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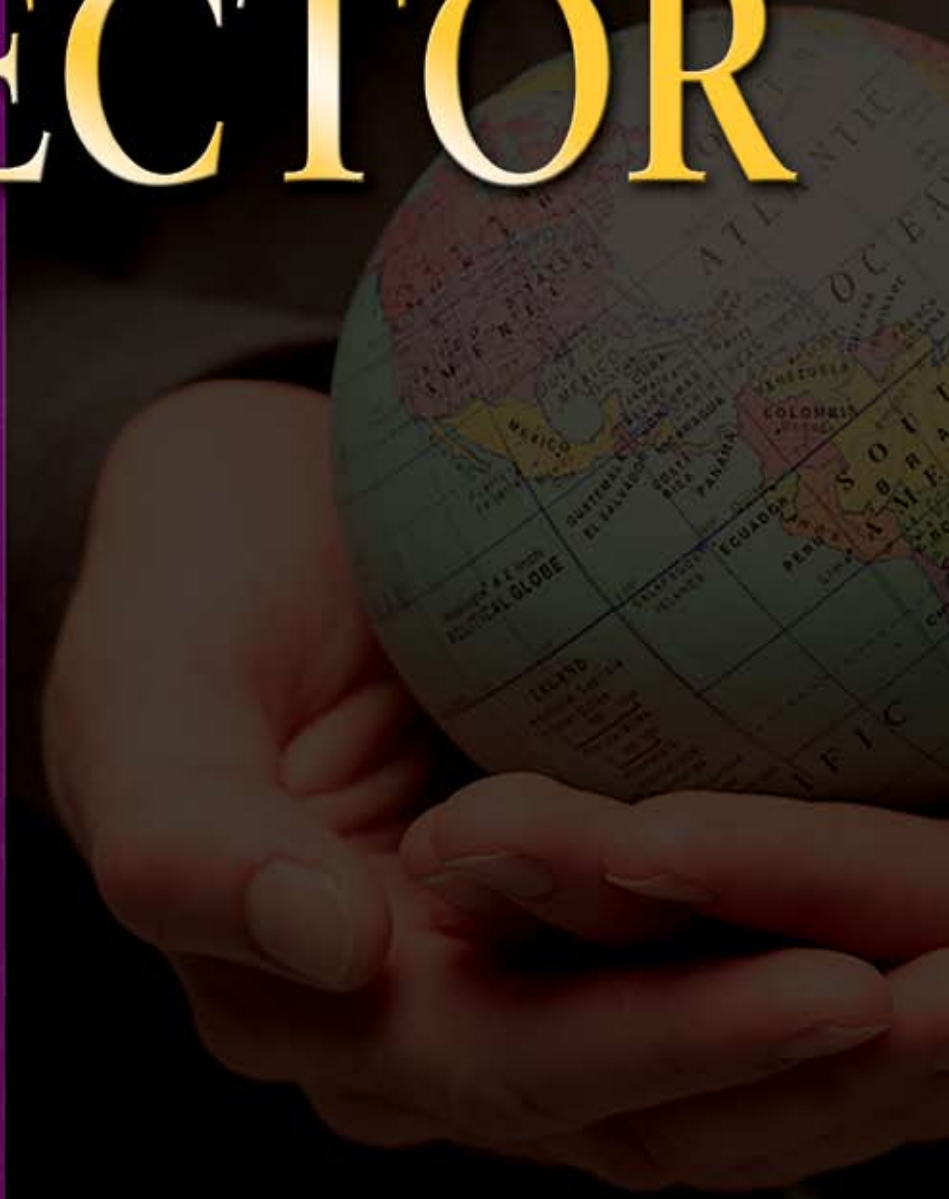
Official Publication of the National Association Directors of Nursing Administration in Long Term Care

# The DIRECTOR



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### Clinical Research and Education Sections



**No one knows what a world of difference you make or all that you go through in one day... no one that is except NADONA**

NADONALTC

NALNA

Premier Edition

The DIRECTOR

NADONALTC
NATIONAL ASSOCIATION DIRECTORS OF NURSING ADMINISTRATION/LONG TERM CARE

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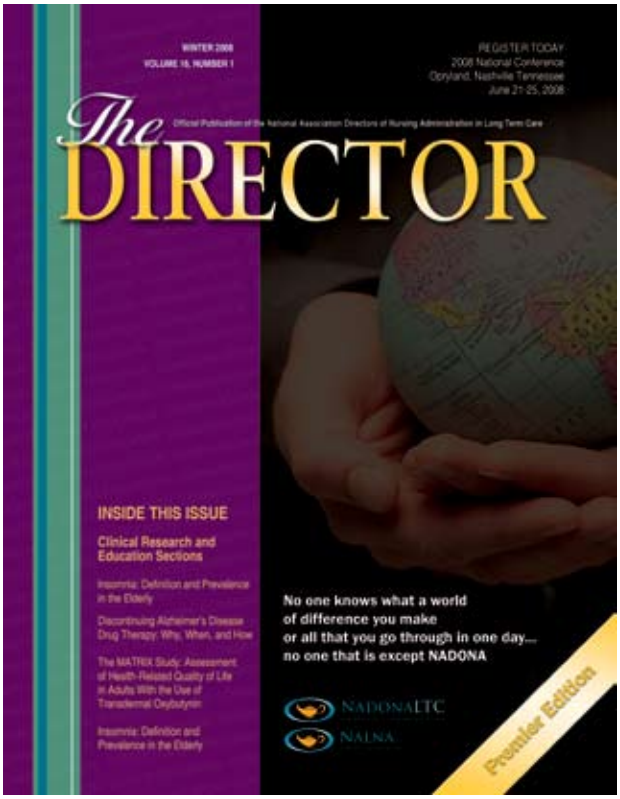


**COVER:**

Welcome to the premier edition of the combination of "The Director" and "The Nurse in Assisted Living" journals. We have had many requests from members to receive both journals, so many that the Board felt it was worth doing and in doing so making us more financially responsible.

We have also heard from our members working in CCRC's that receiving both journals would be a benefit for them as they serve both assisted living and skilled care.

Since members change jobs, moving from assisted living to skilled care or from a free standing unit to a CCRC, where one journal may be more beneficial than the other, there will be no need to call the office to switch what journal you are receiving.

Now all members will be able to keep up on both journals! Going forward with a combination journal the number of pages will fluctuate to accommodate the advertisers and articles scheduled for each issue.

We hope that you will enjoy each issue, and consider submitting an article for publication in the near future!

The DIRECTOR

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The Director

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## NADONA/LTC

# PRESIDENT'S Message

*Sherrie Dornberger - President*

Dear members, associate members, Benefactors, colleagues, advertisers and friends:

The NADONA board and staff have been very busy this fall. We have heard that many of you were looking for us at some of the fall meetings. We are sorry that we were missed but, our hard work has paid off, as we were able to finalize an agreement with a new Interim Executive Director, her name is Norma Skoog.

Norma will be working with the board to put policies and practices in place which will promote the further growth and development of NADONA. Norma will be with NADONA during and throughout the search and hiring of a permanent Executive Director, sometime during 2008.

Norma Skoog is the Owner and Principal of Growth Management Advisors, Inc., a consulting company formed in 1996 that specializes in working with senior management of companies experiencing the issues and challenges often associated with rapid growth.

Ms. Skoog is also an adjunct professor of Business Law at Xavier University and serves as a volunteer mediator for the Hamilton County Court of Common Pleas Mediation Service and the Better Business Bureau.

Ms. Skoog was Vice President, Secretary, and General Counsel of The Future Now, Inc., a Cincinnati based national computer sales and consulting company. Prior to The Future Now, Ms. Skoog was Vice President and Secretary of The Kroger Co., the largest supermarket chain in the United States.

Ms. Skoog received a B.A. and a J.D. from Saint John's University in New York City and an M.B.A. in Finance from the University of Cincinnati. She was named Businesswoman of the Year in 1991 by the Cincinnati Chamber of Commerce and the Cincinnati Business and Professional Women. Ms. Skoog is Chair and a member of the Executive Committee of Cincinnati Works and serves on the Fine Arts Fund Business on Board for the Arts, the boards of Cincinnati Public Radio, Inc., Madcap Productions Puppet Theatre and the Williams College of Business Entrepreneurial Center of Xavier University.

Please join the board in welcoming Norma Skoog, as the new Interim Executive Director!

The board looks forward to working with all of you during this New year. Happy New Year to all!

Sincerely,
The NADONA Board of Directors

Sherrie Dornberger, RNC, CDONA, FACDONA
NADONA President
Sherrie@nadona.org


# State CHAPTER Chatter

## Please join us in welcoming Connecticut and Illinois to the NADONA/LTC family!

**Connecticut**

The Connecticut Chapter for Directors of Nursing (CONNDONA) held its inaugural meeting on November 29th at the Courtyard Marriott in Cromwell. The event was a huge success with the participation of approximately 28 Clinical Directors and 13 vendors. Sarah Jerro represented the corporate office. Dr. Deidre Mole started the day by presenting on Proactive Dementia Management in Long Term Care, followed by author Rosemary Gibson who represented on Medical Mistakes. Aysha Kuhlor RN BA (Director of Clinical Services for Saint Mary Home) was elected as President for CONNDONA and Christine Regan RN (Director of Nursing for the Curtis Home) was elected as Vice President. Other elected officers were Emma Duquette RN as Treasurer, Lourdy Joseph RN as Recording Secretary and Donald Watson Jr. RN as Corresponding secretary. There were a lot of enthusiastic nurse leaders who volunteered their time to participate on various committees. The 2008 educational award for the NADONA conference was raffled off and won by Lourdy Joseph. The day turned out to be promising and exciting and we look forward to great things for the Connecticut chapter. Thanks to McKesson, Eisai, Orth-Biotech, Medline, Smith and Nephew, Saint Mary Home, SCA, Sucampo, Norvatis, Coloplast, Sanofi Aventis, CANPHA, Mr. Rick Brown(CAHCF), and Connecticut Mental Health Services for their generous support in the planning phase of our Founders meeting. Our chapter is working on the next meeting dates and locations which will all be published in our upcoming Newsletter.

CONNDONA is seeking new members. If interested, please contact Aysha Kuhlor at 203 676 2396 or e-mail at ama_sml@yahoo.com

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**Illinois**

We had a successful "kick-off" meeting! We approved our Articles of Incorporation and our Code of Ethics. We elected interim officers. Your officers are:

Kim Sheppard - *Vice President, from Alton,* Dora Seth - *Secretary, from Ottawa*, Donna Fox - *Treasurer, from Peotone* and Matt Whitlock - *President, from Hartford.*

I want to personally thank Kim, Dora and Donna for stepping up to the plate! You all will be seeing great things come from this board!

Your board is in the process of working out

Pictured Bottom L to R: Anjanette Miller, Donna Horn, Matthew Whitlock
Picture Top L to R: Dora Seth, Donna Fox , Suzanne Armstrong, Kim Shepard

the fine details to finish getting the Chapter off of the ground and running! We are starting to plan our next meeting. At our Kickoff meeting in Springfield, it was suggested that we hold our next meeting in the Chicago area. I am open to any of your suggestions on a location. We had only one member from the Chicago area attend our Kickoff in Springfield. I would really like to see partici-

pates from all over the state get together so we can network as a united state and learn from each other. Illinois is a huge state with many Nursing homes, Assisted and Supportive Living Facilities, Skilled Facilities, ....the whole Senior Care Arena....if all of us DON/Nursing Administrators got together and met...Wow!....just think what we could accomplish! Look for more information on our next meeting to come soon! Please plan to attend and bring a fellow DON or ADON!

I also wanted to share that if any of your contact info has changed or your membership is close to expiration, please call the National office at 1-800-222-0539 to update or renew!

Matt Whitlock RN CDONA/LTC, Illinois Chapter of NADONA/LTC President, 201 E. 5th, Hartford, IL 62048, (618) 254-1963 (home), (618) 254-1969 (fax), MWhitlockRN@aol.com

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**Mississippi**

Please contact Sherrie Dornberger if you are interested in joining or participating in the founding of this chapter. sherrie@nadona.org.

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**Massachusetts**

Massachusetts will have it's 17th Annual Chapter Conference on April 23-25th, 2008 at the Mohegan Sun Resort in Connecticut. We will also be sending invitations to other New England NADONA members so that they can join us at this conference.

The MA Chapter extends sincere congratulations to Connecticut for a successful Founding meeting held on November 29th. Great work!

MA Chapter officers Anne Marie Jette and Cathy Bergeron completed work with the Board of Registered Nurses Task Force re: "Unwitnessed Arrest in LTC". The final draft of the Task Force Recommendation was presented to the BRN board in November. News to follow!

Officers Karen Brennan and Cathy Bergeron also represent NADONA on the MA Statewide Fall Prevention Task Force . Great work is being done by all disciplines of Senior Care to support fall safety for our state elders. The LTC subgroup of the Task Force is working on developing Falls assessment/Care planning tools etc.

We were unable to prepare a fall seminar this year but are in the planning stages for a program in January/February to be co-sponsored with our MA Chapter and the MA Chapter of ACHCA. Look for fliers and have a great Winter!

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**New Jersey**

The New Jersey chapter of NADONA is busy planning our 2008 Convention. The dates are April 27-29, 2008 at the Trump Taj Mahal in Atlantic City. Our theme for this years convention is "The ExZOOburent World of Long Term Care". We are working diligently developing an agenda filled with education, networking and fun. Our workshops will include Disaster Planning; Cultural Perspectives at End of Life; Compliance Self Audit Survey; "Down and Dirty" MDS; Regulatory Updates from the DOH and many others. Speakers include Toni Swick; Sheryl Rosenfield; Debbie Hunter; Robin Arnicar and Debbie Afasano, to name a few. We are looking forward to this being our best convention ever! We hope to see you in Atlantic City.

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**North Carolina**

The North Carolina chapter of NADONA is holding its 1st Quarterly Meeting of 2008 at Comfort Suites & Inn, Capitol Lodging Drive, Winston Salem, North Carolina. Located near Hanes Mall, just off Hanes Mall Blvd., January 18, 2007 from 10:00 am until 2:00 pm. The speaker, topic TBA. (CEs will likely be offered)

Room block available at $62.00/ night. Mention NC Directors of Nursing Association. Call (336)774-0805 for room reservations or directions.

Join us at the 2008 NCHCFA Trade Show. Tuesday, January 28th, 2008. The North Carolina chapter of NADONA/LTC will have a booth. Please stop by to register for our door prize and our collection of photos from the 2007 conference. Membership information and event schedule will be available.

2008 NC DONA LTC, Inc Conference dates: Sept. 17 -20; Hilton Myrtle Beach Resort. More information coming soon. Contact any officer regarding vendor exhibits, conference cost, Reservations and speaker/ presentations.

NADONA/LTC

# SCHEDULE of Events

*E-mail us with your meeting dates!*
*media@nadona.org*

February 19 - 20, 2008
North Dakota 14th Annual Meeting
This years Annual Meeting and Conference will be titled "Lessons for Leaders" and will be held at the Holiday Inn, Fargo, ND

March 6-9, 2008
AMDA- Salt Lake City Utah, for more information
www.amda.com

March 13 - 15, 2008
Cleveland Clinic's Palliative Medicine Symposium 2008 to be held on March 13-15, 2008 at The Westin-Kierland Resort & Spa in Scottsdale, Arizona.
Topics to be covered:
- GI Symptom Management
- Grief and Demoralization
- Pancreatic Cancer
- Palliative Pharmacology
- COPD from Gold Standards to Hospice

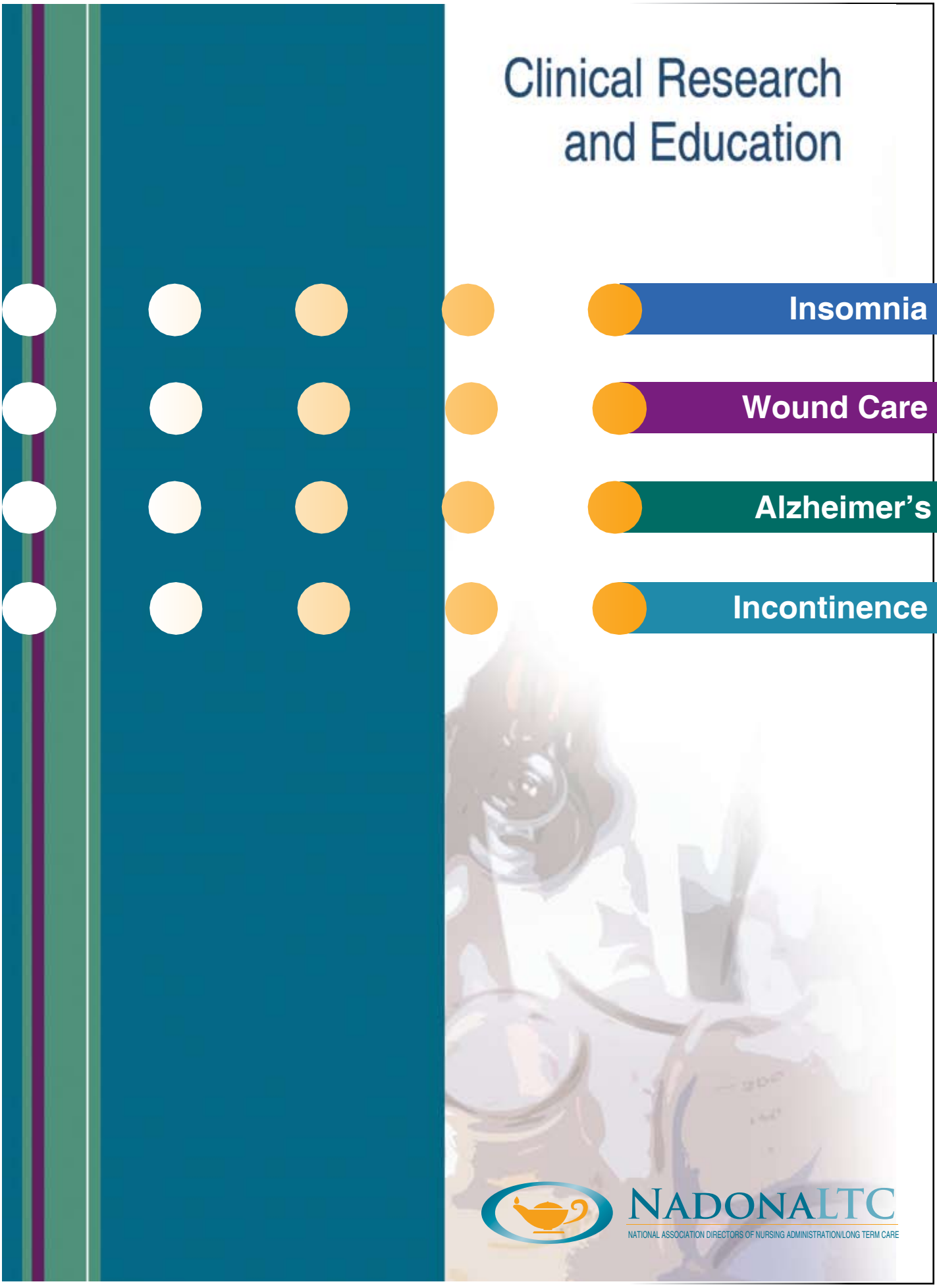
May 17 - 20, 2008
ACHCA: 2008 Annual Convocation and Exposition

**June 21-25, 2008**
**2008 NADONA/LTC National Conference**
**Opryland, Nashville, Tennessee**

## Update your member profile today . . .

**If you have moved, changed jobs, changed your phone number or e-mail address please make sure that we have been notified.**

NADONA/LTC has the capability now for instant access to you via our new e-mail blast system. If you have a current e-mail address registered with us you should have already started receiving important updates regarding NADONA/LTC. If you have not, please let us know. You can now access and update your membership information online at www.nadona.org and go to renew or join to make your changes. Or E-mail the changes to stacey@nadona.org or fax them to: 1-513-791-3699.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# Insomnia: Definition and Prevalence in the Elderly

*Sherrie Dornberger, RNC, CDONA, FACDONA*
*Gerontological Nursing Consultant*
*Mullica Hill, NJ*

Insomnia is a significant problem in the elderly. Practitioners who work with elderly individuals need to have an understanding of the condition and how to recognize it in the older adult. It is imperative that practitioners understand what insomnia is and also how it affects the elderly.

## Definition of Insomnia

Insomnia is defined as difficulty with the initiation, maintenance (which is defined as waking after sleep has been initiated, but before the desired wake time), duration, or quality of sleep that results in the impairment of daytime functioning, despite adequate opportunity and circumstances for sleep.[1] Many elderly people suffer

## Table 1. Classification of Adult Insomnia[2]

**Primary insomnia**

***Idiopathic insomnia*—**Insomnia arising in infancy or childhood with a persistent, unremitting course

***Psychophysiologic insomnia*—**Insomnia due to a maladaptive conditioned response in which the patient learns to associate the bed environment with heightened arousal rather than sleep; onset often associated with an event causing acute insomnia, with the sleep disturbance persisting despite resolution of the precipitating factor

***Paradoxical insomnia (sleep-state misperception)*—**Insomnia characterized by a marked mismatch between the patient's description of sleep duration and objective polysomnographic findings

**Secondary insomnia**

***Adjustment insomnia*—Insomnia associated with active psychosocial stressors**

**Inadequate sleep hygiene—**Insomnia associated with lifestyle habits that impair sleep

***Insomnia due to a psychiatric disorder*—**Insomnia due to an active psychiatric disorder, such as anxiety or depression

***Insomnia due to a medical condition*—**Insomnia due to a condition such as restless legs syndrome, chronic pain, nocturnal cough or dyspnea, or hot flashes

***Insomnia due to a drug or substance*—**Insomnia due to consumption or discontinuation of medication, drugs of abuse, alcohol, or caffeine

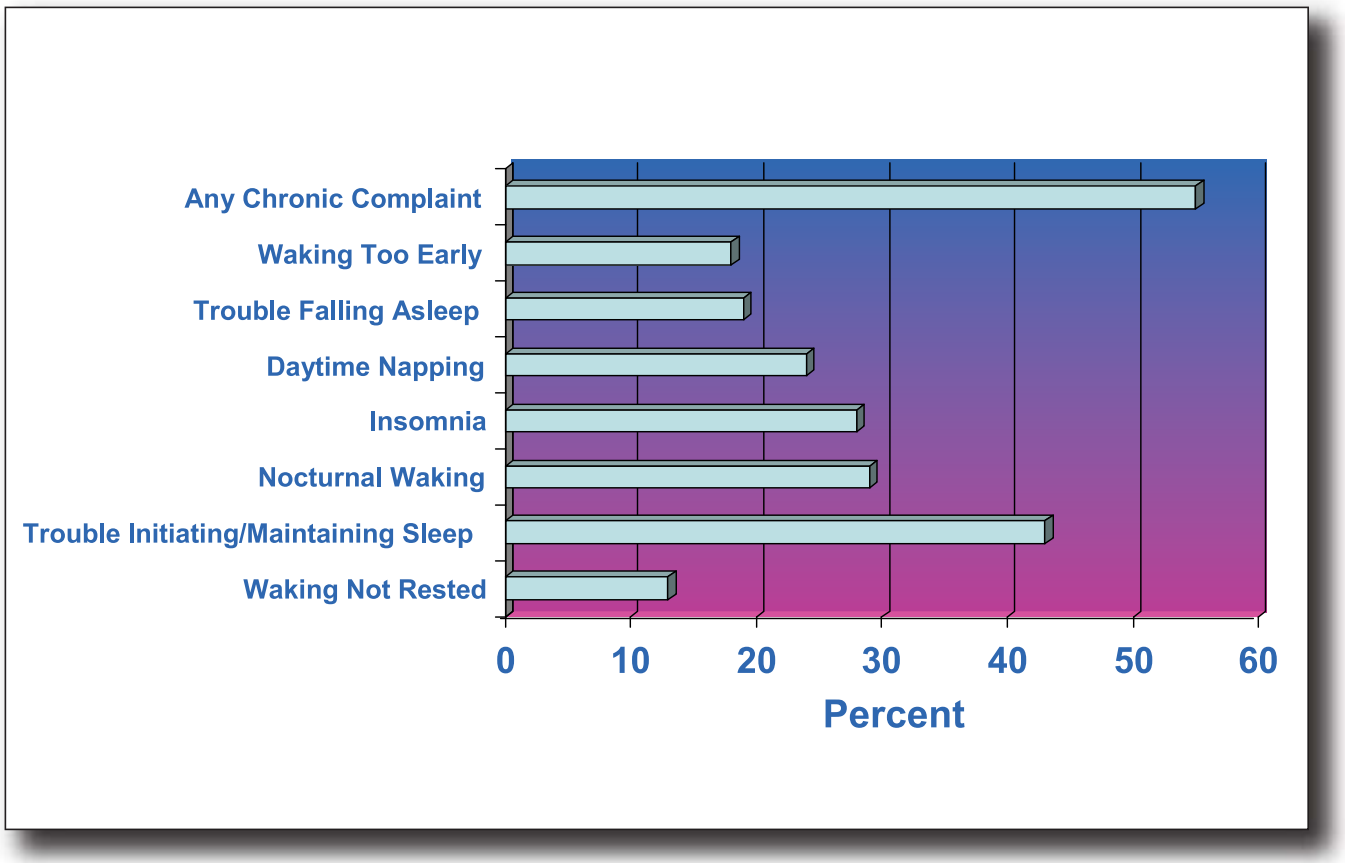
from chronic insomnia, which they believe is a natural part of the aging process. **Chronic insomnia** is insomnia that lasts for 30 days or more.[2] Chronic insomnia often leads to fatigue, mood changes, problems with interpersonal relationships, difficulty concentrating, impaired daytime functioning, and reduced quality of life.[1,3] These consequences of insomnia often prove difficult for elderly people to deal with in their day-to-day functioning. It is important to remember that a diagnosis of insomnia does not refer to just the amount of sleep, but also the quality of sleep. In clinical practice a patient's subjective judgment of sleep quality and quantity is an important factor that must be taken into careful consideration.[1]

Insomnia can be classified as either **primary** or **secondary**. The pathogenesis of **primary insomnia** is not known, but evidence points to a state of hyperarousal. Primary insomnia is classified as idiopathic, psychophysiologic, or paradoxical. **Secondary insomnia** is more commonly called comorbid insomnia, which is insomnia that results from external causes. Comorbid insomnia can be due to a psychiatric disorder, a medical condition, or a drug or substance issue. It can also occur because of inadequate sleep hygiene or adjustment. A person must be excluded or treated for secondary insomnia before a diagnosis of primary insomnia can be made[1] (Table 1).

### Prevalence of Insomnia in Community Settings

The prevalence of insomnia in the elderly population is relatively high, ranging from 18% to 48%. A 3-year longitudinal study conducted by The National Institute on Aging's Established Populations for Epidemiologic Studies of the Elderly (EPESE) found that 42% of community-dwelling seniors had difficulty falling asleep and staying asleep.[4] The 2003 National Sleep Foundation reported that among a random sample of 1508 community-dwelling patients aged 55 to 84 years living in the United

## Figure 1. Sleep Complaints in Older Adults[6]



States, 48% had 1 or more symptoms of insomnia at least a few nights a week, 18% had difficulty falling asleep, 33% reported waking "a lot" during the night, and 27% reported waking up not feeling refreshed.[5] Data on the prevalence of insomnia in older adults come from scattered studies of community settings and LTC facilities. Results from different studies are difficult to compare because of the many variables in data acquisition methodology and criteria used to define insomnia.

## Prevalence of Insomnia: Long-Term Care

In LTC settings there also are instances of underdiagnosis. Experience and drug utilization data suggest that there is a higher prevalence of insomnia in elderly patients in LTC facilities than is stated in the literature due to lack of identification or misdiagnosis. Insomnia has an impact on daily life, and if such a high percentage of the elderly population is suffering, the issue needs to be addressed. Thus, practitioners must be able to identify the signs of insomnia and understand how elderly people are impacted by the condition.

## The Importance of Identifying Insomnia

It is crucial for practitioners to understand how insomnia affects the elderly. Compared with younger adults, the elderly tend to spend more time in bed, but less time asleep. Many elderly adults have a longer sleep latency time, awaken more often, and when they do awaken, they remain awake for longer periods (Figure 1).[6] They often report diminished sleep efficiency.[7] Many elderly people develop issues with sleep and think that this is a natural part of aging. It is critical to understand that poor sleep is not inevitable as a person ages. Elderly persons may require just as much sleep as younger persons, and the fact that they sleep less can have more to do with their ability to sleep, not a lack of need for sleep. It is also crucial that elderly people, and their caregivers, understand that daytime drowsiness or early-morning awakening are not normal changes associated with aging.[8]

## Summary

There is a high prevalence of insomnia in the long-term care setting. This condition needs to be addressed because insomnia affects the quality of life of the resident. It is important for practitioners to differentiate between primary and secondary insomnia so the proper treatment can be given to residents.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*Tablet image not actual size.
For illustrative purposes only.

**References: 1.** AMBIEN CR Prescribing Information. **2.** Data on file, sanofi-aventis. **3.** Ambien Prescribing Information. **4.** Drugs@FDA. Food and Drug Administration Website. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. Accessed June 18, 2007.

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# Debridement Update for Long-Term Care Practitioners

*Pamela Scarborough, PT, MS, CE, CWS, FACCWS*

## Introduction

In chronic wounds, the ordered cellular and molecular processes that lead to healing in acute wounds have become disrupted.[1] The clinician's objective is to remove any barriers to this natural healing process. This is accomplished by assessing and preparing the wound bed and treating underlying medical conditions that may be contributing to the delay in healing. Debridement of necrotic tissue is a key component of the wound bed preparation process, which also consists of treating infection when present and managing exudate levels.[1]

Necrotic debris in the wound bed inhibits healing in several ways. The debris itself slows both the granulation process and the progression of wound contraction.[2] Perhaps more importantly, necrosis provides a fertile environment for overgrowth of bacteria. Removal of necrotic and/or infected tissue from the wound bed reduces the bacterial burden, and its metabolic byproducts, that inhibit the tissue repair process.[2, 3] Once the bacteria vying for available oxygen and nutrients are removed, adequate supply becomes available to support the work of host repair cells.[4]

In debridement, the clinician removes the necrotic debris—that is, the dead, devitalized or damaged tissue as well as particulate matter and/or foreign materials. The process of debridement is complete when 100% of the wound bed consists of sustained healthy tissue. Thus, debridement creates an environment in which the combination of normal host repair mechanisms and other wound care modalities can achieve wound healing. Debridement is the standard of care for attaining a clean and functional wound bed. Clean meaning there is no debris or infection; functional meaning cells that are stalled in terms of contributing to the healing process are stimulated to engage in the ordered cellular processes required for the wound to heal.[1] Sharp/surgical debridement and low frequency ultrasound return wounds to the early inflammatory phase of the wound healing cascade providing opportunities for chronic wounds to become more like acute wounds, which progress from the inflammatory to the proliferation phase and on to the maturation phase of wound healing once reepithelialization is achieved.

Because the pathology of chronic wounds allows necrotic tissue to accumulate, debridement of chronic wounds typically involves regular maintenance debridement rather than a single therapeutic intervention.[1] In maintenance debridement, necrotic tissue is removed as needed at each patient visit in an effort to keep the wound in a state of "readiness to heal". This maintenance approach to debridement has been associated with improved healing rates.[5]

## Assessing Patients and Wounds

In short, debridement is performed to remove necrotic tissue and/or infected tissue that is impeding wound healing. However, additional indications for debridement include fluctuance or drainage under eschar, epiboly or rolled edges which may be impairing the ability of the epithelium to migrate and close the wound, discoloration under callous formation, and callous on the neuropathic foot of patients with diabetes. While debridement is a very effective and widely used modality, it is important to assess not only the wound, but the patient as a whole before deciding to debride. It is imperative to consider patient factors, such as overall health, comorbid conditions, concomitant medications, patient preference and likely compliance, in addition to wound characteristics (type and amount of necrotic tissue and exudate, location of the wound, presence of undermining or tunneling). In addition, a pain assessment should be done prior to wound care and debridement. When performing mechanical or sharp/surgical debridement, it is often necessary to manage the pain associated with these active

debridement interventions with oral, topical or a combination of analgesic interventions.

Outright contraindications to debridement include poorly perfused tissue (i.e., eschar-covered wound in patient with arterial insufficiency) and dry gangrene. When pain control cannot be assured, the clinician may need to consider alternatives to mechanical and sharp/surgical debridement such as enzymatic and/or low frequency ultrasound. Comorbidities and concomitant medications are also important factors to consider when choosing whether to debride or choosing the type of debridement. For example, caution is required when debriding patients taking anticoagulants, and sharp debridement may be contraindicated in such cases. When writing the plan of care for wounds on the lower extremity, it is of paramount importance that vascular studies be conducted. Determining whether the patient has sufficient vascularity to support healing by feeling pedal pulses is not adequate. At minimum, clinicians should perform handheld Doppler studies. When the Doppler ankle-brachial index is abnormal or appears "too good to be true", as may be the case in patients with calcified vessels from diabetes and/or arteriosclerosis, the patient should be referred for higher level studies

## Current Debridement Options

In recent years, new technologies have entered the debridement arena, which has traditionally consisted of autolytic, enzymatic, sharp/surgical, and mechanical debridement. Autolytic debridement continues to employ moisture-retentive or moisture-donating dressings to retain the patient's endogenous enzymes capable of breaking down slough and eschar in the wound. Similarly, enzymatic debridement uses topically applied chemicals (papain-urea, papain-urea-chlorophyllin, or collagenase) capable of emulsifying necrotic tissue. Selective sharp debridement is the removal of nonviable tissue only and can be performed by medical professionals such as physicians, nurses, and therapists. Nonphysicians should receive training in safely executing debridement using sharp instruments. Surgical debridement is performed by physicians (MD, DO, DPM) using surgical instruments, laser, or a hydrosurgery system where they remove nonviable and, if deemed appropriate, damaged viable tissue. Biosurgery is the use of maggots for removal of necrotic tissue. We now have medical grade sterile maggots that are receiving more attention as of late in the United States.

It is among the mechanical debridement modalities that newer technologies offer an alternative to the use of mechanical force, such as scrubbing, wet-to-dry dressings, or hydrotherapy (e.g. whirlpool, pulsed lavage, wound irrigation), to loosen and dislodge necrotic tissue. Low-frequency ultrasound energy, rather than mechanical force, is now available as another method to loosen and remove necrotic slough and eschar.

## Utilizing Ultrasound Energy for Debridement and Wound Healing

Ultrasound is well known for its diagnostic value in fetal monitoring and its therapeutic applications in physical therapy, physical medicine, rehabilitation, and sports medicine. These traditional ultrasound applications use high-frequency ultrasound energy (1 – 3 MHz and involve contact between the ultrasound transducer and the skin via a conduction medium such as a conduction gel or immersed in water. The ultrasound therapies developed for wound care deliver low-frequency (25-40 kHz), nonthermal ultrasound waves to the wound bed via either a solution (contact low-frequency ultrasound) or a fine saline mist (noncontact low-frequency ultrasound).

Low-frequency ultrasound is particularly helpful for removing densely adherent fibrin, biofilm layers, and necrosis that is harboring infection, including resistant organisms. It is a good alternative for wounds that are difficult to debride by nonsurgical methods or for patients with wounds that pose a surgical risk (e.g., patients taking anticoagulants). Given the ability of ultrasound energy to penetrate deep tissue, it can also assist in debriding areas of undermining and tunneling that are not easily or effectively reached with irrigation or sharp debridement.

The contact low-frequency ultrasound systems are effective primary debridement devices that use ultrasound vibration and irrigation solution to cut away necrotic tissue and

cleanse wounds. With these devices, the irrigation solution comes in direct contact with the wound surface. The three devices available in this category are the Soring Sonoca 180®, the Misonix SonicOne®, and the recently introduced Qoustic Wound Therapy System™ from Arobella Medical. The Sonoca 180 is indicated for selected dissection and fragmenting of tissue at the operation site during surgery, including general, neurologic, thoracic, urologic, and gastrointestinal surgeries. The SonicOne is indicated for debridement of wounds (including burns, diabetic ulcers, bedsores, and vaginal ulcers), soft tissues, and cleansing surgical sites. The Qoustic Wound Therapy System™ is indicated for selective dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased, or necrotic tissue), and cleansing irrigation to remove debris, exudates, fragments, and other matter. Unfortunately, the published evidence supporting these contact low-frequency ultrasound devices for primary debridement is limited to a few case series articles and abstracts.[6, 7] There is one poster abstract from Brooke Army Medical Center in San Antonio, Texas that describes in vitro evidence of a bactericidal effect of the Sonoca 180. Although clinical anecdotes are favorable for these devices, more research is needed.

The one noncontact low-frequency ultrasound device on the market, the MIST Therapy® System from Celleration, Inc., is indicated to promote wound healing through cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates, and bacteria. MIST Therapy delivers ultrasound energy to the wound tissues via an atomized, sterile saline mist (i.e., there is no solution flushed through the wound) without the device touching the wound. The published literature demonstrating improved healing with MIST Therapy includes two randomized, controlled trials as well as two prospective, nonrandomized clinical studies. MIST Therapy has been shown to improve healing time in chronic diabetic foot ulcers,[8] wounds complicated by chronic critical limb ischemia,[9] and lower extremity wounds of varying etiology.[10, 11] In addition, it has been shown to destroy the cell walls of Staphylococcus aureus, Pseudomonas aeruginosa, methicillin-resistant Staphylococcus aureus, and vancomycin-resistant enterococci, as demonstrated by scanning and transmission electron micrographs.[11] In one small, retrospective study, patients with painful wounds reported statistically significant reductions in wound pain after starting MIST Therapy.[12] In the absence of prospective research on pain outcomes, one can only speculate as to the reasons for this potential palliative effect (for example, it may be related to the noncontact nature of this therapy). More research in this area would be meaningful and welcome for both patients with and clinicians treating painful wounds.

The wound healing effects of low-frequency ultrasound appear to stem from the activity of ultrasound energy and acoustic vibration at a cellular level. Two effects, in particular, appear to have important implications for wound cleansing and healing: cavitation and microstreaming. Cavitation refers to the production and acoustic vibration of micron-sized bubbles in the fluids present in wound tissues.[13] Microstreaming refers to the unidirectional movement of fluids along acoustic boundaries, such as cell membranes.[14, 15] Together, these two processes provide mechanical energy that can alter cell membrane activity in ways that may loosen necrotic tissue and stimulate cellular processes necessary for healing.[16] Much the same way that the negative pressure applied via negative pressure wound therapy has been shown to cause fibroblast cells to elongate and enter a proliferative state, [17-19] it appears the acoustic pressure of ultrasound energy puts a shear stress on cells that may produce the same effect. More research is needed, however, to fully understand the mechanisms by which low-frequency ultrasound stimulates cells.

## Conclusion

As the primary step in wound bed preparation, debridement of chronic wounds lays the groundwork for healing to begin. Low-frequency ultrasound energy is a welcome addition to the treatment of chronic wounds thanks to its contribution to achieving the objectives of debridement - creating a clean and functional wound bed.

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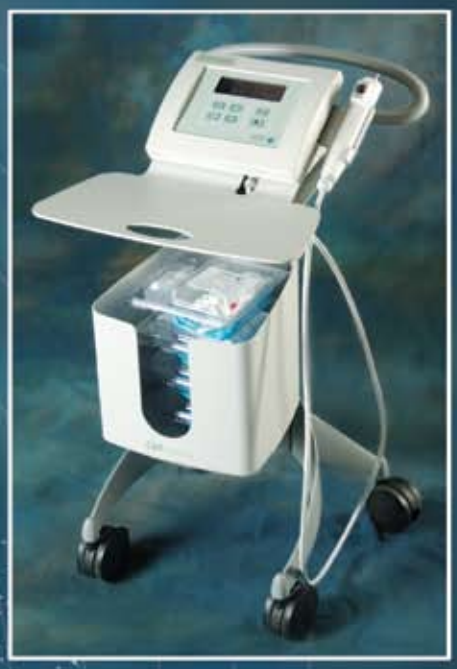

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# Discontinuing Alzheimer's Disease Drug Therapy: Why, When, and How

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Dementia and Alzheimer's disease (AD) are among the most common diseases seen in long-term care facilities. They affect approximately 8-10% of individuals over the age of 65 years and up to 40% of those over 85 years old.[1,2] The prevalence of dementia and AD are even higher in skilled nursing facilities, with prevalence rates reported to be between 25-74%.[3-5] Cognitive dysfunction is the most common cause for admission into a skilled nursing facility.[2]

**Table 1**
Commonly Prescribed Agents for Alzheimer's Disease

| Drug | Indication | Starting Dose | Effective Dose | Maximum Dose |
|---|---|---|---|---|
| Donepezil (Aricept®) | Mild-severe AD | 5 mg QD | 5 mg QD | 10 mg QD |
| Rivastigmine (Razadyne®) | Mild-moderate AD | 1.5 mg BID | 3 mg BID | 6 mg BID |
| Galantamine (Exelon®) | Mild-moderate AD | 8 mg QD | 16 mg QD | 24 mg QD |
| Memantine (Namenda®) | Moderate-severe AD | 5 mg QD | 10 mg BID | 10 mg BID |

## Available Therapies

Currently there are no treatments that can stop or reverse the progression of the disease. There are non-pharmacologic approaches, such as education on the condition and environmental and lifestyle modifications that can be used to maintain a person's activities of daily living and quality of life. However, the only option available to slow the progression of dementia and AD is drug therapy.

There are 5 drugs approved for use in the United States for the management of AD, with 4 being readily available for use.[2] Table 1 provides a list of the four most commonly used medications.[2] The first agent approved to treat AD in the United States, tacrine, is not listed in this table because of its very limited availability due to hepatotoxicity and four times a day dosing.

The first three agents in Table 1—donepezil, rivastigmine, galantamine—are all acetylcholinesterase inhibitors (AChEIs). Acetylcholine receptors have an important role in memory retention. Research has shown that with progression of AD, acetylcholine receptor activity decreases. Acetylcholinesterase is an enzyme that breaks down acetylcholine. These AChEI agents work by blocking acetylcholinesterase, thereby preventing the breakdown of acetylcholine in the neuronal space or synapse.[6] Each of these agents is a little different in its pharmacology, pharmacokinetics and pharmacodynamics, but all have been shown to slow the progression of AD. [6]

Of the 3 agents previously mentioned, only 1—donepezil—has been approved for the management of mild, moderate, and severe AD.[7] The other 2—rivastigmine and galantamine—have been approved for mild and moderate AD only.[8,9] All of these agents are well tolerated, but are associated with adverse events, including nausea, vomiting, diarrhea, abdominal pain, and dizziness.[6] The clinical data has shown that the rate of adverse events increases with higher doses.[6]

The fourth agent in Table 1, memantine, is an N-Methyl-D-aspartate (NMDA) receptor antagonist. It is believed that with AD there is chronic overstimulation of glutamatergic NMDA receptors, which results in neuron death.[6] Memantine is thought to block this overstimulation and control NMDA activity. Like the AChEIs, memantine has been shown to delay cognitive and functional decline associated with

AD. Memantine is approved for the management of moderate to severe AD.[10] The most common adverse events associated with memantine are dizziness, confusion, headache and constipation.[10]

Other agents have been studied in the management of AD including Vitamin E, Vitamin C, hormone replacement therapy, nonsteroidal anti-inflammatory agents, and lipid-lowering agents. To date, no studies have shown these agents to reduce the progression of AD.[6]

## What if the initial therapy is ineffective?

A Mini-Mental State Exam (MMSE) is generally used to assess effectiveness. Clinical guidelines have noted, though, that mental status exams may not measure the full extent of medication effectiveness.[2,11] Studies have shown that when an AChI agent has been discontinued, some patients may not reach baseline cognition values even if the AD medication is reintroduced, therefore it is important for these medications be used for 6 to 12 months to assess cognition and functional effectiveness.[11,12,13]

If initial therapy is determined to be ineffective or cannot be tolerated, there are several clinical strategies available. If the issue is a lack of efficacy, one option is to increase to the largest dose that is tolerated by the resident. It is very important that the resident be monitored closely for signs of adverse events which are more common in the elderly and at higher doses.[14]

Slight worsening of cognitive function should be assessed to determine whether this is due to the disease or co-morbid condition such as infection. Management of this comorbidity may result in improved management of the resident's AD.[14]

If a lack of efficacy or tolerability is the primary problem, switching to another agent is an option. If the resident is currently on an AChEI, this does not preclude switching to a different AChEI. Intolerance to one AChEI does not mean there will be intolerance to a different agent in the same class. Another switch alternative is to test memantine on a resident with moderate to severe AD if the AChEI agent is not effective. When a new agent is initiated, an adequate trial for 3 to 6 months should be given before determining effectiveness.[14]

A third option is combining an AChEI and memantine.[14,15] Combination therapy has been shown to effectively slow the progression of AD and also requires lower doses of both agents. In addition to effectiveness, patients receiving the combination therapy have been shown to stay on this therapy longer than single agent therapy.[15] In combination therapy, memantine should be initiated at 5pm once daily with or without food and titrate up 5-10 mg at a minimum of weekly intervals up to a total daily dose of 20 mg/day (10mg bid).[10]

## When should therapy be discontinued?

As noted at the 2004 Primary Consensus Conference on Alzheimer's Disease, during end stage disease it is the determination of the family, caregivers, and healthcare providers to assess and decide if drug therapy should be continued.[14]

There are primarily 4 reasons why drug therapy should be discontinued in the management of AD. They are as follows:[11]

- Resident has failed attempts at monotherapy with at least two agents or combination therapy
- Resident has demonstrated loss of clinical effect with noted deterioration in cognitive function
- Resident is intolerant to therapy even at lowest doses
- Resident deteriorates to the point where there is no significant effect on quality of life as determined by caregiver or designated healthcare provider

Criteria proposed by the Alzheimer's Disease Management Council Consensus Panel and Scientific Roundtable for discontinuing drug therapy include:

- Discontinuation after 6 months when there is no noted improvement in cognition or when the mini-mental examination (MMSE) score is less than 10 points
- Physician's judgment
- Discontinuation if after 6 to 12 months of treatment, deterioration occurs at the pretreatment rate

It was noted by this group that discontinuation is not necessarily supported with an MMSE <10 because evidence-based medicine has shown substantial benefit in nursing home residents on therapy.

## How to Discontinue AD Therapy

Deciding to discontinue AD therapy may be difficult for the

resident, family, and provider. Little research has been done regarding the long-term impact on cognition when an AChEI or memantine is discontinued.[16] There are no definitive recommendations on how to discontinue therapy, but general recommendation would be to discontinue therapy for up to 4 weeks and monitor for signs of deterioration in cognitive function.[16] If these signs are noted, a decision to reinitiate therapy will need to be made. If no changes or slight changes are noted, the AD agents may be permanently discontinued. This decision should include all people involved with the resident's care.[16]

There have been little data in the clinical literature to support a gradual dose reduction of an AChEI agent or memantine when the decision has been made to discontinue therapy. Generally, the agent(s) are just stopped.[16] Gradual dose reductions without intent to stop the medication is not appropriate, unless the patient does not tolerate a higher dose.

## Summary

Drug therapy is an important component in the management of AD. The agents discussed do not stop or reverse the disease, but can slow its progression. There are currently 3 AChEIs and memantine available to treat AD. Generally, one agent is started and increased up to a maximum dose. If this agent is not effective or not tolerated, another agent is substituted. Combination therapy with an AChEI and memantine is another option that has shown effectiveness in managing AD. Therapy is generally discontinued if these agents prove to be ineffective or are not tolerated. The decision to stop therapy should involve the resident, family, caregivers, and providers.

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# The MATRIX Study: Assessment of Health-Related Quality of Life in Adults With the Use of Transdermal Oxybutynin

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There is a high prevalence of overactive bladder (OAB) in the elderly population, with clinical studies estimating approximately 33 million adults diagnosed with this condition in the United States.[1,2] Symptoms of OAB include urinary urgency, an intense, sudden, and usually uncontrollable urge to urinate; frequency, which is defined as voiding more than 8 times within a 24-hour period; nocturia, which is awakening twice or more at night to urinate; and, in most cases, urge urinary incontinence (UI), which occurs after urgency. Within this segment of adults with OAB, an estimated 17 million suffer from UI.[3] This condition has significant impact on long-term care settings, with the prevalence of UI increasing with age. Studies have reported an occurrence rate of greater than 50% in skilled nursing facilities, with UI being the second leading cause of institutionalization of the elderly.[4] A large percentage of people admitted to residential facilities "arrive" with UI.[5]

OAB and UI impair health-related quality of life (HRQoL) and may affect not just the individual, but also caregivers and the facility in which the person resides.[6,7] This condition may have negative physical, psychological, and social effects on a resident. Facilities have options to treat OAB and UI, including behavioral and drug therapy options, but primarily manage urine leakage through the use of containment products and devices. The Centers for Medicare and Medicaid Services (CMS) surveyor guidance for incontinence and urinary catheter use requires long-term care facilities to have in place systems/procedures to assure that appropriate interventions are defined, implemented, monitored, and revised as appropriate in accordance with current standards of practice.[8] This makes it important for nursing staff to understand all appropriate interventions in elderly populations.

Studies have demonstrated the effectiveness of antimuscarinic agents (overactive bladder medications), such as oral tolterodine and oral oxybutynin to improve OAB and UI; however, there are limited data on the effectiveness of these agents in improving HRQoL. A list of these medications is found in Table 1.[9-14]

**Table 1**
Drugs for Urge UI/OAB

| Type | Dosage |
|---|---|
| ***Transdermal*** | |
| Oxybutynin (OXYTROL®) | 3.9 mg twice/week |
| ***Oral*** | |
| Oxybutynin | |
| Ditropan® | 5 mg tablet (BID-TID) |
| Ditropan XL® | 5, 10, 15 mg (QD) |
| Tolterodine | |
| Detrol® | 1, 2 mg (BID) |
| Detrol® LA | 2, 4 mg (QD) |
| Trospium (Sanctura®) | 20 mg (BID) |
| Solifenacin (VESIcare®) | 5, 10 mg (QD) |

A large clinical study, known as the Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin Transdermal, was undertaken to evaluate the effectiveness of transdermal oxybutynin (OXY-TDS) in improving HRQoL in a community-based adult population.[15] A significant number of study participants had some of the same characteristics as those residing in long-term care settings. This article and subsequent articles will provide an overview of the MATRIX study.

## Study Participants and Methods

MATRIX was an open-label, multicenter, community-based study that enrolled men and women diagnosed with OAB. Participants were required to meet the following criteria:

- ≥18 years of age
- At least 1 symptom of OAB, such as urge UI, urgency, and/or frequency
- Willing to discontinue all prescription and over-the-counter OAB medications
- Capable of completing an HRQoL questionnaire with no assistance

Participants were excluded if oxybutynin was contraindicated; if they had 1 or more treatable conditions that may cause OAB symptoms; if they had previously received OXY-TDS; or if they resided in a long-term care facility.

All participants received OXY-TDS 1 patch twice weekly for up to 6 months. Participants were evaluated at baseline upon completion of HRQoL surveys that are commonly used in persons with OAB and UI. These included the Kings Health Questionnaire and assessment of OAB severity using the Patient Perception of Bladder Condition—an assessment tool that rates the bladder condition on a scale of 1 (no problems) to 6 (severe problems). At the time of baseline assessment, participants were initiated on OXY-TDS. Baseline demographics and a medical history were also performed at this time.

Participants were randomized into 2 groups based on the education they received at the time of baseline evaluation and initiation of OXY-TDS therapy. One group received standard instruction for medication use; the other group received a detailed educational intervention, including informative booklets about behavioral treatments (eg, diet and fluid modification) and dosing reminders.

Follow-up assessments, which included evaluation for adverse events and concomitant medications, took place at 1, 3, and 6 months. At 3 months, the Kings Health Questionnaire and Patient Perception of Bladder Condition were again performed. If a participant withdrew from the study early, these assessments were performed once more at the time of discontinuation.

The primary outcomes evaluated were:

- HRQoL as determined by the results of the Kings Health Questionnaire
- Safety of OXY-TDS
- Effectiveness of OXY-TDS as determined by the results of the Patient Perception of Bladder Condition.

## Overall Results

A total of 2888 participants from various medical practices were recruited for the study. Of this group, 2878 met the study's safety evaluation criteria; 2593 met the criteria for evaluating the efficacy portion of the study (HRQoL and Patient Perception of Bladder Condition). Table 2 provides an overview of the population studied.

**Table 2**
Selected Participant Characteristics

| Selected Characteristic | Value, (%) |
|---|---|
| ***Age (years), n = 2875*** | |
| Mean (SD) | 62.5 (14.8) |
| Median (range) | 63.0 (18-100) |
| Patients ≥ 75 years old, n (%) | 699 (24.3) |
| ***Gender, n (%), n = 2877*** | |
| Female | 2508 (87.2) |
| Male | 369 (12.8) |
| ***Comorbid Diseases, n (%), n = 2878*** | |
| Cardiovascular diseases | 1593 (55.4) |
| Musculoskeletal | 1575 (54.7) |
| Gastrointestinal | 1269 (44.1) |
| Neurological/psychiatric | 1048 (36.4) |
| Endocrine | 1037 (36.0) |
| Respiratory | 666 (23.1) |

Of the entire study population, a significant segment—699 participants (24.3%)—were aged ≥75 years. Many participants had comorbidities, including cardiovascular disease (55.4%), musculoskeletal disease (54.7%), gastrointestinal disease (44.1%), neurological/psychiatric conditions (36.4%), and endocrine disorders (36.0%).

Table 3 shows that most participants had OAB for many years, reporting a history of 2 years or more (69.4%), with almost half (46.4%) experiencing symptoms for 4 years or more. Prior to the study, most participants (78.1%) rated their OAB as moderate or worse, based on the Patient Perception of Bladder Condition

scale. It is interesting to note that more than half of the participants had previously tried another OAB drug to manage their symptoms. These drugs were discontinued, primarily due to a lack of efficacy (53.2%) and adverse effects (22.3%).

**Table 3**
Selected Participant Characteristics

| Selected Characteristic | Value, n (%) |
|---|---|
| ***History of OAB Symptoms, years, n = 2876*** | |
| < 1 | 346 (12.0) |
| 1 to <2 | 533 (18.5) |
| 2 to <4 | 663 (23.1) |
| ≥ 4 | 1334 (46.4) |
| ***Overall OAB severity, n = 2626*** | |
| 1-no problems | 46 (1.8) |
| 2-very minor problems | 120 (4.6) |
| 3-minor problems | 407 (15.5) |
| 4-moderate problems | 867 (33.0) |
| 5-severe problems | 747 (28.4) |
| 6-many severe problems | 438 (16.7) |
| ***History of previous OAB treatment, n = 2859*** | |
| Yes | 1632 (57.1) |
| No | 1227 (42.9) |
| ***Primary reason for stopping previous OAB treatment, n = 2854*** | |
| Ineffective | 1233 (53.2) |
| Adverse events | 516 (22.3) |
| Compliance | 178 (7.7) |
| Unknown | 352 (15.2) |
| Other | 37 (1.6) |

At baseline, most participants rated their overall health as good or very good (74.2%) based on the Kings Health Questionnaire. Even with good health, most participants noted that their OAB affected their lives. Figure 1 shows the change in Kings Health Questionnaire scores from baseline to end of study.

Clinically significant improvement was noted in all parameters in the Kings Health Questionnaire, except general health perception. The greatest improvements were seen in role limitations, emotions, and personal relationships. Researchers noted that a lack of clinical improvement in general health perception is not unusual since this questionnaire is not disease-state specific. Thus, the perceived lack of improvement could be due to other comorbid conditions common in these study participants.

A significantly (P<0.001) greater proportion of study

**Figure 1**
Mean Changes in Kings Health Questionnaire from Baseline to Study End. The percentage improvement in KHQ domain scores from baseline to the end of study. All P ≤ 0.001(one-sample, two-tailed t-test)

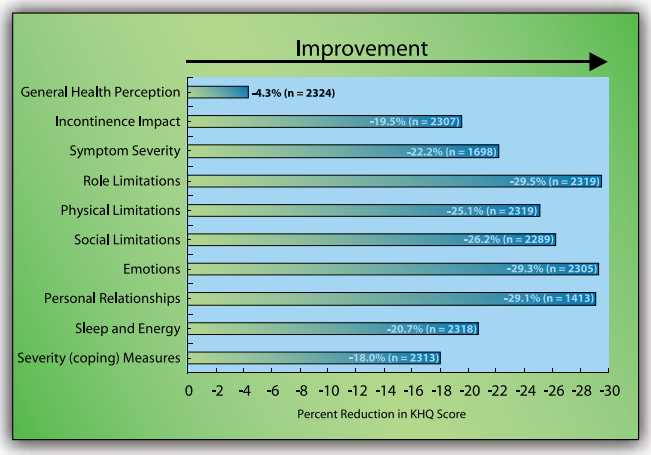


**Figure 2**
The percentage of participants with improvement or worsening from baseline to study end on individual items within selected KHQ domains. *P < 0.001 (K test of symmetry).

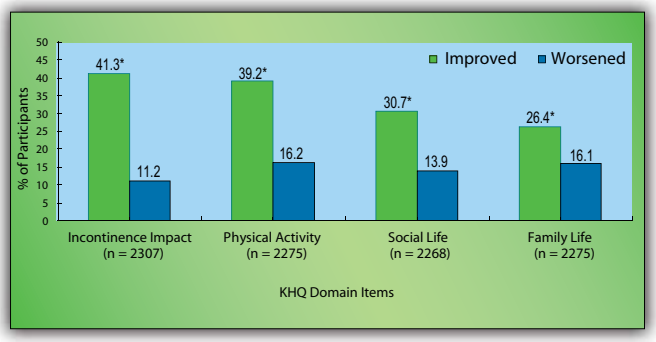


**Table 4**
Drug-related AE's Occurring in ≥ 2% of 2878 Participants

| Adverse Event | Participants, % |
|---|---|
| Application-site reactions | 14.0 |
| Pruritus* | 4.9 |
| Erythema* | 4.6 |
| Dermatitis* | 4.4 |
| Irritation* | 3.2 |
| Other* | 2.0 |
| **Rash** | 3.0 |
| **Dry mouth** | 2.6 |
| **General pruritus** | 2.6 |
| **Skin irritation** | 2.1 |

**The sum of these individual application-site reactions does not equal the percentage of participants who had any application-site reaction (14.0%) because participants could have had more than one type of reaction.*

participants reported improvement rather than worsening on all individual responses under KHQ domains. Figure 2 shows the improvement in selected domains.

No differences were noted in the Kings Health Questionnaire between those receiving standard instruction versus those with an educational intervention.

## Adverse Events

Table 4 provides a summary of the incidence and type of adverse events or side effects reported with the use of OXY-TDS. Thirty percent of participants that received at least 1 dose of OXY-TDS reported an adverse event, the most common being mild to moderate skin reaction at the site of the patch. The incidence of common anticholinergic adverse events was low, with dry mouth reported in 2.6% of participants. All other anticholinergic adverse events were noted in fewer than 2% of participants. This incidence is lower than that reported with other OAB medications.

Among all participants, 16.5% (n = 475) discontinued OXY-TDS due to adverse events.

## Summary

This article provides an overview of the results of the MATRIX study. Subsequent articles will provide more detailed results of other findings in this study.

Overall, this study found that OXY-TDS administration resulted in improvement in HRQoL, with the medication having its greatest effect on the impact of incontinence, severity of symptoms, and role limitations. OXY-TDS was well tolerated, with a low prevalence of anticholinergic adverse events noted.

The next article will focus on results in populations older than 65 years and in those older than 80 years.

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* Plasma concentrations measured after second application (96 hours) of OXYTROL® 3.9 mg/day in 13 subjects.[2]

In Phase 3 clinical studies of OXYTROL®, 49% of patients were 65 years and older. There were no overall differences in safety and effectiveness between older and younger patients, but greater sensitivity of some older individuals cannot be ruled out.[1]

OXYTROL® is the only transdermal system that delivers the power of oxybutynin to treat overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency with the incidence of anticholinergic adverse events not significantly different than placebo.

### Important Safety Information

The most commonly reported adverse events were application site reactions, dry mouth, constipation, diarrhea, dysuria, and abnormal vision. OXYTROL® is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients who are at risk for these conditions. OXYTROL® is also contraindicated in patients who have demonstrated hypersensitivity to oxybutynin or other components of the product. OXYTROL® should be administered with caution in the following patients: those with hepatic or renal impairment; clinically significant bladder outflow obstruction; gastrointestinal obstructive disorders because of the risk of gastric retention; patients with gastroesophageal reflux.

Please see adjacent brief summary of full Prescribing Information.

**References: 1.** OXYTROL full Prescribing Information, Watson Pharma, Inc. **2.** Data on file, Watson Pharma, Inc.

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OXYTROL®
Oxybutynin Transdermal System

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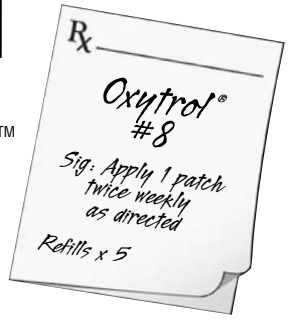


For more information, call **1-888-OXYTROL (1-888-699-8765)** or visit us online at **www.oxytrol.com**.

**BRIEF SUMMARY: Please see package insert for full prescribing information.**

**INDICATIONS AND USAGE**
**OXYTROL** is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

**CONTRAINDICATIONS**
**OXYTROL** is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients who are at risk for these conditions. **OXYTROL** is also contraindicated in patients who have demonstrated hypersensitivity to oxybutynin or other components of the product.

**PRECAUTIONS**
**General**
**OXYTROL** should be used with caution in patients with hepatic or renal impairment.

*Urinary Retention:* **OXYTROL** should be administered with caution to patients with clinically significant bladder outflow obstruction because of the risk of urinary retention (see **CONTRAINDICATIONS**).

*Gastrointestinal Disorders:* **OXYTROL** should be administered with caution to patients with gastrointestinal obstructive disorders because of the risk of gastric retention (see **CONTRAINDICATIONS**).

**OXYTROL**, like other anticholinergic drugs, may decrease gastrointestinal motility and should be used with caution in patients with conditions such as ulcerative colitis, intestinal atony, and myasthenia gravis. **OXYTROL** should be used with caution in patients who have gastroesophageal reflux and/or who are concurrently taking drugs (such as bisphosphonates) that can cause or exacerbate esophagitis.

**Information for Patients**
Patients should be informed that heat prostration (fever and heat stroke due to decreased sweating) can occur when anticholinergics such as oxybutynin are used in a hot environment. Because anticholinergic agents such as oxybutynin may produce drowsiness (somnolence) or blurred vision, patients should be advised to exercise caution. Patients should be informed that alcohol may enhance the drowsiness caused by anticholinergic agents such as oxybutynin.

**OXYTROL** should be applied to dry, intact skin on the abdomen, hip, or buttock. A new application site should be selected with each new system to avoid re-application to the same site within 7 days. Details on use of the system are explained in the patient information leaflet that should be dispensed with the product.

**Drug Interactions**
The concomitant use of oxybutynin with other anticholinergic drugs or with other agents that produce dry mouth, constipation, somnolence, and/or other anticholinergic-like effects may increase the frequency and/or severity of such effects. Anticholinergic agents may potentially alter the absorption of some concomitantly administered drugs due to anticholinergic effects on gastrointestinal motility. Pharmacokinetic studies have not been performed with patients concomitantly receiving cytochrome P450 enzyme inhibitors, such as antimycotic agents (e.g. ketoconazole, itraconazole, and miconazole) or macrolide antibiotics (e.g. erythromycin and clarithromycin). No specific drug-drug interaction studies have been performed with **OXYTROL**.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**
A 24-month study in rats at dosages of oxybutynin chloride of 20, 80 and 160 mg/kg showed no evidence of carcinogenicity. These doses are approximately 6, 25 and 50 times the maximum exposure in humans taking an oral dose based on body surface area.

Oxybutynin chloride showed no increase of mutagenic activity when tested in *Schizosaccharomyces pompholiciformis, Saccharomyces cerevisiae,* and *Salmonella typhimurium* test systems. Reproduction studies with oxybutynin chloride in the mouse, rat, hamster, and rabbit showed no definite evidence of impaired fertility.

**Pregnancy: Teratogenic Effects**
***Pregnancy Category B***
Reproduction studies with oxybutynin chloride in the mouse, rat, hamster, and rabbit showed no definite evidence of impaired fertility or harm to the animal fetus. Subcutaneous administration to rats at doses up to 25 mg/kg (approximately 50 times the human exposure based on surface area) and to rabbits at doses up to 0.4 mg/kg (approximately 1 times the human exposure) revealed no evidence of harm to the fetus due to oxybutynin chloride. The safety of **OXYTROL** administration to women who are or who may become pregnant has not been established. Therefore, **OXYTROL** should not be given to pregnant women unless, in the judgment of the physician, the probable clinical benefits outweigh the possible hazards.

**Nursing Mothers**
It is not known whether oxybutynin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **OXYTROL** is administered to a nursing woman.

**Pediatric Use**
The safety and efficacy of **OXYTROL** in pediatric patients have not been established.

**Geriatric Use**
Of the total number of patients in the clinical studies of **OXYTROL**, 49% were 65 and over. 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 response between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out (see **CLINICAL PHARMACOLOGY, Pharmacokinetics, *Special Populations: Geriatric*** in the full prescribing information).

**ADVERSE REACTIONS**
The safety of **OXYTROL** was evaluated in a total of 417 patients who participated in two Phase 3 clinical efficacy and safety studies and an open-label extension. Additional safety information was collected in Phase 1 and Phase 2 trials. In the two pivotal studies, a total of 246 patients received **OXYTROL** during the 12-week treatment periods. A total of 411 patients entered the open-label extension and of those, 65 patients and 52 patients received **OXYTROL** for at least 24 weeks and at least 36 weeks, respectively.

No deaths were reported during treatment. No serious adverse events related to treatment were reported.

Adverse events reported in the pivotal trials are summarized in Tables 4 and 5 below.

Table 4: Number (%) of adverse events occurring in ≥ 2% of **OXYTROL**-treated patients and greater in **OXYTROL** group than in placebo group (Study 1).

| Adverse Event* | Placebo (N=132) | | OXYTROL (3.9 mg/day) (N=125) | |
|---|---|---|---|---|
| | N | % | N | % |
| Application site pruritus | 8 | 6.1% | 21 | 16.8% |
| Dry mouth | 11 | 8.3% | 12 | 9.6% |
| Application site erythema | 3 | 2.3% | 7 | 5.6% |
| Application site vesicles | 0 | 0.0% | 4 | 3.2% |
| Diarrhea | 3 | 2.3% | 4 | 3.2% |
| Dysuria | 0 | 0.0% | 3 | 2.4% |

*includes adverse events judged by the investigator as possibly, probably or definitely treatment-related.

Table 5: Number (%) of adverse events occurring in ≥ 2% of **OXYTROL**-treated patients and greater in **OXYTROL** group than in placebo group (Study 2).

| Adverse Event* | Placebo (N=117) | | OXYTROL (3.9 mg/day) (N=121) | |
|---|---|---|---|---|
| | N | % | N | % |
| Application site pruritus | 5 | 4.3% | 17 | 14.0% |
| Application site erythema | 2 | 1.7% | 10 | 8.3% |
| Dry mouth | 2 | 1.7% | 5 | 4.1% |
| Constipation | 0 | 0.0% | 4 | 3.3% |
| Application site rash | 1 | 0.9% | 4 | 3.3% |
| Application site macules | 0 | 0.0% | 3 | 2.5% |
| Abnormal vision | 0 | 0.0% | 3 | 2.5% |

*includes adverse events judged by the investigator as possibly, probably or definitely treatment-related.

Other adverse events reported by > 1% of **OXYTROL**-treated patients, and judged by the investigator to be possibly, probably or definitely related to treatment include: abdominal pain, nausea, flatulence, fatigue, somnolence, headache, flushing, rash, application site burning and back pain.

Most treatment-related adverse events were described as mild or moderate in intensity. Severe application site reactions were reported by 6.4% of **OXYTROL**-treated patients in Study 1 and by 5.0% of **OXYTROL**-treated patients in Study 2.

Treatment-related adverse events that resulted in discontinuation were reported by 11.2% of **OXYTROL**-treated patients in Study 1 and 10.7% of **OXYTROL**-treated patients in Study 2. Most of these were secondary to application site reaction. In the two pivotal studies, no patient discontinued **OXYTROL** treatment due to dry mouth.

In the open-label extension, the most common treatment-related adverse events were: application site pruritus, application site erythema and dry mouth.

**DOSAGE AND ADMINISTRATION**
**OXYTROL** should be applied to dry, intact skin on the abdomen, hip, or buttock. A new application site should be selected with each new system to avoid re-application to the same site within 7 days.

The dose of **OXYTROL** is one 3.9 mg/day system applied twice weekly (every 3 to 4 days).

**HOW SUPPLIED**
**Storage**
Store at 25°C (77°F); excursions permitted to 15 - 30°C (59 - 86°F). Protect from moisture and humidity. Do not store outside the sealed pouch. Apply immediately after removal from the protective pouch. Discard used **OXYTROL** in household trash in a manner that prevents accidental application or ingestion by children, pets, or others.

**Rx only**

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DATE OF ISSUANCE: FEBRUARY 2003

# CULTURE CHANGE

## What Is It and How to Get Started

**Culture Change initiatives do not have to be expensive or exhausting. What matters most is that a nursing home empowers those who work there to create a new and living focus on the resident as the center of everything they do.**

*Betty MacLaughlin Frandsen*
*RN, NHA, BSHCA, CDONA/LTC*

When Culture Change first became a topic of interest, there was confusion about its real meaning, and for many that confusion remains, especially if those individuals have no first-hand exposure to this initiative. Some think Culture Change merely requires an increased emphasis on cultural diversity or on changing to a more professional business culture. Others believe it requires extensive and expensive structural changes to create a more appealing environment. While those things may be part of a nursing home's journey to improvement, the reality is that Culture Change is primarily concerned with a renewed focus on the resident as the center of all activity that occurs within the nursing home setting.

Whether a nursing center spends significant renovation money to create small households or merely implements new and more person-centered ways of delivering care to residents, Culture Change is a personalized journey for each setting in which it is implemented. True Culture Change cannot be replicated by following a prescribed formula or through the use of "cookie cutter" type programs. It comes from the collective heart of those who live and work together.

The Culture Change movement as we know it grew out of an early Ombudsmen initiative in Rochester NY beginning in 1992. Early efforts eventually resulted in a meeting of Culture Change "Pioneers" that was held in Rochester NY in 1997 and included individuals from throughout our nation who were drawn together by similar interests and concerns for resident quality of care and quality of life. A second meeting was held by these Pioneers in January 1998 in Seattle WA resulting in formation of a Steering Committee designed to move the initiative forward, followed by a third meeting in August 1998 in Oshkosh WI, a historic gathering from which the now well-known Pioneer Network was formed (1).

Since the early efforts of the Pioneers began, the Culture Change movement has spawned many individual and well known initiatives including Dr. Bill Thomas' Eden Alternative, Joanne Rader's Bathing without a Battle, Barry Barkin's Live Oak Project, and others. It is not necessary for a nursing home to follow one of these prescribed and well-known Culture Change initiatives, although they provide insights that are extremely helpful when incorporated with other home-specific efforts. What matters most is that a nursing home empowers those who work there to create a new and living focus on the resident as the center of everything they do each day.

Culture Change initiatives do not have to be expensive or exhausting. In reality it is best to start small rather than taking on too much and finding the process overwhelming. It is a well-

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known fact that change is often resisted, especially if it is generated from the top without first assuring that those providing direct care are involved. And that is part of the message of Culture Change – seeking input from all levels of employees.

What may seem like baby steps in the decision to adopt this philosophy in reality become a strong foundation for success. For example, inviting Nursing Assistants to participate in Interdisciplinary Care Plan Meetings in a meaningful way, not merely through their attendance, acknowledges that frontline workers know a great deal about the needs and wishes of residents. Who can speak better of the daily habits, likes and dislikes, and care-needs of residents than the CNA? A first Culture Change step then may be as simple as arranging staffing coverage on the unit that allows a CNA as the caregiver of the resident to join the Care Conference to share what he or she knows and experiences daily with the individual.

## Institutional vs Person-Centered Care

Nursing homes historically have been fashioned after hospitals with long sterile-looking hallways and institutional systems and practices. The primary focus has been on tasks to be performed and creation of systems that assure the work gets done. Individuals living in the nursing homes were mainly known for their medical diagnoses and problems. That may work for patients in a hospital who experience a short stay of intense medical treatment, but individuals admitted to long-term beds in nursing homes usually stay for the rest of their lives. Who among us would want to live for the rest of our life in the medical structure of a hospital? Some hospitals actually do a better job than many nursing homes of giving patients a choice through menu selection and other customer service efforts.

The Culture Change movement is guiding nursing homes away from the traditional hospital-based medical model of care that dictates a time to shower, a time for meals, a time for scheduled activities, and a time for lights out. Nursing homes need to re-create their focus from the inside out. Performing an internal self assessment is the place to start.

## Baseline Self Assessment

A baseline self assessment requires an honest look at where the nursing home's focus truly lies at that point in time. Begin by walking through your center and actively looking at the environment and the activity as if with the eyes of one experiencing it for the first time. This active looking goes beyond the daily walk-through in which things that have been seen daily are accepted as normal. Active looking requires time and special

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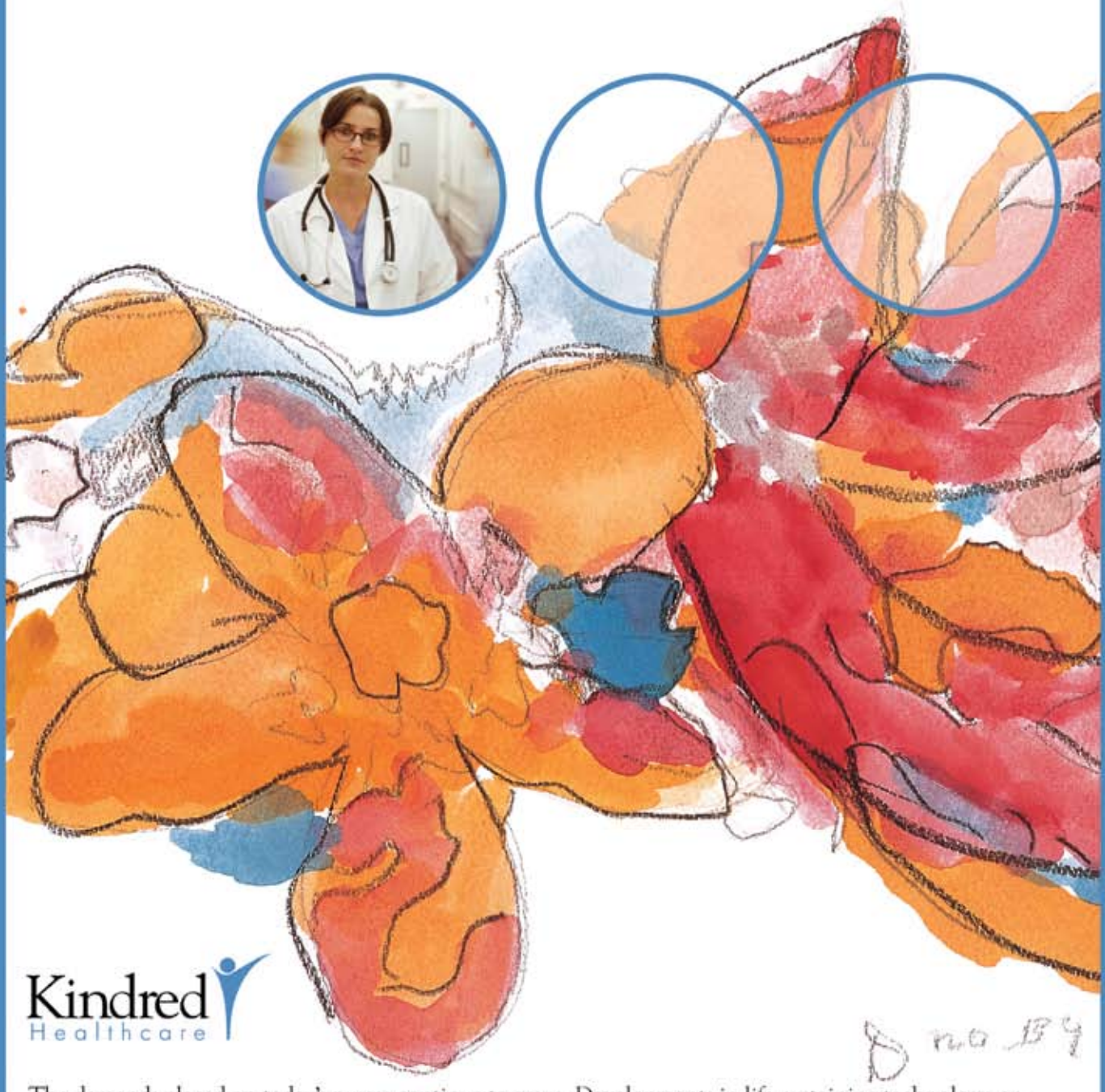

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effort that examines each thing observed and then questions if it should be that way. For example, when entering the lobby, observe to see if the environment appears welcoming and if staff offer friendly greetings and express interest in helping individuals find their way. When exiting an elevator on a unit observe to see if the appearance is pleasant and home-like or is it hospital-like with medical equipment and posted memos the first things that catch one's eye? When observing resident-staff interactions, is a caring attitude portrayed or does it appear that staff have their primary focus on completing tasks, visiting with each other, or going on break rather than truly caring for the people who live there? Observe the appearance of resident rooms, hallways, shower and tub areas, and lounges – do they please the eye? A team effort to remove clutter can make a big difference. If you were admitted to your center, would you see it as a place you would want to live, not just based on eye-appeal but on the level of interactions you observe? This initial observation should reveal opportunities for environmental improvements and targeted staff education.

## Beginning Implementation of Change

Once you have personally completed the exercise of actively looking, replicate it by having your nurses and then your nursing assistants view their work area in the same way. With Culture Change efforts it is best to start small, so you may want to pilot your effort on one specific unit where you expect to find the most cooperation. Offer one-on-one discussion to help them truly "see" the reality of the workspace they have helped create. Send each of them out to spend just five minutes initially in which they actively look and identify areas needing improvement, and then bring them together to discuss their findings. Once you have their attention it is time to begin your Culture Change journey.

Culture Change initiatives require team effort. Nursing Administration's role is not to dictate how change must be done, but rather to facilitate the generation of ideas that come from nursing staff and other departments with whom they interact, and then to assure that suggestions are within the boundaries of regulation and life safety codes. But don't allow regulation to become an excuse for doing nothing. Regulation in reality strives to drive us to deliver person-centered care.

Each separate unit will present its own personality based on those who live and work there. Identify the strengths, special needs, and talents of staff and residents in that area. Then draw from that knowledge to change the environment from a medically-focused nursing unit to a warm and caring neighborhood within the greater community comprised of all your setting's individual neighborhoods and departments.

## Culture Change – Doing It Inexpensively

Initial efforts that awaken understanding to the need for a Culture Change journey are supported by a few quick-fix efforts that create excitement within your team. Just the process of transforming the appearance of the nurses' station from medical to home-like makes a difference. This can be accomplished at minimal cost by removing the scattered posted memos, placing them in a memo binder, and then focusing on an inexpensive "face-lift" for the space. When at all possible, move medical supplies and equipment to a centralized area, such as a clean utility room or other designated area and keep the nurses' station clutter-free. A fresh coat of paint, some wallpaper border, and a few tastefully hung inexpensive pictures will add warmth to the space and soften the reality that it is a medically-focused area.

Review the opportunities identified by your nursing team members during their active looking exercise and work together to identify similar spaces that can be improved easily. This may be as simple as keeping halls uncluttered, creating sitting areas at the end of long hallways through placement of a chair near an interesting picture, placement of plants near end-of-hallway windows, or hanging home-like pictures and curtains in a tub room. Remember to involve direct care workers and others who work there and to ask for the opinion and preferences of residents who live there.

The opportunities for inexpensive Culture Change initiatives are endless. A nursing home does not have to rebuild or reconstruct itself to implement initiatives successfully. Culture Change is first and foremost a philosophy in which the team together places a renewed focus on the resident as the heart and central purpose of all they do. Caring attitudes, opportunities for resident choice in daily routines, and empowered staff interested in making a difference in the lives of those for whom

they care combine to form the foundation of initiatives in your nursing home. Once a team has its first success, the excitement keeps the ball rolling. By empowering staff to think in new ways and to share those thoughts, a huge previously untapped source of ideas is identified.

**Conclusion**

Culture Change as a movement continues to spark interest throughout long term care settings. Significant Culture Change construction and specialty projects receive attention from the media that may make us feel our efforts are so small they don't count, but don't let the inability to do a major makeover at your setting keep you from doing all you can. The greatest Culture Change success occurs in the hearts of residents when team members work together to provide personalized care in a neighborhood that residents collectively call home.

It doesn't have to cost a lot, but it does require the investment of time and energy. Learning to actively look, performing a baseline assessment, and selecting a few simple projects to get started will get your center going on the road to an exciting and rewarding journey. If your nursing home hasn't started yet, why not join the Culture Change initiative by actively looking the next time you make rounds. You may be the change agent who will spark great things to happen in your own corner of the world.

(1) The Pioneer Network: Who We Are. Our History @ www.pioneernetwork.net.

*Betty MacLaughlin Frandsen RN, NHA, BSHCA, CDONA/LTC is the Administrator of Bridgewater Center for Rehabilitation and Nursing, a 331-bed skilled nursing facility in Binghamton, NY. She was a Director of Nursing for 14 years, served for two years as President of NADONA, five years as NADONA's Legislative Coordinator to Washington, DC, and from 2002 to 2006 was a Culture Change Consultant and writer for the Institute for Caregiver Education, Chambersburg, PA.*

# relief

*We're turning our attention to*

In the United States, over 1.5 million people per year have an advanced illness and receive palliative care.[1,2*] Many of them are prescribed opioid-based therapy to ease their pain.[3,4] Opioid analgesics interact with mu-opioid receptors in the central nervous system to inhibit pain.[5] They also bind to receptors in the gastrointestinal tract, decreasing peristalsis and intestinal secretion, ultimately leading to constipation.[5]

Opioid-induced constipation is one of the most common and distressing side effects of opioid use.[3] The GI side effects can sometimes be severe enough to limit opioid use.[3,6] Many patients may receive less than optimal relief of constipation.[7]

Wyeth Pharmaceuticals is committed to continued scientific research to enhance the care of patients with advanced illness receiving palliative care.

*Patients having incurable cancer or other end-stage disease.

# opioid-induced constipation

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# 2008 National Conference

# Registration

## Opryland, Nashville, TN
## June 21-25, 2008

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# 2008 National Conference Attendee Registration Application

Nashville, TN June 21-25, 2008

Registrant Information - *Please print clearly - Use one form for each registrant*

First Name Last Name

Home Address

City State Zip

Facility Name State

Home Phone Daytime Phone

Email Address Corporation Name

*A photographer may capture your image sometime during the conference. If you do not wish your likeness to be represented in our marketing materials please remit a letter of refusal along with this application.*

**PAYMENT METHODS**
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Cincinnati, Ohio 45241

Toll free registration with Visa/MasterCard/American Express:
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fax application to:
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**TO BECOME A MEMBER**
Register on our website at www.nadona.org or www.nalna.org

## Registrant Payment Schedule

The conference fee, when paid in full, will include: All educational meetings, most meals, 1 banquet ticket, exhibit hall admission, all educational materials and breaks

Please mark all that apply. Total your choices.*
Refunds will be assessed $100 until April 27, 2008 (after April 27, 2008 no refunds will be made.) **Inaccurate totals will be assessed on-site.*

**Registration must be post marked by February 1, 2008 to receive a freegift. After February 1, 2008 and by May 1, 2008 to be entered in the grand prize drawing.**

| | | |
|---|---|---|
| **NADONA/LTC MEMBER REGISTRATION** | | |
| Early Registration (Before May 1, 2008) | $ 499 | _____ |
| Late Registration (After May 1, 2008) | $ 599 | _____ |
| **NALNA MEMBER REGISTRATION** | | |
| Early Registration (Before May 1, 2008) | $ 499 | _____ |
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| **NON-MEMBER REGISTRATION*** ☐ **NADONA/LTC** ☐ **NALNA** | | |
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| **COE or PLATINUM WINNER*** ☐ **NADONA/LTC** ☐ **NALNA**<br>Registration $200 OFF (*must fill out COE or Platinum Application)* | $ 299 | _____ |
| **10-YEAR AWARD WINNERS** ☐ **NADONA/LTC** ☐ **NALNA**<br>Registration $200 OFF for 10-year same facility DONs or Facility Nurse | $ 299 | _____ |
| **GUEST TICKETS**<br>Exhibit Hall ticket, all meals, and Banquet ticket<br>*No persons under the age of 18 allowed in Exhibit Hall* | $ 350 | _____ |
| **EXTRA BANQUET/RECEPTION TICKET** | $ 85/EA | _____ |
| | *TOTAL* | _____ |

Payment Method *Please print clearly - Use one form for each registrant*

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*TAX DEDUCTIONS Under the Tax Reform Act of 1986, the cost of education (including tuition fees, travel and lodging) is fully deductible to institutions. Educational costs may be deducted by individuals to the extent that miscellaneous itemized deductions exceed 2% of adjusted gross income. Consult your tax advisor for details.*

# CIRCLE OF EXCELLENCE FACILITY APPLICATION

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NATIONAL ASSOCIATION DIRECTORS OF NURSING ADMINISTRATION/LONG TERM CARE

Please read and complete application in its entirety.

Facility DON/ADON must be an active member of NADONA.

Zero (0) deficiencies from state or federal survey or proof of employment at the same facility as a director of nursing for at least 10 years. Evidence must be submitted at time of application. Evidence accepted for proof of employment is a letter (on facility letterhead) from Administrator/Executive Director.

Award is based on surveys conducted from April 1st to April 1st each year.

Applications must be received on or before May 1, 2008.

Applications must be completed fully. Incomplete applications will not be accepted.

**2008 National Conference Registration . . . $200 OFF for zero deficiency, $200 OFF for 10-year same facility DON's**

**To take advantage of this offer complete the Attendee Registration Application and Circle of Excellence Facility Application.**

FACILITY NAME - *Please print letters clearly in boxes (Print Facility name as you would like it to appear on the plaque.)*

Corporation

Administrator/Executive Director

Director of Nursing

Facility Address

City

State

Zip

Telephone

Email

Will you be sending a representative to the NADONA/LTC CONFERENCE to receive this award? Yes _____ No _____

❒ Over 10 years employment at the same facility (Provide letter from Facility Administrator/Executive Director)

❒ Zero Deficiency (Complete the following)

Date of Facility survey:_____
*Please provide evidence of survey between 4/1/06 and 4/1/07 on a separate sheet and attach to this application.*

To what or whom do you attribute achieving zero deficiencies in your Facility?: *(May use additional paper, if necessary)*

_____

_____

Submit on or before May 1, 2008: NADONA/LTC CIRCLE OF EXCELLENCE AWARDS, Reed Hartman Tower, 11353 Reed Hartman Highway, Suite 210, Cincinnati, Ohio 45241 or fax to 513-791-3699

# PLATINUM COMMUNITY AND 10-YEAR APPLICATION

NALNA
NATIONAL ASSISTED LIVING NURSES ASSOCIATION

Please read and complete application in its entirety.

Community Professional Nurse must be an active member of NALNA.

Zero (0) deficiencies from state survey or proof of employment at the same facility or as a nurse for at least 10 years. Evidence must be submitted at time of application. Evidence accepted for proof of employment is a letter (on community letterhead) from Administrator/Executive Director.

Award is based on surveys conducted from April 1st to April 1st each year.

Applications must be received on or before May 1, 2008.

Applications must be completed fully. Incomplete applications will not be accepted.

**2008 National Conference Registration . . . $200 OFF for zero deficiency, $200 OFF for 10-year same Community Nurse**

**To take advantage of this offer complete the Attendee Registration Application and Platinum Community Application.**

COMMUNITY NAME - *Please print letters clearly in boxes (Print Community name as you would like it to appear on the plaque.)*

Corporation

Administrator

Professional Nurse

Community Address

City

State

Zip

Telephone

Email

Will you be sending a representative to the NADONA/LTC - NALNA CONFERENCE to receive this award? Yes _____ No _____

❒ Over 10 years employment at the same community (Provide letter from Community Administrator/Executive Director)

❒ Zero Deficiency (Complete the following)

Date of Community survey: _____
*Please provide evidence of survey between 4/1/06 and 4/1/07 on a separate sheet and attach to this application.*

To what or whom do you attribute achieving zero deficiencies in your Community?: *(May use additional paper, if necessary)*

_____

_____

Submit on or before May 1, 2008: NALNA PLATINUM COMMUNITY AWARDS, Reed Hartman Tower, 11353 Reed Hartman Highway, Suite 210, Cincinnati, Ohio 45241 of fax to 513-791-3699

## Prepare early to Postpone your survey . . .

Dear: (head of the surveyors in your state)

I am writing to inform you that I (and Admisitrator?) will be attending the National Association Directors of Nursing Administration/LTC (NADONA/LTC) convention June 21-25, 2008 in Nashville, TN.

This convention will not only provide me with contact hours for each workshop I attend, but I will have the opportunity to network with Directors of Nursing from across the country and Canada. Workshops will range from clinical to leadership topics, being presented by the top long term care leaders and researchers in the country. There will be plenty of vendor time, where I can review products and educational materials to improve the quality of life for both my residents and staff members.

Since every survey is an educational experience for DONs, I would be grateful if you would refrain from surveying my facility June 21-25, 2008. I understand if there is an emergency or complaint investigation, that you have no choice but to make a visit. I would be happy to send proof of registration, or have proof of registration sent from NADONA if you require such information.

Thank you in advance for your cooperation with this request as attending this convention is quite important to my functioning to the best of my ability as a DON/ADON (title) at _____ (name and address of facility).

Sincerely,

cc: Administrator

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- The Director, our official journal, along with several other LTC periodicals
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- Access to mentoring from seasoned DONs
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- Discounts to the annual conference
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An Educational Activity for Nurses and Staff

# Assessing the Risk of Osteoporosis in Patients in the Senior Care Setting

*Using patient vignettes as real world examples*

## Program Description:

Using video vignettes as real world examples, this activity will help nurses improve the identification and treatment of patients with osteoporosis in the senior care setting. This activity also includes techniques and information to improve fracture risk assessment, implement appropriate care plans, and adequately treat patients in these facilities.

## Target Audience:

This is an activity for nurses who are interested in the care of patients with osteoporosis in the senior care setting.

## Educational Objectives:

- Appropriately identify patients with osteoporosis during the admission process into a senior care facility.
- Describe how to utilize techniques for assessing patients with osteoporosis to increase the management of these patients.
- Compare and contrast the therapeutic management of osteoporosis to ensure that your patients are on the most efficacious and appropriate medication to reduce fracture risk.

## Program Faculty:


**Sandra Kingsley, RN, MSN**
Director of Clinical Services
Golden Gate National Senior Care
Fort Smith, Arkansas



**Steve Law, PharmD, CGP**
Omnicare, Inc.
Clinical Services Manager – Indiana
Indianapolis, Indiana


## Accreditation:

This activity offers 1.0 contact hour by the National Association of Directors of Nursing Administration in Long-Term Care (NADONA/LTC). NADONA/LTC is an approved provider of continuing education by the Georgia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation, ID # 1087.


*This continuing education activity is supported by an unrestricted educational grant from*
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Jennifer Giroux, registered nurse and mother of nine, invented StethoClean to protect her own children and patients from dirty stethoscopes. Concerned about the spread of infectious disease by carriers of infection


that touch the healthy and sick alike, Giroux secured the patent for StethoClean and paired with Microtek Medical Holdings Inc. (Nasdaq: MTMD), a global leader in barrier infection control solutions for the healthcare environment. Visit www.mystethoclean.com to request a free sample.

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## Why NADONA/LTC for Assisted Living Nurses?

Residents in ALFs require expert healthcare guidance and management on many levels, and this guidance is most often provided by a nurse. From diagnosis to intervention to ongoing management of residents' (guests) varying health conditions, NALNA membership gives nurses in ALFs the resources needed to stay ahead in this ever changing environment.

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This section is dedicated to Assisted Living

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# The Assisted Living Resident Past – Present – Future

*Delia (Dee) McGinnis, RN, BSN*
*(Chairperson) Director of Wellness, Emeritus Assisted Living*

The profile of the assisted living resident has changed over the years along with the United States' shift from a rural economy. During the earlier part of this century when we still had a rural economy the family unit included the extended family. In the past elders were cared for at home and only went elsewhere for care if they were very ill.

The earliest models of caring for persons outside the home came about as the need arose for housing for the elderly who could no longer live alone. Due to our increasingly mobile society, they didn't have the support of the family structure to allow them to stay at home. These early facilities were called board and care homes. They housed a mixed population of the physically frail elderly, persons with developmental disabilities and persons with psychiatric conditions. The resident essentially needed only custodial care. They were provided food, shelter and non-medical care and supervision which may have included some assistance with ADLs. Activities consisted of some socialization, walks and church. The settings were typically large older homes built in the 1920's and 1930's. This model provided a means for poor or low income persons to live relatively comfortably in a home-like environment.

The idea of assisting individuals so they could continue to live independently became popular in the late 1980's. This was in response to the changing needs of residents living in retirement communities. Many residents were aging in place and needed personal care services but didn't want to go into a nursing home. These mostly retirement residences offered their tenants limited personal care services that allowed them to remain independent in their own apartments. The idea was to care for mildly to moderately frail elderly at a modest cost. It was certainly much less expensive than a nursing home and much more palatable to the individual.

By the 1990's most residential care was known as assisted living. This model emphasized the social aspects of care. The goal of the social model was to create a normal, homelike living environment organized around prompting independence.

The present group of elders is made of what is termed the Veteran Generation. We know the most about this group since they make up the majority of the assisted living population today. This generation is what Tom Brokaw calls the "Greatest Generation". They were born between 1925 and 1946. They are products of what occurred during their lifetime.

They lived through the Great Depression. They were influenced by rationing, failed banks and closed businesses. One fourth of the work force had to beg for work. They were young adults during the World War II and fought in the Korean War. They matured in a time where clear lines of authority were drawn and followed. They were comfortable with authority and responded very well to it. This group was very civic minded. When Pearl Harbor was bombed the men went to war and the women went to work. All able bodied individuals were expected to serve and did.

During the post war years the United States experienced an economic resurgence. America had become the "land of plenty". Jobs were plentiful and the middle class was taking off. This meant families had disposable income. They were buying houses and cars. Folks were letting "the good times roll".

By the 1960's and 1970's they were in their 40's. They were rebuilding the world's industries. They were solidly planted as members of the establishment. It was a turbulent time due mostly to the Vietnam war. They couldn't understand how their children could be so rebellious and challenge their authority. How those children could be so contemptuous of the very foundation upon which they had built their lives.

By the 1980's boom or bust cycle these folks were ready for retirement. They had become rebellious too. They rebelled against the concept of institutional care. Going to a nursing home was the worst that could happen. Enter President Reagan's White House Council on Aging and the concept of assisted living as we know it today was born.

The impact of this generation on the general population is huge. From 1950 to 2000 the general population doubled. The 65 years and older segment tripled. The 75 years and older group has quadrupled. The 75 years and older group is the fastest growing segment of the population.

The assisted living industry is now the dominant model of long term care and services. It is currently serving about one million seniors. It is considered to be a cost effective, user friendly option for most seniors who are experiencing living alone safely.

The average age of most persons moving into assisted living is 83.8 for men and 85.7 for women. About two thirds come from their own homes. The women out number

# it's all because of you

At Emeritus, we believe in the value of every employee and what he or she has to offer. Every employee, whether working in a community, a regional office or at our Seattle office, impacts the quality of service we are able to deliver to each individual resident.

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the men three to one and most of them are widowed. Most of the residents require assistance with at least 2 ADL's. About 50% have some form of cognitive impairment. 80% require some assistance with managing their medications. Most are continent of bowel and bladder. This demographic is pretty consistent throughout the industry with the exception of specialized dementia communities. In these communities the residents are younger by four to five years. 50% of this group comes from the home of a family care giver.

These residents are very clear about their expectations. They expect a comfortable, clean and well appointed living environment. They want to remain in reasonably good health. So they can be independent in their daily routines. They want opportunities for choice and self expression. They want to be recognized for their life experiences and roles. They feel they can still contribute and feel fulfilled.

Aging in place is a very predictable and visible trend with our current residents. The challenge is how to deal with them effectively and compassionately.

The assisted living resident of the future will be something different all together. The majority of this group will be baby boomers. 78 million baby boomers were born in the United States between 1945 and 1964. By 2003 they represented 12% of the nation's population. There is an estimated 450 baby boomers world wide today.

The defining event for this generation was the Vietnam war and the protests over the draft. They advocated questioning authority which was a huge departure from their parents' response to authority. They radicalized the social causes of feminism, gay rights, disabled rights and privacy rights. They touted drugs, sex and rock and roll. They are a generation of persons who are experimental, individualistic, free spirited and social cause oriented. They are dropouts from formal religion but explore the religions of the world and follow many other spiritual paths.

This group is very affluent. They have more access to discretionary funds, political influence and financial power than any group in the United States. As a matter of fact, they make up the bulk of the current political, industrial and academic leaders of today.

This group is also called the "Sandwich Generation". They waited until their careers were established to marry and have children. They find themselves caring for their young children and their aging parents at the same time. They are very busy juggling careers, raising children and caring for elderly parents.

This group will change the definition of the aging. By 2015 20% of the workforce will be over age 55. By 2030 there will be 71.5 million persons or 20% of the population over age 65. Their interests and goals are very different than their parents' generation.

This group is very clear about what they want as they age. The want opportunities and settings that focus on the individual versus the group. They want to continue to contribute and to feel fulfilled. They want a stimulating lifestyle that keeps them active and mentally sharp. They want a health system that emphasizes prevention and holistic approaches to wellness. Most of all they want to be appreciated for their past achievements and recognized for what they can still contribute.

As providers we need to take the time to know them. What are their stories? What are their wants and needs? How do they want to live out their lives? They want to be active participants in determining their own destiny. We will need to support them not direct them as they move through their aging process.

# PREPARING FOR A DEPOSITION

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## Preparation is the Key

Depositions of employees are integral to the defense of liability claims against assisted living and skilled nursing facilities. The deposition process can also be utilized to advance risk management and quality assurance goals. A majority of facility employees have not experienced a situation of giving sworn testimony regarding the evaluation, treatment and assessment of a resident. As such, the preparation of employees for a deposition is paramount in protecting the interests of the facility. The deposition of a facility employee carries great importance in the underlying litigation. It can help to establish defense themes and promote litigation strategy. Conversely, a poorly prepared witness can adversely impact the cause of action, and in some instances, give rise to a claim for punitive damages. It is critical that an employee - whether an Administrator, Director of Nursing, nurse, dietician or certified nursing aide - be sufficiently instructed about the deposition process. This preparation contributes to the ultimate defense of a claim as the employee testimony becomes the factual basis to defeat claims.

The preparation process may be broken down into four categories: a) pre-conference review, b) conducting pre-deposition conferences with key personnel, c) attending the deposition with an established game plan and d) conducting a follow-up conference to review the testimony as necessary.

## Pre-Conference Review

Prior to any conferences with employees, it is critical for defense counsel to develop a working knowledge of the facility's policies and procedures, the facility's survey history, any relevant employment issues and its claim history. Only with this understanding, may counsel advise and prepare the employee for anticipated categories of examination. A detailed review of the resident's chart is essential. An evaluation of any documentation concerns is crucial. Verifying proper chart documentation is necessary to determine compliance with the facility's own policies and procedures, and ultimately, the standard of care. At the time of the initial review, an employee list needs to be established identifying those key personnel anticipated to be produced for deposition. Once an employee list is created, an initial meeting with the facility administrator should be arranged along with a site visit. Familiarity with the facility's layout and operation assists in tailoring a strategy for the employee/witness to testify in the context of his/her job performance. Potential problem areas need to be identified in advance and discussed in detail with the employee at his/her respective pre-deposition conference. A thorough chart review also provides an early determination of target employees no longer employed with the facility. The resident's attorney may try to use the former employee to testify against the facility. In the event that there was any negativity associated with their departure, it is especially important to locate and conference with former employees early to address these issues. Once the key employees have been identified, pre-deposition conferences should be scheduled well in advance of any testimony to allow the witness to be adequately prepared.

## The Pre-Deposition Conference

The initial consideration for scheduling conferences with employees is to allow sufficient time for full preparation. In advancing this goal, the personnel files for current and former employees should be obtained and reviewed to determine areas requiring protection in the deposition, as well as preventing surprise. It is important to establish a comfortable relationship between witness and defense counsel to promote comfort and confidence. During the conference, deposition process should be explained in detail, as well as covering the facts relating to the witness. The employee should understand that a deposition is a statement being given under oath, which means they are sworn to tell the truth and that it has an impact on the defense of the facility. The employee should be advised to listen to the question carefully and in its entirety. The witness should also follow the "one-Mississippi rule" prior to answering a question. Taking a full second prior to responding allows the witness fair opportunity to clarify a confusing question and enables counsel to object to an improperly formed question. It is important that the witness answer only the question asked without volunteering information. The employee should

never answer a question which is not understood or is confusing. The employee should also understand their rights as a witness. These rights include: the opportunity to fully explain and correct an answer; to clarify a confusing question; to sufficiently review documents prior to responding to a question; to speak to defense counsel concerning the deposition process; and to take breaks as necessary. Understanding these rights can greatly assist the employee in keeping their focus during the deposition. The witness should also understand the categories of questions to expect. This includes examination of the witness' background, training, education and experience, including employment history in the industry as well as their knowledge of the facts. They may be asked if they have been reprimanded or punished at any time for their work and whether they have been convicted of a crime.

The crux of the pre-deposition conference is a thorough review of the witness' entries in the resident's chart. The primary focus of the deposition is the employee's treatment and observation of the resident. Employees need to understand that in giving sworn testimony regarding their care and treatment that they have three "banks" of knowledge to draw from in giving their responses. Initially, a nurse/aide may rely upon his/her independent recollection of the resident's care. Next, an employee may refer to their documentation in the resident's chart. In this regard, the employee should fully review the chart. Finally, a nurse/aide may testify that, in the absence of an independent recollection or specific documentation, his/her actions were performed on a certain date and time consistent with a regular routine practice. When combined, these three "banks" of knowledge allow a witness to testify with a greater degree of comfort and avoid certain pitfalls of cross-examination.

It is extremely important that the witness discuss any concerns about their care with the attorney before the deposition.

Nurses, LPNs and CNAs, need to confine testimony to the three "banks" of knowledge, and not render opinions, guesstimates and conclusions. In some limited circumstances, the Administrator and/or Director of Nursing may give opinion testimony that benefits the facility. Any such opinion testimony should be limited to issues such as compliance with facility practices and procedures, compliance with industry standards, and the appropriateness of response devices such as a plan of correction related to a survey tag. Each witness needs to understand that their responses need to be truthful and accurate.

The employee also needs to be aware that it is acceptable to state that they do not remember or do not know certain facts. Additionally, an employee may defer to another employee's entry in the chart.

Following from the above discussion, it is important that a witness understand certain pitfalls of a deposition. It is important that the employee understand that the primary motive of the deposition is the resident's counsel's quest for information (particularly negative information) that will assist in the claim against the facility. The employee should not be lulled by opposing counsel's friendly demeanor into a rhythm of free exchange that disrupts the witness' focus. The employee should not let politeness and cordiality disguise an understanding of the ultimate motive. The opposing party has sued the facility and is not there to make friends. Similarly, an employee should guard against arguing with opposing counsel and debating a question. Often during a deposition, the witness may get baffled or confused when the resident's counsel becomes aggressive or poses difficult questions, which may be outside the scope of a witness' knowledge. The defense attorney is there to deal with opposing counsel thereby allowing the witness to focus while keeping an appropriate demeanor. However, the defense counsel cannot assist the witness in deciding how to word their answer during the deposition.

After the employee has been advised of the mechanics and potential substance of the deposition, practice questioning will provide additional benefit. A dry run rehearsal of the anticipated areas of questioning affords the employee an opportunity to practice the above techniques and strategy to further develop the witness' comfort and confidence.

## Deposition

There is no judge at a deposition, just the attorney for each person or facility named as a party and a court reporter. The court reporter will administer the oath which requires the witness to tell the truth. Everything said by anyone will be recorded in shorthand. The court reporter can not record a nod of the head or multiple people talking at once, so only one person can talk at a time and all answers must be in the form of a spoken word. The resident or a family member may attend the deposition. The witness needs to prepare themselves to see the resident or family member.

On the day of the deposition, a brief pre-deposition conference should be conducted. At that time, the subject matter of the deposition can be reviewed and any concerns that have developed since the prior meeting may be addressed. It also gives the witness the opportunity to refresh their knowledge of the chart, which will prevent stress during the questioning. The employee should re-review all entries and documentation. If surveys are available, these should be reviewed as well, since one can anticipate opposing counsel using them within the structure of deposition. Some states allow the resident's attorney to obtain the incident

report and ask questions about those entries. The employee should be reminded that during the deposition it is critical to focus, listen, and focus. The employee should wait for objections from defense counsel and follow instructions not to answer questions when directed. The employee should avoid commenting on the treatment and assessment of other employees. The employee should highlight the positive areas of their treatment that promote a defense theme. It is important that the witness refrain from making any negative references, inferences or otherwise disparaging remarks about the facility, employees or other residents.

Some employee depositions can be lengthy. It is important that the witness not have time constraints that may affect his or her focus. Defense counsel understand that some deposition tactics include "marathon" questioning, which seeks to tire and wear down a witness in attempt to gain an advantage. In such a circumstance, the employee and defense counsel need to schedule routine breaks to insure the witness keeps a calm, comfortable demeanor and maintains focus.

After the deposition has concluded, the witness will be instructed not to discuss their testimony with anyone, including other employees. This prevents other potential witnesses from being influenced by the employee's testimony and minimizes credibility risks.

## The Follow-up Conference - Review of Transcript

After the deposition, the court reporter will prepare a written transcript of the testimony. The witness has the opportunity to review a transcript of their testimony for accuracy. This may require a follow-up conference with the witness. Some circumstances may require that the witness execute an errata sheet correcting or clarifying the transcribed answers. This is a method to insure that the witness understood a question and that the court reporter accurately typed the response. An employee, as well as the facility Administrator, should be aware that any significant changes or amendments to the deposition transcript may require the witness to appear for a follow-up deposition on the corrected issues.

## Trial

In cases that proceed to trial, it will be important for the witness to review their deposition testimony. The employee's transcript will be provided to them in advance and an additional pre-trial meeting will be conducted in order to further prepare the witness. The resident's attorney will ask many of the same questions at trial to see if the witness gives the same answer as they gave in their deposition. This is called impeaching the witness. It is used to attack the credibility of the witness.

## Conclusion

Depositions of facility employees are a central element in the defense of liability claims. The deposition should be viewed as an opportunity to establish defenses and highlight the positive aspects of a resident's admission. If properly prepared, a witness can effectively deal with areas of concern and help support the overall defense of the case. Adequate deposition preparation promotes the employee's comfort and confidence which can prevent unnecessary weaknesses from developing. Emphasis on the positive aspect of care avoids making the witness feel defensive. A witness who feels confident and appears caring will make a good impression on the resident's attorney and the jury. Good preparation is the key.

*This article provided for educational purposes and is not intended to provide advice for a specific situation or to create an attorney-client relationship.*

# LEGAL ISSUES IN THE ASSISTED LIVING SETTING

*Alice Kush, BSN, JD*

## Medication Errors

Medication errors are becoming an increasing concern and the focus of prevention efforts. Most people think of a medication error as inadvertently giving the wrong medication. However, the actual definition is much broader. It includes the classic nursing description of the five Rs: right patient, right medication, right time, right route, right dose. The "right" in this standard definition has always referred to administering medication exactly as it is ordered by the physician. However, the term medication error can also encompass the problems that arise when multiple physicians are all prescribing medications and do not know precisely what is being prescribed by the other physicians involved in that person's care. This is a particular problem in the assisted living setting where there is no medical director who oversees the care and treatment of residents. Often it falls to the nurse who is reconciling the various physician orders to question whether the medications prescribed by two different physicians should both be administered to the resident. Finally, there is a question of whether the drug that has been prescribed is appropriate for the resident. Many residents have been taking the same medication for their hypertension or cardiac disease since they were 55 years old. However, as the body ages, that medication may no longer be the best or even an appropriate choice. These sophisticated questions regarding whether the medications prescribed are safe in combination or even appropriate for the resident can exceed the education that a registered nurse has with regard to medications. It may even exceed the knowledge of some physicians. For that reason, there is a growing interest in geriatric consulting pharmacists who have specialized knowledge regarding drug metabolism and drug interactions in the geriatric population. Their expertise may allow them to question whether a combination drug, or a different route of administration may provide better therapeutic effects. Finally, the pharmacist who dispenses the medications may misinterpret the order, make an error in the labeling or dispensing of medications including pills that contain a larger dose of the medication than prescribed. We have seen situations where residents receive up to seven times the prescribed dosage because of dispensing errors.

Medication administration problems are more complex in the assisted living community because residents may self-administer medications, residents may receive medication reminders, residents may be supervised in the self-administration of medication and residents may have medication administered by licensed personnel and/or medication aides. To complicate this discussion even more, the level of training and the extent of responsibility delegated to medication aides varies from state to state.

## A List of All Medications and Supplements

The simplest and probably first step in approaching this issue is to require that every resident have a complete and up-to-date list of the prescription medications that they are taking as well as the over-the-counter medications that they may take from time-to-time or on a regular basis as well as any vitamins, minerals or herbal supplements that they take. It is important to educate the resident and their family/friends that vitamins, minerals and herbal supplements can have more than just the desired effect. For example, many of them affect blood clotting. Therefore, it is very important that the physician knows which supplements the resident is taking. This list should be developed for all residents regardless who administers the medications. A copy of that list should accompany the resident every time they go to see any physician. It would also be advisable to include on that list any specific considerations regarding the administration of the medication, such as whether it is given with food, 30 minutes before a meal, or cannot be given with certain foods such as juice. Everyone from the resident, the family, the physicians, the pharmacists and the staff needs to be on the same page with regard to what is being taken by the resident. The statistics regarding the risk of adverse interactions between medications and the development of side effects that may affect mental alertness and/or balance are stunning. The effort necessary to create the list is very worthwhile when you consider that it may avoid an injury that occurs as a result of a fall, bleeding or other side effect which could cause the resident to require a higher level of care or die. This list can improve quality of care, may create financial

savings for the resident as well as reducing the risk of civil litigation and even criminal prosecution for care givers.

## Education

The second step is education. This includes education of the resident, education of the family/friends and education of the staff. Some communities schedule consultations with pharmacists for their residents. Lectures on the risks or unexpected side effects of over-the-counter medications or supplements can be provided for residents and families. Reference materials are also very valuable. At a minimum, The Physician Desk Reference provides information regarding the actions and side effects of medications, but most importantly it contains photographs of the actual tablets/capsules. This can be very helpful. The Beers criteria provides information specific to the geriatric population. The most recent compilation of the Beers criteria appears in the Archives of Internal Medicine, Vol. 163, No. 22, published December 8, 2003. This is available on the internet or from the local hospital library. Some other references for the assisted living facility would include:

Http://www.mederrors.com/home Provides reference materials and tools

The Institute for Safe Medication Practices www.ismp.org or call 1-800-fail-saf. Provides a list of error-prone abbreviations, symbols and dosage designations. It also provides a list of high alert medications.

The American Society of Consultant Pharmacists. www.ascp.com Offers a lot of articles on their website regarding geriatric medications including the Geriatric Medication Handbook.

The Institute of Medicine www.iom.edu. It is part of the National Academy of Sciences. It provides independent, objective evidence-based advice to health professionals and the public regarding medications.

The U.S. Food and Drug Administration Center for Drug Evaluation and Research http://www.fda.gov/cder/drug/advsiory. Offers safety warnings and information regarding the use of drugs such as the Fentanyl Transdermal (Skin) patches.

## Risk Increases at Time of Transfer

A time when medication errors are most prone to occur is at the time of transfer between an acute care hospital and a community setting. Many times the transfer occurs as a result of a sudden change in the resident's condition. Documentation that is sent with the resident to an acute care hospital may not be complete, there may be inadequacies in the report between the community and hospital. The problems with the oral report and the documentation can occur in either direction of the transfer, to and/or from the acute care hospital. The significance of this problem has been brought home to those of us who practice in Illinois by a recent case where a resident received a narcotic at the acute care hospital just before being transferred to a facility. When the resident reached the facility, another dose of the narcotic was administered. The resident developed serious sequelae. The nurse at the facility was charged with criminal neglect and prosecuted as a criminal. While nurses worry about civil litigation and loss of license, there is a risk of criminal prosecution because of the duty that prosecutors feel to protect vulnerable adults. In this case, the criminal charges were eventually resolved but not before the resident, the family, the community and especially the nurse suffered as a result of this medication error.

Finally, there needs to be a plan for evaluating and reevaluating a resident's ability to self-administer medication. Some residents will claim that they can self administer medication to avoid the extra cost involved in reminders or supervision. Safety considerations require that a resident who will not comply with careful standards for medication administration should not remain in the facility. You are not doing anyone any favors by accepting a family's claim that even though mother is legally blind, she can administer her own insulin!

## HIPAA and the Patient's Right of Privacy

On July 3, 2007, the New York Times newspaper published an article that described a family's experience with nurses caring for a family member in the emergency room of a hospital in Ingalls, Illinois. The nurses refused to give the family information about their family member and according to the article, even threatened to have the son-in-law arrested because he was "violating HIPAA." Unfortunately, the son-in-law is a nationally recognized HIPAA expert who told his story to the New York Times! This situation helps to point out how confusing and difficult it has been to interpret and apply the HIPAA confidentiality requirements. The article quotes Senator Edward Kennedy, one of the sponsors of the original legislation, as referring to the regulations as a "bazaar hodge-podge" and as being very disappointed with the failure to give adequate guidance for the application of the statute. At this moment, there is legislation proposed to "clarify" some of the confusion surrounding the federal privacy rules. The Department of Health and Human Services has recently revised its website, www.hhs.gov\ocr\hippa which is a possible resource for you.

The particular issue for assisted living communities with regard to HIPAA is the continued difference of opinion regarding whether HIPAA applies to an assisted living facility. Avoiding knowledge that a resident's condition is deteriorating does not avoid responsibility or litigation.

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We have experienced some very significant and dangerous situations that have arisen because of confusion regarding whether an assisted living community can share personal health information about a resident with home health nurses, therapists and even family members. While the HIPAA legislation will continue to evolve, there are some key facts that you must keep in mind. The concept of patient confidentiality and the resident's right to privacy did not begin when the HIPAA legislation was passed. These are longstanding fundamental rights. The confusion that has arisen as a result of the HIPAA legislation seems to have distracted us from the underlying fact that people have a right of privacy but we need good communication between all caregivers to provide a safe environment and quality care. Keep in mind that: 1) since HIPAA went into effect, the only complaints that have been investigated by the government are those filed by patients who were denied access to their own records; 2) HIPAA does NOT interfere with the reporting of crimes such as abuse or with reporting of communicable diseases as required by State law; and 3) courts have held that the resident does not have a private right to sue under HIPAA, although the resident can sue for invasion of privacy.

Respect for a resident's confidentiality and right of privacy requires the use of good judgment. The whole purpose of HIPAA was to improve communication between healthcare providers by creating electronic medical records that were readily accessible regardless of where a person received care. Refusing to share medical information because of a fear that it somehow violates the HIPAA confidentiality clause is an absolute contradiction of the purpose of the statute. Good, safe care requires good communication. We cannot lose sight of the big picture.

While the statute allows care providers to share information, you may find yourself in a disagreement with other care providers over interpretation of the statute when you really need to be exchanging information. We have had several criminal indictments in Illinois which occurred as a result of a refusal to share information between various care providers in an assisted living facility which resulted in a serious deterioration of the resident's condition, including death from sepsis. Keep in mind that every jury is instructed by the judge to use their common sense. When they are faced with an injury that could have been avoided if the various care providers had communicated, they are not going to be interested in your HIPAA defense especially when the prosecutor argues that HIPAA did not prevent appropriate communication. Do not believe for a moment that claiming you are a "social model" allows you to put your head in the sand and ignore a resident's deterioration. While the various state licensure statutes are continuously evolving, and many of them now have multiple different levels of care, most, if not all, require the facility to perform an assessment of the resident's condition when there is a change of condition. In civil litigation, plaintiff's attorneys relish the opportunity to disclose how much money is paid for that "social model" and all of the marketing promises/representations that were made to entice the resident into the facility. They point out that the facility is licensed, usually under the state department of health and surveyed by that same department unlike the average apartment complex. This argument creates angry jurors and it will only become more important as levels of acuity rise in assisted living facilities.

Arguments have been made that the resident tried to conceal the severity of their condition by refusing to allow the home health providers, hired by the resident, to communicate with the facility. As a defense, the facility may argue that if they would have known that the condition clearly exceeded the criteria for a resident in an assisted living facility, they would have discharged the resident. The problem is that jurors say that if the resident is trying to conceal their condition, the facility is on notice of a possible problem.

Trying to keep a resident whose needs exceed the ability of the facility can lead to injury and liability as well as fines. Recognizing your limitations and performing to high standards within those limitations is a recipe for success. As communities experience more and more pressure to allow residents to age in place, despite their need for increasingly sophisticated equipment and caregivers, the need for communication only increases. Most people recognize the need for sharing of health information between an assisted living facility and home healthcare providers or therapists and physicians, and in fact will state that the standard of care requires such communication. However, because there are still some who argue that HIPAA prevents the sharing of such information, it may be best to have a discussion regarding confidentiality at the time of admission. Within the rules for the community, it should be made clear to any resident who enters that if they retain home health nurses, personal aides or therapists, that those providers must communicate fully with the facility. Consent to this communication should be a condition necessary for admission. Likewise, ask and document which members of the family or close friends can receive health information from the facility. Clearly identify who has been appointed, if anyone, as a guardian or who has been named as Power of Attorney for Healthcare. (Remember that the Power of Attorney for Healthcare does not go into effect until the resident loses the ability to make their own healthcare decisions. The Power of Attorney for financial matters has no authority to make healthcare decisions. Check your state laws but this is generally the distinction that is made.) A Release of Information can be signed by the resident and reviewed with a new signature on a regu-

larly scheduled basis.

Keep in mind that sharing health information should be done in an appropriate manner. Personal health information should never be discussed in the dining room, the elevator, and absolutely never in a store or church or other community setting. These conversations should be conducted in a private location where only the people who are involved are present. Family members who are out-of-state should be able to identify themselves in such a way that the facility can be certain they are releasing information to an appropriate person.

In conclusion, the evolving nature of what an assisted living facility can and will provide to its residents creates opportunities and challenges. Fear of violating HIPAA privacy laws should not prevent anyone from maintaining a safe environment that offers quality care and assistance. It is much safer for healthcare information to be shared than to stand by and allow the resident's condition to deteriorate until there is a very serious illness or even death. It is very difficult for marketing and operations to overcome the negative publicity that arises out of a resident's injury or death which results in litigation, especially criminal prosecution, for failing to keep the resident safe.

## Electronic Discovery

During the course of any lawsuit, both parties are allowed to "discover" relevant information from the opposing party. This would allow the opposing counsel to obtain policies and procedures, contracts, personnel files, records of staffing, and of course any records that you maintain about the resident. This has always included access to information that is maintained on a computer. However, in December of 2006, new rules were passed in the Federal Courts which clearly outline the discovery of electronic information. The state courts are rapidly developing their own rules regarding the discovery of electronic information. This development is important to you because it means that anyone who files a lawsuit against the assisted living facility can obtain all of the relevant emails and other documents that may were created on the computer. Many people fail to realize is that even when they delete something from a computer, it is not gone from the hard drive. (That is why the "undo" button works.) When anything is deleted, it is removed from the index but it remains on the hard drive where it is virtually impossible to obliterate. Jurors believe email more than they believe formal documents. They believe that you have exposed your real thoughts and actions in an email. For that reason, there is usually a significant effort made to obtain the relevant email. Therefore, you should never type anything in an email that you do not want to read on the front page of the newspaper. A quick email written in a moment of frustration can come back to haunt you. This is particularly true in cases involving employment issues, ADA and Fair Housing. Be especially careful about writing anything that is confidential in an email because of the risk of alteration of an email and the ability to forward it to countless numbers of people.

Obviously the actions of a facility need to be documented, but you must seriously consider where and how you document. For example, even if you create a document using Word, there is an immense amount of "metadata" that is attached to that document and accessible by whoever receives the document unless it is "scrubbed" or converted into a pdf file. What this means is that if you are working back and forth with individuals to draft a document, someone who can access the metadata is able to see who made what changes when. This is particularly desirable to plaintiff's attorneys in a case where it becomes important to know who knew what when.

Finally, the plaintiff's attorneys' request for electronic information is not limited to the computer sitting on your desk. They can request the information that is contained on your Blackberry or Treo, your voicemail, even back-up tapes and your home computer, if you do any work from your home computer. Obviously, this kind of discovery is extremely expensive for the facility. It usually requires IT consultants as well as attorneys to review the thousands of documents involved.

Now would be a good time to carefully consider what information is appropriate for email transmission throughout your community. Likewise, it is important to consider the fact that someone who is searching the computer system for electronic discovery will be able to identify the specific internet sites that were searched and when. The FBI uses this tactic very effectively. Do not assume that you have any privacy for your activities on your work computer. If you do work on your home computer, your personal information may also be vulnerable to a search. A good retention policy is imperative to manage computer data in light of these new rules.

If you have any questions, please contact Alice Kush at akush@hinshawlaw.com, 312-704-3675 or 630-768-5040, Hinshaw & Culbertson LLP, 222 North LaSalle Street, Suite 300, Chicago, IL 60601

*This article has been prepared by Hinshaw & Culbertson LLP to provide information on legal issues. It is not intended to provide legal advice for a specific situation or to create an attorney-client relationship. We would be pleased to provide such legal assistance as you require on this and other subjects.*

# MEDICATION ISSUES

*By William Simonson, PharmD, FASCP, CGP*

I would like to welcome you to a new feature of the Nurse in Assisted Living a column called "Medication Issues."

As editor and primary author of this column, I'll work hard to make it interesting and applicable, so you will look forward to reading it with every issue but I can only do this with your help. I need your medication questions! Each column will feature answers to questions that you submit to me.

Recently, while attending a national assisted living convention, I listened to an interesting debate between some national leaders in the assisted living industry. One side took the position that assisted living is a hospitality industry while the other side argued that it follows a medical model.

I understand that there many facets to this argument -- certainly assisted living focuses on quality of life and providing people with a living option that is clearly different than nursing homes -- but whatever model you believe it follows, residents of assisted living utilize medications, and sometimes many of them.

As a consultant pharmacist I have had the opportunity to practice in a number of different assisted living facilities and, after performing a medication audit in one particular facility recently, I determined that the average number of medications taken by the residents during the previous month was 11.4. That's even more than many nursing home residents take! So, medical model or not, medications are an important part of the life of an assisted living resident.

What is particularly interesting about that number is that scientific studies have determined that the theoretical chance for someone experiencing an adverse drug reaction or interaction when taking that many medications approaches 100%! I don't mention that figure to be an alarmist, but simply to raise your awareness of the potential for the use of multiple medications to cause problems.

Why would a person in assisted living take that many medicines? Well, there are a number of reasons. When I see someone taking a dozen or so different medications the first thing I think of is a phenomenon called "polymedicine" which refers to the excessive and unnecessary use of medications. Actually, most people use the term polypharmacy but I think my term more accurately reflects what is going on. Whichever term you use, it refers to the excessive and unnecessary use of medicines.

Examples of this type of inappropriate medication use could include a person using two different medicines for the same condition when one would have done the job, or the use of a medicine that was no longer needed. But, in the facility that I was visiting, I determined that all of the medications were being used correctly.

Another reason, and the most appropriate reason for use of multiple medications, is that the resident has a number of different conditions for which drug therapy is an appropriate option.

Let's look at the following example: Mrs. Jones is 78 years old and lives in a lovely apartment in an assisted living facility with her 84 year old husband. She has a number of chronic conditions but is active in her facility and participates in many social events and outings including frequent visits with her great grand children. Included in her list of diagnoses is osteoporosis, for which she takes two vitamins and one prescription medication to prevent a fracture, she also has diabetes for which she takes three different medicines. For her high blood pressure she takes two medications and she also takes two medications to keep her blood cholesterol under control. She also takes another medication to reduce the risk of having a stroke.

That's eleven different medications and each one is contributing to her good health – she has not had a stroke or a fracture or a heart attack, largely because of the medications she is taking.

A key point that I will emphasize in all of these columns is that medications should not be the first option for managing a condition. For many conditions non drug management is preferred. For example, it is best to lower cholesterol through diet and exercise, but if that doesn't work, then drug therapy may be a logical consideration.

The good news as demonstrated by Mrs. Jones, is that with proper use of medicines, even a person taking 11 different pills can benefit from therapy and avoid complications and that's what this column is all about.

From now on each column will include real world questions submitted by you, our readers.

Feel free to ask anything you want – including general questions about medication management for a certain or ask a question about a specific medication. All questions are welcomed.

Please send your questions directly to me at the following e-mail address: AskDrSi@aol.com.

I look forward to hearing from you!

*About the author:*

*William Simonson is an independent consultant pharmacist with more than 30 years experience in geriatrics and long-term care. He is past president of the American Society of Consultant Pharmacists and is the immediate past chair of the Commission for Certification in Geriatric Pharmacy. He has authored two books and more than 100 scientific articles about the use and misuse of medications by the elderly.*

# Apply now for a gerontology focused faculty development institute

*For Release*

GNEC is an innovative national initiative to enhance geriatric content in senior-level baccalaureate courses. Administered by AACN, this program provides nursing educators with the skills, knowledge, and resources needed to ensure that the "best geriatric practices" are imbedded in baccalaureate curricula and subsequently in the clinical care provided by newly educated nurses. Using a "train-the-trainer" approach, nurse faculty attending the GNEC institutes are expected to serve as leaders and mentors by sharing their new expertise with colleagues. This program is generously funded by The John A. Hartford Foundation. AACN is now accepting online applications for the upcoming GNEC Faculty Development Institute coming to St. Louis, MO on October 14-16, 2008. Please note the change in dates for the October 2008 institute from what was originally scheduled. Early applications are encouraged. For more information, see http://www.aacn.nche.edu/gnec.htm.The guidelines describe core precepts and structures of clinical palliative care programs divided into eight dedicated sections:

- Structure and Processes of Care
- Physical Aspects of Care
- Psychological and Psychiatric Aspects of Care

# RWJF seeks applications for executive nurse fellows

*For Release*

The Robert Wood Johnson Foundation Executive Nurse Fellows program is an advanced leadership program for nurses in senior executive roles in health services, public health, and nursing education who aspire to help lead and shape the U.S. health care system. The three-year fellowships allow participating nurses to remain in their current positions while they gain the experiences, insights, competencies, and skills necessary to advance in executive leadership positions in a health care system that is undergoing unprecedented change. The program is designed to give nurses a more influential role across many sectors of the economy. Applications are due February 1, 2008. For more details, see http://www.rwjf.org/applications/solicited/cfp.jsp?ID=19847.

# The WOCNCB Exploring New Level of Certification

*For Release*

The Wound, Ostomy, and Continence Nursing Certification Board (WOCNCB) is exploring the potential opportunity for LPNs/LVNs or RNs with an Associate or Diploma level education to demonstrate proficiency in wound, ostomy and/or continence nursing. Following formal classroom education and precepted clinical experience, the knowledge and skill level of the clinician can be validated by a psychometrically sound and legally defensible examination – within their scope of practice. If you are a LPN/LVN or RN with an Associate or Diploma-level education, or have a team member working in the areas wound, ostomy and/or continence, we invite participation in a job analysis survey regarding current practice. Please send contact information to Kathy Meyer via email to info@wocncb.org or call 1-888-496-2622, no later than January 15, 2008.
The Wound, Ostomy and Continence Nursing Certification Board promotes the highest standard of consumer care and safety by providing credentialing in the areas of wound, ostomy, continence and foot care nursing. WOCNCB currently awards credentials to Registered Nurses who meet stringent qualifications and pass its certification examination. WOC certified nurses provide quality care to patients in a variety of settings, including hospitals, long-term care facilities, and home healthcare. The WOCNCB has certified more than 5,000 nurses in the United States. For more information, contact the WOCNCB, (888) 496-2622, info@wocncb.org or visit the www.wocncb.org website.

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MISC 604091-041306

# Guidelines for Authors

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## Preparing your Manuscript

Do not underestimate the value of papers you have prepared but not published in the past. Members educational background varies from Diploma Graduates and Associate Degree graduates to Ph.D. There will be a broad selection of papers to interest various levels of nursing administrators in long term care.

Guidelines for paper review

*LENGTH:*

The desired length of typed manuscripts is 7-10 double-spaced pages. Shorter and longer articles will be considered, however.

*PAPER;*

Your papers should be typed with 1 inch margins and submitted in Word format accompanied by a hard copy. We will accept your submission on a CD mailed to NADONA/LTC, Reed Hartman Tower, 11353 Reed Hartman Highway, Suite 210, Cincinnati, Ohio 45241.

*TITLE PAGE:*

Your title page should contain the title of the paper and the name and credentials and any institutional affiliation and author's status with that institution. Included on the title page should be the complete mailing address, home and business telephone numbers, fax and e-mail address of the author. Acknowledgements of grant or other assistance should also be listed on this page.

Authors may use one of two referencing systems

*1. Vancouver style.*

References should be consecutively numbered within the text of the paper. Repeated references can utilize the same reference number. Number the references according to the order in which they appear in the text. References in the bibliography should correspond with the numbered references in the text.

When referencing journals, the following sample demonstrates acceptable referencing listings:
Eldrone, Susan RN BSN CDONA. Recruiting and Retaining Professional Staff. The Director, Jan. 1994: 155-72

When referencing books, the following sample document demonstrates acceptable reference listings:

Carnevali,Doris l., Patrick, Maxine, NURSING MANAGEMENT FOR THE ELDERLY,Third edition, Lippincott, Williams and Wilkins, 1993.

Or to specify specific pages:
Carnevali,Doris l., Patrick, Maxine, NURSING MANAGEMENT FOR THE ELDERLY,Third edition, Lippincott, Williams and Wilkins, 1993; 102-15, 196-98

When referencing unpublished materials, proceedings, these, etc. The following sample demonstrates acceptable reference listing:

Stevens, P.N. The Dilemma of Cross-culture Communication. Social Worker Roundtable Chair. New York, May 2, 1992:

2. The American Psychological Association (APA) Format.

APA Text Examples:

- In a recent study of reminiscence, Smith (1991) found that . . . Smith (p.57) demonstrates the impact of . . .
- There are several risk factors that contribute to atherosclerosis (Applebee, 1990: Ferman, 1992; Johnson, 1993).

(Note: multiple authors are listed in alphabetical order).

APA Examples in the List References:

- Applebee, R.O. (1990). The Dying Heart. New York: Random Press.
- Smith, P.Z. (1991). Remiuniscence in the Elderly. The Director, 1 (2), 1-7
- Ralston, R.T., & Putnam, L.M. (1992). Recruiting and maintaining professional staff. Gerontological Abstracts, 37, 232-237
- Thompson, E.N., Hanson R.R., & Fits, F.K. (1990). Nutritional Intervention in the Elderly. In S.P. Haslin (ed), Feeding Problems: Psychological Issues (pp. 240-252). Washington, D.C.: Hampton House.

(Note: All references are listed alphabetically).

Reference:
American Psychological Association (1984) Publication Manual of the American Psychological Association. Washington, D.C.: Author

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Important: Authors may not submit papers which have been submitted to other publications

**Brief Summary**—see package insert for full prescribing information.

**ARICEPT®** (Donepezil Hydrochloride Tablets)

**ARICEPT® ODT** (Donepezil Hydrochloride) Orally Disintegrating Tablets

**INDICATIONS AND USAGE** ARICEPT® is indicated for the treatment of dementia of the Alzheimer's type. Efficacy has been demonstrated in patients with mild to moderate Alzheimer's Disease, as well as in patients with severe Alzheimer's Disease. **CONTRAINDICATIONS** ARICEPT® is contraindicated in patients with known hypersensitivity to donepezil hydrochloride or to piperidine derivatives. **WARNINGS *Anesthesia:*** ARICEPT®, as a cholinesterase inhibitor, is likely to exaggerate succinylcholine-type muscle relaxation during anesthesia. ***Cardiovascular Conditions:*** Because of their pharmacological action, cholinesterase inhibitors may have vagotonic effects on the sinoatrial and atrioventricular nodes. This effect may manifest as bradycardia or heart block in patients both with and without known underlying cardiac conduction abnormalities. Syncopal episodes have been reported in association with the use of ARICEPT®. ***Gastrointestinal Conditions:*** Through their primary action, cholinesterase inhibitors may be expected to increase gastric acid secretion due to increased cholinergic activity. Therefore, patients should be monitored closely for symptoms of active or occult gastrointestinal bleeding, especially those at increased risk for developing ulcers, e.g., those with a history of ulcer disease or those receiving concurrent nonsteroidal anti-inflammatory drugs (NSAIDS). Clinical studies of ARICEPT® have shown no increase, relative to placebo, in the incidence of either peptic ulcer disease or gastrointestinal bleeding. ARICEPT®, as a predictable consequence of its pharmacological properties, has been shown to produce diarrhea, nausea and vomiting. These effects, when they occur, appear more frequently with the 10 mg/day dose than with the 5 mg/day dose. In most cases, these effects have been mild and transient, sometimes lasting one to three weeks, and have resolved during continued use of ARICEPT®. ***Genitourinary:*** Although not observed in clinical trials of ARICEPT®, cholinomimetics may cause bladder outflow obstruction. ***Neurological Conditions:*** Seizures: Cholinomimetics are believed to have some potential to cause generalized convulsions. However, seizure activity also may be a manifestation of Alzheimer's Disease. ***Pulmonary Conditions:*** Because of their cholinomimetic actions, cholinesterase inhibitors should be prescribed with care to patients with a history of asthma or obstructive pulmonary disease. **PRECAUTIONS Drug-Drug Interactions** (see Clinical Pharmacology: Clinical Pharmacokinetics: Drug-drug Interactions) ***Effect of ARICEPT® on the Metabolism of Other Drugs:*** No *in vivo* clinical trials have investigated the effect of ARICEPT® on the clearance of drugs metabolized by CYP 3A4 (e.g. cisapride, terfenadine) or by CYP 2D6 (e.g. imipramine). However, *in vitro* studies show a low rate of binding to these enzymes (mean $K_i$ about 50-130 μM), that, given the therapeutic plasma concentrations of donepezil (164 nM), indicates little likelihood of interference. Whether ARICEPT® has any potential for enzyme induction is not known. Formal pharmacokinetic studies evaluated the potential of ARICEPT® for interaction with theophylline, cimetidine, warfarin, digoxin and ketoconazole. No effects of ARICEPT® on the pharmacokinetics of these drugs were observed. ***Effect of Other Drugs on the Metabolism of ARICEPT®:*** Ketoconazole and quinidine, inhibitors of CYP450, 3A4 and 2D6, respectively, inhibit donepezil metabolism *in vitro*. Whether there is a clinical effect of quinidine is not known. In a 7-day crossover study in 18 healthy volunteers, ketoconazole (200 mg q.d.) increased mean donepezil (5 mg q.d.) concentrations ($AUC_{0\text{-}24}$ and $C_{max}$) by 36%. The clinical relevance of this increase in concentration is unknown. Inducers of CYP 2D6 and CYP 3A4 (e.g., phenytoin, carbamazepine, dexamethasone, rifampin, and phenobarbital) could increase the rate of elimination of ARICEPT®. Formal pharmacokinetic studies demonstrated that the metabolism of ARICEPT® is not significantly affected by concurrent administration of digoxin or cimetidine. ***Use with Anticholinergics:*** Because of their mechanism of action, cholinesterase inhibitors have the potential to interfere with the activity of anticholinergic medications. ***Use with Cholinomimetics and Other Cholinesterase Inhibitors:*** A synergistic effect may be expected when cholinesterase inhibitors are given concurrently with succinylcholine, similar neuromuscular blocking agents or cholinergic agonists such as bethanechol. **Carcinogenesis, Mutagenesis, Impairment of Fertility** No evidence of a carcinogenic potential was obtained in an 88-week carcinogenicity study of donepezil hydrochloride conducted in CD-1 mice at doses up to 180 mg/kg/day (approximately 90 times the maximum recommended human dose on a mg/m$^2$ basis), or in a 104-week carcinogenicity study in Sprague-Dawley rats at doses up to 30 mg/kg/day (approximately 30 times the maximum recommended human dose on a mg/m$^2$ basis). Donepezil was not mutagenic in the Ames reverse mutation assay in bacteria, or in a mouse lymphoma forward mutation assay *in vitro*. In the chromosome aberration test in cultures of Chinese hamster lung (CHL) cells, some clastogenic effects were observed. Donepezil was not clastogenic in the *in vivo* mouse micronucleus test and was not genotoxic in an *in vivo* unscheduled DNA synthesis assay in rats. Donepezil had no effect on fertility in rats at doses up to 10 mg/kg/day (approximately 8 times the maximum recommended human dose on a mg/m$^2$ basis). **Pregnancy *Pregnancy Category C:*** Teratology studies conducted in pregnant rats at doses up to 16 mg/kg/day (approximately 13 times the maximum recommended human dose on a mg/m$^2$ basis) and in pregnant rabbits at doses up to 10 mg/kg/day (approximately 16 times the maximum recommended human dose on a mg/m$^2$ basis) did not disclose any evidence for a teratogenic potential of donepezil. However, in a study in which pregnant rats were given up to 10 mg/kg/day (approximately 8 times the maximum recommended human dose on a mg/m$^2$ basis) from day 17 of gestation through day 20 postpartum, there was a slight increase in still births and a slight decrease in pup survival through day 4 postpartum at this dose; the next lower dose tested was 3 mg/kg/day. There are no adequate or well-controlled studies in pregnant women. ARICEPT® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers** It is not known whether donepezil is excreted in human breast milk. ARICEPT® has no indication for use in nursing mothers. **Pediatric Use** There are no adequate and well-controlled trials to document the safety and efficacy of ARICEPT® in any illness occurring in children. **Geriatric Use** Alzheimer's disease is a disorder occurring primarily in individuals over 55 years of age. The mean age of the patients enrolled in the clinical studies with ARICEPT® was 73 years; 80% of these patients were between 65 and 84 years old and 49% of the patients were at or above the age of 75. The efficacy and safety data presented in the clinical trials section were obtained from these patients. There were no clinically significant differences in most adverse events reported by patient groups ≥65 years old and <65 years old. **ADVERSE REACTIONS *Mild To Moderate Alzheimer's Disease* Adverse Events Leading to Discontinuation** The rates of discontinuation from controlled clinical trials of ARICEPT® due to adverse events for the ARICEPT® 5 mg/day treatment groups were comparable to those of placebo-treatment groups at approximately 5%. The rate of discontinuation of patients who received 7-day escalations from 5 mg/day to 10 mg/day, was higher at 13%. The most common adverse events leading to discontinuation, defined as those occurring in at least 2% of patients and at twice the incidence seen in placebo patients, are shown in Table 1. **Table 1. Most Frequent Adverse Events Leading to Withdrawal from Controlled Clinical Trials by Dose Group (Placebo, 5 mg/day ARICEPT®, and 10 mg/day ARICEPT®, respectively); Patients Randomized (355, 350, 315); Event/% Discontinuing:** Nausea (1%, 1%, 3%); Diarrhea (0%, <1%, 3%); Vomiting (<1%, <1%, 2%). **Most Frequent Adverse Clinical Events Seen in Association with the Use of ARICEPT®.** The most common adverse events, defined as those occurring at a frequency of at least 5% in patients receiving 10 mg/day and twice the placebo rate, are largely predicted by ARICEPT®'s cholinomimetic effects. These include nausea, diarrhea, insomnia, vomiting, muscle cramp, fatigue and anorexia. These adverse events were often of mild intensity and transient, resolving during continued ARICEPT® treatment without the need for dose modification. There is evidence to suggest that the frequency of these common adverse events may be affected by the rate of titration. An open-label study was conducted with 269 patients who received placebo in the 15 and 30-week studies. These patients were titrated to a dose of 10 mg/day over a 6-week period. The rates of common adverse events were lower than those seen in patients titrated to 10 mg/day over one week in the controlled clinical trials and were comparable to those seen in patients on 5 mg/day. See Table 2 for a comparison of the most common adverse events following one and six week titration regimens. **Table 2. Comparison of rates of adverse events in patients titrated to 10 mg/day over 1 and 6 weeks (No titration: Placebo [n=315], No titration: 5 mg/day [n=311], One week titration: 10 mg/day [n=315], Six week titration: 10 mg/day [n=269], respectively):** Nausea (6%, 5%, 19%, 6%); Diarrhea (5%, 8%, 15%, 9%); Insomnia (6%, 6%, 14%, 6%); Fatigue (3%, 4%, 8%, 3%); Vomiting (3%, 3%, 8%, 5%); Muscle cramps (2%, 6%, 8%, 3%); Anorexia (2%, 3%, 7%, 3%). **Adverse Events Reported in Controlled Trials** The events cited reflect experience gained under closely monitored conditions of clinical trials in a highly selected patient population. In actual clinical practice or in other clinical trials, these frequency estimates may not apply, as the conditions of use, reporting behavior, and the kinds of patients treated may differ. Table 3 lists treatment emergent signs and symptoms that were reported in at least 2% of patients in placebo-controlled trials who received ARICEPT® and for which the rate of occurrence was greater for ARICEPT® assigned than placebo assigned patients. In general, adverse events occurred more frequently in female patients and with advancing age. **Table 3. Adverse Events Reported in Controlled Clinical Trials in Mild to Moderate Alzheimer's Disease in at Least 2% of Patients Receiving ARICEPT® and at a Higher Frequency than Placebo-treated Patients (Body System/Adverse Event: Placebo [n=355], ARICEPT® [n=747], respectively): Percent of Patients with any Adverse Event: 72, 74. Body as a Whole:** Headache (9, 10); Pain, various locations (8, 9); Accident (6, 7); Fatigue (3, 5). **Cardiovascular System:** Syncope (1, 2). **Digestive System:** Nausea (6, 11); Diarrhea (5, 10); Vomiting (3, 5); Anorexia (2, 4). **Hemic and Lymphatic System:** Ecchymosis (3, 4). **Metabolic and Nutritional Systems:** Weight Decrease (1, 3). **Musculoskeletal System:** Muscle Cramps (2, 6); Arthritis (1, 2). **Nervous System:** Insomnia (6, 9); Dizziness (6, 8); Depression (<1, 3); Abnormal Dreams (0, 3); Somnolence (<1, 2). **Urogenital System:** Frequent Urination (1, 2). **Other Adverse Events Observed During Clinical Trials.** ARICEPT® has been administered to over 1700 individuals during clinical trials worldwide. Approximately 1200 of these patients have been treated for at least 3 months and more than 1000 patients have been treated for at least 6 months. Controlled and uncontrolled trials in the United States included approximately 900 patients. In regards to the highest dose of 10 mg/day, this population includes 650 patients treated for 3 months, 475 patients treated for 6 months and 116 patients treated for over 1 year. The range of patient exposure is from 1 to 1214 days. Treatment emergent signs and symptoms that occurred during 3 controlled clinical trials and two open-label trials in the United States were recorded as adverse events by the clinical investigators using terminology of their own choosing. To provide an overall estimate of the proportion of individuals having similar types of events, the events were grouped into a smaller number of standardized categories using a modified COSTART dictionary and event frequencies were calculated across all studies. These categories are used in the listing below. The frequencies represent the proportion of 900 patients from these trials who experienced that event while receiving ARICEPT®. All adverse events occurring at least twice are included, except for those already listed in Tables 2 or 3, COSTART terms too general to be informative, or events less likely to be drug caused. Events are classified by body system and listed using the following definitions: *frequent adverse events*—those occurring in at least 1/100 patients; *infrequent adverse events*—those occurring in 1/100 to 1/1000 patients. These adverse events are not necessarily related to ARICEPT® treatment and in most cases were observed at a similar frequency in placebo-treated patients in the controlled studies. No important additional adverse events were seen in studies conducted outside the United States. **Body as a Whole:** *Frequent:* influenza, chest pain, toothache; *Infrequent:* fever, edema face, periorbital edema, hernia hiatal, abscess, cellulitis, chills, generalized coldness, head fullness, listlessness. **Cardiovascular System:** *Frequent:* hypertension, vasodilation, atrial fibrillation, hot flashes, hypotension; *Infrequent:* angina pectoris, postural hypotension, myocardial infarction, AV block (first degree), congestive heart failure, arteritis, bradycardia, peripheral vascular disease, supraventricular tachycardia, deep vein thrombosis. **Digestive System:** *Frequent:* fecal incontinence, gastrointestinal bleeding, bloating, epigastric pain; *Infrequent:* eructation, gingivitis, increased appetite, flatulence, periodontal abscess, cholelithiasis, diverticulitis, drooling, dry mouth, fever sore, gastritis, irritable colon, tongue edema, epigastric distress, gastroenteritis, increased transaminases, hemorrhoids, ileus, increased thirst, jaundice, melena, polydipsia, duodenal ulcer, stomach ulcer. **Endocrine System:** *Infrequent:* diabetes mellitus, goiter. **Hemic and Lymphatic System:** *Infrequent:* anemia, thrombocythemia, thrombocytopenia, eosinophilia, erythrocytopenia. **Metabolic and Nutritional Disorders:** *Frequent:* dehydration; *Infrequent:* gout, hypokalemia, increased creatine kinase, hyperglycemia, weight increase, increased lactate dehydrogenase. **Musculoskeletal System:** *Frequent:* bone fracture; *Infrequent:* muscle weakness, muscle fasciculation. **Nervous System:** *Frequent:* delusions, tremor, irritability, paresthesia, aggression, vertigo, ataxia, increased libido, restlessness, abnormal crying, nervousness, aphasia; *Infrequent:* cerebrovascular accident, intracranial hemorrhage, transient ischemic attack, emotional lability, neuralgia, coldness (localized), muscle spasm, dysphoria, gait abnormality, hypertonia, hypokinesia, neurodermatitis, numbness (localized), paranoia, dysarthria, dysphasia, hostility, decreased libido, melancholia, emotional withdrawal, nystagmus, pacing. **Respiratory System:** *Frequent:* dyspnea, sore throat, bronchitis; *Infrequent:* epistaxis, post nasal drip, pneumonia, hyperventilation, pulmonary congestion, wheezing, hypoxia, pharyngitis, pleurisy, pulmonary collapse, sleep apnea, snoring. **Skin and Appendages:** *Frequent:* pruritus, diaphoresis, urticaria; *Infrequent:* dermatitis, erythema, skin discoloration, hyperkeratosis, alopecia, fungal dermatitis, herpes zoster, hirsutism, skin striae, night sweats, skin ulcer. **Special Senses:** *Frequent:* cataract, eye irritation, vision blurred; *Infrequent:* dry eyes, glaucoma, earache, tinnitus, blepharitis, decreased hearing, retinal hemorrhage, otitis externa, otitis media, bad taste, conjunctival hemorrhage, ear buzzing, motion sickness, spots before eyes. **Urogenital System:** *Frequent:* urinary incontinence, nocturia; *Infrequent:* dysuria, hematuria, urinary urgency, metrorrhagia, cystitis, enuresis, prostate hypertrophy, pyelonephritis, inability to empty bladder, breast fibroadenosis, fibrocystic breast, mastitis, pyuria, renal failure, vaginitis. ***Severe Alzheimer's Disease* Adverse Events Leading to Discontinuation:** The rates of discontinuation from controlled clinical trials of ARICEPT® due to adverse events for the ARICEPT® patients were approximately 12% compared to 7% for placebo patients. The most common adverse events leading to discontinuation, defined as those occurring in at least 2% of ARICEPT® patients and at twice the incidence seen in placebo patients, were anorexia (2% vs 1% placebo), nausea (2% vs <1% placebo), diarrhea (2% vs 0% placebo), and urinary tract infection (2% vs 1% placebo). **Most Frequent Adverse Clinical Events Seen in Association with the Use of ARICEPT®** The most common adverse events, defined as those occurring at a frequency of at least 5% in patients receiving ARICEPT® and twice the placebo rate, are largely predicted by ARICEPT®'s cholinomimetic effects. These include diarrhea, anorexia, vomiting, nausea, and ecchymosis. These adverse events were often of mild intensity and transient, resolving during continued ARICEPT® treatment without the need for dose modification. **Adverse Events Reported in Controlled Trials** Table 4 lists treatment emergent signs and symptoms that were reported in at least 2% of patients in placebo-controlled trials who received ARICEPT® and for which the rate of occurrence was greater for ARICEPT® assigned than placebo assigned patients. **Table 4. Adverse Events Reported in Controlled Clinical Trials in Severe Alzheimer's Disease in at Least 2% of Patients Receiving ARICEPT® and at a Higher Frequency than Placebo-treated Patients (Body System/Adverse Event: Placebo [n=392], ARICEPT® [n=501], respectively): Percent of Patients with any Adverse Event: 73, 81. Body as a Whole:** Accident (12, 13); Infection (9, 11); Headache (3, 4); Pain (2, 3); Back Pain (2, 3); Fever (1, 2); Chest Pain (<1, 2). **Cardiovascular System:** Hypertension (2, 3); Hemorrhage (1, 2); Syncope (1, 2). **Digestive System:** Diarrhea (4, 10); Vomiting (4, 8); Anorexia (4, 8); Nausea (2, 6). **Hemic and Lymphatic System:** Ecchymosis (2, 5). **Metabolic and Nutritional Systems:** Creatine Phosphokinase Increased (1, 3); Dehydration (1, 2); Hyperlipemia (<1, 2). **Nervous System:** Insomnia (4, 5); Hostility (2, 3); Nervousness (2, 3); Hallucinations (1, 3); Somnolence (1, 2); Dizziness (1, 2); Depression (1, 2); Confusion (1, 2); Emotional Lability (1, 2); Personality Disorder (1, 2). **Skin and Appendages:** Eczema (2, 3). **Urogenital System:** Urinary Incontinence (1, 2). **Other Adverse Events Observed During Clinical Trials** ARICEPT® has been administered to over 600 patients with severe Alzheimer's Disease during clinical trials of at least 6 months duration, including 3 double blind placebo controlled trials, one of which had an open label extension. All adverse events occurring at least twice are included, except for those already listed in Table 4, COSTART terms too general to be informative, or events less likely to be drug caused. Events are classified by body system using the COSTART dictionary and listed using the following definitions: *frequent adverse events*—those occurring in at least 1/100 patients; *infrequent adverse events*—those occurring in 1/100 to 1/1000 patients. These adverse events are not necessarily related to ARICEPT® treatment and in most cases were observed at a similar frequency in placebo-treated patients in the controlled studies. **Body as a Whole:** *Frequent:* abdominal pain, asthenia, fungal infection, flu syndrome; *Infrequent:* allergic reaction, cellulitis, malaise, sepsis, face edema, hernia. **Cardiovascular System:** *Frequent:* hypotension, bradycardia, ECG abnormal, heart failure; *Infrequent:* myocardial infarction, angina pectoris, atrial fibrillation, congestive heart failure, peripheral vascular disorder, supraventricular extrasystoles, ventricular extrasystoles, cardiomegaly. **Digestive System:** *Frequent:* constipation, gastroenteritis, fecal incontinence, dyspepsia; *Infrequent:* gamma glutamyl transpeptidase increase, gastritis, dysphagia, periodontitis, stomach ulcer, periodontal abscess, flatulence, liver function tests abnormal, eructation, esophagitis, rectal hemorrhage. **Endocrine System:** *Infrequent:* diabetes mellitus. **Hemic and Lymphatic System:** *Frequent:* anemia; *Infrequent:* leukocytosis. **Metabolic and Nutritional Disorders:** *Frequent:* weight loss, peripheral edema, edema, lactic dehydrogenase increased, alkaline phosphatase increased; *Infrequent:* hypercholesteremia, hypokalemia, hypoglycemia, weight gain, bilirubinemia, BUN increased, $B_{12}$ deficiency anemia, cachexia, creatinine increased, gout, hyponatremia, hypoproteinemia, iron deficiency anemia, SGOT increased, SGPT increased. **Musculoskeletal System:** *Frequent:* arthritis; *Infrequent:* arthrosis, bone fracture, arthralgia, leg cramps, osteoporosis, myalgia. **Nervous System:** *Frequent:* agitation, anxiety, tremor, convulsion, wandering, abnormal gait; *Infrequent:* apathy, vertigo, delusions, abnormal dreams, cerebrovascular accident, increased salivation, ataxia, euphoria, vasodilatation, cerebral hemorrhage, cerebral infarction, cerebral ischemia, dementia, extrapyramidal syndrome, grand mal convulsion, hemiplegia, hypertonia, hypokinesia. **Respiratory System:** *Frequent:* pharyngitis, pneumonia, cough increased, bronchitis; *Infrequent:* dyspnea, rhinitis, asthma. **Skin and Appendages:** *Frequent:* rash, skin ulcer, pruritus; *Infrequent:* psoriasis, skin discoloration, herpes zoster, dry skin, sweating, urticaria, vesiculobullous rash. **Special Senses:** *Infrequent:* conjunctivitis, glaucoma, abnormal vision, ear pain, lacrimation disorder. **Urogenital System:** *Frequent:* urinary tract infection, cystitis, hematuria, glycosuria; *Infrequent:* vaginitis, dysuria, urinary frequency, albuminuria. **Postintroduction Reports** Voluntary reports of adverse events temporally associated with ARICEPT® that have been received since market introduction that are not listed above, and that there is inadequate data to determine the causal relationship with the drug include the following: abdominal pain, agitation, cholecystitis, confusion, convulsions, hallucinations, heart block (all types), hemolytic anemia, hepatitis, hyponatremia, neuroleptic malignant syndrome, pancreatitis, and rash. **OVERDOSAGE Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug.** As in any case of overdose, general supportive measures should be utilized. Overdosage with cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, collapse and convulsions. Increasing muscle weakness is a possibility and may result in death if respiratory muscles are involved. Tertiary anticholinergics such as atropine may be used as an antidote for ARICEPT® overdosage. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response. Atypical responses in blood pressure and heart rate have been reported with other cholinomimetics when co-administered with quaternary anticholinergics such as glycopyrrolate. It is not known whether ARICEPT® and/or its metabolites can be removed by dialysis (hemodialysis, peritoneal dialysis, or hemofiltration). Dose-related signs of toxicity in animals included reduced spontaneous movement, prone position, staggering gait, lacrimation, clonic convulsions, depressed respiration, salivation, miosis, tremors, fasciculation and lower body surface temperature.

# THE *ONLY MONOTHERAPY* APPROVED FOR ALL STAGES OF AD

## ARICEPT preserved function 72% longer in moderate AD patients[1,2*]

*Significant functional benefits included[†]:*

■ Eating ■ Dressing ■ Using the telephone

Results from a community-based, 54-week, double-blind, randomized, placebo-controlled trial. Moderate AD patients (MMSE 12–20; N=431) were treated with either ARICEPT 10 mg (following 4 weeks of treatment with the 5 mg dose) or placebo. The primary end point was time to clinically evident functional decline.

*Kaplan-Meier "survival" estimates of time to clinically evident functional decline as assessed by investigator (≥20% decline in ADLs or IADLs or 1-point increase in CDR); statistical significance was determined using the log-rank test to compare Kaplan-Meier curves.

[†]*P*<.05 vs placebo.

## *Helps patients be more like themselves longer™*

ARICEPT is indicated for the treatment of dementia of the Alzheimer's type. Efficacy has been demonstrated in patients with mild to moderate Alzheimer's disease, as well as in patients with severe Alzheimer's disease.

**Important safety information**

Cholinesterase inhibitors have the potential to increase gastric acid secretion. Patients at risk for developing ulcers, including those receiving concurrent NSAIDs, should be monitored closely for gastrointestinal bleeding.

In clinical trials, syncopal episodes have been reported (2% for ARICEPT versus 1% for placebo).

In clinical trials, the most common adverse events seen with ARICEPT were nausea, diarrhea, insomnia, vomiting, muscle cramps, fatigue, anorexia, and ecchymosis. In studies, these were usually mild and transient.

*Please see brief summary of prescribing information on adjacent page.*

**References: 1.** Mohs RC, Doody RS, Morris JC, et al, for the "312" Study Group. A 1-year, placebo-controlled preservation of function survival study of donepezil in AD patients. *Neurology*. 2001;57:481-488. **2.** Data on file. Pfizer Inc, New York, NY.

ARICEPT® (donepezil HCl) ONCE-A-DAY ODT™ Orally Disintegrating Tablets (5-MG and 10-MG)



ONCE-A-DAY ARICEPT® (donepezil HCl) 5-MG AND 10-MG TABLETS