www.fmda.org Florida Medical Directors Association

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Progress Report

APEX AWARDS FOR PUBLICATION EXCELLENCE

Serving Physicians & Nurse Practitioners Practicing in Florida's Postacute Care Continuum

Control of MRSA in Long-Term Care Facilities

By Allen D. Andrade, MD, DM(Lon), MRCP(UK), ABIM; VA Advanced Academic Research Fellow, Department of Geriatrics, University of Miami/Jackson Memorial Hospital, Miami Fla.

Introduction

Dr. Allen Andrade

Staphylococcus aureus is a bacterium that is found commonly on most surfaces. Since the advent and continued use of antibiotics, these bacteria have developed a natural resistance over time to the most commonly used penicillin-based antibiotics. This has led to more serious infections by Methicillin-resistant staphylococcus aureus (MRSA), which is more difficult to treat. MRSA was first identified as a clinical problem in the early '70s. It tends to reside on human skin. The causes for concern with MRSA are the limited antibiotic arsenal available to treat it and the emergence of more multi-drug resistant strains.

The goal of this article is to guide health care providers in a long-term care (LTC) facility about tackling the spread of MRSA and dispelling some of the myths behind MRSA. Visible contact precautions (gown and gloves) and the media attention generated by MRSA infection make this bacteria seem more virulent. The term "super bug" has been associated with MRSA by various news multimedia, but it is no more virulent than Methicillin-sensitive staphylococcus. However, as MRSA is more difficult to treat in the absence of timely appropriate antibiotics, this infection can rapidly spread through the body and cause serious illness. Medical research has identified various MRSA bacterium properties, such as the Panton-Valentine leukocidin (PVL), which may promote more invasive strains, and the emergence of multi-drug resistant MRSA, which is resistant to many commonly used medications — a great concern for health care providers.

Colonization and Infection

Methicillin-resistant staphylococcus aureus is now very commonly found in health care institutions and extended-care facilities. Once MRSA is introduced into a facility, it is unlikely to be eradicated. A number of infection-control practices that have been developed to combat the spread of this infection are based on standard infection-control policies that govern any bacterium. There are no controlled trials to establish the efficacy of these measures in preventing the spread of this organism.

Identification of the organism is based on swabbing the affected site and growing the bacterium on culture media, followed by antibiotic sensitivity testing. Rapid MRSA tests have been developed to identify these organisms, and they can generate reports in two to three hours, compared to 72 hours with traditional culture methods. The swab sites of potential colonization — nostrils, armpits, perineum, and chronic wounds — are examples of where MRSA resides. A "carrier" is an individual who is colonized with the MRSA bacteria yet has no active infection. Colonization refers to the MRSA bacteria's residing harmlessly on the skin or soft-tissue surface without active infection. MRSA infection usually involves skin and soft tissue, though lung and urinary tract infections can also occur. Transmission is by direct, person-to-person contact, usually by hands. The role of

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INSIDE

President's Letter

We started 2009 with a bang. In January, we hosted a very successful town meeting in Tallahassee, under the direction of Dr. Hugh Thomas. In February, the Industry Advisory Board met in Tampa to discuss many of the upcoming changes in the pharmaceutical industry and their impact on our organization. Under Dr. Malcolm Fraser's able leadership, this has been a very beneficial relationship for all parties involved. Then, in March, FMDA's board of directors met in Charlotte, NC, during AMDA's Annual Symposium.

Our executive director, Ian Cordes, along with two other AMDA chapter EDs, participated in an effort last year to help struggling and emerging AMDA chapters to stabilize and grow. FMDA is considered the most successful state chapter and a model for other states. As a result, at a meeting of the state chapter presidents during the Annual Symposium, AMDA president Dr. David Brechtelsbauer presented FMDA with a plaque in recognition of this effort.

During the months since Best Care Practices 2008, the CME/Education committee working under Chair Dr. John Symeonides and Program Director Dr. Carl Suchar, met in person and via teleconferences to start planning another stellar Best Care Practices Conference 2009. This year, we return to the Buena Vista Palace Hotel in Orlando, where our conference has been held in the past.

Our ex-officio board member, Jo Ann Fisher, FNP-BC, is an active member of AMDA's Transitional Care Clinical Practice Guideline Advisory Committee. Its mission is to help LTC providers across the nation with guidelines to promote effective and safe transitions across the continuum of care.

As you can see, Dr. Karl Dhana is doing a great job at the helm of our ***Progress Report*** newsletter, and I am confident that he can take it to new heights of excellence.

Dr. Dhana, who is the senior vice president of medical affairs at MorseLife in West Palm Beach, arranged for MorseLife and Morse Geriatric Center to host our next CME/Education Committee and Board meeting on Friday, June 26, at their beautiful, 37-acre seniors campus. Thank you, Karl, and thank you, MorseLife, for the gracious invitation.

As you know, my two-year term as president will be up in October. As this time, Hugh Thomas, our vice-president and president-elect, is seeking nominations for our slate of officers and directors to be voted on in October. We already have interest from a number of our members who would like to get involved, but we also need your voice and talent to join our ranks of FMDA leaders.

In case you didn't know, this is my second tour as the FMDA president (the last one was 10 years ago), and I can tell you it has been an absolute pleasure to work with the dedicated members of our board of directors and staff.

Please consider the important work we do and how you can support FMDA and our profession now.

Thank you for all you do for our long-term care patients in Florida.

Yours truly,

John H. Potomski Jr., DO, CMD

Call for Nominations to Serve FMDA

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 long-term care.

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, chair of the Nominations Committee (hwthomas2000@aol.com), or Ian Cordes, executive director, at (561) 659-5581 or ian.cordes@fmda.org.

FMDA Call for Poster Submissions

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

FMDA is hosting its sixth annual poster session during the Best Care Practices Conference, Oct. 30-31, 2009. The first 10 applicants who are accepted by the review committee will receive complimentary registration to the 2009 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 18th 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. 25, 2009. 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**.

2009 Poster Sessions

Buena Vista Palace Hotel,
Lake Buena Vista, Fla.

Schedule*

POSTER SET-UP

FRIDAY, Oct. 30, 11 a.m.–1 p.m.

POSTER VIEWING

FRIDAY, Oct. 30
1:15–2:15 p.m.; 4:30–6 p.m.

SATURDAY, Oct. 31
7–8 a.m., 10:45–11:15 a.m., 12:15–1 p.m.

POSTER TEAR-DOWN

SATURDAY, Oct. 31
1–3 p.m.

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

Combating Fungal Infections: A Case Study

Clinical Pearls

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

Fungal infections are more common today than ever before. There are a number of reasons for this. People are living longer, and older people are more likely than the young to have compromised immune systems, a major risk factor for fungal infections. Similarly, the widespread use of antibiotics has contributed to the growing infection rate.

The most common organism implicated in fungal infections is the ubiquitous Candida, which is found in the human mouth, digestive tract, and genital region. Under normal circumstances, levels of Candida are controlled by beneficial bacteria. However, if the bacteria-fungus balance is upset by the use of antibiotics, or if the immune system is compromised, an overgrowth of Candida can occur, resulting in infection.

This intervention proved to be quite effective in reducing the number and severity of the recurrent intertrigo infections.

Intertrigo, a skin fungal infection, is due to the overgrowth of Candida albicans. These yeasts do not normally live on the skin, so this is considered an infectious process. Intertrigo affects the health of the areas hidden by heavy skin folds. Heat and humidity, along with darkness, combine to create the perfect environment. Moisture builds under the skin folds, and the yeast flourishes, leading to symptoms such as redness, scaling and significant itching. The skin may develop open areas and/or small papules, and pustules. The delicate skin under the breasts is most prone to this type of infection. Other areas of the body that can become affected include the skin found in abdominal, thigh, and pubic folds.

This case study will focus on the treatment and, more importantly, the prevention of intertrigo. Mrs. B is a 95-year-old long-term care resident. Her diagnoses include diabetes mellitus, hypertension, stroke and dementia. She required total care for all her activities of daily living, and was incontinent of bowel and bladder. Her most recent HbA1c was 7.0, and she had significant seborrheic keratosis of her entire back, on her abdomen, and under her breasts.

The clinical challenge was her recurrent intertrigo beneath both her breasts on a monthly basis. The nursing staff would notify the practitioner when Mrs. B had redness under her breasts, and the staff would immediately start treating with nystatin cream and powder. The infections would be resolved, and attempts were made to keep the area as dry as possible. Despite interventions such as placing dry wash-cloths under the breasts and drying the area with a cool hairdryer, the infection would return within two weeks.

At times, the intertrigo had progressed to the point of needing oral fluconazole. The recurrence rate of the infection, the resident's discomfort level, the extensive nursing time, and the expense required development of a preventative measure. In order to identify the measure, the staff asked the basic question: What causes intertrigo in the first place? The answer: suppressed immune system, diabetes, and warm moist areas.

The resident's nutritional status was discussed with the dietician, who found her diet to be adequate and requiring no supplementation. Likewise, her albumin was 4.0. She was a frail elder with multiple chronic disease processes that were stable. Her diabetes was managed well, as evidenced by her HbA1c of 7.0. Numerous attempts to keep dry the area under her breasts failed.

The practitioner identified the need to decrease, if not stop perspiration under Mrs. B's breasts. She concluded the use of an antiperspirant had the potential to control the infections. After healing the most recent intertrigo, the staff was instructed to apply an aerosol antiperspirant under her breasts each morning. This intervention proved to be quite effective in reducing the number and severity of the recurrent intertrigo infections. Since the use of the anti-perspirant was initiated, the resident's quality of life has improved: only on the rare occasion does she have minor skin irritation under her breasts. This method was also found to be very useful in preventing intertrigo and Candida albicans infections in the abdominal folds of obese residents.

Brevard County Transitions of Care Task Force Meets

By Jo Ann Fisher, FNP-BC; Ex-officio Board Member, Florida Medical Directors Association

The Brevard County Transitions of Care Task Force meeting was held at Watersong Assisted Living Facility in Vierra, Fla., on April 21, 2009. It was attended by representatives from skilled nursing facilities, assisted living facilities, seven Brevard County hospitals, Circles of Care Mental Facility, EMS and non-emergency transport organizations, a long-term care pharmacy (LTC) representative, as well as representatives of the Brevard Commission on Aging. The purpose of this meeting was to initiate discussion of the multiple issues surrounding patient transitions in our county, as well as at the state and national level.

This event was organized by Jo Ann Fisher, ARNP, ex-officio board member of FMDA. She and John H. Potomski Jr., DO, CMD, president of FMDA, led the meeting.

There was a PowerPoint presentation followed by a lively open discussion during lunch. The group at large acknowledged that improvements were needed for patient safety, cost reductions across the LTC continuum, and for reductions in readmission rates.

There was an overwhelming agreement by the LTC facilities representatives to utilize a Facility-to-Emergency Department Transfer Form developed by Jo Ann Fisher, as soon as it is available in order to ensure that more complete and accurate information is sent with the patient. Dr. Potomski presented a discharge form with two pages, including a medication reconciliation sheet. All hospital representatives were asked to review it and consider the possibility of a countywide form that would facilitate improved communication between hospitals, transport organizations, and LTC facilities.

Volunteers were asked to contact Jo Ann in order to formulate a "core" workgroup, and many came forward that day. This was a very positive meeting, and all of those present were able to view patient transitions from a different perspective. Every attempt will be made to keep communications open across the continuum of care in Brevard County.

Prescription Drug Licensing Regulations Change

By Matthew Reese, BS; Education Coordinator, FMDA

There is a change in prescription drug licensing regulations for physicians purchasing prescription drugs and for entities that distribute drugs.

In 2008, the Florida Legislature passed HB 7049 as a critical rewrite of the Florida Drugs, Devices, and Cosmetics Act. As a result, a new license called the Health Care Clinic Establishment Permit will be issued by the Department of Health. The law mandates, that in order for a physician's practice to purchase prescription drugs after Jan. 1, 2009, the practice must hold a Health Care Clinic Establishment License. This permit is required only for the purchase of prescription drugs by a group practice in the business entity's name.

Only two types of business entities qualify for a permit. The first is a physician's practice that is formed as a professional corporation, and the second is a physician's practice that is formed as a professional limited liability corporation.

What to Do:

Each practice must designate a qualifying practitioner (one physician) who will be responsible for all legal and regulatory requirements related to the purchase and maintenance of prescription drugs. Individual practitioners may continue to purchase drugs under their own name and under their own license number. However, if there are multiple physicians at the same practice, each would have to purchase drugs under his or her own name and license number.

The application for the Health Care Clinic Establishment License is available and can be obtained from the Florida Department of Health.

For more information, visit the Florida Department of Health website, or call **(850) 245-4292**.

Nursing Homes Asked to be Taxed

By Lisa Jo Desmarteau, Senior VP of Finance, MorseLife

Christine Jordan Sexton opened her February 3, 2009 article in *Florida Health News* with "Florida's fiscal crisis recently spurred two groups to do the unthinkable: Nursing homes asked to be taxed, and the Republican-controlled Legislature agreed to do it."

As a member of the nursing home industry, I assure you that we "asked" to be taxed in about the same way that I "volunteered" to do a thankless task my boss assigned to me last week. But whether you say "tomato" or "tomatoe," I suppose technically we did "ask" to be taxed. Sometimes when faced with a decision, you just have to pick the lesser of the evils.

The issue of a provider tax has been mulled around for quite some time. We just hoped we wouldn't have to go there. In the 1990s, there was a nursing home tax that was paid by private-pay residents similar to a service or sales tax. That didn't last long after it was dubbed the "Granny tax." As one could imagine, it wasn't particularly popular with the aged constituents of Florida.

One of the key differences between the Granny tax of days past and the provider tax that we "asked" for this year is who pays the tax. Beginning April 1, 2009, nursing homes will pay the tax and are specifically prohibited by law from creating a separate line-item charge for the purpose of passing on the tax to our residents. It's not to say that some nursing home providers won't have to increase their rates to cover this tax. However, increases must be made to the per diem rate, rather than billed separately as a tax.

And for the record, I will stop using the word "tax" publicly, though it is likely that I won't be able to stop it from dancing around in my mind. I believe the proper terminology is a user fee, and it is called the Nursing Home Quality Assessment (NHQA).

While the nursing home industry didn't like the idea of the NHQA "fee," we really had no choice. Take a 10.5% cut in reimbursement OR support the legislative position of imposing a fee on nursing homes so the state of Florida could draw down federal funds to help with the Medicaid budget shortfall. It was made pretty clear to us. Our legislators weren't going down this road alone. Either the nursing home industry supported this new fee, or Senate Bill 8-A creating the NHQA would not pass — leaving the industry facing a 10.5% cut in reimbursement to care for the state's indigent elderly.

So here we are. On May 15, 2009, we made our first payment to the state for April 2009's assessment. The amount of the daily assessment was paid on all non-Medicare A resident days. In turn, these quality assessment fees remitted to the state, plus the federal matching funds, will be used exclusively for the following purposes and in the following order of priority per SB8-A:

- To reimburse the Medicaid share of the quality assessment as a pass-through Medicaid allowable cost;
- To restore the rate reductions implemented January 1, 2008 and January 1, 2009;
- To restore other rate reductions for FY 2008-2009 (March 1, 2009 rate cut); and
- To increase the Medicaid rate that accounts for the portion of the total assessment not used to restore rates.

When you read that part of SB-8A and other articles suggesting we taxed ourselves and made more money doing so, you could almost believe it, except that it isn't only Medicaid bed days that are taxed. Nursing homes must pay the assessment on all non-Medicare A bed days, meaning private-pay bed days as well. And while private-pay rates may have to be increased because of this assessment, the increase is likely to be much smaller than it would be if the NHQA had not been implemented, and private-pay residents had to help make up a 10.5% Medicaid cut.

Once all the numbers are known, and assuming the federal government approves a waiver of Medicaid rules for the state of Florida, it might in fact turn out that some nursing homes will receive more Medicaid money than they do now. But I am willing to bet our first month's NHQA "fee," that any Medicaid increase realized won't be nearly enough to cover our added cost of the NHQA fee assessed on private-pay resident days.

So in my book:

- We didn't exactly "ask" to be taxed;
- We definitely won't make money on the deal;
- We didn't like the idea of a NHQA fee; and
- It was the lesser of the evils.

FMDA Hosts Town Meeting in Tallahassee

By Hugh Thomas, DO, CMD; Vice President and Chairman, 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, Coral Gables, and Fort Lauderdale.

We hosted another memorable Town Meeting & Dinner on Jan. 30, 2009. This time, the location was our beautiful state capitol, Tallahassee. Earlier in the day, the CME/Education Committee and the board of directors met for regularly scheduled business meetings. Later, the Town Meeting dinner was generously sponsored by Abbott Laboratories and Jaynie Christenson, our host.

We were joined by AHCA Assistant Secretary Liz Dudek; Polly Weaver, chief of Bureau of Field Operations; and Molly McKinstry with the Nursing Home Unit of Florida's Agency for Health Care Administration (AHCA). Each shared some thoughts about future plans for the Agency. Physicians and nurse practitioners from all over the region attended as did representatives from Florida Health Care Association (FHCA), Florida Geriatrics Society (FGS), and Florida Association of Homes and Services for the Aging (FAHSA).

From left to right: Janegale Boyd (FAHSA), LuMarie Polivka-West (FHCA), AHCA's Asst. Sec. Elizabeth Dudek, FMDA President Dr. John Potomski, Polly Weaver and Molly McKinstry (AHCA)

FMDA Vice President Dr. Hugh Thomas, Dr. Alice Pomidor (FGS), FMDA President Dr. John Potomski, FGS Executive Director Margo Adams, and FMDA member Marci Praetorius, ARNP

From left: FMDA member Marci Praetorius, ARNP; Bill Phelan (FHCA); Tony Marshall (FHCA); and FMDA President Dr. John Potomski

FMDA Chairman Dr. Victor Gambone (from left); FMDA President Dr. John Potomski; Jo Ann Fisher, ARNP, Ex-officio FMDA Director; Dr. Michael Foley; Cheryl Foley, ARNP; Marcie Kutner and her son, Mitchell; and FMDA director Dr. Coy Irvin

Volunteers in Long-Term Care

By Nadine Greenberg, Director of Volunteer Services, MorseLife

Life in a nursing home, even the best of nursing homes, is often scary and lonely. According to the National Center for Health Statistics, more than half of residents have no close relatives, and 46 percent have no living children. These facts are a reason that an estimated 60 percent of nursing home residents never have visitors.

Human contact is critical for optimum health. A University of Maryland study of more than 1,400 "significant others" of nursing home residents found that the number of visits and calls declined by half after an individual entered a nursing home. That's where volunteers come in. They provide that extra touch, a warm voice and smile that can make life better for residents in a nursing home.

In addition to visiting with residents, volunteers can lead sing-a-longs and discussion groups. They can assist with arts and crafts projects and support staff with services that include clerical and computer work. The right volunteers can be involved with newsletters, surveys, reports, task forces, etc.

Almost everyone can be looked upon as a potential volunteer — even pets. Pet therapy provides residents the opportunity to express their affection and enjoy the sense of touch. With their unconditional love, pets give a sense of well-being and self-esteem for many residents. Caregivers report that residents who interact with pets often talk and smile more, are more active, and eat and sleep better.

Organizing a Volunteer Program

A volunteer program requires the same management that any other program would require. The first step in program planning and design is an assessment of why the agency wishes to use volunteers and what the benefits will be.

It is essential that the facility and staff have an appreciation that using volunteers will be worth the investment of resources requires to make it work. Effective operation requires a supportive working relationship between staff and volunteers.

There are six elements in a volunteer program:

1. Job Development & Design – Volunteers need clearly defined jobs and responsibilities. Begin by exploring opportunities with your social work and therapeutic recreation departments.

2. Recruitment – This can include distribution of fliers and brochures, speaker's bureau, notices in periodicals, and word of mouth. Target audiences may include clients, their families/relatives, friends of staff, religious and civic groups, neighboring developments, schools, online volunteer websites, etc. Be sure to emphasize the need to help the elderly in your community, not simply the need of your organization.

3. Screening & Interviewing – Volunteer applications must be created, along with any other forms such as PPD requirements, confidentiality forms, background checks, etc. Prepare a list of questions to discuss in the interview to determine who best suits your needs.

4. Orientation & Training – This involves giving volunteers a background on the facility and its procedures and policies. Orientation is required because the volunteer needs to be made a part of the organizational environment. Training will tell the volunteer how he or she is supposed to perform their job, what they are not supposed to do, and what to do if an emergency or unforeseen situation arises. Staff also must provide on-the-job training.

5. Supervision – Supervision of volunteers is no different from supervision of any other type of staff for an agency.

6. Recognition – Generally, there are two types of "awards" for volunteers – gifts and events. A gift can include certificates, pins, group photographs, T-shirts, small gifts, etc. Events include lunches and dinners, parties and celebrations, including a National Volunteer Week celebration. Rewards are the more intangible day-to-day activities of recognition and motivation. These include saying "thank you," giving respect and equal status to volunteers, involving them in staff meetings, maintaining a personal interest in them, spending time and effort in supervision, and increasing their responsibilities.

Essentially, approach the volunteer program as you would any other program. Plan carefully, work systematically, and the effort will bear success and you will achieve your goals. The service that volunteers perform will enhance the quality of life of your residents and provide invaluable assistance to staff.

Potomski Named 2008 Humanitarian of the Year

In October 2008, Dr. John Potomski Jr., DO, CMD, was awarded the distinguished Brevard County Conscious Living Partnership Humanitarian of the Year at its annual awards banquet.

Dr. Potomski was recognized for his 25 years of service to the elderly citizens of Brevard County as a geriatrics physician and medical director for Osler Medical in Melbourne. He also serves as the president for the Florida and Brevard County Medical Directors associations, and as chair of the Brevard Commission on Aging; and he travels to Tallahassee during the Legislative Session to advocate for elder rights, programs and services.

Shannon Burnett, president and CEO of Conscious Living Partnership, with Dr. John Potomski

The Conscious Living Partnership is an organization that supports people and organizations in making a positive impact on ourselves, our children, and our local communities. The partnership seeks to create an infrastructure that connects individuals, business, and organizations so everyone succeeds in gaining the prosperity and purpose they desire.

Its mission is: To unite conscious living businesses, individuals and community organizations; to become a global network of resources, partners and community builders; to serve as a voice and catalyst for creating abundance, health, and improved quality of life for ourselves, our community, and our world.

Congratulations, Dr. Potomski.

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.

Bone Loss in Chronic Kidney Disease: Understanding the Problem

By Rick Foley, PharmD, CPh, CGP, FASCP; Consultant Pharmacist - Omnicare Central Florida;
Assistant Clinical Professor, University of Florida College of Pharmacy

Calcium, phosphorous, parathyroid hormone (PTH), and vitamin D3 (Calcitriol) play a significant role in bone metabolism and disease in patients with chronic kidney disease (CKD).

Approximately 80% of phosphorus is cleared by the kidneys. Inadequate phosphorus clearance leads to hyperphosphatemia, which leads to secondary hyperparathyroidism (SHPT).

Inadequate phosphorus clearance leads to hyperphosphatemia, which leads to secondary hyperparathyroidism.

Parathyroid hyperplasia should be considered clinically relevant at CKD stage 3 (GFR 30-59) and a near certainty past stage 4 (GFR < 30). The prevalence of SHPT in CKD stage 3 is 40%. Approximately 75% of Stage 4 patients have elevated PTH, although abnormal levels of calcium and phosphate are generally not seen until eGFR drops below 30. Therefore, calcium and phosphate appear to be poor markers for diagnosing elevated PTH[2].

Parathyroid hyperplasia leads to increased parathyroid hormone (PTH). In CKD stage 3, the patient may have normal phosphorus levels, but again, this is because of the increased action of PTH. Progression of CKD leads to decreased vitamin D receptors and calcium-sensing receptors in the parathyroid, making them more resistant to vitamin D and calcium.[3]

This eventual development of hyperphosphatemia and subsequent elevated PTH reduces the conversion of vitamin D to its active form, Calcitriol (vitamin D3) and decreases ionized calcium. The patient with a deficiency of Calcitriol has reduced absorption of

Continued on the next page

Treatment Summary[1]

	CKD Stage 3 GFR 30-60 mL/min/1.73 m^2	CKD Stage 4 GFR 15-29 mL/min/1.73 m^2
Calcium		
Evaluation	At least every 12 months	At least every 3 months
Daily intake (including from P binders)	Should not be >2000mg	Should not be >2000mg
Target (corrected)	Within normal limits of lab	Within normal limits of lab
Ca x P Product	<55 mg^2/dl^2	<55 mg^2/dl^2
Phosphorus		
Evaluation	At least every 12 months	At least every 3 months
Daily intake (adjusted to protein intake)	800-1000 mg	800-1000 mg
Target (corrected)	2.7-4.6 mg/dl	2.7-4.6 mg/dl
Phosphate binders		
Initiate when P or PTH > target for CKD stage	Ca binder	Ca binder
PTH		
Evaluation	At least every 12 months	At least every 3 months
Estimated Target	35-70 pg/mL (opinion)	70-110 pg/mL (opinion)
Vitamin D Prevention and Treatment of Deficiency in CKD Stages 3 and		
Supplement with Vitamin D_2 (ergocalciferol) if:		
Severe deficiency: 25(OH)D <5 ng/mL	Oral: 50,000 IU/wk x 12 wks, then monthly x 6 months or a single IM dose of 50,000 IU/month x 6 months. Measure 25(OH)D after 6 months	
Mild deficiency: 25(OH)D 5-15 ng/mL	Oral: 50,000 IU/wk x 4 wks, then monthly x 6 months. Measure 25(OH)D after 6 months	
Insufficiency: 25(OH)D 16-30 ng/mL	Oral: 50,000 IU monthly x 6 months. Measure 25(OH)D after 6 months	
Monitor Ca, P every 3 months. If P >4.6 mg/dL, add or increase binder. Discontinue ergocalciferol if Ca >10.2 mg/dL or hyperphosphatemia persists. Once depleted with vitamin D, supplement with a vitamin D-containing vitamin and assess annually		
Active Vitamin D Therapy in CKD Stages 3 and 4		
Initiate when 25(OH)D >30 pg/mL, and PTH > target, Ca <9.5 mg/dL and P <4.6 mg/dL in compliant patient with stable kidney function		
Initial oral dose: Calcitriol 0.25 µg, Alfacalcidol 0.25-0.5 µg, Doxercalciferol 2.5 µg		
Monitor Ca, P monthly for the 1st 3 months and then every 3 months. Measure PTH every 3 months for 6 months and then every 3 months		
Hold vitamin D if PTH < target, resume at half dose or alternate day dosing when level is > target		
Hold vitamin D if Ca > 9.5 mg/dL or P>4.6 mg/dL. Resume previous dose when levels are within target		

Dr. John Potomski Honored at Luncheon

In celebration of Older Americans Month, a luncheon was held on May 27 in Melbourne, to honor John H. Potomski Jr., DO, CMD, for being "A Pioneer in Long-Term Care for 25 Years." Dr. Potomski is president of FMDA and chair of the Brevard County Commission on Aging. The master of ceremonies for the event was Tammy Harris, lead human services planner with the Brevard County Housing & Human Services Department, and was generously sponsored by Novartis Pharmaceuticals.

During the luncheon, presentations were made by Trudie Infantini, Brevard County commissioner on behalf of Commissioner Mary Bolin; Heidar Heshmati, MD, MPH, PhD, president of the Brevard County Medical Society; Virginia Wood, sales and marketing manager, Brookdale Living Communities, Clare Bridge Memory Care, Southland Suites and Sterling House I & II; Cindy Flachmeier, CEO, Community Services Council of Brevard; FMDA Executive Director Ian Cordes; Roberta Vandusen, executive director, Hospice of Health First; staff from Life Care Center of Melbourne; Rebecca Schachter, administrator, and the staff at Melbourne Terrace Rehabilitation Center; Jo Ann Fisher, ARNP, Osler Medical; Fire Chief Daniel H. Rocque, Satellite Beach Fire Rescue; Judy Powers, RN, BSN, interim executive director, Wuesthoff Hospice & Palliative Care; Gay N. Williams, director, Brevard County Housing and Human Services Department; and Ron Morgan, Brevard County Commission on Aging.

The administrator, regional vice president, and facility staff with Life Care Center of Melbourne, present Dr. Potomski with an award in honor of his dedicated service.

FMDA Executive Director Ian Cordes (right) presents Dr. Potomski with a framed congratulatory letter from AMDA Executive Director Lorraine Tarnove.

dietary calcium in the intestine. There is an increased resistance to the calcemic action of PTH with concurrent hypocalcemia. In patients with SHPT, calcium is removed from bone in an attempt to correct the percentage of free calcium in the blood stream. This resorption is known as osteitis fibrosa. These patients are now at higher risk for fractures and bone deformities, tendon ruptures, myalgias, and myopathies. [1]

Treating your patient

The evaluation of the CKD patient has traditionally revolved around the predictable anemia associated with the failing kidney. Awareness of the secondary maladies is essential to completely address the underlying disease process. Before the patient is referred to a nephrologist, there are clear guidelines that can be followed as a primary care practitioner. There is an excellent patient care plan tool at **www.kidney.org/professionals/kdoqi/cap/index.html** that allows you to enter specific information to help guide your treatment plan.

The evidence-based clinical practice guidelines developed by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative K/DOQI were designed to provide information and assist with decision-making.

References : [1] K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. *Am J Kidney Dis* 2003. Vol 42 (4): Supplement 3.
[2] Prevalence of abnormal serum vitamin D, PTH, calcium, and phosphorus in patients with chronic kidney disease: Results of the Study to Evaluate Early Kidney Disease, Levin A, Bakris GL, Molitch M, et al. *Kidney Int.* 2007;71:31-38.
[3] *American Journal of Kidney Diseases*, Vol 42, No 4, Suppl 3 (Oct 2003): pp S29-S44.

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,

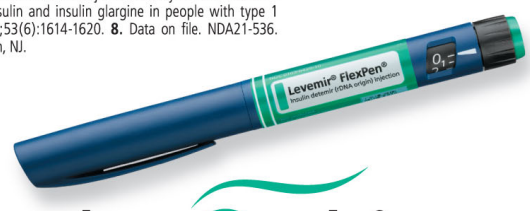
start once-daily Levemir®

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.



Levemir®

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.

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Invitational Leadership Meeting

By Jo Ann Fisher, FNP-BC; Ex-officio Board Member, Florida Medical Directors Association

I was fortunate to be asked to attend, on behalf of GAPNA, the AANP Region 11 Invitational Leadership Meeting, which was held at the Crowne Plaza Orlando Airport in Orlando on Feb. 7, 2009. The meeting was attended by leaders from AANP, state boards of nursing, universities with NP/DNP programs, regional fellows, retail providers and other groups/organizations from Alabama, Mississippi, Georgia and Florida. Cindy Cooke, Region 11 director, welcomed all in attendance and asked that we briefly introduce ourselves to the group. Cindy also gave a brief explanation about to the selection process for attendees.

Dr. Jan Towers, director of health policy, AANP, updated the group on matters of national and state legislative and practice issues. Time was allowed for discussion/questions, and multiple handouts were supplied to the attendees. Specific areas of discussion were health care reform, state regulatory and prescriptive authority, appropriations for nurse practitioner educational programs and traineeships, Medicare reimbursement issues, and the medical home. Dr. Towers is a strong advocate for our profession and very experienced as to the workings of the legislative process. She did state that there is a concern now that the secretary of HHS is unknown and we do not know whether the new selectee will be "a friend to NPs." Also, no one knows whether President Obama will have an interest in nurse practitioner issues.

The IT stimulus package is stalled due to other priorities, and we are included in Medicaid, but not the Medicare package. All of this has to do with funding. In Jan's words, "We are on the front burner, and getting Medicaid dollars is a better option for us at present." Appropriations for nursing may improve under this administration, and the APN grant process was discussed. There is a strong effort to have NPs recognized in all legislation as primary care providers.

The state AANP leaders reported on current issues in their states. There was a focus on "what was and was not working," with good discussion by all in attendance. There was a concern that for every step forward for nurse practitioners, or effort for change, there was frequently an effort by the state medical associations to block the change and/or take away something that was already in place.

The doctorate of nursing practice degree was also discussed, and many of the university representatives stated that they already did or were soon to have these programs. *The Wall Street Journal* article about Columbia University's decision to use the third-year medical students' exam for the DNP graduate was decided by all to be a very poor decision, as it could be another source for conflict with physicians.

This was a very educational experience. Go to FNA or Florida Nurse Practitioner Network websites for updates on the efforts in Florida to advance our state regulatory and prescriptive authority. I personally feel that the best thing we can do to advance our authority in Florida is to continue safe and ethical practice standards of care, and to develop and maintain good relationships with our physician colleagues.

See below for contact information if you are interested in becoming involved with either the American Academy of Nurse Practitioners or GAPNA.

American Academy of Nurse Practitioners (AANP)
PO Box 12846, Austin, Texas 78711
Phone: 512-442-4262 Fax: 512-442-6469
admin@aanp.org; www.aanp.org

Gerontological Advanced Practice Nurse Association (GAPNA), formerly known as the **National Conference of Gerontological Nurse Practitioners** (NCGNP)
7794 Grow Drive, Pensacola, FL 32514
Toll Free: 866-355-1392 Phone: 850-471-7075
Fax: 850-484-8762
gapna@dancyamc.com; www.gapna.org

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New Drug Update: Savella to Treat Fibromyalgia

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

Savella (milnacipran HCl), a selective serotonin and norepinephrine dual reuptake inhibitor, was recently approved by the U.S. Food & Drug Administration (FDA) for the management of fibromyalgia.

Fibromyalgia is a chronic condition characterized by widespread pain and decreased physical function, afflicting as many as six million people in the United States. It is common knowledge that 90% of those diagnosed with fibromyalgia are women. It is also pretty well known that most victims of fibromyalgia are diagnosed between the ages of 20 and 50. However, recent studies show there is a change occurring in these numbers. Many more are being diagnosed after the age of 50, and the numbers continue to rise. Compared to patients under the age of 60, seniors with fibromyalgia syndrome experience unique symptoms. While younger fibromyalgia patients cite pain as the most severe of their fibromyalgia symptoms, seniors are most affected by fatigue, soft-tissue swelling, as well as fibromyalgia-related depression. In addition, while participants over the age of 60 experience similar symptoms of fibromyalgia as participants under the age of 60, the former group are more likely to complain of headaches, anxiety, tension and symptoms aggravated by external factors, such as physical activity.

Fibromyalgia is a complicated chronic pain condition, and it is important that physicians caring for geriatric patients have access to drug therapy that has been shown to help manage the symptoms of fibromyalgia, according to Dr. Daniel Clauw, Professor of Anesthesiology and Medicine (Rheumatology) at the University of Michigan. Savella is important because it is the first drug approved to treat the symptoms of fibromyalgia using a composite responder analysis.

According to Jay D. Kranzler, MD, PhD, chairman and CEO of Cypress Bioscience, Savella is the product of a unique clinical development program, one that considered a patient to be a responder to therapy only if it was demonstrated that there were concurrent clinically significant changes in multiple aspects of the subject's fibromyalgia, including pain, patient global assessment and physical function. Savella is the only product approved for the management of fibromyalgia and using this complete responder analysis as its primary endpoint.

Although the exact mechanism by which Savella improves the symptoms of fibromyalgia is unknown, some researchers believe that abnormalities in certain brain neurotransmitters may be central to fibromyalgia. Savella blocks the reuptake of both norepinephrine and serotonin, with greater selectivity for the inhibition of norepinephrine reuptake in vitro. This may be the mechanism by which Savella acts to improve the symptoms of fibromyalgia.

Forest Laboratories and Cypress Bioscience's Savella (milnacipran hydrochloride), a selective serotonin and norepinephrine dual reuptake inhibitor, is a safe and effective treatment for the management of multiple symptoms of fibromyalgia, according to study results published in the Feb. 1, 2009, issue of *The Journal of Rheumatology*.

The safety and efficacy of Savella was established in two pivotal Phase-III U.S. clinical trials involving more than 2,000 fibromyalgia patients. The studies showed that Savella doses of 100 mg/day and 200 mg/day demonstrated statistically significant and clinically meaningful concurrent improvements in pain, patient global assessment, and physical function.

The 27-week, double-blind, Phase-III trial included 888 fibromyalgia patients who were randomized to receive Savella 100 mg/day (n=224), Savella 200 mg/d (n=441) or placebo (n=223). Researchers evaluated the patients' response to treatment at weeks 15 and 27.

The participants were characterized as fibromyalgia pain responders if they met response criteria for improvements in pain ratings and patient-rated Global Impression of Change scale scores. The participants were characterized as fibromyalgia responders if they met both of these response criteria as well as response criteria for improvement in the Short Form-36 Physical Component Summary score.

At 15 weeks, a significantly higher proportion of the patients in the Savella groups fit the criteria of fibromyalgia responders versus the patients in the placebo group. The percentage of patients classified as fibromyalgia pain responders was significantly higher in the higher-dose Savella group than in the placebo group. In addition, a greater percentage of the Savella-treated patients met the criteria of fibromyalgia pain responders and fibromyalgia responders relative to the placebo-treated patients at 27 weeks. Again, the percentage of patients classified as fibromyalgia pain responders was significantly higher in the Savella 200 mg/d group than in the placebo group. In both Savella groups, significant pain reductions as compared with placebo were seen as early as week one. Significant improvements in pain, fatigue and cognition were seen in the 200 mg group relative to the placebo group at 15 and 27 weeks.

The drug was well-tolerated by the majority of the patients. The percentage of patients who dropped out of the trial early due to adverse events was 27 percent, 19.6 percent and 10.3 percent in the 200 mg, 100 mg and placebo groups, respectively.

The authors concluded that these results are consistent with a growing body of knowledge that the multiple symptoms of fibromyalgia, including pain, fatigue and physical functioning, can be addressed through simultaneous augmentation of norepinephrine and serotonin function.

Sources:
www.savella.com
The Journal of Rheumatology, *Healthcare Business Daily*, *Medical News Today*, National Fibromyalgia Association

Florida On the Move During AMDA's March 2009 Annual Symposium

AMDA President Dr. David Brechtelsbauer (center) presents a plaque to Florida Chapter President Dr. John Potomski (right), and Ian Cordes, executive director, in recognition of FMDA's support of emerging AMDA chapters.

AMDA Foundation Chair Dr. Jonathan Musher (left) accepts a FMDA donation from Florida Chapter President Dr. John Potomski.

FMDA member Dr. Robert Kaplan addresses the FMDA board of directors at its meeting during the AMDA Symposium in Charlotte.

Chairman of AMDA's House of Delegates, Dr. Leonard R. Hock Jr., a Florida chapter member, makes a few remarks during the Florida Chapter reception.

American Association for Long Term Care Nursing Joins FMDA, FL-ASCP, ACHCA, and FGS to Collaborate on Best Care Practices Conference

Florida Medical Directors Association (FMDA) President John Potomski Jr., DO, CMD, is pleased to announce that the American Association for Long Term Care Nursing (AALTCN) has agreed to join the Florida Chapter of the American Society of Consultant Pharmacists (FL-ASCP), American College of Health Care Administrators (ACHCA), Florida Geriatrics Society (FGS), and FMDA in collaborating on "Best Care Practices in the Geriatrics Continuum" (BCP), Oct. 29-Nov. 1, 2009, at the Buena Vista Palace Hotel in Lake Buena Vista.

AALTCN unites all levels of nursing staff to advance excellence in the specialty of long-term care nursing. The association encourages respect for long-term care nursing staff by informing colleagues and consumers about the complexities, competencies, and commitment of the special caregivers who commit to this specialty. As the nation's largest network of caregivers, the mission of the American Association for Long Term Care Nursing is to create community and teamwork, provide educational resources, support and promote excellence in care, and advocate for an improved status and voice for long-term care nursing staff.

"We are very pleased that the American Association for Long Term Care Nursing has decided to join us in our efforts to educate long-term care nurses alongside physicians, pharmacists, nurse practitioners, and administrators all along the continuum of long-term care," said Potomski. "Our annual meeting has earned a national reputation for offering quality education programs with some of the most dynamic national speakers available."

"AALTCN is very excited about joining forces with the team of exceptional organizations from the Best Care Practices conference," said Charlotte Eliopoulos, executive director of AALTCN. "Our organization is unique, in that membership covers an entire nursing department, rather than an individual discipline. And, we are pleased to be able to give our members an opportunity to attend a major LTC and geriatrics conference with a national reputation."

AALTCN Director of Professional Relations Ron Romano stated, "Collaborating with our friends from BCP allows us to better fulfill our mission, and we look forward to seeing a large contingent of our members in attendance in October."

FMDA, FL-ASCP, ACHCA, FGS, and AALTCN are committed to ensuring that their members have access to the latest information, opportunities for educational advancement, and the framework to advocate the positions that will benefit their members and patients/residents. This annual educational program has evolved into a national gathering for physicians, nurse practitioners, senior care pharmacists, directors of nursing, nurses, and administrators, all working in long-term care, assisted living, home care, and in academia. It provides a unique opportunity to network and enjoy educational seminars from the top experts in their fields. More information concerning this conference is available at www.bestcarepractices.org.

Control of MRSA in Long-Term Care Facilities
Continued from page 1

aerosolized transmission by coughing in patients with pneumonia is unknown.

Infection Control: Standard and Contact Precautions

To date, there are no published studies on infection control of MRSA in LTC facilities. MRSA has a high prevalence in LTC facilities, as many of their residents are at high risk for colonization and development of infections. Risk factors associated the MRSA infection or colonization include previous long hospital stays; history of antibiotic treatment; presence of chronic open wounds; and presence of invasive devices such as gastrostomy tubes, indwelling Foley catheters, and vascular access lines.

The current recommendations, based on a Cochrane (comprehensive research) review, advise standard infection-control policies. There is considerable debate about the usefulness of screening for colonization of MRSA, because there is no evidence that treating colonization reduces the risk of infection. Applying hospital-based practices in nursing homes may not be appropriate, as these facilities serve as long-term residential as well as treatment centers. In view of the lack of evidence to support the control of MRSA in nursing homes, general infection-control policies promoting hygiene are being recommended. Standard precautions and contact precautions include hand washing, gloves, masks, and eye protection or face shields when splashing liquid is involved. Gowns must be worn when soiling of the health care worker's clothes is possible during care such as bathing. Contact precautions must be used when a resident is colonized or infected with MRSA in any site other than the nostrils.

The CDC recommendations on MRSA for non-hospital settings include:

Patient Placement:

A) Place the patient in a private room.
B) When a private room is not available, place the patient in a room with a patient who is colonized or infected with the same organism, but does not have any other infection.
C) Third option is to place an infected patient with a patient who does not have risk factors for infection.

Group Activities:

A) Maintain the patients' ability to socialize and have access to rehabilitation opportunities.
B) Infected or colonized patients should be permitted to participate in group meals and activities if draining wounds are covered, bodily fluids are contained, and the patients observe good hygienic practices.
C) It is very unlikely for visitors to become infected with MRSA, but they should wash hands before leaving the room.

The increased prevalence of MRSA in extended-care facilities due to high numbers of at-risk patients requires posted protocols and adequate communication of MRSA status, especially on transfers.

The Maryland and Louisiana departments of health guidelines on MRSA control in LTC facilities recommend:

A) A resident with nasal colonization of MRSA does not need to wear a mask outside of the room and may attend all activities.
B) If the resident has a "cold" with significant nasal discharge, the person does not need a mask if he/she can control secretions and cover the nose and mouth when coughing and sneezing.
C) It is preferable that patients colonized with MRSA in the nares be placed in a private room, even if they do not need to be on contact precautions.
D) Special emphasis should be placed on hand washing. Nursing staff should promote hand washing especially if the individual is cognitively impaired.

Termination of Precautions

A resident can be labeled MRSA-free if two cultures of the colonized or infected site are negative. The first culture should be taken 72 hours from the start of antibiotics, and the second culture taken a week after the

first culture. Cultures should be continued on a weekly basis until two consecutive cultures from the site are negative. When two consecutive negative cultures have been obtained, contact precautions may be discontinued, and standard precautions should be followed for the resident.

Long-term care facilities should have some system, such as labeling the chart or the door of the room, for alerting health care providers and visitors that a resident is on contact precautions without compromising that resident's privacy. LTC facilities that transfer a resident who is colonized or infected with MRSA should inform the recipient hospital or nursing facility. Hospitals and other nursing facilities that transfer a MRSA-colonized or infected resident to a LTC facility should inform that facility of the patient's status. A MRSA patient who is transferring from a hospital or other nursing facility to a LTC facility does not require two negative MRSA cultures before the transfer can occur. Negative cultures serve as criteria only for discontinuing contact precautions.

Conclusion

MRSA has attained significant media attention and warrants careful attention by health care providers in LTC facilities. There is little to no research available to identify strategies for managing patients with MRSA in extended-care facilities. This lack of research evidence has resulted in enforcement of hospital-based practices in out-of-hospital settings, with a negative bearing on some patients' progress due to prolonged isolation. The increased prevalence of MRSA in extended-care facilities due to high numbers of at-risk patients requires posted protocols and adequate communication of MRSA status, especially on transfers. This article emphasizes the lack of knowledge in this area of handling MRSA infections and emphasizes that standard precautions and contact isolation should be followed while dealing with MRSA.

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Nominations for FMDA office now being accepted!

FMDA's *Progress Report* ***Spring 2009***

Ninth Annual IAB Meeting Held in Tampa

IAB Chair Dr. Malcolm Fraser and Co-chair Wayne Morrow with Novartis, with participants (from left) Greg Fort with Sanofi-Aventis; Dr. Dennis Stone, Chief Medical Officer for Signature Health Care; and Immediate Past IAB Co-chair Al Henry with Watson Pharma.

More than 32 industry professionals attended FMDA's 9th Annual Industry Advisory Board meeting on Feb. 10, 2009, at the Marriott Tampa Airport.