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Improved glottis visualization with video laryngoscopy did not lead to a higher success rate for first-pass intubation.

## Worse outcomes with video laryngoscopy

BY AMY KARON  
Frontline Medical News

When used in intensive care units, video laryngoscopy did not improve the chances of successful intubation on the first try, compared with direct laryngoscopy, and was associated with a significantly higher risk of severe life-threatening complications, researchers reported.

In a multicenter, randomized trial of 371 patients, first-pass intubation rates did not differ significantly whether video or direct laryngoscopy was used, at 67.7% and 70.3%, respectively, Jean Baptiste Lascarrou, MD, of District Hospital Centre, La Roche-sur-Yon,

France, and his associates wrote. Meanwhile, the combined rate of death, cardiac arrest, severe cardiovascular collapse, and hypoxemia was 9.5% with video laryngoscopy and just 2.8% with direct laryngoscopy, a significant difference (JAMA. 2017 Jan 24;317[5]:483-93).

“Improved glottis visualization with video laryngoscopy did not translate into a higher success rate for first-pass intubation, because tracheal catheterization under indirect vision was more difficult, in keeping with earlier data,” the researchers concluded. “Further studies are needed to assess the comparative effectiveness of these two strategies in different clinical

See **Intubation** • page 7

## CF guidelines include lower sweat chloride threshold

BY WHITNEY MCKNIGHT

Frontline Medical News

Updated guidelines for the diagnosis and treatment of cystic fibrosis (CF) include two major changes.

The first important update is that clinicians use the latest classifications of the specific CF transmembrane conductance regulator (CFTR) gene mutations, from the Clinical and Functional Translation of CFTR (CFTR2) database, to aid with making a CF diagnosis in any patient, newborn to adult. The other of these

changes relates to the chloride concentration level used to confirm CF diagnosis through a sweat test. Under the new guidelines, the sweat chloride threshold for “possible” CF or a CF-related disease was reduced to 30 mmol/L of chloride concentration from 40 mmol/L across all ages. The guidelines, written by an international team of collaborators and published by the Cystic Fibrosis Foundation, are available online in the Journal of Pediatrics (2017 Feb;181[suppl]:S4-15. doi: 10.1016/j.jpeds.2016.09.064).

Since its inception in See **CF guidelines** • page 4

## Watch and wait often better than resecting in ground-glass opacities

BY WHITNEY MCKNIGHT

Frontline Medical News

FROM CHEST

Three years of follow-up is adequate for partially solid ground-glass opacity lesions that do not progress, while pure ground-glass opacity lesions that show no

progression may require further follow-up care, a study suggests.

The results of the study strengthen the argument for taking a “watch and wait” approach, and raise the question of whether patient outcomes can be improved without more precise diagnostic criteria,

said study author Shigei Sawada, MD, PhD, a researcher at the Shikoku Cancer Center in Matsuyama, Japan, and his colleagues. They drew these conclusions from performing a long-term outcome investigation of 226 patients with pure or mixed ground-glass opacities. See **Ground-glass opacities** page 7

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## Genotyping is recommended

CF guidelines *from page 1*

2008, the CFTR2 project has described over 300 specific variants in the CF gene and their various functional and clinical impacts. The project involves amassing phenotyp-

ic and genotypic information from patient registries to collect, quantify, and describe mutations reported in individuals with CF. Such mutations are categorized as CF causing, car-

rying a variety of potential clinical consequences; non-cystic fibrosis causing; or unknown. The previous guidelines, written in 2008, relied on a 23-mutation panel from the American College of Medical Genetics and Genomics and the American Congress of Obstetricians and Gynecologists.

“We’ve more precisely defined what cystic fibrosis is,” Patrick R. Sosnay, MD, assistant professor of medicine at Johns Hopkins University, Baltimore, and coauthor of the guidelines, said in a statement. “The stakes in categorizing a mutation are particularly high. For example, claiming that a mutation 100% caus-

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The stakes in categorizing a mutation are particularly high. A person's reproductive decisions, for example, might be affected by learning he could have a child with a mutation that is 100% causing cystic fibrosis, according to a statement from Dr. Sosnay.

es cystic fibrosis may affect people's reproductive decisions if they believe their child will have the mutation."

In the CFTR2 project, the "disease-liability" of each mutation is evaluated through a combination

of sweat chloride and functional activity identified in cell-based systems, according to a supplement published simultaneously with the updated guidelines (J Pediatr. 2017 Feb;181[suppl]:S52-7. doi: 10.1016/j.jpeds.2016.09.068). Data from this project led to the discovery of a cohort of 746 persons diagnosed with

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#### VIEW ON THE NEWS

**Susan Millard, MD, FCCP, comments:** A comprehensive supplement in the Journal of Pediatrics entitled, "Introduction to 'Cystic Fibrosis Foundation Consensus Guidelines for Diagnosis of Cystic Fibrosis,'" reflects information introduced at the North American



Cystic Fibrosis Conference in the fall 2016 (J Pediatr. 2017 Feb;181[suppl]:S1-3. doi:10.1016/j.jpeds.2016.09.062). It represents the work of an international committee of cystic fibrosis experts whose goal was to provide consensus on the diagnosis of cystic fibrosis, especially for newborns and for complex cases in older patients. The committee strove to combine the efforts of both the United States and European guidelines so that terminology would be more consistent also. Two highlights are lowering the normal sweat chloride result for all ages to less than 30 mmol/L and using the data from the Clinical & Functional Translation of CFTR team to understand how a specific mutation may or may not cause disease. This set of guidelines will lead to quality improvement in the diagnosis of CF in patients who may have CFTR-related disorders but not meet the criteria for a full CF diagnosis.

CF despite sweat chloride levels less than 60 mmol/L. These findings were the basis for the guideline authors' decision to lower the threshold of chloride concentration in sweat in order for an individual to be considered having a possible CF diagnosis, according to the supplement.

The guidelines include 27 approved consensus statements spanning four overlapping categories, and applying to screened and non-screened populations; newborn screened populations and fetuses undergoing prenatal testing; infants with an uncertain diagnosis and designated as having either CFTR gene-related metabolic syndrome or being CF-screen positive, inconclusive diagnosis; and non-screened patients who present with symptoms, including children before newborn

*Continued on following page*



Continued from previous page

screening implementation, those with false-negative tests, and older, non-screened patients.

Although not specified in the consensus statements, the authors of a second supplement published simultaneously with the updated guidelines (J Pediatr. 2017;181[suppl]:S27-32. doi: 10.1016/j.jpeds.2016.09.063), wrote that they supported genotyping all individuals diagnosed with CF, even if physiologic tests establish the diagnosis, to better understand the disease's genetic epidemiology and to refine future therapies. "If the identified mutations are known to be associated with variable outcomes, or have unknown consequence, that genotype may not result in a CF phenotype. In these cases, other tests of CFTR function may help," this supplement's authors concluded.

The updated guideline authors recommend avoiding the use of terms such as "atypical" or "nonclassical" CF, as there is no consensus on the specific taxonomy of CF, since the

ments can be difficult, the authors say it is possible, especially in full-term infants aged 1 month. Repeat sweat testing is recommended, as is nasal potential difference and intes-

ing organ pathologies typical in CF, such as bronchiectasis or pancreatic insufficiency, along with testing for the presence of CFTR dysfunction with sweat chloride testing, CFTR molecular genetic analysis, or CFTR physiologic tests.

In contrast, the second supplement states that "clinical suspicion should always take precedence" in making a CF diagnoses for individuals in this age group.

"Understanding a disease's genetic epidemiology helps identify patients who may be subject to the clinical manifestations of that disease. As we learn more about the variants in cystic fibrosis genetics and the functional and clinical impacts, there is a greater opportunity to better characterize a CF mutation," noted Vera A. De Palo, MD, MBA, FCCP, of Signature Healthcare in Brockton, Mass. "These guidelines will bring that enhanced knowledge to providers identifying and caring for cystic fibrosis patients."

Dr. Sosnay and Philip M. Farrell, MD, PhD, a coauthor of the guidelines, received funds from the Cystic Fibrosis Foundation, where guideline coauthor Terry B. White, PhD, is an employee. Kris De Boeck, MD, a coauthor of the first supplement, receives funding from Vertex Pharmaceuticals, Ablynx, Aptalis, Galapagos, Gilead, Pharmaxis, and PTC Therapeutics. The guideline and supplements' other authors have no disclosures.

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**"Understanding a disease's genetic epidemiology helps identify patients who may be subject to the clinical manifestations of that disease. As we learn more about the variants in cystic fibrosis genetics and the functional and clinical impacts, there is a greater opportunity to better characterize a CF mutation," Dr. De Palo said.**

genetic data are still emerging.

When a newborn test is administered, the guidelines warn that the heterogenous nature of newborn screening often leads to false-positive results, thus the need for the sweat test.

Although obtaining an adequate sweat specimen for chloride measure-

tinal current measurement in some cases.

Another change to the guidelines is that newborns with a high immunoreactive trypsinogen level and inconclusive CFTR functional and genetic testing may now be designated as having CFTR-related metabolic syndrome/CF-screen positive inconclusive diagnosis (CRMS/CFSPID), instead of CFTR-related metabolic syndrome or CF-screen positive, inconclusive diagnosis. Regarding changes to screening for CRMS/CFSPID, the older guidelines called for such an assessment by age 2 months, repeated every 6-12 months, while the new guidelines say their recommendation on the duration and frequency of follow-up "remains to be determined."

The authors of the first supplement decry the lack of standardized CF diagnostic criteria for those diagnosed with CF outside of the neonatal period, and urge clinicians to rely on clinical evidence includ-

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Vera A. De Palo, MD, MBA, FCCP, is Medical Editor in Chief of CHEST Physician.

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CHEST PHYSICIAN (ISSN 1558-6200) is published monthly for the American College of Chest Physicians by Frontline Medical Communications Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609. Subscription price is \$237.00 per year. Phone 973-206-3434, fax 973-206-9378.

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## AEs higher after video procedure

Intubation *from page 1*

settings and among operators with diverse skill levels.”

Intubation in the ICU carries an inherently high risk because patients are often acutely unstable, and the intubating clinician is usually a non-expert, the investigators noted. At the same time, the procedure must be done quickly to prevent aspiration because patients usually have not fasted. Care bundles and training on simulators have improved safety, but ICU intubations remain riskier than those done in the operating room.

Observational studies and smaller trials in ICUs seemed to support video laryngoscopy over the Macintosh laryngoscope, but raised questions about intubation time and mortality, the investigators noted. To help resolve these issues, they randomly assigned adults needing orotracheal intubation at seven ICUs in France to either video or direct Macintosh laryngoscopy, and followed them for 28 days. Patients averaged 63 years of age, and 37% were women.

For both arms, residents performed the initial intubation attempt in about 80% of cases, and successful intubation usually took 3 minutes. Video laryngoscopy did

not significantly increase the combined risk of esophageal intubation, aspiration, arrhythmia, or dental injury (5.4% versus 7.7% for direct laryngoscopy). But the only death in the study occurred after video laryngoscopy, and there were four cardiac arrests after video laryngoscopy and none after direct laryngoscopy, the researchers said. Furthermore, the rate of severe hypoxemia was nearly six times higher after video laryngoscopy than with direct laryngoscopy, and the rate of hypotension was twice as high.

The researchers did not identify predictors of life-threatening complications with video laryngoscopy, but hypothesized that being able to clearly visualize the glottis might create “a false impression of safety,” especially among nonexperts. “In addition, poorer alignment of the pharyngeal axis, laryngeal axis, and mouth opening despite good glottis visualization by video laryngoscopy can lead to mechanical upper airway obstruction and faster progression to hypoxemia,” they wrote.

“As healthcare providers, we strive to continuously improve outcomes for our patients. As techniques and technologies continue to improve,

minimally invasive adenocarcinomas, and 19 with lepidic predominant adenocarcinomas. Five patients had papillary-predominant adenocarcinomas.

Roughly one-quarter of the cohort did not receive follow-up examinations after 68 months, as their lesions either remained stable or were shown to have reduced in size. Another 45 continued to undergo follow-up examinations.

After initial detection of a pure ground-glass opacity, the CT examination schedule was every 3, 6, and 12 months, and then annually. After detection of a mixed ground-glass opacity, a CT examination was given every 3 months for the first year, then reduced to every 6 months thereafter. In patients with stable disease, the individual clinicians determined whether to obtain additional CT follow-up imaging.

A ground-glass lesion was determined to have progressed if the diameter increased, as it did in about a third of patients; or, if there was new or increased consolidation, as there was in about two-thirds of patients. The table of consolidation/tumor ratios (CTR) used included CTR zero, also referred to as a pure ground-glass lesion; CTR 1-25; CTR 26-50; and CTR equal to or greater than 51. When there were multiple lesions, the largest one detected was the target.

All cases of patients with a CTR of more than zero were identified within 3 years, while 13.6% of patients with a CTR of zero required more than 3 years to identify tumor growth. Aggressive cancer was detected in 4% of patients with a CTR of

### VIEW ON THE NEWS

## Video laryngoscopy creates blind spots

The results of this trial illustrate the fundamental problem with video laryngoscopy: It generates excellent views of the larynx but may not facilitate tracheal intubation.

The use of video laryngoscopy can lead to the creation of blind spots, both visual and cognitive. Because the lens of the laryngoscope is located at the tip of the device, the pharynx and hypopharynx are not visualized during video laryngoscopy. Manipulating the endotracheal tube into view therefore occurs within this blind spot, and this can be difficult depending on the patient's pharyngeal anatomy. This phenomenon has been linked to higher rates of pharyngeal soft tissue injury and longer intubation

times in patients undergoing video laryngoscopy as compared with direct laryngoscopy.

The view during video laryngoscopy can also create a cognitive blind spot: Laryngoscopists may fail to abort a laryngoscopy attempt in a timely manner because they have such a clear view of the larynx.

*Brian O’Gara, MD, and Daniel Talmor, MD, of Harvard Medical School, Boston, and Samuel Brown, MD, MS, of the University of Utah School of Medicine, Murray, Utah, made these comments in an accompanying editorial (JAMA. 2017 Feb 7; doi: 10.1001/jama.2016.21036). None of the authors had relevant financial disclosures.*

clinical study permits us to evaluate new strategies,” noted Vera A. De Palo, MD, MBA, FCCP, of Signature Healthcare in Brockton, Mass.

“While this study demonstrated no difference in first-pass orotracheal intubation rates between video laryngoscopy and direct laryngoscopy, the reported association of higher rates of severe life-threatening complications with video laryn-

goscopy bears further study.”

Centre Hospitalier Département de la Vendée sponsored the study. Dr. Lascarrou reported having no relevant conflicts of interest. Four coinvestigators disclosed ties to Fisher & Paykel, LFB, Merck Sharp & Dohme, Astellas, Basilea Pharmaceutica, Gilead, Alexion, and Cubist. The remaining coinvestigators had no disclosures.

## CT exam frequency

Ground-glass opacities *from page 1*

glass opacity lesions shown by CT imaging to be 3 cm or less in diameter.

Once established that the disease has stabilized in a pure or mixed ground-glass opacity lesion, “the frequency of CT examinations could probably be reduced or ... discontinued,” the investigators wrote. The study is published online in *Chest* (2017;151[2]:308-15).

Because ground-glass opacities often can remain unchanged for years, reflexively choosing resection can result in a patient's being overtreated. Meanwhile, the use of increasingly accurate imaging technology likely means detection rates of such lesions will continue to increase, leaving clinicians to wonder about optimal management protocols, particularly since several guidance documents include differing recommendations on the timing of surveillance CTs for patients with stable disease.

The study includes 10-15 years of follow-up data on the 226 patients, registered between 2000 and 2005. Across the study, there were nearly twice as many women as men, all with an average age of 61 years. About a quarter had multiple ground-glass opacities; about a quarter also had partially consolidated lesions. Of the 124 patients who'd had resections, all but one was stage IA. The most prominent histologic subtype was adenocarcinoma in situ in 63 patients, followed by 39 patients with

### VIEW ON THE NEWS

**Eric Gartman, MD, FCCP, comments:** This study provides further support that the biology of ground-glass and part-solid nodules is different than fully solid nodules – and we should not be in a rush to resect these lesions. While the recommendations are likely to evolve over time as more information becomes available, this conservative approach toward nonsolid nodules is currently adopted in the Lung-RADS guidelines. Invasive action on these nodules is based on solid component size and growth, and usually the interval for following them once they have demonstrated early stability is annually. The optimal duration of follow-up is still in question, but ceasing follow-up for all part-solid nodules at 3 years likely is premature given the variable slow progression these nodules exhibit.



zero and in 70% of those with a CTR greater than 25% ( $P$  less than .001). Aggressive cancer was seen in 46% of those with consolidation/tumor ratios that increased during follow-up and in 8% of those whose tumors increased in diameter ( $P$  less than

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.007). After about 10 years of follow-up after resection, 1.6% of cancers recurred.

There were two deaths from lung cancer among the study's patients. The first, a 54-year-old man, had an acinar-predominant adenocarcinoma, 5 mm in diameter with a consolidation/tumor ratio of 0.75 that increased during follow-up. The recurrence developed in the mediastinal lymph nodes 51 months after resection surgery. The second patient had a papillary-predominant adenocarcinoma appearing as a pure ground-glass opacity 27 mm in diameter. The consolidation/tumor ratio also increased during follow-up, with recurrences in the bone and mediastinal lymph nodes at 30 months post resectioning.

Neither patient was re-biopsied, and both were diagnosed according to CT imaging alone. There were 13 other patient deaths from non-lung cancer related causes.

Given the 3-year timespan necessary to detect tumor growth in all but the CTR zero group, and the study's size and long-term nature, the investigators concluded that a follow-up period of 3 years for patients with part-solid lesions "should be adequate."

By contrast, CHEST recommends CT scans be

done for at least 3 years in patients with pure ground-glass lesions and between 3 and 5 years in the other CTR groups with nodules measuring 8 mm or less. The National Comprehensive Cancer Network guideline advises low-dose CT scanning until a patient is no longer eligible for definitive treatment.

Dr. Sawada and his colleagues did not use an exact criterion for tumor growth in their study, such as a precise ratio of increase in size or consolidation, in part because at the time of the study the most common form of CT evaluation was visual inspection; they reported that tumors exhibiting growth most commonly increased between 2 and 3 mm in either size or consolidation. "Evaluations based on visual inspections can be imprecise, and different physicians may arrive at different judgments," the investigators wrote. "However, [the use of] computer-aided diagnosis systems are not yet commonly applied in clinical practice."

Although imaging should have guided the decision to resect, according to Dr. Sawada and his coauthors, two-thirds of patients in the study were given the procedure even though their lesions were not shown by CT scans to have progressed. This was done either at the patient's request, or per the clinical judgment of a physician.

Although the study "represents a major advance," according to Frank C. Detterbeck, MD, FCCP, surgical director of thoracic oncology at Yale University, New Haven, Conn., who wrote an editorial accompanying the study, the results should spur the field to get more specific, and question whether a 3-year window was enough. "This seems counterintuitive given the chance of it becoming an invasive cancer," Dr. Detterbeck wrote, indicating that not rushing to resection should mean more use of CT. "We should just look at what is already in front of our eyes: the radiographic features of [ground-glass nodules] are highly predictive of biological behavior. It will be hard to do better than this."

Also becoming more specific about changing CTRs would be helpful in developing management protocols, according to Dr. Detterbeck. "In my opinion, we need to start factoring in the rate of change. A gradual 2 mm increase in size over a period of 5 years may not be an appropriate trigger for resection."

Neither the investigators nor the editorial writer had any relevant disclosures.

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## Sarcoidosis doubled risk of hospitalization for infection

BY WHITNEY MCKNIGHT  
Frontline Medical News

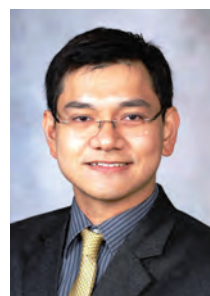
Persons with sarcoidosis were found to have double the risk of hospitalization, compared with age-matched controls in a population-based cohort study that also linked glucocorticoid use with an increased risk of hospitalization in this group.

Using data from the Rochester Epidemiology Project record-linkage system, Patompong Ungprasert, MD, an assistant professor of medicine at the Mayo Clinic in Rochester, Minn., and his colleagues identified 345 incident cases of sarcoidosis recorded between 1976 and 2013, confirmed by individual medical records (Ann Am Thorac Soc. 2017 Feb 8. doi: 10.1513/AnnalsATS.201610-750OC). With use of random selection, each patient was age and sex matched with sarcoidosis-free controls taken from the same database. Medical records across the study were examined for community-acquired infections requiring hospitalization that occurred after the index date or the date of diagnosis.

The nearly all white population across the study had an average age of 45 years and was evenly divided according to sex. The mean length of follow-up was 15 years for the study arm, and 16.8 years for controls.

Risk factors for infection, such as smoking status, obesity, diabetes,

and others were also matched, although there were nearly twice as many controls who smoked, compared with study subjects – 36% vs. 19% ( $P$  less than .001) – whereas the obesity rate was twice as high in the study arm: 41% vs. 21% ( $P$  less than .001). Results were ad-



**These patients should quickly seek medical attention when they develop symptoms of infection.**

DR. UNGPRASERT

justed for sarcoidosis patients who either had or had not been exposed to immunosuppressive therapies.

Dr. Ungprasert and his coinvestigators found that those with sarcoidosis had double the risk of all forms of specific hospitalized infection when compared with controls – a 2.00 hazard ratio (95% confidence interval, 1.41-2.84). The results were similar when adjusted for infection risk factors: 2.13 HR (95% CI, 1.35-3.34).

The risk of hospitalized infection in the sarcoidosis arm was higher than in controls regardless of disease stage: an HR of 1.70 (95% CI, 1.12-2.58,  $P$  = .013) in those with stage I; an HR of 2.00 (95% CI, 1.22-3.29,  $P$  = .006) among those with stage II; and an HR of 2.63 (95% CI, 1.58-4.39,  $P$  less than .001) in those with stage III

and stage IV disease.

Biopsies taken in 251 cases resulted in 229 positive results for noncaseating granuloma, and just over half of patients had stage I disease. Stage II disease was found in 29%, stage III in 15%, and stage IV in 2%.

Patients in the sarcoidosis group who had not been exposed to immunosuppressive treatment had significantly higher risk of hospitalization with an HR of 1.73 (95% CI, 1.16-2.60;  $P$  = .008) when compared with controls. The risk was even higher in study patients who had received immunosuppressive therapy: an HR of 2.41 (95% CI, 1.60-3.64;  $P$  less than .001), when compared with controls. Less than half of all sarcoidosis patients required immunosuppressive therapy at any point during follow-up: about 37% by year 30 after original diagnosis. Oral glucocorticoids were the most commonly prescribed medication, used in 113 cases.

A baseline diffusing capacity of the lung for carbon monoxide was associated with an overall increased risk of hospitalized infection, with an HR of 1.15 per decrease of 10% predicted in diffusing capacity of the lung for carbon monoxide (95% CI, 1.01-1.32). A baseline forced vital capacity was associated with an increased hospitalized pneumonia risk with an HR of 1.15 per decrease of 10% predicted in forced vital capacity (95% CI, 1.01-1.32).

Although the use of immunosuppressive agents was not significantly associated with the risk of hospi-

talized infection (HR, 1.43; 95% CI, 0.94-2.19), current use of oral glucocorticoids, whether alone or as adjunct to immunosuppressive therapy, significantly predicted risk of infection in patients with sarcoidosis, with an HR of 3.03 (95% CI, 1.33-6.90) for oral glucocorticoids up to 10 mg per day, and an HR of 4.48 (95% CI, 1.33-6.90) in patients taking oral glucocorticoids at more than 10 mg per day, when compared with controls.

In an interview, Dr. Ungprasert said the results were not surprising, but provided the following takeaways from this study for physicians caring for patients with sarcoidosis.

"These patients are at an increased risk of serious infection and should seek medical attention as soon as possible when they develop symptoms of infection, such as fever or chills," he said in an interview. "Keeping current with vaccinations is also important for them."

Dr. Ungprasert also said the study serves as a reminder to use oral glucocorticoids judiciously. "When considering their use, the physician should keep in mind that a large number of patients with sarcoidosis will have a spontaneous resolution of the disease."

There were no relevant disclosures. The study was funded in part by the National Institute on Aging.

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# SAVR an option for elderly with aortic stenosis

BY DOUG BRUNK  
Frontline Medical News

HOUSTON – Surgical aortic valve replacement (SAVR) can be performed in intermediate-risk elderly patients with an operative mortality rate of 4.1%, which is better than expected, according to results from a large multicenter analysis. However, the rate of in-hospital stroke was 5.4% – twice what was expected.

“This is most likely secondary to neurologic assessment [that was con-



DOUG BRUNK/FRONTLINE MEDICAL NEWS

**For intermediate-risk patients, mortality was commensurate with national benchmarks, Dr. Vinod H. Thourani said.**

ducted] for all patients postoperatively,” Vinod H. Thourani, MD, said at the annual meeting of the Society of Thoracic Surgeons.

The findings come from an in-depth analysis of SAVR outcomes in patients who participated in the Placement of Aortic Transcatheter Valves trial, known as PARTNER 2A. Conducted from December 2011 to November 2013, PARTNER 2A evalu-

ated 2,032 medium-risk patients with aortic stenosis who were randomized to SAVR or transcatheter aortic valve replacement (TAVR) in 57 North American centers and found no significant difference in the 2-year rate of death or disabling stroke (N Engl J Med. 2016 Apr 28;374[17]:1609-20).

Dr. Thourani’s analysis focused on the 937 patients who underwent SAVR. The main objectives were to describe operative mortality and hospital morbidities compared with STS benchmarks, describe time-related mortality and stroke including preoperative predictors for these outcomes, evaluate the effect of concomitant procedures on mortality and hospital morbidities, and evaluate longitudinal valve performance after SAVR.

The average age of these patients was 82 years, 45% were female, and their mean STS risk score was 5.8. In addition, 26% had prior coronary artery bypass (CABG) surgery, 10% had a previous stroke, and 12% had previous pacemaker placement. Of the 30% of patients with chronic obstructive pulmonary disease, 9.6% were oxygen dependent going into the operating room, reported Dr. Thourani, one of the PARTNER 2A investigators, and a cardiothoracic surgeon at Emory University, Atlanta.

Most of the patients (85%) had a full sternotomy, while 15% had a mini sternotomy. Isolated AVR was done in 79% of patients, 15% of patients had AVR plus CABG, and 6% had AVR and other concomitant procedures. The mean coronary bypass time for isolated AVR was 98 minutes, and rose to a mean of 129 minutes when a concomitant procedure was added. The mean cross-clamp time was 69 minutes, and rose to a

mean of 95 minutes when a concomitant procedure was added.

The investigators observed that all-cause operative mortality was 4.1%, which is lower than STS predicted-risk models. At the same time, mortality for AVR plus a concomitant procedure was 5%, followed by isolated AVR (4.2%) and AVR plus CABG plus a concomitant procedure (2.9%). The rate of in-hospital stroke was 5.4% and the rate of in-hospital deep sternal wound infection was 0.8%. At 2 years postoperatively, mortality was 17% among those who underwent isolated AVR, 18% among those who underwent AVR plus CABG, and 21% among those who underwent AVR plus a concomitant procedure, differences that did not reach statistical significance. The rate of stroke at 2 years also was similar between groups: 12% among those who underwent isolated AVR, 11% in those who underwent AVR plus a concomitant procedure, and 8.2% in those who underwent AVR plus CABG.

The main risk factor for early death after SAVR was longer procedure time ( $P$  less than .0001), while risk factors for later deaths included cachexia ( $P = .02$ ), lower ejection fraction ( $P = .01$ ), higher creatinine ( $P = .03$ ), coronary artery disease ( $P = .03$ ), and smaller prostheses ( $P = .01$ ).

Dr. Thourani and his associates also found that 33% of patients had severe prosthesis-patient mismatch, yet they had survival rates similar to the rates of those without severe prosthesis-patient mismatch.

“From this adjudicated, prospectively collected data in the contemporary era, SAVR can be performed in intermediate-risk elderly patients with mortality commensurate with

## VIEW ON THE NEWS

**G. Hossein Almassi, MD, FCCP, comments:** This analysis of the surgical arm of the PARTNER 2A trial reveals respectable outcome for those so-called intermediate-risk patients with severe symptomatic aortic stenosis. The fact that mortality at 2 years was similar between the surgical and the catheter arm of the trial (upward of 17%), speaks of the multiple comorbidities present in these patients (N Engl J Med. 2016;374:1609-20). The trial proved the noninferiority of the catheter-based aortic valve implantation as compared with surgical AVR. With further refinement and advances in technology and design of these valves, and, more importantly, patients’ demand, the TAVR is destined to become the main stay of the AVR for patients with severe aortic stenosis.



national benchmarks,” he concluded. “Continued surveillance of these patients remains extremely important.”

Dr. Thourani disclosed that he is a consultant for and has received research support from Edwards Lifesciences. Other authors of the study reported having numerous relevant financial disclosures.

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# Can bioprosthetics work for large airway defects?

BY RICHARD MARK KIRKNER  
Frontline Medical News

Large and complex airway defects that primary repair cannot fully close require alternative surgical approaches and techniques that are far more difficult to perform, but bioprosthetic materials may be an option to repair large tracheal and bronchial defects that has achieved good results, without postoperative death or defect recurrence, in a small cohort of patients at Massachusetts General Hospital, Boston.

Brooks Udelsman, MD, and coauthors reported their results of bioprosthetic repair of central airway defects in eight patients in the *Journal of Thoracic and Cardiovascular Surgery* (2016;152:1388-97). “Although our results are de-

rived from a limited number of heterogeneous patients, they suggest that closure of non-circumferential large airway defects with bioprosthetic materials is feasible, safe and reliable,” Dr. Udelsman said. He previously reported the results at the annual meeting of the American Association for Thoracic Surgery, May 14-18, 2016, in Baltimore.

These complex defects typically exceed 5 cm and can involve communication with the esophagus. For repair of smaller defects, surgeons can use a more conventional approach that involves neck flexion, laryngeal release, airway mobilization, and hilar release, but in larger defects these techniques increase the risk of too much tension on the anastomosis and dehiscence along with airway failure. Large and complex defects occur in patients who have had a previous airway operation or radia-

tion exposure, requiring alternative strategies, Dr. Udelsman and coauthors said. “Patients in this rare category should be referred to a high-volume center for careful evaluation by a surgeon experienced in complex airway reconstruction before the decision to abandon primary repair is made,” he said. Among the advantages that bioprosthetic materials have over synthetic materials for airway defect repair are easier handling, minimal immunogenic response, and potential for tissue ingrowth, Dr. Udelsman and coauthors said.

All eight patients in this study, who underwent repair from 2008 to 2015, had significant comorbidities, including previous surgery of the trachea, esophagus, or thyroid. The etiology of the airway defect included HIV/AIDS-associated esophagitis,

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# Most lung recipients gain 2-year survival benefit

BY BIANCA NOGRADY  
Frontline Medical News

**N**early three-quarters of lung transplant recipients are likely to gain at least 2 years of survival, according to new research.

In a study published in the February issue of the *Annals of the American Thoracic Society*, researchers used data from 13,040 adults listed for lung transplantation between May 2005 and September 2011 to develop a structural nested accelerated

**These results reinforce that lung transplantation should be considered an appropriate treatment option for patients with most advanced lung diseases, the researchers noted.**

failure time model of the survival benefit of lung transplantation over time.

“A ‘structural nested model’ is [used to] compare the distribution of counterfactual residual survival if a patient were to receive a transplanted organ with the survival distribution if the patient did not receive that organ and never received one subsequently,” wrote David M. Vock, PhD, from the University of Minnesota, Minneapolis, and coauthors.

Using this approach, they calculated that 73.8% of transplant recipients were predicted to achieve a 2-year survival benefit with transplantation. At 1 year post transplantation, the relative survival benefit was 1.59,

at 2 years it was 1.93, and at 3 years it was 2.23 (*Ann Am Thorac Soc*. 2017;14:172-81. doi: 10.1513/AnnalsATS.201606-507OC).

Patients’ lung allocation score at transplantation (LAS-T) – the score used to prioritize donated lungs for transplantation – had a significant impact on the survival benefit from transplantation. The relative survival benefit of transplantation increased by 59.4% as the lung allocation score increased from 30 to 35, and increased by 45.1% as the lung allocation score increased from 50 to 55.

However patients with a lung allocation score of 32.5 or less were more likely to die with a transplant than without, even over the long term, while patients with a score of 35 or more always gained a survival advantage from transplantation, even if their scores were as high as 50-100. The authors said this showed there should be no upper limit for the lung allocation score.

“It has been suggested that the LAS system may encourage patients who have clinically deteriorated to undergo transplantation even though it would be futile,” they wrote. “Our results reinforce the notion that lung transplantation should be considered an appropriate treatment option for patients with most advanced lung diseases and is expected to confer survival benefit in appropriately selected patients.”

Researchers also observed an interesting, borderline significant association between disease group and survival benefit, with individuals with obstructive lung disease showing the lowest relative survival

## VIEW ON THE NEWS

### Lung transplantation prolongs survival

**L**ung transplantation is the only option available for patients with treatment-resistant end-stage lung disease. However, the ability of this intervention to extend survival is still actively debated. The authors demonstrate that most adults undergoing lung transplantation experience a survival benefit that is mainly driven by the value of the lung allocation score at the time of transplantation and by the underlying lung disease.

It is reassuring to see that the two studies published so far that

accounted for the course of patient disease after placement on a wait list reached essentially the same conclusions: Most of the patients experienced a survival benefit from lung transplantation.

*Gabriel Thabut, MD, is from the service de pneumologie B and transplantation pulmonaire at the University of Paris. These comments are taken from an accompanying editorial (Ann Am Thorac Soc. 2017;14:163-4. doi: 10.1513/AnnalsATS.201611-853ED). No conflicts of interest were declared.*

gains and those with cystic fibrosis showing the highest. Head to head, the relative survival benefit of transplantation for those with cystic fibrosis was 54.4% greater than for those with obstructive lung disease.

Other factors such as transplant type, age, smoking, and center volume also influenced relative survival benefit. Bilateral transplants were associated with a 13.4% greater relative survival benefit, lungs from donors aged under 55 years showed a 17.9% relative survival benefit, and lungs from donors without a history of smoking showed a 10.5% increase in relative survival benefit.

However the researchers noted that their modeling focused on only the survival benefit of transplantation and did not take into account improvements in quality of life. This was likely to be particularly relevant in conditions such as chronic obstructive

pulmonary disease where the quality of life benefits might justify transplantation even in the absence of a clear survival benefit.

“A comprehensive understanding of the survival benefit of lung transplantation and how that benefit varies by recipient characteristics is imperative to inform recipient selection, to justify the intensive health care resources allocated to this treatment, and to achieve an equitable allocation of donor lungs,” the researchers said.

The study was supported by the National Heart, Lung, and Blood Institute; the National Cancer Institute; and the National Institute of Allergy and Infectious Diseases. One author declared grants and personal fees from private industry for consultation on lung transplantation. No other conflicts of interest were declared.

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malignancy, mesh erosion, and complications from extended intubation. Three patients had previous radiation therapy to the neck or chest. Five patients had defects localized to the membranous tracheal wall, two had defects of the mainstem bronchus or bronchus intermedius, and one pa-

tient had a defect of the anterior wall of the trachea.

Dr. Udelsman and coauthors used both aortic homograft and acellular dermal matrix to repair large defects. Their experience confirmed previous reports of the formation of granulation tissue with aortic autografts, underscoring the importance of frequent bronchoscopy and debridement when necessary. And while previous reports have claimed human acellular dermis resists granulation formation, that wasn’t the case in this study. “The exact histologic basis of bioprosthetic incorporation and reepithelialization in these patients is still elusive and will require further study,” Dr. Udelsman and coauthors said.

This study also employed the controversial muscle buttress repair in six patients, which helped, at least theoretically, to secure the repairs when leaks occur, to separate suture lines when both the airway and esophagus were repaired, and to support the bioprosthetic material to prevent tissue soften-

ing, Dr. Udelsman and coauthors said.

Postoperative examinations confirmed that the operations successfully closed the airway defects in all eight patients. Long term, most resumed oral intake, but three did not for various reasons: One had a paryngostomy; another had neurocognitive issues preoperatively; and a third with a tracheoesophageal fistula repair and cervical esophagotomy could resume oral intake but depended on tube feeds to meet caloric needs.

All patients developed granulation at the repair site, two of whom required further debridement and one who underwent balloon dilation. Pneumonia was the most common complication within 30 days of surgery, occurring in two patients. Three patients died within 120 days from metastatic disease, and a fourth patient progressed to end-stage AIDS 6 years after the operation and eventually died.

Dr. Udelsman and coauthors reported having no financial disclosures.

## VIEW ON THE NEWS

### G. Hossein Almassi, MD, FCCP, comments:

This is a small series of 8 patients out of 342 total patients requiring airway repair who underwent repair of complicated major airway defects at a well-known tertiary referral center for airway surgery. The message is clear that complicated airway defects, as defined by the authors, should be referred to a high-volume specialty center with expertise in this field.



# Medicare patients often need pacemaker after TAVR

BY DOUG BRUNK  
*Frontline Medical News*

HOUSTON – About 1 in 10 Medicare patients require implantation of a permanent pacemaker after transcatheter aortic valve replacement, results from a large analysis showed.

“There is conflicting evidence and some debate over permanent pacemaker placement following transcatheter aortic valve replace-



**There is some debate over whether a permanent pacemaker is protective following TAVR.**

DR. MCCARTHY

ment – whether it has a protective or adverse effect, and how often it takes place,” study investigator Fenton H. McCarthy, MD, said in an interview at the annual meeting of the Society of Thoracic Surgeons.

To evaluate the relationship between permanent pacemaker implantation and long-term patient outcomes among Medicare beneficiaries undergoing TAVR, Dr. McCarthy, a cardiothoracic surgery fellow at the University of Pennsylvania, Philadelphia, and his associates used Medicare carrier claims and Medicare Provider Analysis and Review files to identify 14,305 TAVR patients between January 2011 and December 2013.

The mean age of the 14,305 TAVR patients studied was 83 years, and 11% received a permanent pacemaker after TAVR. Of these, 9% received

the pacemaker at index hospitalization, 1% at 30 days after implant, 0.5% at 90 days after implant, and 1% at 1 year after implant. Patient age of greater than 90 years was a significant predictor of pacemaker

placement, with an odds ratio of 1.7 (*P* less than .01).

Dr. McCarthy and his associates observed that the readmission rates for pacemaker placement and no pacemaker placement at index hos-

pitalization were similar at 30 days (21% vs. 19%, respectively), at 90 days (33% vs. 31%) and at 1 year (43% in both groups of patients).

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## VIEW ON THE NEWS

**G. Hossein Almassi, MD, FCCP, comments:** The need for new permanent pacemaker implantation in TAVR patients has been higher as compared with surgical AVR. The current analysis on the administrative database of Medicare patients undergoing TAVR has the advantage of a large sample size but lacks details at the patient level. The PARTNER 2A trial in medium-risk patients (*N Engl J Med.* 2016;374:1609-20) found no statistical difference between TAVR and surgical AVR for the need for permanent pacemaker implantation at 30 days (8.5% and 6.9%, respectively; *P* = 0.17).

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# Maintain conjugate vaccine schedule with preemies

BY DAN WATSON  
*Frontline Medical News*

**T**here should be no hesitation in administering the routine vaccination schedule for 13-valent

pneumococcal conjugate vaccine (PCV13) on account of gestational age or birth weight in preterm infants, researchers concluded.

In a phase IV study, researchers compared 100 term with 100 preterm

infants; both groups were vaccinated on the routine schedule at ages 2, 3, 4, and 12 months. After the 12-month (toddler) dose of the PCV13, the infants were evaluated for serum antibody persistence at 12 and 24

months. "To date, no studies have examined the long-term persistence of immune responses to PCV13 in formerly preterm infants," noted Federico Martín-Torres, MD, PhD, of Hospital Clínico Universitario de

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Santiago de Compostela, Spain, and his coauthors.

In the study, at six sites in Spain and five sites in Poland between October 2010 and January 2014, both groups were checked for geometric mean concentrations (GMC) of serotype-specific anticapsular immunoglobulin G-binding

antibodies and for opsonophagocytic activity. All 200 subjects were white and were generally healthy; the preterm infants were grouped by gestational age at birth of less than 29 weeks (n = 25), 29 weeks to less than 32 weeks (n = 50), or 32 weeks to less than 37 weeks (n = 25). Twelve subjects dropped

out of the study by the first year's evaluation, and another eight of the term subjects and seven of preterm subjects dropped out by the second year's evaluation (Ped Infect Dis J. 2017. doi: 10.1097/INF.0000000000001428).

At both follow-up time points, no discernible patterns were observed

in IgG GMCs for any serotype or in opsonophagocytic activity geometric mean titers across preterm subgroups based on gestational age.

"The vaccination phase of the study demonstrated that preterm infants are able to generate an immune response to PCV13 that is likely to

*Continued on page 25*

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# Shunts often fail rapidly in neonates and infants

BY DOUG BRUNK  
*Frontline Medical News*

HOUSTON – Among neonates and infants who underwent shunt construction as a source of pulmonary

blood flow, early, in-hospital shunt failure occurred in 7.3% of cases, results from a large retrospective study showed.

“Approximately one in seven patients who experiences cardiac

surgery in the first year of life undergoes construction of a systemic to pulmonary artery shunt of some type,” one of the study investigators, Marshall L. Jacobs, MD, said in an interview. The study was presented at

the annual meeting of the Society of Thoracic Surgeons.

“Early failure of such shunts is an incompletely understood phenomenon which accounts for important morbidity and mortality among in-

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**Of the at-risk neonates and infants, 7.3% experienced early, in-hospital shunt failure.**

DR. DO

fants and neonates. Much of what is known about shunt failure is based on experiences reported from individual institutions. The few multicenter studies to date have been clinical trials that focused primarily on pharmacologic strategies intended to reduce the risk of shunt failure due to thrombosis. Their utility for

guiding clinical decision making has been limited. Some have been underpowered; some have had limited risk adjustment of subjects.”

The current investigation, which began when Nhue Do, MD, was a cardiac surgery chief resident at Johns Hopkins Hospital, Baltimore, is the largest reported analysis of

factors associated with postoperative in-hospital shunt failure in neonates and infants with congenital heart disease. It is the first multicenter study to define preoperative risk factors and patient characteristics associated with early shunt failure.

Dr. Do, who presented the find-

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ings at the meeting and is currently a Congenital Heart Surgery Fellow at the Children's Hospital of Philadelphia, and a team of 11 other investigators utilized the STS Congenital Heart Surgery Database to identify 9,172 neonates and infants

who underwent shunt construction as a source of pulmonary blood flow at 118 institutions from 2010 to 2015. Criteria for shunt failure included a documented diagnosis of in-hospital shunt failure, shunt revision, or catheter-based shunt intervention. The investigators used multivariable logistic regression to evaluate risk factors for

in-hospital shunt failure.

Of the 9,172 at-risk neonates and infants, 674 (7.3%) experienced early, in-hospital shunt failure. "The observed rate of early shunt failure varied across the many specific types of shunts, and was lower with systemic ventricle to pulmonary artery shunts (as in the Sano modification of the

Norwood procedure) than with the systemic artery to pulmonary artery shunts," said Dr. Jacobs, who is a cardiothoracic surgeon at Johns Hopkins University, Baltimore.

In multivariable analysis, risk factors for in-hospital shunt failure included lower weight at operation for both neonates and infants, preoperative hypercoagulable state, and the collective presence of any other STS Congenital Heart Surgery Database preoperative risk factors. Neither cardiopulmonary bypass nor single ventricle diagnosis were risk factors for shunt failure. The investigators also observed that patients with in-hospital shunt failure had significantly higher rates of operative mortality (31.9% vs. 11.1%) and major morbidity (84.4% vs. 29.4%), and

**"The observed rate of early shunt failure varied across the many specific types of shunts, and was lower with systemic ventricle to pulmonary artery shunts ... than with the systemic artery to pulmonary artery shunts," said Dr. Jacobs.**

longer postoperative length of stay among survivors (a median of 45 vs. 22 days).

"Understanding the characteristics of the patient groups found to be at highest risk for early shunt failure is helpful in identifying individual patients that may warrant expectant surveillance, enhanced pharmacologic management, or other strategies to reduce the risk of shunt failure," Dr. Jacobs concluded.

"But perhaps more importantly it provides key information that may be helpful in the design and development of future clinical trials and/or collaborative quality improvement initiatives designed to reduce the cost in lives and resources that is associated with early shunt dysfunction."

He acknowledged certain limitations of the study, including its retrospective observational design and the voluntary nature of the STS Congenital Heart Surgery Database. "In addition, some potentially important variables, such as detailed data concerning preoperative test results of coagulation assays are not collected in the STS Congenital Heart Surgery Database," he said.

The research was supported by the STS Access & Publications Research program. The investigators reported having no financial disclosures.

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# Double-dose influenza vaccine gives best protection

BY DEEPAK CHITNIS  
Frontline Medical News

A double-dose inactivated quadrivalent influenza vaccine (IIV4) could be administered to all children aged 6-35 months, as it not only offers the best protection against influenza type B but also allows for simplifying the current vaccination schedule considerably.

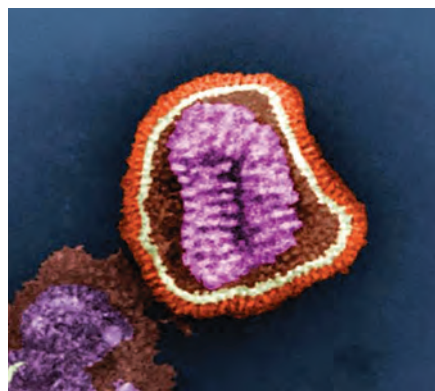
“The introduction of IIV4 provides an opportunity to review long-accepted practices in administration of influenza vaccines,” explained Varsha K. Jain, MD, formerly employed by GlaxoSmithKline Vaccines, King of Prussia, Pa., and associates.

“If the double-dose vaccine could be administered in young children without adverse effects on tolerability, this age group may benefit from potentially improved immunogenicity,” they wrote.

Giving a lower dose to young children was planned to reduce reactogenicity and febrile convulsions observed with the whole virus vaccines that were in use in the 1970s. But young children have a variable immune response to lower doses, especially against vaccine B strains,

they noted (J Ped Infect Dis. 2017 Jan 6. doi: 10.1093/jpids/piw068).

Dr. Jain and coauthors enrolled 2,430 children aged 6-35 months during the 2014-2015 influenza season in the United States and Mexico in this phase III study. Children were



CYNTHIA GOLDSMITH/CDC PHOTO #10073

randomized into one of two cohorts: one cohort received a standard-dose IIV4 vaccination, while the other received a double dose. Data on age (6-17 months, 18-35 months), health care center, and influenza primer status also were taken into consideration.

The standard-dose vaccine contained 7.5 mcg of A/California/7/2009 (A/H1N1), A/Texas/50/2012 (A/H3N2), B/Bris-

bane/60/2008 (B/Victoria), and B/Massachusetts/2/2012 (B/Yamagata), while the double-dose vaccine contained 15 mcg, or twice the amount each, of the same strains. The former was developed by Sanofi Pasteur and the latter by GSK Vaccines.

Primed children who completed the study numbered 1,173; 586 received the standard dose and 587 received the double dose. On the unprimed side, 868 completed the study: 442 standard dose and 426 double dose. Each dose's immunogenic noninferiority was quantified by calculating the geometric mean titer (GMT) ratio.

“Immunogenicity was higher in the double-dose group compared with the standard-dose group, particularly against vaccine B strains in children 6-17 months of age and unprimed children,” Dr. Jain and associates said. Both vaccines performed well against the influenza B strain, with the double dose yielding a GMT of 1.89 against the B/Yamagata strain and 2.13 against the B/Victoria in children aged 6-17 months. Across the entire age spectrum of the study population, unprimed children registered a GMT of 1.85 and 2.04 against the same strains, respectively. For comparison, none of

the A strains in any cohort based on age or primed/unprimed registered a GMT above 1.5.

“Increased protection against influenza B [would] be a beneficial clinical outcome [and] use of the same vaccine dose for all eligible ages would

**Immunogenicity was higher in the double-dose group, particularly against vaccine B strains in children 6-17 months of age and unprimed children.**

also simplify the annual influenza vaccine campaign and reduce cost and logistic complexity,” the authors concluded. “This study provides evidence to support a change in clinical practice to use [double-dose IIV4] in all children 6 months of age and older, once that dosing for a vaccine product has been approved.”

Dr. Jain now is employed by the Bill and Melinda Gates Foundation. Dr. Jain and several coauthors disclosed ties to GlaxoSmithKline, which funded the study.

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## Bronchiolitis pathway adherence tied to reduced LOS, costs

BY LORI LAUBACH  
Frontline Medical News

High adherence to bronchiolitis clinical pathway recommendations in health care settings is associated with shorter length of stay (LOS) and lower health care costs, according to Mersine A. Bryan, MD, of the University of Washington, Seattle and her associates.

In a retrospective cohort study, researchers looked at 267 patients less than 24 months old diagnosed with bronchiolitis from December 2009 to July 2012. Levels of adherence were then categorized into low, middle, and high tertiles. Results show that adherence was highest for the inpatient quality indicators (mean score, 95) and lowest for the emergency department quality indicators (mean score, 79). The mean ED LOS was significantly shorter for cases with ED adherence scores in the highest ver-

sus the lowest tertile (90 vs. 140 minutes;  $P$  less than .05). There were no significant differences in mean inpatient LOS by inpatient adherence score tertiles. “However, the mean inpatient LOS was approximately 17 hours shorter for cases with combined ED/inpatient adherence scores in the highest, compared with the lowest tertile,” they said.

The mean ED costs for cases with ED adherence scores in the highest tertile were significantly lower than cases with scores in the lowest tertile ( $-\$84$ ;  $P$  less than .05). It is noted there were no significant differences in mean total costs by inpatient adherence score tertile, but “for cases where the combined ED/inpatient adherence scores were in the highest tertile, the mean total costs were significantly lower than for cases with combined adherence scores in the lowest tertile, the researchers noted. Also, cases with ED adherence scores in the highest tertile had lower odds of inpatient

admission, compared with those with scores in the lowest tertile (odds ratio, 0.38). There were no significant differences in the odds of return ED visits or readmissions by adherence score tertile.

“Our study demonstrates that high adherence to evidence-based recommendations within a clinical pathway across the entire continuum of care, from the ED to the inpatient setting, is associated with lower costs and shorter LOS,” Dr. Bryan and associates concluded. “By improving adherence to evidence-based recommendations within a clinical pathway, we may be able to provide higher-value care by optimizing the quality of bronchiolitis care at lower costs and with shorter LOS.”

Read the full study in *Pediatrics* (doi: 10.1542/peds.2016-3432).

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protect against invasive pneumococcal disease.

However, IgG GMCs were lower in preterm than term infants for nearly half of the serotypes at all time points.

Antipneumococcal IgG levels in preterm infants were generally lower

than in term infants, but fewer differences in opsonophagocytic activity were seen between the groups,” Dr. Martín-Torres and his associates reported.

They concluded by recommending “timely vaccination of infants against *Streptococcus pneumoniae* starting at the chronologic age of 2 months, regardless of gestational age

or weight at birth,” and “giving the toddler dose at the earliest possible opportunity.”

Pfizer funded the study.

Dr. Martín-Torres reported receiving research grants and/or honoraria as a consultant/adviser and/or speaker and for conducting vaccine trials for GlaxoSmithKline, MedImmune, Merck, Novartis, Pfiz-

er/Wyeth, Sanofi Pasteur, and the Carlos III Health Institute.

Several coauthors disclosed ties with pharmaceutical companies; four are stock-holding employees of Pfizer, and another is an employee of a company contracted by Pfizer.

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# 48% of pediatric HA-VRIs caused by rhinovirus

BY KATIE WAGNER LENNON  
*Frontline Medical News*

**H**ealth care–associated viral respiratory infections (HA-VRIs) were common in two pediatric hospitals, with rhinovirus the most frequent cause of the infections in a 3-year analysis.

The incidence rate of laboratory-confirmed HA-VRIs was 1.29/1,000 patient-days in an examination of the hospitals' patient data. Forty-eight percent of all 323 HA-VRI cases were caused by rhinovirus, with an overall incidence rate of 0.72/1,000 patient-days. Additionally, rhinovirus was the most frequently identified virus in cases of HA-VRI in almost all units of both hospitals, followed by parainfluenza virus and respiratory syncytial virus. The exception was the medical/surgical ward of Steven and Alexandra Cohen Children's Medical Center (CCMC) of New York; in this unit of the CCMC, the incidence rate of parainfluenza virus was higher than that of rhinovirus (0.21/1,000 patient-days vs. 0.15/1,000 patient-days) (*J Ped Inf Dis*. 2016. doi: 10.1093/jpids/piw072).

The researchers used infection prevention and control surveillance databases from Montreal Children's Hospital and the CCMC to identify HA-VRIs that occurred between April 1, 2010, and March 31, 2013. In both hospitals, HA-VRIs were attributed to the unit to which the patient was admitted at the time of transmission. Both hospitals used a multiplex nucleic acid amplification test for respiratory virus detection on nasopharyngeal swabs or aspirates.

"An HA-VRI with an onset of symptoms after hospital discharge would be detected and included only for patients who presented to the emergency department or were readmitted for VRI and tested," according to Caroline Quach, MD, of the Montreal Children's Hospital, McGill University Health Centre, and her colleagues.

The HA-VRI rate was 1.91/1,000 patient-days at Montreal Children's Hospital, compared with 0.80/1,000 patient-days at the CCMC (*P* less than .0001). At the CCMC, the HA-VRI incidence rate was lowest in the neonatal ICU, but at Montreal Children's Hospital, the hematology/oncology ward had the lowest rate of HA-VRI.

Having less than 50% single rooms in a given unit was associated with a

statistically significantly higher rate of HA-VRI, after the investigators adjusted for unit type and took the correlation of HA-VRI rates within a hospital into consideration. The study authors' model predicted

that units with less than 50% single rooms have 1.33 times higher HA-VRI rates than units with at least 50% single rooms, regardless of unit type.

Dr. Quach has received funding

from GlaxoSmithKline, Pfizer, Sage, and AbbVie for an unrelated research project, while the other authors disclosed no financial relationships.

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# RSV is preemies' top severe respiratory disease source

BY BIANCA NOGRADY  
*Frontline Medical News*

**R**espiratory syncytial virus is the number one virus causing severe lower respiratory disease

in preterm infants, while those of younger age and those exposed to young children are at greatest risk, Eric A. F. Simões, MD, of the University of Colorado at Denver, Aurora, and his coauthors reported in the

Nov. 29 edition of PLOS ONE.

“These data demonstrate that higher risk for 32 to 35 wGA [weeks gestational age] infants can be easily identified by age or birth month and significant exposure to other young

children,” they wrote. “These infants would benefit from targeted efforts to prevent severe RSV disease.”

The prospective RSV Respiratory Events Among Preterm Infants Out-  
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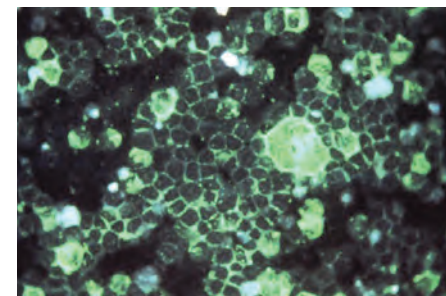
comes and Risk Tracking (REPORT) study in 38 states followed 1,642 preterm infants born at 32-35 weeks' gestational age who had medically attended acute respiratory illness.

The overall rates of lower respiratory infections per 100 infant-seasons – a

season being 5 months of observation from November 1 to March 31 in 2009-2010 or 2010-2011 – were 13.7 for respiratory syncytial virus (RSV), 2.9 for adenovirus, 1.7 for parainfluenza virus type 2, 1.3 for human metapneumo virus, and 0.3 for parainfluenza virus type 2 (PLoS One. 2016 Nov 29. doi: 10.1371/journal.pone.0166226).

Infants who had been exposed to young children, either through attending day care or living with non-multiple birth preschool-age siblings, had a twofold higher risk of RSV and human metapneumovirus, and a 3.3-fold greater risk of adenovirus.

The youngest infants showed the highest rate of hospitalizations with



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**Infants born in May, before the RSV season, had much lower rates of hospitalization and ICU admission, compared with infants born at the height of RSV season in February.**

RSV: The incidence ranged from 8.2 per 100 infant-seasons in those aged less than 1 month to 2.3 per 100 infant-seasons in those aged 10 months of age. Similarly, the incidence of admission to ICU was significantly higher among younger infants.

Infants born in May, before the RSV season, had a much lower incidence of hospitalization, compared with those born in the height of RSV season in February. ICU admission rates also were higher among those born in February, compared with those born in May.

The highest overall rates of hospitalization with RSV – 19 per 100 infant-seasons – were among those born in February, and also those who were exposed to other young children.

“The current results are unique in that they provide continuous age-based risk models for outpatient and inpatient disease for infants with and without young child exposure,” wrote Dr. Simões and his coauthors.

The study was supported by AstraZeneca, parent company of MedImmune. Two authors declared grant support and research funding from AstraZeneca, one author was a former employee of AstraZeneca, and one author was a former employee of MedImmune and now contractor to AstraZeneca. One author was a current employee of AstraZeneca and holds stock options. Two authors also declared funding and consultancies with AbbVie.

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#### VIEW ON THE NEWS

**Susan Millard, MD, FCCP, comments:** The American Academy of Pediatrics has a consensus statement on the use of palivizumab (Synagis) in preterm infants and infants with congenital heart disease. It is important for pediatric primary care providers and subspecialists to review these guidelines in the Red Book.

# Strokes cut by extended NOAC prophylaxis

BY MITCHEL L. ZOLER  
Frontline Medical News

NEW ORLEANS – Thromboprophylaxis for 35-42 days with the new oral anticoagulant betrixaban led to a significant reduction in all-cause and ischemic strokes in medically ill patients who required hospitalization as compared with conventional prophylaxis for 10 days, based on a post-hoc analysis of data from a randomized trial with more than 7,500 patients.

But the trial's unusual design left it unclear whether the incremental benefit seen from prolonged prophylaxis with a NOAC resulted primarily from a longer period of treatment, the drug used, or both.

The Kaplan-Meier analysis showed that stroke incidence in the two intervention arms began to diverge during the first 10 days when all patients received an anticoagulant, suggesting that betrixaban surpassed enoxaparin when the two therapies went head to head. C. Michael Gibson, MD, said at the American Heart Association scientific sessions. Beyond the first 10 days and out to 77 days of follow up – during the period when standard enoxaparin prophylaxis in the control patients had ended but the novel regimen with betrixaban continued – the curve of strokes in the betrixaban group continued to separate sharply from that of the control group, indicating extended prophylaxis offered substantial benefit, said Dr. Gibson, a professor of medicine at Harvard Medical School and an interventional cardiologist at Beth Israel Deaconess Medical Center, both in Boston.

The safety analysis showed that prolonged treatment with betrixaban roughly doubled the rate of major or clinically relevant nonmajor bleeding events during the period of treatment and for the first 7 days after treatment stopped. The incidence of these bleeds was 1.6% among control patients on 10 days of enoxaparin treatment and 3.1% among patients who received extended treatment with betrixaban, a statistically significant difference. The rates of fatal bleeds and intracranial hemorrhages in the two study groups did not significantly differ.

The data Dr. Gibson reported came from the Multicenter, Randomized, Active-Controlled Efficacy and Safety Study Comparing Extended Duration Betrixaban With Standard of Care Enoxaparin for the Prevention of Venous Thromboembolism in Acute Medically Ill Patients (APEX). The study's primary aim was testing in 7,513 hospitalized medically ill patients the safety and efficacy of prolonged prophylaxis with the oral, factor Xa inhibitor betrixaban, compared with 10 days of prophylaxis with the low molecular weight heparin enoxaparin. The primary endpoint was the rate of venous thromboembolic events and deaths from venous thromboembolism (VTE) out to 47 days after the start of treatment.

APEX enrolled patients hospitalized for acute decompensated heart failure, chronic respiratory failure, acute infection without septic shock, acute rheumatic disorders, or acute ischemic stroke. All enrolled patients had to be expected to be immobilized for at least 24 hours following randomization and to be hospitalized for at least 3 days. Patients also had to have an additional risk marker for high thrombotic risk: They had to be at least 75 years



Dr. Gibson: Betrixaban surpassed enoxaparin.

old, or 60-74 years old with a d-dimer level at least twice the upper limit of normal, or 40-59 years old with a d-dimer level at least twice the upper limit of normal and a history of either VTE or cancer.

Results for the primary endpoint, reported in 2016, showed that prolonged betrixaban prophylaxis linked with an absolute 1.6% reduction in the combined endpoint, which resulted in a 19% relative risk reduction that fell just short of the trial's prespecified definition of statistical significance. The study's primary safety endpoint was the occurrence of major bleeding events through 7 days after the stop of treatment, which occurred in 0.7% of the betrixaban patients and in 0.6% of those on enoxaparin (N Engl J Med. 2016 Aug 11;375[6]:534-44).

Even though the primary results from this pivotal trial failed to meet the prespecified threshold for statistical significance, the company developing betrixaban, Portola, submitted an application to the Food and Drug Administration to approve marketing of extended-duration betrixaban for VTE pro-

phylaxis in acute medically ill patients with VTE risk factors. In December 2016, Portola announced that the FDA had given the application priority status for a decision.

The post-hoc analysis that Dr. Gibson presented at the meeting looked at the impact of betrixaban compared with enoxaparin on the incidence of all-cause and ischemic stroke during 77 days of follow-up after the start of treatment in the 7,432 patients who received at least one dose of their assigned drug, two endpoints that weren't even secondary outcomes in APEX's original design.

Among the 3,716 treated with betrixaban, the all-cause stroke incidence was 0.54%; among the 3,716 patients treated with enoxaparin, the all-cause stroke incidence was 0.97%. The 56% relative risk reduction was statistically significant. The incidence of ischemic strokes was 0.48% with betrixaban and 0.91% with enoxaparin, a 53% relative risk reduction that was also statistically significant.

The post-hoc analysis also looked specifically at the comparison between betrixaban and enoxaparin for stroke prevention in a subgroup of patients who had the highest stroke rate, the patients who were hospitalized because of an index stroke or an index heart failure episode. In this high-risk subgroup, prophylaxis with betrixaban cut the all-cause stroke rate compared with enoxaparin by 49% and the ischemic stroke rate by 45%, both statistically significant effects.

Dr. Gibson has been a consultant to Eli Lilly, Gil-ead, The Medicines Company, Novo Nordisk, Pfizer, and St. Jude. He has received research support from Portola and several other companies.

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## VIEW ON THE NEWS

### Extended-duration thromboprophylaxis may help

The APEX study identified a group of patients hospitalized for medical reasons who were at high risk for both venous thromboembolism and for stroke. We are comfortable with the concept of thromboprophylaxis for hospitalized patients who are at high risk for venous thromboembolism, but we have generally not paid attention to prophylaxis against stroke during and immediately after hospitalization.

The results suggest that extending thromboprophylaxis beyond the standard period of 10 days may be a good idea. Because patients in the two treatment arms of the study differed in both the drugs they received and in the duration of prophylaxis, the results cannot distinguish which of these two variables was more important. Treating patients with enoxaparin for 35-42 days may provide a similar benefit to what was seen with extended-duration betrixaban. Although daily treatment at home with injected enoxaparin is less convenient than outpatient treatment with an oral drug like betrixaban, extended-duration enoxaparin is a

feasible option. The Kaplan-Meier curves that Dr. Gibson presented indicate that most of the incremental benefit from betrixaban occurred after 10 days, once it was compared with no prophylaxis at all in the control arm with short-duration enoxaparin.

The findings are a wake-up call to the high thromboembolic risk faced by the types of patients enrolled in APEX, and they point to a new way to manage these patients. Guidelines already call for putting high-risk patients, such as those with heart failure, on anticoagulant prophylaxis if they have no contraindications. These new data suggest that thromboprophylaxis in appropriate patients should extend beyond 10 days and beyond acute hospitalization.

Steven R. Lentz, MD, is a professor of medicine and a hematologist oncologist at the University of Iowa in Iowa City. He has been a consultant to Novo Nordisk and Opko, has an ownership interest in Celgene, and has received research grants from Novo Nordisk. He made these comments in an interview.





# Infections plummet with new catheter interventions

BY ABIGAIL CRUZ  
Frontline Medical News

**Q**uality improvement (QI) interventions related to the use of central venous catheters (CVCs) were, on average, associated with 57% fewer infections and \$1.85 million in net savings to hospitals within 1-3 years of implementation, based on the results of a meta-analysis of data from 113 hospitals.

“Hospitals that have already attained very low infection rates (through the use of quality improvement checklists) would likely see smaller clinical benefits and savings than in the studies we have reviewed,” said Dr. Teryl Nuckols of Cedars-Sinai Medical Center, Los Angeles. “Nonetheless, we found that QI interventions can be associated with declines in CLABSI (central line-associated bloodstream infection) and/or CRBSI (catheter-related bloodstream infection) and net savings when checklists are already in use, and when hospitals have CLABSI rates as low as 1.7-3.7 per 1,000 CVC-days.”

Dr. Nuckols and colleagues did a literature search and examined results from 15 unique studies representing data from 113 acute care hospitals. All studies addressed quality improvement interventions designed to prevent CLABSI and/or CRBSI.

Studies were eligible for the analysis if they reported or estimated the quality improvement intervention’s clinical effectiveness, measured or modeled its costs, compared alternatives to the intervention, and reported both program

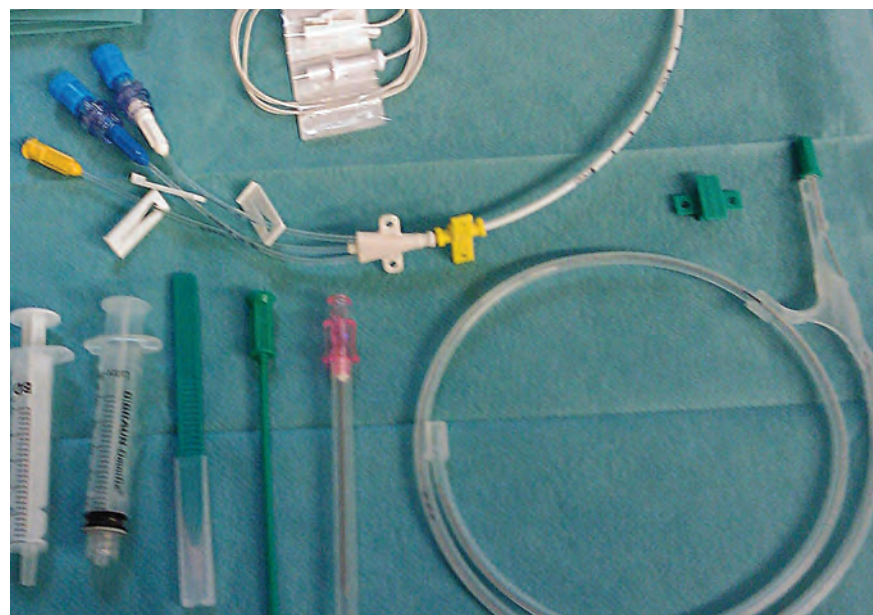
and infection-related costs.

Insertion checklists were examined in 12 studies, physician education in 11 studies, ultrasound-guided placement of catheters in 3 studies, all-inclusive catheter kits in 5 studies, sterile dressings in 5 studies, chlorhexidine gluconate sponge or antimicrobial dressing in 2 studies, and antimicrobial catheters in 2 studies.

Overall, the weighted mean incidence rate ratio was 0.43 (95% confidence interval, 0.35-0.51) and incremental net savings were \$1.85 million (95% CI, \$1.30 million to \$2.40 million) per hospital over 3 years (2015 U.S. dollars). Each \$100,000 increase in program cost was associated with \$315,000 greater savings (95% CI, \$166,000-\$464,000; *P* less than .001). Infections and net costs declined when hospitals already used checklists or had baseline infection rates of 1.7-3.7 per 1,000 catheter-days (doi: 10.1001/jamainternmed.2016.6610).

Dr. Nuckols acknowledged that the price tag for achieving these savings “may be burdensome for hospitals with limited financial resources ... wages and benefits account for two-thirds of all spending by hospitals, and a quarter of hospitals have had negative operating margins in recent years. We found that, for CLABSI- and CRBSI-prevention interventions, median program costs were about \$270,000 per hospital over 3 years – but reached \$500,000 to \$750,000 in some studies.”

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Hospitals that have already attained very low infection rates would likely see smaller clinical benefits than in the studies reviewed, noted Dr. Teryl Nuckols.

# Moderate artery stenosis often becomes severe

BY DOUG BRUNK  
Frontline Medical News

**H**OUSTON – Most nongrafted, moderately stenosed coronary arteries progress to severe stenosis or occlusion in the long term, results from a large, long-term study have shown.

“Not uncommonly, patients referred for coronary surgery have one or more coronary arteries with only moderate stenosis,” Joseph F. Sabik III, MD, said at the annual meeting of the Society of Thoracic Surgeons.



DR. SABIK

“There is controversy as to whether arteries with only moderate stenosis should be grafted during coronary surgery, and if it should be grafted, with what conduit?” For example, the Fractional Flow Reserve-Guided PCI Versus Medical Therapy in Stable Coronary Disease study, known as FAME, suggests not intervening on moderate stenosis, since stenting non-ischemia-producing lesions led to worse outcomes (N Engl J Med. 2012 Sep 13;367:991-1001). However, Dr. Sabik, who chairs the department of surgery at University Hospitals Cleveland Medical Center, and his associates recently reported that grafting moderately stenosed coronary arteries during surgical revascularization is not harmful and can be beneficial by improving survival if an internal thoracic artery graft is used (J Thoracic Cardiovasc Surg. 2016 Mar;151[3]:806-11).

In an effort to determine how grafting moderately stenosed coronary arteries influences native-vessel disease progression, and whether grafting may be protective from late ischemia, Dr. Sabik and his associates evaluated the medical records of 55,567 patients who underwent primary isolated coronary artery bypass graft (CABG) surgery at the Cleveland Clinic from 1972 to 2011. Of the 55,567 patients, 1,902 had a single coronary artery with angiographically moderate stenosis (defined as a narrowing of 50%-69%) and results of at least one postoperative angiogram available. Of these moderately stenosed coronary arteries (MSCAs), 488 were not grafted, 385 were in-

ternal thoracic artery (ITA)-grafted, and 1,028 were saphenous vein (SV)-grafted. At follow-up angiograms, information about disease progression was available for 488 nongrafted, 371 ITA-grafted, and 957 SV-grafted MSCAs, and patency information was available for 376 ITA and 1,016 SV grafts to these MSCAs. Grafts were considered patent if they were not occluded. Severe occlusion was defined as a narrowing of more than 70%.

The researchers found that at 1, 5, 10, and 15 years, native-vessel disease progressed from moderate to severe stenosis/occlusion in 32%, 52%, 66%, and 72% of nongrafted MSCAs, respectively; in 55%, 73%, 84%, and 87% of ITA-grafted MSCAs, and in 67%, 82%, 90%, and 92% of SV-grafted MSCAs.

After Dr. Sabik and his associates adjusted for patient characteristics, disease progression in MSCAs was significantly higher with ITA and SV grafting, compared with nongrafting (odds ratios, 3.6 and 9.9, respectively). At 1, 5, 10, and 15 years, occlusion in grafts to MSCAs was 8%, 9%, 11%, and 15%, respectively, for ITA grafts and 13%, 32%, 46%, and 56% for SV grafts. At these same time points, protection from myocardial ischemia in ITA-grafted vs. nongrafted MSCAs was 29%, 47%, 59%, and 61%.

“Our opinion is you that shouldn’t ignore moderate lesions,” Dr. Sabik, surgeon-in-chief and vice president for surgical operations for the University Hospitals system, said in an interview at the meeting. “Although it may not help that patient over the next short period of time, over their lifespan it will. What works for intervention doesn’t necessarily mean it’s right for bypass surgery. If you have a vessel that’s only moderately stenosed you should at least consider grafting it, because moderate lesions progress over time. Bypassing it helps people live longer when you use an internal thoracic artery graft, because they are likely to remain patent. You always have to individualize the therapy, but the key is to use your grafts in the best way possible.”

Dr. Sabik disclosed that he has received research grants from Medtronic, Abbott Vascular, and Edwards Lifesciences.

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# Nailfold can predict cardiopulmonary problems

BY JENNIE SMITH  
Frontline Medical News

**N**ailfold videocapillaroscopy can help to predict which patients with systemic sclerosis may develop serious cardiopulmonary complications, according to findings from a Dutch cross-sectional study.

While individual autoantibodies seen in systemic sclerosis (SSc) are known to be associated with greater or lesser risk of cardiopulmonary involvement, in this study nailfold vascularization patterns independently predicted pulmonary artery hypertension or interstitial lung disease.

For their research, Iris M. Markusse, MD, PhD, and her colleagues at Leiden (the Netherlands) University Medical Center collected data on nailfold videocapillaroscopy (NVC) patterns and SSc-specific autoantibodies from a cross section of 287 patients in an established SSc cohort (*Rheumatology [Oxford]*. 2016 Dec 10. doi: 10.1093/rheumatology/kew402).

All patients in the study had NVC pattern data as well as anti-extractable nuclear antigen (anti-ENA) antibodies. The mean age of the patients was 54 years; 82% were female, and median disease duration was 3 years. Just over half the cohort had interstitial lung disease, and 16% had pulmonary artery hypertension.

Among the anti-ENA autoantibody subtypes, anti-ACA was seen in 37% of patients, anti-Scl-70 in 24%, anti-RNP in 9%, and anti-RNAPIII in 5%; other subtypes were rarer.

SSc-specific NVC patterns were seen in 88% of patients, with 10% of the cohort showing an early (less severe microangiopathy) pattern, 42% an active pattern, and 36% a late pattern.

One of the study's objectives was to determine whether one or more mechanisms was responsible for both autoantibody production and the microangiopathy seen in SSc.

If a joint mechanism is implicated, "more severe NVC patterns would be determined in patients with autoantibodies (such as anti-Scl-70 and anti-RNAPIII) that are associated with more severe disease," wrote Dr. Markusse and her colleagues. "On the other hand, if specific autoantibodies and stage of microangiopathy reflect different processes in the disease, a combination of autoantibody status and NVC could be helpful for identifying patients at highest risk for cardiopulmonary involvement."

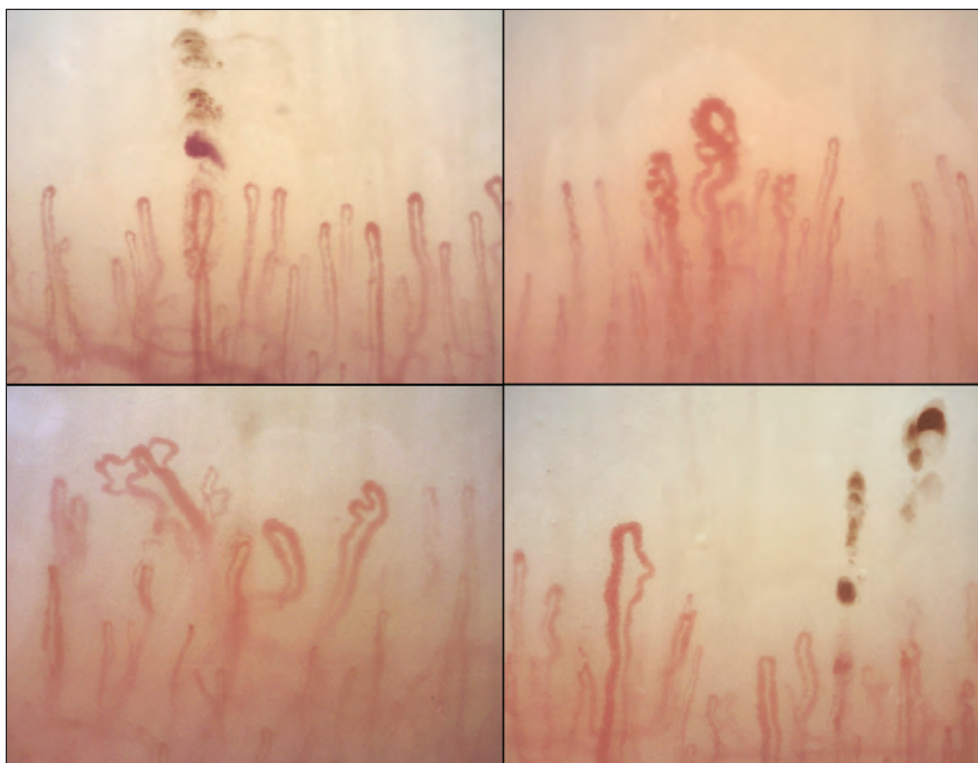
The investigators reported finding a similar distribution of NVC abnormalities across the major SSc autoantibody subtypes (except for anti-RNP-positive patients), suggesting that combinations of the two variables would be most predictive of cardiopulmonary involvement. More severe NVC patterns were associated with a higher risk of cardiopulmo-

nary involvement, independent of the presence of a specific autoantibody. Notably, the researchers wrote, "prevalence of ILD [interstitial lung disease] is generally lower among ACA-positive patients. According to our data, even among ACA-positive patients there was a trend for more ILD being associated with more severe NVC patterns (OR = 1.33)."

A similar pattern was seen for pulmonary artery hypertension. "Based on anti-RNP and anti-RNAPIII positivity, patients did not have an in-

creased risk of a [systolic pulmonary artery pressure] greater than 35 mm Hg; however, with a severe NVC pattern, this risk was significantly increased (OR = 2.33)."

The investigators cautioned that their findings should be confirmed in larger cohorts. The study by Dr. Markusse and her colleagues was conducted without outside funding, though manufacturers donated diagnostic antibody tests. One of the 11 study coauthors disclosed receiving financial support from Actelion.



**Nailfold capillaroscopy images show progressively worsening damage: microhemorrhage and hemosiderin (top left), an isolated dilated loop (top right), lower capillary density and microhemorrhage (lower right), and architectural derangement (lower left).**

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# Macitentan boosts quality of life in PAH patients

BY RANDY DOTINGA  
Frontline Medical News

FROM CHEST

**M**acitentan, a recent addition to the drugs that treat pulmonary arterial hypertension (PAH), improves and stabilizes quality of life for patients with the condition, according to an industry-funded study.

Macitentan (Opsumit) remains tremendously expensive, costing as much as \$100,000 per year in the United States, and the study provides little in the way of direct comparison to other drugs in its class. Still, the drug's effects on quality of life are dramatic, said study lead author Sanjay Mehta, MD, FRCPC, FCCP, professor of medicine at the University of Western Ontario and director of the Southwest Ontario Pulmonary Hypertension Clinic at the London (Ont.) Health Sciences Center.

Researchers found that those who took the 10-mg dose, versus placebo, reported significant improvement in seven of eight quality-of-life domains, and in

physical and mental components scores, as measured by the 36-item Short Form Health Survey (SF-36). In addition, the study linked 10-mg doses, versus placebo, to a lower risk of a decline of three points or more in the physical component score (hazard ratio, 0.60; 95% confidence interval, 0.47-0.76; *P* less than .0001] and the mental component scores (HR, 0.76; 95% CI, 0.61-0.95; *P* = .0173) until end of treatment.

"The drug has shown stability in patients' quality of life over 6 months and 12 months," Dr. Mehta said in an interview. "I can't cure anybody, and they'll get worse at some point, but I can improve them. They physically feel better, they're less short of breath with less body pain, and they feel better psychologically."

Macitentan, an endothelin receptor antagonist, received Food and Drug Administration approval in 2013 following a study that year (*N Engl J Med*. 2013 Aug 29;369[9]:809-18) that linked 10-mg doses to a significantly lower risk of death and various complications, compared with placebo

and the 3-mg dose. The new study (*Chest*. 2017 Jan;151[1]:106-18) is an analysis of data from the 2013 study.

The PAH patients were randomly assigned to one of three groups: macitentan 10 mg once daily (234), macitentan 3 mg (237), and placebo (239). The study examined responses from 710 patients (76.9% were female, 55.2% were white, mean age was 45.5) to the SF-36 at baseline, 6 months, 12 months, and end of treatment.

Dr. Mehta noted that macitentan has not been clinically compared to the other drugs. The study, however, notes that it is the first PAH treatment to show improvement in seven of eight domains in the quality-of-life survey.

The study was funded by Actelion Pharmaceuticals, maker of macitentan. Dr. Mehta has received consulting and speaking fees and institutional support for clinical trials from Actelion, among other drug companies. The other authors report various disclosures, including relationships with Actelion.



# Federal judge blocks Anthem-Cigna merger

BY ALICIA GALLEGOS  
Frontline Medical News

A federal district court judge has blocked health insurer Anthem from acquiring Cigna, ruling the megamerger would violate antitrust laws and stifle competition.

The decision came weeks after another U.S. district court judge barred a merger between health insurance giants Aetna and Humana.

The U.S. Department of Justice praised the latest ruling, calling the decision a victory for patients.

“This merger would have stifled competition, harming consumers by increasing health insurance prices and slowing innovation aimed at lowering the costs of health care,” Acting Assistant Attorney General Brent Snyder said in a statement.

Anthem intends to appeal the decision, said Joseph R. Swedish, Anthem’s chair, president, and chief executive officer. “Anthem is significantly disappointed by the decision, as combining Anthem and Cigna would positively impact the health and well-being of millions of Americans – saving them more than \$2 billion in medical costs annually,” Mr. Swedish said

in a statement. “If not overturned, the consequences of the decision are far reaching and will hurt American consumers by limiting their access to high-quality affordable care, slowing the industry’s shift to value-based care and improved outcomes for patients, and restricting innovation, which is critical to meeting the evolving needs of health care consumers.”

In a statement, a Cigna official said the company intends to carefully review the opinion and evaluate its options in accordance with the merger agreement.

“Cigna remains focused on helping to improve health care by delivering value to our customers and clients and expanding our business around the world,” the statement said.

The DOJ, 11 states, and the District of Columbia sued Anthem and Cigna in July over their proposed \$54 billion consolidation in what would have been the largest merger in history.

The DOJ argued the merger would substantially harm competition and negatively impact the entire insurance industry if allowed to proceed. The consolidation would enhance Anthem’s power to profit at the expense of consumers and the doctors and hospitals

who provide their medical care, DOJ attorneys said in their complaint.

Anthem and Cigna argued the proposed acquisition was “procompetitive,” and that the merger would result in efficiencies that would directly benefit consumers via greater access to affordable health care. The benefits of the merger outweigh any alleged anticompetitive effects, according to Anthem.

A trial before Judge Amy Berman Jackson of the U.S. District Court for the District of Columbia ran from November through January.

Judge Berman’s opinion is temporarily under seal to allow parties to review for confidentiality.

The ruling is the second victory for the DOJ in as many weeks. In a Jan. 23 decision, Judge John D. Bates of the U.S. District Court for the District of Columbia denied Aetna’s \$37 billion plan to purchase Humana, following a month-long trial that began in early December. Judge Bates ruled the consolidation would violate antitrust laws and reduce competition.

Aetna and Humana did not respond to requests for comment.

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## VIEW ON THE NEWS

**Michael E. Nelson, MD, FCCP, comments:** Any business

owner who has been required to absorb yearly double-digit increases in employee health insurance costs cannot help but wonder where Mr. Swedish learned his “new math.” His second statement is even more incogitable – since when were insurers known for expanding access to health care. Anyone who has been unfortunate enough to participate in a peer-to-peer conference with an insurer in an attempt to get a patient needed care knows otherwise. Although health insurance companies did not exist in 1890, the Sherman Antitrust Act of the same year was perfectly scripted to proscribe this type of merger over a century later.



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# Trump travel policy may affect medical meetings

BY ALICIA GALLEGOS  
*Frontline Medical News*

President's Trump's revised executive order blocking travelers from six Muslim-majority countries from entering the United States could land a damaging blow to global cooperation in scientific research and could impede assemblies of the world's top medical experts.

The March 6 executive order bars citizens of Iran, Libya, Somalia, Sudan, Syria, and Yemen from obtaining visas for 90 days and blocks refugees from those countries from entering the United States for 120 days. The measure, which takes effect March 16, supersedes President Trump's Jan. 27 travel ban. The new order exempts citizens of the six countries who are legal permanent U.S. resi-

dents or who have current visas.

The policy could have detrimental effects on future collaboration between U.S. and international scientists and may ultimately endanger the health and well-being of patients, said International Antiviral Society—U.S.A. executive director and president Donna M. Jacobsen.

There is "serious reason for concern" that the policy will dissuade scientists and researchers "from traveling to the [United States] in the future overall and sharing their work with colleagues here," she said.

Thousands of academics from around the world, including physicians, researchers, and professors, have vowed to boycott U.S.-based conferences in light of the Trump administration policy.

The new executive order comes nearly 2 months after President

Trump's original travel ban caused nationwide protests and led to a series of legal challenges. The states of Washington and Minnesota, which sued President Trump over his original ban, argued that such a ban harms the teaching and research missions of their universities and prevents students and faculty from traveling for research and academic collaboration. In addition, the executive order restricts universities from hiring attractive candidates from countries affected by the ban, state officials said. A federal court temporarily blocked the original travel ban on Feb. 3, a decision upheld by the 9th U.S. Circuit Court of Appeals on Feb. 9. The circuit judges said the plaintiffs were likely to succeed in their arguments and that the president had demonstrated no evidence that his executive order advances national security.

The new executive order excludes Iraq and also removes language that had indefinitely banned Syrian refugees. In a March 6 memorandum, the White House said the purpose of the ban is to prevent "foreign nationals who may aid, support, or commit violent, criminal, or terrorist acts," while the administration enhances the screening and vetting protocols and procedures for granting visas and admission to the United States.

"This nation cannot delay the immediate implementation of additional heightened screening and vetting protocols and procedures for issuing visas to ensure that we strengthen the safety and security of our country," the memo states.

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## Societies voice concern for travel ban

February 7, 2017

**The Honorable John F. Kelly**  
Secretary

U.S. Department of Homeland Security  
Washington, DC 20528

Dear Secretary Kelly:

The undersigned organizations are greatly concerned that the executive order signed by President Trump on January 27, 2017 will result in discrimination against foreign-born persons from certain predominantly Muslim countries. We are particularly concerned that by restricting entry of physicians and medical students from seven designated Muslim majority countries, the order will undermine medical education and result in patients losing access to their doctors. We are also greatly concerned that the 120 day ban on accepting refugees, and the indefinite ban on Syrian refugees, will contribute to an ongoing public health crisis for those affected, needlessly subjecting them to violence, injury, illness, deprivation and even death. While we are pleased that the courts have temporarily halted implementation of the executive order, the underlying issues of concern about the harm caused by the executive order remain.

The restrictions in the executive order will hinder the free exchange of information and travel among medical students, residents and physicians around the world and result in Americans having poorer access to care. In 2016, 3,769 non-U.S. citizen international medical graduates (IMGs) obtained first-year residency positions. More than half of internal medicine residency positions were filled by IMGs. Approximately 25% of the nation's physicians are IMGs and provide a disproportionate share of the care to Americans in underserved communities that have a shortage of U.S. born and trained physicians. They also add

necessary diversity and cultural competency to our healthcare workforce. If the executive order prevents IMGs from being able to come to the U.S. this could potentially affect the care for thousands of patients.

Our organizations are also especially concerned about refugees with dire medical conditions who had been approved for visas to enter the U.S. but since the executive order, have been unable to enter the country to receive much needed medical care.

While we urge that the executive order be rescinded and replaced with non-discriminatory policies that support families, public health, and medical education, and are pleased that the courts have temporarily halted implementation, there are steps that DHS can take immediately to selectively ease travel restrictions that impact medical education, access to health care services, and public health for individuals who otherwise meet the criteria for immigration, including those from the seven countries identified in the executive order. Specifically, we urge the Department of Homeland Security to:

1. Reinstate the Visa Interview Waiver Program. Suspension of the program "risks creating substantial backlogs in the processing of new and renewal visas for trainees from any foreign country — delays that create substantial problems for residency programs with trainees on visas and that could interfere with the residency match process this year."
2. Remove restrictions on entering the U.S. for physicians from the seven designated countries who have been approved for J-1 or H-1B visas and students from those countries with F-1 visas who have been accepted to U.S. medical schools.
3. Develop and implement a plan to allow physicians from the seven designated countries to

obtain travel visas to travel to the U.S. for medical conferences and other medical and research-related engagements.

4. Make it a priority to implement a process to admit refugees, without further delay, who had already been vetted and approved for entry prior to the executive order and who are in need of urgent medical care. We note that even with such revisions, the executive order will still inappropriately bar immigrants and refugees based on discriminatory criteria (religion and country of origin) including family members of physicians and medical students in the U.S.

Our organizations are committed to non-discrimination against physicians, medical students and others in immigration policies and offer our assistance in developing policies that support access to health care services, public health, and medical education while balancing the nation's security needs. Until or unless the executive order is completely rescinded or permanently blocked, it is essential that DHS move forward to ensure that restrictions on physicians and medical students are not reimposed, and that priority is given to refugees with medical conditions needing treatment.

Sincerely,

*Alliance for Academic Internal Medicine  
American College of Chest Physicians  
American College of Physicians  
American Society for Gastrointestinal Endoscopy  
American Society of Hematology  
American Society of Nephrology  
American Thoracic Society  
Infectious Diseases Society of America  
Renal Physicians Association  
Society for Adolescent Health and Medicine  
Society of Critical Care Medicine  
Society of General Internal Medicine*



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# HFNC bests conventional O<sub>2</sub> therapy

BY WHITNEY MCKNIGHT  
Frontline Medical News

FROM CHEST

In patients with acute respiratory failure, high-flow nasal cannula (HFNC) is more reliable than is conventional oxygen therapy at reducing rates of endotracheal intubation, although no significant difference was found when HFNC was compared with noninvasive positive pressure ventilation, a new study found.

An increasing awareness of the high rate of adverse events and mortality rates associated with invasive mechanical ventilation in hospitals has led to a rise in the use of noninvasive positive pressure ventilation (NIPPV). While this has effectively cut the use of conventional oxygen therapy (COT), its application in clinical practice is limited by a host of complications such as interface intolerance, skin damage, and other hazards. HFNC, because of its demonstrated efficacy and relatively easier application, and better tolerance in patients, also has been gaining popularity. Despite the known benefits of HFNC, this therapy is not given to all adults with acute respiratory failure (ARF). This may be due to the lack of consistency in data regarding how HFNC's effectiveness at decreasing intubation and reintubation rates compares with COT's and NIPPV's.

Researchers in China conducted a meta-analysis and systematic review of all superiority and nonsuperiority data on the outcomes of using HFNC, COT, and NIPPV to treat ARF. Their examination included 18 trials comprising 3,881 patients, which compared the results of receiving HFNC with the results of receiving NIPPV or COT. The study

is published in CHEST (10.1016/j.chest.2017.01.004).

The investigators concluded that HFNC was associated with significantly lower rates of the need for endotracheal intubation, compared with COT ( $P = .01$ ). When HFNC was compared with NIPPV, however, the rates of patients needing intubation were not statistically different from each other ( $P = .16$ ). HFNC was not associated with significant improvements in mortality rates or lengths of stay in the intensive care units, when compared with both COT and NIPPV.

According to the researchers' subgroup analysis conducted of HFNC in 2,741 patients following extubation, those patients who received HFNC had a significantly lower reintubation rate than that of those who received COT (odds ratio, 0.39;  $P = .0003$ ). In this analysis, again, no significant differences in outcomes were seen between patients who received HFNC and NIPPV (OR, 1.07;  $P = .60$ ).

Bin-Miao Liang, MD, PhD, a researcher in the department of respiratory and critical care medicine at Sichuan (China) University, and coauthors noted that "concomitant complications such as acute kidney dysfunction and cardiac impairment may contribute to ICU mortality and ICU [lengths of stay] besides respiratory status itself." Factors such as available beds, a patient's insurance status, and other resources may also have impacted outcomes, they said.

The researchers wrote that they found "[significant] statistical heterogeneity" in the rates of endotracheal intubation and ICU mortality between HFNC and NIPPV. A lack of raw data, which prevented a sub analysis of individual respiratory failure from being performed, is one

## VIEW ON THE NEWS

### Is HFNC better than NIPPV? It depends

The introduction of high-flow nasal cannula (HFNC) fundamentally has changed how patients with acute respiratory failure are treated – both in avoidance of intubation and prevention of reintubation. Its use is supported by some very high quality studies over the last few years done in a variety of types of critically ill patients. While its clinical superiority to noninvasive ventilation (NIV) is still open to debate, the comfort and other attributes that HFNC provides increasingly are making it the first-choice modality (e.g., the patient can continue to eat, speak, and wear for longer periods of time).

Regarding this meta-analysis, given that most would agree that both HFNC and NIV are better than COT, the outcomes of interest are



the comparisons between HFNC and noninvasive positive pressure ventilation (NIPPV). Given the heterogeneity in the included trials, populations, and study quality, there unsurprisingly is a significant I-squared statistic for high heterogeneity in outcomes between studies. As such, little conclusion can be drawn regarding whether HFNC would be more beneficial than NIPPV in a given patient. It is likely that HFNC is better in some patients, while NIPPV is more appropriate for others ... and this meta-analysis just doesn't offer much in that regard.

Eric J. Gartman, MD, FCCP, is assistant professor of medicine at Brown University, Providence, R.I. He is an editorial board member of CHEST Physician.

possible cause of the statistical heterogeneity, the authors concluded.

"The finding that rates of intubation in patients with acute respiratory failure are reduced with [HFNC] use when compared to standard oxygen administration has important implications for critical care practitioners," said Danielle R. Ouellette, MD, FCCP, of Henry Ford Hospital, Detroit, in an interview. "It seems likely that this effect is a result of improvement in not only oxygenation, but also ventilation by such catheters. HFNC may be a useful adjunct not only in patients with respiratory failure, but also post-extubation, and

may be more tolerable than noninvasive ventilation."

China-Japan Friendship Hospital is continuing the search for more data on the success rates of HFNC and NIPPV at reducing intubation and mortality rates. The hospital is sponsoring a multicenter, randomized, noninferiority trial titled, "High Flow Nasal Cannula vs. NPPV in Moderate Chronic Obstructive Pulmonary Disease Exacerbation," according to ClinicalTrials.gov. No results were available for this trial as of March 1.

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# In ICU, pair MRSA testing method with isolation protocol

BY DAN WATSON  
Frontline Medical News

An ICU's method of testing for methicillin-resistant *Staphylococcus aureus* (MRSA) should be paired with its patient isolation policy, according to researchers at the University of Colorado at Denver.

In an ICU with all patients preemptively isolated, it is worth the added expense to opt for the polymerase chain reaction (PCR) test – which generates results in a few hours – so that patients negative for the infection can be moved out of isolation more quickly, wrote Melanie D. Whittington, PhD, and her coauthors. But if the ICU is isolating only MRSA-positive patients, the authors

instead recommend the less expensive but slower chromogenic agar 24-hour testing.

The other two MRSA tests the researchers assessed – conventional culture and chromogenic agar 48-hour testing – are less expensive. But when paired with either ICU isolation policy, those tests lead to excessive inappropriate isolation costs while waiting for the results, the study investigators cautioned (Am J Infect Control. 2017 Jan 23. doi: 10.1016/j.ajic.2016.12.014).

Adding together the cost per patient of the test, the "appropriate isolation costs," and "inappropriate isolation costs," the universal isolation policy is least expensive per patient with PCR, at \$82.51 per patient. With conventional culture, which can take

several days, this cost ballooned to \$290.11 per patient, with high inappropriate isolation costs.

Doing the same math with the more targeted isolation policy, the least expensive screening method was the 24-hour chromogenic agar, at \$8.54 per patient, while the expense of the PCR test made it the most expensive method when paired with this isolation policy, at \$30.95 per patient.

"With knowledge of the screening test that minimizes inappropriate and total costs, hospitals can maximize the efficiency of their resource use and improve the health of their patients," Dr. Whittington and her coauthors wrote.

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# High NIV volume not a predictor of good outcomes

BY MARY ANN MOON  
*Frontline Medical News*

Hospitals that frequently treat acute chronic obstructive pulmonary disease (COPD) exacerbations using noninvasive ventilation – a practice known to reduce mortality, length of stay, and the need for more invasive treatment – did not have better patient outcomes than did hospitals that used noninvasive ventilation less frequently, according to a report published in *Annals of the*

**“Contrary to our hypothesis, we did not observe significantly lower COPD mortality” in hospitals with high volumes of noninvasive ventilation, the researchers noted.**

American Thoracic Society.

Acute COPD exacerbations are “one of the few conditions with high-level evidence demonstrating the benefits of noninvasive ventilation in patients with respiratory distress,” and the treatment has been widely adopted for this patient population. However, for noninvasive ventilation to succeed, patients must be carefully selected and closely monitored, and a multidisciplinary team of nurses, respiratory therapists, and physicians must coordinate the treatment, often across multiple hospital settings, said Anuj B. Mehta, MD, of The Pulmonary Center, Boston University, and his associates.

Until now, it was not known

whether hospitals with a high volume of noninvasive ventilation develop specialized expertise and thus deliver superior patient outcomes, or whether a high volume results from suboptimal patient selection or other-

wise puts a strain on a hospital’s staff and thus produces poor outcomes. To examine this question, Dr. Mehta and his associates analyzed information in a database enrolling adults treated at 252 California hospitals for

acute COPD exacerbation. They focused on 37,516 hospitalizations that occurred during a single year.

Overall, 9.3% of these patients received noninvasive ventilation. The

*Continued on following page*

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## VIEW ON THE NEWS

**Eric Gartman, MD, FCCP,**

**comments:** It is unclear what conclusions can be drawn from this study given the likely heterogeneity between the included hospitals. For instance, hospitals with high volumes of NIV use also seemed to have patients with more significant comorbidities – and thus it would not be appropriate to compare these high-acuity hospitals to lower acuity hospitals. Further, as mentioned in the article there are many other support systems and monitoring that potentially can affect the outcomes of these patients – and such factors would be very difficult to control for in an analysis like this.

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*Continued from previous page*

median annual case volume of noninvasive ventilation for any indication was 64 per hospital. But rates of noninvasive ventilation varied widely across hospitals, with 40% of facilities significantly deviating from this median rate.

“Contrary to our hypothesis, we did

not observe significantly lower COPD mortality” in hospitals with high volumes of noninvasive ventilation. For individual patients, admission to a hospital with a high volume of noninvasive ventilation was associated with significantly higher odds of treatment failure (adjusted odds ratio, 1.95), and such failure was associated

**“Hospitals with higher total noninvasive ventilation case volume tended to use [it] in patients with more comorbidities and acute organ failures,” the authors said.**

with significantly higher odds of death (adjusted OR, 1.81). In addition, at the hospital level, a high volume of noninvasive ventilation was associated with

a significantly higher risk of treatment failure, which in turn was associated with higher patient mortality.

“Hospitals with higher total nonin-

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vasive ventilation case volume tended to use [it] in patients with more comorbidities and acute organ failures, suggesting potential overuse among patients at higher risk of treatment failure. [This] may partially explain why hospitals with high rates of using an evidence-based intervention did not achieve significant mortality

benefits," Dr. Mehta and his associates said (*Ann Am Thorac Soc*. 2016;13[10]:1752-9).

They added that the wide variation between hospitals in failure rates for noninvasive ventilation were likely attributable to unmeasured hospital factors, speculating that the site of treatment (regular ward vs. ICU);

staffing ratios for nurses, respiratory therapists, and physicians; and the intensity of patient monitoring, such as the frequency of blood-gas measurement, may contribute.

"High rates of treatment failure at some hospitals suggest that further work is needed to maximize the real-world effectiveness of noninvasive

ventilation, even for an indication [backed by] strong evidence," the investigators said.

The National Institutes of Health; the National Heart, Lung, and Blood Institute; and Boston University supported the study. The investigators' financial disclosures are available at [www.atsjournals.org](http://www.atsjournals.org).

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# Vitamin D reduces respiratory infection risk

BY DEEPAK CHITNIS  
*Frontline Medical News*

**A**dministering doses of a vitamin D supplement to patients can significantly mitigate their

risk of developing acute respiratory tract infections, according to a recent study published by the BMJ.

“[Existing] epidemiological and in vitro data have prompted numerous randomized controlled trials to deter-

mine whether vitamin D supplementation can decrease the risk of acute respiratory tract infection,” wrote the authors of the study, led by Adrian R. Martineau, PhD, of Queen Mary University of London. “A total of five

aggregate data meta-analyses incorporating data from up to 15 primary trials have been conducted to date [but] all but one of these aggregate data meta-analyses reported statistically significant heterogeneity of

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effect between primary trials.”

Dr. Martineau and his colleagues conducted a search of the Medline, Embase, and Web of Science databases, the Cochrane Central Register of Controlled Trials, ClinicalTrials.gov, and the International Standard Randomized Controlled Trials Number registry to find trials that were

randomized, double blind, and placebo controlled involving patients receiving vitamin D supplementation, either with D<sub>2</sub> or D<sub>3</sub>.

A total of 532 studies were reviewed by a panel, of which 25 studies were ultimately selected for inclusion in this analysis. The studies included were of varying lengths in

terms of trial periods and involved a total of 11,321 subjects ranging from 0 to 95 years of age. Of these, 10,933 (96.6%) subjects experienced at least one acute respiratory tract infection.

No significant benefit was found in subjects who had already experienced an infection, yielding an odds ratio of 0.98 (95% confidence interval, 0.80-

1.20;  $P = .83$ ). Analysis performed to quantify the risk of infection with or without vitamin D showed that taking vitamin D supplements significantly decreased infection risk, with an OR of 0.88 (95% CI, 0.81-0.96;  $P$  less than .001) after adjusting for age, sex, and the duration of the trial.

*Continued on page 49*

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# In suspected VAP, ultrashort antibiotics may work

BY AMY KARON  
*Frontline Medical News*

**U**ltrashort courses of antibiotics led to similar outcomes as longer durations of therapy

among adults with suspected ventilator-associated pneumonia but minimal and stable ventilator settings, according to a large retrospective observational study.

The duration of antibiotic therapy

did not significantly affect the time to extubation alive (hazard ratio, 1.2; 95% confidence interval, 1.0-1.4), time to hospital discharge (HR, 1.1; 95% CI, 0.9-1.3), rates of ventilator death (HR, 0.8; 95% CI, 0.6-1.2), or rates

of hospital death (HR, 1.0; 95% CI, 0.8-1.31), said Michael Klompas, MD, and his associates at Harvard Medical School in Boston. If confirmed, the findings would support surveillance of serial ventilator settings to “identify candidates for early antibiotic discontinuation,” the investigators reported (*Clin Infect Dis*. 2016 Dec 29. doi: 10.1093/cid/ciw870).

Suspected respiratory infections account for up to 70% of ICU antibiotic prescriptions, a “substantial fraction” of which may be unnecessary, the researchers said. “The predilection to overprescribe antibiotics for patients with possible ventilator-associated pneumonia (VAP) is not due to poor clinical skills per se, but rather the tension between practice guidelines that encourage early and aggressive prescribing [and] the difficulty [of] accurately diagnosing VAP,” they wrote. While withholding antibiotics in suspected VAP is “unrealistic” and can contribute to mortality, observing clinical trajectories and stopping antibiotics early when appropriate “may be more promising,” they added.

To test that idea, the researchers studied 1,290 cases of suspected VAP treated at Brigham and Women’s Hospital between 2006 and 2014. On the day antibiotics were started and during each of the next 2 days, all patients had a daily minimum positive end-expiratory pressure (PEEP) of no more than 5 cm H<sub>2</sub>O and a daily minimum fraction of inspired oxygen (FiO<sub>2</sub>) of no more than 40%.

A total of 259 patients received 1-3 days of antibiotics, while 1,031 patients received more than 3 days of therapy. These two groups were similar demographically, clinically, and in terms of comorbidities. Point estimates tended to favor ultrashort course antibiotics, but no association reached statistical significance in the overall analysis or in subgroups based on confirmed VAP diagnosis, confirmed pathogenic infection, or propensity-matched pairs.

The results suggest “that patients with suspected VAP but minimal and stable ventilator settings can be adequately managed with very short courses of antibiotics,” Dr. Klompas and his associates concluded. “If these findings are confirmed, assessing ventilator settings may prove to be a simple and objective strategy to identify potential candidates for early antibiotic discontinuation.”

The work was supported by the Centers for Disease Control and Prevention’s Prevention Epicenters Program.

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# Smoking cessation drugs' warning labels are changing

BY WHITNEY MCKNIGHT  
Frontline Medical News

Labels on two smoking cessation treatments will offer less severe warnings for mental health risk potentials in people with no history of psychiatric disorders, the Food and Drug Administration has announced.

Varenicline (Chantix) will no longer include a boxed warning for serious mental health side effects. The label for bupropion (Zyban) will still include a boxed warning, but language describing the potential for serious psychiatric adverse events will no longer appear within it. Updates will also be made to both labels to describe side effects on mood, behavior, or thinking.

"The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past," FDA officials stated in an online notice.

In addition, varenicline's label will reflect trial data showing its superior efficacy, compared with oral bupropion or nicotine patch. Although a patient medication guide will still be included with each

prescription, the risk evaluation and mitigation strategy that prompted the guide will no longer be in place.

Earlier this year, two FDA advisory committees voted in favor of updating varenicline's label, based on data from a randomized, controlled trial of more than 8,000 smokers, half of whom had a history of psychiatric disorders.

The trial showed no clinically significant difference in risk of adverse events across the smoking cessation treatments varenicline, bupropion, nicotine patch, or placebo study arms, although the risk was higher in the psychiatric cohorts in each. Overall, 2% of those without a history of mental illness experienced neuropsychiatric adverse events, compared with between 5% and 7% of those with such a history. Pfizer, maker of Chantix, and GlaxoSmithKline, maker of Zyban, cosponsored the trial.

FDA officials advised clinicians to guard against changes in mental health status in smokers using varenicline and bupropion, but noted that the results of the trial confirm the benefits of stopping smoking outweigh the risks of these medicines.

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# Most smokers attempt quitting without meds

BY RICHARD FRANKI  
Frontline Medical News

More than half of cigarette smokers have received advice to quit from a health care professional, but less than a third used medication or counseling in their cessation attempt, according to investigators from the Centers for Disease Control and Prevention.

In 2015, just over 57% of adult smokers said that a health care professional had advised them to quit in the past year. Of those who tried to quit, 29% used medication such as nicotine patches or gum, varenicline, or bupropion; 7% used counseling (including a stop-smoking clinic, class, or support group and a telephone help line); and 31% used counseling and/or medication, the investigators reported (MMWR. 2017;65[52]:1457-64).

Data from the 2015 Nation-

al Health Interview Survey show that cigarette smokers who were white (60%) or of multiple races (70%) were the most likely to have a health professional tell them to quit, while Asians (34%) and American Indians/Alaska natives (38%) were the least likely. Whites were most likely to use counseling and/or medication (34%) and Hispanics were least likely (19%), although the rate for American Indians/Alaska Natives was not reported because of a small sample size or large margin of error.

"[It] is critical for health care providers to consistently identify smokers, advise them to quit, and offer evidence-based cessation treatments, and for insurers to cover and promote the use of these treatments and remove barriers to accessing them," the researchers noted.

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Continued from page 47

Results also demonstrated that bolus doses of vitamin D did not offer any beneficial value to subjects. Those who received daily or weekly doses without bolus had a better OR, compared with those who did receive at least one bolus dose: 0.81 (95% CI, 0.72-0.91) versus 0.97 (95% CI, 0.86-1.10), respectively ( $P = .05$ ). Individuals whose baseline 25-hydroxyvitamin D levels were lower than 25 nanomols per liter experienced a greater benefit than those whose levels were above 25: OR of 0.30 (95% CI, 0.17-0.53) and OR of 0.75 (95% CI, 0.60-0.95), respectively ( $P = .006$ ).

"Our study reports a major new indication for vitamin D supplementation: the prevention of acute respiratory tract infection," Dr. Martineau and his coauthors concluded, adding that a potential application for these findings would be "the introduction of public health measures such as food fortification to improve vitamin D status, particularly in settings where profound vitamin D deficiency is common."

The study was funded by a grant from the National Institute of Health Research.

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## VIEW ON THE NEWS

### Results are 'underwhelming'

While the work undertaken by Dr. Martineau et al. is commendable, the results themselves are ultimately underwhelming. The study's results are too heterogeneous and offer too slight a reduction in overall risk to justify a complete overhaul of clinical procedure and prescribing protocols. These findings should not change clinical practice in any significant

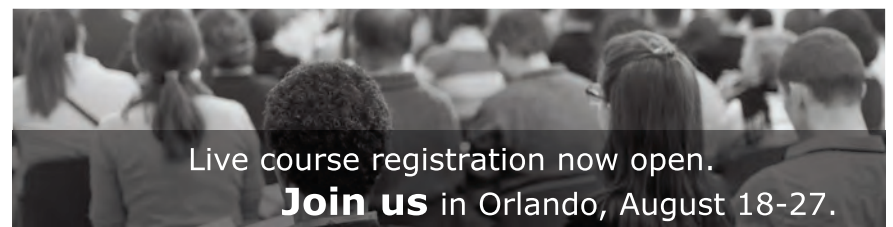
way, and there are other groups of individuals, such as those with low serum concentrations of vitamin D, that were omitted from this analysis altogether.

Mark J. Bolland, PhD, is an associate professor of medicine at the University of Auckland (New Zealand). Alison Avenell, MD, is a professor at the University of Aberdeen.

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## PRESIDENT'S REPORT Strategic planning, travel ban, CHEST 2017

### Dear Colleagues,

It doesn't seem possible, but I have just completed the first quarter of my term as your 79th President and recently returned from chairing my first board meeting – a scary experience to be sure. All in all, it went well. We officially offered Steve Welch the position of Executive Vice President, thereby ushering in one of our own to lead the organization. Steve has successfully served as CHEST's interim EVP/CEO since May 2016, after 22 years of service with this organization, most recently as Senior Vice President of Publications and Digital Content. I am utterly and completely confident in our choice and want you to know he has the full backing of the board, the Past Presidents, and nearly every doctor he has come in contact with.

We also started the strategic planning process for the next 5 years. I am a big believer in planning and have confidence that the team of physicians and staff we have assembled to provide us with guidance will lead us through this process, and we will be a much stronger organization for it. I hope you will all take the opportunity to weigh in as we progress. Ideas from all parts of the organization will be needed so that we don't miss opportunities for improvement.

One of our strategic areas of focus for the past 5 years is how we serve our international members. CHEST is now truly a global organization. Our international membership continues to grow, and that impacts all areas of the College. In 2016, we provided education for more than 4,300 international members through our national meeting and courses provided all around the globe. In addition,



DR. SILVESTRI

tion, the College has, in partnership with Chinese CHEST leadership and ministry of health officials, led the effort to begin the first pulmonary and critical care fellowship training programs in China. This was an amazing undertaking. The first four graduates were introduced and honored at CHEST

2016, and 20 more are scheduled to graduate next year. An additional 25 more fellowship training programs are to start this next year, and the Chinese National Health and Family Planning Commission recently approved the program as one of only three official fellowship training programs in China. I firmly believe we will look back on this endeavor as one of the greatest accomplishments in our organization's long and storied history. Countless lives of patients with pulmonary diseases and critical illness are likely to be saved or extended in that country because of this work.

This brings me to CHEST's position on the travel ban recently imposed and currently on hold in the United States. We, along with 11 other medical societies, sent a letter to the Secretary of Homeland Security underscoring our concern for such a ban, as it could most definitely adversely affect health-care delivery worldwide in ways not previously contemplated. For example, international medical graduates reportedly make up 25% of our physician workforce and provide a disproportionate amount of care to underserved communities. Should we not allow them to come and train here, we could be putting patients in those areas at risk. The ban could result in patients who need specialized health care being denied entrance to the country. We worry that our

global physician colleagues will be unable to travel to the United States for educational programs meant to provide them with the tools they need to care for their patients back home. I encourage you to read the full letter if you are interested.

On a brighter note, the program committee is busy planning CHEST 2017, which will be held in Toronto, Oct 28 to Nov 1. Our theme is Team-Based: Patient-Centered. Our advanced practice providers, critical care nurses, and respiratory therapists, among others, will participate in the planning and help shape different aspects of the program. We encourage our physician members to invite a friend, and come and enjoy the meeting. The traditional CHEST program with simulation and interactive, interdisciplinary symposia will be back by popular demand. There will be something in this meeting for everyone.

I would be remiss if I didn't mention that we are working closely with the American Board of Internal Medicine on Maintenance of Certification (MOC) and getting credit by using CHEST products, such as CHEST SEEK, e-learning modules, and live learning opportunities. In fact, CHEST 2016 made getting MOC points easy. Much of the program this year will qualify for MOC, and I would encourage you to take advantage of it. For those who I have had the pleasure of working with and hearing from this year, I thank you for your comments, welcome all opinions, and hope to hear from any member who has something CHEST-related on their mind.

Gerard A. Silvestri, MD, MS, FCCP  
President

See letter on page 40.

## This month in CHEST

### Editor's picks

BY RICHARD S. IRWIN, MD, MASTER FCCP  
Editor in Chief, CHEST

#### GIANTS IN CHEST MEDICINE

Paul M. O'Byrne, MBBCh, FCCP.  
By S.E. Wenzel, MD.

#### ORIGINAL RESEARCH

Prevalence and Localization of Pulmonary Embolism in Unexplained Acute Exacerbations of COPD: A Systematic Review and Meta-Analysis.  
By F.E. Aleva, MD, et al.



#### COMMENTARY

The American College of Radiology Lung Imaging Reporting and Data System: Potential Drawbacks and Need for Revision.  
By H. J. Mehta, MD, et al.

#### SPECIAL FEATURE

Improving the Management of COPD in Women.  
By C.R. Jenkins, MD, et al.

## Plan to attend CHEST 2017 in Toronto

Oct 28 – Nov 1  
Toronto, Ontario, Canada

Join us in wonderful Toronto for CHEST 2017, where we'll connect a global community in clinical chest medicine. Our program will deliver current pulmonary, critical care, and sleep medicine topics presented by world-renowned faculty in a variety of innovative instruction formats. Take advantage of these opportunities to get involved now:

#### Submit Abstracts and Case Reports

Submission deadline: March 31

Submit an abstract of your original investigative work, case reports, and clinical case puzzlers for presentation at CHEST 2017. Submission is free, and accepted abstracts become eligible for investigative awards from the CHEST Foundation. Accepted

abstracts and case reports (excluding clinical case puzzlers) will be published in an online supplement to the journal CHEST. Slide or poster presentations will be considered, along with poster discussion presentations for abstracts. Four types of case reports will be considered:

- Fellow Case Reports.
- Medical Student/Resident Case Reports.
- Global Case Reports.
- Clinical Case Puzzlers.

Learn more and submit at [chest2017.abstractcentral.com](http://chest2017.abstractcentral.com).

#### Apply for 2017 CHEST Foundation Grants

Application deadline: March 31

The CHEST Foundation has started accepting applications for its clinical research, distinguished scholar, and community service grants. Every year, the CHEST Foundation awards

more than a half-million dollars to the next generation of lung health champions.

The grants available are:

- GlaxoSmithKline Distinguished Scholar Research Grant in Respiratory Health: \$150,000 over 3 years
- CHEST Foundation Research Grant in Lung Cancer: \$50,000-\$100,000\* over 2 years
- CHEST Foundation Research Grant in Pulmonary Arterial Hypertension: \$25,000 1-year grant
- CHEST Foundation and Alpha-1 Foundation Research Grant in Alpha-1 Antitrypsin Deficiency: \$25,000 1-year grant
- CHEST Foundation Research Grant in Nontuberculous Mycobacteria: \$10,000-\$30,000\* 1-year grant
- CHEST Foundation Research Grant in Venous Thromboembolism: \$30,000 1-year grant

Continued on page 53



# Catching up with our CHEST Past Presidents

*Where are they now? What have they been up to? CHEST's Past Presidents each forged the way for the many successes of the American College of Chest Physicians, leading to enhanced patient care around the globe. Their outstanding leadership and vision are evidenced today in many of CHEST's strategic initiatives. Let's check in with Dr. Mathers.*

**James A.L. Mathers Jr., MD, FCCP**  
**President 2008-2009**

It was a great honor to be inaugurated as President of the American College of Chest Physicians at the 2008 Annual Meeting in Philadelphia. My chosen vocation was community-based private practice, and from my early years in practice, I found the opportunity to interact with the clinically oriented scholars of CHEST invaluable. My wife Susan and I fondly remember activities with staff, others in leadership, and their families. My immediate goals for my presidential year were to ensure the financial security of the College, in light of the evolving restrictions on industry funding, and to raise the profile of telemedicine for the care of patients with chronic conditions and the critically ill. However, that year is probably most remembered for the unanticipated need to formulate a step-down agreement with then-CEO Alvin Lever, who had served the College for the preceding 17 years.

To assist with financial planning, we were able to engage Master's degree candidates from the Kellogg School of Business at Northwestern University in Evanston, Illinois, to perform a detailed cost and benefit analysis of our programs and to help develop recommendations for streamlining and improving our budgeting process. In partnership with the American Thoracic Society, the Society of Criti-

cal Care Medicine, and the American Association of Critical-Care Nurses, we developed a grant proposal to host a multisociety conference to examine the use of telemedicine for the care of critically ill patients. The grant was funded by the National Institutes of Health, and the results of the conference were published in CHEST. Following my presidential year, I continued to speak at numerous meetings about the po-

tential for telemedicine to improve the care of patients with pulmonary disease.

I retired from my community-based private practice at the end of 2010. Susan and I divide our time between Richmond, Virginia, engaging with our grandchildren, and the west coast of Florida, where I am working on my saltwater fly-fishing creden-

tials. Regular rounds of golf with former colleagues, some retired and some still in practice, keep me abreast of the pressures on and changes in the clinical environment.

Early in my practice, I became interested in addressing federal policies that interfered with the ability to provide state-of-the-art care to my patient population. My first committee appointment with CHEST was the Government Relations Committee. Our activities were closely coordinated with the National Association for Medical Direction of Respiratory Care (NAMDRC) and the American Thoracic Society. During my year as Immediate Past President of the College, I was approached by NAMDRC and invited to write their monthly publication, *The Washington Watchline*. I have continued to enjoy that opportunity, as well as interacting with their membership. When called upon by NAMDRC, I travel to Washington, DC, to meet with Medicare staff to discuss policy issues important in the care of pulmonary patients.



DR. MATHERS

This advertisement is not available for the digital edition.

**CHEST**™ Physician  
THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

*Continued from page 50*

- CHEST Foundation Research Grant in Pulmonary Fibrosis: \$30,000 1-year grant
- CHEST Foundation Research Grant in Chronic Obstructive Pulmonary Disease: \$50,000 1-year grant
- CHEST Foundation Research Grant in Women's Lung Health: \$10,000 1-year grant
- CHEST Foundation Research Grant

in Asthma: \$15,000 - \$30,000\* 1-year grant

- CHEST Foundation Research Grant in Cystic Fibrosis: \$30,000 1-year grant
- Community Service Grant Honoring D. Robert McCaffree, MD, Master FCCP: multiple awards up to \$15,000 per 1-year grant

\*Amount contingent on funding. Apply for grants at [chestfoundation.org/grants](http://chestfoundation.org/grants).



# Household air pollution: Foundation grantee champions lung health

BY CATHERINE OBERG, MD

*In 2016, Catherine Oberg, MD, was awarded the CHEST Foundation Research Grant in Women's Lung Health for her project on household air pollution in Ghana. In this recent interview with Dr. Oberg, she describes how she is championing lung health.*

## How I got involved

In medical school, I was very interested in international medicine and took a trip to Tanzania to do primary care work when I was in my fourth year. I saw firsthand how the people, women especially, sleep, cook, eat, and take care of their children and animals all in one house. I saw how direct smoke exposure from cooking caused symptoms of cough, phlegm, and shortness of breath. I knew this was an area where I could make an impact.

When you're looking for grants to do this kind of work, it's a very nebulous area.

Fortunately, I learned about CHEST Foundation grants through

my mentor, Alison Lee, MD, who was a CHEST Foundation grant recipient early in her career. With the help of the grant, I was able to furnish my own supplies, get everything to Ghana, train native health-care providers, and start doing assessments. I received the CHEST Foundation grant at the perfect time. I am so appreciative and honored to be a CHEST Foundation grant recipient. It's such a humbling experience to be able to act on these things that I've been looking into for so many months. I'm just excited and thankful, and can't wait to see what we're able to show.

## Tackling a leading cause of lung disease

In rural areas around the world, people cook with ineffective fuels, such as animal dung, that cause damaging household air pollution. This is a leading cause of asthma, COPD, and lung cancer worldwide, and it preferentially affects women and children because of their roles



John Howington, MD, FCCP, then President of the CHEST Foundation, presenting the CHEST Foundation Research Grant in Women's Lung Health to Dr. Oberg during CHEST 2016.

in the household. My project focuses on household air pollution with a goal to measure the effectiveness of utilizing a clean burning stove as an intervention.

We have a cohort of women in Ghana and have had randomized clusters using either a liquefied petroleum gas (LPG) clean burning stove or a traditional cook stove for 18 months now. We're going to look at their lung function, inflammatory markers, and respiratory symptoms and compare the groups to see if the intervention has made a difference.

## The impact

Being able to breathe is a function

many of us take for granted. The ability to impact something this vital to everyday life is a really exciting and important challenge. It's an area where I think we can make a big impact.

This grant is allowing us to run our entire inflammatory marker component. As we are learning more about asthma and COPD, we're seeing phenotypes of people that don't fit the standard. This cohort of women illustrates that heterogeneity of disease, as we're seeing more overlap in the symptoms they have. Currently, there are really no data looking at this, and we now have the resources to dive into this research.

## The future

This project could bring about further research and hopefully provide evidence supporting these types of interventions. The impact could affect millions of people around the world. The CHEST Foundation grant is providing materials that are the foundation of our project. This grant allows us to design better studies in the future, to educate patients in a more effective manner, and to prevent these life-threatening diseases.

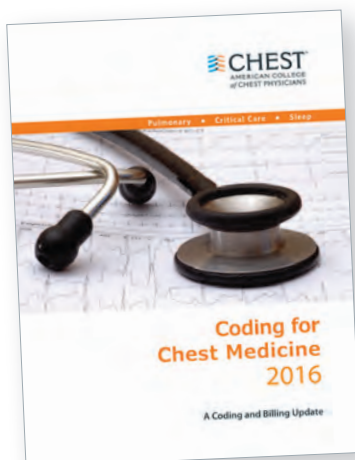
*The next CHEST Foundation grants cycle is open from February 1 to March 31, 2017. How will you champion lung health? Learn more about foundation grants and how you can apply at <https://chest.realmagnet.land/chest-foundation-grants>.*

AVAILABLE NOW

## Coding Resource



An updated edition of *Coding for Chest Medicine*



Updates in the 2016 edition include:

- Complex Chronic Care Services
- Examples With ICD-10-CM coding
- Advance Care Planning Services
- EBUS Services
- ECMO Services
- Clarification for 94640 inhalation treatments

*Coding for Chest Medicine 2016* is an ideal resource for physicians, nonphysician providers, practice administrators/managers, office managers, and business managers, and this edition will contain important updates for pulmonologists, pediatricians, and interventional bronchoscopists.

**CHEST**  
AMERICAN COLLEGE  
of CHEST PHYSICIANS

**CHEST**  
Annual Meeting  
2017



**TORONTO**  
CANADA

October 28 - November 1

## Alternative to 10-year ABIM exam starts 2018

**O**n December 14, the American Board of Internal Medicine (ABIM) announced an alternative to the 10-year Internal Medicine recertification exam, effective 2018. Currently, ABIM board-certified physicians can participate in Maintenance of Certification (MOC) by earning 100 MOC points every 5 years and passing a maintenance of certification exam every 10 years.

Beginning in 2018, physicians who are certified by the ABIM in Internal Medicine will have the option to take a lower-stakes exam every 2 years, rather than taking the current

high-stakes exam every 10 years. The low-stakes exam option provides greater flexibility to the diplomate by allowing one to complete the examination at a convenient time set by the physician at home or in the office. While this new option will initially be available only to Internal Medicine diplomates, the ABIM intends to extend this alternative recertification model to subspecialties in the future.

CHEST is exploring how our education will evolve to address these key changes. For additional information, please visit ABIM's website.

## Pulmonary Hypertension Care Center initiative moves forward

**T**he Pulmonary Hypertension Association (PHA) launched its Pulmonary Hypertension Care Center (PHCC) initiative 2 years ago. This initiative was designed to raise the quality of care, as well as long-term outcomes for this disease that is often misdiagnosed and progressive. The PHCC program has designated 41 adult and 6 pediatric sites as Comprehensive Care Centers with ongoing accreditation of new sites. As part of this program, the PHA Registry was established to provide input to improve the care of PH patients. The PHA Registry (PHAR) is a multicenter, prospective observational registry of newly evaluated patients with pulmonary arterial hypertension

(PAH) and has enrolled 200 patients to date. PHAR participation is open to any PHCC-accredited center.

PHCC accreditation has two pathways: Comprehensive Care Centers and Regional Care Centers. Accreditation is based on adherence "to consensus guidelines for the diagnosis and treatment of PH, the scope of PH-related services provided at the center, and the expertise of the center's PH Care Team members." PHCC accreditation is potentially available to all PH centers that meet the established criteria that can be found at the PHCC website.

Additional information may be found at the PHCC website (<https://phassociation.org/PHCareCenters>).

## Calls for faculty participation in the CHEST PREP program

### About PREP

The CHEST PREP Clinical Immersion program is an unbranded, disease-state program that educates industry members and partners to advance their knowledge into understanding that builds their confidence for engagement in clinical conversations with health-care teams.

We are seeking faculty for the following initiatives:

1. The CHEST PREP program is embarking on a curriculum and content development initiative and is seeking interested faculty members to consider participating in the development of content in the areas of **CTEPH, Alpha-1 Antitrypsin, and Bronchiectasis**.

2. The CHEST PREP program is seeking interested CHEST members in Chicago-based institutions to consider participating as faculty presenters in the following disease areas: **COPD, Asthma, PAH, CTEPH, IPF, SCLC, and NSCLC**.

*Continued on following page*



## 2017 Education Calendar

> Learn More [livelearning.chestnet.org](http://livelearning.chestnet.org)



### Live Learning Courses Courses held at the CHEST Innovation, Simulation, and Training Center in Glenview, Illinois.

#### Bronchoscopy Procedures for the ICU

May 6-7

#### Advanced Critical Care Echocardiography

June 2-4

#### Difficult Airway Management

July 14-16

#### Bronchoscopy and Pleural Procedures for Pulmonary and Critical Care Medicine Fellows

July 21

#### Mechanical Ventilation: Advanced Critical Care Management

July 28-30

#### Comprehensive Pleural Procedures

August 4-5

#### Critical Skills for Critical Care: A State-of-the-Art Update and Procedures for ICU Providers

August 11-13

#### Ultrasonography: Essentials in Critical Care

September 15-17

December 1-3

#### Cardiopulmonary Exercise Testing

September 22-24

#### Comprehensive Bronchoscopy With Endobronchial Ultrasound

September 29 - October 1

#### Critical Care Ultrasound: Integration into Clinical Practice

November 10-12



Continued from previous page

### Requirements for participation

1. PREP welcomes faculty who would be interested in creating two or more presentations and/or cases on an assigned topic using a flipped classroom, interactive design. A minimum of four faculty experts will be needed per disease state indicated previously. Honorarium provided.
2. PREP welcomes faculty from Chicago-based institutions who would be interested in participating as faculty presenters in the disease states indicated previously. Honorarium provided.

### Selection criteria

To be considered, please indicate the disease area in which you are interested in participating as content developer or faculty presenter, as well as providing the best way to contact you. For the asthma curriculum, we have a specific need for expertise/interest in moderate to severe asthma and the use of biologics in treatment.

If you are interested in participating in this initiative, please contact Jasmine Turner (jturner@chestnet.org). Thank you.

# Bipartisan Budget Act (BBA) of 2015 threatens growth of pulmonary rehab

BY PHIL PORTE

Executive Director, National Association for Medical Direction of Respiratory Care (NAMDRRC)

In late 2015, Congress passed the Bipartisan Budget Act (BBA) to address numerous wide-ranging budget concerns, including issues related to agriculture, pensions, the strategic petroleum reserve, along with some Medicare issues. Section 603 of BBA is now coming back to haunt pulmonary rehabilitation services.

The intent of Section 603 is reasonable – to address the phenomenon of hospitals purchasing physician practices to take advantage of payment differentials between identical or virtually identical services when comparing the hospital outpatient prospective payment system (HOPPS) and the physician fee schedule (PFS). For example, an orthopedic practice might own its own MRI and related support services. It will bill for those services under the PFS. However, if the practice sells that segment of the revenue stream (the MRI assets, etc) to a hospital, the hospital can bill Medicare for

**A hospital that wishes to expand its current program and bill under the hospital outpatient methodology MUST do so by expanding at its current location. An expansion at a new location that is not within 250 yards of the main hospital campus triggers Section 603 provisions.**

those same services under the hospital outpatient prospective payment system at an amount notably higher than the PFS payment.

To address this payment aberration, Congress instructed the Centers for Medicare & Medicaid Services to craft a system to preclude a hospital from such behavior. If a hospital

offers new or expanded outpatient services, it could NOT bill Medicare under the hospital outpatient services methodology and would be required to bill under the PFS payment methodology. Importantly, a few exemptions exist. If the new or expanded service is within 250 yards

Continued on following page

## Medicare Payments for HCPCS code G0424 through the physician fee schedule

	2012	2013	2014
<b>TOTAL PAYMENTS</b>	\$688,489.27	\$589,116.95	\$535,512.81
<b>Pulm Disease Specialty</b>	\$340,805.64	\$310,065.29	\$229,832.58

(Source: Physician Supplier Procedure Summary File)

**CHEST**  
Conference

**Amsterdam**  
THE NETHERLANDS • 7-9 MAY, 2017



### COPD: Current Excellence and Future Development

7-9 May 2017  
Amsterdam, The Netherlands



Complete programme and speaker information now available.

Don't miss this review of research, clinical focus, and therapeutic development for COPD.

The global burden of COPD is increasing, and the disease is projected to be the third leading cause of death and fifth leading cause of overall disability worldwide by 2020. It is one of the leading causes of disability worldwide and is the most common disease whose prevalence and mortality rates continue to rise.

COPD: Current Excellence and Future Development aims to disseminate cutting-edge findings on COPD and provide a unique, intimate platform for clinicians, experts, and specialists to come together for discussion on current best practices and future directions in diagnosis, treatment, and therapeutic innovations.

#### Session themes:

- History and burden of COPD
- Polymorbidity in COPD
- Infections and exacerbations in COPD
- Current treatment of COPD
- The future of COPD

> Learn More and Register [chestcopdconference.com](http://chestcopdconference.com)

## Build Your Ultrasound Portfolio

Innovation, Simulation, and Training Center  
Glenview, Illinois



Build your critical care ultrasonography skills with courses designed to help you in diagnosis and management of critically ill patients.

### Advanced Critical Care Echocardiography June 2-4

Learn practical measurement skills relevant to the diagnosis and management of patients with cardiopulmonary failure, and participate in case-based, interactive image interpretation sessions focused on bedside assessments patients using advanced critical care echocardiography.

### Ultrasonography: Essentials in Critical Care September 15-17 • December 1-3

Practice image acquisition with human models using high-quality ultrasound machines.

### Critical Care Ultrasonography: Integration Into Clinical Practice November 10-12

Acquire faculty will provide comprehensive training in protocol-driven image acquisition, case-based image interpretation, and ultrasound-guided procedures.

**CHEST**

> Learn More and Register  
[livelearning.chestnet.org/ultrasonography](http://livelearning.chestnet.org/ultrasonography)

#### Who Should Attend?

Our ultrasonography courses are ideal for critical care team members interested in enhancing their proficiency in the field of point-of-care ultrasonography. Frontline intensivists; pulmonary/critical care specialists and fellows; hospitalists; emergency medicine/critical care, anesthesia/critical care, and surgical/critical care fellows; physicians; and advanced practice providers are encouraged to attend.



Continued from previous page

of the main hospital campus, the outpatient billing methodology is permitted. Likewise, if expansion of a current off-campus service occurs **at the same location of the current off-site service**, the hospital may continue to bill under the outpatient rules. Several other technical exceptions are permitted, for example construction planned prior to passage of BBA.

The implications for pulmonary rehabilitation are critical to its

evidence that pulmonary practices simply do not provide pulmonary rehab services.

These data strongly indicate that **G0424** pulmonary practice physician office billing for the most recent year data are available (\$230K), compared with hospital outpatient allowed charges (\$119M), is **less than two-tenths of 1%** of billing through the hospital setting. To argue that hospitals are purchasing pulmonary practices for financial gain tied to pulmonary rehab services defies

**While congressional logic may be relatively understandable, for pulmonary medicine, it is based on the premise that a hospital would purchase a pulmonary practice because that practice had a lucrative pulmonary rehabilitation services cash flow. NAMDRC and other societies were able to document major flaws in the basic premise, resulting in very problematic unintended consequences.**

growth. A hospital that wishes to expand its current program and bill under the hospital outpatient methodology **MUST** do so by expanding at its current location. An expansion at a new location that is not within 250 yards of the main hospital campus triggers Section 603 provisions, and the hospital will bill at the physician fee schedule rate. Because the PFS payment rate is just over half of the payment rate for HOPPS payment, it is unlikely that a hospital would expand an existing program or establish a new one if it would be forced to bill under the lower rate.

While congressional logic may be relatively understandable, for pulmonary medicine, it is based on the premise that a hospital would purchase a pulmonary practice because that practice had a lucrative pulmonary rehabilitation services cash flow. NAMDRC and other societies were able to document major flaws in the basic premise, resulting in very problematic unintended consequences. A detailed review of Medicare claims data provides strong

Medicare data, as well as financial logic. If the CMS premise was valid, one would expect the aggregate physician office billing to be much greater than \$535K.

In discussions with CMS, the Agency did agree that there are likely to be unintended consequences related to Section 603 implementation. The Agency also emphasizes that it does not have the statutory authority for a “carve out” exemption. CMS stated that even if it agreed with us, it simply lacked the authority to exempt pulmonary rehab services. CMS also agreed that there is growing evidence that pulmonary rehab is a underutilized service that may very well save the program money through reduced hospitalizations and rehospitalizations, but it has little choice to implement the statute as Congress so mandated.

Therefore, the only solution is a legislative one. NAMDRC and other societies are seriously considering approaching Congress for such resolution.

## G0424 total allowed charges though hospital outpatient prospective payment

Year	Total Allowed Charges	Unique # of Providers
2012	\$108,515,429	1,260
2013	\$115,238,410	1,320
2014	\$119,809,898	1,350

(Source: 100% Outpatient SAF)

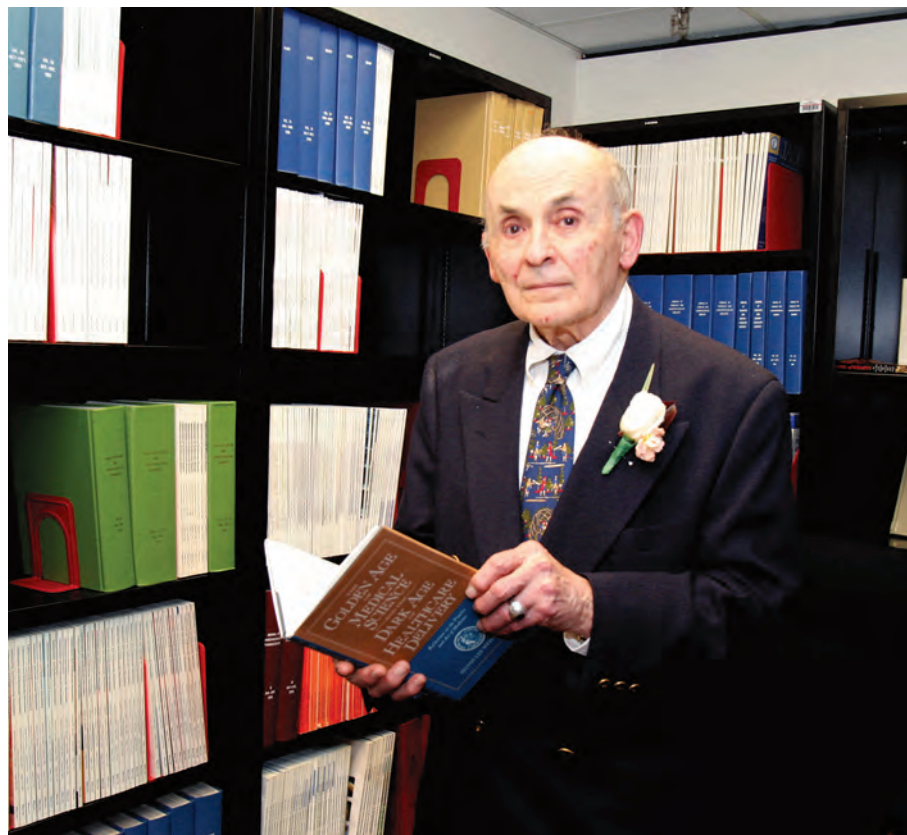
## In memoriam

**S**ylvan Lee Weinberg, MD, FCCP, MACC, a Past President of the American College of Chest Physicians (1983-1984), died Jan 17, 2017, in Dayton, Ohio. Dr. Weinberg was born in Nashville, TN, and received both his bachelor of science and doctor of medicine degrees from Northwestern University in Evanston, IL. He spent his time as an intern, medical resident, and fellow in cardiology at the Michael Reese Hospital in Chicago and went on to serve as a physician at Good Samaritan Hospital in Dayton, Ohio, for more than 40 years, ultimately becoming chief of cardiology and founder of the first coronary care unit in Ohio. Dr. Weinberg was also a clinical professor of medicine at the Wright State University School of Medicine in Dayton, and led a group cardiology practice until his retirement in 2000.

A past president also of the Amer-

ican College of Cardiology (ACC) and the Montgomery County Medical Society, Dr. Weinberg was the founding editor of the *American Heart Hospital Journal*, founding co-editor of *Heart & Lung*, and founding editor of the *Journal of The Heart Institute of Dayton*. He also was associate editor of the *AMA Archives of Internal Medicine*, the *ACC Review Journal*, and served on numerous editorial boards, including CHEST, the *Journal of the American College of Cardiology*, and the *Clinical Cardiology and Heart Journal*, formerly the *British Heart Journal*. He was editor-in-chief of ACC's *ACCEL* audio journal for 15 years, recognized and known as, “the voice of cardiology,” traveling around the world and interviewing the world's leaders in cardiology.

CHEST extends its heartfelt condolences to Dr. Weinberg's family and friends.



Dr. Sylvan Lee Weinberg

## Connect to CHEST members and leaders

**B**uild your network and access the CHEST Member and Leader Directory. Use the directory to search for members and leaders. Easily search by name, specialty, location, or CHEST committee name to find others in the CHEST community. All members current

in their dues are included in the directory.

Access to the directory is an exclusive CHEST member benefit. To view the directory, visit the following address: <https://www.chestnet.org/Get-Involved/Membership/Member-Directory>.

## NETWORKS: Mass shootings, MACRA, asthma in pregnancy

### Disaster Response

#### Mass shootings

There are multiple definitions for a mass shooting. Some definitions require a certain number of people be killed. Some definitions require a certain number of people be shot. Some definitions do not include gang violence. Regardless of the definition used, the number of mass shootings in the United States is increasing.



DR. GAILLARD

There are also multiple definitions of what qualifies as a medical disaster. These definitions can be summarized with the statement that a medical disaster is an event that produces

a number of casualties that overwhelms the local health system.

In the first 31 days of 2017, there have been 30 shootings in the United States, in which four or more people were injured ([www.gunviolencearchive.org/reports/mass-shooting](http://www.gunviolencearchive.org/reports/mass-shooting)). On average, 309 people are shot every day in the United States. Ninety-three (30%) of those victims die of their injuries ([www.bradycampaign.org/key-gun-violence-statistics](http://www.bradycampaign.org/key-gun-violence-statistics)).

Most mass shootings fit the definition of a medical disaster. When a mass shooting occurs, medical resources are diverted from current

patients to those injured in the shooting. Patients with acute medical problems unrelated to the shooting must endure a prolonged wait for medical care.

The CHEST Disaster Response NetWork feels that it is necessary to take action to reduce the

**Most mass shootings fit the definition of a medical disaster. When a mass shooting occurs, medical resources are diverted from current patients to those injured in the shooting. Patients with acute medical problems unrelated to the shooting must endure a prolonged wait for medical care.**

number of mass shootings. Unlike natural disasters, mass shootings are man-made. As such, we should proactively work to prevent them. Prevention is a large part of medicine. Working together with community leaders, law enforcement, and government officials, we can and should work to eliminate mass shootings so that we can minimize gun-related injury and death.

*John Gaillard, MD, FCCP  
Steering Committee Member*

### Practice Operations

#### MACRA: Reincarnation of Medicare physician reimbursement model

In April 2015, President Obama signed the Medicare Access and CHIP Reauthorization Act (MA-



DR. ANJUM

CRA) eradicating the detested sustainable growth rate (SGR) formula. If this is your first dive into MACRA as an eligible professional (EP), it may be a bit baffling trying to understand its impact on your practice. MACRA affects physician offices, not hospitals. For 2017-2018, EPs include physicians, physician-assistants, nurse practitioners, clinical nurse spe-

cialists, and nurse anesthetists. Providers in their first year of Medicare participation or with a low Medicare volume are excluded. Additionally, there are two participation pathways, Merit-Based Incentive Payment System (MIPS), which combines the current Physician Quality Reporting System, Value Modifier, and Meaningful Use programs into a single pay-for-performance payment system; or Alternative Payment Models (APMs) that provide incentives in certain alternative payment models based on proposed CMS criteria. Accountable Care Organizations, Patient-Centered Medical Homes,

*Continued on following page*

## CLASSIFIEDS

Also available at [MedJobNetwork.com](http://MedJobNetwork.com)

### PROFESSIONAL OPPORTUNITIES



#### Pulmonary/Critical Care with Sleep Opportunity Cambridge Health Alliance • Cambridge, MA

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and Bundled Payment Models are a few examples of an APM.

Under MIPS, rules are divided into four categories. During the first year, each category will make

**MACRA affects physician offices, not hospitals. For 2017-2018, [eligible professionals] include physicians, physician-assistants, nurse practitioners, clinical nurse specialists, and nurse anesthetists.**

up a certain percentage to the physician's overall score, which will result in a penalty or payment as a lump sum in 2019. If you are an Advanced APM in 2017 and receive 25% of Medicare payments or see 20% of your Medicare patients through this model, you can earn up to a 5% incentive payment in 2019.

The performance period started on January 1, 2017. Submission of performance data is due by March 31, 2018. MACRA is complicated and here to stay. Learn and educate yourself to avoid downward payment adjustment. For full details, please visit [https://qpp.cms.gov/docs/QPP\\_Executive\\_Summary\\_of\\_Final\\_Rule.pdf](https://qpp.cms.gov/docs/QPP_Executive_Summary_of_Final_Rule.pdf).

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Humayan Anjum, MBBS  
Steering Committee Member

## Transplant

### Frailty in lung transplantation

Two of the greatest challenges in lung transplantation are to identify optimal transplant candidates and to help those transplant recipients thrive in the years following surgery. Frailty is emerging as a marker of increased posttransplant morbidity

and may represent an area where both the recipient selection process and posttransplant outcomes can be optimized. Described by some as "biologic age" rather than "chronologic age," frailty is a syndrome of functional impairment and weakness that predisposes to adverse health outcomes. The adverse effects of frailty have been described in multiple clinical scenarios, including the ICU, chronic lung diseases, heart failure, liver transplant, kidney transplant, geriatrics, and others.

Approximately 10% to 45% of lung transplant patients are considered to be frail, depending on the measurement used. In a cohort of lung transplant recipients, frail patients had increased 1-year mortality (21.2% increase) and 3-year mortality (24.8% increase), compared with nonfrail patients (Wilson et al. *J Heart Lung Transplant*.



DR. WILSON

2016;35[2]:173-178). In a cohort of patients on the lung transplant waiting list, frailty was associated with an increased risk of delisting or death before lung transplant (Singer et al. *Am J Respir Crit Care Med*. 2015;192[11]:1325-1334). In addition, frailty may be associated with an increased risk of hospital readmissions and acute rejection following transplant (Wilson et al. *J Heart Lung Transplant*. 2016;35[4]:S317).

Remaining challenges include determining which clinical assessments best define frailty in the lung transplant population, documenting the adverse effects of frailty in well-designed multicenter prospective studies, and developing interventions to mitigate the adverse effects of frailty.

Michael E. Wilson, MD  
Fellow-in-Training Member

## Women's Health

### Asthma treatment during pregnancy

Asthma is common in pregnancy, occurring in 3% to 8% of pregnant women. While the course of asthma during pregnancy is variable, the objectives of asthma treatment do not change and aim to prevent acute exacerbations and optimize management. Uncontrolled asthma is associated with an increased risk of perinatal morbidity. Published guidelines on pharmacologic therapies

during pregnancy recommend the same step-wise approach as in nonpregnant women. Despite this, many providers are reluctant to prescribe medications during pregnancy, and data show a reduction of refills of asthma medications during pregnancy, likely due to safety concerns. Some recent studies



DR. BOURJEILY



DR. LOUIS

have suggested an increase in major congenital anomalies among pregnant asthmatics using ICS (Garne E et al. *BJOG*. 2016;123[10]:1609-18), albeit with large confidence intervals. These findings have not been consistently confirmed (Kallen B et al. *Eur J Clin Pharmacol*. 2007;63:383-8). Furthermore, studies showing a dose response association of ICS with congenital anomalies (Blais L et al. *J Allergy Clin Immunol*. 2009;124[6]:1229-34) suggest that disease severity may be a confounder in these associations.

The diagnosis of asthma, the use of other concurrent medications, and medication compliance may all be potential confounders. ICS use in pregnancy was associated with endocrine and metabolic

disturbances in the offspring in a national cohort (Tegethoff M et al. *Am J Respir Crit Care Med*. 2012;185[5]:557-63). However, this study did not report on systemic steroid use, asthma severity, or details of these disturbances. In summary, ICS use remains justifiable in pregnancy (Smy L et al. *Can Fam Physician*. 2014;60[9]:809-12) as the risk of untreated or poorly treated asthma outweighs the possible risk of ICS use, especially when alternative drugs such as systemic steroids are not without risk. Ultimately, it should be stressed that asthma control is the goal of treatment. This should be achieved with close interaction between the pregnant woman and her health-care provider.

Ghada Bourjeily, MD, FCCP  
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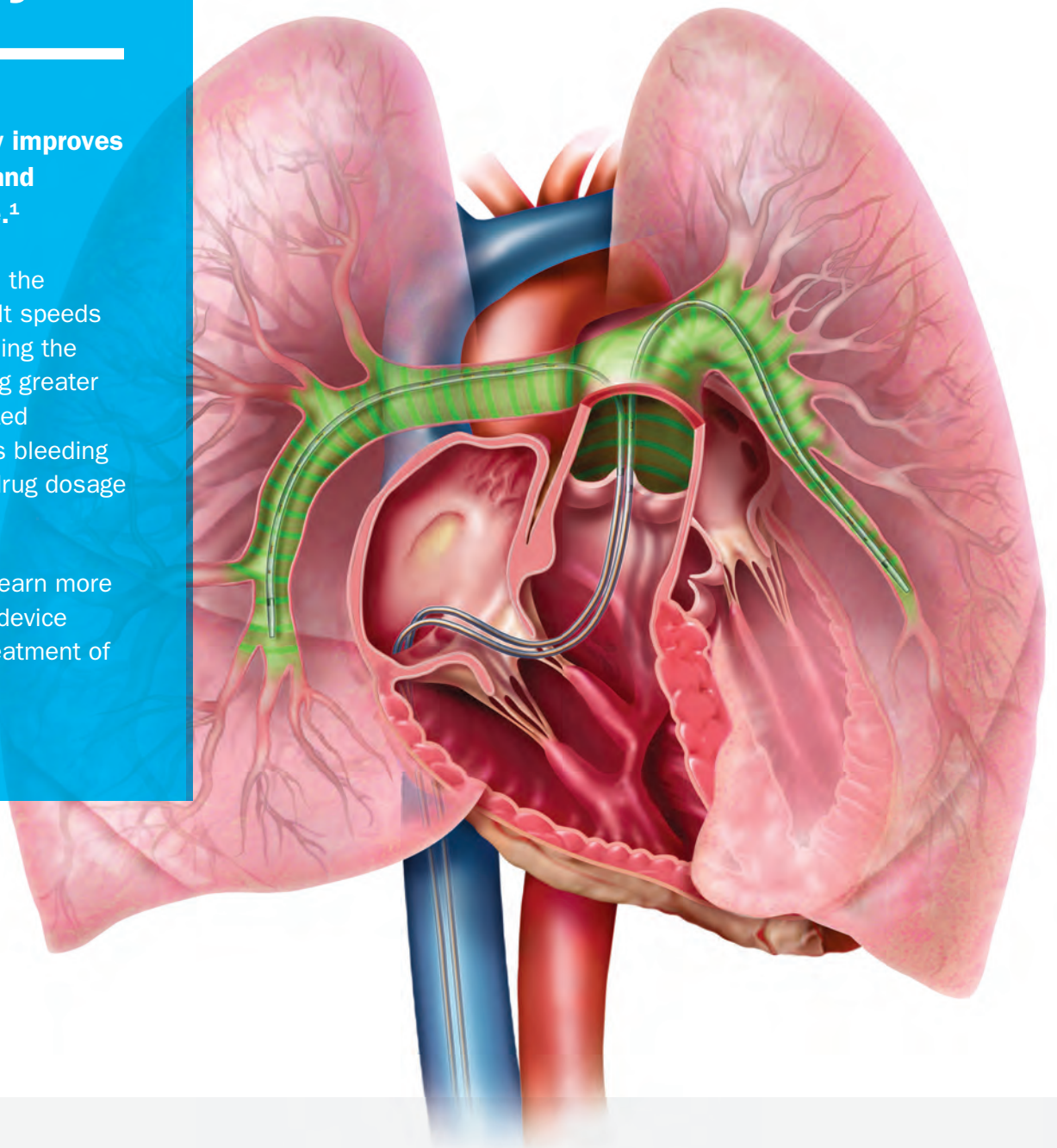


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<sup>2</sup> Braaten, J et al., *Thromb Haemost* 1997;78:1063-8; Francis, C et al. *Ultrasound in Medicine and Biology* 1995; 21(3):419-424; Soltani, A et al., *Physics in Medicine and Biology* 2008; 53:6837-6847

<sup>3</sup> Kucher, N., et al., *Circulation*, Vol. 129, No. 4, 2014, 479-486.

<sup>4</sup> Piazza, G., et al., *American College of Cardiology 63rd Annual Scientific Session, Wash D.C., March 30, 2014.*

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