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fmda™

Dedicated To Florida Long Term Care Medicine

Progress Report

WINNER 2010 APEX AWARDS FOR PUBLICATION EXCELLENCE

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

President's Letter

The CME/Education Committee, which plans our annual conference, has been extremely busy putting together another outstanding program for Best Care Practices in the Geriatrics Continuum 2011. Dr. Symeonides, the program director, and Dr. Rhonda Randall, the committee chair, and the committee members recently met in Gainesville and mapped out a series of topics with interesting and unique approaches. Its next meeting will be on March 25 at AMDA's annual symposium. All members are invited to attend. See page 11 for place and time.

As part of the CME/Education Committee's master plan, it launched the first "Call for Speaker Presentations" for the Best Care Practices in the Geriatrics Continuum conference. Speakers who wish to present a lecture at the conference are invited to submit an online proposal now with details about the intended presentation. For more details, go to our website at **www.bestcare practices.org**.

Another first this year is the introduction of an "Early-bird registration fee" that will be good through July before the regular fees go into effect. By the time you read this newsletter, you should be able to register with the discounted registration fee and book your hotel room — all at **www.best carepractices.org**.

In February, I was impressed with the guest list of our annual Industry Advisory Board (IAB) meeting. Held in Orlando for the first time, it included representatives from our association friends in LTC and geriatrics, as well as such healthcare providers as Evercare, Humana, and Vitas Innovative Hospice; members of the legal profession; the pharmaceutical industry; and American Health Associates Clinical Laboratories. Please see the group photo on page 5 of this highly successful event.

Two days before the IAB meeting, we gathered in Gainesville for another exceptional Town Meeting Reception and Trade Show, followed by a scientific presentation, a Town Meeting filled with great dialogue, and a wonderful dinner. Our thanks go to Herb Grigg with Boehringer Ingelheim for sponsoring this program and to Dr. Carl Suchar for working so hard to make this night such a big hit.

A few months ago, we reached out to our members about a position statement supporting prescriptive authority for nurse practitioners and physician assistants. We appreciate all the effort that our members took to respond so thoughtfully to this potentially polarizing issue. As you know by now, the board listened to its members, and at its last meeting the board passed a motion to approve the position statement. Not surprisingly, we issued a news release and received additional positive support from our peers in Florida and beyond. For information, go to page 15.

Please see the list of upcoming FMDA activities on page 11. We would love to see you there.

My thanks to Dr. Karl Dhana, who is the editor of *Progress Report*, for his excellent work on this issue and to his medical students at Nova Southeastern University College of Medicine for their scholarly contributions.

Late last year, Disney asked us whether we would consider moving our 2011 conference from *Disney's Contemporary* Resort to Disney's Grand Floridian Resort & Spa. While we love the Contemporary, the opportunity to host our 20th Anniversary Conference at its flagship resort in Orlando was too good to refuse. We were able to negotiate for you an amazing list of perks that I know you will appreciate. Even though there is an article about this on page 4, the list of amenities is worth repeating here:

- $160 room rate (Online, you are likely to see room rates ranging from $500 to $700 per night.)
- Conference room rate is good three days before and after our conference.
- No resort fee
- Complimentary self-parking
- Complimentary hotel-room Internet connections (wired)
- As long as you stay at the hotel on our peak nights of Friday and Saturday, Oct. 21-22, you will also receive (certain special rules may apply):
  - ✓ One complimentary "After 4 p.m. Disney Theme Park Ticket" per room to any one of the parks
  - ✓ One complimentary $25 Disney Dining Card per room.

Now you understand why we are so excited!

In 2010, we introduced our "Ambassador" program, which connects FMDA members with first-time attendees in order to enhance their conference experience. We are very pleased to bring it back for our 2011 conference. Please volunteer by calling the business office (see page 10)! Let's share some of our southern hospitality.

With the help and guidance of membership chair Dr. Carl Suchar, we will soon be introducing a new membership recruitment contest. Please stay tuned!

I continue to be very grateful for the fine stewardship provided by the dedicated officers and directors. It is through their efforts that we push forward to maintain and improve the level of services to our members.

I look forward to seeing you in person at the "Best Care Practices in the Geriatrics Continuum 2011" conference in Orlando, Oct. 20-23, 2011.

Sincerely yours,

Hugh W. Thomas, DO, FAAFP, CMD
President

Plans Under Way for Another Outstanding Conference

— Register today for the Best Care Practices in the Geriatrics Continuum 2011

Dear Friends:

Here is an update on our 20th Annual Conference, "Best Care Practices in the Geriatrics Continuum 2011," to be held Oct. 20-23, 2011, in Orlando.

We are very pleased to welcome Arthur E. Wharton, RPh, MPA, Director of Continuing Pharmacy Education, Clinical Associate Professor from the University of Florida's College of Pharmacy, to our CME/Education Committee as our planning committee's liaison from UF.

If you haven't already heard, we recently issued our first "Call for Presentations," which has already produced some very interesting presentation proposals for our conference. This process will add a new and dynamic dimension to our conference programming.

We will be providing a review and update of major geriatric diseases, as well as illnesses and risks found in nursing home patients, residents of assisted living facilities, and seniors living at home. Topics will include a wide range of clinical and administrative talks, an annual forum with national leaders, including American Medical Directors Association President Karen Leible, MD; and American Geriatrics Society President Barbara Resnick, PhD, CRNP.

At this time, we have developed the educational program to address the most requested topics from last year's conference. Some of these broad topics include patients at risk and the medical director's role; cardiovascular, dermatologic, endocrine, and musculoskeletal diseases; infection control; neurologic disease; nutritional/hydration disorders; ophthalmology; psychiatric disorders; medication-induced disease, etc.

Of course, there will be some cutting-edge administrative talks, as well.

We are working with AMDA again this year to provide another "optional" advanced Clinical Practice Guidelines (CPG) intensive on Thursday, Oct. 20, a preconference day. In addition, on that same day we will also host the approved mandatory licensure-renewal courses required of all licensed health-care practitioners in Florida.

This conference has earned a great reputation for its unique multidisciplinary approach to educating physicians, physician assistants, nurse practitioners, directors of nursing in LTC, registered nurses, senior-care pharmacists, consultant pharmacists, and long-term-care administrators, as well as geriatricians, primary-care and home-care physicians, physicians considering becoming long-term-care or home-care medical directors, and others with an interest in geriatrics and its continuum of care. The faculty will include national and regional authorities in the fields of medical direction, senior-care pharmacology, LTC and geriatric medicine, and LTC administration.

Your traveling companions will not be bored. 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 **Annual Halloween Horror Nights** (**www.halloweenhorror nights.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 2011"** at *Disney's* Magic Kingdom.

Check page 4 for our amazing package deal for Disney's Grand Floridian. This special group rate will apply three (3) days prior to and three (3) days following the main program dates, subject to availability.

We know that demand for hotel rooms will be very strong, so book your rooms now, and register to attend one of the finest geriatrics conferences in the country.

Yours truly,

John Symeonides, MD, CMD; Program Director
Best Care Practices in the Geriatrics Continuum 2011

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Front Cover

The beautiful artwork on the front cover is titled "A Resident's Domain" and was painted by William Jenkins, a resident at Park Meadows Health and Rehabilitation Center in Gainesville. It was featured in Florida Health Care Association's (FHCA) Art From the Heart annual calendar.

William Jenkins was born in Illinois and always had an affection for art from coloring books to sketching and painting. He was a machinist toolmaker until he became disabled in 2004 and retired as a machinery inspector. He had advanced COPD and got around with help from a wheelchair, but he still had good use of his hands. Mr. Jenkins has since passed away.

Park Meadows Health and Rehabilitation Center is a 154-bed skilled nursing facility in Gainesville. Managed by Greystone Healthcare Management, the facility is a member of FHCA.

20th Anniversary FMDA Conference to be Celebrated at Disney's Grand Floridian Resort

FMDA is excited to announce that its 20th Anniversary conference, "Best Care Practices in the Geriatrics Continuum 2011," will be moving from *Disney's Contemporary* Resort to Disney's flagship property, the Grand Floridian Resort & Spa (**www.bestcarepractices.org/venue.html**).

Disney's Grand Floridian Resort, in a beautiful setting across the lake from the Magic Kingdom, offers luxurious sleeping rooms, intimate conference meeting space, and excellent restaurants. It is one of the stops on the Monorail on the way to the Magic Kingdom.

FMDA negotiated an amazing hotel rate with added perks at the Grand Floridian (certain special rules may apply). Check these out:

- **$160 room rate**
- **Room rate is good three days before and after our conference**
- **No resort fee**
- **Complimentary self-parking**
- **Complimentary hotel-room Internet connections (wired)**
- **As long as you stay at the hotel on our peak nights of Friday and Saturday, Oct. 21-22, you will also receive:**
  - **One complimentary "After 4 p.m. Disney Theme Park Ticket, per room to any one of the Disney parks**
  - **One complimentary $25 Disney Dining Card per room**

FMDA's president, Dr. Hugh Thomas, is thrilled to be able to offer attendees a fabulous room rate and other all-star amenities.

"FMDA is very proud of its annual Best Care Practices conference. It is our goal to provide health-care practitioners in long-term care and geriatrics, the highest quality education in a relaxed and comfortable environment. This is a great opportunity for attendees to experience a top-notch medical education program in a world-class resort-style venue," he said.

The Best Care Practices in the Geriatrics Continuum conference offers a unique paradigm of providing quality educational programs, poster presentations, and nationally-recognized speakers to a wide range of health-care practitioners who are long-term care and geriatric based. The program is widely known as one of the best medical conferences available to health-care practitioners in geriatrics and long-term care. The program gathers participants from around the country.

To learn more about the change in venue or about the conference in general, please contact **Matthew Reese** at **(561) 659-5581** or by e-mail at **mattr@fmda.org**.

To get the ***"New Early-Bird Registration Fee,"*** go to **www.bestcarepractices.org** and register today.

Inaugural "Call for Presentations" Issued for Best Care Practices Conference

By Matthew Reese, BS, Educational Programming Coordinator

FMDA is now accepting submissions for its inaugural "Call for Speaker Presentations" for its Best Care Practices in the Geriatrics Continuum conference.

Speakers who wish to present a lecture at the conference are invited to submit an online proposal now with details about the intended presentation. Submissions should be based on FMDA's needs assessment, with topics related to long-term care and geriatrics. The submission deadline for all applicants is May 10, 2011.

FMDA launched the "call for presentations" because it falls into its mission of providing the highest-quality education to health-care practitioners in LTC. High-profile and relevant educational programs have always been the pinnacle objective of the annual conference. Attendees expect clinical topics to be strong, evidence-based lectures with cited references and administrative topics relevant to their setting and focused on current best-care practices. It is the Review Committee's intention that the best presentations incorporate attendee networking, case discussion (Q&A), small groups, and take-home tools such as handouts, key points, guides, or quick tips. These types of presentations are highly encouraged.

Dr. Naushira Pandya, chair of the Poster Presentations Review Committee, is gearing up for this year's poster-presentation submissions. This will be FMDA's 8th Annual Poster Presentations Session, taking place during the Best Care Practices conference, October 20-23, 2011, at Disney's Grand Floridian Resort. 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. The first 10 applicants who are accepted by the review committee will receive complimentary registration to the 2011 conference (only one applicant per poster presentation will be considered). See page 8 for more details.

FMDA president, Dr. Hugh Thomas, is enthusiastic about the potential success of the "call for presentations" process. He is also looking forward to the call for poster proposals, in which there are always a great number of worthy presentations.

"FMDA is committed to providing unsurpassed education to our health-care practitioners working in LTC and geriatrics," said Dr. Thomas. "The unique process of accepting calls for presentations undoubtedly improves the strength of our annual conference, and FMDA is eager to evaluate this year's crop of poster submissions, to add to our already stellar program."

To learn more about FMDA's "Call for Presentations" or its "Call for Poster Presentations" or to submit a proposal, go to **www.bestcarepractices.org**.

11th Annual IAB Meeting Held in Orlando

Steven Selznick, DO, CMD, chairman of the Industry Advisory Board (IAB), and John Maddox, the co-chair, convened the 11th annual meeting with a stellar list of attendees. The presentations were varied and included such topics as an FMDA overview and update; *Trends, Opportunities & Challenges* by Janegale Boyd from FAHSA; *Litigation in LTC in Florida: Trends and Pending Legislation Trends, Opportunities & Challenges* by attorney Pamela A. Padilla; *Prescribing Authority for Nurse Practitioners in Florida* by FL-GAPNA president Jo Ann Fisher; *Managed Care & LTC in 2011* by Ken Tuell from Humana; *Medicare Fraud & Abuse Update* by attorney Greg Chaires; *Understanding Short-Cycle Dispensing* by Rick Foley from FL-ASCP/Omnicare; *Upcoming Changes in CMS-LTC Standards of Care and Nursing Home Surveyor Interpretative Guidelines* by Jane Merritt, VITAS Innovative Hospice Care; and *Challenges Facing LTC Providers* by FHCA President Nina Willingham.

Co-chair John Maddox led the lively industry discussion about educational grants and how the application process has changed dramatically over the years. Compliance guidelines implemented by the pharmaceutical companies was also discussed.

The IAB was founded in 1999 as a way for the Florida Medical Directors Association and other interested organizations to enhance lines of communication and work together to develop solutions for our common problems. Membership is by invitation only and is limited to a select few vendors, but it has been expanded to related organizations in long-term care. Meeting twice a year, participants have provided valuable input into planning the annual program and trade show and in supporting FMDA in other areas of mutual interest.

For more information concerning the Industry Advisory Board, please contact Ian Cordes, executive director of FMDA, at **(561) 659-5581**, or via e-mail at **icordes@fmda.org**.

Annual FMDA Industry Advisory Board; Tuesday, Feb. 7, 2011; Hyatt Regency Orlando Airport

From left: Matthew Reese, BS, educational programming coordinator, FMDA; Dr. Robert Kaplan, FMDA director; Jim Jackson, chief financial officer, American Health Associates Clinical Labs; Walt Banket, national account manager, Senior Care, Amgen; Brian Stembridge, director for LTC area manager in the SE, Novartis Pharmaceuticals; Janegale Boyd, RN, president & CEO, Florida Association of Homes & Services for the Aging; Michael Pocza, LTC account manager, Novartis Pharmaceuticals; Debbie Martin, president, American Health Associates Clinical Labs; Pamela A. Padilla, JD, McEwan, Martinez & Dukes, P.A.; Jane Merritt, regional director of market development, VITAS Innovative Hospice Care; Hugh Thomas, DO, CMD, FMDA president; Steven Selznick, DO, CMD, IAB chairman, CFP Physicians Group; Gregory A. Chaires, JD, Chaires, Brooderson & Guerrero; John Maddox, IAB Co-Chair, Corporate Account Director, Astellas Pharma; John Potomski, DO, CMD, FMDA immediate past president; Jo Ann Fisher, FNP-BC, President, Florida Chapter of GAPNA; John Symeonides, MD, CMD, vice president; Ken Tuell, RPh, CGP, Humana Pharmacy Solutions Medicare Pharmacy Division Consultant; Gregory James, DO, Medical Director, State of Florida, Evercare, a division of United Healthcare; Rick Foley, PharmD, Omnicare/FL-ASCP; and Nina Willingham, CNHA, president, Florida Health Care Association. Missing: Ian Cordes, executive director, FMDA

CMS Publishes Proposed Rule for LTC Facilities

By Leonard R. Hock Jr., DO, CMD; Chief Medical Officer, Hospice by the Sea, Boca Raton

Since the new Hospice Conditions of Participation (CoPs) became effective 2008, there has been confusion or disagreement about who takes responsibility for services to hospice residents of nursing homes. Hospice believes they have ownership of the "overall care plan," while most nursing homes and nursing home medical directors have more knowledge of care and support for the frail end-of-life geriatric patient.

I see this proposed change as clearly delineating the responsibilities of each. It does not appear to me to be a bad thing (and CMS regulations can be). It is also consistent with the 2011 Office of Inspector General work plan.

Hospice believes they have ownership of the "overall care plan," while most nursing homes and nursing home medical directors have more knowledge of care and support for the frail end-of-life geriatric patient.

Here is a summary of the rules that were issued this past October: *CMS published a proposed rule for long-term care (LTC) facilities and specified the responsibilities of the LTC facility when contracting with a Medicare-certified hospice for hospice services. The proposed rule mirrors the standard in the Medicare Hospice CoPs (418.112), which specifies the hospice's responsibilities when contracting with a LTC facility.*

The Regulatory Committee for the National Hospice and Palliative Care Organization (NHPCO) were to gather comments on the proposed rule and submit a comment letter on or before the due date of Dec. 21, 2010.

Introduction: On Oct. 22, 2010, the *Federal Register* published a proposed rule for long-term care facilities that choose to contract with Medicare-certified hospices, saying that a written agreement between the facility and the hospice must be in place to specify the roles and responsibilities of each entity.

This proposed rule is a companion rule to the section (418.112) in the Medicare Hospice CoPs, which outlines the requirements that the Medicare-certified hospice provider must meet when it provides hospice services to residents of a LTC facility. This rule proposes to make the requirements for LTC facilities consistent with the June 2008 Hospice CoPs. The goal, as stated by CMS, is to "ensure that both entities are held equally responsible for the written agreement." CMS goes on to state that the "problems LTC facilities and hospices have with the coordination of care is a direct result of the lack of Medicare requirements specifically related to the provision of contracted hospice care in the current regulatory requirements for LTC facilities."

Please note that these are proposed rules, and will not take effect until CMS gathers comments from the field and publishes a final rule. The development of a final rule could take a maximum of three years.

Why is this important? Since the new Medicare Hospice CoPs were published in final form in June 2008, hospices have had regulatory requirements for their relationships with LTC facilities, spelled out in §418.112. LTC facilities have not had a similar regulatory requirement in their regulations. This proposed rule, when finalized, adds that regulatory requirement for LTC facilities, mirroring the requirements for hospices.

The NHPCO Regulatory team and Regulatory Committee reviewed this proposed rule in detail and prepared an NHPCO comment letter before the comment deadline of Dec. 21, 2010. In addition, there is already discussion with the national nursing home associations to collaborate about this proposed rule and the development of resource materials for providers.

The proposed rule may be found in the *Federal Register*, October 22, 2010 (PDF), and questions may be directed to **regulatory@nhpco.org**.

Red Legs: Stasis Dermatitis vs. Cellulitis

— *Should we treat with antibiotics or not?*

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

This is a common scenario that we as clinicians all face on a daily basis, especially when it is in regards to lower-extremity weeping and redness. This article will review the similarities and differences of cellulitis and stasis dermatitis and clarify the treatment modalities for both.

Cellulitis is a common, potentially serious bacterial skin infection that appears as a swollen, red area of skin that feels hot and tender, and it may spread. Stasis dermatitis is an eczematous dermatitis of the legs, associated with edema, varicosed and dilated veins, and hyperpigmentation. It is a chronic problem and commonly relapses.

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

The signs and symptoms of cellulitis include redness, swelling, tenderness, pain, warmth and fever. The signs and symptoms of stasis dermatitis include darkening of the skin at the ankle or legs, itching, leg pains, open sores and ulcers. The skin appears thin and tissue-like, along with skin irritation of the legs, swelling of the legs, ankles or other areas. Thickening of skin at the ankles or legs can also be seen.

Cellulitis occurs when one or more types of bacteria enter through a crack or break in the skin. The two most common types of bacteria are streptococcus and staphylococcus. Although cellulitis can occur anywhere on the body, the most common location is the lower leg. Disrupted areas of skin, such as recent surgery, cuts, skin tears, ulcers, or stasis dermatitis, all serve as the most likely areas for bacteria to enter. Stasis dermatitis occurs because extra fluid builds up in the body, making it hard for the blood to feed cells and get rid of waste products. The tissue becomes poorly nourished and fragile, resulting in stasis dermatitis. What makes this difficult to differentiate is that both cellulitis and stasis dermatitis occur most often in the lower extremities. Poor circulation, varicose veins, conges-tive heart failure all increase the risk for stasis dermatitis.

Stasis dermatitis may occur in bilateral lower extremities at the same time, while this would be unusual for a patient to have cellulitis in both legs at the same time.

The diagnosis is primarily based on the appearance of the skin. You may get a mild to moderate leukocytosis and a mildly elevated erythrocyte sedimentation rate with a cellulitis, but ESRs are not commonly used to diagnose cellulitis. Stasis dermatitis may occur in bilateral lower extremities at the same time, while this would be unusual for a patient to have cellulitis in both legs at the same time.

Treatments for stasis dermatitis and cellulitis vary greatly. The condition that is causing the stasis dermatitis must be controlled. Treatments may include surgery to correct varicose veins (less likely in the LTC setting), medications to control heart failure, and diuretics to remove excess fluid. Cool-water dressings can be applied for 10-20 minutes twice a day for acute exudative inflammation. Group II-V topical steroids are applied twice a day (cream if acute, and ointment if chronic) for 2-3 weeks. An oral antihistamine may be given every 4-6 hours as needed to control itching. Compression (20-30mmHg) is accomplished with stockings or ace wraps (after being sure to check the Ankle-Brachial Index to make sure it is greater than 0.8 before using compression) and can be helpful in controlling the edema.

Treatment for cellulitis includes elevation of the affected limb, empiric treatment with antibiotics aimed at staph and strep (dicloxacillin 500mg q6h, augmentin 875mg bid, keflex 250mg qid). The average time for healing after initial treatment is 12 days. Most patients respond to simple oral antibiotic therapy.

As you can see, many of the signs and symptoms of these two problems are very similar. But with a little more history gathering and assessment of other systems, one should be able to delineate the difference and treat appropriately.

FMDA News & Updates. . .

Members of FL-GAPNA Enjoy FMDA's Town Hall Meeting in Gainesville

On February 5, 2011, FL-GAPNA had its first quarterly meeting in 2011. The meeting was held at the Hilton University of Florida Conference Center in Gainesville — GO GATORS — and was attended by 11 members and two guests.

Chapter elections were finalized, and our president-elect is Karen Jones from North Palm Beach and our secretary is Marva Edwards-Marshall of Palm Bay.

Chapter President Jo Ann Fisher and Karen Jones had just come from the FMDA board meeting and were excited to report that its board had approved a position statement supporting prescriptive authority for advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) working in the long-term care setting in the state of Florida.

Front Row (Left to Right): Michelle Lewis, Marva Edwards-Marshall, Charlene Demers, Back Row: Andrea Clayman, Lori Cruger, Jo Ann Fisher, Jan Cripanuk, Karen Jones, Rosilind Slevin, Bea Matthews

This is the first time a medical organization has supported this scope-of-practice issue in Florida, and we are very grateful for their support!

Susan Lynch and Cindy Drew from the Council of Advanced Practice Nurses Political Action Committee (CAP PAC), **www.cap-pac.org**, were welcome guests and provided an update on the status of legislative initiatives. As the sessions are about to begin, there will not be a bill brought forward in relation to prescribing authority; however, FMDA's support may give us a better chance in 2012. Rallies were planned for February 26 in five areas around the state, and everyone was encouraged to attend if possible.

The chapter decided that we will move forward in planning a CEU day, tentatively April 2, 2012. Bea Matthews, president of the Florida Gulfcoast Chapter, was present and felt her group would definitely want to participate. Charlene Demers, treasurer, agreed to chair the committee. The first planning meeting was held on February 26 following the rally in Orlando.

Our next meeting will be in early May in Melbourne. Keep an eye on our website for more updates at **www.flgapna.org**.

FMDA Call for Poster Submissions Now Being Accepted Online

FMDA is hosting its 8th Annual Poster Session Oct. 21-22, 2011, during the Best Care Practices Conference. The first 10 applicants who are accepted by the review committee will receive complimentary registration to the 2011 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.

Poster abstract proposals must be submitted online on our website at **www.bestcarepractices.org/posters.html**. 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. 23, 2011. 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**.

2011 Poster Sessions Schedule*

Disney's Grand Floridian Resort, Lake Buena Vista, Fla.

POSTER SET-UP

FRIDAY, Oct. 21, 11 a.m.–1 p.m.

POSTER VIEWING

FRIDAY, Oct. 21, 1-2:30 p.m.; 5:15-7:15 p.m.

SATURDAY, Oct. 22
8-9 a.m., 11:45 a.m.-12:30 p.m.,
Luncheon: Poster Recognition–12:45-2:15 p.m.

POSTER TEAR-DOWN

SATURDAY, Oct. 22, 2:15-4:15 p.m.

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

FMDA News & Updates. . .

FMDA Meets in Gainesville

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, Daytona Beach, and now Gainesville.

Front row (from left): FMDA director Dr. Leonard Hock; Matthew Reese, FMDA educational programming coordinator; FMDA director Dr. Robert Kaplan; Standing: Dr. Steve Rothstein, chief medical officer, Haven Hospice; FMDA chairman of the board Dr. Carl Suchar; Jerry Burroughs, regional manager of professional relations, Haven Hospice; FMDA president Dr. Hugh Thomas; Susan Mollick and Herb Grigg, of Boehringer Ingelheim, which sponsored the dinner-program

On Feb. 5, FMDA hosted another memorable Town Meeting & Dinner at Mark's Prime Steakhouse in Gainesville. More than 50 guests joined us. The dinner and scientific presentation were sponsored by Herb Grigg and Boehringer Ingelheim. We started the evening with an intimate trade show with support from AAA Auto South, Biocodex, Boehringer Ingelheim, Haven Hospice, Medtronic, Novo Nordisk, and Vitas Innovative Hospice.

Seated (from left): Palms of Ocala DON Tina Vanaman; FMDA immediate past president Dr. John Potomski. Standing: John Mikula, PhD, NHA; Dr. David LeVine; Palms of Ocala administrator Jennifer Mikula; FMDA director Rhonda Randall; FMDA president Dr. Hugh Thomas; FMDA chairman of the board Dr. Carl Suchar; and FOMA-FMDA liaison Dr. Gregory James.

Earlier in the day, the CME/Education Committee and the FMDA board of directors met for regularly scheduled business meetings. The board meeting was generously sponsored by Haven Hospice.

More than 20 members and special guests attended the CME/Education Committee and board meetings in Gainesville.

Another Town Meeting is being planned for July 8 in the Jacksonville area. In addition to our regularly scheduled meetings on Sunday, July 9, we plan to offer a 3.0-hour CME program on the afternoon of Saturday, July, 8. Stay tuned for more information.

Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

AGENCY: Centers for Medicare & Medicaid Services (CMS)
ACTION: Final rule with comment period.
SUMMARY: This final rule with comment period addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It finalizes the calendar year (CY) 2010 interim relative value units (RVUs) and issues interim RVUs for new and revised procedure codes for CY 2011. It also addresses, implements, or discusses certain provisions of both the Affordable Care Act (ACA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

In addition, this final rule with comment period discusses payments under the Ambulance Fee Schedule (AFS), the Ambulatory Surgical Center (ASC) payment system, and the Clinical Laboratory Fee Schedule (CLFS), payments to end-stage renal disease (ESRD) facilities, and payments for Part B drugs. Finally, this final rule with comment period also includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, CMS-1503-FC 2 and supplies (CBP DMEPOS), and provider and supplier enrollment issues associated with air ambulances.

DATES: These regulations became effective on January 1, 2011.

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FMDA News & Updates. . .

FMDA News & Updates
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Public Policy Institute Publication Alert

AARP's Public Policy Institute informs and stimulates public debate on the issues we face as we age. Through research, analysis, and dialogue with the nation's leading experts, PPI promotes development of sound, creative policies to address our common need for economic security, health care, and quality of life.

Here are some recent articles that may be of interest to you:

Weathering the Storm: The Impact of the Great Recession on Long-Term Services and Supports

Preliminary findings of an all-state survey show the impact of economic conditions on long-term services and supports, including both Medicaid and non-Medicaid programs. By Susan Reinhard–AARP Public Policy Institute; Martha Roherty–National Association of States United for Aging and Disabilities (NASUAD); Kathy Gifford–Health Management Associates. (**www.aarp.org/health/health-care-reform/info-10-2010/health-panel-10201.html**).

Trends in Disability, Community Living, and Caregiving: Analysis of Data from the National Long-Term Care Survey

Two new AARP Public Policy Institute research reports explain important trends in disability, institutional use, community living, family caregiving, and paid home care. By Donald L. Redfoot, Ari Houser, Mary Jo Gibson. (**www.aarp.org/relationships/caregiving/info-09-2010/0927-ltc-health.html**)

Care Management Practices in Integrated Care Models for Dual Eligibles

State-authorized health plans whose members are qualified to receive both Medicare and Medicaid benefits face administrative challenges. The plans' objectives and approaches differ in some respects but are similar in many. By Brian Burwell–Thomson Reuters; Paul Saucier–Thomson Reuters; Lina Walker–AARP Public Policy Institute (**www.aarp.org/health/medicare-insurance/info-09-2010/health-dual0910.html**)

Access to Long-Term Services and Supports: A 50-State Survey of Medicaid Financial Eligibility Standards

Updates existing data on Medicaid financial eligibility standards for nursing home and home- and community-based waiver services for older persons and adults with disability. AARP Public Policy Institute and the Congressional Research Service surveyed all 50 states to obtain 2009 data on state selection of optional pathways for Medicaid eligibility, income and asset standards for eligibility, and cost-sharing and other post-eligibility financial requirements. By Lina Walker and Jean Accius–AARP Public Policy Institute. (**www.aarp.org/health/health-care-reform/info-09-2010/i44-health.html**)

Provision for Advanced Care Planning Discussions in Annual "Welcome to Medicare" Visit

At the end of 2010, The Centers for Medicare and Medicaid (CMS) posted the 2000+ page physician payment final rule and comments on the OFR website. The final rule includes reimbursement requirements for the new annual wellness/preventive care exam under the Medicare changes that were included in the healthcare reform bill. CMS agreed, in response to comments urging CMS to require that physicians offer voluntary advance care planning (ACP) as part of the annual exam.

You may recall that a legislative provision to offer voluntary ACP every five years was dropped from the PPACA bill. ACP had already been a required part of the "Welcome to Medicare" visit since the Medicare Modernization Act of 2003. Since ACP requires an ongoing conversation, it makes a lot of sense to revisit it at least annually. This is a big step forward in promoting patient self-determination and encouraging physicians to be engaged in their patients' advance care planning process.

You can access the final regulations at **www.ofr.gov/OFRUpload/OFRData/2010-27969_PI.pdf**. The relevant pages are pp. 766-768 for the commentary and pp. 1488-1494 for the regulatory language.

Conference Ambassadors Wanted

Do you have some mileage in the business, some successes as well as scars? Then 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 2011" conference. This year's conference will be at Disney's Grand Floridian Resort & Spa in Lake Buena Vista, Oct. 20-23, 2011.

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-mails and the mail for the complete conference brochure and registration form. Or call the office at **(561) 659-5581**, or visit **www.bestcare practices.org**.

Success Story: 21st Annual LTC Symposium

Dr. John Potomski's 21st Annual Long-Term Care Symposium was held in conjunction with the Brevard County Medical Directors Association (BCMDA) at the Rialto Hilton in Melbourne, Fla., this past November 17, 2010.

Dr. John H. Potomski Jr., DO, CMD, president of BCMDA, has been a medical provider for residents in Brevard County's nursing and rehabilitation centers as well as assisted living facilities for more than 27 years. The purpose of this event, which is free to attendees, has been to offer an educational dinner meeting for the facility staff, as he has always felt that educating staff would improve patient/resident care. This symposium has grown over the years from 80 attendees to more than 480, and the quality of the program has always exceeded the expectations of those in attendance.

Pictured with Dr. John Potomski (left), is Maxine Zimmerman, LPN, staff nurse at Life Care Center of Melbourne, and the LTC award winner for 2010.

This event was supported by Wuesthoff Brevard Hospice and Palliative Care, and Andrea Miller, MD, spoke on "Palliative Care Planning and Pain Management in the Long-Term Care Setting." Eli Lilly and Novo Nordisk supported Naushira Pandya, MD, CMD, whose presentation was "A Practical Approach to Managing Diabetes in the LTC Setting." Thomas W. Oates, MD, presented "A New Approach in the Treatment of Postmenopausal Osteoporosis in Women at High Risk for Fracture," which was supported by Amgen. Several pharmaceutical firms, health-care diagnostic and product companies, hospice and home health organizations, as well as some of Brevard County's LTC facilities, pharmacies and hospitals also supported the symposium as exhibitors. The symposium was organized by Jo Ann Fisher, MSN, FNP-BC, executive director of BCMDA, with support from the staff of Osler Geriatrics and Brevard Geriatric Assessment Services.

Father Robert Bruckart, MDiv, PhD, director of Health First Pastoral Care, gave the invocation.

The Pledge of Allegiance was led by Maj. Kevin Hamm, Georgia Army National Guard; he is also with Eli Lilly.

Attendees included health care professionals affiliated with skilled nursing and assisted living facilities in Brevard County. They included medical directors, physicians, nurse practitioners, physician assistants, nurses, directors of nursing, administrators, pharmacy consultants, hospice and home health care representatives and facility department heads.

Dr. Potomski is the medical director of Osler Geriatrics and has always been an advocate for the most vulnerable elders in Brevard County. He has advocated at the state and local legislative levels, is chairman of the Brevard County Commission on Aging, has been a member of all medical organizations involved in issues concerning elders at state and national levels, and is a two-time president of FMDA.

~ Volunteers Needed Now ~

FMDA is looking for one or more volunteers to help us revive the Medicare-focused *Coding Corner* feature article for the *Progress Report* newsletter.

FMDA Job Fair

FMDA's 2nd job fair will be held on Friday, Oct. 21, 2011, during its 20th annual conference and trade show. Attendees will be able to network with health care recruiters and learn about new and interesting opportunities.

Technology Guru Needed

The board of directors is also looking for a technology guru to advise the board about new and interesting technological opportunities.

You're Invited to the Following FMDA Activities:

~ **CME/Education Committee and Board meetings** — **11:30 am-1 pm, Friday, March 25, 2011**, during AMDA's annual symposium in Tampa; **Meeting Room 4, Tampa Marriott Waterside**. RSVPs required: **mattr@fmda.org**.

~ **Visit** the **Florida Chapter exhibit** in the trade show at AMDA's annual symposium in Tampa, **Booth 120** in the exhibit hall at the **Convention Center**.

~ **Florida Chapter Reception** during AMDA's annual symposium in Tampa, FL — **6:30-7:30 pm**, Friday, March 25, 2011; **Grand Salon C, Tampa Marriott Waterside**.

~ **Weekend Retreat: July 8-9**: Lunch and afternoon program with 3.0-hour CME program followed by a reception and mini trade show, and Town Meeting Discussion and dinner-program on Saturday. On Sunday morning, we will hold the CME/Education Committee and Board meetings. **Venue**: TBD

~ **Best Care Practices in the Geriatrics Continuum 2011** — FMDA's 20th Anniversary Conference at Disney's Grand Floridian Resort, **Oct. 20-23**.

In patients with type 2 diabetes, the TITRATE® study demonstrates

Once-daily Levemir® gets the majority of patients to goal safely[1]

64% of patients achieved A1C goal <7% with once-daily Levemir®*

The Levemir® TITRATE trial shows how a majority of patients with type 2 diabetes taking a basal insulin, some with A1C levels as high as 9%, achieved the ADA-recommended target of A1C <7%.[1,2] Patients experienced a mean A1C decrease of −1.2%* and achieved goal safely with low rates of hypoglycemia, nearly all of which were minor or symptoms only.[†]

*70 to 90 mg/dL group.

To see how Levemir® can help your patients achieve their goals, and to learn more about TITRATE, visit TITRATEstudy.com.

Model is for illustrative purposes only.

[†] Minor hypoglycemia rates were 0.42 (70-90 mg/dL) and 0.26 (80-110 mg/dL) per patient-month. A single major hypoglycemic event was reported in the 70 to 90 mg/dL group; no major hypoglycemic events in the 80 to 110 mg/dL group.[1]

Results from a 20-week, randomized, controlled, multicenter, open-label, parallel-group, treat-to-target trial using the PREDICTIVE® 303 self-titration algorithm in insulin-naive patients with type 2 diabetes, A1C ≥7% and ≤9% on OAD therapy randomized to Levemir® and OAD (1:1) to 2 different FPG titration targets (70-90 mg/dL [n=121] or 80-110 mg/dL [n=122]).[1]

PREDICTIVE = Predictable Results and Experience in Diabetes through Intensification and Control to Target: an International Variability Evaluation.

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.

Levemir® should not be diluted or mixed with any other insulin preparations.

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.

Needles and Levemir® FlexPen® must not be shared.

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. 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. Less common but more serious are severe cases of generalized allergy, including anaphylactic reaction, which may be life threatening.

Please see brief summary of Prescribing Information on adjacent page.

References: 1. Blonde L, Meriläinen M, Karwe V, Raskin P, for the TITRATE™ Study Group. Patient-directed titration for achieving glycaemic goals using a once-daily basal insulin analogue: an assessment of two different fasting plasma glucose targets—the TITRATE™ study. *Diabetes Obes Metab.* 2009;11(6):623-631. **2.** American Diabetes Association. Standards of medical care in diabetes—2010. *Diabetes Care.* 2010;33(suppl 1):S11-S61.

Levemir®
insulin detemir (rDNA origin) injection

novo nordisk®

Levemir® (insulin detemir [rDNA origin] injection)

Rx ONLY

BRIEF SUMMARY. Please see package insert for full 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. Needles and LEVEMIR® FlexPen® must not be shared.

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

* See CLINICAL STUDIES section for description of individual studies
** 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 upon request.

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Manufactured for: Novo Nordisk Inc., Princeton, NJ 08540, www.novonordisk-us.com
Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

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Levemir®
insulin detemir (rDNA origin) injection

Inpatient Medical Management of Benign Prostatic Hyperplasia

By Chantelle Dufresne, MS-III, Nova Southeastern University College of Medicine

Chantelle Dufresne

Benign Prostatic Hyperplasia (BPH) is a very common occurrence in the geriatric patient population with a frequency of greater than 80 percent among men older than 80 years old.[4] When BPH progresses, patients experience symptoms of increased frequency of micturition, hesitancy, nocturia, and urinary urgency. If untreated, Benign Prostatic Hyperplasia can lead to urinary retention, recurrent urinary tract infections, hydronephrosis, and renal failure.[3]

The prostate is an exocrine gland that's main function is to store and secrete the alkaline component of semen. The gland is under hormonal control and contains a variety of Alpha 1 receptors, which are also present in the bladder. Anatomically, the prostate is divided into the transition, central, and peripheral zones. Hypertrophy occurs in the transition zone of the prostate, which is under hormonal control. In contrast, prostate carcinoma primarily involves the peripheral zone of the prostate, indicating that BPH is not a risk factor for prostate malignancy. Hypertrophy of the gland is also very slow growing.

This combination of therapy with an alpha-antagonist also confirms that BPH symptoms are better treated with a multi-factorial approach, rather than monotherapy.

The treatment of benign prostatic hyperplasia is dependent on the severity of the symptoms. The American Urological Association symptom-scale grades determine the severity of BPH symptoms in seven categories. Each division (frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying, and urgency) is ranked from zero to six points with a total score of 35 indicating the most severe symptoms.[1] Treatment of BPH is generally medically managed once the patient becomes symptomatic — corresponding to an AUA symptom score greater than seven.

Medical treatment of symptoms of benign prostatic hyperplasia has been the use of alpha-antagonists and 5-Alpha Reductase medications. Alpha 1-antagonists act by relaxing the smooth muscle of the bladder and prostate, thus reducing the physiological obstruction. Currently used alpha 1 antagonists Tamsulosin, alfuzosin, terazosin, and doxazosin are effective in reducing AUA symptoms by an average of 4-6 points.[1]

These drugs are beneficial for short-term and more immediate relief of symptoms and are fairly safe. They should be initiated at bedtime, as common side effects are orthostatic hypotension and dizziness.[2] In contrast, 5-Alpha Reductase inhibitors target the structural obstruction caused by BPH. In contrast to Alpha 1 antagonists, finasteride and dutasteride are not rapid acting, but demonstrate more long-term reduction in prostate volume that can be evident as early as six months to a year. These drugs also have the additional benefit of reducing the need for prostatic surgery in the future.[2] Side effects of 5-alpha reductase inhibitors consist of decreased libido as well as orthostatic hypotension.

Both classes of drugs are effective at diminishing the symptoms of benign prostatic hyperplasia; however, each drug achieves this through a different mechanism of action. Studies comparing monotherapy versus combination therapy have demonstrated that reduction of symptoms was superior when both drugs were used together.[1]

In a study performed by McConnell et al., the symptoms' progression was reduced by 66%, urinary retention risk was reduced by 81%, and the need for invasive therapy was reduced by 67%.[1] In addition, a randomized controlled trial by Kaplan et al concluded that treatment with tolterodine and tamsulosin significantly reduced symptoms of lower urinary tract symptoms and overactive bladder over monotherapy and placebo when treating symptomatic BPH patients.[3] Tolterodine is an antispasmodic that antagonizes acetylcholine receptors, thus reducing the symptoms of an overactive bladder. This combination of therapy with an alpha-antagonist also confirms that BPH symptoms are better treated with a multi-factorial approach, rather than monotherapy.

References

1. E. Darracott, Vaughan Jr., et al, "Medical Management of Benign Prostatic Hyperplasia – Are Two Drugs Better than One?" *New England Journal of Medicine*. 349.25 (2003): 2449. Print
2. Cunningham, Glenn R. MD et al, "Medical treatment of benign prostatic hyperplasia." *Uptodate®*. September 2010. **www.uptodate.com**. April 8, 2010
3. Kaplan, Steven A. MD et al, "Tolterodine and Tamsulosin for Treatment of Men With Lower Urinary Tract Symptoms and Overactive Bladder." *JAMA*. 296.19 (2006): 2319-2329. Print.
4. Cunningham, Glenn R. MD et al, "Clinical Manifestations and Diagnosis of Benign Prostatic Hyperplasia." *Uptodate®*. September 2010. **www.uptodate.com**. September 24, 2009.

Haven't seen the 2010 Annual Conference photos yet?

Visit...
www.bestcarepractices.org/index3.html.

FMDA Becomes First Medical Society to Support ARNP/PA Prescribing Authority in Florida

By Ian Cordes, MBA, NHA; Executive Director, FMDA

FMDA made a big step by becoming the first medical society in Florida to advocate for nurse-practitioner and physician-assistant prescribing authority for controlled substances. The members and leadership of FMDA understand that ARNPs and PAs are often the "front line" health-care providers for patients in the long-term care community, where pain medications are often indicated. The inability of these health-care providers to prescribe controlled substances can affect the timely administration of medications for the relief of pain and other medical conditions. This has the potential to impact the quality of life for this vulnerable group of patients.

FMDA's position regarding ARNP/PA prescribing authority recommends that, with the written permission of his or her collaborating/supervising physician(s) and successful completion of mandatory continuing education, that ARNPs and PAs be granted the legal authority to prescribe controlled substances in long-term care settings, including skilled nursing facilities, home care, assisted living, residential care, and hospice programs. These settings are very well-regulated and controlled by current federal and state governance, as well as other credentialing organizations. Individual physicians would ultimately decide which, if any, of the controlled substances could be prescribed by which, if any, ARNPs and PAs in their practice. Hence, this would be an option, not a mandate. Furthermore, individual ARNPs/PAs would not be required to pursue DEA licensure.

FMDA president Dr. Hugh Thomas views this position statement as a positive step forward for improved access and quality of care for patients in long-term care settings: "It is the view of FMDA that the highest quality of care be given to our residents in long-term care. Furthermore, collaboration between the inter-disciplinary team has never been more important. This is why, for the interest of our patients, that we support prescribing authority of controlled substances for nurse practitioners and physician assistants."

Florida is one of only two states that do not allow ARNPs to prescribe controlled medicines. FMDA's support for prescriptive authority of controlled substances for ARNPs/PAs shows a commitment to full access to health care and improved quality of care for our Florida long-term care patients. FMDA's full position statement can be found on its website, **www.fmda.org**.

NPs/PAs work under protocols set up between themselves and their supervising physician, and FMDA does not support independent practice for NPs or PAs.

Editor's Note: There is an excellent article in the *The New England Journal of Medicine* (NEJM), December 15, 2010, "Broadening the Scope of Nursing Practice" by Julie A. Fairman, PhD, RN; John W. Rowe, MD; Susan Hassmiller, PhD, RN; and Donna E. Shalala, PhD. I think it's worth reading. Here is the link for those who are interested: **healthpolicyandreform.nejm.org/?p=13387**.

Hypercalcemia in the Elderly

By Philip W. Yun, MS-III, Nova Southeastern University College of Medicine

Hypercalcemia, a common condition in the elderly population, can range in its clinical manifestations from asymptomatic in mild cases to altered mentation and coma. With screening of serum calcium concentration and an aging population, more cases of hypercalcemia have been identified. Often, it is an incidental finding in a seemingly asymptomatic individual, but further workup is necessary to determine the etiology, which may tailor course of treatment or prevention of progression.

Philip W. Yun

Hypercalcemia is generally caused by increased absorption of calcium, decreased renal clearance of calcium, and/or increased bone resorption. Most common etiologies include primary hyperparathyroidism and malignancy, which account for 90% of cases of hypercalcemia.[1] It is important to be able to exclude and differentiate between these two diagnoses when working up unexplained hypercalcemia.

With the increased incidence of hypercalcemia as previously mentioned, incidence of primary hyperparathyroidism has increased as well.[2] Primary hyperparathyroidism is often an incidental finding, because levels of serum calcium are usually chronically elevated at a relatively mild level. Therefore, classic symptoms of hypercalcemia, such as abdominal pain, changes in mood, and renal calculi, are often said to be absent in a patient with primary hyperparathyroidism.[2] This, however, is met with some skepticism, especially in the elderly population, as some of the nonspecific neuropsychiatric symptoms of hypercalcemia may be mistaken for symptoms of functional decline.[3]

Initial workup for hypercalcemia starts with a serum PTH concentration.[1,2] 95% of cases of normal to elevated serum PTH are attributed to primary hyperparathyroidism, and it therefore confirms the diagnosis.[2] Serum alkaline phosphatase may also be elevated in response to increased bone turnover. There is utility in a bone density scan to evaluate the hip and spine, as elevated PTH levels tend to increase resorption of cortical bone greater than cancellous.[2]

In the setting of low serum PTH, primary hyperparathyroidism is excluded, as the negative feedback from elevated serum calcium is intact. Hypercalcemia of malignancy must then be evaluated. Serum PTH-related peptide is a reasonable step to consider, and elevated serum levels confirm humoral hypercalcemia of malignancy.

In the elderly patient, other less common causes of hypercalcemia need to be evaluated when primary hyperparathyroidism and malignancy are ruled out. Hypercalcemia can be induced by drugs, namely lithium and thiazide diuretics.[1,2] An often overlooked cause of hypercalcemia in the geriatric population also includes immobilization.[4] Sarcoidosis, thyrotoxicosis, vitamin D intoxication, and Addison disease are among other rare etiologies of hypercalcemia that is usually accompanied by other manifestations helping to make the diagnosis.[1]

Treatment of hypercalcemia is generally targeted toward the underlying cause, but management of serum calcium levels can be critical to reduce complications and symptomatology. Mild hypercalcemia associated with primary hyperparathyroidism does not mandate urgent intervention and is often just monitored. However, 40% of those with the condition will progress with complications.[6] Therefore, parathyroidectomy, being the only definitive treatment, is considered even in the asymptomatic elderly patient as it can be done as an outpatient procedure with a low rate of complications and has been reported to decrease fracture risk.[3] Furthermore, some studies indicate that with minimally invasive parathyroidectomy, cost-effectiveness combined with efficacy of surgical treatment outweighs medical management.[7] Hypercalcemia of malignancy is usually more acute and severe, and treatment is geared towards minimizing serum calcium concentrations with hydration and bisphosphonates.[8]

Hypercalcemia of malignancy is usually more acute and severe, and treatment is geared towards minimizing serum calcium concentrations with hydration and bisphosphonates.

Due to its nonspecific and often nonexistent symptoms, hypercalcemia in the elderly individual is a condition that is commonly identified only through routine screening. Appropriate workup to determine its etiology is then essential in management and formulating a plan of treatment.

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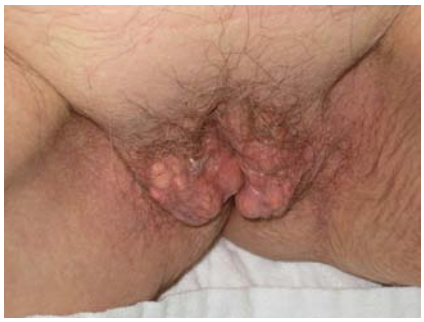
Chronic Perineal Lesions in the Elderly Woman: A Case History

By Chantelle Dufresne, MS-III, Nova Southeastern University College of Medicine

This is an 82-year-old Caucasian female who was discharged from the hospital for angina and a vertebral compression fracture and was admitted to a geriatric rehabilitation facility. Upon admission, her daughter stated that she was concerned about a lesion on her mother's vulval skin. The patient reported seeing her gynecologist two months prior to admission, and he did not mention anything abnormal. She denied any urinary symptoms such as discharge, dysuria, hematuria, or pruritis. She reported occasional discomfort when sitting, but it was alleviated with a topical barrier cream. On physical examination, the patient was found to have multiple superficial yellow cysts on bilateral labia majora. The cysts were movable to palpation but adherent to the overlying skin, with minor erythema. The patient was diagnosed with epidermoid cysts based on clinical examination, instructed to follow up with her gynecologist, and treated with barrier cream as needed.

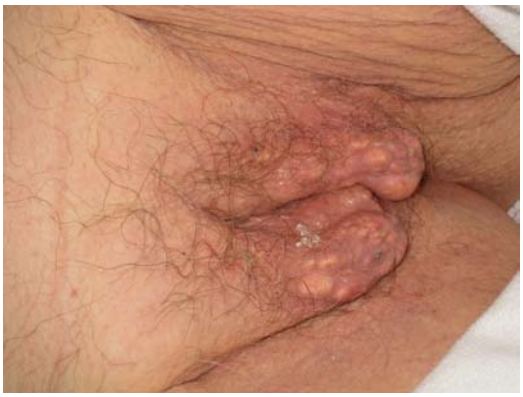


Discussion

Epidermoid cysts are the most common cause of cutaneous cysts and are diagnosed based on clinical appearance and physical examination. An epidermoid cyst is a firm, subcutaneous, keratin-filled cyst originated from true epidermis, most often from a hair follicle.[3]

The cysts are commonly found on the trunk and areas prone to friction. The wall of the cyst consists of keratin and squamous epithelium, which is delicate and prone to rupture. Upon rupture, these lesions become susceptible to infection and foreign-body reaction with subsequent inflammation. Epidermoid cysts can remain stable or progressively enlarge.[2] Clinically, the lesions appear as firm, moveable, dome-shaped, pale yellowish intradermal or subcutaneous fluid-filled nodules ranging from 0.5-5.0 cm in size. When cysts are inflamed or they rupture, the patient may complain of tenderness to palpation, discomfort, as well as inflammatory sequelae of erythema and warmth. Histologically, the cysts are filled with layers of cornified lamellated keratin.[3] Uninfected cysts resolve spontaneously and do not need any intervention. Although the lesions may cause intermittent positional discomfort, intervention is merely cosmetic. Periods of inflammation can be alleviated by injection of Kenalog and reduce risk for infection.[2] Fluctuant cysts may require incision and drainage. Multiple sebaceous cysts seen on extremities and face should raise suspicion of Gardner syndrome, especially if the lesions appear before puberty. This familial condition is a rare autosomal-dominant inherited disorder consisting of epidermal cysts, osteomas, and colon polyps, which have an association with colon cancer.

Vulvar lesions may represent a wide range of pathology. Lesions can vary from benign to malignant conditions, and many can be differentiated on history and clinical presentation alone. A differential diagnosis consists of flesh-colored or non-pigmented papules or nodular lesions. Benign lesions that can mimic the appearance of vulvar epidermoid cysts consist of vestibular papillae, acrochordons, cysts, condyloma acuminata, molluscum contagiosum, and syringoma. Epidermoid cysts can also be mistaken for Bartholin gland or pilonidal cysts. Neoplasms of eccrine sweat glands, syringomas, are rarely seen on the vulva. These lesions appear in symmetrical distribution, and can be excised or symptomatically treated with topical atropine. Vestibular papillae are discrete, small papules located symmetrically around the edge of and confined to the vestibule.[1] These lesions are typically untreated, as this condition is benign and asymptomatic. Vestibular papillae and condyloma acuminata can mimic one another on appearance of the individual lesions, but condyloma can coalesce and are not solely restricted to the vaginal vestibule. Condyloma acuminata, commonly referred to as genital warts, are caused by human papillomavirus.



Genital wart lesions vary from pale pink to white and have rough, barely raised papules. The surface may be smooth, velvety and moist, and lacks hyperkeratosis of warts found elsewhere.[3] Papillomatosis can also be misdiagnosed as HPV, as the lesions turn white upon acetic acid treatment. These lesions are commonly found in the inner labia and appear as flesh-colored micropapillae.[4] In contrast, Molluscum contagiosum are umbilicated papules due to the poxvirus family. These lesions are typically seen in patients with underlying immunosuppression. Genital warts and molluscum contagiosum are both treated with cryotherapy or immunomodulating therapy. Acrochordon, or skin tags, are seen as pedunculated growths of normal skin and, like epidermoid cysts, are seen in areas prone to friction.

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Pradaxa, a New Anticoagulant

By Gaylon Fruit, BS, RPh; Geriatric Consultant Pharmacist, Managing Partner, Senior Care Consultant Group

Undoubtedly, since early last year, we have been hearing about a new anticoagulant that would be available very soon. In early discussions with each other, we had great expectations, the most prominent being no more PT/INR lab work. Could we really believe it? Well, folks, Pradaxa (Dabigatran etexilate) from Boehringer Ingelheim is finally here with FDA approval in tow. As with most new drugs, we need to take a closer look before we all get too excited.

Dabigatran etexilate (Pradaxa) is the first oral anticoagulant approved in the U.S. in more than 50 years. Pradaxa is a prescription medicine used to reduce the risk of stroke and blood clots in people who have atrial fibrillation. With atrial fibrillation, part of the heart does not beat the way it should, leading to blood clot formation and increasing the risk of a stroke.

Dabigatran is a competitive, direct thrombin (factor IIa) inhibitor. Thrombin enables the conversion of fibrinogen into fibrin during the coagulation progression. Inhibition of thrombin prevents the development of thrombi. Dabigatran also inhibits free thrombin, fibrin-bound thrombin, and thrombin-induced platelet aggregation. Dabigatran etexilate is rapidly absorbed in the GI tract and converted to dabigatran by plasma esterase and in the liver.

Pradaxa is indicated for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Pradaxa is available as 75 mg and 150 mg oral capsules, in bottles of 60 capsules each or blister cards. Dabigatran capsules should be dispensed in the original container to protect from moisture and loss of stability. Once a bottle of dabigatran capsules has been opened, the capsules must be used within 30 days. Dabigatran capsules should not be chewed or opened before swallowing, as this increases bioavailability up to 75%.

Pradaxa should be dosed at 150 mg twice daily if renal function is normal. For patients with creatinine clearance (CrCl) of 15 to 30 mL/min, the recommended dose of Pradaxa is 75 mg twice daily. There is no dose recommendation for patients with creatinine clearance <15 mL/min, or for patients on dialysis.

If you change from dabigatran to warfarin, the starting time is based on CrCl as follows:

CrCl >50 mL/min: start warfarin three days before stopping dabigatran;
CrCl 31 to 50 mL/min: start warfarin two days before stopping dabigatran;
CrCl 15 to 30 mL/min: start warfarin one day before stopping dabigatran;
CrCl <15 mL/min: no recommendation

Changing from warfarin to dabigatran requires warfarin to be stopped first, then dabigatran can be started when the patient's INR is less than 2. If a patient misses a dose, we should recommend taking the missed dose, as soon as possible, unless it is less than six hours before the next dose in which case, the patient should wait until the next dose is due, and resume taking the drug then. If a dose is missed, we do not recommend doubling the next dose. If a patient is having surgery or an invasive procedure, dabigatran should be stopped one to two days prior for patients with creatinine clearance of >50 mL/min and three to five days prior for patients with creatinine clearance of <50 mL/min.

Pradaxa can cause bleeding that can be serious and lead to death. Pradaxa should not be taken by patients with certain types of abnormal bleeding. Approximately 17% of patients taking 150 mg twice daily experienced some type of bleeding with dabigatran. About 3% of patients receiving this dose had a major bleeding event. Dabigatran should be stopped if a patient has active pathological bleeding.

There can be higher risk of bleeding with Pradaxa in patients over 75 years old, those with kidney problems, or those that have a condition that causes bleeding, like a stomach ulcer. Medications that can increase bleeding risk in general can increase the risk for bleeding when used together with dabigatran; these include anti-platelet agents, such as Plavix, aspirin, heparin, fibrinolytics, and routine use of NSAIDs.

Immediate medical care should be provided for any unexpected bleeding or signs of bleeding such as unusual bruising, coughing up or vomiting blood, or changes in the color of a patient's urine or stools. There is no antidote for reversing the effect of dabigatran. Some options for management of bleeding include administration of fresh frozen plasma or red blood cells. Dabigatran is dialyzable, so hemodialysis can be used to remove the drug in the case of overdose.

Gastrointestinal side effects are somewhat common with dabigatran. Approximately 33% of patients taking dabigatran 150 mg twice daily experienced GI side effects including dyspepsia and gastritis-like symptoms. For patients who complain of dyspepsia with dabigatran, the drug can be taken with food. If this is ineffective, an H-2 blocker or proton pump inhibitor may be used. Changing to warfarin is an option for patients who cannot tolerate GI side effects of dabigatran. Patients should not stop taking Pradaxa unless their doctor tells them to, as this could increase their risk of having a stroke.

Dabigatran is not metabolized by, and does not affect, cytochrome P450 enzymes. The prodrug of dabigatran is a substrate for P-glycoprotein, a drug transporter found in the intestine. P-glycoprotein inducers (e.g., rifampin, St. John's wort, etc.) are likely to reduce blood levels of dabigatran, thus concomitant use of these drugs with dabigatran should be avoided. Pantoprazole may reduce dabigatran levels by up to 30%, but this does not appear to affect the efficacy of dabigatran.

Pradaxa has not been studied in pregnant women and is therefore not recommended during pregnancy unless the benefit outweighs the risk. Caution should be exercised if Pradaxa is taken by women who are breast feeding, as it isn't known whether dabigatran is excreted into human breast milk.

In all the aforementioned, the prescriber should always consider the risk/benefit ratio in the decision process. So after a thorough review, some of our patients will surely benefit greatly with this new pharmaceutical addition. Our excitement may not be quite as strong as it initially was, but it is good to know that we now have one more arrow in our quiver to battle atrial fibrillation and the potential reduction of stroke.

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