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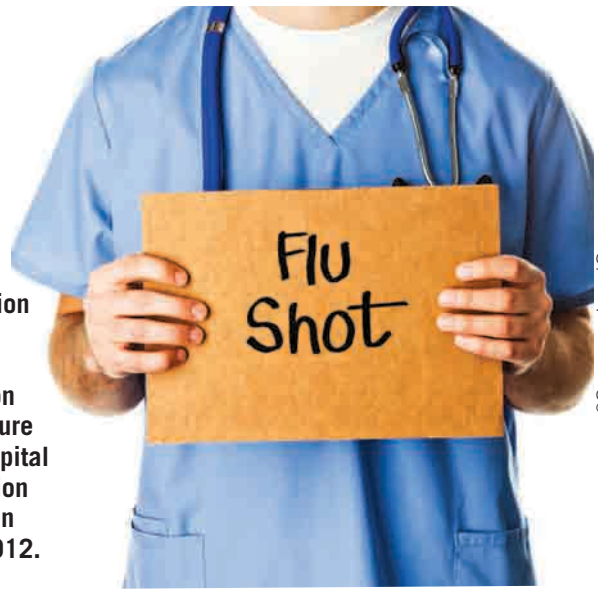

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Inpatient influenza immunization became a Joint Commission core measure set for hospital accreditation programs in January 2012.

Inpatient Protocols Can Up Flu Vax Rates

BY HEIDI SPLETE
IMNG Medical News

It's late October, and a 70-year-old woman with a medical history of type 2 diabetes and hypothyroidism, as well as a remote history of laryngeal cancer, presents with a COPD exacerbation. The records say she hasn't had a flu shot. Would she get one at your center?

Experience says if there's a protocol in place designed for people like her, she's in luck. But if there's not … her case points to room for quality improvement.

"The reason vaccinating patients has become a safety measure is that we have found that many patients will encounter health care by being seen in an emergency department, being admitted to a hospital, or being seen by their physician, and not receive the recommended vaccines, and later go on to develop illnesses that might be quite serious," said Dr. Thomas Talbot, author of the Society for Healthcare Epidemiology's vaccination guidelines and chief hospital epidemiologist at Vanderbilt University Medical Center in Nashville, Tenn.

"These are missed opportunities when we have had patients in our health care system and haven't taken advantage of the opportunity to vaccinate them," Dr. Talbot said.

"That has been the impetus for a lot of new quality measures for those patients who are admitted to the hospital. Once their acute issue has been cared for and they are getting ready to go home, get them their vaccines while you have them there," to protect them against influenza, and also pneumococcal disease, he said.

But it's not always an easy thing to do, Dr. Talbot said.

"It is challenging to implement an inpatient vaccination program," he said. "During a hospitalization, you are trying to get the patient supported for the illness that brought them into the hospital. You don't want to do anything that may interrupt that care plan," he said.

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Variety of Payment Models May Replace SGR

Contact your member of Congress.

BY MARY ELLEN SCHNEIDER
IMNG Medical News

Congress needs to act soon to avert a scheduled 27% cut in physicians' Medicare pay – and find a way to fix the failed system that calls for that cut – but, increasingly, experts say that the solution must be multipronged and adaptable to a variety of practice situations.

One reason that the current system has failed is that it holds individual physicians responsible for group behavior at a national level, according to Dr. Barbara Levy, vice president for health policy at the American College of Obstetricians and Gynecologists. Instead of leading to lower health costs, it actually increases them because the payment system drives physicians to increase their volume to make up for low reimbursement.

The sustainable growth rate (SGR) formula – the mechanism that ties doctor pay to the gross domestic product in an effort to control costs – "was never really useful in terms of accomplishing the goal to bend the cost curve," Dr. Levy said.

Potential alternatives being evaluated provide an opportunity to get the incentives right, she said, and gear the system toward individual, not group, accountability.

Payment models, however, will all need to be carefully studied over multiple years, she said, to know for sure if they will work.

For instance, good preventive care is expensive in the short term but saves money over time. Looking at just 6 months of data is not enough to see if savings are possible, she said.

See **Variety** • *page 10*

Coinfection Rare in Ped Bronchiolitis

BY PATRICE WENDLING
IMNG Medical News

COVINGTON, KY. – Providers continue to rely on blood cultures to detect serious bacterial infections in children with bronchiolitis, even though urinary tract infections are the most common culprit, a chart review showed.

"Even though there is outstanding evidence in the literature that cultures are unnecessary in the vast majority of infants with clinical bronchiolitis, this practice is common, has a cost, and false-positive results can result in prolonged length of stay and exposure to antibiotics that is unnecessary," Dr. Brian Alverson said.

Dr. Alverson of Hasbro Children's Hospital in Providence, R.I., said the chart review supports other studies that show that the rate of UTI positivity is approximately the same as reported rates of benign transient bacteriuria in infants. Indeed, the incidence of UTI in the analysis was only 2.9% among patients who underwent urine testing, and the rates

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FRANKLIN A. MICHOTA, M.D.

COMMENTARY

Shortcut Is Wrong Route for Hospitalists

Recently, the Society of Hospital Medicine and the Society of Critical Care Medicine released a position paper that proposed a 1-year expedited training pathway for experienced hospitalists to achieve critical care board eligibility. This proposal was in response to the worsening shortage of intensivists in the United States and the reality that the vast majority of hospitalists already work in ICUs. The primary goal would be to increase the pool of qualified intensivists to better meet the LeapFrog safety standard of 24/7 ICU coverage by critical care specialists and thus improve patient outcomes.

The SHM/SCCM position paper acknowledges that such a cohort of hospitalist-trained intensivists would need to be formally evaluated and studied against patient outcomes, but presumed that the hospitalist-trained intensivists would improve care compared with the gap that currently exists (J. Hosp. Med. 2012;7:359-64).

I commend SHM for engaging subspecialty groups seeking solutions to a problem that is clearly affecting us all. However, I am left with an overall sense that SHM is putting the cart before the horse.

By current numbers, hospitalists are 34,000 strong. Yet despite being woven into the fabric of the U.S. health care system, we remain a heterogeneous workforce with no standards for training, no board certification of our own, and ultimately little consistency from one hospitalist to another. Board-eligible internists with little practice experience are called hospitalists, just like board-certified (and recertified) internists with 15 years under their belt. The variability in procedural competency is even greater than the cognitive divide. If the prerequisite for an expedited training pathway to board certification in critical care begins with an experienced hospitalist, don't we need to address what a hospitalist is first?

In 2006, SHM developed and published the Core Competencies in Hospital Medicine. This seminal work should have become the foundation for a 1-year hospitalist fellowship and a requirement for board eligibility in hospital medicine. Instead, you may complete any residency you wish and call yourself a hospitalist if your primary professional focus is the general medical care of the hospitalized patient. The Focused Practice in Hospital Medicine Maintenance of Certification program was a landmark achievement, but we continue to set the bar too low. This program is voluntary and lacks the supervised practice experience that a fellowship would provide.

It is interesting to note that the SHM/SCCM proposal mandates that the hospitalist participate in the Focused Practice in Hospital Medicine Maintenance of Certification program (i.e., it is not voluntary) – thus ensuring that hospitalists are certified in their primary board, that hospital medicine modules are completed, and that scholarly work in the form of quality improvement is accomplished. But I can't help but agree with the recent response from the American College of Chest Physicians (ACCP) and American Association of Critical-Care Nurses (ACCN), which states that they "believe that 1 year is an inadequate training period for hospitalist physicians to achieve competence in the subspecialty of critical care medicine" (Chest 2012;142:5-7).

Why do you suppose that the ACCP/ACCN feels this way? Could it be they have worked with "hospitalists" who are not up to par? Could it be they have observed variability in both cognitive and procedural skill?

I appreciate that the critical care shortage is not going away and that the SHM/SCCM proposal will produce more trained physicians to work in the ICU. But creating a new variability among intensivists may not be much of a solution.

Any training pathway to critical care board certification must be as rigorous as the existing pathways. We must resist replacing rigor with expediency. SHM should put the horse back in front of the cart. ■

DR. MICHOTA *is director of academic affairs in the hospital medicine department at the Cleveland Clinic. He reported having no relevant financial conflicts.*

IN THIS ISSUE

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Dr. W. Michael Alberts, FCCP, is Medical Editor in Chief of CHEST PHYSICIAN.

COMMENTARY

Dr. Steven Q. Simpson, FCCP, comments: Dr. Michota makes some cogent points that I can underscore. What was once a "hospitalist movement" and is now the subspecialty of Hospitalist Medicine came about because of patient need. Likewise, the specialty of Critical Care Medicine. It was because of overwhelming unmet need that the certification horse has outstripped the cart of patient need, to borrow a phrase from Dr. Michota. However, patients have no need of inadequately trained or haphazardly trained physicians in any specialty. We must ensure that these two groups of physicians, who provide care to patients in their times of greatest vulnerability, are rigorously trained in their own right, and that patients can count on a high level of knowledge, skill, and professionalism. When we are certain that our training programs have met that hurdle, then we can legitimately discuss training more of that kind of physician.

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EHR REPORT

Show Me the Money: Getting Paid for Meaningful Use

BY CHRISTOPHER NOTTE, M.D., AND NEIL SKOLNIK, M.D.

While the government incentives offered for meaningful use compliance are important, there are many questions about the specifics of each program, who is eligible for which incentives, and when the actual checks will arrive in the mail. Admittedly, it can be somewhat mystifying, so here we will help to lay out what to expect.

Let's start with the basics:

► Which program do I qualify for?

By now, you likely know that the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as a part of the American Reinvestment and Recovery Act of 2009, promises financial incentives for hospitals and clinicians who meet the requirements for meaningful use. There are two separate programs under which institutions and "eligible providers" (EPs) can qualify for a payout: Medicare and Medicaid. We won't cover the hospital programs here, but will focus just on the incentives for EPs.

First, under the Medicare Program, any doctor (which includes any MD or DO, dentist, podiatrist, optometrist, or chiropractor) who treats Medicare patients can qualify as an eligible provider. EPs who adopt a certified electronic health record and comply with an extensive set of rules defining how they use it will receive up to $44,000 in increased Medicare payments over a 5-year period.

Below, we will discuss in detail how the money is allocated, but it is worth noting here that EPs who do not charge a defined minimum annual dollar amount to Medicare will not receive the full incentive. Instead, they will receive a percentage of their total billing.

Also worth noting is the absence of care extenders such as nurse practitioners (NPs) and physician assistants (PAs) from the list of eligible providers under the Medicare program. The Medicaid program is quite different.

Fewer providers will qualify for the Medicaid incentive, but there is greater financial benefit and flexibility for those who do fall under this program. To be eligible, any physician (MD or DO), nurse practitioner, certified nurse-midwife, or dentist must have a minimum of 30% Medicaid patient volume (or 20% if the provider is a pediatrician). Physician assistants can also be eligible if he or she provides care in a federally qualified health center or rural health clinic that is led by a physician assistant.

The maximum financial incentive is raised to $63,750; but unfortunately, the Medicaid incentive program is not available in every state. Currently absent from the list of participating states are Hawaii, Minnesota, Nevada, New Hampshire, and Virginia. One additional note: A provider eligible under both Medicare and Medicaid will need to choose just one program in which to participate, but may switch once during the total duration of the incentive initiative.

► How does the money get paid out?

As mentioned above, the Medicare incentive program pays out a maximum of $44,000 over a 5-year period. It is not divided equally over each year, and several factors may affect the total amount.

First, only providers who adopt a certified EHR and begin attesting by the 2012 incentive year can receive the maximum benefit. To receive any benefit at all, an EP must begin attesting by 2014. To give a more tangible example, if one were to successfully attest starting in 2012 and continue to successfully attest every year, he or she would receive the following annual payments: $18,000 in 2012, $12,000 in 2013, $8,000 in 2014, $4,000 in 2015, and $2,000 in 2016, for a total of $44,000.

If he or she were to delay attesting by just 1 year, the maximal payout amount would decrease to $39,000, as the first payment drops to $15,000 and final year incentive is lost.

As mentioned earlier, any EP not meeting a minimum threshold in Medicare charges will not be eligible for the full incentive, but instead will receive a percentage of their billing. For example, in year 1, any EP not submitting at least $24,000 in Medicare charges will receive 75% of their billing as their incentive.

Thankfully, a provider need not wait to attest until that $24,000 is reached. Medicare will hold the payment until the threshold is met or until the end of the calendar year, whichever is first. At that point, an EP can expect to see the incentive check within 4-8 weeks, according to CMS statements.

The Medicaid program works a bit differently. First, the EP may receive an incentive payment in year 1 of the 6-year attestation period for simply adopting, implementing, or upgrading to a certified electronic health record. (Following the initial year, that provider will need to follow the same guidelines outlined under the Medicare program).

Second, delaying implementation does not limit the amount of incentive money available to the EP – so a provider who waits to begin the process in 2016 can receive the same $63,750 incentive as one who begins in 2012.

Finally, the CMS requires that states disburse the payments within 45 days of attestation, and there are no billing thresholds to meet.

► What about the penalties?

Providers who are eligible under the Medicare program will begin to see "payment adjustments" if they fail to comply with meaningful use by 2015. This amounts to a 1% penalty per year, and will max out at 5%. Under the Medicaid program, there is no penalty for not adopting an EHR.

Either way, the timeline should provide plenty of time for anyone who is serious about switching to electronic health records. Those who eschew technology and refuse to make the jump can decide on their own if the outlined penalties are a reasonable price to pay. ■

DR. SKOLNIK *is associate director of the family medicine residency program at Abington (Pa.) Memorial Hospital and is a professor of family and community medicine at Temple University, Philadelphia. He is also editor in chief of Redi-Reference, a software company that creates medical handheld references.* DR. NOTTE *practices family medicine and health care informatics at Abington Memorial Hospital. Dr. Skolnik and Dr. Notte are partners in EHR Practice Consultants, helping practices move to EHR systems. Contact them at info@ehrpc.com.*

COMMENTARY

Dr. Stuart M. Garay, FCCP, comments: Meaningful use is here! Fueled by the HITECH Act's provision to compensate physicians, adoption of EHR has significantly increased this past year. But time is running out to qualify for full reimbursement from Medicare. If you have begun implementing an EHR, don't delay to attest for 2012! If you haven't begun the process, there is still time to qualify for significant incentive money in 2013. However, beware of the penalties if you don't adopt a meaningful use EHR by 2015.

Vaccinate Before Discharge

Inpatient • *from page 1*

"I think the places that have seemed to hard-wire [a vaccination program] have locked it into a nurse-directed order set that may be implemented upon discharge, along with education. Or, [it] may be implemented a few days into the hospitalization so as to avoid that first 48 hours when a lot of activity is happening around the acute illness," Dr. Talbot said. This approach helps ensure that vaccination doesn't fall off the radar, and allows time to get the vaccine as well as educate patients, he said.

"One of the challenges with this type of program is making sure that the patient's outpatient provider is aware that they have received immunizations," Dr. Talbot added. "We don't want individuals to get an unnecessary additional flu shot or pneumococcal vaccination." Documentation and communication are key factors, as is having a mechanism in the health care facility or hospital to track vaccinations so a returning patient does not receive a second vaccine unnecessarily, he said.

Another challenge to implementing inpatient immunization is the concern that some sick patients who receive a flu vaccine won't mount the same immune response as they would while healthy, Dr. Talbot said.

"In particular populations, such as those immediately post transplant, where we know that the immune response would not be robust, immunization should be deferred," he emphasized.

"However, there is no evidence to suggest that giving a vaccine during a hospitalization will adversely impact the course of most illnesses for which people are admitted," he said.

Dr. Talbot also emphasized the importance of vaccination for health care workers. (See box below.)

In developing its Hospital Inpatient Quality measures, the Joint Commission looked to a 2006 National Quality Forum workgroup recommendation that "influenza and pneumococcal vaccination measures should apply to all patients regardless of diagnosis."

As of August 2012, a proposal from the Centers for Medicare and Medicaid Services requiring certain Medicare providers and suppliers to offer all eligible and consenting patients flu vaccination during flu season had not been approved, and flu vaccination policies and practices vary among hospitals.

However, inpatient immunization is becoming a quality measure for hospitals, and it will be necessary for reaccreditation, according to the Joint Commission. Starting on Jan. 1, 2012, inpatient influenza immunization officially became a core measure set for hospital accreditation programs, and will be phased in over time for different programs.

Polishing a Protocol

An inpatient immunization program is working in Boston at Beth Israel Deaconess Medical Center. BIDMC first initiated an inpatient flu immunization protocol in 2006, and it has been refined over time, according to Dr. Alexander Carbo, a hospitalist in the division of general medicine and primary care at BIDMC; Jaime Levash, project administrator for QI and professional development; and Margie Serrano, RN, who work together as part of the medical center's Influenza Inpatient Immunization Initiative. They described the BIDMC protocol as follows:

► When adult patients (aged 18 years and older) are admitted to BIDMC, the online medical record automatically checks to see when patients have been immunized (or have contraindications such as an allergy).

► If the patient's vaccine status is unknown in the BIDMC system, or if the patient previously refused vaccine, upon admission the ordering providers are prompted to write for the influenza vaccine protocol, or to provide a reason for not initiating the protocol (such as a prior immunization, or allergy).

► If the protocol is initiated, the nursing staff screens the patient for appropriateness for vaccine and then either provides vaccine (with documentation) or documents the contraindication in the online medical record.

► During subsequent admissions, providers will be reprompted to write for the vaccine protocol if the patient previously refused vaccine or if vaccine was not given (for a reason other than listed contraindications); otherwise, the prompt will not appear (the computer system tracks prior immunizations and contraindications, so as not to revaccinate patients or reprompt for patients with contraindications during the same influenza season).

The BIDMC team has tweaked the protocol over time to make it more effective at the 650-bed center. For example, "we have added a hard stop at discharge to ensure that each patient's immunization status is accounted for during their admission," Dr. Carbo said.

Plans for the 2012-2013 flu season are similar to last year's protocols, but will incorporate some of the newer CDC guidelines for immunizing patients with egg allergies, Dr. Carbo said.

In addition, "BIDMC mandates immunization for all employees in patient care areas (allowing exceptions for previously noted contraindications) and strongly encourages vaccination for all other staff," he noted.

Dr. Carbo's advice to physicians about how to succeed in inpatient immunizations: "Work with a multidisciplinary team," he said. "When we started in 2006, I did this in collaboration with one of the nursing leaders. Now we have a multidisciplinary team that includes representatives from the nursing staff, the pharmacy staff, information systems, and communications," he said.

Read the Sign

The 566-bed University of Wisconsin Hospital Center (UWHC) in Madison is also harnessing the power of protocol.

"We realized that, as one of our quality control measures, we were monitoring what proportion of our patient population was being vaccinated against pneumonia and influenza and we weren't doing as well as we would have liked," said Dr. Nasia Safdar, hospital epidemiologist for the UWHC.

Immunizing inpatients was a top choice among UWHC's efforts to optimize vaccination, but "it turned out quickly that it was easier said than done," Dr. Safdar said.

The Wisconsin hospital faced the challenge with a protocol similar to the one used at BIDMC. "It took a lot of the repeated questioning and thinking out of the equation because everyone is familiar with the protocol," Dr. Safdar said. "If a patient meets the criteria, they will be vaccinated."

Status is checked upon admission, and barring any specific objection or event, eligible patients get the vaccine at some point during their relationship with the Wisconsin hospital. For example, a transplant patient would not receive a vaccine at the time of the hospital stay for the transplant, but could be vaccinated at a follow-up visit 6 months later, she explained.

"Another thing we have done is to put notices on patients' doors that say, 'Eligible for Vaccination Before Discharge,' and the pharmacist, who is typically involved in the discharge medication process, knows right away that this is a patient who needs to be vaccinated," she said. "It is a visible marker of something that needs to be done," Dr. Safdar said.

Dr. Talbot, Dr. Carbo, and Dr. Safdar reported having no financial conflicts to disclose. ■

Stopping the Flu Starts With You

Immunization. It's not just for patients anymore. But was it ever?

"It is extremely important for health care workers to get vaccinated every year," said Dr. Talbot. Health care workers are diligent by nature, and they often come to work when they are sick, he said. Also, healthy adults often shed the flu virus before they are infected, and they might attribute a runny nose or early flu symptoms to a cold, he added.

Safety issues aside, some hospitals and organizations have made immunization a condition of employment, Dr. Talbot said. "It is now being seen as a professional responsibility," he said. The Joint Commission made staff immunization a core measure for hospitals in July of this year.

Dr. Talbot served on the review panel for "Strategies for Implementing Successful Influenza Immunization Programs for Health Care Personnel Project." A 10-month effort completed in 2009, the Joint Commission project sought to provide information about barriers to successful flu vaccine programs along with strategies for overcoming them. The Centers for Disease Control and Prevention has also weighed in, recommending flu vaccination for all health care personnel, based on the advice of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee.

According to the CDC, health care facilities should offer easy-access vaccination sites and "targeted education about the disease, including disease risk among HCP and patients, and about the vaccine."

"You have to really try to address the misconceptions of the vaccine and there are things that are not proven by science," Dr. Talbot said.

Flu immunization programs for health care workers are more likely to succeed if they are presented in a nonadversarial way, with an emphasis on improving safety for patients, Dr. Talbot added.

Flu Vaccine Approved for Upcoming Season

BY ELIZABETH MECHCATIE

IMNG Medical News

The influenza vaccine for the 2012-2013 season has been approved by the Food and Drug Administration, the agency has announced.

The three strains that are included are an A/California/7/2009 (H1N1)-like virus, which was included in the 2011-2012 influenza vaccine, and two new strains: an A/Victoria/361/2011 (H3N2)-like virus and a B/Wisconsin/1/2010-like virus.

"It is especially important to get vaccinated this year because two of the three virus strains used in this season's influenza vaccines differ from the strains included in last year's vaccines," Dr. Karen Midthun, director of the FDA's Center for Biologics Evaluation and Research, said in a statement.

Six manufacturers are licensed to produce and distribute influenza vaccine in the United States. The approved products are Afluria (CSL); Fluarix (GlaxoSmithKline); FluLaval (ID Biomedical); FluMist (MedImmune); Fluvirin (Novartis); and Fluzone, Fluzone High-Dose, and Fluzone Intradermal (Sanofi Pasteur).

Each year, the selection of strains to be included in the influenza vaccine is based on information about influenza virus circulating worldwide during the previous season and on recommendations from the FDA's Vaccines and Related Biological Products Advisory Committee.

For the latest information on this season's flu vaccine and vaccine safety, go to www.cdc.gov/flu/professionals/vaccination. ■

H3N2v Flu Infections Take a Big Jump

BY KERRI WACHTER
IMNG Medical News

Infections due to the influenza A(H3N2) variant virus have soared to 276 cases as of Aug. 24, according to the Centers for Disease Control and Prevention.

"This increase is partly based on the change in reporting requirements … but in fact, the increase reflects accurately what is going on in these outbreaks," Dr. Joseph Bresee said during a telephone press conference held by the CDC.

The 276 confirmed cases of Influenza A(H3N2) variant infection include 113 cases in Indiana, 56 cases in Ohio, 12 in Maryland, and 6 in Wisconsin.

In early August, the CDC provided guidance to state laboratories and is now allowing states to confirm their own H3N2v cases, prior to laboratory confirmation at CDC. "Cases that were positive at the state level were overwhelmingly being confirmed also at CDC," said Dr. Bresee, who is a medical epidemiologist with the CDC's influenza division.

"Given this, and in the context of an outbreak situation, with very little seasonal influenza circulating, we felt that it was appropriate for states to begin reporting their positives as confirmed cases rather than waiting for CDC confirmation," he said. "We anticipate that the change in reporting requirements will provide for a more real-time indication of how these outbreaks are evolving."

Positive samples will still be forwarded to the CDC, where these will be confirmed using genetic sequencing.

"The severity of human illness associated with this virus continues to resemble that of seasonal flu. Most of the cases are mild, self-limited, and resolve on their own," Dr. Bresee said.

The CDC has not received any reports of deaths associated with the virus and only two hospitalizations.

Importantly, there is no evidence of sustained human-to-human spread in the community. "This is not a pandemic situation," Dr. Bresee said. However, "these viruses are all the same. They're not completely genetically identical, but they're very close to being so. All of the viruses that we're seeing so far, in this latest increase in cases, are the viruses with the M gene." The M gene may confer increased transmissibility to and among humans.

Most of the cases have involved contact or exposure to swine prior to illness onset, and many have been associated with state agricultural fairs, where swine were present.

Signs and symptoms of H3N2v virus infection are similar to those of seasonal influenza virus infection. If H3N2v virus infection is suspected because of recent exposure to pigs, testing of respiratory specimens should be performed at a state health department; rapid influenza diagnostic tests may not detect H3N2v virus in human respiratory specimens, resulting in false-negative results.

Two antivirals – oseltamivir (Tamiflu) and zanamivir (Relenza) – are expected to be effective for treating H3N2v illness. Antiviral treatment is most effective when started as soon as possible after illness onset, according to the CDC. ■

COMMENTARY

Dr. Vera DePalo, FCCP, comments: Normally swine flu viruses do not infect humans. But sporadic human infections with influenza viruses that normally circulate in swine have occurred, the CDC notes. When this happens, these viruses are called "variant viruses" and are denoted by adding the letter "v" to the end of the virus subtype designation. With the approach of flu season, the rapid rise in the number of influenza A variant virus (H3N2v) cases may pose diagnostic difficulties for the clinician. If suspected, tests of respiratory specimens should be performed at state health department labs as rapid influenza diagnostic tests may not detect H3N2v virus. The CDC confirms the diagnosis. It should be suspected in those who had contact with or exposure to swine prior to illness onset.

Influenza H3N2v: Efficacy Varies Among Rapid Tests

BY MIRIAM E. TUCKER
IMNG Medical News

The ability to detect the recently circulating influenza variant H3N2v was low in some commercially available rapid detection tests, according to an analysis conducted by the Centers for Disease Control and Prevention.

"The ability to detect H3N2v virus varied substantially among the tests. This evaluation emphasizes the fact that a negative [rapid influenza detection test (RIDT)] result should not be considered as conclusive evidence of lack of infection with influenza A(H3N2)v. … Results from RIDTs, both positive and negative, always should be interpreted in the broader context of the circulating influenza strains present in the area, level of clinical suspicion, severity of illness, and risk for complications in a patient with suspected infection," the CDC said (MMWR 2012;61:1-3).

H3N2v viruses can be definitively identified only at qualified U.S. public health laboratories using a polymerase chain reaction–based influenza diagnostic panel that is not available as a point-of-care test for clinicians. Specimens that test positive for influenza A, H3, and pandemic influenza A markers and negative for H1 and pandemic H1 markers are called "presumptive positive for influenza A(H3N2)v virus," until confirmed as influenza A(H3N2)v, the CDC said.

The CDC analyzed seven Food and Drug Administration–cleared RIDTs for their ability to detect H3N2v viruses. Each of the seven RIDTs – the BinaxNOW, Directigen, FluAlert, QuickVue, Sofia, Xpect, and Veritor – was tested with seven different H3N2 viruses, according to their respective package instructions.

Only four of the seven RIDTs (Directigen, Sofia, Veritor, and Xpect) detected all influenza A(H3N2)v viruses. BinaxNOW detected five of seven, and QuickVue detected three of seven. FluAlert detected only one of seven, the CDC said.

Additional CDC guidance on interpretation of RIDTs for testing of patients with suspected H3N2v infection is available at http://www.cdc.gov/flu/swineflu/h3n2v-testing.htm. ■

COMMENTARY

Dr. Marcos I. Restrepo, FCCP, comments: The variable efficacy observed with different rapid influenza detection tests (RIDTs) confirms the lack of consistency in identifying influenza H3N2v in different communities. It also alerts clinicians to request information regarding the RIDT used to assess the patient with suspected influenza infection and to interpret the results of the test in the context of the patient's clinical criteria, severity of disease, and epidemiologic factors. In addition, health care providers should look for updated information regarding influenza tests, diagnosis, treatment, and prevention at the Centers for Disease Control and Prevention website.

Genomics Project Begins to Unravel Lung Cancer

BY PATRICE WENDLING
IMNG Medical News

CHICAGO – Researchers are beginning to unravel the genomics of lung squamous cell carcinoma, revealing a disease characterized by complex genomes with frequent and unique rearrangements.

Exome and RNA sequence analyses of 178 patients identified 48,690 nonsilent mutations in total, Dr. Ramaswamy Govindan reported at the annual meeting of the American Society of Clinical Oncology.

"This is not a disease like CML [chronic myeloid leukemia] with one mutation," he said. "This is a tobacco-related lung cancer with an average of 228 nonsilent mutations per tumor."

Lung squamous cell carcinoma (LSCC) was found to have 8.3 somatic mutations/megabase, far surpassing, for example, the 0.5 mutations/megabase found in acute myeloid leukemia. The average number of mutations was 360 per tumor.

"It's quite significant the amount of mutational burden," Dr. Govindan said. "Many of them are passenger mutations, but still it's a fairly disordered genome."

Dr. Govindan and his fellow researchers with The Cancer Genome Atlas (TCGA) Lung Cancer Project are attempting to characterize the poorly understood genomic and epigenomic landscape of LSCC and to identify potential therapeutic targets. No molecularly targeted therapy has been approved for use in LSCC, which accounts for roughly 30% of lung cancer deaths or 45,000 deaths/year in the United States.

The researchers hope to sequence about 1,000 lung cancers in the next year, with data presented on 178 LSCC patients, most of whom smoked (96%), were male (74%), and had early stage I/II disease (76%). Their median age was 68 years.

The tumor protein 53 (TP53) gene was almost universally altered in the cohort, along with frequent loss of cyclin-dependent kinase inhibitor 2A (CDKN2A) function, said Dr. Govindan, an oncologist/hematologist and professor of medicine at Washington University in St. Louis. Other significantly mutated genes were phosphatase and tensin homolog (PTEN), Kelch-like ECH-associated protein 1 (KEAP1), nuclear factor-erythroid 2 related factor 2 (NFE2L2), human leukocyte antigen–A (HLA-A), and phosphoinositide-3-kinase catalytic alpha (PIK3CA).

Therapeutic targets were identified in 127 patients or roughly three-fourths of patients with LSCC. "So it's really rich in targets," he said.

Most of the samples had distinct genes that are significant in terms of therapy and that are altered in a mutually exclusive fashion. Targets include the fibroblast growth factor receptors (FGFR), phosphoinositide-3 (PI3) kinase pathway (47%), epidermal growth factor receptor (EGFR)/erythroblastic leukemia viral oncogene homolog 2 (ErbB-2), and the cyclin-cyclin dependant kinase complexes.

The researchers also conducted whole genome sequencing on 19 tumors, detecting an average of 165 rearrangements/tumor. This is far more than has been seen in the TCGA database for breast or colon cancer, Dr. Govindan said.

mRNA expression profiling confirmed a recent report that LSCC is composed of four biologically distinct mRNA expression subtypes, suggesting the need for different therapies (Clin. Cancer Res. 2010;16:4864-75).

Pathway alterations in LSCC fell into two major categories. Not surprisingly, the squamous differentiation pathway was altered in 44% of patients, but the oxidative stress response was also found to be altered in 34% of patients and 62% of those with the classic mRNA subtype. Oxidative stress has a role in chemotherapy resistance.

Finally, Dr. Govindan said the lung cancer community is witnessing a revolution. "We are at the dawn of a new era. … We used to see the alterations in the cancer genes through a key hole, and now we can actually have this panoramic view."

The full paper on the TCGA Lung Cancer Project findings is expected to be published shortly and will be deposited in a public database, Dr. Govindan said.

The Cancer Genome Atlas is supported by the National Institutes of Health. Dr. Govindan reported ties to Bayer, Boehringer Ingelheim, and Merck Serono. ■

BY STEPHEN J. BEKANICH, M.D.

COMMENTARY

New Steps in In-Hospital Delirium

"I expect that [insert patient name here] will have a hospital stay measured in a period of days. During that time we will do our best to prevent complications of hospitalization, which include things such as blood clots and infections. We will also do our best to quickly recognize and treat other complications such as confusion or pain." This is a conversation I have with most patients' families when their medically complicated loved one is hospitalized.

I was certain that one gentleman, who had esophageal cancer with metastasis to the spine causing cord compression, would suffer from delirium during his hospital stay. His advanced age, multiple comorbidities, urgent surgery, ICU stay, and pain medications (which initially included a fentanyl PCA [patient-controlled analgesia] later augmented by a ketamine infusion) all seemed to put him at high risk for delirium. Yet, even during his time on our ketamine protocol, he had clear and appropriate conversations with our team.

Another elderly woman, with previously undiagnosed dementia, was living at home with family assistance until coming to the hospital after a fall. During her hospital stay, she experienced side effects of pain medications and developed a urinary tract infection. The delirium that ensued was severe. She required ICU admission because of the intense nursing supervision she needed to keep her out of physical restraints. After 2 weeks, she was discharged to a skilled nursing facility rather than home because of persistent cognitive problems.

Delirium in hospitalized patients is a common problem. Its presence is often partnered with extended lengths of stay, escalation of care, and poorer outcomes. Once it occurs, we turn to screening tools and treatment protocols that evidence has shown to be useful. Therefore, it should come as no surprise that a hospital's approach to delirium management is now recognized as a quality-of-care marker.

Two new studies highlight the impact of delirium and provide a new tool for predicting this condition. They expand our body of knowledge, and one may even allow us to head off delirium before it occurs.

The first study is a prospective cohort enrolled between 1991 and 2006 into a patient registry for Alzheimer's disease (AD). The 771 participants were over the age of 65 years with a clinical diagnosis of AD in this community setting. Databases identified those who were hospitalized, experienced delirium, died, or were institutionalized. Cognitive decline was also evaluated and based upon a validated test score (Ann. Intern. Med. 2012;156:848-56).

A total of 367 patients (48%) were hospitalized, and 194 (25%) developed delirium. Patients who did not experience delirium in the hospital had an increased risk of death or institutionalization (relative risks of 4.7 and 6.9, respectively), but an even more dramatic increase in risk was noted in those with delirium (RRs of 5.4 and 9.3). Delirium was associated with 6% of deaths, 15% of institutionalizations, and 21% of cognitive declines in hospitalized patients with AD.

This is the first time the relative contributions of hospitalizations and episodes of delirium to adverse outcomes for AD patients have been evaluated. The results clearly showed that hospitalization is a danger to this patient population and that the outcomes are worse for those with delirium. This clinical cohort was created by merging multiple databases, so incomplete medical records were a limitation. Two other aspects of the study are worth noting. As this study was nonrandomized, the hospitalized patients had lower baseline cognitive function than those who avoided admission. Also, ethnic minorities made up only 5% of the study population.

The second work is a multicenter observational study that entailed the development of the Prediction of Delirium in ICU Patients (PRE-DELIRIC) model in a prospective cohort of 1,613 patients (see story below).

The PRE-DELIRIC model contains 10 risk factors (see graphic below). The main outcome measured was development of delirium within the ICU. The model's ability to predict delirium was compared with the ability of ICU physicians and nurses to independently predict delirium within 24 hours of admission.

The model's area under receiver operating characteristics curve (AUROC) was 0.85 pooled across three cohorts. The AUROC for both physicians' and nurses' predictions of delirium was 0.59. Providers' predictive accuracy did not differ by level of clinical experience.

PRE-DELIRIC is the first predictive model published for the ICU population experiencing delirium. The model clearly outperformed the physicians and nurses, who were equally inferior when it came to predicting delirium, and more experienced clinicians fared no better than their greener colleagues. Limitations included a varied case mix from multiple specialties and inclusion of risk factors that were not based on the authors' systematic review for factors associated with delirium.

Both of these studies move us forward. The first should heighten our level of awareness that hospitalization with delirium is a major marker for adverse outcomes. It also should prompt proactive communication with our AD patients' families about expectations in this scenario. The second study should help create a mindset of predicting and preventing delirium rather than our current model, which is to screen and then treat. ■

DR. BEKANICH *is an internist and medical director of palliative care at Seton Healthcare in Austin, Tex.*

COMMENTARY

Dr. Carl Kaplan, FCCP, comments: It is one thing to successfully treat a disease and another to make an early diagnosis, but it is the most rewarding if you can identify a focused vulnerable population at risk and provide the resources to prevent the occurrence of the disease altogether. This material expands our knowledge and understanding of delirium in the ICU, which is a common problem.

Tool Boosts Power to Predict Delirium in Adult ICU

BY HEIDI SPLETE
IMNG Medical News

A recently developed tool could help doctors stay ahead of the game in preventing delirium in ICU patients.

Dutch researchers say their delirium prediction model was significantly more successful than doctors and nurses at predicting delirium in ICU patients.

Preventive measures for delirium can limit its incidence, severity, and duration. While several assessment tools exist for other populations of hospitalized patients, "no evidence-based prediction model for general intensive care patients is available," Mark van den Boogaard, Ph.D., of Radboud University Nijmegen (Netherlands) Medical Centre and his colleagues said (BMJ 2012;344:e420 [doi: 10.1136/bmj.e420]).

For PRE-DELIRIC (Prediction of Delirium in ICU Patients), the authors defined 10 risk factors that can be assessed within 24 hours of admission (see graphic).

"The use of the PRE-DELIRIC model to identify and consequently preventively treat high-risk patients could offer an important contribution to intensive care practice and ensure efficient use of research resources to study only high-risk patients," the researchers said.

Clinically, the model may improve the use of nondrug measures to prevent delirium in high-risk patients, the researchers added. Such measures include cognitive stimulation, early mobilization, and listening to music, they said. PRE-DELIRIC also could inform the choice to use prophylactic haloperidol in ICU patients, the authors said.

After testing their model for temporal validation, the researchers conducted an external validation study of data from patients admitted to four Dutch ICUs between Jan. 1 and Sept. 1, 2009. The pooled data included information from 3,056 patients aged 18 years and older.

The researchers compared the predictions of patient delirium made using their model to predictions made by doctors and nurses in the hospital, using a convenience sample of 124 patients.

The pooled area under the receiver operation charactertics curve (AUROC) for the PRE-DELIRIC model (0.85) was significantly higher than that for the doctors and nurses (0.59).

No significant differences were seen in the predictions of ICU nurses, student ICU nurses, intensivists, fellow-intensivists, and residents, the researchers said.

The findings were limited by the static nature of the model, which does not account for changes in health status that might affect the development of delirium.

The researchers reported having no financial conflicts of interest. ■

Formula for PRE-DELIRIC Model

Risk of Delirium = 1/(1 + exp – (–6.31 + all applicable risk factors below)

0.04 × age
0.06 × APACHE-II score
1.05 for infection
0.29 for metabolic acidosis
1.39 for use of sedatives
0.03 × urea concentration (mmol/L)
0.40 for urgent admission

Coma
0 for non-coma
0.55 for drug-induced coma
2.70 for miscellaneous coma
2.84 for combination coma

Admission category
0 for surgical
0.31 for medical
1.13 for trauma
1.38 for neurology/neurosurgical

Morphine use
0 for none
0.41 for 0.01-7.1 mg/24h
0.13 for 7.2-18.6 mg/24h
0.51 for >18.6 mg/24h

Note: Model was developed with data for 1,613 consecutive patients from one hospital ICU.
Source: BMJ 2012;344:e420 (doi:10.1136/bmj.e420)

IMNG MEDICAL MEDIA

Pages 8a—8b

Sepsis Deaths Increased With Hydroxyethyl Starch

VITALS

Major Finding: Death or kidney failure occurred within 90 days in 51% of sepsis patients treated with colloidal HES 130/0.4, compared with 43% of those treated with Ringer's acetate.

Data Source: A 2-year, blinded, randomized international clinical trial compared outcomes between 400 ICU patients with severe sepsis who received HES 130/0.4 vs. 400 who received Ringer's acetate for hypovolemia.

Disclosures: This study was supported by the Danish Research Council, the Rigshospitalet Research Council, and the Scandinavian Society of Anesthesiology and Intensive Care Medicine. Dr. Perner reported receiving grant support from Fresenius Kabi.

BY MARY ANN MOON

IMNG Medical News

Hydroxyethyl starch 130/0.4, widely used for fluid resuscitation in hypovolemia due to severe sepsis, raises the risk of death within 90 days, compared with Ringer's acetate, according to a report published online in the New England Journal of Medicine.

The low-molecular-weight hydroxyethyl starch (HES) is a colloid solution thought to afford more rapid and lasting circulatory stabilization, compared with standard IV fluids such as Ringer's acetate. HES 130/0.4 has been widely adopted in ICUs around the world, even though data about its effectiveness are limited and several trials have raised concerns about its safety, said Dr. Anders Perner of the department of intensive care, Copenhagen University Hospital, and his associates.

Their Scandinavian Starch for Severe Sepsis/Septic Shock study was an international trial to compare the effects of HES 130/0.4 against Ringer's acetate on the composite outcome of death or end-stage kidney failure within 90 days of treatment. The study population comprised 800 septic shock patients treated at 13 university-affiliated ICUs and 13 nonacademic general ICUs in Denmark, Norway, Finland, and Iceland between December 2009 and November 2011.

When their physicians decided that volume expansion was required, the study participants were randomly assigned in equal numbers to receive fluid resuscitation with either HES 130/0.4 or Ringer's acetate in a manner that concealed treatment assignment from patients, clinicians, research staff, and study committee members. The median cumulative volume of fluid administered was 3,000 mL.

The primary outcome measure (a composite of death or dependence on dialysis), occurred in 51% of patients who received the starch, compared with 43% of those who received Ringer's solution. When the two outcomes were analyzed separately, this difference was found to be entirely due to an increased risk of death in the starch group, the investigators said (N. Engl. J. Med. 2012 July 27 [doi:10.1056/NEJMoa1204242]).

In multiple further analyses of the data, including logistic regression and per-protocol analyses, these results persisted. The separation of the survival curves indicated that HES 130/0.4 tends to induce death late in the course of hospitalization, Dr. Perner and his colleagues said.

In addition, more patients in the starch group than in the Ringer's group required renal replacement therapy (61% vs. 44%) or developed bleeding complications (10% vs. 6%).

Previous studies suggested that a high proportion of HES "is taken up and deposited in tissues, where it cannot be metabolized and it acts as a foreign body. Long-term toxic effects of HES deposition have been described in the kidney, liver, and bone marrow.

"Together, all these negative effects of HES may have caused the late deaths observed in our trial" and in previous studies, the researchers noted.

This study also raises the question of whether HES 130/0.4 is actually more potent than crystalloids in patients with severe sepsis. "We did not observe significant differences in trial fluid volumes between the study groups," a result that has been reported in a previous study, they added.

The study findings should be applicable to other populations because this trial had broad inclusion criteria and very few exclusion criteria. It even included patients who had acute kidney injury at baseline, the authors said. ■

SGR Bill Referred to Commitee

Variety • *from page 1*

Legislation Offers Permanent Fix

One proposal favored by many physicians comes from Rep. Allyson Schwartz (D-Pa.) and Rep. Joe Heck (R-Nev.), an osteopathic physician. The bill (H.R. 5707) would permanently eliminate the SGR and set up a 10-year path to a new payment system.

During the initial years, physicians would receive small pay increases while Medicare officials tested new payment models, with primary care doctors getting slightly more during the transition.

After testing, physicians could choose from a menu of alternative payment and delivery options. Those who didn't participate in one of the new quality-based models would see their fee-for-service payments reduced starting in 2019.

Rep. Schwartz said there is an "outside hope" that the bill, now in the House Subcommittee on Health, could be considered during the lame-duck session that follows the Nov. 6 election. If not then, it could come up in early 2013.

Overall, she said that she's encouraged by the increasing agreement between physicians and lawmakers to move toward innovative payment models.

ALICIA AULT/ IMNG MEDICAL MEDIA

Dr. Ardis D. Hoven (left) of the American Medical Association and Dr. Glen R. Stream of the American Academy of Family Physicians testify before the Senate.

She advised doctors to keep talking to their members of Congress about the need to adopt a new system that pays adequately for high-quality care. The more bipartisan agreement around that concept, the better, she said. "There's no question that physicians should be looking at ways they can participate in new payment models," Rep. Schwartz said.

The House and Senate committees that oversee Medicare – the Senate Finance Committee, the House Energy and Commerce Committee, and the House Ways and Means Committee – also have been talking to physicians and insurers about what type of payment system could replace the SGR.

Committee members appear to be working toward legislation that would extend current Medicare payment rates temporarily while moving toward value-based payment models, according to Bob Doherty, senior vice president of governmental affairs and public policy at the American College of Physicians.

If lawmakers went forward with that type of plan, physicians would probably have the chance to earn a small pay increase for participating in programs that reward value or care coordination. That approach would still leave the SGR in place, though, at least in the short term.

"The hope is that, as more physicians begin to move to these other models and you get more experience with them, that will create a roadmap to eventually sunsetting the entire SGR and replacing it with these value-based payment models," Mr. Doherty said. Although the emphasis on getting away from the current system is encouraging, Mr. Doherty said he's concerned about any approach that falls short of repealing the SGR.

Variety Is Needed

It's also looking like a plan to replace the SGR could include a variety of payment models, not just a single alternative, said Ray Quintero, director of government relations for the American Osteopathic Association. "Every physician practices differently, the patients that they serve are different, the services that they provide are different, and the payment models should be reflective of that," he said.

Some of those new models may come from the Center for Medicare and Medicaid Innovation, which was created under the Affordable Care Act and is testing new ways to pay for and deliver health care, but Congress is also looking to the private health plans for solutions that have already been tested and produced savings, Mr. Quintero said.

Time to Act Is Now

Dr. William Zoghbi, president of the American College of Cardiology, said

Continued on following page

COURTESY OFFICE OF REP. ALLYSON SCHWARTZ

Rep. Allyson Schwartz is cosponsoring legislation to replace the SGR.

Continued from previous page

that the problem is urgent and members of Congress need to look to payment models ready for implementation today.

The ACC has developed SMARTCare, a program to address variation in cost and quality in treatment for stable ischemic heart disease. SMARTCare uses registry data to help physicians employ the most appropriate diagnostics and treatments. Such a program could be used hand-in-hand with a bundled payment model, he said.

He called on Congress and the administration to provide leadership. Physicians want to be involved in changing the system, but they are only one piece, he said. Policy makers also need to work with drug and device companies and hospitals to cut back on waste and make the health care system more sustainable.

"The further we delay these decisions, the more costly it is," Dr. Zoghbi said.

Gail Wilensky, Ph.D., who ran the Medicare and Medicaid programs from 1990 to 1992, agreed.

She suggested a number of payment alternatives Congress could consider, including bundling physician payments for high-cost, high-volume interventions.

Now Congress needs to direct the Centers for Medicare and Medicaid Services or the Medicare Payment Advisory Commission to come up with a plan and give them a firm deadline, she said. With that plan in hand, it would be easier for Congress to justify spending $300 billion to replace the SGR system.

"Until they do that, you don't have anything to talk about," said Dr. Wilensky, who is currently an economist and senior fellow at Project HOPE.

Physicians can do their part to speed the legislative heavy lifting by presenting concrete alternatives with a real capacity to cut costs for the health care system, said Dr. Mark B. McClellan, who was the CMS administrator from 2004 to 2006 and is now director of the Engelberg Center for Health Care Reform at the Brookings Institution.

He cited some of the medical-home models that have been implemented by private health plans as good examples. These medical homes provide substantially better up-front payments for primary care physicians but also make them accountable for keeping costs down.

"Leadership on this is going to have to come from physicians and physician organizations," Dr. McClellan said. "Congress and the Medicare program are under a lot of pressure to do more to balance the budget, to do more to keep costs down while keeping quality up. They don't have the best ideas. Physicians do."

Dealing With the Status Quo

Although most physicians don't believe that Congress will allow large cuts to physician payment to go into effect, the trend of enacting temporary payment patches could continue for a few years, which would make it increasingly difficult for physicians to plan their expenses and run their offices, said Dr. Glen R. Stream, president of the American Academy of Family Physicians.

"It tests people's willingness to continue to participate in the Medicare program," Dr. Stream said. "So often we don't look at doctors' offices, particularly small offices, as businesses. And yet they are businesses and they have expenses that are going up all the time as far as insurance, utilities, and staff." More practices will critically evaluate their continued participation in Medicare, he said.

No matter what the outcome of November's election, lawmakers will have to address the physician payment issue, Dr. Stream said. His biggest concern right now is a continued partisan stalemate, which "could actually be more harmful to evolving so many things about our health care system, including the physician payment piece," he said. ■

Note: The ACCP continuously monitors this situation and has partnered previously with the AMA to support replacement of the SGR.

COMMENTARY

Dr. Lary Robinson, FCCP, comments: The brainchild of economist Robert C. Higgins in 1977, the *sustainable growth rate* (SGR) is a financial strategy in business that was adapted by Congress in 1997 for Medicare (CMS) to attempt controlling costs. The SGR was intended to ensure that the yearly increase in the expense per Medicare beneficiary does not exceed the growth in GDP.

However, with medical costs consistently exceeding the SGR each year, this automatically threatens drastic physician payment cuts (27% for the end of 2012). The SGR system has proven to be an ineffective cost-containment tool and, in fact, it has become a political football that Congress "kicks down the road" at the last minute each of the last 15 years. Cries have become louder for change to more useful tools to control rising Medicare costs that reward "higher quality care," a concept that is easier to state than to measure. This article describes many of the ideas and concerns about new proposed payment models voiced by leaders in national health care policy.

HHS Cuts Red Tape on Electronic Payments

BY MARY ELLEN SCHNEIDER
IMNG Medical News

The federal government is requiring health plans to make it easier for physicians to get paid electronically.

On Aug. 7, the Department of Health and Human Services released new rules for health care electronic funds transfers (EFT) and electronic remittance advice (ERA). Starting Jan. 1, 2014, health plans must offer a standardized, online form for physicians and hospitals to enroll to electronically receive payments, as well as notices about claims adjustments and denials. The new rules are required under the Affordable Care Act.

"These new rules will cut red tape, save money, and ensure doctors spend more time seeing patients and less time filling out forms," HHS Secretary Kathleen Sebelius said in a statement.

The requirements could help shift more physician practices away from paper billing. About 70% of health care claim payments are still made in paper check form, according to HHS.

The interim final rule from HHS does not require physicians and hospitals to accept electronic payments. However, if they do, the agency estimates that they will save time and money. For example, practices will save time in handling payment denials since health plans are required to simplify the codes used to explain whether a claim is paid and why.

The net savings to the health care industry from the new electronic standards will be between $300 million and $3.3 billion over 10 years, according to the final rule. HHS officials predicted that most of the implementation cost would be borne by health plans, but most of the benefits would go to providers.

The interim final rule with comment period was published in the Federal Register on Aug. 10. The public comment period closes on Oct. 9. ■

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INDICATION

BROVANA is indicated for the long term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

IMPORTANT SAFETY INFORMATION

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta$_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including arformoterol, the active ingredient in BROVANA (see WARNINGS). The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

Please see the Brief Summary of Prescribing Information on the following pages for additional Important Safety Information.

Please visit **www.brovana.com** for full Prescribing Information.

References: 1. Baumgartner RA, Hanania NA, Calhoun WJ, Sahn SA, Sciarappa K, Hanrahan JP. Nebulized arformoterol in patients with COPD: a 12-week, multicenter, randomized, double-blind, double-dummy, placebo- and active-controlled trial. *Clin Ther*. 2007;29(2):261-278. **2.** BROVANA [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; 2012.

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BRIEF SUMMARY

WARNING: ASTHMA RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta$_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including arformoterol, the active ingredient in BROVANA (see WARNINGS). The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

INDICATIONS AND USAGE

BROVANA (arformoterol tartrate) Inhalation Solution is indicated for the long-term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

CONTRAINDICATIONS

BROVANA (arformoterol tartrate) Inhalation Solution is contraindicated in patients with a history of hypersensitivity to arformoterol, racemic formoterol or to any other components of this product.

All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication. (see **WARNINGS**).

WARNINGS

- **ASTHMA RELATED DEATH**

  Long-acting beta$_2$-adrenergic agonists may increase the risk of asthma-related death. The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).
  - A 28-week, placebo-controlled US study comparing the safety of salmeterol with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in patients receiving salmeterol (13/13, 176 in patients treated with salmeterol vs. 3/13, 179 in patients treated with placebo; RR 4.37, 95% CI 1.25, 15.34). The increased risk of asthma-related death may represent a class effect of the long-acting beta$_2$-adrenergic agonists, including BROVANA. No study adequate to determine whether the rate of asthma related death is increased in patients treated with BROVANA has been conducted.
  - Clinical studies with racemic formoterol (Foradil® Aerolizer™) suggested a higher incidence of serious asthma exacerbations in patients who received racemic formoterol than in those who received placebo. The sizes of these studies were not adequate to precisely quantify the differences in serious asthma exacerbation rates between treatment groups.
- **The studies described above enrolled patients with asthma. Data are not available to determine whether the rate of death in patients with COPD is increased by long-acting beta$_2$-adrenergic agonists.**
- **BROVANA is indicated for the long term, twice daily (morning and evening) maintenance treatment for bronchoconstriction in chronic obstructive pulmonary disease (COPD), and is not indicated for the treatment of acute episodes of bronchospasm, i.e., rescue therapy.**
- **BROVANA should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition. The use of BROVANA in this setting is inappropriate.**
- **BROVANA should not be used in children as the safety and efficacy of BROVANA have not been established in pediatric patients.**
- **BROVANA should not be used in conjunction with other inhaled, long-acting beta$_2$-agonists. BROVANA should not be used with other medications containing long-acting beta$_2$-agonists.**
- **When beginning treatment with BROVANA, patients who have been taking inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., four times a day) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief of acute respiratory symptoms.**
- **See PRECAUTIONS and Information for Patients.**

Paradoxical Bronchospasm

As with other inhaled beta$_2$-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, BROVANA should be discontinued immediately and alternative therapy instituted.

Deterioration of Disease

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If BROVANA no longer controls the symptoms of bronchoconstriction, or the patient's inhaled, short-acting beta$_2$-agonist becomes less effective or the patient needs more inhalation of short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dosage of BROVANA beyond the recommended 15 mcg twice daily dose is not appropriate in this situation.

Cardiovascular Effects

BROVANA, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of BROVANA at the recommended dose, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QT_c interval, and ST segment depression. The clinical significance of these findings is unknown. BROVANA, as with other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension (see **PRECAUTIONS, General**).

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of BROVANA as demonstrated by cases of anaphylactic reaction, urticaria, angioedema, rash and bronchospasm.

Do Not Exceed Recommended Dose

Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. As with other inhaled beta$_2$-adrenergic drugs, BROVANA should not be used more often, at higher doses than recommended, or with other long-acting beta-agonists.

PRECAUTIONS

General

BROVANA (arformoterol tartrate) Inhalation Solution should not be used to treat acute symptoms of COPD. BROVANA has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. When prescribing BROVANA, the physician should also provide the patient with an inhaled, short-acting beta$_2$-agonist for treatment of COPD symptoms that occur acutely, despite regular twice-daily (morning and evening) use of BROVANA. Patients should also be cautioned that increasing inhaled beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated (see **Information for Patients**).

BROVANA, like other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines. Clinically significant changes in systolic and/or diastolic blood pressure, pulse rate and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with arformoterol tartrate. Doses of the related beta$_2$-agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

Beta-agonist medications may produce significant hypokalemia in some patients, possibly though intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation.

Clinically significant changes in blood glucose and/or serum potassium were infrequent during clinical studies with long-term administration of BROVANA at the recommended dose.

Information for Patients

Patients should be instructed to read the accompanying Medication Guide with each new prescription and refill. Patients should be given the following information:

1. Patients should be informed that long-acting beta$_2$-adrenergic agonists, such as BROVANA, increase the risk of asthma-related death. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see **CONTRAINDICATIONS**).
2. BROVANA is not indicated to relieve acute respiratory symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting, beta$_2$-agonist (the health-care provider should prescribe the patient with such medication and instruct the patient in how it should be used). Patients should be instructed to seek medical attention if their symptoms worsen, if BROVANA treatment becomes less effective, or if they need more inhalations of a short-acting beta$_2$-agonist than usual. Patients should not inhale more than one dose at any one time. The daily dosage of BROVANA should not exceed one ready-to-use vial (15 mcg) by inhalation twice daily (30 mcg total daily dose).
3. Patients should be informed that treatment with beta$_2$-agonists may lead to adverse events which include palpitations, chest pain, rapid heart rate, tremor, or nervousness.
4. Patients should be instructed to use BROVANA by nebulizer only and not to inject or swallow this inhalation solution.
5. Patients should protect BROVANA ready-to-use vials from light and excessive heat. The protective foil pouches should be stored under refrigeration between 2ºC and 8ºC (36º–46ºF). They should not be used after the expiration date stamped on the container. After opening the pouch, unused ready-to-use vials should be returned to, and stored in, the pouch. An opened ready-to-use vial should be used right away. Discard any ready-to-use vial if the solution is not colorless.
6. The drug compatibility (physical and chemical), efficacy and safety of BROVANA when mixed with other drugs in a nebulizer have not been established.
7. Women should be advised to contact their physician if they become pregnant or if they are nursing.
8. It is important that patients understand how to use BROVANA appropriately and how it should be used in relation to other medications to treat COPD they are taking.

Drug Interactions

If additional adrenergic drugs are to be administered by any route, they should be used with caution because the pharmacologically predictable sympathetic effects of BROVANA may be potentiated.

When paroxetine, a potent inhibitor of CYP2D6, was co-administered with BROVANA at steady-state, exposure to either drug was not altered. Dosage adjustments of BROVANA are not necessary when the drug is given concomitantly with potent CYP2D6 inhibitors.

Concomitant treatment with methylxanthines (aminophylline, theophylline), steroids, or diuretics may potentiate any hypokalemic effect of adrenergic agonists.

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

BROVANA, as with other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QT_c interval because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QT_c interval have an increased risk of ventricular arrhythmias. The concurrent use of intravenously or orally administered methylxanthines (e.g., aminophylline, theophylline) by patients receiving BROVANA has not been completely evaluated. In two combined 12-week placebo controlled trials that included BROVANA doses of 15 mcg twice daily, 25 mcg twice daily, and 50 mcg once daily, 54 of 873 BROVANA-treated subjects received concomitant theophylline at study entry. In a 12-month controlled trial that included a 50 mcg once daily BROVANA dose, 30 of the 528 BROVANA-treated subjects received concomitant theophylline at study entry. In these trials, heart rate and systolic blood pressure were approximately 2-3 bpm and 6-8 mm Hg higher, respectively, in subjects on concomitant theophylline compared with the overall population.

Beta-adrenergic receptor antagonists (beta-blockers) and BROVANA may interfere with the effect of each other when administered concurrently. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in COPD patients. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-blockers in patients with COPD. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies were conducted in mice using oral administration and rats using inhalation administration to evaluate the carcinogenic potential of arformoterol.

In a 24-month carcinogenicity study in CD-1 mice, arformoterol caused a dose-related increase in the incidence of uterine and cervical endometrial stromal polyps and stromal cell sarcoma in female mice at oral doses of 1 mg/kg and above (AUC exposure approximately 70 times adult exposure at the maximum recommended daily inhalation dose).

In a 24-month carcinogenicity study in Sprague-Dawley rats, arformoterol caused a statistically significant increase in the incidence of thyroid gland c-cell adenoma and carcinoma in female rats at an inhalation dose of 200 mcg/kg (AUC exposure approximately 130 times adult exposure at the maximum recommended daily inhalation dose). There were no tumor findings with an inhalation dose of 40 mcg/kg (AUC exposure approximately 55 times adult exposure at the maximum recommended daily inhalation dose).

Arformoterol was not mutagenic or clastogenic in the following tests: mutagenicity tests in bacteria, chromosome aberration analyses in mammalian cells, and micronucleus test in mice.

Arformoterol had no effects on fertility and reproductive performance in rats at oral doses up to 10 mg/kg (approximately 2700 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis).

Pregnancy: Teratogenic Effects

Pregnancy Category C

Arformoterol has been shown to be teratogenic in rats based upon findings of omphalocele (umbilical hernia), a malformation, at oral doses of 1 mg/kg and above (AUC exposure approximately 370 times adult exposure at the maximum recommended daily inhalation dose). Increased pup loss at birth and during lactation and decreased pup weights were observed in rats at oral doses of 5 mg/kg and above (AUC exposure approximately 1100 times adult exposure at the maximum recommended daily inhalation dose). Delays in development were evident with an oral dose of 10 mg/kg (AUC exposure approximately 2400 times adult exposure at the maximum recommended daily inhalation dose).

Arformoterol has been shown to be teratogenic in rabbits based upon findings of malpositioned right kidney, a malformation, at oral doses of 20 mg/kg and above (AUC exposure approximately 8400 times adult exposure at the maximum recommended daily inhalation dose). Malformations including brachydactyly, bulbous aorta, and liver cysts were observed at doses of 40 mg/kg and above (approximately 22,000 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis).

There are no adequate and well-controlled studies in pregnant women. BROVANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Labor and Delivery

There are no human studies that have investigated the effects of BROVANA on preterm labor or labor at term. Because beta-agonists may potentially interfere with uterine contractility, BROVANA should be used during labor and delivery only if the potential benefit justifies the potential risk.

Nursing Mothers

In reproductive studies in rats, arformoterol was excreted in the milk. It is not known whether arformoterol is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BROVANA is administered to a nursing woman.

Pediatric

BROVANA is approved for use in the long term maintenance treatment of bronchoconstriction associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. This disease does not occur in children. The safety and effectiveness of BROVANA in pediatric patients have not been established.

Geriatric

Of the 873 patients who received BROVANA in two placebo-controlled clinical studies in adults with COPD, 391 (45%) were 65 years of age or older while 96 (11%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Among subjects age 65 years and older, 129 (33%) received BROVANA at the recommended dose of 15 mcg twice daily, while the remainder received higher doses. ECG alerts for ventricular ectopy in patients 65 to ≤75 years of age were comparable among patients receiving 15 mcg twice daily, 25 mcg twice daily, and placebo (3.9%, 5.2%, and 7.1%, respectively).

A higher frequency (12.4%) was observed when BROVANA was dosed at 50 mcg once daily. The clinical significance of this finding is not known. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Experience in Adult Patients with COPD

Of the 1,456 COPD patients in the two 12-week, placebo-controlled trials, 288 were treated with BROVANA (arformoterol tartrate) Inhalation Solution 15 mcg twice daily and 293 were treated with placebo. Doses of 25 mcg twice daily and 50 mcg once daily were also evaluated. The numbers and percent of patients who reported adverse events were comparable in the 15 mcg twice daily and placebo groups.

The following table shows adverse events where the frequency was greater than or equal to 2% in the BROVANA 15 mcg twice daily group and where the rates of adverse events in the BROVANA 15 mcg twice daily group exceeded placebo. Ten adverse events demonstrated a dose relationship: asthenia, fever, bronchitis, COPD, headache, vomiting, hyperkalemia, leukocytosis, nervousness, and tremor.

Secondhand Smoke May Harm Kids' Bladders

BY MICHELE G. SULLIVAN
IMNG Medical News

ATLANTA – Children exposed to secondhand tobacco smoke have an increased risk of urinary urgency, frequency, and incontinence, prospective data showed.

Among children with these bladder symptoms, 28% were exposed to tobacco smoke on a daily basis – 13% higher than the overall child exposure rate in New Jersey, Dr. Kelly Johnson said at the annual meeting of the American Urological Association.

In addition to irritating a child's bladder, childhood exposure to tobacco smoke is directly linked to the development of bladder cancer as an adult, she said in a press briefing.

Dr. Johnson, chief urology resident at the Robert Wood Johnson University Hospital, New Brunswick, N.J., presented prospective data on 45 children, aged 4-17 years, who presented with irritative bladder symptoms – frequency, urgency, and incontinence.

About half of the group (21) had very mild or mild symptoms, while the rest had moderate or severe symptoms.

None of the children with mild scores were exposed to secondhand smoke on a daily basis, and none had mothers who smoked. However, 23% of those with moderate to severe scores had mothers who smoked, and 50% were exposed to smoke in a car on a regular basis.

"On our measures of environmental tobacco smoke exposure, children with greater exposure had significantly higher symptom severity scores than children who weren't exposed," Dr. Johnson said. "This relationship was particularly striking for the younger children aged 4-10 years old."

Physicians who see children with bladder dysfunction should ask parents about smoke exposure, she advised. "It's a teachable moment" that can have a long-lasting positive impact on both the child and the parent.

Dr. Johnson said that she had no relevant financial disclosures. ■

COMMENT

Dr. Susan Millard, FCCP, comments: Now we have more information to tell parents who pollute their homes and cars with secondhand smoke.

Infant Pneumococcal Disease Tanks in 2011

BY SHERRY BOSCHERT
IMNG Medical News

STANFORD, CALIF. – A huge drop in U.S. cases of invasive pneumococcal disease in infants younger than 2 years bodes well for possible similar trends in older age groups.

Preliminary data not yet published by the Centers for Disease Control and Prevention suggest that only 40 cases of invasive pneumococcal disease with serotypes covered by the previous vaccine were reported in infants under 2 years of age in 2011, Dr. Yvonne "Bonnie" Maldonado said at Stanford University's annual pediatric update.

That's a big, "exciting" drop from nearly 140-180 cases in infants under 2 years of age reported in each of 2006, 2007, 2008, and 2010, and it is most likely due to the introduction of the 13-valent pneumococcal conjugate vaccine (PCV13) in 2010, said Dr. Maldonado, chief of pediatric infectious disease and professor of pediatrics at the university.

The previous PCV7 vaccine, introduced in 2000, lost some effectiveness over time as some covered serotypes mutated, and serotypes not included in the vaccine became more prominent.

With the introduction of the PCV13 vaccine, rates of invasive pneumococcal disease in this young age group "really dropped off dramatically," she said. "It bodes very well for our ability to significantly reduce the amount of pneumococcal disease in the population."

Data for 2009 were not included because pandemic influenza contributed to so many cases that year, she said.

"I suspect that what's going to happen, because it did happen with the PCV7 vaccine, is that you're going to see this herd immunity affect older populations as well," she said.

Dr. Maldonado has been a speaker for Merck and Novartis. ■

COMMENTARY

Dr. Susan Millard, FCCP, comments: This is exciting news because pneumococcal infections still cause childhood pneumonia and empyemas. This improved coverage is more information to pass along to parents who have unfortunate skeptism about immunizations.

Test Urine, Not Blood

Bronchiolitis • *from page 1*

of meningitis and bacteremia were zero.

The study comprised 652 children, aged 1-24 months, with a discharge diagnosis of bronchiolitis. Of those, 26% had a blood culture obtained and 18.4% had a urinalysis or urine culture. Of patients undergoing blood cultures, 55% also had a urinalysis or urine culture.

"People who are going to look for infections aren't looking in the right place," the study's lead author, Dr. Jamie Librizzi, said at Pediatric Hospital Medicine 2012.

The findings are noteworthy since children in the analysis were discharged during 2007-2008 – after the American Academy of Pediatrics bronchiolitis practice guidelines recommending that clinicians should diagnose bronchiolitis and assess disease severity on the basis of history and physical examination.

The 2006 guidelines (Pediatrics 2006;118:1774-93) state that "the clinical utility of diagnostic testing in infants with suspected bronchiolitis is not well supported by evidence" and that "the occurrence of serious bacterial infections (SBIs) such as urinary tract infections (UTIs), sepsis, and meningitis is very low."

Despite the cohort being drawn from Hasbro Children's Hospital and University of Missouri Children's Hospital in Columbia, the misdirected testing could be explained by a knowledge gap and a wide variation in providers including residents, emergency department physicians, and referring community physicians, Dr. Librizzi said.

"Even though we know these guidelines are out there, the practices maybe still haven't caught up to the evidence," she said. "It's also hard when a kid comes in febrile, not looking great, to sit back and be assured that the numbers are really low for a concurrent infection."

"It's a good reminder that we still have work to do educating our emergency departments," Dr. Paul Hain, now with Children's Medical Center, Dallas, commented in a separate interview. "A lot of kids are seen in adult EDs, and folks who are not familiar with children are mostly scared of adult bacteremia and think that blood cultures are what they need, even though bronchiolitis is a special subset."

Children who were evaluated for an SBI received significantly more antibiotics and had significantly longer hospital stays, said Dr. Librizzi, formerly with Hasbro and now at Children's National Medical Center in Washington.

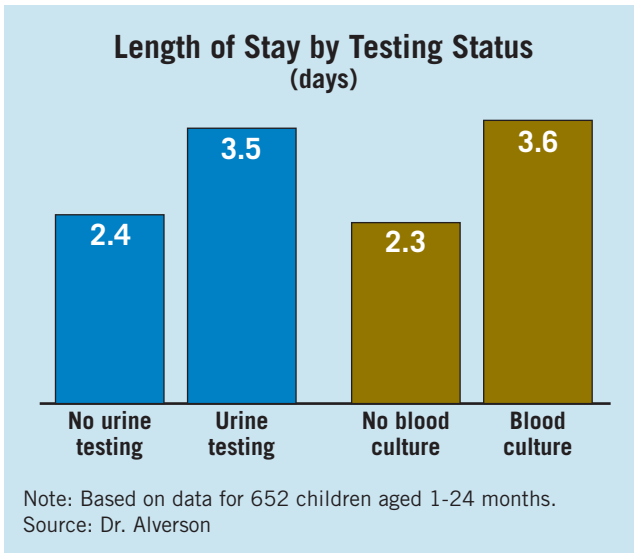
Length of stay (LOS) was 3.6 days for patients with blood cultures and 2.3 days for those without blood cultures, and 3.5 days for patients undergoing urine testing alone vs. 2.4 days for those without urine testing. More than half (56.6%) of patients who underwent testing for an SBI received antibiotics, compared with 24% who did not.

Specifically, the percentage receiving antibiotics was 17.5% among children with no urine testing (48/445); 48.6% for those with urine testing (51/105); 14% for those without blood cultures (58/411); and 51% for those with blood cultures (71/139), Dr. Librizzi said.

LOS for patients without an SBI who were on antibiotics was significantly longer than for patients off antibiotics (3.7 days vs. 2.5 days).

The mean age of the children in the study was 5.6 months, 19% were premature infants, and 57% were male, the authors reported in a poster at the meeting, sponsored by the Society of Hospital Medicine, American Academy of Pediatrics, and Academic Pediatric Association.

The authors and Dr. Hain reported no conflicts of interest. ■

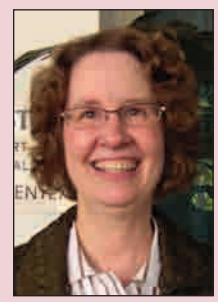


Note: Based on data for 652 children aged 1-24 months.
Source: Dr. Alverson

IMNG Medical Media

COMMENTARY

Dr. Susan Millard, FCCP, comments: UTIs are a culprit in respiratory distress for home-ventilation patients, but this study provides information regarding a common reason for pediatric admissions, bronchiolitis.



Racemic Epinephrine May Be Better for Bronchiolitic Preemies

BY PATRICE WENDLING
IMNG Medical News

COVINGTON, KY. – Racemic epinephrine may be more effective in premature than in full-term infants who are hospitalized for bronchiolitis, a chart review suggested.

The positive response rate to inhaled racemic epinephrine was significantly higher at 54.3% among premature infants, compared with 28% among full-term infants ($P = .003$).

In contrast, there was no significant difference in documented positive response rates to albuterol among premature and full-term infants (43.4% vs. 38%; $P = .18$), Dr. Russell J. McCulloh reported in a poster at the Pediatric Hospital Medicine 2012 meeting.

He said that few studies have examined the effectiveness of commonly used bronchiolitis therapies in children with a history of premature birth, even though these children are commonly affected by bronchiolitis and are at higher risk of severe outcomes and prolonged stay.

The chart review included 1,222 infants admitted for bronchiolitis to two academic medical centers. Of these, 229 (19%) were premature.

At baseline, preemies were significantly older than full-term infants (6.6 vs. 5.4 months) and less likely to have day care exposure (15.3% vs. 24%), but more likely to have a history of wheeze (18% vs. 14%).

Premature patients had a significantly longer mean length of stay of 3.8 days, compared with 2.5 days among full-term infants, although this did not differ significantly based on systemic steroid use (31% vs. 27.6%; $P = .3$), noted Dr. McCulloh of the pediatrics division at Rhode Island Hospital, Providence.

In logistic regression analyses, premature birth was independently associated with improved responsiveness to epinephrine (odds ratio, 1.89), he said.

Dr. McCulloh reported having no conflicts of interest. ■

COMMENTARY

Dr. Burt Lesnick, FCCP, comments: This study reminds us that the pulmonary physiology is altered by premature birth and may remain so for an extended time period. Therapies that have been discarded for non-premature infants may have therapeutic use in the subset of premature infants. The astute clinician must assess individual children to determine which physiology is operative at the time of illness.

SLEEP STRATEGIES

Obstructive Sleep Apnea in Bariatric Surgery Patients

Obstructive sleep apnea (OSA) is very common in patients being evaluated for bariatric surgery. While 25% of all adults are estimated to have OSA, defined as an apnea-hypopnea index (AHI) of five events per hour or greater, the prevalence of obstructive sleep apnea in obese patients presenting for gastric bypass surgery has been reported to be as high as 78% (Lopez et al. *Am Surg*. 2008;74[9]:834). This is becoming increasingly relevant, as weight loss surgeries have become more common, presumably as a marker of the epidemic of obesity; 124,838 bariatric procedures were performed in the United States in 2008 (Nguyen et al. *J Am Coll Surg*. 2011;213[2]:261).

Interrelationship of Obesity and OSA

Obesity is a well-documented risk factor for OSA. The anatomic changes of obesity narrow the upper airway and decrease functional residual capacity, which raises the critical pressure for airway occlusion, increasing the risk for obstructive events. However, the relationship between obesity and OSA may not be unidirectional. The sleep fragmentation caused by OSA can lead to excessive daytime sleepiness, resulting in a more sedentary lifestyle with subsequent weight gain. Additionally, hormones, important in satiety and weight control, may be affected by OSA and sleep deprivation. Leptin, a hormone that promotes satiety, is elevated in obese patients, presumably due to relative leptin insensitivity; the level can also be elevated in patients with OSA and may improve with continuous positive airway pressure (CPAP) therapy (Zirlik et al. *Med Sci Monit*. 2011;17[3]:159), suggesting that sleep apnea may induce insensitivity to the awareness of satiety, leading to worsened obesity. Furthermore, the treatment of OSA with CPAP was recently shown to reduce body mass index and abdominal fat in obese patients (Sharma et al. *N Engl J Med*. 2011;365[24]:2277). Given this potential reciprocal relationship of OSA and obesity, it stands to reason that identification and treatment of OSA may be beneficial in the treatment of obesity.

Benefits of Identifying OSA in Patients Undergoing Bariatric Surgery

The goals of weight loss surgery include improving the overall health of obese patients and decreasing the subsequent incidence of obesity-related comorbidity. Concomitant treatment of OSA also assists in achieving these goals. The metabolic syndrome, defined by the presence of three of five criteria (central obesity, elevated triglycerides, low HDL, hypertension, or elevated fasting plasma glucose level), is highly prevalent in the bariatric population and is associated with an increased incidence of OSA. In the Sharma study previously referenced, of 86 patients with moderate-to-severe OSA and metabolic syndrome, the treatment of OSA with CPAP led to lower blood pressure and partial reversal of metabolic abnormalities.

Preoperative identification of OSA can potentially reduce postoperative complications associated with surgery. Sedative, analgesic, and anesthetic agents are CNS depressants, leading to decreased skeletal muscle tone, a relaxed upper airway, and suppression of the arousal response, which can increase the frequency and duration of obstructive events postoperatively. Complications such as hypoxemia, cardiac arrhythmias, myocardial injury, and unanticipated admission to the ICU have been associated with OSA in the perioperative period (Liao et al. *Can J Anaesth*. 2009;56[11]:819). Adequate screening and proper postoperative monitoring and intervention, including initiation of CPAP, can reduce these complications. Despite the theoretical risk of anastomotic injury by positive pressure in the immediate postoperative period, no correlation was found between CPAP use and anastomotic leak in a large prospective study of CPAP safety in postbariatric surgery patients with OSA (Huerta et al. *J Gastrointest Surg*. 2002;6[3]:354).

Strategies for Screening the Bariatric Population for OSA

It is now common to screen patients for OSA during evaluation for bariatric surgery. Many clinical prediction rules exist to raise suspicion for OSA in the perioperative period. Ramachandran et al (*Anesthesiology* 2009;110[4]:928) performed a meta-analysis of clinical screening tests for OSA in a general preoperative population and identified 26 different clinical prediction tests, including eight questionnaires. Although the majority of these questionnaires were inferior to models that incorporated components of the physical examination and other physiologic data, the STOP-BANG questionnaire (Snoring, Tiredness, Observed apnea, elevated blood Pressure, Body mass index, Age, Neck circumference, Gender) was reported to be highly sensitive (100% sensitivity and 36% specificity in this study) in identifying severe OSA (AHI >30). Its sensitivity for identifying milder OSA was less impressive (83% sensitivity and 55% specificity).

In the prebariatric surgery population, with a very high prevalence of OSA, these prediction models may have an insufficient negative predictive value for clinical use; one could argue that routine polysomnographic testing for all patients undergoing bariatric surgery should be standard. In particular, bariatric surgery patients with moderate-to-severe OSA have significantly lower Epworth Sleepiness Scale scores than nonbariatric patients referred to a sleep clinic, even those who are not found to have frank sleep apnea on polysomnography, further calling into question the utility of clinical prediction rules, most of which include self-reported sleepiness (Sharkey et al. *Sleep Breath*. April 13, 2012.Epub ahead of print). Carneiro et al (*Sleep Breath*. 2012;16[1]:163) recently studied 132 severely obese patients undergoing bariatric surgery to assess characteristics that were predictive of the presence of sleep apnea. Based upon gender and age being the most significantly associated with OSA, the authors recommended screening polysomnography for all severely obese men and for severely obese women over 49 years of age, regardless of screening assessment or symptoms.

While polysomnography is the gold standard for diagnosing OSA, it is expensive and time-consuming. In many parts of the country, long wait times limit the availability of these studies. Because unattended portable sleep studies have been most well-validated when used in high-risk populations (Collop et al. *J Clin Sleep Med*. 2007; 3[7]:737), screening the bariatric population may be an ideal use for portable studies. Patients would subsequently undergo an in-lab titration or start auto-adjustable CPAP; the latter option may be particularly attractive to allow for automatic pressure reduction as the patient loses weight.

Bariatric Surgery as a Treatment Option for OSA

Is weight loss surgery a viable treatment option for OSA? Several reports have demonstrated the therapeutic effect of weight loss on OSA severity. Smith et al (*Ann Intern Med*. 1985;103[6, pt1]:850) showed a significant decrease in AHI and improvement in sleep architecture and daytime hypersomnolence after medical weight loss. A recent meta-analysis of 12 studies (342 patients) demonstrated that bariatric surgery (mean BMI change from 55.3 kg/m^2 to 37.7 kg/m^2) significantly improved sleep apnea. Unfortunately, the mean AHI after surgery was consistent with residual moderate OSA (Greenburg et al. *Am J Med*. 2009;122[6]:535); the mean baseline AHI of 54.7 events/h was reduced to 15.8 events/h. While OSA may resolve in some patients, it appears that for a significant number of patients, there is persistent disease. Therefore, it is important that these patients continue to follow-up in clinic with re-evaluation for residual sleep apnea as they lose weight.

Care for the OSA Patient After Undergoing Bariatric Surgery

Postbariatric surgery patients need continued CPAP therapy starting immediately postoperatively and close longitudinal follow-up. While patients may be content to undergo preoperative evaluation for OSA (as one of the many hoops they must jump through to qualify for bariatric surgery), they may be less likely to seek follow-up once they have lost weight and are feeling better. Patients should be reminded that, although resolution of OSA is a goal of bariatric surgery, reassessment is necessary once symptoms have resolved. Though the ideal time to repeat polysomnography has not been definitively established, weight loss tends to stabilize at 6 months postoperatively, which may make this the optimal timeframe in which to perform repeat testing. While it is not clear which patients are more likely to achieve total resolution of their sleep-disordered breathing, patients with high preoperative severity of OSA, older age, and male sex may be less likely to improve. As symptoms improve and patients subjectively report increasing discomfort with positive airway pressure, some patients may discontinue use on their own, potentially putting them at-risk for complications of untreated sleep apnea. While auto-adjustable CPAP may be beneficial in this regard (Lankford et al. *Obes Surg*. 2005;15[3]:336), patients should be reminded that reevaluation after bariatric surgery is necessary to identify those patients who may be able to discontinue treatment.

Summary

OSA is highly prevalent in patients undergoing evaluation for bariatric surgery and is a correctable cause of morbidity in these patients. Identification and appropriate treatment of these patients are critical to avoid perioperative complications. While sleep apnea is expected to improve after bariatric surgery, residual OSA is seen in a significant number of patients, and continued therapy and close follow-up is indicated postoperatively to avoid the chronic health consequences of untreated sleep apnea. ■

Dr. Aneesa M. Das, FCCP
Assistant Professor of Clinical Medicine; and
Dr. Rahel A. Teferra
Pulmonary and Critical Care Fellow

Division of Pulmonary, Allergy, Critical Care, and Sleep Medicine
The Ohio State University
Columbus, Ohio

For PAH (WHO Group 1) patients on oral monotherapy

TYVASO: the ONLY inhaled prostacyclin analogue approved for 4x-daily dosing[1]

Short treatment sessions: just 2 to 3 minutes each[2]

ONLY inhaled prostacyclin analogue approved as an add-on to oral PAH monotherapy[1]

- 52% of patients improved 6MWD by greater than 20 m[3]
- Improvement in 6MWD at peak (20 m) and trough (14 m) exposure[3]

Dosing regimen fits into patients' schedules

- Short treatment sessions: just 2 to 3 minutes, 4x daily[2]
- Set up once daily[1,2]
  - —One plastic ampule per day—no need to replace ampule for each treatment session[1]
  - —About 5 minutes a day for device preparation—once in the morning, and the device is ready to go all day[2]
- Treatment timing can be adjusted for planned activities[1]

Adverse events

- The most common adverse events seen with Tyvaso in ≥4% of PAH patients and more than 3% greater than placebo in the placebo-controlled clinical study were cough, headache, throat irritation/pharyngolaryngeal pain, nausea, flushing, and syncope[1]

STUDY DESIGN: TRIUMPH I was a 12-week, randomized, double-blind, placebo-controlled, multicenter study of patients (N=235) with PAH who were receiving a stable dose of bosentan or sildenafil for 3 months before study initiation. Patients were administered either placebo or Tyvaso in 4 daily treatment sessions with a target dose of 9 breaths (54 mcg) per session over the course of the 12-week study. Primary endpoint was change in 6MWD at 12 weeks. Secondary endpoints included time to clinical worsening, Borg dyspnea score, NYHA functional class, trough 6MWD at week 12 (obtained at least 4 hours after study drug administration), peak 6MWD at 6 weeks, quality of life as measured by the MLWHF questionnaire, and PAH signs and symptoms.[3]

INDICATION

Tyvaso is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).

The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

IMPORTANT SAFETY INFORMATION

- Tyvaso is intended for oral inhalation only. Tyvaso is approved for use only with the Tyvaso Inhalation System
- The safety and efficacy of Tyvaso have not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease) and in patients under 18 years of age. Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and loss of drug effect
- Tyvaso may increase the risk of bleeding, particularly in patients receiving anticoagulants
- In patients with low systemic arterial pressure, Tyvaso may cause symptomatic hypotension. The concomitant use of Tyvaso with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension
- Hepatic or renal insufficiency may increase exposure to Tyvaso and decrease tolerability. Tyvaso dosage adjustments may be necessary if inhibitors of CYP2C8 such as gemfibrozil or inducers such as rifampin are added or withdrawn
- The most common adverse events seen with Tyvaso in ≥4% of PAH patients and more than 3% greater than placebo in the placebo-controlled clinical study were cough (54% vs 29%), headache (41% vs 23%), throat irritation/pharyngolaryngeal pain (25% vs 14%), nausea (19% vs 11%), flushing (15% vs <1%), and syncope (6% vs <1%)
- Tyvaso should be used in pregnancy only if clearly needed. Caution should be exercised when Tyvaso is administered to nursing women

Please see brief summary of Full Prescribing Information on following page. For more information, please see Full Prescribing Information, Patient Package Insert, and the Tyvaso Inhalation System Instructions for Use manual. These items are available at www.tyvaso.com.

6MWD=6-minute walk distance. MLWHF=Minnesota Living With Heart Failure. NYHA=New York Heart Association. WHO=World Health Organization.

References: 1. Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2011. **2.** Tyvaso [patient package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2011. **3.** McLaughlin VV, Benza RL, Rubin LJ, et al. Addition of inhaled treprostinil to oral therapy for pulmonary arterial hypertension: a randomized controlled clinical trial. *J Am Coll Cardiol*. 2010;55(18):1915-1922.

www.tyvaso.com **www.livingpah.com** **1-877-UNITHER**

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United Therapeutics CORPORATION

TYVASO® (treprostinil) INHALATION SOLUTION

PROSTACYCLIN MADE PRACTICAL

ACCP Guideline-Based Resources on Thrombosis

BY JOSEPH ORNELAS, MS, PHD(C); AND SANDRA ZELMAN LEWIS, PHD

The *Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines* were published in *CHEST,* in February 2012. These comprehensive guidelines include more than 600 recommendations for the prevention, diagnosis, and treatment of thrombosis, addressing a comprehensive list of clinical conditions, including medical, surgery, orthopedic surgery, atrial fibrillation, stroke, and cardiovascular disease, plus conditions in pregnant patients, neonates, and children.

To disseminate these recommendations, the ACCP has developed several types of clinical resources for chest physicians available for download from the chestnet.org website:

- A series of educational slide sets are available to highlight the treatment recommendations from all content chapters, as well as some background areas. Physicians may download these slide sets to incorporate into their own educational presentations for teaching colleagues and medical professionals and for lay audiences.
- A series of clinical pocket cards are available for purchase for physicians interested in detailed information, with figures and tables that present the treatment recommendations. This is a practical tool containing screening, diagnostic, and treatment algorithms, drug therapy, dosing information, patient monitoring, and counseling points for select antithrombotic guideline topics.
- A quick reference guide to the guideline treatment recommendations is a clinical resource that will be available for download in the near future. It lists the recommendations in an easily searchable format by patient population, treatment, outcome, and grade of recommendation. This high-level clinical resource is designed to be useful to the chest physician at the point of care or in any setting.
- Besides physicians, the ACCP has also developed a series of resources for patients, available for download from the onebreath.org website. This includes education guides in select topic areas, with a frequently-asked-questions format for patients who desire to learn more about the guideline recommendations. The answers are targeted to patients who may not be familiar with medical terminology.

Other resources based on the guidelines include podcasts and the original journal publications. These may be accessed at http://journal.publications.chestnet.org. For further information, contact Dr. Ornelas at jornelas@chestnet.org. ■

This Month in *CHEST:* Editor's Picks

BY DR. RICHARD S. IRWIN, MASTER FCCP

http://publications.chestnet.org/

- Randomized Clinical Trial of Endobronchial Ultrasound Needle Biopsy With and Without Aspiration. *By Dr. R. F. Casal et al.*
- Bronchoscopic Lung Volume Reduction Coil Treatment of Patients With Severe Heterogeneous Emphysema. *By Dr. D-J Slebos et al.*

- Long-term Outcomes of Pandemic 2009 Influenza A(H1N1)-Associated Severe ARDS. *By Dr. C-E Luyt et al.*
- Correlation of Cough With Disease Activity and Treatment With Cyclophosphamide in Scleroderma Interstitial Lung Disease: Findings From the Scleroderma Lung Study. *By Dr. A. C. Theodore et al.*

SPECIAL FEATURE

- Radiation and Chest CT Scan Examinations: What Do We Know? *By Dr. A. Sarma et al.*

CHEST 2012: Destination Atlanta

October 20 - 25
Atlanta, Georgia

CHEST 2012 is taking place soon, October 20-25 in Atlanta. You can begin planning your meeting now using the CHEST 2012 website at accpmeeting.org or the online program at chestportal.org.

And, once you have your meeting agenda worked out, you can turn your attention to food!

Atlanta is a world-class, modern city with delectable restaurants that can take you on a culinary adventure you won't soon forget. ACCP members who live in Atlanta have shared their favorite places to eat throughout the city, along with places for a quick bite near the Georgia World Congress Center, site of CHEST 2012.

Favorite Restaurants in Atlanta

- Atlanta Fish Market
Fresh fish selections
- Aria
Menu changes daily to reflect seasonal ingredients
- Bacchanalia
Contemporary American cuisine
- Bistro Niko
French cuisine
- BLT Steak
Steakhouse combining bistro ambiance with steakhouse fare
- Bones Steak House
Steaks and seafood
- Kyma
Greek with great seafood
- La Tavola
Italian
- Murphys
Contemporary American comfort food, focusing on fresh, local ingredients
- Neuvo Laredo Cantina
Mexican
- Quinones
Menu changes daily, focusing on use of Southern ingredients
- Restaurant Eugene
Menu changes daily, formal
- Tacqueria del Sol
Mexican
- Vortex
Famous burgers
- Wisteria
Contemporary American with a Southern twist
- Woodfire Grill
Menu changes daily to reflect seasonal ingredients

Courtesy Georgia World Congress Center

The Georgia World Congress Center is the site of CHEST 2012, taking place October 20-25 in Atlanta.

Places for a Quick Bite Near the Convention Center

- Don Juan
- Park Avenue Deli
- Stats
- Taco Mac
- Thriv
- Many small eateries along Northside Drive

There are also several eateries within the Georgia World Congress Center.

Many thanks to ACCP members Dr. Salim Harianawala, FCCP; Ms. Ellen Hillegass; Dr. Saeid Khansarinia, FCCP; Dr. Burt Lesnick, FCCP; Dr. Greg Martin, FCCP; Dr. Jonathan Popler, FCCP; and Dr. David Schulman, FCCP, for sharing their favorite places to eat in Atlanta.

Be sure to check out their suggestions, and bon appétit! ■

CHEST 2012

Southern Hospitality Meets CHEST Hospitality

October 20 - 25
Atlanta, Georgia

Think of Atlanta, and you're likely to think of peaches, CNN, Coca-Cola®, *Gone with the Wind*, and southern hospitality. Known for outstanding education opportunities and camaraderie, CHEST 2012 will dish up a little hospitality of its own.

Recognized around the world as the authority in clinical chest medicine, the meeting will feature a learning program in pulmonary, critical care, and sleep medicine. Popular features and sessions will be back by demand, while new offerings will meet your changing education needs.

Check out what's new.

Daily Opening Sessions

Kick off your day at opening sessions, themed to address current issues affecting clinical chest medicine.

Sunday, October 21
Leadership: There Must Be a Better Way
Keynote speaker: Emmanuel Gobillot

Monday, October 22
Driving Diversity
Keynote speaker: Marilyn Tam

Tuesday, October 23
CHEST Challenge Championship

Wednesday, October 24
Innovations in Health Care
Keynote speaker: Aneesh Chopra

1-Day or Weekend Registration Opportunity

If you have trouble scheduling time away from your practice, consider attending CHEST 2012 for a shorter length of time with the 1-day rate. Or, attend for the weekend by registering for the postgraduate course package or an additional Saturday course, along with a Sunday 1-day registration. Sunday features a pulmonary focus, so busy pulmonologists can attend a concentration of relevant sessions.

Radiology Focus

Sessions focusing on radiology will be included to add depth to the already robust program. Sessions will highlight clinical-radiologic algorithms on the diagnosis of disease entities.

Clinical-Care Focused Tracks

Thursday, October 25

Five tracks will provide intensive study of a single topic.

- Antithrombotic Guidelines and Implementation Strategies
- Clinical Advances in COPD and Asthma You Should Know
- Common Challenges You Can Address With Your Critical Care Team
- Options in Treating Bronchiectasis
- Tough Decisions and Clinical Considerations in Thoracic Oncology and Interventional Pulmonology

The OneBreath® Evening at the Georgia Aquarium

Sunday, October 21

The world's largest aquarium will host an unforgettable evening supporting OneBreath. Two admission options allow you to choose your access to unique, don't-miss attractions.

Learn More and Register

Early registration discounts are available through August 31.
accpmeeting.org

ATLANTA

PRESIDENT'S CORNER: THE MEMBERSHIP SPEAKS

Helping ACCP Members Prepare for Health Reform

Whether it is the implementation of the Patient Protection and Affordable Care Act (ACA) and related amendments, new reimbursement models based on quality, or the emergence of health IT, medical specialty associations play an important role in the development and communication of health reform policies. As the leader in the provision of chest medicine education, the ACCP helps members navigate through the vast and complex policies that will affect their practice of chest medicine.

The ACCP keeps its members abreast of health reform-related changes in the chest medicine field. The College also provides resources and products that are helping our members prepare for changes in their practice environment. When possible, the ACCP also advocates on behalf of its members in the areas of quality improvement, reimbursement, and other issues that are important to ACCP members. ACCP expert committees and councils serve as the central forum for health reform issues that are specific to their areas of expertise. In this article, the chairs of these committees and councils will acquaint the reader with their committees and the work they are doing on behalf of ACCP members and others.

Chest Medicine Affairs Committee

Dr. Robert Aranson, FCCP, Chair

Health-care reform laws and policies are complex and lengthy, as exemplified by the ACA. Advocacy on behalf of our members is crucial to ensuring that chest medicine is well represented in policy-making forums. Many ACA programs and other health reform initiatives are implemented through regulations. The Chest Medicine Affairs Committee (CMA) monitors the *Federal Register* to keep abreast of these ongoing new and updated regulations from Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS), the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), and other relevant federal agencies that affect the practices of chest physicians.

The CMA provides comments on pertinent regulations and joins with other organizations and medical societies to advocate on appropriate implementation of health reform policies. For example, the CMA provided comment and signed on to letters regarding the Physician Sunshine Payment Act and the Medicaid Parity of Payment for Primary Care this past year.

In specific instances that directly impact chest physicians, the CMA will help the ACCP develop a position on legislation or regulations by consulting with appropriate expert ACCP committees and other members. Going forward, the CMA will educate members on key changes arising out of health reform, by working with the Council of US and Canadian Governors.

Council of US and Canadian Governors

Dr. Paul H. Sammut, FCCP, Chair

Health reform has implications at both the federal and state level. State ACA and health IT examples include state health insurance exchanges, local health IT exchanges, malpractice laws, and Medicaid reimbursement and expansion. Other ACA issues may start off nationally but ultimately trickle down to the states. For example, state fraud and abuse legislation tends to mimic fraud and abuse laws at the national level, many of which have been changed by the ACA. It is important for our members to be able to share health reform-related concerns and experiences with chest physicians in other states. Members may learn from initiatives in states other than their own.

US ACCP Governors will serve an important communication role in informing the ACCP of local health reform-related issues. For example, the state definition of health benefits in the ACA's proposed health insurance exchanges is one issue that we will be monitoring. Individual ACCP Governors will be able to track state issues using the ACCP's State Track Tool online, and relay information to their regional CMA committee representative. Governors will also serve an important role in disseminating national information regarding major health reform changes down to the state level.

Quality Improvement Committee

Dr. Jo Ann Brooks, PhD, MSN, FCCP, Chair

The QIC is an important resource for our members in keeping an eye on health-care changes related to quality and providing education and tools to assist in daily practice. The Quality Improvement Committee (QIC) is a strong advocate for our members in a variety of ways. The QIC advocates for improved health-care outcomes for our patients by participating in the development, review, endorsement, and implementation of performance measures related to pulmonary, sleep, and critical care medicine. We work closely with a number of quality-driven organizations and groups, as well other professional organizations to review, provide comments, and, potentially, endorse measures that will improve the care of our patients. We work in concert with the Guidelines Oversight Committee (previously ACCP Health and Science Policy Committee) to identify specific recommendations for ACCP evidence-based clinical practice guidelines to be proposed as potential performance measures.

The QIC is also active in nominating or endorsing members to serve on important national committees and groups related to health-care quality. We work to develop educational materials with the ACCP Education Committee and others related to quality tools, physician performance improvement, and use of the AQuIRE Registry.

Practice Management Committee

Dr. Robert De Marco, FCCP, Chair

Changes in reimbursement are central to the ACA. The wish to bundle payments, value-based purchasing, quality reporting, and coordination of care are all meant to reduce the costs of health care while improving quality but not necessarily address the progressive rise in the cost of doing business. Advocacy on behalf of our members is crucial to ensuring that the practice of chest medicine continues to thrive in these economically challenging times.

The PMC is actively involved in every aspect of the business side of medicine. We are your voice at the AMA CPT and RUC processes. We carefully review and monitor Medicare's proposed rules and vigorously defend the need to maintain reimbursement for your hard work. This also extends to contractor issues through our CAC with representatives from almost every state. For the first time, the 2013 "*Coding for Chest Medicine*" will be available in either an electronic or print-on-demand format. Remember, issues important to you are important to us.

Guidelines Oversight Committee

Dr. Mark Metersky, FCCP, Chair

As clearly illustrated by its new name, the Guidelines Oversight Committee (formerly the Health and Science Policy Committee) has overall responsibility for vetting and prioritizing guideline proposals and defining and overseeing the process by which ACCP guidelines are created. In doing so, the Guidelines Oversight Committee ensures that the resulting guidelines are based on a rigorous, evidence-based methodology.

The ACCP guidelines benefit ACCP members and their patients in important areas. It is clear that quality measurement, with accountability (pay for performance and public reporting), is a key component of health-care reform efforts. The guidelines provide easily searchable and retrievable support for the decisions that we all

Continued on following page

Dr. Darcy D. Marciniuk, FCCP, Next ACCP President

Darcy Marciniuk, MD, FCCP, will be inaugurated as the 75th President of the American College of Chest Physicians during CHEST 2012. He is the Ferguson Professor of Medicine and Head of the Division of Respirology, Critical Care, and Sleep Medicine at the University of Saskatchewan, Saskatoon, SK, Canada.

Dr. Marciniuk received his medical degree from the University of Saskatchewan and underwent specialty training in internal medicine and respiratory medicine at the University of Western Ontario and at the University of Manitoba.

DR. DARCY D. MARCINIUK, FCCP

Dr. Marciniuk has held a number of leadership positions in the ACCP, including the first Chair of the Pulmonary Physiology, Function, and Rehabilitation NetWork and Co-Chair of CHEST 2005. He is a Trustee of The CHEST Foundation, an editorial board member for the journal *CHEST* and for *ACCP-SEEK*. He was bestowed the Distinguished Scientist Honor Lecture by the ACCP in 2011.

Dr. Marciniuk has also been active outside the ACCP and was a founding Steering Committee member of Canada's National Lung Health Framework, Chair of the Royal College of Physicians and Surgeons of Canada National Examination Board in Respirology, and President of the Canadian Thoracic Society in 2006. Dr. Marciniuk has published more than 100 peer-reviewed publications, chapters, and reviews. His interests in pulmonary medicine include COPD, pulmonary rehabilitation, exercise testing, and clinical physiology.

We asked Dr. Marciniuk about his thoughts for this upcoming ACCP presidential year.

What would you like to accomplish as President of the ACCP?

I will work hard to help the ACCP deliver on its commitment to optimize health and patient care by providing the very best educational opportunities for our members and colleagues. The College is all about education, specifically, education designed to enable our members and our profession to deliver the best possible clinical care. This is an exciting time for the ACCP, and we will be rolling out new and expanded educational offerings this year in pulmonary, critical care, and sleep medicine.

What do you consider to be the greatest strength of the ACCP, and how will you build upon this during your Presidency?

The ACCP listens very closely to its members and clinical colleagues and is focused on delivering what clinicians around the world want most. The ACCP does not purport to be everything to everyone, as you often achieve very little when you try to do too much. We've adopted a disciplined approach that allows us to excel at what we do – provide the very best and essential learning opportunities for the practicing clinician. Our journal *CHEST*, the annual CHEST conference, board review courses, simulation offerings, leadership development, the OneBreath® initiative, and other innovative programs are all designed with that focus and important goal in mind.

What are some challenges facing the ACCP, and how will you address these challenges?

The face of health care is changing, in so many different ways, and it is important we adapt to meet the new realities. Our profession and our members want to know what these changes mean for them, and how these changes will affect the patient care they provide. This year's "Health-Care Reform: Is Anyone Listening?" series in *CHEST Physician* is a great beginning. We will be delivering more ongoing information to help our profession understand and manage these changes.

And finally, what is your charge to the members and new Fellows of the ACCP?

To the new Fellows being initiated this year, congratulations for this outstanding accomplishment. Allow the ACCP to help you in your clinical practices, in providing optimal care for your patients, and in ensuring you keep abreast with the latest in clinical pulmonary, critical care, and sleep medicine.

I'd also want to ask the new Fellows and the other 18,499 members of the ACCP to help me as we move forward together this year. I will need your support and your guidance. When you are asked, "What can the ACCP do for you?," share your thoughts and your opinions. And remember that no one is alone – we've got a skilled line-up of devoted College staff and dedicated volunteers on our side. I fully appreciate the value of an effective team and know there is so much we will accomplish together. ■

Continued from previous page

caring for our patients, thus facilitating our ability to provide high quality care.

It is also clear that health care in the United States is too expensive and that meaningful health-care reform must include efforts to reduce expenditures on services that provide minimal benefit. Both public and private payers are enthusiastically searching for services for which there is limited evidence of benefit in order to limit reimbursement. ACCP guidelines provide robust support for the benefit of diagnostic and therapeutic services that otherwise might be subjected to limitations in coverage.

Council of NetWorks

Dr. Jay I Peters, FCCP, Chair

The ACCP's Council of NetWorks is actively working with the College to make the transition into the pay-for-performance era easier for physicians in private practice, as well as those in academic settings. The Council is represented by every NetWork and will look at how the changes in health-care policy will affect each area of our members' practices.

There are many changes that will impact the way we evaluate our practice of medicine and how we are reimbursed. CMS is developing a data bank to track billing on 47 million patients with the ability to develop "report cards" on both hospitals and individual physicians. This will enable CMS to derive "value modifiers" that modify reimbursement passed on "quality care" and "cost efficiency."

The ACA has reinforced the concept of pay-for-performance and quality metric scores. Already, hospitals will receive penalties in 2013 for readmissions for acute myocardial infarcts, congestive heart failure, and pneumonia. The transition to ICD 10 is now scheduled to go into effect October 1, 2014, and our members will have to modify their billing sheets and payer contracts. While these changes may seem overwhelming, the Council of NetWorks and the ACCP are working to make the transition easier. Each NetWork has representatives on the ACCP's new "e-Community," and information, tool kits, and discussion groups are being formed around these issues to allow members to educate themselves and communicate problems and solutions to the challenges we face as pulmonary/critical care and sleep physicians.

To speak with members of ACCP's expert committees and councils on these important topics, we invite you to visit the Education booth in Experience ACCP during CHEST 2012 in Atlanta! ■

Health-care Reform: Is Anyone Listening?

This represents the last of seven articles (March to September) that the College has published in *CHEST Physician* on health-care reform. The intent of these articles was to keep the membership informed of the associated changes—some already in place and others on the horizon. Several members of the College have expertise in this arena and have shared their thoughts and made recommendations on how best to adapt and conform.

DR. SUHAIL RAOOF, FCCP

A vast range of topics has been covered, ranging from a description of health reform changes; to how they will impact pulmonary, critical care, and sleep medicine; to what practicing pulmonologists and intensivists should do to brace their practices for these major changes.

In this issue of *CHEST Physician,* the chairs of several ACCP committees have described what their committees plan to do to keep our membership educated and informed of the changes.

The leadership of the College, with the help of staff (Joyce Bruno Reitzner, Sharmi Mahajan, Marla Brichta, and Pam Goorsky) have discussed ways to keep the momentum of this project going. The College has come up with a preliminary strategy that rests on two main pillars:

1. Monitoring, communicating, and prioritizing

- Involvement of ACCP's standing committees to monitor and proactively respond to issues that impact chest medicine
- Building up the role of the ACCP Governors and CMA Regional Representatives to closely monitor state and local issues and to communicate them to their constituency
- Creation of an online submission form that members can use to convey any HCR issues to the College
- A membership survey to understand the professional needs of our membership

2. Education and improved awareness

- The committees will decide what may be the most appropriate action that should be taken for each issue identified.
- Disseminating the information and preparing education material for the membership, including various tools that may be utilized to keep the membership informed such as sessions at CHEST, Web-based resources, blogs, and other special resources.

This is a work in progress. The process will be modified and refined as we move forward. However, the College remains steadfast in its mission to provide timely information to its members on health-care reform. Articles in this series are available on the *CHEST Physician* home page at www.chestnet.org/accp/chest-physician.

Note: The views expressed in these articles are those of the authors and do not represent the views of the ACCP, its leadership, members, or staff.

CLASSIFIEDS

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Email CV: **cindy.baeder@piedmont.org** or call 770-801-2703, **www.piedmont.org**

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If this sounds like the opportunity for you please contact me at your earliest convenience. I look forward to speaking with you!

Contact : **Amber Chavez**
Manager Physician Recruitment
Advanced ICU Care
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Email: achavez@icumedicine.com

Pulmonary/ Critical Care

Busy Pulmonary /Critical Care Practice, located in the Phoenix metropolitan area is looking to add a physician to our group. We offer an excellent salary, a benefits package and the opportunity to become a partner in 1-2 years. Call is 1:4 nights and weekends. Weekday call is covered by a well-run hospitalist group. We work in a single hospital with a busy open heart program and a 31 bed critical care complex. Interested Candidates please e-mail CV to **b.blanchard@cox.net**

Director of Hospital Intensivist Service Position

Applicant sought to build Intensivist Critical Care Platform Program at Community Hospital. Work with existing pulmonary group to build on site unit based program in exciting Long Island location one hour from NYC. Excellent competitive compensation package with bonus potential which includes full malpractice coverage and comprehensive benefits. Applicant MUST be fellowship trained and be BC/BE in Pulmonary and Critical Care Medicine and have strong communication procedural and leadership skills.

Interested applicants should send CV in confidence to:

Patrickm.O'Shaughnessy@chsli.org or call 631.862.3100. EOE

Pulmonary/ Critical Care, North of Boston

A close affiliate of Massachusetts General Hospital, North Shore Medical Center and North Shore Physicians Group, seeks a Pulmonary and Critical Care physician (Sleep optional) to join busy and growing Division of Pulmonary, Critical Care, and Sleep Medicine. NSMC is an academic community hospital near Boston. Generous compensation and fringe benefits (including malpractice insurance) with teaching opportunities. No night ICU call.

Interested candidates must be BC/BE in both Pulmonary and Critical Care Medicine (Sleep optional) and should forward their CV to Louis Caligiuri, Director of Physician Recruiting at **lcaligiuri@partners.org**
No visas or agencies please.

Moving

Look to Classified Notices for practices available in your area.

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NETWORKS

Environmental Health, Palliative Care, AARC, Sleep

Occupational and Environmental Health NetWork

State of the Matter: Water, Gas, Foam, and Stone: A Preview of Our NetWork Sessions in Atlanta

CHEST 2012 promises to be superb, and the excellent conference website is up-to-date. Bright and early at 7:30 am on Tuesday, listen to featured speaker, Dr. Stella Hines, discuss "From Foam to Fracking." This will increase understanding of possible risks of exposure to airborne components of spray polyurethane foam used in homes and hydraulic fracking fluids used in natural gas drilling. Later on Tuesday, Drs. Yuh-Chin Huang, Paul Blanc, and Lisa Maier speak on novel environmental exposures and their effects on asthma, bronchiolitis, and interstitial lung disease using a case-based approach and literature review. On Wednesday afternoon, there is a poster session moderated by Dr. Gerardi.

The global use of artificial stone has an urgent need for prevention and discussion. You can discuss local/global environmental health issues at the various CHEST sessions.

As technology progresses and creates better lifestyles, we must not neglect the impact on human health. As doctors are keenly focused on the science of these exposures, we must also begin to participate in dialogue with our communities in making life safer. The next generation will probably set foot where tire treads have already gone: Mars. We don't yet know what Martian dust holds in store for human lungs—maybe a session at CHEST 2050 ;)? Our NetWork looks forward to interacting with new members and carrying on the conversation far into the future.

Dr. Yuh-Chin Huang, FCCP
Steering Committee Member

Palliative and End-of-Life Care NetWork

Sleep and Palliative Care in Advanced Life-Limiting Illness

Those with advanced life-limiting illness often complain of tiredness, which may be due to a sleep disorder. The first task in recognizing sleep disorders is to differentiate between two different conditions with the complaint of being "tired." If, given the opportunity, the patient falls asleep easily or "dozes off" unintentionally, this is hypersomnolence, and may be due to a sleep disorder, medications, or CNS effects of the underlying disease (eg, uremia, hepatic encephalopathy). If the patient reports an inability to fall asleep readily, but a "tired body with an active mind," this is fatigue. Fatigue is common and often overbearing. There is a dynamic, two-sided relationship between these conditions. Chronic pain at night will disturb sleep and frequently causes insomnia, in part because medication effects wear off during the night. In addition, sleep deprivation/disruption lowers the pain threshold, rendering patients hyperalgesic and increases their suffering (Roehrs et al. *Sleep*. 2006;29[2]:145), while disruption of deep stage N3 sleep may result in musculoskeletal pain and tenderness (Moldofsky. *Sleep Med Rev*. 2001;[5]:385). REM sleep is promoted by TNF-alpha, IL-1-beta, and nuclear factor kappa-beta, but the latter is inhibited by steroids. Palliative care of those with advanced life-limiting illness should be directed to relief of unwarranted excessive sleepiness or difficulty sleeping by first identifying the causes and then treating the individual factors. This entails analgesia according to chronotherapeutic principles with pain relief during hours of sleep and treating underlying sleep disorders (sleep apnea, restless legs, insomnia, and circadian rhythm disorders).

Dr. Richard J. Castriotta, FCCP
Steering Committee Member

Respiratory Care NetWork

2015 and Beyond

Four years ago, the American Association for Respiratory Care (AARC) decided to advance its vision statement, which reads in part "The AARC will encourage and promote professional excellence, (and) advance the science and practice of respiratory care." In the years 2008-2011, the AARC sponsored three conferences to define the future of respiratory care and examine the changes in respiratory therapy education that might be needed to meet these future needs.

The first conference convened to answer two questions: How will the health-care system of the future appear; and what then will be expected of respiratory therapists (RTs)? The conference decided "the health-care system in the United States is on the verge of dramatic change, driven by the need to decrease costs and improve quality; and that it will require the "use of evidence-based protocols that follow nationally accepted standards of practice." The second conference "was to identify specific competencies needed to assure safe and effective execution of RT roles and responsibilities in the future."

The third conference had two objectives: (1) evaluate the results of surveys regarding the success of educational programs in achieving the competencies identified in the second conference; and (2) develop a consensus on how to implement the vision of 2015 and Beyond.

The how's, what's, and when's of implementing the advances identified by 2015 and Beyond have yet to be determined. The ACCP was represented at these conferences and will continue to advise the AARC to further our common goal of improving the medical care of all our patients.

Dr. Thomas Fuhrman, FCCP
Chair

Sleep Medicine NetWork

Strategic Vision for Sleep Medicine in the ACCP

These are challenging times for the practice of medicine facing reorganization of the health-care system. Changes in processes will be driven by increasing funding limitations, regardless of the status of the Affordable Health Care Act. As a relatively new subspecialty, this is particularly true of sleep medicine. In many parts of the country, third party payers rather than physicians are determining the specific type of diagnostic studies, which can be performed without regard for subtleties of diagnosis. There is an increasing trend for in-home diagnosis and initiation of treatment of sleep-disordered breathing mandated by the patient's insurance carrier. While this may be an appropriate strategy for some patients, it is clearly not in the best interest of all. Many physicians have passed the board certification examination in sleep, but there remains a large pool of candidates who are board-eligible. Even so, perhaps paradoxically, many patients are diagnosed and treated by physicians without dedicated training in sleep medicine.

In response to these and other issues, the ACCP created an ad hoc task force to explore a "Strategic Vision for Sleep Medicine in the ACCP." A series of teleconferences and meetings of representatives from the Sleep Medicine NetWork, Education Committee, Chest Medicine Affairs Committee, and the Board of Regents resulted in a framework of priorities and recommendations, which will be put in operation over the next several months. The Sleep Medicine NetWork will have a central role in enacting these initiatives. The Sleep Medicine NetWork hopes to expand the active membership of the NetWork to accomplish these important tasks.

Dr. Kenneth Casey, FCCP
Chair

Living Xtreme With Cystic Fibrosis Documentary

Supported by The CHEST Foundation.

At CHEST 2011, Dr. Thomas Lahiri, FCCP, received the D. Robert McCaffree, MD, FCCP Humanitarian Award to assist in funding an inspiring documentary project of the Cystic Fibrosis Lifestyle Foundation. The award is given each year by The CHEST Foundation to recognize ACCP members who volunteer their time and expertise in their communities and throughout the world.

Living Xtreme: Beyond Cystic Fibrosis, co-produced by CysticLife (www.CysticLife.org), Cystic Fibrosis Lifestyle Foundation (www.CFLF.org), and Essential Image Source Foundation (www.EISF.org), highlights the lives and stories of people with cystic fibrosis who engage in extreme activities and physical lifestyles. The subjects are individuals who not only choose to be empowered by their disease but also overcome challenges in living beyond any perceived limitations of cystic fibrosis.

This short film demonstrates to members of the cystic fibrosis community, along with the general public, how exciting, active, and rich life with cystic fibrosis can be. Brian Callanan, Executive Director of the Cystic Fibrosis Lifestyle Foundation; and Ronnie Sharpe, founder of Cystic Life, both live active lifestyles as adults with cystic fibrosis. In addition, a full-length documentary, which will build upon the short film, is to follow.

To sign up for notification about the release and to receive updates about the project's progress, visit. www.LivingXtreme.org. For more information on grants for humanitarian projects and clinical research through The CHEST Foundation's annual awards program, visit www.onebreath.org, or contact Lee Ann Fulton at lfulton@chestnet.org. ■

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