

Changing the Face of Pain Management
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Changing the Concept of the Integrated Clinic Means Demonstrating Verifiable Efficacy

Every approach to pain management produces the best outcomes for patients. Clinicians who embrace this approach must avoid repeating the mistakes of the past and concentrate on providing quality service.

Discrepant Goals in Pain Management: Strategies for Balancing the Needs of the Physician, and Other Stakeholders” (SIS-19)

Michael E. Schatman, PhD, CPE, DASPE
 Tuesday, September 8
 10:00am – 12:10pm
 Room 4, Mont-Royal Ballroom

Interdisciplinary pain clinics are an endangered species. Patient numbers keep dwindling, and their budgets are cutting, all because financial considerations of hospitals and insurance companies.

Government would compel hospitals to maintain insurance coverage to cover treatment, says Michael E. Schatman, PhD, CPE, DASPE, Executive Director of the Center for Ethics in Pain Care. Until such mandates

are in place, Schatman says, “This strategy works because interdisciplinary pain management really does help nearly all stakeholders. The trick is learning to demonstrate that.”

To illustrate the challenges pain specialists face, Schatman will start by tracing the sad decline of interdisciplinary pain management and explaining why a nation that had more than 1,000 integrated clinics in 1998 has fewer than 100 today.

Integrated pain management clinics initially opened, both inside hospitals and independently, because researchers consistently found that coordinated teams of complementary pain specialists—usually a physician, a psychologist, a physical therapist, a nurse practitioner, and possibly several others—provide the best care for serious chronic pain.

Indeed, the research looked so good that insurers became (by their standards) positively enthusiastic about pain clinics, many of which responded to the easy money by adding services and padding bills. Worse, the flow of insurance money inspired under-qualified (and occasionally dodgy) practitioners to open their own clinics to make a quick buck.

Costs rose. Outcomes worsened. Insurers began slashing reimbursement rates and dropping coverage altogether. Clin-

icians have to see things from the other perspective and show how he benefits the patient. This works because interdisciplinary pain management really does help nearly all stakeholders. The trick is learning to demonstrate that.

However, Schatman has some advice for clinicians who want to revive the integrated pain program, he says. “Patients suffered because everyone got greedy,” Schatman

Needless, according to Schatman.

“Patients suffered because everyone got greedy,” Schatman



RECAP

Research into the Interaction of Music and Neurobiology May Unlock New Treatments

New data is demonstrating the healing power of music and suggesting new applications for pain management

Several presentations during PAINWeek explored the ways in which the brain interacts with music, by, pain. On Tuesday, Michael B. Elnitsky, MD, PhD, and Daniel F. Cleary presented on the ways in which music can help to alleviate pain. On Wednesday, Rebekah spoke about how our brains can be positively affected by pain differently. The trend continued Friday morning with a presentation by Mark J. Tramo, MD, PhD, Director Institute for Brain Science; Department of Neurology, David Geffen School of Medicine at UCLA. His presentation, “The Neuromodulation of Pain Responses,” provided a look at how the human brain processes sound. While Tramo specializes in the management of pain, he has published studies that have examined the correlation between music and that way it impacts our bodies.

Tramo began by telling the audience that the concept of music as a healing power dates back thousands of years. In mythology, Apollo was associated with both music and healing. Asclepius, a Greek god of healing, was believed to help rid sick patients of their disease. While the scientific figures, the fact is that there have been numerous anecdotal reports over the centuries about the ability of music to ameliorate pain and suffering across a wide range of conditions, and clinical settings. Yes, it is important when dealing with any kind of anecdotal data, but some of these recounted experiences have been the subject of a study of the correlation of music and healing.

There is also a growing body of evidence from randomized-controlled trials demonstrating music’s effectiveness in pain management, said Tramo. He went on to discuss the pathways by which the brain processes sound, that, basically, our brains have an auditory v-

(con

Experience the expanded Living Beyond Breast Cancer
 a “multimedia showcase that presents

...to the fourth and final day of the conference. The schedule today features the four sessions of this Complementary and Alternative Medicine presentation that focus on pain medicine nursing presented by pain management experts from the institution, the second half of the pharmacotherapy module also includes a trio of sessions on regional including pelvic pain, arm and hand pain, and ("phantom tooth pain"). The Special Interest cover topics in pharmacy-based pain services, differences in pain management, new develop-public policy, and the influence of various pain holders on the physician-patient relationship.

At 7:00am with **Hal S. Blatman, MD**, present-nutrition and pain that will explain the ways in s in our patients' diets actually stop their bod-and get in the way of rehabilitation." Blatman ecific nutrients that will augment healing and/duce pain." **Debra J. Drew, MS, ACNS-BC**, ne the challenges associated with pain assess-care setting, especially in special populations. **er, PharmD, BCPS**, will give a talk on phar-

pharmacokinetic pain and pallia- **M. Fitzgerald**, e epidemiology le chronic pelvic s in pathophysi-diagnosis, and s and treatment drome. **bert A. Bonak-** view the preva-and most com-pies as well as he patient con-complementary



therapies in pain management. **Helen N. Turner, NS-BC**, on the use of multimodal analgesia in She will also cover various nonpharmaceutical to be effective additions to multimodal pain **McPherson, PharmD, BCPS**, will elucidate cokinetic and pharmacodynamic properties of mysterious methadone," covering a range of appropriate titration strategies as well as how to converted from another drug to methadone."

...first of three satellite programs scheduled for Patients and Your Practice: The Role of Drug Pain and Risk Management," sponsored by Alere ture **Jennifer E. Bolen, JD**, and **Jeffery A.** ussing practical approaches to incorporating comprehensive chronic pain and risk manage-

bbert A. Bonakdar, MD, continues the and Alternative Medicine track with "Overview Dietary Supplements," during which he will ence of supplement use in specific pain condi-

medication facts." **Roger B. Fillingim, PhD**, will discuss sex and gender differences in pain management and explore possible answers to the question "Do we need pink and blue pills?" **Carri-Ann Gibson, MD**, and **Ilene R. Robeck, MD**, will exam-ine key topics and challenges in evaluating and treating chronic pain in veterans following deployment.

Following the morning break, at 11:10am, **Lora McGuire, MS, RN**, will explore topics in the management of postoperative pain, including preemptive analgesia, special methods of delivery of pain control, and nonopioid, opioid, and adjuvant analgesics. **Srinivas Nalamachu, MD**, will discuss the clinical characteris-tics, assessment, diagnosis, and treatment of arm and hand pain. **Michael E. Schatman, PhD**, will talk about the evolving influence of non-patient and non-physician stakeholders in pain management (insurance, hospital, pharmaceutical, implantable device, and urine drug testing industries, etc) and explain why these various actors must coalesce into a "mutually cooperative system" if the suffering of pain patients is to be ameliorated.

At 12:30pm, the schedule features the final two satellite events of PAINWeek 2012. The faculty of "Persistent and Breakthrough Pain: Responsible Opioid Prescribing for Multidimensional Disorders" will consolidate clinically relevant scientific studies and evidence-based guidelines into practical approaches to persistent pain and break-through pain assessment, responsible opioid prescribing, and repeated re-eval-uation of patient outcomes. "Mission: Pain Management – The Efficient First Visit (An IDEAL® Clinical Encounter)" will discuss nociceptive, neu-ropathic, and centrally-me-di-ated chronic pain; the risks and benefits of nonpharma-cologic and pharmacologic treatments for chronic pain; barriers to the optimal use of opioid analgesics in chronic pain; and methods for screening and risk miti-gation in the initial and follow-up care of patients with chronic pain.

At 2:10pm, **Hal S. Blatman, MD**, will present "a wide range of options for treatment, recovery, and body maintenance for a healthy and pain-free life" for women at midlife. **Bill Paquin**, CEO of Vertical Health, will explore "the pivotal role that Web and mobile applications will play to both increase the efficiency of physician practices and improve patient outcomes" in pain management. **Edward S. Lee, MD**, and **Tu A. Ngo, PhD, MPH**, will offer a plenary session focus-ing on managing psychiatric comorbidities in chronic pain. **Gary W. Jay, MD**, will present a master class on the differential diagnosis and management of migraine and tension-type headache.

Following the afternoon break, **Carol P. Curtiss, MSN, RN-BC**, will discuss key principles involved in balancing effective pain management and screening for risk of substance misuse and addiction in persons with pain. **Peter A. Foreman, DDS**, will examine the difficult diagnostic and treatment challenges associated with orofacial neuropathies. **Mary Lynn McPherson, PharmD**, and **Kathryn A. Walker, PharmD**, will duke it out as

Today's Schedule of Recommended Courses for First-time PAINWeek Attendees

7:00am-8:00am

Nutrition and Pain: Simple Recipes for Pain-Free Health

Hal S. Blatman, MD

7:00am-8:00am

Pelvic Pain

Colleen M. Fitzgerald, MD

8:10am-9:10am

Analgesia: What are the Options?

Helen N. Turner, DNP, RN-BC, PCNP

9:20am-10:20am

Speed Dating with Pharmacists: 50 Top Medication Tips at ER

Mary Lynn McPherson, PharmD, BCPS

Kathryn A. Walker, PharmD, BCPS

11:10am-12:10pm

Pre- and Postop Pain Management

Lora McGuire, MS, RN

2:10pm-3:10pm

Women on the Verge: Sleep, Stress, and Pain at Midlife

Hal S. Blatman, MD

5:20pm-6:20pm

VA Health Care: This is Not Just Your Father's VA

Lucile Burgo-Black, MD, and Stephen...

MD, MPH

Effect in Patients Taking Opioids for Chronic Pain

Prescribe opioids should be aware of the symptoms of opioid-induced constipation and the pharmacologic options for managing this condition

Opioid-induced Constipation: Considerations to Appropriate Early Targeted Therapy for Better Outcomes," a CME-accredited session yesterday that focused on opioid-induced constipation, its management and the pharmacologic options that are currently used to treat this condition, presenters Bill McCarberg, MD; and Michelle Rhiner, RN-BC, MSN, provided information that clinicians can apply to daily practice. The session by talking about the scope of the opioid-induced constipation (OIC). Because prescription opioids are most commonly used medications in the pain management care settings, and because OIC is "one



Patients with chronic pain experience OIC to some degree. In fact, OIC is reported in up to 90% of patients with cancer pain and 80% of patients with chronic nonmalignant pain. She noted that because chronic pain patients rarely develop a tolerance to OIC, most of them will require some form of pharmacologic therapy for constipation (up to 94% of patients with advanced illness who take opioids need laxatives, the most commonly used therapy for OIC).

Untreated or undertreated OIC can compromise pain management in patients with cancer. Rhiner said that surveys have shown that OIC can cause patients to switch to a different opioid, reduce their opioid dose (either in conjunction with their health care provider, or on their own without telling their provider), or even stop taking opioids altogether. Patients with OIC also use more health care resources (they have more hospital admissions and doctor visits, use more home health services, etc). Rhiner said that OIC also has a negative impact on quality of life and functionality in patients with chronic noncancer pain, leading to missed work, reduced productivity, and compromised mental and physical health.

Rhiner concluded her portion of the session by briefly reviewing normal colorectal functional processes. She said that bowel function is "governed by the enteric brain, an organ comprised of billions of neurons," and that any disruption in the neurotransmitters and mechanisms that regulate bowel function (such as those produce by opioids) can lead to constipation and bowel dysfunction. She said that OIC results when opioids bind with periphery sensors in the gut and in the enteric system. This affects not only the colon, but other components of the bowel/gastrointestinal system, producing a spectrum of opioid-induced bowel dysfunction. This can include cramping, bloating, decreased appetite, nausea and other symptoms in addition to constipation. She said that many of these symptoms are often missed by patients and providers and not attributed to the patient's opioid therapy.

Assessing patients for OIC and selecting an appropriate management option

During his portion of the presentation, McCarberg discussed the assessment and management of OIC. He said that "there are no good diagnostic criteria for OIC." Although many patients and clinicians focus on stool frequency when discussing OIC, McCarberg said that this might not provide a complete picture because "there is wide variability in stool frequency" from patient to patient. Thus, when assessing patients for OIC, clinicians should also focus on other factors, such as those outlined in the Rome III criteria for functional constipation. McCarberg reminded the audience that these "are not necessarily for OIC, just for functional constipation. There are no OIC-specific criteria."

When assessing patients for OIC, taking a history is important to find out the patient's normal bowel/defecation routine in order to establish a baseline. "You have to ask the right questions" about the patient's previous and current bowel pattern and activity level, their amount of daily fiber and fluid intake, and laxative use prior

to find out the patient's normal bowel/defecation routine in order to establish a baseline. "You have to ask the right questions" about the patient's previous and current bowel pattern and activity level, their amount of daily fiber and fluid intake, and laxative use prior

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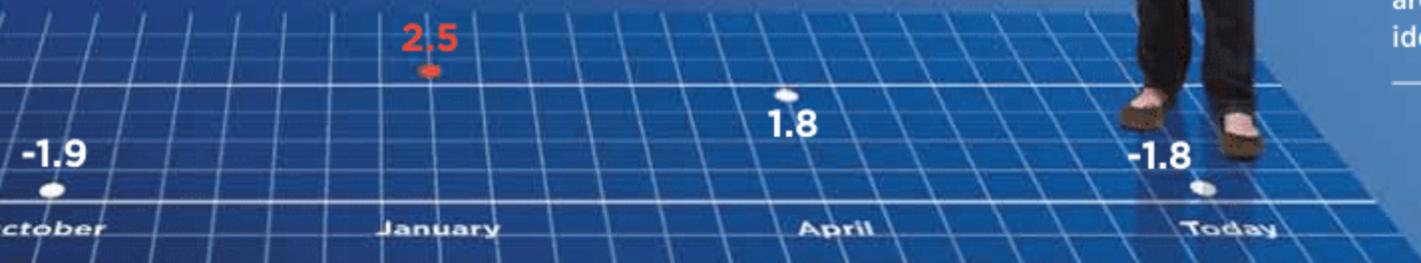
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ain-fighting diet that calls for eliminating trans fats, artificial sweeteners, nutritionally deficient foods, digestive tract disruptors, and other ingredients, patients may be able to effectively reduce the severity of their pain without the use of prescription medications.

and Pain: Simple Rules for Health" (CAM-01)

S. Blatman, MD, DAAPM, ABIHM
y, September 8
00am
el 3, Castellana 1

e owes much of its success to a quality that's
l among foodstuffs: an utter inability to sup-
ost forms of life.

o eat it. Mold takes no root inside it. Even
e it a miss. Industrial food makers, who have
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what they are designed to do: heal them-
prevent medications from working properly,"
o runs the Blatman Pain Clinic in Cincinnati.
oods and your patients will hurt less. They'll
er to opioid medications—and develop less
can prescribe lower doses and stop worrying
kicking down your door."

ent the past couple of decades testing ingre-
fighting diet he will outline during his talk. He
very credible book and study he can find on
he conducts tiny experiments, first on himself,
I friends, and finally on patients.

of testing have left him with a reasonably
elines that seem to provide at least some
every patient who sticks to them for any
tman says that he cannot scientifically prove
ness because he recommends it to every
an maintaining control groups, but he be-

hypothesize from what I've read about the mechanisms by which particular compounds increase pain. But case after case demonstrates a major impact. It's common for my patients with fibromyalgia to report that pain goes down by as much as half when they eliminate all artificial sweeteners," Blatman says.

The insufficiently nutritious category includes many of the usual suspects: sugar, potatoes, fruit juices, and many other foods with high glycemic indexes.

As for the digestive tract disruptors, the list there includes excessive red meat and all wheat products. "The gut plays an incredibly important role in good health," Blatman says. "The good flora that are inside of it break down your food so you can absorb nutrients properly. They also keep your immune system working right, which is why patients with autoimmune diseases get particular relief when they start eating a gut-healthy diet."

Blatman's dietary recommendations are simple. Sticking to them, however, can be tricky. Many diets advise patients to cut back on certain foods and ingredients. Blatman tells patients to avoid them completely, a maxim that requires not only iron self-discipline but also frequent detective work. Many of the forbidden ingredients are found in a wide variety of foods, and often turn up in unexpected places. Blatman remembers one patient who "gave up" wheat but saw no health benefits--because she had no idea about the wheat in her favorite soy sauce.

Patients must also be willing to wait long p
start to see any benefits. Blatman cautions
foods take weeks to work their way entirely
Others take as long as four months, and a
bite of the wrong thing can set the clock bac
can see significant benefits just by cutting bo
ingredients I advise against, but in most case
only come from total abstinence," Blatman sa

Many patients, obviously, will sabotage th
ing here and there. Many end up simply ab
altogether.

"Patients obviously have the right to cho
but I make it clear to them that they are doin
ing to be in pain. I also make it clear to the
changes come before any unusually large
Blatman says.

"If they follow the diet religiously and the
try what I can to fix that. But if the pain isn't e
a patient to eat better, then it certainly isn't b
to risk his or her health by increasing the op
and again," Blatman says. "This diet isn't an e
anything, but it produces very impressive res
and it can do the same for yours."

"Eliminate problem foods and ingredients and your patients will hurt less. They'll also respond better to medications—and develop less tolerance—so you can prescribe lower doses and stop worrying about the kicking down your door."



Effective **24-hour pain control**¹

Once-daily oral dosing with
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Low incidence of dizziness
and somnolence¹

Titration to an 1800 mg dose
2 weeks¹

There was a reported incidence of dizziness
(5.5% vs 2.2% placebo) and somnolence
(5.5% vs 2.7% placebo) at 1800 mg once daily.¹

For more information,
please visit **Booth 316**.

Indication and Usage

GRALISE[®] is indicated for the management of
trigeminal neuralgia (PHN). GRALISE is not
interchangeable with other gabapentin products
due to differing pharmacokinetic profiles
which may affect the frequency of administration.

Important Safety Information

GRALISE is contraindicated in patients who have
demonstrated hypersensitivity to the drug or its ingredients.

Antiepileptic drugs (AEDs) including gabapentin, the active ingredient in GRALISE, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

The most common adverse reaction to GRALISE ($\geq 5\%$ and twice placebo) is dizziness.

In all GRALISE clinical trials the other most common adverse reactions ($\geq 2\%$) are
somnolence, headache, peripheral edema, diarrhea, dry mouth, and nasopharyngitis.
The types and incidence of adverse events were similar across age groups except for
peripheral edema, which tended to increase in incidence with age.

See next page for Brief Summary of Prescribing Information.

Prescribing Information and Medication Guide are available at [redacted]



Orion[®]

EFTA01114709

of one week or longer (at the discretion of the prescriber). Dose should be adjusted in patients with reduced renal function. GRALISE should not be used in patients with CrCl less than 30 or in patients on hemodialysis. For postherpetic neuralgia, GRALISE therapy should be initiated and titrated as follows:

Recommended Titration Schedule

Day 2	Days 3-6	Days 7-10	Days 11-14	Day 15
600 mg	900 mg	1200 mg	1500 mg	1800 mg

GRALISE should be initiated in patients with demonstrated hypersensitivity to the drug or its ingredients.

Dosage Based on Renal Function

Once-daily dosing	
CrCl (mL/min)	GRALISE dose (once daily with evening meal)
>30	1800 mg
30-50	600 mg to 1800 mg
<30	GRALISE should not be administered
on hemodialysis	GRALISE should not be administered

CAUTIONS

Interchangeable with other gabapentin products because of differing pharmacokinetic profiles that may affect the safety and effectiveness of GRALISE in patients with epilepsy has not been established. **Behavior and Ideation** Antiepileptic drugs (AEDs), including gabapentin, the active ingredient in GRALISE, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients taking AEDs for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or any unusual changes in mood or behavior.

Concomitant Medication for Antiepileptic Drugs (including gabapentin, the active ingredient in GRALISE) - Clinical Analysis

	Epilepsy	Psychiatric	Other	Total
Events per 1000 patients	1.0	5.7	1.0	2.4
Events per 1000 patients	3.4	8.5	1.8	4.3
Events per 1000 patients	3.5	1.5	1.9	1.8
Events per 1000 patients	2.4	2.9	0.9	1.9

The incidence of suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric conditions, but the absolute risk differences were similar for the epilepsy and psychiatric conditions. When prescribing GRALISE must balance the risk of suicidal thoughts or behavior with the benefits of GRALISE. GRALISE and many other illnesses for which products containing active components of GRALISE (including gabapentin, the active component in GRALISE) are prescribed are themselves associated with suicidal thoughts and behavior. Should suicidal thoughts or behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms may be related to the illness being treated. Patients, their caregivers, and families should be advised that GRALISE contains gabapentin which is also used to treat epilepsy and that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behaviors, or self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Withdrawal Gabapentin should be withdrawn gradually. If GRALISE is discontinued, this should be done over a minimum of 1 week or longer (at the discretion of the prescriber). **Tumorigenic Potential** In *in vivo* lifetime carcinogenicity studies, an unexpectedly high incidence of pancreatic acinar adenomas was identified in male, but not female, rats. The clinical significance of this finding is unknown. In patients receiving GRALISE therapy in epilepsy comprising 2,085 patient-years of exposure in patients over 65 years of age, tumors were reported in 10 patients, and preexisting tumors worsened in 11 patients, during treatment with GRALISE. Discontinuing the drug. However, no similar patient population untreated with gabapentin was available for background tumor incidence and recurrence information for comparison. Therefore, the effect of GRALISE on the incidence of new tumors in humans or on the worsening or recurrence of previously existing tumors is unknown.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Allergic Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as DRESS, has been reported in patients taking antiepileptic drugs, including GRALISE. Some cases have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, and organ system involvement, such as hepatitis, nephritis, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is a characteristic feature of this disorder. Eosinophilia is a variable in its expression, other organ systems not noted here may be affected. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may precede the rash. If such signs or symptoms are present, the patient should be monitored closely. GRALISE should be discontinued if an alternative etiology for the signs or symptoms is not established.

Laboratory Tests Clinical trial data do not indicate that routine monitoring of clinical laboratory tests is necessary for the safe use of GRALISE. The value of monitoring gabapentin blood levels has not been established.

Warnings Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug. **Postherpetic Neuralgia** In clinical trials of GRALISE for the treatment of postherpetic neuralgia, the incidence of postherpetic neuralgia was similar in patients with postherpetic neuralgia, 9.7% of the 359 patients treated with GRALISE and 9.7% of the 359 patients treated with placebo discontinued prematurely due to adverse reactions. In the GRALISE clinical trials, the most common reason for discontinuation due to adverse reactions was dizziness. Of GRALISE-treated patients who experienced adverse reactions in clinical studies, the majority of those adverse reactions were mild to moderate. Table 4 lists all adverse reactions, regardless of causality, occurring in at least 1% of patients in the GRALISE group for which the incidence of postherpetic neuralgia was similar in the GRALISE group for which the incidence of postherpetic neuralgia was similar in the placebo group.

Adverse Reaction Incidence in Controlled Trials in Neuropathic Pain In clinical trials of GRALISE for the treatment of postherpetic neuralgia, the incidence of postherpetic neuralgia was similar in the GRALISE group for which the incidence of postherpetic neuralgia was similar in the placebo group.

Adverse Reaction Incidence in Controlled Trials in Neuropathic Pain In clinical trials of GRALISE for the treatment of postherpetic neuralgia, the incidence of postherpetic neuralgia was similar in the GRALISE group for which the incidence of postherpetic neuralgia was similar in the placebo group.

Dizziness	10.9	0.3
Somnolence	4.5	2.7
Headache	4.2	4.1
Lethargy	1.1	0.3

In addition to the adverse reactions reported in Table 4 above, the following adverse reactions with a causal relationship to GRALISE were reported during the clinical development for the treatment of postherpetic neuralgia. Events in more than 1% of patients but equally or more frequently in the GRALISE-treated patient than in the placebo group included blood pressure increase, confusional state, gastroenteritis viral, herpes zoster, hypertension, joint swelling, memory impairment, nausea, pneumonia, pyrexia, rash, seasonal allergic rhinitis, respiratory infection. **Postmarketing and Other Experience with other Formulations of Gabapentin** In addition to the adverse experiences reported during clinical testing of gabapentin, the following adverse experiences have been reported in patients receiving other formulations of marketed gabapentin. These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish a causal relationship. Listing is alphabetized: angioedema, blood glucose fluctuation, breast hypertrophy, erythema multiforme, liver function tests, fever, hyponatremia, jaundice, movement disorder, Stevens-Johnson syndrome, following the abrupt discontinuation of gabapentin immediate release have also been reported. The reported events were anxiety, insomnia, nausea, pain and sweating.

DRUG INTERACTIONS

An increase in gabapentin AUC values has been reported when administered with hydrocodone and morphine. An antacid containing aluminum hydroxide and magnesium hydroxide reduced the AUC of gabapentin immediate release by about approximately 20%, but by only 5% when gabapentin immediate release was administered 2 hours after antacids. It is recommended that GRALISE be taken at least 2 hours following antacid administration. There are no pharmacokinetic interactions between gabapentin and the following antiepileptic drugs: carbamazepine, valproic acid, phenobarbital, and naproxen. Cimetidine decreased the apparent clearance of gabapentin by 14% and creatinine clearance by 10%. The effect of gabapentin immediate release on the pharmacokinetics of norethindrone (2.5 mg) or ethinyl estradiol (0.02 mg) administered as a single tablet, except that the C_{max} of norethindrone was increased by 13%. This increase was considered to be clinically significant. Gabapentin immediate release pharmacokinetic parameters were similar with and without probenecid, indicating that gabapentin does not undergo renal tubular secretion that is blocked by probenecid.

USE IN SPECIFIC POPULATIONS

Pregnancy Pregnancy Category C: Gabapentin has been shown to be fetotoxic in rodents, causing ossification of several bones in the skull, vertebrae, forelimbs, and hindlimbs. There are no adequate data from controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefits justify the potential risk to the fetus. To provide information regarding the effects of *in utero* exposure to gabapentin, physicians are advised to recommend that pregnant patients taking GRALISE enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. This can be done by calling the toll free number 1-877-574-2542 and must be done by patients themselves. Information on the registry can also be found at the website www.naaedpregnancyregistry.org/. **Nursing Mothers** Gabapentin is secreted into human milk following oral administration. A nursing infant could be exposed to a maximum dose of approximately 1 mg/kg/day of gabapentin. The effect on the nursing infant is unknown, GRALISE should be used in women who are nursing only if the potential benefits clearly outweigh the risks. **Pediatric Use** The safety and effectiveness of GRALISE in the management of postherpetic neuralgia in patients less than 18 years of age has not been studied. **Geriatric Use** In clinical trials of patients treated with GRALISE in controlled clinical trials in patients with postherpetic neuralgia, which 63% were 65 years of age or older. The types and incidence of adverse events were similar to those in younger groups except for peripheral edema, which tended to increase in incidence with age. GRALISE is excreted primarily in its unchanged form in the urine. Reductions in GRALISE dose should be made in patients with compromised renal function. [see Dosage and Administration]. **Hepatic Impairment** Because GRALISE is metabolized, studies have not been conducted in patients with hepatic impairment. **Renal Impairment** GRALISE is known to be substantially excreted by the kidney. Dosage adjustment is necessary in patients with renal impairment. GRALISE should not be administered in patients with CrCL between 15 and 30 or in patients on hemodialysis [see Dosage and Administration].

DRUG ABUSE AND DEPENDENCE

The abuse and dependence potential of GRALISE has not been evaluated in human studies.

OVERDOSAGE

A lethal dose of gabapentin was not identified in mice and rats receiving single oral doses as high as 1000 mg/kg. Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, and coma. Acute oral overdoses of gabapentin immediate release in humans up to 49 grams have been reported. In these cases, double vision, slurred speech, drowsiness, lethargy and diarrhea were observed. All patients recovered with supportive care. Gabapentin can be removed by hemodialysis. Although hemodialysis has not been shown to be effective in the few overdose cases reported, it may be indicated by the patient's clinical state or in patients with renal impairment.

CLINICAL PHARMACOLOGY

Pharmacokinetics *Absorption and Bioavailability* Gabapentin is absorbed from the proximal small intestine through a saturable L-amino acid transport system. Gabapentin bioavailability is not dose proportional; as the dose increases, bioavailability decreases. When GRALISE (1800 mg once daily) and gabapentin immediate release (1800 mg three times a day) were administered with high fat meals (50% of calories from fat), GRALISE has a higher AUC at steady state compared to gabapentin immediate release. Time to reach maximum plasma concentration for GRALISE is 8 hours, which is about 4-6 hours longer compared to gabapentin immediate release.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility Gabapentin was given in the diet to mice at 600, 1200, and 2000 mg/kg/day and to rats at 250, 1000, and 2000 mg/kg/day for 2 years. A statistically significant increase in the incidence of pancreatic acinar cell adenoma and carcinomas was found in male rats at the high dose; the no-effect dose for the occurrence of carcinomas was 1000 mg/kg/day. Peak plasma concentrations of gabapentin in rats receiving the high dose of 2000 mg/kg/day were more than 10 times higher than in humans receiving 1800 mg per day and in rats receiving 1000 mg/kg/day peak plasma concentrations were more than 6.5 times higher than in humans receiving 1800 mg/day. The pancreatic carcinomas did not affect survival, did not metastasize and were not locally invasive. The relevance of these findings to carcinogenic risk in humans is unclear. Studies designed to investigate the mechanism of gabapentin-induced carcinogenesis in rats indicate that gabapentin stimulates DNA synthesis in rat pancreatic acinar cells *in vitro* and, thus, may be acting as a tumor promoter by enhancing mitogenic activity. It is not known if gabapentin has the ability to increase cell proliferation in other cell types or in other species, including humans. Gabapentin did not demonstrate mutagenic or genotoxic potential in 3 *in vitro* and 4 *in vivo* assays. No effects on fertility or reproduction were observed in rats at doses up to 2000 mg/kg (approximately 10 times the human dose).

Headache Classifications and Treatments

Diagnosis and treatment requires an understanding of the signs, symptoms, and clinical presentation of the multiple forms of tension-type headache

Headache and Tension-Type Headache: Differential Diagnosis and Treatment" (MAS-06)

Gary W. Jay, MD, FAAPM, DAAPM

September 8

10pm

September 4, Nolita 3



Successfully address
patients' needs and to
reducing treatment-
related adverse outcomes,
physicians need to be able
to determine the type of
headache their patient is

The way headache specialists think about the relationship between tension-type and migraine headaches has shifted considerably over the last several decades. "At one point, not that far back, people thought of headaches as a spectrum; a straight line with tension-type headaches (TTHA) at one end and migraines at the other end. Everything in between were gradations," says Gary W. Jay, MD, FAAPM. He says that the question nowadays is whether they are essentially one headache with two different clinical pictures.

To bring attendees of PAINWeek 2012 up to speed on the latest trends in headache medicine, Jay will present a two-hour master class, "Migraine and Tension-Type Headache: NOT Two Ends of a Spectrum!," on Saturday afternoon. During this comprehensive session, he will review the pathophysiologies and varieties of migraine headaches and TTHAs, as well appropriate treatment options.

According to Jay, a major challenge faced by health care providers who treat patients with headache is recognizing the multiple forms of TTHAs and migraines. "I will review what we know about what happens in the brain, particularly different forms of migraine headaches," says Jay.

When many people think about migraines, they still think of the classical migraine headache—typically, a woman with a one-sided throbbing headache who has pain that is triggered by sound or light. Jay says that there are "multiple types of migraine and they can occur with or without aura." He also notes that the nature of aura varies widely, "Aura is visual in 80 to 85 percent of patients; patients can have neurological aura that may elicit speech difficulty or even hemiplegia."

To successfully address patients' needs and to avoid inducing treatment-related adverse outcomes, physicians need to be able to determine the type of headache their patient is experiencing. As an example, triptans and ergot alkaloids are typical abortive treatments for migraines. "Both of these are vasoconstrictors and you never want to offer them to a patient that may have significant aura secondary to vasoconstriction," says Jay. "This can cause further vasoconstriction and neurological deficit and very possibly lead to long-term or permanent damage. It can induce infarction."

The ability to differentiate between symptoms and possible causes can have a profound impact on outcomes and quality of life. "If a patient calls you in the middle of night and tells you something is happening, you need to be able to make a decision on whether to meet them at the emergency room as soon as possible," Jay says. In some visual auras, patients may develop transient monocular vision loss. This presents similarly to amaurosis fugax, a transient ischemic attack involving a retinal artery. During his session, Jay will discuss strategies for confidently and accurately assessing these types of episodes and others.

Earlier this year, the American Academy of Neurology and the American Headache Society jointly published updated evidence-based guidelines on preventive pharmacologic treatment for episodic migraine headaches. The guideline authors used stringent evaluation criteria to review existing evidence.

ops," he says. "So what starts as possibly just a peripheral headache becomes centralized."

In addition to reviewing TTHA pathophysiology and treatments, Jay will talk about diagnostic criteria for common TTHAs. Certain types of headaches arise from reproducible patterns of pericranial muscle tenderness and trigger point activation. "Pericranial muscle tenderness has multiple etiologies, but arises most commonly from myofascial pain syndrome," says Jay. Myofascial pain along the masseter muscle refer pain to the temple. Trigger points may also elicit autonomic dysfunction in the sternocleidomastoid muscle where trigger points associated with lacrimation and redness, in addition to pain.

"An example of what often happens is a patient who comes in with temporomandibular joint (TMJ) pain after multiple surgeries for it, and the real problem is that the TMJ is being referred by a muscle," says Jay.

In cases like this, "It is the job of the physician to determine what the patient needs." Physicians need to determine the origin of the pain. Jay hopes to convey the message that asking the right questions is an important part of treating tension-type headaches. "Patients don't know what to tell you, so you need to tell them what you need to know," he says.

Gary W. Jay is a neurological consultant in pain and disorders of the central nervous system, president-elect of the Eastern Pain Association, and president of the American Pain Society. He is a fellow of the American Academy of Pain Management and the American Academy of Pain Medicine. He was one of the first members of the American Academy of Pain Medicine in

pain assessment means going beyond matching a patient's pain to a number on a scale; it requires clinicians to consider
ors and approaches.

Pain Assessment in Acute Care" (NRS-01)

Debra Drew, MS, ACNS-BC, RN-BC

September 8

10:00am

Room 3, Gracia 7

Pain assessment is gaining traction as an important foundation of pain management. In August 2012, the Joint Commission issued a Sentinel Event Alert re-emphasizing the need to assess and monitor pain as part of the patient management program.

As a pain management specialist on this topic, Debra Drew, MS, will present "Pain Assessment in Acute Care" at the National Pain Week 2012. The presentation will provide an overview of pain assessment, including tools and approaches for special populations relevant to acute care settings. "We need to understand the complexities of the pain and all its facets before they can design a plan that is comfortable," says Drew.

She will emphasize the importance of viewing pain assessment as a process that involves much more than administering a questionnaire to assign a score to the patient's level of pain. "The notion of good pain management begins with a thorough assessment," says Drew. "Is the 0-10 pain intensity scale what you think of when you think of pain assessment? Or is that 'yes,' you may be missing the boat."

In her presentation, Drew will review the latest findings on pain assessment and discuss some of the challenges associated with pain assessment in special populations (such as children and the elderly), as well as patients who are sedated, intubated, ventilated, or developmentally delayed. "We need to assess patients who can't verbalize their pain, who can't tell us what they are feeling or can't speak," says Drew. "We will discuss how to optimally assess pain when you are dealing with a challenging population."

She will also discuss the pain of patients in the intensive care unit and how to use objective measures like blood pressure or pulse

are often used to measure patient pain—represents one example of a challenging pain assessment scenario. Because blood pressure and pulse are not reliable pain indicators, providers are often left feeling helpless when trying to manage pain in this setting. "There are some observational tools that can be introduced in the ICU that provide a better way to assess whether or not a patient has pain, rather than relying on unreliable variables," she says. "Pain assessment and management become complex when a patient cannot tell you what they are feeling. The fact that pain is a totally subjective and complex experience amplifies the difficulties."

For some challenging populations, nurses and physicians may believe that pain assessment is not possible. But, Drew asserts that there is no such thing as a patient who cannot be assessed. "I would like to debunk that notion," she says. "There

I think as a pain community we are realizing how limited those simple, unimodal pain measures are, especially for patients with chronic pain. I think there is going to be an evolution where we will be focusing more and more on pain and functional status.

is always something you can consider for each patient; some patients are more complex than others, but they can all be assessed." Drew will recommend approaches to consider for a variety of special populations.

Drew's presentation will also offer attendees a summary of assessment tools with which many providers are not comfortable or familiar. Along with general background information on these tools, she will provide a framework for how and when to use them in practice. She will also offer clinical examples throughout the presentation to supplement the information provided.

She will also relate assessment to patient selection for chronic opioid analgesia. The Diagnosis, Intractability, Risk, Efficacy (DIRE) scale is an example of a tool that can be used to help practitioners decide whether their patient is a good candidate for long-term opioid therapy. It takes into account factors like substance abuse history and characteristics of the home set-

ting. During her presentation, Drew will provide information on how to use the DIRE scale. "Primary care physicians are very helpful because they are trying to make a diagnosis and guess on how to help their patients after they are discharged from the hospital," she says.

Drew cautions that comprehensive pain assessment takes time to do properly. "But a good pain assessment takes time in the end because it will get a patient through without adverse events in the beginning," she says. "We don't try to take shortcuts because we are busy and we want to do the assessment up front, it can lead to a lot of redundancy later on and a lot of adverse outcomes for the patient." She compares assessment with obtaining a medical history and conducting a thorough physical exam. "These take time, too; yet if you miss some-

badly for the patient."

Drew also plans on talking about the importance of functional status as it relates to pain. "The focus is moving from assessment focused on pain intensity. "I think as a pain community we are realizing how limited those simple, unimodal pain measures are, especially for patients with chronic pain, and there is going to be an evolution where we will be focusing more and more on pain and functional status. We will be using some of these earlier tools." The focus will shift to helping patients with activities of their daily lives.

Debra Drew, MS, ACNS-BC, RN-BC is a pain management specialist for pain management at the University of Maryland Medical Center, Fairview. In addition to her clinical responsibilities, she is involved in patient and staff education and institutional committees on pain and patient safety.

(Continued from cover)

to serve the patients who very much need us, we need to show the stakeholders what's changed and what we can do for them."

Every starts with verifiable efficiency.

It will never roll again, so Schatman notes that to provide integrated pain care must learn to focus on how they confine their efforts to clinically-validated interventions at reasonable costs.

Healthcare providers can responsibly offer payers far bet-

ters' compensation policy, and the insurer's primary goal will be returning the patient to productive employment. In such cases, pain clinicians should bombard the insurer with studies that show how interdisciplinary pain treatment restores patient function better than any alternative.

If, on the other hand, a patient is injured at home, the medical bills will fall to a regular health insurer that will focus primarily on minimizing long-term costs. In such cases, caregivers should bombard the insurer with studies that show cost

costs a fortune because he keeps seeking new treatments for years on end."

Hospitals, likewise, have their own special concerns, which caregivers need to consider before they open (or, in many cases, reopen) pain clinics. There is no plausible way to argue that hospital pain services will become directly profitable again, but he does think that pain clinics could generate indirect profits by retaining hospital employees from their existing



The conference room where Thomas B. Gregory, PharmD, BCPS, DASPE, CPE, gave his presentation "Opioids A to Z" was so jam-packed on Friday morning that Gregory joked that "You guys are such hardcore pain guys that you bypassed the breakfast spread just to be in here early this morning." (Luckily there were still leftover urns of coffee and trays of croissants for those who waited for the session to end to grab breakfast.)

If there is one thing that serves as a common denominator for all PAINWeek 2012 attendees—which includes physicians, pharmacists, nurse practitioners, physician assistants, and even social workers—it is a unified interest in the dosing strategies, side effects, and patient and medication variables associated with opioids. That is exactly what Gregory spoke about during his engaging presentation.

Beginning with the patient and medication variables, Gregory started by discussing the importance of knowing the distinction between opioids that are pure agonists, which have no ceiling effect and are not problematic in terms of increasing dosage (until side effects become intolerable) and those that are partial agonists, which can have a ceiling effect (ie, once a plateau dose is achieved, there will be no further analgesic activity).

Gregory also touched on many different aspects of patient variables in opioid therapy. He said that clinicians who are prescribing or administering opioids must consider a patient's age, particu-

larly because metabolic enzymes in our bodies. Muscle mass must also be considered due to patterns. Comorbidities must be taken into account. Renal dysfunction, for instance, can cause serious problems in patients on chronic opioid therapy. The cost of medication can be a factor, and not just in terms of the patient's ability to pay, but about whether the medication allows the patient to maintain their normal daily routine," said Gregory.

As far as medication pharmacokinetics is concerned, the absorption rate of opioids must be considered. When administered transdermally via a patch, Gregory said, the rate will vary depending on age. During this part of the presentation, one of the audience members asked Gregory what he thought to be the best method for disposing of opioids. Gregory said that although there is no one correct answer, he thinks that patches should be absorbed and then disposed of, and that the diffused drug should then be flushed down the drain. He added that attendees should make sure they are abiding by the law.

The discussion segued into various opioid de-

(continues)

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change in patient condition, or even health care. Gregory reminded the audience that when they change a patient's dosage formulation or route of administration, it is necessary to review opioid equianalgesic dosing. He said should "serve as a guide and not a gospel" because cross tolerance is not universal in nature. He discussed specific scenarios, such as what health care providers should be aware of when switching patients from one

medication to another. Additionally, bioequivalence between routes of administration must be considered before beginning the 5-step opioid conversion process:

1. Globally assess pain complaint.
2. Determine total daily dose of current opioid.
3. Decide which opioid analgesic will be used for the new agent and consult established conversion tables to determine new dose.

Gregory conveyed a significant amount of information about opioids during his session, and left the audience with a number of excellent instructions, resources, and information on dosing, conversion charts, and many

Complementary and Alternative Medicine: Putting Evidence Into Practice

Use of complementary and alternative medicine (CAM) use among chronic pain patients range from 30 to 60%. Many patients are willing to try CAM approaches, including for pain management.

Complementary and Alternative Medicine: Overview and Effective Therapies in Pain" (CAM-02)

Robert Bonakdar, MD
Friday, September 8
10am
Room 3, Castellana 1

difficult to define because it consists of diverse practices and it is constantly changing. Many CAM approaches have gained attention as safe and effective or adjuncts to pharmacologic intervention of chronic pain. With increasing use of CAM and integrative medicine is mentioned in evidence-based guidelines. Despite these recommendations, many practitioners remain hesitant to integrate them into their own practice or to discuss CAM with their patients.

Dr. Bonakdar, MD, will present "Complementary and Alternative Medicine: Overview and Effective Therapies in Pain" on Saturday, September 8, 2012, at the American Academy on Pain Medicine Week 2012. His presentation will review existing recommendations for CAM use and offer guidance on how to implement these recommendations in practice. "The key to success is to engage patients and discuss CAM approaches with them most out of them in conjunction with everything else we are doing," says Bonakdar.

The integration of CAM as part of mainstream treatment is a new paradigm for many physicians. "In many cases, we are learning these approaches on the fly, through conferences we may not have learned about in residency, or fellowship," says Bonakdar. This is changing as residencies and fellowships are starting to incorporate CAM into their training programs. In his presentation, Bonakdar says, "Physicians need to get more comfortable with CAM, especially if the evidence is saying we should."

In fact, Bonakdar says that discussions about CAM happen so infrequently that the National Institutes of Health has developed a packet to guide doctors and patients on how to approach the topic of CAM. He will review this and other resources to guide CAM usage during his talk.

He plans to address many of the factors that contribute to providers' lack of motivation to use CAM. The presentation will include useful information about a variety of CAM interventions that are backed by strong evidence. "I will go into a host of treatments and help providers know what to consider, and more importantly, how to coordinate care," says Bonakdar. He will provide guidance on accessing and obtaining products and services, dosing, side effects, and potentially dangerous interactions.

The inclusion of CAM in practice guidelines represents advancement in the fields of CAM and pain management. At the same time, this development has actually posed some barriers to implementation because not all of the guidelines are in agreement. "Part of my talk will be about how to arrive at a bottom line you are comfortable suggesting to your patient," says Bonakdar. "Along with practical advice for how to use the guidelines, I will talk about who is a good candidate for CAM."

Providers also need to be updated and aware of important safety issues related to CAM usage. When using CAM approaches that are backed by trial evidence, for example, Bonakdar recommends using the standardized version used in the trial. He will review this and other safety considerations that must be kept in mind during patient selection and follow up.

Financial considerations may play a role in whether patients and providers pursue CAM therapies. "If you ask most physicians who have not considered billing through their office whether any of these interventions would be covered, they would think no," says Bonakdar. "My clinic tries to put everything through insurance and we have found reasonable reimbursement." He will discuss reimbursement and other financial factors that may be posing a barrier to integrating CAM recommendations into clinical practice.

In terms of cost-effectiveness of CAM, not many analyses have been performed. Bonakdar says, "There can be cost savings, but the care needs to be coordinated." Cost savings will not be achieved if a patient goes to a CAM provider three times a week indefinitely. "If a patient is self-choosing a CAM therapy, it may not be cost-effective because there is no over-



In many cases, physicians are learning about CAM approaches on the fly, especially treatment options they may not have learned about in medical school, residency, or fellowship. Physicians need to get more comfortable with CAM.

KEY EVENTS

Patients and Your Practice: The Role of Chronic Pain and Risk Management

September 8, 8:25-9:55am

Opera Ballroom

Cost: NO

Breakfast: YES (breakfast)

Registration required: NO

Topic: Core Toxicology

Faculty: Jennifer E. Bolen, JD, and Jeffery A. Gudin, MD, will discuss practical approaches to incorporating drug screening into comprehensive chronic pain and risk management plans. They will also address key topics in legal and regulatory considerations for drug testing frequency, documentation, and the interpretation of results.

They will also address key topics in legal and regulatory considerations for drug testing frequency, documentation, and the interpretation of results.

Persistent Pain and Breakthrough Opioid Prescribing for Multidimensional Disorders

Time: Saturday, September 8, 12:30-2:00pm

Room: Level 4, Gracia 1

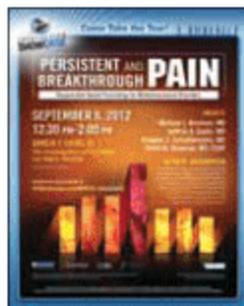
CE/CME certified: YES

Meal served: YES (lunch)

Preregistration required: N/A

Supported by an educational grant from Teva Pharmaceutical Industries Ltd.

This activity was designed to "consolidate clinically relevant scientific studies and evidence-based guidelines into practical approaches to persistent pain and BTP assessment, responsible opioid prescribing, and repeated re-evaluation of patient outcomes." The faculty of Michael J. Brennan, MD; Jeffrey A. Gudin, MD; Douglas C. Schottenstein, MD; and David M. Simpson, MD, FAAN, will discuss the diagnostic criteria for BTP pain and clinical characteristics of its subtypes, strategies for individualizing opioid therapy for persistent pain



and BTP, and multidisciplinary approaches that address a range of biopsychosocial causes and symptoms of persistent pain and BTP.

Mission: Pain Management – The First Visit (An IDEAL® Clinical Encounter)

Time: Saturday, September 8, 12:30-2:00pm

Room: Level 4, Gracia 1-4

CE/CME certified: YES

Meal served: YES (lunch)

Preregistration required: N/A

Supported by educational grants provided by Teva and Mallinckrodt, the pharmaceuticals business.

The faculty will discuss the underlying pathophysiology and transmission mechanisms associated with nociceptive, and centrally-mediated chronic pain; evaluate risks and benefits of nonpharmacologic and pharmacologic treatment options for chronic pain; explain how to overcome barriers to the optimal use of opioid analgesics for chronic pain; and assess methods for screening and follow-up care of patients with chronic pain.

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Chronic Pain and Comorbidities

Administration hospitals have a unique and extensive expertise when it comes to treating post-deployment chronic pain and its associated comorbidities. During a plenary session, PAINWeek attendees will learn more about what the VA has to offer and how clinicians in the private sector can improve patient outcomes by liaising with the VA.

Post-Deployment Chronic Pain and Comorbidities" (VHA-02A)

Dr. Terri-Ann Gibson, MD, and Ilene R.

Friday, September 8

10:20am

Room 4, Nolita 1

Veterans who served in Iraq and Afghanistan have had a tremendous impact on US troops and their loved ones. Many veterans are returning home with physical and emotional difficulties, such as post-traumatic stress disorder (PTSD).

In 2012, two specialists in caring for returning veterans, Dr. Terri-Ann M. Gibson, MD, DAAPM, Chief of Special Operations, Mental Health and Behavioral Sciences at the James A. Haley Veterans' Hospital in Tampa, and Dr. Ilene R. Robeck MD, Co-Chair of the National Primary Care in St. Petersburg, FL will be presenting "Chronic Pain Comorbidities" in a Plenary session.

Dr. Gibson will review the prevalence of PTSD and theoretical models that explain the maintenance of these conditions, and the challenges faced by providers who care for these patients. In addition, Dr. Robeck will present *Department of Veterans Affairs*

(VA)/Department of Defense (DOD) VA/DOD Clinical Practice Guideline for Management of Post-Traumatic Stress, with special attention to chronic pain.

"Limited scientific evidence supports specific care and treatment of PTSD and chronic pain, and this challenges providers to investigate and research potential treatment options. This presentation will focus on the techniques and strategies to address not only PTSD and chronic pain, but other conditions, including substance dependence and depression," Gibson says.

All veterans who have honorably served our country have earned and truly deserve the most comprehensive, individualized, and holistic treatment approaches that can be made available to address their physical and emotional conditions.

"We have many patients coming back from Iraq and Afghanistan with chronic pain problems. Many people assume that all of these patients are seen by the VA; however only 50% of returning veterans actually foot into a VA. The rest are cared for by outside providers. Many of the patients who do get seen by VA do not seek care by outside providers, so outside providers do not understand the dynamics of what happens and their comorbidities, even if they are being seen in part by the VA."

Importantly, 100% of the family members of returning veterans are seen by outside providers, and are not seen by the VA. Unfortunately, many of the problems of returning veterans also impact their families, Robeck notes. It is important for non-VA providers to understand what is involved in terms of chronic pain in returning veterans and their families."

It can be challenging to treat post-deployment chronic pain with comorbidities, and this makes it imperative for outside providers to learn what the VA has learned about treating returning veterans, Robeck says.

"The important thing to keep in mind is that many of our patients are young and resilient and when they are treated appropriately, they respond to treatment. This fact further emphasizes the importance of learning about their problems and what the VA has learned about treating them. It is important to know what resources are available for co-management of these conditions," she says.

Outside providers should know that it is important to get care at both the VA and their own private clinics. They should also know that if they have established patients at the VA, this does not mean that the VA will get all of their care at the VA. What it does mean is that the non-VA provider can then work with the VA and be able to access the VA services and resources, Robeck says.

"The VA welcomes the partnership or collaboration with an outside provider. We understand that some patients may remain with their own family doctor and that is fine, but their own family doctor may end up feeling overwhelmed, so I think there is a need for us to be better equipped to do everything, so I think there is a need for us to be better equipped," she says.

"That family doctor knows the family or the patient for years. We don't want to lose that relationship. But we also want to make sure that the full range of services available to these patients is understood, and that any misconceptions about how to access care are addressed. We want to make sure that our desire to be able to collaborate with the outside provider is well understood."

"All veterans who have honorably served our country have earned and truly deserve the most comprehensive, individualized, and holistic treatment approaches that can be made available to address their physical and emotional conditions."



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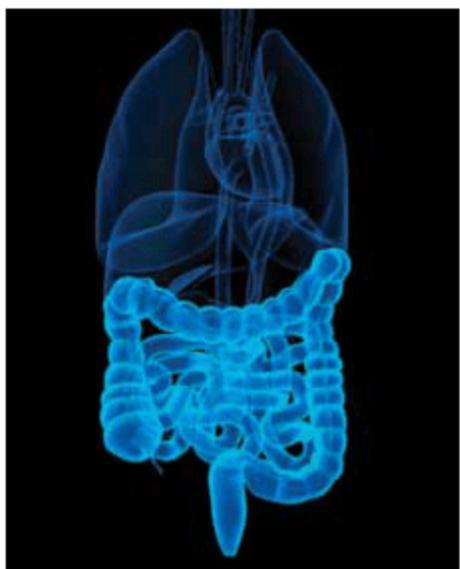


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...do to manage OIC? McCarberg said that with OIC requires a "professional and sensitive" approach to size any potential embarrassment for patients. "Older patients, especially older patients, are uncomfortable with defecation. Many will attempt to self-treat with laxatives and other medications. The current standard of care for prevention and treatment of OIC is PEG. Although there are no formal guidelines for the use of PEG, McCarberg said that the goal is to initiate treatment with PEG. The use of stool softeners and laxatives is recommended that clinicians avoid the use of bulk-forming agents in patients with OIC. If a patient fails to produce a satisfactory response, clinicians can treat with PEG. The PEG approach doesn't work, then try an opioid receptor antagonist like methylnaltrexone. Doses are the same for all forms of treatment. For OIC, but you have to be cautious with doses of bowel stimulants," McCarberg said.



...produce symptoms of opioid withdrawal). Several short-term trials using a range of doses and frequency of administration of oral naloxone in patients with OIC have produced mixed results, with some producing significant increases in stool frequency and improvement in symptoms. Some reversal and analgesia and/or opioid withdrawal symptoms were observed in most of the trials.

Methylnaltrexone is approved for the treatment of OIC in patients with advanced illness who are receiving palliative care and have demonstrated insufficient response to laxative therapy. It is currently available for subcutaneous administration. Peppin said that methylnaltrexone "does not stimulate the bowel, it just returns it to normal," which is why it is important to take the patient's history to know what the patient's normal bowel process and routines are.

In one study, nearly half of patients with OIC treated with methylnaltrexone plus laxative therapy achieved rescue-free laxation after three doses (0.15 mg/kg) administered over five days. In another study, patients with advanced illness (including patients with cancer, cardiovascular disease, COPD, and Alzheimer's disease or dementia) who were receiving opioid therapy and who also had OIC were treated with repeated dosing of either placebo plus laxatives or methylnaltrexone plus laxatives.

Nearly half (48%) of patients treated with methylnaltrexone demonstrated laxation response within four hours of receiving their first dose. More than half (52%) of patients treated with methylnaltrexone demonstrated laxation response within four hours after two or more of their first four doses of the medication. Peppin noted that the data indicates that "you may have to try up to four doses before seeing a response."

In another trial involving patients with chronic noncancer pain (including back pain, cervical/neck pain, fibromyalgia, hip pain, and osteoarthritis) who were receiving opioid therapy and who also had OIC were treated with either placebo or methylnaltrexone (12 mg QD or QOD). More than one-third (34%) of patients achieved rescue-free bowel movement within four hours after receiving their

The most common adverse effects associated with methylnaltrexone use reported by patients in controlled trials were abdominal pain (28.5% of patients), flatulence, and bloating (11%). Other adverse effects reported included constipation, diarrhea, and hyperhidrosis.

Another option for OIC, alvimopan, does not cross the blood-brain barrier and demonstrates higher binding to mu-opioid receptors than methylnaltrexone. It is approved for the treatment of OIC. "It is approved for use in patients with advanced illness who are receiving palliative care and have demonstrated insufficient response to laxative therapy." Peppin said that alvimopan is "a hospital-only drug" (ie, only surgeons can write for it).

The chloride-channel activator lubiprostone is approved for use in chronic idiopathic constipation in women. In one 12-week trial of lubiprostone in patients with chronic noncancer pain and OIC, 26% of patients achieved rescue-free bowel function. The most common adverse effects reported were nausea, and abdominal pain.

According to Peppin, there are currently several other therapies in trials for OIC, including prucalopran, which is an oral PEGylated naloxol conjugate. Peppin said that promising results in a short-term trial of patients with OIC, including increased frequency of spontaneous bowel movements, were reported during the first week of therapy.

Peppin concluded the presentation by reminding clinicians of the following:

- OIC is a significant and increasingly common problem for patients with chronic pain
- OIC can compromise a patient's quality of life and the effectiveness of pain management
- Laxatives are the main therapy for prevention and treatment of OIC, but their usefulness may be limited by adverse effects
- There is not much data on treatment for OIC in patients with chronic pain
- Peripheral mu-opioid receptor antagonists in patients with advanced illness without inducing opioid withdrawal symptoms and reversing analgesia, producing "rapid laxation without central analgesic effects"
- There are a number of pharmacologic agents in development that have demonstrated benefit for the treatment of OIC

Diagnosing, Assessing and Treating Diabetic Gastroparesis

The prevalence of diabetes is increasing worldwide, according to the International Diabetes Federation. In 2007 alone, the United States spent \$218 billion on diabetes, with more than 50% of spending related to hospitalization for diabetes-related complications.

...though, when it comes to diabetes and GI symptoms, "we tend to think of them as GI symptoms," Michael Bottros, MD, said during his PAINWeek 2012 presentation, "Diabetes, Pain, and GI Pain." His talk focused on the prevalence of GI symptoms associated with diabetes and the treatment options as well as possible future research areas to prevent or treat GI symptoms in patients with diabetes.

The session was of particular use and interest because of the effect this particular population is having in health care as they have repeated hospital admissions. "These patients are coming to the hospital and they describe upper GI pain," Bottros said. "They have nausea, they have bloating, so we tend to think that most of the problems... occur in the upper GI tract. That's

...the neuronal degeneration and changes that affect the gastrointestinal tract. Bottros said that, in this patient population, the prevalence of upper and lower GI symptoms is high and there is a considerable amount of turnover in symptoms. Over time, as a

...pain. So, when you talk about GI pain in relation to diabetes, you're essentially talking about diabetic gastroparesis."

Bottros stressed the importance of performing a thorough differential diagnosis. "It will enable the physician to be sure that they have not missed any major problem with these patients, as it will be a diagnosis of exclusion. To make a diagnosis, physicians should perform a physical examination and imaging studies to rule out other causes. Scintigraphy can be used to objectively measure gastric emptying.

Although advances have been made in understanding the cellular changes that underlie diabetic gastroparesis, there are few treatments for diabetic gastroparesis. Pharmacologic treatments for the condition include antiemetic agents, tricyclic antidepressants, and anticonvulsants. Bottros said that opioids should be used sparingly with these patients. "Management of diabetic gastroparesis needs to focus on assessing the severity of the disorder, correcting nutritional deficiencies, and treating symptoms," he said.

comprehensive, ethical, and offer societal benefit.

At the 2012 presentation, "Analgesic Development: From Bench to Bedside and Back," Dr. Wallace, MD, highlighted the process of clinical trial design. During the session, Wallace discussed the purpose and role of institutional review boards, and the importance of informed patient consent.

In discussing clinical trials related to the development of analgesics, Wallace said physicians should be aware of institutional review board guidelines and federal regulations as well as ethical considerations for research with human subjects. "One of the biggest hurdles with trial design is the issue of informed consent," Wallace said.

Wallace also discussed the history behind institutional review board regulations dates back to Nazi Germany and the development of the Nuremberg Code. "Individuals should be treated as autonomous individuals, not as a group," Wallace told attendees. "So we do these clinical trials, and we tend to think of the population, and you forget the individual. You have to look at each individual in a clinical trial."

Wallace noted that some patient populations are entitled to certain protections that make clinical trial design and development more difficult. Children, people with cognitive disabilities, and prisoners require special consideration. "We're seeing more and more research in the pediatric population," Wallace said. "There is actually a movement of research to include children. We should be. We need better analgesics for children. We shouldn't be excluding children."

One of the biggest hurdles for clinicians designing clinical trials in pain management is finding participants. "The biggest hurdle for clinicians designing clinical trials in pain management is finding participants. The biggest hurdle for clinicians designing clinical trials in pain management is finding participants," Wallace told the audience. "It's just

Physicians should remember that any procedure done solely to determine eligibility for a clinical trial is a part of the research and requires patient consent before the procedure.

Wallace also highlighted the guiding principles of the Belmont Report on the ethics of research for the protection of participants in clinical trials, which include:

- **Beneficence:** Clinical trials should do no harm, maximize possible benefits and avoid unnecessary burdens. The principle should be applied at an individual level for participating patients as well as a population level.
- **Justice:** Clinical trials should have fair distribution of the benefits and burdens. The principle of justice requires that the participant selection should involve groups that will benefit from the research and that are not 'convenient' populations.

Wallace emphasized to attendees that if the risks outweigh the benefits, the trial should not be approved by the institutional review board. He also stressed the importance of informed consent. The general accepted principle is that, if it is practicable to get consent, consent should be obtained, and documented.

Some of the elements of informed consent include an explanation of the purpose of the research, a description of the procedures, the risks and benefits, the expected duration of the study, and a reminder that participation is voluntary.

Wallace's presentation examined the difficulties of designing clinical trials while maintaining the importance of maintaining participant autonomy and maximizing societal benefit.

By

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ATTENDEES SCHEDULE INDUSTRY SCIENTIFIC POSTERS RESOURCES BLOG SCRAPBOOK

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PAINWEEK

conference on pain for frontline practitioners.

The Cosmopolitan of Las Vegas

CE/CME credit hours

3

Global Education Group

CME/CE Credit Instructions for PAINWeek

To obtain your CME/CE certificates, you will be required to complete evaluations for each course as well as an overall PAINWeek evaluation. These evaluations must be completed online (eg, on a smartphone, or in the Cyber Café).

When entering a session, please scan the square bar code on your name badge, which will record your attendance for ease of completing evaluations. Each evening of the conference (starting with Wednesday) you will receive an e-mail notification indicating you have evaluations to complete.

Please click the link in the e-mail, and you will be taken to a listing of evaluations for courses in which you have participated. In the event courses are missing or additional courses have been recorded, you will have the ability to edit the courses you wish to evaluate.

To ensure accuracy and streamline issuing of credit for the various disciplines at PAINWeek, certificates will be issued electronically after the evaluation system closes.

The evaluation system will be available until OCTOBER 31, 2012. You will only be eligible to receive credit for sessions if the respective evaluations are completed by this date.

Regrettably we will be unable to grant any extensions or make any exceptions to this deadline.

SPECIAL NOTE TO PHARMACISTS:

Please note: pharmacy learners will not be eligible to receive partial credit. Individual courses must be attended in their entirety in order to be eligible to receive credit for those 1.0 or 2.0 credit hour sessions. If you still need to create a NABP e-Profile and obtain an ID number, please visit <http://www.nabp.org> or https://store.nabp.net/OA_HTML/xxnabpibeGblLogin.jsp.

specialist and I do not want to be. I am a family physician and I try to care for my patients in as comprehensive a manner as possible. While I certainly value and make use of specialists, I believe that in many cases a patient's medical needs are best met effectively satisfied within the boundaries of a primary care medical home. Furthermore, my patients are underserved. I am fortunate to have the support of my colleagues which facilitates my patients' access to medical supplies and services. This access is limited. Finally, by education and training, I am as much a humanist as a scientist. When it comes to specific diseases or injuries, my job is to address my patients' medical reality within the context of their lives to promote their well-being.

My colleagues recently observed that I have a particular interest in pain management. It is true that I have made an effort to educate myself with orthopedic and rheumatologic medicine so that I perform a fair number of injections—and some of my partners' patients—and that I am comfortable and willing to prescribe pain medication, whether narcotic, non-narcotic, disease-modifying, or otherwise. My interest in the field stems from my belief that I am obligated to use to the best of my ability those processes that threaten their well-being. To deny these obligations would be no different from denying their heart disease or diabetes.

Economic and demographic factors lead to an increase in the prevalence of endocrine and cardiovascular disease. In addition, these same patients suffer from a high incidence of chronic pain. Furthermore, my patients have a great deal of comorbidity, and addictive comorbidity. Even when my patients are referred to an orthopedist, rheumatologist, or pain management consultant, they are limited in what interventions they can receive and are sometimes hesitant to do so for economic, legal, and logistical reasons. My practice is to treat medical disease to a level at which

patients elsewhere would have been referred to specialists. While I believe that my partners and I usually rise to the occasion and meet this demand, I fear that this is not often enough the case when it comes to chronic pain. This is detrimental to our patients' health and well-being.

I, like most of my peers, learned little about the management of chronic pain in medical school or residency training. I have been actively trying to increase my knowledge in this area through face to face, online, and print resources, as well as interacting with specialists, but I have much yet to learn. I have also recently had the opportunity to join a regional collaborative focusing on the safe treatment of chronic pain in a primary care setting, but this program focuses on systems and

learning how to collaborate with specialists to meet our goals. I am also working on ways to make sure that these patients in the primary care setting are being cared for by primary care practitioners.

Rudolph Virchow—a pioneer in social medicine and pathology—observed that “medicine is politics on a grand scale.” This is nowhere more true than at the intersection of socio-economic need, medical practice, and chronic pain. I am neither a pain specialist nor a pain educator, but a family doctor and a patient advocate. I have been successful in the treatment of chronic pain because it is what my patients need and will not get elsewhere. When my patients had pain, it is a fact of their—and

“I, like most of my peers, learned little about the management of chronic pain in medical school or residency training. I have been actively trying to increase my knowledge in this area through face to face, online, and print resources, as well as interacting with specialists, but I have much yet to learn.”

processes more than therapeutic strategies. I hope that through resources like PainEDU and attending PAINWeek I can increase my skills, knowledge base, and strategies. I am especially interested in increasing my comfort with treating pain in patients with medical, psychiatric, and addictive comorbidities, and in

managing it is not only an ethical obligation, but also many of the social and existential issues that are inherent to primary care medicine. I do the best I can and I am trying to improve my skills in this area to the help I can get.

Congratulations to the 2012 PainEDU.org PAINWeek Scholarship Recipients

Visit the PainEDU.org website (www.PainEDU.org) to learn more about the scholarship and read several of the prize-winning essays.

Moshe Usadi, MD (grand prize winner)

Charlotte Medical Center - Biddle Point
Charlotte, NC

Kelly Brewer, LCSW

Center for Wellness & Pain Management
Kalispell, MT

Maria Foglio, RN

Ashtabula County Medical Center
Ashtabula, OH

Maria Maldonado, MD

Stamford Hospital
Stamford, CT

Michelle Dahring, MSN, RN, CP

Toni L. Glover, MSN, FNP-BC

Rebecca A. Maxson, PharmD

...y four women of reproductive age suffers from chronic pelvic pain. Pain Clinicians who want to provide comprehensive care to this po...
...nd the general diagnosis of chronic pelvic pain and learn more about the subtypes and etiologies of this complex condition.

...n" (REG-01)

...een M. Fitzgerald, MD
...y, September 8
...00am
...el 4, Nolita 3

...ions of pelvic pain are wide ranging. The...
...gatively affects quality-of-life, jobs, relation-
...ction. Additionally, it puts women at greater
...g invasive procedures such as laparoscopy

...vic Pain" symposium on Saturday morning
...2, Colleen Fitzgerald, MD, will provide an
...related to clinical management of the condi-
...tion will be broad in scope," says Fitzgerald.
...subtypes and etiologies; risk factors; patient
...symptoms; differential diagnosis—including
...ons, imaging, and other workups; treatment;
...gerald will also talk about pregnancy-related

...g medical help for pelvic pain are labeled
...diagnoses that can be gynecologic, urologic,
...musculoskeletal, or psychological in nature.
...depends on the type of specialist seen. The
...men evaluating a woman who presents with
... Fitzgerald, is not to assign a general diagnosis
...ain. "It should be broken down into a real
...or, in some cases, more than one diagnosis,"
...ould like to help the audience think beyond
...gnosis and be more specific in terms of sub-
...gy, because it makes a difference in terms
...gnosis of pelvic pain can be confusing. For
...may present as a musculoskeletal response
...problem with an internal organ such as the

...review treatment options, including medica-
...jections, surgical interventions, and comple-

mentary alternative medicine possibilities. She plans on spend-
ing a significant amount of time talking about rehabilitation
and reasonable therapeutic goals.

"Anyone who treats women with chronic pelvic pain knows
that these are some of our toughest cases," says Fitzgerald. She
attributes this to lack of training and guidelines and to the com-
plexity of the problem. "Any time pain persists for more than six
months, there is a large psychological overlay," she says. "I am
hopeful that many will attend the session just because pelvic
pain is such an unknown; the field is really in its infancy in terms
of understanding of causes."

"The field is so new in research; we have some guidelines, but
we don't have guidelines based on subtype yet," says Fitzger-
ald. "Minimal guidelines exist for musculoskeletal causes." Pelvic
girdle pain guidelines, such as the "2008 European Guidelines
on Pelvic Girdle Pain," may not be applicable for every patient;
it really depends on their diagnosis. In 2011, the American Uro-
logical Association published guidelines for interstitial cystitis/
bladder pain syndrome. The group suggests general relaxation
and stress management as first-line treatment, followed by
second-line physical therapy and oral medication (eg, amitrip-
tyline, cimetidine, hydroxyzine, or pentosan polysulfate).

Fitzgerald contrasts those recommendations with standards-
of-care for women with pelvic floor or myofascial pain. For
those diagnoses, immediate first-line physical therapy is recom-
mended. Since the evidence shows that physical therapy works,
practitioners should try to avoid complex medications and po-
tential drug-related side effects.

To help attendees truly understand how to apply the infor-
mation in practice, Fitzgerald will walk through the physical
exam, differential diagnosis, and treatment selection using spe-
cific patient examples.

Fitzgerald will also offer some insight into the future of the
field and talk about some recent progress made in understand-
ing chronic pelvic pain. She says that "One of the things we
are working on in research is to look at not just the organ as
the problem—for example, the uterus, bladder, or muscle—but
really looking at the whole patient as one who has gone into
chronicity as a neurologic pain processing problem."

Fitzgerald is part of a team that is using neuroimaging to
evaluate the neurobiology of chronic pelvic pain. Their research

has showed that women with
chronic pelvic pain actually
have a different way of pro-
cessing pain compared with
the brains of normal healthy
control women. "We found
changes in the central ner-
vous system that suggest the
way to address this may be
along the neuroaxis," says
Fitzgerald. "Maybe the insult
was initially to an organ or
muscle, but over time, as pain
signals get transmitted and
perpetuated, the body's abil-

how the central nervous system changes as
pelvic pain.

Colleen Fitzgerald, MD, is an associate p...
rics and gynecology and female pelvic medi...
versity of Chicago and associate professor o...
and rehabilitation at Northwestern Universi...
of Medicine. She specializes in treating and...
nancy-related musculoskeletal disease, wom...
pain, and pelvic floor disorders.



**The important thing v...
evaluating a woman...
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diagnosis or, in some...
more than one diagn...**



Approaches to Pain Management

Exist to treat pain and awareness is growing that non-pharmacologic approaches can be just as effective, if not more so, than pharmacologic. In this talk, clinicians will learn about some of the newer non-pharmacologic options for treating pain, and will also learn how combining them in a sensible medication plan can result in optimal pain relief.

What are the Options?"

Lee N. Turner, DNP, RN-BC,

FAAN

September 8

10am

Level 3, Gracia 7

Lee N. Turner, DNP, RN-BC, PCNS-BC, FAAN, Clinical Specialist, Pediatric Pain Management, Oregon Health Science University in Portland, OR, will be presenting "What are the Options?" today at PAINWeek.

Turner will be talking about newer, non-analgesic approaches to pain and how they can best be combined with traditional approaches to provide good pain relief.

Turner says that a lot of time and days could be spent on analgesic topics. There are two general categories of pain management: pharmacologic and non-pharmacologic—and a lot of effort recently to get clinicians to use them together.

Turner says there has been a very heavy use of the pharmacologic approach and we know that some of the non-pharmacologic approaches in fact stand on their own. We also know that, in many cases, you can often use much less medication, and that's less dangerous for the patient," she says.

Non-pharmacologic analgesia include physical therapy, massage, transcutaneous electronic nerve stimulation, relaxation methods, biofeedback, hypnosis, guided imagery, and virtual reality. "We use virtual reality with kids," Turner says. "You can be in their mind."

Virtual reality involves having the child wear what looks like a helmet that has a screen inside. "You put the helmet on and watch something. One of the more common things is a mountain, skiing, and it comes with all of the sounds. Their minds are able to actually go there on a screen. They can be present in that virtual space, and those kids

can block out almost everything going on around them. One of the children's hospitals in Ohio actually uses virtual reality when they are doing burn care, with phenomenal results. Their use of virtual reality medication in doing that has declined significantly," Turner says.

Turner adds that people are just beginning to understand the connection between body and mind. "There are tons of knowledge out there around opioids and the traditional pain medicines, and there's getting to be more understanding about some of the adjuvants, like antidepressants and anticonvulsants. But knowledge about non-pharmacologic methods is still a little behind," she says.

"Even something like acupuncture is still considered to be voodoo by some people; however, there is a lot of science now to support that acupuncture is not voodoo. But it's taking time to catch on," Turner says.

In her presentation, Turner says a main goal will be to show her audience how the non-drug and drug modes of analgesia can work well together. She says, "We shouldn't just reach for the medications; we need to incorporate those other modalities, as well."

Turner is a pediatric pain specialist. She says that it is harder for adults to adapt to non-pharmacological methods of pain control "because we have forgotten how to play. We dampen our imagination, and we can be very skeptical. Some of these non-drug modalities can be harder to believe in for older people, whether you are the provider or the patient, and that can be challenging to deal with. I've got it really easy with kids; they are open to anything. Plus, a lot of the non-pharmacological approaches are technologically based, which kids love."

Different types of pain respond to different types of analgesia, and this can often be due to the person's past experience of pain, she says. "Pain is a very subjective experience and is based on the individual's life experience with pain and pain treatment, and all of that plays into how they deal with pain and how their body and mind have been programmed. If pain is very fear-based, it will be completely different than pain in someone who doesn't mind getting hurt because they were doing rock climbing or something they really want to do," says Turner.

Being able to identify what the patients' stressors are, and helping them manage those stressors, are important aspects of pain management. "It's incredibly complex. It's hardly scratching the surface with this talk, because there is so much you can go into. My intent is more to increase awareness and to think

about adding these other modalities of treatment to reach for the medications," she says.

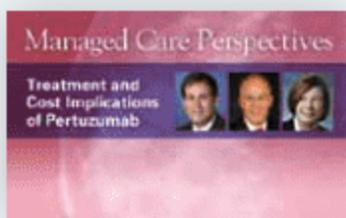
Nevertheless, Turner will be discussing medication and adjuvant medications that, when added to traditional analgesics as the opioids and anti-inflammatories, can help patients effectively. She will also discuss the role of over-the-counter analgesics. "Many consumers think that the types of analgesics you can buy in the drug store without a doctor's prescription are weaker. That is not necessarily the case. Indeed,

"Pain is a very subjective experience and is based on the individual's life experience with pain and pain treatment, and all of that plays into how they deal with pain and how their body and mind have been programmed."

especially if you have inflammation, a non-steroidal anti-inflammatory drug to get that inflammation down," she says.

Her talk promises to give lots of food for thought. "I won't have time for a lot of detail, but I want to give you awareness about all of the options. Right now, the common buzz word in the pain world, and it's not just in analgesia. It's using multiple methods to get to the goal, and it encompasses a wide variety of aspects: physical, psycho, social, and spiritual aspects of the patient."

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MANAGED CARE



To examine the treatment benefits, cost concerns, and potential insurance coverage strategies for pertuzumab, AJMC's Co-Editor-in-Chief, Michael E. Chernew, PhD, moderated this audio panel discussion with Lee N.



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and Palliative Care

potential drug-drug interactions in the pain and palliative care settings requires a proactive approach that relies on the proper tools and the patient's medications and pain care needs.

Pharmacokinetic and Pharmacodynamic Drug Interactions in Palliative Care" (PHM-06)

Kathryn A. Walker, PharmD, BCPS, CPE
September 8
10:00am
Room 3, Castellana 2

therapy for patients with chronic pain or receiving palliative care is typically complex and prone to drug-drug interactions (DDIs). In 2011, Walker conducted a retrospective chart review (N = 631) of potential drug interactions among patients in a palliative care setting. Patients in this population have advanced disease and are receiving multiple medications. In the 2011 study, a median of 14 drugs were prescribed per patient during the hospital stay.

Walker, PharmD, BCPS, CPE, will present "Pharmacokinetic and Pharmacodynamic Drug Interactions in Pain Management" this morning at PAINWeek 2012. During the session, she will review the basic pharmacology of frequent drug interactions relevant to these populations, and offer guidance on how to monitor for and manage these interactions.

It is important when seeing a pain or palliative care patient to bring an issue to rule out whether it is something the patient is causing or something that needs to be addressed. Walker says, "Whether to order additional medication or to change medication is not a straightforward decision." Understanding drug interactions plays a big part in this. Walker says, "I will review the kinds of drug interactions that providers should worry about in these settings." Her research on DDIs among pain and palliative care patients has substantive implications for a particular challenge to care for these patients.

Walker says that some providers assume that pharmacists will catch a DDI before prescriptions are filled and administered. "I don't see a lot of providers routinely checking for DDIs in practice," she says. But, pharmacists may not always be aware of the interaction and, practically speaking, they cannot call the doctor for every potential drug interaction. Walker says that it is better to think about DDIs for these populations before prescriptions are written and to keep in mind the red flag drugs that can cause problems, she says. Automated DDI checklists can overwhelm providers who are often overwhelmed by the large number of DDIs flagged by these systems; deciding which DDIs are clinically relevant is difficult.

Walker says that providers should know how to check for DDIs using recommend-

Walker says that if the potential for DDI exists, "it does not mean that you cannot use the drug, you just have to use it with a plan." This means that if a provider decides to use a medicine with a potential for interaction, he or she needs to know what to monitor and consider dosing and administration schemes that may prevent or minimize interactions. "For example, some interactions are based on timing," she points out. "If you give the drugs at different times, you may avoid an interaction."

For many drugs, providers only pay attention to a subset of potential interactions or complications related to that drug. One example of this is methadone. "It is a complicated drug to use, in general," says Walker. "People worry

about the impact on the family's whole plan for end-of-life care."

"Palliative care patients are so complex; it is difficult to prevent additional burden to these patients," Walker says. Drug effects can make a big difference in the quality of life experience. "Our duty is still to do the best we can for the days a patient has left, a time that may be the most important in their life," she says.

Kathryn A. Walker, PharmD, BCPS, CPE is an associate professor at the University of Maryland School of Medicine, a palliative care clinical specialist at MedStar Washington Hospital Center, and oversees the hospital's pain consult team.



"I am hoping to convince people that it is better to think about the important drug-drug interactions in these populations before prescribing medications and to keep in mind the red flag drugs that may cause problems."

about dosing, administration, and monitoring because they are all complicated." But, Walker cautions that methadone is prone to many drug interactions that are not widely recognized. "Many drug interactions for methadone often go overlooked," she says.

Bleeding risk for patients on warfarin is another common concern. "Sometimes providers focus on whether or not to keep a patient on warfarin, but they neglect to consider other things that may impact bleeding," she says. Bleeding risk is one of the most recognized DDIs. Yet, oversedation, confusion, and delirium are common results of DDIs that can be quite scary to families and patients. "Even if a patient is not aware, these symptoms can alarm families, making them worry about whether they can care for the patient at home; it can change a



ly and modern Las Vegas French brasserie with an emphasis on quality ingredients" and traditional fare that is "accessible yet provocative, delicious yet chic." Daily specialties include beef wellington, housemade sausage, a selection of offal, and dayboat scallops. Dinner entrees include tarte flambee, steak tartare, roasted beets, and French onion soup. Lunch entrees include omelette, oxtail benedict, steamed mussels, and roasted lamb sandwich. Diners can enjoy a three-course "Quick Lunch." Dinner standouts include the roasted bone marrow and oxtail benedict (highly recommended!), brick roasted chicken, slow-cooked veal, a classic bouillabaisse, and more. Comme Ça also offers a multi-flight "Bistronomy" tasting menu. Diners will also find favorites from the chef's menu in Las Vegas, handmade pastas, delectable charcuterie and cheese plates, and a daily happy hour menu. The tipplers among our readers will not want to miss Comme Ça's menu of handcrafted classic cocktails shaken with Chef David Myers' modern sensibility."

Location:

- 10:00pm (Monday-Thursday)
- 10:00pm (Friday-Sunday)
- 12:00pm (Friday-Sunday)

Jaleo

Looking to take a break from steaks, pastas, and heavier fare? Then an evening of small plates at Jaleo may be just what you're looking for. Choose from a selection of small plates (sausages and cured meats, including the famous Jamón Ibérico ham made from Iberian pigs), quesos (including several varieties of sheep's and goat's milk cheeses), bocadillos (sandwiches), frituras (chicken, ham, dates—just about everything tastes better fried), and other classic tapas. And, as the menu says, Chef José Andrés "knows small plates, too," including some of the best paella you will ever have (in fact, Jaleo's paella changes throughout the day).

Hours of Operation:

- Sunday-Thursday: 5:00pm-11:00pm
- Friday-Saturday: 5:00pm-12:00am



"burger concept" that was "tailor-made for The Cosmopolitan of Las Vegas with fresh, natural and organic ingredients," Holsteins serves custom-crafted specialty burgers, housemade sausage, and "riff[s] on traditional American snacks and appetizers, as well as shakes and sides." Start things off with a high-octane "bam-boozled shake" (one of our favorites, the "Bam-Bowl," combines Crunch cereal with Absolut Vanilla) and a selection from the chef's menu. Dinner choices include southern fried chicken fingers-n-waffles, buffalo wings, onion rings, and more. The "Tiny Buns" menu features sliders, crispy pork belly, lobster rolls, and meat-

Scarpetta

Described as a modern Italian restaurant with an earthy-yet-sophisticated cuisine, Scarpetta features "a satisfying and soulful menu of seasonally-inspired Italian offerings include braised short ribs, creamy polenta with mushrooms, and other classic Italian dishes. Course selections include duck & foie gras ravioli, black tonarelli with king crab and short rib agnolotti. For the main course (piatti), diners at Scarpetta can choose from a variety of northern Italian-inspired dishes, including several fish entrees, Colorado lamb chops, and duck breast. Scarpetta also offers a delectable "signature tasting menu," as well

THE
BEST
EFFECTIVE
DOSE

FOR THE
SHORTEST
PERIOD OF
TIME

AT THE LOWEST HEALTHY CONCERN



PAIN SOCIETY



American Chronic Pain Association



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PHYSICIAN ASSISTANTS
Protecting PAs, Transforming Care



Alliance for Rational
Use of NSAIDs

The management of pain and inflammation—whether acute or chronic—requires proper consideration and attention to individual patients' therapeutic needs and the issues that may affect appropriate and effective treatment. Nonsteroidal anti-inflammatory drugs (NSAIDs), whether over the counter (OTC) or by prescription, are some of the most commonly used and effective drugs for pain relief, but, like all medication, only appropriate use can maximize their therapeutic benefit while minimizing risk.^{1,2}

Unfortunately, prescription and OTC NSAID use often falls outside of explicit but simple guidance. The US Food and Drug Administration, European Medicines Agency, and numerous medical societies recommend their use at the lowest effective dose for the shortest period of time required to provide therapeutic effect.³

Data demonstrate an unequivocal relationship between dose and duration of NSAID use and the increased risk of gastrointestinal, renal, and cardiovascular adverse events.⁴ Only by following guidance for use, taking patients' clinical needs and risk factors into account, fully understanding what medications patients may be taking, educating them about what NSAIDs are, and facilitating an open dialogue can we maximize the therapeutic benefits of NSAIDs, minimize the likelihood of adverse events, and prevent patients from living in pain due to fear of pain medications.

The Alliance for Rational Use of NSAIDs—a public health coalition—aims to bridge the gap between guidance and clinical practice by educating health care professionals and the public at-large to ensure appropriate and safe use of NSAIDs.

Please join us in our efforts to ensure appropriate and relief for people with pain. To download educational materials and learn more about the Alliance for Rational Use of NSAIDs, visit [www.allianceforrationaluse.org](#)

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