Use of Guidelines for the Management of Pain

Harvey J. Hanel, PharmD, R.Ph.
Pharmacy Director
ND Workforce Safety & Insurance
Objectives

* Describe the various treatment guidelines that are available for the management of various pain types or syndromes.
* Identify the differences that exist between various treatment guidelines.
* Identify the actions taken by state or federal regulatory agencies with regards to the use of pain treatment guidelines.
Where do the Guidelines Come From?

* Consensus statements or evidence-based reviews generated by various entities
  * Federal Agencies or Departments
    * E.g. VA/DoD
  * State Agencies or Departments
    * Washington State Department of Labor and Industries
    * Colorado Division of Workers’ Compensation
  * Professional Associations
    * American College of Occupational and Environmental Medicine
Guideline Title

VA/DoD clinical practice guideline for management of opioid therapy for chronic pain

Bibliographic Source(s)

Guideline Status

* This is the current release of the guideline.
* This guideline updates a previous version: Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar. Various p. [51 references]
FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

Drug Withdrawal

November 19, 2010 – Propoxyphene (Darvon, Darvocet): The U.S. Food and Drug Administration notified healthcare professionals that Xanodyne Pharmaceuticals has agreed to withdraw propoxyphene, an opioid pain reliever used to treat mild to moderate pain, from the U.S. market at the request of the FDA, due to new data showing that the drug can cause serious toxicity to the heart, even when used at therapeutic doses.
National Guideline Clearinghouse
Standardized Format (Scope)

- Disease/Condition(s)
  - Chronic pain
- Guideline Category
  - Evaluation
  - Management
  - Treatment
National Guideline Clearinghouse
Standardized Format (Scope)

* Clinical Specialty
  * Anesthesiology
  * Family Practice
  * Internal Medicine
  * Neurology
  * Pharmacology
  * Physical Medicine and Rehabilitation
  * Psychiatry
  * Rheumatology
Intended Users

- Advanced Practice Nurses
- Health Care Providers
- Nurses
- Pharmacists
- Physician Assistants
- Physicians
- Substance Abuse Disorders Treatment Providers
Guideline Objective(s)
- To update the evidence base of the 2003 guideline
- To promote evidence-based management of individuals with chronic pain
- To identify the critical decision points in management of patients with chronic pain who are candidates for opioid therapy
- To improve patient outcomes (i.e. reduce pain, increase functional status, and enhance the quality of life)
- To decrease the incidence of complications
- To allow flexibility so that local policies or procedures, such as those regarding referrals to or consultation with substance abuse specialty, can be accommodated
Target Population

- Adults (18 or older) with chronic pain conditions who are treated in any Department of Veterans Affairs (VA) or Department of Defense (DoD) clinical setting

- Special populations; Patients with polytrauma, traumatic brain injury (TBI), mild traumatic brain injury (mTBI), post-traumatic stress disorder (PTSD), substance misuse, and psychiatric co-morbidity
Interventions and Practices Considered
- Evaluation
- Treatment and Management
- Pharmacological Treatment

Major Outcomes Considered
- Pain reduction
- Complication rates
- Functional status
- Quality of life
- Adverse effects of therapeutic interventions
- Mortality
Methods Used to Collect/Select the Evidence

- Hand-searches of Published Literature (Secondary Sources)
- Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

- Details how the reviewers/panel selected specific references to be included in the guidelines
- Includes the types of studies or published articles and any specific topics that were searched
Selection of Evidence

Will detail what study types (e.g. peer-reviewed randomized controlled studies, meta-analyses, etc) were included and the hierarchy or general weighting given to the various study types.

Also includes more specific information on which databases were searched

- Cinhahl/Medline
- Cochrane
- OVID
National Guideline Clearinghouse
Standardized Format (Methodology)

* Number of Source Documents
  * Not stated
* Methods Used to Assess the Quality and Strength of Evidence
  * Weighting According to a Rating Scheme (Scheme Given)
  * One of the most important parts of the guideline evaluation/comparison process
* Rating Scheme for the Strength of Evidence
  * Quality of Evidence
    I At least one properly done randomized controlled trial (RCT)
    II-1 Well-designed controlled trial without randomization
    II-2 Well-designed cohort or case-control analytic study, preferably from more than one source
    II-3 Multiple time series evidence with/without intervention, dramatic results of uncontrolled experiment
    III Opinion of respected authorities, descriptive studies, case reports, and expert committees
Rating Scheme for the Strength of Evidence

Overall Quality

Good - High-grade evidence (I or II-1) directly linked to health outcome

Fair - High-grade evidence (I or II-1) linked to intermediate outcome; or Moderate-grade evidence (II-2 or II-3) directly linked to health outcome

Poor - Level III evidence or no linkage of evidence to health outcome
Graded strength exercises – C
Recreational activities – I
Oral NSAIDs – I
Concomitant cytoprotective agents with oral NSAIDs in high risk patients – C
Acetaminophen – I
Tricyclic antidepressants – I
Duloxetine – I
Short-term use of gabapentin or pregabalin – C
Bisphosphonates after NSAIDs and physical therapy have been trialed - A
ACOEM CRPS Guidelines
Recommended Treatments

- Calcitonin if inadequate symptom relief with NSAIDs, corticosteroids, physical and/or occupational therapy, and bisphosphonates – C
- Clonidine po or via regional blockade for moderately severe CRPS that is unresponsive to rehabilitation therapy, NSAIDs or corticosteroids – C
- Short-term glucocorticosteroids – C
- Lidocaine patches after other treatments have been tried - I
ACOEM CRPS Guidelines
Recommended Treatments

- Dimethylsulfoxide (DMSO) as an adjunct to exercise therapy – C
- N-acetylcysteine (NAC) as an adjunct to exercise therapy – I
- Vitamin C for prevention of CRPS in patients with wrist fractures or other extremity trauma – C
- Opioids for select patients – I
- Screening of patients prior to initiation of opioids – I
- Routine use of a treatment agreement – I
- Routine use of urine drug screening - C
Anti-convulsants for patients with CRPS not managed by NSAIDs, other medications with documented efficacy, and exercise (Considered 4th or 5th line agents) – I

- Long-term use of gabapentin or pregabalin (> 4 weeks) – I
- Epidural clonidine – I
- Muscle relaxants – I
- Capsicum creams – I
- Eutectic mixture of local anesthetics (EMLA) – I
- Other creams/ointments – I
ACOEM CRPS Guidelines
No Recommendation Treatments

- Hyperbaric oxygen – I
- Infrared therapy – I
- Massage – I
- Transcutaneous electrical nerve stimulation – I
- Botulinum injections – I
- Intrathecal baclofen – I
- Lidocaine infusions – I
- Phentolamine bier blocks - I
ACOEM CRPS Guidelines
Not Recommended Treatments

- SSRIs, bupropion or trazodone for CRPS without depression – I
- Willow bark – I
- N-methyl-D-aspartate (NMDA) receptor antagonists including dextromethorphan – I
- Ketamine infusion – I
- Thalidomide – I
- Tumor necrosis factor-alpha blockers – I
- Wheatgrass cream – I
- Complimentary and alternative treatments, dietary supplements, etc. - I
ACOEM CRPS Guidelines
Not Recommended Treatments

* Routine use of opioids – I
* Magnets and magnetic stimulation – I
* Acupuncture – I
* Application of heat by health care provider – I
* Myofascial release – I
* Reflexology – I
* Iontophoresis – I
* Intrathecal drug delivery systems – I
* Spinal cord stimulators for long-term relief (> 3 years) - C
The guidelines address the following:

- Proper assessment, management, and documentation for opioid use for chronic pain.
- The continued use of opioids for greater than 6 months in an IW not back to work.
- Precautions in prescribing opioids

WA includes several helpful tools

- Opioid Treatment Agreement
- Opioid Progress Report Supplement
- Functional Progress Form
Assessment for chronic use needs to address the following:

- Are there reasonable alternatives to the use of opioids?
- Is the patient likely to improve with opioids?
- Is the patient likely to abuse opioids or have other adverse outcomes?
May improve

- Has taken opioids for acute phase with some improvement in pain and function
- Other conservative measures have failed and opioids have not been trialed
- Pain falls into one of these categories
  - Nociceptive pain (e.g. ischemia, tissue destruction, arthritis, cancer)
  - Neuropathic pain (e.g. sciatica, carpal tunnel syndrome, trigeminal neuralgia, phantom limb pain)
  - Mixed nociceptive and neuropathic pain
Is the Patient Likely to Improve?

* Probably will not improve
  * Patient has taken opioids in the acute phase with NO improvement in pain and function
  * Pain diagnosis is that of a somatoform disorder
    * Conversion disorder
    * Somatization disorder
    * Pain disorder associated with psychological factors
  * Opioids are not warranted
Is the Patient Likely to Abuse Opioids or Have Other Adverse Outcomes?

- Risk of abuse is high with the following:
  - Hx of ETOH or other substance abuse
  - Active ETOH or other substance abuse
  - Borderline personality disorders
  - Mood disorders (e.g. depression or psychotic disorders)
  - Off work for more than 6 months
  - Poor response to opioids in the past.
- If any are present, referral to pain specialist is warranted
Assessment

* Perform a baseline hx and physical, complete exam, review of previous diagnostic and therapeutic trials, and assessment for co-existing conditions
* Obtain relevant baseline lab studies and/or urine drug screen
* Identify the pain diagnosis
* Document baseline pain and functional assessments
* Assess the ability to participate in a return-to-work program (work hardening, voc rehab)
* Assess the likelihood IW can be weaned from opioids if needed
* Decide if referral to pain specialist is needed
Management of a Formal Trial of Chronic Opioids

- Consider a second opinion
- Submit documentation on the Opioid Progress Report Supplement
- Have a contingency plan for each of these
  - Need to wean off opioids if no improvement in pain and function
  - Continuation of opioids beyond MMI
- Treatment agreement
Management of a Formal Trial of Chronic Opioids

* Help the patient return to work
  * Includes team conference with the IW, the employer, claims adjustor, voc consultant, and others
* Follow principles for prescribing opioids
  * Single prescribing physician
  * Single pharmacy
  * Lowest possible dose
  * Look for appearance of misuse of medications
Management of a Formal Trial of Chronic Opioids

- Laboratory studies and drug screens
- Make decision on discontinuation or continuation at 6 months
  - If no overall improvement in function discontinuation is usually warranted (extenuating circumstances need to be documented)
  - If IW has returned to work or has significant improvement in both pain and function continue with reasonable doses (WA does not pay for opioids once MMI is reached)
Management of a Formal Trial of Chronic Opioids

* Visit Frequency
  * At least every 2 weeks for the first 2-4 months
  * At least every 6-8 weeks afterwards

* Consultation with a pain specialist
  * If dose exceeds 100 – 150 mg MED
  * Pain and function have not improved after 3 months
  * IW has hx of chemical dependency
  * IW has significant depression, anxiety or irritability
Weaning of Opioids

- In pain or drug rehabilitation center: 1 - 2 weeks
- In office-based practice slowly taper
  * Should not exceed 3 months
Long-Term Issues

* If IW has been on opioids for 6 months or more and is not back to work (or new patient)
  * Reassess
    * Is original diagnosis still present? Other diagnoses?
    * Has IW been given other medications for pain?
    * Has IW tried other tx methods or seen other specialists?
    * Has there been a functional improvement?
    * Would a psych consult be warranted?
    * Has a screening for addiction been completed?
  * Summarize findings and send to CA
  * Help the IW return to work
  * Triage on one of 3 pathways
    * Modify the tx plan to achieve optimum opioid benefit
    * D/C opioid tx
    * Continue opioid tx
The guidelines are comprehensive (113pgs):

- They cover all aspects of chronic pain management:
  - Treatment duration, evaluation and diagnostic procedures, active therapy, passive therapy, return-to-work, delayed recovery, abuse and addiction, alternative therapies, surgical intervention, injections, maintenance therapy
General Guideline Principles

* Education: Importance of educating all key principles is stressed (employer, patient, family members, etc)
* Treatment parameter duration begins once treatment is initiated, not at the date of injury
* Active interventions are emphasized over passive therapies
* Active therapeutic exercise program is crucial
* Response to treatment is re-evaluated every 3 to 4 weeks
General Guideline Principles

- Surgical interventions must have an outcome of restoration of function, no merely for pain relief
- Goal is return to work within 6 months of injury
- Return-to-work is therapeutic and specific written limitations are to be provided. Patient should never be released to “sedentary” or “light duty”
- By definition, patients with chronic pain fit into the category of delayed recovery
Interdisciplinary Rehabilitation Programs

- CO guidelines stress the following components:
  - Communication must be coordinated and consistent
  - Documentation by all involved in the case
  - Treatment modalities may be necessary
  - Therapeutic exercise programs should be initiated at the start of the rehabilitation program
  - Return-to-work should be evaluated continually
  - Patient education
  - Psychosocial evaluation and treatment should be initiated
  - Vocational assistance should be part of the program
Guidelines define tolerance, dependence, and addiction

Stress that results of treating cancer pain cannot be assumed to be true when treating chronic non-malignant pain

Only 50% of patients tolerate opioid side effects

Includes information on deaths due to unintentional drug overdoses
Choice of Opioid

* No evidence that one long-acting opioid is superior to another with regards to improving pain or function
* No evidence that long-acting opioids are superior to short-acting opioids for improving pain or function or for decreasing potential for addiction although they may produce less euphoria and fewer sedative or cognitive effects
* Methadone may cause arrhythmias
* Fentanyl is not recommended for the treatment of chronic musculoskeletal pain
Risk Factors for Opioid Abuse

* Unusual knowledge of controlled substances
* Request for a specific controlled substance or claims of allergies or ineffectiveness of other medications
* Demanding treatment after usual clinic hours
* Early refills or lost drugs
* Signs of mood disorders or other psychiatric conditions
* Physical signs of drug abuse
* Failure to keep appointments
* Exaggeration of physical problems
* Subjective complaints exceeds objective findings
* Attempts to transfer care after refusal to fill Rx
Recommendations for Opioid Use

- Colorado’s guidelines are similar to WA state guidelines
- Expect a small change in the VAS of 2 – 3 points. Larger change may be indication of abuse or diversion
- State that a therapeutic trial of opioids should only be done in the setting of multi-disciplinary pain management
- Recommend physical and psychological and/or psychiatric assessment
- State that drug screening is a mandatory component of the program
Initially and then randomly at least once a year and as deemed appropriate by the prescribing physician

Suggested for any patient who have been receiving opioids for 90 days

Should be thoroughly covered in the narcotic contract, including appearance of substances not prescribed (i.e. illicit drugs, marijuana, ethanol)
Where to Find Guidelines

* National Guideline Clearinghouse

http://guideline.gov