FMDA 31rs Annual Conference and Trade Show Best Practices in the Post-Acute and Long-term Care Continuum

Best Practices in Pain Management in PALTC

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This presenter gets royalties from Handbook of Pain Relief in Older Adults.

"The winning combination of overview and details from current evidence-based medicine will make this handbook attractive to all pain professionals as well as to other professional communities in the health care system, such as nursing staff in hospitals and facilities for the elderly."

Matthias Karst, MD, PhD JAMA, May 4, 2011—Vol 305, No. 17

Other Resources

- Revised Beer's Criteria (https://geriatricscareonline.org/ProductAbstract/american-geriatrics-society-updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults/CL001)
- Gloth FM. (Ed). Handbook of Pain Relief in Older Adults. 2nd Edition. Springer Publishing, New York, NY, 2011 (http://dx.DOI.org/10.1007/978-1-60761-618-4).
- Federation of State Medical Boards Policy (https://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf)
- www.cdc.gov/drugoverdose/prescribing/guideline.html

Objectives

- Address Epidemiology
- Guidelines
- Educate about Opioid Issues
 - Addiction
 - Diversion
 - Additional Concerns
- Prescribing, E-prescribing, & Discontinuing

Pain is inadequately treated

- 25-50% of older adults suffer from pain that interferes with daily activities
- 45-80% in nursing home residents have pain
- Age > 70 years is the number one risk factor for inadequate pain management

Cost of Chronic Pain

- Chronic Pain affects 116 million U.S. Adults
- Annual U.S. economic costs for chronic pain is \$560-630 Billion Dollars!

By the Numbers

- Each year between 15-20% of the US population experiences acute pain
- Chronic pain affects approximately 30% of the population annually
- PAIN IS THE MOST COMMON REASON PATIENTS SEEK
 MEDICAL ATTENTION

AGS Guidelines for the Management of Persistent Pain in Older Persons

- Pain not a normal part of aging
- Assessment & Management
- Health System Barriers
 - Administrative
 - Regulatory
 - Revise Regulations that have created barriers
 - QI

JCAHO Standards for Pain Management

- Recognize patients' rightst to appropriate pain management
- Screen for presence and intensity of pain
- Ereasess pain regularly
- Ensure staff competency in pain assessment and management
- Educate pts and family about effectic pain management
- Address patient needs for pain management in discharge planning
- Maintain pain control performance improvement plan

Reasons for Inadequate Pain Management

Physician Reasons

 Insufficient Assessment 	(>70%)
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•Fear of using some medication, esp. opioids (>60%)

•Inadequate knowledge (>50%)

Patient Reasons

- Inadequate Reporting
- Fear of stigma of opioids

Wong-Baker FACES Pain Rating Scale



(Wong DL, Hockenberry-Eaton M, Wilson D, et al. Whaley & Wong's Nursing Care of Infants and Children. 6th ed. St Louis, MO: Mosby-Year Book, Inc; 1999)

Visual Analogue Scale (VAS)



Pain Scales

- In a study of 129 subjects with MMSE<11 (mean age 84 y.o.)...
- > a third of these severely demented individuals couldn't comprehend the verbal, horizontal visual, or faces scale

Modified Functional Pain Scale

- 0 No Pain
- 2 Tolerable (Doesn't interfere with activities)
- 4 Tolerable (Interferes with some activities)
- 6 Intolerable (Able to use phone, TV, or read)
- 8 Intolerable (Unable to use phone, TV, or read)
- 10 Intolerable (Unable to verbally communicate)

Gloth et al. J Am Med Dir Assoc. 2001; 2(3): 110-114.

The Functional Pain Scale

		Standardized			Rank
	Relative	Response	Effect	Paired	(Resp.
<u>Scale</u>	Efficiency	Means	Size p-value	<u>t-test</u>	Index)
FPS	1.00	0.29	0.29 0.0054	2.85	1(7)
VAS	0.32	0.46	0.47 0.04	2.14	2(12)
PPI	0.36	0.25	0.25 0.02	2.21	3(13)
MPQ	0.30	0.22	0.21 0.037	2.11	4(19)
VNS	0.18	0.25	0.22 0.067	1.87	5(24)

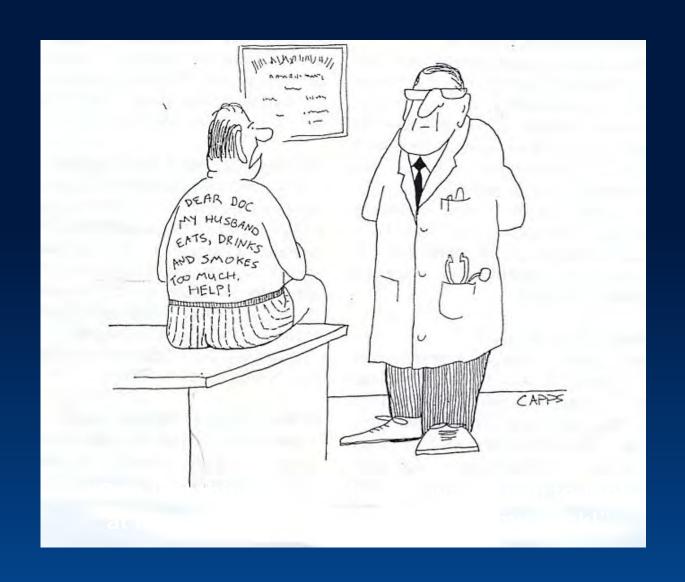
Legend: FPS = Functional Pain Scale; VAS = Visual Analog Scale; PPI = Present Pain Intensity; MPQ = McGill Pain Questionnaire-Short Form; VNS = Visual Numerical Pain Scale.

Gloth FM III, Scheve AA, Stober CV, Chow S, Prosser J. The Functional Pain Scale: reliability, validity, and responsiveness in an elderly population. *J Am Med Dir Assoc*. 2001;2(3):110-114.

Assessing Analgesia in Patients with Limited Ability to Communicate

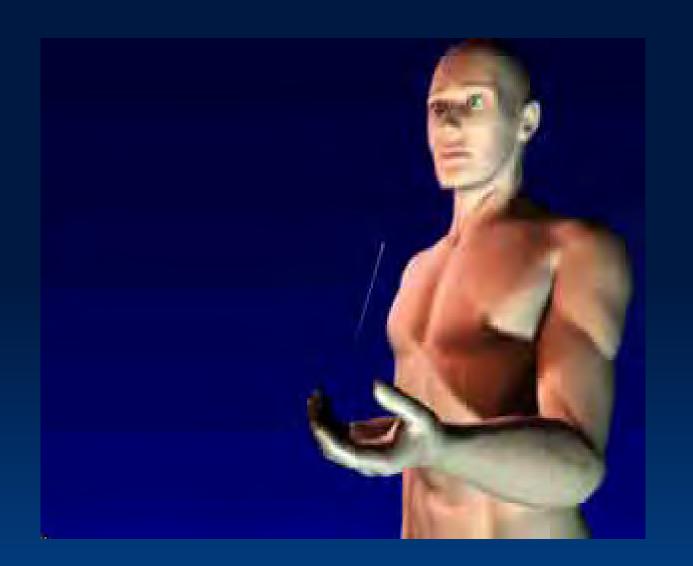
- Behavioral observation is necessary to make a judgment about pain intensity
 - Facial expressions
 - Movement patterns
 - bracing, guarding, distorted postures, avoidance of activity
 - Nonverbal sounds
 - moans, cries, respiratory pattern
 - Reports of significant others
 - partner, spouse, child

Caregiver Assessment

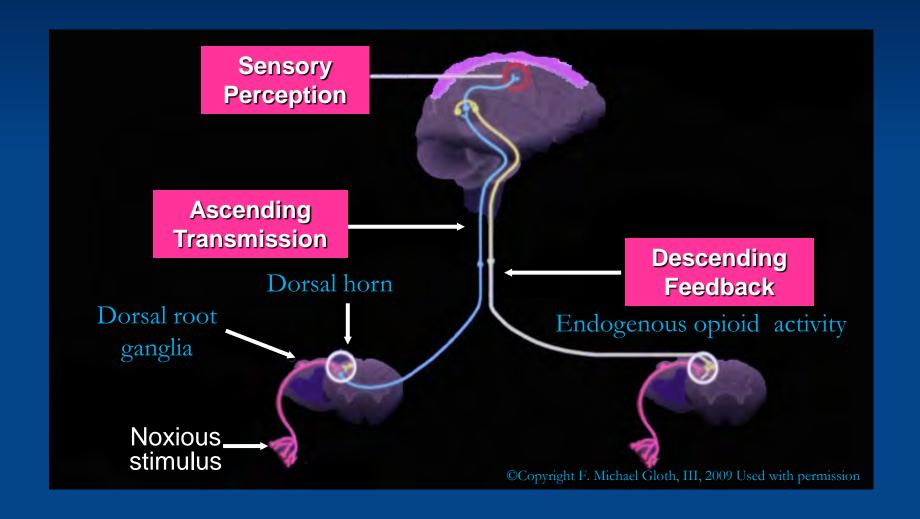


Pain

- Nociception (A-delta vs C fibers, opioid receptors)
- Psychological (Secondary Gain, Depression, Mental Focus, Prior Experience, & Anxiety)

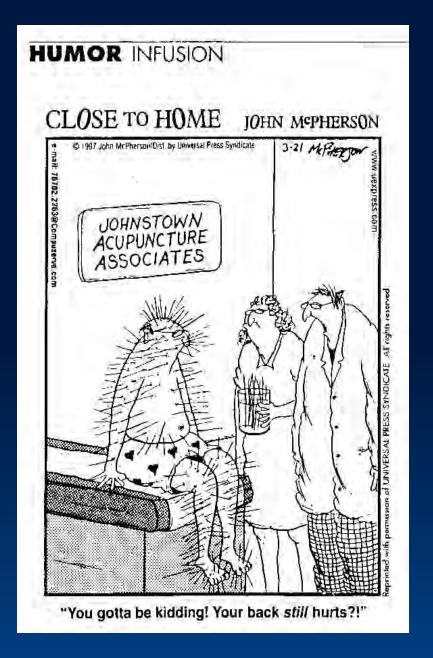


The Pain Pathway



Opioid, NMDA, & GABA Receptors

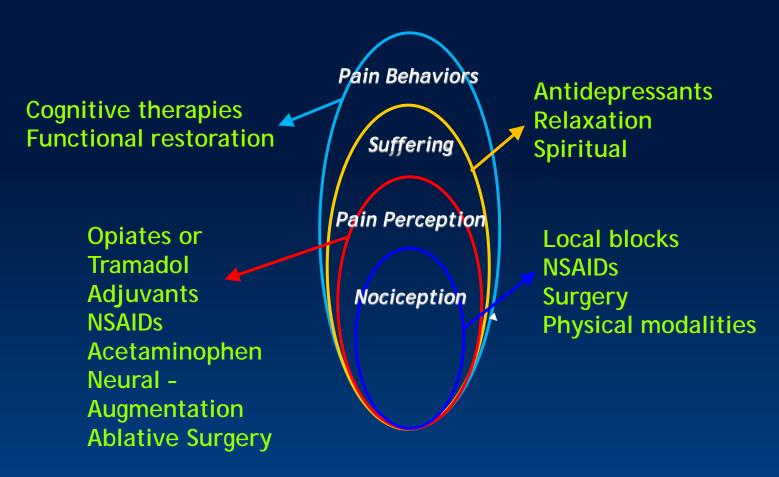
- μ analgesia, miosis, respiratory depression, and euphoria
- κ analgesia, miosis, sedation, and psychotomimetic activity
- \triangleright δ analgesia, miosis, and hypotension
- N-methyl-D-aspartate (NMDA)
- Gamma aminobutyric acid (GABA)



Pain Management

- Nonpharmacological
 - Cold, Heat, PT/OT, Exercise
 - TENS, Acupuncture
 - Radiation
 - Blocks, Relaxation, Hypnotism, Biofeedback, Massage, Vibration, Magnets...

Comprehensive Approach to Treatment Chronic Non-Malignant Pain



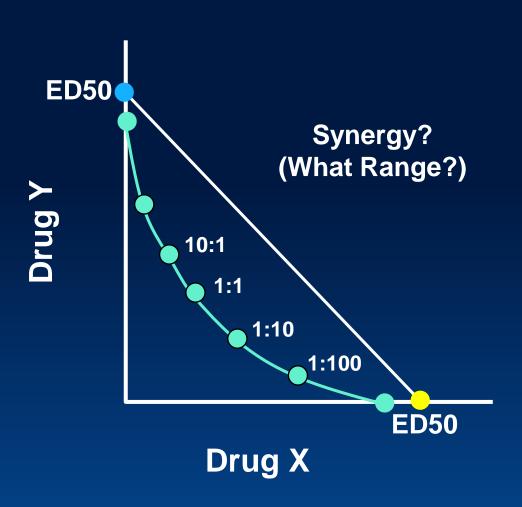
Wiech K, Farias M, Kahane G, Shackel N, Tiede W, Tracey I. An fMRI study measuring analgesia enhanced by religion as a belief system. *Pain.* 2008;139(2):467-476. Epub 2008 Sep 5.



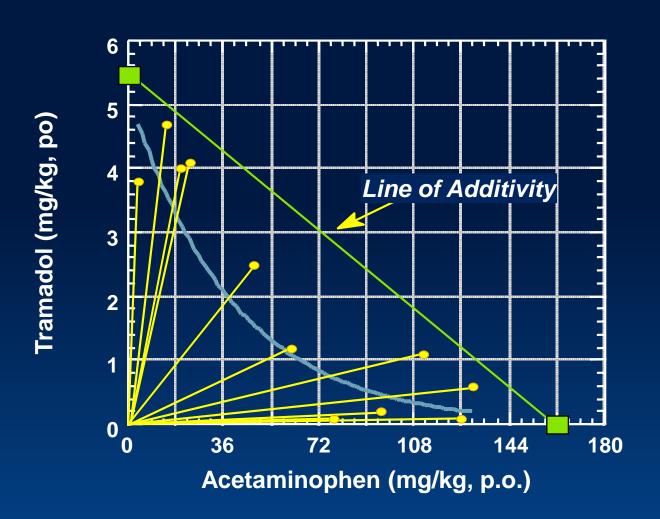
Bupivacaine as pre-emptive analgesia in third molar surgery: Randomised controlled trial

- 45 patients who had bilateral impacted third molars removed
- Bupivacaine was injected on one side, the other side acting as control
- VAS
- Significant reduction (p = 0.05) in postoperative pain on the injected side at 6, 12, and 72 h and an overall reduction in pain up to 7 days

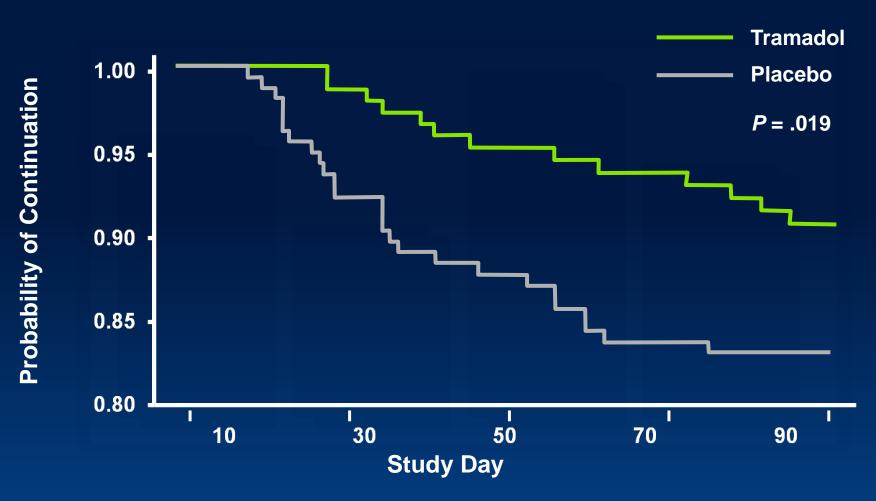
Isobolographic Analysis



Tramadol + Acetaminophen



Tramadol/Acetaminophen as COX-2 Add-On Therapy Probability of Continuation



Emkey R, et al. *J Rheumatol*. 2004;31(1):150–156.

Vitamin D Deficiency & Pain

- Osteomalacia (Deep musculoskeletal pain)
- Vitamin D Deficiency Pain Syndrome (Pain with superficial light pressure, pressure sores painful)
- Fractures

Gloth et al. Arch Intern Med. 1991; 151: 1662-1664.

Metastatic Bone Pain Management

- Non Opioids
 - NSAID's COX-2
 - Bisphosphonates (pamidronate, zoledronic acid, alendronate, risedronate, ibandronate)
 - Radionuclides (strontium 89, samarium 153)

Gloth III FM. The use of a bisphosphonate (etidronate) to improve metastatic bone pain in three hospice patients. Clin J Pain. 1995; 11: 333-5.

Other agents (may augment opioid response, especially, in neuropathy)

- Gabapentin and Pregabalin in neuropathic pain (such pain rarely responds adequately to opioids alone)
 - an FDA indication for post-herpetic neuralgia.
- Immunize against pain V-Z vaccine
- Duloxetine and some Tricyclic Antidepressants
 - addressing both neuropathic pain and depression, which commonly accompanies chronic pain

Cunningham AL, Lal H, Kovac M, et al, for the ZOE-70 Study Group. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. *N Engl J Med*. 2016;375(11):1019-1032.

Lal H, Cunningham AL, Godeaux O, et al, for the ZOE-50 Study Group. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med.* 2015;372(22):2087-2096

Patient Assisted Intervention for Neuropathy:
Comparison of Treatment in Real Life Situations
(PAIN-CONTRoLS)Bayesian Adaptive
Comparative Effectiveness Randomized Trial

"Conclusions and Relevance: ... nortriptyline and duloxetine outperformed pregabalin and mexiletine when pain reduction and undesirable adverse effects are combined to a single end point."

Duloxetine for Chronic Pain in OA

- Two 13-week placebo-controlled RCTs demonstrated significant efficacy for pain, physical function and patient global assessment of improvement
- Could be used either alone or as adjunctive therapy in patients taking oral NSAIDs and/or opioid analgesics
- No new safety signals in OA patients
- FDA approved for indication of chronic musculoskeletal pain

Opioids

- Short-acting
 - Morphine
 - Codeine
 - Hydrocodone
 - Oxycodone
 - Hydromorphone
 - Oxymorphone
 - Fentanyl

 $C \rightarrow M$



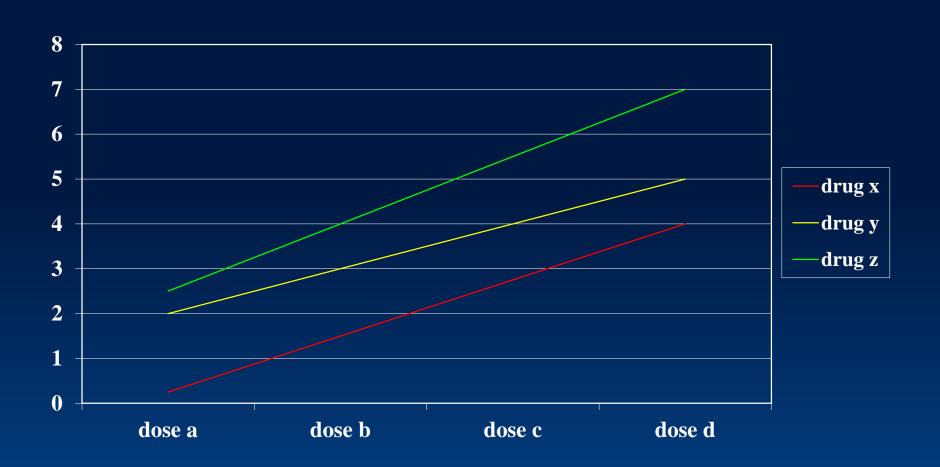
Pain Management

- Opioids
 - -Morphine CR
 - Oxycodone CR
 - Oxymorphone CR
 - Hydrocodone CR
 - Hydromorphone CR
 - Fentanyl
 - Buprenorphine
 - Tapentadol ER

Opioids - Fentanyl Patch

- 18-hour reservoir
- 12-hour delay in onset with new patch
- Increased absorption with fever (heat)
- Deaths in opioid-naïve patients

Equianalgesic Conversions





Changing Role of Opiate Analgesics

- Controversial in the management of chronic non-cancer pain (CNCP)
- Reluctance among practitioners
- In the last decade, the APS, AAPM and AGS advocated for more and better use of opiate analgesics in the management of CNCP
- Pain as the "fifth vital sign" raised awareness and increased utilization
- About 20 years ago the public felt that physicians were not adequately treating pain with narcotics. *Malpractice suits* were filed and won for under treatment resulting in a \$15 million verdict in 1991 (James cases, North Carolina) and \$1.5 million in the Chin case (1998, California)

Under treatment was the theme

- A joint statement from 21 health care organizations and the Drug Enforcement Agency, October 23, 2001
- <u>"Under-treatment of pain</u> is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death"
- <u>"Effective pain management</u> is an integral and important aspect of quality medical care, and pain should be treated aggressively"
- "For many patients, opiate analgesics, when used as recommended by established pain management guidelines, are the most effective way to treat their pain, and often the only treatment option that provides significant relief."

FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC.

Model Guidelines for the Use of Controlled Substances for the Treatment of Pain

- Evaluation of the Patient
- Treatment Plan
- Informed Consent and Agreement for Treatment
- Periodic Review
- Consultation
- Medical Records
- Compliance with Controlled Substances Laws and Regulations

FSMB. Model Policy for the Use of Controlled Substances for the Treatment of Pain. J Med Licensure Discipline. 2005. 91:31-5; www.fsmb.org

Things have Changed

- A spike in opiate prescriptions and overdose deaths has lead to public outcry and government intervention.
- Western Virgina Oxycontin deaths
- State Level: "Pill Mills" in south Florida resulted in 2012 Florida Statute 456.44 on Controlled Substance Prescribing
- Federal Level: CDC Guidelines for opiate prescribing for Chronic Pain

2012 Florida Legal Requirements for Controlled Substance Prescribing

- Physician must designate themselves as a controlled substance practitioner and
- Have written treatment plan and
- Have written controlled substance agreement and
- See patient at least once every three months and
- Meet strict medical record documentation and
- Refer patients with signs of substance abuse to pain management

Risk Factors for Opioid-Related Aberrant Behaviors

- Family history of substance abuse
 - Alcohol, illegal drugs, prescription drugs
 - Prescription drug abuse history carries greater risk
- Personal history of substance abuse
 - Alcohol, illegal drugs, prescription drugs
 - Prescription drug abuse history carries greater risk
- Age 16 to 45 years
- History of preadolescent sexual abuse
 - Increases risk for women
- Psychological disease
 - Attention deficit disorder (ADD) or depression
 - ADD carries higher risk

Opioids in Persistent Pain Recommendations

 X. Clinicians should anticipate, assess for, and identify potential opioid-associated <u>adverse effects</u>.

(moderate quality of evidence, strong recommendation)

- Tolerance develops to many symptoms within days
- Constipation still requires:
 - peripheral opioid antagonists (methylnaltrexone, naloxegol, naldemadine, alvimopan)
 - hydration
 - bulk fiber (only if hydration can be maintained)
 - activity
 - senna (others tegaserod, lubiprostone, linaclotide)
 - polyethylene glycol, sorbitol (20cc 70% BID < 3 d's).</p>



Opioids for Neuralgia

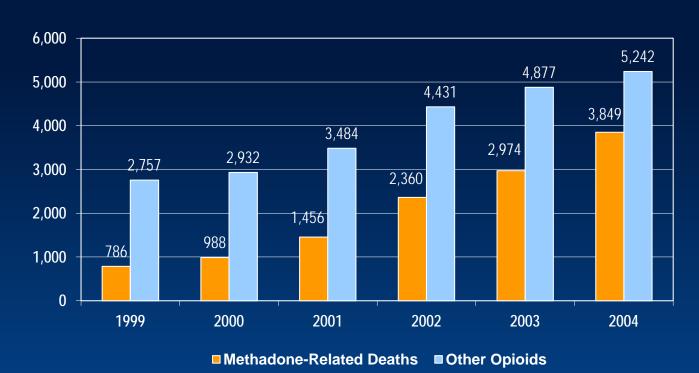
Treatment of post-herpetic neuralgia

- 1. Opioids perform as well as tricyclic antidepressants (TCA) for pain relief
- 2. Opioids and TCA significantly better than placebo (Avoid Amitriptyline and Imipramine in seniors):
 - 38% opioid and 32% TCA vs. 11% placebo; p< 0.001
- 3. Patient preference was for opioids:
 - 54% opioids vs 30% TCA; p=0.02

Opioids in Persistent Pain Recommendations (cont'd)

 XIII. <u>Methadone</u> should be initiated and titrated cautiously only by clinicians well versed in its use and risks. (moderate quality of evidence, strong recommendation)

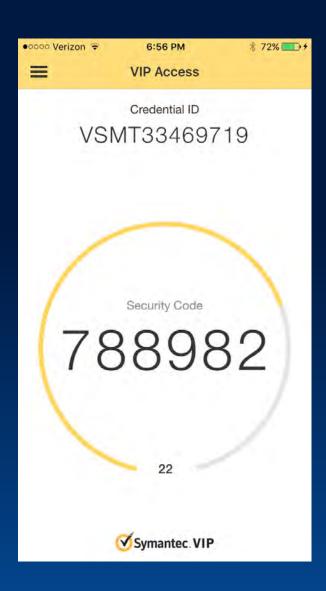
Methadone and Other Opioid Deaths, 1999-2004



FSMB: Breaches

- Inadequate attention to initial assessment
- Inadequate monitoring
- Inadequate attention to patient education and informed consent
- Unjustified dose escalation without adequate attention to risks or alternative treatments:
- Not making use of available tools for risk mitigations

Electronic prescribing



DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

Tapering and D/C'ing ER/LA Opioids

- Titrate downward to prevent signs and symptoms of withdrawal in the physically dependent patient
 - Do not abruptly discontinue these products
 - Decrease original dose by 10% per week
- Abrupt discontinuation of chronic opioids may cause withdrawal characterized by:
 - Stomach cramps, diarrhea, rhinorrhea, sweating, elevated heart rate, increased blood pressure, irritability, dysphoria, hyperalgesia, and insomnia

CDC Guidelines

- The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.
- Non pharmacologic and non opioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients
- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

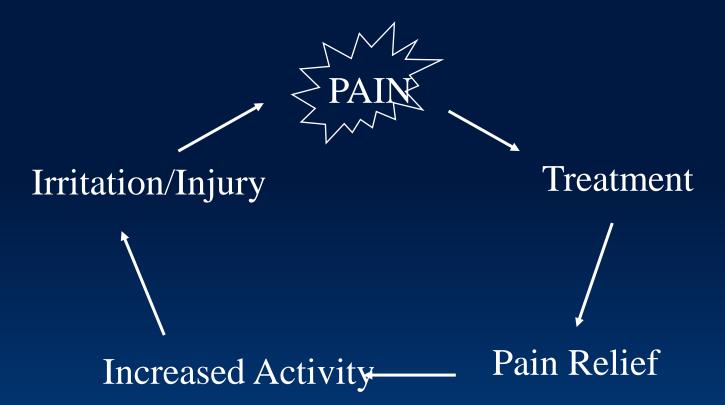


Interventional Techniques

- Proliferative Therapies
 - Nerve Blocks
 - Facet Denervation
 - Intrathecal Pumps
 - Dorsal Cord Stimulation

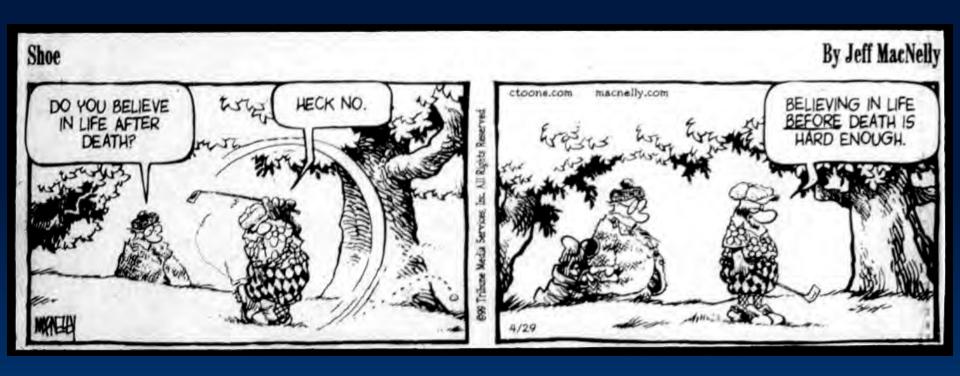


Pain Pentagon®



Summary

- FPS to help assess pain in seniors
- Pre-emptive Analgesia
- Synergy
- Prevent pain with CR opioids or vaccine
- Pain Pentagon



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References

- Evidence-Based
 - Quigley C. Hydromorphone for acute and chronic pain,
 - Cochrane Library, Issue 2, 2003.
 - McQuay HJ, et al. Radiotherapy for the palliation of painful bone metastases. Cochrane Library, Issue 2, 2003.
 - Mailis A, Furlan A, Sympathectomy for neuropathic pain, Cochrane Library, Issue 2, 2003.
- Recommended Reading
 - World Health Organization, Cancer pain relief, 2nd Ed.,
 Geneva, 1996.
 - Abrahm JL, A Physicians Guide to Pain and Symptom Management in Cancer Patients, J. Hopkins University Press, Baltimore, 2000.

References

- AAFP Lecture, Management of Chronic Pain, by Gary I. Levine, MD, FAAFP
- Florida Marijuana Policy Project
- https://www.mpp.org/states/florida/
- Images courtesy of Bing image search

Federal Regulations

21 CFR 1306.07

- May treat acute / chronic pain with a Schedule II narcotic in a recovering narcotic – addicted patient
- Federal law or regulations do not restrict the prescribing, dispensing or administering of a narcotic medication to a narcotic-addicted patient for the purpose of alleviating pain, if such prescribing is medical appropriate within standards set by the medical community.
- One must keep good records to document the physician is treating a pain syndrome, not the disease of narcotic addiction.

More from the CDC

- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids
- When opioids are started, clinicians should prescribe the lowest effective dosage.
- Long-term opioid use often begins with treatment of acute pain.
- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain

And More

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.
- Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose



Yet More

- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible
- Clinicians should offer or arrange evidence-based treatment (usually medication assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder

Marijuana

- Amendment 2 in 2016 vote, signed by Gov. Rick Scott into law in June 2017
- Working on decriminalization from the Federal level (due to Florida Statute 893.13)
- Studies done that show
 - Evidence for clinical benefit in HIV neuropathic pain
 - MS patients report less spasticity

Marijuana continued

- Three forms available: oils, pills, Vape pen
- No reversal available for overdose (overdose can include psychosis and anxiety symptoms), however no documented deaths from overdose.
- HUGE patient financial burden as no banks allowed to be involved in transactions (due to Federal illegal status). It is a cash only business.

Marijuana Prescribing

- Prescribing and dispensing are NOT the same thing
- Prescribers must complete training course
- Patient must register on the Office of Compassionate Use website (managed by Moffitt Cancer Center), provide passport photos and receive a treatment card

Indications for Marijuana

- Qualifying Disease States
 - Cancer, HIV/AIDS, Seizure Disorders, Sleep Disorders, Anorexia, Crohn's Disease, Parkinson's, Multiple Sclerosis, PTSD, ALS
 - Medical conditions of the same kind or class/comparable to those listed above
 - Any Terminal Condition

Legal Update 2019

- In 2019, Governor Ron DeSantis signed <u>Senate Bill 182</u> which repealed the previous ban on smokable medical marijuana. According to Florida's <u>Office of Medical Marijuana Use</u>:
- "The qualified physician must determine that smoking is an appropriate route of administration for medical marijuana and have the patient sign an updated consent form before placing an order for medical marijuana in a form for smoking for the patient in the Medical Marijuana Use Registry."
- Medical cannabis patients are now permitted to receive up to 2.5 ounces of whole flower cannabis every 35 days. They may not possess more than 4 ounces at any given time. Patients under the age of 18 must have a terminal disease and receive the additional approval of a pediatrician to receive smokable cannabis

Take Home Message on Marijuana

- DOH Handout for patients
 - http://www.floridahealth.gov/programs-andservices/office-of-medical-marijuanause/patients/_documents/ommu-patient.pdf
- May be a much better alternative to Opioids
- Expensive
- Lots of hurdles to jump through
- RECREATIONAL Marijuana still illegal
- RAPIDLY CHANGING LANDSCAPE HERE IN FLORIDA

Other Reasons...

- <1% of the thousands of papers published on pain focus on the aging society
- Lack of time in the nursing home for assessment and treatment of pain
- Fear of being labeled a complainer
- Belief that pain is a normal part of aging

Ferrell BA. Ann Intern Med. 1995; 123:681-7 Weiner DK et al. J Am Geriatr Soc. 2002; 50: 2035-40.

Pain Management Costs

- Always consider cost!
 - Individual Costs and Ability to Pay
 - Societal Costs
 - Cheaper per Pill may NOT be less costly
 - If pill is more expensive, but it prevents serious complications associated with ADR's, then overall health care costs may be reduced.