

Pennsylvania Medical Directors Association:  
Annual Meeting and Symposium

## Practical Aspects of Pain Management in LTC

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## Regulatory Obstacles

- DEA no longer accepts nurses in LTC as “agents”
- Burdensome requirements and inconsistency with prescribing Schedule II vs III-V
- Triplicate Prescriptions
- MDS 3.0: J0600. Pain Intensity - Administer ONLY ONE of the following pain intensity questions (A or B).
  - A. Numeric Rating Scale (00-10). Ask resident: "Please rate your worst pain over the last 5 days on a zero to ten scale, with zero being no pain and ten as the worst pain you can imagine." (Show resident 00 -10 pain scale)
  - B. Verbal Descriptor Scale. Ask resident: "Please rate the intensity of your worst pain over the last 5 days." (Show resident verbal scale) 1. Mild; 2. Moderate; 3. Severe; 4. Very severe, horrible; 9. Unable to answer.

## Regulatory Issues in LTC

- F-Tag
  - F309 (Quality of Care)
  - F272 (Assessment)
  - F329 (Unnecessary drugs)
  - F386 (Physician review of total plan of care)
  - F279/280 (Comprehensive Care Plans)
- MDS 3.0:
  - J0100. Pain Management - Complete for all residents, regardless of current pain level – J0850

## The Functional Pain Scale

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

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

## Pain Management

- Pharmacological
  - Non-opioids
  - Opioids

## Pain Management- Pharmacological

- Non-opioids
  - Acetaminophen
  - NSAID's (Topical preferred)
  - Tramadol (Ultram or Ultracet)
  - Capsaicin
  - EMLA, etc.

## Coxibs: Platelet Aggregation

Treatment (n)	Mean % inhibition ± SE
Placebo (n = 15)	~0
Rofecoxib 25 mg (n = 12)	~2
Diclofenac 50 mg tid (n = 8)	~15
Ibuprofen 800 mg tid (n = 8)	~75
Naproxen 500 mg bid (n = 8)	~90
Aspirin 81 mg (n = 12)	~90

1mM arachidonic acid as agonist

## Changes in GFR: Celecoxib vs Naproxen

### Day 1

Time (min)	Placebo	Celecoxib 200 mg	Celecoxib 400 mg	Naproxen 500 mg
60 min	~0	~-5	~-18	~0
120 min	~0	~-2	~-10	~0
180 min	~0	~5	~-10	~0

P < 0.05 Celecoxib 400 mg vs Placebo

### Cardiovascular System: Clinical Profile of Rofecoxib

#### Overall Mortality and CV Mortality in OA Studies: Events per 100 Patient-Years<sup>1</sup>

	Rofecoxib N=3,595	NSAIDs <sup>1</sup> N=1,565	Placebo N=783
Total mortality	0.1	1.1	0.0
Cardiovascular mortality	0.1	0.8	0.0

<sup>1</sup>Based on nine double-blind studies lasting from 6 weeks to a maximum duration of 89 weeks. The average duration of treatment was 5.5 months.  
<sup>2</sup>NSAIDs include diclofenac 150 mg, ibuprofen 2400 mg, and nabumetone 1500 mg.

- Rofecoxib is not a substitute for aspirin for cardiovascular prophylaxis.
- Concomitant administration of low-dose aspirin with rofecoxib may result in an increased rate of GI ulceration or other complications compared with use of rofecoxib alone.

1. Daniels B, Seidenberg B. Cardiovascular safety profile of rofecoxib in controlled clinical trials. Paper presented at: 1999 Annual Scientific Meetings; November 13-17; Boston, MA. Arthritis Rheum. 1999;42(9 suppl):S143. Abstract 435.

## NSAID's and ASA: Cardioprotective Impact

Follow-up (years)	Aspirin alone	Aspirin plus other NSAIDs	Aspirin plus diclofenac	Aspirin plus ibuprofen
0	100	100	100	100
1	~95	~90	~85	~80
2	~90	~85	~80	~75
3	~85	~80	~75	~70
4	~80	~75	~70	~65
5	~75	~70	~65	~60
6	~70	~65	~60	~55
7	~65	~60	~55	~50
8	~60	~55	~50	~45
9	~55	~50	~45	~40

MacDonald & Wei. Lancet 2003 361:573

## CV Risk with NSAID's

- Hernandez-Diaz S, Varas-Lorenzo C, Garcia Rodriguez LA. Basic Clin Pharmacol Toxicol. 2006 Mar;98(3):266-74. **Ibuprofen with ASA inc'd risk of MI; Naproxen w/o ASA showed dec'd risk of MI.**
- Do selective cyclo-oxygenase-2 inhibitors and traditional non-steroidal anti-inflammatory drugs increase the risk of atherothrombosis? Meta-analysis of randomised trials. Kearney PM, Baigent C, Godwin J, Halls H, Emberson JR, Patrono C. BMJ. 2006 Jun 3;332(7553):1302-8.
- McGettigan P, Henry D. CV risk & inhibition of cyclooxygenase: a systematic review of the observational studies of selective & nonselective inhibitors of COX-2. JAMA '06 296:1133-44

## Topical Diclofenac 1% Gel

- Significant pain reduction
- Recommendation for OA of Knee
- Side effect profile comparable to placebo for CV, Renal and GI ADR's.
- For limited joint pain, this may be a superior recommendation over oral NSAID's

Baraf HSB, Gloth FM, Barthel HR, and Gold MS. Safety and Efficacy of Topical Diclofenac Sodium Gel for Knee Osteoarthritis in Seniors and Younger Patients. *Drugs and Aging*. 2010; 28: 27-40.

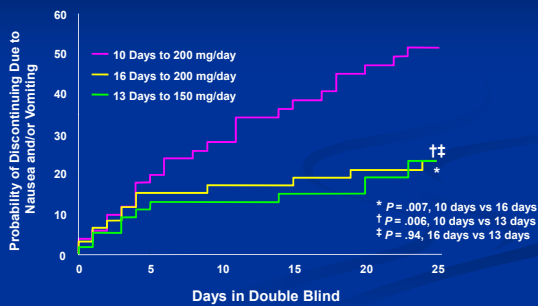
## Bupivacaine as pre-emptive analgesia in third molar surgery: Randomised controlled trial

- 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

M. Sharif Nayyara and C. Yates. *British Journal of Oral and Maxillofacial Surgery* Volume 44, Issue 6, December 2006, Pages 501-503

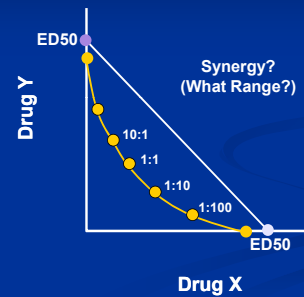
## Tramadol (Ultram®) Dose Titration Study II

### Summary of Time to Discontinuation Due to Nausea and/or Vomiting

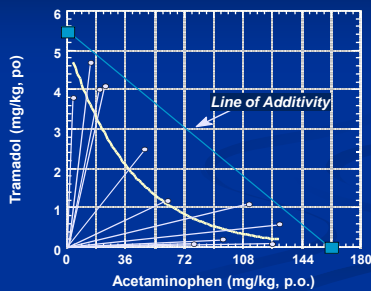


Petrone D, et al. *J Clin Pharm Ther*. 1999;24:115-23.

## Isobolographic Analysis



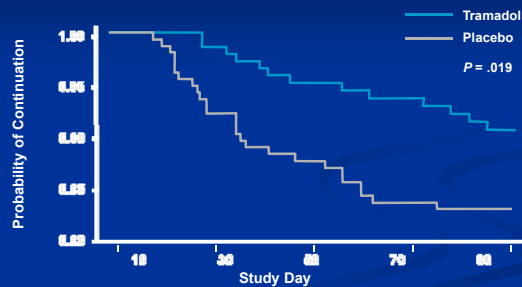
## Tramadol + Acetaminophen



Tallarida RJ, Raiffa RB. *Life Sci*. 1996;58:PL23-28.

## 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 to combine with opioids

- Gabapentin (Neurontin®) and Pregabalin (Lyrica®) in neuropathic pain (such pain rarely responds adequately to opioids alone) now with an FDA indication for post-herpetic neuralgia.
- Duloxetine (Cymbalta®) and some Tricyclic Antidepressants may also be useful in addressing both neuropathic pain and depression, which commonly accompanies chronic pain

Chappell AS et al. Pain 2009;146:253-60 and Pain Pract 2011;11:33-41.

## Pain Management

- Opioids
  - Morphine CR
  - Oxycodone CR
  - Oxymorphone CR
  - Hydromorphone CR
  - Fentanyl
  - Buprenorphine

## Opioids - Fentanyl Patch

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

## Opioids in Persistent Pain Recommendations

- VIII. All patients with moderate-severe pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy. (low quality of evidence, strong recommendation)
- IX. Patients with frequent or continuous pain on a daily basis should be treated with ATC time-contingent dosing aimed at achieving steady state opioid therapy. (low quality of evidence, weak recommendation)

AGS Panel on Persistent Pain in Older Persons. Pharmacological Management of Persistent Pain in Older Persons. J Am Geriatr Soc. 2009; 37 (8) 1331-46.

### Opioids in Persistent Pain Recommendations (cont'd)

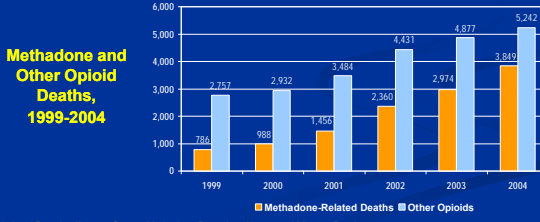
- X. Clinicians should anticipate, assess for, and identify potential opioid-associated adverse effects. (moderate quality of evidence, strong recommendation)
  - Tolerance develops to many symptoms within days
  - Constipation still requires:
    - methylnaltrexone
    - hydration
    - bulk fiber (only if hydration can be maintained)
    - activity
    - senna
    - sorbitol (20cc 70% BID < 3 d's).



Thomas J, Karver S, Cooney GA, et al. Methylnaltrexone for opioid-induced constipation in advanced illness. *N Engl J Med*. 2008;358:2332-2343.

### Opioids in Persistent Pain Recommendations (cont'd)

- XIII. Methadone 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**

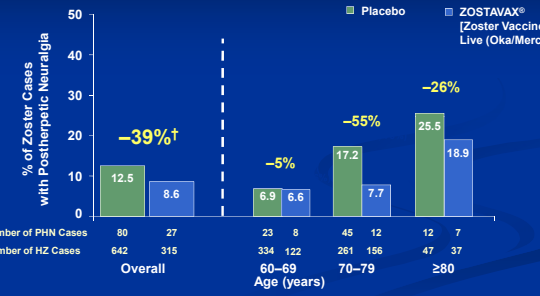
Year	Methadone-Related Deaths	Other Opioid Deaths
1999	786	2,757
2000	968	2,932
2001	1,456	3,484
2002	2,360	4,431
2003	2,974	4,877
2004	3,819	5,242

National Drug Intelligence Center, Methadone Diversion, Abuse, and Misuse: Deaths Increasing at Alarming Rate. November 16, 2007. Source: National Center for Health Statistics.

### Pain Management – Additional pearls

- Never “prn” (Pain Relief Negligible)
- Regular Schedule (patient may refuse)
- Patient-Controlled Analgesia (PCA)

### Postherpetic Neuralgia\* in the Shingles Prevention Study




Age (years)	Placebo (% PHN)	ZOSTAVAX (% PHN)
Overall	12.5	8.6
60-69	6.9	6.6
70-79	17.2	7.7
≥80	25.5	18.9

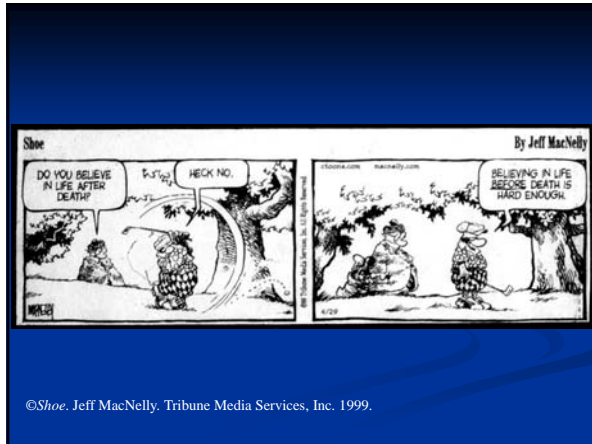
Number of PHN Cases: Overall (80 vs 27), 60-69 (23 vs 8), 70-79 (45 vs 12), ≥80 (12 vs 7). Number of HZ Cases: Overall (642 vs 315), 60-69 (334 vs 122), 70-79 (261 vs 156), ≥80 (47 vs 37). Percentages are relative to the placebo group. †p < 0.05.

### Summary

- FPS to help assess pain in seniors
- AVOID NSAIDs If needed consider Topical Diclofenac or oral Naproxen (& PPI)
- Pre-emptive Analgesia
- Synergy
- Vitamin D (1-800-345-1199)
- Prevent pain with CR opioids or vaccine



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## Pharmacologic Management of Pain in Older Adults

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[www.SeniorHealthCare.org](http://www.SeniorHealthCare.org)  
[www.WHCoA.gov](http://www.WHCoA.gov)

## Other Resources

- Revised Beer's Criteria (Arch Intern Med. 2003; 163:2716-24)
- [www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf](http://www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf)  
(<http://www.painpolicy.wisc.edu/>)
- American Geriatrics Society Guidelines for Management of Persistent Pain in Older Persons (J Am Geriatr Soc 2002; 50 (6 Suppl): S205-24)
- AGS Panel on Persistent Pain in Older Persons. Pharmacological Management of Persistent Pain in Older Persons. J Am Geriatr Soc. 2009; 37 (8) 1331-46.
- Federation of State Medical Boards Policy ([http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/2004\\_model\\_pain\\_policy.asp](http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/2004_model_pain_policy.asp))

## Other Guidelines and Online Resources

Organization	Link to Resources
The American Academy of Pain Medicine	<a href="http://www.painmed.org/clinical_info/guidelines.html">http://www.painmed.org/clinical_info/guidelines.html</a>
American Pain Society	<a href="http://www.ampainsoc.org/pub/cp_guidelines.htm">http://www.ampainsoc.org/pub/cp_guidelines.htm</a> <a href="http://www.ampainsoc.org/links/clinician1.htm">http://www.ampainsoc.org/links/clinician1.htm</a>
Knowledge 360 and American Pain Foundation	<a href="http://www.painknowledge.org">http://www.painknowledge.org</a> <a href="http://www.painfoundation.org/">http://www.painfoundation.org/</a>
American Academy of Pain Management	<a href="http://www.aapainmanage.org/literature/Publications.php">http://www.aapainmanage.org/literature/Publications.php</a>
SOAPP and other Tools from PainEDU.org	<a href="http://www.painedu.org/soap.asp">http://www.painedu.org/soap.asp</a>

## 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](http://www.fsmb.org)



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1-800-345-1199

### The Comparative Safety of Analgesics in Older Adults With Arthritis

- “Propensity Score Matching” couldn’t correct for smoking, alcohol use, and over-the-counter medication use
- **Functional status** of patients in each group was unknown, so it is possible that confounding remained, as further testing of their model suggested.
- **Did not distinguish between the type of medication** used within a given class (methadone vs codeine, for example), its dose, or its duration
- Residual bias in this study among the comparator groups, including the likelihood that sicker patients preferentially received opioids

Solomon DH, Rassen JA, Glynn RJ, et al. The Comparative Safety of Analgesics in Older Adults With Arthritis. *Arch Intern Med.* 2010;170(22):1968-1978.

### 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

Raja SN, Haythornthwaite JA, Pappagallo M, Clark M R, Trivison T G, Sabeen S, Royall R M, Max M. Opioids versus antidepressants in postherpetic neuralgia: a randomized, placebo-controlled trial. *Neurology* 2002;59(7):1015-21

### 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

Chappell AS et al. *Pain* 2009;146:253-60 and *Pain Pract* 2011;11:33-41.

### 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

Pautex S, Michon A, Guedina M et al. Pain in Severe Dementia: Self-Assessment or Observational Scales. *J Am Geriatr Soc.* 2006; 54: 1040-5.

### The Functional Pain Scale

Scale	Relative Efficiency	Standardized Response Means	Effect Size	p-value	Paired t-test	Rank (Resp. 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.