



AN OFFICIAL PUBLICATION OF  
AMDA – DEDICATED TO  
LONG TERM CARE MEDICINE

# Caring *for the Ages*

A Monthly Newspaper for Long-Term Care Practitioners

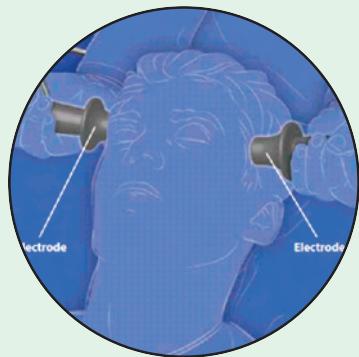
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## The Buzz: Facilities Are Going Alarm-Free

BY JOANNE KALDY

It's 2 a.m. and the buzzing of a bed alarm signals that Mrs. Jones is getting up to go to the bathroom. Now alerted, staff can assist her and keep her safe. That is the ideal that makes bed and chair alarms part of many facilities' fall-prevention programs.

However, the flip side to these alarms – the noise, the agitation, and the frustration that they can cause – is creating its own buzz and causing many facilities to look at other ways to prevent falls.

"Few studies have proven with any significance that bed or chair alarms are effective in preventing falls," said Carmen Bowman, a Colorado-based author, consultant, and former surveyor.

"Originally, bed and chair alarms ... were meant to be a short-term tool designed to get to know someone's patterns," said Barbara Frank, cofounder of B & F Consulting in Warren, R.I. However, over the years, the alarms began to be used longer term for some residents and crept into formal fall-prevention programs, he said.

"Limiting movement is psychologically disturbing and clinically iatrogenic," Ms. Frank said. "The research is pretty solid. The best way to prevent falls is to strengthen mobility, core strength, and movement. Something that deters movement actually has the opposite effect to preventing falls."

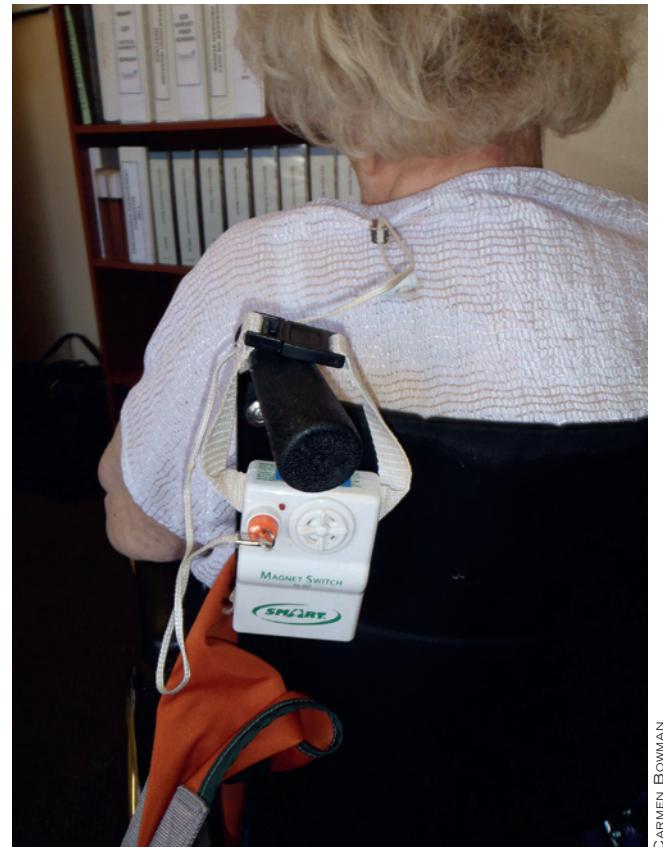
Ms. Bowman agreed, "Alarms are causing immobility, and immobility

causes a lot of problems: imbalance, infections, pressure ulcers, constipation, and muscle weakening. Additionally, alarms contribute to isolation, depression, and other psychological problems."

Also, said Ms. Frank, alarms "give a false sense of security that a person is safe. Alarms only prevent falls if we happen to be nearby or run fast enough to get there in time to prevent the fall."

Ms. Frank said that not only do alarms not necessarily prevent falls, but they actually may contribute to them. "Alarms have such a distressing impact on people that there is a discussion around second-hand falls." She said that the noise from the alarms contributes to agitation and stress in roommates and other residents. In their hurry to get away from the noise, they are at risk of falling.

Making the commitment to eliminate alarms from a nursing facility can be a



Originally tools for tracing a person's patterns, bed and chair alarms became part of fall-prevention programs. But experts now think that the devices limit a resident's movement while not necessarily preventing falls.

bold step, and it's not always welcomed by everyone. "You'll get pushback, so you have to start with education," said Ms. Bowman.

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## New Heart Failure Guidelines Improve Prognosis, Quality of Life

BY MICHELE G. SULLIVAN

The newest heart failure management guidelines make a bold statement: Heart failure should no longer be considered a death sentence but can instead be managed in a way that can add years of quality life for some patients.

Guideline-directed medical therapy (GDMT) can significantly

improve survival, with up to a 43% reduction in the risk of death, said Dr. Clyde W. Yancy, chair of the guidelines-writing committee. The document was published in the online edition of the Journal of the American College of Cardiology (<http://content.onlinejacc.org/article.aspx?articleid=1695825>).

"For so long, we had assumed that, by definition, heart failure

was a fatal diagnosis – that all we could do was tell patients to get their affairs in order and perhaps make them feel a little better, but that death was almost a *fait accompli*," said Dr. Yancy, chief of cardiology at Northwestern University, Chicago. "But in the past few years, a lot of tough work has been done showing there are effective therapies and that when given correctly,

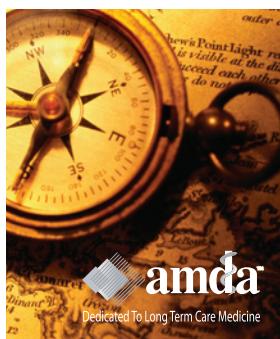
major improvements in survival do occur."

A joint effort of the American College of Cardiology Foundation and the American Heart Association, the "2013 Heart Failure Guidelines" are a revision from 2009, Dr. Yancy said in an interview. Although the years between the documents are few, the strides in research have been many, he said.

"The emergence of new and important data sets generated the impetus for the 2013 guideline not as an update, but as a complete rewrite," he said.

The document is the first in the United States to employ the concept of GDMT – a new designation that allows clinicians to easily determine the

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### CORE CURRICULUM

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# Begin Palliative Care Early in Patients With Heart Failure

BY MIRIAM E. TUCKER

**D**r. Tanya Stewart and Dr. James Mudd had an unusual take-home message to deliver when the spoke in a session last March at the AMDA Long Term Care Medicine – 2013 conference: The approach to palliative care for patients with advanced heart failure should be as proactive and patient-centered as that undertaken for people with cancer.

Half of heart failure patients die within 5 years of the diagnosis, a rate worse than that for most cancers, (Eur. J. Heart Fail. 2001;3:315-22). And more recent data show that even with optimal medical management and pacemaker or defibrillator use, mortality is still around 30% at 2-3 years. “This is a progressive disease and an incredibly morbid disease. ... The earlier we talk about palliative care with our patients, the better,” said Dr. Mudd, director of heart failure and heart transplantation at Oregon Health & Science University, Portland.

For patients with implanted cardiovascular electronic devices, palliative care includes initiating discussion of the wishes of the patient and the family concerning deactivation of these devices when the heart continues to fail despite repeated shocks.

“For individuals with [implanted devices], we have to have the conversation prior to the implant,” he advised.

Noncompliance of patients to therapy and continued smoking can make matters worse, as can depression, low literacy, impaired cognition, and sleep-disordered breathing. “All these things conspire to make the challenges of what is already a morbid condition even more challenging,” he noted.

## Symptom Management

The prolonged course of heart failure provides many opportunities for palliative intervention, noted Dr. Stewart,

medical director of Optum Care Delivery and Management, in Portland, Ore.

In a survey, 78% of caregivers said that the last year of a heart patient’s life includes pain, 61% dyspnea, 59% low mood, and 30% anxiety (Prim. Care 2011;38:265-76). Dr. Stewart summarized the evidence for palliative approaches to this significant symptom burden. Of the major drugs used to manage heart failure, beta blockers, angiotensin-converting-enzyme (ACE) inhibitors, and aldosterone antagonists are essentially palliative, rather than curative. They help maintain homeostasis and can minimize diuretic needs as the disease progresses, she noted.

Often, these drugs will be stopped when a patient is hospitalized and not restarted when they return to long-term care. It is important to re-evaluate and restart these drugs if clinicians determine that the patient will continue to benefit, she advised.

The causes of dyspnea in heart failure are several but should be discovered and treated, Dr. Stewart said. There is strong evidence for the role of diuretics – with or without thiazides – for treating volume overload. Afterload reduction can be accomplished with isosorbide dinitrate, although its use may be limited by hypotension. There is also evidence supporting the use of a fan to blow air on the patient, which stimulates the second branch of the trigeminal nerve and decreases the sense of air hunger, she said.

Opioids may also play a role in dyspnea management, since dyspnea and pain share the same cortical-spinal pathway. Opioids are not approved for use in heart failure, but evidence suggests that very low doses of oral or parenteral opioids may alleviate dyspnea.

Evidence is less convincing for remedies such as nebulized narcotics, Hawthorn extract, breathing training, neuroelectric muscle stimulation, and walking aids.

Evidence is also weak for two common dyspnea treatments – benzodiazepines and oxygen in the absence of hypoxia – Dr. Stewart said. Oxygen is expensive and makes the patient feel no better than does fan-blown air, she commented.

A recent review found that benzodiazepines, commonly used off label for dyspnea, do not seem to benefit patients either (Curr. Heart Fail. Rep. 2010;7:140-7), although some small studies have suggested benefit. “I would say there is controversial evidence to support [benzodiazepines] use... Maybe it’s time to rethink, especially as benzodiazepines have the potential for complications in this population,” Dr. Stewart said.

For etiology-specific pain management, strong evidence supports bisphosphonates for bone pain and nitrates for angina. Evidence also supports opioid use for other moderate to severe pain, with the caveat of “start low, go slow.”

Short-acting opioids (morphine, oxycodone, hydrocodone) are preferable in advanced heart failure patients, due to the risk of renal failure progression that the disease carries. However, if a long-acting opioid is necessary for chronic pain, fentanyl carries less risk of neurotoxicity than the others. Bowel stimulants should be given concurrently, Dr. Stewart advised.

Nonsteroidal anti-inflammatory agents are contraindicated in patients with heart failure because they increase the risk of gastrointestinal bleeds, renal failure, fluid retention, and interaction with ACE inhibitors, Dr. Stewart said. For nausea, try addressing volume overload, diet modification, and antiemetics, she suggested.

The evidence supporting antidepressants in heart failure is fairly weak, Dr. Stewart said. Serotonin norepinephrine reuptake inhibitors should be avoided because of the increased risk they carry for hyponatremia and fluid retention. Selective serotonin reuptake

inhibitors might carry less of that risk, but sodium and fluid levels should still be monitored in patients taking them. Tricyclics should be avoided because of the risk of QT prolongation.

Methylphenidate, although not indicated for treating depression, actually works very well and very rapidly with few side effects, Dr. Stewart said.

Anxiety has not been well studied in heart failure. Potential interventions, however, backed by limited data, include spousal engagement and mindfulness therapy. Benzodiazepines have been used, but no study shows that their efficacy outweighs their risks, she noted.

For fatigue, a common heart failure symptom, it is important to rule out underlying causes such as anemia, infection, and thyroid or sleep problems. Exercise can help, as can low-dose methylphenidate. There is also moderate evidence for Hawthorn extract.

## Cardiac Devices at the End of Life

Dr. Mudd outlined issues at play during end-of-life management of patients who have implanted cardiovascular electronic devices. He recommended an expert consensus statement issued jointly in 2010 by several prominent medical societies, available for free online at <http://europace.oxfordjournals.org/content/12/10/1480.full.pdf>.

According to that document, “it is appropriate to consider [implanted cardiovascular electronic device] deactivation when the patient’s clinical status worsens and death is near.”

Dr. Mudd advised that advance directives specifically addressing the cardiac device should be encouraged.

Dr. Mudd is an investigator for a study, sponsored by the Thoratec Corporation. Dr. Stewart reported no relevant conflict of interest.

MIRIAM TUCKER is a freelance writer based in Washington, D.C.



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CARING FOR THE AGES (ISSN 1526-4114) is published monthly by Elsevier Inc., 360 Park Avenue South, New York, NY 10010. Business and Editorial Offices: Elsevier Inc., 360 Park Avenue South, New York, NY 10010. Accounting and Circulation Offices: Elsevier Health Sciences Division, 3251 Riverport Lane, Maryland Heights, MO 63043. Periodicals postage paid at New York, NY and additional mailing offices.

**POSTMASTER:** Send change of address to CARING FOR THE AGES, Elsevier, Elsevier Health Sciences Division, Subscription Customer Service, 3251 Riverport Lane, Maryland Heights, MO 63043. Subscription price is \$219.00 a year (individual).

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## Dear Dr. Jeff



By Jeffrey Nichols, MD

# Yes, Pain Management Can Be Painfully Difficult

**Dear Dr. Jeff:**

*Adequate control of pain in the elderly is a quality measure, but the means to get there are becoming increasingly confusing. Ibuprofen and the other nonsteroidal pain medications are on the Beers list of inappropriate drugs, which makes them a red flag for surveyors. So is tramadol, while codeine is poorly tolerated and frequently ineffective.*

*The consulting pharmacist is on a campaign to decrease our dosing of acetaminophen, which he says damages the liver. My state is taking major steps to discourage physicians from prescribing narcotics for chronic pain. Besides, I worry about using narcotics in cognitively frail seniors. These are all the choices on the World Health Organization pain ladder. What do you suggest?*

**Dr. Jeff responds:** First, it is wonderful to see that the transformation in the care of the elderly has brought issues of pain control out in the open. We have gone from an era in which experts tried to persuade practitioners that pain is a significant issue to a new era in which pain management scores are reported and posted on the Web.

No one ever said practicing medicine was easy. But the situation is not nearly as bleak as you suggest, particularly if we listen more to our patients, carefully review the evidence, and perhaps worry less about regulators. I believe that the risks of many of the alternatives that you discuss are overblown, particularly when they are individualized to the patient. All these medications are readily available throughout most health systems and most (except tramadol and certain rarely used nonsteroidal anti-inflammatory drugs [NSAIDs] or narcotics) are relatively inexpensive.

Moreover, the choices available are much more extensive than those listed above. Many other modalities are (or should be) available to the postacute and long-term care resident.

The World Health Organization pain ladder was designed to guide practitioners through internationally available pain medications for the treatment of cancer pain. Its authors suggest that cancer patients quickly get pain medications, starting with acetaminophen or NSAIDs. If or when these are ineffective, the guidelines suggest adding mild narcotics such as codeine or tramadol.

When pain worsens or is uncontrolled, the mild narcotic is to be replaced by a stronger narcotic, such as morphine. Much cancer pain arises from the visceral organs, nerves, or bones, so a stepwise medication regimen is entirely appropriate. But this was not a pattern designed for typical residents.

Of course, we have some advanced cancer patients in nursing homes. They may be appropriate candidates for the proposed ladder. When simple approaches are ineffective, it is wise to use the expertise of pain or palliative care specialists. Hospice programs also help manage pain, as well as other common symptoms, while allowing seniors to stay in their familiar surroundings.

But most of the pain that needs to be controlled in postacute and long-term care is not cancer pain. Instead, it is the chronic musculoskeletal discomfort typically associated with aging. This includes arthritis, back pains often complicated by osteoporosis or spinal stenosis, polymyalgia, and a wide variety of other disorders of the joints, muscles, ligaments, bursae, and tendons. Even pain that is typically transitory in patients after fractures or surgeries will persist in elderly skilled nursing patients and, at times, cause more discomfort than the acute problem.

Most of these painful conditions are neither new nor life-threatening. They are the residue of lifetimes of wear and tear on the body and of chronic diseases lasting decades. But they do significantly affect our patients' quality of life. Those of us who frequently make home visits know that frail elders' homes are typically outfitted with a variety of do-it-yourself pain-relief modalities. These include hot water bottles, heating pads, neck pillows, slings, liniments, salves, ace bandages, ice packs, and that oxymoronic substance called "IcyHot." My wife's grandmother never wanted to travel too far from the hydrocollator she used for her sore shoulder. For those unfamiliar with this common piece of physical therapy equipment, it is basically a tub that produces warm, moist heating pads.

### What Works, Works

Many residents can describe the various maneuvers they used for pain control at home. Often, it was one technique for a shoulder and something different for the knees. If the resident is too cognitively impaired to give a pain control history, family caregivers or home health aides often know the details of the daily ritual. Yet, in doing medication reconciliations and taking medical histories, we rarely, if ever, inquire about these modalities.

One facility where I worked had a large resident population born in Southern China. Nearly a third of the residents had routinely or periodically used tiger balm prior to admission (an inexpensive topical preparation that is primarily menthol and camphor with some added herbal ingredients – the name relates to similar preparations produced over a

thousand years ago that reportedly used ground tiger bones as an ingredient). They were mystified that our pharmacy didn't routinely supply it.

But even the products that are nearly universal among physical trainers are missing from postacute and long-term care, even though they minimize the potential for drug interactions, have no long-term toxicity, and are inexpensive. Unfortunately, in nursing homes, all these treatments require a physician's order and some are considered beyond the scope of routine nursing practice.

A 90-year-old great-grandmother can apply a warm, moist towel to her neck at home, but in our regulated environment, a nurse would need (or at least want) an order that specified the temperature and length of time for the application. And the skilled caregiver might be uncomfortable preparing the towel or even be forbidden to use the equipment required to prepare it.

In some facilities, the physical therapy staff will prepare such treatments before they leave, allowing the nursing staff to apply them in the evening, when musculoskeletal pains tend to be worst. Where policies and procedures are arranged to allow this scenario, the orders usually should be "for routine use" not "as needed" because, as with medication, heat and ice and balms are most effective when used before the pain becomes severe. Furthermore, cognitively impaired residents may have difficulty understanding or expressing their need for pain therapy.

Pharmaceutical analgesics certainly have a place in postacute and long-term care pain management. Despite Food and Drug Administration (FDA) concerns about acetaminophen toxicity, the orders I have seen for this useful medicine are frequently underdosed. The usual half-day between doses vastly exceeds the medication's half-life, leaving the resident with extended periods of breakthrough pain. Much of the FDA concern prompting a maximum-daily-dose reduction from 4 g to 3 g (for which the agency's expert panel was sharply divided) related to acute liver damage from excessive dosing. Patients are obviously at risk when so many common drugs (combination analgesics and over-the-counter cough-and-cold preparations, sleep medications, and headache preparations) also contain acetaminophen or the drug by its European name, paracetamol, or even its FDA-banned biologically active precursor, phenacetin.

However, in the controlled environment of a nursing home, these risks are minimal to nonexistent. Also, the FDA's concern about blood tests suggesting

liver toxicity from high doses of acetaminophen may be an issue primarily for patients who abuse alcohol (which is not easy to do in the nursing home).

In theory, one might order liver function tests for signs of toxicity. For patients whose pain was well controlled on the 4 g daily dose, but poorly controlled after a decrease to the FDA's recommended 3 g maximum, I would encourage a return to the effective dose with such monitoring – of course, with chart notations explaining awareness of the FDA's and consulting pharmacist's concerns, but justifying the use in this particular patient.

### Real and Unreal Risks

Concerns regarding the use of narcotics in the elderly, and particularly in those with dementia, are also greatly overblown. Although narcotics appear on nearly every list of medications possibly producing delirium, a careful reading of the literature would show that the justification for this is almost always very old articles referencing meperidine (Demerol). This medication, which is not and should not be used under normal circumstances, had significant anticholinergic properties that placed its recipients at significant risk for confusion.

This was exacerbated by meperidine's metabolic pathways, which included multiple active metabolites that needed to be cleared by the kidney and could persist in an elderly body for days. The oral narcotics usually needed by postacute and long-term care residents, such as oxycodone and hydromorphone, are generally well tolerated by the elderly and do not appear on the updated 2012 Beers Criteria of medications inappropriate for use in the elderly. Of course, as with so many medications prescribed for the elderly, your mantra should be "Go low, go slow."

Unaddressed pain is, by itself, a risk factor for delirium. More importantly, for frail seniors near the end of life, it is certainly a major quality of life issue. Studies show that confused elderly patients are still at risk for being undertreated for pain in emergency and hospital settings. There is no excuse for this to happen in postacute and long-term care. 

DR. NICHOLS is the medical director of Our Lady of Consolation and Good Samaritan Nursing Homes in Suffolk County, N.Y., and senior vice president for clinical effectiveness of the Catholic Health Care System of Long Island. He invites your questions for possible discussion in this column, to [caring@elsevier.com](mailto:caring@elsevier.com). You can also comment on this and other columns at [www.caringfortheages.com](http://www.caringfortheages.com), under "Views."

# Data Support Shock Therapy for Major Mood Disorders

BY SHARON WORCESTER

LOS ANGELES – Data continue to affirm the efficacy of electroconvulsive therapy, or ECT, for the treatment of major depression and other mood disorders, and numerous studies show that the benefits are particularly pronounced in older patients.

ECT experts at the annual meeting of the American Association for Geriatric Psychiatry shared some of these findings, along with newer data on optimal electrode placement and an emerging indication for ECT.

Among adults aged 18-85 who were treated with ECT for unipolar depression in one study, for example, older patients responded better than did younger patients, Dr. Georgios Petrides said.

That study, the first from the Consortium for Research in Electroconvulsive Therapy (CORE), compared ECT with combination antidepressant-antipsychotic pharmacotherapy as a strategy for depression-relapse prevention in 201 patients who had remitted after a course of bilateral ECT. Patients from five sites were randomized to receive either 10 continuation ECT treatments or 6 months of treatment with lithium and nortriptyline, said Dr. Petrides of the department of psychiatry at the Albert Einstein College of Medicine, New York, and director of ECT research at the Zucker Hillside Hospital, Glen Oaks, N.Y.

Both groups fared better than a historical placebo control group, but did not differ significantly from each other with respect to remission rates: 46% of patients in both groups remained in remission. Also, no difference was seen between the groups with respect to time to relapse (*Arch. Gen. Psychiatry* 2006;63:1337-44).

However, a later analysis of the data by age (18-45 years; 46-64 years; and 65 years and older) showed that the remission rates were significantly greater – at up to 90% – for the older patients, compared with the youngest group, Dr. Petrides said.

Of note, the age-based advantage also was apparent among patients with psychotic depression, he said.

## Age and Electrode Placement

A more recent CORE study, looking at electrode placement for optimal efficacy and minimal cognitive impairment, also demonstrated age-based differences.

In a randomized, controlled, double-blind trial, outcomes in 230 patients with major depression and a mean age of nearly 60 years were found to be similar with a novel bifrontal placement using 1.5 times the seizure threshold, a standard bitemporal placement using 1.5 times the seizure threshold, and with standard right unilateral placement using 6 times the seizure threshold, Dr. Charles H. Kellner said.

All placements resulted in clinically and statistically significant improvements, noted Dr. Kellner, professor of

psychiatry, director of the division of geriatric psychiatry, and director of the ECT service at Mount Sinai School of Medicine, New York (*Br. J. Psychiatry* 2010;196:226-34).

A more rapid decline in symptoms was seen with bitemporal placement, said Dr. Kellner. Also, the remission rate was “remarkably greater” with right unilateral electrode placement in people over age 65 years, compared with younger patients (nearly 75% vs. about 40%-50%), and the remission rate was worse for bifrontal placement in those over age 65 years, compared with younger patients (about 45% vs. 65%).

“If this finding is replicated – and we’ve already partially replicated it (in the Prolonging Remission in Depressed Elderly [PRIDE] study),” he said, “this is good news that for geriatric patients. Right unilateral ECT, the more benign form of the treatment, may be preferentially effective.”

The finding that all three electrode placements are effective underscores the argument that “ECT in contemporary practice is not a technical issue,” he said. The data are clear about the effects of ECT, he said, so it is important to “fight to continue to get it accepted as a standard treatment – to move it up on the treatment algorithm so it is not considered a last resort for treatment.”

Among the concerns about ECT that have impeded efforts to “move it up on the treatment algorithm” are those having to do with cognitive effects, Dr. Kellner said. Cognitive effects should be considered a tolerability issue rather than a safety issue when it comes to ECT, but regardless, in this study, few differences were found with respect to cognitive effects between the three placements studied, he said.

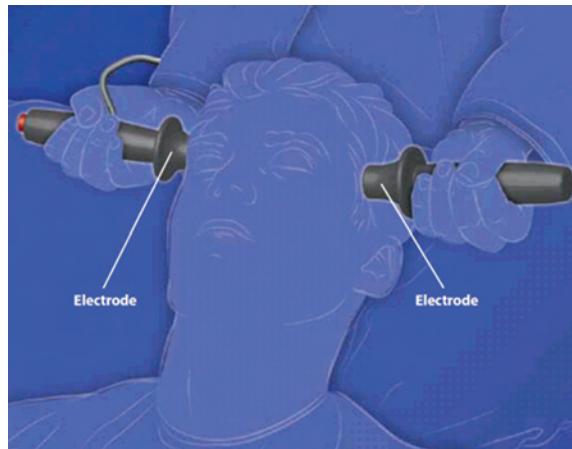
One exception was with reorientation. “Patients wake up much more easily from right unilateral ECT,” he said, noting that this also appears true in the PRIDE study, which is an ongoing evaluation of right unilateral ultrabrief pulse ECT.

## Right Unilateral Ultrabrief Pulse

Preliminary data from the PRIDE study also suggest that right unilateral ultrabrief pulse ECT is extremely effective in elderly patients: Of the first 152 patients from that study, 62% experienced remission, 11% did not, and 27% dropped out of the study.

The patients in that multicenter study have a mean age of 70 years and severe depression. An interesting finding is that a small percentage of patients “get completely well with a short course of ECT,” Dr. Kellner said.

Although most require the usual treatment course and some might require a longer treatment course, some remit



**Among newer indications for ECT in older patients is agitation in dementia. The therapy has worked in some small trials as a last resort after failure of multiple pharmacologic and nonpharmacologic approaches.**

very quickly. Thus, it is inappropriate to prescribe a fixed number of treatments in advance, he said. Also, other ECT studies have shown that outcomes with right unilateral ultrabrief pulse ECT improve with age. “The older you get, the better ECT works,” he said.

Remission rates were 62%-67% for those aged 70-79 years and 80 years or older, compared with 59% for those aged 60-69 years.

## An Emerging ECT Indication

Among newer indications for ECT in older patients is agitation in dementia, according to Dr. Robert M. Greenberg.

Dementia is generally not a contraindication to ECT, and although most data on ECT in dementia involve patients with comorbid depression, psychosis, or both, many case reports and two small case series suggest that the therapy is effective for agitation alone in patients with dementia, said Dr. Greenberg, director of geriatric services and chief of geriatric psychiatry and ECT services at Lutheran Medical Center, N.Y.

Behavioral and psychological symptoms, including agitation, occur at some point in up to 90% of patients with dementia, and agitation and aggression occur in 60%-80% of patients with Alzheimer’s disease. These symptoms account for much of the functional impairment, caregiver burden, hospitalization, and health care costs in dementia patients, and treatment options are limited, he said.

Case reports over the past 2 decades suggest that from two to eight courses of ECT result in up to 12 months of improvement in symptoms. In the largest retrospective case series published to date, 15 of 16 patients who underwent a mean of nine treatments – mostly administered bilaterally – experienced improvement in symptoms, Dr. Greenberg said.

In that study, three patients had mild dementia, eight had moderate-to-severe dementia, and five had severe dementia. Only two patients experienced severe postictal confusion (*Am. J. Geriatr. Psychiatry* 2012;20:61-72).

Although the evidence base for ECT for agitation in dementia remains fairly weak, the existing data do provide

some support for its use. In the cases reported, ECT was usually a last resort after failure of multiple pharmacologic and nonpharmacologic approaches, the impact of behavioral disturbance was severe, and reported benefits were usually of major clinical significance, Dr. Greenberg said, noting also that when addressed, global cognitive function was usually improved following ECT.

Thus, ECT is a reasonable option for dementia with severe agitation in cases after a careful diagnostic evaluation, including assessment for inciting and exacerbating causes, and after failure of behavioral and pharmacologic management.

In patients for whom ECT is deemed appropriate – and for whom proper consent is obtained – Dr. Greenberg recommended starting with titrated unilateral ultrabrief pulse stimulus (in nonemergent cases), and widening the treatment interval if the patients experience significant cognitive worsening. ECT should be stopped when improvement plateaus, he said.

Also, consider an ECT taper to ensure stability of response and to allow for optimization of continuation pharmacotherapy, he said. Continuation ECT can be considered if symptoms recur. Environmental triggers of agitation also should be addressed, he said.

Dr. Petrides and Dr. Greenberg reported having no conflict of interest relevant to their presentations. Dr. Kellner reported receiving research support from the National Institute of Mental Health. He also reported serving as a paid contributor to UpToDate, a clinical-decision-support service and as a paid ECT course teacher at Northshore-LIJ Health System.

SHARON WORCESTER is an IMNG Medical News freelance writer based in Birmingham, Ala.

## Editor’s Note

ECT has had a bad rep ever since “One Flew Over the Cuckoo’s Nest,” but it is an exceptionally effective treatment for refractory and extreme depression. It’s expensive, it requires anesthesia, and it tends to worsen cognition to some degree, but for someone truly suffering with severe depression, I believe the benefits of ECT substantially outweigh these burdens.

Some of the newer techniques may reduce post-ECT morbidity and thus reflect promising advances in our treatment options. Please keep this modality in mind for your catatonic, severe, or multiple-treatment-resistant depressed patients. And perhaps with more research, this will become another option for recalcitrant and agitated dementia patients who are in severe distress or a danger to themselves or others.

—Karl Steinberg, MD, CMD,  
Editor in Chief

# Medicare Would Limit PET Scanning for Beta-Amyloid

BY MICHELE G. SULLIVAN

Medicare coverage for amyloid brain imaging should be severely limited, according to a Centers for Medicare & Medicaid Services proposal released in July.

The federal health program would cover only one scan per patient and only as part of a clinical study or to rule out Alzheimer's disease in narrowly defined and clinically difficult differential diagnoses. The procedure isn't "reasonable and necessary" otherwise, because there are not enough data to conclude that beta-amyloid imaging with positron emission tomography (PET) improves outcomes for patients with Alzheimer's disease.

PET amyloid imaging would be covered only in CMS-approved, prospective, randomized trials that include appropriate populations and, when appropriate, employ postmortem diagnosis.

Furthermore, studies must address at least one of the following questions:

- ▶ Does PET amyloid imaging lead to improved health outcomes including avoidance of futile treatment or tests, improving or slowing the decline of quality of life, and survival?
- ▶ Does treatment guided by PET amyloid imaging identify specific

subpopulations, patient characteristics, or differential diagnoses that predict improved health outcomes?

▶ Can PET amyloid imaging enrich the patient populations of Alzheimer's trials by selecting patients on the basis of biological as well as clinical and epidemiologic factors? And if so, can this lead to improved health outcomes?

The draft decision is a disappointment for both patients and the drug companies that are developing amyloid-imaging agents. "Neither families directly impacted by the disease, nor our federal government, can afford to wait as much as 7 years for a final decision about national coverage, as was the case with the National Oncology Patient Registry and the evaluation by CMS of FDG [fluorodeoxyglucose] PET coverage," a statement from the Alzheimer's Association said. "If the federal government follows this example and timeline, it will hinder coverage of a badly needed, already FDA [Food and Drug Administration]-approved diagnostic tool in limited populations in which sufficient evidence indicates this technology has meaningful impact."

Avid Radiopharmaceuticals, which manufactures the imaging agent florbetapir F-18 injection (Amyvid), agreed. "CMS appears to be challenging

the value of an adjunctive tool that can assist physicians in making a more informed diagnosis for patients with cognitive impairment," said Dr. Daniel Skovronsky, the company's president and chief executive officer. "Restricting coverage could hinder a timely and accurate diagnosis, which is in conflict with the advice of Alzheimer's disease experts and with the administration's National Alzheimer's Project Act."

Last January, the Alzheimer's Association and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) issued revised appropriate use criteria for these agents. Imaging should be reserved for people with persistent or progressive unexplained mild cognitive impairment, MCI that has an atypical presentation, and MCI which develops at an atypically young age, the document maintained.

Imaging was not considered appropriate for asymptomatic patients, for those with typical-onset dementia, as a substitute for risk genotyping in patients with a family history, or to determine dementia severity.

The SNMMI criteria address a small but important group not addressed under the CMS proposed payment scheme, said Dr. Richard J. Caselli, professor of neurology at the Mayo Clinic in Scottsdale,

Ariz., and clinical core director of Mayo's Alzheimer's Disease Center.

"While I can understand the rationale for not reimbursing this in the typical elderly dementia patient, there is another population, albeit smaller, that would clearly benefit: the working patient," he said in an interview. "Imagine a 52-year-old man with no family history, who starts developing memory loss, has trouble on the job as a result, and seeks help. In this case, a diagnosis of Alzheimer's is unexpected, and will result in disability."

While Medicare does not provide health insurance for working adults, such a diagnosis could lead to Medicare disability coverage.

"In this case, a [PET amyloid scan] with positive evidence for Alzheimer's would in fact save everyone a lot of angst and expense, and the patient could be properly managed in terms of disability," Dr. Caselli said. "Further, young patients with altered mental status may have other serious illnesses, such as autoimmune encephalopathy, so having access to such a scan might save someone trials of steroids or other immunosuppressive agents." 

MICHELE G. SULLIVAN is with the Mid-Atlantic bureau of IMNG Medical News.



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## New Techniques

Heart Failure • from page 1

best course of heart failure care for an individual patient. Schematic algorithms provide easy-to-follow treatment pathways that should be helpful for anyone who treats heart failure patients, from specialist to primary care provider, said Dr. Yancy.

A major focus of the guidelines is treating heart failure with preserved ejection fraction (HFpEF) with the goal of preventing or delaying progression. HFpEF is “a real entity” that constitutes about half of heart failure diagnoses, Dr. Yancy said, but as yet, has no specific intervention.

Until research provides further answers, the best way to manage HFpEF is holistically, he said. “About 90% of these patients have comorbid conditions like hypertension, coronary artery disease, diabetes, renal insufficiency, and atrial fibrillation. In the absence of a specific intervention for HFpEF, focusing on these other conditions will provide us the opportunity to modify the natural history of this disease.”

The guidelines contain “critical” new indications for the use of aldosterone antagonists, he said. The drugs saw a surge in use in the early 2000s, but the rush to embrace them brought challenges as well. “Some of the applications led to missteps resulting in elevated potassium levels and emergency admissions,” Dr. Yancy said. Since then, additional trials have pinpointed the best ways to use aldosterone antagonists in patients who have heart failure with reduced ejection fraction or cardiac injury after heart attack. Data now confirm their benefit in patients with mild and moderate disease, as well as those with more advanced disease.

“This is the first document in the United States to embrace the benefit of aldosterone antagonists for these patients,” Dr. Yancy said. Provided that patient renal function is “reasonably intact,” the drugs are a valuable addition to GDMT.

The guidelines also offer a refinement of the recommendations for cardiac resynchronization device therapy (CRT) – another change supported by the results of recent, large-scale trials. “We now have three separate, well-done trials that suggest a significant benefit of cardiac resynchronization in patients with mild to moderate disease,” Dr. Yancy said.

“We gave the greatest strength of recommendation [of resynchronization] for patients with a wide QRS interval and left bundle branch block, a modest recommendation for patients with a less wide interval, and an equivocal recommendation for those without left bundle branch block. We think this will allow better discrimination of those who are most likely to benefit from CRT from those unlikely to benefit.”

There are also more plentiful data in favor of mechanical circulatory support for patients with advanced heart failure. “This is no longer a proof of concept strategy,” Dr. Yancy said. “Left

ventricular assist devices for advanced chronic heart failure represent an important component of a contemporary treatment algorithm for heart failure.”

The guidelines even reach past the mechanics of heart failure into its possible genetic origins. “We’ve discovered that idiopathic dilated cardiomyopathy may not really be idiopathic, but instead related to genetic abnormality. We’ve coalesced observations and data from this emerging field to come up with recommendations about when we might consider genetic testing in patients and screening in family members. It’s something new, and we’re delighted that it’s presented in this document.”

The guidelines also offer a new outlook on reducing heart failure readmissions – a problem that comes with a \$25 billion annual price tag, Dr. Yancy said. Four simple, low-tech interventions stood out as practical and effective:

- ▶ Using in-hospital systems that identify heart failure patients appropriate for GDMT and prompt physicians to advance this care and assess response.
- ▶ Developing transitional care and discharge planning that emphasize patient education to increase treatment compliance, manage comorbid conditions effectively, and tackle psychosocial barriers to care.
- ▶ Harnessing the cooperative power of a nurse-led multidisciplinary heart failure disease-management program.
- ▶ Following up every patient with a phone call within 3 days of discharge and a physician appointment within 2 weeks.

“The beauty of this is that while everyone is looking for the silver bullet to decrease readmission – including high-tech interventions like device implantation and home electronic monitoring – we believe that these simple, straightforward, evidence-based approaches will work.”

Finally, Dr. Yancy said, the document places great importance on patient-centric outcomes like quality of life issues, shared decision making, care coordination, and palliative care. Over the past decade, the physician-patient relationship has changed from almost paternalistic to an active partnership. “We need to include the patient’s point of view in this whole process. We need to put a greater emphasis on quality of life, and we need not fear a discussion on quality of death.”

Dr. Yancy expressed a firm belief that integrating the guidelines into daily practice could have an enormous impact on the way heart failure patients are treated.

“We have come so far in our understanding and ability to treat these patients. These are dramatically effective interventions. We can shift the culture to the belief that heart failure is something that we can treat – to the idea that you can help your patients feel better and live longer. If we use this correctly, we can make a difference.”

MICHELE G. SULLIVAN is with the Mid-Atlantic bureau of *IMNG Medical News*.

Encourage neurologic patients to open up about PBA by asking,  
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82%

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at 12 weeks<sup>1</sup>

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### NUEDEXTA Important Safety Information

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Studies to support the effectiveness of NUEDEXTA were performed in patients with amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS). NUEDEXTA has not been shown to be safe and effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementias.

NUEDEXTA (dextromethorphan hydrobromide and quinidine sulfate) 20/10 mg capsules can interact with other medications causing significant changes in blood levels of those medications and/or NUEDEXTA which may lead to serious side effects. Adjust dose or use alternate treatment of the other medication when clinically indicated.

NUEDEXTA is contraindicated in patients concomitantly taking: QT-prolonging drugs metabolized by CYP2D6 (eg, thioridazine and pimozide); monoamine oxidase inhibitors (MAOIs) within the preceding or following 14 days; other drugs containing quinidine, quinine, or mefloquine and in patients with a known hypersensitivity to these drugs or any of NUEDEXTA's components.

Discontinue use of NUEDEXTA if hepatitis, thrombocytopenia, serotonin syndrome or a hypersensitivity reaction occurs.

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Reference: 1. Data on file, Avanir Pharmaceuticals, Inc.

NUEDEXTA is contraindicated in patients with certain risk factors for arrhythmia: Prolonged QT interval; congenital long QT syndrome, history suggestive of torsades de pointes; heart failure; complete atrioventricular (AV) block or risk of AV block without an implanted pacemaker.

NUEDEXTA causes dose-dependent QTc prolongation. When initiating NUEDEXTA in patients at risk for QT prolongation and torsades de pointes, electrocardiographic (ECG) evaluation should be conducted at baseline and 3-4 hours after the first dose. Risk factors include left ventricular hypertrophy or dystrophy or concomitant use of drugs that prolong QT interval or certain CYP3A4 inhibitors.

The most common adverse reactions are diarrhea, dizziness, cough, vomiting, asthenia, peripheral edema, urinary tract infection, influenza, increased gamma-glutamyltransferase, and flatulence. NUEDEXTA may cause dizziness. Precautions to reduce the risk of falls should be taken, particularly for patients with motor impairment affecting gait or a history of falls.

These are not all the risks from use of NUEDEXTA. Please refer to the adjacent page for the Brief Summary of the Prescribing Information or see full Prescribing Information at [www.NUEDEXTA.com](http://www.NUEDEXTA.com).



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### INDICATIONS AND USAGE

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### DOSE AND ADMINISTRATION

The recommended starting dose of NUEDEXTA (20 mg dextromethorphan hydrobromide and 10 mg quinidine sulfate) is one capsule daily by mouth for the initial seven days of therapy. On the eighth day of therapy and thereafter, the daily dose should be a total of two capsules a day, given as one capsule every 12 hours. The need for continued treatment should be reassessed periodically, as spontaneous improvement of PBA occurs in some patients.

### CONTRAINDICATIONS

**Quinidine and related drugs:** NUEDEXTA contains quinidine, and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine. **Hypersensitivity:** NUEDEXTA is contraindicated in patients with a history of NUEDEXTA, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression or lupus-like syndrome; also in patients with known hypersensitivity to dextromethorphan [see *Warnings and Precautions (5.1 in full PI)*]. **MAOIs:** NUEDEXTA is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious and possibly fatal drug interactions, including serotonin syndrome. Allow at least 14 days after stopping NUEDEXTA before starting an MAOI [see *Drug Interactions (7.1 in full PI)*]. **Cardiovascular:** NUEDEXTA is contraindicated in patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, and in patients with heart failure [see *Warnings and Precautions (5.3 in full PI)*]. NUEDEXTA is contraindicated in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide), as effects on QT interval may be increased [see *Drug Interactions (7.2 in full PI)*]. NUEDEXTA is contraindicated in patients with complete atrioventricular (AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block.

### WARNINGS AND PRECAUTIONS

**Thrombocytopenia and Other Hypersensitivity Reactions:** Quinidine can cause immune-mediated thrombocytopenia that can be severe or fatal. Non-specific symptoms, such as lightheadedness, chills, fever, nausea, and vomiting, can precede or occur with thrombocytopenia. NUEDEXTA should be discontinued immediately if thrombocytopenia occurs, unless the thrombocytopenia is not drug-related, as continued use increases the risk for fatal hemorrhage. Likewise, NUEDEXTA should not be restarted in sensitized patients, because of the risk of more rapid and more severe thrombocytopenia. NUEDEXTA should not be used if immune-mediated thrombocytopenia from structurally related drugs including quinine and mefloquine is suspected, as cross-sensitivity can occur. Quinidine-associated thrombocytopenia usually resolves within a few days of discontinuation of the sensitizing drug. Quinidine has also been associated with a lupus-like syndrome involving polyarthritis, sometimes with a positive ANA. Other associations include rash, bronchospasm, adenopathy, hemolytic anemia, vasculitis, uveitis, angioedema, agranulocytosis, the sicca syndrome, myalgia, elevated serum levels of skeletal muscle enzymes, and pneumonitis. **Hepatotoxicity:** Hepatitis has been reported in patients receiving quinidine, generally during the first few weeks of therapy. **Cardiac Effects:** NUEDEXTA causes dose-dependent QTc prolongation [see *Clinical Pharmacology (12.2 in full PI)*]. QT prolongation can cause torsades de pointes-type ventricular tachycardia, with the risk increasing as prolongation increases. When initiating NUEDEXTA in at risk patients, ECG evaluation of QT interval should be done at baseline and 3-4 hours after the first dose. This includes patients concomitantly taking drugs that prolong the QT interval or that are strong or moderate CYP3A4 inhibitors, and patients with left ventricular hypertrophy (LVH) or left ventricular dysfunction (LVD). LVH and LVD are more likely to be present in patients with chronic hypertension, known coronary artery disease, or history of stroke. LVH and LVD can be diagnosed utilizing echocardiography or another suitable cardiac imaging modality. Reevaluate ECG if risk factors for arrhythmia change during the course of treatment. Risk factors include concomitant use of drugs associated with QT prolongation, electrolyte abnormality (hypokalemia, hypomagnesemia), bradycardia, and family history of QT abnormality. Hypokalemia and hypomagnesemia should be corrected prior to initiation of therapy with NUEDEXTA, and should be monitored during treatment. If patients experience symptoms that could indicate cardiac arrhythmias, e.g., syncope or palpitations, NUEDEXTA should be discontinued and the patient further evaluated. **Concomitant use of CYP2D6 Substrates:** The quinidine in NUEDEXTA inhibits CYP2D6 in patients in whom CYP2D6 is not otherwise genetically absent or its activity otherwise pharmacologically inhibited [see *CYP2D6 Poor Metabolizers (5.8 in full PI)*, *Pharmacokinetics (12.3 in full PI)*, *Pharmacogenomics (12.5 in full PI)*]. Because of this effect on CYP2D6, accumulation of parent drug and/or failure of active metabolite formation may decrease the safety and/or the efficacy of drugs used concomitantly with NUEDEXTA that are metabolized by CYP2D6 [see *Drug Interactions (7.5 in full PI)*]. **Dizziness:** In a controlled trial of NUEDEXTA, 10% of patients on NUEDEXTA and 5% on placebo experienced dizziness. **Serotonin Syndrome:** When used with SSRIs or tricyclic antidepressants, NUEDEXTA may cause serotonin syndrome, including altered mental status, hypertension, restlessness, myoclonus, hyperthermia, hyperreflexia, diaphoresis, shivering, and tremor [see *Drug Interactions (7.4 in full PI)*, *Overdosage (10 in full PI)*]. **Anticholinergic Effects of Quinidine:** Monitor for worsening clinical condition in diseases that may be adversely affected by anticholinergic effects. **CYP2D6 Poor Metabolizers:** The quinidine component of NUEDEXTA is intended to inhibit CYP2D6 so that higher exposure to dextromethorphan can be achieved compared to when dextromethorphan is given alone [see *Concomitant use of CYP2D6 substrates (5.4 in full PI)*, *Pharmacokinetics (12.3 in full PI)*, *Pharmacogenomics (12.5 in full PI)*]. Approximately 7-10% of Caucasians and 3-8% of African Americans are poor metabolizers (PMs) lacking capacity to metabolize CYP2D6. In patients who may be at risk of significant toxicity due to quinidine, consider genotyping to determine if they are PMs prior to treating with NUEDEXTA.

### ADVERSE REACTIONS

A total of 946 patients participated in four Phase 3 controlled and uncontrolled PBA studies and received at least one dose of the combination product of dextromethorphan hydrobromide/quinidine sulfate in various strengths at the recommended or higher than the recommended dose. In a 12-week, placebo-controlled study (N=326), the most commonly reported adverse reactions (incidence  $\geq 2\%$  and greater than placebo) that led to discontinuation were muscle spasticity (3%), respiratory failure (1%), abdominal pain (2%), asthenia (2%), dizziness (2%), fall (1%), and muscle spasms (2%). The most common adverse reactions ( $\geq 3\%$  and  $\geq 2X$  placebo) were diarrhea (13%), dizziness (10%), cough (5%), vomiting (5%), asthenia (5%), edema (5%), urinary tract infection (4%), influenza (4%), flatulence (3%) and increased GGT (3%). Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. **Safety Experience of Individual Components:** *Dextromethorphan:* Drowsiness, dizziness, nervousness or restlessness, nausea, vomiting, and stomach pain. *Quinidine:* Cinchonism (nausea, vomiting, diarrhea, headache, tinnitus, hearing loss, vertigo, blurred vision, diplopia, photophobia, confusion, and delirium) is most often a sign of chronic quinidine toxicity, but it may appear in sensitive patients after a single moderate dose of several hundred milligrams. Other adverse reactions occasionally reported with quinidine therapy include depression, mydriasis, disturbed color perception, night blindness, scotomata, optic neuritis, visual field loss, photosensitivity, keratopathy, and abnormalities of skin pigmentation.

### DRUG INTERACTIONS

**MAOIs:** Do not use NUEDEXTA with monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days [see *Contraindications (4.3 in full PI)*]. **Drugs that Prolong QT and are Metabolized by CYP2D6:** Do not use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide) [see *Contraindications (4.4 in full PI)*]. **Drugs that Prolong QT and Concomitant CYP3A4 Inhibitors:** Recommend ECG in these patients who are taking NUEDEXTA [see *Warnings and Precautions (5.3 in full PI)*]. **SSRIs and Tricyclic Antidepressants:** Use of NUEDEXTA with SSRIs or tricyclic antidepressants increases the risk of serotonin syndrome [see *Warnings and Precautions (5.6 in full PI)*]. **CYP2D6 Substrate:** The co-administration of NUEDEXTA with drugs that undergo extensive CYP2D6 metabolism may result in altered drug effects [see *Warnings and Precautions (5.4 in full PI)*]. **Desipramine (CYP2D6 substrate):** This tricyclic antidepressant is metabolized primarily by CYP2D6. A drug interaction study was conducted between a higher combination dose of dextromethorphan (dextromethorphan hydrobromide 30 mg/quinidine sulfate 30 mg) and desipramine 25 mg. This dose increased steady state desipramine levels approximately 8-fold. If NUEDEXTA and desipramine are prescribed concomitantly, the initial dose of desipramine should be markedly reduced. The dose of desipramine can then be adjusted based on response, but a dose above 40 mg/day is not recommended. **Paroxetine (CYP2D6 inhibitor and substrate):** When the combination dose of dextromethorphan hydrobromide 30 mg/quinidine sulfate 30 mg was added to paroxetine at steady state, paroxetine exposure (AUC<sub>0-24</sub>) increased by 1.7 fold and C<sub>max</sub> increased by 1.5 fold. Consider initiating treatment with a lower dose of paroxetine if given with NUEDEXTA. The dose of paroxetine can then be adjusted based on response, but dosage above 35 mg/day is not recommended. **Digoxin:** Quinidine is an inhibitor of P-glycoprotein. Prescribing quinidine with digoxin, a P-glycoprotein substrate, results in serum digoxin levels that may be as much as doubled. **Alcohol:** As with any other CNS drug, caution should be used when NUEDEXTA is taken in combination with other centrally acting drugs and alcohol.

### USE IN SPECIFIC POPULATIONS

**Pregnancy Category C:** There are no adequate studies of NUEDEXTA in pregnant women. **Labor and Delivery:** The effects of NUEDEXTA on labor and delivery are unknown. **Nursing Mothers:** It is not known whether dextromethorphan and/or quinidine are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NUEDEXTA is given to a nursing mother. **Pediatric and Geriatric Use:** The safety and effectiveness of NUEDEXTA in these populations has not been determined. **Renal and Hepatic Impairment:** Dose adjustment of NUEDEXTA is not required in patients with mild to moderate renal or hepatic impairment. Increases in dextromethorphan and/or quinidine levels are likely to be observed in patients with severe renal or hepatic impairment.

### DRUG ABUSE AND DEPENDENCE

NUEDEXTA contains dextromethorphan, and dextromethorphan abuse has been reported, predominately in adolescents. These observations were not systematic and it is not possible to predict on the basis of this experience the extent to which NUEDEXTA will be misused once marketed. Therefore, patients with a history of drug abuse should be observed closely.

### OVERDOSAGE

Evaluation and treatment of NUEDEXTA overdose is based on experience with the individual components. Treatment of dextromethorphan overdose should be directed at symptomatic and supportive measures. Treatment of quinidine overdose requires monitoring the QTc interval and should involve a healthcare provider experienced in cardiac arrhythmia prevention and treatment and  $\alpha$ -blockade-induced hypotension. Because of the theoretical possibility of QT prolongation that might be additive to those of quinidine, antiarrhythmics with Class I (procainamide) or Class III activities should (if possible) be avoided.

### PATIENT COUNSELING INFORMATION

Physicians should discuss the following topics with patients when prescribing NUEDEXTA: **Hypersensitivity:** [see *Contraindications (4.2 in full PI)*, *Warnings and Precautions (5.1 in full PI)*]. **Cardiac effects:** Consult their healthcare provider immediately if they feel faint or lose consciousness. Inform their healthcare provider if they have any personal or family history of QTc prolongation [see *Contraindications (4.4 in full PI)*, *Warnings and Precautions (5.3 in full PI)*, *Drug Interactions (7 in full PI)*]. **Dizziness:** [see *Warnings and Precautions (5.5 in full PI)*, *Adverse Reactions (6.1 in full PI)*]. **Drug Interactions:** [see *Drug Interactions (7 in full PI)*]. **Dosing:** Instruct patients to take NUEDEXTA exactly as prescribed, not to take more than 2 capsules in a 24-hour period, to be sure that there is an approximate 12-hour interval between doses, and not to take a double dose after a missed dose. **General:** Contact their healthcare provider if their PBA symptoms persist or worsen. Advise patients to keep this and all medications out of reach of children and pets.

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NUE-0421-ADV-0413



## Alarm-Free Living

The Buzz • from page 1

“You have to help everyone understand what you are doing, how, and why.”

Ms. Bowman went into one facility and eventually convinced certified nurse assistants (CNAs) and other staff that removing alarms from residents would make them more comfortable and that would enable them to become more engaged with other residents. “We make them more comfortable with keeping people engaged in real life,” said Ms. Bowman.

It also is helpful to share real stories about how residents feel about alarms, Ms. Bowman said. “We have stories of people hiding them or sneaking out of them.” One woman realized that the alarm went off when she got out of bed normally, so she would climb out the foot of the bed and over the dresser.

It is important to address providers’ fear of being cited by surveyors for not using alarms, said Ms. Bowman, although the concern is valid. “It’s not really surveyors’ fault. ... They just know that alarms have become one way to prevent falls, and they’ve become accustomed to citing facilities for not using them. ... I am trying to encourage states to meet with surveyors to address this issue and promote not using alarms.”

Sometimes, the pushback can come from family members, said Theresa Laufmann, codirector of nursing at Oakview Terrace in Freeman, S.D. However, this can be addressed with communication and understanding. “If someone insists that we use an alarm for their family member, we discuss the serious consequences of decreased mobility,” she said. “We also address psychosocial issues such as depression and isolation. Once you do this, they look at it a little differently.

“People know that we are very family oriented and open about our processes. ... Going alarm-free has not hurt our status. In fact, it actually has improved it.

We are seen as more caring and proactive in meeting resident needs.”

Starting slowly, documenting results, and communicating success to staff can ease the elimination of alarms, said Ms. Bowman. “Start by not using alarms with new residents, then those that have them but have no recent history of falling.” Facilities are listening to residents.

Ms. Frank suggested eliminating alarms case by case. “Work with the easiest situation [e.g., those residents who haven’t fallen at all or in a long time] and remove those alarms, so we can learn from those.” She also recommended giving staff time to get to know residents and their routines.

“Have a [quality-improvement] huddle on the unit with CNAs who know the residents well,” she said. “Assess the resident in his or her personal environment.” Consider triggers for movement, such as hunger and the need to toilet, and address them accordingly.

Not having alarms forces staff to come up with creative ways to prevent falls, Ms. Frank said.

### Homes of the Brave

Ultimately, it only takes “a few brave nurses to say, ‘Let’s do this on my shift,’” said Sue Ann Guilderman, director of education at the Minnesota-based Empira cooperative of nursing homes. “Once you start to see results, more are willing to follow suit. One facility agreed to take residents off bed-chair alarms on one shift, and falls went down significantly. Nurses on the other shifts soon wanted to know when it would be their turn.”

Once facilities go alarm-free, said Ms. Guilderman, they can’t imagine going back. “It’s so quiet, and residents love it.” One nurse noted “that it was all so peaceful, and the residents were so calm.”

Along this journey, the medical director has a key role, Ms. Frank said. She suggested that the facility leader direct a root cause analysis of falls in a facility and, in response, encourage providers to “address the living environment, build

## Editor’s Note

I think we all agree that alarms are not an ideal solution to the problem of falls in our facilities. Like physical restraints and antipsychotic medication, alarms should not be used indiscriminately. I just have to take issue with the notion of “alarm-free” buildings in the same way that I take issue with “restraint-free” buildings – any policy that is enforced dogmatically has the potential to harm residents.

Yes, alarms work only if the resident either is able to respond by stopping his or her attempt to self-ambulate or is too slow to get in trouble before a staff member can get there to assist. It is just not ethical to let people fall indiscriminately by withholding an intervention that can work. Each case needs to be evaluated individually via an interdisciplinary approach – that is what resident-centered care is all about.

There are also some residents for whom a physical restraint is medically reasonable and appropriate, even though we have all read the statistics demonstrating that the injuries sustained with restraints are worse than those of unrestrained residents. This is why the nationwide rate is not zero.

Mindless adherence to these 100% restraint-free policies will result in unnecessary falls, injuries, citations, and lawsuits. Don’t get me wrong. I support large-scale reduction in the use of these measures wherever possible, and the progress with physical restraints has been heartening.

But unless you have a facility where you can afford one-on-one supervision in the form of a sitter for high-risk residents, there are always going to be a limited number of people who, on balance, benefit from interventions such as alarms and even actual restraints. They should not be categorically deprived of interventions designed to protect them.

—Karl Steinberg, MD, CMD, Editor in Chief

assistive devices and aids, and increase core strength.”

Physician leaders also can “get rehab orders to help people maintain function, use their medical knowledge around what keeps people ambulatory and moving, and actively participate in QI [quality improvement] meetings and care planning.” Physicians need to bring in best practices from other facilities, said Dr. Paul Takahashi, associate professor of medicine at the College of Medicine, Mayo Clinic in Rochester, Minn. “It takes a leap of faith and commitment from all stakeholders to eliminate alarms. ... I think we all need to be creative with changes in care patterns.”

### Silenced Forever?

Ms. Bowman said that there remains some justification for limited alarm use. “Some of my colleagues advocate [the] use of alarms in short-stay rehab patients on admission for 48-72 hours as a sort of diagnostic.” On the other hand, she added, “I have other colleagues who [once did that routinely], but they now say that watching residents and checking on them every hour will replace that ‘noisy alarm.’”

Senior contributing writer JOANNE KALDY is a freelance writer in Harrisburg, Pa., and a communications consultant for AMDA and other organizations.

## Joint Commission Issues Alert on ‘Alarm Fatigue’

BY MARY ELLEN SCHNEIDER

The Joint Commission has warned health care providers that they can quickly become desensitized to patient alarms because so many occur. But ignoring these alarms can have fatal consequences for patients, the Joint Commission warned.

Citing hospital data between January 2009 and June 2012, the commission’s Sentinel Event Alert database recorded 98 alarm-related adverse events, 80 of which resulted in death. Another 13 resulted in permanent loss of function and 5 led to unexpected additional care or an extended stay in the hospital.

The analysis found that inadequate alarms, improper settings, and signals that were not loud enough all contributed to the reported adverse events. Alarms that were improperly turned off also were a problem.

The Joint Commission recommended several steps to curb “alarm fatigue.”

- ▶ Set up a process for alarm management and response, especially in high-risk areas.
- ▶ Perform an inventory of all devices with alarms in high-risk areas and their default settings.
- ▶ Establish guidelines for alarm settings in high-risk areas and for high-risk conditions.
- ▶ Establish guidelines for tailoring alarm settings to individual patients.
- ▶ Inspect and maintain devices.

“Alarm fatigue and management of alarms are important safety issues that we must confront,” Dr. Ana McKee, executive vice president and chief medical officer at the Joint Commission, said in a statement.

The alert also calls on organizations to provide training and education on safe alarm management and response to all members of the care team.

MARY ELLEN SCHNEIDER is with the New York bureau of IMNG Medical News.

## The Power of Personal Experience

Oakview Terrace in Freeman, S.D., has been alarm-free since 2008. Years before then, “when we tried alarms, we expected our falls number to decrease, but in tracking this, we found that it didn’t,” said codirector of nursing Theresa Laufmann. “So we started looking at what we could do instead of using alarms.”

The facility started by turning off alarms during activities and meals. Then they eliminated the devices one resident at a time. They wrote out the facility’s position against alarms, to be given to new residents and their families.

Since Oakview has stopped using bed and chair alarms, Ms. Laufmann said, the number of falls has declined. “We don’t have all the answers. We can’t prevent all falls, but restraints and alarms didn’t either.”

Dr. Paul Takahashi, associate professor of medicine at the College of Medicine, Mayo Clinic in Rochester, Minn., also has experience with eliminating bed alarms. The process was fairly simple, he said.

“Initially, we did not add alarms to new admissions,” Dr. Takahashi said. “We eventually eliminated all the alarms within the next 3 months. We had good input from the ... care manager, the administrator, and myself.” While there was some concern among staff about eliminating the alarms, he said, the fall rate actually has dropped slightly and the environment “is much quieter.”

Sue Ann Guilderman, director of education at the Minnesota-based Empira cooperative of nursing homes, stressed the impact that eliminating alarms has on resident well-being by sharing a story: “One resident, a man in his 40s, came into our facility for extensive rehab after a massive stroke. At his discharge interview, he said that the worst part of his stay was ‘that damn alarm they put on me.’ He said it was humiliating and made him feel like an animal. He said that this negative experience eclipsed the excellent care he received. That was powerful to us.”

## Public Policy

By Alex Bardakh

# Are We Finally Ready for Medicare-Pay Reform?

It is said that repeatedly doing the same thing and, on the next try, expecting a different outcome is the definition of insanity. To at least the cynic, the analogy pertains to a near decade-long effort to repeal and replace the sustainable growth rate (SGR) formula that determines physician Medicare reimbursement rates. Over that time span, the size of rate cuts demanded by SGR has grown exponentially and has been outpaced only by the volume of congressional hearings, debates, and proclamations that “now is the time to repeal SGR.”

There is not a single member of Congress who actually believes, at least publicly, that the current approach is sustainable. A number of legislative efforts have been introduced over the years, but ultimately they all failed to produce real reform. Congress, annually, has instead fallen to temporary.

At this writing in July, physicians face a near 25% cut to Medicare Part B payments on Jan. 1, 2014, and again there are congressional hearings and proclamations that it is time to address this

issue. So we are left to wonder: Can we actually achieve meaningful physician-payment reform?

Several recent trends provide a cautiously optimistic outlook on a path toward SGR reform.

First, the Congressional Budget Office (CBO) has projected that the cost to repeal SGR, and give up on the huge fee cuts that current law demands, will be \$138 billion over the next 10 years. That is not a low number, but it is more than \$100 billion less than previous projections. The demand that the cost of repeal be offset by other government spending cuts has been one of the biggest barriers to broad support for SGR reform and political compromise on it. The significantly lower “CBO score,” which is more likely to go back up than to go further down as inflation returns, provides a window for Congress to reach an agreement.

The lower CBO score is in line with the recent Medicare trustees’ projection that the current slowdown in health spending growth will run until

2026. However, the Medicare trustees also warned that a solution to the SGR problem is paramount to stability in the Medicare program. That is because, should the big SGR cuts ever actually take effect, Medicare reimbursement rates will drop to 61% of what private insurers pay for the same health services and below what Medicaid pays.

The current urgency to address SGR has led to activity by the three congressional committees of jurisdiction, and the result seems to be some progress. The House Energy and Commerce Committee, House Ways and Means, and the Senate Finance Committee are all working on proposals for a period of Medicare pay stability as the system moves to an assortment of payment models, including accountable care organizations, bundled payment systems, and various forms of fee-for-service. All three committees have sought input from the physician community.

Although, the House Energy and Commerce Committee is the only committee as of now that has issued draft legislation, Rep. Dave Camp (R-Mich.), chairman of the House Ways and Means Committee, has stated that at least the two House committees are “completely in-sync” on SGR. Energy and Commerce Committee Chairman Rep. Fred Upton, also a Michigan Republican, has said that the goal is to get the legislation through the committee process by the August congressional recess.

Separately, Rep. Allyson Schwartz (D-Pa.) and Rep. Joe Heck (R-Nev.) have introduced the Medicare Physician Payment Innovation Act of 2013, an alternative approach that permanently repeals SGR. The bill, supported by AMDA, seeks to boost primary care, focus on best practice, emphasize the importance of clinical registries, and test proposed payment models.

### Challenges Remain

There is undoubtedly momentum and support for meaningful SGR reform this year. However, Congress will have to fill in many details.

First, lawmakers must define the transition period for physicians to adjust to new models of care. Second, they will have to decide whether to freeze Medicare payments during this transition or provide payment updates. Third, Congress will have to decide whether to rely on an array of payment models that are promising but still being tested.

Finally, Congress will have to deal with the issue of offsetting the cost of SGR repeal with other spending cuts. This challenge has derailed SGR reform in the past. Both Rep. Upton and Rep. Camp have been reluctant to talk about the issue of offsets, stating that they would like to get the overall reform right and deal with the “pay-for” issue later.

While the ultimate outcome of SGR reform remains unclear, it’s obvious that lawmakers wish to move away from the volume-driven system of physician payments to one that rewards quality and lowers cost to government.

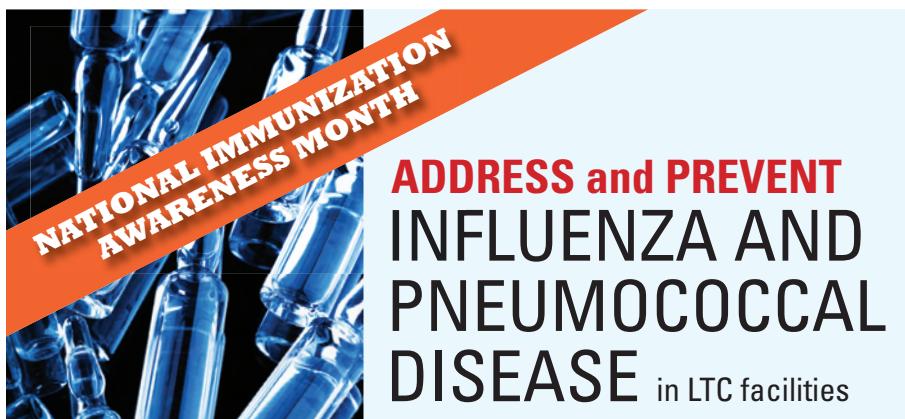
In various hearings of the three congressional committees, members of both parties have asked questions ranging from the best way to integrate existing quality measures in a reformed payment system to the appropriate level of stakeholder input in the process. Many questions have related to the time necessary for physicians to adjust to changes and the best quality-based payment system.

In its response to the Energy and Commerce Committee, AMDA stated that it supports repealing SGR in favor of a quality-based, flexible payment system that rewards effort and improvement, but we cautioned that several steps need to be undertaken to achieve these goals: developing a peer-reviewed system of quality measures for postacute and long-term care (PA/LTC) providers, creating an option for physicians who are unable to conform to the new system, and setting at least a 5-year adjustment period that would include incentives, rather than penalties, for those physicians who effectively transition into the new system.

In its response to Senate Finance Committee request for feedback, AMDA also urged congressional leaders to develop policies that align incentives between nursing facilities and physicians, encourage PA/LTC clinical quality measures, provide timely feedback, and separately identify policies for PA/LTC physicians who remain in the current fee-for-service system. Given that the array of existing quality measures was developed for the acute care setting, it will be important for organizations such as AMDA to lead in developing and overseeing implementation of quality measures appropriate for PA/LTC settings.

It is still unclear whether the cynic or the eternal optimist will be proven right regarding SGR reform. Regardless, it is difficult to ignore the progress that has been made toward reforming the current volume-driven Medicare-reimbursement system. All health care providers and, in particular, those practicing in PA/LTC settings should understand and avail themselves for current quality improvement projects and be ready to lead the development and transition into a new payment system, especially if insanity finally gives way to progress. 

ALEX BARDAKH is AMDA’s senior manager, public policy. AMDA staff members Gaby Geise and Mira Dilal contributed to this column. You can comment on this and other columns at [www.caringfortheages.com](http://www.caringfortheages.com), under “Views.”



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# 2014 Medicare Fee Proposal Includes More Management Pay

BY MARY ELLEN SCHNEIDER

In a move away from the traditional visit-based payment system, officials at the Centers for Medicare & Medicaid Services are considering paying physicians for their non-face-to-face work in chronic disease management. The proposal, which would be a boon for primary care physicians, would create two new G-codes for the non-face-to-face care management services for Medicare patients with two or more significant chronic conditions.

The services would include physician development and revision of a care plan, communication with other treating physicians and health providers, as well as medication management. CMS is proposing to establish two G-codes for establishing a plan of care and for providing care management over 90-day periods.

Physicians could use the codes if their patients have had either Medicare's Annual Wellness Visit or an Initial Preventive Physician Examination. CMS also plans to establish some practice standards to go along with the codes, such as requiring the use of an electronic health record at the time of service.

**'These codes will be a significant step ... but they will not apply to long-term care, as they were structured to account for substantial office staff time employed by the physician practice.'**

The new codes would go into effect Jan. 1, 2015.

Currently, Medicare pays only for primary care management that occurs during an office visit. However, last year the agency established codes for transitional care management services for patients moving from a hospital or a skilled nursing facility to home, which included some non-face-to-face activities.

The new codes were among policy changes being floated as part of the proposed 2014 Medicare Physician Fee Schedule. CMS will accept public comment on the proposal until Sept. 6 and a final rule is expected in November.

Physicians currently face a 24.4% across-the-board pay cut in 2015 due to the Sustainable Growth Rate (SGR) formula. Congressional action is required to avoid the steep pay cut. Members of Congress are currently drafting legislation that would permanently eliminate the SGR formula but it is unclear if the bill would be voted on this year.

Dr. Jeffrey Cain, president of the American Academy of Family Physicians, praised the CMS proposal for complex chronic care management, but said the agency can only make so much progress on payment reform within the current system.

"In light of the SGR's mandate that CMS slash Medicare physician payment by 24.4%, these incremental increases do nothing to sustain primary medical care, much less build the primary care physician workforce," he said in a statement. "The SGR-required payment cut shines a bright light on the need for Congress to replace this dysfunctional system."

The fee schedule proposal also offers more specifics for rolling out the physician value-based payment modifier, an Affordable Care Act program to pay physicians based on both the quality and cost of the care they provide to Medicare beneficiaries. The program is being phased in until Jan. 1, 2017.

Since the program is "budget neutral," higher payments for some physicians mean pay cuts for others. Under the program, physician groups could see a payment cut of between 1% and 2% in 2016 based on their performance on quality and cost.

The latest fee schedule proposal sets out an implementation schedule for the value modifier program. Physician groups with 100 or more eligible professionals will be subject to the modifier starting in 2015. In 2016, the program will apply to physician groups of 10 or more. However, Medicare officials will begin measuring their performance on cost and quality in 2014 to determine the payments in 2016. The expansion of the program to groups of 10 or more will mean that nearly 60% of physicians will be affected by the modifier in 2016, according to CMS. The remainder of physicians will see their payments affected by the modifier in 2017, based on performance during 2015.

"AMDA was part of the RUC-CPT [Relative Value Scale Update Committee-Current Procedural Terminology] subcommittee that helped develop the chronic care management codes that

CMS has refined and is proposing to pay for in 2015," said Dr. Charles Crecelius, PhD, CMD, AMDA Public Policy Committee chair and medical director at Missouri-based Delmar Gardens Enterprises. "These codes will be a significant step for improved recognition and payment for the complicated care necessary for frail elders in the outpatient setting, but they will not apply to long-term care, as they were structured to account for substantial office staff time employed by the physician practice."

"The requirements for use of the 'annual wellness visit' or 'initial preventative physician examination,' along with the proposed practice standards,

will make it difficult for small practices or those using assisted living codes to utilize these codes. AMDA will continue to seek recognition for the work done in long-term care and by the smaller practice."

Physicians can see how they are performing on cost and quality through annual Quality and Resource Use Reports produced by CMS. The agency will be providing these reports to groups of 25 or more eligible professionals in September. CMS officials said they expect to provide the reports to physician groups of all sizes in 2014.

MARY ELLEN SCHNEIDER is with the New York bureau of IMNG Medical News.

## Electronic Health Records Are at a 'Tipping Point'

More than half of the nation's physicians and other health care providers use electronic health records in their practices, new statistics from the Health and Human Services department show.

"We have reached a tipping point in adoption of electronic health records," HHS Secretary Kathleen Sebelius said in a statement. "More than half of eligible professionals and 80% of eligible hospitals have adopted these systems, which are critical to modernizing our health care system."

As of the end of April, more than 291,000 physicians and other eligible professionals received incentive payments from the Medicare and Medicaid EHR Incentive Programs. This is a significant jump in adoption since the incentives

were created under the 2009 Recovery Act. In 2008, only 17% of office-based physicians reported that they had a basic EHR system and 4.4% had a fully functional system, according to the Centers for Disease Control and Prevention.

The number of hospitals using EHRs is also reaching critical mass, according to HHS. More than 3,800 facilities have received incentive payments for their EHR use as of the end of April.

Under the Medicare program, physicians can earn up to \$44,000 in bonus payments from the government over 5 years by using electronic systems to meet and report on a set of quality measures. Under Medicaid, the bonus payments add up to \$63,750 over 6 years.

—Mary Ellen Schneider

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The AMDA Foundation 2014

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A panel of experts appointed by the AMDA Foundation will make awards to three facilities for programs they have implemented to improve the quality of life for their residents. At least one of the awards will be given specifically for improved advanced care planning and/or palliative care programs.

The award winning programs will be highlighted during a session at LTC Medicine – 2014, Nashville, TN, February 27-March 2, 2014, following the formal awards presentation. Award winners will be spotlighted in future AMDA publications and join our esteemed list of QI Program Award recipients on our website where the LTC community can review their QI program for the benefit of all.

#### Examples of programs might include:

- Initiatives on patient centered care
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- Improved consistency of staffing
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All nursing home facilities are eligible for these awards. Facilities may be profit or not-for-profit and/or an individual facility, regional chain or national chain.

#### Program Criteria:

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Full eligibility criteria and application materials can be found online at [www.amdafoundation.org](http://www.amdafoundation.org). For more information, please contact the AMDA Foundation at 410-992-3134 or [programs@amdafoundation.org](mailto:programs@amdafoundation.org).

# Parkinson's Symptoms Improved in New Drug Trials

BY ELIZABETH MEHCATIE

**P**arkinson's disease symptoms that affect the quality of life of patients with the condition improved in studies of new drugs under investigation, according to new research originally made public earlier this year at the annual meeting of the American Academy of Neurology.

The reports include phase II studies evaluating a novel, nondopaminergic adjunctive treatment with levodopa and an oral precursor to norepinephrine to treat neurogenic orthostatic hypotension, as well as a phase IV study testing an already approved therapy as an add-on treatment for Parkinson's patients not well controlled on a dopamine agonist.

"All of these treatments are promising news for people with Parkinson's disease," said Dr. Robert Hauser, in a statement issued by the American Academy of Neurology. He is an author in all three studies and is a neurologist at the University of South Florida, Tampa.

In the first of the phase II studies, patients with Parkinson's treated with tozadenant as an adjunct to levodopa experienced significant reductions in off-time without worsening dyskinesia, compared with those on placebo. Tozadenant is an oral, selective adenosine 2-alpha receptor antagonist.

The international, 12-week, double-blind study enrolled patients who had had Parkinson's for about 9 years, were on stable doses of levodopa, and had at least 2.5 hours of off-time per day. A total of 337 patients (mean age 63 years) completed treatment. Comparisons against placebo for four different doses of the drug taken twice daily showed that those on the 120-mg and 180-mg twice-daily doses had a mean 1.1-1.2 hours' reduction in off-time over placebo.

Scores on the Unified Parkinson's Disease Rating Scale (UPDRS) motor subscale also improved significantly among people on these two doses, with a mean reduction of 2.2 and 2.5 among those on the 120-mg and 180-mg twice-daily doses, respectively, compared with placebo. The Patient Global Impression of Improvement scores also significantly improved among patients on 120 mg twice daily.

Dyskinesia, nausea, dizziness, constipation, and worsening of Parkinson's were the most common adverse events among all the patients on tozadenant.

"With our most effective doses, we were able to show significant reductions in off-time in comparison with placebo, but importantly, we were able to do that without seeing a worsening of dyskinesia," said the lead author, Dr. C. Warren Olanow. There were also some improvements in motor skills, he added in an interview.

While it is too early to make a statement on how tozadenant compares with other drugs, "the fact that it is nondopaminergic and well tolerated is very promising," said Dr. Olanow, the Henry P. and Georgette Goldschmidt professor of neurology and professor of

neuroscience at Mount Sinai School of Medicine, New York.

"Now that we have shown benefit and identified what we think are the good doses," the next step is to conduct phase III confirmatory studies, which will evaluate the two doses that were effective in the phase II study, he said.

In another phase II randomized, double-blind study, 225 people with Parkinson's received droxidopa, an oral precursor of norepinephrine, or placebo

to treat symptomatic neurogenic orthostatic hypotension. The 10-week study evaluated changes in the Orthostatic Hypotension Questionnaire, dizziness/light-headedness (based on the Orthostatic Hypotension Symptom Assessment Item 1), standing systolic blood pressure, and frequency of falls.

The dosing regimen for droxidopa was titrated to 100-600 mg three times a day over a 2-week period. After 1 week on the drug, patients on droxidopa had significant

improvements in dizziness and light-headedness, compared with those on placebo. At 8 weeks, there was a trend toward improvement over placebo, but the difference was no longer significant, according to the investigators. Significant improvement in standing systolic blood pressure at 1 week (a 6.8 mm Hg difference over placebo) also did not hold up at 8 weeks (a 2.2 mm Hg improvement over placebo).

In the treated patients, there was also a drop in the number of falls per patient

per week (0.38 fewer among those on placebo vs. 1.73 fewer among those on droxidopa), which was not statistically significant. Headache, dizziness, hypertension, nausea, and fatigue were each reported in more than 5% of patients taking droxidopa and in more than 5% of untreated patients.

A third study, called ANDANTE (Add on to Dopamine Agonists in the Treatment of Parkinson's Disease), evaluated rasagiline as add-on therapy to a dopamine agonist in 321 patients with early Parkinson's whose symptoms were not well controlled on the

dopamine agonist. The patients were on stable doses of a dopamine agonist and were randomized to receive 1 mg of rasagiline per day or placebo, while remaining on stable doses of the dopamine agonist (ropinirole or pramipexole).

Approved in 2006, rasagiline (Azilect), a selective irreversible MAO-B inhibitor, is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy and as adjunct therapy to levodopa.

Over the first 18 weeks of the post-marketing, randomized, double-blind

study, those treated with rasagiline had a significantly greater change from the baseline in the total UPDRS score (a mean reduction of 2.4 vs. placebo), the primary endpoint.

There were also significant improvements in UPDRS motor scores among those on rasagiline, but no significant differences between the two groups in UPDRS activities of daily living scores. The rates of adverse events and serious adverse events were similar between the two groups: Among those on rasagiline, the overall rate of adverse events was 64% (5% were serious), compared

with 61% (3% serious) for the placebo group.

Dr. Olanow disclosed that he is a consultant for various manufacturers of drugs for Parkinson's, including Biotie Therapies, the maker of tozadenant, which also supported the study. The droxidopa study was supported by Chelsea Therapeutics, the drug's manufacturer. The ANDANTE study was supported by Teva Pharmaceuticals, the manufacturer of rasagiline. 

ELIZABETH MEHCATIE is a senior writer with *IMNG Medical News*.

## Caring Transitions

By James Lett II, MD, CMD



# Trouble When Professionals Shoot From the Lip

Sarah, 89 years old, was living functionally in her apartment until her fall against the bathtub. Her left side hurt a great deal, but she refused to go to the emergency department until her

shortness of breath, purulent cough, and low-grade fever alarmed her daughter. In the ED, her chest x-ray revealed left-lower lobe pneumonia, and her oxygen saturation had dropped to 82%.

During a 5-day hospital stay, her ever-attentive daughter felt something was not right with Sarah's gait. Another daughter, an ED nurse, suspected a pinched nerve and said that a neurology

evaluation would be in order. But as Sarah was rapidly reaching her maximum length of stay, a hospitalist felt she should be discharged. Regarding Sarah's gait, the hospital physician indicated that a skilled nursing facility physician would see Sarah the day after she would arrive, laboratory work and x-ray imaging would be done as needed, and Sarah could be evaluated by a neurologist at the nursing facility.

Upon arrival at the SNF on a Tuesday, one of the daughters sought information from the director of nursing about how to obtain the follow-up promised at the hospital. She was distressed to learn that the SNF doctor would not be in to see Sarah until Thursday, that there is no on-site laboratory or x-ray machine, and that no neurologist ever comes to the SNF. When questioned about why her mother was discharged to such circumstances, the director of nursing told her, "Hospitals have those DOGs or DRGs or whatever they are, so people have to leave so the hospital doesn't lose money."

**The director of nursing told her, 'Hospitals have those DOGs or DRGs or whatever they are, so people have to leave so the hospital doesn't lose money.'**

Two days later, Sarah was found to be lethargic after taking little in the way of fluids. An on-call doctor filling in for the regular SNF physician indicated that he wasn't fond of nursing homes and told the nurse who called him that the resident should go to the ED. There, Sarah was diagnosed as having a urinary tract infection (UTI) and, according to the daughter, "severe dehydration" and was admitted to the hospital, where Sarah received intravenous antibiotics and fluids. A urinalysis showed 8 white blood cells (WBC) per high-power field and was negative for nitrites; a urine culture grew <10,000 colonies of *Staphylococcus epidermidis*; there was a WBC count of 11.2 on the complete blood count; and chemistries showed a blood urea nitrogen of 25 and a creatinine of 0.8.

After returning to the SNF, the orders from the hospital, written by hand and on the third carbonless copy of discharge instructions, were difficult to interpret. It appeared that the order was for oral doxycycline 100 mg po QID. The nurse practitioner who was on call for the SNF doctor questioned this dose, but back at the hospital, the physician and nurses who saw Sarah were by then off-duty.

The staff who were at the hospital said that their copy of the discharge instructions also appeared to read doxycycline (100 mg 4 times a day), which was initiated.

Sarah soon became nauseated and anorexic, and her weight dropped 5 lb within a week. She became more lethargic and was unable to participate well in therapy. One evening her bed alarm was activated, and Sarah was found on the floor with left hip pain. Back in the ED, Sarah was found to have an intertrochanteric fracture and was admitted, again, to the hospital. Livid, one of Sarah's daughters asked an ED nurse how this could have happened. The response was, "This happens all the time in nursing homes."

### Livid, one of Sarah's daughters asked an ED nurse how this could have happened. The response was, 'This happens all the time in nursing homes.'

Sarah underwent hip surgery, but it did not go well. She never regained her prior level of alertness and progressively declined. One week postoperatively, she was placed in hospice and died 4 days later.

When the daughter questioned hospital staff about Sarah's death, they indicated that there was little that could be done, given how ill Sarah was when she came from the SNF. In contrast, the SNF director of nursing told the daughter, "What do you expect when an 89-year-old has major surgery?" and "Confidentially, it seems like a lot of our residents die after surgery" at that hospital.

A frustrated family sought legal counsel to sort this all out and then sued the SNF, coming to a settlement after 2 years of litigation.

#### Lessons Learned

Poor transition efforts by hospital, SNF, and ED personnel transformed Sarah's case from a medical one to a legal one. Even more important, it caused patient harm. At several critical junctures, this progression could have been diverted or even halted.

► Be careful what you say. When health care practitioners are tired and frustrated, which seems to be more and more often as fiscal pressures grow, destructive comments are uttered. Sarah's daughter heard hospital personnel disparage the SNF environment, and vice versa.

It was her perception that the ED doctor or nurse diagnosed "severe dehydration" and a UTI, when no criterion for either was established. Words, even adjectives, are powerful, and based upon them, the daughter harshly judged the quality of care given her mother. In the end, offhand remarks cause everyone – except plaintiffs' attorneys – to lose.

► Reach out to your care-continuum colleagues to share the SNF experience. Misinformation about postacute and long-term care abounds among clinicians, residents, and families. In this case, the hospitalist unrealistically promised

on-site laboratory tests and x-rays at the SNF, the presence of a neurologist, and that the SNF physician would see Sarah the day after she was admitted. Unfulfilled expectations generate anger and litigation. Dispel inaccurate preconceptions about SNF care, and you are likely to prevent a great deal of angst and anger among residents and families.

► Consider instituting the Interventions to Reduce Acute Care Transfers (INTERACT) II program (<http://interact2.net>). Doing so probably would have avoided visits to the ED and its improper diagnosis of "dehydration" and "UTI." The "Stop and Watch" procedures within INTERACT II and the program's algorithms for dehydration evaluation and communication with the physician may well have kept Sarah at the SNF.

► Recognize that covering practitioners may be setting you up for failure. When they don't answer calls from staff, lack understanding of SNF regulations, or make ill-advised comments to SNF staff and families, covering clinicians make your job tougher. Poor follow-through by the nurse practitioner in this case set the stage for a medication error and rehospitalization of the patient.

As a primary care physician in a nursing facility, perform a little quality assurance on call-coverage partners by calling families after your first visit. This is also an opportunity to educate families about the long-term care environment and to learn how your call partners are perceived by families.

► Let information flow. Poor handoffs result when it trickles. Establish policies

on what medical data are to be sent with transitioning residents. Then, utilize a standard transfer form, such as the examples noted in the AMDA "Transitions of Care in the Long-Term Care Continuum" clinical practice guidelines ([www.amda.com/tools/clinical/toccp.pdf](http://www.amda.com/tools/clinical/toccp.pdf)), to ensure that the right information gets to the right place at the right time. 

*A past AMDA president, DR. LETT chaired the AMDA workgroup that created the clinical practice guideline "Care Transitions in the Long-Term Care Continuum" and currently is chairman of the AMDA Transitions of Care Committee. You can comment on this and other columns at [www.caringfortheages.com](http://www.caringfortheages.com), under "Views."*

## And the winner is...

The AMDA Foundation recognizes the unique and exceptional qualities of its membership and invites you to submit your nominations for the following 2014 awards:



#### William Dodd Founder's Award for Distinguished Service

The William Dodd Founder's Award for Distinguished Service recognizes significant contributions to building the organizational strength, image, and mission of AMDA (to promote Medical Direction and Physician Services in long term care, to enhance the reputation of AMDA, and to advance goals enabling the association to improve care delivered to patients throughout the long term care continuum).

#### James Pattee Award for Excellence in Education

The James Pattee Award for Excellence in Education recognizes significant contributions to the educational goals of AMDA, to enhance the educational structure and framework of AMDA, to advance education specific to long term care physician practice, and to promote AMDA leadership via educational endeavors within the long term care continuum.

#### Medical Director of the Year Award

The Medical Director of the Year Award recognizes those individuals whose vision, passion, leadership, knowledge, and commitment succeed in taking patient care in the facilities they serve as medical director to exceptional levels of quality, excellence, and innovation.

Submit a nomination at [www.amda.com/awards](http://www.amda.com/awards).

### Submission deadline: November 1, 2013

All awards will be announced at AMDA's Long Term Medicine-2014 in Nashville, TN, February 27-March 3, 2014. For conference details, please visit [www.LTCmedicine.com](http://www.LTCmedicine.com).



## Thinking about a career in long term care ?

The AMDA Foundation Futures Program is waiting for you!  
*apply today...* for the AMDA Foundation's Futures Program

The AMDA Foundation is pleased to announce an exciting opportunity for residents and fellows interested in long term care practice - the AMDA Foundation Futures Program. Held during Long Term Care Medicine-2014, this intensive one-day learning experience is designed to expose residents and fellows to the numerous career opportunities available in long term care.

Participants selected for the AMDA Foundation Futures Program will receive the following benefits:

- Admission to AMDA Foundation Futures Program on February 27, 2014
- Registration to the Long Term Care Medicine-2014 from February 28-March 2, 2014 in Nashville, TN
- AMDA membership for one year beginning March 2014

Applicants will be asked to complete an application form and attach a Curriculum Vitae (CV) and letter of interest, of no more than 250 words, describing the applicant's interest in long term care practice and why the applicant feels he or she will benefit from this program. A letter of support from the program director or an AMDA member is also required. All applications must be submitted online; the committee will not review any applications that are not submitted through our website. Applications are available at [www.amdafoundation.org](http://www.amdafoundation.org).

For program agenda details, visit our website at [www.amdafoundation.org](http://www.amdafoundation.org)



### ELIGIBILITY

- PGY II or III Internal Medicine or Family Physician Residents
- PGY IV or V Geriatric Medicine Fellows
- Previous participants are not eligible to apply

**Application Deadline: November 1, 2013**

# Tool Outperforms Stroke Physicians in Predicting Patient Outcomes

BY BRUCE JANCIN

HONOLULU – Even doctors with expertise in acute stroke care are wildly inaccurate in predicting key clinical outcomes in patients with acute ischemic stroke, a study has shown.

Indeed, in the JURASSIC (Clinician Judgment Versus Risk Score to Predict Stroke Outcomes) trial, physician estimates as to whether patients would be dead or disabled at discharge were

accurate in only 16.9% of cases, or one out of six times. In contrast, a validated predictive model of stroke mortality known as the iScore was on the mark 90% of the time. Dr. Gustavo Saposnik originally reported the results at the International Stroke Conference.

Dr. Saposnik and his coworkers developed the iScore because they saw the need for an objective, simple tool to stratify mortality risk in acute ischemic stroke patients.

For the JURASSIC trial, the investigators involved a convenience sample of 111 Ontario physicians with expertise in acute stroke care. Half were neurologists, and the rest were internists or emergency physicians, each seeing an average of 98 stroke patients annually.

Each physician was presented with case summaries for five acute ischemic stroke patients and asked to predict their likelihoods of death or disability at discharge as well as 30-day mortality. The

five cases were representative of the most common clinical scenarios extracted from a pool of more than 12,000 patients admitted to Ontario stroke centers.

The 111 physicians collectively made 1,661 outcome predictions. Only 16.9% of their predictions regarding death or disability at discharge were within the 95% confidence interval for the actual observed outcomes. The physicians' accuracy at predicting 30-day mortality was 46.9%. The iScore-based outcome estimates were within the 95% confidence interval in 90% of cases.

The easily obtainable variables incorporated into the iScore are age, sex, stroke severity and subtype, coronary artery disease, heart failure, smoking, cancer, hyperglycemia upon admission, history of atrial fibrillation, and renal disease requiring dialysis. Thus, it is suitable for use in community hospitals, said Dr. Saposnik of the University of Toronto.

The score enables physicians to classify patients into one of five categories of estimated risk of mortality. In a validation study (*Circulation* 2011;123:739-49), the 30-day mortality risk ranged from a low of 1.19% in group 1 to 41.57% in group 5.

The iScore is available as a Web-based tool ([www.sorcan.ca/iscore](http://www.sorcan.ca/iscore)).

Dr. Saposnik reported having no relevant financial conflict of interest. 

BRUCE JANCIN is with the Denver bureau of *IMNG Medical News*.

## Caring *for consumers*

### Helping Residents Come Eye to Eye With Loss

*Dr. J. Kenneth Brubaker, CMD, a Pennsylvania-based medical director and former AMDA Medical Director of the Year honoree, talks about how to help an elder deal with loss.*

Loss is an unfortunate but real part of aging, especially for postacute and long-term care (PA/LTC) facility residents. They give up their homes and independent lives and have to deal with the passing of old friends and fellow residents. You can help make losses easier for your family member or friend in PA/LTC.

Feelings of loss can start when people enter a facility. They may feel sad or angry about giving up their home, possessions, pets, and routines. You can help by making sure that they keep with them favorite personal possessions, such as photos, knick knacks, and jewelry. With the facility's permission, you may be able to bring in special furniture, such as an easy chair or dresser.

Your elder family member or friend may redirect anger at you or try to make you feel guilty for his or her losses and entry to the nursing home or assisted living facility. Instead of getting angry, arguing, or staying away, try to be patient. Visit regularly and bring tokens such as favorite flowers or foods, or bring the family pet or grandkids for a visit. If things don't get better, talk to the physician. And get the support you need to deal with your own feelings of guilt or anger.

Once a resident settles in, he or she may have to deal with the deaths of other residents, elderly friends, and relatives. You can help when these losses happen by simply listening or offering a hug. It helps people who are grieving to feel connected to others and to share feelings, without fear of being judged. Give your family member or friend an opportunity to honor a lost friend or relative by attending a memorial service or meeting with a member of the clergy or another spiritual leader.

It is common to be sad about a loss, and there is no time limit on grieving. However, if your family member or friend is always sad or shows signs of

depression, such as not eating, not sleeping, or crying all the time, talk to his or her physician. Medication or other treatment, such as psychotherapy or joining a support group, may help.

Staying active and being social can help a person get through grief and loss. Continue to visit your family member or friend. When possible, take him or her out for special events, such as family functions, birthday dinners, and religious services. Encourage your loved one to be involved in activities that he or she enjoys. Arrange to join in activities such as exercise or gardening.

#### ► Questions to Ask Your Physician:

- How long will it take for my family member or friend to feel better after a loss?
- How can I help my family member or friend find peace and heal damaged relationships?

#### ► What You Can Do:

- Seek help if your family member or friend's anger or sadness is overwhelming.
- Bring family and pets to visit whenever possible. Try to keep visits positive and happy.
- Recognize that there may be some activities or interventions that may trigger grief, anxiety, or anger. It is important to recognize these so you can avoid them in the future.
- Give your family member or friend events to look forward to – a weekly dinner together, church on Sundays, trips to the mall, etc.
- Give your family member or friend a chance to resolve relationships and address regrets.

#### ► For More Information:

- Grief, Mourning, and Bereavement: <http://tinyurl.com/cz4y2ce>
- What's "Normal" When It Comes to Mourning: <http://tinyurl.com/kwg6cv>



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## Agency Releases Discharge Toolkit

The Agency for Healthcare Research and Quality has published an expanded version of the Re-Engineered Discharge (RED) Toolkit, including tools for dealing with patients with limited English proficiency.

The RED Toolkit, which was developed by researchers at Boston University Medical Center, outlines a series of steps that hospitals can take both during and after a hospital stay to ensure a smooth transition at the time of discharge.

In one randomized controlled trial, patients who were discharged using the RED process had a 30% lower rate of hospital utilization within 30 days of discharge, compared with patients receiving usual care. And use of the RED toolkit prevented one readmission or emergency department visit for every seven patients, according to the Agency for Healthcare Research and Quality (AHRQ).

In the updated version of the toolkit, the RED developers added several new tools, including health literacy strategies to help patients learn how to care for themselves once they return home. The expanded toolkit also includes more details on how to conduct a postdischarge follow-up telephone call within 72 hours of discharge and how to monitor a hospital's progress on reducing readmissions. 

—MARY ELLEN SCHNEIDER

## LTC Pharmacy

## A New Diabetes Drug Class

By William Simonson, PharmD, CGP, FASCP

**O**n March 29, the Food and Drug Administration approved the first of a new class of drugs for the management of diabetes. Canagliflozin (Invokana) is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The drug works by blocking renal reabsorption of glucose and increasing glucose excretion. It is not for the treatment of type 1 diabetes or diabetic ketoacidosis.

Clinical trials in over 10,000 patients with type 2 diabetes demonstrated improvement in both hemoglobin A1c and fasting plasma glucose levels, although smaller reductions were seen in patients  $\geq$  age 65 compared with younger patients. Canagliflozin has been studied as monotherapy and in combination with other type 2 diabetes therapies. The apparent terminal half-life of the drug is 10.6 hours and 13.1 hours for the 100 mg and 300 mg tablets, respectively. The recommended starting dose is 100 mg once daily. It can be taken with or without food, but is recommended to be taken prior to the first meal of the day. The drug is partially eliminated renally, and the product labeling specifies that the dose be limited to 100 mg once daily in patients who have an estimated glomerular filtration rate (eGFR) of 45 to  $<$  60 mL/min/1.73 m<sup>2</sup> and that it should not be given to those with a eGFR  $<$  45 mL/min/1.73 m<sup>2</sup>. Renal function should be assessed before initiating therapy and periodically during therapy.

According to the FDA, the most common side effects of canagliflozin are vulvovaginal candidiasis and urinary tract infection. Because the drug has a diuretic effect, it can cause orthostatic or postural hypotension. This may result in symptoms such as dizziness or syncope (which most commonly occurs during the first 3 months of therapy) in patients  $\geq$  age 65, and is even more prominent in those  $\geq$  age 75.

The drug has been found to increase serum creatinine and decrease eGFR, and patients with hypovolemia may be more susceptible to these changes. The drug can also cause hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion (such as potassium-sparing diuretics) or medications that interfere with the renin-angiotensin-aldosterone system (such as angiotensin-converting-enzyme inhibitors and angiotensin receptor blockers) are more likely to develop hyperkalemia.

This is a new class of drugs for diabetes management. However, with its dosing limitations based on renal function and side-effect profile, it remains to be seen whether canagliflozin will have a place in long-term care.

### Pharmacy Tip

I recommend that consultant pharmacists and dietitians maintain an ongoing dialog. Contact is not always easy because, as consultants, both professionals are in facilities

only intermittently; however, a common meeting such as the quality assurance committee may provide such an opportunity.

In one of my facilities, a dietician was an overly strong advocate for megestrol to maintain residents' weights, while I was (and remain) a skeptic because of questionable efficacy and side effects. The attending physicians were receiving

differing recommendations from us. The dietician and I discussed the pros and cons and arrived at a reasonable approach for use of this product.

Some of the many other potential topics of collaboration include selection of medications based on sodium or sugar content, avoiding the administration of protein supplements with

levodopa-containing drugs, and avoiding medications that may cause dry mouth or taste disturbances. 

WILLIAM SIMONSON, PharmD, CGP, FASCP, has specialized in senior-medication issues for more than 35 years. He is senior research professor (pharmacy practice) at Oregon State University.

# REM Sleep Problems Predict Parkinson's, Lewy Body Dementia

BY M. ALEXANDER OTTO

SAN DIEGO – Rapid eye movement (REM) sleep behavior disorder (RBD) is the earliest indication that elderly patients are destined to develop Parkinson's disease, Lewy body dementia, or another synucleinopathy, and it precedes the onset of motor and cognitive problems by years, according to a growing body of research. Its presence also distinguishes synucleinopathies from Alzheimer's

disease and other problems that can have similar early presentations.

RBD "equals synucleinopathy," said Dr. Ronald Postuma of the department of neurology at McGill University in Montreal. "The way I explain RBD to patients is that normally, when most people dream, they are paralyzed, but you are not. Therefore, you are capable of acting out the content of your dreams." Dr. Postuma made his comments at the annual meeting of

the American Academy of Neurology. Also there, researchers from the Mayo Clinic in Rochester, Minn., presented an autopsy study, now published in *Sleep Medicine*.

The Mayo team analyzed neuropathologic findings from 172 patients diagnosed with RBD before death. They found that 160 (94%) were synucleinopathies. Among them were 136 patients with Lewy bodies and 19 with multiple-system atrophy. The remaining few had

findings consistent with Alzheimer's disease or other nonsynucleinopathies.

RBD was diagnosed at a mean age of 62 years. It preceded the diagnosis of Parkinsonism in 151 patients by a mean of 6 years. The diagnosis of RBD preceded death by a mean of 13 years.

"Lewy body disease was by far the most common underlying neurologic disorder. ... We've been looking for [cases of] Alzheimer's associated with RBD for well over 10 years, and they are just hard to find," said lead investigator Dr. Bradley Boeve, chair of the division of behavioral neurology at Mayo. The findings "argue that the selective vulnerability involves ... REM sleep circuitry."

At autopsy, 98% of polysomnography (PSG)-confirmed cases had a synucleinopathy, Dr. Boeve noted.

The take-home message is that "if you have a pretty good history of RBD but don't have a PSG to confirm it, there's a 94% chance that you have a synucleinopathy. If you do have PSG, there's a 98% chance of having a synucleinopathy," Dr. Postuma said. "Asking about REM sleep behavior disorder in your clinics tomorrow will help you diagnose disease."

Investigators from Barcelona, Spain, came to similar conclusions in a paper published recently in *Lancet Neurology* (*Lancet Neurol.* 2013;12[5]:443-53). For most, RBD "represents the prodromal phase of a Lewy body disorder ... such as Parkinson's disease (PD) or dementia with Lewy bodies. ... [RBD] is a candidate for the study of early events and progression of this prodromal phase, and to test disease-modifying strategies to slow or stop the neurodegenerative process," they concluded.

The Spanish team followed 44 RBD cases diagnosed between 1991 and 2003. By 2012, 82% had developed a synucleinopathy: 16 with Parkinson's disease, 14 with Lewy body dementia, and 1 with multiple system atrophy. "The rates of neurological-disease-free survival from time of [RBD] diagnosis were 65.2% at 5 years, 26.6% at 10 years, and 7.5% at 14 years," they reported.

Most RBD patients "developed a Lewy body disorder with time. Patients who remained disease-free at follow-up showed markers of increased short-term risk for developing PD," including lesions "in the brainstem nuclei that regulate REM sleep atonia," the Spanish researchers found.

Asked to comment on the Spanish study, Dr. Postuma said that the findings "emphatically confirm the incredible risk that patients with RBD have for developing neurodegenerative disease." The ability to identify a neurodegenerative disease 10 years before it can be diagnosed "provides profound opportunities to study early stages of disease."

Dr. Boeve's research has been supported by Cephalon, Allon Therapeutics, and GE Healthcare. Dr. Postuma disclosed personal support from Teva and Novartis.

M. ALEXANDER OTTO is with the Seattle bureau of *IMNG Medical News*.

## Journal Highlights

Journal of the **JAMDA**  
American Medical Directors Association

From the August Issue of JAMDA

### Guidelines for Protein Intake

Elders' typical shortfall in protein consumption promotes muscle loss, increasing risk of such conditions as sarcopenia and osteoporosis and the falls, fractures, and disabilities that can result.

With this in mind, the European Union Geriatric Medicine Society, the International Association of Gerontology and Geriatrics, and others (the PROT-AGE Study Group) updated evidence-based recommendations for optimal protein intake by older people.

"Muscle function is really a key issue here," said lead author Dr. Jürgen Bauer of the Geriatrics Centre Oldenburg (Germany) in an interview. "We want, of course, to stabilize muscle strength as soon as possible and to stop a decline of functionality in this population." Older individuals should have a protein intake of 25 g to 30 g per meal to prevent loss of lean body mass, he added. The group recommended that individuals ages 65 and older receive an average daily protein intake of at least 1.0 g/kg to 1.2 g/kg of body weight to maintain physical function.

He added that "more than 50% of protein consumed should be of high biological value, which means that the sources for protein should contain the full spectrum of amino acids."

Older adults with either an acute or chronic disease require 1.2 g/kg to 1.5 g/kg body weight daily. One exception: Older individuals who have severe kidney disease and are not on dialysis need to limit protein intake. "We would limit the maximum protein intake to 0.8 g/kg body weight in those who have severe renal disease with a glomerular filtration rate below 30 mL/min," Dr. Bauer said. He added that renal function should be checked twice a year in this population.

The PROT-AGE Study Group concluded that protein quality, timing of intake, and amino acid supplementation may influence the benefit of protein intake but that further studies are needed to make explicit recommendations. Also, in combination with increased protein intake, the group recommended exercise at safe levels that are safe and well tolerated by individuals.

► **Source:** *Evidence-Based Recommendations for Optimal Dietary Protein Intake in Older People: A Position Paper from the PROT-AGE Study Group* – Bauer et al.

### Diabetes and Muscle Mass

Elderly patients with type 2 diabetes show an accelerated decline in leg lean mass, muscle strength, and functional capacity when compared with normoglycemic controls, according to a study in the Netherlands.

Marika Leenders of the Top Institute Food and Nutrition in Wageningen and her colleagues compared muscle mass, strength, functional capacity, and reaction time between 60 community-dwelling men with type 2 diabetes and 32 age-matched controls.

Analysis of covariance showed significant deficits in individuals with type 2 diabetes: lean leg mass (a mean of 19.1 kg in the diabetes group vs. 19.7 kg in controls), appendicular skeletal mass (25.9 kg vs. 26.7 kg), and leg-extension strength (84 kg vs. 91 kg).

Functional performance also was impaired. Sit-to-stand was 9.1 seconds for

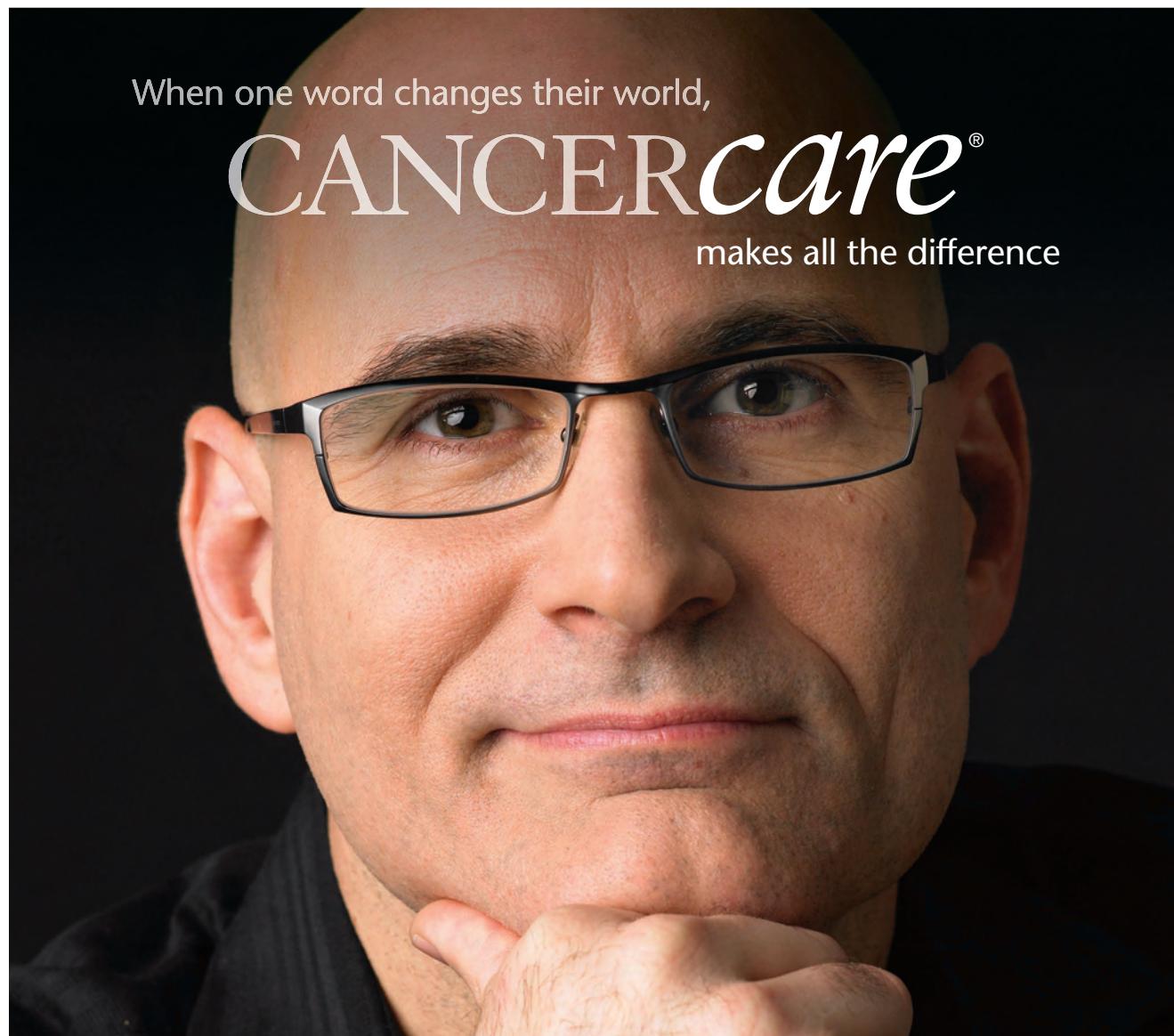
the diabetes group vs. 7.8 seconds for the controls, and hand grip strength was 39.5 kg vs. 44.6 kg. There was no difference in muscle fiber size or reaction times.

The findings suggest that interventional strategies are necessary to counteract the loss of muscle mass and strength in older diabetic patients, the researchers said. These include exercise

and nutritional and pharmacological programs to avoid sarcopenia.

► **Source:** *Patients With Type 2 Diabetes Show a Greater Decline in Muscle Mass, Muscle Strength, and Functional Capacity With Aging* – Leenders et al.

JEFFREY S. EISENBERG, a freelance writer based in Philadelphia, compiled this report.



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## NEWS FROM THE ASSOCIATION

### AMDA Introduces Easy-to-Use Tools for Legislation Advocacy

AMDA has introduced a new comprehensive, grassroots advocacy and engagement tool – the website <http://cqrcengage.com/amda/home> – to provide members the opportunity to influence important legislation affecting postacute and long-term care providers. The site features a number of features that AMDA members can use to make their voices heard.

These include legislative-action alerts, congressional letter writing campaigns, legislation tracking, the latest policy news and updates, and talking points and issue briefs on AMDA's priority policy issues. Members also can find contact information for their elected state and federal officials.

Health care has taken center stage in Congress and state legislations in recent months, and it can be challenging for busy practitioners to stay current on policy issues and actions. "This new website's tools help give AMDA members an easy way to actively participate on a grassroots level to make sure long-term care

providers are never left out of the important conversations going on in Washington, D.C.," said Alex Bardakh, AMDA senior manager of public policy.

It has never been more important for practitioners to be involved in health care advocacy. As AMDA members heard over and over from speakers at AMDA Long Term Care Medicine – 2013, their input makes a difference.

For example, at the Saturday General Session, Dr. Paul McGann, codirector of the Partnership for Patients and Deputy Chief Medical Officer for Campaign Leadership at CMS's Center for Medicare & Medicaid Innovation, said, "My request to you is for your leadership. Now is the time to step up and lean in. If you do, we believe you can make a huge difference in this country." By using the new AMDA advocacy website and tools, AMDA members everywhere – no matter how busy or politically inexperienced – can make this difference.



### The AMA Adopts AMDA Resolutions on Geriatric Training, ACO Exclusivity

The American Medical Association adopted as policy two AMDA-authored resolutions in the AMA's House of Delegates at the organization's annual meeting this summer. AMDA's House of Delegates had asked AMDA's delegate to the AMA house to offer Policy B-13: Improving Access to Physicians with the Special Skills Required in Geriatric Care Policy ([www.amda.com/governance/resolutions/B13.cfm](http://www.amda.com/governance/resolutions/B13.cfm)) and Policy C-13: Exclusion of Medical Providers in Long Term Care from Accountable Care Organizations Primary Care Physician Restriction ([www.amda.com/governance/resolutions/C13.cfm](http://www.amda.com/governance/resolutions/C13.cfm)). Both were adopted as AMDA policy at the March 2013 Annual Meeting.

The AMA adopted the policies as stated:

► Improving Access to Physicians with the Special Skills Required in Geriatric Care asks the AMA to explore and advocate for policies that best improve access to, and the

availability of, high-quality geriatric care for older adults in the postacute and long-term care continuum.

► Physician Participation in Multiple Medicare Accountable Care Organizations asks the AMA to continue to work with the Centers for Medicare & Medicaid Services to address accountable care organization (ACO) rules that preclude physician participation in multiple Medicare ACOs.

Dr. Eric Tangalos, CMD, AMDA's delegate to the AMA house, testified on both resolutions and received broad support among physicians attending the AMA meeting. The resolution advocating that medical directors and attending physicians in postacute and long-term care setting practice in multiple ACOs was broadened to include all physicians, regardless of specialty. As the policy notes, AMDA and the AMA have been working with the Centers for Medicare & Medicaid Services to address these concerns.

### Conference Attendee Recommends 'Behavior Challenges' to Colleagues

Dr. Sing Palat, a long-term care physician in Colorado, went home after attending the "Navigating Mood and Behavior Challenges in Long Term Care: Strategies for Optimal Outcomes" program at AMDA LTC Medicine – 2013 and applied what she learned right away.

"A long-time elderly nursing home resident with dementia had become increasingly agitated," Dr. Palat explained. "I learned at the workshop to make sure we characterize the agitation and carefully assess her for physical problems, depression, and other possible underlying issues that might be causing or contributing to the behavior." As a result, Dr. Palat's team carefully assessed the patient and tried various non-pharmacologic interventions ahead of medications.

"I was able to help staff better understand the clinical, quality of life, and regulatory reasons to attempt nonpharmacologic interventions and seek nondrug solutions to behavioral problems," she said.

Since attending the program, Dr. Palat said she is more confident about managing dementia-related behaviors: "There is not a lot of evidence behind the management of dementia-related behaviors. I wanted to know what is scientifically proven to help so that we could determine and implement interventions more systematically. I wanted a stronger knowledge base, which I got at this program. I came back more inspired and confident. The program gave me some concrete advice to share with my facility. I was energized – I had a

whole list of ideas I wanted to initiate when I got home."

For example, Dr. Palat wanted to talk to the Minimum Data Set coordinator to learn more about the tools being used to assess cognition. "She was surprised by my inquiry," Dr. Palat said. "A physician had never asked her about this before."

The program speakers were "fantastic" and shared information about useful tools such as the Brief Interview for Mental Status tool and the AMDA clinical practice guideline on dementia, Dr. Palat said. While she appreciated the clinical evidence the speakers presented, Dr. Palat noted, "The anecdotal stories were helpful; I could relate to them. ... There was a lot of compassion coming through. These weren't just clinicians but practitioners who care about their patients."

Dr. Palat also learned much from her fellow program participants, including some familiar colleagues. "I went to the meeting with several other physicians from Colorado. I often talked with these people, but we never had a forum before to discuss this topic. I found out about some great ideas one of my colleagues was using in her facility that I didn't know about before."

For clinicians who missed this program in March, "Navigating Mood and Behavior Challenges in Long Term Care: Strategies for Optimal Outcomes" will be held live on Sept. 21 in New Orleans. For information about the day-long program or to register, go to <http://www.amda.com/education/moodandbehavior/index.cfm>.

### Trend Shows Growth in Number of CMD Recertifications

The American Medical Director Certification Program's (AMDCP) recertification rates have trended higher in the past three recertification cycles, with rates rising an average of 15% in 18 months. Since 1991, the average annual rate for CMD recertification has held around 56%. However, since December 2012, the recertification rate has grown to an average of 71%. Among CMDs due to recertify in June 2013, 73% submitted applications.

Based on information requests from constituents and feedback from current CMDs, AMDCP Program Manager Suzanne Harris attributes

the uptick in recertification to an increase in support for medical director certification from nursing facility chains, facility administrators, and state legislatures, along with a focus in recent years by the AMDCP Board of Directors on removing barriers to recertification.

Applications for certification and recertification are due April 1 and Oct. 1 of each year. The AMDCP Board of Directors reviews applications in June and December annually. The next deadline for applications is Oct. 1, 2013. Contact Ms. Harris at [cmd@amda.com](mailto:cmd@amda.com) or 410-992-3117 if you have any questions.

## NEWS FROM THE ASSOCIATION



## AMDA Appoints State Chapter Liaison for Local Support

AMDA is committed to helping state chapters provide member advocacy and support on a local level. Toward that end, the organization recently appointed Suzanne Harris as state chapter liaison. Ms. Harris has been with AMDA for 9 years and looks forward to her newly expanded responsibilities.

Ms. Harris has worked closely with the state chapters in joint sponsorship for CME and CMD programs, as well as in service as the webmaster for the AMDA State Chapter Website Network, and she continues in her primary role as AMDCP program manager.

“Strong state chapters are essential to the proliferation of quality post-acute and long-term care throughout the country,” Ms. Harris said. “I am pleased to have the opportunity to work with our chapters to help them make sure their PA/LTC physicians have access to the information, education, certification, resources, and connection with colleagues they need to be effective and efficient in their work.”

If you have a question about state chapters, contact Ms. Harris at [statechapters@amda.com](mailto:statechapters@amda.com) or 410-992-3117.

## Practitioners Need Different Tools and Techniques to Care for Younger Residents

Dr. Rebecca Ferrini, CMD, medical director at Edgemoor Hospital in Santee, Calif., knows the unique challenges presented by caring for younger residents in post-acute and long-term care (PA/LTC). “We are responsible for complying with the same regulations that apply to and were developed for older residents,” Dr. Ferrini said. “These regs never were designed for younger residents who likely will be living in the facility for 5, 10, 15, or 20 years and who have different expectations.”

For example, they often may be bigger and physically stronger, or they may be completely disabled and unable to feed or dress themselves.

They are more likely to want to leave the facility and spend time with friends, some of them engaging in unhealthy lifestyle choices such as drinking, eating junk food, smoking, or even using drugs. With younger residents, another unusual challenge arises for practitioners and staff. They are more likely to be dealing with parents and spouses, as opposed to adult children, and many younger residents have children who are still dependents.

One key to working with this population is to “clarify for patients and families what the facility can and cannot do,” said Dr. Ferrini. “They need to understand the services that can and can’t be provided, and they need to understand the implications if they don’t abide by the rules and take appropriate responsibility for their behavior.” She added that facilities must be prepared to negotiate. “You might have a resident who wants an elaborate beauty routine but is physically unable to do it herself,” she said.

“You might agree to do that for her one day a week.”

Dr. Ferrini sees a wave of younger residents coming into PA/LTC. “We are seeing a historic level of younger, physically disabled patients, and they are living longer than ever. We also are seeing a growing patient population with brain injuries and mental illness,” she said. “Nursing homes need to know that they will have to fill some beds with these younger patients. Facilities have to be ready, because these patients are coming.”

To help her colleagues ride this wave, Dr. Ferrini – with several AMDA colleagues – created “The Younger Adult in the Long Term Care Setting,” AMDA’s newest addition to its LTC Information Series. However, putting together the kit presented a challenge. “You want to make these tools practical and evidence-based, but we found a dearth of information on the younger population in long-term care,” Dr. Ferrini said. So she and her committee “put together our cumulative experience and compiled the information in the form of storytelling.”

Dr. Ferrini summarized: “We accumulated the wisdom and experience of those who have worked with this population – how to deal with married couples, transgender issues, drug seeking behaviors, etc.” She added that everyone was “very generous” in sharing their policies and procedures, forms, progress notes, and other information and resources. “I like the kit because it’s very readable and practical,” she said.

For more information or to order the kit, go to [www.amda.com/resources/ltcis.cfm#LTCYA13](http://www.amda.com/resources/ltcis.cfm#LTCYA13).

## Mark the Rest of National Immunization Awareness Month With AMDA Tool Kit

August is National Immunization Awareness Month (NIAM), and AMDA is celebrating with a special discount – available only this month – on its “Immunizations in the Long Term Care Setting” Information Tool Kit.

This important resource teaches users how to boost vaccination compliance among both residents and staff, identify barriers to immunization and strategies to overcome them, review federal regulations, learn processes for managing influenza outcomes in post-acute and long-term care (PA/LTC) facilities, go beyond standard flu preparedness plans to additional steps to ensure that your facility is ready, and educate others about immunizations for diseases relevant to the PA/LTC setting, such as herpes zoster, tetanus, pertussis, and diphtheria.

The tool kit contains 53 pages of information, educational materials, and other resources. It includes two

DVDs – “Influenza Immunization and the Health Care Worker” and “Caring in the Community: Immunization and the Older Adult” – plus a CD-ROM that includes many tools that may be customized according to a facility’s needs.

The Department of Health and Human Services’ Office of Disease Prevention and Health Promotion has said, “Vaccines (shots) help prevent dangerous and sometimes deadly diseases. National Immunization Awareness Month is the perfect time to promote vaccines and remind family, friends, and coworkers to get caught up on their shots.

... We can all use this month to raise awareness about vaccines and share what we know with our community.”

To take advantage of a special 10% member discount, use the code POM-0813. For more information or to order the tool kit, go to [www.amda.com/resources/ltcis.cfm#LTCIMM3](http://www.amda.com/resources/ltcis.cfm#LTCIMM3).



## Don't Miss These Events

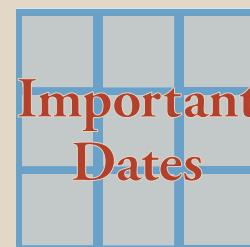
### Aug. 16-17 23rd Annual Caring for the Frail Elderly Conference

Columbia, Mo.  
Website: <http://medicine.missouri.edu/cme/>  
Contact: [cookba@health.missouri](mailto:cookba@health.missouri)

Contact: AMDA Registrar  
Phone: 410-992-3116  
E-mail: [registration@amda.com](mailto:registration@amda.com)  
Website: [www.amda.com/education/advanced/index.cfm](http://www.amda.com/education/advanced/index.cfm)

### Sept. 14 Excellence in Long Term Care: Virginia Medical Directors Association 2013 Annual Conference

Virginia Beach, Va.  
Website: [www.vamda.org](http://www.vamda.org)  
Contact: Angel Rivera  
Phone: 757-889-4383  
E-mail: [Arivera@longtermcareofva.com](mailto:Arivera@longtermcareofva.com)



### Oct. 17-20 FMDA Annual Conference

#### Best Care Practices in the Geriatrics Continuum 2013

Lake Buena Vista, Fla.  
Contact: Ian Cordes  
Phone: 561-659-5581  
Website: [www.bestcare-practices.org/index3.html](http://www.bestcare-practices.org/index3.html)

### Sept. 21 AMDA Navigating Mood and Behavior Challenges in Long Term Care: Strategies for Optimal Outcomes

New Orleans, La.  
Contact: AMDA Registrar  
Phone: 410-992-3116  
E-mail: [registration@amda.com](mailto:registration@amda.com)  
Website: [www.amda.com/education/moodandbehavior/index.cfm](http://www.amda.com/education/moodandbehavior/index.cfm)

### Nov. 2-8 AMDA Core Curriculum on Medical Direction in Long Term Care

Orlando, Fla.  
Contact: AMDA Registrar  
Phone: 410-992-3116  
Email: [registration@amda.com](mailto:registration@amda.com)  
Website: [www.amda.com/education/core/](http://www.amda.com/education/core/)

### Oct. 4-6 AMDA Advanced Curriculum on Medical Direction in Long Term Care

Atlanta, Ga.

**Feb. 27–March 2, 2014**  
**AMDA Long Term Care Medicine – 2014**  
Nashville, Tenn.

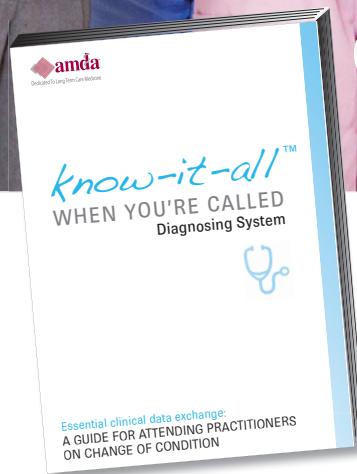
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WHAT TO  
REPORT?

# PROBLEM? SOLUTIONS

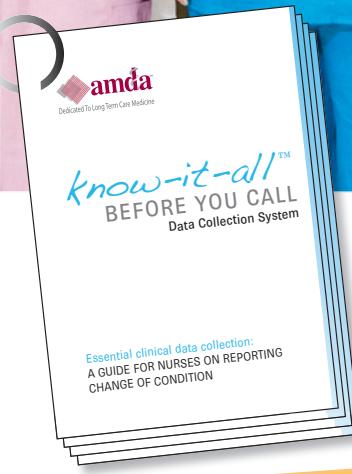
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for Nurses

Product Code:  
KNOW



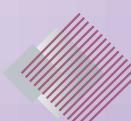
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**WHEN YOU'RE CALLED** Diagnosing System

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