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Caring for the Ages

A Monthly Newspaper for Long-Term Care Practitioners

In This Issue

Freedom of Choice: Updated Dining Practice Standards Call for Diet Liberalization

BY LINDA HANDY, MS, RD

Nursing facility staffs across the country are on a challenging journey to improve their residents' dining experience while ensuring compliance with regulatory requirements. The true stories of two residents illustrate different tactics to approaching residents' rights to eat what they want.

The first resident, Mr. C, wanted non-pureed foods and his favorite thin liquids after he was assessed by a speech language pathologist (SLP), who determined he needed a pureed diet with nectar-thick liquid. Staff informed the resident and documented the risk/benefit. The resident's preferences and choices were incorporated into his plan of care, and the facility arranged a negotiated risk agreement with him. Facility staff continued to monitor Mr. C and offered alternatives, which he accepted and rejected as he defined his own quality of life.

The second resident, Mrs. A, had been encouraged by staff to accept a tube feeding status, but she repeatedly asked if she could dine on pureed food with her long-time companions. The facility leadership was surprised when given the F 151 deficiency for not informing Mrs. A of her rights. They shouldn't have been.

Respecting residents' diet preferences is becoming standard procedure in post-acute/long-term care. An article

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Not respecting a resident's dietary preferences may put your facility in the surveyor's crosshairs.

in *Mayo Clinic Proceedings* provides thorough guidance to a patient's right to eat the way they want (*Mayo Clin Proc* 2005;80:1461-76). In a case example, the authors wrote: "The patient expressed a desire to eat small amounts of food, despite the risk of aspiration. It is ethically and legally permissible for patients with decision-making capacity to refuse unwanted medical interventions and to ignore recommendations of the clinician. … [A] patient's choice not to adhere to a clinician's recommendations may be at odds with a clinician's desire to 'do good' or avoid harm. If the patient is sufficiently informed about the risks and benefits of … [informed] refusal of a proposed intervention or treatment and refuses, the clinician should respect the patient's decision."

Creating Ten Standards

Shortly after I retired as a dietitian specialty surveyor, I was asked to participate

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Dextromethorphan/Quinidine Effective for Agitation

BY MITCHEL L. ZOLER

WASHINGTON — Daily treatment with a combined formulation of dextromethorphan and quinidine led to a significant and clinically meaningful decrease in agitation episodes among patients with Alzheimer's disease in a controlled, phase II, 10-week study with 159 patients.

The combined, oral formulation was generally well tolerated, without appearing to cause somnolence or cognitive decline, Jeffrey L. Cummings, MD, ScD, reported at the Alzheimer's Association International Conference 2015.

A treatment that cuts the frequency and severity of agitation in Alzheimer's disease patients would be very helpful as this is "one of the most difficult symptoms for patients. [Agitation] makes it very difficult to care for a family member with Alzheimer's disease," said Dr. Cummings, professor of neurology at the Cleveland Clinic and director of the clinic's Lou Ruvo Center for Brain Health in Las Vegas.

"Agitation is one of the most disturbing and disabling symptoms associated with Alzheimer's disease," commented Mary Sano, PhD, professor of psychiatry and director of Alzheimer's disease research at Mount Sinai Hospital in New York. "Movement on treating this symptom has the potential to make a real difference

See **Drug Combo** • *page 15*

Aerobic Exercise Beneficial for MCI With Prediabetes

BY MICHELE G. SULLIVAN

WASHINGTON — For the first time, a randomized study has demonstrated that vigorous physical exercise not only improves cognition but also moves Alzheimer's disease biomarkers in the right direction.

Six months after subjects with mild cognitive impairment (MCI) began aerobic exercise, scores on a composite measure of cognition rose significantly. Not only that, hypometabolic brain regions associated with Alzheimer's symptoms were reperfused. And phosphorylated tau — a marker of neuronal injury — fell significantly in cerebrospinal fluid (CSF), Laura Baker, PhD, said at the Alzheimer's Association International Conference 2015.

The finding of reduced tau is especially intriguing, said Dr. Baker of Wake Forest University, Winston-Salem, NC. The biggest improvements occurred in subjects older than 70 years, who were carrying a double hit of both MCI- and age-related tau.

"I hope that we are moving toward being able to demonstrate that regular, moderate aerobic exercise can attenuate the effects of both aging and Alzheimer's. This is a potential intervention that combats two diseases — if we regard aging as a disease process."

'These kinds of interventions with diversified target portfolios may be our most potent means to prevent and slow Alzheimer's.'

Aerobic exercise is easy to institute, inexpensive to continue, and confers numerous physical and mental benefits, Dr. Baker said: "Like other lifestyle interventions, exercise targets multiple, health-restoring biological processes. It's not just one molecule affecting one part of our chemistry, but multiple targets. These kinds of interventions with diversified target portfolios may be our most potent means to prevent and slow Alzheimer's."

She and her colleagues conducted a 6-month exercise trial with 71 sedentary adults who had both MCI and prediabetes (hemoglobin A_{1c} of 5.7%–6.4%). The subjects, ranging in age from 55 to 89 years, were randomized to either a control program of stretching three times per week, or to an exercise program of aerobic exercise for 45 to 60 minutes three times per week. Most subjects used a treadmill, but other forms of exercise were also allowed, including stationary bike and approved group classes.

The intervention group aimed to maintain an exertion level of 70% to 80% of their maximum heart rate, whereas the control group exercised at below 35% of it. Both interventions were carried out under the supervision of a study researcher. This is an important point, Dr. Baker noted, because it means that both groups were getting the benefit of leaving their house several times a week and experiencing social interactions in classes at the gym.

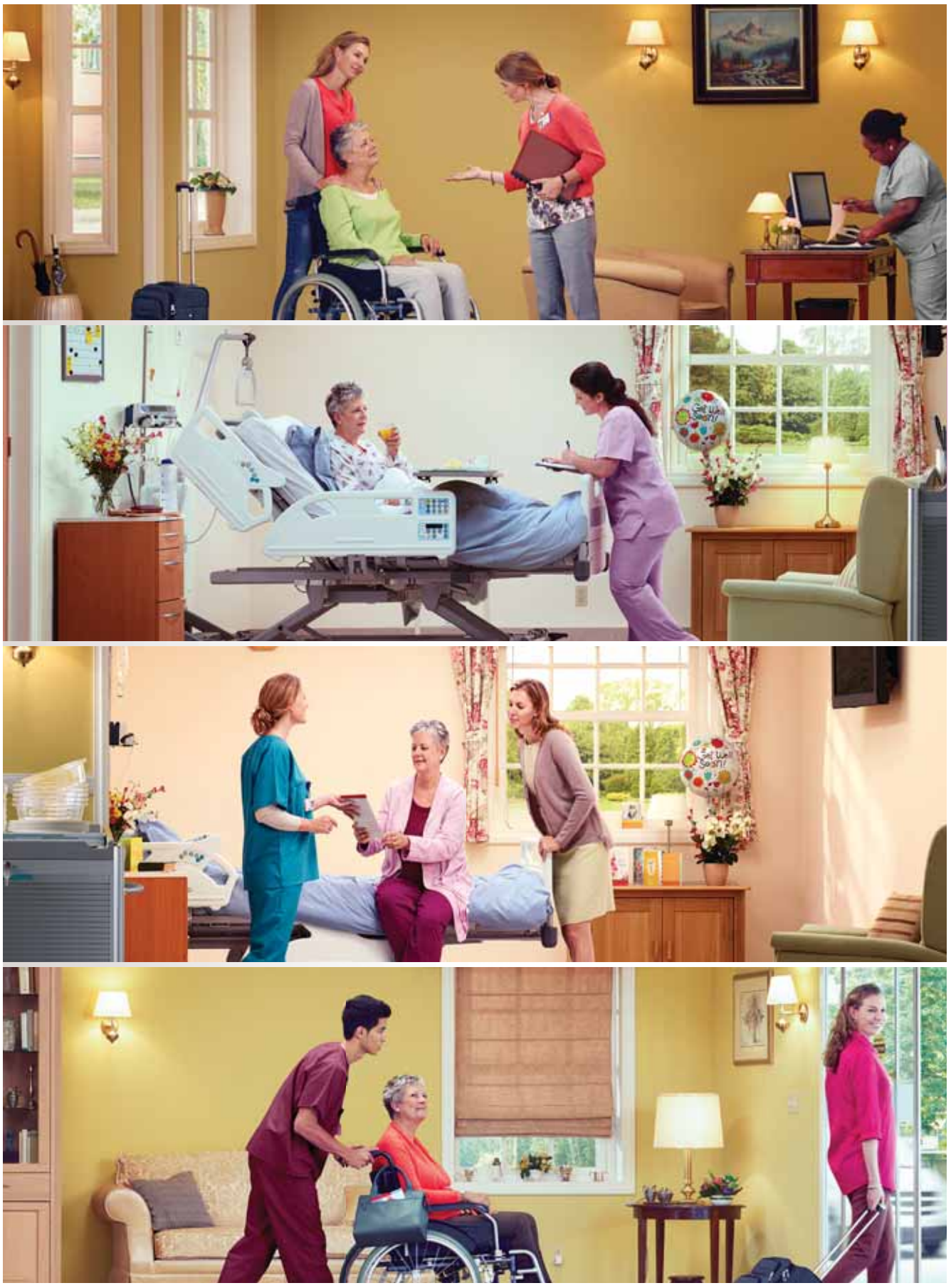
At baseline and 6 months, everyone completed cognitive testing (verbal recall, tests of executive function); a 400-meter timed walking test; glucose tolerance test; body fat assessment; and blood and CSF collection. Forty participants also underwent structural and functional brain MRI. All results were controlled for age and education.

For the analysis, Dr. Baker stratified the group by those younger and older than 70.

There were no reductions in CSF tau in either age group in the stretching cohort. However, in the exercise cohort, both age groups experienced significant declines in CSF tau. Tau is released when neurons are damaged; reductions in tau suggest a slowing of that damage. The older group's tau levels declined by 10 pg/mL — especially impressive given that their baseline levels were elevated not only from their cognitive disorder but also from normal aging.

"In fact, the greatest drops in tau occurred among the folks who were starting with the highest levels," Dr. Baker said.

She found a trend — albeit nonsignificant — for a positive change in CSF



amyloid-beta-42 among the intervention group. "In the stretching group, we expected to see continuation of disease, and this was reflected in the CSF amyloid levels, which increased over 6 months. In the aerobic group, this increase appeared to be attenuated."

Whole brain blood flow also improved significantly in the exercise group and was driven by increased flow in regions particularly associated with aging and Alzheimer's: the superior frontal cortex, posterior cingulate, and cingulate gyrus.

"In all three regions blood flow was increased bilaterally, and these increases were similar. This was encouraging and suggests that changes related to aging and Alzheimer's benefited. Typically, the signature profile of aging is reduced flow in the superior frontal region, and the profile for Alzheimer's is reduced flow in the posterior cingulate and cingulate gyrus. These are exactly the regions that were boosted by exercise."

The cognitive measure was a compilation of several tests of executive function. "Independent of age and APOEε4 [apolipoprotein E ε-4] status, we saw significantly improved performance."

Dr. Baker said that she is eager not only to find out how many have independently continued to exercise but also to retest them and see if the effects were transient or imparted some lasting benefit. She also plans to initiate an 18-month, phase III trial of the two interventions at 15 sites throughout the United States.

"We really hope these results will help us move this work forward," she said.

Dr. Baker had no financial disclosures.

Michele G. Sullivan is with the Mid-Atlantic bureau of Frontline Medical News.

Age-Related Cognitive Deficits Differ by Sex

BY MITCHEL L. ZOLER

WASHINGTON — Age-related cognitive declines have a different presentation in women and in men.

As men age they show a steeper decline, compared with women, in their ability to name words from a list, to name words that start with a specific letter, and in trail-making tests, according to initial, baseline results from 587 people enrolled in an online program designed to assess and intervene against age-related declines in cognitive function.

In contrast, age-related declines among women showed up more commonly for reading comprehension, three-dimensional rotation, and clock rotation tests, Thomas Beaudry said at the Alzheimer's Association International Conference 2015. Scores on reaction time and on the Wisconsin Card Sorting Test declined with age at roughly similar rates regardless of sex.

These sex differences in rates of age-related cognitive declines in various mental function tests "suggest that careful thought needs to be put into the selection of tests used for diagnosis" of early-onset Alzheimer's disease and other forms of age-related dementia, said Mr. Beaudry, a researcher at the McGill University Research Centre for Studies in Aging in Montreal.

Mr. Beaudry and his associates developed a website that allows registered participants to undergo assessments of their cognitive function at baseline. Participants are also encouraged to regularly play a variety of "brain games" online designed to improve or at least help maintain their cognitive function. Known as the Prevention of Neurodegenerative Diseases in Everyone at Risk (P.O.N.D.E.R.) program, it had enrolled 1,536 participants as of July, Mr. Beaudry said. The enrollees averaged 57 years old, and 79% were women.

At the time of enrollment, participants complete a panel of eight cognitive function tests. In addition to completing these assessments at baseline, participants receive follow-up requests to undergo reassessment every 6 months.

"What makes P.O.N.D.E.R. unique is the training approach" in which participants are asked to play brain games on the website, he said. The games are designed to challenge and develop the same cognitive skills addressed by the assessments. "The presymptomatic phase of Alzheimer's disease presents a window for intervention through cognitive training to delay the onset and progression of the disease," Mr. Beaudry said.

Mitchel L. Zoler is with the Philadelphia bureau of Frontline Medical News.

Alzheimer's Disease Drug Development Targets Disease Modification

BY MITCHEL L. ZOLER

WASHINGTON — Finding a drug therapy for patients with Alzheimer's disease that not only improves symptoms but also slows or stops the underlying disease process and results in disease modification will be a major challenge.

Disease modification "indicates the drug is attacking the underlying biology of the disease. The medications we have now affect only symptoms and are palliative," David S. Knopman, MD, said in an interview during the Alzheimer's Association International Conference 2015.

Designing trials capable of identifying disease-modifying drugs "turns out to be very challenging. In principle, a drug with disease-modifying effects would have bigger and more enduring effects, could be started earlier in the disease, and would ultimately be of greater benefit to patients and to society," said Dr. Knopman, a professor of neurology at the Mayo Clinic in Rochester, MN. He participated in a session at the meeting focused on the potential design of trials that could test a drug's disease-modifying effect.

'In principle, a drug with disease-modifying effects would have bigger and more enduring effects, could be started earlier in the disease, and would ultimately be of greater benefit to patients and to society.'

Delayed Start

The most likely design that researchers seem ready to use is a "delayed-start" trial, in which placebo-treated patients who serve as controls in the initial, blinded, and randomized phase of an efficacy trial then cross over to open-label treatment once the first segment primary-endpoint stage is finished. In most trials "the open-label, long-term extension will occur anyway," so adding a delayed-start element following the end of an efficacy trial "does not add a lot of complication to the design," he said.

Two factors make a delayed-start analysis challenging. First, the drug needs to show efficacy during the initial, double-blinded phase. "Only if you see both a cognitive and some sort of functional-outcome benefit can you engage in the delayed-start analysis, to see if the effect is enduring," Dr. Knopman said. The second limitation is patient dropout. "An open-label, long-term extension over another 1, 2, or 3 years will invariably lead to subjects dropping out because of health issues or social matters and that makes the statistical analysis more complicated." During one trial that was discussed in depth at the session, about 40% of patients who entered the delayed-start phase had left the study by the time this stage finished 2 years later.

FDA Support

Despite these issues, adding a delayed-start phase to drug trials likely will become increasingly common, Dr. Knopman predicted. Drug developers "will probably include this as a secondary analysis because it doesn't add much expense or added burden on participants, so it seems like a win-win." Plus, representatives from the Food and Drug Administration who participated in the session seemed to endorse the general concept, he noted. But the most important caveat remains, he stressed. "You have to first show primary-outcome results. Only then you can talk about disease modification."

The delayed-start trial design was developed by Eli Lilly. Dr. Knopman received an honorarium from Lilly for chairing the data and safety-monitoring committee for two of their trials through 2012, but since then he has not had a financial relationship with the company. He currently is an investigator in a trial sponsored by Lilly. He said he has no other disclosures.

MITCHEL L. ZOLER *is with the Philadelphia bureau of Frontline Medical News.*

Estrogen Therapy Linked to Brain Atrophy in Women With Diabetes

BY MICHELE G. SULLIVAN

WASHINGTON — Women with type 2 diabetes who take estrogen therapy showed lower total gray matter volume, with atrophy particularly evident in the hippocampus.

A new analysis of the Women's Health Initiative Memory study suggested that these hormone therapy–related decrements in brain volume seem to stabilize in the years after treatment ends. However, said Christina E. Hugenschmidt, PhD, of Wake Forest University, Winston-Salem, NC, the findings also suggested caution when considering a prescription for estrogen therapy for a woman with emerging or frank diabetes.

"The concern is that prescribing estrogen to a woman with diabetes could increase her risk of brain atrophy," she said at the Alzheimer's Association International Conference 2015.

Dr. Hugenschmidt reviewed data from the Women's Health Initiative Memory Study–MRI (WHIMS-MRI). The parallel placebo-controlled trial randomized women 65 years and older to placebo, or 0.625 mg conjugated equine estrogen with or without 2.5 mg progesterone. They were all free of cognitive decline at baseline.

Dr. Hugenschmidt focused on 1,400 women who underwent two MRI brain scans: one 2.5 years after beginning the study and another about 5 years after that. The primary outcomes were total brain volume, including any ischemic lesions, total gray matter, total white matter, frontal lobe and hippocampal volume, and ischemic white matter lesion load.

At enrollment, the women were a mean age of 70 years old; 124 had type 2 diabetes. About 42% had long-standing disease of 10 years or longer. Not surprisingly, there were some significant differences between the diabetic and nondiabetic groups: Body mass index, waist girth, and waist/hip ratio were all significantly larger in the women with diabetes.

Diabetes = Less Brain Volume

At the first scan, women with diabetes who had been randomized to estrogen therapy had about 18 cc less total brain volume than those without diabetes. The brain volumes of women with diabetes who were taking placebo were nearly identical to those of the nondiabetic women, regardless of what treatment they were taking.

The difference seemed to be driven by a loss of gray matter, Dr. Hugenschmidt said. There was no significant effect on white matter. The hippocampus appeared to have a similar amount of shrinkage. However, she added, there were no differences in cognitive scores on the Mini Mental State Exam.

Insulin use didn't appear to ameliorate the findings of smaller brain volume among those with diabetes. Atrophy didn't progress, however; findings at the same scan were similar.

Interrupted Brain Metabolism

The findings may be linked to the suppression of a natural process that occurs during the perimenopausal transition, Dr. Hugenschmidt said. Estrogen is crucial in maintaining the brain's energy metabolism. It works by increasing glucose transport and aerobic glycolysis. But during this time of life, as estrogen wanes, it becomes uncoupled from the glucose metabolism pathway. The female brain then begins to use ketone bodies as its primary source of energy. Intact estrogen levels normally downregulate the use of alternative energy sources before menopause; supplementing them seems to prevent this transition from occurring.

"Among older women with diabetes for whom the glucose-based energy metabolism promoted by estrogen is already compromised, this downregulation of alternative energy sources may lead to increased atrophy of gray matter, which has a greater metabolic demand relative to white matter," Dr. Hugenschmidt and her colleagues wrote in an article published online ahead of print in *Neurology* (2015 July 10 [doi:10.1212/WNL.0000000000001816).

Dr. Hugenschmidt reported having no relevant financial disclosures.

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

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CDC: Coordinated Strategy Will Curb Resistant Infections

BY KARI OAKES

A coordinated approach to infection control and antibiotic stewardship would dramatically reduce the number of people affected by antibiotic-resistant pathogens and health care-associated infections (HAIs), saving tens of thousands of lives and billions of dollars over the next 5 years, according to a federal report.

With a nationwide prevention and antibiotic stewardship program, the total number of HAIs could be reduced by 619,000 over the next 5 years, saving 37,000 lives and reducing direct medical costs by $7.7 billion, Thomas Frieden, MD, MPH, director of the Centers for Disease Control and Prevention, said in a telebriefing sponsored by the agency.

The coordinated approach requires both a public health tracking and alerting system and robust interfacility infection control practices. "Facilities that go it alone can't effectively protect their own patients," he said.

In a CDC Vital Signs report, Rachel Slayton, PhD, of the Center for Emerging and Zoonotic Infectious Diseases, used carbapenem-resistant *Enterobacteriaceae* (CRE) as the test case to determine the effect size of coordinated compared with institution-based infection control and alerting practices.

She and her coauthors projected that the number of health care-associated CRE infections would rise about 10% over the next 5 years, from 310,000 to 340,000, under current practices. Using these prevalence figures, a coordinated approach would result in CRE prevalence within a health care network of just 2% after 5 years, compared with a 12% baseline prevalence and an 8.6% prevalence with augmented individual efforts.

Infection control practices that are enhanced by interfacility coordination may include maintaining regional databases that permit alerts when an individual with an HAI transfers from one facility to the other; having interinstitution agreement about best practices for gowning, gloving, and isolation; and commencing enhanced screening for HAIs when public health officials identify a potential outbreak. Implementation of the coordinated approach would be supported by the CDC's Antibiotic Resistance Solutions Initiative, with $264 million requested in the federal fiscal year 2016 budget for a broad set of programs and laboratory facilities for improved surveillance for resistant pathogens.

KARI OAKES *is with the Midwest bureau of Frontline Medical News.*

PA/LTC Perspective

The CDC is to be commended for its push toward a more coordinated approach to infection control. Although evidence supports the efficacy of specific antimicrobial stewardship programs in PA/LTC settings, the prerequisites for success vary considerably, depending on the context and scope of the program. At a minimum, success requires buy-in from the medical and nursing staff. There need to be clear lines of accountability and efficient means of interprofessional communication. A close partnership with the pharmacy and consulting pharmacist is also a must and may require more on-site presence than is the norm. In addition, the medical director, the director of nursing, and the administrator must work collaboratively to ensure timely communication and the sharing of content expertise with their acute care partners.

A major challenge in accomplishing the CDC's objectives is to overcome the current dearth of infection control practitioners in post-acute/long-term care. Resources must also be directed toward the real time collection of facility-specific microbial data, including resistance patterns, as well as the dissemination of evidence-based treatment algorithms. While there is clearly much to do, doing nothing and accepting the status quo is not an option.

—Paul Katz, MD, CMD
Tallahassee, FL

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Dear Dr. Jeff

By Jeff Nichols, MD, CMD

Fixing Potholes in the Road to Better Communication

Dear Dr. Jeff:
You recently responded to the issue of homes troubled by a single disruptive family member creating turmoil. Our problem is different. We have a hundred families, each seemingly reasonable, who exhaust our staff with minor complaints and questions. It feels as though we hardly have time to actually care for the residents. Yet the residents themselves appear happy. Any suggestions?

Dr. Jeff responds:
In the classic movie *Cool Hand Luke,* the warden responds to each conflict with the hero-convict Paul Newman, before punishing him, saying, "What we've got here is a failure to communicate." But sometimes the problem really is a communications failure, particularly when the care is competent and compassionate, but the families are still unhappy. Although some LTC professionals dream of a facility caring only for childless orphans, the reality is that chronic disease in our society generally plays out in the context of the family, and excellent care requires that family anxieties be addressed as well. When the families and the nursing home work together as a team, the work is easier and more satisfying.

Communication with families begins at the time of admission. Thirty years ago, families and often prospective residents routinely visited and toured the facility prior to admission. Sometimes they selected the floor or room they preferred, met relevant staff and reviewed facility practices. Admissions were arranged for the morning and often lunch had been ordered in advance. Although occasional family tours still occur at some facilities, they are generally in the context of an anticipated hospital discharge the following day.

More often, new residents come directly from the hospital barely knowing to which facility they are being discharged, or where it is located, before being hustled into an ambulance or ambulette. A common question on admission is: "Does my family know I'm here?" Often families insist that discharges be delayed until after working hours so that they may accompany a loved one during the transfer for reassurance or even simply to find out where they are going. Whether for hospital or family convenience, admissions now generally occur in the late afternoon or evening, long after the day shift has left. Indeed, many facilities will still accept a new resident until 11:59 p.m. to get credit for another filled bed for the day. Anxious residents and staff arrive when the facility is typically less staffed. Senior administrative, rehabilitation, dietary, and social work personnel have usually already gone home. Frequently, there is no physician or nurse practitioner there.

Families, already suspicious of the quality of nursing home care, are unlikely to be reassured by this scenario. So, even if everything the first night and following morning proceeds relatively smoothly, the facility is already working to catch up from a poor initial impression.

Shouldering Blame

Unfortunately, the first night rarely goes smoothly. Perhaps the admissions department has failed to alert the unit of the anticipated arrival of the resident or their variety of special needs. Transfer documentation may have been misplaced. Medication lists and discharge summaries are often inaccurate, inconsistent, or simply missing. Cognitively intact patients and involved family caregivers may not be adequately informed about the major diagnoses for which patients have been treated, much less the results of significant tests or the anticipated prognosis. Weight-bearing status may be unspecified or unclear, complex diets inappropriate for long-term care may be requested, and braces or other supportive equipment may be in place without instructions regarding their use or permission for their removal at night.

Often the floor staff, whether directly or nonverbally, conveys the message that they weren't prepared for the resident and wish the new arrival hadn't come. Unprepared rooms and unmade beds, prolonged pharmacy delays, missing meals, lack of required translators, and a general air of confusion reinforce a negative first impression that may take weeks or months to overcome, if at all. Once a family has been persuaded that the facility is disorganized and disinterested, they will understandably be vigilant in protecting their loved one from our mistakes and ignorance.

Even if we blame many of these problems on the hospitals, evil insurance plans regulating lengths of stay, or the chaotic medical system that creates silos and inadequately funds long-term care (indeed, all of them deserve some of the blame), the families will ultimately blame us. Complainers, even chronic complainers, are not always wrong. And, after all, we are providers presenting ourselves as caring for the old and frail. Facilities that fail to create an orderly and welcoming transfer process invite family conflict.

Family perceptions of disrespect and disinterest typically lead to demands to speak with the medical director, whom they incorrectly assume runs the facility. A brief exploration of their questions and concerns is advisable. Time will ultimately be saved if the relevant disciplines are also present, particularly the unit nurse manager or the director of nursing.

In the Know

Federal law requires facilities participating in Medicare and Medicaid to collect significant information regarding every resident's prior history and preferences, complete an elaborate assessment process (the MDS [Minimum Data Set]), create a care plan based on all the information obtained, and deliver care based on the combination of all that data and the written orders of a licensed physician. Everyone working in skilled nursing facilities knows this, but virtually no one outside of our world knows it.

For example, many New York nursing homes have been meeting regularly with networks of local hospitals to improve care coordination and assist in a statewide process attempting to integrate physical and behavioral health. As part of that process, facilities were asked what percentages of new admissions are screened for depression or dementia using validated measures, and whether these screens are ever repeated. The hospital representatives were totally shocked to learn that the number for every nursing home was 100%, and that periodic reevaluations are standard practice. If major teaching hospitals with sophisticated case management departments don't know about the MDS and that it embeds the PHQ-9 (Patient Health Questionnaire) and BIMS (Brief Interview for Mental Status) screening tests, why would we expect families to know anything about it?

When the family is oriented to this process, their anxiety is relieved, opening the door to better communication. They should be informed that we will be reaching out to them with important information regarding their loved one's habits and preferences. Families are generally amazed at the comprehensiveness and resident-focused nature of this process. Next, families should be instructed that the designated representative will be invited to a care planning meeting where they will be fully informed of the results of all assessments and will be encouraged to participate in the creation of the care plan. When informed about the process, few families will barrage every department requesting information or making suggestions.

Caregivers should also be told about ways they may be able to improve their loved one's stay. These ways include locating or supplying appropriate clothing and shoes for a post-acute stay and bringing dentures, eyeglasses, or hearing aids, which may have been left at home or taken home from the hospital for safety. Other personal items such as reading materials, puzzles, photographs, comforters, and a device to listen to favorite music may also make the nursing home experience more enjoyable and home-like.

Making Allies

The care planning meeting is another opportunity to make the family into an ally. Unrealistic expectations can be addressed while priority areas can be incorporated into the care plan. Unfortunately, since the family's presence often necessitates extra time in an otherwise time-consuming process, many facilities discourage family participation. Those meetings are scheduled during work hours, often in locations without adequate telephone or Skype connections to allow outside participation. Times are rarely adjusted for family convenience but may be shifted at the last minute to meet staff needs.

If timing conflicts do not allow family participation, arrangements should be made for the family to meet with one of the team members who can summarize the findings from each of the disciplines and fully inform the family about the care plan and all medications. That individual, who may be a nurse, social worker, or rehabilitation therapist, should be prepared to resolve any outstanding concerns for the family.

Many professionals try to minimize the severity of resident disabilities in an attempt to reassure families. We may describe a resident who is continent and ambulatory, but forgetful, disoriented to time, and having a tendency to wander off at night as having "early Alzheimer's." But from the family's perspective, these are devastating changes. Failure to clarify functional deficits can produce false expectations regarding the trajectory of recovery. Of course, miracles do happen, but false hope only produces poor decisions and ongoing recriminations. Ironically, family guilt is allayed when the facility demonstrates exactly why nursing home placement is absolutely necessary.

Families who feel welcomed, listened to, and informed are unlikely to be suspicious, demanding, or obstructive. Communication is a sign of respect. In order to get respect, we must demonstrate respect.

Dr. Nichols *is president of the New York Medical Directors Association and a member of the* Caring for the Ages *Editorial Advisory Board.*

Glycopyrronium Improves Health Status, Lung Function in COPD

BY SHARON WORCESTER

DENVER — Twice-daily treatment with the long-acting muscarinic antagonist glycopyrronium improved health status and lung function in patients with chronic obstructive pulmonary disorder and moderate to severe airflow limitation in the randomized, double-blind, placebo-controlled GEM2 (Glycopyrronium Effect on Symptoms and Lung Function) study.

In patients with stable symptomatic COPD with moderate to severe airflow limitation, twice-daily 12.5-mcg dosing of glycopyrronium provides clinically meaningful improvement in lung function over the 12-hour dosing interval, has early onset, and is sustained over 12 weeks when compared with placebo. It is also associated with significant improvements in COPD symptoms, health status, and rescue medication use, as well as numerical improvement in dyspnea scores, Edward Kerwin, MD, of the Clinical Research Institute of Southern Oregon, PC, Medford, and his colleagues reported in a poster at an international conference of the American Thoracic Society.

Lung function — as measured by forced expiratory volume in 1 second (FEV_1) area under the curve from 0 to 12 hours (AUC 0-12h) — was significantly better both at day 1 and at week 12 of treatment in 216 patients who were randomized to receive a 12.5 mcg twice daily dose of the fast-onset, long-acting muscarinic antagonist (Novartis), compared with 216 patients who received placebo; there was a "significant and clinically meaningful between-treatment difference of 119 and 123 mL, respectively," the researchers wrote.

"Glycopyrronium also showed consistently significant improvements in trough FEV_1 vs. placebo at all assessed time points," they said, adding that glycopyrronium showed an early onset of bronchodilation with significant improvements in FEV_1 at 5 and 15 minutes post dose, compared with placebo at day 1 and week 12.

The least squares mean treatment differences for glycopyrronium vs. placebo for change from baseline in trough forced vital capacity (FVC) were 171 mL on day 2, and 130 mL at week 12. Peak FEV_1 and peak FVC were significantly improved with glycopyrronium vs. placebo on day 1 (least squares mean treatment differences of 137 and 223 mL, respectively) and at week 12 (least squares mean treatment differences of 148 and 201 mL, respectively).

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Patients in the study needed fewer daily puffs and had less need for rescue medications.

Health status was improved at week 12, with both significant and clinically meaningful improvements in St. George's Respiratory Questionnaire total score in the treatment vs. placebo group (–6.4 vs. –1.2), and the percentage of patients achieving minimal clinically important differences (MCID), defined as at least 4 units, was significantly higher in the treatment vs. placebo group (54.9% vs. 42.3%), the investigators said.

Additionally, numerical improvements in transition dyspnea index total score and percentage of patients achieving a MCID, defined as at least one unit, were observed at week 12 in the glycopyrronium vs. placebo group.

Wide-Ranging Improvement

Patients in the glycopyrronium group showed improvement on all symptoms scores and endpoints, according to data recorded in patient e-diaries, and those in the treatment group also were able to perform usual daily activities significantly more often than those in the placebo group.

"A statistically significant decrease in daily, daytime, and nighttime number of puffs, and a significant increase in the percentage of days with no rescue medication use were observed," the investigators noted.

Patients included in the multicenter GEM2 study were adults aged 40 years and older with moderate to severe airflow limitation (GOLD 2011 strategy level 2 or 3), who were either current or former smokers with a smoking history of at least 10 pack-years. All had postbronchodilator FEV_1 of at least 30% and less than 80% of the predicted value, and postbronchodilator FEV_1/forced vital capacity ratio of less than 0.70 at a run-in visit.

They also all had a modified Medical Research Council grade of 2 or greater at the run-in visit. Patients with a history of asthma or with a COPD exacerbation requiring treatment with antibiotics and/or systemic corticosteroids, and/or with hospitalization within 6 weeks of the screening and run-in periods were excluded, as were those with a history of long QT syndrome or whose corrected QT was greater than 450 ms at the run-in visit.

All underwent an initial 1- to 7-day washout period and a 2-week run-in period prior to randomization, as well as a safety follow-up period. Patients received either glycopyrronium 12. 5 mcg or placebo twice daily delivered via the Neohaler device for 12 weeks.

Well Tolerated

Treatment was generally well tolerated; of the 430 patients included in the safety set, 44 permanently discontinued treatment due to adverse events (4.6% and 4.2% in the treatment and placebo groups, respectively). The number who experienced at least one adverse event during the treatment period was similar in the two groups; COPD was the most common adverse event, occurring in 20.8% of those in the treatment group and 21.5% in the placebo group.

A nonfatal myocardial infarction occurred in one patient in the treatment group.

Laboratory parameters and vital sign findings were comparable in the two groups.

Based on the findings of the GEM studies, Novartis has submitted a New Drug Application to the Food and Drug Administration; glycopyrronium is already approved in more than 70 countries, including countries in Latin America and the European Union, as a once-daily treatment marketed as the Seebri Breezhaler.

The GEM2 study was sponsored by Novartis Pharmaceuticals. Two of the study researchers are Novartis employees.

SHARON WORCESTER is with the Southeast bureau of Frontline Medical News.

Umeclidinium Triple Therapy Improves Lung Function

DENVER — Lung function and health-related quality of life improved for patients with chronic obstructive pulmonary disorder who received the long-acting muscarinic agent (LAMA) umeclidinium with fixed-dose inhaled corticosteroid/long-acting beta antagonist (LABA) therapy, based on a post hoc analysis of pooled data from four phase III trials.

Compared with inhaled corticosteroid (ICS)/LABA therapy alone, the triple therapy increased the number of rescue-free days, Thomas Siler, MD, a pulmonologist with Midwest Chest Consultants, St. Charles, MO, reported at an international conference of the American Thoracic Society.

The analysis involved 819 patients treated with 62.5 mcg of umeclidinium (Ellipta) — an approved maintenance treatment for COPD — plus ICS/LABA, 821 patients treated with 125 mg umeclidinium plus ICS/LABA, and 818 who received placebo and ICS/LABA. Statistically significant improvements were seen with active triple therapy vs. dual therapy plus placebo in forced expiratory volume in 1 second (FEV_1) at day 85 (0.130 L) and at all other time points, as well as in 0 to 6 h weighted mean FEV_1 at day 84 (0.152 L), Dr. Siler said.

With active triple therapy vs. dual therapy plus placebo, overall rescue use was reduced by 0.3 puffs/day, and the number of rescue-free days increased by 7.1%. Also, St. George's Respiratory Questionnaire (SGRQ) score at day 84 decreased by 1.55 vs. placebo, and the proportion of SGRQ responders was 41% vs. 31% for umeclidinium vs. placebo (odds ratio, 1.6).

Moderate/severe COPD exacerbations were experienced by 88 patients: 31 (4%) of the umeclidinium group patients and 57 (7%) of the placebo group patients.

The findings were similar in the patients who received off-label 125-mg dosing of umeclidinium, and the incidence of adverse events and serious adverse events was similar across treatment groups, Dr. Siler noted.

Data on the benefits of LAMAs in triple therapy in patients with moderate to very severe COPD are limited. This pooled analysis of data from four randomized, double-blind, parallel-group 12-week trials of once-daily add-on umeclidinium included COPD patients who entered a 4-week run-in on open-label ICS/LABA (either fluticasone furoate/vilanterol 100/25 mcg or fluticasone propionate/salmeterol 250/50 mcg), and who were then randomized to receive 62.5 or 125 mcg of umeclidinium or placebo.

GlaxoSmithKline funded the study.

—SHARON WORCESTER

More Older Adults Needed in Cancer Trials

BY MARY ANN MOON

Cancer research must include more older adult participants because the evidence base for treating this patient population is too sparse, according to an American Society of Clinical Oncology position statement published online in the *Journal of Clinical Oncology.*

Key evidence is lacking because older adults are usually excluded from clinical trials, even though most cancer patients are 65 and older. Both patients and their clinicians are forced to base treatment plans on data from younger, healthier patients, from studies that often don't even consider endpoints that matter most to them: not just survival rates but quality of life measures and rates of functional independence.

'We need to see clinical trials that mirror the age distribution and health risk profile of patients with cancer.'

Moreover, older adults respond differently than younger adults to cancer treatments because age-associated physiologic changes, higher incidence of comorbidities, and greater use of medications may interact with cancer therapies. "We need to see clinical trials that mirror the age distribution and health risk profile of patients with cancer," said Arti Hurria, MD, coauthor of the statement and director of the cancer and aging research program at City of Hope, Duarte, CA, and her associates.

The position statement includes five recommendations and 16 specific action items to achieve this goal.

First, the cancer research community — regulatory agencies, study funders, and researchers — must expand eligibility criteria so that more older adults can participate in studies. A rationale must be provided for all restrictions based on age, performance status, or comorbidities. And funders such as the National Cancer Institute and the National Institute on Aging should incentivize research that includes older adults.

Second, research design and infrastructure must be used to incentivize the inclusion of older adults. For example, Medicare could cover the off-label use of cancer therapies in older patients in selected trials, and research databases could be encouraged to collect information pertaining to older patients.

Third, the Food and Drug Administration should be given authority to both incentivize and require studies to include older adults. For example, the agency could reward drug manufacturers for including older patients in trials of new cancer therapies by granting them 6-month patent extensions, or it could encourage the development of new agents by expediting their review. Alternatively, the FDA could limit the compensation available to manufacturers that don't include older study subjects. And the FDA should include geriatrics experts on its advisory boards, such as the Oncology Drug Advisory Committee.

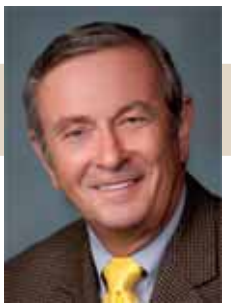
Fourth, clinicians should encourage the recruitment of their older patients into clinical trials. The single most important predictor of whether or not a cancer patient enrolls in a study is that his or her clinician has recommended it. And one way to increase such recommendations is to increase reimbursement for the time and effort it takes clinicians to find and explain relevant studies to patients.

Finally, professional journals should incentivize researchers to report on the substantial data they already collect about older study subjects, but do not analyze or report on. And professional journals should include geriatric oncology experts on their editorial boards and as peer reviewers, to ensure that cancer research results are applicable to the majority of people who have cancer, according to the position statement (*J Clin Oncol* 2015 July 20 [doi:10.1200/JCO.2015.63.0319]).

This position statement was supported by a subcommittee of the American Society of Clinical Oncology's cancer research committee.

MARY ANN MOON *is a Frontline Medical News freelance writer based in Clarksburg, MD.*

Community LTC



By Bill Kubat, LNHA

Geriatric Med Ed Preps New Recruits for a Fast-Changing Future

Remember Bob Dylan's classic song, "The Times They Are A-Changin' "? That's true of many things, but it's certainly true of geriatric medical education. How and when geriatrics is introduced broadly into the medical school curriculum is one aspect of that evolution; postdoctoral geriatric fellowship program (GFP) curriculum is another.

Geriatric medical education in American medical schools has improved over the past 30 years, yet it is still facing many challenges. The familiar statistics tell the story: The number of Americans older than 65 will nearly double by 2025, making them the fastest growing age group in the country. As of 2014, there were fewer than 7,500 geriatricians in the United States. Only eight of the country's 145 academic medical centers have full geriatrics departments, while only 44% of the nation's 350 geriatric fellowship positions are filled.

The history of geriatric medicine and geriatric medical education is relatively recent. Geriatric medicine originated in the 1950s in the United Kingdom. In the United States, backed by significant financial support from Congress in the 1970s, the specialty of geriatrics slowly grew into more formalized academic programs. In 1988, geriatric board certification was initiated.

But despite the growth of the field and the looming number of practitioners that will be required to care for the nation's elders, it is difficult to attract and recruit family and internal medicine residents into geriatrics.

Continuing Education

Regarding community LTC, the question is this: As the health care environment changes, how is medical education changing to prepare physicians to be effective and successful in adapting new models and settings of care delivery? How are the postdoctoral fellowship programs changing? Are experiences in the nuances of facility-based care, ambulatory care, and home-based care adequately addressed?

There are promising indications that medical education is keeping up. One significant sign is recognizing that caring for elderly patients must include an understanding of the care setting. An article reported in the *Journal of the American Geriatrics Society* by Susan M. Parks, MD, and colleagues (*J Am Geriatr Soc* 2014;62:930-5) described the current thinking about "curricular milestones" for geriatric fellows, terminology used by the Accreditation Council for Graduate Medical Education to describe competency-based medical education.

The milestones fall into three domains:

- Caring for the elderly patient: This is made up of seven areas including gerontology, diseases in older adults, and functional impairment and rehab, among others.
- Geriatric syndromes: These syndromes comprise nine areas including cognitive, affective, and behavioral health.
- Care settings and systems-based care for the elderly patient: These areas include hospital care, ambulatory care, home care, long-term care, and nursing home care. Understanding the care setting is as important as the impact of polypharmacy.

Leaders in Geriatrics

I visited with two credible voices from the trenches of geriatrics practice, geriatric medical education, and geriatric fellowship programs: David Sandvik, MD, CMD, from the Sanford School of Medicine (SSOM), University of South Dakota, Vermillion, SD, and Laura Morton, MD, CMD, from the University of Louisville, Louisville, KY.

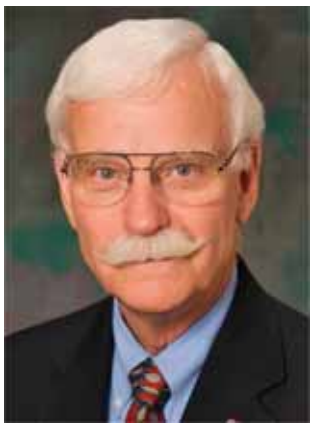
Dr. Sandvik began his practice in Rapid City in 1980 and is currently professor of internal and family medicine at SSOM. He also has served as program director for the SSOM geriatric fellowship program since its inception in 2010. Dr. Morton is an assistant professor in the department of family and geriatric medicine and is director of the geriatric medicine fellowship program at the University of Louisville School of Medicine.

I asked Dr. Sandvik and Dr. Morton about their own perspectives related to the changes they've seen in health care delivery and medical education.

In reflecting on more than 35 years of practice, Dr. Sandvik holds two convictions closely. First, he said the goal of geriatric health care has never changed, and that is "to get people home," regardless of where they are currently or where they consider to be their home. Second, "hospitals can be very dangerous places for older people," he said.

To that end, he and others pioneered the implementation of a comprehensive geriatric assessment process in Rapid City Regional Hospital years ago. In this process, an interdisciplinary team focuses on evaluation, care coordination, and rehabilitation. "If the admission was on Monday, the team met on Wednesday," Sandvik said. Few older patients can meet or tolerate the hospital rehab threshold of 3 hours of therapy daily, and so for many, "the ticket home is through the skilled nursing facility."

Dr. Sandvik also added that the increased emphasis on continuity and transitions of care is not completely new; this focus began with the introduction of diagnosis-related groups in the 1980s. Today, with accountable care organizations and bundled payments, the focus on care transitions has increased.



David Sandvik, MD, CMD, and Laura Morton, MD, CMD, agree that student exposure to the geriatrics field is growing, but there is still room for improvement.

Dr. Morton said that she "grew up in nursing homes" and worked as a certified nursing assistant in college. She admitted to a bias toward facility-based care because working with the interdisciplinary team is easier than in home-based or ambulatory care. Generally, in the nursing home, the team is right there and easier to convene. The team-based approach thrives as well in the clinic or in home-based care, but communication and subsequent delivery of care can be fragmented.

Both Dr. Sandvik and Dr. Morton referenced the Veteran's Affairs' Home Based Primary Care program as a model that both fellowships include in their rotations. The program's purpose is to better serve veterans' care needs and preferences by more effectively caring for complex patients at home. A key component of the model is that the interdisciplinary team meets once a week to review all clients. As Morton said, that is effective, but "hard to do elsewhere."

Although almost 30 years separate the medical school/residency experience for Dr. Sandvik and Dr. Morton, both agree that the exposure to geriatrics is better now than it used to be, but there is still room for improvement. Even given Dr. Morton's relatively recent experience in medical school, she still had to seek out ways for geriatrics to receive exposure. These are now built into the curricula — perhaps not as extensively or universally across all students, but there are more opportunities than before.

How do these two fellowships help prepare the next generation of LTC physician leaders?

In South Dakota, which has had a program since 2011, there have been seven fellows, and all but one have been mid-career practitioners as opposed to those directly out of residency. Last year, the fellowship also recruited part-time practicing physicians; for example, currently, the program has two hospitalists as part-time fellows. This has required creative thinking about how to "take the GFP to the fellow," not vice versa. Dr. Sandvik described the model as building toward a multi-campus experience with rotations across settings and communities. The rotations are key: nursing home, hospital, VA, home health, and a rural, remote telemedicine nursing home support system (*e*LTC) rotation. The fellows' CMD certification is also built into the fellowship year.

Recruitment Successes, Woes

The University of Louisville School of Medicine recently celebrated the 15th anniversary of its geriatric fellowship program. As with most programs, if not all, recruitment has been a challenge. There used to be three slots for fellows; this has been reduced to two. The strength of the Louisville program is its faculty, who serve as medical directors at five facilities, and the diversity of its practice settings, including the VA home-based primary care program, VA palliative care unit, the physical medicine, and rehabilitation rotation at the university hospital. An in-depth continuity nursing home experience that involves both a clinical and an administrative rotation, and a didactic component that prepares the fellow for leadership and active participation in preparing lectures on case review, serve as a strong foundation for geriatric education and practice.

The respective GFPs of Dr. Sandvik and Dr. Morton certainly align with what Dr. Parks described as "curriculum milestones" for graduating geriatric fellows — the inclusion of "systems-based care for the elderly patient" that accounts for the nuances of different care settings.

Mr. Kubat *is director of mission integration for the Evangelical Lutheran Good Samaritan Society. He is an editorial adviser for* Caring for the Ages *and coordinates the work of various authors for this column.*

Insulin Resistance Linked to Decreased Brain Metabolism

BY AMY KARON

Insulin resistance was linked to decreased brain glucose metabolism and predicted worse memory function among late–middle-aged adults at risk for Alzheimer's disease, researchers reported online in *JAMA Neurology.*

Based on the findings, "midlife may be a critical period for initiating treatments aimed at preventing or delaying the onset of Alzheimer's disease," said Auriel A. Willette, PhD, of Iowa State University, Ames, and his associates. Targeting insulin signaling might affect central glucose metabolism and should be studied in presymptomatic Alzheimer's disease, the researchers added.

The investigators performed cognitive testing, blood assays, and fludeoxyglucose F^{18} (FDG)–labeled positron emission tomography (PET) for 150 cognitively normal, late–middle-aged adults who averaged almost 61 years old. In all, 72% of participants were women, 69% had a parent with Alzheimer's disease, about 41% had an APOEε4 allele, and almost 5% had type 2 diabetes mellitus, the investigators reported (*JAMA Neurol* 2015 July 27 [doi:10.1001/jamaneurol.2015.0613]).

Based on the homeostatic model assessment, increased peripheral insulin resistance was significantly associated with decreased glucose metabolism, both globally and in large areas of the frontal, lateral parietal, and medial and lateral temporal lobes, Dr. Willette and his associates found.

Insulin resistance and lower glucose uptake were especially robustly associated in the left medial temporal lobe, and lower glucose metabolism in this lobe was associated with worse immediate and delayed memory performance factors. "This finding provides a potential link between insulin resistance and cognitive decline," they wrote.

The findings also support results from previous studies of older adults that have linked insulin resistance, hyperglycemia, and diabetes mellitus to hypometabolism on FDG-PET. "Insulin resistance and hyperglycemia are related conditions, and hyperglycemia, even in the prediabetic range, is associated with a significantly increased risk for later development of dementia," they noted.

The investigators reported no relevant conflicts of interest.

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Blacks With Alzheimer's Have Mixed Pathologies

BY LUCAS FRANKI

Black patients with Alzheimer's disease dementia are much more likely to have an Alzheimer's pathology mixed with another pathology than are white patients, according to Lisa Barnes, PhD, and her associates.

In a prospective study of 122 patients enrolled in the Rush Alzheimer's Disease Clinical Core, just under 20% of black patients had Alzheimer's pathology as the only cause of dementia, compared with 42% of white patients. About 71% of black patients had Alzheimer's pathology mixed with another pathology, such as Lewy bodies and infarcts, while just over half of white patients had mixed pathology. Black dementia patients also had higher rates of arteriolar sclerosis and atherosclerosis. The 41 black decedents were matched two-to-one to 81 white decedents according to age at death, sex, and cognition proximate to death.

"Given that most current therapeutic strategies focus primarily on the modification of amyloid, a central AD pathology, it will be important to develop new treatments that target other common pathologies, particularly in African Americans," the investigators noted in their study (*Neurology* 2015;85:528-34).

Lucas Franki is a web content editor at Frontline Medical News.

Freedom of Choice

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on a National Symposium Task Force, partnering the Pioneer Network with the Centers for Medicare & Medicaid Services. At the time, many facilities were having difficulties complying with two separate and distinct sets of regulations.

The first, or the "care" regulations (requiring the best evidence-based and clinical expertise), said facilities must:

- Determine and offer care for assessed needs.
- Follow physician's diet orders and regularly scheduled dining times.
- Ensure residents are safe from negative outcomes such as choking, aspiration pneumonia, and high blood glucose.

The other "rights" regulations stipulated that facilities must:

- Allow the resident the right to decline medical therapy.
- Respect the quality of life decisions of residents.
- Provide reasonable accommodation for dining place and time.

The "care" and "rights" regulations were often at odds with each other, and facilities were concerned about receiving a deficiency practice citation if they respected rights and failed to deliver or ensure that care needs were met (see "Survey Interpretation of Regulations" at www.pioneernetwork.net/Data/Documents/CreatingHomeOnline/Paper-Handy.pdf).

The task force was fortunate to have two medical directors who were actively involved in AMDA: Matthew Wayne, MD, CMD, chief medical officer, Summa Physicians and New Health Collaborative, Summa Health System, in northeast Ohio, and Karyn Leible, MD, CMD, geriatrician, Centura Health, Westminster, CO. Their paper, entitled "The Role of the Physician's Order," contained a concise recommendation list at the end that would become the basis of ten dining practice standards (www.pioneernetwork.net/Data/Documents/CreatingHomeOnline/Paper-WayneandLeible.pdf). The task force emphasized the removal of negative terms such as "noncompliant" or "refuses" from care planning and encouraged respectful terms such as "honoring" resident choice and preferences.

Although it is not a simple, clear cut process, the facility staff has a responsibility to "assess and offer" appropriate, individualized care needs. This is followed by discussion and documentation with the resident (or surrogate decision maker on behalf of the resident), to determine his or her desires and identify the potential outcomes. The ten Dining Practice Standards (DPS), approved by 12 national organizations (including AMDA), was issued in August 2011 by the Pioneer Network (www.pioneernetwork.net/Providers/DiningPracticeStandards), to guide staff in making the best decisions for their residents. These are:

- Individualized Nutrition Approaches/ Diet Liberalization
- Individualized Diabetic/Calorie Controlled Diet
- Individualized Low Sodium Diet
- Individualized Cardiac Diet
- Individualized Altered Consistency Diet
- Individualized Tube Feeding
- Individualized Real Food First
- Individualized Honoring Choices
- Shifting Traditional Professional Control to Individualized Support of Self Directed Living
- New Negative Outcome

The first standard, Individualized Nutrition Approaches/ Diet Liberalization, includes the following statement from AMDA: "Weight loss is common in the nursing home and associated with poor clinical outcomes such as the development of pressure ulcers, increased risk of infection, functional decline, cognitive decline and increased risk of death. One of frequent causes of weight loss in the long-term care setting is therapeutic diets. Therapeutic diets are often unpalatable and poorly tolerated by older persons and may lead to weight loss. The use of therapeutic diets, including low-salt, low-fat, and sugar-restricted diets, should be minimized in the LTC setting. Swallowing abnormalities are common, but do not necessarily require modified diet and fluid textures, especially if these restrictions adversely affect food and fluid intake."

Each dining practice standard concludes that all decisions are to default to the resident. One unique standard is the "New Negative Outcome," based upon a paper by Judah Ronch, PhD, entitled, "Dining, Memory and Aging: Food for Thought." In it, he uses the term "surplus safety," which means "conditions that prevent autonomous thinking or action and the satisfaction that decision-making brings because of an exaggerated fear that harm will come to the elder. This prevents the consequent cognitive, motor, emotional or other adaptive growth and development that would result if novelty had been pursued. Surplus safety assumes that the person will not be able to recover from the error or restore homeostatic balance if she makes a bad choice, and further that an elder does not have the developmental readiness to take the risk that the novel stimulus presents and to learn from the experience" (https://www.pioneernetwork.net/Data/Documents/CreatingHomeOnline/Paper-Ronch.pdf

The survey process evaluates how the facility staff prevents physical negative outcomes (weight loss, skin breakdown, labs that are not within normal limits). How will this new negative outcome standard be evaluated? It may be helpful to ask the following questions:

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Real food options, including high calorie/high protein choices, are preferred over supplementation.

- Will residents be informed and feel empowered to partner with facility staff in making quality of life dining decisions?
- Are facility staff members steadfast in old practices and reluctant to allow residents to make decisions that would put them at risk?
- Are attending physicians liberalizing diets that come from hospital transfer orders based on diagnosis?
- Are diet orders customized according to the resident's wishes (e.g., "regular diet with sugar-free desserts and sugar substitute" instead of "carbohydrate controlled" or "diabetic," and "regular diet with no-salt packet and low potassium foods of resident choice" instead of "renal diet")?

Implementing Choice on Record

Customizing and individualizing diets according to a resident's wishes has become the standard for one of the largest nursing home groups in the country, and facilities in the group now embrace the new dining practice standards. This group has determined that only one diet can be checked off on the diet list, which has invited liberalization and thoughtful change in the ordering of diets. Originally this determination was a reaction to deficiencies being given when dietary staff could not produce and have on the tray line all the restricted items of multiple diet orders, and could not follow multiple columns on tray lines from the "modified" menu.

The "one diet" concept means one column to follow for tray line or when serving in the dining room. The diet that is checked off may be a regular diet or a texture-modified or puree diet. Then the customized diet adds a drop down menu in the PointClickCare electronic health record, with specifics aimed at individual patient requirements and portion size. When the diet list is printed as a reference to nurses and activities staff, it includes all the specifics for each individual resident.

When the Resident Arrives

The process of developing an appropriate diet starts with the resident's admission to the nursing home. One of the first staff interactions for a new resident is held with the dietary manager, who usually prescreens the

PA/LTC Perspective

This is an interesting article, remarking on the ongoing tension between fear of survey deficiencies and respect for resident rights, with unwritten references to today's hot topics of patient-centered care, quality of life and goals of care. The link is how an involved medical director can think outside the box to directly improve resident satisfaction.

And this isn't even about any specific medical issue — we're talkin' food here! Food, universally acknowledged as one of the most important aspects of resident quality of life across the spectrum of post-acute/long-term care. The concept of liberalization of diet is long-recognized, both for resident satisfaction and lowering error rates in facilities. It's unfortunate that the Dining Practice Standards approved in 2011 have not achieved as much traction as one might have hoped, despite the involvement of two esteemed AMDA past-presidents Karyn Leible, MD, CMD, and Matthew Wayne, MD, CMD.

There are certainly barriers in the area of ordering diets and using best practices in this arena:

- Physicians don't regard this as a "medical" issue.
- Speech language pathologist evaluations don't always correlate clinically (we have all seen residents made NPO who are able to eat without apparent difficulty).
- An unpalatable therapeutic diet can be under-recognized as a cause of weight loss.
- Sodium restriction has become more of a knee-jerk order as congestive heart failure protocols become increasingly common, based on lowering hospital readmission rates (arguably based on financial imperatives, not resident wishes).
- Frequently, attending physicians do not change any admission orders from the hospital, including the diet — in fact, the type of diet is commonly not even mentioned or looked at by health care providers.

Unfortunately, achieving the "right" diet for a resident can turn into a no-win situation for the facility. Giving a less restrictive diet means a resident's medical concerns are not addressed, while a more restrictive diet runs counter to the resident's wishes — in either case, leading to a survey deficiency. Education, communication, and documentation (the holy triad of good medical care) are essential here. Although other members of the interdisciplinary team are crucial in establishing best practices for diet liberalization, the medical director can provide assistance, support, and current references to help champion this cause, as well as provide leadership through the use of the QAPI process.

—Daniel Haimowitz, MD, FACP, CMD
Levittown, PA

patient for traditional dietary preferences, allergies, intolerances, and preferred location of dining (i.e., in room or dining room). Many dietary managers are expanding this initial interview with questions about the resident's diet preferences and when the resident normally eats (i.e., late breakfast, snacking throughout the day, late evening snack). New residents are informed that they may sleep in and have a right to a reasonable accommodation of a late breakfast and food opportunities throughout the day, as close to their usual home-like pattern as possible.

The nursing home should have clearly defined procedures for ensuring that there is follow-up documentation, education of risk/benefit, and alternatives offered by the physician, dietitian, and speech language pathologist.

Dietary managers use this prescreening opportunity to inform new residents about their dining rights by using open-ended questions, such as "Do you want to follow the ordered diet?" or "Do you know that you have a right to decide what diet is best for you?" When the resident does not want to follow the ordered diet, the first step is to try to get the order liberalized to honor the resident's choice. The nursing home should have clearly defined procedures for ensuring that there is follow-up documentation, education of risk/benefit, and alternatives offered by the physician, dietitian (for therapeutic diets), and speech language pathologist (for texture modified diets and thickened liquid restrictions.) Facilities can develop detailed negotiated risk agreements when high-risk diet items are provided to honor the resident's choice.

Other concerns that may be addressed during the prescreening of the resident include:

- Are the residents who are NPO (tube feed) also informed of their rights? Does the facility staff offer oral gratification of food with sips of water coupled with effective oral hygiene programs, such as the Frazier Free Water Protocol, which is defined in Pioneer Network's "Dining Standards Toolkit" (see "Ensuring Quality With Dining Standards Toolkit")?
- When nutrition interventions are required, are real food options, fortification programs, and high-protein/high-calorie snacks of choice emphasized vs. health shakes and supplements?
- Is the TwoCal Med Pass (60 cc or 120 cc of high calorie/protein supplement) considered for extra nutrition without diminishing the resident's appetite?
- Are creative hydration stations/carts and snack carts being implemented?

High Calorie/High Protein Needs

When a high-risk resident requires an increase in calories/protein, the attending physician, dietitian, and dietary manager should collaborate to implement the standard of "Real Food First." Does the dietitian make recommendations to the attending physician to obtain orders for fortified real food commercial products (e.g., Magic Cup Frozen Dessert, Home Care Nutrition, Hormel Health Labs) or for a planned "fortified diet" using specific fortification recipes for hot

See **Freedom of Choice** • *page 14*

For More Information

The Centers for Medicare & Medicaid Services announced surveyor training on the DPS and stated, "Research has indicated that many older individuals may not need to be limited to very restrictive diets, pureed foods, and thickened liquids even though they may have many chronic conditions. Conversely, restricting food choices can result in loss of appetite and eventual weight loss." For more information, see www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-13.pdf; and http://surveyortraining.cms.hhs.gov/pubs/VideoInformation.aspx?id=1101&cid=0CMSNEWDINPRSTAN.

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super cereal, soup, cheesy mash potatoes, or pudding, based upon resident preferences? Are cook staff trained to follow fortification recipes as ordered? This diet can provide 3000 calories/100 g protein daily if fortified items are consumed. Often the most at-risk resident is overwhelmed by a standard full meal and wants a small portion, so a fortified small portion ensures that every bite counts. Fortified small portions also reduce the plate waste/cost (feeding the garbage can) so prevalent in nursing homes.

Often residents come with established eating patterns of five or six small meals a day, which is now being implemented by some nursing homes. Diet orders can effectively redistribute the daily food allowance. Some have diet orders for a "fortified small portion" with high calories/protein snacks of choice between meals (cheese sticks, yogurt, peanut butter and crackers, fortified pudding, half a sandwich, fortified cookies and milk) vs. health shakes and supplements. Sometimes supplements may be necessary, such as when a resident will not eat but will drink; however, these should be ordered as the last resort.

Finally, adequate documentation of the additional calories/protein offered should be provided by the dietitian so that attending physicians and surveyors are able to follow up on how planned interventions are being accepted by the patient, and how they are meeting assessed nutrition needs. Constant monitoring is important. If the interventions are not being consumed, then consider trying new interventions.

Facility residents have a right to a diet that is enjoyable and nourishing. Implementing the dining practice standards described here will help serve our residents with the very best quality of life during their post-acute stay or during their long-term last days.

Ensuring Quality With Dining Standards Toolkit

The Pioneer Network issued a Dining Standards Toolkit in 2014, which can be found on the Pioneer Network website. The toolkit serves to "help communities and care teams in decision making to support individual choice and also mitigate risks that may arise due to honoring choice." It includes references to CMS regulations and interpretive guidance, demonstrating CMS support in enabling individuals to eat their preferred foods. It includes model policies and procedures, tip sheets, benchmark templating, resources, and printable brochures for residents and family (www.pioneernetwork.net/Store/DiningStandardsToolkit).

One of the reference documents in the toolkit is this author's presentation at Pioneer Network's annual conference on August 14, 2013, entitled "Applying CMS Mandated QAPI 5 Elements to Ensure the New Dining Practice Standards [DPR], Resident Rights, and Resident Performance Improvement Leaders" (www.cms.gov/SurveyCertificationGenInfo/Downloads/fiveelementsqapi.pdf). The presentation was based upon Deming's "Performance Improvement Method: Plan, Do, Study, Act" (www.ihi.org/knowledge/Pages/HowtoImprove/default.aspx). Highlights from this method include:

The Plan: Evaluate the regulatory requirements and standards of practice for liberalizing or eliminating resident diets when a resident refuses nutrition medical therapy (therapeutic or texture modified diet orders). Evaluate the facility's current practices compared to the regulatory requirements.

The Do: Develop and approve new protocols for staff to inform residents of their dietary rights, ensure staff training, and ensure appropriate documentation according to new protocols.

The Study: Monitor staff with audits to determine if the new protocols are followed.

The Act: Evaluate staff compliance to regulatory requirements and new approved protocols. Provide corrective actions when approved protocols are not followed, with additional training to meet and sustain goal thresholds.

Linda Handy *is a consultant for Crandall Corporate Dietitians. She works with long-term care facilities, including Brookdale, and develops manuals including, "Culture Change in Dining." She serves on the* Caring for the Ages *Advisory Board. For more information, visit www.handydietaryconsulting.com.*

Drug Combo

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for Alzheimer's disease patients and their caregivers," she said.

Approved for PBA

The formulation of dextrometh-orphan and quinidine used in the study already has Food and Drug Administration marketing approval with the brand name Nuedexta for treating pseudobulbar affect (PBA), which can occur in patients with, for example, amyotrophic lateral sclerosis or multiple sclerosis. In addition, the primary active ingredient in the combination, dextromethorphan, appears in many over-the-counter formulations of cough syrup that are labeled to deliver roughly similar dosages of the drug as those used to treat PBA and tested in the current trial to treat agitation. But the OTC formulations of dextromethorphan do not include quinidine, which inhibits dextromethorphan's metabolism and results in a roughly 20-fold increase in the bioavailability of the active agent, Dr. Cummings explained.

'Movement on treating this symptom has the potential to make a real difference for Alzheimer's disease patients and their caregivers.'

"With quinidine, we can use smaller dosages of dextromethorphan" than might be required if the drug were used by itself and thereby avoid the lethargy that could occur in patients who might require larger dosages of dextrometh-orphan without quinidine, he said in an interview.

The results he reported came from a study run at 44 U.S. centers that enrolled patients 50 to 90 years old with probable Alzheimer's disease and "meaningful" agitation secondary to their condition, who scored at least 4 on a Clinical Global Impression-Severity Scale for Agitation. The researchers excluded patients who had any other cause for their agitation. Enrolled patients averaged age 78 years, somewhat more than half were women, and they had an average score on the Mini Mental State Examination of about 17. The enrolled patients "looked like the population that you treat for agitation" secondary to Alzheimer's disease, Dr. Cummings said.

The 93 patients randomized to the investigational treatment started on 20 mg dextromethorphan and 10 mg quinidine administered orally once daily for a week, followed by an up-titration schedule over 2 weeks to reach 30 mg dextromethorphan twice daily plus 10 mg quinidine twice daily, the dosage they continued for an additional 7 weeks. The study design allowed patients to also continue on stable, preexisting regimens of memantine, cholinesterase inhibitors, and psychotropic medications.

After 10 weeks, the 93 patients on dextromethorphan plus quinidine had their average neuropsychiatric inventory domain score for agitation and aggression cut roughly in half — compared with baseline — compared with about a 25% drop in average score among 66 control patients, a statistically significant difference for the study's primary endpoint, Dr. Cummings reported. The results also showed statistically significant declines in the active-treatment vs. control arm in certain secondary efficacy measures, including patient-reported quality of life and caregiver-reported strain.

The active treatment also appeared generally well tolerated, compared with placebo. The most noteworthy safety finding was an increased rate of falls among patients on dextromethorphan plus quinidine, a 9% rate, compared with a 4% rate in the controls, a signal for this adverse effect not previously seen in other studies of dextromethorphan plus quinidine. "We were surprised with the increased falls," Dr. Cummings said. By chance, patients randomized to the active-treatment arm had an increased history of falls, compared with patients enrolled in the control arm, which may explain the safety finding, he noted. "We will monitor falls very closely in our follow-up studies," he said.

Effective for Dementia

A separate report at the meeting presented a new analysis of data from an open-label study that examined the same dextromethorphan plus quinidine formulation to treat 134 patients for 12 weeks with PBA secondary to dementia, stroke, or traumatic brain injury. The overall results showed that the combined formulation effectively reduced PBA in all enrolled patients, including those with dementia, a subset that predominantly included Alzheimer's disease patients. The results also showed a modest 2% rate of falls, said Rachelle S. Doody, MD, PhD, a professor of neurology and director of the Alzheimer's Disease and Memory Disorders Center at Baylor College of Medicine in Houston. The new findings she reported at the meeting showed that the combined drug formulation worked equally effectively in the subset of patients with dementia, regardless of whether or not they concurrently received treatment with an antidepressant.

Clinicians should avoid using the formulation to treat agitation in Alzheimer's disease patients until data become available from phase III studies that involve at least 6 months of chronic therapy.

Despite availability of the dextromethorphan plus quinidine formulation, clinicians should avoid using it to treat agitation in Alzheimer's disease patients until data become available from phase III studies that involve at least 6 months of chronic therapy, Dr. Cummings said. "We don't want to encourage off-label use of the combined formulation until we understand it better when treating agitation in Alzheimer's disease," he cautioned.

He also highlighted the difficulty in enrolling Alzheimer's disease patients with agitation as a significant symptom into trials, which means that completing a phase III trial could take perhaps as long as 2 more years and that FDA approval of this indication could be as long as 3 years off.

The study was sponsored by Avanir, the company that markets Nuedexta. Dr. Cummings has been a consultant to and has received honoraria from Avanir as well as from several other drug companies. He also owns stock or stock options in several companies developing drugs or other products aimed at Alzheimer's disease patients. Dr. Sano has been a consultant to Eisai, Eli Lilly, and Takeda. Dr. Doody has been a principal investigator for trials sponsored by Avanir and several other drug companies. She also has been a consultant to several drug companies.

MITCHEL L. ZOLER *is with the Philadelphia bureau of Frontline Medical News.*

Editor's Note

Many clinicians have been using this product off-label for dementia-related agitation, although coverage can be a challenge and it is priced very high (over $700 a month) for those paying cash for it. It will be a welcome addition to the armamentarium if and when it is FDA approved for this indication, and certainly appears to be much safer than currently available off-label alternatives like antipsychotics. Although in my experience it's not dramatically effective, dextromethorphan/quinidine has definitely provided appreciable improvement in some of my agitated nursing home residents with dementias — probably more noticeably in those with vascular dementia and emotional lability, although that's not the indication being studied for possible FDA approval.

—Karl Steinberg, MD, CMD
Editor in Chief

Cognitive Impairment Signals Subclinical Vascular Disease

BY SARA FREEMAN

VIENNA — Measuring cognitive function might help determine if an elderly patient is at risk for developing a host of vascular diseases, including stroke and transient ischemic attack, research presented at the annual European Stroke Conference suggested.

The research, which has been accepted for publication in the *Journal of Neurology,* showed that lower performance in a measure of global cognitive function was associated with a 57% increase in the risk of stroke and a 69% increase in the risk of coronary heart disease.

"If a person has a poor performance or clinical impairment in cognitive function, it means that the clinician should perhaps be careful because the patient might be at risk of developing diseases such as stroke, [TIA], myocardial infarction, and so on," Somayeh Rostamian, PhD, a nurse scientist at Leiden (the Netherlands) University Medical Center, said in an interview.

During her presentation, she explained that it was well known that cardiovascular risk factors and diseases were associated with mild cognitive impairment. Data also have shown that mild cognitive impairment might signal the onset of common age-related neurologic diseases such as dementia.

"We hypothesized that mild cognitive impairment might be an early manifestation of vascular diseases in subjects without clinically recognized disease," Dr. Rostamian explained, suggesting it could be "the tip of the iceberg."

To test their hypothesis, the research team first performed a systematic review and meta-analysis (*Stroke* 2014;45:1342-8) to look at the available evidence on the association between cognitive impairment and stroke risk. The results showed that stroke risk was increased by 15% overall, although individual study estimates ranged from 1% up to 49%.

Deficits in executive function, rather than memory, were predictive of stroke and coronary heart disease.

"We then decided to look at the association between cognitive function, stroke, and coronary heart disease, and to evaluate the association between cognitive function domains and the risk of such diseases," Dr. Rostamian said.

Data on the cognitive function of 3,926 men and women between 70 and 82 years old were obtained from the randomized controlled Prospective Study of Pravastatin in the Elderly at Risk (PROSPER). This trial looked at the role of statin therapy in an elderly cohort that had or was at high risk of developing cardiovascular disease and stroke (*Lancet* 2002;360:1623-30). Results of the trial suggested that statin therapy might reduce the incidence of TIAs by up to 25%, but it did not reduce the risk for stroke or have an effect on cognitive function.

Nevertheless, the trial provided information on cognitive function that was assessed at enrollment and then annually, which could be used for the current study. Dr. Rostamian noted that the team used data from the Stroop Color and Word test, the Letter Digit Substitution test, and the Picture-Word Learning test, which evaluate selective attention, processing speed, and immediate and delayed memory, respectively. A composite score for executive function was obtained by combining the results of the Stroop and the Letter Digit Substitution tests, and a composite score for memory was obtained from the Picture-Word Learning test results.

Over a follow-up of just more than 3 years, there were 155 stroke and 375 coronary events, giving incidences of 12.4 and 30.5 per 1,000 person-years, respectively.

After adjusting for multiple confounding factors, patients in the low tertile of cognitive function had the higher risk of both stroke and CHD, compared with those in the high-cognitive function tertile who were used as a reference. Patients in the middle tertile also had an increased risk for both diseases.

The results also suggested that deficits in executive function, rather than memory, were predictive of stroke and CHD. So, it might be more important to assess patients' ability to perform tasks that involve their ability to pay attention or process information.

Indeed, when comparing patients in the low-cognitive and high-cognitive tertiles, the risk for stroke was 51% higher and the risk for CHD was 85% higher. In contrast, there was no increased risk linked to memory deficits, with an RR of 0.87 for stroke and 0.99 when comparing patients in the low- and high-cognitive tertiles.

"Impaired executive function, but not memory, was associated with increased risk of cardiovascular diseases and can be considered as an indicator of cardiovascular events. Lower performance in global cognitive function was associated with a higher risk of stroke and coronary heart disease," Dr. Rostamian summarized.

"Cognitive assessment might provide a tool for clinicians to identify older subjects at an extra risk for future cardiovascular events," she concluded.

Dr. Rostamian had no conflicts.

Sara Freeman is a Frontline Medical News freelance writer based in London.

FDA Approves First-in-Class Combo Drug for Heart Failure

BY JUDITH M. ORVOS, ELS

A pill combining valsartan and sacubitril has received first-in-class approval for heart failure under the Food and Drug Administration's priority review program. Entresto offers practitioners a new option for reducing risk of cardiovascular death and hospitalization in patients with NYHA class II-IV heart failure and reduced ejection fraction.

Previously known as LCZ696, Entresto (Novartis) is an angiotension receptor-neprilysin inhibitor that exerts effects on and beyond the renin-angiotensin system. It is the only treatment to show a significant mortality benefit in a head-to-head trial against the angiotensin-converting enzyme (ACE) inhibitor enalapril. The FDA approval was based on results from the PARADIGM-HF (Prospective Comparison of ARNI [Angiotensin Receptor-Neprilysin Inhibitor] with ACEI [Angiotensin-Converting-Enzyme Inhibitor] to Determine Impact on Global Mortality and Morbidity in Heart Failure) randomized clinical trial, which were presented at the European Society of Cardiology 2014 Congress in Barcelona, Spain.

More than 8,000 adults with class II, III, or IV heart failure and an ejection fraction of 40% or less were enrolled in PARADIGM-HF. Most of them were also receiving currently approved heart failure treatments, such as beta-blockers, diuretics, and mineralocorticoid antagonists. Compared with enalapril, the combination pill was found to reduce risk of death from cardiovascular causes by 20%, risk of heart failure hospitalizations by 21%, and risk of all-cause mortality by 16%. Statistically significant decreases in symptoms and physical limitations of heart failure were also reported. The trial was stopped early at median follow-up of 27 months because an overwhelming benefit for the combination pill was found. Death from cardiovascular causes occurred in 914 (21.8%) of patients taking the combination drug compared with 1,117 (26.5%) in the enalapril group.

Cardiologist Javed Butler, MD, MPH, co-director of the Heart Institute at Stony Brook University in Stony Brook, NY, said he found it encouraging that all of the subgroups studied in PARADIGM-HF showed benefit from receiving the combination pill. "In the absence of a specific trial in long-term care facility residents," said Dr. Butler, "we would have to assume that the drug would work in that population."

Jeffrey Nichols, MD, CMD, vice president of Home Care Services at Cabrini Eldercare in Dobbs Ferry, NY, felt that $400 per month that the company is likely to be charging for this "first-in-class" medication may give LTC facilities pause. "Nursing homes that manage post-acute heart failure patients will be torn over its use when evidence suggests marginal or unknown effectiveness, and its impact on long-stay residents will be minimal," he said. Dr. Nichols also noted that Entresto is primarily used for systolic heart failure, whereas the majority of residents in skilled nursing facilities with failing hearts have primarily diastolic dysfunction.

Analysis of safety data from PARADIGM-HF showed that the combination pill had a tolerability profile similar to that for enalapril. The most common adverse effects in the individuals taking it were hypotension, seen in 588 (14%) patients vs. 388 (9.2%) in the enalapril group, and elevations in levels of serum creatinine and potassium. Differences between the two groups for the latter two adverse events did not rise to statistical significance. Falls were reported in 1.9% of the group taking the combination pill vs. 1.3% of the patients treated with enalapril. Angioedema also was reported with the combination pill and the risk was higher in black patients (2.4% vs. 0.5%) and in patients with a prior history of angioedema.

Practitioners should be aware that Entresto should not be taken with any drug from the ACE inhibitor class because of the increased risk of angioedema. When switching patients on ACE inhibitors to Entresto, a 36-hour washout period between the administration of drugs is required. Dr. Nichols said he believes it is likely that some SNF residents who are taking enalapril or another ACE inhibitor may be switched to Entresto for the presumed benefit in fewer deaths that was associated with the drug in initial trials.

The recommended starting dose of Entresto is 49/51 mg twice daily and it is typically given in conjunction with other heart failure therapies in place of an ACE inhibitor or an angiotensin II receptor blocker (ARB). For patients with limited renal function or who are taking other drugs to control blood pressure, Dr. Butler suggested starting with half the dose and titrating upward. In some individuals with a low ejection fraction, he said, use of Entresto may make it possible to reduce the dosage of or eliminate medication for high blood pressure.

The tolerability and safety of uptitrating Entresto from an initial dose of 50 mg twice daily to a target dose of 200 mg twice daily was studied in TITRATION. A broader range of patients were enrolled in that randomized, double-blind trial than in PARADIGM-HF, including inpatients and individuals who had not taken ACE inhibitors or ARBs. More than 70% of the 429 patients who completed the study, which was open-label, achieved the target dose of 200 mg twice daily over a 3- or 6-week uptitration regimen.

Dr. Butler is on the steering committee for Novartis's pharmacovigilance registry.

JUDITH M. ORVOS, ELS, *is a freelance medical writer and president of Orvos Communications in Washington, DC.*

Legal Issues

By Janet K. Feldkamp, JD, RN, LNHA

CMS Sharpens Focus on Medication-Related Adverse Events

Although prescribed to address conditions and diagnoses, medications are inherently dangerous if not administered and monitored correctly. Residents in PA/LTC facilities are prescribed numerous medications and are very vulnerable to medication-related adverse events. Not only are nursing facilities required to administer medications per appropriate physician orders, but also the facilities must consistently follow policies and procedures for monitoring medication levels for a number of medications. The Centers for Medicare & Medicaid Services issued a Survey and Certification Memo on July 17, 2015 (www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-47.pdf). highlighting the agency's concerns about the prevalence of medication-related adverse events. The concern over medication-related injuries is not a new concern for CMS, state survey agencies, or nursing facilities.

Failure to Monitor Anticoagulants

Medication-related adverse events have resulted in many regulatory citations with resulting civil money penalties and other sanctions imposed by CMS. Two Departmental Appeals Board (DAB) cases outline concerns cited related to anticoagulant therapy and the potential dangers to residents, with failure to monitor for potential negative resident outcomes and failure to follow the standards of care. A 2011 DAB appellate case of Universal Health Care-King (Dec. No. 2383, June 2011) upheld the immediate jeopardy determination with more than 180 days cited by the North Carolina state survey agency related to a failure to adequately monitor warfarin (Coumadin) anticoagulant therapy. The three-judge appellate panel upheld the administrative law judge's findings that the facility failed to timely obtain laboratory monitoring and also failed to timely notify the physician of critically high blood levels, which placed the resident at significant risk of bleeding. In this instance, one resident was receiving warfarin therapy with the need for daily laboratory monitoring. On several occasions, the facility failed to timely obtain the necessary laboratory testing, which resulted in wide fluctuations in the blood activity level of warfarin and placed the resident either at risk of excessive bleeding or of potential thrombotic complications. The state survey agency cited, and the administrative law judge and the appellate panel upheld, the significant length of time for the immediate jeopardy based upon the failure to monitor and the failure to fully implement an effective system to prevent medication-related adverse events, particularly for anticoagulants.

Similarly, the DAB administrative law judge upheld the Louisiana State Agency's immediate jeopardy citation to Grace Nursing Home (CR2250, September 2010) and the issuance of a per instance civil money penalty for the failure to monitor anticoagulant therapy resulting in one resident's hospitalization for warfarin toxicity. The facility failed to obtain the ordered laboratory tests to monitor the warfarin activity (using International Normalized Ratio [INR] levels) for more than a week. The resident's INR rose to a critical level, resulting in approximately one week's hospitalization. These cases are just two examples of a number of DAB cases challenging immediate jeopardy citations related to the failure to adequately administer and monitor anticoagulants.

Tools for Surveyors, Providers

The recently issued CMS S & C: 15-47-NH DAB decision discusses the importance of preventing adverse medication events for a variety of medication types. Medications have significant potential side effects, and careful administration and adequate monitoring are necessary to protect residents' safety and well-being. The CMS issuance discusses the Office of Inspector General's (OIG) report of February 2014 on adverse events for Medicare beneficiaries in skilled nursing facilities. The OIG report found that 37% of the adverse events were related to medication and that the second most frequent cause of medication adverse events is related to excessive bleeding from anticoagulants.

CMS also reported that it has developed and is now pilot testing a Focused Survey on Medication Safety. The newest Focused Survey's objectives include:

- Identifying preventable adverse drug events that have occurred or potentially may occur
- Determining if the facilities are identifying risk factors for adverse drug events and implementing individualized interventions to eliminate or mitigate the risk factors
- Determining if facilities are implementing effective systems to prevent adverse drug events and recognizing and responding appropriately if and when adverse drug events do occur

Included with the S & C issuance was a CMS Adverse Drug Event Trigger Tool (www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf). This tool was developed in collaboration with the Agency for Healthcare Research & Quality. Surveyors were instructed to utilize the tool to identify complaint investigations related to adverse events. Use of this tool by providers can strengthen risk management programs and can be used as an educational tool for clinicians and management personnel. The tool provides adverse drug events, risk factors, triggers of signs and symptoms, and triggers for clinical interventions and surveyor probes. The tool is provided in an easy to use matrix format that is divided by types of adverse events.

The prevention of adverse medication events is an important component for the delivery of quality care to post-acute care residents. Nursing facilities must have robust policies and procedures for medication administration and monitoring. Good policies and procedures must be coupled with ongoing and consistent clinical and laboratory monitoring to avoid potential negative effects of medications. Without diligent policies, consistent administration and monitoring, and knowledgeable staff, medication errors can cause significant injury and even death to residents.

This column is not to be substituted for legal advice. The writer, Janet Feldkamp, *practices in various aspects of health care, including long-term care survey and certification, certificate of need, health care acquisitions, physician and nurse practice, managed care and nursing related issues, and fraud and abuse. She is affiliated with Benesch Friedlander Coplan & Aronoff LLP of Columbus, OH.*

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FDA Issues New Heart Attack, Stroke Risk Warnings for NSAIDs

BY JEFF EVANS

The Food and Drug Administration has taken new action to strengthen existing warning labels about the increased risk of heart attack or stroke with the use of prescription and over-the-counter nonaspirin nonsteroidal anti-inflammatory drugs.

In a recent drug safety communication, the agency did not provide the exact language that will be used on NSAID labels but said that they "will be revised to reflect" information describing that:

- Increased risk of heart attack or stroke can occur as early as the first weeks of using an NSAID.
- The risk may increase with longer use and at higher doses of the NSAID.
- The drugs can increase the risk of heart attack or stroke even in patients without heart disease or risk factors for heart disease, but patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use.
- Treatment with NSAIDs following a first heart attack increases the risk of death in the first year after the heart attack, compared with patients who were not treated with NSAIDs after their first heart attack.
- NSAID use increases the risk of heart failure.

The new wording will also note that although newer information may suggest that the risk for heart attack or stroke is not the same for all NSAIDs, it "is not sufficient for us to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID."

The update to NSAID labels goes against the recommendations given by panel members from a joint meeting of the FDA's Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee in February 2014 in which they said that the evidence about potentially new cardiovascular risks with NSAIDs that had been presented to them over the 2-day meeting was not sufficient to change labeling. The panelists also voted that there were not enough data to suggest that naproxen presented a substantially lower risk of cardiovascular events than did either ibuprofen or selective NSAIDs, such as cyclooxygenase-2 inhibitors.

Jeff Evans is a senior editor with Frontline Medical News.

Caring *for consumers*

More Isn't Always Better

Barney Spivack, MD, CMD, a post-acute and long-term care medical director and physician, talks about why some cancer screenings may not be advised for elders.

Although many tests, treatments, and interventions are useful and appropriate for frail elderly people, some screenings may not provide sufficient value, and they may subject individuals to unnecessary inconvenience, discomfort, and possible harm.

Patients in the post-acute and long-term care setting may have many chronic illnesses and health problems, limited mobility and cognitive loss, and life expectancies of less than 10 years. Studies about the impact of screenings for breast, colorectal, and prostate cancer in older adults in general, especially in PA/LTC residents, suggest that benefits of these screenings are limited.

While it's true that these screenings may help detect cancers before they spread, they are not without risks. For example, mammograms expose women to radiation and may cause discomfort. This test isn't perfect — false negatives, as well as false positives, are common. Some women may be subjected to additional tests, including biopsies, and the stress that accompanies these. Cost is another factor; working up false positive mammogram results can cost thousands of dollars.

Prostate cancer is usually slow-growing, and most nursing home residents will die of something else before cancer spreads beyond the prostate. The possible risks of prostate screenings include pain, bleeding, and infection associated with biopsies, as well as the mental stress and anxiety associated with false-positive test results. It also is important to note that this test doesn't always produce an accurate result.

The most common screening test for colorectal cancer, the colonoscopy, lets the doctor see the entire colon and rectum and remove abnormal tissue, such as polyps, and take samples for biopsies. However, the test might not detect all small polyps and cancers. Additionally, it involves several risks. For instance, it requires complete colon cleansing beforehand; and this means temporary diet, fluid, and medication changes. These can cause discomfort and other problems for older adults. At the same time, sedation is almost always needed, and this can be risky. Complications of the test also may include internal bleeding, cramping, bloating, and perforation.

Of course, all screening and care decisions should involve conversations with the individual's physician and other practitioners. These should include discussions about personal preferences, current illnesses, life expectancy, and health care goals. However, for most nursing home residents, experts generally discourage these screenings.

▶ Questions To Ask Your Practitioner

- What is my loved one's or my risk of having/getting various types of cancer?
- What lifestyle changes can my loved one or I make now to limit these risks?
- What are the benefits/risks of various cancer screenings for my loved one or me personally?
- What cancer screenings are likely to be of greatest benefit for my loved one or me, given personal health, life expectancy, and other issues?

▶ What You Can Do

- Make lifestyle changes to reduce your cancer risk, including not smoking, eating healthy, and staying physically active.
- Discuss the risks and benefits of various screenings and tests with your trusted practitioner.
- Complete an advance directive, physician order for life-sustaining treatment (POLST) form, or other document to outline your care preferences.

▶ For More Information:

- Colon Cancer Screening: Weighing the Options: http://mayocl.in/1nqvNYY
- The Pros and Cons of Screening for Three Cancers: http://bit.ly/1NEAGXE
- Mammography's Limits, Seldom Understood: http://nyti.ms/1gXjGBf
- Prostate Cancer Screening: Should You Get a PSA Test?: http://mayocl.in/1nLo31h

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Coding Errors Cost Millions in Overpayments

BY ALICIA GALLEGOS

Coding mistakes made on behalf of physicians and other health providers led to more than $35 million in Medicare overpayments for outpatient drugs, according to results from an audit by the Department of Health & Human Services Office of Inspector General (OIG).

Medicare contractors in 13 jurisdictions overpaid Medicare Part B providers by $35.8 million between July 2009 and June 2012. Erroneous codes and incorrect units of service submitted on behalf of those providers were the top reasons for the overpayments, according to the OIG report.

The medications most frequently overpaid because of incorrect units of service were adenosine, rituximab, infliximab, leuprolide acetate, and bortezomib.

Other common billing mistakes by physicians that resulted in overpayments included insufficient documentation about patient services; billing for outpatient drugs in which payment was already included in that of a primary procedure; incorrect use of Healthcare Common Procedure Coding System codes; and billing Medicare for noncovered outpatient drugs. As of May 4, the Centers for Medicare & Medicaid Services had recovered 63% of the overpayments found in the OIG audit, according to the report.

Alicia Gallegos is a Frontline Medical News freelance writer based in Chicago.

CLASSIFIEDS

PROFESSIONAL OPPORTUNITIES

Journal Highlights

Journal of the JAMDA American Medical Directors Association

From the September Issue of JAMDA

Cognitive Health Panel

When combined with medical and lifestyle interventions, identification of early cognitive impairment through case findings is an important step toward enhancing brain health among older individuals. This was the consensus of a panel convened by the International Association of Gerontology and Geriatrics (IAGG) and its Global Aging Research Network (GARN).

The panel, which met in St. Louis earlier this year, consisted of neurologists, psychiatrists, geriatricians, social workers, and psychologists. Using a survey of the panelists and results of focus groups made up of individuals with dementia, caregivers, and nursing home staff and volunteers, the IAGG-GARN panel examined the importance of early recognition of impaired cognitive health.

Key Areas Addressed

▶ *Screening vs. case finding.* The panel was divided about which was more essential for identifying early cognitive dysfunction: universal screening of all individuals within a certain category, such as age, or case finding among individuals with known risk factors, such as family history of dementia.

"Basically, there has been a lot of argument about whether there should be screening or case function for people with early cognitive dysfunction," said panel co-chair and JAMDA's chief medical editor, John E. Morley, MD, of Saint Louis University School of Medicine. "It's very hard to accept that physicians can't make the diagnosis, that they must have some sort of structured way."

The panel recommended using any of the validated screening tests that take 3 to 7 minutes to administer. "The committee recommended anything that takes under 5 to 6 minutes," Dr. Morley said. "[In] any family care practice, the quicker you can screen the better."

The panel also decided that a combination of patient- and information-based screens is the most appropriate approach for identifying early cognitive impairment.

▶ *Brain health.* The panel believed that using the term "cognitive health" rather than "mild cognitive impairment" might reduce public fears and encourage early detection and taking positive steps toward preserving cognitive function.

"We feel brain health is what this is about because there are things that clearly help everybody's brain," Dr. Morley said. "This is really a brain health initiative as well as to pick up [not only] people who may be going on to develop Alzheimer's but who may have a more treatable cause of cognitive dysfunction."

Indeed, research has shown numerous potentially reversible causes of cognitive impairment, especially when discovered early. Reversible causes include anticholinergic medications, polypharmacy, metabolic disorders, circulatory disorders, ischemic brain disorders, infections, sleep apnea, and depression, to name a few.

The consensus group also believed that health care providers can suggest preventive measures against cognitive decline. For example, studies have shown that adoption of a Mediterranean type diet can slow the progress of cognitive impairment, and that development of cognitive impairment is less likely in individuals who follow this diet. Some additional measures include physical activity, engagement in intellectual activity, learning to play a musical instrument, and even use of video games — all of which have been shown to slow cognitive decline.

"It makes no sense not to tell the patient they can do these things," Dr. Morley said.

▶ *Cognitive frailty.* This term considers potential parallel links between cognitive decline and physical frailty. Research suggests that a subgroup of individuals with cognitive impairment have reduced resilience and functional decline that coincide with physical frailty; converging evidence suggests that the cognitive status represents an important dimension of the frailty syndrome. Dr. Morley and the panel said that there isn't enough data to recommend screening for cognitive frailty and that more research is needed.

In addition to identifying early cognitive dysfunction in health care offices, Dr. Morley said, these concepts are essential in nursing homes to detect reversible causes of cognitive decline, enable temporary residents to leave sooner, take steps to slow the progress of the decline, and maintain quality of life.

▶ ***Source:*** *Brain Health: The Importance of Recognizing Cognitive Impairment, an IAGG Consensus Conference — Morley JE, et al.*

Diabetes and Frailty

Individuals with diabetes mellitus are more likely to become frail than non-diabetic individuals, but they can reduce this risk by improving how well they control their disease, according to a prospective cohort study in Spain.

Led by Esther García-Esquinas, PhD, of Universidad Autónoma de Madrid (Autonomous University of Madrid), researchers analyzed data on 346 individuals 60 and older who had diabetes, and 1,404 individuals without the disease. During a mean 3.5 years of follow-up, they identified 76 cases of frailty among the diabetic individuals, and 39 cases among those without diabetes.

After adjusting for age, sex, and educational level, participants with diabetes had 2.18 times the risk of developing frailty. This odds ratio dropped to as low as 1.01 after adjusting for obesity; health behaviors, such as smoking and alcohol consumption; morbidity at baseline; cardiometabolic biomarkers, especially HbA1c, lipoproteins, and triglycerides; and treatment with oral antidiabetic agents. The odds ratio increased to 1.64 when adjusting for nutritional therapy.

The increased risk of frailty was partly explained by unhealthy behaviors and obesity, poor glucose control, and altered serum lipid profile among diabetic individuals, the researchers said. High concentrations of glucose also might lead to chronic inflammation, a risk factor for frailty, and loss of skeletal muscle strengths.

"Our results suggest that the increased risk of frailty observed among diabetic individuals is mainly driven by reductions in walking speed and, to a lesser extent, by an increased risk of unintentional weight loss and weakness," the researchers wrote.

Nutritional therapy, however, might lessen these risks due to improved blood glucose and cholesterol control, the researchers said, adding that individuals who initiate nutritional therapy are likely to make other lifestyle changes such as regular exercise, smoking cessation, and weight loss, which also reduce the risk of frailty.

▶ ***Source:*** *Diabetes and Risk of Frailty and Its Potential Mechanisms: A Prospective Cohort Study of Older Adults — García-Esquinas E, et al.*

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amda The Society for Post-Acute and Long-Term Care Medicine

Caring for the Ages

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Caring for the Ages is the official newspaper of AMDA – The Society for Post-Acute and Long-Term Care Medicine and provides long-term care professionals with timely and relevant news and commentary about clinical developments and about the impact of health care policy on long-term care. Content for **Caring for the Ages** is provided by AMDA and by Elsevier Inc.

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BPA

NEWS FROM THE ASSOCIATION

Awards Open to NPs, PAs

Two of AMDA's top awards, which honor practitioners who display exemplary leadership and innovation, are now open to nurse practitioners and physician assistants.

"You never expect something like this, but you certainly appreciate it when you get it," said J. Kenneth Brubaker, MD, CMD, 2015 recipient of the William Dodd Founder's Award.

The Dodd Award, named after AMDA's founder, William Dodd, recognizes contributions to building AMDA's organizational strength, image, and mission, enhance the Society's reputation, and advance goals enabling AMDA to improve patient care. The James Pattee Award for Excellence in Education, named after the practitioner considered to be the "father" of the Core Curriculum in Medical Direction, recognizes significant contributions to AMDA's efforts to advance education specific to PA/LTC physician practice, and to promote Society leadership via educational endeavors within the care continuum.

As Dr. Brubaker observed, winning these awards is a true honor that validates the commitment and passion of AMDA members who make a difference for their patients, colleagues, teams, and communities.

You can show a colleague that his or her work has had a powerful impact on you and others. The deadline for nominations for 2016 awards is Nov. 9, 2015. Awards will be presented at AMDA's 2016 annual conference. For more information on the Dodd Award, visit www.amdafoundation.org/index.php/our-work/recognize-awards/william-dodd-founder-s-award. For details about the Pattee Award, visit www.amdafoundation.org/index.php/our-work/recognize-awards/james-pattee-award-for-excellence.

Foundation Futures Program Calls for New Applicants

Anyone who questions the value of the AMDA Foundation Futures program need only talk to Rebecca King-Tucker, MD, CMD. "In rural Montana [where she lived at the time], it was hard to find mentors. So I was really excited about participating in the Futures program and connecting with people there — other fellows and certified medical directors."

She wasn't disappointed. "I was impressed with the incredible amount of thought that goes into the Futures Program. They bring together a top-notch group of experts to provide an incredible snapshot of post-acute and long-term care."

The Futures program, which brings fellows and residents to the AMDA annual conference for a special 1-day introduction to PA/LTC medicine and medical direction, is a popular initiative that fills up quickly every year. In addition to participation in the 1-day Futures program, participants receive a full registration for the AMDA annual conference and a 1-year AMDA membership. Futures participants receiving a full scholarship also receive complementary transportation to and from the meeting, plus 4 nights of lodging.

Dr. King-Tucker was grateful for the AMDA membership that came with her Futures participation, and she quickly discovered AMDA's value. "Questions would arise at my facility, and I was able to get evidence-based, proven answers and information from AMDA," she said. She added that she is still struggling with issues such as care transitions and bundled payments, and is pleased that "AMDA has been out ahead on these issues and has related tools and information." Now, Dr. King-Tucker said, "AMDA is my group. It is more important than any other organization I belong to."

The AMDA Foundation is now accepting applications for the 2015 Futures program, scheduled for March 17, 2016, in Orlando, FL. For more information, go to www.amdafoundation.org/index.php/our-work/futures.

AMDA Joins Work group

AMDA has been appointed to the National Quality Forum MAP Post-Acute Care/Long-Term Care Workgroup, which will provide input on matters related to the selection and coordination of measures for post-acute care and long-term care providers, including hospices, inpatient rehabilitation facilities, long-term care hospitals, skilled nursing facilities, and home health care. AMDA will appoint an organizational representative to serve on the work group and will participate for a 3-year term (2015-2018).

Advanced Course Provides Unique Group Dynamic

The Advanced Curriculum on Medical Direction in Long-Term Care is different every iteration, and the agenda is based on participant feedback, insights from AMDA education committee members and others, and hot topics that arise on the national stage.

Last year course chair Laura Trice, MD, CMD, started the program by urging attendees to put away technological devices and to really pay attention to their colleagues and faculty members. "Several people came to me during the weekend and thanked me for doing this," Dr. Tice said. "I intend to start the October program the same way."

Areas of focus for the upcoming course including billing and coding updates, falls prevention, immunizations, managing ethical dilemmas, nutrition, payment reform, pharmacology update, PA/LTC practice management, shared decision-making, and transitions of care.

The course is scheduled for October 2–4, 2015, in St. Louis. For registration information, go to www.amda.com/education/advanced/info.cfm#registration.

Don't Miss These Events

September 19, 2015
Virginia Medical Directors Association Annual Conference
Virginia Beach, VA
Contact: Angel Rivera
Phone: 757-889-4383
Email: ARivera@LongTermCareofVA.com
Website: www.vamda.org/conference.html

September 23, 2015
AMDA Live Webinar: Cultural Diversity in PA/LTC
Contact: AMDA Registrar
Phone: 410-992-3116
Email: registration@amda.com
Website: www.amda.com/cmedirect/#web

October 2–4, 2015
AMDA Advanced Curriculum on Medical Direction in LTC
St. Louis, MO
Contact: AMDA Registrar
Phone: 410-992-3116
Email: registration@amda.com
Website: www.amda.com/education/advanced/index.cfm

October 9–10, 2015
The Wisconsin Society for Post-Acute and Long-Term Care Medicine Annual Meeting
Madison, WI
Email: karenmiller.rio@gmail.com
Website: www.wamd.org/annual-meeting.html

October 10–11, 2015
Michigan Medical Directors Association Educational Conference
Traverse City, MI
Email: michiganmda@gmail.com
Website: www.mimda.org/attendees/

October 16–17, 2015
The Pennsylvania Society for Post-Acute and Long-Term Care Medicine Annual Educational Symposium
Hershey, PA
Website: www.pamda.org/upcoming-symposium/

October 22–25, 2015
FAMDA Best Care Practices in the Geriatrics Continuum
Lake Buena Vista, FL
Website: www.bestcarepractices.org/index3.html

October 23–25, 2015
State of Ohio Long-Term Care Conference
Dublin, OH
Phone: 517-410-3474
Email: ohiomda@gmail.com
Website: www.ohioamda.org/conference.html

November 5–8, 2015
AMDA Core Curriculum on Medical Direction in Long-Term Care Medicine Part II
Philadelphia, PA
Contact: AMDA Registrar
Phone: 410-992-3116
Email: registration@amda.com
Website: www.amda.com/education/core/index.cfm

December 9, 2015
AMDA Live Webinar: The Role of the Physician in Person-Centered Care
Contact: AMDA Registrar
Phone: 410-992-3116
Email: registration@amda.com
Website: www.amda.com/cmedirect/#web

March 17–20, 2016
AMDA – The Society for Post-Acute and Long-Term Care Medicine Annual Conference 2016
Orlando, FL
Contact: AMDA Registrar
Phone: 410-992-3116
Email: registration@amda.com
Website: www.paltcmedicine.org

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