CHRONIC PAIN AND OPIOIDS

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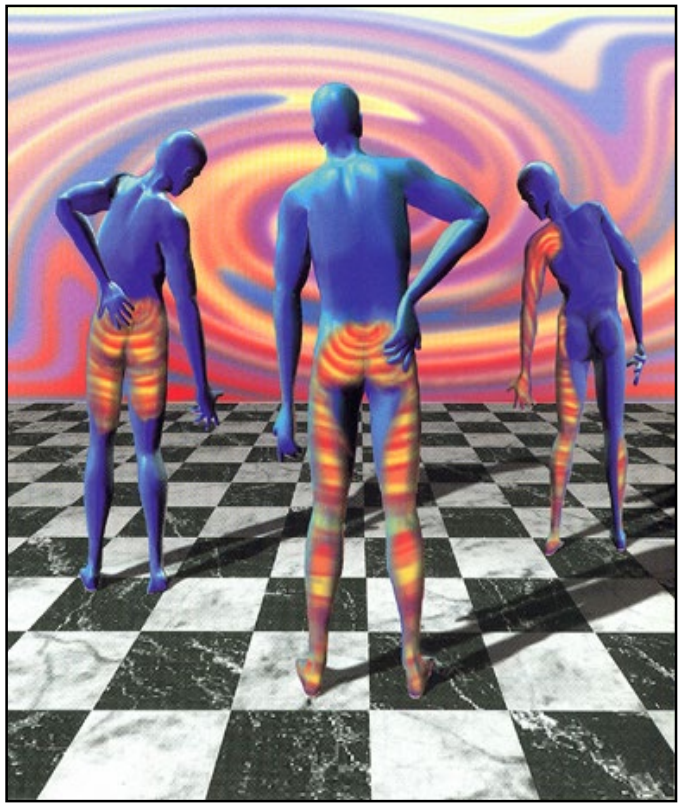
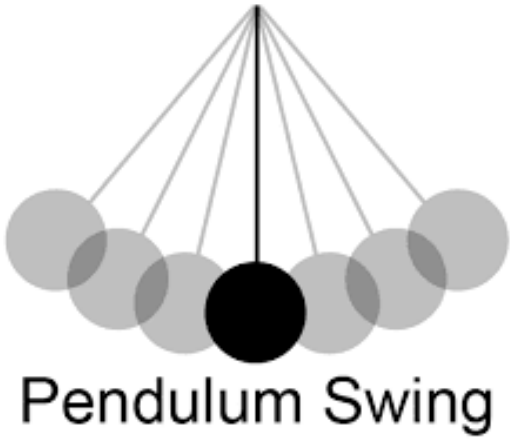
Pain Puzzle



SUMMARY

- **Chronic pain is:**
  - Never purely physical or solely psychological
  - Responded to differently depending on the person's physical, psychological, social, educational and cultural variables
  - Not measurable by any objective test
  - Limited usefulness of opioids
  - Best treated with whole person approach

The Opioid Dilemma



The GOOD News

- *Decreasing opioid prescribing & usage*
  - 2018: 17% decline in morphine milligram equivalents (MME)
  - Prescription opioid volume declined 43% since the peak in 2011, with high-dose prescriptions of 90 MMEs per day or greater declining by 61%

The BAD News

- *MDs stopping Rx opioids and discharging IWs*
- *MDs hesitant to take on IWs on opioids*
- *Some IWs abruptly weaned or denied opioids*
- *Some transition to illicit substances*
- *Denial of alternative, yet MTUS appropriate, treatments*

Chronic Opioid Analgesic Therapy (COAT)

- No evidence to support long term efficacy
- Not superior to non-opioids in reducing pain
  - NSAIDs, acetaminophen
  - Tricyclic antidepressants (e.g., amitriptyline, etc.)
  - Anticonvulsant drugs (e.g., gabapentin, etc.)
- Ample evidence of significant risk for harm
  - *Opioid therapy associated with side-effects*
    - Nausea and vomiting
    - Constipation
    - Drowsiness, lethargy and cognitive impairment
    - Depression
    - Hormonal changes
    - Sexual dysfunction
    - Urinary retention
    - Hypotension and peripheral edema
    - Respiratory depression

Opioid Facts

- Increase risk of opioid misuse with
  - high daily doses (>50-80 mg/day MED)
  - greater daily supply of pills
- The longer the opioid prescription, the greater chance of being on an opioid a year later
- Strong association between chronic daily opioid use and mortality, even at intermediate doses

MTUS ACOEM Opioids Guideline

- Not the first line of treatment for pain
- Avoid in patients with opioid abuse risk factors
  - *History of addiction to opioids, alcohol and/or other drugs*
  - *Personal or family substance abuse history*
  - *Adverse childhood experiences (ACE)*
    - Neglect
    - Physical, emotional, sexual abuse
  - *Comorbid psychiatric disorders*
- Should not in general be used for mild injuries
- Prescribe at the lowest dose for a limited time
- Patient educated about opioids and expectation clear for use only short-term
- For chronic usage
  - *Monitor function, not just pain reduction*
  - *Repeated weaning trials recommended*

MTUS Drug Formulary

- Opioid use is moderately not recommended for treatment of subacute and chronic nonmalignant pain
- Max. daily opioid dose recommended for 50 MED
- Opioid weaning/tapering recommended – safely
- Select group of patients benefit from opioids

MTUS Criteria for Prescribing Opioids

- Limited to cases in which other treatments are insufficient and criteria for opioid use are met
- Efficacy (pain relief & increased function)
- No or manageable side-effects
- Physician must be documented opioid benefit

Weaning
Tapering
Detoxification

- Should never be abrupt
- Best done slowly – *perhaps 10% a week*
- In conjunction with other pain treatment approaches
- Consideration for conversion to buprenorphine
- Patients who have been on long-term chronic opioids may be difficult to completely wean
- *Remember: not about the drug but about function*

Should Chronic Opioids be prescribed?

- Maybe; an individual choice
- If yes, should follow EBM guidelines
  - *Opioid Rx justification*
  - *Opioid Agreement / Informed consent*
  - *Urine Drug Testing*
  - *CA PDMP CURES*
    - Prescription Drug Monitoring Program
    - Controlled Substance Utilization Review & Evaluation System
  - *Monitor compliance and document efficacy*
  - *Treat side-effects*
  - *Regular weaning/tapering trials*

Pain Management Treatment Options

Alternative Treatment Modalities to Opioids

PASSIVE

- Medications
  - Non-opioid & opioid analgesics
  - Antidepressants
  - Sedatives & tranquilizers
  - Anticonvulsants
- Therapies
- Invasive interventions
- Surgical

Pain Management Treatment Options

Alternative Treatment Modalities to Opioids

ACTIVE *(MTUS Supported)*

- Education
- Physical rehabilitation: Stretching / Exercise / Conditioning
- Psychological Interventions to change perception and emotional response to pain
  - Cognitive behavioral therapy (CBT)
  - Anger management
  - Anxiety and depression reduction
  - Biofeedback
  - Relaxation training
  - Teaching stress reduction skills
  - Mindfulness meditation
  - Hypnosis
- Biopsychosocial functional restoration approach

What's unique about a Functional Restoration Approach?

- **Coordinated, multidisciplinary care**
  - Physician
  - Psychologist
  - Physical therapist
- **Colocated services**
- **Continued communication between disciplines**
- **Focus of treatment**
  - Locus of control IW based
  - Medication optimization with weaning of meds
  - Increased function with return to life and work activities

UTILIZATION REVIEW ISSUES

DOUGLAS A. BENNER, MD, FACOEM

Common Issues Seen In Utilization Review of Pain Cases

- Lack of patient specific rationales for the treatment requested
- Lack of reasons for care outside of guidelines *(no other guideline or recent research)*
- Lack of documentation of appropriate patient management in opiate cases, *(i.e. checking CURES)*
- Lack of documentation of functional benefit of previous procedures or drugs when requesting additional procedures or refills *(job or home improved ADLs, not just pain score)*

Common Issues Seen In Utilization Review of Pain Cases *(continued)*

- Requests for excessive PT, OT, Chiro or Acupuncture visits
- Prescribing long-acting opiates in acute and postoperative care instead of short acting opiates
- Prescribing multiple sedating medications with opiates such as benzodiazepines and sleeping medications
- Prescribing high doses of opiates long-term without functional benefits for months & years

Common Issues Seen In Utilization Review of Pain Cases *(continued)*

- Requesting inappropriate procedures such as epidurals for non-radiating pain
- Requesting repeat epidurals or other injections without documentation of appropriate benefits from previous injections
- Providers not attempting weaning on chronic opiate cases with lack of documented benefit or on dangerous high doses
- Prescribing opiates on working patients with safety sensitive jobs

Common Issues Seen In Utilization Review of Pain Cases *(continued)*

- Prescribers ignoring requests for additional information needed to approve treatments
- Prescribers not providing additional information for reconsideration after a “denial for lack of information”
- Prescribers not being available to discuss cases when called by peer reviewing physicians
- Prescribers not taking advantage of Appeal process before requesting an IMR

Pain Itself is Very Subjective

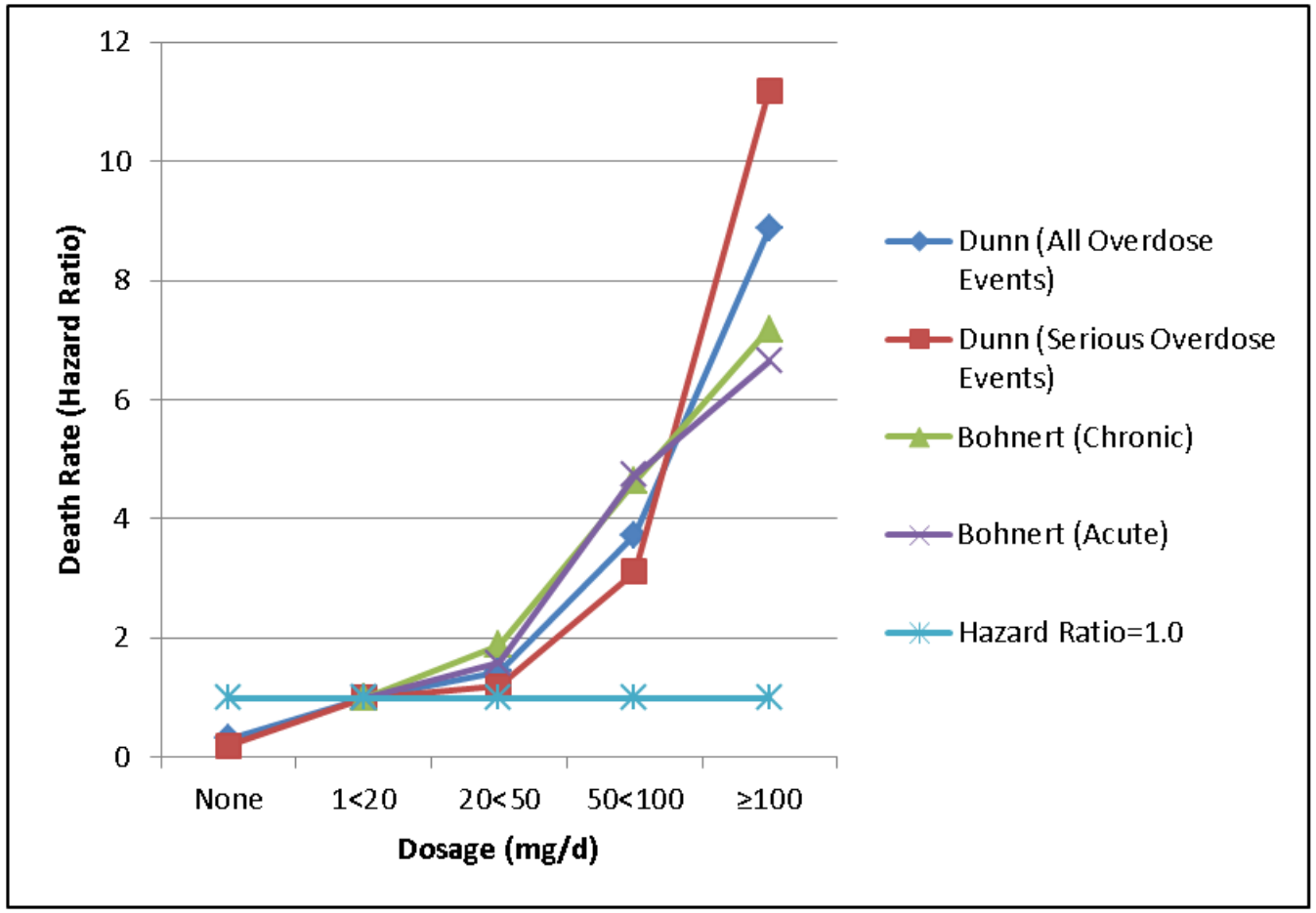
- Since we can not measure pain, we measure it's impact on objective observation of physical, behavioural, and occupational performance:
  - *Active range of motion*
  - *Endurance*
  - *Strength*
  - *Job performance*
  - *Job duties*
  - *Social interaction*
  - *Activities of Daily Living (ADLs)*
  - Basic
  - Instrumental

Utilization Review Will Often Suggest Weaning

- **Patients with acute pain treated with continuous opioids over 50mg MED for longer than 2-3 weeks**
  - No demonstrated functional gain
  - Non-compliance
  - Aberrant drug screening results, or diversion
  - Adverse effects (cognitive impairment, falls, poor judgement, untreated sleep apnea, psychological disorders, and concurrent use of depressant medications
  - Urine drug testing showing unexpected absence of the prescribed drug or illicit substance(s)
- **May suggest consultation with addiction specialist for complex patients with high doses, prior withdrawal problem or complex psychological or medical conditions**

Death Rate vs. Morphine Equivalent Dosage

(WHY 50 MED IS IMPORTANT)



Adapted from Dunn 2010 and Bohnert 2011.

*Statistical significance present for acute and chronic pain at and above 50 mg per day of oral morphine equivalent dose.

INTERVENTION PROGRAMS

AIMEE BOGGS, RN, MSHI, CCM, CPHIMS

Prescription Intervention Programs

- **Claims appropriate for a Prescription Intervention Program (PIP):**
  - Less than two years old (early intervention)
  - Single prescriber
  - High Morphine Equivalent Dosage
  - Opioids prescribed outside of the immediate operative period
  - Multiple medications/ polypharmacy including the "***holy trinity***" of opioids, benzodiazepines (Xanax, Valium, Ativan, etc.), and Carisoprodol (Soma)
  - Medication costs exceeding $500/month

Prescription Intervention Programs

- File Handling:
  - Nurse case manager completes a file review
  - Specialty physician(s) completes a file review and makes recommendations specific to each medication being utilized
  - UR requests that are appropriate for the reviewing physician will be assessed
  - A peer-to-peer conversation is held with the treating physician and recommendations for medication management are made
  - After the peer-to-peer has been completed, a letter summarizing the treatment recommendations and any agreements is sent to the treating physician
  - Response to the summary letter is requested from the treating physician to indicate agreement or offer clarification
  - Nurse case manager follows-up with the physician office for the next 3-4 office visits to review compliance and reminds them of the peer-to-peer recommendations

Intervention Programs

- **Claim types appropriate for more aggressive intervention:**
  - Claims greater than 2 years old or with more complexity *(multiple body parts/conditions)*
  - Single or multiple prescribers
  - High Morphine Equivalent Dosage
  - Opioids prescribed outside of the immediate operative period
  - Multiple medications/ polypharmacy including the "***holy trinity***" of opioids, benzodiazepines (Xanax, Valium, Ativan, etc.), and Carisoprodol (Soma)
  - Medication costs exceeding $500/month
  - Claims with additional, non-medication issues that may need addressing *(examples include, but not limited to, over-utilization of services or high medical supply costs that may not longer be appropriate for the medical care)*

Claim Intervention Strategies

STEP 1

- Nurse case manager completes a detailed file review
- Specialty physicians completes a peer review and makes recommendations specific to each file in regards to medical treatment and medications
- Any UR requests that are appropriate for the reviewing physician will be assessed
- Completion of cost projection to determine current exposure and treatment cost drivers

STEP 2

- Round table meeting including claims personnel, defense attorney as applicable, Specialty reviewing physician and case manager
- Peer-to-peer conversation(s) initiated with treating provider(s)

STEP 3

- Continue round table meetings with claims team to review progress and decide on best course of action
- Continue peer-to-peer conversation with treating provider(s)

STEP 4

- Upon mutual agreement from Next Step team and claims team, file will move be closed.
- Issuance of a final report detailing efforts and outcomes, and completion of another cost analysis to determine program impact

UR and Claim Intervention Integration

- UR is integrated directly with Intervention Program in coordination with claims team/TPA
- Specialty Physician Reviewer performs all UR for Intervention Program cases, as they have the benefit of reviewing of all medical records and not just recent reports
- The Specialty Physician Reviewer participates in Peer-to-Peer contact with the requesting/treating physician to discuss rationale for determinations
- UR determinations are distributed to all stakeholders including the adjuster and defense attorney to ensure claims team is on the same page

IMPACT OF MEDICATIONS ON MEDICARE SET-ASIDES

JAKE REASON

MSA 101
Brief Overview

- MSP Statute established in 1980
  [42 U.S.C. 1395y; Section 1862 of the Social Security Act]
- Enacted to ensure Medicare is not paying for care where a 3rd party is responsible
- Primary subsections specific to WC claims:
  - 42 U.S.C. 1395y(b)(2) [Medicare always secondary to WC]
  - 42 U.S.C. 1395y(b)(2)(B)(ii) [Medicare entitled to re-payment of conditional payments
- WC has always been primary to Medicare since inception of Medicare program in 1965
- Medicare's "secondary" status gives the federal government a right of recovery against primary payers

Current Methods for Allocation of Medications in an MSA

- **Per CMS's Current Guidelines:**
  - Allocation for medications must be made on the current medical records, and pharmacy and claims payment histories
  - Records have to clearly document what medications are being used *(including brand vs. generic formulation, dosage & frequency)*
  - Absence of information does not equate to a basis for excluding medications from an MSA. For example, latest medical report is from 9-months ago. There are no current indications of payments for medications and no RFAs. CMS will very likely include medications in an MSA as there is no documented evidence they have been discontinued
  - CMS will always give more weight to the recommendations of the treating physician rather than med/legal opinions or non-certifications issued through UR & IMR
  - If UR & IMR non-certifications have been issued, then in order to exclude the medication from the MSA the treating physician's recommendations, post IMR, have to be in-line with the IMR decision. CMS is wanting to see that the treatment plan is now in accordance with IMR

Current Methods for Allocation of Medications in an MSA

- **Per CMS's Current Guidelines:**
  - CMS routinely ignores Evidenced Based Medicine treatment guidelines and allocates for all medications, including opioids, over the full duration of life expectancy on a daily basis
  - CMS requires that each medication be priced according to the lowest Average Wholesale Price (AWP) for the relevant dosage (per pill/tablet costs)
  - Typically, AWP is 25-to-35% higher than the rates current being paid on active claims through a Pharmacy Benefit Manager
  - CMS does not take into account when a patent will end on a particular medication and prices everything on current rates
  - Weaning or tapering of opioids will only be recognized if a clear and specific schedule/plan has been implemented

Current Methods for Allocation of Medications in an MSA

Cost examples per CMS's Current Guidelines:

Medications - reimbursable under Medicare (based on average wholesale price)

Medications	NDC Code	Treatment Frequency	Every # of Years	Life Expectancy	Per Item Cost	Lifetime Cost
Eszopiclone 2mg, one daily *($11.66 per tablet)*	53217-0149-60	12	1	18	$349.85	$75,567.17
Buprenorphine HCL, 2mg, three daily *($4.14 per sublingual tablet)*	00054-0176-13	12	1	18	$372.60	$80,481.60
Hydrocodone-APAP, 10/325mg, eight daily *($0.46 per tablet)*	71930-0021-52	12	1	18	$109.44	$23,639.04
Cyclobenzaprine HCL 5mg, two-and-a-half daily *($0.06 per tablet)*	10135-0594-01	12	1	18	$3.90	$842.40
					TOTAL MEDICATIONS REIMBURSABLE UNDER MEDICARE:	**$180,530.21**

ALTERNATIVE Methods for Allocation of Medications in an MSA

- Some payers now have Non-Submission programs which take Evidenced Based Medicine treatment guidelines in account
- They have also incorporated the decisions issued through both the UR and IMR processes and allocations for medication are consistent with UR certifications and IMR upholds
- Pricing for medications can be determined in a number of different ways:
  - Utilization of current fee schedule price – based on State of Jurisdiction
  - Utilization of Pharmacy Benefit Manager pricing *(either current pricing on active claims or post-settlement program price if available)*
- Allocations for medications can be based on current and anticipated usage rather than simply allocating over life expectancy on a daily basis
- Weaning & tapering programs can be used on a realistic basis (i.e. 10% reduction in dosage per month)

ALTERNATIVE Methods for Allocation of Medications in an MSA

Cost example using a Non-Submission approach:

Medications - reimbursable under Medicare (based on pharmacy benefit manager price)

Medications	NDC Code	Treatment Frequency	Every # of Years	Life Expectancy	Per Item Cost	Lifetime Cost
Eszopiclone 2mg, one daily *($8.75 per tablet)*	53217-0149-60	6	1	18	$262.50	$28,350.00
Buprenorphine HCL, 2mg, three daily *($3.11 per sublingual tablet)*	00054-0176-13	12	1	1	$279.90	$3,358.80
Hydrocodone-APAP, 10/325mg, eight daily *($0.30 per tablet)*	71930-0021-52	6	1	4	$72.00	$1,728.00
Cyclobenzaprine HCL 5mg, two-and-a-half daily *($0.04 per tablet)*	10135-0594-01	6	1	4	$2.40	$57.60
					TOTAL MEDICATIONS REIMBURSABLE UNDER MEDICARE:	**$33,494.40**

Suggestions & Tips

Ensure your cases are ready prior to requesting an MSA proposal

- If the MSA is 6 months or older or if a significant change in treatment/condition has occurred, have the MSA revised prior to settlement
- The Claims & Pharmacy Payment Histories must be current and the rated age must not be expired
- Know the claimant's current medication regimen (or lack thereof) and have documentation of the same
- Have current physician's specifically document the anticipated future treatment & prescription drug needs
- If there is the potential for tapering of medications, have physician document and institute tapering prior to submitting the MSA if possible
- Ensure treating physician's current treatment plan is in-line with any decisions issued through the UR & IMR processes