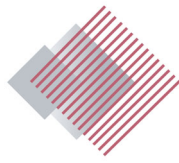


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**fmda**<sup>TM</sup>

Dedicated To Florida Long Term Care Medicine

# Progress Report



*Serving Physicians, Nurse Practitioners, and Physician Assistants  
Practicing in Florida's Postacute Care Continuum*





Dedicated To Florida Long Term Care Medicine

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## President's Letter



It's hard to believe, but soon my two years as president of the Florida Medical Directors Association will come to a close. Thanks to all of you who gave me this outstanding opportunity to serve our wonderful association one more time. This organization truly functions to serve its members and promote the best care possible for our patients in long-term care.

The steady growth in our membership has been gratifying to witness. Also, the increased involvement in our leadership by so many qualified and dedicated young physicians, along with the continued commitment by our senior members, points to a bright future for the Florida Medical Directors Associations for many years to come. We continue to strengthen our ties to the long-term care professional community with the Florida Health Care Association and Florida Association of Homes and Services for the Aging as well as to the organized medical community through formal affiliations with FMA and FOMA.

The focal point for FMDA's year is our "Best Care Practices in the Geriatrics Continuum" conference. We continue to improve the quality of this program to best serve our members and guests from around the country, and we continue to strengthen our relationships with our health care partners for the benefit of all. In particular, the Florida Chapter of the American Society of Consulting Pharmacists must be recognized for all they do to help our organizations grow together. Another group I would like to thank is the American College of Health Care Administrators as well as its Florida Chapter. They have quietly supported our conference for the past few years and have really stepped up their involvement this year. I am also proud to welcome our newest affiliated group, the American Association for Long Term Care Nursing — we are proud to have you join us this year.

I am very grateful for the fine stewardship provided by our dedicated members of our board of directors. Despite a difficult economy, we prudently push forward to maintain and improve the level of services and opportunities provided to our members. I am also thankful to our newest director, Karl Dhana, MD, CMD, who is the senior vice president of medical affairs at MorseLife in West Palm Beach and the editor of our award-winning *Progress Report* newsletter.

That leads me to the sad news that our comrade Jeffrey M. Behrens, MD, FACP, CMD, CHCQM, passed away suddenly on June 9, at the age of 57. Jeffrey joined VITAS Innovative Hospice in 2003 as a part-time team physician and became a full-time medical director of the program in 2007. He was a member of AMDA, was an active FMDA member and its former treasurer (2003-2007), and was currently a member of FMDA's board of directors. He was survived by his wife, Donna, and three children, and he will sorely be missed by all who knew him.

I look forward to supporting President-Elect Hugh Thomas, DO, CMD, who will be taking over the mantle of the presidency. He's going to do an outstanding job! I plan to remain active on the board in the coming years to continue the excellence that the Florida Medical Directors Association has come to represent.

Thanks for all your support.

Looking forward to seeing you in person at our "Best Care Practices in the Geriatrics Continuum 2009" conference in Orlando, Oct. 29-Nov. 1, 2009.

Sincerely yours,

  
John Potomski Jr., DO, CMD  
President



# Another Outstanding Educational Program

— Register today for the **Best Care Practices in the Geriatrics Continuum 2009**

**D**ear Friends:  
We are very pleased to present you with this year’s outstanding educational agenda, which is available at [www.bestcarepractices.org](http://www.bestcarepractices.org).

**SPECIAL PROGRAMMING:** In addition to the strong main educational program, which is already approved for more than 20 CMEs/CMDs/CEs, please consider signing up for one of the two optional, daylong pre-conference sessions on Thursday, Oct. 29. You can choose between *“Implementing AMDA’s ‘Pain Management in the LTC Setting’ Clinical Practice Guidelines”* or the *“1-Day Intermediate Quality Indicator Survey (QIS) Course.”* And for lunch, you will have the option of attending one of two luncheon presentations hosted by Forest Labs or Abbott Labs. Whether or not you attend any of the earlier on Thursday, you are definitely invited to a non-CME dinner & presentation on the *“Advances in the Treatment of Gout in the Elderly,”* hosted by Takeda.

**YOUR GUESTS:** Your traveling companions will not be bored one bit. Epcot will be hosting its **International Food & Wine Festival** while you are there. In addition, there is no better place than Orlando to spend Halloween.

Universal Studios Orlando is hosting its **18<sup>th</sup> Annual Halloween Horror Nights** ([www.halloweenhorrinnights.com/for more information](http://www.halloweenhorrinnights.com/for_more_information)). Plus there’s the **Halloween Spooktacular** at SeaWorld Orlando. And, if that isn’t enough, there’s also **Mickey’s “Not So Scary Halloween Party for Halloween 2009”** at *Disney’s Magic Kingdom*.

**HOTEL RESERVATIONS:** If you haven’t already done so, please make your hotel reservations. We have reserved

a block of rooms at the **Buena Vista Palace Hotel & Spa**, a beautiful 27-story luxury hotel directly across the street from Downtown Disney. It is located at 1900 Buena Vista Drive, Lake Buena Vista, FL 32830.

The special group rate is only \$168 single/double occupancy plus a discounted resort fee of \$10 per day. To make a reservation, please call **(866) 397-6516** and mention that you are attending the “Florida Medical Directors Association” or “Best Care Practices in the Geriatrics Continuum” conference, or you may also reserve a room online at [www.bestcarepractices.org/venue.html](http://www.bestcarepractices.org/venue.html). To guarantee rate and room availability, you should make your reservations no later than Sept. 27. This special group rate will be applicable three (3) days prior to and three (3) days following the main program dates, subject to availability. Free self-parking is available.

Yours truly,



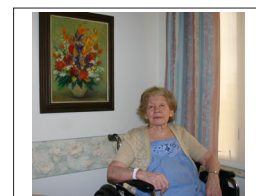
Carl Suchar, DO, CMD  
Immediate Past-President  
Program Director  
Best Care Practices in the Geriatrics Continuum 2009

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## FRONT COVER

The beautiful artwork on the front cover is titled “St. John’s River,” painted by Helene Kereluk. She resides in DeLand at The Cloisters, an Independent and Assisted Living Facility that is a part of the Retirement Housing Foundation.



Helene Kereluk was born in Germany 82 years ago. After the war, she came to the United States and “married the man of my dreams.” They worked together in their own business and raised two children.

Helene’s passion is painting. She studied art in Chicago and then continued her studies after moving to DeLand in 1971.

She has taught art at local venues, and she privately and currently teaches a monthly class at the Cloisters for her fellow residents. Her apartment and the community dining rooms are filled with examples of her work, including a full wall mural depicting a peaceful beachfront scene.



# The ABCs of Vitamin D Supplementation for Elderly Nursing Home Residents

By Jan Cripasuk, ARNP, BC; Jennifer Hawkins ARNP, BC; and Jill Banister, ARNP, BC

**C**linicians caring for the geriatric population are very likely to be familiar with the recent hot topic of vitamin D supplementation. This area of interest has been highlighted in the media, as well as in multiple recent clinical trials, medical conferences, and journal articles. Vitamin D plays an essential role in the maintenance of bone health and muscle strengthening, as well as endocrine functions, blood pressure regulation, cancer prevention and autoimmunity. There is data suggesting that residents who receive vitamin D and calcium supplements may improve their physical function and reduce their risk of falls, resulting in a better quality of life and increased longevity.



Jill Banister (from left), Jan Cripasuk, and Jennifer Hawkins are nurse practitioners at MorseLife in West Palm Beach.

## Making the Diagnosis

A blood test is required to determine a resident's vitamin D status. Measurement of the serum 25 hydroxyvitamin D (25 [OH] D) concentration is regarded as the best indicator of vitamin D status. It reflects vitamin D produced cutaneously as well as that obtained from food and supplements, and it has a fairly long circulating half-life of 15 days. The

clinician needs to consider the varying levels of inadequate vitamin D. Overt vitamin D *deficiency* is defined as a level less than 10ng/mL. It is uncommon in most developed countries and is characterized by hypocalcemia or hypophosphatemia, and rickets or osteomalacia. The individual may complain of bone pain and muscle weakness, but such symptoms are often subtle and go undetected in the early stages. Vitamin D *insufficiency* is defined as a serum 25 hydroxyvitamin D level of less than 30 to 32ng/mL. It is quite common in the elderly, especially in the housebound and in residents of nursing facilities. Studies have shown that 40% to 90% of older adults have insufficient vitamin D levels, even in places that have sunny climates such as South Florida. The general population does not need to be screened, but elderly patients who are homebound or institutionalized, who have known or suspected malabsorption, and those being evaluated for osteoporosis should have a lab test performed to measure vitamin D levels.

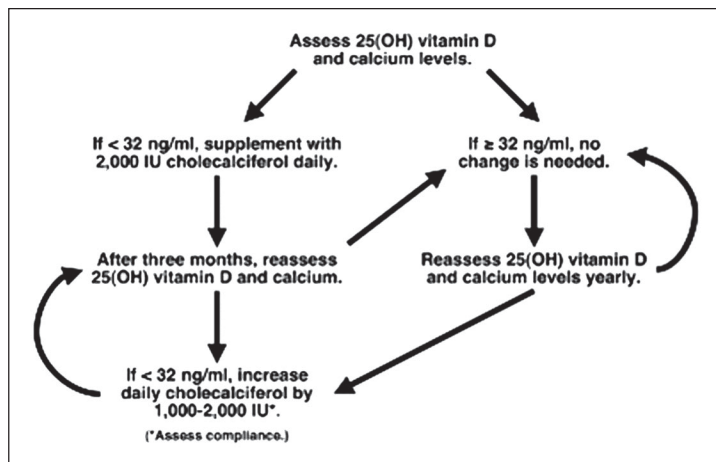
## Preparations and Dosing

Multiple preparations of vitamin D and its metabolites are available for the treatment of vitamin D *deficiency*. Vitamin D rather than its metabolites is used whenever possible because of the lower cost. Two commonly available forms of vitamin D supplements include vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol). Some, but not all studies show that vitamin D3 increases serum 25(OH)D more efficiently than vitamin D2. In addition, vitamin D2 is not accurately measured in all assays. The dosing of vitamin D depends upon the nature and the severity of the deficiency. Individuals with vitamin D *deficiency* require higher doses than those with vitamin

**Some, but not all, studies show that vitamin D3 increase serum 25(OH)D more efficiently than vitamin D2.**

The challenge for clinicians providing medical care to elderly residents in nursing facilities is to use the data available from these resources to positively impact practice patterns. Knowledge about the health benefits of vitamin D supplementation, diagnose of vitamin D deficiency, laboratory monitoring practices, and accepted prescribing practices will ensure that elderly residents are receiving adequate therapy.

D insufficiency, but practice patterns vary with regard to the best dose and frequency of vitamin D supplementation. There is currently no gold standard. One recently published study showed that supplementation with vitamin D was achieved equally well with daily, weekly, or monthly dosing. Two frequently used prescribing regimens include 50,000 IU of vitamin D given once a week for eight to 12 weeks and 800 IU vitamin D given daily. A treatment algorithm, shown in the diagram below by Cherniack, recommends starting with 2,000 IU of vitamin D daily.



While prescribing practices may vary, there is agreement that it is always necessary to measure calcium and 25 hydroxyvitamin D (25OH) levels after three months of therapy. The goal level is at least 30ng/ml to 32ng/ml. Often the nursing facility resident will not reach that goal, and higher doses of vitamin D supplementation will be required. Adequate calcium intake is important as well, because calcium directly affects the absorption of vitamin D.

### Summary

Clinicians caring for elderly nursing facility residents need to be aware of the incidence of suboptimal vitamin D levels as well as appropriate prescribing practices. Adequate vitamin D is important in the preservation of health for elderly nursing home residents. Studies have shown that adequate supplementation results in decreased mortality rates. Clinicians must be proactive and use the data currently available to identify and treat residents with suboptimal vitamin D levels. Additional studies are needed to establish the best diagnostic tests and supplementation approaches as well as to identify the types of resident most apt to benefit from supplementation.

## AMDCP Seeks Board Candidates



Would you or someone you know be interested in serving on the Board of the American Medical Directors Certification Program?

Responsibilities include:

- Review of applications for certification and recertification,
- Attendance at the August meeting, held in Columbia, Maryland,
- Participation in both June and December teleconference meetings,
- Active e-mail participation in discussions toward decisions on emerging issues, and
- Representation of AMDCP at AMDA symposia and other meetings.

The AMDCP Board strives to provide balance in areas of credentials (MDs and DOs), experience, and geographic location. Qualifications for selection of AMDCP Board members include demonstrated intellectual integrity, board or committee experience, respect for confidentiality, current certification as a Certified Medical Director, a commitment to the mission of AMDA and the certification program, and a time commitment of three years.

You may nominate yourself or a suitable candidate for the AMDCP Board position by following this link: [www.amda.com/certification/AMDCP\\_BOD\\_nomination.cfm](http://www.amda.com/certification/AMDCP_BOD_nomination.cfm).

Please contact anyone you wish to nominate, prior to submitting the nomination, to learn of their availability and willingness to serve on the board if elected. For further information, please contact AMDCP Executive Director Mary Logan via e-mail at [malogan@amda.com](mailto:malogan@amda.com).

Nominations must be received by December 15, 2009.

### The ABCs of Vitamin D Supplementation for Elderly Nursing Home Residents — *Continued*

One may go slow, but it is clear that clinicians must go! Our residents' quality of life is dependent on it.

### References

Cherniack, E., Levis, S., Troen, B. (2008) Hypovitaminosis D: A stealthy epidemic that requires treatment. 2008: *Geriatrics*, 63(4) 24-27.

# Review of VTE Prophylaxis Guidelines

By Tim Fusiak, Osteopathic Medical Student IV, Nova Southeastern College of Medicine

One of the most common issues presented to the physician in a skilled nursing, rehabilitation, or extended care facility is that of the prevention of venous thromboembolism (VTE). Often, patients are transferred to these facilities following medical or surgical treatment in a hospital setting and have already had prophylactic measures initiated.

Primary prophylaxis — use of pharmaceutical agents or other methods to prevent VTE — is greatly preferred over secondary prophylaxis — the effective early diagnosis and treatment of VTE in an early stage. Pharmacologic agents currently available to clinicians include warfarin, unfractionated heparin (UFH), low molecular weight heparin (LMWH) and fondaparinux (a substituted pentasaccharide). Unless warfarin is initiated 24-48 hours prior to surgery, concomitant use of heparins will be required until INR=2.0-3.0.<sup>1</sup> While aspirin provides a modest degree of VTE prophylaxis, it is greatly inferior to the previously mentioned agents, especially in light of its side effect profile<sup>3</sup>, and is not recommended by the American College of Chest Physicians (ACCP). In all cases, the manufacturers' dosing recommendations should be used.<sup>1</sup>

Mechanical means of prophylaxis include early ambulation, intermittent pneumatic compression devices, and compression stockings. These are typically used for low-risk patients or those with a contraindication to pharmacologic therapy.<sup>1</sup>

The ACCP revised its guidelines for VTE prophylaxis in 2008. These guidelines require stratifying patients into a risk category. The categories of low, moderate or high are delineated in Table 1.<sup>1</sup>

Guidelines for surgical patients have been clearly delineated and examined.<sup>1,2</sup> VTE prophylaxis in medical patients is much more ambiguous. A great deal of clinician discretion is involved with these patients, with the ACCP offering only general guidelines. In general, only patients who are immobile or have risk factors will require prophylaxis. Mechanical prophylaxis is effective for most

medical patients.<sup>1,4</sup> Risk factors for VTE are presented in Table 2. Patients in CHF, with severe respiratory disease, sepsis, inflammatory bowel disease or acute neurological disease should generally be considered for prophylaxis with LMWH, UFH or fondaparinux. Pharmacologic prophylaxis should also be considered in patients with multiple risk factors and an extended period of immobilization.<sup>1</sup>

The guidelines were revised to allow more freedom to the physician to determine how high a risk each individual patient may be. A patient who is ambulating earlier than most after total hip arthroplasty may not require as aggressive a prophylactic regimen.<sup>1</sup> This review will present several situations to demonstrate the application of these guidelines.

Procedure	Risk	Recommendation
Minor Surgery Arthroscopic Surgery	Low	Early ambulation, mechanical prophylaxis
General Surgery Gynecologic Surgery	Moderate	UFH, LMWH
Knee Arthroplasty Hip Arthroplasty Femur Fracture	High	LMWH, warfarin, fondaparinux at least 10d LMWH, warfarin, fondaparinux 10-35d UFH, LMWH, warfarin, fondaparinux 10-35d

**Table 1. Risk stratification and VTE prophylaxis recommendations in surgical patients. (1)**

Age >50	Prior VTE
Varicose Veins	Obesity
Prior Myocardial Infarction	Heart Failure
Cancer	Paralysis
Atrial Fibrillation	Inherited or Acquired Hypercoagulable
Ischemic Stroke	Disorder (Factor V Leiden, Protein C
Diabetes Mellitus	deficiency, etc.)

**Table 2. Risk factors for VTE. (2)**

**Case Studies Below:** TKA — total knee arthroplasty; THA — total hip arthroplasty; ORIF — open reduction internal fixation; s/p — status post

## 76 y/o M s/p right TKA

This patient may require only the minimum recommended 10 days of LMWH if he is tolerating rehab well. Warfarin is an inexpensive option to spare the patient daily injections, but will require titration of the dose and monitoring the INR.

## 92 y/o M s/p left THA

LMWH is preferred, but since this type of surgery requires a longer period of anticoagulation, warfarin may be the least expensive option. Assuming this patient was

# FMDA Hosts Town Meeting in Lake Worth

By Hugh Thomas, DO, CMD; Vice President and Chairman, Membership Committee

**O**n average, the FMDA board of directors travels around the state at least twice a year to connect with its members and potential new members at the local level. We've had the pleasure of hosting events from Pensacola to Jacksonville, Orlando, Tampa, Sarasota, Fort Myers, West Palm Beach, Miami, St. Petersburg, Coral Gables, and Fort Lauderdale.

We hosted another memorable Town Meeting & Dinner on June 30, 2009. This time, the location was beautiful downtown Lake Worth.



From left: Dr. Dennis Stone, Dr. Barbara Phillips, Dr. Carl Suchar, with Stacy Symeonides and Dr. John Symeonides

Earlier in the day, the C M E / Education Committee and the board of directors met for

regularly scheduled business meetings, which were hosted at MorseLife in West Palm Beach. Later, the Town Meeting dinner was generously sponsored by Boehringer Ingelheim and Herb Grigg, our host.

Future Town Meetings planned for 2010 include one in February in the Daytona Beach area, and another in April in Fort Lauderdale. Stay tuned for more information.



From left: Presenter Joseph A. Giaimo, DO, 3<sup>rd</sup> vice president of the American Osteopathic Association and past president of the Florida Osteopathic Medical Association; Herb Grigg with Boehringer Ingelheim; and FMDA President Dr. John Potomski

## Review of VTE Prophylaxis Guidelines — Continued

not on any anticoagulants prior to surgery, LMWH will be required at least until the INR is between 2.0 and 3.0 if warfarin is selected for prophylaxis.

### 87 y/o F s/p ORIF right femur fracture, history of heparin induced thrombocytopenia

UFH is obviously contraindicated. LMWH therapy has a lower incidence of HIT, although with the other anticoagulation options available, the risk is not be worth taking. This patient would likely be started on warfarin. The use of fondaparinux until a therapeutic INR is attained may be considered.

### 73 y/o F s/p total abdominal hysterectomy and bilateral salpingo-oophrectomy with a history of hypertension and atrial fibrillation

Despite this being a low-risk procedure, this patient should be placed on warfarin therapy (if not already) due to the history of atrial fibrillation. Without the history of fibrillation, mechanical prophylaxis would be sufficient.

### 70 y/o M s/p hospitalization for statin induced rhabdomyolysis. No other medical history

Aside from age, this patient has no risk factors for VTE. If this patient is too weak to ambulate safely, mechanical prophylaxis is warranted.

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3. Hovens, MM, Snoep, JD, Tamsma, JT, Huisman, MV. "Aspirin in the prevention and treatment of venous thromboembolism." *J Thromb Haemost* 2006; 4:1470.
4. Amarigiri, SV, Lees, TA. "Elastic compression stockings for prevention of deep vein thrombosis." *Cochrane Database Syst Rev* 2000; :CD001484.

# FDA Approves First Medical Food Therapy for Alzheimer's Disease



By Gaylon E. Fruit, BS, RPh; Consultant Pharmacist President, SeniorCare Consultant Group

**A**ccera, Inc., a biotechnology company, recently launched Axona™ in the United States for Alzheimer's disease. Axona is the first medical food therapy for Alzheimer's disease (AD). It is a medical food for the clinical dietary management of the metabolic processes associated with mild-to-moderate Alzheimer's. A prescription product that targets the metabolic deficiencies and imbalances associated with AD, it provides an alternative energy source for brain cells. Axona represents a new approach to helping manage AD symptoms and has been shown in clinical trials to safely improve cognitive function and memory in patients diagnosed with mild-to-moderate AD.

A medical food is an FDA-regulated product in a relatively new category of medical protocols defined by Congress as part of the Orphan Drug Act. A medical food is formulated to be consumed or administered orally under the supervision of a physician and is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods are often prescription products, but are different from drugs or dietary supplements (also called "nutraceuticals") in several aspects, such as their claims. Claims for both medical foods and drugs must be supported by solid laboratory and clinical data. Medical food ingredients have the "Generally Recognized As Safe" (GRAS) designation, the highest FDA standard of safety given to foods. Medical foods, sometimes prescribed in addition to drugs, represent an entirely different scientific and medical approach to managing diseases.

AD, the most common form of dementia, is a progressive and fatal disease for which there is no cure. It attacks the brain's nerve cells, resulting in loss of memory, executive function, thinking and language skills. According to recent data, every 71 seconds someone in America develops AD.

In the U.S., 5.2 million people are living with AD, and it has become the sixth leading cause of death. These numbers are expected to increase as the baby boomer generation ages and as medical technology continues to advance. In fact, it is estimated that 10 million U.S. baby boomers alive today will develop Alzheimer's disease. With the lack of innovative new medications, both patients and caregivers

are seeking alternative therapies to improve quality of life.

Axona approaches a metabolic abnormality of Alzheimer's disease that has not previously been examined. The goal of Axona therapy is to optimize cognitive function, and is safe to be used with other common therapies for Alzheimer's.

Alzheimer's disease is characterized by a substantial decrease in the brain's ability to metabolize glucose, which is the brain's primary source of energy. Known as hypometabolism, this defect may contribute to both the clinical and pathological course of the disease. Axona targets the metabolic defects of glucose utilization in the brain by providing an alternative energy source. Axona is digested and metabolized by the liver to form ketone bodies, naturally occurring compounds produced by the body at low levels. These ketone bodies act as a secondary energy source for the brain to help maintain and improve cognitive function.

The theory behind Axona is that if brain cells aren't getting or using enough glucose, you can substitute ketone bodies for glucose. A ketone body is a substance that results from fats being broken down in the body. The amount of ketone bodies circulating in the blood can be increased by a diet very high in fat and very low in sugar.

The main ingredient of Axona, caprylic acid, causes an increase in ketone bodies in the blood without the need for a high-fat diet; so theoretically, Axona provides an alternate fuel for brain cells. Caprylic acid is found in coconut oil, and there have been anecdotal reports that coconut oil improves memory.

"It's a novel and effective approach to Alzheimer's disease," said Steve Orndorff, PhD, founder and CEO, Accera, Inc. "Similar to how insulin helps diabetics, Axona supplements energy for the brain so that neurons can continue to function properly and patients can maintain cognition."

Axona was evaluated in a double-blind, randomized, placebo-controlled study performed at multiple U.S. clinical centers in a population of 152 patients with probable mild-to-moderate Alzheimer's disease. Patients taking Axona demonstrated significant improvements in cognitive function by day 45 (as measured by the Alzheimer's Disease Assessment Scale-Cognitive subscale or ADAS-Cog score). These patients also maintained a



slight improvement from baseline after 90 days of daily Axona administration, whereas the placebo group demonstrated a decline. In these trials, Axona was demonstrated to be safe, effective and generally well-tolerated.

Axona is supplied as a powder formulation in individual 40-gram packets (containing 20 grams of caprylic triglyceride). Both the patients and their caregivers should be instructed in the correct administration amount and schedule for Axona based on medical evaluation of the patient by the supervising physician.

It is recommended that patients take one packet of Axona once a day with breakfast. The contents of each packet of Axona should be added to 4 to 8 ounces (118 to 236 milliliters) of water in an appropriate container, shaken until fully blended, and consumed immediately. Axona is available by prescription in the U.S. only, and the cost for a month's supply ranges from \$83 to \$110. The product is not covered by most insurance plans or by Medicare.

Patients who experience unacceptable gastrointestinal adverse events (such as diarrhea, flatulence, dyspepsia,

and feeling of "unsettled stomach") should be reminded to take Axona with food. Over-the-counter medications such as simethicone, antacids, and antidiarrheals can be useful. Patients with persistent unacceptable gastrointestinal adverse events may take one-half packet of Axona until adverse events have resolved and then resume taking a full packet of Axona.

No significant interactions with commonly prescribed medications for Alzheimer's disease have been observed. Axona has been studied in patients taking Aricept® (donepezil HCl) and/or Namenda® (memantine HCl). No significant differences were noted in the concentrations of serum total cholesterol, very low-density lipoprotein cholesterol, LDL cholesterol, or HDL cholesterol between 40 grams of medium-chain triglycerides (twice the regularly prescribed amount) and 40 grams of long-chain triacylglycerols (blended vegetable oil).

For more information, visit [www.acerpharma.com](http://www.acerpharma.com).

**References:** Accera, Inc., Broomfield, CO; Associated Press; *The Tangled Neuron*; and PRNewswire

## F M D A M e m b e r s h i p A p p l i c a t i o n

There are three classes of dues-paying FMDA members. **A. Regular Membership:** Every medical director or attending physician of a long-term care medical facility or organization in the state of Florida and neighboring states shall be eligible for Regular membership in FMDA. Members in this classification shall be entitled to a vote, shall be eligible to be a member of the Board of Directors and to hold office. **B. Affiliate members:** Composed of two categories, they may be any individual or organization in the medical, regulatory or political fields of long-term care and wishing to promote the affairs of FMDA. An Affiliate member shall have all FMDA privileges except shall not be eligible to vote or hold office. The two categories are: **1. Professional Affiliate members.** This category is comprised of physician assistants and advanced registered nurse practitioners. Professional Affiliate members may be appointed by the Board of Directors to serve on FMDA committees, and **2. Organizational Affiliate members.** Includes vendors, other professionals, and organizations. **C. Allied Health Professional Relations Committee:** Health care practitioners who provide essential services to patients in the postacute setting are eligible to join, including dental professionals, podiatrists, opticians, psychiatrists, senior care pharmacists, psychologists, etc. Committee members are non-voting and may be appointed by the Board of Directors to serve on other FMDA committees.

This is the only organization in the state devoted to physicians, physician assistants and nurse practitioners of all specialties practicing in hospital-based, skilled nursing units through subacute care to traditional long-term care. To become a member of FMDA, please complete the following and mail to the address below:

**Yes! I would like to join FMDA.** Enclosed is a check for \$65 for annual dues for **Regular, Professional Affiliate members, and Allied Health Professional Relations Committee.** Dues for **Organizational Affiliate members** are \$325 per year.

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# Reducing Potentially Avoidable Hospitalizations of Nursing Home Residents: The INTERACT II Project

By Joseph G. Ouslander, MD

**H**ospitalization of nursing home (NH) residents can cause discomfort and anxiety for residents and families, morbidity from complications during hospitalization, and excess health care costs. Many hospitalizations of NH residents may be preventable through improved assessment and management of acute changes in condition in the NH; or inappropriate, because the transfer exposes NH residents to additional risks associated with hospitalization, without substantial potential benefit for the residents' clinical and functional status, or quality of life. One study of hospital transfers from eight Los Angeles NHs reported that 45% of 100 hospitalizations were rated as "inappropriate" when assessed by experienced physicians using a structured implicit record review.<sup>(1)</sup> In 2004, close to \$200 million was spent on hospitalizations of long-stay NH residents in the state of New York for "Ambulatory Care Sensitive Diagnoses," a proxy measure for potentially unnecessary hospitalizations.<sup>(2)</sup> This is an underestimate of the overall costs of these hospitalizations, because short-stay residents, among whom hospitalizations are more common than long-stay residents, were excluded from this analysis.

Reducing potentially avoidable hospitalizations of NH residents therefore presents an opportunity to both improve care quality and avoid unnecessary health care expenditures. Savings from reducing these avoidable hospitalizations could be used to support staff and other infrastructure to improve the quality of NH care through the Center for Medicare and Medicaid Services (CMS) "value based purchasing" or "pay for performance" initiatives.

In 2006-2008, in preparation for the Medicare Quality Improvement Organization 9<sup>th</sup> scope of work related to care transitions (which is now under way in 14 sites across the U.S., including Miami), CMS supported a contract with the Georgia Medical Care Foundation (GMCF), the Medicare Quality Improvement Organization for the state of Georgia, to conduct a special study to develop and pilot test tools and strategies that might help reduce the frequency of avoidable hospitalizations of NH residents.

As a component of this special study, 200



Dr. J. Ouslander

hospitalizations of NH residents from 20 NHs (10 with high and 10 with low rates of hospitalizations) in Georgia were reviewed by an expert panel of experienced long-term care clinicians. They rated two-thirds of these hospitalizations as potentially avoidable for a variety of reasons that are not unexpected — including lack of on-site availability of primary care providers, inadequate assessment of acute changes in status, lack of ability to initiate or maintain IV fluids, and transfer of residents who may have been more appropriate for palliative or hospice care in the NH. Calculated savings from reducing such avoidable hospitalizations would be enough to hire a full-time advance practice nurse or physician assistant in all NHs in Georgia (paper currently under review).

**Reducing potentially avoidable hospitalizations of NH residents presents a timely and important opportunity to both improve quality of care and avoid unnecessary health care expenditures.**

A toolkit was developed after review of these hospitalizations, interviews with providers, and input from the expert panel, which was named "INTERACT" (Interventions to Reduce Acute Care Transfers). The INTERACT tools included three basic types of tools: 1) Communication tools; 2) Care paths; and 3) Advance care planning tools. The INTERACT tools were pilot-tested in three Georgia NHs with high baseline rates of hospitalization. Although NH staff viewed the tools

## Interact II Tools

Communication Tools	Use
<b>Early Warning Tool “Stop and Watch” Pocket Card and Report</b>	Certified Nursing Assistants <ul style="list-style-type: none"> <li>▪ Regular evaluation of and recognition of changes in residents under their care</li> <li>▪ Reporting changes to licensed nurses</li> <li>▪ May be produced as laminated cards or half sheets on colored paper</li> </ul>
<b>SBAR Communication Tool and Progress Note</b>	All nursing home licensed nursing staff <ul style="list-style-type: none"> <li>▪ Evaluation and communication of acute changes to MD, NP, and/or PA</li> <li>▪ Documentation of evaluation and communications</li> <li>▪ May be printed as two-sided with progress note on back</li> </ul>
<b>Change in Condition File Cards</b>	All nursing home licensed nursing staff <ul style="list-style-type: none"> <li>▪ At nurse’s station for quick reference</li> <li>▪ Provide guidance on when to communicate acute changes in status to MD, NP, and/or PA</li> <li>▪ May be laminated and placed in a file box at the nurses station or on the med cart, or cards may be spiral bound</li> </ul>
<b>Resident Transfer Form</b>	All nursing home licensed nursing staff and emergency room staff <ul style="list-style-type: none"> <li>▪ Standardized form completed at the time of acute care transfer</li> <li>▪ May be printed as two-sided or single sided on 3M paper</li> </ul>
Acute Care Transfer Envelope with Checklist	All nursing home staff at time of transferring residents to acute care <ul style="list-style-type: none"> <li>▪ Complete the checklist on the front of the envelope</li> <li>▪ Place copies of all documents in the envelope</li> <li>▪ Send with the resident to the acute care facility</li> <li>▪ Checklist may be printed on outside of a 11x14 or 15x20 envelope</li> </ul>
<b>Quality Improvement Tool For Review of Acute Care Transfers</b>	This Communication tool is used for facility-based quality improvement focused on reducing the number of avoidable acute care transfers. Nursing home staff involved in Quality Improvement or Performance Improvement Committees; medical director, medical staff in building <ul style="list-style-type: none"> <li>▪ Standardized form completed for every acute care transfer</li> </ul>
Care Paths	
<ul style="list-style-type: none"> <li>▪ <b>Mental status change</b></li> <li>▪ <b>Fever</b></li> <li>▪ <b>Symptoms of Lower Respiratory Infection</b></li> <li>▪ <b>Symptoms of CHF</b></li> <li>▪ <b>Symptoms of UTI</b></li> <li>▪ <b>Dehydration</b></li> </ul>	All nursing home licensed nursing staff, administrative nurses, medical director, primary care physicians, nurse practitioners, physician assistants <ul style="list-style-type: none"> <li>▪ Used as an educational tool and reference for guiding evaluation of specific symptoms that commonly cause acute care transfers</li> <li>▪ Care paths may be enlarged and printed as posters for nursing station or med room, or printed and placed in a binder</li> </ul>
Advance Care Planning Tools	
<b>Identifying Residents to Consider for Palliative Care and Hospice – Pocket Card</b>	All nursing home staff <ul style="list-style-type: none"> <li>▪ Educational tool for guidance on how to identify residents who may be appropriate for a palliative or comfort care plan, or hospice care</li> </ul>
<b>Advance Care Planning Communication Guide – File Cards</b>	Social workers, licensed nurses, primary care providers (MDs, NPs, PAs) <ul style="list-style-type: none"> <li>▪ Educational tool for guidance on how to communicate with residents and family members for those appropriate for a palliative or comfort care plan, or hospice care</li> </ul>
<b>Comfort Care Order Set – File Cards</b>	Primary care providers (MDs, NPs, PAs), licensed nurses <ul style="list-style-type: none"> <li>▪ Guidance on examples of orders that may be appropriate for residents on palliative or comfort care plans</li> </ul>
<b>Educational Information</b>	Directed at Residents and families <ul style="list-style-type: none"> <li>▪ Reprints on Advance Directives, Palliative Care, Artificial Nutrition</li> </ul>

favorably, their use in the three facilities varied, and none of the facilities fully implemented all of the tools. Despite only partial implementation, the quality improvement initiative was associated with a 50% reduction in the overall rate of hospitalizations during the 6-month intervention period compared to baseline. The proportion of hospitalizations rated as potentially avoidable was also reduced by 36% (in press, *JAMDA*).

In 2008, the Commonwealth Fund ([www.commonwealthfund.org](http://www.commonwealthfund.org)) funded a multidisciplinary team to carry out a follow-up project to refine the INTERACT tools, and test them in 30 NHs — 10 each from Florida, New York, and Massachusetts. The team includes faculty from Florida Atlantic University and the University of Miami, as well as the Stein Gerontological Institute in Miami, and Mass Senior Care (a foundation affiliated with AHCA). The tools and implementation strategies were revised after extensive input from front-line NH staff, and experts nominated by more than 10 national organizations. The “INTERACT II” tools are listed in the Table, and the strategy for incorporating them into everyday practice is outlined in the figure on page 12. The INTERACT II tools themselves are available at: <http://interact.geriu.org/>.

The current Medicare fee-for-service system is a barrier to INTERACT II implementation because it provides financial incentives for physicians, NHs, and acute hospitals that favor hospitalization of NH residents. The unreimbursed costs of implementing tools and strategies such as INTERACT II, as well as the potential regulatory and legal

*Continued on page 12*

**Reducing Potentially Avoidable Hospitalizations of Nursing Home Residents: The INTERACT II Project**

*Continued from the previous page*

liabilities of caring for sicker residents, are potent disincentives to managing residents with acute changes in status in the NH. Managed care programs, such as Evercare and others, mitigate these financial incentives and have been shown to reduce hospitalization of NH residents when more care is provided in the NH by teams of physicians and NPs or PAs.<sup>(3-5)</sup> The number of NH residents in these programs, however, remains relatively small.

Medicare is beginning a demonstration of a value-based purchasing initiative in four states to reward NHs based in part on lower rates of potentially avoidable hospitalizations. In addition, Medicare is exploring “bundling” payments for 30-day episodes of care for certain conditions. If skilled NH care is included in these bundled payments, hospitals and NHs would have a potent financial incentive to collaborate and communicate better to avoid hospitalization of NH residents whenever safe and feasible.

Reducing potentially avoidable hospitalizations of NH residents presents a timely and important opportunity to both improve quality of care and avoid unnecessary health care expenditures. The INTERACT II tools hold promise for helping to achieve these goals, but need further refinement and testing for optimal incorporation into everyday practice. The INTERACT II project supported by the Commonwealth Fund will provide valuable experience that will be used to develop future dissemination projects designed to improve the quality of NH care, while reducing overall the costs of caring for our growing elderly population.

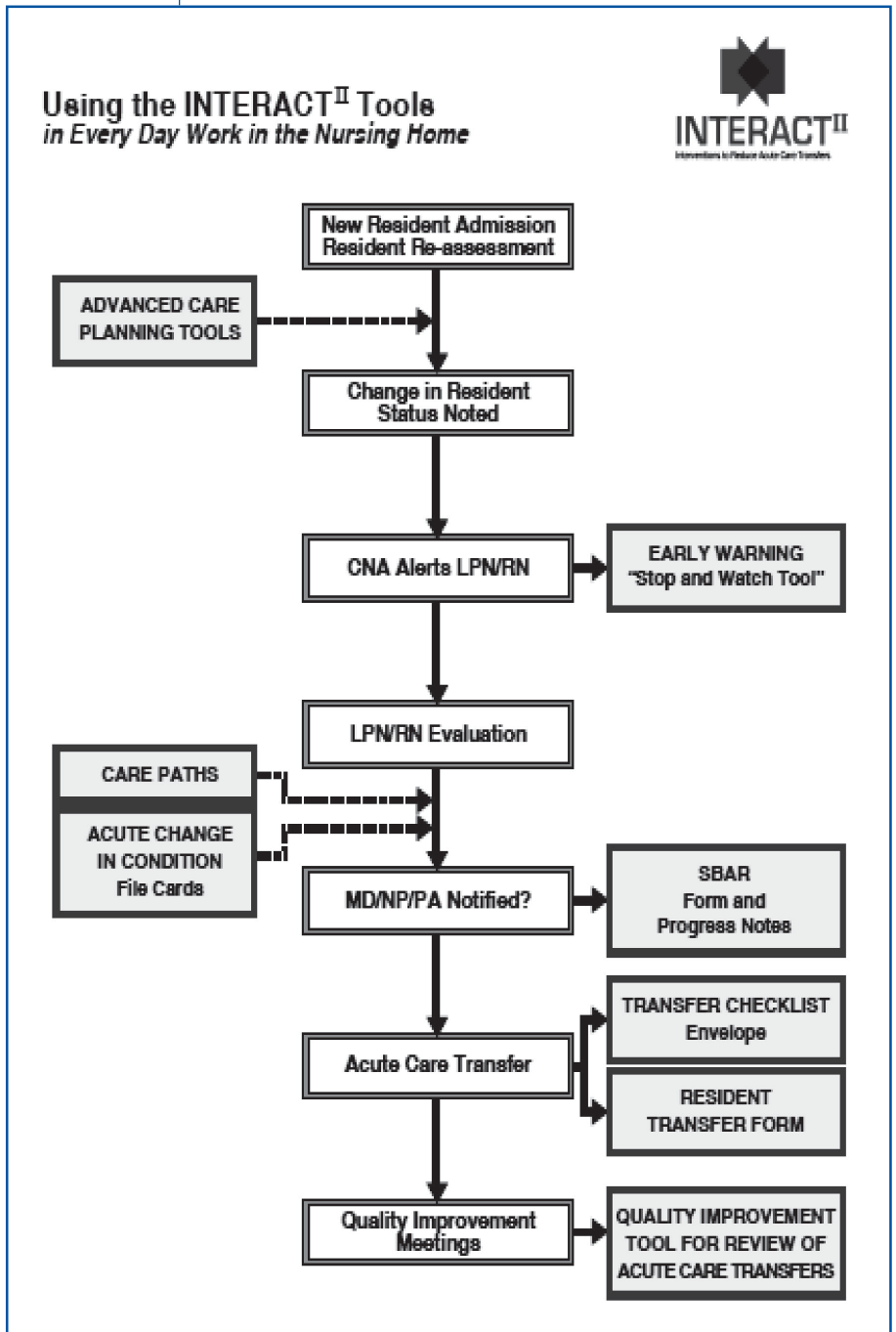
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**About the Author**

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# The Federal Government's Carrot and Stick Approach to Ambulatory EMR

By Yervant Khatcherian, MD

**I**f you are a hospitalist or plan to retire before 2016, you do not have to read any further. For the rest of us, this is a new reality, to be taken seriously.

The Feds want all medical records in an electronic format and information freely flowing among all entities caring for patients within a geographic area.

The plan is to pay doctors \$44,000 over a period of five years, starting 2012, if certain criteria called "meaningful use" are met, (insert "meaningful use" in Google for a matrix of the criteria). This will be divided over five years, starting in 2012 with \$18,000, then \$12,000 in 2013, \$8,000 in 2014, \$4,000 in 2015, and \$2,000 in 2016. After 2016, CMS would cut 1% per year from the total CMS reimbursement for the next three years. If a physician starts reporting in 2012, then the checks would start in 2013 and so on, with less of the carrot being given. The longer one waits, the smaller the carrot gets.

Compliance with these criteria is based on using electronic medical record (EMR) software that is "certified." So far CCHIT is the only certifying agency, but that may change. These entities will make sure that the various EMRs meet the "meaningful use" criteria, and a physician getting such an EMR, fully implementing it in the office, and complying with the various reporting criteria is deemed to have met the "meaningful use" standards and be eligible for the carrot. EMR implementation takes about one year, at which point a practice will be able to report on data the following year, so there is a lag time between getting an EMR and actually starting to report.

One of the problems will be the tidal wave of demand that will outstrip the supply of EMR companies and information technology (IT) support. As EMR penetration in various doctors' practices are in the 20% range, the remaining 80% will have to realize the need and get moving to get in. Once they do, they will have to compete with other practices for scarce resources.

I have already come across stories from doctors being told that a certain EMR is certified when it's not, and another case where the doctor was told he would be "reimbursed the difference," if the EMR does not get certified.



Yervant  
Khatcherian

The message here is to find a certified EMR. Do not trust what the vendor says; go to [www.CCHIT.org](http://www.CCHIT.org) and check for yourself. A client server (owned) model is cheaper in the long run than an ASP (leased) model; the break-even point depends on practice size, anywhere from 2.5-5 years.

Check with the local hospital: which EMR do they intend to interface with? In Pinellas County, Baycare hospital systems and HCA hospital systems have already decided. I would advise the doctor to do the searching; assigning an office manager to this task will backfire, as it is ultimately the doctor who will spend all the time in front of a monitor trying to enter data.

**If you are a hospitalist  
or plan to retire before  
2016, you do not have  
to read any further.**

Secure reliable IT help, which is easier said than done. Check references, not the glossy brochure or the alphabet soup after someone's name. Don't sign any service agreement; they are always in favor of the IT company.

A local bank in Pinellas County is willing to finance this project, so talk to your banker if you do not want to put up the whole amount yourself.

Get going sooner, rather than later.

### About the Author

Dr. Khatcherian has been using EMRs for the last 10 years. He has gone through two EMR implementations and eight IT companies, before finding his current IT company. He has survived one server meltdown and various IT, backup, and disaster recovery issues. Dr. Khatcherian practices internal medicine and geriatrics in Clearwater. You can contact him at [Ykhatch@MainDr.com](mailto:Ykhatch@MainDr.com).

# Progressive Supranuclear Palsy

By Susan W. Arvan, Osteopathic Medical Student IV, Nova Southeastern College of Osteopathic Medicine



More than 50 years have passed since Canadian neurologist Dr. J. Clifford Richardson was consulted by a friend who was experiencing clumsiness, forgetfulness and vision difficulties. Richardson was intrigued and similarly identified these distinct symptoms in three middle-age veterans. The presentation of these symptoms led Richardson to recognize them as part of a unique new disorder.



Susan W. Arvan

**Late stage disease-induced immobility may lead to infectious complications such as pneumonia, UTIs, and sepsis.**

A post mortem in the 1960s classified these veterans' deaths as post-encephalitic Parkinsonism. Richardson disagreed with these findings as there had been no history of encephalitis. His resident, John Steele, and neuropathology professor, Jerzy (George) Olszewski, re-evaluated these cases. Their findings, presented at the American Neurological Association meeting in June 1963, provided the first clinical report of progressive supranuclear palsy (PSP), a syndrome marked by defects in ocular gaze, spasticity of facial musculature with dysarthria and occasional dysphagia, extensor rigidity of the neck with head retraction, and dementia.

## Pathology

Progressive supranuclear palsy is defined as a predominate four-repeat Tau pathology with numerous

tangles and threads in the brainstem and basal ganglia. Classification is by the star-shaped astrocytic tufts and neurofibrillary tangles observable by light microscopy upon staining with immunostain specific for Tau. Diagnosis is based on clinical acumen, as several clinical variants exist, yet there are no reliable biomarkers.

## Progressive Supranuclear Palsy (PSP)

In its classic presentation, progressive supranuclear palsy is known as Richardson's disease. The disease is marked by a gradual onset of postural instability resulting in falls within the first two years of disease onset, accompanied by supranuclear gaze palsy and rigidity and bradykinesia unresponsive to levodopa. Richardson's disease usually develops in the sixth decade of life. While geographically-sporadic, frequency is 4-6 percent of those with Parkinsonism.

A study of New Jersey residents revealed a prevalence of 1.39/100,000 population. Male and female prevalence was 1.53 and 1.23 respectively. Disease prevalence for those 55 and older was 7/100,000. Fatality averages six years upon onset with a range of 1-17 years. The disease is most prevalent in Caucasians with a slight male predominance (1.5:1). Mean onset is 63 years with an interval between onset and diagnosis of three years.

Another study reported younger patients survived longer; however, this study's findings have not been supported by others. Also, conflicting reports exist concerning age at diagnosis and influence on survival.

## Clinical Diagnosis/History

Richardson's disease begins with a prolonged phase of fatigue, headache, arthralgias, dizziness, depression, acute personality changes, memory problems, and pseudobulbar symptoms. This initial phase is followed by unexplained imbalance, falls and then dysarthria, dysphagia and visual symptoms. Presentations can differ and present with one particular symptom; however, eventually the other symptoms appear. The vertical gaze palsy is the most prominent clinical feature.

*Continued on the next page*

## Physical

Document cognitive function, and perform a cranial nerve exam with analysis of ocular motility. Look for slow vertical saccades and square wave jerks, as these present early with the disease. There will also be a classic palsy gaze. Supranuclear palsy spares ocular motor nuclei, nerve fascicles, neuromuscular junction, and extraocular muscles. Examination to establish these as intact (i.e., lesion is supranuclear) include extra-volitional pathway activation utilizing either Vestibular ocular reflex (VOR) or Bell phenomenon testing. VOR involves manually flexing and extending the neck while the patient focuses on a distant target. Bell phenomenon is the upward deviation behind closed lids. Vertical movement improvement with these procedures indicates a supranuclear lesion. Other symptoms include bradykinesia and masked facies with a startled expression, associated dysarthria, imbalance and increased rigidity (without cog-wheeling or tremor) and frontal release signs.

## Diagnosis/Treatment

Differential diagnosis includes Alzheimer's disease, ALS, Lewy Body Disease, Huntington's Disease, Wilson's disease, Whipple's disease, Syringomyelia, NPH, Neuroacanthocytosis, MG, Parkinson's, prion-related disease, multi-system atrophy, multi-infarct dementia, catatonia and dizziness/vertigo/imbalance. Labs only rule out (ex. Whipple's pcr). Imaging can show the "penguin sign" indicating atrophy of the rostral midbrain seen on mid-sagittal plain MRI. Treatment includes rehab for

ambulation, prism glasses and swallow studies. Medications such as bromocriptine and tricyclic anti-depressants may have short-term effect. Botox may be used for spasticity.

## Complications

Impaired balance, decreased mobility and impaired cognition lead to falls and orthopedic injury. Dysphagia can predispose to aspiration pneumonia. Late-stage disease-induced immobility may lead to infectious complications such as pneumonia, UTIs, and sepsis. Dudley Moore, who admitted to having PSP in 1999, died in 2002 from pneumonia.

## Resource

CurePSP (The Society for Progressive Supranuclear Palsy)  
Executive Plaza III, 11350 McCormick Road, #906  
Hunt Valley, MD 21031  
Toll free: 800-457-4777; Phone: 410-785-7004;  
Fax: 410-785-7009; e-mail: [info@curepsp.org](mailto:info@curepsp.org)  
[www.curepsp.org](http://www.curepsp.org)

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Levemir® is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

#### Important safety information

Levemir® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir®. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Levemir® is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. Levemir® should not be

diluted or mixed with any other insulin preparations. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir® from other intermediate or long-acting insulin preparations. The dose of Levemir® may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation.

\*Whether these observed differences represent true differences in the effects of Levemir®, NPH insulin, and insulin glargine is not known, since these trials were not blinded and the protocols (eg, diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.

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**Levemir®**

insulin detemir (rDNA origin) injection



Please see brief summary of Prescribing Information on adjacent page.

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# Levemir®

insulin detemir (rDNA origin) injection

**Rx ONLY**  
**BRIEF SUMMARY.** Please see package insert for prescribing information.

## INDICATIONS AND USAGE

LEVEMIR is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia.

## CONTRAINDICATIONS

LEVEMIR is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

## WARNINGS

**Hyperglycemia is the most common adverse effect of insulin therapy, including LEVEMIR. As with all insulins, the timing of hypoglycemia may differ among various insulin formulations.**

**Glucose monitoring is recommended for all patients with diabetes.**

**LEVEMIR is not to be used in insulin infusion pumps.**

**Any change of insulin dose should be made cautiously and only under medical supervision. Changes in insulin strength, timing of dosing, manufacturer, type (e.g., regular, NPH, or insulin analogs), species (animal, human), or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted.**

## PRECAUTIONS

### General

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. The first symptoms of hyperglycemia usually occur gradually over a period of hours or days. They include nausea, vomiting, drowsiness, flushed dry skin, dry mouth, increased urination, thirst and loss of appetite as well as acetone breath. Untreated hyperglycemic events are potentially fatal.

LEVEMIR is not intended for intravenous or intramuscular administration. The prolonged duration of activity of insulin detemir is dependent on injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia. Absorption after intramuscular administration is both faster and more extensive than absorption after subcutaneous administration.

**LEVEMIR should not be diluted or mixed with any other insulin preparations** (see PRECAUTIONS, Mixing of Insulins).

Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Lipodystrophy and hypersensitivity are among potential clinical adverse effects associated with the use of all insulins.

As with all insulin preparations, the time course of LEVEMIR action may vary in different individuals or at different times in the same individual and is dependent on site of injection, blood supply, temperature, and physical activity.

Adjustment of dosage of any insulin may be necessary if patients change their physical activity or their usual meal plan.

### Hyperglycemia

As with all insulin preparations, hypoglycemic reactions may be associated with the administration of LEVEMIR. Hypoglycemia is the most common adverse effect of insulins. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control (see PRECAUTIONS, Drug Interactions). Such situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to patients' awareness of hypoglycemia.

The time of occurrence of hypoglycemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen or timing of dosing is changed. In patients being switched from other intermediate or long-acting insulin preparations to once- or twice-daily LEVEMIR, dosages can be prescribed on a unit-to-unit basis; however, as with all insulin preparations, dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia.

### Renal Impairment

As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with renal impairment.

### Hepatic Impairment

As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with hepatic impairment.

### Injection Site and Allergic Reactions

As with any insulin therapy, lipodystrophy may occur at the injection site and delay insulin absorption. Other injection site reactions with insulin therapy may include redness, pain, itching, hives, swelling, and inflammation. Continuous rotation of the injection site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to a few

weeks. On rare occasions, injection site reactions may require discontinuation of LEVEMIR.

In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique.

Systemic allergy: Generalized allergy to insulin, which is less common but potentially more serious, may cause rash (including pruritus) over the whole body, shortness of breath, wheezing, reduction in blood pressure, rapid pulse, or sweating. Severe cases of generalized allergy, including anaphylactic reaction, may be life-threatening.

### Intercurrent Conditions

Insulin requirements may be altered during intercurrent conditions such as illness, emotional disturbances, or other stresses.

### Information for Patients

LEVEMIR must only be used if the solution appears clear and colorless with no visible particles. Patients should be informed about potential risks and advantages of LEVEMIR therapy, including the possible side effects. Patients should be offered continued education and advice on insulin therapies, injection technique, life-style management, regular glucose monitoring, periodic glycosylated hemoglobin testing, recognition and management of hypo- and hyperglycemia, adherence to meal planning, complications of insulin therapy, timing of dosage, instruction for use of injection devices and proper storage of insulin. Patients should be informed that frequent, patient-performed blood glucose measurements are needed to achieve effective glycemic control to avoid both hyperglycemia and hypoglycemia. Patients must be instructed on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, or skipped meals. Refer patients to the LEVEMIR "Patient Information" circular for additional information.

As with all patients who have diabetes, the ability to concentrate and/or react may be impaired as a result of hypoglycemia or hyperglycemia.

Patients with diabetes should be advised to inform their health care professional if they are pregnant or are contemplating pregnancy (see PRECAUTIONS, Pregnancy).

### Laboratory Tests

As with all insulin therapy, the therapeutic response to LEVEMIR should be monitored by periodic blood glucose tests. Periodic measurement of HbA<sub>1c</sub> is recommended for the monitoring of long-term glycemic control.

### Drug Interactions

A number of substances affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring.

The following are examples of substances that may reduce the blood-glucose-lowering effect of insulin: corticosteroids, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, albuterol, terbutaline), isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives).

The following are examples of substances that may increase the blood-glucose-lowering effect of insulin and susceptibility to hypoglycemia: oral antidiabetic drugs, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAO inhibitors, propoxyphene, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics.

Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia. In addition, under the influence of sympatholytic medicinal products such as beta-blockers, clonidine, guanethidine, and reserpine, the signs of hypoglycemia may be reduced or absent.

The results of *in-vitro* and *in-vivo* protein binding studies demonstrate that there is no clinically relevant interaction between insulin detemir and fatty acids or other protein bound drugs.

### Mixing of Insulins

If LEVEMIR is mixed with other insulin preparations, the profile of action of one or both individual components may change. Mixing LEVEMIR with insulin aspart, a rapid acting insulin analog, resulted in about 40% reduction in AUC<sub>(0-2h)</sub> and C<sub>max</sub> for insulin aspart compared to separate injections when the ratio of insulin aspart to LEVEMIR was less than 50%.

**LEVEMIR should NOT be mixed or diluted with any other insulin preparations.**

### Carcinogenicity, Mutagenicity, Impairment of Fertility

Standard 2-year carcinogenicity studies in animals have not been performed. Insulin detemir tested negative for genotoxic potential in the *in-vitro* reverse mutation study in bacteria, human peripheral blood lymphocyte chromosome aberration test, and the *in-vivo* mouse micronucleus test.

### Pregnancy: Teratogenic Effects: Pregnancy Category C

In a fertility and embryonic development study, insulin detemir was administered to female rats before mating, during mating, and throughout pregnancy at doses up to 300 nmol/kg/day (3 times the recommended human dose, based on plasma Area Under the Curve (AUC) ratio). Doses of 150 and 300 nmol/kg/day produced numbers of litters with visceral anomalies. Doses up to 900 nmol/kg/day (approximately 135 times the recommended human dose based on AUC ratio) were given to rabbits during organogenesis. Drug-dose related increases in the incidence of fetuses with gall bladder abnormalities such as small, bilobed, bifurcated and missing gall bladders were observed at a dose of 900 nmol/kg/day. The rat and rabbit embryofetal development studies that included concurrent human insulin control groups

indicated that insulin detemir and human insulin had similar effects regarding embryotoxicity and teratogenicity.

### Nursing mothers

It is unknown whether LEVEMIR is excreted in significant amounts in human milk. For this reason, caution should be exercised when LEVEMIR is administered to a nursing mother. Patients with diabetes who are lactating may require adjustments in insulin dose, meal plan, or both.

### Pediatric use

In a controlled clinical study, HbA<sub>1c</sub> concentrations and rates of hypoglycemia were similar among patients treated with LEVEMIR and patients treated with NPH human insulin.

### Geriatric use

Of the total number of subjects in intermediate and long-term clinical studies of LEVEMIR, 85 (type 1 studies) and 363 (type 2 studies) were 65 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly.

### ADVERSE REACTIONS

Adverse events commonly associated with human insulin therapy include the following:

**Body as Whole:** allergic reactions (see PRECAUTIONS, Allergy).

**Skin and Appendages:** lipodystrophy, pruritus, rash. Mild injection site reactions occurred more frequently with LEVEMIR than with NPH human insulin and usually resolved in a few days to a few weeks (see PRECAUTIONS, Allergy).

### Other:

**Hypoglycemia:** (see WARNINGS and PRECAUTIONS).

In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, the incidence of severe hypoglycemia with LEVEMIR was comparable to the incidence with NPH, and, as expected, greater overall in patients with type 1 diabetes (Table 4).

### Weight gain:

In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, LEVEMIR was associated with somewhat less weight gain than NPH (Table 4). Whether these observed differences represent true differences in the effects of LEVEMIR and NPH insulin is not known, since these trials were not blinded and the protocols (e.g., diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences has not been established.

**Table 4: Safety Information on Clinical Studies**

Treatment	# of subjects	Weight (kg)		Hypoglycemia (events/subject/month)		
		Baseline	End of treatment	Major*	Minor**	
<b>Type 1</b>						
Study A	LEVEMIR	N=276	75.0	75.1	0.045	2.184
	NPH	N=133	75.7	76.4	0.035	3.063
Study C	LEVEMIR	N=492	76.5	76.3	0.029	2.397
	NPH	N=257	76.1	76.5	0.027	2.564
Study D	LEVEMIR	N=232	N/A	N/A	0.076	2.677
Pediatric	NPH	N=115	N/A	N/A	0.083	3.203
<b>Type 2</b>						
Study E	LEVEMIR	N=237	82.7	83.7	0.001	0.306
	NPH	N=239	82.4	85.2	0.006	0.595
Study F	LEVEMIR	N=195	81.8	82.3	0.003	0.193
	NPH	N=200	79.6	80.9	0.006	0.235

\* Major = requires assistance of another individual because of neurologic impairment

\*\* Minor = plasma glucose <56 mg/dl, subject able to deal with the episode him/herself

### OVERDOSAGE

Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. After apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid recurrence of hypoglycemia.

**More detailed information is available on request.**

### Rx only

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# Hyponatremia and the Use of Tolvaptan

By Shawn Iverson, Osteopathic Medical Student III, Nova Southeastern College of Osteopathic Medicine

**H** yponatremia is the most common electrolyte abnormality in clinical practice and can have serious consequences when left untreated<sup>1</sup>. The geriatric population is particularly at risk secondary to susceptibility to underlying causes. Decreased water-excretory capacity, heart failure, and SIADH are just a few of the mechanisms that commonly cause hyponatremia in the elderly. Numerous studies have shown hyponatremia to be a poor prognostic factor and its severity to be associated with increased morbidity and mortality.

Depending on the rapidity of onset, symptoms may vary greatly, from asymptomatic to nausea, malaise, headache, lethargy, confusion, obtundation, stupor, seizures, or even coma and death. Correcting the hyponatremia can reverse most of these symptoms, and the vasopressin receptor antagonists offer a new means of doing so. This drug review will discuss the indications, prescribing information, and adverse effects of tolvaptan (Samsca™) use.

brain and are currently being investigated for their role in anxiety and depression.  $V_2$  receptors are found predominantly in the distal convoluted tubule and collection, and antagonism causes a marked aquaresis.<sup>2-6</sup> There are two vaptans currently FDA-approved for treatment of hyponatremia. Conivaptan, a non-selective  $V_{1a}/V_2$  receptor antagonist, and the recently-approved tolvaptan, a selective  $V_2$ -receptor antagonist. Tolvaptan's affinity for the  $V_2$ -receptor is 29 times greater than the  $V_{1a}$ -receptor, which limits its effects to aquaresis. The mechanism described limits the use of  $V_2$ -receptor antagonists to hypervolemic and euvolemic hyponatremia. Tolvaptan is available only in the PO form, which, along with its selectivity, gives it a marketable advantage over conivaptan (available as IV only). Both drugs must be administered in the hospital setting, where serum sodium can be monitored.

## Indications

Hyponatremia is classified as hypervolemic, euvolemic, or hypovolemic (See figure 1). A correct diagnosis of hyponatremia is essential before prescribing vaptans, as causing an aquaresis in a hypovolemic patient can result in death. According to the SALT-1 and SALT-2 trials, tolvaptan significantly increased serum sodium when compared to placebo at 4 days and 30 days from baseline ( $p < 0.001$ ). Urine output was measured on day 1 in both trials and was significantly higher in the tolvaptan group.<sup>7</sup>

Tolvaptan has little effect on other electrolytes, with the exception of potassium in patients on ACE inhibitors, ARBs or potassium-sparing diuretics. Studies showed that, upon discontinuation of tolvaptan, serum sodium concentrations reverted to hyponatremia levels; and stopping the drug requires other means of managing the

**“Vaptans” are a relatively new class of drugs that antagonize vasopressin receptors by preventing the binding of endogenous arginine vasopressin (AVP).**

## Mechanism

“Vaptans” are a relatively new class of drugs that antagonize vasopressin receptors by preventing the binding of endogenous arginine vasopressin (AVP). A defining feature of drugs in this class is selectivity for vasopressin  $V_{1a}$  ( $V_{1a}$ ),  $V_{1b}$ , or  $V_2$ -receptors.  $V_{1a}$ -receptors are found primarily in the vascular smooth muscle, and blocking these receptors prevents vasopressin-mediated vasoconstriction.  $V_{1b}$ -receptors have been found in the

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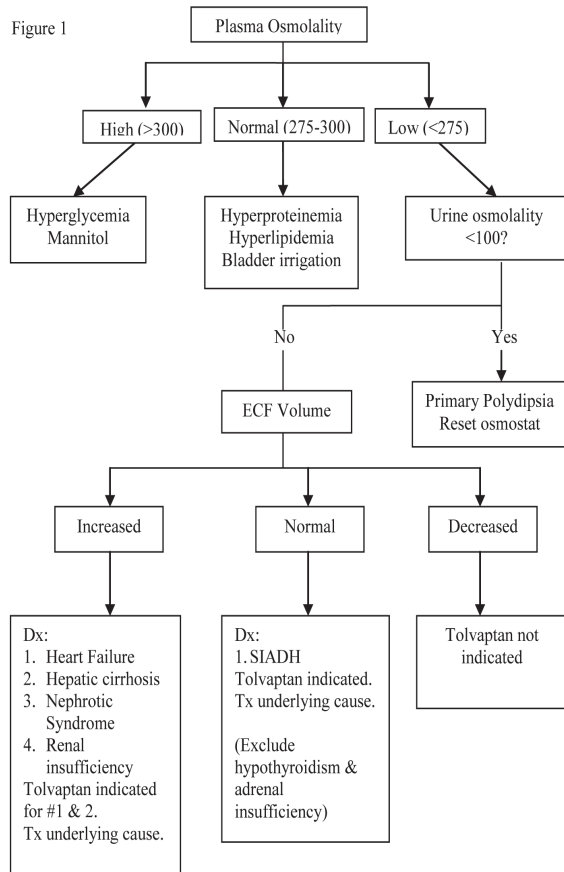
hyponatremia. Tolvaptan should be used only when serum sodium is <125mEq/L or in less marked hyponatremia in a symptomatic patient. Dosing is as follows:

- Start your hospitalized patient on 15mg daily for > 24 hours and monitor sodium and volume status.
- You may increase the dose to 30mg daily at > 24 hours.
- A maximum of 60mg daily can be started after an additional 24 hours.
- It is important to avoid fluid restriction for the first 24 hours.
- Resume fluid restriction upon discontinuation of the drug and monitor serum sodium.

Table 1 (Common CYP3A Inhibitors and Inducers)

CYP3A Inhibitors	CYP3A Inducers
Clarithromycin	Rifampin
Ketoconazole	Rifabutin
Fluconazole	Rifapentin
Itraconazole	Barbiturates
Ritonavir	Phenytoin
Indinavir	Carbamazepine
Nelfinavir	St. John's Wort
Saquinavir	
Cimetidine	
Grapefruit juice	

Figure 1



**Adverse Effects**

V<sub>2</sub>-receptor antagonism from a pharmacologic standpoint sounds like an ideal way to treat hyponatremia, and, in fact, studies showed an impressive correction in serum sodium levels. It is important to note, however, that this drug is not without its side effects, which have the potential to be quite serious. The most common adverse reactions, which occurred at least > 2% more than placebo, include nausea (21%), thirst (16%), dry mouth (13), polyuria (11%), asthenia (9%), constipation (7%), and hyperglycemia (6%). A more serious known risk associated with too rapid a correction in serum sodium (>12mEq/L/24hours) is osmotic demyelination syndrome (ODS). To prevent ODS, it is important to tell patients to drink in response to thirst for the first 24 hours. Symptoms of ODS include dysarthria, mutism, dysphagia, lethargy, change in affect, spastic quadriplegia, seizures, coma, and death.

This drug is not intended for urgent intervention to raise sodium acutely and cannot be used for patients in a hypovolemic state. Because tolvaptan is metabolized via CYP3A4, drug interactions are another important concern to note; concomitant administration of inhibitors or inducers of this enzyme (see table 1) markedly alter the efficacy of this drug and increase the risk of adverse events. Tolvaptan is also a substrate of P-gp and co-administration of P-gp inhibitors (cyclosporine) may necessitate a decrease in tolvaptan dose. This drug is pregnancy category C due lack of available information.

In summary, tolvaptan has been effective in managing hypervolemic and euvolemic hyponatremia in heart failure, cirrhosis, and SIADH patients, with the caveat of continual daily administration to maintain the sodium at desired level.

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# New Medicare Nursing Home Guidance Includes Quality of Life and Environment Requirements

**T**he Centers for Medicare & Medicaid Services (CMS) recently issued new guidance for nursing home surveyors, further defining and clarifying several important dimensions of care to help improve nursing home residents quality of life and environment.

Beginning June 12, 2009, nursing home surveys are being conducted with a sharpened focus on resident rights in key areas such as:

- Ensuring they live with dignity;
- Offering choices in care and services;
- Accommodating the environment to each of their needs and preferences; and
- Creating a more homelike environment including access for visitors.

Currently, nearly 1.5 million individuals live in approximately 15,800 nursing homes on any given day, and about 3 million people will spend some time in a nursing home each year.

“These groundbreaking revisions matter in the daily lives of people who live in the nation’s long-term care facilities,” said CMS Acting Administrator Charlene Frizzera. “The improvements in the guidance are intended to support efforts underway to transform nursing homes into environments that are more like their homes through both environmental changes and resident-centered caregiving.”

The new guidance also calls on nursing homes to deinstitutionalize their physical environments. The guidance highlights institutional practices that facilities should strive to eliminate, including meals served on institutional trays and noise from overhead paging systems, alarms, and large nursing stations.

A homelike environment is not achieved simply through enhancements to the physical environment, according to the new guidance. It concerns striving for person-centered care that emphasizes individualization, relationships, and a psychological environment that welcomes each resident and offers comfort.

The guidance also makes clear that residents have the right to choices concerning their schedules — consistent

with their interests, assessments, and plans of care. Choice over schedules includes, but is not limited to, those matters that are important to the resident, such as daily waking, eating, bathing, and going to bed at night. The facility should gather this information in order to be proactive in assisting residents to fulfill their choices.

CMS inspects nursing homes periodically to ensure that they meet the federal regulations requiring that each resident receive good quality care in a home that also provides good quality of life. CMS provides guidance, to help surveyors interpret those regulations.

The new guidance provides a substantial roadmap for environmental and culture change in nursing homes, while noting that some facilities are further along than others. As noted in the guidance, many facilities cannot immediately make these types of changes, but it should be a goal for all facilities that have not yet made such changes to work toward them.

The guidance can be found at [www.cms.hhs.gov/transmittals/downloads/R48SOMA.pdf](http://www.cms.hhs.gov/transmittals/downloads/R48SOMA.pdf).

## Senate Bill 720 Passes



B 720 relating to physician practice, was signed by Gov. Crist on June 16, 2009, and is now Chapter 2009-177, Laws of Florida.

The bill provides that a supervising physician may not be required to review and co-sign charts or medical records of a physician assistant (PA) under the physician’s supervision.

According to the Florida Osteopathic Medical Association (FOMA), which supported this legislation, it believes that PAs are valuable partners on the health care team. PAs are dependent practitioners who have a supervising physician with personal knowledge of their individual qualifications.

Currently, Florida Statutes specify that the supervising physician is responsible for every act of omission or commission of a PA working under his / her supervision. As such, the physician should decide how best to supervise those PAs.

# Study Links CMD with Improved Nursing Home Quality

**A** new IRB-approved study, commissioned by the American Medical Directors Certification Program (AMDCP), suggests that having an AMDA certified medical director (CMD) contributes positively to a

nursing home's quality. Analysis of data showed that quality scores represented a 15% improvement in quality for facilities with certified medical directors (CMDs). The study appeared in the July issue of the *Journal of the American Medical Directors Association* (JAMDA) accessible at [www.jamda.com](http://www.jamda.com).

AMDCP commissioned the Cowles Research Group to assist in designing a study that would allow for the quantification of care quality within facilities and quantify the effect of a Certified Medical Director on that quality. The Cowles Group used its extensive OSCAR database of nursing home survey results, and focused the review on F-tags for areas that the medical director is most likely to influence — such as restraint use, pressure ulcers, freedom from abuse, weight loss and nutrition, unnecessary drugs, and infection control.

The Cowles Group was provided a list of 547 homes where the AMDA database confirmed the presence of a CMD as medical director. The “standardized quality scores” of these facilities then were compared to the rest of the long-term care facilities in the country. The Cowles Group and Craig Dickstein, its associate statistician, performed the OSCAR database search and the statistical analysis.

Results were impressive. The study states, “Holding other predictors constant, the presence of a CMD will improve quality by about 15%.” According to Cowles Group Owner Mick Cowles, “This difference is both materially and statistically significant.”

Study co-author Fred Rowland, PhD, MD, CMD; Chief of the Section of Geriatric Medicine at St. Francis Hospital and Medical Center and Medical Director of the Mercy Community Health Campus, both in Connecticut, states, “We long have thought that a CMD makes a difference in terms of quality; but until now, this just has been an assumption. We now know that it is a measurable truth.”

“This study is just a first step to see if there is a difference,” Dr. Rowland suggests. “There is room now to look further into databases at specific areas where and ways that the CMD has an impact.” He also suggests that additional studies could

look at a possible relation between quality and cost-effectiveness of care.

Keith Krein, MD, CMD, Chief Medical Officer at Kindred Healthcare, HSD, and an AMDA past-president says, “The

**“The CMD’s positive effect on quality of care, as measured by tangible survey outcomes, is certainly not surprising.”**

*– Keith Krein, MD, CMD*

CMD’s positive effect on quality of care, as measured by tangible survey outcomes, is certainly not surprising. I would argue, however, that this finding represents the tip of the iceberg in terms of the value they bring to their centers. The education, knowledge, and networking experiences that CMDs can draw upon, make them

uniquely suited to impact a range of quality outcomes such as improving the coordination of care by the medical staff, the professionalism and morale of the facility staff, the satisfaction of patients and their families, and therefore the facility’s reputation in the community.”

## Implementing AMDA’s Pain Management in the Long-Term Care Setting Clinical Practice Guideline

### WORKSHOP DATE/TIME:

9 a.m.–4:30 p.m., Thursday, Oct. 29, 2009

### LOCATION: Buena Vista Palace Hotel, Lake Buena Vista

**PAIN MANAGEMENT CPG:** Staff and practitioners in the LTC setting commonly face challenges in pain management. The Clinical Practice Guideline (CPG) “Train the Trainer” program is an interactive workshop that will walk you through each step of implementing any CPG in your facility — and specifically implement the newly revised Pain Management CPG. This workshop includes a general course in the geriatric clinical care process and the pain management CPG, its importance and impact on care, and trains you to assess and evaluate facilities’ current processes and protocols. Everyone will receive a Pain Management Implementation Tool Kit, which provides you with the tools needed to implement the Pain Management CPG in your facility.

**SPACE IS LIMITED:** Registration fee is only \$75 and is accepted on a first-come, first-serve basis. Register now, at the same time you sign up for the “Best Care Practices in the Geriatric Continuum 2009” conference at [www.bestcarepractices.org](http://www.bestcarepractices.org).

# Dogs and Other Pets Living in Close Contact with Humans who Carry MRSA can Become Colonized with the Disease.

**A** recent study about the possibility that therapy dogs could transmit MRSA and/or *C. difficile* to humans<sup>1</sup> received some attention in the media. However, such studies aren't really new. For example, back in 2004, another study<sup>2</sup> concluded that dogs and other pets living in close contact with humans who carry MRSA can become colonized with the disease. The authors stressed a need to detect and treat colonized pets to help avoid human colonization and infection. Nonetheless, this issue has received some attention in the media and on the Internet; and that means facility staff, as well as residents, family members, and other members, may have questions and concerns.

Susan Levy, MD, CMD, medical director at Levindale Hebrew Geriatric Center in Baltimore, suggests that staff and others should not overreact to such studies. "The message here really is the need for solid infection control practices. We need to step back and survey the situation and look at the volume of contact. Staff, residents, and visitors alike need to be educated about infection control and the importance of hand washing and other efforts," she says.

It also is important to have detailed policies and procedures regarding residents and visiting pets. These should address issues such as:

- How to minimize contact with animal saliva, urine, feces, and dander.
- Hand hygiene associated with animal contact.
- Responsibilities of handlers of animals in the facility.
- How bites or scratches will be handled, reported, and documented.
- Restriction of animals from patient care, food preparation, dining, laundry, medication preparation, and sterile areas.
- What species/types of animals are accepted for visits/residence at the facility.
- What vaccinations and other veterinary care animals must have before entering the facility.
- How service animals will be handled and what will happen if a resident must be separated from his/her service animal for any reason (e.g., what arrangements will be made for the animal's care).
- How/when cages, tanks, litter boxes, etc. will be cleaned and how waste will be disposed.
- Precautions to mitigate allergic responses to animals.
- Cleaning procedures for housekeeping surfaces after animal-assisted therapy sessions or pet visits.

## What would you do if you discovered the Golden Egg?

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**Job Seekers may post their résumés (it's FREE) — confidentially, if preferred — so employers can actively search for you.**

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# Thank You!



*Best Care Practices in the Geriatrics Continuum 2009* ❖ Oct. 29-Nov. 1, 2009 ❖ Buena Vista Palace Hotel

**FMDA wishes to thank the following organizations for providing support for our 2009 annual program:**

**AMDA's CPG "Train the Trainer" Implementation Workshop (#101)**

- Supported by an educational grant from **Purdue Pharma L.P.**

**Appropriate Management of Anemia in Long-Term Care: The Essentials of Recognition & Treatment (#111)**

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**Treatment Guidelines for Depression, Anxiety, and Bipolar Disorder in the Nursing Home (#116)**

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**Improving Nursing Home Care by Reducing Potentially Avoidable Hospitalizations (#118)**

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**Translating Patients' Wishes into Medical Orders: The POLST Paradigm (#126)**

- Supported by an educational grant from the **Florida State University Foundation.**

**FMDA wishes to thank the following companies for their support throughout the past year:**

*Abbott Laboratories*  
January 2009 Town Meeting in Tallahassee

*Boehringer Ingelheim*  
June 2009 Town Meeting in Lake Worth

**FMDA wishes to thank the following organizations for providing non-educational support for our 2009 annual program:**

*American Health Associates* — Name Badge Holders

*American Health Associates* — Co-sponsor of the Presidents' Wine & Cheese Reception

*Greystone Health Care Management*  
— Saturday's Continental Breakfast

*Watson Pharma* — Handouts on CD

*Watson Pharma* — Printed conference syllabus

*Wyeth* — Co-sponsor of Presidents' Wine & Cheese Reception

**FMDA wishes to thank the following organizations for hosting Product Theatres on Friday, Oct. 30:**

**1:30-2 p.m.** ❖ *Treating BPH with Speed* ❖ **Watson Pharma**

**5-5:30 p.m.** ❖ *Disease Management of Moderate to Severe Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis* ❖ **Abbott**

**5:30-6:30 p.m.** ❖ *Managing Constipation in the Elderly* ❖ **Takeda**

**FMDA wishes to thank the following organizations for hosting non-CME/CPE/CE/CEU sessions during our 2009 annual program:**

LUNCHEON & PRESENTATION — Thursday, Oct. 29

*Additional Therapeutic Options for Patients with Mixed Dyslipidemia*

— Hosted by **Abbott Labs**

LUNCHEON & PRESENTATION — Thursday, Oct. 29

*A Professional Lecture on the Beta Blocker Bystolic (nebivolol)*

— Hosted by **Forest Pharmaceuticals**

DINNER & PRESENTATION — Thursday, Oct. 29

*Advances in the Treatment of Gout in the Elderly*

— Hosted by **Takeda**

LUNCHEON & PRESENTATION — Friday, Oct. 30

*Alzheimer's Disease in the Long-Term Care Setting*

— Hosted by **Eisai and Pfizer**

DINNER & PRESENTATION — Saturday, Oct. 31

*Reducing Exacerbations in COPD*

— Hosted by **GlaxoSmithKline**



See you at “Best Care Practices in the Geriatrics Continuum 2009”

FMDA’s Progress Report

Fall 2009

# C. a difference

*Florastor, improving conventional C. difficile therapy<sup>†</sup>*

- Florastor can reduce CDAD recurrence rates by up to 50%<sup>1</sup>
- Complements your standard of care for recurrent C. difficile<sup>†</sup>
- Florastor destroys C. difficile toxins A & B<sup>2</sup>
- Prevents and treats diarrhea<sup>†</sup>
- Promotes recovery<sup>†</sup>
- Resistant to all antibiotics; unlike Lactinex™  
Florastor can be taken at the same time  
as antibiotics<sup>3</sup>.



[www.sbouldarii.com](http://www.sbouldarii.com)

1. McFarland, et al. A randomized Placebo-Controlled Trial of *Saccharomyces boulardii* in combination with standard antibiotics for *Clostridium difficile* Disease. *JAMA*. 1994. 271: No. 24: 1913-1918.

2. Castagliuolo, et al. *Saccharomyces boulardii* protease, inhibits the effects of *Clostridium difficile* toxins A and B in human colonic mucosa. *Infection and Immunity*. 1999. 67: (1): 302-307.

3. Data online: <http://www.bd.com/ds/technicalCenter/productFaq/FaqLactinex.asp>

<sup>†</sup>These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.