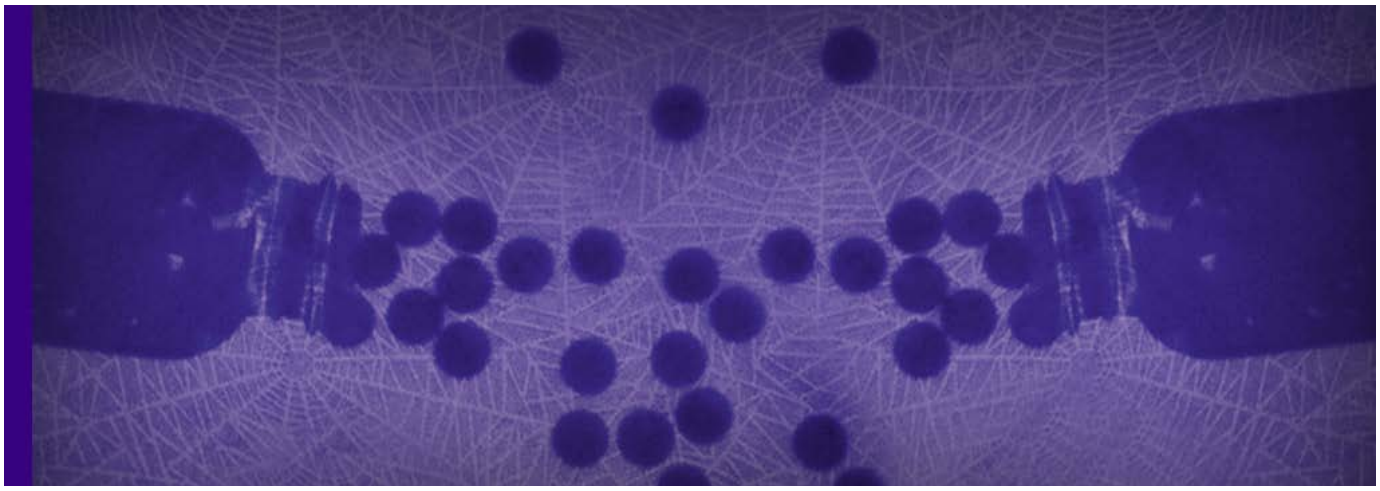
John Campbell, the Advocacy & Government Affairs Committee member from Arkansas, agrees that the AARC’s long history of government advocacy is essential to everyone who calls themselves a respiratory therapist.

“The AARC and PACT members are vigilant in looking out for the patient’s and profession’s best interests,” he said. “Knowing the threats to patient care and threats to funding that I have seen over the years, I shudder to think where the profession would be without the AARC and PACT members’ interventions.”

It’s a legacy of representation that will play out again and again, any time the AARC sees an issue or concern that could impact the profession or its patients.

# Are you breathing clean air?
# Chances are you're not — no matter where you live.

by Tonya Winders, MBA



Health effects of climate change and air pollution are an increasingly serious worldwide problem. A recent report by the World Health Organization says air pollution kills 7 million people every year, and 93% of children under the age of 15 breathe so much polluted air it puts their health and development at risk. Environmental exposures to indoor and outdoor pollutants influence asthma severity and control, and it may play a role in asthma inception. Children are disproportionately affected by the negative health effects of air pollution.[1]

For those living with chronic respiratory disease, air pollutants breathed into the lungs can exacerbate symptoms. A primary pollutant is fine particulate matter, a combination of solid and liquid droplets that get into the air via emissions from factories, power plants, and vehicles (including airplanes). Some particles, such as dust, dirt, soot, and smoke, are large enough to be visible; others are microscopic. When these particles are inhaled, they can affect the heart and lungs, causing serious health issues.

In fact, a 2018 systematic review examining the effects of air pollution on asthma exacerbations reported similar findings.[2] Within the Detroit urban area, 46% of air pollution-related asthma hospitalizations were attributed to $NO_2$ exposure with greater disease burden among Latino and low-income populations.[2] Similar to $NO_2$, $SO_2$ exposure has been linked to reductions in $FEV_1$ and FVC and an increased rate of asthma-related emergency department visits. Moreover, particulate matter exposure is implicated in multiple cardiopulmonary disease processes and is associated with premature death. Exposure to particulate matter 10 micrometers or less in diameter ($PM_{10}$) exposure during the first year of life was associated with a reduction in $FEV_1$ of 60 mL by age 8, and $PM_{10}$ near the home was associated with increased risk of asthma-related hospitalization. Even short-term exposure to particulate matter can be harmful, with one study showing a positive correlation between the daily concentration of particulate matter and pediatric asthma-related hospital visits. [2] Some of this effect likely results from poor housing conditions and living in closer proximity to major roadways. Bowatte et al reported that living less than 200 meters from a major road was associated with current wheeze (aOR, 1.38; 95% CI, 1.06–1.80) and atopy (aOR, 1.26; 95% CI, 0.99–1.62), and lower prebronchodilator and postbronchodilator $FEV_1$ .[5] Recent studies have shown a link between $NO_2$ exposure and reduced lung

function, increased need for rescue medications, and elevated risk and severity of asthma exacerbations.[2]

Emissions also include high levels of heat-trapping greenhouse gases, such as carbon dioxide, methane, and nitrous oxide, which are then trapped in the Earth's atmosphere. As a result, the planet cannot cool off, thus altering our weather patterns. Mild winters cause plants, flowers, and trees to bloom earlier, releasing more pollen and mold spores — both are common asthma and allergy triggers — into the air and leading to longer and more potent allergy seasons.[3]

Air pollution can reach harmful levels — and lead to a greater risk for asthma flares and allergy symptoms — when temperatures rise in the spring and summer, the days are longer, and air becomes more stagnant. Heat waves can also trigger asthma flares. When power plant, factory, and vehicle emissions mix with heat and sunlight, it forms smog (also called ground level ozone), which is another powerful respiratory irritant most prevalent in urban areas.[4]

As government officials and scientists debate climate change policy and the impact on health, respiratory therapists and people with chronic respiratory conditions can take matters into their own hands by minimizing the effects of climate change in their daily lives and promoting clean air in their communities. It is important to identify and avoid symptom triggers for all respiratory patients. Everyone can make their homes or businesses more energy efficient and advocate for ways to reduce air pollution.
Here are six tips respiratory therapists can share with patients:

1. Talk with your health care provider about how to prevent symptoms on days when the pollen count is high or air quality is poor. Make sure you have an updated Asthma Action Plan, and know what triggers to avoid. If breathing problems occur, ask your provider if your medication needs to be adjusted.
2. Monitor local air-quality reports every day and take warnings seriously. Visit the National Allergy Bureau at *www.aaaai.org/nab* for pollen counts and the Environmental Protection Agency's *www.airnow.gov* for daily air quality updates in your hometown.
3. Stay inside if possible when pollen counts are high or air quality is poor. Avoid or limit strenuous outdoor activity to early morning hours, when pollen and ozone levels tend to be lower. Instead of jogging outdoors, work out at a fitness center or take a power-walk through the mall.
4. Minimize allergens and irritants inside your home, especially the bedroom. Keep doors and windows closed as much as possible. Air conditioning keeps air cool and dry; electrostatic, pleated or allergy-proof filters help reduce circulation of allergens. Shower in the evening to remove pollen that collects on your body or in your hair and put your clothes in the wash.
5. Help slow climate change by using less energy at home. Seal and insulate your home. Turn off lights and unplug TVs, computers, and electronic gadgets when not in use. Use energy-efficient light bulbs. Consider installing solar panels on your roof — although expensive, they may be well worth it in the long run, depending on your family's finances.
6. Reduce pollution from motor vehicles by carpooling when possible. Don't idle your car when parked. Take public transit or ride a bike to work.

Air pollution clearly impacts health, contributing to increased asthma symptoms, rescue medication use, emergency department visits, and hospitalizations, resulting in significant social and economic burden. Further study is needed to identify factors that increase the susceptibility of children to pollutants and poor asthma outcomes. Reducing exposure to air pollutants has been associated with improved respiratory health. Coordinated efforts between scientists, health care workers, and local, state, and federal governments are needed to successfully implement policy changes that will reduce exposure to air pollutants and improve the health of respiratory patients.

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## about the author...

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# Who are the Champions in your life?

by Karen S. Schell, AARC President, DHSc, RRT, RRT-NPS, RRT-SDS, RPFT, RPSGT, AE-C, CTTS

Champions are with you no matter what happens, they impact people, and they make a difference in someone else's life. RTs strive to fill their potential and to be their best. RTs are Champions!

RTs are now in a position not only to be a champion but to champion their cause by moving forward, taking the profession to higher levels, and taking ownership with actions that demonstrate a noble purpose.

RTs are used to overcoming adversity. They are hardworking, mentally tough, and adaptable; they demonstrate courage and earn respect, and they are focused, motivated, and a positive influence on others. RTs are dedicated to the profession, value teamwork, have character, are consistent, and always do their best.

Champions have vision for what they want to create. RTs have a vision to be more. Vision changes over time and circumstances. What is important is that RTs are working toward their vision by turning the vision into achievable goals. Goals are milestones and landmarks to work toward the vision. It is not so much about the goal but what the goal forces RTs to become in order to achieve it.

While we need to focus on the process and the present, we need to see far enough in front of us to make the next move. This is how vision changes. We work toward one thing but are open to new possibilities as they emerge. Connecting the vision to a bigger purpose can take us even further. Our passion for our profession and our patients connects our purpose to our vision. Champions take risks and face setbacks. Champions are willing to make their goals a reality. We need to focus on RTs' strengths.

Champions have a strong team around them. This means they surround themselves with people who are going to move them forward. Belief in oneself is a strong component of being a champion. A deep inner knowledge that it is all going to work out, maybe not as we imagined, but we can trust that there is something better waiting for us ahead. And, together with strong belief, we will be unstoppable.

RTs are all champions in their own right and in their own lives. Each of us just needs to decide if we are going to settle for good alone or if we choose to be great together.

Every day we have an opportunity to become a champion. Inclusion, collaboration, positive engagement, understanding, tolerance, and willingness to grow all contribute to championing our cause to show the world during this health care crisis who we really are, what we are capable of, and who we want to be in the future. It is time to build each other up, show the public our professionalism, educate the public, and show our passion for our profession. Be a champion of the profession, advocate in your community, set the bar higher, and demonstrate your worth by actions and kind words.

Thank you for your dedication to our patients during this uncertain time. You are all champions!

**about the author...**

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**Article and Feature Contribution:** AARC Tımes welcomes AARC member contributions of feature articles and information for the regular columns. Send an outline and objectives of your article idea to Communications Manager Heather Willden at heather.willden@aarc.org.

# War

by Anthony L. DeWitt, JD, RRT, FAARC

Imagine you're a general and you're preparing for war. You know that you have to get supplies like food and ammunition to the front lines, so you get the Army to buy a thousand trucks from a supplier. When the war comes, you deliver your trucks to the port on trains, and then you realize that you didn't train anyone to drive them.

In a nutshell, this is the situation facing the country today in light of this pandemic. Thousands upon thousands of respiratory therapists are suiting up in scrubs and going to work every day to manage patient loads that are extreme, and loads that at any other time would be deemed unsafe. But because we do not have enough respiratory therapists in the country, patients are being managed on ventilators by people untrained for that job.

Like most respiratory therapists, I have followed the media stories about not having enough ventilators, and I thought back to my own experience. Every year I would go to hospital administration and ask for new ventilators, and every year my four ventilators would be cut back to two, or sometimes one. There were never enough funds to buy ventilators, but there were always funds for management retreats. Now the decision-making at hospitals — particularly those affiliated with government entities — is being placed under a microscope. People are beginning to wonder how hospitals could be caught without sufficient numbers of life-support equipment.

The lawsuits are coming, and they're inevitable. Hospitals are going to have to explain how they were not ready for this. It will not matter that the scope of this problem is something unseen in modern times. The last time there was a pandemic was the 1950s, and that involved polio (and the original crop of respiratory therapists). It will not matter to attorneys that this was something difficult to predict. The allegation will be negligence, and there are going to be plenty of people angry enough to sue.
While the media has focused largely on the lack of ventilators, it has not focused nearly enough on the small number of trained and experienced therapists available in the job market. It has not yet identified the fact that most hospitals do not have sufficient numbers of pulse oximeters and other monitoring gear to track oxygenation and ventilation on a large number of patients. But as the pandemic winds down, these discoveries will be made.

Therapists out there managing these ventilators are working 12- and 16-hour shifts covering for their sick colleagues. They are working tired, and likely exhausted. People who are tired and exhausted make mistakes. Management needs to be especially proactive when making assignments. Tired clinicians are not as likely to pick up on subtle clinical signs. Management may have to roll up their lab coat sleeves and go to the bedside. Heroes step up when the situation calls, and the crisis is real.

At times like these, it is important to remember that the law requires therapists to do what a reasonable therapist under the same or similar circumstances would do. In other words, it does not require perfection of therapists, only reasonable judgment. It is also important to remember that not every bad outcome is evidence of negligence.

Perhaps more important even than the legal standards involved is the friendship and mentoring that has to happen at the department level. Therapists need to be their own cheerleaders. They need to cheer their victories and examine their failures objectively to learn from them, not for the purpose of denigration. Therapists need to back up and support their colleagues.

Robert Schuller tells us that "tough times never last, but tough people do." As a community of therapists, it's time to toughen up and get through the worst of this pandemic.

**about the author…**

**Anthony L. DeWitt, JD, RRT, FAARC, is an attorney and a partner in the firm Bartimus, Frickleton, 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.**

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# RC Currents

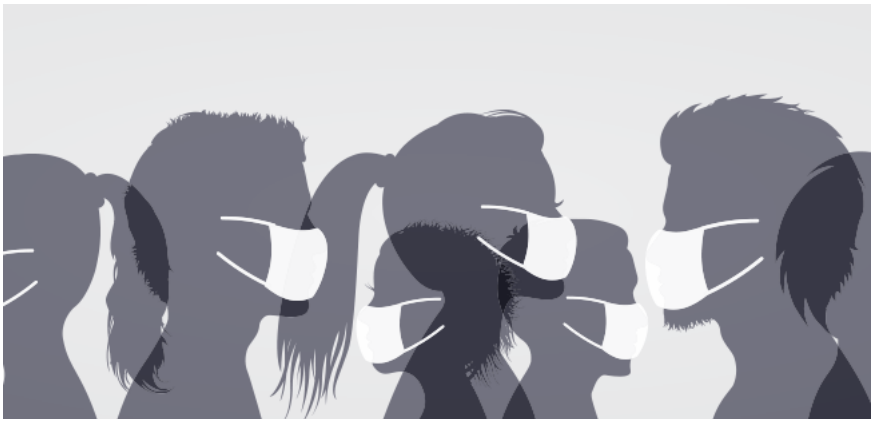
## IN THE NEWS


**Convalescent plasma shows promise**

Chinese investigators publishing a Preliminary Communication in *JAMA* on Mar. 27 reported good results for the use of convalescent plasma to treat COVID-19. The treatment was given to five critically ill patients with ARDS who met these criteria: severe pneumonia with rapid progression and continuously high viral load despite antiviral treatment, $PAO_2/FIO_2 < 30$, and mechanical ventilation.

Body temperature normalized within three days in four out of the five patients, the SOFA score decreased, $PAO_2/FIO_2$ increased within 12 days, viral loads decreased and were negative after 12 days, and SARS-CoV-2–specific ELISA and neutralizing antibody titers increased. In four patients, ARDS resolved at 12 days after transfusion, and three patients were weaned from mechanical ventilation within two weeks. At the time of publication, three had been discharged from the hospital and the other two were in stable condition.

While the authors note that the small sample size and the uncontrolled nature of the study preclude any definitive conclusions, they believe more study is warranted to see if convalescent plasma has a role to play in treating COVID-19.



**Virus may linger despite resolution of symptoms**

A research letter published online by the *American Journal of Respiratory and Critical Care Medicine* on Mar. 27 suggests COVID-19 patients may still harbor the virus for up to eight days after they cease to experience symptoms of the disease.

Researchers from Yale School of Medicine collaborated with investigators from Beijing on the study, which analyzed samples from throat swabs taken from 16 patients who suffered from mild disease and were treated and released from the hospital after confirmation of negative viral status by at least two consecutive tests. The time from infection to onset of symptoms was five days among all but one patient, and on average symptoms lasted eight days. However, the length of time patients remained contagious after the end of their symptoms ranged from one to eight days. Two patients had diabetes and one had tuberculosis, but neither affected the timing of the course of COVID-19 infection.

The authors believe these findings send a sobering message to health care workers: "COVID-19 patients can be infectious even after their symptomatic recovery, so treat the asymptomatic/recently recovered patients as carefully as symptomatic patients."

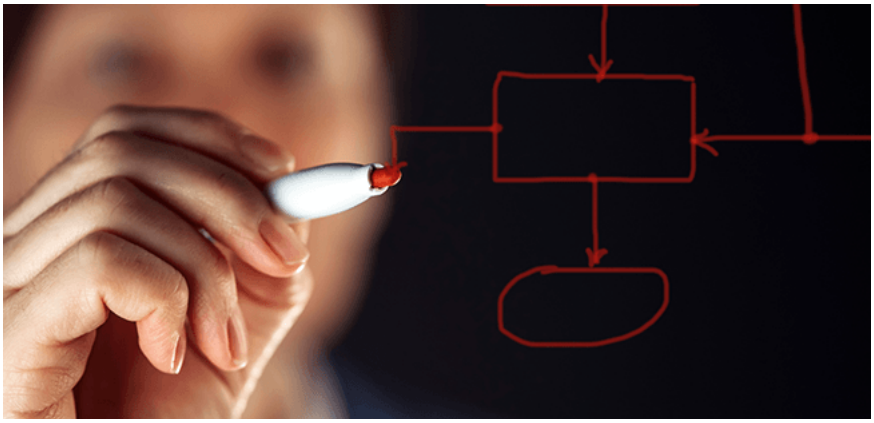
**Other testing may be needed**

Pharyngeal swabs are widely used to determine when a patient with COVID-19 can be discharged from the hospital or leave isolation. New research out of China suggests that the test may not be the only indicator of whether the patient still harbors the virus. Other testing may be needed, too.

The investigators arrived at that finding after retrospectively identifying a convenience sample of 133 patients admitted to Beijing Ditan Hospital with a diagnosis of COVID-19. For each patient, they paired reverse transcription polymerase chain reaction (RT-PCR) testing of pharyngeal swabs with either

sputum or feces. The authors identified 22 patients with an initial or follow-up positive sputum or fecal sample paired with a follow-up negative pharyngeal sample. A positive RT-PCR test for SARS-CoV2 of sputum and feces was seen up to 39 and 13 days, respectively, after the pharyngeal samples were negative.

The researchers note that this study was not conducted in a systematic fashion, and they do not know if the positive sputum and fecal results indicate that a patient could still spread the virus. But they believe their findings do suggest more study is needed to find out. The research was reported by the *Annals of Internal Medicine* on Mar. 30.



**AI tool predicts severity in COVID-19**

New York University researchers working with colleagues in China believe artificial intelligence (AI) techniques could help predict which newly diagnosed COVID-19 patients are most likely to develop severe disease.

The investigators used decision trees to track series of decisions between options and model the potential consequences of choices at each step in a pathway. Demographic, laboratory, and radiological findings from 53 patients who initially presented with mild symptoms were used in the study.

The AI techniques revealed somewhat surprising results. For example, some characteristics linked to the disease, such as ground glass opacities on lung images, fever, and strong immune responses, were not useful in predicting which patients would go on to develop more severe symptoms. Age and gender also were not useful. The AI tool instead linked more severe disease to three factors: levels of the liver enzyme alanine aminotransferase, reported myalgia, and hemoglobin levels. When they combined these with other factors, the team was able to predict risk of ARDS in these patients with up to 80% accuracy.

The authors admit their results are limited by their small data set and a mean age of 43 among the study participants. But they believe that paying attention to these three factors may help clinicians decide which patients should be more closely monitored. The research was published by *Computers, Materials & Continua* on Mar. 30.

**Good news for pregnant women**

Encouraging news for pregnant women who come down with COVID-19: according to researchers publishing in the *Archives of Pathology & Laboratory Medicine* on Mar. 19, the virus does not appear to travel across the placenta and cause infection in the fetus.

The study included 38 women who were in their third trimester when they were diagnosed with COVID-19. None had any preexisting chronic illnesses, but several did develop complications during pregnancy that included influenza, gestational hypertension, preeclampsia, gestational diabetes, and preterm labor. COVID-19 symptoms included cough, sore throat, muscle pain, discomfort, gastrointestinal symptoms, and shortness of breath. However, none of the women developed severe pneumonia or required intensive care. In those cases where amniotic fluid, placenta, umbilical cord blood, and throat swabs of newborns were tested, all were negative for the virus, despite some cases of pre- and post-birth complications.

**Updated data from IMPACT trial**

An expanded post hoc analysis of data from the multicenter, 37-country, Phase 3 IMPACT trial has reported that an inhaler combining fluticasone furoate (FF), umeclidinium (UMEC), and vilanterol (VI) reduced all-cause mortality by 42% in patients with COPD compared to VI/UMEC. According to study author David A. Lipson, MD, the finding was primarily driven by the steroid component and its effect on reducing exacerbations, especially hospitalized exacerbations.

“Frequently exacerbating patients are at higher risk of hospitalization and death,” he said. “These are the patients who appear to achieve the greatest survival benefit with once-daily FF/UMEC/VI triple therapy.”

The initial IMPACT study showed that daily inhalation of FF/UMEC/VI led to more significant reductions in moderate/severe exacerbations and COPD hospitalizations, as well as improved lung function and health-related quality of life, than the dual combination therapies. Patients on triple therapy also had lower death rates than those on VI/UMEC. However, data from 5.5% of participants were removed from the one-year analysis because some investigators did not report vital status data for all-cause mortality at the end of the study. The new analysis includes vital status data for 99.6% of IMPACT participants. The current study was published in the *American Journal of Respiratory and Critical Care Medicine*.

**Researchers underscore value of spirometry**

A new study out of the United Kingdom confirms the vital role that spirometry plays in diagnosing COPD.

The study was conducted among patients who had taken part in a clinical trial designed to enhance the participation of high-risk, low-income individuals in low-dose computed tomography (CT) screening for lung cancer. All participants were given spirometry testing, and airflow limitation was classified according to accepted standards. Overall, the 986 participants were divided into three groups based on spirometry results and their reported history of COPD: "no COPD," "undiagnosed COPD," and "known COPD." Participants' CT scans were read by radiologists specializing in lung disease, and COPD was subjectively classified by the radiologists as "none," "mild," "moderate," or "severe" based on visual inspection of their CT images.

Thirty-two percent of those with "undiagnosed COPD" had no emphysema on their CT scans. Fifty-seven percent had pre-bronchodilator spirometry consistent with COPD. Sixty-seven percent did not have a prior history of COPD and were considered "undiagnosed." Emphysema prevalence in those with known COPD was 73%, whereas those considered "undiagnosed" had a prevalence of 68%. Inhaler use and symptoms were more common in the "known" than in the "unknown" COPD group, while comorbidities were common in all groups. Statistically adjusted odds of respiratory symptoms were more significant for air-flow obstruction than emphysema.

"Based on our findings, reliance on CT alone to diagnose COPD risks missing individuals who may actually have this condition while overdiagnosing others," said study author Mamta Ruparel, MRCP. "Since individuals at risk for lung cancer are also at risk for COPD, we recommend including spirometry in low-dose CT lung cancer screening programs to assist in making accurate diagnoses."

The study was published in the *Annals of the American Thoracic Society*.

**Secondhand smoke and worldwide deaths**

Researchers from the United States and The Netherlands who analyzed data on global smoking behavior have concluded that for every 50 smokers, one nonsmoker dies from exposure to secondhand smoke. The investigators arrived at that finding after tabulating the number of lifetime smokers in each country and the premature deaths related to secondhand smoke in that country. They reported that, in 2016, 52 current lifetime smokers were associated with the death of one nonsmoker worldwide. The secondhand smoke index was more favorable in North America, at around 90 smokers related to one death, most likely because there are more protective laws against smoking in public areas. Regions like the Middle East and Southeast Asia had less favorable numbers — around 40 smokers to one death — due to minimal or no protective measures. The researchers believe their results could help policymakers better understand the scale of harm inflicted by secondhand smoke and develop new measures to protect nonsmokers. The study appeared in *JAMA Open Network* earlier this year.

**How mold leads to asthma**

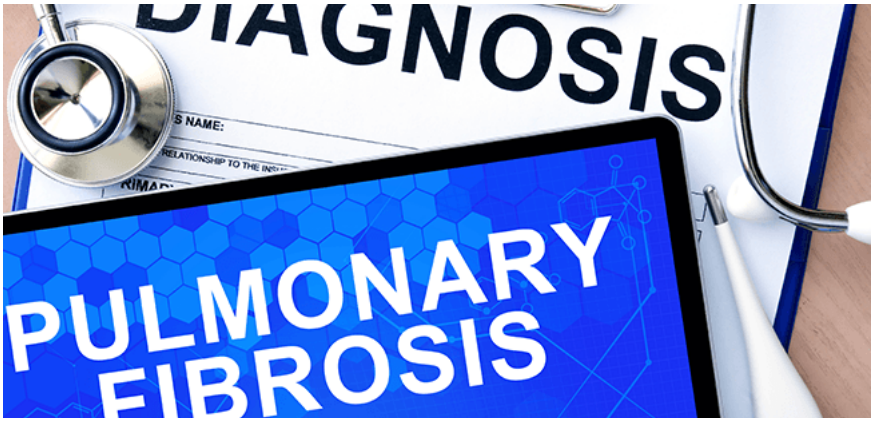
Mold is known to exacerbate asthma. Now researchers from the University of Wisconsin-Madison have discovered that common *Aspergillus* molds may induce asthma by first attacking the protective tissue barrier deep in the lungs. An especially strong response to this initial damage was associated with developing an overreaction to future mold exposure and the constricted airways characteristic of asthma in both human and mice studies. The investigators believe their work paves the way for more research on understanding and possibly even preventing the development of asthma. The study was published in *Cell Host and Microbe*.

**TB cough trigger identified**

Researchers from UT Southwestern believe they may be on the track to stopping the trigger for the cough that spreads tuberculosis. Working with rodents, they set out to identify the components or products of the *Mycobacterium tuberculosis* that cause coughing or trigger nociceptors, nerve cells that respond to pain stimuli. In the process, they identified a fatty acid called sulfolipid-1 (SL-1) as a pain-response trigger, then reproduced that response in isolated human nociceptor cells. When they altered a strain of *M. tuberculosis* to not produce SL-1, rodents who were infected with that strain developed other tuberculosis symptoms, but not coughing. The investigators believe if they can show that suppressing cough does not worsen tuberculosis in patients, a drug that inhibits SL-1 production may help prevent the spread of the disease.

"People with active tuberculosis can cough for months and spread disease even when they are receiving appropriate treatment," said study author Dr. Michael Shiloh. "Someday, doctors may give antibiotics in conjunction with a medication that prevents coughing, which in turn could prevent spread."

The study was published in a recent edition of *Cell*.




**Pulmonary fibrosis awareness**

Pulmonary fibrosis (PF) is a serious lung disease, but according to a new survey conducted by the Pulmonary Fibrosis Foundation (PFF), most Americans are unaware of symptoms and other key factors of the condition. Among the findings —

- 91% of those aged 60 and over did not know the symptoms of PF, and 96% had never talked to their doctor about PF.
- Among those who currently smoke or have smoked, more than 80% did not know the symptoms of PF, and only 9% had ever talked to their doctor about the disease.
- Those with a history of smoking were three times more likely to have had PF or known someone affected by PF.
- 80% said they would see a doctor if they experienced shortness of breath for longer than a month.
- Nearly four in five would go to the doctor if they had symptoms of a lingering cough and fatigue.
- One in two would wait less than three weeks to visit a doctor if they had symptoms of a lingering cough and fatigue.
- Despite the overall lack of awareness of PF symptoms, 82% considered PF to be a serious disease.
- About one in two said that finding a cure for PF is very important; 61% were unsure if there will be a cure for PF within their lifetime.

"Because many symptoms of PF are similar to those of other illnesses, like the common cold, it can be difficult to diagnose and treat, leading to late-stage diagnoses," said William Schmidt, president and CEO of the PFF. "Our national survey results show a clear need to increase understanding of PF, so patients are better able to recognize the early signs of the disease and start conversations with their physicians."

The PFF National Awareness Survey 2020 was published on the PFF website earlier this year.

**Hospital readmission reduction programs that work**

Hospitals have tried many means to reduce readmissions since the implementation of the Hospital Readmissions Reduction Program, including collaborating with certified home health care agencies; using telehealth programs, post-discharge phone calls, or house-call programs; implementing interdisciplinary case-management or discharge-planning programs; and creating partnerships with primary care practices. Researchers from Binghamton University, State University of New York, have identified those that work best in a new study published in *Professional Case Management*.

Looking specifically at heart failure and pneumonia patients, the investigators gathered data on hospital readmission reduction programs (HRRPs) used by hospital organizations, and then analyzed the relationship between the type and number of HRRPs used by the hospital organization and the facility's readmission and reimbursement outcomes. Results indicated that collaborating with home health care agencies and using telehealth or implementing house calls for follow-up with post-discharge patients lowered the incidence of readmission for patients who had previously been hospitalized for heart failure or pneumonia. Lower rates of readmission were seen in facilities that employed more than one HRRP,

and including an advanced practice nurse on interdisciplinary case management teams resulted in better patient outcomes and lower readmission rates.

**New PF treatment shows promise**

North Carolina State University investigators have discovered that lung stem cell secretions delivered via a nebulizer can help repair lung injuries caused by multiple types of pulmonary fibrosis (PF) in mice and rats. They hope the findings may one day lead to more effective, less invasive treatments for people afflicted by the disease.

The researchers specifically tested lung spheroid cell secretome (LSC-Sec) and lung spheroid cell exosomes (LSC-Exo) against commonly used mesenchymal stem cells (MSCs) in mouse and rat models of chemically induced and silica- or particle-induced PF. The stem cell-derived therapeutics were delivered through a "stem cell sauna," a nebulizer that allowed the therapeutic proteins, small molecules, and exosomes to be inhaled directly into the lungs.

In the mouse model of chemically induced PF, the researchers observed that, although inhalation treatment with either LSC-Sec or MSC-Sec led to improvements compared to the saline-treated control, LSC-Sec treatment resulted in a nearly 50% reduction of fibrosis compared to a 32.4% reduction with MSC-Sec treatment. In the mouse model of silica-induced PF, LSC-Sec treatment resulted in a 26% reduction of fibrosis compared to a 16.9% reduction with MSC-Sec treatment.

Similar results for both LSC-Exo and LSC-Sec treatments versus MSC-Exo were seen in rat models of both types of pulmonary fibrosis. Additionally, while LSC-Exo inhalation treatment alone elicited a therapeutic effect similar to LSC-Sec treatment, the full secretome was still the most therapeutic.

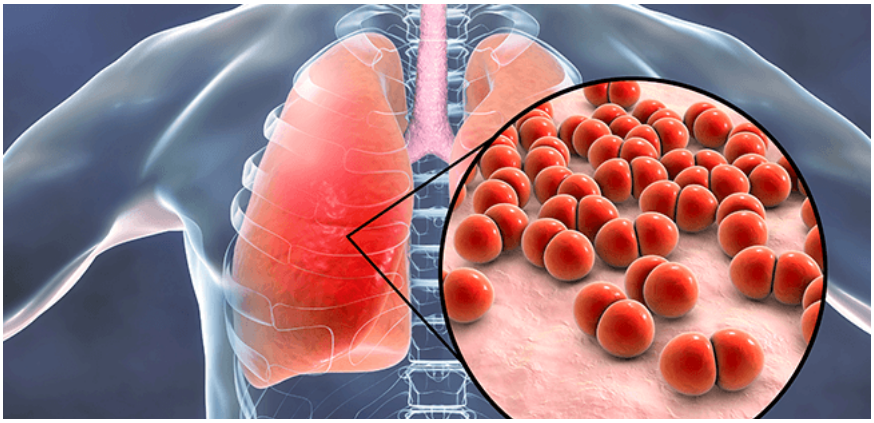
The study appeared in a recent edition of *Nature Communications*.

**Adults like sweet e-cig flavors, too**

Public health officials have pushed for a ban on flavors in e-cigarettes because they appeal to children and are fueling an epidemic of youth use of these devices. A new study out of Penn State suggests that children aren't the only ones attracted to sweet e-cigarette flavors.

The finding is based on online e-cigarette surveys conducted between 2012 and 2014 and between 2017 and 2019 among adults age 22 to 75. Preference for fruit flavors remained stable over time, whereas preference for tobacco, menthol, or mint flavors decreased from 40% to 22%. Preference for chocolate or candy and other sweet flavors was most noticeable in younger adults and increased from 16% to 29%.

When participants in the latest survey were asked to describe their anticipated reactions to potential FDA regulations of e-cig flavors, about half indicated they would find a way to buy their preferred flavor or add flavoring agents themselves if their preferred, non-tobacco flavors were banned. The study was published by the *Annals of the American Thoracic Society* earlier this year.



**Vancomycin should not be first line of defense in pneumonia**

Broad-spectrum antibiotics have no place in initial pneumonia treatment, say Utah researchers publishing in a recent edition of *JAMA Internal Medicine*. Their study of more than 88,000 veterans found that pneumonia patients given these medications in the first few days after hospitalization fared no better than those receiving standard medical care.

In one of the largest ever conducted to look at the issue, the investigators retrospectively examined the medical records of pneumonia patients age 62 to 81, tracking whether these patients were initially treated with standard antibiotic therapy for pneumonia — such as ceftriaxone and azithromycin — or with anti-methicillin-resistant *Staphylococcus aureus* (MSRA) treatments, such as standard therapy plus vancomycin or vancomycin without standard therapy.

Results indicated that, as doctors became more aware of and concerned about MRSA infection in the lungs, they became more likely to use anti-MRSA therapies as an initial treatment, even though MRSA only accounts for about 2% of pneumonia cases. Over time, use of anti-MRSA therapies rose from about 20% of patients to nearly half, despite the fact that no discernable benefit was seen. In fact, these therapies were associated with a 40% higher risk of dying within 30 days of discharge, perhaps due to the potentially severe side effects of vancomycin. The researchers believe further study is needed to fully determine the underlying causes of this increased risk.

**Weight loss surgery and smoking**

Patients who need to have weight loss surgery generally quit smoking before the surgery. But according to researchers from Pitt Public Health, many of them have resumed smoking within seven years of the operation. Most interesting, however, is that some who never smoked before ended up becoming smokers as well.

These findings came from a study that followed 1,770 adults enrolled in an NIH-funded study of patients undergoing weight-loss surgery at one of ten hospitals across the United States. More than 45% of the participants reported a history of smoking prior to surgery, with 14% still smoking in the year before surgery. That fell to 2% in the month before surgery, but the rate rebounded to nearly 10% in the year following surgery and steadily climbed back to 14% by seven years post-surgery.

Two out of five people who smoked after surgery had quit more than a year before their operation or had never smoked before. People who identified as smokers post-surgery also smoked more, going from an average of a dozen cigarettes per day in the year before surgery to more than 15 cigarettes per day seven years post-surgery. A prior history of smoking was the greatest risk factor for smoking post-surgery, but younger age, poverty, being married or living as married, and drug use were associated with increased risk as well.

The study was published in the *Annals of Surgery*.

**Restoring balance**

UCLA researchers have identified a new molecule that helps to maintain a healthy balance of cells in airway and lung tissue and may one day lead to new treatments for lung cancer.

The discovery came from an analysis of airway cells from biopsies of healthy people, people with premalignant lung cancer lesions, and people with squamous lung cancer. One group of molecules — collectively called the Wnt/beta-catenin signaling pathway — was present at different levels in the basal stem cells of the samples from subjects with lung cancer or pre-cancer versus the basal stem cells from healthy subjects.

When the researchers altered the levels of these molecules in healthy airway cells from mice, the balance between stem cells and mucociliary cells shifted, mimicking the imbalance seen in lung pre-cancers. When the team screened more than 20,000 chemical compounds for their ability to reverse this effect in human cells, one compound stood out for its ability to limit the proliferation of basal stem cells and restore the balance of the stem cells and mucociliary cells to normal. The compound was also less toxic to

airway cells than other, previously discovered, molecules that block Wnt/beta-catenin signaling. The team named the compound Wnt inhibitor compound 1, or WIC1.

"The identification of this new drug is a nice tool to tease apart the biology of the Wnt/beta-catenin signaling pathway and its effects on lung health," said study author Cody Aros. "It's also very exciting that it may act in a new way than other existing Wnt/beta-catenin signaling pathway inhibitors and has such low toxicity."

The study was published in a recent edition of *Cell Reports*.

**Amenities, please**

What drives patient selections on hospital satisfaction surveys? You might think the quality of care they received, or the outcome of the treatments given to them would matter most, but according to researchers from Cornell University, you would be wrong. Patients are more likely to grade their hospitals according to the amenities they provide. The findings were based on an analysis of Centers for Medicare and Medicaid Services data on patient satisfaction, mortality, and technical medical quality for roughly two thirds of U.S. general and acute care hospitals between 2007 and 2010. While patient satisfaction was higher at hospitals with the lowest death rates, the difference was only 2% compared to hospitals with the highest death rates. In contrast, interpersonal communication by nurses — such as their responsiveness and compassion — was a far bigger factor in patient satisfaction, with scores varying by nearly 27%. The tidiness and quietness of rooms also had much bigger impacts on satisfaction than death rates or medical quality.

**Strange but true . . .**

**Kidneys need clean air, too:** Air pollution may harm more than just the lungs. Johns Hopkins investigators who examined data on 10,997 U.S. adults reported that exposure to higher amounts of fine particulate matter was associated with a higher degree of a marker of kidney dysfunction called albuminuria and a higher risk of developing chronic kidney disease over time.

**So does the gut:** Can air pollution make you fat? University of Colorado Boulder researchers believe the answer may be yes. They noted that young adults exposed to higher levels of ozone showed less microbial diversity in their guts and higher quantities of certain species associated with obesity and disease.

**Good fat:** Fat has long been associated with heart problems, but according to Michigan State University researchers, fat around the arteries may actually be a good thing. They reported that the fat, known as

perivascular adipose tissue, or PVAT, helps arteries reduce the tension that blood vessels experience when stretched, making it possible for the blood vessels to expend less energy.

**Fur-friendly monitors:** Wearable devices are increasingly changing the way health care providers monitor their patients. British researchers have now developed a wearable for pets that monitors their vital signs through their fur. It works on people wearing up to four layers of clothing, too.

**Facebook clues:** U.S. researchers have reported that people are more likely to make Facebook posts containing more formal language or descriptions of physical pain just prior to going to the emergency department. They believe this finding adds to the evidence that social media is often an unseen signal of medical distress and could potentially be used to trigger health care interventions.

**Contribute to the AARC "Transitions" Column**

The AARC "Transitions" column is devoted to sharing news about the passing of AARC members. Submit news about your colleagues' recent passing using our Transitions online form. Please provide any information about the member's recent death, such as an obituary, so that we can share it with our members and pay tribute.

**Tell Your Story**

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

# Industry Watch

**Real world study of asthma patients**

TARGET PharmaSolutions, Inc., has launched its seventh observational cohort study, TARGET-ASTHMA. The longitudinal study is currently being conducted among people being treated for asthma and will capture additional respiratory diseases in the future. Structured and unstructured medical record data are being received from community and academic sites to build the database, including patient-reported outcome measures and biorepository samples. Partners are using the real-world data throughout pharmaceutical development and commercialization processes to inform optimal treatment approaches and potential solutions.

"This will not only aid in mapping the natural history of asthma but will also provide insights into the impact of different treatment paradigms on patient populations over time and collect real-world data as new agents are proceeding to market," said Steering Committee Chair Michael Wechsler, MD, from the National Jewish Health Cohen Family Asthma Institute.

**COVID-19 immunotherapy in the works**

CEL-SCI Corporation is developing an immunotherapy with the potential to treat the COVID-19 coronavirus using its patented LEAPS peptide technology. The LEAPS peptides will use conserved regions of coronavirus proteins to stimulate protective cell-mediated T-cell responses and to reduce viral load. The technology can be used to construct immunotherapeutic peptides that exhibit both antiviral and anti-inflammatory properties, not only targeting the virus against which they are directed, but also to elicit the appropriate protective response(s) against it.

**Test to allow for rapid diagnosis of TB**

Researchers at Tulane University School of Medicine, Baylor College of Medicine, and NanoPin Technologies, Inc., are developing a reliable and highly specific test to allow rapid diagnosis of all forms of tuberculosis (TB). The research effort is being funded with a $3.8 million grant from the Department of Defense and will address health threats to military men and women deployed to overseas battlefields and on humanitarian missions.

"Our test has several advantages over currently existing TB tests, including the gold standard of bacterial culture," said Tony Hu, the Weatherhead Presidential Chair in Biotechnology Innovation at Tulane. "It requires only a small blood sample and directly measures TB-derived proteins to detect all forms of TB disease, including those missed by most other available TB tests. Notably, this approach can discriminate TB cases from those caused by related pathogens that produce similar symptoms but require different treatments."

**Partnership aimed at developing human antibodies for COVID-19, other diseases**

Mount Sinai Health System and Harbour BioMed have started a multi-year, multifaceted collaboration to develop novel, fully human antibodies for the treatment and prevention of various diseases, including those in the areas of oncology and immunology. The collaboration will also use the H2L2 Harbour Mouse platform to generate monoclonal antibodies against COVID-19. These fully human monoclonal antibodies could be used therapeutically for people who have been exposed to the virus, or prophylactically for individuals with a high risk of exposure, such as health care workers. The antibodies have the potential to prevent spread of the virus by blocking infection of cells.

**Grant funds work on sarcoidosis biomarkers**

With the help of a recent $1.98 million grant from the National Heart, Lung, and Blood Institute, a team of researchers at Wayne State University plans to move forward with work to develop biomarker technology for the identification of biomarkers of sarcoidosis. They have already developed a complex epitope library derived from materials of sarcoidosis patients. This cDNA library contains large numbers of epitopes immunoscreened with sera from patients with sarcoidosis containing high-titer IgG antibodies and the cloned phages, which have been used to construct an antigen microarray to detect antibodies against sarcoid antigen(s) in the sera of test subjects.

**New journal from the ATS**

The American Thoracic Society launched a new, open-access journal called ATS Scholar. The online, peer-reviewed journal focuses on content related to education and training of health professionals relevant to adult and pediatric pulmonary, critical care, and sleep medicine. Topics covered by the journal will range from the training of the next generation of scientists to interprofessional education and education technology. The journal will also tackle relevant issues related to the culture of medicine, such as wellness and bias. In keeping with its digital format, authors will be invited to make submissions with a video component, as well as standalone educational videos. The journal will also leverage social media to engage the modern learner.

**COVID-19 vaccine development**

The Tulane National Primate Research Center (TNPRC) is establishing a COVID-19 research program to develop a vaccine and test treatments against the virus. The investigators will first create a nonhuman primate model to study the disease's clinical progression, how it is transmitted through the air, and how it specifically affects aging populations. They hope to answer many of the unknowns about the disease, including why older individuals are more susceptible to complications and death from it. Tulane's facility is the only National Primate Research Center with a Regional Biocontainment Laboratory onsite that is capable of the high level of biocontainment required to study an emerging infectious disease like COVID-19, and it was one of the first research facilities to obtain CDC approval to receive samples of the virus. It also has the nation's largest capacity for studying the transmission of infectious agents in nonhuman primates at this level of biocontainment, which is critical as public health responders rush to understand and thwart the spread of this disease.

**Lung cancer projects announced**

The National Comprehensive Cancer Network Oncology Research Program (ORP) has selected three research projects to receive funding focused on enhancing patient care and outcomes for people with advanced non-small cell lung cancer (NSCLC). The projects, which will be funded through a collaboration with AstraZeneca, include: Developing a PREcision meDICine Thoracic (PREDICT) Service in a Large Practice Network: Focus on Implementation, Physician, and Patient Impact (University Hospitals-Seidman Cancer Center); Randomized Trial of a Supportive Care Mobile Application to Improve Symptoms, Coping, and Quality of Life in Patients with Advanced NSCLC (Massachusetts General Hospital Cancer Center); and System-Wide Integration of Plasma-Based Next-Generation Sequencing into Clinical Pathways for Detection of National Comprehensive Cancer Network–Recommended Biomarkers to Improve the Management of Patients with Metastatic Non-Squamous NSCLC (Hospital of the University of Pennsylvania).

**Antibody in development to prevent and treat ARDS in COVID-19 patients**

Roivant Sciences has engaged with regulators in the United States, Europe, and Asia to rapidly advance the clinical development of gimsilumab for the treatment of ARDS associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Gimsilumab is a clinical-stage, fully human monoclonal antibody targeting granulocyte-macrophage colony-stimulating factor (GM-CSF).

"Upregulation of GM-CSF appears to characterize progression to ARDS and death in COVID-19," said Dr. Elizabeth Volkmann, founder and co-director of the UCLA Connective Tissue Disease-Related Interstitial Lung Disease Program. "Targeting GM-CSF represents a promising strategy for curbing lung damage while allowing time for the virus to clear. It is my hope that gimsilumab will reduce mortality from COVID-19 and help improve the lives of those affected by this emerging public health crisis."

**FDA issues final rule on new health warnings on cigarette packages**

The FDA has issued a final rule to require new health warnings on cigarette packages and in cigarette advertisements. The warnings feature textual statements with photo-realistic color images depicting some of the lesser-known but serious health risks of cigarette smoking, including impact to fetal growth, cardiac disease, diabetes, and more.

"Research shows that the current warnings on cigarettes, which have not changed since 1984, have become virtually invisible to both smokers and nonsmokers, in part because of their small size, location, and lack of an image," said Mitch Zeller, JD, director of FDA's Center for Tobacco Products. "Additionally, research shows substantial gaps remain in the public's knowledge of the harms of cigarette smoking, and smokers have misinformation about cigarettes and their negative health effects. The new cigarette health warnings complement other critical FDA actions, including outreach campaigns targeted to both adults and youth, to educate the public about the dangers associated with using cigarettes, as well as other tobacco products."

**LungPrint technology receives new funding**

VIDA Diagnostics, Inc., announced an $11 million initial close of its Series C financing. The company will use the funds to address market deficits in the early assessment, monitoring, and treatment of lung disease by accelerating the commercialization of its leading LungPrint solution suite and by expanding LungPrint's clinical portfolio.

“By equipping care teams with LungPrint, patient care and quality of life can be positively affected,” said VIDA CEO Susan A. Wood, PhD. “VIDA is endlessly thankful for the extensive support of the people, resources, and programs from the State of Iowa leading to this expansive funding. VIDA can now accelerate LungPrint’s market access, further connecting its benefits to the many millions of patients with lung disease.”

**Companies top list of innovators in asthma market**

In ongoing research conducted by KMK Consulting, Inc., GlaxoSmithKline was ranked as the top company delivering superior customer value and sales force engagement, as well as therapeutic innovation, in the asthma market. The research was conducted among pulmonary disease specialists in February 2020, using KMK’s Rapid Pulse Survey platform. AstraZeneca, Genentech, and Novartis rounded out the top organizations driving innovation and customer value in this space. The two most important product launches in the asthma space over the past two years were deemed to be Dupixent (marketed by Regeneron and Sanofi Genzyme) and Fasenra (marketed by AstraZeneca). Both brands were cited by 45% of the pulmonary disease specialists polled.