



Finding Support
and Furthering
Alzheimer Disease
Research

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On the cover: Jane and Harvey Levy of Henderson, Nevada. Mr. Levy is a patient at Cleveland Clinic Lou Ruvo Center for Brain Health.

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Cleveland Clinic's Center for Geriatric Medicine is ranked the No. 10 geriatrics program in the country by *U.S. News & World Report*. For details, visit clevelandclinic.org/geriatricmedicine.



Ronan Factora, MD

Dear Colleagues,

The mission of Cleveland Clinic's Center for Geriatric Medicine is to improve care for the oldest and frailest members of society. This is why we are so pleased to be bringing you *Geriatric Times*. Its aim is to provide timely and useful information on topics related to the full spectrum of care for the aging population.

I am honored to be taking over as medical editor of *Geriatric Times* from my colleague Dr. Barbara Messinger-Rapport, who has moved on to work on a large-scale demonstration project to improve nursing home quality of care at several facilities.

As individuals age, there can be a general acceptance that most health issues are part of the normal aging process. But we have an extensive body of evidence showing that this is not always true. In fact, I often tell my patients they should not explain away a symptom or event as "normal aging" lest we miss something that can be corrected. We want to encourage patients to talk to us right away when a health event happens. The topics in this issue focus on planning and preventive care as follows:

- New research trials for Alzheimer disease, featuring Dr. Jeffrey Cummings, Director of Cleveland Clinic Lou Ruvo Center for Brain Health
- Screening elderly patients for cancer and the need for a multidisciplinary treatment team, by Dr. Dale Shepard in the Department of Hematology and Oncology
- News on the shingles vaccine for people over 60 and what's on the horizon, by Dr. Michael Rothberg, Vice Chair for Research in the Medicine Institute, and Dr. Phuc Le, a Fellow in the Medicine Institute
- A new process of detecting dementia and providing dementia care for hospital inpatients, featuring Dr. Leo Pozuelo, Section Head of Consultation Liaison Psychiatry and a staff psychiatrist
- Insomnia in the elderly, recognizing it and treating it, featuring Dr. Jessica Rundo of the Cleveland Clinic Sleep Center
- Finally, I have penned the last article about the hot-button issue of the elderly being victims of financial fraud — what to look for and resources to help our patients.

The diseases and concerns addressed in this issue have interventions meant to reduce risk of occurrence, because when a problem arises the consequences can be quite dire.

We appreciate our partnership with you. Please don't hesitate to contact me at 216.444.8091, or factorr@ccf.org, with any questions, concerns or suggestions on how we might improve future services to you and your patients.

Sincerely,

Ronan Factora, MD

Director, Geriatric Medicine Fellowship Program
Center for Geriatric Medicine
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From Wrong Turns to the Right Stuff: A Strategy for Clinical Trial Success in Alzheimer Disease

Featuring Jeffrey L. Cummings, MD, ScD

There's no sugarcoating it: Alzheimer disease (AD) researchers have been unsuccessful in the quest for new therapies to prevent the disease or delay its onset, slow its progression or improve its symptoms.

That's the inescapable conclusion of a comprehensive review published in July 2014 by researchers at Cleveland Clinic's Lou Ruvo Center for Brain Health (LRCBH). The analysis (*Alzheimers Res Ther.* 2014;6[4]:37) found that between 2002 and 2012, 99.6 percent of AD drugs that entered the clinical trial pipeline failed.

"Traditionally, most clinical trials have studied drugs to treat AD once an individual has signs of dementia," says the study's lead author, Jeffrey L. Cummings, MD, ScD, Director of the LRCBH. "By that point, it may be too late to make a significant impact."

FOCUSING ON THE 'RIGHT STUFF'

Armed with that insight, Dr. Cummings and his colleagues are shaping the LRCBH's clinical trial program for AD — one of the largest such programs in the nation — to help change the trajectory of success in AD trials.

The multisite program (with four locations — in Las Vegas; Weston, Florida; and Cleveland and Lakewood, Ohio) is pursuing a bold three-pronged mission of developing strategies to transform the clinical trial process, improve the quality of trials and develop new therapies for AD.

"We now believe that treating patients in the dementia phase is too late because the neuropathological changes are already well-established."

— Jeffrey L. Cummings, MD, ScD

Central to the program is a commitment to improve the track record of investigational therapies for AD by doggedly focusing on the "right" things, including:

- The right patients
- The right drugs (or other interventions)
- The right outcomes and biology

THE RIGHT PATIENTS — AT THE RIGHT TIME

Although AD trials historically have focused on patients with Alzheimer dementia, researchers have come to realize that AD has a long existence in the brain before signs of dementia manifest. "We now believe that treating patients in the dementia phase is too late because the neuropathological changes are already well-established," Dr. Cummings explains.

Therefore, much of the LRCBH's current AD research is focused on:

- **Prevention** in individuals who are overtly normal but at high risk of developing AD
- **Earlier intervention** in patients who are symptomatic for mild disease but do not yet meet the criteria for Alzheimer dementia

The table profiles a sampling of prevention and early-intervention studies now underway at the LRCBH. Two of the major prevention studies are outlined below.

TOMMORROW. The largest worldwide AD prevention study to date, TOMMORROW focuses on age and genetics to determine AD risk among 65- to 83-year-olds who are still cognitively normal. It is recruiting more than 5,000 healthy participants across three continents. Individuals at high risk for AD are randomized to placebo or pioglitazone (currently FDA-approved to treat type 2 diabetes) to determine whether the latter therapy can delay or prevent AD.

Table. Selected Cleveland Clinic AD Trials Focused on Prevention or Early Intervention

| Study name/ descriptor | LRCBH location(s) | Subject profile | Subject age (yr) | Intervention | Duration |
|---------------------------|--|--|---------------------|--|-------------------------|
| TOMMORROW | Las Vegas and Weston, Fla. | Normal cognition | 65-83 | Daily dose of pioglitazone | 5 yr |
| A4 | Las Vegas | Normal cognition | 65-85 | Monthly infusion of solanezumab (monoclonal antibody) | 3 yr |
| Donepezil | Cleveland | Normal cognition but has first- degree relative with AD diagnosis | 60-75 | Donepezil (cholinesterase inhibitor) 5 mg/d for 4 wk, then 10 mg/d | 9 visits over 7-8 mo |
| NOBLE | Las Vegas | Mild to moderate AD | 55-85 | Daily oral tablet (T-817MA) | 52 wk |
| Rasagiline | Las Vegas, Cleveland, and Lakewood, Ohio | Mild to moderate AD | 50-90 | MAO inhibitor (1 mg/d) | 28 wk |

A complete list of AD clinical trials offered by the Lou Ruvo Center for Brain Health (LRCBH) is at clevelandclinic.org/BrainHealthTrials. Read the AD Case Study about a NOBLE trial participant on p. 7.

The study is also investigating whether gene-based biomarkers can determine the risk of developing mild cognitive impairment due to AD within five years. One of the genetic biomarkers being studied is TOMM40, a protein encoded by the TOMM40 gene, which inspired the study name.

Anti-Amyloid Treatment in Asymptomatic Alzheimer’s Disease (A4) Study. In this three-year investigation, cognitively normal 65- to 85-year-olds with evidence of amyloid plaque in the brain are receiving placebo or the experi-

mental monoclonal antibody solanezumab, which attacks the abnormal protein. The LRCBH is participating in the study through the Alzheimer’s Disease Cooperative Study, a cohort of 40 top U.S. academic medical centers. “This is the most advanced neuroscience trial in AD currently being conducted,” Dr. Cummings notes.

Along with the priority given to prevention, other studies in patients with diagnosed AD are trending toward an increased focus on mild to moderate disease, where early interventions may have a more significant impact. For

A Strategy for Clinical Trial Success in Alzheimer Disease

continued

example, a randomized trial is evaluating transcranial magnetic stimulation to improve cognitive functioning in patients with early-stage disease (Table). The therapy stimulates targeted brain areas affected by AD to make them more receptive to cognitive training.

THE RIGHT DRUGS

Current treatments for AD, which include cholinesterase inhibitors and memantine, do not modify the underlying disease process. There is an urgent need to identify therapies that slow disease progression as well as drugs that further improve AD symptoms.

The LRCBH is investigating novel drug therapies, including antibodies administered intravenously or subcutaneously, oral medications to improve mitochondrial function, and other agents that impact AD pathology.

The center's researchers also are embracing a "multiple shots on goal" strategy. For example, a rasagiline study is testing this multifunctional molecule (currently FDA-approved for Parkinson disease) to determine its potential to affect several aspects of neurobiology in AD. "This approach promises to be very important in identifying therapies that eventually will be effective," Dr. Cummings says.

Additionally, LRCBH immunotherapy studies are looking at ways in which the body's immune response can be stimulated or antibodies can be developed artificially to potentially reduce AD's effects on the brain.

THE RIGHT OUTCOMES AND BIOLOGY

Measuring the success of therapies hinges on measuring the right clinical outcomes, including cognitive-behavioral assessments and biomarkers.

Researchers at LRCBH are collaborating with the FDA's Coalition Against Major Diseases to develop new cognitive-behavioral assessments to measure outcomes in patients with very mild AD. "Just as we need to move to studying and treating patients with more mild disease,

we also need to adjust the instrumentation so we can capture changes induced by the drugs," Dr. Cummings says. "If the FDA accepts the recommendations, they could become new standard outcome assessments for clinical trials."

Thinking is also evolving around which biomarkers provide the most useful information in AD research. For the first time, two studies at LRCBH are focusing on pathologies reflected by tangles of tau protein on brain scans, rather than plaques shown by amyloid imaging. "We are finding that tau may be more closely related to cognition than plaques are," Dr. Cummings notes.

HOPE FOR A NEW ERA

"Collectively, these clinical trials and studies represent an exciting new era in AD research," Dr. Cummings observes. "We are helping transform the approach to clinical trials through innovation, with an ultimate goal of finding more — and more effective — options for patients with AD." ■



Dr. Cummings, MD, ScD, is Director of Cleveland Clinic's Lou Ruvo Center for Brain Health (LRCBH). He can be reached at cumminj@ccf.org or 702.483.6031.

This article is updated and reprinted from the Cleveland Clinic *Neurological Institute 2014 Year In Review*.

AD CASE STUDY: Finding Support and Furthering Research

An initial conversation with Harvey and Jane Levy reveals a little about the fact that Mr. Levy, 71, is battling Alzheimer disease. Both husband and wife have a good sense of humor and an obvious love of life. After nearly 50 years together, Mr. Levy's diagnosis is one of the biggest challenges they've had to face. When Mr. Levy, a retired electrical contractor in Los Angeles, was diagnosed five years ago, they turned to Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas. "The disease affects everybody differently. With Harvey, it's unfortunately his speech," says Mrs. Levy. "He knows what he wants to say, but he can't always get it out."

PAVING THE WAY FOR NEW TREATMENTS

Today, numerous clinical trials are underway to help patients like Mr. Levy. He is currently participating in the NOBLE study at the Lou Ruvo Center for Brain Health, coordinated by the Alzheimer's Disease Cooperative Study. This study is evaluating an investigational oral drug for patients with mild to moderate Alzheimer disease. The study includes 450 patients at research sites across the country. Total participation time is about 14 months, during which Mr. Levy is being carefully monitored. Studies have shown that this investigational drug may work by protecting brain cells, which could result in slowing the progress of the memory loss.

Clinical research coordinator Yolande Mucharbach at the Lou Ruvo Center for Brain Health says clinicians speak with patients and caregivers about clinical trials and encourage them to think about participating if they are eligible. "It's people like Harvey and Jane Levy and others in the study who are paving the way to find a new treatment for Alzheimer disease," she says.

CAREGIVER SUPPORT

At the Lou Ruvo Center for Brain Health, there are weekly caregiver support groups available to help family members of individuals with Alzheimer disease in dealing with the significant changes their loved ones face. Led by a psychologist, the meetings are confidential, free and open to the community. Meetings are structured so members



As part of the AD trial he is in, Harvey Levy has a monthly checkup with his physician, Charles Bernick, MD, Medical Director of the Lou Ruvo Center for Brain Health in Las Vegas.

can share their experiences with others and exchange ideas and resources for coping with challenging situations that may arise in their role as care partners.

Mrs. Levy says the group meetings provide a safe and nonjudgmental place. Thanks to the group, she says she has made friends with other people who understand what she's going through. "We met this fabulous couple, and we go out with them all the time," she says. "Her husband has trouble with short-term memory, and Harvey has trouble with speech, but we get along great." Mrs. Levy also has a weekly lunch date with some of the women from the group.

Other programs and classes at the center are designed to keep patients engaged in life. For the past year, the Levys have been attending an art class where they learn about various pieces of art. Now, they're signed up for another art class in which they'll be creating the art. "Cleveland Clinic has been a godsend for us on so many levels," Mrs. Levy says. "The support, the interaction and the hope that it might actually work make it well worth it."

And Mrs. Levy goes on to say that she and Mr. Levy have three sons who could potentially inherit the disease. The couple wants to do everything it can to further research and help others. ■

Cancer Screening and Treatment

Optimizing care of patients whose chances of solid tumor increase with age

By Dale Shepard, MD, PhD

As the population ages, we will be faced with a significant increase in the number of patients with cancer, mostly among the elderly. Cancer is a disease of aging with a 1 in 2 chance of a man developing an invasive cancer in his lifetime and a 1 in 3 chance in women. With a projected 400 percent increase in Americans over age 85 by the year 2050, this will lead to many more cases of malignancy. Cancer screening and the proper approach to treatment in the elderly are topics that need special consideration.

THE APPROACH TO TESTING AND DETERMINING TREATMENT

It is important that primary care physicians and geriatricians develop a standardized approach to cancer screening in the elderly. Most cancer screening guidelines for solid tumors recommend screening until age 75. As the population ages, and with many of these patients still relatively healthy at age 75, an alternative approach is to screen until patients have an estimated 10-year life expectancy.

It is important that patients and their families understand that guidelines to stop screening at age 75 means not looking for cancers in patients with no symptoms of disease. This does not mean that if a patient develops symptoms suggestive of a cancer that we should not do the necessary diagnostic testing to try to identify a cancer. It also doesn't mean that any cancers that are identified shouldn't be treated. Patients, their families and, unfortunately, some healthcare providers are often confused by these distinctions.

Too many elderly patients have a cancer identified by screening, who are then told that they are too old for treatment. If a provider commits to screening an elderly patient and a tumor is diagnosed, the patient must be referred to a surgeon or medical oncologist for a discussion of treatment options. While there is often controversy over what age to start screening for cancer when guidelines are published, we should adopt more consistent ways to address screening parameters in the elderly.

Once a tumor is identified in an older patient, it is important that he or she be treated by a surgeon and medical oncologists who are experienced in dealing with the unique needs of this population. An initial consideration is the importance of using physiologic or functional age and not chronologic age to determine whether a patient

is fit enough to receive chemotherapy. There are many patients in their 70s who are more fit than patients 20 years younger.

The field of geriatric oncology over the past couple of decades has been dominated by tools to assess patients for their fitness to receive treatment with little consideration for how to actually treat these patients once they are identified as good candidates for systemic therapy. There are now good tools that are gaining more widespread acceptance among geriatric oncologists, including one published by the Cancer and Aging Research Group (CARG) that can predict the likelihood of toxicity based on easy to determine factors. These include standard blood tests, tumor type, type and dose of chemotherapy, and some simple geriatric assessments and patient characteristics.

COMMUNICATING TO UNDERSTAND PATIENT GOALS

While determining the patient's goals from therapy is important for all cancer patients, it is crucial for elderly patients. Elderly patients may agree to treatment because they think that their family or their oncologist wants them to, but they may also refuse treatment due to concerns about losing independence or becoming a burden to their families. It is important to remember that the 76-year-old man who is being seen by the oncologist for his metastatic colon cancer may not be the sickest one in the home. He may be the primary caretaker for a spouse with even more debilitating medical conditions.

So a tumor is diagnosed, the patient is fit enough for treatment, and he or she has agreed to proceed with therapy — all the work is done, right? What can be done to optimize success? One consideration is treating the patient with the proper chemotherapy at the proper dose. Too often, oncologists will start an elderly patient with

Ideally, elderly patients with cancer will be treated by a team that includes an oncologist, an advanced practice provider, and a nurse to help with administration of the chemotherapy and management of the toxicities of this treatment.



a reduced dose of chemotherapy due to concern about toxicity. The patient has already been evaluated and is fit enough to get treatment. It has been established for many different tumors that reducing the dose of chemotherapy by just 20 percent can significantly impact the overall survival benefit. If the patient needs a dose reduction due to toxicity, this is appropriate. But if not, the patient is still at risk for toxicity with far less likelihood for benefit.

A MULTIDISCIPLINARY APPROACH TO CARE

Elderly patients are also likely to get through therapy more effectively when treated by an oncologist who adopts a multidisciplinary approach. Ideally, elderly patients with cancer will be treated by a team that includes an oncologist, an advanced practice provider, and a nurse to help with administration of the chemotherapy and management of the toxicities of this treatment. Additional providers who also have crucial roles in their care include a nutritionist, physical therapist, social worker and geriatrician or primary care provider skilled in managing geriatric syndromes. This is because it is well-established that a patient's diet, mobility and mental health all play large roles in the assessment of fitness to receive chemotherapy.

One example is that an elderly patient can have impaired mobility from the cancer, a previous chemotherapy

(which may have caused neuropathy) and/or age-related osteoarthritis. A risk factor for toxicity in the CARG assessment mentioned above is a fall in the previous six months. Working with a physical therapist to increase or maintain mobility may help a patient successfully receive chemotherapy. Geriatricians who can help identify geriatric syndromes before and during treatment can have a tremendous impact on the outcome of an elderly patient with cancer.

As the population continues to age, the proper diagnosis and treatment of cancer in elderly patients is becoming more of a necessity. While there has been progress in the past few years, good screening guidelines, validating the best way to predict who will benefit from chemotherapy, and more research on the appropriate doses and schedules of chemotherapy for elderly patients with cancer are needed. ■



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News on the Herpes Zoster (Shingles) Vaccine and What's on the Horizon

By Michael Rothberg, MD, MPH, and Phuc Le, PhD, MPH

One million Americans experience shingles every year. Overall lifetime risk is about 30 percent. The incidence of HZ rises sharply after age 50 and ranges from 8 and 11 per 1,000 person-years among people over age 65. Incidence appears to be increasing, although the reasons are unknown. Following HZ infection, individuals have a 6 percent lifetime chance of recurrence.

The initial episode, characterized by clusters of clear vesicles in a dermatomal distribution, generally lasts two to four weeks. Patients usually experience pain, itching or tingling. About 10 percent of patients develop herpes ophthalmicus, which can result in vision loss. Infection of the ear (herpes oticus) can cause deafness, as well as facial paralysis.

The most common complication is post-herpetic neuralgia (PHN), defined as a persistent pain for greater than three months from the onset of the rash. PHN is often described as a spontaneous aching or burning pain and can be debilitating. Risk of developing PHN is between 8 percent and 32 percent and increases with age. A small percentage of PHN patients have symptoms that last for years and have serious adverse impact on quality of life.



PREVENTION OF HERPES ZOSTER AND POST-HERPETIC NEURALGIA

Treatment for HZ includes prompt initiation of antivirals (acyclovir, valacyclovir or famciclovir). If administered within 72 hours of rash onset, antivirals can reduce the acute symptoms of HZ, but they do not reduce the risk of developing PHN. Efforts to prevent PHN have focused on vaccination.

The Food and Drug Administration (FDA) approved the first HZ vaccine in 2006. The shingles vaccine (Zostavax®), which contains the live attenuated Oka strain of VZV, works by boosting VZV — specific cellular immunity. The vaccine is licensed to prevent HZ and PHN in immunocompetent people aged 50 years and older, based on results of two large phase III clinical trials.

In the Shingles Prevention Study (SPS), conducted among more than 38,000 people aged 60 and older, the vaccine reduced HZ incidence by 51 percent and PHN by 67 percent. The efficacy of the vaccine for preventing HZ decreased with age, but the efficacy against PHN remained high even after age 70. Recently, long-term follow-up data revealed that the vaccine efficacy wanes sharply after the first year, and the vaccine is no longer effective after 10 years. Vaccine adverse reactions were mild and mostly at the injection site.

ZOSTER VACCINATION IN CLINICAL PRACTICE

Although HZ vaccine prevents HZ and PHN among adults aged 50 and older, the Advisory Committee on Immunization Practices (ACIP) recommends the vaccine only for immunocompetent people 60 and older. Medicare covers the vaccine as a medication under Part D, but the cost to the patient will vary depending on the patient's Part D coverage.

Herpes zoster (HZ), or shingles, is caused by a reactivation of the varicella-zoster virus (VZV), which can occur decades after the primary infection. The most prominent manifestation of zoster is a unilateral vesicular rash, often accompanied by radicular pain and discomfort.

According to the ACIP's recommendation, all people aged 60 years and older, including those who have had shingles in the past, should receive a single dose of HZ vaccine subcutaneously. The vaccine should not be used for the prevention of primary varicella infection (chickenpox) and should not be given to children or adolescents.

Contraindications to vaccination include history of allergic reaction to any vaccine component, immunosuppression or immunodeficiency conditions, and pregnancy. The vaccine should not be administered in the presence of acute illness (e.g., fever) or active untreated tuberculosis. Zoster vaccine can be given concomitantly with the trivalent inactivated influenza vaccine without any effect on the antibody response. However, zoster vaccine should not be administered at the same time as the 23-valent pneumococcal polysaccharide vaccine (PNEUMOVAX® 23). Concurrent use of these two vaccines leads to a lower antibody level of the VZV.

FUTURE OF ZOSTER PREVENTION

There are currently no recommendations to add a booster dose. However, recent data on vaccine duration suggest a booster may be necessary after 10 years. A clinical study on the safety and immunogenicity of a booster dose of zoster vaccine among adults older than 70 found that a booster dose administered more than 10 years after a previous dose was safe and immunogenic. Antibody responses were similar between the boosted group and the newly vaccinated group, but cell-mediated immunity was higher in the boosted group. Because prevention of HZ is gener-

ally via cell-mediated immunity, the booster may be more effective than the original vaccine, but longer clinical trials will be necessary to prove that.

At the same time, a new two-dose HZ has been tested in a phase III randomized trial. The trial enrolled 15,000 people aged over 50, and the vaccine had an efficacy of 97 percent in preventing HZ. The efficacy did not vary by age; however, only 23 percent of recipients were aged 70 years or older. The vaccine was well-tolerated, but had a higher rate of grade III adverse reactions than the live attenuated vaccine. The rates of serious adverse reactions were similar in the two groups.

Because of its greater efficacy, the new vaccine has the potential to change practice, but it has not yet been licensed. The initial trial lasted only three years. Long-term efficacy will not be known for some time. A clinical trial is currently being conducted to compare the HZ/su vaccine to the live attenuated vaccine.

In addition, a trial of the HZ/su vaccine among 70-year-olds is underway to evaluate its impact on PHN and hospitalization, the two most common HZ-related complications. Given the apparent superiority of the new vaccine, patients under the age of 70 may wish to wait until the new vaccine is licensed and priced before deciding on which vaccine to receive. For older patients, who are at higher risk of PHN and who have shorter life expectancies, it may be prudent to vaccinate with the current vaccine. ■



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Everyone Owns Delirium: A Comprehensive Approach to Diagnosing and Minimizing Its Impact

Featuring Leo Pozuelo, MD

Delirium has been referred to as the “geriatrician’s code blue.” It is a medical emergency that requires prompt recognition and intervention to minimize or prevent serious consequences. It is recognized as a brain dysfunction characterized by an acute and fluctuating disturbance of consciousness with a change in cognition or the development of perceptual disturbances.

It is sometimes associated with hallucinations and hyperactivity, with the patient becoming inaccessible to normal contact. Delirium can be caused by a number of conditions, including infection, drug use, seizures, brain tumor, poisoning, head injury and metabolic disturbances.

Unfortunately, delirium is a grossly unrecognized and poorly managed problem in acute care hospitals across the country. Busy clinical settings, lack of knowledge and training, and the rapid transfer of patients are some of the reasons delirium can be missed, with patient behavior often attributed to depression or a normal progression of aging.

Not only is it distressful for the patient and caregivers, delirium increases morbidity, mortality and neuropsychological impact as well as patient length of stay and patient readmissions.

“We can and must do better,” says Leo Pozuelo, MD, Section Head for Consultation Liaison Psychiatry at Cleveland Clinic and a staff member in the Center for Geriatric Medicine. He believes every healthcare discipline has a role in the prevention, identification and treatment of delirium and an interdisciplinary approach is required.

CREATING A DELIRIUM CARE PATH

In 2012, Cleveland Clinic created a multidisciplinary delirium task force to tackle this complex problem at all levels. The idea was that “everyone owns delirium,” and the goal was to take a comprehensive approach to delirium across the health system. The task force wanted to raise awareness, implement regular screenings, and provide easily accessible tools for clinical interventions.

Dr. Pozuelo led the multispecialty delirium task force, which has created a delirium care path and a comprehensive delirium tool kit. The care path rolled out across the system in 2014 after research and pilot tests were completed.

Today the effort focuses on four key areas:

1. Preventing delirium in high-risk individuals
2. Routine screening using evidence-based tools
3. Standardized management using pharmacologic and nonpharmacologic measures
4. Delirium through the continuum of care

PREVENTION

Preventing delirium begins by fully understanding it. In 2014 a full-scale education campaign began for bedside clinicians, nurses and physicians of all levels and inpatient specialties. The task force created a dynamic online learning module with video vignettes as well as an abundance of classes and real-time learning emphasizing risk factors, recognition and strategies for prevention.

REGULAR SCREENING

Because the prevalence for delirium is so high and so often unrecognized, nurses throughout the Cleveland Clinic health system began screening all adult acute care patients with standardized tools at least once a day. The Confusion Assessment Method for the ICU (CAM-ICU) tool was expanded to all intensive care patients. It is the widely recognized gold standard tool for this environment.

Outside the ICU, the task force looked at several evidence-based tools, with bedside nurses trialing three different screening tools. They eventually decided on the Brief Confusion Assessment Method (bCAM) because they found it to be the easiest to use with the closest relationship to the CAM-ICU tool. Nurses and physicians alike preferred the bCAM.

Beginning in late 2014, the bCAM went live on Cleveland Clinic’s electronic medical record system and nurses began completing it daily. Now all adult patients in ICU

and medical/surgical areas are screened on admission, a change in condition or a change in the level of care. To aid in the review of the screens, a delirium accordion report was developed to give clinicians a snapshot view of prior delirium screens, abnormal lab values and high-risk medications.

MANAGEMENT

“Early on, the task force realized the importance of standardizing the management of delirium,” says Dr. Pozuelo. “We were all over the map as to how we treated delirium.” In any setting, treatment of delirium consists of taking care of the underlying medical condition and removal or discontinuation of the precipitating factors, whether environmental or medication related, he notes.

Through much collaboration among psychiatrists, geriatricians, hospitalists, intensivists, neurologists, nurses and pharmacists, two order sets were developed — one for the ICU patient and one for the non-ICU patient. These order sets give guidance to physicians about diagnostic evaluation and select medications to use to control symptoms of agitation and psychosis.

The order sets limit variation in testing and prescribing, yet allow for flexibility and individualization in a controlled fashion. They also include evidence-based, nonpharmacologic interventions such as uninterrupted sleep, adequate hydration and ambulation.

ONGOING CARE

Delirium has traditionally been considered a short-term, benign and transient cognitive disorder. But we have found that this is not the case. Delirium is a leading cause of preventable conditions in elderly patients who are hospitalized, and patients with delirium fare worse than their counterparts who do not suffer from delirium.

Research tells us that the longer the duration of delirium, the greater the chance for long-term cognitive impairment. This is because delirium itself can cause cognitive decline due to long-term psychological distress and other behavioral issues such as poor nutrition, sleep disturbances and falls.

According to the American Delirium Society, more than 7 million hospitalized Americans suffer from delirium each year. The incidence varies depending on the patient population but has been reported to be 10 to 30 percent in hospitalized medically ill patients, 42 percent of hospice patients and 56 percent in hospitalized geriatric patients.¹

This has implications in terms of post-discharge follow-up for patients who developed delirium while hospitalized.

Through improved documentation and coordinated care programs, delirium also is being watched more closely during post-acute care. These efforts are gradually changing the culture of Cleveland Clinic to make everyone aware of delirium and individuals at high risk for it.

“Delirium is finally being seen as an acute brain dysfunction with possible long-term consequences,” says Dr. Pozuelo. “Via collaborative efforts at various institutions, we are learning how to better detect, prevent and treat delirium. We owe this to our patients and their families.” ■

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Insomnia in the Elderly

Recognizing the signs and addressing the issue for better quality of life

Featuring Jessica Vensel Rundo, MD, MS

When an older person has difficulty sleeping, the causes and treatments may be different than for a younger adult, according to Jessica Vensel Rundo, MD, MS, staff physician at the Cleveland Clinic Sleep Disorders Center. For geriatric insomnia, medical conditions play a greater role as triggers, and hypnotic medications play a lesser role in treatment.

RECOGNIZING INSOMNIA

Some 40 to 50 percent of adults aged 60 and older experience insomnia, compared with 10 to 20 percent of younger adults,¹ according to Dr. Rundo.

“Even so, insomnia is easy to miss if you don’t ask older patients about it. They might believe poor sleep and daytime fatigue are normal with aging,” she says.

Sleep in later life is characterized by less slow-wave sleep (deepest stage). Sleep latency — the time it takes to fall asleep — tends to increase, and more awakenings occur at night. Despite these changes, people do not need substantially more or less sleep as they age, Dr. Rundo says.

She suggests three screening questions for insomnia, which is defined as difficulty falling asleep or staying asleep for as long as desired:

1. Are you having difficulties with falling or staying asleep at night?
2. How much sleep do you think you’re getting at night?
3. Do you have daytime fatigue or sleepiness?

You could ask a family member similar questions about an individual with Alzheimer dementia who may be sundowning. This syndrome of increased confusion and agitation in the evening can interfere with sleep through the night.

“Think of insomnia if someone reports taking longer than 30 minutes to fall asleep or waking too early and being unable to go back to sleep,” Dr. Rundo says.

The seven-question Insomnia Severity Index² can help quantify the severity of symptoms such as daytime fatigue and struggles with chores, work, concentration, memory or mood. This validated self-reporting scale also can help monitor treatment over time. “If insomnia is affecting a

person’s daytime functioning, it should be treated,” Dr. Rundo says.

STEP ONE: IDENTIFY MEDICAL FACTORS

Begin by identifying and managing medical conditions that may be interfering with sleep, Dr. Rundo recommends. Common underlying factors include chronic pain, asthma, gastroesophageal reflux, obstructive sleep apnea (OSA), restless legs syndrome, anxiety, depression and medications that affect sleep.

Bowel problems and frequent urination also can interrupt sleep. “A pattern of getting up frequently and having difficulty falling back to sleep can develop. Even if the problem resolves, the disrupted sleep pattern may remain,” Dr. Rundo says. Similarly, frequent awakenings by individuals with Alzheimer disease or other dementias can perpetuate insomnia.

Psychological stress manifests as several insomnia patterns. “Anxious people tend to report ruminating thoughts and excessive worry that cause difficulty with falling asleep, whereas depressed people report sleeping for four or five hours and then having a hard time going back to sleep,” according to Dr. Rundo.

Loss of muscle tone with aging contributes to collapse of the oral pharyngeal airway and OSA. “Probably 40 to 50 percent of individuals over age 60 have some sleep-disordered breathing,” Dr. Rundo says. In her experience, OSA that develops after menopause is a frequent cause of insomnia in women.

“Individuals with OSA may complain of difficulty falling asleep, but more frequently we hear about difficulty staying asleep. They awake multiple times at night, may have been told they snore or stop breathing, and feel excessively sleepy during the day,” Dr. Rundo says. She recommends referral to a sleep specialist for further testing.

STEP TWO: MODIFY BEHAVIORS

After managing medical causes, Dr. Rundo addresses behaviors and beliefs that may reinforce insomnia in patients of all ages. “People with insomnia often lie awake in bed for hours. This conditions them to think it’s OK to be awake in bed. It also conditions them to expect poor sleep,” she says.

Dr. Rundo advises patients to leave the bedroom if they do not fall asleep after 20 minutes and to read a book or listen to relaxing music. When drowsy, they can go back to bed. “One of those times they will fall asleep, and that is the new conditioned response. The body eventually will go into the bedroom and remember to fall asleep,” she explains.

She also recommends trying these sleep hygiene behaviors:

- Controlling stimuli: No TV or computer in the bedroom, no excess noise or light at bedtime
- Going to bed only when drowsy
- Getting up at the same time every day
- Eliminating caffeine after 2-3 p.m.
- Avoiding exercise within 3-4 hours of bedtime

Patients with insomnia often try these behaviors briefly without success. “It takes weeks to months to condition your body to behave differently,” Dr. Rundo explains. Referral to a psychologist for cognitive-behavioral therapy (CBT) can help people persevere in their efforts to change sleep behaviors and negative thoughts about sleep.

MEDICATION OPTIONS

Medication is an option for patients who decline CBT or who have severe insomnia. Dr. Rundo advises caution with sedating histamines, such as diphenhydramine, which can cause memory and cognitive problems in the elderly.

As first-line medication, she suggests a sedating agent to treat a coexisting problem, such as mild depression, anxiety or chronic pain. Options include doxepin, which is indicated for depression and insomnia; other sedating antidepressants such as trazodone or amitriptyline; or the



anticonvulsants gabapentin or pregabalin for neuropathic pain and insomnia.

“Ultimately, I wouldn’t be against using a small dose of a hypnotic, but I would monitor closely for side effects,” she says. Potential risks include daytime sedation, falls and cognitive impairment. For older people, she recommends one-half the usual starting dose (e.g., zolpidem tartrate, 2.5 milligrams). Avoid combining hypnotics with other sedating agents, such as antidepressants, antihistamines, anti-nausea medications, opioids and benzodiazepines, Dr. Rundo advises.

“When you start medication or CBT for insomnia, follow up within a month or two. If an office visit is not possible, at least do a phone follow-up,” she says. ■



Dr. Rundo of Cleveland Clinic’s Neurological Institute is on the staff of the Sleep Disorders Center and serves as the Fellowship Program Director and a Quality Officer. She can be reached at 216.444.0917 or venselj@ccf.org.

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Financial Exploitation of the Elderly Is on the Rise

Looking for signs and offering resources to avert problems

By Ronan Factora, MD

As geriatricians, our ultimate goal is to keep a person residing in the community as independently as possible. Financial strains or a decline in financial management can threaten this ability, leading to significant stress on older persons. All of this can add to the effects of chronic illness on our patients. By paying attention to patients' functional status and possible financial concerns, geriatricians can recognize clues that a person's independence is at risk.

Since the Great Recession, retirees have become frequent targets for those who see them as easy prey. In fact, financial exploitation has become the most common form of reported elder abuse. Recent national surveys have found that around 5 percent of older adults have experienced some form of financial exploitation. This prevalence is similar to that of heart attacks and even higher than that of systolic hypertension. Considering the number of patients we are used to treating for hypertension, we have to wonder how many of these patients are missed in practice.

Many physicians have reported in surveys that their training in the area of elder abuse was poor or nonexistent, particularly when compared with their training in recognition of child abuse or domestic violence. Given the prevalence of this problem, disseminating any information that could increase the detection of financial exploitation could help preserve the quality of life of our older population.



IDENTIFYING PATIENTS

There are several characteristics we can look for to help identify those patients most vulnerable to exploitation. Older persons who are socially isolated, who suffer from bereavement or depression or any mental illness, or who have a history of alcohol or drug abuse could be at risk. Detection of any new impairments in ability to perform basic activities of daily living, change in appearance or hygiene, or accompaniment of the patient by a caregiver who seems overly protective or domineering should also be “red flags” prompting a closer look.

Patients who have been diagnosed with mild cognitive impairment have been observed to have higher risk-taking behavior, and as cognitive impairment advances to clinical dementia, risk also increases. People suffering from dementia may provide personal financial information such as credit card numbers, Social Security numbers and bank account information to strangers or callers masquerading as friends or family. They may also withdraw large amounts of cash only to misplace it or leave the monies in unsecured areas.

THE PHYSICIAN'S ROLE

We can be proactive. As physicians, we can help facilitate discussions with patients to help them plan for the future. We can detect subtle differences in our patients' behaviors and begin the discussion about seeking financial guidance when and if necessary. Often we can refer patients to a number of community resources that are available to help formalize assignment of responsibilities in the form of financial powers of attorney or a conservator.

The consequences for victims of financial exploitation can be long lasting and in the worst of circumstances can lead to the inability to pay for food, medications and housing expenses. But very frequently, physicians only see the

later ramifications of financial exploitation in the form of progressive weight loss, uncontrolled chronic illness, recurrent emergency department visits or hospitalizations. In retrospect, the risk factors that brought the patient to this point may be more apparent.

Much like addressing many of the other geriatric syndromes encountered in clinical practice, a proactive and collaborative approach to dealing with this problem can be effective in identifying, investigating and, when necessary, prosecuting financial exploitation.

Everyone from the bank teller to the pharmacist to a patient's volunteer organization needs to step up today. But often individuals in the community have such brief encounters with a victim of elder fraud or they say "it is not my problem." More often than not, the problem goes on without anyone taking responsibility until it is too late. As physicians, we can help change this.

All states have a list of mandated reporters who are tasked with reporting suspicions of elder abuse to the local adult protective services for investigation. The mistake that many people make is believing that proof is required in order to file a report. The truth is that a report can be made even if there is just a suspicion that abuse is occurring, as long as the report is made in good faith.

Once the process gets started, social workers at adult protective services can work with physicians, attorneys and law enforcement to investigate a report. Physicians are often tasked with evaluating the victims of elder abuse and financial exploitation to determine whether the individual had risk factors for abuse/exploitation, particularly if there is any sign of significant cognitive impairment.

Beyond caring for the individual and understanding the resources available, physicians can assist in increasing the attention of practicing clinicians to this problem by discussing cases of elder abuse and exploitation with trainees. We can also participate in didactics or workshops with colleagues in practice to increase our knowledge and awareness of the topic. ■

Community Resources

There is a wealth of information and tools available to practicing clinicians to learn about elder abuse and financial exploitation. Here are a few:

National Center on Elder Abuse has links to additional state directories of helplines, hotlines and elder-abuse prevention resources in all 50 states and the District of Columbia.

National Academy of Elder Law Attorneys (703.942.5711) offers a search for lawyers specializing in durable powers of attorney, conservatorship, estate planning, elder abuse and other concerns.

National Adult Protective Services Association provides a national map with links to abuse-reporting hotlines by state.

AARP's Scams and Fraud page offers information on the latest frauds against older people.

Better Business Bureau Scam Stopper has information on common scams and instructions on reporting a scam. You can sign up for scam alerts on the site.



Dr. Factora is Director of the Geriatric Medicine Fellowship Program and on staff with the Center for Geriatric Medicine. He recently edited the book *Aging and Money: Reducing Risk of Financial Exploitation and Protecting Financial Resources*. He can be reached at 216.444.8091 or factorr@ccf.org.

Center for Geriatric Medicine Staff Publications

Journals

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Book

Factora RM. *Aging and Money: Reducing Risk of Financial Exploitation and Protecting Financial Resources*. New York, NY: Humana Press; 2014. 212 pgs.

Blog

Geriatric Times Medical Editor Ronan Factora, MD, writes a monthly blog post on the *U.S. News & World Report* website to provide aging consumers with timely health information. To read Dr. Factora's consumer blog, go to usnews.com/topics/author/ronan-factora-md.

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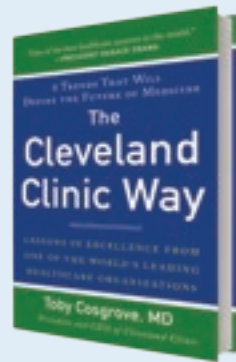
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By Toby Cosgrove, MD
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