CHEST 2019

Join Us for an Expert Speaker Program With Interactive Discussion

Considerations for Tumor Biopsy, Staging, and Diagnostic Testing in Non–small Cell Lung Cancer

Michael Pritchett, DO, MPH
Director of Thoracic Oncology
Director, Chest Center of the Carolinas
FirstHealth of the Carolinas, Pinehurst Medical Clinic
Pinehurst, North Carolina

Wednesday, October 23, 2019

12:30 PM – 1:15 PM CDT

Light refreshments will be provided.

Exhibit Hall • Learning Theater 2 • Ernest N. Morial Convention Center

900 Convention Center Blvd • New Orleans, LA 70130

This is a non-CME event and does not qualify for CME, CE, or MOC credit. This event is not part of the official CHEST 2019 conference sessions. This event is not an endorsement by CHEST and does not reflect the views or opinions of CHEST. Only CHEST 2019 registrants can attend this symposium

AstraZeneca

Q&A with **CHEST 2020** Program Chair

Victor J. Test, MD, FCCP, will take over as CHEST Program Chair for 2020, succeeding this year's Chair William Kelly, MD, FCCP. Dr. Test has been an active CHEST member for years and was this year's Chair of the CHEST Educator Development Subcommittee. As Chair, he focused on continuing to ramp up the Clinician Educator track at CHEST, ensuring the programs and courses are up to par with how medical education is evolving through active and interactive learning. *Daily News* asked him a few questions about plans for CHEST 2020 in Chicago.

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>
> **VICTOR J. TEST, MD, FCCP**

What plans or goals would you like to accomplish at next year's meeting?

→ We're going to continue to push our training members' programming to the spotlight and focus on their contributions to the meeting, including highlighting the *CHEST Challenge* as we always do. We're also going to focus more on CHEST legends, masters, and Past Presidents to get them more involved in the meeting in a way where they can interact with our membership and the attendees. I think that's going to be an important cornerstone of what we do. We're going to continue to move away from a strictly lecture-based format and continue to push the envelope in terms of creative ways to deliver content, in addition to live-streaming more of our content. It's going to be really hard for me to be more creative than Dr. Schulman and Dr. Kelly (former Chairs) who just seem to come up with a new idea every other minute. I'm hopeful that I'll be able to at least come up with some other contributions. But I think putting the spotlight on our training members and their contributions to the meeting is the foremost thing.

How will you incorporate interdisciplinary learning into the 2020 meeting?

→ We have been making a move the last few years to ensure diversity in gender, race, levels of training, and also in career disciplines. We try to reflect our education in the way that we give care, which is almost always in some degree team-based. We're going to continue to teach our team-based learning with interdisciplinary sessions and also in simulation. We encourage people to bring some of their team and have them go through a critical care simulation together, for example.

What are some of the perks of having the meeting in Chicago?

→ It's a draw for people to come to Chicago because of the city experiences and because it's easier for people to transport to, including international attendees. It's traditionally the best attended of all of our meetings.

How is the planning going?

→ The planning has definitely already started. We have a really large and dedicated group of staff that do miracles in terms of making this meeting come off smoothly every year. But we also have a very large group of volunteer health-care professionals who are dedicated and already participating in program development for this meeting. We start planning for things like simulation and interdisciplinary programs more than a year in advance, and we expect them to keep getting better and better every year.

What to look forward to in Chicago for #CHEST2020

AS YOU ENJOY YOUR FINAL HOURS IN NEW Orleans, keep in mind that it's never too early to start making preparations for next year's event. CHEST 2020 will be held October 17-21 at McCormick Place in Chicago. Here's a glimpse of what to look forward to in the Windy City.

VIBRANT, SPRAWLING DISTRICT

The McCormick Place convention center district continues to grow, thanks to The Collection at McCormick Square. The area boasts many specialty shops, breweries, and restaurants offering everything from Chicago-style pies to barbecue. Visit the lakefront for a selfie or explore Chicago's Chinatown neighborhood, where you'll find landmarks such as the Nine Dragon Wall, which is made of glazed tile from China, and the 12-acre Ping Tom Memorial Park.

RIVER SIGHTSEEING

If you're looking for a relaxing getaway, head to the south bank of the Chicago River to explore the Chicago Riverwalk, a pedestrian waterfront trail stretching from Lake Shore Drive to Lake Street. You'll get to see breathtaking architecture, enjoy fine dining, and access kayak rentals, pier fishing, shopping, and water taxis.

RENOWNED DINING

Chicago features a plethora of world-class restaurants, celebrity chefs, and ethnic cuisine. Home to 25 Michelin-starred restaurants, the city hosts the James Beard Awards Gala, celebrating the best and brightest culinary professionals in America, through 2021.

→ DON'T MISS THESE WINDY CITY STAPLES.

THE ART INSTITUTE OF CHICAGO

artic.edu

Escape for an inspiring day at the Art Institute of Chicago, one of the world's great museums.

CHICAGO BOTANIC GARDEN

chicagobotanic.org

Explore this world-renowned garden located right in Chicago's backyard. This 385-acre, living museum features 23 specialty gardens and three natural areas set on a series of islands and lakes. The Garden is always in bloom, featuring year-round exhibits, festivals, tours, and special events.

NAVY PIER

navypier.org

A Chicago landmark with more than 50 acres of parks, shops, restaurants, and entertainment attractions. Enjoy the Centennial Wheel, musical carousel, and Wave Swinger. Visit the Chicago Children's Museum or take a tour boat ride. Many dining options are available.

SKYDECK CHICAGO

Get out on the ledge—if you dare—for the best view of Chicago from one of the world's tallest buildings. The Skydeck Experience offers 360-degree views of up to four states plus a short movie detailing Chicago's rise to prominence in the world of architecture.

THE SECOND CITY

secondcity.com

Since 1959, The Second City has established itself as a Chicago landmark and a national treasure offering the best in Chicago comedy every night of the week.

SHEDD AQUARIUM

sheddaquarium.org

The Shedd Aquarium offers more than 8,000 animals from around the world. New at the Shedd is Underwater Beauty, featuring 100 species from around the world that embody living art shaped by the unmatched forces of nature and time. Discounted pricing is available for groups and Chicago city residents.

ANORO HAS BROAD COVERAGE

93%

Nationally, ANORO is covered without restrictions* for 93% of Commercial and Medicare Part D patients†

This may mean fewer callbacks for prior authorizations and/or step edits‡

Individual access may vary by geography and plan benefit design.

Source: Managed Markets Insight & Technology, LLC (MMIT), database as of June 2019.

ANORO is covered without restrictions for 92% of Commercial and 97% of Medicare Part D patients nationally.

*"Covered without restrictions" means reimbursement from a health plan without accompanying step edits or prior authorizations.

†"Patients" means covered lives for all Commercial and employer payer types (excluding Managed Medicaid), and covered lives enrolled in Medicare payer types as calculated by MMIT as of June 2019. Commercial calculations do not include Indian Health Service or Department of Veterans Affairs lives.

‡Source: American Medical Association. 2016 AMA Prior Authorization Physician Survey. 2016;1-2.

What You Need to Know About This Formulary Information

Formulary status may vary and is subject to change. Formulary coverage does not imply clinical efficacy or safety. This is not a guarantee of partial or full coverage or payment. Consumers may be responsible for varying out-of-pocket costs based on an individual's plan and its benefit design. Each plan administrator determines actual benefits and out-of-pocket costs per its plan's policies. Verify coverage with plan sponsor or Centers for Medicare & Medicaid Services. Medicare Part D patients may obtain coverage for products not otherwise covered via the medical necessity process.

PAY NO MORE THAN **$10** EACH MONTH§

100% of eligible, commercially insured patients will pay no more than $10 a month§ for ANORO for up to 12 months, guaranteed with use of this coupon.

Please visit ANORO.com for full Requirements and Restrictions.

§Subject to eligibility. Restrictions apply. Not for use by Medicare or government program participants.

Important Safety Information (cont'd)

ADVERSE REACTIONS

- The most common adverse reactions (≥1% and more common than placebo) reported in four 6-month clinical trials with ANORO (and placebo) were: pharyngitis, 2% (<1%); sinusitis, 1% (<1%); lower respiratory tract infection, 1% (<1%); constipation, 1% (<1%); diarrhea, 2% (1%); pain in extremity, 2% (1%); muscle spasms, 1% (<1%); neck pain, 1% (<1%); and chest pain, 1% (<1%).
- In addition to the 6-month efficacy trials with ANORO, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence ≥1% and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

DRUG INTERACTIONS

- Caution should be exercised when considering the coadministration of ANORO with ketoconazole and other known strong CYP3A4 inhibitors as increased systemic exposure to vilanterol and cardiovascular adverse effects may occur. See prior Warning and Precaution regarding CYP3A4 inhibitors.
- ANORO should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval, or within 2 weeks of discontinuation of such agents, because they may potentiate the effect of vilanterol on the cardiovascular system.
- Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.
- Use with caution in patients taking non–potassium-sparing diuretics, as ECG changes and/or hypokalemia associated with these diuretics may worsen with concomitant beta-agonists.
- Avoid coadministration of ANORO with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects.

References: 1. Donohue JF, Worsley S, Zhu C-Q, et al. Improvements in lung function with umeclidinium/vilanterol versus fluticasone propionate/salmeterol in patients with moderate-to-severe COPD and infrequent exacerbations. *Respir Med*. 2015;109(7):870-881, Appendix B. **2.** Data on file, GSK.

Learn more at StartWithANORO.com

ANORO ELLIPTA was developed in collaboration with INNOVIVA

ANORO ELLIPTA
(umeclidinium 62.5 mcg and vilanterol 25 mcg inhalation powder)

BRIEF SUMMARY

ANORO ELLIPTA
(umeclidinium and vilanterol inhalation powder), for oral inhalation use

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

ANORO ELLIPTA is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Important Limitations of Use

ANORO ELLIPTA is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma. The safety and efficacy of ANORO ELLIPTA in asthma have not been established.

4 CONTRAINDICATIONS

The use of ANORO ELLIPTA is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to umeclidinium, vilanterol, or any of the excipients *[see Warnings and Precautions (5.6), Description (11) of full prescribing information]*.

Use of a long-acting beta$_2$-adrenergic agonist (LABA) without an inhaled corticosteroid (ICS) is contraindicated in patients with asthma *[see Warnings and Precautions (5.1)]*. ANORO ELLIPTA is not indicated for the treatment of asthma.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Asthma-Related Events—Hospitalizations, Intubations, Death

The safety and efficacy of ANORO ELLIPTA in patients with asthma have not been established.

ANORO ELLIPTA is not indicated for the treatment of asthma *[see Contraindications (4)]*.

Use of LABA as monotherapy (without ICS) for asthma is associated with an increased risk of asthma-related death. Available data from controlled clinical trials also suggest that use of LABA as monotherapy increases the risk of asthma-related hospitalization in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone.

A 28-week, placebo-controlled, US trial comparing the safety of another LABA (salmeterol) with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol vs. 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). The increased risk of asthma-related death is considered a class effect of LABA, including vilanterol, one of the active ingredients in ANORO ELLIPTA.

No trial adequate to determine whether the rate of asthma-related death is increased in subjects treated with ANORO ELLIPTA has been conducted.

Available data do not suggest an increased risk of death with use of LABA in patients with COPD.

5.2 Deterioration of Disease and Acute Episodes

ANORO ELLIPTA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. ANORO ELLIPTA has not been studied in subjects with acutely deteriorating COPD. The initiation of ANORO ELLIPTA in this setting is not appropriate.

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

When beginning treatment with ANORO ELLIPTA, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs and to use them only for symptomatic relief of acute respiratory symptoms. When prescribing ANORO ELLIPTA, the healthcare provider should also prescribe an inhaled, short-acting beta$_2$-agonist and instruct the patient on how it should be used. Increasing inhaled, short-acting beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated. COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If ANORO ELLIPTA no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting beta$_2$-agonist becomes less effective; or the patient needs more short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting a reevaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of ANORO ELLIPTA beyond the recommended dose is not appropriate in this situation.

5.3 Excessive Use of ANORO ELLIPTA and Use with Other Long-acting Beta$_2$-agonists

ANORO ELLIPTA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using ANORO ELLIPTA should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

5.4 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors

Caution should be exercised when considering the coadministration of ANORO ELLIPTA with ketoconazole and other known strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased cardiovascular adverse effects may occur *[see Drug Interactions (7.1), Clinical Pharmacology (12.3) of full prescribing information]*.

5.5 Paradoxical Bronchospasm

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

5.6 Hypersensitivity Reactions

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of ANORO ELLIPTA. Discontinue ANORO ELLIPTA if such reactions occur. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder medications containing lactose; therefore, patients with severe milk protein allergy should not use ANORO ELLIPTA *[see Contraindications (4)]*.

5.7 Cardiovascular Effects

Vilanterol, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms *[see Clinical Pharmacology (12.2) of full prescribing information]*. If such effects occur, ANORO ELLIPTA may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiographic changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

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

In a 52-week trial of subjects with COPD, the exposure-adjusted rates for any on-treatment major adverse cardiac event, including non-fatal central nervous system hemorrhages and cerebrovascular conditions, non-fatal myocardial infarction, non-fatal acute myocardial infarction, and adjudicated on-treatment death due to cardiovascular events, was 2.2 per 100 patient-years for fluticasone furoate/umeclidinium/vilanterol 100 mcg/62.5 mcg/25 mcg (n = 4,151), 1.9 per 100 patient-years for fluticasone furoate/vilanterol 100 mcg/25 mcg (n = 4,134), and 2.2 per 100 patient-years for ANORO ELLIPTA (n = 2,070). Adjudicated on-treatment deaths due to cardiovascular events occurred in 20 of 4,151 patients (0.54 per 100 patient-years) receiving fluticasone furoate/umeclidinium/vilanterol, 27 of 4,134 patients (0.78 per 100 patient-years) receiving fluticasone furoate/vilanterol, and 16 of 2,070 patients (0.94 per 100 patient-years) receiving ANORO ELLIPTA.

5.8 Coexisting Conditions

ANORO ELLIPTA, like all medicines containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis and in those who are unusually responsive to sympathomimetic amines. Doses of the related beta$_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

5.9 Worsening of Narrow-Angle Glaucoma

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

5.10 Worsening of Urinary Retention

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

5.11 Hypokalemia and Hyperglycemia

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Beta-agonist medicines may produce transient hyperglycemia in some patients. In 4 clinical trials of 6-month duration evaluating ANORO ELLIPTA in subjects with COPD, there was no evidence of a treatment effect on serum glucose or potassium.

6 ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Serious asthma-related events–hospitalizations, intubations, death. LABA, such as vilanterol (one of the active ingredients in ANORO ELLIPTA), as monotherapy (without ICS) for asthma increase the risk of asthma-related events. ANORO ELLIPTA is not indicated for the treatment of asthma [*see Warnings and Precautions (5.1)*].
- Paradoxical bronchospasm *[see Warnings and Precautions (5.5)]*
- Cardiovascular effects *[see Warnings and Precautions (5.7)]*
- Worsening of narrow-angle glaucoma *[see Warnings and Precautions (5.9)]*
- Worsening of urinary retention *[see Warnings and Precautions (5.10)]*

6.1 Clinical Trials Experience

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

The clinical program for ANORO ELLIPTA included 8,138 subjects with COPD in four 6-month lung function trials, one 12-month long-term safety study, and 9 other trials of shorter duration. A total of 1,124 subjects have received at least 1 dose of ANORO ELLIPTA (umeclidinium/vilanterol 62.5 mcg/25 mcg), and 1,330 subjects have received a higher dose of umeclidinium/vilanterol (125 mcg/25 mcg). The safety data described below are based on the four 6-month and two 12-month trials. Adverse reactions observed in the other trials were similar to those observed in the confirmatory trials.

6-Month Trials

The incidence of adverse reactions associated with ANORO ELLIPTA in Table 1 is based on four 6-month trials: 2 placebo-controlled trials (Trial 1, NCT #01313650 and Trial 2, NCT #01313637); N = 1,532 and N = 1,489, respectively) and 2 active-controlled trials (Trial 3, NCT #01316900 and Trial 4, NCT #01316913); N = 843 and N = 869, respectively). Of the 4,733 subjects, 68% were male and 84% were white. They had a mean age of 63 years and an average smoking history of 45 pack-years, with 50% identified as current smokers. At screening, the mean postbronchodilator percent predicted forced expiratory volume in 1 second (FEV_1) was 48% (range: 13% to 76%), the mean postbronchodilator FEV_1/forced vital capacity (FVC) ratio was 0.47 (range: 0.13 to 0.78), and the mean percent reversibility was 14% (range: -45% to 109%). Subjects received 1 dose once daily of the following: ANORO ELLIPTA, umeclidinium/vilanterol 125 mcg/25 mcg, umeclidinium 62.5 mcg, umeclidinium 125 mcg, vilanterol 25 mcg, active control, or placebo.

Table 1. Adverse Reactions with ANORO ELLIPTA with ≥1% Incidence and More Common than Placebo in Subjects with Chronic Obstructive Pulmonary Disease

Adverse Reaction	ANORO ELLIPTA (n = 842) %	Umeclidinium 62.5 mcg (n = 418) %	Vilanterol 25 mcg (n = 1,034) %	Placebo (n = 555) %
Infections and infestations				
Pharyngitis	2	1	2	<1
Sinusitis	1	<1	1	<1
Lower respiratory tract infection	1	<1	<1	<1
Gastrointestinal disorders				
Constipation	1	<1	<1	<1
Diarrhea	2	<1	2	1
Musculoskeletal and connective tissue disorders				
Pain in extremity	2	<1	2	1
Muscle spasms	1	<1	<1	<1
Neck pain	1	<1	<1	<1
General disorders and administration site conditions				
Chest pain	1	<1	<1	<1

Other adverse reactions with ANORO ELLIPTA observed with an incidence <1% but more common than placebo included the following: productive cough, dry mouth, dyspepsia, abdominal pain, gastroesophageal reflux disease, vomiting, musculoskeletal chest pain, chest discomfort, asthenia, atrial fibrillation, ventricular extrasystoles, supraventricular extrasystoles, myocardial infarction, pruritus, rash, and conjunctivitis.

12-Month Trials

In a long-term safety trial (Trial 5, NCT #01316887), 335 subjects were treated for up to 12 months with umeclidinium/vilanterol 125 mcg/25 mcg or placebo. The demographic and baseline characteristics of the long-term safety trial were similar to those of the placebo-controlled efficacy trials described above. Adverse reactions observed with a frequency of ≥1% in the group receiving umeclidinium/vilanterol 125 mcg/25 mcg that exceeded that in placebo in this trial were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus**.**

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during postapproval use of ANORO ELLIPTA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, or causal connection to ANORO ELLIPTA or a combination of these factors.

Cardiac Disorders

Palpitations.

Eye Disorders

Blurred vision, glaucoma, increased intraocular pressure.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis, angioedema, and urticaria.

Nervous System Disorders

Dysgeusia, tremor.

Psychiatric Disorders

Anxiety.

Renal and Urinary Disorders

Dysuria, urinary retention.

Respiratory, Thoracic, and Mediastinal Disorders

Dysphonia, paradoxical bronchospasm.

7 DRUG INTERACTIONS

7.1 Inhibitors of Cytochrome P450 3A4

Vilanterol, a component of ANORO ELLIPTA, is a substrate of CYP3A4. Concomitant administration of the strong CYP3A4 inhibitor ketoconazole increases the systemic exposure to vilanterol. Caution should be exercised when considering the coadministration of ANORO ELLIPTA with ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) *[see Warnings and Precautions (5.4), Clinical Pharmacology (12.3) of full prescribing information]*.

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants

Vilanterol, like other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

7.3 Beta-adrenergic Receptor Blocking Agents

Beta-blockers not only block the pulmonary effect of beta-agonists, such as vilanterol, a component of ANORO ELLIPTA, but may also produce severe bronchospasm in patients with COPD. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents for these patients; cardioselective beta-blockers could be considered, although they should be administered with caution.

7.4 Non–Potassium-Sparing Diuretics

The electrocardiographic changes and/or hypokalemia that may result from the administration of non–potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, such as vilanterol, a component of ANORO ELLIPTA, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of ANORO ELLIPTA with non–potassium-sparing diuretics.

7.5 Anticholinergics

There is potential for an additive interaction with concomitantly used anticholinergic medicines. Therefore, avoid coadministration of ANORO ELLIPTA with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects *[see Warnings and Precautions (5.9, 5.10), Adverse Reactions (6)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are insufficient data on the use of ANORO ELLIPTA or its individual components, umeclidinium and vilanterol, in pregnant women to inform a drug-associated risk. *(See Clinical Considerations.)* In animal reproduction studies, umeclidinium administered via inhalation or subcutaneously to pregnant rats and rabbits was not associated with adverse effects on embryofetal development at exposures approximately 50 and 200 times, respectively, the human exposure at the maximum recommended human daily inhaled dose (MRHDID). Vilanterol administered via inhalation to pregnant rats and rabbits produced no fetal structural abnormalities at exposures approximately 70 times the MRHDID. *(See Data.)*

The estimated risk of major birth defects and miscarriage for the indicated populations is unknown. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Labor and Delivery: There are no human studies evaluating the effects of ANORO ELLIPTA, umeclidinium, or vilanterol during labor and delivery. Because of the potential for beta-agonist interference with uterine contractility, use of ANORO ELLIPTA during labor should be restricted to those patients in whom the benefits clearly outweigh the risks.

Data

Animal Data: The combination of umeclidinium and vilanterol has not been studied in pregnant animals. Studies in pregnant animals have been conducted with umeclidinium and vilanterol individually.

Umeclidinium: In separate embryofetal developmental studies, pregnant rats and rabbits received umeclidinium during the period of organogenesis at doses up to approximately 50 and 200 times the MRHDID, respectively (on an AUC basis at maternal inhalation doses up to 278 mcg/kg/day in rats and at maternal subcutaneous doses up to 180 mcg/kg/day in rabbits). No evidence of teratogenic effects was observed in either species.

In a perinatal and postnatal developmental study in rats, dams received umeclidinium during late gestation and lactation periods with no evidence of effects on offspring development at doses up to approximately 26 times the MRHDID (on an AUC basis at maternal subcutaneous doses up to 60 mcg/kg/day).

Vilanterol: In separate embryofetal developmental studies, pregnant rats and rabbits received vilanterol during the period of organogenesis at doses up to approximately 13,000 and 450 times, respectively, the MRHDID (on a mcg/m^2 basis at maternal inhalation doses up to 33,700 mcg/kg/day in rats and on an AUC basis at maternal inhaled doses up to 5,740 mcg/kg/day in rabbits). No evidence of structural abnormalities was observed at any dose in rats or in rabbits up to approximately 70 times the MRHDID (on an AUC basis at maternal doses up to 591 mcg/kg/day in rabbits). However, fetal skeletal variations were observed in rabbits at approximately 450 times the MRHDID (on an AUC basis at maternal inhaled or subcutaneous doses of 5,740 or 300 mcg/kg/day, respectively). The skeletal variations included decreased or absent ossification in cervical vertebral centrum and metacarpals.

In a perinatal and postnatal developmental study in rats, dams received vilanterol during late gestation and the lactation periods at doses up to approximately 3,900 times the MRHDID (on a mcg/m^2 basis at maternal oral doses up to 10,000 mcg/kg/day). No evidence of effects in offspring development was observed.

8.2 Lactation

Risk Summary

There is no information available on the presence of umeclidinium or vilanterol in human milk, the effects on the breastfed child, or the effects on milk production. Umeclidinium was detected in the plasma of offspring of lactating rats treated with umeclidinium suggesting its presence in maternal milk. *(See Data.)* The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ANORO ELLIPTA and any potential adverse effects on the breastfed child from umeclidinium or vilanterol or from the underlying maternal condition.

Data

Subcutaneous administration of umeclidinium to lactating rats at ≥60 mcg/kg/day resulted in a quantifiable level of umeclidinium in 2 of 54 pups, which may indicate transfer of umeclidinium in milk.

8.4 Pediatric Use

ANORO ELLIPTA is not indicated for use in children. The safety and efficacy in pediatric patients have not been established.

8.5 Geriatric Use

Based on available data, no adjustment of the dosage of ANORO ELLIPTA in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

Clinical trials of ANORO ELLIPTA for COPD included 2,143 subjects aged 65 years and older and 478 subjects aged 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

8.6 Hepatic Impairment

Patients with moderate hepatic impairment (Child-Pugh score of 7-9) showed no relevant increases in C_{max} or AUC, nor did protein binding differ between subjects with moderate hepatic impairment and their healthy controls. Studies in subjects with severe hepatic impairment have not been performed *[see Clinical Pharmacology (12.3) of full prescribing information]*.

8.7 Renal Impairment

There were no significant increases in either umeclidinium or vilanterol exposure in subjects with severe renal impairment (CrCl <30 mL/min) compared with healthy subjects. No dosage adjustment is required in patients with renal impairment *[see Clinical Pharmacology (12.3) of full prescribing information]*.

10 OVERDOSAGE

No case of overdose has been reported with ANORO ELLIPTA.

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

10.1 Umeclidinium

High doses of umeclidinium may lead to anticholinergic signs and symptoms. However, there were no systemic anticholinergic adverse effects following a once-daily inhaled dose of up to 1,000 mcg of umeclidinium (16 times the maximum recommended daily dose) for 14 days in subjects with COPD.

10.2 Vilanterol

The expected signs and symptoms with overdosage of vilanterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms of beta-adrenergic stimulation (e.g., angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, hyperglycemia, hypokalemia, metabolic acidosis). As with all inhaled sympathomimetic medicines, cardiac arrest and even death may be associated with an overdose of vilanterol.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

ANORO ELLIPTA

No studies of carcinogenicity, mutagenicity, or impairment of fertility were conducted with ANORO ELLIPTA; however, studies are available for the individual components, umeclidinium and vilanterol, as described below.

Umeclidinium

Umeclidinium produced no treatment-related increases in the incidence of tumors in 2-year inhalation studies in rats and mice at inhaled doses up to 137 and 295/200 mcg/kg/day (male/female), respectively (approximately 20 and 25/20 times the MRHDID in adults on an AUC basis, respectively).

Umeclidinium tested negative in the following genotoxicity assays: the in vitro Ames assay, in vitro mouse lymphoma assay, and in vivo rat bone marrow micronucleus assay.

No evidence of impairment of fertility was observed in male and female rats at subcutaneous doses up to 180 mcg/kg/day and at inhaled doses up to 294 mcg/kg/day, respectively (approximately 100 and 50 times, respectively, the MRHDID in adults on an AUC basis).

Vilanterol

In a 2-year carcinogenicity study in mice, vilanterol caused a statistically significant increase in ovarian tubulostromal adenomas in females at an inhalation dose of 29,500 mcg/kg/day (approximately 7,800 times the MRHDID in adults on an AUC basis). No increase in tumors was seen at an inhalation dose of 615 mcg/kg/day (approximately 210 times the MRHDID in adults on an AUC basis).

In a 2-year carcinogenicity study in rats, vilanterol caused statistically significant increases in mesovarian leiomyomas in females and shortening of the latency of pituitary tumors at inhalation doses greater than or equal to 84.4 mcg/kg/day (greater than or equal to approximately 20 times the MRHDID in adults on an AUC basis). No tumors were seen at an inhalation dose of 10.5 mcg/kg/day (approximately equivalent to the MRHDID in adults on an AUC basis).

These tumor findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown.

Vilanterol tested negative in the following genotoxicity assays: the in vitro Ames assay, in vivo rat bone marrow micronucleus assay, in vivo rat unscheduled DNA synthesis (UDS) assay, and in vitro Syrian hamster embryo (SHE) cell assay. Vilanterol tested equivocal in the in vitro mouse lymphoma assay.

No evidence of impairment of fertility was observed in male and female rats at inhaled vilanterol doses up to 31,500 and 37,100 mcg/kg/day, respectively (both approximately 5,490 times the MRHDID based on AUC).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA approved patient labeling (Patient Information and Instructions for Use).

Serious Asthma-Related Events

ANORO ELLIPTA is not indicated for the treatment of asthma. Inform patients that LABA, such as vilanterol (one of the active ingredients in ANORO ELLIPTA), when used alone (without ICS) for asthma increase the risk of asthma-related hospitalization or asthma-related death.

Not for Acute Symptoms

Inform patients that ANORO ELLIPTA is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Advise patients to treat acute symptoms with an inhaled, short-acting beta$_2$-agonist such as albuterol. Provide patients with such medicine and instruct them in how it should be used.

Instruct patients to seek medical attention immediately if they experience any of the following:

- Decreasing effectiveness of inhaled, short-acting beta$_2$-agonists
- Need for more inhalations than usual of inhaled, short-acting beta$_2$-agonists
- Significant decrease in lung function as outlined by the physician

Tell patients they should not stop therapy with ANORO ELLIPTA without healthcare provider guidance since symptoms may recur after discontinuation.

Do Not Use Additional Long-acting Beta$_2$-agonists

Instruct patients not to use other medicines containing a LABA. Patients should not use more than the recommended once-daily dose of ANORO ELLIPTA.

Instruct patients who have been taking inhaled, short-acting beta$_2$-agonists on a regular basis to discontinue the regular use of these products and use them only for the symptomatic relief of acute symptoms.

Paradoxical Bronchospasm

As with other inhaled medicines, ANORO ELLIPTA can cause paradoxical bronchospasm. If paradoxical bronchospasm occurs, instruct patients to discontinue ANORO ELLIPTA and contact their healthcare provider right away.

Risks Associated with Beta-agonist Therapy

Inform patients of adverse effects associated with beta$_2$-agonists, such as palpitations, chest pain, rapid heart rate, tremor, or nervousness.

Worsening of Narrow-Angle Glaucoma

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

Worsening of Urinary Retention

Instruct patients to be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develop.

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CHEST 2019 ATTENDEE PROFILE

JANNA LANDSPERGER, APRN-BC
Nurse Practitioner, MICU,
Vanderbilt University Medical Center

CHEST 2019
Co-Chair Critical Skills for Critical Care
Live Learning Subcommittee Member

Hometown:
St. Louis, MO

Residence:
Nashville, TN

This is the first time the CHEST Annual Meeting has taken place in New Orleans since 1997. What were you doing in that year?
In 1997, I was in high school! I was probably listening to the debut 98˚ album.

If you could arrange a one-on-one mentor session with one presenter, who would it be and why?
Ruth Kleinpell. She is an amazing leader for advanced practice providers working in critical care.

Do you think your pet knows you're away from home? What is its name?
I do not have a pet, but I have two young sons who definitely know that mama is away.

How did you get your start in the critical care field?
I started working in critical care when I was in my first year of nursing school. I got a job in the ICU as a care partner and was immediately drawn to critical care. After I finished nursing school, I worked in the ICU as an RN while attending NP school. So it was only natural that when I graduated NP school, I continued working in the ICU.

What is your favorite thing to do outside of work?
Spend time with my family—taking bike rides with my sons, visiting live music venues around Nashville, and vacationing at the beach

What do you enjoy most about the CHEST Annual Meeting?
Seeing old friends, meeting new friends, and the live learning opportunities

Who is your favorite person to follow on Twitter in the critical care profession?
I am not on any social media, but if I was, I'd follow Todd Rice!

What is your favorite thing about New Orleans and your favorite Cajun or Creole dish?
The music in New Orleans is amazing! And I love crawfish étouffée.

Caregiver education on technology highlighted in tracheostomy session

As an advanced practice nurse in the division of pulmonary medicine at The Children's Hospital of Philadelphia, Laura Miske, MSN, is committed to illuminating the dangers facing technology-dependent patients every day. On Wednesday, Miske, chair of the session, and her co-presenters will shed light on the unique issues presented by one apparatus through the session *Management of Tracheostomy: Before Placement, Before Home, and During Emergencies* at 3:45 PM in room 262 of the convention center. Miske sat down with *Daily News* to discuss issues in educating caregivers about tracheostomies, in anticipation of her session.

SESSION PREVIEW

WEDNESDAY
3:45 PM – 4:45 PM
Management of Tracheostomy: Before Placement, Before Home, and During Emergencies
Convention Center, Room 262

→ ***Daily News:*** Over 1,500 people in the U.S. alone die, are permanently disabled, or otherwise hurt in connection with a tracheostomy annually. Why do tracheostomy tubes lead to medical emergencies and fatalities?

→ **Miske:** A tracheostomy tube is an artificial airway that the patient uses instead of his natural airway to breathe. The tracheostomy tube does not enable the natural movement of secretions from the airways towards the mouth, and its presence can increase the amount of secretions made by the airway lining cells. In some situations, the tracheostomy bypasses a life-threatening narrowing of the natural airway; if prompt recognition of its inadvertent displacement or blockage does not occur, patients can be harmed. In addition, many patients with a tracheostomy tube cannot replace it themselves, and once this type of emergency occurs, they may not be able to call for help—even if they normally could talk.

→ ***Daily News:*** What are some observations you've made about how caregivers are educated or miseducated about tracheostomy tubes?

→ **Miske:** The scope of education varies greatly from facility to facility. Sometimes only the basics are shown to the caregivers at home. They may not be required to demonstrate competence prior to discharge. Discharge teaching can range from a few hours in one day to a 6-8 week program. A delay in intervention or lack of knowledge regarding the correct intervention or what constitutes an emergency can mean the difference between a successful discharge or readmission and increased morbidity.

→ ***Daily News:*** Your session will address the diversity of education programs for tracheostomy management. What would you identify as the three most fundamental tenets of an effective caregiver program for tracheostomies?

→ **Miske:** 1. Discussion of tracheostomy, 2. Global respiratory assessment and skill practice for routine care as well as recognition of emergencies, and 3. Competency demonstration in all aspects of care.

→ ***Daily News:*** Share your vision with us: What does the development and rollout of a standardized training program for managing and responding to tracheostomy emergencies look like?

"It is vital that caregivers understand how the placement of a tracheostomy will affect the global function of the patient and how the tracheostomy would impact their families and themselves as caregivers."

LAURA MISKE, MSN

→ **Miske:** This really depends on the facility, type of patient, and airway anatomy. Younger and more disabled patients require skilled caregivers with a better knowledge base. Standardized programs for discharge with all components of care taught and practiced prior to a 24-72-hour independent stay prior to discharge would be the ideal. Simulation labs can be very helpful in offering practice for situations that caregivers need to know the correct interventions, but may not have the opportunity to practice on their loved one, prior to discharge. A true standardized program would have a dedicated team of educators of this information, rather than staff RTs and RNs trying to fit it into their daily workload.

→ ***Daily News:*** Your session is being presented at a time of increased focus on the identities, education, and care of caregivers. How would you recommend that the medical practitioners attending your session better support the needs of caregivers overall?

→ **Miske:** Medical caregivers view a tracheostomy tube as the defining step toward discharge. This may or may not be true and a tracheostomy does not always make life better for patients or family members. True education would include the pros and cons of placing vs refusing a tracheostomy tube, so including quality of life in the education decision-making process would be important. Once the tracheostomy is placed, involving the caregivers on a daily basis in decision-making and skill improvement is vital to a successful discharge. Helping to recognize patients that may benefit from a tracheostomy but are not suitable for discharge to home is also an important role of health-care providers, so that patients and family members feel supported in whatever decision they make. It is vital that caregivers understand how the placement of a tracheostomy will affect the global function of the patient and how the tracheostomy would impact their families and themselves as caregivers.

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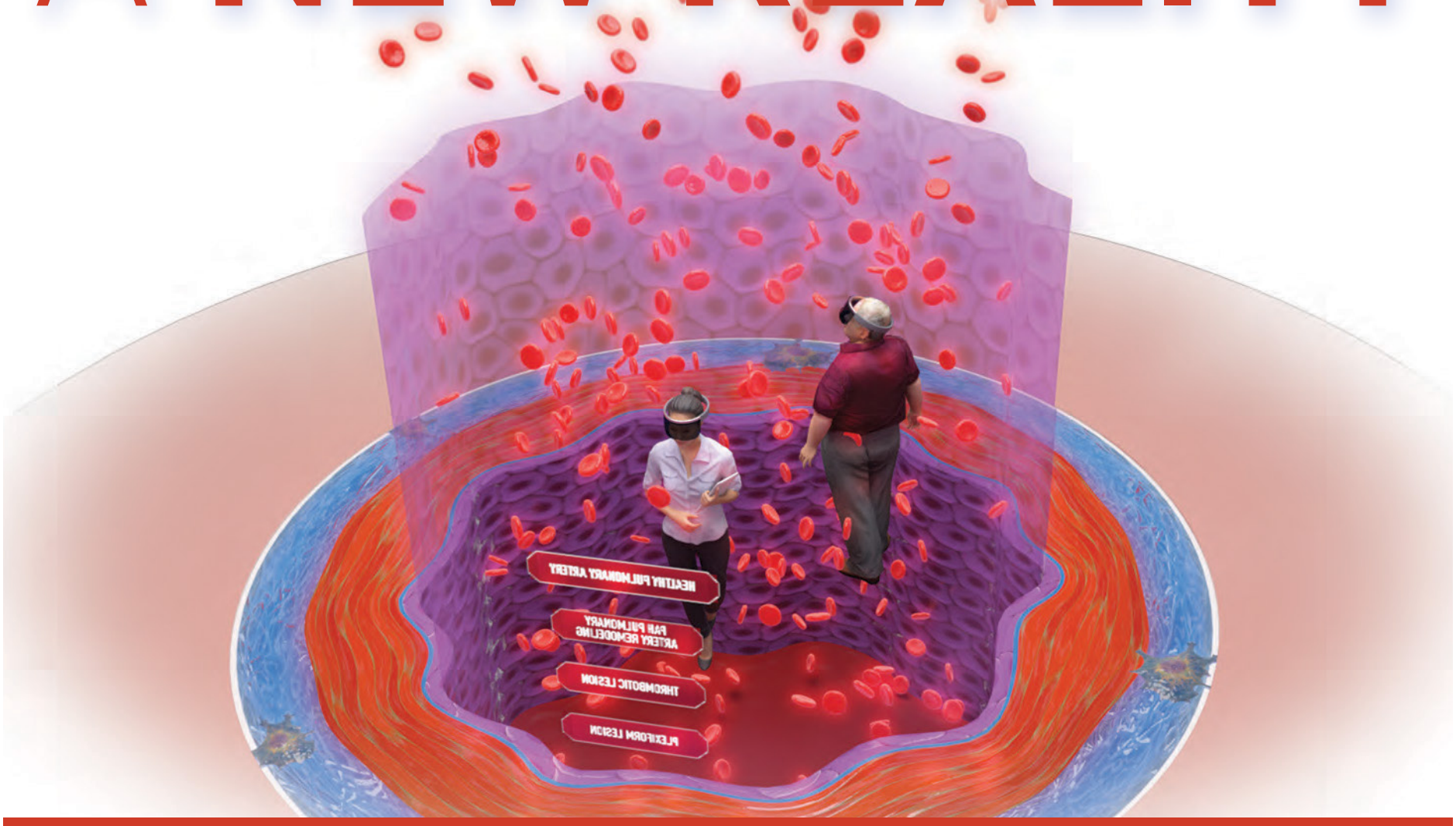

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Fresh multidisciplinary perspectives inform timely Case Puzzlers session

As director of the pulmonary and critical care medicine fellowship at New York-Presbyterian Brooklyn Methodist Hospital, Anthony Saleh, MD, FCCP, is committed to extending opportunities for expertise honing and presentation to individuals who have not yet achieved fame in the field.

"It gives me such pleasure to see fellows come in wet behind the ears, and by the time they leave, they're experts in pulmonary and critical care," Dr. Saleh said, reflecting on working with fellows. "Then through 'case puzzlers' programs, these people who don't have big faculty appointments get a chance to have well-known academic physicians look at how they've managed cases. Often times, the well-known academicians are appreciative of the management insights provided by physicians who are early in their careers."

This is one of several reasons why Dr. Saleh is excited to chair the *Cystic/Cavitary Lung Disease Case Puzzlers* session on Wednesday at 8:45 AM in room 295 of the convention center.

The session will feature a panel presentation of two cavitary and cystic lung disease cases—one based in the U.S. and the other international. After each case is presented, a clinician, a pathologist, and a radiologist will then dissect it, share their own field-based strategies for understanding it, and arrive at a diagnosis together. Then, Dr. Saleh will open the floor to the session attendees, inviting them to explain why they agree or disagree with each diagnosis.

Although the session has been designed primarily for pulmonary-critical care physicians seeking to augment their knowledge of cystic and cavitary lung diseases, Dr. Saleh believes that it is timely and broad in its relevance.

"In many instances, these cavitary and cystic lung diseases are systemic," Dr. Saleh said. "Many people diagnosed with them have cardiac issues, gastrointestinal issues, and rheumatological issues that began in their lungs."

One recent social phenomenon appears to be a growing factor in cystic and cavitary lung disease cases, as Dr. Saleh reports: "Vaping is having devastating consequences. The lung diseases it causes can manifest as cystic and cavitary. This is not only a medical issue; it's also a societal issue requiring people to get their acts together and not vape."

Ultimately, Dr. Saleh hopes that attendees will leave the session as better advocates for their patients. He believes this will come from enhanced understanding of how to work together as clinicians, pathologists, radiologists, and other medical practitioners to make prompt diagnoses for cystic and cavitary lung diseases, which can manifest as lung cancer, tuberculosis, lymphangioleiomyomatosis, and a number of other deadly diseases. These diseases often cause rapid deterioration, Dr. Saleh explains, so prompt treatments are required for them.

Attendees should arrive at the session knowing that it will be interactive, with input even from newcomers to the field welcomed and multidisciplinary perspectives encouraged throughout the hour.

ANTHONY SALEH, MD, FCCP

SESSION PREVIEW

WEDNESDAY
8:45 AM – 9:45 AM

Cystic/Cavitary Lung Disease Case Puzzlers

Convention Center, Room 295

Investigators to share data on links between sleep pnea-related hypoxia, disease

THE PREVALENCE OF OBSTRUCTIVE sleep apnea has reached epidemic levels in the United States, increasing the need for a better understanding of how intermittent hypoxia related to this disorder contributes to pathology.

This Wednesday morning, two expert investigators will demonstrate which patterns of chronic hypoxia play a role in causing disease and organ dysfunction. The session, *Sleep Apnea-Related Intermittent Hypoxia and End-Organ Dysfunction: Insights Into Mechanistic Pathways*, will take place at 7:30 AM in room 295 of the convention center.

KRISHNA SUNDAR, MD, MBBS, FCCP

Session chair Krishna Sundar, MD, MBBS, FCCP, who is medical director of the Sleep-Wake Center at the University of Utah, said chronic intermittent hypoxia appears to be the primary mechanism by which sleep apnea causes widespread disease. Understanding these mechanistic pathways is important to understanding how sleep apnea leads to disease, he said.

"With sleep-disordered breathing—or sleep apnea—one of the main ways it manifests is with anomalies in oxygenation," Dr. Sundar said. "These anomalies in oxygenation are thought to be the main way sleep apnea leads to or aggravates problems like atherosclerotic vascular disease, dementia, heart failure, chronic kidney disease, nonalcoholic fatty liver disease, etc. There's a plethora of problems that have been linked to sleep apnea, and intermittent hypoxia appears to be a predominant pathway that leads to all of these problems.

"One of the big problems for researchers has been trying to understand the risk of these diseases in relation to the measures we use to categorize the severity of sleep apnea and the subsequent oxygenation abnormalities."

Indeed, there's a vast body of literature—particularly at the basic science level—looking at associations between oxygen abnormalities and disease occurrence.

"The earlier we start understanding this relationship between oximetry anomalies and disease risk, the better we'll be able to prognosticate the implications of these anomalies," he said.

While the area of chronic hypoxia research has grown, Dr. Sundar said it's time to translate the growing knowledge into clinical care so practitioners can be aware of the knowledge gaps and the mechanistic pathways to understand how abnormal oxygen values translate into disease.

SESSION PREVIEW

WEDNESDAY
7:30 AM – 8:30 AM

Sleep Apnea-Related Intermittent Hypoxia and End-Organ Dysfunction: Insights Into Mechanistic Pathways

Convention Center, Room 295

As part of his presentation, Dr. Sundar will also review data on various kinds of hypoxia and demonstrate how hypoxia related to sleep apnea is different and more detrimental than other forms of hypoxia, such as those seen in chronic lung disease or high altitude exposure.

The session also will include a lecture by researcher Vsevolod Y. Polotsky MD, PhD, professor of medicine at Johns Hopkins University School of Medicine, who will discuss adipocyte and hepatic dysfunction in intermittent hypoxia.

"Dr. Polotsky has worked extensively with mice models and has significant data on intermittent hypoxia to share with the audience," Dr. Sundar said. "It's time to start moving this research to clinical applications. Even though this session will be heavy on basic science, the clinical implications regarding how hypoxia is sensed by different tissues and how it can affect patients is critical for clinicians to understand."

"With sleep-disordered breathing—or sleep apnea—one of the main ways it manifests is with anomalies in oxygenation. These anomalies in oxygenation are thought to be the main way sleep apnea leads to or aggravates problems like atherosclerotic vascular disease, dementia, heart failure, chronic kidney disease, nonalcoholic fatty liver disease, etc. There's a plethora of problems that have been linked to sleep apnea, and intermittent hypoxia appears to be a predominant pathway that leads to all of these problems."

KRISHNA SUNDAR, MD, MBBS, FCCP

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Critical care experts to examine efficacy of common ICU practices

SESSION PREVIEW

WEDNESDAY
8:45 AM – 9:45 AM

Choosing Wisely in the ICU: When Less is More

Convention Center, Room 287

For many years, ICU medicine has meant aggressive care—many catheters and devices, multiple medications, and frequent tests of various kinds. However, little evidence exists to support these practices. And, in fact, some of these common protocols may be causing unwanted adverse effects for ICU patients.

During a session this Wednesday morning, four experts will review the relevant evidence in four key areas: nutrition, invasive lines and catheters, sedation and paralysis, and diagnostic tests and imaging. The session, *Choosing Wisely in the ICU: When Less is More*, will take place at 8:45 AM in room 287 of the convention center.

Session chair Mangalore Amith Shenoy, MBBS, of New York University's Langone Health, will begin the discussion with a look at nutrition in the ICU.

"I will primarily focus on low-calorie nutrition, including why we should choose enteral over parenteral nutrition whenever feasible," he said. "One of the main takeaways is that patients do just as well with lower calorie diets. We will also look at the utility of nutritional supplementation in the ICU."

MANGALORE AMITH SHENOY, MBBS

Next, Michelle Royse, MSN, APN, NP-C, an ICU nurse practitioner at Carle Foundation Hospital, will discuss the appropriate use of invasive lines and catheters in the ICU.

"When we're talking about lines, especially central lines, there are some areas where you don't need them," Dr. Shenoy said. "For example, you don't always need a central line for hypertonic saline. You don't always need a urinary catheter. Royse will review what the evidence says about when you can minimize the use of invasive lines and devices and discuss the alternatives. This is particularly important because many times these invasive devices predispose patients to complications."

Vishesh Paul, MD, FCCP, a critical care and pulmonary specialist also at Carle Foundation Hospital, will then discuss how the practice of sedation and paralysis has changed during the past few years in the ICU.

"He will share evidence that shows how switching to less sedation and paralysis is helping reduce important ICU parameters like days on ventilator and length of stay," Dr. Shenoy said.

Finally, Seth J. Koenig, MD, FCCP, director of education in the division of pulmonary medicine at Montefiore Medical Center, will review data on the use of ultrasound in the ICU and how clinicians can use ultrasound for daily imaging to make clinical decisions.

"By utilizing ultrasound, clinicians can minimize the use of other imaging like chest x-rays, which are widely used in the ICU. Patients do not need daily chest x-rays," Dr. Shenoy said. "There is data now that shows reducing x-rays may improve outcomes in the ICU.

"By reviewing the data on these common ICU practices, attendees will know what studies they can turn to for further information. They should also come away with a better understanding of when certain interventions are truly helpful and when they may be harmful."

CME/CE Credit and ABIM MOC Points

PHYSICIAN CREDIT

The American College of Chest Physicians is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The American College of Chest Physicians designates this live activity for a maximum of 33.5 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

SLEEP MEDICINE CREDIT

The CME certificate will designate the total amount of Sleep Medicine credit available for the meeting.

NURSING CREDIT

Provider approved by the California Board of Registered Nursing, Provider Number 16433, for 33.5 contact hours.

RESPIRATORY THERAPIST (CRCE) CREDIT

Application has been made to the American Association for Respiratory Care (AARC) for continuing education contact hours for respiratory therapists.

PHYSICIAN ASSISTANT CREDIT

American Academy of Physician Assistants (AAPA) accepts certificates of participation for educational activities certified for *AMA PRA Category 1 Credit*™ from organizations accredited by ACCME or a recognized state medical society. PAs may receive a maximum of 33.5 Category 1 credits for completing this activity.

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The American Academy of Nurse Practitioners Certification Board (AANPCB) accepts *AMA PRA Category 1 Credit*™ from organizations accredited by the ACCME. Individuals are responsible for checking with the AANPCPB for further guidelines.

FOR EUROPEAN ATTENDEES

The European Board for Accreditation in Cardiology (EBAC) will recognize certificates obtained by European physicians who attend cardiovascular medicine activities offered by US providers accredited within the ACCME system. Those physicians would submit their CME certificate from CHEST directly to EBAC in order to have EBAC credit awarded.

ABIM MOC STATEMENT

Successful completion of this CME activity enables the participant to earn up to 33.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC points.

Upon successful completion of this course, CHEST will submit your completion data to ABIM via ACCME's Program and Activity Reporting System (PARS) for MOC points. Please allow 3-5 business days after claiming for points to appear on your ABIM record.

DISCLOSURE STATEMENT

CHEST remains strongly committed to providing the best available evidence-based clinical information to participants of this educational activity and requires an open disclosure of any relevant financial relationships that create a conflict of interest. It is not the intent of CHEST to disqualify anyone from participating in this educational activity, but to resolve any conflicts of interest that may arise from financial relationships with commercial interests. All conflicts of interest are reviewed by the educational activity course director/chair, the Education Committee, and/or the Professional Standards Committee to ensure that such situations are properly evaluated and, if necessary, resolved. CHEST educational standards pertaining to conflict of interest are intended to maintain the professional autonomy of the clinical experts inherent in promoting a balanced presentation of science. Through our review process, all CHEST CME activities are ensured of independent, objective, scientifically balanced presentations of information. Disclosure of any or no relevant financial relationships will be made available on-site during all educational activities.

WHERE AT THE CHEST MEETING IS DR. KELLY?

Keep an eye out for CHEST 2019 Program Chair William Kelly, MD, FCCP, throughout the meeting. He'll be popping up throughout the convention center with a variety of surprises at CHEST 2019.

→ Follow his **#CHEST2019** adventures on Twitter **@williamkellymd**.

Four things to know about biowarfare and chest physician empowerment now

Joel Anthony Nations, MD, MBA, is a Navy pulmonary and critical care physician stationed at Walter Reed National Military Medical Center. He is also a graduate of the Naval War College with a specialization in irregular warfare. Dr. Nations has assembled a team of experts to discuss the relationship between biological warfare and epidemics that mirror it in terms of their impact and treatment on Wednesday at 10:45 AM in room 294 of the convention center. They will present *Measles, Ebola and Anthrax Oh My! Are You and Your Hospital Ready?* to discuss biological warfare alongside other emerging, preventable diseases.

Here, Dr. Nations shares four things you should know about the subject before attending the session:

JOEL ANTHONY NATIONS, MD, MBA

1. Biological warfare would uniquely impact the work of chest physicians.
Several of the high-priority biological agents include organisms that can present as respiratory illness and/or critical illness, including anthrax, smallpox, tularemia, and the viral hemorrhagic fevers. Therefore, chest physicians would be involved in the initial diagnosis and eventual care of patients affected by biological warfare.

> "The session will ensure that attendees understand the current biowarfare threat, the surveillance and support systems that exist to address, the similarities and differences between naturally occurring disease outbreaks and intentional use of biologic agents, and the likely agents of biowarfare."
>
> **JOEL ANTHONY NATIONS, MD, MBA**

2. Preventive measures for biological warfare are currently a priority for the U.S. Department of Homeland Security.
Surveillance systems, such as the U.S. Department of Homeland Security's Biowatch Program, are actively monitoring the United States for biologic agents in order to assist with the early detection and treatment of them. The Centers for Disease Control and Prevention's Strategic National Stockpile is maintained for public health emergencies, including agents of biological warfare.

3. Outbreaks of diseases such as anthrax, tularemia, plague, or other potentially weaponizable agents may be natural or due to human action. However, our immediate actions taken to address these outbreaks would be similar regardless of cause or motive.
Historical lessons have been learned from intentional use of biological agents in the United States, including Salmonella in the 1980s and anthrax in 2001. Naturally occurring outbreaks of SARS and Ebola provide a framework to understand the risk of intentional use of biologic agents.

4. In the unlikely event of a biological agent outbreak, chest physicians should feel empowered to address it after participating in the session.
The session will ensure that attendees understand the current biowarfare threat, the surveillance and support systems that exist to address, the similarities and differences between naturally occurring disease outbreaks and intentional use of biologic agents, and the likely agents of biowarfare. Presentation, transmission, and treatment options will be shared and discussed during the hour.

All conference registrants are invited to participate.

SESSION PREVIEW

WEDNESDAY
10:45 AM – 11:45 AM

Measles, Ebola and Anthrax Oh My! Are You and Your Hospital Ready?

Convention Center, Room 294

Obesity experts to examine severity of epidemic, offer tools to address it

Pulmonologists encounter obesity in clinical practice on a daily basis. Unfortunately, experts say the impact of obesity on a patient's pulmonary problems is underappreciated.

In an effort to change that, Lauren Tobias, MD, an assistant professor of pulmonary, critical care, and sleep medicine at Yale School of Medicine, will chair a session this Wednesday morning to highlight the severity of the obesity epidemic and give clinicians tools to address it.


LAUREN TOBIAS, MD

The session, *The Obesity Epidemic: Implications for Pulmonologists,* will take place at 8:45 AM in room 294 of the convention center. The session will review the relationship between obesity, which affects 40% of adults worldwide, and pulmonary disorders.

Dr. Tobias said she is excited for this opportunity to educate attendees about the impact obesity has on their patients.

"Despite frequently encountering patients with obesity, we often struggle to help patients manage their weight," Dr. Tobias said. "My goal in proposing this session was to not only highlight the scope of the problem but also to equip providers with tools to help address it. We will first review the evidence linking obesity to pulmonary disease and then discuss the efficacy of treatments including medical, behavioral, and surgical options."

Dr. Tobias said that although many obesity-related conditions, such as heart disease, stroke, and type 2 diabetes, are well recognized, the impact of obesity on pulmonary diseases— including asthma, obstructive sleep apnea, and obesity hypoventilation—has received less attention. Obesity also disproportionately affects certain socioeconomic groups and may thereby contribute to worsening health-care disparities.

During this session, pulmonologists will learn about the physiologic effects of obesity on the lung, the impact of obesity on asthma control, and interventions to help patients with weight management, including medications, behavioral strategies, and weight loss surgery.

"I hope participants leave feeling they have a better understanding of when and how to address obesity in the pulmonary clinic," Dr. Tobias said. "Like tobacco cessation, helping our patients with weight management is every clinician's responsibility."

Dr. Tobias will begin the session with a talk on the effects of obesity on respiratory physiology, which will be followed by a talk on the evidence-based management of obesity by Donna Ryan, MD, associate executive director for clinical research at Pennington Biomedical Research Center.

Then, Fernando Holguin, MD, professor of medicine at the University of Colorado School of Medicine, will discuss recent evidence suggesting that obesity is becoming an increasing determinant of asthma morbidity. He will review data that demonstrate that interventions targeting weight, dietary components, lifestyle, and metabolism may improve outcomes in asthma.

Next, Sairam Parthasarathy, MD, professor of medicine at the University of Arizona College of Medicine, will present "Obesity & Sleep: Are We Failing to Detect Obesity Hypoventilation?"

Finally, John W. Baker, MD, an expert on weight loss surgery and past president of the American Society for Metabolic & Bariatric Surgery, will review the current evidence on efficacy of various weight loss modalities, including their impact on lung function.

SESSION PREVIEW

TUESDAY
8:45 AM – 9:45 AM
The Obesity Epidemic: Implications for Pulmonologists
Convention Center, Room 294

Honor and Memorial Lectures and Annual Awards

Each year, CHEST honors physicians and others who are making significant or meritorious contributions to chest medicine. All honorees are recognized for advancing work in specific areas of chest medicine, mentorship, training, furthering the work of CHEST, and more. The individuals who are selected for these lectureships have been nominated and selected by their peers.

THE 2019 HONOR AND MEMORIAL LECtures and Annual Awards cover the areas of educators, critical care, cardiopulmonary physiology, interventional medicine, mechanical ventilation, COPD, sarcoidosis, and more.

WEDNESDAY | 8:45 AM – 9:45 AM

Om P. Sharma, MD, Master FCCP, Memorial Lecture

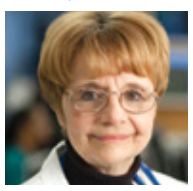

MICHAEL C. IANNUZZI, MD, FCCP

This lecture award honors the memory of Om P. Sharma, MD, Master FCCP, whose passionate work on the clinical aspects of sarcoidosis and other granulomatous disorders spanned 40 years. This award is conferred to a CHEST Fellow (FCCP) known for their work in sarcoidosis and other granulomatous disorders, including state-of-the art innovations, advancing understanding of the disorders, pathogenetic mechanisms, clinical evaluation, and treatment.

The lecture is generously funded by the CHEST Foundation.

WEDNESDAY | 10:45 AM – 11:45 AM

Murray Kornfeld Memorial Founders Lecture


DIANE E. STOVER, MD, FCCP

This lecture was established in 1974 in memory of Murray Kornfeld, founder of the Federation of American Sanatoria, which later became CHEST. This award is conferred to a leader in pulmonary and critical care medicine, particularly in infection and inflammation, who is developing therapies expected to guide medicine into the future.

The lecture is generously funded by the CHEST Foundation.

ANNUAL AWARDS

Distinguished Service Award


DOREEN ADDRIZZO-HARRIS, MD, FCCP

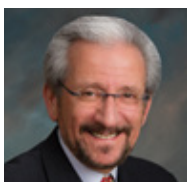
This award is conferred to a CHEST Fellow (FCCP) who has held a CHEST leadership position and has led significant achievements and/or has donated time, leadership, and service to CHEST.

Master Fellow Award


DARCY D. MARCINIUK, MD, FCCP

Masters of CHEST are national or international Fellows of CHEST who have distinguished themselves by attaining professional preeminence. Because of their personal character and leadership; extraordinary contributions to medical research, clinical practice, quality improvement, or medical education; and years of enduring and outstanding service to CHEST, they have advanced chest medicine.

Alfred Soffer Award for Editorial Excellence


RICHARD IRWIN, MD, MASTER FCCP

This award honors Alfred Soffer, Master FCCP, Editor in Chief of the journal *CHEST*® from 1968 to 1993, and Executive Director of CHEST from 1969 to 1992. Recipients have made significant contributions to CHEST and are often world experts in their fields, have written numerous papers and abstracts, have served as primary investigators, and/or have served as a department editor for the journal *CHEST*.

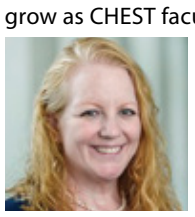
Master Clinician Educator Award

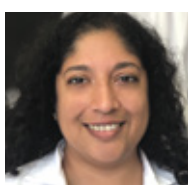

ERIC EDELL, MD, FCCP

The Master Clinician Educator Award recognizes long-term achievements of one clinician educator who has made significant contributions to CHEST activities and has demonstrated a strong commitment to medical education throughout their career.

Early Career Clinician Educator Award

The Early Career Clinician Educator Award recognizes the achievements of a clinician educator who has already made significant contributions to CHEST educational activities and is committed to continuing to grow as CHEST faculty.


CASSIE KENNEDY, MD, FCCP


PARU PATRAWALLA, MD, FCCP

Distinguished CHEST Educator (DCE)

The Distinguished CHEST Educator (DCE) designation recognizes the achievements of members who have made significant and long-term contributions to the design and delivery of CHEST education. The DCE provides national-level recognition of excellence in continuing medical education. Designees will be honored at Monday's *Opening Session*.

SCIENTIFIC ABSTRACT AWARDS

Alfred Soffer Research Awards

Presented abstracts will be judged by session moderators, and award recipients will be selected for their outstanding original scientific research. Finalists will be evaluated on the basis of their written abstract and the quality of their oral presentation. This award is named in honor of Alfred Soffer, MD, Master FCCP, who was Editor in Chief of the journal *CHEST*® from 1968 to 1993, and Executive Director of CHEST from 1969 to 1992.

Young Investigator Awards

Investigators who are enrolled in a training or fellowship program or who have completed a fellowship program within 5 years prior to CHEST 2019 are eligible for Young Investigator Awards. Presenters will be evaluated on the basis of their written abstract and presentation. Recipients will be selected by judges from the Scientific Presentations and Awards Committee for their outstanding original scientific research.

Top Five Poster Awards

Awards will be granted to the finalists presenting the top scientific research posters. Presenters will be evaluated on the basis of their written abstract, the quality of their research, and their oral presentation. Award recipients will be selected by judges from the Scientific Presentations and Awards Committee for their outstanding original scientific research and receive a ribbon on-site.