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fmda™

Dedicated To Florida Long Term Care Medicine

Progress Report

APEX® AWARDS FOR PUBLICATION EXCELLENCE

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

President's Letter

We've started the year off with a bang! In January, we held our first board and CME/Education Committee meetings via conference call and continued our planning for 2010. This year, we will be celebrating our 19th anniversary conference, not to mention the 10th annual meeting since we were joined by the Florida Chapter of the American Society of Consultant Pharmacists. So, we hope to celebrate with them and salute our pharmacist brothers and sisters.

In February, FMDA's Industry Advisory Board (IAB) met in Tampa for a highly informative meeting as well as a celebration of IAB Founding Chairman Dr. Malcolm Fraser's 10th Anniversary — since he founded it. Also, on February 19, we held another set of board meeting and CME/Education Committee meetings, this time in Daytona Beach Shores. After successfully meeting in person during the day, that evening we hosted another Town Meeting with nearly 100 guests in attendance at the dinner-program which was sponsored by Jake McDowell and Eli Lilly. Our thanks also go to Alpha Physician Services for allowing us to host our Town Meeting as part of their annual physician's forum (see page 8).

March was another busy month as we traveled to Long Beach, Calif., to participate in AMDA's annual symposium for medical directors. In addition to attending educational sessions, some of our members were presenters, and our executive director participated in a number of AMDA leadership and training programs. FMDA exhibited there to promote its annual conference and also held a set of board and CME/Education Committee meetings.

Friday night at AMDA was set aside for state chapter receptions and Florida took advantage of the occassion to host more than 40 guests. In between the politicking of AMDA candidates seeking office, FMDA took a few moments to honor Dr. Dennis Stone and to thank him for his contribution to FMDA over the years. In a FMDA twist of fate, we had the pleasure of honoring Dr. Victor Gambone with a plaque in appreciation of his many, many years of dedicated service to FMDA. This was presented to him as a result of his recent move to Laguna Beach, Calif.

He was an active FMDA member and its former chairman of the board (2007-2009) and past-president (2002-2005), and was currently a member of FMDA's board of directors (see page 5).

As a symbolic gesture, Dr. Gambone officiated at the formal swearing-in ceremony of the appointed replacement on the FMDA board — Dr. Robert Kaplan.

Plans for the 2010 conference are progressing very well. Our hotel this year is the Walt Disney World Swan and Dolphin — a beautiful property, where all the sleeping rooms have been remodeled and where you can catch a ferry ride to Epcot from its docks. We worked out a deal with the hotel to offer our participants a discounted pre-convention hotel room rate that everyone should take advantage of by May 31.

We're introducing a new and exciting "Ambassador" program for members to connect with first-time attendees in order to make them feel more welcome. Please consider volunteering in this worthwhile effort (see page 9)!

With another year upon us, it is time for a new membership recruitment effort. So, with the help and guidance of our trusty Membership Chair Dr. Carl Suchar, who is also the chairman of the board, we are introducing a unique and fun approach to reaching out to our peers and co-workers. For more details, please go to page 9. I am certain that with a grand prize for the most new member referrals being an Apple iPad, we will all have a lot of competition and a great time.

I am very grateful for the fine stewardship provided by our dedicated members of our board of directors. Despite a difficult economy, we've remained prudent as we pushed forward to maintain and improve the level of services and opportunities provided to our members.

Looking forward to seeing you in person sometime between now and the "Best Care Practices in the Geriatrics Continuum 2010" conference in Orlando, Oct. 28-31, 2010.

Sincerely yours,

Hugh W. Thomas, DO, FAAFP, CMD
President

BCP: Another Outstanding Educational Program

— Register today for the Best Care Practices in the Geriatrics Continuum 2010

Dear Friends:

Here is an update on plans for our 2010 annual conference. We are already working with AMDA to provide you an "advanced" Clinical Practice Guidelines implementation course. This optional course will be offered on Thursday, Oct. 28, a preconference day.

In addition, we will be hosting another program for new practitioners and those new to long-term care and geriatrics. This course covers what any physician, pharmacist, PA, or nurse practitioner needs to know to practice in a skilled nursing facility. Presenters will include an expert physician, senior care pharmacist, nurse practitioner, director of nursing, and nursing home administrator.

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 **19th Annual Halloween Horror Nights** (**www.halloweenhorrornights.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 2010"** at *Disney's* Magic Kingdom.

HOTEL RESERVATIONS: This year's conference will be held at the beautiful **Walt Disney World Swan and Dolphin,** 1500 Epcot Resorts Blvd., Lake Buena Vista, FL 32830. Visit their website at **www.Swandolphin.com**/ and see all they have to offer our attendees.

The special group rate is only **$175** single/double occupancy plus a discounted resort fee of $10 per day, and $9 for self-parking and $14 for valet parking per day. To make a reservation, please call **(800) 227-1500** 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**. To guarantee rate and room availability, you should make your reservations no later than Sept. 26. This special group rate will be applicable three (3) days prior to and three (3) days following the main program dates, subject to availability.

And for a limited time, we've arranged for a special pre-conference hotel room rate of **$165** — but it is only good until May 31, 2010. After that, the rate during our conference will be **$175**.

Yours truly,

John Symeonides, MD, CMD
Program Director
Best Care Practices in the Geriatrics Continuum 2010

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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.

Greetings From FMDA's New NP/PA Board Member

My name is Karen Jones, and I would like to introduce myself as the newly elected ex-officio NP/PA liaison to the board of directors of the Florida Medical Directors Association.

Karen Jones

I am a geriatric nurse practitioner in West Palm Beach, Florida, and I have been involved with long-term care for approximately 10 years. I graduated from Florida State University with a bachelor's degree in communications and then went into nursing, with oncology as my specialty. From there, I received my master's degree in advanced geriatric nursing from Florida Atlantic University. I have been involved in skilled and long-term care facilities for the past five years, loving every minute of it. I have found my calling.

Recently, I became involved with FMDA as a Professional Affiliate member and as a member of the CME/Education Committee. It has been an exciting time, getting to know everyone and being a part of planning such great educational conferences as our "Best Care Practices" conference held in Orlando this past October.

The next year and a half will be a thrilling time for me, and I look forward to helping plan one of the best conferences of the year through my continued involvement on the Committee.

Some of my other goals are to promote FMDA membership and promote involvement within the PA/ARNP communities throughout the state. Because of new health-care reforms coming our way, this is an important time for all of us to become involved with our profession. We need to stay abreast of changes, and we can do this only through education and communication.

I would also like to get more PA/ARNPs involved with the several committees within FMDA, whether it be Governmental Affairs, Newsletter, or the Poster Review Committee. We, as practitioners, have much to offer our organization and our profession.

I look forward to serving and to this being one of the most rewarding times of my life.

— Karen Jones, ARNP

FMDA Shines at AMDA

FMDA President Hugh Thomas, DO, CMD, (right) bestows a "Lifetime FMDA Membership" to Dennis Stone, MD, CMD.

Florida Chapter Reception guests (from left): Bruce Robinson, MD; Ladislav Volicer, MD, PhD; and Naushira Pandya, MD, CMD

AMDA Foundation Immediate Past Chair Dr. Jonathan Musher (left) accepts a $3,000 FMDA donation from FMDA President Dr. Hugh Thomas.

Florida Chapter Reception (from left): Michael Ward, chief operating officer, and Ben Atkins, president and chief executive officer of Traditions Management; with Barbara Eckes and former FMDA Chairman of the Board and Past-President Victor Gambone, MD, CMD. Dr. Gambone is corporate medical director for Traditions Management.

AMDA transitions-of-care presentation panelists (from left) Dr. Alice Bonner; Dr. Jim Lett, past-president of both AMDA and FMDA; Dr. Joseph Ouslander; former FMDA Ex-Officio Board member Jo Ann Fisher; FMDA Immediate Past-President Dr. John Potomski, and Dr. Cornelius Foley

Stand Up and be Counted

We invite each member to become more involved in the Florida Medical Directors Association (FMDA) by becoming a volunteer. Numerous opportunities are available to serve for a year, a month or a day. You can help guide our organization through committees, task forces, and subsections that advise the board of directors, provide advice, facilitate or lead various programs, or even start a new subsection.

Volunteers are the heart of FMDA. Our strength is a result of the time and effort provided by those who volunteer their time and knowledge to serve their colleagues and to further all medical directors in LTC.

Participating as a volunteer provides a gateway to develop and hone leadership skills, increase professional contacts, and give back to the profession. Let us know what types of volunteer opportunities interest you.

We look forward to your participation in FMDA. Should you have any questions, please contact Dr. Hugh Thomas, president (**hwthomas2000@aol.com**), or Ian Cordes, executive director, at **(561) 659-5581** or **ian.cordes@fmda.org**.

Living Through Art: With Help from Edna Hibel

By Karen Jones, ARNP; NP/PA Director of FMDA

It started out as an empty space. No one was using it except for storage of miscellaneous ice carts and chart racks. It was the perfect size for *something*, but it took me a while to figure out what could be done with this oddly shaped outdoor room that no one wanted.

Space in nursing homes is so precious these days that we need to become creative and use every possible nook and cranny. This particular area was open, and the sun shines in when skies are blue, but there was also the dilemma of rainy days, even in sunny South Florida.

All of a sudden, it came to me! Why not create a "My Space" for the residents?

In nursing homes, there is so little that residents can call their own. Why not give space to resident artists who wanted to paint? They would be immortalized on the walls of this funny little room they could call their own.

Slowly, the plan formed in my head: We could divide the walls into spaces and give a painting space to anyone who wanted it.

From left to right: Karen Jones, Edna Hibel, a Lakeside Life Care Center resident; and Daniel Fortier, MD, CMD, medical director at Lakeside Life Care Center, and treasurer of FMDA

Edna Hibel was there to help the residents and encourage them every step of the way in their creative encounters with painting in "their space." She was even so kind as to give some of the residents an art lesson!

First, I needed the administrator's approval. That was the easy part; she was all for it and gave me the green light to proceed with my plan. I solicited the help of my family and friends, and we spent a day measuring symmetrical spaces on all four walls. This turned out to be much harder than anticipated. Precise measuring was necessary, and taping off the spaces had to be perfect. Painting between the lines to actually form the spaces was challenging.

The painting took two coats for a good true color. It sounded easy until we had to put up the tape and paint on the outside textured wall! What a chore that became, but we all made the best of it by having a picnic, with music playing and a lot of laughter.

The best part was seeing the residents wander by, stop, and watch to see what was transpiring at their home. They would look and walk by, then turn around and come back, and stand and watch for the longest time. I must point out that the nursing home has many residents with dementia or a psychiatric diagnosis, so this was quite something for them to see.

Upon completion of the "spaces," the residents began to paint. At first, it started off with just one or two who painted. This took much encouragement because, as we all know, new items and ideas do not come easily to long-term-care residents. Though quite skeptical at first, more and more residents trickled

in to partake of our "living through art" project. Before we knew it, all the spaces were being painted, and the talent and the imagination were amazing.

This project is a long-term one, and it is forever evolving. At Lakeside Life Care Center in West Palm Beach, where the project is located, we were fortunate to have a famous local artist assist us with our painting. Edna Hibel helped the residents and encouraged them every step of the way in their creative encounters in "their space." She was even so kind as to give some residents an art lesson! We are so fortunate to have her; she is very kind and generous with her time and knowledge. She even painted her own version of "living through art" on our walls and columns, becoming immortalized at Lakeside.

This project has been included in the Lakeside Life Care Dementia Program, which evaluates residents' cognitive level and then puts together a plan of care and list of activities that engage and stimulate each resident. This way, we can best treat each resident according to his/her personal needs. There are stimulating day programs and relaxing, wind-down night programs for all levels of dementia.

Utilizing a formerly "empty" space and turning it into a positive environment for residents has been a totally worthwhile experience not only for our staff, but also for the administration, family members, and me.

It is so heartwarming when the residents ask, "Can we paint today?" Not only has this project gotten the residents outside, but it has also given them a sense of worth, while improving their coordination and upper-body muscular development.

Edna Hibel's instruction became a wonderful learning experience, and what better way to spend a nice sunny day outside in Florida!

Edna Hibel

Born in Massachusetts, in 1917, the internationally-renowned artist Edna Hibel, has been painting for more than 70 years. Her talent was encouraged and first developed under the direction of noted portraitist Gregory Michaels. She then studied with the renowned Russian and German masters, Alexander Yakovlev and Karl Zerbe, at the Boston Museum School of Fine Arts. Completing her training at the Museum School in 1939, Hibel was awarded the Ruth B. Sturtevant Traveling Fellowship for study and painting in Mexico.

Over the past 40 years, the artwork of Edna Hibel has met with growing critical and popular acclaim, as major museums and galleries in 20 countries on four continents have held numerous exhibitions of her work. Her paintings are in the collections of many of America's outstanding universities and public museums.

More recently, Edna Hibel's artwork has been exhibited in prestigious museums, galleries, universities, and palaces in Austria, Belgium, Costa Rica, the People's Republic of China, Israel, Japan, Russia, Switzerland, Yugoslavia, and the United States. She is also the only foreign artist to twice exhibit her work in the Soviet Union, and the only foreign woman to produce a television documentary in that country.

— Source: Hibel Studio, Inc.

News From the New Florida Chapter of GAPNA

By Jo Ann Fisher, MSN, FNP-BC; President of FL-GAPNA

The newly-approved Florida chapter of Gerontological Advanced Practice Nurses Association (GAPNA) met in Daytona Beach Shores at The Shores Resort & Spa on Feb. 19, 2010. Our chapter met early Friday evening, with complimentary meeting space arranged by Alpha Physician Services.

Following our meeting, we were guests at the Florida Medical Directors Association's (FMDA) Town Meeting, with a dinner-presentation supported by Eli Lilly. Some of our members stayed on Saturday to attend the Alpha Physician Services' meeting "Collaborative Best Practices in Long-Term Care Achieving Excellence 2010."

Chapter officers who were confirmed included: Jo Ann Fisher, president; Patricia Wallace, president-elect; Wendy Huckery, secretary; and Charlene Demers, treasurer.

Debi Hunt will be on the Education Committee with Marsha Rauch, and Barbara Phillips, volunteered to be the chapter historian.

Jo Ann Fisher presented the application process for state chapter approval, and Charlene Demers gave a brief treasurer's report. Jo Ann reported that GAPNA has a new management company, Anthony J. Jannetti, Inc.; and she gave an update on how state dues would be sent to us by GAPNA. Patty Wallace reviewed the bylaws, and there were some minor recommendations for change.

ENP Network, a communication utility for nursing, is an ANP advocate; a website — **www.flgapna.org** — was discussed and approved by all in attendance. John Rauch had reserved several domains for us, and it was agreed that he would contact Andrew Keller, founder of ENP Network, to turn over a domain for us to own. Since our meeting, he has provided two sites at no cost to FL GAPNA!

Our special guest, Chris Saslo is president of FNPN. He discussed the NP movement in Florida and offered some good advice, based on his many years' experience with FNPN.

In the next year, we hope to increase membership and involve others through mentorship. While we don't view ourselves as a political organization, Debi Hunt is active in FNA and will keep us updated, and Chris advised that we could have a link on his organization's website. We also committed to traveling for meetings so that we could go to different regions quarterly. We will meet in St. Augustine on May 22, in West Palm Beach on Aug. 21, and in Orlando in conjunction with FMDA's convention, "Best Care Practices in LTC," October 28-31 at the Swan and Dolphin Hotel at Disney. Everyone present was encouraged to attend GAPNA's annual meeting in Albuquerque in September.

FMDA Hosts Town Meeting in Daytona Beach

By Carl Suchar, DO, CMD; Chairman of the Board and Chairman of the Membership Committee

On 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, Fort Lauderdale, Lake Worth, Tallahassee, and now Daytona Beach.

We hosted another memorable Town Meeting & Dinner on Feb. 19.

From left: Ex-officio NP/PA Director Karen Jones, Treasurer Dr. Daniel Fortier, President Dr. Hugh Thomas, new Director Dr. Robert Kaplan, Director Dr. John Symeonides, and Chairman of the Board Dr. Carl Suchar

This time, the location was The Shores Resort in Daytona Beach Shores. Earlier in the day, the CME/Education Committee and the board of directors met for regularly scheduled business meetings. Later that evening, our Town Meeting was held in conjunction with Alpha Physician's Annual Physicians' Forum and the dinner was generously sponsored by Eli Lilly and Jake McDowell, our host.

Another Town Meeting is being planned for the summer, when spouses and guests will be invited to attend. Stay tuned for more information.

Historic 10th Annual IAB Meeting Held in Tampa

FMDA President Hugh Thomas, DO, CMD, (right) presents founding IAB Chairman Malcolm Fraser, MD, CMD, with an award to honor the 10th anniversary of the Industry Advisory Board and his chairmanship.

10th Anniversary of FMDA's Industry Advisory Board; Tuesday, Feb. 2, 2010; Marriott Tampa Airport *(from left): Al Henry, executive director, Senior Care, Watson Pharma; Matthew Reese, BS, educational programming coordinator, FMDA; Jo Ann Fisher, FNP-BC, president of the Florida Chapter of GAPNA; Michael Pocza, director for LTC AM in the Southeast, Novartis Pharmaceuticals; Robert Kaplan, MD, vice president of Medical Services, Alpha Physician Services; Steve Selznick, DO, CMD, CFP Physicians Group; Jaynie Christenson, regional account manager, Abbott Laboratories; Hugh Thomas, DO, CMD, FMDA president; Rhonda Randall, DO, VP of Clinical Performance, Ovations, National Medical Director Advanced Illness, Evercare Hospice & Palliative Care; Harry Novotny, MBA, national account manager, Strativa Pharmaceuticals; Scott Petersen, Forest Senior Care, account manager/Florida, Forest Laboratories; IAB Co-Chair John Maddox, corporate account director, Astellas Pharma; Steve McLaughlin, regional LTC account manager/Florida, Novartis Pharmaceuticals; IAB Chairman Malcolm Fraser, MD, CMD, president, Bay Geriatrics; Niel Patel, channel strategy manager, Takeda Pharmaceuticals; Kent Pearson, RPh, JD, Esq., Pharmaceutical Products Division, government customer marketing manager, Integrated Managed Health Care, Abbott Laboratories; Walt Banket, national account manager, Senior Care, Amgen; and Chris Gregg, account representative, American Health Associates Clinical Labs*

2010 Membership Campaign is Here

By Carl Suchar, DO, CMD; Chairman of the Board; Chairman of the Membership Committee

The Membership Committee of FMDA is happy to announce the start of its new 2010 Membership Campaign. Our goal is for each current FMDA member (physician, NP, or PA) to personally sign up at least one new member this year.

To accomplish this goal, every current member will be assigned another member "buddy," who is to be called and encouraged until that person has signed up a new FMDA member.

Incentives for both old and new members will include:

1) Recruiting member gets 50% off renewal dues and 20% off 2010 conference registration fees as long as the new member attends the 2010 annual conference.

2) New Member: If the new recruit has not been a member in the last three years, he or she will receive 50% off FMDA membership dues and 20% off the 2010 annual conference registration fee.

3) If an FMDA member recruits at least two (2) new members, he or she is given a coupon worth 50% off annual dues, plus 40% off 2010 conference registration fees – but both new members must register to attend the conference.

4) **Door Prizes** – Will be given away during the ***Best Care Practices in the Geriatrics Continuum 2010*** conference:

a. All FMDA members who recruited at least one new member will be eligible for the prize drawings.

b. There will also be separate raffles during the conference door for NPs/PAs and physicians.

c. There will also be a separate drawing for most referred new members — You could win an **Apple iPad**!

As the leading organization in Florida promoting the multidisciplinary approach to long-term and rehabilitative care at Florida's nursing homes, we hope to reach the highest possible number of physicians, nurse practitioners, and physician assistants as possible. We need all of your help if we are to succeed.

Here is what a couple of our members have said about the value of FMDA membership:

"It's simple. More than 15 years ago, I joined FMDA to network with colleagues in long-term care, and access quality education programs. Today, having established many personal and professional relationships, I continue to find immeasurable value as a FMDA member."

— Robert Kaplan, MD, Longwood

"As a nurse practitioner, being a member FMDA has given me many opportunities to network with other nurse practitioners and physicians in long-term care. Membership in FMDA has also provided me with a base of knowledge for new and innovative advances for my practice in geriatrics. The conference alone is one of the best I have attended, besides all the latest updates you receive on what is new in the health care arena."

— Karen Jones, ARNP, West Palm Beach

Thanks again, for all that you do for Florida's frail and elderly nursing home patients.

Conference Ambassadors Wanted

If you have got some mileage in the business, some successes as well as scars, you have a lot to offer newcomers attending their first annual conference.

So, whether you are a physician, pharmacist, nurse practitioner, physician assistant, director of nursing, or nursing home administrator, please sign up to be an "Ambassador" to newcomers at the upcoming "Best Care Practices in the Geriatrics Continuum 2010" conference. This year's conference will be at Disney's Swan and Dolphin in Lake Buena Vista from Oct. 28-31, 2010.

Being an Ambassador is actually pretty light duty, says FMDA President Hugh Thomas, DO, CMD. Volunteers will be assigned to a newcomer prior to the conference, and will be asked to touch base with that person throughout the conference.

"This is a way to get new people engaged," says Dr. Thomas. Ambassadors will also be asked to follow up with the newcomer after the conference, to find out what value he or she derived from it, and to explore how FMDA can benefit him or her on an ongoing basis.

You can sign up to be an Ambassador when you receive your conference registration materials, which will arrive at your desk in the summer.

Watch your e-mail and the mail for the complete conference brochure and registration form. Or, call the office at **(561) 659-5581**, or visit **www.bestcarepractices.org**.

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.

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.

For your patients with type 2 diabetes,

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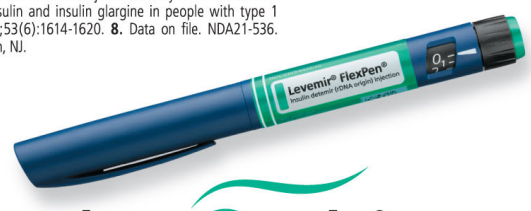
Levemir® helps patients with diabetes achieve their A1C goal.[2,3]

- 24-hour action at a once-daily dose[4,5]
- Provides consistent insulin absorption and action, day after day[4,6,7]
- Less weight gain[8]*

To access complimentary e-learning programs, visit novomedlink.com/Levemir

References: 1. Data on file. Novo Nordisk Inc, Princeton, NJ. **2.** Meneghini LF, Rosenberg KH, Koenen C, Meriläinen MJ, Lüddeke H-J. Insulin detemir improves glycaemic control with less hypoglycaemia and no weight gain in patients with type 2 diabetes who were insulin naive or treated with NPH or insulin glargine: clinical practice experience from a German subgroup of the PREDICTIVE study. *Diabetes Obes Metab.* 2007;9(3):418-427. **3.** Hermansen K, Davies M, Derezinski T, Ravn GM, Clauson P, Home P, for the Levemir Treat-to-Target Study Group. A 26-week, randomized, parallel, treat-to-target trial comparing insulin detemir with NPH insulin as add-on therapy to oral glucose-lowering drugs in insulin-naive people with type 2 diabetes. *Diabetes Care.* 2006;29(6):1269-1274. **4.** Klein O, Lynge J, Endahl L, Damholt B, Nosek L, Heise T. Albumin-bound basal insulin analogues (insulin detemir and NN344): comparable time-action profiles but less variability than insulin glargine in type 2 diabetes. *Diabetes Obes Metab.* 2007;9(3):290-299. **5.** Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B. Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. *Clin Ther.* 2006;28(10):1569-1581. **6.** Danne T, Endahl L, Haahr H, et al. Lower within-subject variability in pharmacokinetic profiles of insulin detemir in comparison to insulin glargine in children and adolescents with type 1 diabetes. Presented at: 43rd Annual Meeting of the European Association for the Study of Diabetes; September 17-21, 2007; Amsterdam, Netherlands. Abstract 0189. **7.** Heise T, Nosek L, Rønn BB, et al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. *Diabetes.* 2004;53(6):1614-1620. **8.** Data on file. NDA21-536. Novo Nordisk Inc, Princeton, NJ.



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insulin detemir (rDNA origin) injection

novo nordisk®

Please see brief summary of Prescribing Information on adjacent page.

133236-R2 November 2008

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

Hypoglycemia 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.

Hypoglycemia

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_{1c} 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 $AUC_{(0\text{-}2h)}$ and C_{max} 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_{1c} 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

			Weight (kg)		Hypoglycemia (events/subject/month)	
	Treatment	# of subjects	Baseline	End of treatment	Major*	Minor**
Type 1						
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
Type 2						
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 reoccurrence of hypoglycemia.

More detailed information is available on request.

Rx only

Date of issue: October 19, 2005

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FMDA Weighs in on DEA and Diversion Issues in Support of Long-Term Care Patients

By Ian Cordes, MBA, NHA; Executive Director

A continuing care retirement community (CCRC) provider recently tried to convince the Florida legislature that up to 30,000 nursing home patients in Florida nursing homes could be better cared for in assisted living. As a result of their lobbying efforts, FMDA issued the position statement on the right which was to be submitted into the public record at a legislators' committee meeting in Tallahassee.

In looking at the facts, FMDA's leadership determined that it did not share the same view as the CCRC provider and in the end, the legislators agreed and killed the measure.

Another industry-related issue impacts LTC from the federal level. FMDA has been following the impact of the enforcement policies of the DEA with regard to nursing homes and controlled substances and has received a number of phone calls and e-mails from its members who have grown increasingly concerned.

Dec. 15, 2009

The Honorable Bill Nelson
United States Senator
720 Hart Building
Washington, DC 20510

Dear Senator Nelson,

On behalf of the Florida Medical Directors Association, I am writing to urge your personal support on proposed regulatory changes to the Controlled Substances Act of 1970.

As you know, the Senate Special Committee on Aging sent Attorney General Holder a letter on October 19, 2009 which included proposed legislative changes to the Controlled Substances Act (CSA). The proposed legislation aims to improve the timely and appropriate treatment of pain for long-term care residents.

Both in Florida and nationally, we have seen dramatic changes in health care since 1970 when the CSA was passed into law. This is particularly true of long-term care medicine which provides care for an estimated 1.6 million nursing facility residents on any given day. More importantly, of those over the age of 65, roughly 40% are expected to spend at least part of their remaining lives in a nursing facility. Unlike 1970, today's long-term care residents are substantially more debilitated and have multiple, complex medical problems. As would be anticipated with such a frail population, chronic pain is a major issue. It is estimated that between 45 and 80% of nursing facility residents have chronic pain, yet often this pain is undertreated. The CSA has never been updated to reflect these changes in the health care system. The CSA is health care of the 1960s. Increasing the barriers to adequate pain management for our long-term care residents is simply untenable.

The organization I represent is witnessing numerous situations in which patients are suffering delays in appropriate pain management as a direct result of the CSA. I respectfully ask that you act promptly to move forward with the legislation proposed by the Senate Special Committee on Aging. Both myself and the Florida Medical Directors Association supports this legislation.

I would be happy to assist you in any efforts or to answer any questions you may have.

Respectfully,

Hugh W. Thomas, DO, FAAFP, CMD
Assistant Professor of Medicine, University of Central Florida School of Medicine
President, Florida Medical Director's Association

This effort is supported by:
– Florida Academy of Family Physicians
– Florida Association Directors of Nursing Administration/LTC
– Florida Association of Homes and Services for the Aging
– Florida Chapter, American Society of Consultant Pharmacists
– Florida Health Care Association
– Florida Nurses Association

Enclosures:
• Letter to Attorney General Holder
• Senate Special Committee on Aging Proposed Legislation

Position Statement

The Florida Medical Directors Association (FMDA) recognizes that the state of Florida desires a policy (based upon the settlement of "Long v. Benson lawsuit") that would strengthen the provision of home- and community-based service (HCBS) options for Medicaid recipients needing long-term care (LTC). The testimony attached is the opinion of one diversion provider (American Eldercare) and does not necessarily reflect the position of the other diversion providers or FMDA. For example, another diversion provider (Evercare) believes the number of custodial Medicaid patients in Florida nursing homes (NH) who would choose to and are capable of being safely transitioned to a HCBS setting are much closer to DOEA's estimate (800) than the number used in American Eldercare's testimony (29,750). In other states where this has been studied, such as in Arizona, it has been demonstrated that over time there is an increase in HCBS options and slower rate of growth in NH custodial care. However, that is primarily driven by offering alternatives to people currently living in the community and minimally due to transitioning residents out of NHs (i.e., delay or defer NH placement rather than promote discharge).

FMDA supports the concept that care of the elderly should be individualized and provided in the least restrictive appropriate environment, consistent with OBRA 87. Representing physicians in the LTC continuum, FMDA is supportive of expanding programs that protect LTC Medicaid patients' right to choose HCBS options when they can be safely cared for in the community. However, there must be clear guidance, oversight and accountability to any process of transitioning less frail long-term nursing home residents out of the nursing home to ensure it is done in a manner that protects patients' health, safety and independence. There is work underway at American Medical Directors Association to address this through the development of medical care protocols for assisted living facilities. Finally, we have concerns that the number of persons currently living in Florida's nursing homes that could safely be transitioned to a HCBS setting presented in the attached testimony are significantly inflated and lack supporting evidence.

Hugh Thomas, DO, FAAFP, CMD
President

John Potomski Jr., DO, CMD
Chairman Government Affairs
Immediate Past President

In response, FMDA wrote letters to Florida U.S. senators Nelson and LeMieux this past December, to share its strong concerns over the DEA's enforcement of existing rules and our expectation that nurses in nursing homes be considered agents of the prescribing physician.

In addition, FMDA sought and received formal support for these official letters from the following statewide organizations, for whom we are very appreciative:

Florida Academy of Family Physicians, Florida Association Directors of Nursing Administration/LTC, Florida Association of Homes and Services for the Aging, Florida Chapter, American Society of Consultant Pharmacists, Florida Health Care Association, Florida Nurses Association

If you are having related issues in your facility, please let us know how your patients are being effected.

FMDA *Progress Report* has a circulation of more than 1,000 physicians, physician assistants, nurse practitioners, directors of nursing, administrators and other LTC professionals. *Progress Report* is a trademark of FMDA. Editor Karl Dhana, MD, CMD, welcomes letters, original articles and photos. If you would like to contribute to this newsletter, please e-mail your article to ian.cordes@fmda.org. Any statements of fact or opinion expressed here are the sole responsibility of the authors.

DEA Publishes Interim Rule to Allow Prescribing of Controlled Substances Electronically

The Department of Justice and the Drug Enforcement Administration (DEA) published an "Interim Final Rule with Request for Comment" in the *Federal Register* on Wednesday, March 31, 2010. The rule was in reference to 21 CFR Parts 1300, 1304, 1306, and 1311 [Docket No. DEA–218I], RIN 1117–AA61, Electronic Prescriptions for Controlled Substances.

The following summary was published by the DEA: The DEA is revising its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically.

The regulations will also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are in addition to, not a replacement of, the existing rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances dispensing; additionally, the regulations will reduce paperwork for DEA registrants who dispense controlled substances and have the potential to reduce prescription forgery. The regulations will also have the potential to reduce the number of prescription errors caused by illegible handwriting and misunderstood oral prescriptions.

Moreover, they will help both pharmacies and hospitals to integrate prescription records into other medical records more directly, which may increase efficiency, and potentially reduce the amount of time patients spend waiting to have their prescriptions filled.

DATES: This rule has been classified as a major rule subject to Congressional review. The effective date is June 1, 2010.

How is Long-Term Care Impacted?

This revised rule eliminates the need for the simultaneous signing and transmission of e-prescriptions. Specifically affecting LTC is the revised provision that would enable a prescriber (on- or off-site) to write an electronic prescription in their clinic system, "lock" the core prescription contents by electronically signing it and then forward it to a skilled nursing facility for review before sending it to the pharmacy.

Since these regulations are in addition to and not a replacement of existing regulations governing prescribing controlled substances, it is unlikely that e-prescribing will alleviate the delays patients in LTC are currently experiencing given the current technical impediments to immediately implementing e-prescribing in LTC.

FMDA Membership Application

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 specialities 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.

Name: _____ **Title:** _____

The mailing address below is for _____ **the facility, or** _____ **my regular office address. Referred by FMDA member:** _____

Facility Name/Affiliation: _____

Organization's Name: _____

Mailing Address: _____ **City:** _____ **State/ZIP:** _____ **County:** _____

Phone: _____ **Fax:** _____ **E-mail:** _____

Please make check payable to FMDA and mail to: 200 Butler Street, Suite 305 • West Palm Beach, FL 33407

(561) 659-5581 • fax: (561) 659-1291 • www.fmda.org • e-mail: ian.cordes@fmda.org

Please share this information with a colleague who would benefit from membership in FMDA!

FMDA is a not-for-profit corporation. Its federal tax identification number is 59-3079300.

A Review of 2009 Published Scientific Articles: Part I

A recent AMDA presentation during its Long-Term Care Medicine 2010 presented a dozen articles published in the past year about medical practice and processes in the care of frail elders. All articles were chosen and critically appraised by experienced, multidisciplinary practitioners and educators to identify updated treatments, diagnosis methods, and care management of acute or chronic disease. The categories below summarize those presentations.

I. OSTEOPOROSIS

a) *A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures*, by R. Buchbinder et al, appeared in the *New England Journal of Medicine*, August 6, 2009. Though vertebroplasty has become a common treatment for these painful fractures, there is limited evidence to support its use. The authors performed a multicenter, randomized, double-blind, placebo-controlled trial in which 78 participants with one or two painful osteoporotic spinal fractures of less than 12 months' duration, yet unhealed as confirmed by MRI, were randomly assigned to undergo vertebroplasty or a sham procedure.

Outcomes were assessed at 1 week and at 1, 3, and 6 months. Though there were significant reductions in overall pain in both study groups at each follow-up, and both groups reported improvements in pain at night and at rest, physical functioning, quality of life, and perceived improvement, the authors found "no beneficial effect of vertebroplasty as compared with a sham procedure in patients with painful osteoporotic vertebral fractures."

b) *Fall prevention with supplemental and active forms of vitamin D: A meta-analysis of randomized controlled trials*, by H.A. Bischoff-Ferrari et al in *BMJ* (*British Medical Journal*), explored the efficacy of supplemental vitamin D and active forms of vitamin D with or without calcium in preventing falls among older individuals.

The group searched multiple databases for published articles and studies, and reviewed information from clinical experts, bibliographies, and abstracts. They wanted to include only double-blind, randomized, controlled trials of older individuals (mean age 65+) receiving a defined oral dose of supplemental vitamin D3 (cholecalciferol) or vitamin D2 (ergocalciferol) or an active form such as 1alpha-hydroxyvitamin D3 or 1,25-dihydroxyvitamin D3 — and having a sufficiently specified fall assessment.

Eight trials met their inclusion criteria, and their study concluded that supplemental vitamin D in a dose of 700-1000 IU per day reduced the risk of falling among older individuals by 19% and to a similar degree as active forms of vitamin D. Doses of supplemental vitamin D of less than 700 IU or serum 25-hydroxyvitamin D concentrations of less than 60 nmol/l may not reduce the risk of falling.

II. CARDIOVASCULAR

a) A study by S. Zoungas et al, *Combined effects of routine blood pressure lowering and intensive glucose control on macrovascular and microvascular outcomes in patients with type 2 diabetes: New results from the advance trial*, appeared in *Diabetes Care*, Nov. 2009. To assess the magnitude and independence of the effects of routine blood-pressure lowering and intensive glucose control in patients with long-standing type 2 diabetes, the group did a multicenter, factorial randomized trial of 1) perindoprilin-dapamide vs. placebo, and 2) intensive glucose control with a gliclazide MR-based regimen vs. standard glucose control in 11,140 participants during an average of 4.3 years of follow-up.

They concluded that the effects of routine blood-pressure lowering and intensive glucose control were independent of one another, but combination treatment reduced the risk of new or worsening nephropathy by 33%, new onset of macroalbuminuria by 54%, and new onset of microalbuminuria by 26%. Combination treat-ment was associated with an 18% reduction in the risk of all-cause death.

The group concluded that doubling the dose of influenza vaccine increased protection-related responses among LTC residents, especially those with low pre-vaccination titers.

b) S.J. Connolly et al studied *Dabigatran versus warfarin in patients with atrial fibrillation*, published in *New England Journal of Medicine*, 17 Sept. 2009. Though Warfarin reduces the risk of stroke in patients with atrial fibrillation, it increases the risk of hemorrhage and is difficult to use. Dabigatran is a new oral direct thrombin inhibitor. In the noninferiority trial, Connolly's group randomly assigned 18,113 patients who had atrial fibrillation and a risk of stroke to receive, in a blinded fashion, fixed doses of dabigatran — 110 mg or 150 mg twice daily — or in an unblinded fashion, adjusted-dose warfarin. Median duration of the follow-up period was 2 years.

The primary outcome was stroke or systemic embolism. They concluded that in patients with atrial fibrillation, dabigatran given at the 110 mg dose was associated with rates of stroke and systemic embolism that were similar to those associated with warfarin, as well as lower rates of major hemorrhage. At a dose of 150 mg, dabigatran — compared with warfarin — was associated with lower rates of stroke and systemic embolism but similar rates of major hemorrhage.

c) *BNP-guided vs. symptom-guided heart failure therapy: The trial of intensified vs. standard medical therapy in elderly patients with congestive heart failure (TIME-CHF) randomized trial*, a study by M. Pfisterer et al, appeared in *JAMA*, Jan. 28, 2009.

Because it is uncertain whether intensified heart-failure therapy guided by N-terminal brain natriuretic peptide (BNP) is superior to

Continued on the page 19

FMDA Call for Poster Submissions

— Submissions from physicians, pharmacists, PAs, and nurse practitioners now accepted online.

FMDA is hosting its 7th Annual Poster Session Oct. 28-31, 2010, during the Best Care Practices Conference. The first 10 applicants who are accepted by the review committee will receive complimentary registration to the 2010 conference (only one applicant per poster presentation will be considered).

Poster sessions provide an opportunity for practicing physicians, pharmacists, and nurse practitioners to share with colleagues the results of research, best practices, and outcomes. The sessions are visual presentations using diagrams, charts, and figures. Poster presentations may be on any aspect of the following categories: clinical care, pharmacology of medicine, medical education, history of medicine, medical direction, medical care delivery, medical ethics, economics of medicine, and pediatric long-term care — and in any long-term care setting.

The first 10 applicants who are accepted by the review committee will receive complimentary registration to FMDA's 19th Annual Program.

All poster abstract proposals must be submitted online on our website at **www.fmda.org**. All submissions that are complete and follow the Criteria for Acceptance of Posters will be considered and reviewed based on the content contained within the proposal.

Submission of a proposal is a commitment by at least one author to be present at the designated times to discuss the information in the poster with symposium participants.

We have arranged the schedule so that there is no overlap between educational sessions and poster exhibit times. The primary presenter listed on the proposal will be informed of its status no later than Sept. 26, 2010. Guidelines for presentation and preparation of visual material will be sent to the primary presenter upon acceptance.

Authors whose abstracts are accepted for presentation at the symposium will have their abstracts submitted for publication in the *Journal of the American Medical Directors Association (JAMDA)*.

To learn more, or to submit a proposal, go to **www.fmda.org**, or call Ian Cordes, FMDA executive director, at **(561) 659-5581**.

2010 Poster Sessions

Disney's Swan & Dolphin
Lake Buena Vista, Fla.

Schedule*

POSTER SET-UP

FRIDAY, Oct. 29, 11 a.m.–1 p.m.

POSTER VIEWING

FRIDAY, Oct. 29
1-2:30 p.m.; 5-7 p.m.

SATURDAY, Oct. 30
8-9 a.m., 11:45 a.m.-12:45 p.m.,
Luncheon: Poster Recognition–12:45-2:15 p.m.

POSTER TEAR-DOWN

SATURDAY, Oct. 30
2:15-3:45 p.m.

*Subject to change. Presenters are not required to be present during all viewing hours.

First-of-its-Kind Program Equips Professionals to Lead "Culture Change"

By Charlotte Eliopoulos RN, MPH, PhD; Executive Director, American Association for LTC Nursing

Consumers are demanding it... CMS is encouraging practices that support it and nursing homes are recognizing they need to adapt it in order to be competitive. We're talking about culture change, the dynamic movement that is changing the complexion of nursing homes.

Core Elements of Culture Change

Although some people think that culture change equates to pets, plants, and pretty objects in the nursing home, cultural transformation implies considerably more than that and consists of several core components. Perhaps the most important element of culture change is that of providing a high quality of life for residents. Achieving this requires that residents not only receive individualized care that supports their highest level of function, but that the care is directed by the residents. This means that residents determine when they sleep and arise, when and what they eat, what they wear, and the activities in which they want to participate.

Creating a home-like environment is an important component. Residents' rooms are personalized to reflect the individual who resides within. Kitchens are established on the units to enable made-to-order meals and afford residents the opportunity to access food and drink when they'd like. Long hallways and shared rooms are replaced with small groups of private rooms that open into common living room areas. The look of the institution is replaced by a softer appearance of a home.

Because it is a clinical setting in addition to being a home, high quality care is promoted. Caregiving strategies are based on best practices, and education is provided to equip staff with competencies to function at their best.

In addition to residents being empowered, staff also is empowered. Frontline staff is afforded opportunities to make decisions related to their work activities. Concern is given to staff satisfaction and to establishing a high-quality work environment.

Equipping Professionals for Culture Change

It is important that all members of the team understand culture change and their role in its implementation. To assist in this effort, the American Association for Long Term Care Nursing (AALTCN) has developed the Culture Change Nurse Coordinator Certification Program. The program reviews the evolution of nursing homes, core principles of culture change, best practices to support high quality services, actions to support holistic care, strategies for implementing culture change in the average nursing home, and measures to empower residents and frontline staff.

Although the Culture Change Nurse Coordinator Certification Program aims to prepare nurses to be facility resources and champions for culture change, the program offers content appropriate for other professionals as well. Nursing home physicians, social workers, and other professionals can benefit from the in-depth understanding and implementation strategies obtained through this program.

Take advantage of this unique and challenging program and the daylong prep course offered on Oct. 28, the pre-conference day for the FMDA's Best Care Practices in the Geriatrics Continuum 2010! Register today at www.bestcarepractices.org. For information, go to www.LTCNursing.org.

Secondary Prevention in the Post-CABG Patient: A Brief Review of Recent Literature

By Jakub Bartnik MS3, Tanaz Berahman MS3; NSU College of Osteopathic Medicine, Fort Lauderdale

Coronary Artery Bypass Graft (CABG) is one of the most common major operations performed, with more than 400,000 performed annually.[1] Secondary prevention is likely the most important consideration in the post-operative treatment. This article serves to aid the general practitioner in the care of these complicated patients. It is not intended to serve as a comprehensive review, but rather as an update on the most recent published literature pertaining to secondary prevention. The authors utilized a MEDLINE search to locate the most pertinent articles published in the past three years.

There is unquestionable proof of the benefits of lipid-lowering therapy following CABG.[2] Ideally, life-long statin therapy should be initiated pre-operatively. In spite of the overwhelming evidence, statin use was found to be underutilized in the post-operative population, with only 61% of Medicare patients being discharged on statins in 2004. Paradoxically, statins were used more sparingly in patients with higher risk, such as those with a history of stroke or diabetes mellitus.[3]

A high-powered trial published in the *Journal of American College of Cardiology* examined the use of atorvastatin to aggressively lower LDL levels. They found that intensive LDL-cholesterol lowering to a mean of 79 mg/dl with atorvastatin 80 mg/day in patients with previous CABG reduces major cardiovascular events by 27% and the need for repeat coronary revascularization by 30%, compared with less intensive cholesterol-lowering to a mean of 101 mg/dl with atorvastatin 10 mg/day.[4] This data suggests that LDL levels should be kept under more strict control than current recommendations if graft disease reduction is the goal.

Although the benefits of statins are clear, the choice of statin is more controversial. Current literature, including *Statin Therapies for Elevated Lipid Levels Compared Across Doses to Rosuvastatin (STELLAR)* trial, shows that for milligram-equivalent doses, rosuvastatin has the greatest ability in allowing more patients to reach LDL-C targets.[5] Monitoring of LDL-C levels following CABG and dose titration of statins is currently performed poorly. As rosuvastatin allows a greater number of patients to achieve target levels at doses of 10 mg or less, the absence for the need for titration is clearly favorable. Rosuvastatin was also found to be more cost-effective than atorvastatin and simvastatin.[2] However, there are currently no observational or randomized controlled trials that have evaluated outcomes post-CABG with rosuvastatin compared to other statins. In fact, *The Post Coronary Artery Bypass Graft Trial* is the only large randomized study of statins specifically designed to report on patients after CABG. The study reinforced the need for aggressive statin therapy by proving that it could reduce graft disease significantly.[6]

Another topic of discussion is the use of aspirin with or without clopidogrel following surgery. Most articles agree that the use of aspirin pre- and post-operatively is recommended. However, a recent meta-analysis published in the *Journal of Cardiology* states that there are no randomized, controlled, double-blind, clinical trial data to suggest that clopidogrel when added to aspirin, prevents or reduces adverse clinical outcomes (death, myocardial infarction, stroke, unstable angina, or recurrence of angina) after CABG, compared with aspirin treatment alone. Thus, they conclude that the routine use of clopidogrel in addition to aspirin after CABG cannot be recommended.[7,8] Of note, this analysis applies strictly to post-operative management and should not influence preoperative care. Of note, a conflicting report suggests aspirin resistance is a transient phenomenon present in the majority of patients undergoing CABG, may then need to be covered with clopidogrel.[9] There are several ongoing trials, including *Clopidogrel After Surgery for Coronary Artery Disease (CASCADE)*, which are designed to shed more light on this topic.

Although not addressed in this brief review, it is imperative to note that lifestyle changes such as weight loss, diet, exercise, and smoking cessation are important considerations in secondary prevention. These changes should be combined with appropriate pharmacotherapy such as aspirin and life-long statin in patients that tolerate their use.

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Understanding Glaucoma in the Elderly

By Jackie Lee White MS3; NSU College of Osteopathic Medicine, Fort Lauderdale

Glaucoma is currently the leading cause of irreversible blindness in the United States and worldwide, and it is on the rise. As the baby boomer generation becomes the senior citizens of our society, glaucoma will become even more of a public health issue. "Open-angle glaucoma affects an estimated 2.2 million Americans and with the aging population, the prevalence of glaucoma is projected to increase by 50% to about 3.4 million by 2020."[4] Considering the magnitude of glaucoma and its impacts on the quality of life of patients afflicted with the disease, it is important for physicians to understand glaucoma in the elderly and the pharmaceutical treatment options currently available.

Glaucoma is a group of ocular diseases that causes optic nerve neuropathy by the destruction of retinal ganglion cells. Without treatment, the optic nerve destruction leads to progressive visual field loss and eventually blindness. The vision loss begins in the periphery and is subtle; therefore, initially patients are asymptomatic. As the disease advances centrally, visual acuity is affected, and there is a decrease in visual functioning. "Activities that require contrast sensitivity, such as dark adaptation, and functional peripheral vision, such as navigation and mobility, are particularly affected in patients with advanced glaucoma."[4] These visual impairments must be taken into consideration when managing the care of glaucoma patients. For example, patients may have decreased compliance due to an inability to read the prescription on the eye drop container.

Furthermore, since a large number of patients with advanced glaucoma are elderly, management needs to encompass not only the visual limitations but also their physical limitations. For example, a patient with weakness or decreased grip strength may physically be unable to properly administer eye drops. The physical limitation may mistakenly be perceived as patient noncompliance. This example shows that the limitations imposed on an individual by disease processes or even the natural physiological changes that occur with aging should be evaluated in the medical management of a patient. Humans are complex beings. The patient as a whole may need to be assessed to uncover these complex intra-relationships. An evaluation of manual dexterity, coordination and cognitive abilities in an elderly glaucoma patient may be necessary.

Why do visual impairments from glaucoma disproportionately affect the elderly population? First, the natural history of glaucoma is progressive with a cumulative effect on visual field loss. Second, as any individual ages, there is a natural destruction of retinal ganglion cells over time. The age-related destruction is additive, and a glaucomatous individual's destruction leads to an increased loss of retinal ganglion cells and visual field.

The recommended time frames for glaucoma screening take into account the increased prevalence of glaucoma in the elderly. "The current American Academy of Ophthalmology guidelines recommend a routine adult eye exam for glaucoma at least once every 10 years in those younger than age 40, every four years for patients 40 to 54, every three years for those 55 to 64 and every one to two years for patients 65 years of age or older."[2]

Who is at risk for developing glaucoma? There are several risk factors, including increased intraocular pressure, age, race (African-American) and family history. The only risk factor that can be treated is increased intraocular pressure. Treatment options consist of topical medications, laser trabeculoplasty and surgery. Typically, the initial therapy for lowering intraocular pressure is topical agents. Table 1.1 on the next page shows a review of the topical glaucoma medications based on the class of drug.

Topical glaucoma agents are beneficial to the patient because of their effects on lowering intraocular pressure, but ocular and systemic side effects can occur. A common ocular side effect to all topical glaucoma agents is periocular allergic dermatitis. It is caused directly by the drug itself or by the preservatives in the eye drops. The symptoms of periocular allergic dermatitis are "lower eyelid erythema, edema and excoriation that follows the pathway of an eye drop after it leaves the conjunctiva sac."[1]

Topical glaucoma agents not only have ocular side effects, but they can also have systemic side effects. For example, a patient on a beta blocker such as Timolol could experience dyspnea after administration of the medication. "The systemic effects can be immediate because eye drops are systemically absorbed via the nasal mucosa and are not subject to first-pass hepatic metabolism."[2] Therefore, patients should be monitored for the development of systemic side effects when starting ocular agents and continually during the management of glaucoma.

How long will topical glaucoma agents be part of the standard of care for treating glaucoma? Currently, patients are being treated with topical pharmaceutical agents that lower intraocular pressure. However, the current medications are targeting the treatment of a risk factor and not the cause of glaucoma: optic neuropathy. The use of a neuroprotective agent that prevents the destruction of the optic nerve may one day be the new standard of care in treatment of glaucoma. The alpha adrenergic agonist brimonidine may be the beginning of this wave of change. "A future indication for brimonidine is its potential for neuroprotection. It has been shown to reduce the loss of retinal ganglion cells in the optic nerve crush-injury model for rats and mice and in laser-induced glaucoma models. Whether this translates to neuroprotection in humans with glaucoma is presently unknown."[2] Further development of neuroprotective medications give hope for conquering the number one cause of irreversible blindness: glaucoma.

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Understanding Glaucoma in the Elderly

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Table 1.1

Drug	Mechanism of Action	Ocular Side Effects	Systemic Side Effects	Additional Notes	Examples
Prostaglandins	-Increases outflow of aqueous humor via uveoscleral outflow -Decreases IOP by 25-37%	-Hyperpigmentation of iris, periorbital area and lashes -Conjunctival hyperemia -Increased lash growth -Foreign body sensation -Cystoid macular edema	-None noted in clinical trials	-Higher efficacy than Timolol -Uniform pressure control over 24 hrs	-Latanoprost/Xalatan -Travaprost/Travatan -Bimatoprost/Lumigan
Carbonic Anhydrase Inhibitors	-Decreases aqueous humor secretions by direct antagonistic activity on ciliary epithelium **Oral** Decreases IOP by 21-30% **Topical** Decreases IOP by 19-20%	**Transient ocular** stinging and irritation	**Topical** -Transient bitter taste -Hyper-sensitivity reaction **Oral** -Paresthesias of the fingers and toes -Anorexia -Abdominal discomfort -Diarrhea -Electrolyte imbalance -Loss of libido -Depression -Aplastic anemia (rare)	C/I: Sulfa Allergy	**Topical** -Dorzolamide/Trusopt -Brinzolamide/Azopt **Oral** -Acetazolamide/ Diamox -Methazolamide /Neptazane
Drug	**Mechanism of Action**	**Ocular Side Effects**	**Systemic Side Effects**	**Additional Notes**	**Examples**
Cholinergics	-Increases the aqueous humor outflow by contraction of the longitudinal ciliary muscle -Increase in outflow through the trabecular meshwork -Decreases IOP by 20%	-Miosis -Ciliary spasm -Induced myopia	-Diarrhea -Abdominal cramps -Salivation -Bronchospasm -Diaphoresis -Bradycardia -Nausea -Tremor -Headache	Deterioration of mental status in Alzheimer's patients	-Pilocarpine/Ocusert -Carbachol/Carboptic -Physostigmine / Eserine Sulphate -Echothiophate /Phospholine Iodide
Alpha Adrenergic Agonists	-Decreases aqueous humor synthesis by uveoscleral outflow	-Follicular conjunctivitis	-Oral dryness -Sedation -Headache -Drowsiness -Fatigue -Tachyphylaxis		-Brimonidine/Alphagan -Apraclonidine/Iopidine
Beta Blockers	-Decreases aqueous humor secretion by the nonpigmented ciliary epithelium -Decreases IOP by 20-30%	-Burning sensation -Transient blurred vision -Allergic blepharoconjunctivitis	-Bronchospasm -Depression -Impotence -Decreased HDL -Decreased heart rate -Weakened myocardial contractility -Heart failure -Syncope -Anxiety -Confusion -Fatigue -Disorientation	-C/I in asthma, COPD, symptomatic sinus bradycardia, second or third degree heart block without a pacemaker	-Timolol/Timoptic -Betaxolol/Betoptic -Carteolol/Ocupress
Combination Beta Blocker + Carbonic Anhydrase Inhibitor Beta Blocker + Alpha Adrenergic Agonist	-IOP-lowering effects of the combination medication are similar to each of the drugs given individually -More effective at lowering IOP, compared with either medication alone	-Same side effects as individual components -Same side effects as individual components	-Same side effects as individual agents -Same side effects as individual agents	-Approved for IOPs not controlled by Beta Blockers alone	-Timolol + Dorzalamide/Cosopt -Brimonidine + Timolol/Combigan

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symptom-guided therapy, Pfisterer's group compared 18-month outcomes of the two therapies in 499 patients aged 60 or older with systolic heart failure (ejection fraction < or = 45%), New York Heart Association class II or greater, prior hospitalization for heart failure within 1 year, and N-terminal BNP of twice the upper limit of normal or higher.

The study was conducted at 15 outpatient centers in Switzerland and Germany between Jan. 2003 and June 2008. Their conclusion was that heart-failure therapy guided by BNP did not improve overall clinical outcomes or quality of life compared with symptom-guided treatment.

d) A study by V. Tibaldi et al, *Hospital-at-home for elderly patients with acute decompensation of chronic heart failure: A prospective randomized controlled trial*, appeared in *Archives of Internal Medicine* on Sept. 28, 2009. Although the hospital is the standard venue for short-term medical care, it may be hazardous for older persons. Tibaldi wanted to evaluate the feasibility and effectiveness of a physician-led hospital-at-home service for selected elderly patients with acute decompensation of CHF. From April 2, 2004, through April 31, 2005, patients 75 years or older admitted for decompensating CHF were randomly assigned to the general medical ward (53 patients) or to the Geriatric Home Hospitalization Service (GHHS; 48 patients), which provided diagnostic and therapeutic treatments by hospital healthcare professionals in the home of the patient. At the 6-month follow-up, patient mortality was 15% in the total sample, without significant difference in the two groups, though GHHS patients' mean time to readmission was longer. Only GHHS patients experienced improvements in depression, nutritional status, and quality-of-life scores. The conclusion was that substituting hospital-at-home care is a viable alternative to traditional hospital inpatient care for elderly patients with acutely decompensating CHF.

III. Nursing Home

a) *Using video images to improve the accuracy of surrogate decision-making: A randomized controlled trial*, by A.E. Volandes et al, was published in the *Journal of the American Medical Directors Association*, Oct. 2009. When elderly patients are unable to make end-of-life decisions, doctors turn to surrogate decision-makers, whose knowledge of patient desires often is poor. Volandes' group wanted to compare the concordance, or agreement, of preferences in care goals among patients and their surrogates after 1) listening only to a verbal description of advanced dementia or 2) viewing a video decision support tool of the disease after hearing the verbal description. Care choices included life-prolonging care (CPR, mechanical ventilation), limited care (hospitalization, antibiotics, but not CPR), and comfort care only to relieve symptoms.

This article review is based on a presentation that was held on March 12 during the American Medical Direcftors Association LTC Medicine 2010 conference. Presenters included Barbara J. Messinger-Rapport, MD, PhD, CMD; John Morley, MB, BCh; Julie Gammack, MD, CMD; and Mary Patt Rapp, PhD, RN.

— "A Review of 2009 Published Scientific Articles: Part II" *will be published in the next issue of* **Progress Report**.

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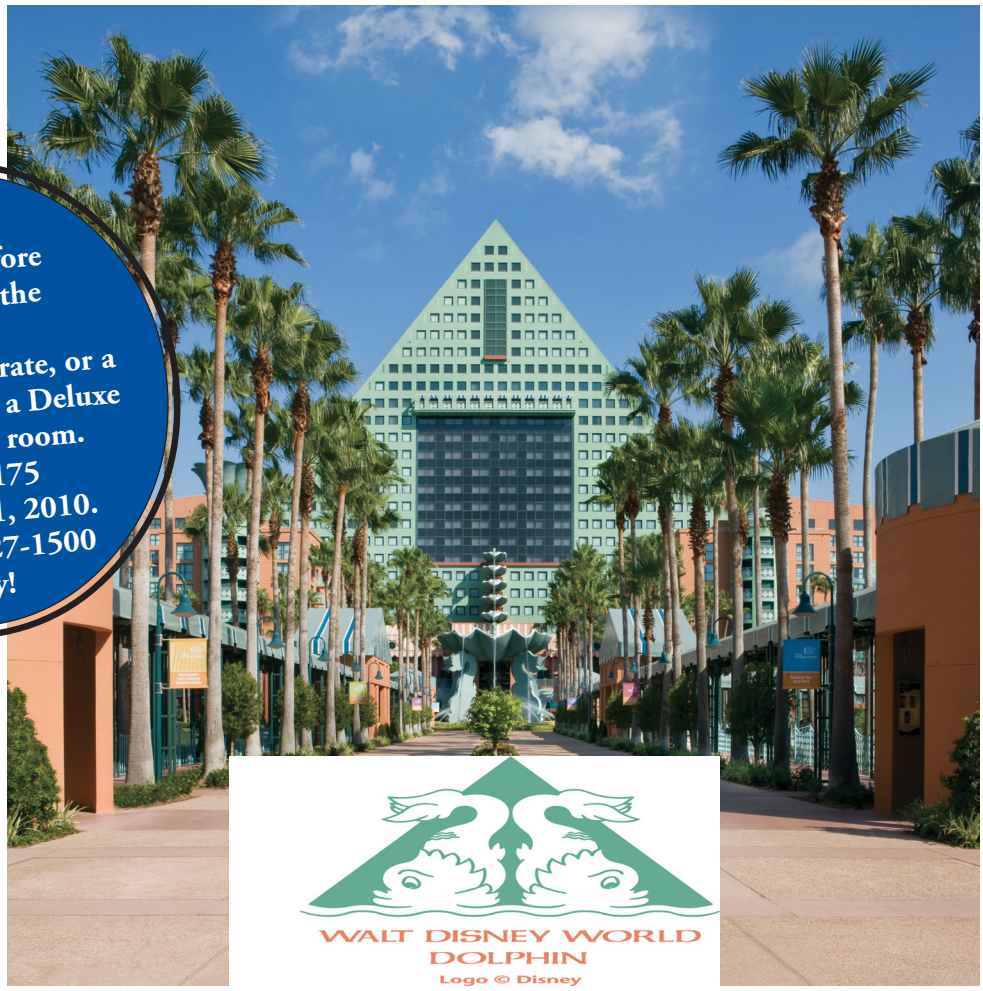

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