

# Community Principles of Pain Management

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## PRACTICE PRINCIPLES

**Practice Guidelines and Principles:** Guidelines and Principles are intended to be flexible. They serve as reference points or recommendations, not rigid criteria. Guidelines and Principles should be followed in most cases, but there is an understanding that, depending on the patient, the setting, the circumstances, or other factors, care can and should be tailored to fit individual needs.

### **Purpose and Scope:**

Chronic pain and prescription opioid misuse are both major public health problems that exist across the continuum of care. Pain is a major driver for visits to physicians, a major reason for taking medications, a major cause of disability, and a key factor in quality of life and productivity. These principles aim to identify and promote the essential elements of acute, chronic and palliative pain assessment and management for both children and adults, as well as recognize the risks of opioid use disorder.

*The Community Principles of Pain Management provide recommendations for primary care clinicians who are assessing, managing and prescribing treatment, including opioids, for acute, chronic pain and active cancer treatment, palliative care, and end-of-life care. The Principles were revised to align with national guidelines developed by a panel of experts and aim to help clinicians meet federal and state regulations. Improving the way opioids are prescribed through clinical practice guidelines and principles can ensure patients have access to safe and effective chronic pain treatments, while reducing the number of people who misuse or overdose from these drugs. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Deaths from drug overdose are up among men and women, all races, and adults of nearly all ages.*

### **Key Recommendations/Messages:**

- While all patients should be screened for pain, identifying a specific etiology for pain is challenging. A complete assessment, including physical, mental, emotional, and spiritual components is helpful in determining the appropriate course of management.
- It is essential to establish and focus treatment on patient specific **SMART (Specific, Measurable, Agreed Upon, Realistic, Time-based)** goals that result in improved function and quality of life and reduction in suffering.
- All patients should be engaged in active management of their pain (active approach.) Because chronic pain affects the whole person (body, mind, and spirit), patient-centered nonpharmacologic therapies that acknowledge the patients' roles in their own healing processes have the potential to provide more efficient and comprehensive chronic pain management. Active self-care therapies allow for a more diverse, patient-centered treatment of complex symptoms, promote self-management, and are relatively safe and cost-effective.
- Treat acute pain actively to avoid transition to chronicity.
- Treat chronic pain thoughtfully and systematically.
- Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids & no greater quantity than needed for the expected duration of pain severe enough to require opioids.
- Check Prescription Drug Monitoring Program for opioids or benzodiazepines from other sources. Follow State and federal regulations.
- **Use risk assessment tools (e.g. Opioid Risk Tool), treatment agreements (1 Prescriber, 1 Pharmacy), and medically necessary urine drug testing.**
- **Opioids are not first line for chronic pain**, which should be managed with an active approach and non-opioid pain relievers, *if possible*.
- When opioids are indicated (e.g. patients with cancer, palliative and end-of-life care), combine with an active approach and adjuvant medications as needed.
- Consider opioid therapy based on a careful risk assessment that determines the expected benefits for both pain & function are anticipated to outweigh risks. If opioids are used, establish treatment goals. Combine with an active approach & nonopioid pharmacologic therapy as indicated.
- Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- If benefits do not outweigh harms of continued opioid therapy, optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.
- Avoid abrupt cessation of opioids.
- Address opioid-seeking behavior and addiction behaviors without moving patients to illegal means of obtaining opioids.
- Consider Medication-Assisted Therapy (MAT) for opioid use disorder; prescribe naloxone for patients at increased risk for opioid overdosing

**When to Refer:**

- For acute pain, refer early to appropriate specialist or pain center if diagnosis unclear or pain refractory to treatment.
- For chronic pain, refer “difficult to treat” cases to a physician with pain management expertise.
- For opioid-seeking behavior and addiction behaviors, refer to addiction or pain specialist and community services as needed.

**Distributed to:** All primary care physicians, specialists and allied health professionals including nurse practitioners, physician assistants, nurses, nursing assistants, rehabilitation specialists, physical therapists, occupational therapists, chiropractors, acupuncturists, other complementary medicine providers, dentists, clergy, psychologists, pharmacologists, social workers, skilled nursing facilities, assisted living centers, homecare agencies, and hospice organizations.

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**Approved by:** Quality Management Committee (QMC) – Approved: April 2017; next revision: 2019.

Use the “Order Resources” button on the home page of [CompassionAndSupport.org](http://CompassionAndSupport.org) to place a free order for:

- *Pain Management Patient Guide (available in English and Spanish)*
- *Equianalgesic Table for Adults (Pocket Card)*
- *Equianalgesic Table for Pediatrics (Pocket Card)*

The comprehensive *Practice Principles* and all individual components, along with additional resources, including a web page dedicated to abuse and misuse, can be found in the *Pain Management Professionals* section of [CompassionAndSupport.org](http://www.compassionandsupport.org/index.php/resource_directory/pain_management): [http://www.compassionandsupport.org/index.php/resource\\_directory/pain\\_management](http://www.compassionandsupport.org/index.php/resource_directory/pain_management)

Information can also be found on the Monroe County Medical Society website: <http://mcms.org/communityprinciples>

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Approved April 2017. Next Scheduled Update in 2019.

# COMMUNITY PRINCIPLES OF PAIN MANAGEMENT (CPPM)

## Table of Contents

### *Professional Resources*

1. Faces Pain Scale - Revised
2. Principles of Pain Management: Adult Guide  
Tool for assessment, diagnosis, treatment, and management of pain
3. Principles of Pain Management: Pediatric Guide  
Tool for assessment, diagnosis, treatment, and management of pain
4. Principles of Pain Management: Bedside Nursing Assessment Tool  
Includes Pain Assessment in Advanced Dementia
5. Non-Pharmacologic Interventions for Pain - Health Care Professional Guide
6. Equianalgesic Table for Adults  
Pocket trifold guideline for effective opioid dosing
7. Equianalgesic Table for Pediatrics  
Pocket trifold guideline for effective opioid dosing
8. Opioid Guidelines for Adult Patients
9. Opioid Guidelines for Pediatric Patients
10. Opioid Risk Tool and Reference
11. Pain Management Agreement and Informed Consent  
For use with patients
12. Opioid Use Disorder
13. Methadone Dose Conversion Guidelines
14. Buprenorphine Guideline for Treatment of Pain
15. Protocol for Naloxone Use (NEW)
16. Opioid & Sedative Guidelines for Emergency Department and Urgent Care Providers
17. References

## Faces Pain Scale-Revised (FPS-R)

### Purpose:

To assess pain intensity in persons who are able to self report, but unable to use a numeric rating scale (NRS). Some studies show African Americans and Asians prefer the FPS.

### When to Use:

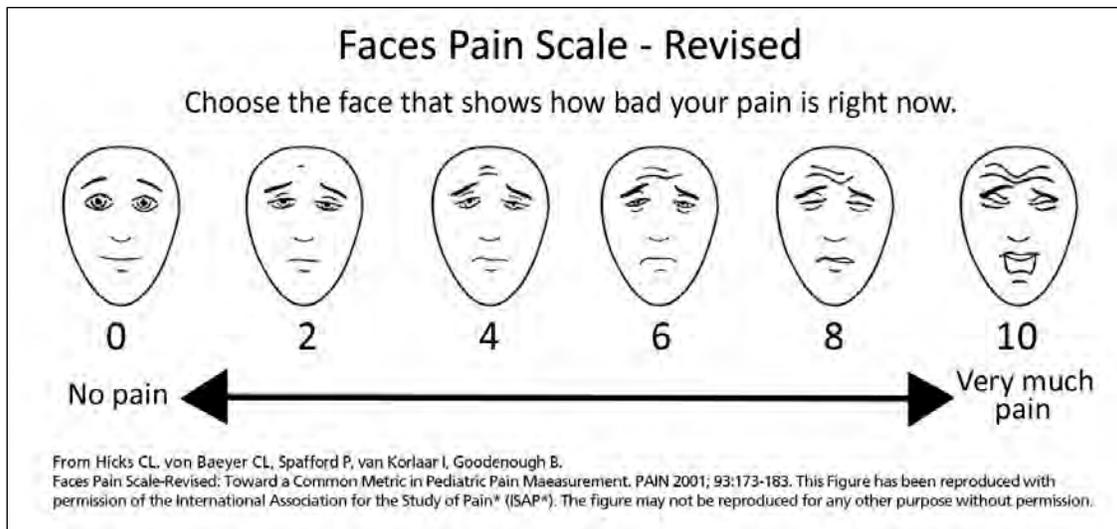
- 1) At admission
- 2) At each quarterly nursing review
- 3) Each shift in resident with pain
- 4) Each time a change in resident pain status is reported
- 5) Following a pain intervention to evaluate treatment effectiveness

### How to Use:

Instruct the person that "The faces show how much pain or discomfort one is feeling. The face on the left shows no pain. Each face shows more and more pain up to the last face that shows the worst pain possible. Point to the face that shows how bad your pain is right now."

Then score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so '0' = 'no pain' and '10' = 'very much pain.'

*NOTE: This tool is not to be used by the health care provider to look at the resident's facial expression and pick a face.*



### Documentation:

Document/record all scores in a location that is readily accessible by other health care providers.

### Note:

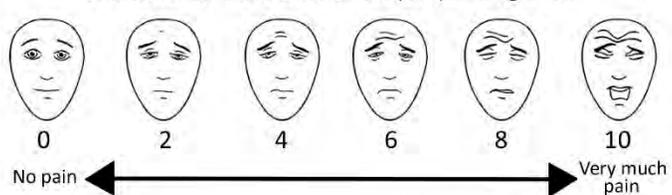
To use as a pocket guide, print the FPS-R and directions document front to back on card stock paper to create two tools. Cut to size and laminate for increased durability.

Additional information about the Faces Pain Scale-Revised (FPS-R) including instructions in 33 translations can be found at [www.painsourcebook.ca](http://www.painsourcebook.ca).

### Reference:

Hicks, C, L., von Baeyer, C.L., Spafford, P.A., van Korlaar & Goodenough, B. 2001. The Faces Pain Scale-Revised Toward A Common Metric In Pediatric Pain Measurement. *Pain* 93: 173-183.

## ADULT GUIDE: ASSESSMENT and MANAGEMENT of PAIN

Assessment and Diagnosis	Treatment	Management and Monitoring
<p>While all patients should be screened for pain, identifying a specific etiology for pain is challenging. A complete assessment, including physical, mental, emotional, and spiritual components is helpful in determining the appropriate course of management. All patients should be actively engaged in self-management of their pain (an 'active' approach.) If necessary, therapies that represent a 'passive' approach may be utilized to encourage self-management strategies to help achieve patient centered goals.</p> <p><b>History: Assess</b></p> <ul style="list-style-type: none"> <li>Onset, location, quality, intensity, temporal pattern, aggravating and alleviating factors, associated symptoms</li> <li>Characteristics of pain</li> <li><b>Red flags:</b> indicative of underlying pathology</li> <li><b>Yellow flags:</b> Psychosocial factors shown to be indicative of long term chronicity and disability: A negative attitude that pain is harmful or potentially severely disabling; fear avoidance behavior and reduced activity levels; an expectation that passive, rather than active, treatment will be beneficial; a tendency to depression, low morale, and social withdrawal; social or financial problems</li> <li>Previous methods of treatment</li> <li>Other medical and surgical conditions</li> <li>Substance use</li> </ul> <p><b>Psychosocial History: Assess</b></p> <ul style="list-style-type: none"> <li>Depression, anxiety, PTSD, sleep pattern, suicide risk</li> <li>Impact on quality of life, ADLs &amp; functional status</li> <li>Pain coping skills</li> <li>Patient, family, and caregiver's cultural and spiritual beliefs</li> <li>Secondary gain: psychosocial/financial</li> </ul> <p><b>Assessment</b></p> <ul style="list-style-type: none"> <li>Order and evaluate appropriate diagnostic testing</li> <li>Evaluate pain on all patients using the 0-10 scale: <ul style="list-style-type: none"> <li>A. mild pain: 1-3</li> <li>B. moderate: 4-7 (interferes with work or sleep)</li> <li>C. severe: 8-10 (interferes with all activities)</li> </ul> </li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center;"><b>Faces Pain Scale - Revised</b></p> <p style="text-align: center;">Choose the face that shows how bad your pain is right now.</p>  <p style="text-align: center;">0 ←—————→ 10 No pain Very much pain</p> <p style="font-size: small;">From Hicks CL, von Baeyer CL, Spafford P, van Koraar I, Goodenough B. Faces Pain Scale-Revised: Toward a Common Metric in Pediatric Pain Measurement. PAIN 2001; 93:173-183. This figure has been reproduced with permission of the International Association for the Study of Pain® (IASP). The figure may not be reproduced for any other purpose without permission.</p> </div>	<p><b>Treatment</b></p> <p><b>Goals</b></p> <ul style="list-style-type: none"> <li>Treat acute pain actively to avoid transition to chronicity.</li> <li>Treat chronic pain thoughtfully and systematically.</li> <li>If possible, identify and address the etiology of pain, including potential confounders (such as psychosocial issues.)</li> <li>Maintain an active approach that enables the ability to function safely and productively</li> <li>Allow emergence of emotions associated with pain</li> <li>Establish patient specific SMART (Specific, Measurable, Agreed Upon, Realistic, Time-based) goals that result in improved function and quality of life &amp; reduction in suffering.</li> </ul> <p><b>Nonpharmacologic Therapy: Active Approach</b></p> <ul style="list-style-type: none"> <li>Patient and Family Education</li> <li>Community and Web-based Support Groups</li> <li>Cognitive Behavioral Therapy; Supportive Psychotherapy</li> <li>Physical Therapy; Chiropractic/Osteopathic Care</li> <li>Exercise: Yoga, Tai Chi, Qi Gong, Walking, Water Therapy</li> <li>Cutaneous Stimulation: Ice, Heat; Counterstimulation: TENS</li> <li>Acupressure (trigger point therapy)</li> <li>Relaxation Techniques: Biofeedback,</li> <li>Meditation, Mindful Practice; Visualization/Interactive Guided Imagery; Prayer, Spiritual &amp; Pastoral Support</li> </ul> <p><b>Nonpharmacologic Therapy: Passive Approach</b></p> <ul style="list-style-type: none"> <li>Massage, Music, Hydrobath</li> <li>Cutaneous Stimulation: Ice, Heat; Counterstimulation: TENS</li> <li>Acupuncture (trigger point therapy)</li> <li>Therapeutic Touch, Reiki, Healing Touch</li> </ul> <p><b>Pharmacologic Therapy</b></p> <ul style="list-style-type: none"> <li>Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for treatment of pain.</li> <li>For neuropathic pain, use anti-epilepsy drugs (AEDs) first</li> <li>Use adjuvant therapies or analgesics as needed</li> <li><b>Opioids are not first line for chronic pain, which should be managed with an active approach and non-opioid pain relievers, if possible.</b></li> <li>Consider opioid therapy based on a careful risk assessment that determines the expected benefits for both pain &amp; function are anticipated to outweigh risks. If opioids are used, establish treatment goals, combine w/active approach &amp; nonopioid analgesics as indicated.</li> <li>When opioids are indicated (e.g. patients with cancer, palliative and end-of-life care), combine with an active approach &amp; adjuvant medications as indicated. See Opioid Guidelines on Equianalgesic Table for Adults.</li> <li>Avoid inappropriate use of opioids; prevents potential misuse</li> </ul>	<p><b>Management and Monitoring</b></p> <p><b>General</b></p> <ul style="list-style-type: none"> <li>Reassess pain, quality of life and function regularly, focusing on patient-centered goals</li> <li>Follow amount and duration of response</li> <li>Partner with patient/family in setting goals of care</li> <li>Balance function vs. acceptable control of pain</li> </ul> <p><b>Referrals</b></p> <p><b>Acute pain</b></p> <ul style="list-style-type: none"> <li>Refer early to appropriate specialist or Pain Center, if diagnosis unclear or pain refractory to treatment</li> </ul> <p><b>Chronic pain</b></p> <ul style="list-style-type: none"> <li>Set realistic chronic care goals</li> <li>Transition from passive recipient to patient-directed management.</li> <li>Refer "difficult to treat" cases (H/O substance abuse, neuropathic pain, rapidly escalating opioid doses) to MD with pain management expertise</li> </ul> <p><b>Special Considerations for Patients on Opioids</b></p> <ul style="list-style-type: none"> <li>Use risk assessment tools (e.g. Opioid Risk Tool), treatment agreements, and medically necessary urine drug testing for compliance/diversion</li> <li>Check Prescription Drug Monitoring Program for opioids or benzodiazepines from other sources</li> <li>Follow state and federal regulations</li> <li>Evaluate benefits &amp; harms w/patients in 1-4 wks. of starting opioid for chronic pain or dose escalation.</li> <li>Be wary of dose escalation over time due to tolerance.</li> <li>Evaluate benefits &amp; harms of continued therapy with patients every 3 months or more frequently.</li> <li>If benefits do not outweigh harms of continued opioid therapy, optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.</li> <li>Avoid abrupt cessation of opioids</li> <li>Address opioid-seeking behavior and addiction behaviors without moving patients to illegal means of obtaining opioids. Refer to addiction or pain specialist and community services as needed</li> </ul> <p><b>Special Situations</b></p> <p><b>Anxiety and depression</b></p> <ul style="list-style-type: none"> <li>Refer to Depression Guidelines</li> </ul> <p><b>Verbally non-communicative patients</b></p> <ul style="list-style-type: none"> <li>See Nurse's Guide</li> </ul>

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## ADULT GUIDE: NONOPIOID PHARMACOLOGIC THERAPY

Drug/Class	Common Uses in Pain Management	Clinical Considerations
<b>Analgesics</b>		
Acetaminophen	Mild-moderate pain	NOT anti-inflammatory; maximum 3 grams/24 hours from ALL sources for ALL purposes and 2-3 grams/day for frail elders, alcohol use (3 or more drinks per day), renal impairment; limit to 325mg or less per dose; leading cause of acute liver failure (including accidental overdose); monitor for severe liver injury & acute renal failure
Nonselective nonsteroidal anti-inflammatory drugs (NSAIDs)	Mild-moderate pain	Assess risk of nephrotoxicity, drug interactions, CV disease and GI toxicity prior to prescribing; administer with PPI or H2 blocker if GI intolerance or high risk; risk of cardiac adverse events (ibuprofen > naproxen); COX 2 agents mabe preferred agents for cardiac & renal safety; consider topical agents for individuals unable to use oral therapy
Cyclooxygenase (COX)-2 selective NSAIDs (coxibs)	Mild-moderate pain	Caution in patients with cardiovascular disease or at high risk for CV disease. Improved upper GI safety compared to NSAIDs ; use celecoxib if contraindication or severe intolerance to NSAID
Botulinum Toxin	Neuropathic pain	Randomized, double-blind, placebo-controlled study; further investigation needed
<b>Anesthetics</b>		
Lidocaine (systemic)	Local and regional anesthesia, nerve block, epidural	Do not use in patients with severe degrees of SA, AV or interventricular heart block
<b>Anticonvulsants</b>		
Carbamazepine	Pain associated with trigeminal or glossopharyngeal neuralgia	Watch for BMD, many DDI's Boxed Warning: Blood dyscrasias, Dermatologic toxicity, Asian ancestry (HLAB*1502 allele)
Gabapentin	Post-herpetic neuralgia, diabetic neuropathy, peripheral neuropathy, fibromyalgia, post-op pain adjunct	CNS depression when combined with other sedatives. May cause peripheral edema
Pregabalin	Fibromyalgia, neuropathic pain, post-herpetic neuralgia	May cause weight gain, watch for CNS depression when combined with other sedatives. May cause hallucinations and peripheral edema.
Valproic Acid	Diabetic neuropathy, post-herpetic neuralgia	Many drug-drug interactions. Boxed warning: hepatotoxicity, use in mitochondrial disease, pancreatitis
Topiramate	Neuropathic pain, cluster headache prophylaxis	May cause weight loss, drug-drug interactions Trokendi ER: do not use if ETOH use within 6 hours, may cause metabolic acidosis in patients taking metformin
<b>Anti-Depressants</b>		
TCA's: Amitriptyline, desipramine, imipramine, nortriptyline	Neuropathic and chronic pain	Anticholinergic effects, older adults more sensitive to adverse effects including orthostatic hypotension, use cautiously with comorbid CV disease. Boxed Warning: Suicidal thinking/behavior
Other antidepressants: Duloxetine, venlafaxine, milnacipran	Neuropathic pain, fibromyalgia, depression	May increase bleeding risk especially if combined with ASA or NSAIDs; taper dose prior to discontinuing; adjust dose with renal impairment Boxed Warning: Suicidal thinking/behavior
<b>Muscle Relaxants</b>		
Cyclobenzaprine, baclofen, methocarbamol, tizanidine, metaxalone	muscle spasm associated with acute, painful musculoskeletal conditions	Recommend short term use for relief of acute pain; avoid in the older adults due to limited efficacy and adverse effects. May cause hypotension.
<b>Topical Medications</b>		
Lidocaine	Localized neuropathic pain	Avoid use on traumatized mucosa, skin irritations
Diclofenac (gel, patch)	Osteoarthritis pain, minor strains, sprains and contusions	Avoid use on non-intact/damaged skin including dermatitis, eczema, burns or wounds.
Capsaicin (OTC)	Only use: dermal neuropathic pain	Avoid use on wounds, damaged/broken/irritated skin. Do not cover with bandage or use with external heat source
<b>Herbal/Homeopathic</b>		
Alpha Lipoic Acid	Diabetic nerve pain	Low evidence
Butterbur	Migraine prophylaxis	Low evidence
Feverfew	Migraine prophylaxis, anti-inflammatory	Low evidence

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## PRINCIPLES OF PAIN MANAGEMENT: PEDIATRIC GUIDE

Assessment and Diagnosis	Treatment	Management and Monitoring
<p>While all patients should be screened for pain, identifying a specific etiology for pain is challenging. A complete assessment, including physical, mental, emotional, and spiritual components is helpful in determining the appropriate course of management. All patients and families, where appropriate, should be actively engaged in self-management of their pain.</p> <p><b>History: Assess</b></p> <ul style="list-style-type: none"> <li>• Onset, location, quality, intensity, temporal pattern, aggravating and alleviating factors, associated symptoms</li> <li>• Characteristics of pain; previous methods of treatment</li> <li>• Other medical and surgical conditions. • Substance use</li> </ul> <p><b>Psychosocial History: Assess</b></p> <ul style="list-style-type: none"> <li>• Depression, anxiety, PTSD, sleep pattern, suicide risk</li> <li>• Impact on quality of life, ADLs &amp; performance status</li> <li>• Patient, family, and caregiver's cultural and spiritual beliefs</li> <li>• Secondary gain: psychosocial/financial</li> </ul> <p><b>Assessment</b></p> <ul style="list-style-type: none"> <li>• Order and evaluate appropriate diagnostic testing</li> <li>• Evaluate pain on all patients using the age/developmentally appropriate scale:               <ol style="list-style-type: none"> <li>1. Numeric scale &amp; FPS-R: Adolescents and older children                   <ol style="list-style-type: none"> <li>A. mild pain: 1-3</li> <li>B. moderate: 4-7 (interferes with work or sleep)</li> <li>C. severe: 8-10 (interferes with all activities)</li> </ol> </li> <li>2. Faces Pain Scale-Revised (FPS-R): Younger children (~6-10 years old)</li> <li>3. FLACC-revised scale: &lt;6 years old/developmentally delayed</li> <li>4. NIPS: Neonatal Infant Pain Score</li> </ol> </li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center;"><b>Faces Pain Scale - Revised</b></p> <p style="text-align: center;">Choose the face that shows how bad your pain is right now.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  0 No pain           </div> <div style="text-align: center;">  2           </div> <div style="text-align: center;">  4           </div> <div style="text-align: center;">  6           </div> <div style="text-align: center;">  8           </div> <div style="text-align: center;">  10 Very much pain           </div> </div> <p style="font-size: small; margin-top: 5px;">From Hicks CL, von Baeyer CL, Spafford P, van Korlaar I, Goodenough B. Faces Pain Scale-Revised: Toward a Common Metric in Pediatric Pain Measurement. PAIN 2001; 93:173-183. This Figure has been reproduced with permission of the International Association for the Study of Pain® (IASP). The figure may not be reproduced for any other purpose without permission.</p> </div>	<p><b>Treatment</b></p> <p><u>Goals</u></p> <ul style="list-style-type: none"> <li>• Treat acute pain aggressively to avoid chronic pain</li> <li>• Treat chronic pain thoughtfully and systematically</li> <li>• Identify and address the cause of pain</li> <li>• Maintain alertness, ability to function safely/productively</li> <li>• Allow emergence of feelings other than pain</li> <li>• Intervene as noninvasively as possible</li> <li>• Negotiate target with patient/family</li> </ul> <p><u>Non-Pharmacological Therapy</u></p> <ul style="list-style-type: none"> <li>• Patient/Family Education (Consider Child life)</li> <li>• Community &amp; Web-based Support Groups</li> <li>• Cognitive Behavioral Therapy; Supportive Psychotherapy</li> <li>• Physical Therapy; Chiropractic/Osteopathic Care; Massage</li> <li>• Exercise: Yoga, Tai Chi, Qi Gong, Walking, Water Therapy</li> <li>• Cutaneous Stimulation: Ice, Heat; Counterstimulation: TENS</li> <li>• Acupuncture &amp; Acupressure (trigger point Rx)</li> <li>• Relaxation techniques: Biofeedback, Music, Hydrobath, Reiki, Therapeutic Touch, Healing Touch</li> <li>• Meditation, Mindful Practice, Visualization/Interactive Guided Imagery; Prayer; Spiritual &amp; Pastoral Support</li> </ul> <p><u>Pharmacologic Therapy</u></p> <ul style="list-style-type: none"> <li>• Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for treatment of pain.</li> <li>• For neuropathic pain, use anti-epilepsy drugs (AEDs) first</li> <li>• Use adjuvant therapies or analgesics as needed</li> <li>• Opioids are not first line for chronic pain, which should be managed with an active approach and non-opioid pain relievers, if possible.</li> <li>• Consider opioid therapy based on a careful risk assessment that determines the expected benefits for both pain &amp; function are anticipated to outweigh risks. If opioids are used, establish treatment goals, combine w/active approach &amp; nonopioid analgesics as indicated.</li> <li>• When opioids are indicated (e.g. patients with cancer, post-trauma, palliative and end-of-life care), combine with an active approach &amp; adjuvant medications as indicated. See Opioid Guidelines on Equianalgesic Table for Children.</li> <li>• Avoid inappropriate use of opioids; prevents potential misuse</li> <li>• Older children and adolescents are not immune to opioid dependence, addiction, abuse and experimentation. Opioids are often prescribed for acute sports injuries and other trauma: the lowest possible doses and briefest duration of therapy should be used to minimize risk of dependence and addiction. See Adult Guide &amp; key recommendations on page 1.</li> </ul>	<p><b>Management and Monitoring</b></p> <p><u>General</u></p> <ul style="list-style-type: none"> <li>• Reassess regularly</li> <li>• Assess pain using tools (i.e. numeric scale, face scale); respond urgently to pain ≥8</li> <li>• Follow amount and duration of response</li> <li>• Assess performance status</li> <li>• Partner with patient/family in setting goals of care</li> <li>• Balance function vs. complete absence of pain</li> </ul> <p><u>Referrals and Management</u></p> <p><i>Acute pain</i></p> <ul style="list-style-type: none"> <li>• Refer early to appropriate specialist or Pain Center, if diagnosis unclear or pain refractory to treatment</li> </ul> <p><i>Chronic pain</i></p> <ul style="list-style-type: none"> <li>• Set realistic chronic care goals</li> <li>• Transition from passive recipient to patient-directed management of therapies where appropriate</li> <li>• Refer “difficult to treat” cases (H/O substance abuse, neuropathic pain, rapidly escalating opioid doses) to MD with palliative care or pain expertise</li> </ul> <p><i>Neuropathic pain</i></p> <ul style="list-style-type: none"> <li>• Use anti-epilepsy drugs (AEDs) first</li> <li>• Use step 2 drug to help Rx</li> </ul> <p><u>Special Situations</u></p> <p><i>Anxiety and depression</i></p> <ul style="list-style-type: none"> <li>• Refer to Depression Guidelines</li> </ul> <p><i>Verbally non-communicative patients</i></p> <ul style="list-style-type: none"> <li>• Infants, children &amp; cognitively impaired all feel pain</li> <li>• Evaluate patient's non-specific signs: noisy breathing, grinding teeth, bracing, rubbing, crying, agitation</li> </ul> <p><i>Infants (use appropriate pain scale)</i></p> <ul style="list-style-type: none"> <li>• Start at ¼ - ½ usual dose</li> <li>• Watch carefully for toxicity from accumulation</li> </ul> <p><i>Patients with substance abuse history</i></p> <ul style="list-style-type: none"> <li>• May need higher starting dose (tolerance)</li> <li>• Use prescribing contracts for outpatient use</li> <li>• Consider abuse-deterrent formulations</li> </ul> <p><i>Be aware of potential for addiction and misuse</i></p> <ul style="list-style-type: none"> <li>• Encourage established functional goals</li> <li>• Ensure follow-up</li> </ul>

### Diagnostic Terms

**Somatic pain:** localized; ache, throb, or gnaw

**Visceral pain:** often referred; cramp, pressure, deep ache, squeeze

**Neuropathic pain:** burns, electric shock, hot, stab, numb, itch, tingle

**Acute Pain:** ↑HR, HBP, diaphoresis, pallor, fear, anxiety

**Chronic pain:** sleep difficulties, loss of appetite, psychomotor retardation, depression, career/relationship change

## QUEST Principles of Pain Assessment<sup>1</sup>

- Question the child
- Use pain rating scales
- Evaluate behavior and physiological changes
- Secure parent's involvement
- Take cause of pain into account
- Take action and evaluate results

## Neonates<sup>2</sup>

Signs of Acute Pain	Signs of Chronic Pain
Crying and moaning	Apathy
Muscle rigidity	Irritability
Flexion or flailing of the extremities	Changes in sleeping and eating patterns
Diaphoresis	Lack of interest in their surroundings
Irritability	
Guarding	
Changes in vital signs and pupillary dilatation	

## Older Children

- Children < 6 years old or unable to communicate, clinicians should use the FLACC-revised scale
- Children >~6-10 may use the Faces (FPS-R) scale
- Children over 5 may be able to use descriptor words (stinging, burning)<sup>2</sup>
- Children over 6, who understand the concepts of rank and order, can use scales<sup>2</sup>

## Categories of Pain<sup>3</sup>

### Procedure-Related Pain

- Anticipation of intensity, duration, coping style and temperament child, type of procedure, history of pain and family support system

### Operative Pain and Trauma-Associated Pain

- Postoperative pain management should be discussed prior to surgery
- Control pain as rapidly as possible

### Acute Illness

- Determine severity of pain by the particular illness and situation (e.g. otitis media, meningitis, pharyngitis, etc.)

## Pharmacological Therapy<sup>2</sup>

- Oral or IV administration of pain medication is the preferred method.
- Avoid painful IM injections.
- The initial choice of analgesic should be based on the severity and type of pain (see table below).
- IV Opioids can be safely titrated to effect in the pediatric inpatient setting
- For older children PCA is an acceptable form of administering pain medication with proper patient and family education.

Pharmacologic therapy is based on severity of pain:

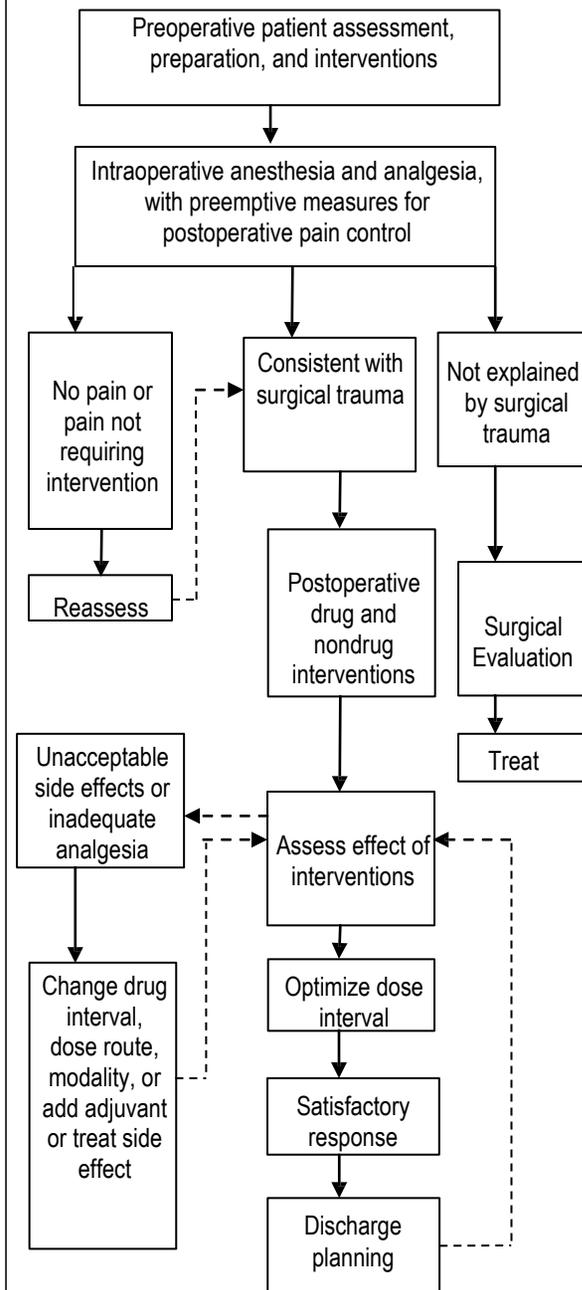
Pain Severity	Analgesic Choice	Examples
Mild (pain score 1-3)	Acetaminophen*(APAP) or NSAID**	Tylenol®, Ibuprofen, Naproxen
Moderate (pain score 4-7)	PO APAP/opioid combinations IV/PO low dose MSO4	Toradol®, Vicodin®, Tylox®
Severe (pain score 8-10)	Opioid	Morphine, Fentanyl®, Hydromorphone

Drug	Oral Dose	
	Children	Adolescents
Mild Pain		
Ibuprofen**	5-10 mg/kg	400-600 mg q6 hrs prn
Acetaminophen (APAP)*	10-15 mg/kg	300-600 mg q4-6 hrs prn
Use APAP* or ibuprofen** to enhance analgesia		
Moderate or Severe Pain	Children & Adolescents	
Morphine	0.15-0.3 mg/kg/dose q3-4 hrs	
Hydromorphone	0.03-0.06 mg/kg/dose q3-4 hrs	
Oxycodone	0.1-0.2 mg/kg/dose q3-4 hrs	

\*Daily dosing of Acetaminophen not to exceed 15 mg/kg/dose or 5 doses per day (75 mg/kg/24 hrs) in children <40 kg and 3000 mg/24 hrs in adolescents ≥40 kg.

\*\*NSAIDs – monitor in patients on anticoagulation therapy and/or history of bleeding disorder; limit use ≤5 days.

## Operative Pain Management



1. Baker CM and Wong DL. 1987. Q.U.E.S.T.: A Process of Pain Assessment in Children. *Orthopaedic Nursing*. 6(1):11-21. <http://www.wongbakerfaces.org/wp-content/uploads/2010/08/QUEST.pdf>. Accessed: 25 August 2014.

2. American Academy of Pediatrics, Committee on Psychosocial Aspects of Child and Family Health and American Pain Society, Task Force on Pain in Infants, Children and Adolescents. 2001. The Assessment and Management of Acute Pain in Infants, Children, and Adolescents. *Pediatrics* 108(3): 793-797. <http://pediatrics.aappublications.org/content/108/3/793.full.pdf+html>. Accessed: 25 August 2014.

3. Agency for Health Care Policy and Research, United States Department of Health & Human Services. 1992. Clinicians' Quick Reference Guide to Acute Pain Management in Infants, Children and Adolescents: Operative and Medical Procedures. *Journal of Pain and Symptom Management* 7(4):229-42.

## PRINCIPLES OF PAIN MANAGEMENT: BEDSIDE NURSING ASSESSMENT TOOL

Assessment and Diagnosis	Treatment	Management and Monitoring
<p>“Pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does.” (McCaffery, 1999)</p> <p><b>History &amp; Comprehensive Assessment</b></p> <ul style="list-style-type: none"> <li>Onset, location, quality, intensity, temporal pattern, aggravating and alleviating factors, associated symptoms</li> <li>Characteristics of pain           <ul style="list-style-type: none"> <li>Somatic pain: localized; ache, throb, or gnaw</li> <li>Visceral pain: often referred; cramp, pressure, deep ache, squeeze</li> <li>Neuropathic pain: burns, electric shock, hot, stab, numb, itch, tingle</li> <li>Acute Pain: ↑HR, HBP, diaphoresis, pallor, fear, anxiety</li> <li>Chronic pain: sleep difficulties, loss of appetite, psychomotor retardation, depression, career/relationship change</li> </ul> </li> <li>Underlying causes of pain to target treatment</li> <li>Impact of pain on physical function (i.e. mobility, ADLs, impact on activities) and psychosocial function (i.e. depression, anxiety, sleep)</li> <li>Patient, family and caregiver’s cultural and spiritual beliefs</li> <li>Previous and current methods of treatment: effectiveness, adverse events, OTCs</li> <li>Other medical and surgical conditions</li> <li>Substance use and risk for misuse (e.g. Opioid Risk Tool)</li> </ul> <p><b>Routine Assessment</b></p> <ul style="list-style-type: none"> <li>Evaluate pain on all patients using the 0-10 scale capturing impact of pain on function:           <ul style="list-style-type: none"> <li>A. mild pain: 1-3</li> <li>B. moderate: 4-7 (interferes with work or sleep)</li> <li>C. severe: 8-10 (interferes with all activities)</li> </ul> </li> </ul> <div data-bbox="107 1019 802 1352" style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center;"><b>Faces Pain Scale - Revised</b></p> <p style="text-align: center;">Choose the face that shows how bad your pain is right now.</p> <p style="font-size: small;">From Hicks CL, von Baeyer CL, Spafford P, van Korlaar I, Goodenough B. Faces Pain Scale-Revised: Toward a Common Metric in Pediatric Pain Measurement. PAIN 2001; 93:173-183. This figure has been reproduced with permission of the International Association for the Study of Pain® (IASP®). The figure may not be reproduced for any other purpose without permission.</p> </div>	<p><b>Goals</b></p> <ul style="list-style-type: none"> <li>Based on patient values/preferences considering pain intensity, improved function, and cognitive function.</li> <li>Balance pain relief, improved function and adverse events</li> <li>Treat acute pain aggressively to avoid chronic pain</li> <li>Treat chronic pain thoughtfully and systematically</li> <li>Identify and address the cause of pain</li> <li>Intervene as noninvasively as possible</li> </ul> <p><b>Active Approach</b></p> <ul style="list-style-type: none"> <li>Patient / Family Education</li> <li>Community &amp; Web-based Support Groups</li> <li>Cognitive Behavioral Therapy; Supportive Psychotherapy</li> <li>Physical Therapy; Chiropractic/ Osteopathic Care</li> <li>Exercise: Yoga, Tai Chi, Qi Gong, Walking, Water Therapy</li> <li>Cutaneous Stimulation: Ice, Heat; Counterstimulation: TENS</li> <li>Acupressure (trigger point therapy)</li> <li>Relaxation Techniques: Biofeedback,</li> <li>Meditation, Mindful Practice; Visualization/Interactive Guided Imagery; Prayer, Spiritual &amp; Pastoral Support</li> </ul> <p><b>Passive Approach</b></p> <ul style="list-style-type: none"> <li>Massage, Music, Hydrobath</li> <li>Cutaneous Stimulation: Ice, Heat; Counterstimulation: TENS</li> <li>Acupuncture (trigger point therapy)</li> <li>Therapeutic Touch, Reiki, Healing Touch</li> </ul> <p><b>Pharmacological Therapy</b></p> <ul style="list-style-type: none"> <li>Dispense medication as ordered using the 5 Rights: dose, patient, time, medication and dose</li> <li>Administer analgesics based on assessment of pain severity and available prescriptions</li> <li>Evaluate treatment effectiveness based on goal achievement and/or adverse events</li> <li>Communicate unrelieved pain or AE to PCP for changes in treatment plan</li> </ul> <p><b>Anticipate side effects</b></p> <ul style="list-style-type: none"> <li>Prevent constipation: start senna, sorbitol</li> <li>Nausea: treat with antiemetics or change meds</li> <li>Pruritus: treat with antihistamines or change meds</li> <li>Mental impairment: avoid driving/hazardous situations until side effect profile stabilizes; reassess safety periodically</li> </ul>	<p><b>General</b></p> <ul style="list-style-type: none"> <li>Reassess regularly for pain, pain relief &amp; function</li> <li>Consistently use valid tools (i.e. numeric scale, face scale); respond urgently to severe pain ≥8</li> <li>Clearly document time medication is given and response to pain medication</li> <li>Assess mobility and ADL status</li> <li>Partner with patient/family in setting goals of care</li> <li>Balance function versus complete absence of pain</li> </ul> <p><b>Special Situations</b></p> <p><i>Anxiety and depression</i></p> <ul style="list-style-type: none"> <li>Provide emotional support</li> <li>Advocate for psychosocial consultation or analgesic management prn</li> </ul> <p><i>Verbally non-communicative patients</i></p> <ul style="list-style-type: none"> <li>Cognitively impaired all feel pain but may not be able to communicate pain</li> <li>Infants, children feel pain – see Pediatric Guide</li> <li>Evaluate patient’s behaviors related to discomfort such as grimacing, moaning/groaning, bracing, rubbing, guarding, crying, noisy breathing, grinding teeth, frightened facial expressions, tense, fidgeting, agitation, disruptive behavior</li> <li>Use valid and reliable nonverbal pain behavior tool appropriate to the population (e.g. PAINAD, FLACC)</li> <li>Autonomic changes in acute pain may not be blunted in dementia</li> </ul> <p><i>Older adults or people with renal or hepatic disease</i></p> <ul style="list-style-type: none"> <li>Watch carefully for toxicity from accumulation</li> </ul> <p><i>Prevent opioid misuse/abuse</i></p> <ul style="list-style-type: none"> <li>Monitor for signs of misuse and/or abuse</li> <li>Encourage established functional goals</li> <li>Ensure follow-up and evaluation of treatment effectiveness</li> </ul>

Guidelines & principles are intended to be flexible. They serve as reference points or recommendations, not rigid criteria. Guidelines & principles should be followed in most cases, but there is an understanding that, depending on the patient, the setting, the circumstances, or other factors, care should be tailored to fit individual needs. Approved in April 2017; Next Scheduled Update in 2019.

**Pain Assessment In Advanced Dementia- PAINAD (Warden, Hurley, and Volicer, 2003)**

<b>ITEMS</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>SCORE</b>
<b>Breathing</b> Independent of vocalization	Normal	Occasional labored breathing. Short period of hyperventilation	Noisy labored breathing. Long period of hyperventilation. Cheyne-stokes respirations.	
<b>Negative vocalization</b>	None	Occasional moan or groan. Low- level of speech with a negative or disapproving quality	Repeated troubled calling out. Loud moaning or groaning. Crying	
<b>Facial expression</b>	Smiling or inexpressive	Sad, frightened, frown	Facial grimacing	
<b>Body language</b>	Relaxed	Tense. Distressed pacing. Fidgeting	Rigid. Fists clenched. Knees pulled up. Pulling or pushing away. Striking out	
<b>Consolability</b>	No need to console	Distracted or reassured by voice or touch	Unable to console, distract or reassure	
<b>TOTAL*</b>				

\* Total scores range from 0 to 10 (based on a scale of 0 to 2 for five items), with a higher score indicating more severe pain (0=“no pain” to 10=“severe pain”).

**Instructions:** Observe the older person both at rest and during activity/with movement. For each of the items included in the PAINAD, select the score (0, 1, or 2) that reflects the current state of the person’s behavior. Add the score for each item to achieve a total score. Monitor changes in the total score over time and in response to treatment to determine changes in pain. Higher scores suggest greater pain severity.

**Note:** Behavior observation scores should be considered in conjunction with knowledge of existing painful conditions and surrogate report from an individual knowledgeable of the person and their pain behaviors.

Remember that some patients may not demonstrate obvious pain behaviors or cues.

**Reference:** Warden V, Hurley AC, and Volicer V. 2003. Development and psychometric evaluation of the Pain Assessment in Advanced Dementia (PAINAD) Scale. *Journal of the American Medical Directors Association* 4(1): 9-15.

Developed at the Geriatric Research, Education Clinical Center at Edith Nourse Rodgers Memorial Veterans Medical Center, Bedford, MA.

Reviewed and Approved: April 2017; Next Scheduled Update in 2019.

## Non-Pharmacologic Interventions for Pain

Intervention	Summary Comments
<b>PASSIVE</b>	
Acupuncture	<p>Has been found to be effective in the treatment of a variety of conditions, including chronic low back pain (LBP) and osteoarthritis (OA). NIH considers acupuncture a “reasonable” option for OA (<a href="http://nccih.nih.gov">nccih.nih.gov</a>). Low to moderate level of evidence for chronic back pain according to AHRQ (<a href="http://www.effectivehealthcare.ahrq.gov/low-back-pain">www.effectivehealthcare.ahrq.gov/low-back-pain</a>).</p> <p>Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.</p> <p><b><u><a href="#">Acupuncture for chronic pain: individual patient data meta-analysis.</a></u></b> Vickers AJ, Cronin AM, Maschino AC, Lewith G, MacPherson H, Foster NE, Sherman KJ, Witt CM, Linde K; <b>Acupuncture</b> Trialists' Collaboration. <i>Arch Intern Med.</i> 2012 Oct 22;172(19):1444-53.)</p> <p>Additionally, in a recent systematic review and meta-analysis, acupuncture was found to provide significant relief of low back pain compared to sham acupuncture and no treatment (Yuan QL, Guo TM, Liu L, Sun F, Zhang YG. Traditional Chinese medicine for neck pain and low back pain: a systematic review and meta-analysis <i>PLoS One.</i> 2015;10 (2):e0117146).</p>
Neuromodulation	<p>High-level evidence exists for the safety and efficacy, (Level I–II) of traditional spinal cord stimulation therapies in the treatment of chronic refractory low back with predominant limb pain and specific neuropathic pain syndromes (e.g. complex regional pain syndrome, causalgia). There is compelling evidence that both dorsal root ganglion and high-frequency stimulation also have analgesic efficacy in certain chronic neuropathic syndromes.</p> <p>Deer, TR, et al. (2017, April). Dorsal Root Ganglion Stimulation Yielded Higher Treatment Success Rate for Complex Regional Pain Syndrome and Causalgia at 3 and 12 months: A Randomized Comparative Trial. <i>Pain, 158</i>(4), 669-681.</p> <p>Kapural, L, et.al. (2015). Novel 10-kHz High-Frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain; The SENZA-RCT Randomized Controlled Trial. <i>Anesthesiology, 123</i>, 851-60.</p> <p>Turner, J. A., et.al.. (2004). Spinal Cord Stimulation for Patients with Failed Back Surgery Syndrome or Complex Regional Pain Syndrome: A Systematic Review of Effectiveness and Complications. <i>Pain, 108</i>, 137-147.</p>

<p>Massage</p>	<p>May be helpful for low back pain. There is a low level of evidence for acute and subacute low back pain (nccih.nih.gov). This is consistent with the findings of the AHRQ analysis for massage as a treatment of acute and subacute low back pain (<a href="http://www.effectivehealthcare.ahrq.gov/low-back-pain">www.effectivehealthcare.ahrq.gov/low-back-pain</a>.)</p> <p>Similar findings can be found for massage as a treatment for fibromyalgia, neck pain, and osteoarthritis, with generally short-term improvements in pain, and no significant long-term improvements in function (Nahin RL et al. Evidence-based evaluation of complementary health approaches for pain management in the united states. 2016; 91 (9): 1292-1306.)</p>
<p>Manipulation</p>	<p>Manipulation has been studied extensively for the treatment of low back pain (LBP). Manipulation has been found to be effective in reducing pain and improving function in people with LBP. There is low-to-moderate level evidence that it is effective in the chronic LBP population (<a href="http://www.effectivehealthcare.ahrq.gov/low-back-pain">www.effectivehealthcare.ahrq.gov/low-back-pain</a>).</p> <p>It is recommended for the treatment of non-specific low back pain in the majority of national clinical guidelines for LBP management. There is less evidence to support its use in the treatment of neck pain. It has been found to be effective in the treatment of some types of headache and osteoarthritis.</p> <p>Chiropractors, Osteopathic Physicians, and Physical Therapists most commonly utilize manipulation in back pain management. Although it is a passive intervention, it is often combined with exercise in patient management.</p>
<p>Electrotherapy/ TENS</p>	<p>Passive physical modalities as a whole have small-to-no effect on treating common pain problems (AHRQ).</p> <p>Systemic reviews suggest that TENS is effective for post-operative pain, osteoarthritis, diabetic neuropathy, and some acute pain conditions when applied at adequate intensities.</p> <p>There is insufficient evidence to recommend specific TENS regimes at this time. (Vance, C., Dailey, D., Rakel, B., &amp; Sluka, K. (2014). Using TENS for pain control: the state of evidence. <i>Pain Management</i>, 4(3), 197-209 and Chou, R., Gordon, D., de Leon-Casasola, O., Rosenberg, J., et al. (2016). Guidelines on the Management of Postoperative pain. <i>Journal of Pain</i>, 17(2), 131-157)</p>

<b>ACTIVE</b>	
Exercise	<p>Exercise is defined as physical activity that is planned and structured. There are many different types of exercise, including aerobic, strengthening, and flexibility, and this should be considered when interpreting evidence. There is a moderate level of evidence supporting exercise as an intervention for chronic LBP (<a href="http://www.effectivehealthcare.ahrq.gov/low-back-pain">www.effectivehealthcare.ahrq.gov/low-back-pain</a>).</p> <p>The benefit of exercise for pain control likely comes from the impact of exercise on the endogenous opioid system and on central pain modulatory systems. Patients with some chronic pain conditions seem to have a dysfunctional endogenous pain modulatory system, which should be considered when prescribing exercise. The prescription of exercise for chronic pain must address the biomechanical issues and the psychosocial factors that contribute to the patient's pain and disability. Patient education, coordination of care within the health care team, and selecting an exercise regimen that is meaningful to and achievable by the patient are all-important components to promote a successful rehabilitation program.</p> <p><a href="#">Exercise therapy for chronic pain.</a> Kroll HR. Phys Med Rehabil Clin N Am. 2015 May;26(2):263-81</p> <p><a href="#">Exercise, not to exercise, or how to exercise in patients with chronic pain? Applying science to practice.</a> Daenen L, Varkey E, Kellmann M, Nijs J.</p>
Yoga	<p>Growing body of evidence supports yoga as an effective approach to treating chronic pain conditions, including low back pain, osteoarthritis, and fibromyalgia. <a href="https://nccih.nih.gov/health/yoga">https://nccih.nih.gov/health/yoga</a></p> <p>Yoga has been found to reduce pain and improve function in these populations (Nahin RL et al. Evidence-based evaluation of complementary health approaches for pain management in the united states. 2016; 91 (9): 1292-1306.). Yoga required active participation, can be practiced individually or in groups, and can be combined with mindfulness practices.</p>
Mindfulness Meditation	<p>Although there is not a large pool of evidence available on the effectiveness of meditation on pain, recent individual studies are promising, for example: Zeidan F, Adler-Neal AL, Wells RE, et al. Mindfulness-meditation-based pain relief is not mediated by endogenous opioids. <i>Journal of Neuroscience</i>. 2016;36(11):3391-3397 – this study found that meditation was effective in reducing experimentally induced pain.</p> <p>Two RCT's, one published in <i>JAMA</i>, found meditation to be effective in treating chronic low back pain: Cherkin DC, Sherman KJ, Balderson BH, Cook AJ, Anderson ML, Hawkes RJ, Hansen KE, Turner JA. Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back PainA Randomized Clinical Trial. <i>JAMA</i>. 2016;315(12):1240-1249. doi:10.1001/jama.2016.2323</p>

<p>Psychological Approaches (Cognitive-Behavioral, Relaxation techniques)</p>	<p>Systematic reviews provide evidence that cognitive-behavioral interventions improve function and decrease pain in the non-specific <i>low back pain</i> population when compared to no intervention (Richmond H et al, 2015). Evidence for effectiveness in treating <i>headaches</i> is equivocal (Harris P et al, 2015).</p> <p>According to AHRQ, when considered in conjunction with other psychological approaches including relaxation techniques and biofeedback, the strength of evidence is low for reducing pain and improving function in the chronic low back pain population (<a href="http://www.effectivehealthcare.ahrq.gov/low-back-pain">www.effectivehealthcare.ahrq.gov/low-back-pain</a>).</p> <p>May include multiple different interventions.</p> <p>CBT is effective in altering mood and catastrophising outcomes, when compared with treatment as usual/waiting list, with some evidence that this is maintained at six months. Behaviour therapy has no effects on mood, but showed an effect on catastrophising immediately post-treatment.</p> <p>Sturgeon JA. Psychological therapies for the management of chronic pain. <i>Psychology Research and Behavior Management</i>. 2014;7:115-124. doi:10.2147/PRBM.S44762.</p>
<p>Relaxation Techniques</p>	<p>Relaxation training follows a specific method, process, procedure, or activity with the intent to release physical tension and refocus the mind away from anxious, angry, or disturbing thoughts in order to reduce stress and/or pain and achieve a sense of well-being and calmness</p> <p>Lee C, Crawford C, Hickey A. Active Self-Care Therapies for Pain (PACT) Working Group. <i>Pain Med</i>. 2014 Apr;15 Suppl 1:S21-39. doi: 10.1111/pme.12383.</p>
<p>Superficial Heat</p>	<p>There is moderate level evidence that heat decreases pain and improves function for acute phase low back pain – at 4-5 days. There is low level evidence that heat is more effective than acetaminophen or ibuprofen for acute phase pain.</p> <p>Qaseem A, Wilt TJ, McLean RM, Forciea MA, for the Clinical Guidelines Committee of the American College of Physicians. <a href="#">Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians</a> [published online February 14, 2017]. <i>Ann Intern Med</i>. doi:10.7326/M16-2367.</p>

**AHRQ Levels of Evidence:**

**High:** High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate:** Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.

**Low:** Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.

**Insufficient:** Evidence either is unavailable or does not permit a conclusion.

MEDICATION	EQUIANALGESIC DOSE (for chronic dosing)		USUAL STARTING DOSES FOR ADULT>50kg* (♦1/2 dose for elderly or severe renal or liver disease)		COMMENTS	
	IM/IV onset 15-30 min	PO onset 30-60 min	PARENTERAL	PO		
<b>MORPHINE</b>	10 mg	30 mg	2.5-5 mg SC/IV q3-4h (♦1.25–2.5 mg)	5-15 mg q3-4h IR or Oral Solution (♦2.5-7.5 mg)	IR tablets (15,30mg); Rectal suppository (5,10,20,30mg) Oral solution (2mg/ml, 4 mg/ml); Concentrate (20mg/ml) can give buccally ER tablets (15,30,60,100,200mg) q8-12h (MS Contin) ER capsules (10,20,30,40,50,60,70,80,100,130,150,200mg) q12-24h (Kadian) Morphine/Naltrexone capsules (20/0.8, 30/1.2, 50/2, 60/2.4, 80/3.2, 100/4mg) q12-24h – Designed with abuse-deterrent properties (Embeda) <b>Use carefully in renal failure.</b>	
<b>HYDROCODONE</b>	Not available	30 mg	Not Available	5 mg q3-4h (♦2.5 mg)	APAP combo tablets - 2.5-10mg hydrocodone with 300-325mg APAP; APAP combo solution - 2.5mg hydrocodone with 108mg APAP per 5ml IBU combo tablets - 2.5-10mg hydrocodone with 200mg ibuprofen ER capsules (10,15,20,30,40,50) ER tablets (20,30,40,60,80,100mg) – designed with abuse-deterrent properties <b>Use carefully in renal failure.</b>	
<b>OXYCODONE</b>	Not Available	20 mg	Not Available	5-10 mg q3-4h IR or Oral Solution (♦2.5 mg)	IR capsule (5mg); IR tablets (5,10,15,20,30mg) Oral solution (5mg/5ml) Concentrate (20mg/ml) ER tablets (10,15,20,30,40,60,80mg) q8-12h (Oxycontin) - designed with abuse-deterrent properties APAP combo - 2.5-10mg oxycodone combined with 300-325mg APAP; Ibuprofen combo and ASA combo also available. <b>Combos generally not recommended for chronic use.</b> <b>Not enough literature regarding dosing in renal failure. Use caution.</b>	
<b>FENTANYL</b>	100 mcg (single dose) t ½ and duration of parenteral doses variable	24 hour MS dose 30-59 mg 60-134 mg 135-224 mg 225-314 mg 315-404 mg	Initial patch dose 12 mcg/h 25 mcg/h 50 mcg/h 75 mcg/h 100 mcg/h	25-50 mcg IM/IV q1-3h (♦12.5-25 mcg)	Transdermal patch 12 mcg/h q72h (use with caution in opioid naïve and in unstable patients because of 12h delay in onset and offset)	Transdermal patch (12,25,37.5,50,62.5,75,87.5,100mcg) If transitioning from IV fentanyl to patch, hourly rate is the patch dose; eg. if patient is on 50mcg/h IV, start with 50mcg patch. <b>N.B. Incomplete cross-tolerance already accounted for in conversion to fentanyl; when converting to other opioid from fentanyl, generally reduce the equianalgesic amount by 50%.</b> IV: very short acting; associated with chest wall rigidity. IR: Buccal tablet, Nasal solution, SL tablet, Lozenge; SL spray - <b>Indicated for breakthrough cancer pain only.</b> <b>Seek consult.</b> <b>Acceptable in renal failure, monitor carefully if using long term.</b>
<b>HYDROMORPHONE</b>	1.5 mg	7.5 mg	0.2-0.6 mg SC/IV q2-3h (♦0.2 mg)	1-2 mg q3-4h (♦0.5-1 mg)	Tablets (2,4,8mg); Oral solution (1mg/ml); Suppository (3mg) ER tablets (8,12,16,32mg) <b>Use carefully in renal failure.</b>	
<b>OXYMORPHONE</b>	1 mg	10 mg	1-1.5 mg IM/SQ q4-6h (♦0.5 mg)	10 mg q4-6h IR TABLE (♦5 mg)	IR tablets 5,10mg ER tablets 5,7.5,10,15,20,30,40mg – designed with abuse-deterrent properties <b>Use carefully in renal failure and liver impairment.</b>	
<b>BUPRENORPHINE</b>	Not available	24 hour MS dose <30 mg 30-80 mg	Initial patch dose 5 mcg/h 10 mcg/h	Not Available	5 mcg/h patch q7 days (opioid-naïve) (no adjustment) 75 mcg buccally q12- 24h (37.5 mg severe hepatic failure only)	Transdermal patch (5,7.5,10,15,20mcg/h) q7 days (Butrans) Maximum dose 20mcg/h for patch Buccal film (75,150,300,450,600,750,900mcg) q12-24h (Belbuca) Initiate treatment with 75mcg film qd or q12h as tolerated, before increasing dose. Half-life of 20-70 hours. Caution for risk of QTc prolongation. <b>No dosage adjustment required for renal failure.</b>
<b>CODEINE</b> (information provided for conversion to opioids only)	130 mg	200 mg	15-30 mg IM/SC q4h (♦7.5-15 mg) IV Contraindicated	30-60 mg q3-4h (♦15-30 mg)	Tablets (15,30,60mg); Solution (30mg/5ml); APAP combo solution (12mg with 120mg APAP/5ml) APAP combo tablets (15,30,60mg codeine w/300mg APAP) <b>Monitor total acetaminophen dose.</b>	
<b>METHADONE</b> (see separate sheet with detailed dosing information)	1/2 oral dose 2 mg PO methadone = 1 mg parenteral methadone	Seek Consult	1.25-2.5 mg q8h (♦1.25 mg) Consider Palliative Care or Pain Service Consult	2.5-5 mg q8h (♦1.25-2.5 mg) Consider Palliative Care or Pain Service Consult	Tablets (5,10mg); Solution (1mg/ml, 2mg/ml); Concentrate (10 mg/ml) Usually q12h or q8h; Long variable t½; and high interpatient variability. Small dose change makes big difference in blood level. Tends to accumulate with higher doses; always write "hold for sedation." <b>Because of long half-life, do not use methadone prn unless experienced.</b> <b>Acceptable with renal disease.</b>	

\* - "Usual starting doses" applies to opioid naïve patients, not for patients who have been on opioids and whose starting dose should take their usual consumption into account.

HALF LIFE (hours)	DURATION (hours)
1.5-2	3-7
3.3-4.5	4-6
3-4	4-6
13-22 (Patch) 7 (Lozenge) 12-22 (Buccal) 15-25 (Intranasal)	48-72 (Patch) 60+ min (Lozenge) 120+ min (Buccal) 120+ min (Intranasal)
2-3	4-5
7-10	4-6
26 (Patch) 27.6 ± 11.2 (Buccal)	168 (Patch) 12-24 (Buccal)
3	4-6
15-190 (N.B. Huge Variaton)	6-12

## GUIDELINES

- Assess and manage pain in adult patients using the CPPM Adult Guide.  
**N.B. Opioids are not first line for chronic pain, even moderate to severe pain, which should be managed with an active approach and non-opioid pain relievers whenever possible. When opioids are indicated, based on a careful risk assessment, combine with an active approach and other measures. Be wary of dose escalation over time due to tolerance.**
- How to dose opioids:
  - Give baseline medication around the clock.
  - For breakthrough pain order 10% total daily dose as a PRN given q 1-2h for oral and q 30-60 min for SC/IV.
  - For continuous infusion, PRN can be either the hourly rate q 15 min or 10% of total daily dose q 30-60 min.
  - Adjust baseline upward daily in amount roughly equivalent to total amount of PRN.
  - Balance function vs. acceptable control of pain.
- In general, oral route is preferable, then trans-cutaneous > subcutaneous > intravenous.
- If parenteral medication is needed for mild to moderate pain, use half the usual starting dose of morphine or equivalent.
- Use a short-acting medication for acute pain exacerbation. Switch to long-acting preparations when pain is chronic and the total daily dose is determined.
- Avoid multiple agents of similar duration.
- When converting from one opioid to another, some experts recommend reducing the equianalgesic dose by 1/3 to 1/2, then titrate as in #2 above.
- Older adults, or those with severe renal or liver disease, should start on half the usual starting dose. Watch carefully for toxicity from accumulation.
- Use care with combinations. Ensure total consumption of APAP from ALL sources & ALL purposes does not exceed 3 g/day (2-3 g for frail elders).
- Patients with substance abuse history may need a higher starting dose due to tolerance. Monitor urine drug screenings. Consider abuse-deterrent opioids.
- Refer to product information fentanyl use. Review CPPM methadone and buprenorphine guidelines.
- Refer to Bassett protocol for naloxone use.
- Avoid codeine and tramadol if breastfeeding.

# Equianalgesic Table for Adults

Half-life, Duration,  
Dosing and Guidelines  
(Tailor care to individual needs.)

## Community Principles of Pain Management

Adapted by Specialty Advisory Group, 2002  
Reviewed and approved every other year  
Reviewed and adopted by AAHPM, 2009

Approved in April 2017.  
Next scheduled update in 2019.

Additional pain management resources are available at [CompassionAndSupport.org](http://CompassionAndSupport.org)



Compassion and Support  
at the End of Life  
[CompassionAndSupport.org](http://CompassionAndSupport.org)

MEDICATION	EQUIANALGESIC DOSE (for chronic dosing)		USUAL STARTING DOSES Pediatric patients > 6 months (decrease dose by 1/4 to 1/2 for age < 6 months or severe renal or liver disease)		COMMENTS  (Not all dosage forms are available for inpatients, consult pediatric pharmacy for availability)	
	IM/IV onset 15-30 min	PO onset 30-60 min	PARENTERAL	PO		
<b>MORPHINE</b>	10 mg	30 mg	<40 kg: 0.05-0.1 mg/ kg/dose q 2-4 hrs  ≥40 kg: 2 - 5 mg q 2-4 hrs	<40 kg: 0.15-0.3 mg/ kg/dose q 3-4 hrs  ≥40 kg: 5 - 15 mg q 3-4 hrs	Oral Solution (2 mg/ml); Concent. oral solution (20 mg/ml) can be given buccally In some post-op patients, up to 0.2mg/kg IV may be required as an initial IV dose IR tablets (15, 30 mg) ER tablets (15, 30, 60, 100, 200 mg) q8-12h (MS Contin) ER capsules(10,20,30,50,60,70,80,100,130,150,200) q12-24h (Kadian) ER capsules (30,45,60,75,90,120) q24h (Avinza) <b>Not recommended in renal failure.</b>	
<b>OXYCODONE</b>	Not Available	20 mg	Not Available	<40 kg: 0.1-0.2 mg/ kg/dose q 3-4 hrs  ≥40 kg: 5 - 10 mg q 3-4 hrs	Oral solution (5mg/5ml); Concentrate (20mg/ml) can be given buccally IR capsule (5mg); IR tablets (5, 10, 15, 20,30) ER tablets (10, 15, 20, 30, 40, 60, 80) q8-12h (Oxycontin)Designed with abuse-deterrentproperties Combos available with acetaminophen or ibuprofen (generally not recommended) <b>Not enough literature regarding dosing in renal failure. Use with caution.</b>	
<b>HYDROMORPHONE</b>	1.5 mg	7.5 mg	<40 kg: 0.015 mg/kg/dose q 3-4 hrs  ≥40 kg: 0.2 - 0.6 mg q 3-4 hrs	<40 kg: 0.03-0.06 mg/ kg/dose q 3-4 hrs  ≥40 kg: 1 - 2 mg q 3-4 hrs	Oral Solution (1mg/ml); Suppository (3mg); Tablets (2,4,8mg) ER tablets (8, 12, 16, 32mg) - Designed with abuse-deterrent properties <b>Use carefully with renal failure.</b>	
<b>METHADONE</b> (see text for dosing conversations)	1/2 oral dose 2 mg PO methadone = 1 mg parenteral	24 hour oral morphine <30 mg 31-99 mg 100-299 mg 300-499 mg 500-999 mg 1000-2100 mg >1200mg	Oral morphine: methadone ratio 2:1 4:1 8:1 12:1 15:1 20:1 consider consult	Consult Pediatric Supportive (Palliative) Care or Anesthesia Pain Service	Consult Palliative Supportive (Palliative) Care or Anesthesia Pain Service	Oral Solution (1mg/ml, 2mg/ml); Concentrate (10 mg/ml) Tablets (5, 10mg); Usually q12h or q8h; Long variable t½ and high interpatient variability; Small dose change makes big difference in blood levels; Tends to accumulate with higher doses, always advise "hold for sedation" Because of long half-life, do not use methadone prn unless experienced Many drug interactions with commonly used medications When converting from oral to parenteral, decrease dose by HALF for safety; When converting from parenteral or oral, keep dose the same <b>Acceptable with renal disease.</b>
<b>FENTANYL</b>	100 mcg (single dose) t ½ and duration of parenteral doses variable	24 hour MS dose 30-59 mg 60-134 mg 135-224 mg 225-314 mg 315-404 mg	Initial patch dose 12 mcg/h 25 mcg/h 50 mcg/h 75 mcg/h 100 mcg/h	<40 kg: 0.5 - 2 mcg/ kg/dose q 1-3 hrs  ≥40 kg: 25 - 50 mcg q 1-3 hrs	Consult Pediatric Supportive (Palliative) Care or Anesthesia Pain Service	Transdermal patch (12,25,50,75,100mcg); If transitioning from IV Fentanyl to patch, the hourly rate is the patch dose; eg. if patient is on 50mcg/hr IV, start with a 50mcg patch Buccal film (200-1200mcg), Buccal tablet (100-800mcg), Nasal solution (100 & 400mcg/act), SL tablet (100-800mcg), Lozenge (200-1600mcg); SL spray (100- 1600mcg) Indicated for breakthrough cancer pain only <b>NB: Incomplete cross-tolerance already accounted for in conversion; when converting to other opioid from fentanyl, generally reduce equianalgesic amount by 50%</b> IV: very short acting; associated with chest wall rigidity if given quickly or in high dose. <b>Acceptable in renal failure, monitor carefully if using long term.</b>
<b>HYDROCODONE</b>	Not available	30 mg	Not Available	<40 kg: 0.2 mg/kg/dose q 4-6 hrs  ≥40 kg: 5 - 10 mg q 4-6 hrs	APAP combo tablets - 2.5-10mg hydrocodone with 300-325mg APAP; APAP combo solution - 2.5mg hydrocodone with 108mg APAP per 5ml IBU combo tablets - 2.5-10mg hydrocodone with 200mg ibuprofen ER tablets (10, 15, 20, 30, 40, 50mg) – Not an abuse-deterrent formulation <b>Monitor total acetaminophen or ibuprofen dose.</b>	

HALF LIFE (hours)	DURATION (hours)
1.5-2	3-7
3-4	4-6
2-3	4-5
15-90 (N.B. Huge Variation)	6-12
13-22 (patch)	48-72 (patch)
3.3-4.5	4-6

## GUIDELINES

These guidelines do not apply to infants in the NICU.

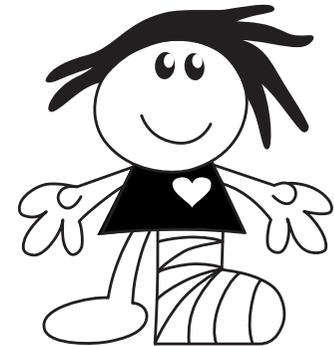
**Codeine and Tramadol are CONTRAINDICATED in children under 12 years of age.**

- Evaluate pain on all patients using a developmentally appropriate scale.  
**N.B. Opioids are not first line for chronic pain, even moderate to severe pain, which should be managed with an active approach and non-opioid pain relievers whenever possible. When opioids are indicated, based on a careful risk assessment, combine with an active approach and other measures. Be wary of dose escalation over time due to tolerance.**
- How to dose opioids:
  - Give baseline medication around the clock.
  - For breakthrough pain order 10% total daily dose as a PRN given q 1-2h for oral and q 30-60 min for SC/IV.
  - For continuous infusion, PRN can be either the hourly rate q 15 min or 10% of total daily dose q 30-60 min.
  - Adjust baseline upward daily in amount roughly equivalent to total amount of PRN.
  - Negotiate with patient/family to target level of relief, balancing function vs. complete absence of pain.
- In general, oral route is preferable, then transcutaneous > subcutaneous > intravenous. Determine route as appropriate for situation/acuity and type of pain.
- If parenteral medication is needed for mild to moderate pain, use half the usual starting dose of morphine or equivalent.
- Short-acting preparations should be used acutely & post-op. Switch to long-acting preparations when pain is chronic and the total daily dose is determined.
- Avoid multiple agents of similar duration.
- When converting from one opioid to another, some experts recommend reducing the equianalgesic dose by 1/3 to 1/2, then titrate as in #2 above.
- Infants < 6 months or those with severe renal or liver disease should start on 1/4 to 1/2 the usual starting dose.
- Administering opioids to children <24 months:
  - Infants < 6 months: place on apnea/bradycardia monitor and pulse oximeter
  - Infants/children 6 months - 24 months: place pulse oximeter (consider for children with developmental disabilities, h/o prematurity and known respiratory difficulties)
- Naloxone (Narcan) should only be used in emergencies: Dilute naloxone (0.4 mg/ml) 0.1 mg (0.25 ml) with 9.75 ml NS (final strength 10 mcg/ml). Give 2 mcg/kg IV, repeat q2minutes for total of 10mcg/kg. Monitor patient q15 minutes for at least 90 minutes. May need to repeat naloxone again in 30-60 minutes.

# Equianalgesic Table for Pediatrics

## Half-life, Duration, Dosing and Guidelines

(Tailor care to individual needs.)



## Community Principles of Pain Management for Children

Adapted for pediatrics by University of Rochester Medical Center and Golisano Children's Hospital, 2012  
Reviewed and approved every other year

Approved in April 2017.

Next scheduled update in 2019.

Additional pain management resources are available at [CompassionAndSupport.org](http://CompassionAndSupport.org)



Compassion and Support  
at the End of Life

[CompassionAndSupport.org](http://CompassionAndSupport.org)

## OPIOID GUIDELINES

1. Assess and manage pain in adult patients using the CPPM Adult Guide.

**N.B. Opioids are not first line for chronic pain, even moderate to severe pain, which should be managed with an active approach and non-opioid pain relievers whenever possible. When opioids are indicated, based on a careful risk assessment, combine with an active approach and other measures. Be wary of dose escalation over time due to tolerance.**

### 2. How to dose opioids:

A. Give baseline medication around the clock

B. For breakthrough pain order 10% total daily dose as a PRN given q 1-2h for oral and q 30-60 min for SC/IV

C. For continuous infusion, PRN can be either the hourly rate q 15 minutes or 10% of total daily dose q 30-60 minutes.

D. Adjust baseline upward daily in amount roughly equivalent to total amount of PRN

e. Balance function vs. acceptable control of pain.

3. In general, oral route is preferable, then trans-cutaneous > subcutaneous > intravenous.

4. If parenteral medication is needed for mild to moderate pain, use half the usual starting dose of morphine or equivalent.

5. Use a short-acting medication for acute pain exacerbation. Switch to long-acting preparations when pain is chronic and the total daily dose is determined.

6. Avoid multiple agents of similar duration.

7. When converting from one opioid to another, some experts recommend reducing the equianalgesic dose by 1/3 to 1/2, then titrate as in #2 above.

8. Older adults, or those with severe renal or liver disease, should start on half the usual starting dose. Watch carefully for toxicity from accumulation.

9. Use care with combinations. Ensure total consumption of APAP from ALL sources & ALL purposes does not exceed 3 grams/day (2-3 grams for frail elders.)

10. Patients with substance abuse history may need a higher starting dose due to tolerance. Monitor urine drug screenings. Consider abuse-deterrent opioids.

11. Refer to product information fentanyl use. Review CPPM methadone and buprenorphine guidelines.

12. Refer to Bassett protocol for Naloxone use.

13. Avoid Codeine and tramadol if breastfeeding.

## Opioid Guidelines for Pediatric Patients

**These guidelines do not apply to infants in the NICU.**

**Codeine and Tramadol are CONTRAINDICATED in children under 12 years of age.**

1. Evaluate pain on all patients using a developmentally appropriate scale.

**N.B. Opioids are not first line for chronic pain, even moderate to severe pain, which should be managed with an active approach and non-opioid pain relievers whenever possible. When opioids are indicated, based on a careful risk assessment, combine with an active approach and other measures. Be wary of dose escalation over time due to tolerance.**

2. How to dose opioids:

A. Give baseline medication around the clock

B. For breakthrough pain order 10% total daily dose as a PRN given q 1-2h for oral and q 30-60 min for SC/IV.

C. For continuous infusion, PRN can be either the hourly rate q 15 minutes or 10% of total daily dose q 30-60 minutes.

D. Adjust baseline upward daily in amount roughly equivalent to total amount of previous day's PRNs

E. Negotiate with patient/family to target level of relief, balancing function vs. complete absence of pain.

3. In general, oral route is simplest/preferable, then transcutaneous > subcutaneous > intravenous. Determine route as appropriate for situation/acuity and type of pain

4. If parenteral medication is needed for mild to moderate pain, use half the usual starting dose of morphine or equivalent.

5. Short-acting preparations should be used acutely & post-op. Switch to long-acting preparations when pain is chronic and the total daily dose is determined.

6. Avoid multiple agents of similar duration

7. When converting from one opioid to another, some experts recommend reducing the equianalgesic doses by 1/3 to 1/2, then titrate as in #2 above.

8. Infants < 6 months or those with severe renal or liver disease should start on 1/4 to 1/2 the usual starting dose.

9. Administering opioids to children <24 months:

A. **Infants < 6 months:** place on apnea/bradycardia monitor and pulse oximeter

B. **Infants/children 6 months - 24 months:** place pulse oximeter (consider for children with developmental disabilities, h/o prematurity & known respiratory difficulties)

10. Naloxone (Narcan) should only be used in emergencies:

Dilute naloxone (0.4 mg/ml) 0.1 mg (0.25 ml) with 9.75 ml NS (final strength 10 mcg/ml)

Give 2 mcg/kg IV, repeat q2minutes for total of 10mcg/kg

Monitor patient q15 minutes for at least 90 minutes

May need to repeat naloxone again in 30-60 minutes

Date \_\_\_\_\_

Patient Name \_\_\_\_\_

## OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
<b>1. Family History of Substance Abuse</b>	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
<b>2. Personal History of Substance Abuse</b>	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
<b>3. Age</b> (Mark box if 16 – 45)		[ ]	1	1
<b>4. History of Preadolescent Sexual Abuse</b>		[ ]	3	0
<b>5. Psychological Disease</b>	Attention Deficit Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
<b>TOTAL</b>			_____	_____

### Total Score Risk Category

Low Risk 0 – 3

Moderate Risk 4 – 7

High Risk  $\geq 8$

## RESEARCH ARTICLES

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# Predicting Aberrant Behaviors in Opioid-Treated Patients: Preliminary Validation of the Opioid Risk Tool

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Lifetree Pain Clinic and Clinical Research, Salt Lake City, Utah, USA

### ABSTRACT

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*Objective.* To provide clinicians with a brief screening tool to predict accurately which individuals may develop aberrant behaviors when prescribed opioids for chronic pain.

*Design.* One hundred and eighty-five consecutive new patients treated in one pain clinic took the self-administered Opioid Risk Tool (ORT). The ORT measured the following risk factors associated in scientific literature with substance abuse: personal and family history of substance abuse; age; history of preadolescent sexual abuse; and certain psychological diseases. Patients received scores of 0–3 (low risk), 4–7 (moderate risk), or  $\geq 8$  (high risk), indicating the probability of their displaying opioid-related aberrant behaviors. All patients were monitored for aberrant behaviors for 12 months after their initial visits.

*Results.* For those patients with a risk category of low, 17 out of 18 (94.4%) did not display an aberrant behavior. For those patients with a risk category of high, 40 out of 44 (90.9%) did display an aberrant behavior. The authors used the  $c$  statistic to validate the ORT, because it simultaneously assesses sensitivity and specificity. The ORT displayed excellent discrimination for both the male ( $c = 0.82$ ) and the female ( $c = 0.85$ ) prognostic models.

*Conclusion.* In a preliminary study, among patients prescribed opioids for chronic pain, the ORT exhibited a high degree of sensitivity and specificity for determining which individuals are at risk for opioid-related, aberrant behaviors. Further studies in a variety of pain and nonpain settings are needed to determine the ORT's universal applicability.

*Key Words.* Assessment; Screening; Chronic Pain; Opioids; Abuse; Addiction

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### Introduction

The prevalence of opioid abuse in chronic-pain practices is unknown but is often believed to be no greater than the prevalence of opioid abuse in the general population [1]. Other studies disagree and estimate the danger of abuse for pain patients to be higher than the norm [2,3]. One

study puts the prevalence of addictive disorders as high as 60% among patients who sustain major trauma [4].

Patients who abuse opioid prescriptions will generally display one or more aberrant drug-related behaviors [5,6]; however, patients who are not abusing opioids may also display aberrant behaviors (see Table 3 for a list). A request for an early refill, for example, may result from intentional overuse of medication (abuse) or a one-time incident where an individual accidentally destroys a few pills. Most physicians would not consider the latter incident an example of abuse. Nonetheless,

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it seems reasonable that the more aberrant behaviors an individual exhibits, the more likely the individual is abusing or is addicted to opioids. For the purposes of this article, abuse means the deliberate overuse of controlled or illegal substances, and addiction means the pursuit of such substances for no medical purpose despite resulting physical or psychological harm. These definitions are rooted in the most recent definitions for abuse and dependence found in the Diagnostic and Statistical Manual for Mental Disorders for 2001, although the authors prefer the term “addiction” to the more confusing and conflicting term “dependence” [7]. Concepts of “tolerance” and “withdrawal” have been separated from the phenomenon of “addiction” in the belief that these first two phenomena may not indicate addiction at all.

A number of screening and diagnostic tools exist to assess for aberrant behaviors that may help clinicians detect when a patient is currently abusing or is addicted to prescription medications [8–22]. Yet there also exists a need for a tool to measure the likelihood of whether a patient will abuse opioids in the future. Because abuse and addiction are diagnosed by observing aberrant behaviors, knowing which patients are at greatest risk for displaying aberrant behaviors can be useful in establishing appropriate levels of monitoring for abuse. This article describes the office-based Opioid Risk Tool (ORT), designed to predict the probability of a patient displaying aberrant behaviors when prescribed opioids for chronic pain.

**Methods**

All new patients (N = 185; females: 108; males: 77) referred to the first author’s pain clinic from January 2000 through May 2001 were asked to complete the self-administered ORT (Table 1), which screened for the presence of several risk factors. The ORT assessed new patients for family and personal history of alcohol; illegal drug and prescription substance abuse; age; history of preadolescent sexual abuse; and specific mental disorders. Each risk factor was weighted and attributed a point value believed to reflect its risk relative to the other risk factors. This was carried out based on the authors’ personal clinical experience and a review of the literature on the best-known risk factors associated with abuse [23–53]. These weights were derived entirely before any data used in this study were collected and were not modified after the study began. The validity of the weighting was indirectly assessed in this present study as part of the ORT’s validity testing; however, a larger sample size would be required to test the validity of weights attributed to the individual risk factors.

Patients in the sample were grouped by score into one of three risk categories: high (likely to abuse opioids), moderate (as likely will as won’t abuse opioids) or low (unlikely to abuse opioids). The selected cutoff points for these categories are ≥8, 4–7, and 0–3, respectively. Each patient was assigned a pain type based on his or her chief complaint (Table 2). Patients were treated with a

**Table 1** Opioid Risk Tool

Item	Mark Each Box That Applies	Item Score If Female	Item Score If Male
1. Family history of substance abuse			
Alcohol	[ ]	1	3
Illegal drugs	[ ]	2	3
Prescription drugs	[ ]	4	4
2. Personal history of substance abuse			
Alcohol	[ ]	3	3
Illegal drugs	[ ]	4	4
Prescription drugs	[ ]	5	5
3. Age (mark box if 16–45)	[ ]	1	1
4. History of preadolescent sexual abuse	[ ]	3	0
5. Psychological disease			
Attention deficit disorder, obsessive-compulsive disorder, bipolar, schizophrenia	[ ]	2	2
Depression	[ ]	1	1
Total		—	—
Total score risk category			
Low risk: 0–3			
Moderate risk: 4–7			
High risk: ≥8			

**Table 2** Patient characteristics by risk category

Characteristic	Low Risk (N = 18)	Moderate Risk (N = 123)	High Risk (N = 44)	P Value*
Age, mean $\pm$ SD (min, max)	50.9 $\pm$ 14.9 (28, 78)	44.1 $\pm$ 13.1 (17, 82)	41.1 $\pm$ 9.2 (20, 64)	0.067
Gender, n (%)				0.540
Female	12 (67)	73 (59)	23 (52)	
Male	6 (33)	50 (41)	21 (48)	
Pain types, n (%)				0.744
Spine: lumbar	6 (33)	43 (35)	23 (52)	
Spine: cervical	1 (6)	9 (7)	1 (2)	
Headache	4 (22)	24 (20)	5 (11)	
Neuropathic	3 (17)	22 (18)	5 (11)	
Musculoskeletal	3 (17)	19 (15)	7 (16)	
Visceral	1 (6)	6 (5)	3 (7)	

\* Comparison of three risk groups: Kruskal–Wallis test for age, chi-square test for gender, Fisher–Freeman–Halton test for pain types.

variety of opioids, breakthrough pain medications, and anticonvulsants. The philosophy of treatment was to titrate patients to optimal pain-relief levels with the upper dosage limited only by side effects. Some patients reached several 100 mg of morphine equivalents. Patients were seen weekly until successfully titrated, then monthly thereafter.

Behaviors defined as aberrant used in this study are listed in Table 3. All patients were monitored for aberrant behaviors for 12 months after their initial visits. The first author, also the clinic's medical director, recorded each aberrant behavior as present when it was first documented in the patient's medical chart. The aberrant behavior was documented in the chart by any member of the clinical staff after being observed directly, reported

by the patient or a family member or detected by a lab test. This procedure was intended to minimize the authors' subjective interpretation and bias in recording the behaviors.

When possible, a query of the state's prescription-monitoring program was completed before the patient's first visit to assess whether the patient had been receiving opioid prescriptions from more than one physician. Further queries were completed at 6-month intervals and whenever an aberrant behavior triggered a concern by the provider that the patient may be soliciting opioids from other providers.

For tabulation, the authors created a spreadsheet listing new patients and the type and frequency of aberrant behaviors. The authors

**Table 3** Aberrant behaviors indicating abuse of opioids prescribed for chronic pain

Aberrant Behaviors	Females (N = 108) n (%)	Males (N = 77) n (%)	P Value*
Used additional opioids than those prescribed	8 (7)	8 (10)	0.477
Used additional opioids than those prescribed more than once	6 (6)	8 (10)	0.220
Forged prescription	2 (2)	2 (3)	1.000
Sold prescription	0 (0)	1 (1)	0.416
Admitted to seeking euphoria from opioids	0 (0)	2 (3)	0.172
Admitted to wanting opioids for anxiety	1 (1)	2 (3)	0.571
Overdose and death	0 (0)	5 (6)	0.012
Injected drug	0 (0)	1 (1)	0.416
Abnormal urine/blood screen	12 (11)	10 (13)	0.698
Abnormal urine/blood screen positive for 2 or more substances	2 (2)	1 (1)	1.000
Solicited opioids from other providers	20 (19)	13 (17)	0.775
Unauthorized ER visits	7 (6)	2 (3)	0.309
Concurrent abuse of alcohol	0 (0)	3 (4)	0.070
Unauthorized dose escalation	11 (10)	14 (18)	0.117
Resisted therapy changes/alternative therapy	6 (6)	5 (6)	1.000
Reported lost or stolen prescriptions	6 (6)	5 (6)	1.000
Canceled clinic visit	10 (9)	8 (10)	0.798
Requested early refills	9 (8)	7 (9)	0.857
Requested refills instead of clinic visit	13 (12)	7 (9)	0.525
Abused prescribed drug	11 (10)	11 (14)	0.396
Was discharged from practice <sup>†</sup>	7 (6)	7 (9)	0.508
No show or no follow-up	12 (11)	11 (14)	0.519
Third party required to manage patient's medications	8 (7)	6 (8)	0.922

\* Chi-square test or Fisher's exact test as appropriate.

<sup>†</sup> Because of egregious aberrant behavior (e.g., forging prescriptions).

thoroughly reviewed each patient's chart after 12 months in the practice to confirm the presence or absence of aberrant behaviors.

### Statistical Methods

Several statistical methods were used to compare risk factors and aberrant behaviors between males and females and to determine the predictive value of the risk factors of the ORT.

For statistical comparisons of a categorical variable between two groups, a chi-square test was used, or Fisher's exact test if contingency table cell counts were sparse. The Fisher–Freeman–Halton test is the Fisher's exact test generalized by Freeman and Halton to greater than  $2 \times 2$  cross-tabulation tables [54].

For continuous variables, a *t*-test was used for comparisons between two groups and a one-way analysis of variance was used for comparisons between three groups. The assumption of normality of these two tests was assessed using the Shapiro–Wilk test, and the assumption of equality of variances was assessed using Levene's test. If either assumption was not satisfied, the nonparametric Wilcoxon–Mann–Whitney test or the Kruskal–Wallis analysis of variance test was substituted respectively.

To validate the ORT, the authors used it to compute a total score for every patient in the sample, the sample serving as the validation dataset (Table 1). Then the total scores, along with the actual observed outcome of one or more aberrant behaviors, were used to compute the concordance index (popularly called the *c* statistic). The *c* statistic was used to validate the ORT, as it simultaneously assesses the sensitivity and specificity [55,56]. The *c* statistic is a measure of the predictive ability (measure of diagnostic discrimination) of a prognostic model. For validating the ORT in this study, the *c* statistic is the likelihood that a patient who exhibits an aberrant behavior will have a higher predicted risk of such a behavior than does a patient who does not exhibit an aberrant behavior [55].

The general rule for interpreting the *c* statistic:  $c = 0.5$  suggests no discrimination (i.e., no better than flipping a coin),  $0.7 \leq c < 0.8$  is considered acceptable discrimination,  $0.8 \leq c < 0.9$  is considered excellent discrimination, and  $c \geq 0.9$  is considered outstanding discrimination [56].

The validation dataset was not large enough to validate directly that the weights assigned to the ORT's risk factors represent the optimal weights.

Such a validation would require fitting a multivariable logistic regression model separately for males and females and then basing the ORT weights on the relative size of the regression coefficients. Fitting such a model would require at least 10 patients with an aberrant behavior outcome for every predictor variable in the model to avoid "overfitting" and structural collinearity [55]. The validation dataset only had 37 female patients and 39 male patients with aberrant behaviors, so that only four predictor variables could appropriately be modeled out of the required 10 predictor variables composing the ORT.

Despite the sample size limitation which precluded fitting a multivariable logistic regression model, a large *c* statistic derived from applying the existing ORT would suggest that the weights used in the ORT are sufficiently satisfactory, thereby providing an indirect validation of the weights. This was the approach, then, used in this current validation study.

To account for potential regression-toward-the-mean bias in the *c* statistic calculations, nonparametric bootstrap resampling was used. The bootstrap-resampled *c* statistic is what one would more likely observe in future patients [55,57]. Both the *c* statistic observed for the validation dataset and the *c* statistic computed by nonparametric bootstrap resampling are reported.

To determine if the weights used with the ORT were more predictive than simply summing the items, where every item is assumed to have equal importance, the *c* statistic for the ORT was compared with the *c* statistic derived for the unweighted total score and tested for significance [58].

### Results

No difference was found among the three risk groups for age ( $P = 0.067$ ), gender ( $P = 0.540$ ), or pain type ( $P = 0.744$ ) (Table 2). Lumbar spine-related pain was the most common pain type. Headache, neuropathic pain, and musculoskeletal pain were fairly evenly distributed among the three risk groups. Cervical spine-related pain was the least common pain type in all three risk groups.

The most common aberrant behaviors for both men and women were solicited opioids from other providers (males: 17%, females: 19%), unauthorized dose escalation (males: 18%, females: 10%), abnormal urine/blood screen (male: 13%, females: 11%), used additional opioids than those pre-

**Table 4** Presence/absence of one or more aberrant behaviors by risk category computed from Opioid Risk Tool (ORT)

Risk Category* by Actual Outcome	Females N (%)	Males N (%)
Patients with no aberrant behaviors	71	38
Low (0–3) <sup>†</sup>	12 (16.9)	5 (13.2)
Moderate (4–7)	56 (78.9)	32 (84.2)
High (≥8)	3 (4.2)	1 (2.6)
Patients with one or more aberrant behaviors	37	39
Low (0–3) <sup>†</sup>	0 (0.0)	1 (2.6)
Moderate (4–7)	17 (46.0)	18 (46.2)
High (≥8)	20 (54.0)	20 (51.3)

\* Based on total score from ORT.

<sup>†</sup> Low risk = unlikely to abuse opioids; moderate risk = as likely will as won't abuse opioids; high risk = likely to abuse opioids.

scribed (males 10%, females 7%), used additional opioids than those prescribed more than once (males: 10%, females 6%), no show or no follow-up (males: 14%, females: 11%), abused prescribed drug (males: 14%, females: 10%), and cancelled clinic visit (males: 10%, females: 9%) (Table 3).

For those patients with a risk category of low, 17 out of 18 (94.4%) did not display an aberrant behavior, in close agreement with the category label of “unlikely to abuse opioids” (Table 4). For those patients with a risk category of high, 40 out of 44 (90.9%) did display an aberrant behavior, in close agreement with the category label of “likely to abuse opioids.” The data showed that the moderate-risk patients were 2.5 times as likely not to abuse opioid prescriptions as to abuse opioid prescriptions. (35 or 28% did; 88 or 72% did not).

**Table 5** Risk factors for opioid-related aberrant behavior (items composing the Opioid Risk Tool)

Risk Factor	Females (N = 108) n (%)	Males (N = 77) n (%)	P Value*
Family history of substance abuse			
Alcohol	54 (50)	53 (69)	0.011
Illegal drugs	21 (19)	12 (16)	0.499
Other (prescription drugs)	10 (9)	2 (3)	0.070
Personal history of substance abuse			
Alcohol	17 (16)	22 (29)	0.035
Illegal drugs	14 (13)	13 (17)	0.457
Prescription drugs	23 (21)	12 (16)	0.328
Age ≤45	62 (57)	43 (56)	0.832
History of preadolescent sexual abuse	43 (40)	6 (8)	<0.001
Psychological disease			
Attention deficit disorder, obsessive-compulsive disorder, bipolar, or schizophrenia	28 (26)	13 (17)	0.144
Depression	77 (71)	44 (57)	0.046

\* Chi-square test.

**Table 6** Number of aberrant behaviors

	Females (N = 108) n (%)	Males (N = 77) n (%)	P Value*
Total number of aberrant behaviors			
0	71 (66)	38 (49)	
1–2	15 (14)	20 (26)	
≥3	22 (20)	19 (25)	
Median (25th, 75th percentiles)	0 (0, 2)	1 (0, 2)	0.057
Range (min–max)	0–14	0–13	
Total number of aberrant behaviors			
0	71 (66)	38 (49)	
≥1	37 (34)	39 (51)	0.026
Total number of aberrant behaviors			
0–2	86 (80)	58 (75)	
≥3	22 (20)	19 (25)	0.487

\* Wilcoxon–Mann–Whitney test for the first comparison, chi-square test for last two comparisons.

Therefore, the label of “as likely will as won't abuse opioids” reflects cautious patient management.

The need for gender-specific numerical weights for the risk factors composing the ORT is indirectly supported by the difference in prevalence of these risk factors between genders (Table 5). The capacity of a risk factor to impact an outcome will, in part, depend on the prevalence of other risk factors, especially potent ones [59]. For example, a fivefold greater prevalence of a history of preadolescent sexual abuse was observed among females relative to males (females: 40%, males: 8%,  $P < 0.001$ ).

Most aberrant behaviors considered in the validation dataset were essentially equally common among males and females (Table 3). When cumulated, however, males had a greater incidence of at least one aberrant behavior (females: 34%, males: 51%,  $P = 0.026$ ) (Table 6). No significant gender difference was observed in the incidence of at least three aberrant behaviors (females: 20%, males: 25%,  $P = 0.487$ ). Of the total sample, 41% displayed at least one aberrant behavior.

The female prognostic model had  $c = 0.85$  and the male model had  $c = 0.82$  (Table 7). The

**Table 7** Discrimination performance of Opioid Risk Tool total score

	Observed <i>c</i> Statistic (95% CI)*	Bootstrapped <i>c</i> Statistic (95% CI)*
Males	0.82 (0.73–0.91)	0.82 (0.72–0.90)
Females	0.85 (0.78–0.93)	0.85 (0.77–0.92)

The observed *c* statistic is the estimate computed for the validation dataset. The bootstrapped *c* statistic is the estimate derived from nonparametric bootstrap resampling, which is less subject to regression toward the mean bias.

\* 95% confidence interval for *c* statistic.

**Table 8** Percent of one or more aberrant behaviors for each total score from the Opioid Risk Tool

Probability Category	Total Score	Females c/n (%)	Males c/n (%)
Low (0–3)	0–1	0/3 (0)	0/3 (0)
	2	0/7 (0)	0/0 (0)
	3	0/2 (0)	1/3 (33)
Moderate (4–7)	4	2/17 (12)	4/22 (18)
	5	4/28 (14)	4/8 (50)
	6	6/12 (50)	6/10 (60)
	7	5/16 (31)	4/10 (40)
	8	2/3 (67)	4/4 (100)
High (≥8)	9	4/5 (80)	6/6 (100)
	10	4/5 (80)	1/2 (50)
	11–18	10/10 (100)	9/9 (100)
	Total	37/108	39/77

c = count of patients with that total score who had one or more aberrant behaviors; n = number of patients with that total score; % =  $c/n \times 100$ .

observed  $c$  statistic estimates were identical to the bootstrapped  $c$  statistic estimates.

The ORT, with its present item weights, outperformed the unweighted total score of the items, where each item was given a weight of one if the risk factor was present. For females, the ORT exhibited significantly greater discrimination ( $c = 0.85$ ) than its unweighted counterpart ( $c = 0.77$ ,  $P = 0.046$ ). For males, the ORT exhibited greater discrimination ( $c = 0.82$ ) than its unweighted counterpart ( $c = 0.78$ ), but failed to reach statistical significance ( $P = 0.234$ ).

Table 8 lists the percent of one or more aberrant behaviors by gender for each total score from the ORT. The number and percent of aberrant behaviors generally increased with the total score. All patients with a score of 11 or more displayed at least one aberrant behavior. Of patients in the high-risk group, 90.9% displayed aberrant behaviors. Although 33% of males who had a score of 3 (in the low-risk group) displayed at least one aberrant behavior, this represented only one patient. Patients with a score of 2 or lower did not display aberrant behaviors.

## Discussion

It is difficult to predict which patients are at risk for abusing the opioids prescribed for chronic pain. Of the currently available diagnostic tools, such as the Addiction Severity Index (ASI) [8–10] and the Structured Clinical Interview for DSM-IV (SCID) [11–14], many take a long time to administer and require unique skills to interpret. This makes them impractical for most physicians. By contrast, brief screening tools are less cumbersome

but have two frequent problems: 1) they are designed to identify patients who already have problems with substances, not to predict who may develop problems; and 2) they are not designed to screen specifically for opioid abuse. For example, the widely used alcohol-screening tool CAGE (from the key words “Cut,” “Annoyed,” “Guilty,” “Eye”) [15] has not proven to be effective in predicting opioid abuse [16]. Likewise, a tool called TICS (from Two-Item Conjoint Screening tool), a two-question measure of sensitivity to substance abuse [17], is neither opioid-specific nor designed to be predictive, as is the ORT.

These preliminary findings show that the ORT predicted which patients were at highest risk of displaying aberrant behaviors when prescribed opioids for the treatment of chronic pain in the author’s practice. The ORT displayed excellent discrimination for both males and females for interpreting the  $c$  statistic (see Statistical Methods section). In addition, the observed  $c$  statistic estimates were identical to the bootstrapped  $c$  statistic estimates, suggesting the ORT will discriminate just as well in future patients. Although the ORT provides information regarding potential risk factors that might have universal applicability, the validity of the ORT across practices with different demographics remains to be assessed.

The weights assigned to the risk factors reflect the well-documented link between substance abuse and the risk factors studied. Many individual risk factors for substance abuse are not included in the ORT, in keeping with the goal of providing clinicians with an assessment that is both effective and brief. The risk factors were chosen for what was believed to be their predictive power based on a review of related scientific literature. Part of the focus of future testing should be to ensure which factors are indeed most predictive of aberrant, drug-related behaviors and whether the significant results from this preliminary study can be duplicated. It is possible the weights will be adjusted to their optimal values after further testing.

What follows is a brief review of the literature pertaining to the risk factors studied.

Several studies show genetic and environmental links to developing alcohol abuse and other drug addiction [23–36]. Even biological children of alcohol-dependent parents adopted and raised in nonalcoholic environments show a two- to nine-fold increased risk of developing alcohol abuse or dependency [31]. The ORT attributed more relative risk to family history of alcohol abuse among men than women. This is based on evidence of a

higher prevalence of alcohol abuse among men, coupled with evidence that the risk of a person related to an alcoholic-developing alcoholism is greater when the relative and the alcoholic are of the same sex [32].

Alcohol abuse is included as a risk factor based on evidence of polysubstance abuse among alcoholics [35]. However, alcohol abuse was not weighted as heavily as a personal or family history of prescription drug abuse. One study showed that while an abuser of one drug is more likely than nonabusers to go on to abuse a different category of drug, most of the genetic influence on heroin/opioid abuse is specific to heroin/opioids and not shared with other drugs. The same research showed that genetic influence in the abuse of marijuana, stimulants, and sedatives is shared across drugs [29]. The high degree of genetic influence on opioid abuse is the reason why prescription drug abuse (both personal and family history) is weighted most heavily. Illegal drug abuse was considered next in line as being predictive of opioid abuse [36], followed by alcohol abuse. In one study, polysubstance abusers admitted for alcohol-abuse treatment rated their nonalcohol drug use as more problematic than their drinking [35]. The authors also reported that those who used nonalcoholic substances tended to abuse alcohol less.

The age range included on the ORT reflects findings that drug dependence or abuse rates tend to rise with age to peak in the twenties, then fall off at middle age [37].

Substance abuse has been associated with numerous psychological disorders [38–53]. It is generally accepted that women who experienced preadolescent sexual abuse have increased risk for mental and substance-abuse disorders [42]. Preadolescent sexual abuse gives rise to post-traumatic stress disorder (PTSD), which is associated with substance abuse and is two to three times more common in women than in men. Some 30–59% of women in drug abuse treatment have been reported to have PTSD [47].

The select group of mental disorders included on the ORT were chosen based on the prevalence of their association with substance abuse found in the literature [48–52]. Regier et al. found that having a lifetime mental disorder is associated with more than twice the risk of having an alcohol disorder and over four times the risk of having another drug-abuse disorder [51]. Thus, the ORT weighting scale was supported by the literature and proved to be very predictive of abuse in the

current sample but may need to be revised to more optimal levels after further research.

A limitation of the study is that the clinician who recorded aberrant behaviors in a patient's chart was not blinded to that patient's ORT score. Because the study took place in a clinical setting, the ORT score was visible as part of a patient's medical history. Future studies should eliminate this limitation to avoid any possibility of bias on the part of the recording clinician.

Another limitation of the current validation study was the small sample size relative to the number of risk factors. A second validation study therefore with a much larger sample size is called for to determine if the weights assigned to the ORT are optimal or if they need to be modified. Furthermore, the ORT should be tested in multiple pain clinics and in nonpain clinic settings to further assess its applicability to a wider population.

It has been demonstrated that for many scales, a simple total score of the items without weights works just as well as a weighted scale [60]. The ORT, with its present weights, exhibited greater discrimination than its unweighted counterpart for both male and female patients, being significantly so in females. Therefore, even though the weights were not empirically derived, which will require a further study, the present weights appear to have merit at this stage of development.

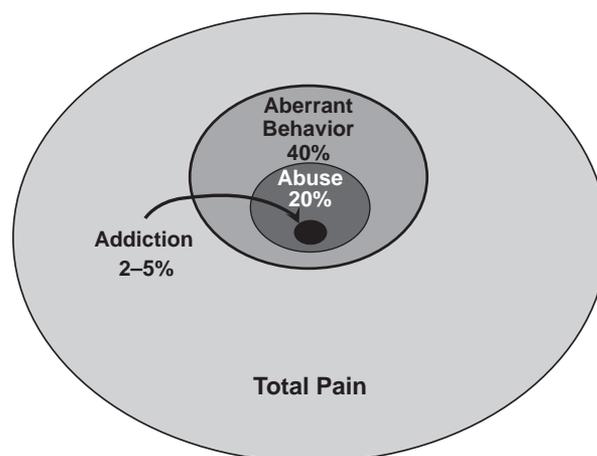
The ORT yielded additional useful findings. The data suggest that the prevalence of aberrant behaviors related to abuse or addiction among patients treated for chronic pain with opioids is much higher than previously reported. A fifth of the women and a quarter of the men in the total sample displayed three or more aberrant behaviors. It should be noted that the authors recorded only those aberrant behaviors that were observed. Other behaviors that might indicate abuse might have gone undetected or were not recorded because they did not fit the list of behaviors chosen to measure.

Aberrant behaviors have been described as less predictive or more predictive of abuse [5]. Alternatively, we suggest aberrant behaviors exist on a continuum from nonexistent to egregious. The authors are not aware of a consensus on what is deemed egregious behavior compared with what would be considered relatively inconsequential behavior. This is an area ripe for research. Passik and Kirsh found little agreement among doctors as to how to interpret certain behaviors but found the most common factors among the abusers they

studied to be unscheduled visits, multiple phone calls to the clinic, unsanctioned dose escalations, and obtaining opioids from more than one source [61]. In a separate study of pain physicians' perceptions, Passik et al. found wide variation in the perception of 13 drug-related behaviors but noted that physicians found illegal activity the most troubling [62]. Selling prescription drugs and forging prescriptions were the top two behaviors considered most indicative of abuse by physicians. Compton suggested three behaviors were predictive of addictive disease: the tendency to increase analgesic dose or frequency, to have a preferred route of administration, and to consider oneself an addict [19]. It is apparent that patients who inject oral medication are displaying more egregious behavior than the individual who uses an occasional extra pill for breakthrough pain. Therefore, although 41% of the current study's total sample displayed at least one aberrant behavior, the importance of this number should not be overstated as the severity of the behaviors varies.

The egregious behaviors are likely to be consistent with behaviors that meet the criteria from the DSM-IV-TR for "dependency" or addiction. It would seem logical that patients with opioid addiction would display multiple egregious behaviors. In a prior, similar study, the author reported that patients who are in the ORT's high-risk group displayed an average of 4.21 aberrant behaviors compared with an average of 0.81 aberrant behaviors in the moderate-risk group over the same time interval [6]. In that study, the high-risk group also demonstrated multiple aberrant behaviors sooner than the moderate- and low-risk groups. While it took an average of nearly 11 months to see three or more aberrant behaviors in the moderate-risk group, it took only about 4 months for the high-risk group. The current study also demonstrated that patients categorized as high risk for abusing opioids demonstrated more aberrant behaviors than the moderate- or low-risk groups (Table 8).

The more egregious the behavior, the greater the likelihood egregious abuse or addiction is taking place. Likewise, the quantity of behaviors can be a prime indicator, with greater numbers of aberrant behaviors likely indicating that significant abuse or addiction is taking place. However, no single indicator clearly marks an addict. Instead, there exists a large gray area, a diagnostic no-man's land, where a patient can display strong indications of addiction, yet not be a true addict. It is probably fair to state that while all addicts are abusers, not all abusers are addicts (see Figure 1).



**Figure 1** Relationships among aberrant behavior, abuse, and addiction in total pain population.

Even aberrant behaviors that suggest abuse or addiction may only reflect a patient's attempt to feel normal. The phrase *chemical copers* refers to patients who, knowingly or unknowingly, inappropriately use opioids to treat a comorbid disease such as depression or anxiety. Although not technically an addict, such a person, fearing withdrawal, is abusing a drug and may even be buying it illegally. In addition, some patients who demonstrate aberrant behavior in an attempt to feel normal are only displaying *rational abuse* of the type that arises from under-treated pain or a failure of treatment management. While a chemical coper's function may not improve as a result of misusing medication, a rational abuser's function and mental status tend to improve.

Despite these cautions, the potential for drug abuse or addiction clearly exists for pain patients as it does for the population at large. Given this reality, it is vital that patients be adequately assessed for abuse potential. The purpose is not to deny high-risk patients adequate pain treatment but to ensure that their psychological and substance-abuse disorders are also treated, and that their opioid intake is closely monitored. In the absence of a laboratory test to detect abuse or addiction, the observation of behavior is the best avenue open to clinicians who wish to avoid contributing to opioid abuse.

### Conclusion

Accurately predicting behavior is difficult regardless of the behavior one is trying to predict. In predicting who will abuse opioids, however,

known risk factors may help determine the general probabilities of who may display behavioral cues suggesting abuse or addiction.

This article documents the results of a preliminary study showing the instrument was predictive in the setting in which it was administered and indicates the instrument may have broad applicability. Using the ORT, this study found that patients who had a high probability of abusing opioids demonstrated more aberrant behaviors than the moderate- or low-risk groups (Tables 4, 8). In the sample tested, the ORT demonstrated validity and accuracy in predicting who is at high risk and at low risk for opioid-related, aberrant behavior.

By having a clinical instrument to assess the probability of an individual developing aberrant behavior, the clinician can tailor the monitoring of patients according to their risk profiles. More importantly, patients who are at high risk could be identified before opioid treatment and directed to appropriate counseling or treatment of the disorders that make them high risk. It is hoped this awareness would result in better clinical outcomes and less abuse.

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# Community Principles of Pain Management

## Pain Management Agreement and Informed Consent

Approved in April 2017; Next Scheduled Update in 2019

Patient Name: \_\_\_\_\_

Medical Record#: \_\_\_\_\_

Medicines called opioids (o-pee-oyds) have been prescribed for my chronic pain. Opioids are sometimes called narcotics. I understand they may be helpful. I also recognize that these medicines are dangerous if not taken correctly. They may be misused. Because of possible danger and misuse, they are closely controlled by my medical providers and by law. The following conditions will help give me the best pain relief and avoid misuse. I agree to follow them:

- \_\_\_\_\_ 1. **I will take my pain medicines correctly.** I agree to take the medicine only as prescribed. I will contact my provider before making any changes.
- I understand that taking more of my medicine than prescribed could lead to a **drug overdose**. An overdose may cause my heart or breathing to become very slow or stop. This could lead to death.
  - I understand that physical dependence is normal and expected when using these medicines for a long time. I understand that physical dependence is not the same as addiction. I understand that decreasing or stopping my medicine suddenly could lead to **withdrawal symptoms**. These include sweating, chills, and joint pain. I may also have trouble sleeping or be sick to my stomach. If I need to stop taking my medicine, I will follow my provider's direction to do so slowly.
  - I understand that my pain medicine may cause **addiction or opioid use disorder**. Addiction means a lack of control over the use of the medicine. Lack of control includes using the medicine in spite of harm to me or craving the medicine. Harm could be physical, mental or social.
  - I understand that **tolerance** means that I may require more medicine to obtain the same amount of pain relief. Taking more medicine may not lessen my pain. Instead, it may cause distressing side effects. Tolerance or failure to respond well to my medicine may lead my provider to choose another form of treatment.
  - I understand that my provider will review the effect of my medicine with me on a regular basis. If my quality of life does not get better, the medicine may be stopped. In that case, I will follow my provider's direction to slowly stop my opioid medicine.
- \_\_\_\_\_ 2. **I will report side effects.** I understand that there are side effects from my opioid medicine. I will tell my provider at my next appointment about any side effects that are new, don't go away, or affect my thinking. These may include:
- |                |                         |
|----------------|-------------------------|
| • Drowsiness   | • Itching               |
| • Confusion    | • Dizziness             |
| • Constipation | • Slowed breathing      |
| • Nausea       | • Slowed reaction times |
| • Vomiting     |                         |

For most people, these side effects decrease with continued use of the medicine.

- I will not involve myself in any activity that may be dangerous to me or someone else if I feel drowsy or am not thinking clearly. Such activities include but are not limited to:
    - Driving a motor vehicle or using heavy equipment
    - Being responsible for another individual who is unable to care for himself
- \_\_\_\_\_ 3. **I will tell all of my medical providers that I am taking opioid medicine. I understand that other medicines and substances can affect the way opioid medicines work in my body.**
- I understand that taking opioid medicines with alcohol may cause:
    - very slow breathing
    - very low blood pressure
    - extreme drowsiness
    - and even death.
  - I understand that I should not drink alcohol or take medicines containing alcohol while taking my opioid medicine.

- I understand that I must talk with my provider before taking other medicines. Some common medicines that may interact with my opioid include:
  - Anxiety medicines (example: lorazepam (Ativan), diazepam (Valium), alprazolam (Xanax))
  - Muscle relaxers (example: cyclobenzaprine (Flexeril))
  - Sleeping medicine (example: zolpidem (Ambien), over-the-counter sleep medicine)
  - Allergy/cold medicine (example: diphenhydramine (Benadryl))
- I will tell my provider as soon as possible if I need to visit another provider or the Emergency Room due to pain. If I go to the Emergency Room, I will tell the Emergency Room provider that I have signed this pain agreement. Failure to do so may result in my discharge from care.

\_\_\_\_\_ 4. **I will not use street drugs while on opioid medicine.** If I have misused substances or alcohol in the past, I have discussed this with my provider. I agree to provide urine and blood for drug screening at any time my provider asks me. These tests will show the use of prescription and street drugs.

- I will not use any drugs that were not prescribed for me.

\_\_\_\_\_ 5. **I will tell my provider right away if I become pregnant or am planning to become pregnant.**

\_\_\_\_\_ 6. **I will keep my appointments.**

\_\_\_\_\_ 7. **I will keep track of my medicine and prescription refills.** I understand that prescription refills:

- Will be written for a time period that my prescriber believes is safe.
- Will **not** be given if I:
  - Run out early
  - Lose the prescription
  - Spill or misplace the medicine
  - Have the medicine stolen.
- Will be refilled at the same pharmacy unless I have made other plans with my provider.

\_\_\_\_\_ 8. **I will keep my opioid medicine safe in a LOCKED place.**

- I understand that the opioid medicine is **only for my use**. The medicine should never be given or sold to others.
- If I have children in the house, I will ask the pharmacy for a childproof top.
- If my medicine is stolen, I will report this to my local police department. I will also get a stolen item report.

\_\_\_\_\_ 9. **I have received education about my opioid medicine. I have had the chance to ask my provider questions about my opioid medicine.**

\_\_\_\_\_ 10. **I understand that I need to follow all of the above conditions. If I do not follow these conditions, my provider may no longer prescribe opioid medicines for me.** I also understand that if I have a problem or question with any of the above information, I will discuss this with my provider.

\_\_\_\_\_ 11. **I understand the importance of obtaining my opioid prescription from one prescriber and one pharmacy.**

**My Prescriber I agree to obtain my opioid prescription from:** \_\_\_\_\_

**My PHARMACY I agree to obtain my opioid prescription from:** \_\_\_\_\_

**I will report side effects to:** \_\_\_\_\_

**The OPIOID medicine that I have been prescribed is:** \_\_\_\_\_

I understand that the effect of my medicine will be reviewed with my provider on a regular basis. If my daily function or quality of life does not get better from the opioid medicine, it may be stopped. In that case, I will follow my provider's direction to slowly stop my opioid medicine.

I have read the above information (or it has been read to me) and have received a copy of the agreement. I understand my responsibilities and agree to these conditions while receiving opioid medicines.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date

## Opioid Use Disorder

### Community Principles of Pain Management

Prescription drug abuse continues as a health care problem in our nation and state. Despite the fact that the NYS PDMP (Prescription Drug Monitoring Program, has yielded a 75% improvement in “doctor shopping” for opioid prescriptions, since 2013, death by overdose on prescription opioids remains significant in NYS (4.9/100,000 in 2012,2013,2014)<sup>1</sup>

In 2005-2014 unintentional injury (where overdoses are classified) was the Number one cause of death for ages 15-44. (Suicide was number 4. Homicide number 5 for this age group)<sup>2</sup> According to the 2009 Partnership Attitude Tracking Study, over half of teens agree prescription drugs are easier to get than illegal drugs. Most teens surveyed believe that the prescription drugs are being taken from the family medicine cabinet. 1 in 7 teens in grades 9-12 have reported taking a prescription pain reliever for non-medicinal purposes in the past year.

Though the most recent data in NYS shows a significant increase in heroin and fentanyl in overdose deaths (4.2/100,000)<sup>1</sup>, prescription opioids remain a major source of addiction, and overdose deaths.

When treating a patient with chronic pain, there must be a balance of controlling the individual's pain with minimizing the risks of treatment. Risk assessment should be conducted prior to initiating opioid therapy. Patients should be assessed for known risk factors. Here is a list of items that elevate a patient's risk for medication misuse and addiction:

- Personal or family history of substance or ETOH abuse
- History of pre-adolescent sexual abuse
- Psychiatric illnesses
- Poor reliability/compliance with medical care
- Poor social support or unstable living circumstances
- Youth (age <45)
- Smoking

These risk factors do not exclude an individual from receiving proper pain treatment, but would suggest that this patient may require strict or frequent monitoring. Some aberrant drug taking behaviors are more obvious (such as doctor shopping, prescription forgery, inappropriate route of administration), while others are less suggestive (such as requesting specific drugs, multiple occasions of non-adherence with therapy, resistance to a change in therapy).<sup>6</sup>

Numerous screening tests are available to assist with risk assessment, including the Opioid Risk Tool (ORT)<sup>5</sup>, the DIRE (diagnosis, intractability, risk, efficacy)<sup>6,7</sup>, and the SOAPP (screeener and opioid assessment for patients with pain)<sup>8</sup>. The Opioid Risk Tool ORT<sup>8</sup> is a simple five question survey that can predict an individual's risk. The ORT and DIRE are probably the two most widely used screening tools. Other helpful tools include prescription monitoring programs (available in most states, including New York State), random urine drug screening, pill counts and patient education.

Terms associated with drug therapy are often used interchangeably; however, they have drastic differences in definition. Below is some of the terminology associated with opioid therapy.<sup>9,10</sup>

- **Opioid Use Disorder** is a medical condition characterized by the compulsive **use of opioids** despite adverse consequences from continued **use** and the development of a withdrawal syndrome when **opioid use** stops.
- **Physical dependence** is a state of adaptation that is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation or rapid dose reduction of a drug, or by administration of an antagonist. This will occur in 100% of patients on chronic opioids.
- **Psychological dependence** is a subjective sense of a need for a specific psychoactive substance, either for its positive effects or to avoid negative effects associated with its abstinence.
- **Tolerance** is increasing amounts of drug are required to produce an equivalent level of efficacy. This too will occur in 100% of patients on chronic opioids.
- **Addiction** is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death. Addictive behavior is much more common in those at risk as identified in a risk assessment tool which should be utilized before prescribing opioids.

The New York State Department of Health maintains a secure website which provides information as to whether a patient has received controlled substance prescriptions from two or more physicians and filled them at two or more pharmacies during the previous calendar month. To access this information, a current Health Commerce Account (formerly HPN) is needed. If you do not have an account, visit this website to establish one: <https://hcsteamwork1.health.state.ny.us/pub/top.html>. If you currently have a HCS account but are having difficulty logging in, please contact the Commerce Accounts Management Unit (CAMU) at 1-866-529-1890.

If you have identified an individual who has a problem with opioid use disorder and you are not qualified to treat the patient, assistance is available. Qualified physicians are able to dispense or prescribe medications for the treatment of opioid addiction in treatment settings other than the traditional Opioid Treatment Program (i.e. methadone clinic.) Visit <http://www.buprenorphine.samhsa.gov/> for more information.

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**Methadone is not a first line pain medication and should be used primarily by those with pain and palliative expertise. Despite representing only 2% of opioid prescriptions, methadone has been involved in 30% of opioid related deaths in recent years. Inexperienced prescribers should seek consultation.**

## Background

Methadone is a potent opioid with several favorable characteristics, including oral bioavailability of 80%, no active metabolites requiring dose adjustments in renal impairment, low cost, steady analgesic effect, and (possibly) more efficacy when used for neuropathic pain than other opioids. However, methadone has a long, variable half-life (ranging from 6 to 190 hours depending on the dosage). The rapid titration guidelines used for other opioids do not apply to methadone. The dose should not be increased more frequently than every 4 days in lower doses and 1 to 2 weeks in higher doses. Small changes in total daily dosage may progressively have a larger effect on blood levels when patients are on dosages greater than 30 mg per day. Dose-conversion ratios are complex, non-linear, and vary based on current opioid dosage and individual factors (see table below).

## Conversion table from morphine to methadone (most commonly used in the USA)

24 hour total dose of oral morphine	Conversion ratio (oral morphine: oral methadone)
<30mg	2:1 (2mg morphine to 1mg methadone)
31-99mg	4:1
100-299mg	8:1
300-499mg	12:1
500-999mg	15:1
1000-1200mg	20:1
>1200mg	Consult with palliative care or pain specialist prior to prescribing

Because of the potential for drug accumulation from the long half-life, always write “hold for sedation” when initially prescribing or changing dosages of methadone.

Converting from methadone back to morphine or other opioids is especially complex, because methadone affects more opioid receptors than other opioid analgesics. Assistance from palliative care or pain management experts is highly recommended for such a transition if patients have been more than 30 mg for more than a few weeks.

Because of its long half-life, methadone is better used as a baseline, scheduled analgesic, with shorter-acting opioids such as morphine or hydromorphone used prn. There is some literature suggesting methadone can be used as a prn, however the risks if overused are much greater with methadone. Under most circumstances, unless the prescriber is very familiar with methadone pharmacokinetics and the patient is very reliable, it is safer to use an immediate release opioid as a prn when using methadone as the baseline opioid. The usual calculation ratios and intervals used for determining breakthrough doses of other opioids do not apply to methadone (and fentanyl).

Although the ratio of oral methadone to intravenous methadone may vary from 1:1 to 2:1, when converting from oral to intravenous methadone it is prudent to reduce the total daily dose of methadone by 50%. On the other hand, when converting from intravenous methadone to oral methadone, it is recommended to use the most conservative 1:1 conversion to avoid over-medicating the patient. Closely monitor for under- and over-dosing in all transitions.

## Cautions about Methadone

- The long half-life causes drug accumulation, and can lead to possible sedation, confusion, and respiratory depression, especially in the elderly or with rapid dose adjustments. Respiratory depression must be treated with naloxone infusion due to methadone’s long half-life.
- Methadone in moderate to high dosages can prolong the QTc interval and increase the risk of the potentially lethal *torsades de pointes* arrhythmia. (See below for greater detail)
- Medications that can decrease methadone levels include rifampin, phenytoin, corticosteroids, carbamazepine, bosentan, Phenobarbital, St. John’s Wort, and a number of antiretroviral agents.
- Medications that can increase methadone levels include tricyclic antidepressants,azole antifungals (especially voriconazole), macrolides and fluoroquinolones, amiodarone, selective serotonin reuptake inhibitors (SSRIs), and diazepam. Grapefruit juice and acute ETOH use also can increase methadone levels.
- Methadone has some serotonin activity and can contribute to serotonin syndrome.
- Careful patient selection and counseling should be undertaken to outline risks and benefits when using methadone.

### Sample Calculation – Complete Conversion to Methadone

A 50-year-old woman with metastatic breast cancer has good pain control with sustained-release oral morphine 200 mg, two tablets twice a day. However, she develops persistent myoclonus. A decision is made to rotate opioids to methadone. (Our conversion table [Table 2.1] always requires that the equianalgesic amount of oral morphine be determined to calculate a daily dosage of methadone.)

#### Step 1. Calculate the total daily oral morphine dosage.

- Two tablets of 200 mg each, taken twice daily = 800 mg total oral morphine per day

#### Step 2. Convert to methadone.

- For a dosage of 800 mg per day, the conversion ratio of morphine to methadone is 15:1 (see “Conversion table from morphine to methadone” on previous page).
- $800 \text{ mg per day oral morphine} \times 1 \text{ mg methadone}/15 \text{ mg oral morphine} = 53 \text{ mg methadone per day}$

#### Step 3. Reduce the dosage because of incomplete cross-tolerance.

- Reduce the equianalgesic dose by 1/2 when switching opioids because of incomplete cross-tolerance.
- $53 \text{ mg} \times 1/2$  equals about 26 mg methadone
- Total daily dosage should be about 26 mg methadone per day.

#### Step 4. Determine dosing schedule.

- Methadone is initially dosed in divided doses three times per day (the analgesic effect is shorter than the half-life, so methadone should be generally given three times per day for pain, even though for methadone maintenance it can be given daily or even less frequently).
- A dosage of about 26 mg per day of methadone can be given as 7.5 mg to 10 mg of methadone three times per day (total daily dose of methadone being either 22.5mg or 30mg respectively).
- When ordering methadone, because of its long and variable half-life, always write “hold for sedation.”

#### Step 5. Choose a prn medication.

- Because of its potentially long half-life, prn doses of methadone are difficult to manage correctly and are subject to completely different rules than other prn opioids. Therefore, *unless you are a very experienced methadone prescriber*, an opioid with a short half-life is highly preferable for prn dosing.

#### Step 6. Determine the prn dose (morphine).

- The prn dose should be 10% of the total daily opioid dosage.
- Because the patient was already on 800 mg per day of oral morphine, the prn dose based on the prior total daily dosage of morphine would be:  $800 \text{ mg oral morphine} \times 10\% = 80 \text{ mg oral morphine every 1 to 2 hours as needed}$ .
- This could be given as 4 cc of 20 mg/cc morphine concentrate or equivalent every 1 to 2 hours as needed.

#### Step 7. Adjustments to regimen

- Due to the variable and often long half life, changes in dosing should be made no more frequently than 4 days. In cases like this where higher doses of methadone are being used, 7-14 days is advised.
- Due to multiple drug interactions, close monitoring of the complete medication list of methadone patients is critical

#### Alternative to Complete Conversion Methadone: Adding Methadone to other LA opioid

- There is theoretical advantage to adding methadone to patients with persistent pain already on other opioids due to its activity on unique opioid and nonopioid receptor sites.
- Several case series are reported with methadone doses ranging from 1mg-2.5mg TID being added to patients with daily morphine equivalent doses of below 100 to over 1000mg. In a few patients, methadone doses reached 40-60mg/day, but many were maintained on as little as 2.5-5mg BID with marked improvement in reported pain.
- Extreme caution should be exercised adding and escalating methadone to other long acting opioids and should only be in special and unusual circumstances. Consultation is strongly advised prior to considering this action.

#### Practical facts

- Tablets 5, 10mg; Liquid 1mg/mL, 2mg/mL; 10mg/ml. The 40mg tablets are approved for detox and addiction tx only.
- Tablets can be crushed and are reasonably well absorbed rectally if necessary.
- Cost of methadone: 1/10 morphine sulfate ER, 1/75 oxycodone ER, 1/15 of transdermal fentanyl.
- Any physician with a Schedule II DEA license can prescribe methadone for pain. A special license is only required when using for the treatment of addiction. **(N.B. Must write “for pain” on the prescription when used for pain.)**
- Seek consultation if converting from large doses of other opioids, converting to IV, or if inexperienced.

## QTc Prolongation

- Depending on the goals of treatment, the presence of associated heart disease, the patient's prognosis, and the presence of other medications that prolong QTc, ECG monitoring may be indicated.
- If risk factors present, get baseline QTc.
  - Previous QTc > 450ms or known congenital long QTc syndrome
  - Underlying cardiac abnormalities, especially hx of ventricular arrhythmias
  - Use of other medications that prolong QTc (e.g. antipsychotics)
  - Electrolyte abnormalities (especially low K and Mg)
  - Hypothyroidism
- Begin monitoring after each dosage change for patients when they approach 30-60mg mg of methadone per day. Exactly what dose to begin monitoring in low risk patients remains unclear.
- For high-risk patients, monitor after initiation and each increase.
- Once a new steady state has been achieved, repeat ECG; generally about 4-7 days.
- There is no need for repeated checking unless dose is changed or another drug is added that would raise the blood level or affect the QTc.
- If QTc becomes significantly prolonged (QTc 450-499 milliseconds = moderate risk; QTc > 500 milliseconds = high risk), consider lowering the methadone dosage or rotating to an alternate opioid. Formal or informal consultation with palliative care, acute pain service, cardiology, and pharmacy should be considered.

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## Buprenorphine for the Treatment of Pain

### Background

Buprenorphine is a semi-synthetic thebaine derivative, categorized as a mixed partial agonist opioid receptor modulator (opioid agonist-antagonist). It binds to various opioid receptors, and acts as a partial agonist at mu-opioid receptors and as an antagonist at kappa receptors. This opioid is used to treat opioid addiction in higher doses and chronic pain in lower doses. There are two properties that distinguish buprenorphine from other opioids. First, a ceiling effect occurs as the dose is increased. This contributes greatly to its safety profile but may limit its usefulness for treatment of severe, escalating pain. In other words, at high doses, the respiratory depressive and analgesic effects level off. In overdose situations, however, respiratory depression can still occur and will be more difficult to treat with naloxone compared to overdoses with other opioids due to buprenorphine's very tight binding to opioid receptors (very high naloxone doses of 10-35mg may be required).

Secondly, it has a bell-shaped dose-response curve. At moderate to high doses, the euphoric effects also level off, thus lowering its potential for misuse and overdose. The abuse potential of buprenorphine, although low, is further reduced in a transdermal preparation because the plasma levels slowly rise to a therapeutic level, unlike the rapid peak level that occurs with other formulations.

Buprenorphine has poor oral bioavailability due to significant first pass metabolism and therefore is not offered as an oral formulation. Buprenorphine is highly lipophilic and well absorbed by the oral mucosa. As such, transdermal, sublingual, and buccal formulations are available in addition to an injectable (intravenous/intramuscular) formulation.

Buprenorphine is currently available in four types of single agent products:

1. Butrans transdermal patch
2. Belbuca buccal film
3. Subutex sublingual tablet
4. Buprenex injectable solution

Butrans and Belbuca are FDA indicated for the treatment of chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. Subutex is **not** FDA indicated for treatment of acute or chronic pain and carries a manufacturer warning against use as an analgesic due to reported deaths of opioid naïve patients receiving a buprenorphine 2 mg sublingual dose. Sublingual buprenorphine has been successfully studied for postoperative pain control, although caution is warranted if using off label for this indication given the manufacturer warning of fatal overdose at 2 mg in opioid naïve patients (Johnson, Fudala, Payne, 2005). Buprenex is indicated for acute moderate to severe pain. Buprenex has a slow onset of analgesic effect (15 minutes to onset, 1-3 hours to peak effect) and therefore may not be considered an ideal analgesic choice for acute pain management in comparison to other injectable opioids. Parenteral buprenorphine is approximately 30 times more potent than parenteral morphine (buprenorphine 0.3 mg ~ morphine 10 mg). Please note that all buprenorphine formulations do still carry a black box warning due to the risk of severe, life-threatening respiratory depression

Buprenorphine is also available in combination with naloxone for the treatment of substance abuse disorder in products such as Bunavail, Suboxone, and Zubsolv. These medications when used for opioid dependence are limited for use by qualified prescribers.

### Initial dosing of Butrans patch:

For Opioid naïve patients: initiate treatment with a 5mcg/hr patch, replaced weekly.

Conversion from Other Opioids to Butrans: Discontinue all other around-the-clock opioids when Butrans therapy is initiated to reduce potential of precipitated withdrawal. Initial Butrans dose:

Previous Opioid Analgesic Daily Dose (Oral Morphine Equivalent)	<30 mg	30-80 mg
	↓	↓
Recommended BUTRANS Starting Dose	5 mcg/hour patch	10 mcg/hour patch

BUTRANS 20 mcg/hour may not provide adequate analgesia for patients requiring greater than 80 mg/day oral morphine equivalent. Consider the use of an alternate analgesic. Limitations of Use: Do not exceed a dose of one 20 mcg/hour Butrans system due to the risk of QTc interval prolongation. Use with caution when prescribing with other medications which increase the QTc interval.

### Initial dosing of Belbuca buccal strips:

For Opioid naïve patients: initiate treatment with a 75 mcg film once daily or, if tolerated, every 12 hrs.

Conversion from Other Opioids to Belbuca: To reduce the risk of opioid withdrawal, taper patients to no more than 30mg oral morphine equivalent daily before beginning Belbuca. Initial Belbuca dose:

Previous Opioid Analgesic Daily Dose (Oral Morphine Equivalent) before taper	<30 mg	30-89 mg	90-160 mg
	↓	↓	↓
Recommended BELBUCA Starting Dose	75mcg QD-BID	150mcg q12h	300mcg q12h

BELBUCA may not provide adequate analgesia for patients requiring greater than 160 mg oral morphine equivalent per day. Consider the use of an alternate analgesic. The maximum daily dose of Belbuca is 900mcg.

### Initial dosing of Buprenex injectable (IV/IM) formulation:

The usual dosage for persons 13 years of age and over is 1 mL buprenorphine hydrochloride injection (0.3 mg buprenorphine) given by deep intramuscular or slow (over at least 2 minutes) intravenous injection at up to 6-hour intervals, as needed. Repeat once (up to 0.3 mg) if required, 30 to 60 minutes after initial dosage, giving consideration to previous dose pharmacokinetics, and thereafter only as needed.

In high-risk patients (e.g., elderly, debilitated, presence of respiratory disease, etc.) and/or in patients where other CNS depressants are present, such as in the immediate postoperative period, the dose should be reduced by approximately one-half. Extra caution should be exercised with the intravenous route of administration, particularly with the initial dose.

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## Naloxone for Opioid Safety:

### A guideline for increasing community access to naloxone.

On March 15, 2016, the Centers for Disease Control and Prevention (CDC) published *Prescribing Opioids for Chronic Pain*. These guidelines indicate clinicians should offer naloxone when factors that increase risk for opioid overdose are present, such as history of overdose, history of substance use disorder, higher opioid dosages ( $\geq 50$  mg oral morphine equivalents/day), or concurrent benzodiazepine use.<sup>^</sup>

Nationally, many key stakeholders endorse increasing community access to naloxone, including the [CDC, Attorney General, Surgeon General, Food and Drug Administration, World Health Organization, American Medical Association, American Society of Addiction Medicine, American Public Health Association, National Association of Drug Diversion Investigators, and the Office for National Drug Control Policy](#).

**Naloxone may be offered to anyone who feels they are at risk for witnessing a drug overdose.**

**Naloxone may be prescribed to patients at increased risk for opioid overdose including:**

- History of addiction, drug abuse, or drug overdose
- Moderate or high risk of opioid addiction (score of 4 or greater on the Opioid Risk Tool)
- Long-acting opioid use (sustained or extended-release oral formulation, fentanyl patch, or methadone)
- Oral morphine equivalents of 50 mg or more per day (*50 mg oral hydrocodone/day, 30 mg oral oxycodone/day, 12.5 mg oral hydromorphone/day, ~12 mg oral methadone/day, any strength fentanyl patch*)
- Concurrent opioid and benzodiazepine use

**There are two ways to offer naloxone:**

#### NON-PRESCRIPTION

Any patient or non-patient community member may pick up a Naloxone Kit.

Kits contain two prefilled naloxone syringes that require a nasal atomizer be affixed prior to administration. Free Kits are available at NYS Dept of Health registered programs found at: [http://www.health.ny.gov/diseases/aids/general/resources/ooop\\_directory/index.htm](http://www.health.ny.gov/diseases/aids/general/resources/ooop_directory/index.htm).

Some community pharmacies also carry kits for purchase (approximately \$60).

#### PRESCRIPTION

Patients may pick up a prescription for naloxone at their usual pharmacy.

Insurance coverage of prescription naloxone is required by the Centers for Medicare and Medicaid Services.

Naloxone may be prescribed via any of the following regimens:



	INTRA-NASAL	INTRA-NASAL RELEASED IN 2016	IM	AUTO-IM
<b>STRENGTH</b>	Naloxone 1mg/1mL	Naloxone 4mg/0.1mL	Naloxone 0.4mg/1mL	Naloxone 0.4mg/1mL
<b>QUANTITY</b>	Two 2 mL prefilled Luer-Jet™ Luer-Lock needleless syringe PLUS 2 mucosal atomizer devices (MAD-300)	#1 two pack	Two single-use 1 mL vials	#1 two pack
<b>SIG</b> <i>for suspected opioid overdose</i>	Spray 1 mL (half of the syringe) into each nostril. Repeat after 2-3 minutes if no or minimal response.	Spray full dose into one nostril. Repeat into other nostril after 2-3 minutes if no or minimal response.	Inject 1 mL in shoulder or thigh. Repeat after 2-3 minutes if no or minimal response.	Use as directed by voice-prompt. Press black side firmly on outer thigh. Repeat after 2-3 minutes if no or minimal response.
<b>REFILLS</b>	Two	Two	Two	Two

Graphic reprinted with permission from *Preventing Fatal Opioid Overdose Among Your Patients* [www.prescribetoavoid.org](http://www.prescribetoavoid.org)

<sup>^</sup>Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>.

## Opioid & Sedative Guidelines for Emergency Department and Urgent Care Providers

ED or Urgent Care providers **should not**

- dispense prescriptions for controlled substances that were lost, destroyed, stolen, or finished prematurely.
- prescribe or provide doses of methadone, buprenorphine (Suboxone), or long acting pain medications.

ED or Urgent Care providers **should** prescribe opiates for acute, short term pain for the shortest duration appropriate with national guidelines, generally no more than 3 days.

ED providers are **strongly encouraged** to access iStop when they have a reasonable suspicion that the patient has recently been prescribed a controlled substance by another provider, or if they suspect inappropriate use of opiates.

A dedicated primary care provider or relevant long-term care specialist (rather than ED or Urgent Care) should provide all opiates and sedatives to treat chronic ongoing condition.

An acute need for an opioid prescription **is not indicated** for any of the following signs/symptoms/conditions<sup>1</sup>:

- Abrasions
- Cellulitis
- Chest pain
- Chronic pain, such as back pain, abdominal pain, extremity pain, and headaches
- Contusions
- Cough
- Dental pain without acute trauma
- Dysuria
- Ear pain
- Hemorrhoids
- Lacerations
- Neck pain
- Sexually transmitted disease
- Sprains/strains from trauma
- Throat pain
- Urinary tract infection

Many patients who present to the ED showing signs of addiction are often at their most vulnerable. These patients may be open to active discussion regarding their addictions and receptive to suggestions for treatment of their addiction. ED providers are **encouraged to 1)** counsel patients on appropriate use of opiates when prescribed for acute pain and 2) provide guidance on resources available for addiction treatment when inappropriate use of opiates or addiction is suspected.

Resources and provider listings can be found on this website:

<https://ncadd-ra.org/news-resources/resources-advocacy-research>

<sup>1</sup> Guidelines do not exclude the use of clinical judgment in the management of patients, but detailed documentation is indicated to support treatment outside of the recommended guidelines.

*Opiate medications include, but are not limited to: codeine; hydrocodone (Norco, Vicodin, Lortab); oxycodone IR (Percocet) and SR (OxyContin); morphine IR and SR (MS Contin); hydromorphone IR (Dilaudid) and ER (Exalgo ER); methadone; fentanyl; oxymorphone ER (Opana ER).*

*Sedative medications include, but are not limited to: alprazolam (Xanax); clonazepam (Klonopin); diazepam (Valium); lorazepam (Ativan).*

Guidelines reviewed by Rochester Regional Healthcare Association Medical Director Committee subgroup and Chiefs of Emergency Medicine from member hospitals.

## 2017 Community Principles of Pain Management References

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Visit [CompassionAndSupport.org](http://CompassionAndSupport.org) for additional resources.

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