



IMPROVING ACCESS TO RESPIRATORY CARE

A White Paper from the **Respiratory Therapy Access** Working Group

**Respiratory
Therapy Access**
Working Group

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Respiratory illnesses are pervasive, chronic conditions that exist quietly in millions of Americans. Patients manage their breathing with varying degrees of success, since the ability to keep on top of symptoms depends heavily on a patient's personal circumstances.

Paradoxically, respiratory health rarely gets the policy attention it deserves. The current health care paradigm is one of disease treatment, rather than disease prevention. Though prevention is the cornerstone of good respiratory health, the United States has fallen behind in addressing health care delivery for day-to-day treatment of chronic conditions.

This lack of focus comes at great cost to both patient and the health care system. A full 26 million Americans suffer from asthma—a condition for which there is no cure—and over 7 million of those suffering are children.¹ Chronic obstructive pulmonary disease (COPD), which includes conditions limiting airflow to the lungs, like bronchitis and emphysema, affects an estimated 24 million Americans.²

The cost of just these two conditions to our health care system is staggering. Asthma costs the United States approximately \$56 billion annually; \$1.6 billion from asthma inpatient costs alone.³ National COPD costs were estimated at \$49.9 billion in 2010, including \$29.5 billion in direct health care spending.⁴

The good news is that mortality from respiratory illness is going down, as treatment options improve and the quality of care from health care professionals continues to excel. But in the delivery of respiratory treatments and care, patients still lack the access they need.

Patients are often not sick enough to be in critical care but not well enough to manage symptoms without consistent intervention.

Respiratory conditions are insidious because patients are often not sick enough to be in critical care, but not well enough to deal with their symptoms without consistent intervention. This makes them particularly susceptible to small changes in co-pays and drug switching, exacerbated by patients' own demography. Most respiratory conditions must be managed on a daily basis, or the chronic turns to the acute, driving patients into hospital emergency rooms.

ACCESS TO APPROVED THERAPIES

Respiratory disease presents patients with a unique set of challenges to accessing medication and approved therapies. Though this is not an exhaustive list, here we've prioritized

This white paper details the most pressing access barriers facing patients suffering from respiratory health conditions—and related policy solutions.

the access issues that accompany several major respiratory conditions.

Asthma

Asthma, as a chronic condition, can be controlled only with the continuous, long-term use of medication. That means patient co-pays are a constant in asthma care, and growing out-of-pocket expenses can put patients at risk. A 2015 study found that an increased co-pay for albuterol inhalers meant patients used less of the medications.⁵ And another 2012 study found that in 85% of cases, an increase in co-pays led to a decrease in adherence.⁶

There's also an obvious racial disparity in adhering to medication regimen; the greatest rise in asthma rates is among black children, with an almost 50 percent increase from 2001 through 2009. Rates of asthma-related hospitalization and death are three times higher for African Americans than for white patients.

Increased co-pays for albuterol inhalers led to decreased patient adherence in 85% of cases,

according to a 2012 study.

Sadly, these vulnerable children are the exception to an overall trend of declining asthma-related deaths. Minority children are both more likely to have asthma and less likely to take medication as prescribed.

Patients also often lack access to inhaled corticosteroids that are used to prevent attacks. “The co-pays are often prohibitive. For patients with Bronze plans and high deductibles, the

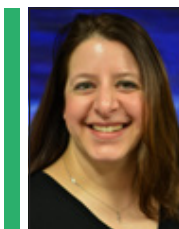
cost can be \$300 per month,” says J. Allen Meadows, MD, a community-based practitioner in Montgomery, Alabama. “Even many of the plans that cover it limit coverage to less expensive, low potency inhaled steroids, which are appropriate for only a minority of patients.”

There are also barriers to access for other asthma treatments. For instance, insurance companies often favor a dry powder inhaler for steroids instead of a metered dose inhaler (MDI).

“The problem comes when a provider wants to order an MDI with a holding chamber or nebulizer because that is what the patient is capable of using correctly and consistently,” says Natalie Napolitano, a respiratory therapist with The Children's Hospital of Philadelphia. “They have problems getting approval and then these are top tier drugs that have a high out of pocket cost for the patient.” Napolitano explains that this interferes with caregivers' ability to make the patient-specific choice of medications.

Innovative procedures and therapies can introduce added access challenges, despite their importance for patients who simply don't respond to standard therapies. Bronchial thermoplasty, for example, treats lung airways to prevent asthma attacks but may face utilization management requirements such as prior authorization. Cell- or tissue-derived medications known as biologics may provide a breakthrough for patients because they attack asthma's source, not simply the symptoms. But they too are associated with access barriers.⁷

In particular, insurers frequently place biologics on the highest, “specialty” level of its tiered payment structure.



“The provider should have the ability to choose the medication and type of administration that suits the ability of the patient.”

Natalie Napolitano, RT

Figure 1-Asthma Cost-sharing

Cost-Sharing Discourages Asthma Care

Percent of families who delay or avoid care for their child's asthma



Source: JAMA Pediatrics, "Financial Barriers to Care in Low-Income Children with Asthma: Health Reform Implications"

This requires burdensome cost-sharing for patients, who may be required to pay a percentage of the drug as opposed to a flat co-pay. As biologics become increasingly important for patients with respiratory conditions, policymakers must consider the impact of barriers to access.

The non-discrimination provisions of the Affordable Care Act (ACA) demand that the U.S. health care system not discriminate against patients with chronic diseases by requiring higher out-of-pocket costs for their medicines. If payers limited specialty tiers, costs could come down, bringing insurers into full compliance with the ACA.

Allergy

Access to allergy immunotherapy, commonly known as the allergy shot, is one of the most urgent challenges to respiratory health access today. Allergy immunotherapy's role in treatment shouldn't be understated: It is the only treatment that can be disease modifying for patients with asthma, allergic rhinitis, and allergic conjunctivitis. Other therapies offer only symptom control, which—if that treatment stops—leads to recurrence. Not so with allergy shots.

Yet regulatory challenges may erase patient access to and reimbursement for this life-altering treatment. United States Pharmacopeia (USP), a non-profit organization that publishes

recommendations for drug standards and quality, has proposed revisions to existing rules that would affect allergen immunotherapy by challenging the sterility of the current standard practices. The aseptic technique used for allergen immunotherapy extract preparation has a well-established safety record. "There have been no reports of infection in over 100 years of use," says Dr. Meadows.

Moreover, loss of immunotherapy access would come at great cost to both patients and the health care system. In a Florida study of Medicaid patients with allergic rhinitis between 1997 and 2009, immunotherapy treatment saved 38 percent in health care costs—over \$6,500 average per patient—in just 18 months. Savings to the system materialized within a mere three months. With the direct cost of allergic rhinitis to the U.S. health care system estimated at \$14 billion in 2011, it's clear that loss of access to allergy immunotherapy would be costly.⁸

Removing and restricting the use of allergy immunotherapy is troubling because once access to a medical therapy is removed, it is extraordinarily difficult to reinstate that access for patients.

COPD

COPD is the third-leading cause of death in the United States, killing more than 130,000 Americans annually. From those statistics alone,

it's clear that patients need full access to the scope of therapies and interventions available.

But COPD is also a major cause of disability because, like so many respiratory ailments, symptoms worsen over time and can limit patients' ability to do routine activities. Further, COPD has no cure. But treatments and lifestyle changes can help slow the progress of the disease.

"COPD is a childhood disease with old-age consequences," says Samuel Louie, MD, a physician at the University of California, Davis. Factors—like smoking and environmental exposure to dust and chemicals—that patients experience at a relatively young age can be felt only years later. Education on smoking cessation and avoiding second-hand smoke is important. So, too, is early screening of symptomatic patients, which can help get ahead of disease progression with proper education and intervention. Essential to this task is creating and implementing thoughtful screening questionnaires for at-risk populations, as well as placing value on increased clinical time with health care providers.

A 2015 recommendation from the U.S. Preventive Services Task Force, however, could limit COPD screening opportunities. The task force weighed the use of screening questionnaires along with spirometry, an office test that gauges lung function by measuring the speed and volume of air a patient exhales and inhales. The task force found no value in the combined screening measures, though it did not consider the value of screening questionnaires independently. Thus, its decision could eliminate opportunities for physicians and asymptomatic patients to have an important conversation about COPD.

Another challenge for COPD patients is non-medical switching; changing a patient's medication mid-course based on health plan cost considerations with little regard to the physician-

prescribed course of treatment. "It's basically taking decisions out of the physician's hands," says Dr. Louie.

Considering a patient's quality of life is as important as determining a patient's longevity on new treatment.

This is a dangerous practice for those with COPD. If not accompanied by appropriate training for the patient, these changes in medication are associated with poorer clinical outcomes and increased use of costly health care resources.¹⁰ Physicians and patients, not health plans, need to manage which medications and which delivery systems (such as inhalers) work best for their patients.

Idiopathic Pulmonary Fibrosis (IPF)

This debilitating ailment causes a buildup of scar tissue, preventing the lungs from taking in enough air. It may prove fatal in a matter of two or three short years. Because it is a resource-intensive ailment, experts estimate that this disease's cost to the U.S. health care system nears \$2 billion, despite it affecting a relatively small 200,000 patients in this country.¹⁰

Those suffering with IPF have historically had almost no options for treatment. Now two new treatments, nintedanib and pirfenidone—recently approved for use by the FDA—can slow progression of the disease.¹¹ But they come at great cost, nearly \$94,000 a year.

The cost is so prohibitively high that it presents a barrier for an average patient to access treatment. It's critical to lower the cost-sharing for these drugs, as recent research found the number of people suffering from IPF is likely much higher than estimated. A recent report in the Wall Street Journal found that IPF diagnoses in those aged 65 and older have doubled in the period between 2001 and 2011.¹²

For such a costly disease, the health care system can't afford to simply wait for prices to come down.

Life-prolonging medications must be carefully considered on an individual basis; determining a patient's quality of life is as important as determining a patient's longevity on new treatment. Though the new course of medication for IPF isn't right for every patient, any therapy choice should be available for discussion between a patient and physician.

ACCESS TO FULL SCOPE OF RESPIRATORY CARE

To address the urgent needs of the U.S. population with respiratory health concerns, the care paradigm for respiratory diseases must be updated and revisited in the following ways.

Expanding environmental remediation and patient education

Educating patients on how to use medical devices and prescriptions properly is crucial in the field of respiratory health. Improper use of inhalers can lead to hospitalizations when chronic conditions progress to acute reactions. Patients who are shown how to use inhalers properly see significant decreases in medication errors.¹³

Yet patients are often shortchanged because the system at present invests few resources to provide detailed education and instruction, especially in the physician practice setting. Though a CMS code exists for patient education, it can't be billed separately. This effectively disincentivizes busy health care providers from being able to spend extra clinical time discussing the multi-faceted environmental issues facing each patient in his or her individual circumstances.

Trigger mediation—addressing and mitigating respiratory triggers in a patient's home environment—is another useful proactive tool to which many patients have no access. Asthma can often be controlled with the elimination of triggers and allergy

testing to identify which allergens trigger a patient in his environment. "Studies have shown that universal avoidance of dust mites, for example, does not improve health nor reduce cost," says Dr. Meadows. "Mite avoidance is only effective in the population allergic to mites."

Adequate reimbursement for detection and elimination can assist with stabilization of the disease; for example, to conduct home visits and determine the specific needs of one patient, or simple smoking cessation support for caregivers.

In a Michigan study, an environmental program visited families four times over six months to assess for asthma triggers based on participants' pre-tested allergies. The result was a 47 percent drop in unscheduled visits to doctors.¹⁴ And other states are taking notice: Last year, the Missouri State Legislature approved funding for asthma home assessments for children on Medicare. Current funding for home assessments is mostly done on a state-by-state basis with contracts through private insurance.

Proposed changes to the hospital discharge planning process require education for patients and training on the triggers and symptoms of their disease.

This is a start in the effort to increase education. But, to be effective, training by respiratory therapists should be ongoing to ensure proper use and patient compliance, especially for patients who use complex respiratory equipment and medications.



“Telemedicine is not just for rural areas; urban patients are demanding it.”

Allen Meadows, MD

Acknowledging the expanding role of respiratory therapists (RTs)

The U.S. is facing a shortage of allergists. Projections between 2006 and 2020 by the American College of Allergy, Asthma and Immunology show the number of allergist/immunologists will decline by seven percent, while demand for these doctors will increase 35 percent between 2006 and 2020.¹⁵

Meanwhile, asthma and related diseases are becoming more prevalent. Thus, it's clear why the need for respiratory therapists is skyrocketing.

The Bureau of Labor Statistics projects the number of RTs will grow by 12 percent in the next decade, faster than the average of all other U.S. occupations,¹⁶ while the demand for these professionals will grow by 20 percent. Respiratory therapists provide specialized ongoing care for respiratory problems like COPD, chronic ventilator dependence, pneumonia and cardiovascular disease, and also emergency care for patients with various traumas, heart attack, drowning or shock.¹⁷

Their role is essential in keeping patients out of emergency rooms. In a study of nursing home patients, those who received RT services during an initial stay had better health outcomes and cost the system less than those who weren't treated by an RT.¹⁸ Another 2010 study tested a disease management program that relied heavily on RTs as respiratory disease managers. After just one year, hospital readmissions went down for all causes by 28 percent.¹⁹

The majority of respiratory therapists work in acute care hospitals, but there is a pressing need for their expertise

in all health care settings. Recent emphasis by the Medicare program on coordinating care among providers and alternative payment models that focus on quality care and lowering costs offer new incentives for respiratory therapists, especially as baby boomers continue to age into the program.

But it is simply not enough to improve access to these health care professionals. From the federal perspective, respiratory therapists are not recognized in Medicare statute, which can limit Medicare beneficiaries who suffer from chronic respiratory conditions from having access to their skills.

Respiratory therapists treating patients in the home—patients whose lives often depend on complex medical devices such as oxygen systems, nebulizers, aerosol inhalers and mechanical ventilators—are not reimbursed by Medicare under its durable medical equipment benefit, a serious oversight in the respiratory health care paradigm.

Increasing access to telemedicine


Rural and underserved communities often lack access to specialized medical care. The current landscape of integrated technology, however, provides the unprecedented ability for health care providers to reach patients without physical infrastructure. Telemedicine provides real-time, face-to-face interaction between health care provider and patients.

For chronic conditions, frequent medical care and advice is needed. So it's essential that patients can access quality telemedicine providers to address their needs. It also means geographic obstacles to care are particularly consequential



“I have patients ask me to make difficult choices for them, such as a grandmother who questioned whether she should buy food for her grandchildren or medicine for herself. I have no words for those moments.”

Samuel Louie, MD



for respiratory patients; they need supervised training to get the full benefit of their treatments. Studies have shown that telemedicine can be a vital tool and is both feasible and safe.²⁰ In a study of RTs caring for pediatric patients on ventilators, telemedicine was found to be equivalent in quality as face-to-face interactions.²¹

While the private sector has moved to embrace telemedicine, unfortunately, CMS payment policies haven't kept pace with advancements in this important aspect of health care. Lists of providers who can care for patients via telemedicine are restrictive, and there are a number of geographic limitations and site of care restrictions.

Legislators are attempting to address these issues through numerous bills that have been introduced in Congress. Key among these is the Medicare Telehealth Parity Act of 2015, which would expand telemedicine providers and services to include respiratory therapists and respiratory care as well as geographic locations available for telemedicine.²² Remote monitoring for patients with chronic conditions, including COPD, are also among the provisions in a number of legislative initiatives.

OTHER ACCESS BARRIERS

Cost, co-pays and medication adherence

It is a sad fact of our health care system today that many fixed and low-income patients have to choose between care and cost. In respiratory health, this is strikingly apparent, since many of the treatments for respiratory disease are ongoing and represent a consistent resource drain over time. It's all too easy for a patient to choose to stop treating asthma or other chronic respiratory ailments for economic reasons. Consider, for example, that increasing the cost of co-pays for inhalers has been shown to reduce adherence, especially for those with higher cost-sharing medical plans.

Given respiratory conditions' disproportionate effect on children, minorities and low-income Americans, dealing with the cost sharing of respiratory treatments is critical.

Medical Devices

For respiratory patients who need long-term mechanical ventilation, home-based medical devices can provide useful, cost-effective therapy, saving the health care system about 77 percent over hospital-based care and over \$170,000 a year in savings per patient.²³ "The importance of home oxygen therapy should not be underestimated," says Kent Christopher, MD, a pulmonologist at the University of Colorado School of Medicine. Yet barriers to using ventilators and other medical devices such as oxygen systems, portable oxygen concentrators and liquid oxygen delivery systems in the home have long been a problem for health care professionals. Competitive bidding under the Medicare program has impacted the availability of suppliers and the ability to ensure that patients receive the most appropriate equipment that meets their medical needs. In addition, obtaining authorization and reimbursement presents an ongoing challenge.²⁴

The current health care climate's switch to in-home care and containment of cost for chronic disease means access to medical devices is of critical importance.

Emerging Medical Reimbursement Models

Hospitals and physicians have traditionally operated in a fee-for-service model, where services are paid for separately. This system can reward

health care providers on the volume of services provided. Under the ACA, the government will implement a “pay for performance” model, to focus on outcomes with bundled services.

The switch from volume to value, on its face, is an admirable goal. But it has the potential to threaten individualized care, which is essential to respiratory patients.

At the current time, these new payment models are in test and evaluation stages, and some preliminary studies have found little financial impact in the new pay for performance projects.²⁵ Though the baseline of coordinating care based on outcomes is a positive step for patient-centered care, it has the potential to limit or restrict access to some therapies based on cost alone.

CONCLUSIONS

The incidence of COPD, asthma and other respiratory conditions is on the rise. Americans diagnosed with asthma increased by 28 percent between 2001 and 2011.²⁶ And since half of COPD patients aren’t aware they have the condition, the Center for Disease Control and Prevention estimates the actual number of those suffering is significantly higher than the data shows. Though treatments continue to improve, in 2011 more people died of COPD than of diabetes and breast cancer combined.²⁷

To address this mounting health concern, clinicians must help frame the discussion on respiratory care and coverage. The voices of medical caregivers can keep the physician-patient relationship at the forefront, and ensure that the professionals at the bedside are empowered to determine the therapies and course of care best suited for each individual patient, in every case.

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Please note that the views expressed in this document do not necessarily reflect those of the institutions with which working group members are affiliated.

JOIN AFPA’S RESPIRATORY THERAPY ACCESS WORKING GROUP

The mission of AfPA’s Respiratory Therapy Access Working Group is to ensure that policymakers hear the perspectives of health care providers treating patients who suffer from asthma, chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis and other respiratory conditions. Working group members collaborate in the development of educational resources and participate in advocacy initiatives designed to promote informed policy making on issues affecting patient access.



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