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***Ward Scholarship** (from left): Bonnie Cruz, Alicia Davis (DON), Wade Thomas, scholarship winner Manda Thomas, LPN, with Homer, Jeff and Mike Ward*

***Certificate of Recognition** (from left): Administrator Jennifer Mikula and award recipient Tina Vanaman, both from Palm Garden of Ocala; Sharon Michota, Clinical Services Manager for Evercare (sponsor), and FADONA President Bonnie Cruz*

***2009 Director of Nursing Administrator of the Year Award** (from left): Susan Mutua-Brown, RN at Health Central Park; Sharon Michota, Clinical Services Manager for Evercare (sponsor); FADONA President Bonnie Cruz; Award Winner Reuben Bowie, DON at Health Central Park; Lori Jowett, administrator at Health Central Park; Marlene Blye; and Deb Strickland, ADON at Health Central Park*

***Certificate of Recognition:** Award recipient Hope Caldwell, DON at Largo Rehabilitation Center (holding certificate); with members of her nursing team, and Scott Elsass, her facility's executive director*

***CNA Awards:** Second-place CNA award winner Casseta Findlay from Villa Maria Nursing Center in Miami*

***CNA Awards** (from left): Bonnie Cruz (right) presents 1st-place award to Corrie Lovelady from Avante of Mount Dora. She is pictured alongside her administrator Angie Dimura, DON Anne Lenington, and her husband, Abraham Rodriguez.*

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Message from the President

It was the board's pleasure, seeing everyone at the 2009 FADONA Convention in Orlando. Your feedback and suggestions for future convention planning were very well received. We appreciate hearing from you along the way, as this helps the board serve the membership. We are excited to let you know that once again the 2010 convention shall be hosted at the Buena Vista Palace Hotel in Orlando in April 2010. We have a new convention room rate of $140 per night — so please save the date.

Bonnie Cruz

What is next? The FADONA board is working and planning its regional symposiums around the state. These one-day educational venues offer facility nurse managers and administrators an opportunity to learn and collaborate on best practices while earning CEs. Last year, these seminars were a huge success. Our goal is to offer these symposiums in the Panhandle, Central, and South Florida areas during September and October 2009. The Board participants have previewed an exciting lineup of speakers and agendas in the pre-planning stages. Again, be on the lookout for more information regarding these regional symposiums.

I would also like to take this opportunity to thank you for allowing my term as president to continue for two more years. This has and continues to be an amazing experience, working with such a prestigious board and a wonderful staff. We are also working with dedicated and committed vendors who are there to offer their services and support. Finally, the teamwork and networking with FADONA members has been enlightening and gratifying.

Over the next two years, I would like to continue this plan of growing FADONA into a stronger and unified group of nurses who have a voice and strive for quality in long-term care. United, we are making a difference in many residents' lives. Thank you again for your support.

FADONA is working in collaboration with the Agency for Health Care Administration on a hospital transfer form. Long-term care facilities and hospitals have said that pertinent resident transfer information is missing on admissions to the facilities.

The goal in piloting a universal transfer form shall be to capture valuable data for the residents'/patients' continued quality of care. This transfer form was designed by a committee of LTC and hospital staff under the direction of AHCA and is being piloted in South Florida. The next step shall be to broaden the sample used and have FADONA pilot the transfer form and offer feedback to AHCA. FADONA is excited to be a part of this process.

The most recent FADONA board meeting was Aug. 7, 2009. Our meeting agenda was packed as we reviewed possible topics and proposed speakers for the 2010 Annual Convention. This starts another season of collaboration and educational planning to bring you the up-to-date information and tools you need to be the best you can be. Keep up the hard work and stay the course as you move through the next hurdle of challenges, which includes 2.9 CNA staffing requirements.

Sincerely and at your service,

Bonnie Cruz

Bonnie Cruz, RN, BSN, MEd
President

Regional Reports

Regional REPORTS


Sharyn Figgins

REGION I

Region I—Northwest
1A—Bay, Escambia, Holmes, Okaloosa, Santa Rosa, Walton, Washington; 1B—Jefferson, Madison, Calhoun, Leon, Taylor, Franklin, Gadsden, Gulf, Jackson, Liberty, Wakulla

As the new regional coordinator, I would like to thank you for supporting me in this position. If you have ideas for improvement, have questions, or would like to volunteer to help, just let me know. Otherwise come to the meetings and enjoy.

The Pensacola Chapter meets the third Wednesday of the month at noon for education, networking and a good meal. The meetings rotate locations among local facilities with a few months at a restaurant for variety. The DONs can show off their facilities; attendees get a tour and new ideas. Everyone has been open and willing to share what works at their facility, which is GREAT!

Recent topics have included legislative issues and managing and documenting pain. The July meeting, held at McGuire's Restaurant, was on wound care. Attendees were encouraged to discuss their difficult wound care issues. The August topic is "culture change;" the meeting will be at Baptist Medical Center. In September, we will be at Bayside Manor for "Caregiver Boundaries" with a CEU provided by Covenant Hospice. If you would like a schedule or more information, call or e-mail me.

The Fort Walton Beach Chapter meetings are held monthly with excellent support from Sucampo and Ortho Biotech. This chapter has strong participation and meets the second Friday of the month at 12:30. The sites are rotated monthly; the next meeting is at the local hospice office in Niceville. Contact **Bonnie Cruz** at Manor at Blue Water Bay in Niceville at **(850) 897-5592** for more information.

There is interest in starting a chapter in the Tallahassee area. Please e-mail or call me if you are interested in helping establish a chapter.

I am the director of nursing at Rosewood Manor in Pensacola and can be reached at **(850) 435-8400.**
Sharyn Figgins, RN, MSN
Region I Coordinator


Tina Vanaman

REGION II

Region II—Northeast
2A—Hamilton, Lafayette, Alachua, Marion, Clay, Nassau, Suwannee; 2B—Dixie, Union, Putnam, Baker, St. Johns, Columbia, Gilchrist; 2C—Levy, Bradford, Duval, Flagler

Hello! My name is **Tina Vanaman**, and I was recently appointed by our FADONA president **Bonnie Cruz** to lead Region II. I am very excited about this opportunity and want to encourage all RNs to get involved. I recently had our first meeting in this region in over a year, and only one person attended.

So, I have set my goal low right now, and my goal is to get one extra person involved at every meeting. I have vendors willing to offer CE credits and

sponsorship. If you would be interested in attending a meeting, or being the host in your area for a meeting, please contact me and I will be glad to help get this scheduled. Region II is very large in square mileage, and I cannot do this alone. I am reaching out to each of you to help me make Region II successful in promoting and improving our profession.

You can reach me at Palm Garden of Ocala, **(352) 854-6262**; my cell is **(352) 553-7475**; or my e-mail address is **tinavanaman@aol.com**.

Thanks in advance for your support and assistance.

Tina Vanaman, RN
Region II Coordinator

Region III—Centraleast
3A—Lake, Osceola, Orange, Seminole
3B—Volusia, Hardee

Active membership continues to grow as everyone looks forward to the meetings, which allows for exchange of ideas and experiences and the making of new relationships. The June meeting was held at The Crown Plaza Universal; the topic was COPD; and our speaker was **Dr. O'Brian**, sponsored by Boehringer Ingelheim. We look forward to participation from Volusia county. Please tell us what it would take to get you involved. FADONA members have a wealth of information, and we enjoy sharing it.

I can be reached via the FADONA office and or my e-mail at **normac1212@aol.com**.

Norma D. Collins, RN, BS, LHRM
Region III Coordinator

Region IV—Centralwest
4A—Hillsborough, Pinellas, Highlands, Polk
4B—Hernando, Sumter, Citrus, Pasco

Region IV's Annual Seminar is on schedule for Sept. 16 at Embassy Suites near USF. Mark your calendars, because we have some great speakers lined up. One of them is **Sheila Nicholson**, an attorney with Quintairos, Prieto, Wood & Boyer. She is a dynamic speaker, and you do not want to miss her.

FADONA in Hillsborough County is growing. Our June meeting was last Tuesday at Mimi's Café, and the room was full. We are enjoying vendor support at every meeting.

Regional REPORTS

Any questions about Hillsborough County may be directed to **Mariann Calta** at **(813) 329-6061**.

Pinellas County FADONA has its regular meetings the second Tuesday, 5:30 p.m. at Banquet Masters. Any questions about Pinellas County may be directed to **Liz Raymond** at **nurse_raymond@yahoo.com**.

Polk, Hardee, and Highlands counties are having meetings quarterly. Please contact **Sandy Kenyon** at **(863) 422-8656** or **(863) 632-6367** if you have questions or want to volunteer to help.

If you have any questions, suggestions, or just want to chat, feel free to call me at **(813) 960-1969**. My cell is **(813) 503-2810**, and my fax is **(813) 960-8510**. My e-mail addresses are **crusso@filtc.com** or **tyler48m@aol.com**.

Carla Russo, RN, CDONA/LTC
Region IV Coordinator

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Regional Reports

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Regional REPORTS

Cherryl Chmielewski

REGION V

Region V—Southwest
***5A**—Manatee, Charlotte, Collier*
***5B**—Desoto, Lee, Sarasota*

Region V needs your help. If you wish to become involved or are interested in serving on any committees, please contact Cherryl at **cchmielewski@greystonehcm.com**, or **(813) 635-9500**.

Cherrl A. Chmielewski, RN
Region V Coordinator

Nancy Henderson

REGION IV

Region VI—Southeast
***6A**—Dade, Monroe, Broward, Palm Beach*
***6B**—Brevard, Indian River, St. Lucie, Martin, Okeechobee; **6C**—Hendry, Glades*

Summer in South Florida. . . can't beat it! Time to enjoy the surf and sand. But we can't forget that health care and its challenges go on. Nursing administrative staff in long-term care must continue to promote the environment in which we work and address the challenges that face us daily.

The DONs in South Florida rallied together and planned a meeting on July 1. I understand there was a strong force of more than 60 leaders from long-term care. By the time this is published, these strong forces will have already come together to share thoughts, ideas, and concerns.

They must be an example to us all. Every area of Region VI can use more of these dynamic people to champion a group of DONs in their area. Though there is time, effort, and energy involved, the results are support for all. Who better to understand our day-to-day challenges than those of us who experience it daily?

We are all in this environment of health care because it is a calling, certainly not for the financial reward. Please, consider coordinating a local group meeting. There are a lot of resources available to sponsor the food, help with notifications, etc.

Please call if there are any support, help, questions, or information needed to urge you toward this valiant goal.

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Here is the following local chapter contact information:

1. ***Indian River County*** — We invite you to attend our next meeting by calling **Nancy Henderson** for details. She is the local contact, and she can be reached at **(772) 288-0060**.
2. ***Palm Beach County*** — **Deborah Grotke** at **(561) 588-4333**.

The Palm Beach County DON Association continues to meet monthly on the third Wednesday.

We have an active, growing group of members and associate members. Lunch and CEs are usually provided with support from our vendors. These meetings allow us to network and share valuable information with our fellow nursing administrators and associates. This in turn helps increase the quality of care that our facilities can provide to our residents and supports our efforts to be survey-ready.

We do need your help to re-energize Region VI. If you are interested in helping out, or know someone you think would be a great asset, please contact **Nancy Henderson** at **(772) 341-9261**, or e-mail: **nursenancyh@comcast.net**.

Nancy Henderson, RNC/CDONA
Region VI Coordinator

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★ ***"Managing Pain Effectively for LTC Patients"*** ★
This program was supported by educational grants from **Endo Pharmaceuticals & Purdue Pharma, LP.**

★ ***"It's More than Care – Customer Service in the LTC Setting"*** ★
This program was sponsored by **Greystone Health Care Management.**

★ ***"Best Practices in the Management & Treatment of Diabetes in Frail Seniors"*** ★
This program was supported by an educational grant from **Novo Nordisk.**

★ ***"Management of Depression & Generalized Anxiety Disorder in LTC"*** ★
This program was supported by educational grants from **AstraZeneca and Forest Laboratories.**

★ ***"Optimal Management of Anemia in the LTC Setting"*** ★
This program was supported by an educational grant from **Amgen.**

★ ***"The Benefits Vs. the Myths of Hospice Care in the LTC Continuum"*** ★
This program was supported by an educational grant from **Vitas Innovative Hospice.**

FADONA Honors the Best of the Best at 22nd Annual Convention, "Carrying the Torch of Leadership"

FADONA President Bonnie Cruz is pleased to announce that the 22nd Annual Convention, "Carrying the Torch of Leadership 2009," was a resounding success. The convention, held at the Buena Vista Palace Hotel in Orlando, reached record numbers in attendance, gathering more than 500 participants, including speakers, attendees, and exhibitors.

One of the most anticipated events at this year's conference was the Annual Awards Luncheon, featuring presentations to the winners of various awards given by FADONA. Each year, FADONA acknowledges a nurse administrator who has demonstrated professional responsibility by mentoring and nurturing, as well as commitment to the standards of nursing practice and excellence in long-term care. The 2009 winner of the Director of Nursing Administrator of the Year Award is **Reuben Bowie**, RN, MS, CDONA/LTC; DON at Health Central Park in Winter Garden; she also serves as FADONA's treasurer.

"We are very fortunate to have health care professionals such as Reuben Bowie dedicated to improving nurse executive leadership and excellence in long-term care. She is a true leader in our field," Cruz said.

This year, the first Imogene Ward Scholarship was presented to **Manda Thomas**, an LPN and MDS Coordinator at the Health Center at Lake City. The Imogene Ward Scholarship program was established in 2008 in honor of Imogene Ward and her dedication to nursing and long-term care. The program was established to provide financial assistance to individuals in nursing as they look to continue their education in the LTC setting.

FADONA also presented its 9th annual CNA awards, which recognize certified nursing assistants (CNAs) across the state of Florida. Participants were asked to write a 100-word essay demonstrating commitment and devotion to their profession, by answering "Why I Like Being a Certified Nursing Assistant." **Corrie Lovelady** from Avante of Mount Dora, **Casseta Findlay** from Villa Maria Nursing Center in North Miami, and **Angel Nevills** from Palm Garden of Ocala, were recognized as first-, second-, and third-place winners, respectively, of this year's award.

Another group of leaders that were honored during the luncheon were FADONA's Ambassadors — former FADONA officers and directors whose tremendous contributions to the profession and association still live on.

FADONA's Ambassadors — former FADONA officers and directors whose tremendous contributions to the profession and association still live on — were honored during the convention (from left): Sharon Walters, Kay Trugillo, Patches Bryan, Mary Wilson, Carmen Shell, and Jocelyne Cameau. Note: Gilda Osborn (inset) was not able to be there in person, so FADONA made a special presentation at her facility in Boca Raton.

In addition to the awards, the board of FADONA acknowledged former board member **Patches Bryan**, RN, BSN, CDONA/LTC; chief executive clinical officer of Greystone Health Care Management, as the recipient of a very special Award of Excellence for her dedicated service, commitment to excellence and contribution to FADONA.

Also during the Annual Awards Luncheon, **Hope Caldwell**, RN, DON of Largo Rehabilitation Center, and **Tina Vanaman**, RN, DON of Palm Garden of Ocala and FADONA's new Region II Coordinator, received Certificates of Recognition for their dedicated professionalism to long-term care.

The Florida Association Directors of Nursing Administration/LTC, otherwise known as FADONA, is a statewide coalition of professional, administrative long-term care (LTC) nurses holding director, assistant director of nursing (ADON/DON) or other administrative nursing roles. FADONA is a state chapter of the National Association of Directors of Nursing Administration in Long-Term Care, and its primary goal is to ensure that the residents entrusted to their members enjoy the highest possible quality of life while receiving the finest-quality care available.

— Visit the convention photo album at www.fadona.org/convention.html.

FADONA Salutes the Generous Sponsors of its 22nd Annual Convention!

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★ Therapy Management Corp. ★ HS Pharma ★

New Nursing Home Guidance to Include Quality-of-Life and Environment Requirements

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

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

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

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

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

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

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

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

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

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

The guidance can be found at **www.cms.hhs.gov/transmittals/downloads/R48SOMA.pdf**.

Miami-Dade Chapter Revitalized

By Robin A. Bleier, RN, LHRM, FACDONA; FADONA 1st Vice-President

FADONA members **Cora Rich**, **Agnes Alejandre'**, and **Joyce Galbut** have joined with local Alliance Council members and friends, **Mia Rego** and **Aida de Salamanca**, from Allied Mobile X-Ray & Ultra Sound (AMX), **Cathy Sallitto** from American Medical Technologies, **Gail Allison** from SenTech Medical, and **Kristine Schiff**.

Together, they planned their first meeting, which was held on Wednesday, July 1, 2009, at Don Shula's in Miami Lakes.

One of the key speakers was **Ric Garcia**, a supervisor with the local area office of the Agency for Health Care Administration. He discussed his and **Neil Walker**'s roles at the Miami-Dade Emergency Operations Center (EOC) during hurricanes and other disaster-related circumstances. He reviewed AHCA's role with regard to the EOC and how it supports the providers. He also mentioned that ESS became mandatory for ALFs and SNFs as of July 1, 2009.

As the other speaker, I presented a program on quality improvement programs.

In addition, a chapter business meeting was held to discuss the bylaws and elections. **Cora Rich** did an outstanding job, marketing FADONA membership to those in attendance. She showed a 10-minute PowerPoint presentation she had prepared to highlight the many benefits of FADONA membership. Cora is from Plaza Health Network and works with **Joyce Galbut**.

For more information about the Miami-Dade chapter or how you can start a local chapter, contact our director of operations, **Ian Cordes**, at **(561) 659-2167** or **icordes@bellsouth.net**.

FADONA's 2nd Annual Think Tank Convened

Nearly 30 statewide nurse executives came together to participate in an exciting 2nd Annual FADONA Think Tank during the annual convention this past April.

The Think Tank was once again facilitated by **Mary Tellis-Nayak**, whom we all know and respect. She works with My InnerView and has spent many years working in the LTC areas of nursing and operational management. Mary helped FADONA develop a historic document, titled "FADONA's Principles of Excellence for Florida Directors of Nursing," to which the Think Tank members contributed during their session. The "Principles" were divided into five areas: Mission & Vision, Culture of Quality, Resident Care & Quality-of-Life, Caregivers & Staff, and Finance.

The resulting document was discussed and provided to each attendee at a Think Tank general session during the convention. Attendees were asked to evaluate each proposed principle and to choose its inclusion or exclusion in the final document, noting any suggestions for modifying the principle's wording.

As a follow-up to the convention, FADONA also mailed this same survey document to all FADONA members so everyone had an opportunity to provide input into this important decision-making process.

The results of the survey have been tabulated, and the Board of Directors of FADONA has decided to approve the final "Principles of Excellence for Directors of Nursing in Long-Term Care."

It is FADONA's goal that these principles will support the provision of long-term health care services that are desired, meaningful, successful and efficient. They are intended to assist directors of nursing in achieving these objectives and to guide and inspire creative leadership in long-term care.

The principles encourage the director of nursing to follow a reasonable course of action based on current knowledge, available resources, and the needs of the facility so that effective and safe care can be delivered. They are aspirational in nature and intended to foster self-appraisal and continuous performance improvement.

The principles are neither inflexible rules nor requirements of practice. They are not intended nor should they be used to establish a legal standard of care under any circumstances.

Please look for a copy of the final document, posted at **www.fadona.org**.

If you have any questions, please do not hesitate to direct them to **Ian Cordes**, director of operations, at **icordes@bellsouth.net**, or co-chairs **Carmen Shell** at **vpnursing@morselife.org** and **Robin Bleier** at **robinbleier@yahoo.com**.

The Increased Focus on Pressure Ulcers

By Karen Goldsmith, JD; Goldsmith Grout & Lewis, PA

We consistently hear over the grapevine that CMS has an enhanced focus on pressure-ulcer prevention and treatment and is focusing on specific issues.

Karen Goldsmith

One of those issues is the use of LPNs in assessing residents' skin problems, whether pressure sore or other problems. Remember that the Florida Board of Nursing has taken the position that RNs can assess; LPNs can't. That does not preclude your LPNs from making observations so long as the RN is assessing what those observations mean.

The problem in many facilities is the use of the term "assessment" on forms and in policies and procedures. Many of these forms are filled out by LPNs based on their observations of the resident. This is a good time to remind your LPNs (and RNs) that the LPN can only observe and that any information put on that form must be an observation and properly documented as such. Watch the language they use; language that reads like conclusions can create problems. RNs should also document their assessment when an LPN, or review of a form completed by an LPN, brings a skin problem to their attention. Your form may not have a place for such notation, but the RN can always place a note in the chart.

Documentation continues to be the big problem during surveys. The RN's making a notation of his/her assessment takes only a moment, but it is time well spent. This is particularly critical if you have high turnover, because the nurse may no longer be there when the surveyors arrive.

Here are additional points to remember relative to pressure sores. State administrative law judges have held that the burden is on the Agency to establish that a pressure ulcer was inhouse-developed. Once that burden is met, the facility must show unavoidability. These decisions have been adopted by the Agency, so the concept is most likely treated as policy. If your resident has an inhouse-acquired decubitus, make sure your documentation is impeccable. Take the time to follow the nurses and be certain that all necessary documentation establishes the reason for the decubitus' development — that it was because of the resident's condition, not a lack of care (unavoidability).

If you have a difficult resident (e.g. refuses to turn), so document. If you have a resident who is out of the building a lot and thus out of your control, make sure that information is prominently documented in that resident's records. Think outside the box. You would be amazed at the thoughts that develop after the facility is cited and the nurses are under the gun to show they did their jobs. These are usually legitimate reasons why the person could develop a pressure ulcer despite the best of care, but they were not thoughts that the staff had, and could share with the surveyors, during the survey process.

Sometimes it takes talking to the right person. In the 30 years I have represented long-term care providers, it is astonishing how many times we have unexpectedly turned up a stellar witness. For example in one case, a nurse made it a point to walk around the wing and verify that the CNAs had properly turned everybody, but he had not told anyone that he did it routinely.

Try to avoid gaps in records, but even if you do have gaps, there are arguments you can make to the surveyors that the care must have been provided. For example, if the surveyors accuse staff of not doing appropriate skin checks, thus trying to place blame on the staff for the development of a pressure ulcer, go to the bathing records. A resident who is bathed by a CNA should have a quasi-skin check. This is the nature of the bathing function. If a person has only developed one ulcer and has been in your facility a period of time, the fact that no ulcer previously developed speaks to the good care given that resident.

Do not cave immediately on the classification of an ulcer as a pressure sore. Look for other reasons why an area could ulcerate. Perhaps the person has chafing from a diaper. Perhaps a person has a new condition that results in decreased circulation. You know better than I that many "sores" are not pressure ulcers.

Look to your policies. How do your policies define decubitus ulcer? Are your policies consistent with federal and state law as well as community standards?

I cannot emphasize enough the need to use the proper nomenclature. For example, one facility got a Class I deficiency for putting information relative to a stasis ulcer on a pressure-ulcer reporting form. You do not need to stop using those forms. Just be sure your policy encompasses use of that form for other than strictly identified pressure ulcers and that the nurse making the notes documents in a simple sentence that the area has not been identified as a decubitus ulcer.

The survey process' increased emphasis on pressure ulcers puts your facility at risk. You can minimize the risk by being diligent in preventing LPNs from performing assessments, having good policies and procedures and following them. Reviewing charts on at-risk residents or those who have developed pressure ulcers (or other skin problems) while in your facility is time well-spent.

If you are cited, there are several state cases that help you win on appeal; however, your time is better spent on prevention.

This column is a regular feature of ***FADONA Focus***. If you have a subject matter that you want discussed, please e-mail **Karen Goldsmith** at **klgoldsmith@cfl. rr.com**.

Lessons Learned from NADONA

By Reuben Bowie, RN, MS, CDONA/LTC; Treasurer, FADONA

On July 9, 2009, I took an evening flight to Phoenix, Arizona, to attend the 23rd Annual Convention of the National Association of Directors of Nursing Administration/Long Term Care. The four-hour flight was uneventful, except that I was able to arrive only an hour after leaving, due to the time-zone change. By the time I was checked in, my body did not care what the clock said, I was ready for bed, knowing that I had made arrangements for an all-day tour that required me to leave the hotel at 6:30 a.m., Friday.

That early the next morning, in the air-conditioned comfort of the tour van, I didn't even think about the desert heat. I learned about many different kinds of cacti and watched the landscape change as we ventured into more mountainous territory. Sedona was a quaint little town surrounded by breathtaking mountains. I managed to spend too much on souvenirs and learned that Florida's sales tax is not so bad when compared to 9 ½ % there or 11% at the Grand Canyon. It was a clear, breezy day with temperatures in the low 80s when we arrived at the Canyon. As I'm sure you have heard, the most fitting description is "awe-inspiring." When it was time to return to Phoenix, we detoured to a Native American reservation and again did a bit of shopping. What a wonderful day!

When I got out of the van, 107-degree heat hit me. On the elevator to my room I encountered a family, and the gentleman called me by name. I was somewhat dazed since I was hot, tired and didn't expect anyone to know me. After he said, "Don't you remember me? It's Tony," I did remember, and he introduced me to his family. I had met him 13 years earlier at the 1996 NADONA Convention.

LESSON 1: When you share common problems and common goals, the friendships that develop are lasting ones.

It's always good to have friends. I met Patches Bryan coming in as I was going for dinner. She would be teaching QIS.

Be assured, this was not just a vacation. Classes started at 7:30 a.m. the next day with sessions continuing all day until 5 p.m. I attended the Presidents' Roundtable as the representative for Bonnie Cruz. I was very proud to learn that Bonnie is an active participant on committees at the national level, and she is well-respected by other state presidents. Some state presidents, showing state pride, shared their state pins with varied designs.

FADONA Treasurer Reuben Bowie carries the Florida state flag at the NADONA Annual Convention.

LESSON 2: The concerns we have in Florida are not unique to us, but are shared all over the country. Solutions will come through broader team effort and unified organizations. Together, we are stronger.

LESSON 4:
You can teach an old dog new tricks, if you can get him/her to sit still long enough.

By Sunday, I realized that classes start at 7:30 a.m. every day, and today would continue until 8 p.m. The theme of this convention was "MISSION: POSSIBLE." With that as the theme, I knew I could do anything (13-hour day Friday, 13-hour day Sunday: yes, I could)! Of course, the only thing I had to do was represent Florida by carrying our state flag in the opening ceremony, and that I did proudly.

LESSON 3: Perseverance really is all about attitude. (FADONA meetings are NOT too far away. . . NOT a bad time... and you are NOT too tired to attend.) "Just do it!"

The topics were relevant, and the speakers generally dynamic throughout the conference.

I remember thinking, though, what I would learn about urinary incontinence, pain, and pressure sores — I have been in LTC 22 years — but I did learn.

LESSON 4: You can teach an old dog new tricks, if you can get him/her to sit still long enough. Sometimes we just need to be quiet and listen.

I found myself being disappointed that I could not attend both of some concurrent sessions, but Patches and I shared key points with each other after we went to different ones. I also enjoyed spending time with LTC administrators from several other states during classes, dinners, and even at the casino. As it was with Tony, I look forward to connecting at some future convention.

LESSON 5: You get out of it what you put into it.

Thank you, NADONA, for a great convention. Thank you, FADONA, for allowing me to represent you. I had a great time.

Memories from FADONA's 22nd Annual Convention

To view the entire convention photo album, please go to www.fadona.org/convention.html.

Kerry Cranmer, MD, CMD, lecturing the audience during his session on pain management.

FADONA Think Tank (from left): Co-chair Carmen Shell; Moderator Mary Tellis-Nayak, Vice-President, My InnerView; Co-chair and FADONA 1st Vice-President Robin Bleier; and FADONA President Bonnie Cruz

FADONA Think Tank (from left): Patches Bryan with Greystone Healthcare, Joyce Galbut and Cora Rich with Plaza Health Network, and Richardean Bruce with the Fla. Dept. of Veterans' Affairs, as Paul Barnard from MobilexUSA, the event sponsor, looks on.

AHCA's Polly Weaver at FADONA's 22nd Annual Convention

Naushira Pandya, MD, CMD, addresses the audience during her presentation on diabetes.

Pam Johnson, RPh, and general manager of PharMerica in Largo, gives a presentation on preventing medication errors.

FADONA President Bonnie Cruz (left) and 1st Vice-President Robin Bleier, present Gail Allison, and Cathy Sallitto with certificates of appreciation.

Aegis Therapies' Violet Parker (left) and FADONA President Bonnie Cruz

Speaker Albert Riddle, MD, CMD, presents to conference-goers at FADONA's 22nd Annual Convention.

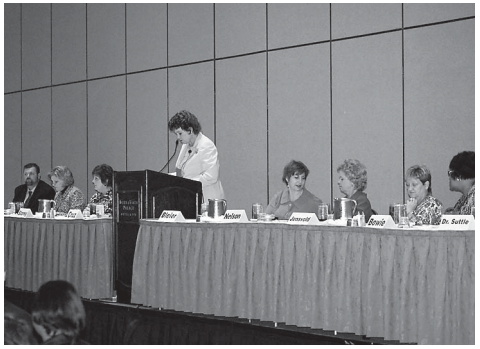
Neala Asser, RN, MA, CDONA/LTC; Director of Clinical Services for Senior Health Management, presenting her talk at this year's convention.

Moderator Margery Shake, introduces hospice expert Gary Miller, MD, CMD.

50/50 raffle winner Steve Frick of Functional Pathways (left) with Larry Cubi of American Medical Technologies, and FADONA 1st Vice-President Robin Bleier

FADONA President Bonnie Cruz (left) and 1st Vice-President Robin Bleier cut the ribbon to kick off the 2009 Trade Show.

From left: Patches Bryan; Liz Jensen, Carmen Shell, Julie Dawkins, Robin Bleier and Mary Tellis-Nayak (at the podium)



Annual Awards Luncheon (from left): FHCA Executive Director Emmett Reed, Cathy Ates, Robin Storey, Bonnie Cruz, Robin Bleier, Jean Nelson, Susie Jensvold, and Reuben Bowie

NADONA VP Robin Storey (right) swears in the region coordinators while Bonnie Cruz (left) looks on (from left): Cherryl Chmielewski (V), Tina Vanaman (II), Norma Collins (III), and Sharyn Figgins (I).

Guardian Pharmacy booth (from left): FADONA President Bonnie Cruz, Brian Rosoti, Matt Depenbrock, and Rand Fingles.

MobilexUSA exhibitors Paul Barnard, Brinn Helton, and Nancy Arnold surround FADONA President Bonnie Cruz (third from left).

FADONA President Bonnie Cruz (second from left) with Forest Pharmaceuticals' Bruce Bellingar, Scott Petersen, and Craig Moss.

American Health Associates' Chris Gregg, Debbie Martin, and Jim Jackson, with FADONA President Bonnie Cruz (second from left).

Conference attendees enjoy a night of dancing at this year's "Tribute to Excellence" celebration.

From left: Cathy Ates, Bonnie Cruz, FADONA Award of Excellence recipient Patches Bryan, NADONA Vice-President Robin Storey, and Robin Bleier.

Robert MacDonald, Director of Dental Care and Health at Florida Dental Association, reviews key points during his presentation.

Susie Jensvold (from left), Susan McDevitt, Robin Bleier, and Dr. Katherine Hyer from University of South Florida (at the podium)

F-Tag 309: Update & Refresher

By Deborah Afasano, BSN, RNC, CDONA, RAC-CT, HCRM; Vice President of Clinical Operations, Traditions Management

"Highest practicable physical, mental, and psychosocial well-being" is language that is meant to direct facility processes and systems of care. This expectation is the foundation for F309, which refers to what is "possible" in regard to a resident's level of functioning.

Debbie Afasano

The facility is expected to provide necessary care and services, understanding that outcome may be influenced by the individual's recognized pathology and normal aging process. "Highest practicable" is determined through the comprehensive resident assessment. Appropriate assessment requires the interdisciplinary team to competently and thoroughly address the physical, mental or psychosocial needs of the individual, continually evaluating the resident's outcome and changing interventions if needed. Interventions should focus on a working knowledge of the resident's customary daily routine. New guidance at F309 includes surveying for a resident who receives either hospice or ESRD services, which was formerly in appendix P.

Determination of compliance begins with resident review. The survey team looks at the resident assessment, care plan and orders to determine whether the facility recognized and addressed the concerns and resident care needs being investigated. Surveyors will observe "whether staff consistently implement the care plan over time and across various shifts."

It is important that day-to-day operations and communication strategies reflect individualized resident needs as established through the RAI process, and implementation of the care plan. As a facility looks at F309, they should assess facility performance and systems of care by asking: "How do our nursing assistants know how, what, when, and to whom to report changes in condition to?" How does the charge nurse monitor for the implementation of the care plan and changes in condition. Established systems for daily report, walking rounds, communication systems, and standard quality reviews are essential.

The concepts of person centered care are evident in guidance that explores whether the facility developed a care plan that was consistent with a) the resident's specific conditions, risks, needs, behaviors, preferences, and b) with current standards of practice and included measurable objectives and timetables with specific interventions.

Surveyors will interview residents or their representatives and along with staff, decide whether there is adequate awareness of current conditions and diagnoses, involvement in the care plan, and the establishment of goals and interventions that reflect choice and preference. They will explore how changes are made to the care plan and communicated and carried forth by staff.

Assessment effectiveness is determined through a review of orders, medication administration records, multi-disciplinary progress notes, the RAI/MDS, and any specific assessments and related documentation that may have been completed. Though assessments have assigned federal time lines, the assessment process as a whole should be fluid and ongoing.

Care planning and revision to the care plan looks at whether the facility developed a care plan consistent with the resident's specific conditions, risks, needs, behaviors, preferences and current standards of practice. It questions: Are there measurable objectives and timetables with specific interventions? If there are treatment regimens, guidelines suggest that the treatment protocol must be available to the caregivers, and staff should be familiar with the protocol requirements. The bottom line is whether staff has monitored the resident's condition, effectiveness of the plan, and revised as needed to achieve the desired outcomes.

First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity.

When looking at the intent of F309, it is important for a facility to monitor resident status and conditions via processes such as: QM/QI reviews, established clinical communication and

monitoring systems, the care plan process, incident and adverse monitoring, grievance reports, satisfaction surveys, and an integrated risk and QA/QI program. When seeking the cause of a potential unavoidable decline, a facility should probe: Has care been appropriate and consistent in relationship to accepted standards of practice? Has the physician been a part of medical and treatment decisions? How were risks identified, changes in condition addressed, interventions chosen, and treatment options evaluated?

Once the survey team has completed its investigation (which includes analysis of data, regulatory review, and determination of non-compliance), the team decides the severity of each deficiency, based on the harm or potential for harm to the resident.

The key elements for severity determination for F309, Quality-of-Care requirements are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care, such as decline in function, or failure to achieve the highest possible level of well-being.
2. Degree of harm (actual or potential) related to the non-compliance. Identify how facility practices caused, resulted in, allowed or contributed to the actual or potential for harm.
   - If harm has occurred, determine whether the harm is at the level of serious injury, impairment, death, compromise, or discomfort to the resident(s); and
   - If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident(s).
3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity.

The concepts of person centered care are evident in guidance that explores whether the facility developed a care plan that was consistent with a) the resident's specific conditions, risks, needs, behaviors, preferences, and b) with current standards of practice.

Additional concerns that may be investigated as associated requirements include but are not limited to:

- 42 CFR 483.10(b)(11), F157, Notification of Changes
- 42 CFR 483.(20)(b), F272, Comprehensive Assessments
- 42 CFR 483.20(k)(2)(iii), 483.10(d)(3), F280, Care Plan Revision
- 42 CFR 483.20(k)3)(i), F281, Services Provided Meets Professional Standards of Quality
- 42 CFR 483.20(k)(3)(ii), F282, Care Provided by Qualified Persons in Accordance with Plan of Care
- 42 CFR 483.30(a), F353, Sufficient Staff
- 42 CFR 483.40(a)(1)&(2), F385, Physician Supervision
- 42 CFR 483.75(f), F498, Proficiency of Nurse Aides
- 42 CFR 483.75(i)(2), F501, Medical Director
- 42 CFR 483.75(l), F514, Clinical Records

A Refresher and Update

In regard to pain, some of the key aspects are: Recognition and Management of Pain. In order to help a resident attain or maintain his or her highest practicable level of well-being and to prevent or manage pain, the facility, to the extent possible:

- Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;
- Evaluates the existing pain and the cause(s), and
- Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current clinical standards of practice, and the resident's goals and preferences.

Overview of Pain Recognition and Management

The resident's needs and goals as well as the etiology, type, and severity of pain are relevant to developing a plan for pain management. The facility is expected to address, as known, underlying causes that may permit pain management with fewer analgesics, lower doses, or medications with a lower risk of serious adverse consequences.

The interpretive guidelines remind us that challenges to successfully evaluating and managing pain may include communication difficulties due to illness or language and cultural barriers, stoicism about pain, and cognitive impairment.

Continued on page 27

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— Current as of July 21, 2009
*** Patron member**

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

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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.

Rx only

Date of issue: October 19, 2005

Manufactured for Novo Nordisk Inc., Princeton, NJ 08540

Manufactured by Novo Nordisk A/S, 2880 Bagsvaerd, Denmark

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Clostridium Difficile: Our Experience with A Changing Infection in LTC

By Sharyn Figgins, RN, MSN; FADONA Region I Coordinator

Clostridium difficile is emerging as a more aggressive and resistant infection in acute-care hospitals, long-term care (LTC) facilities and in the community. Following guidelines and practices recommended for hospitals is not always possible in LTC for a variety of reasons. I would like to share one facility's experience and the changes we put in place to address medical treatment, nursing care, and infection control issues.

Sharyn Figgins

As the director of nursing in a rehab and LTC facility, I monitor the incidence and prevalence of infections and am responsible for infection control. This can be tricky as we have an older facility with 155 beds, but only seven private and 18 semi-private rooms. Most of our residents are in 4-bed wards with sinks but no bathrooms. This year, I noticed an alarming change in our residents with Clostridium difficile commonly known as C. diff or CDAD (Clostridium difficile — associated disease). We had an increased number of residents with infections, and most of these residents had a recurrence of this infection within 2-3 weeks. Also, the disease was more virulent; our residents were sicker, weaker, more uncomfortable, and experienced more weight loss than previously.

We had four residents in 2007 and three in 2008 diagnosed with C. diff, and only one needed to repeat a course of therapy. So far this year, we have had 12 cases of C. diff: six admitted and six acquired. All but one resident had been on antibiotics prior to developing symptoms of C. diff. One resident was just admitted this week, and one had a positive result the day of discharge. Of the 10 remaining, we admitted through hospice, two seriously ill residents with C. diff; they died within weeks of admission. Two residents died of other serious illnesses (co-morbidities of COPD and heart problems), though having C. diff may have contributed to their decline and certainly to their discomfort.

Our elderly residents with C. diff have been embarrassed and become more dependent because of the copious and smelly diarrhea, they are anorexic but want to limit their intake even more to decrease the diarrhea; and they have more falls due to weakness. One resident needed five courses of therapy (over four months), two needed four courses, and three needed only one course of therapy to resolve the disease. In addition, one family member who does the resident's laundry acquired the infection.

We have five resident halls, and all our residents with C. diff were located on two non-adjacent halls. We looked for patterns, but there was no evidence of cross-infection and no roommates became infected. We had not changed our infection control practices from previous years, our turnover is low (about 13% annualized for nursing this year), and our antibiotic usage is comparable to previous years. We

checked with local hospitals and found their experience was similar to ours with increased severity of symptoms and resistance to treatment. Our nurse practitioner started researching treatment issues, and I investigated disease issues and infection control recommendations.

C. diff is a gram positive anaerobic bacterium found throughout the environment in soil, water, and human and animal feces. Healthy people may carry the bacterium in their colon, but it is much more common in patients in hospitals and health care facilities. It is the most common cause of infectious diarrhea in LTC facilities.[1] It has the ability to form spores that are resistant to heat and many disinfectants, and are able to survive for long periods on dry surfaces. The spores produce at least two toxins, A and B.[2] These toxins cause GI mucosal injury and an acute inflammatory response resulting in watery diarrhea (generally frothy and foul smelling), abdominal pain, nausea, anorexia, and fever. Severe cases can progress to pseudo-membranous colitis, toxic colon, perforation of the colon, occasionally sepsis and death.[2]

The prevalence of C. diff has increased by about 25 percent a year each year since 2003 and is seven times higher in people over 65 than those 45 to 64. A new, more virulent strain of the bacterium has recently emerged and produces much higher amounts of both toxins A and B.[4,5] Also, some researchers suggest a third toxin has been identified, though they are unclear about its effect.[5]

C. diff is an opportunistic organism, and the risk of developing the infection depends on three groups of factors: the overall health and immune status of the person, exposure to C. diff or its spores, and impairment of colonization resistance. Impairment of colonization resistance occurs by interrupting the healthy benefits of normal flora in the gut through such methods as antibiotic use, GI surgery (even the intense prep for GI procedures), chemotherapy, colitis or inflammatory bowel disease.[3] Certain antibiotics seem to have a higher risk of impairment: especially clindamycin, cephalosporins, and floroquinolones. It has also been suggested that decreased stomach acid from use of protein pump inhibitors impairs colonization resistance, increasing risk of infection.[4] The roommate(s) or associates of an infected resident may have been exposed to the bacterium or spores, but not show symptoms of infection (or test positive for the toxins) unless they are given antibiotics, experience an exacerbation of their primary disease, or become immuno-compromised.

The prevalence of C. diff has increased by about 25 percent a year each year since 2003 and is seven times higher in people over 65 than those 45 to 64.

Diagnosis is suggested by the onset of diarrhea after antibiotic use (sometimes up to weeks later) and usually confirmed by an enzyme immunoassay (EIA) lab test for the presence of the toxins in a stool specimen. The result from this test is usually available the same day, but it may produce a false negative 15-25 percent of the time. Repeat tests are indicated in the continued presence of symptoms after a negative result. A stool culture is more sensitive, but it is expensive and takes up to 96 hours to get results, so it is rarely used.

The first treatment option is stopping or changing antibiotics. Often, this is not an acceptable option as the antibiotic is required. Metronidazole (Flagyl) is the initial choice of therapy, because it is less expensive and can be administered PO or IV. Oral Vancomycin is the second-choice drug, but it may lead to Vancomycin resistance. It can be given through a PEG, but it is not effective IV. With the development of the more virulent and resistant strains of C. diff, some prescribers are adding Rifampin to the regimen, though research is inconclusive.[3]

Prevention and infection control require good hand-washing, contact isolation, and frequent environmental cleanings. Person-to-person or environment-to-person via hands is the most common method of transmission of this infection. Alcohol-based products are not very effective against the bacterium or spores;[1,4] therefore soap and water, not alcohol-based hand sanitizers, should be used. Reinforce the need to briskly wash hands for at least 15 seconds. Contact isolation is required. A private room is recommended, or two residents with the infection may be in the same room. This is great in hospital situations, but not always feasible in long-term care.

As mentioned previously, the spores can exist for long periods of time on dry surfaces such as overbed tables, call lights, doorknobs, even bathroom light switches. These spores are difficult to kill with health-care-grade disinfectants. Most studies recommend a hypochlorite (bleach)-based disinfectant. Check closely when looking for what to use, as even Clorox Disinfecting Wipes are bleach-free. Cleaning and disinfecting the environment is crucial to prevent or control spread of this infection.

By March of this year, we had our third resident on at least a second course of therapy. After researching the

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Clostridium Difficile: Our Experience with A Changing Infection in LTC

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literature, we made several changes to our infection control practices (see table). We tested the stool for C. diff when the medication regimen was completed, even when negative, we maintained contact isolation and infection control practices for four weeks until a second negative test was obtained.

Our occupancy rate is high, and we could not always provide private rooms. We evaluated the health/immune status of our residents when diagnosed and cohorted only two residents (one whose roommate was on dialysis). We re-educated staff on contact isolation, posted precautions and instructions. We also added stethoscopes, blood pressure cuffs, and disposable thermometers to each isolation cart.

After several 10-day courses of either Metronidazole or Vancomycin therapy, our medical practitioner started residents on an extended course of Vancomycin: TID for seven days, BID for seven days, daily for seven days. For the resident needing five courses, Rifampin was added the last week. Apparently our changes are working. At the time of writing, all residents except the one newly admitted have had two negative tests for the infection.

I feel the three most effective nursing practice changes we made are 1) the frequency of washing each resident's hands, 2) the frequency of disinfecting the handrails in the hall, and 3) keeping contact isolation and infection control practices in place until the second negative test four weeks after symptoms stopped.

Our QA team developed these infection control and environmental hygiene changes based on a "best guess" theory, since specific references for LTC were hard to find. These changes were difficult to implement because of the increased perceived workload of the nursing and environmental staff and the natural reluctance to change. I would love to know your experiences with this infection, if you are having the same issues we are, and what you are doing. Please e-mail me at **sfiggins@deltahealthgroup.com**.

INFECTION CONTROL PRACTICES

All Residents

- CNAs wash each resident's hands before meals. We bought small coolers & add hot water, washcloths, & no-rinse soap
- CNAs clean the overbed tables, siderails, call light and commode seat each shift.
- An assigned CNA cleans handrails along halls with a disinfectant wipe each shift.
- Housekeeping disinfects rooms, bathrooms, doorknobs, etc., daily

Residents on Isolation

- Each shift – CNAs clean the overbed tables, siderails, call-light and commode seat with a disinfectant wipe.
- Daily – Housekeeping uses hypocloride solution to clean bathroom & commode.
- Weekly – Housekeeping deep-cleans rooms with a hypocloride solution: floors, beds, mattresses, table tops, etc. The cubicle curtains are also changed.
- Staff and families use only soap and water to wash their hands.

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FADONA Takes Lead on Agency's PACT Initiative

By Bonnie Cruz, RN, BSN, MEd; President, FADONA

Legislative changes have mandated the dissolving of the Quality Monitor group, which had assisted long-term care (LTC) facilities with quality improvement. Facilities must continue on the quality improvement track by setting goals and utilizing resources for best practices. FADONA has a vested interest in maintaining quality and offering educational venues to assist with goal setting in Florida. One such way is that FADONA has taken the lead with the PACT initiative project.

PACT stands for Positive Action Critical Thinking. It was formed by CMS in Atlanta to reduce pressure sores and restraints as stated on the Government Performance and Results Act (GPRA) goals. The information gathered to report on pressure sores is generated from the 90-day MDS. CMS has challenged states to reduce pressure sores and restraints. According to the data, Florida has shown great improvement in restraints and some decline in pressure sores. Pressure sore reduction in LTC is a No. 1 goal for the PACT initiative over the next three years for many reasons. The increased interest in this topic relates to cost and expense with healing wounds (labor, supplies, etc.), potential medical complications, and pain associated with wounds.

AHCA has spearheaded this PACT initiative over the past year but has turned to FADONA to take the lead and reach out to all parts of Florida. The Agency has been very supportive with this venture and has collaboratively worked with the PACT Committee to offer guidance and resources to assist with pressure-sore reduction. The PACT group had piloted an all-inclusive "designed" universal hospital/LTC transfer form to use for residents going to and from hospitals in Miami. Feedback from the Miami-based pilot committee was positive, yet

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DEA Interpretation Fails to Recognize LTC Nurses as Agents

Here is the most recent DEA information relative to its startling interpretation that the LTC nurse is NOT an agent of the physician. The final position statement is still outstanding. However, the DEA is not swaying from its position at this time.

SOURCE: *From the American Society of Consultant Pharmacists —DEA remains fixed.*

DEA Responds to Senator Brown on Nurses' Role as Agent of the Prescriber

In a letter dated June 25, 2009, DEA's Sheldon Shoemaker responded to Senator Sherrod Brown's letter forwarding ASCP's concerns regarding the failure of DEA to acknowledge that nurses in long-term care facilities act as agents of the prescriber when drugs, including controlled drugs, are being prescribed. In his response, Shoemaker advised Senator Brown that DEA has recently met with ASCP representatives and plans to meet again with ASCP in the coming weeks. Further, the letter indicates that if DEA ultimately determines that any revisions to its regulations are warranted and can be reconciled with the Controlled Substances Act, DEA would proceed with appropriate rulemaking under the Administrative Procedures Act (APA). In the meantime, until APA rulemaking occurs, the letter states, "the existing regulations remain in effect."

According to Claudia Schlosberg, ASCP's Director of Policy and Advocacy, "the letter is a pretty clear indication that for now, DEA is standing by its current interpretation of the CSA. Unfortunately, this means that residents in long-term care and hospice patients could experience delays in receiving appropriate pain management."

ASCP is staffing a broad-based multi-disciplinary working group that is advocating for changes in DEA policy. For more information contact ASCP at **govaff@ascp.com**.

FADONA Takes Lead on Agency's PACT Initiative

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more work needs to be done. This is an example of collaborative efforts of the PACT Committee working with LTC and hospitals to reduce pressure sores.

PACT Nursing Home Providers for Miami Pilot Project:

Miami Jewish Home
Riverside Care Center
St. Anne's Nursing Center
Victoria Nursing Center

PACT Hospital Providers for Miami Pilot Project:

Baptist Hospital of Miami
Coral Gables Hospital
Douglas Gardens Hospital
Jackson Memorial Hospital
Jackson South Community Hospital
Kendall Regional Medical Center
Mercy Hospital
University of Miami Hospital

The next goal for the PACT Committee is to reduce pressure sores statewide. FADONA will spearhead this effort over the next few years and will assist facilities with pressure-sore reduction through continued best practices and up-to-date resources and educational symposiums with interactive discussions. AHCA has verbalized its support with pressure-sore reduction and is working with the PACT Committee to meet the GPRA goals of pressure sore reduction.

From April 1 through June 30 of this year, the PACT providers (see above for Florida PACT Providers) were asked to use a newly designed form to document when they transfer a resident from the nursing home to the hospital and when a hospital discharges a resident to a nursing home. Based on feedback from this pilot, it was decided to continue the PACT project.

F-Tag 309: Update & Refresher

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Staff must be aware that those who cannot report pain may present with nonspecific signs, such as grimacing, increases in confusion or restlessness, or other distressed behavior. Effective pain management may decrease distressed behaviors that are related to pain. Advancing Excellence provides an excellent framework for pain management, as do tools such as the Wong Baker Pain Scale.

Changes to F309 include provisions for a Resident Receiving Hospice Services. Hospice and the nursing home must communicate, establish, and agree upon a coordinated plan of care. It must be based on an assessment of the individual's needs and unique living situation in the facility. The plan of care must include interventions to manage pain and uncomfortable symptoms with noted revisions and updates to reflect the needs of the individual.

To summarize, other requirements include:

- Medications/medical supplies are provided by the hospice as needed for the palliation and management of the terminal illness and related conditions;
- The hospice and the facility communicate with each other when any changes are indicated to the plan of care;
- Hospice and the facility are aware of the other's responsibilities in implementing the plan of care. Facility services are consistent with the plan of care developed in coordination with the hospice, and the SNF/NF offers the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. The resident has the right to refuse services in conjunction with the provisions of 42 CFR 483.10(b)(4), F155.

Changes to F309 also include a review of a Resident Receiving Dialysis Services as summarized: When dialysis is provided in the facility by an outside entity, or the resident leaves the facility to obtain dialysis, the nursing home must have an agreement or arrangement with the entity. The agreements should include how care will be managed to include medical and non-medical emergencies:

- Development and implementation of the resident's care plan
- Interchange of useful information for the care of the resident; and responsibility for waste handling, sterilization, and disinfection of equipment.

The facility is expected to address, as known, underlying causes that may permit pain management with fewer analgesics, lower doses, or medications with a lower risk of serious adverse consequences.

A sampled resident receiving dialysis care will be evaluated to: ensure medications are administered after dialysis as ordered by the physician, with optimal timing to maximize effectiveness and avoid adverse effects of the medications; determine whether staff know how to manage emergencies and complications, including equipment failure and alarm systems (if any), bleeding/hemorrhaging, and infection/bacteremia/septic shock; and if facility staff are aware of the care of shunts/fistulas, infection control, waste handling, nature and management of end-stage renal disease (including nutritional needs, emotional and social well-being, and aspects to monitor. They will also determine if the treatment affects the quality-of-life, rights or quality-of-care for other residents, e.g., restricting access to their own space, and risk of infections.

For a copy of F309, visit the FADONA website at **www.fadona.org/regulatory.html**.

— A related version of this article was recently printed in the **FHCA Pulse** *newsletter and is printed here courtesy of the author.*

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