Managing Chronic Pain: A Multi-Modal Approach Involving Pharmacotherapy

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Objectives/Expectations

At the completion of this activity, the participant will be able to:

- Review a chronic pain framework and describe the multi-modal approach to chronic pain management and how pharmacological therapy applies
- Review the pharmacology of commonly used medications to manage chronic pain
- Understand the applications of naloxone in opioid overdose

Correct Assessment of Chronic Pain Should Inform the **Rational Selection** of Pharmacotherapy

TYPES OF PAIN

Nociceptive Pain

Pain related to *damage* of somatic or visceral tissue, due to trauma or inflammation

EXAMPLES: rheumatoid arthritis, osteoarthritis, gout

Neuropathic Pain

Pain related to damage of peripheral or central nerves

EXAMPLES: painful diabetic peripheral neuropathy, postherpetic neuralgia

Sensory Hypersensitivity

Pain **without identifiable nerve or tissue damage**; thought to result from persistent neuronal dysregulation

EXAMPLE: fibromyalgia

FIRST-LINE PHARMACOLOGIC TREATMENT (based on strength of clinical evidence)

NSAIDs, acetaminophen[1-5]
Treatment of underlying inflammatory condition may include corticosteroids, biologics and disease-modifying agents

AEDs, SNRIs, TCAs[1,3,5-8]

OPIOID USE

When other treatment options are inadequate, Opioids should be considered for the management of pain severe enough to require daily, around-the-clock, long-term treatment [3,5,6,8-12]

Opioids should be avoided in patients with sensory hypersensitivity.[13-15]

Adapted from Stanos et al. Postgrad Med. 2016 May 11. [Epub ahead of print]

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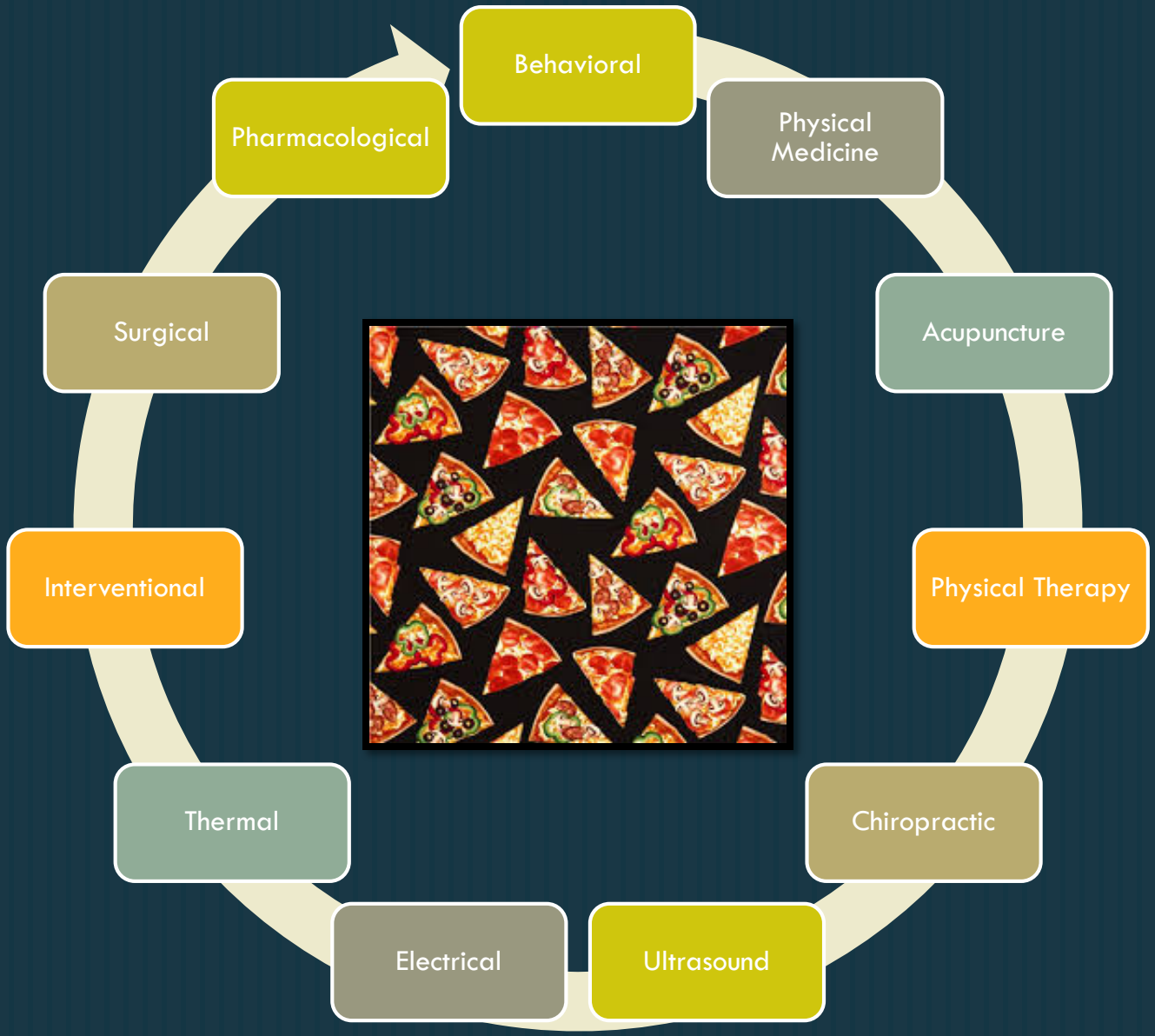
The Multi-Modal Approach to Pain



Pharmacological therapy is only ONE slice of the pie

Pharmacological Options

Mild/Moderate Pain

- Non-opioid analgesic
  - APAP, Aspirin, NSAIDs, COX-2 Inhibitors
- Tramadol

Neuropathic pain

- Anti-depressants (TCAs or SNRIs)
- Anti-epileptics (gabapentin, pregabalin)

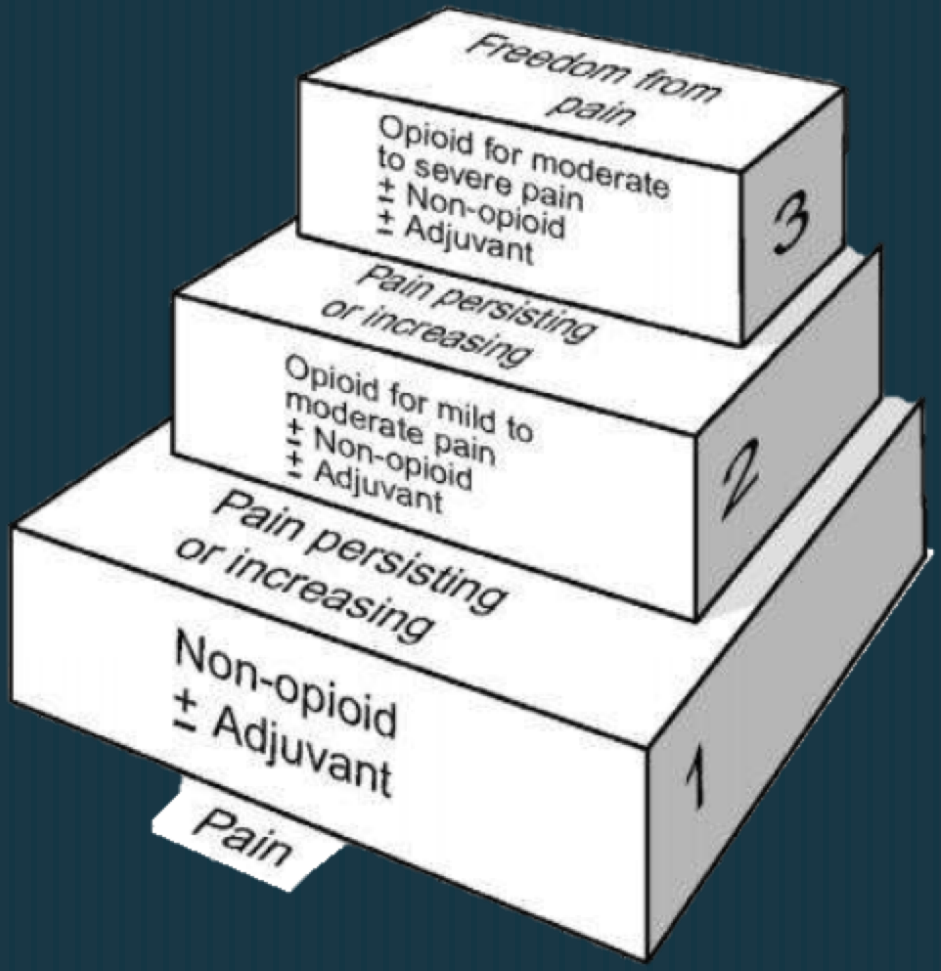
Adjuvant

- Muscle relaxants
- Topical analgesics

Severe pain

- Opioids

World Health Organization Step Ladder



Severe
(Pain Score: 7-10)

Moderate to Severe
(Pain Score: 4-6)

Mild to Moderate
(Pain Score: 1-3)

Table of Select Non-Opioid Analgesics

Drug	Average Dose	Frequency	Maximum Dose	Side effects
Acetaminophen	500-1000mg	Q4-6H	4 grams	Liver toxicity in overdose
Aspirin	500-1000mg	Q4-6H	4 grams	GI, bleeding, renal
Ibuprofen	200-400mg	Q4-6H	2400mg	GI, bleeding, renal
Naproxen	250-500mg	Q6-8H	1500mg	GI, bleeding, renal
Ketorolac	15-30mg	Q6H	150 mg first day then, 120mg thereafter. 5 day maximum	GI, bleeding, renal
Celecoxib	100-200mg	Q12H	400mg	GI (less), bleeding, renal Cardiac/Stroke risk?

Acetaminophen (Tylenol)

Most commonly administered OTC analgesic

Known as paracetamol in Europe

Useful in mild pain, headaches, fever

- NO anti-inflammatory properties

Commonly combined with opioids to reduce the opioid dose (difficult to titrate)

Ex. Acetaminophen Combination Prescription Products

Product Name	Components	APAP strength
Tylenol w/ Codeine®	APAP Codeine	300mg
Lortab®	APAP Hydrocodone	500mg
Norco®	APAP Hydrocodone	325mg
Vicodin®	APAP Hydrocodone	500, 750mg (ES)
Percocet®	APAP Oxycodone	325, 500, 650mg
Ultracet®	APAP Tramadol	325mg
Fioricet®	APAP Butalbital Caffeine	325mg

FDA Update: March 26, 2014

All manufacturers have discontinued combination products with APAP >325mg

NSAIDs

Primarily used for mild to moderate pain

- Anti-inflammatory at higher doses

Ketorolac often used for severe pain (it works)

- 5 day maximum (bleeding risks)

Tissue injury, strains, sprains, headaches, arthritis, gout

Synergistic with opioids

Common side effects:

- Bleeding (interfering with platelet aggregation)
- GI upset
- Nephrotoxic (reversible, vasoconstriction)
- CVD (interferes with ASA, potentiate heart failure, raises BP)?

NSAIDs and Cardiovascular Risk

FDA Warnings for all NSAIDs

- The risk of CV events can occur as early as the first weeks and may increase with longer use
- Risk appears greater at higher doses
- Individual CV risk profiles should be evaluated prior to prescribing
- Administration of NSAIDs may interfere with apsirin's cardioprotective effect
- NSAIDs should be avoided in heart failure patients
- Lowest effect dose should be used for the shortest duraction
- Use with caution in HTN patients

https://www.fda.gov/Drugs/DrugSafety/ucm451800.htm

Tramadol and Tapentadol

Not acetaminophen

- Can be an option in cirrhosis/alcoholic patients

Not an NSAID

- Can be an option in GI bleeds/ARF
- Note: Avoid in severe renal impairment

Not a true opioid

- Binds to the mu-receptor + inhibits serotonin/NE
- Similar side effects as opioids (but less)

Dosing

- Tramadol (Ultram) 25mg PO Q4-6H (max 300mg…Schedule IV in NY)
- Tapentadol (Nucynta) 50mg PO Q4-6H (max 600mg)…Schedule II in NY)

Note: Risk of interaction with serotoninergic drugs (serotonin syndrome)

Q2

A patient with a history of cirrhosis and GI bleeds complains of moderate pain.

The healthcare provider is reluctant to start opioids.

Which of the following would be a good option for this patient?

A. Acetaminophen 500mg PO Q6H
B. Ibuprofen 400mg PO Q8H
C. Oxycodone 5mg PO Q6H
D. Tramadol 25mg PO Q6H

Neuropathic Pain

Anti-depressants (TCAs)

- Neuropathic Pain
  - Amitriptyline
  - Doxepin
  - Imipramine
  - Nortriptyline
  - Desipramine

Anti-depressants (SNRIs)

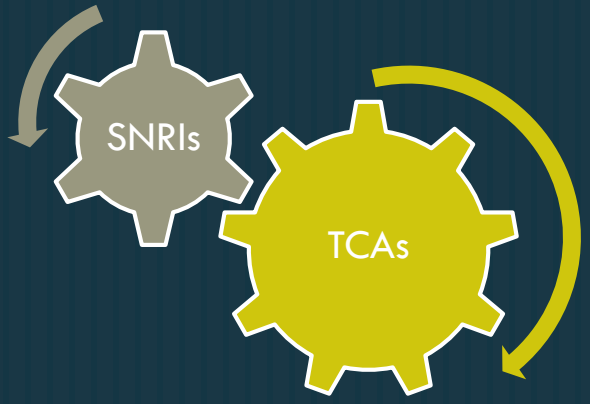
- Neuropathic Pain
  - Duloxetine
  - Milnacipran
  - Venlafaxine

Anti-convulsants

- Neuropathic Pain
  - Gabapentin
  - Pregabalin
  - Carbamazepine

Anti-depressants for Pain

- Considered 1st or 2nd line for neuropathic pain
- Analgesic effect appears sooner vs. anti-depressant effects
- Doses are lower for pain vs. depression
- All TCAs are used off-label for pain (no FDA indication)
- Some SNRIs (duloxetine & milnacipran) have FDA indications



Structurally similar agents

TCAs

Drug	Starting Doses for Pain	Frequency	Maximum Dose	Side effects
Amitriptyline (Elavil)	25-50mg	daily	150mg/day	• Anticholinergic • Orthostatic hypotension • QT prolongation • Sedation
Desipramine (Norpramin)	25mg	daily	150mg/day	
Imipramine (Tofranil)	50mg	daily	150mg/day	
Nortriptyline (Pamelor)	10-20mg	daily	160mg/day	

Should all be taken at bedtime for sedation reasons

SNRI's

Drug	Starting Doses for Pain	Frequency	Maximum Dose	Side effects
Duloxetine (Cymbalta)	60mg	daily	120mg/day	• Headache • Drowsiness • Weight loss
Milnacipran (Savella) ***Approved only for Fibromyalgia***	50mg	Twice daily	200mg/day	• Headache • Hot flashes • Nausea
Venlafaxine (Effexor) ***Used "off label"***	37.5 – 75mg	daily	225mg/day	• Headache • Drowsiness • Sweating • Weakness • Hypertension

Anti-convulsants for Pain

- Considered 1st or 2nd line for neuropathic pain
- Binds to calcium channels to inhibit neurotransmitter release
- Used for diabetic neuropathy, post-herpetic neuralgia, fibromyalgia
- Pregabalin may work faster than gabapentin
- Pregabalin is a Schedule V medication (euphoria)
- Carbamazepine approved for Trigeminal Neuralgia (5th cranial nerve)

Anti-convulsants for Pain

Drug	Starting Doses for Pain	Frequency	Maximum Dose	Side effects
Gapabentin (Neurontin)	300mg	daily	3600mg/day	• Dizziness • Sedation
Pregabalin (Lyrica)	75mg	Twice daily	600mg/day	• Peripheral edema • Dizziness • Drowsiness
Carbamazepine (Topamax)	100mg	Twice daily	1200mg/day	• Dizziness • Nausea

Muscle Relaxants

Antispasmodics (skeletal muscle relaxants)

Effect may be more from sedation

May cause CNS depression (careful in combination)

Drug	Starting Doses	Frequency	Maximum Dose	Side effects
Cyclobenzaprine (Flexeril)	5mg	TID	30mg/day	• Drowsiness • Low muscle tone • Hypotension • Bradycardia
Baclofen (Lioresal)	5mg	TID	80mg/day	
Methocarbamol (Robaxin)	1500mg	QID	6000mg/day	
Metaxalone (Skelaxin)	800mg	QID	3200mg/day	

Don't forget your Topical Options..

NSAIDs	• Diclofenac 1.5% topical (Voltaren Gel)
Local Anesthetics	• 5% Lidocaine patch or gel • Good for localized neuropathic pain
Counterirritants	• Capsaicin 0.025% cream (Zostix) • Methylsalicylate 15% cream (BenGay) • Menthol 2.5% cream (Icy Hot) • Camphor 11% (Tiger Balm)

Opium Poppy Plant

The Good

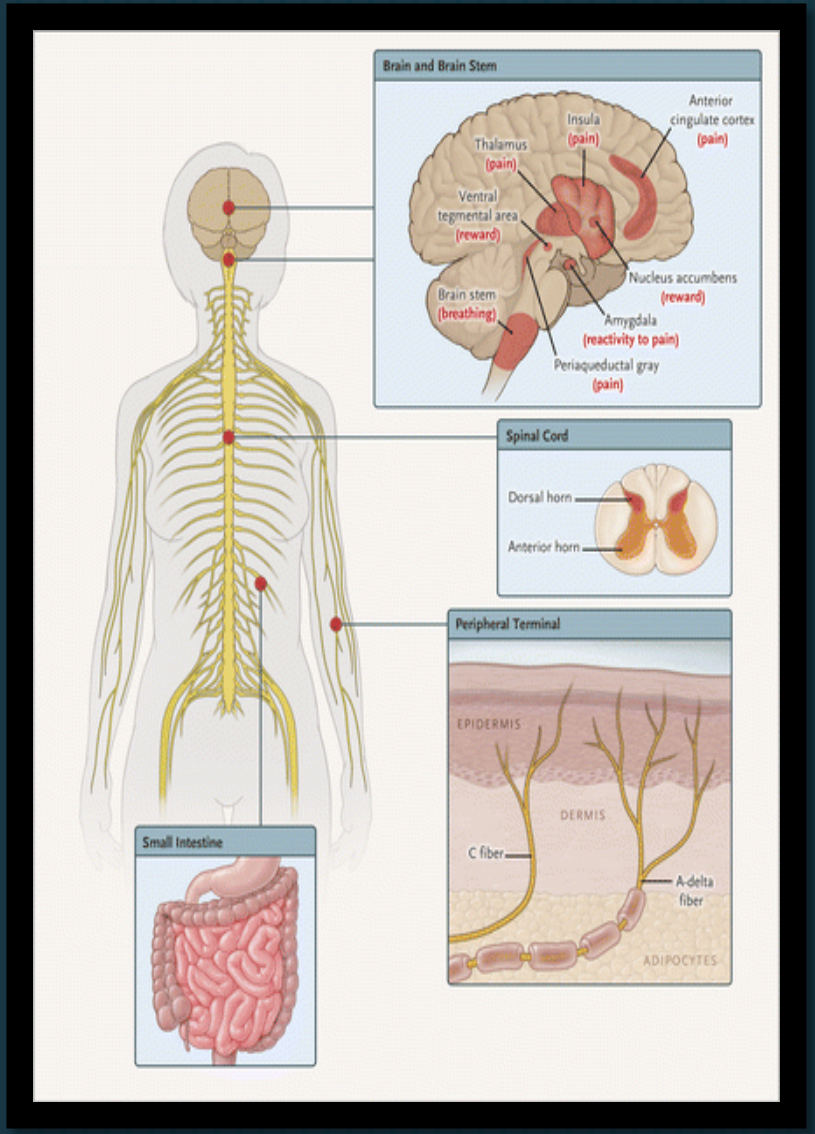
The Bad

The Ugly

Opioid Receptors

- Three opioid receptors:
  - mu (μ)
  - delta (δ)
  - kappa (κ)

- Mechanism of Action:
- All opioids produce effects through binding mu-receptors
  - Full agonists
  - Partial agonists
  - Mixed (partial agonists/antagonists)
  - Antagonists



mu receptors found throughout the body (CNS + PNS + Stomach)

Note: we have endogenous opioids called "endorphins"

http://www.nejm.org/na101/home/literatum/publisher/mms/journals/content/nejm/2016/nejm_2016.374.issue-13/

Opioid	mu (μ)	delta (δ)	kappa (κ)
Morphine Hydromorphone Oxymorphone Methadone Fentanyl	+++ (full)		
Codeine Hydrocodone Oxycodone	± (partial)		
Buprenorphine	± (mixed)	-- (mixed)	-- (mixed)
Naloxone Naltrexone Methylnaltrexone	--- (antagonist)	- (antagonist)	- (antagonist)

Binding: mu receptors

Desired: analgesia

Other Effects: bradycardia, sedation , euphoria, respiratory depression, dependence , miosis

Medical Uses of Opioids

Severe acute pain	• #1 reason patients seek medical attention • Surgery • Trauma • Opioids indicated
Severe cancer pain	• Opioids indicated
Severe chronic pain	• Very controversial

Cough suppressant	• Dry, non-productive
	  • Example: promethazine + codeine syrup
	  • Dextromethorphan is a derivative of opioids

Diarrhea	• Tincture of Opium • Loperamide is a derivative of opioids
Sedation	• Palliative care
Detoxification	• Opioid abuse

Common Opioids

Codeine	• Used mainly for mild pain or cough (off-label) • Antitussive effects directly suppresses cough reflex in the medulla • Converted to active morphine via CYP2D6
Hydrocodone	• Used in moderate pain with APAP • Converted to hydromorphone by CYPD6
Morphine	• Used for moderate to severe pain • Standard to compare all opioids
Oxycodone	• Used in moderate-severe pain • IR also available with ibuprofen or aspirin
Hydromorphone	• Very potent opioid (severe pain)
Fentanyl	• Most potent opioid (doses are in mcg and NOT mg) • Mainly used in cancer pain or palliative care (sedation)

All C-II medications

Starting Opioids…Not so fast!

Define Treatment Success:

- Weigh expected benefits vs. risks ***carefully*** before initiating opioids
- Relieves pain while body heals and improves function

Opioids do not eliminate the pain:

- Decreases the unpleasantness of pain (perception)
- Patients will report that although pain is still present, it bothers them less

Short acting

- Can be used for severe acute pain
- Start with the lowest dose
- Start with easiest route (PO/IV/PR/PCA)

Long acting

- Not recommended upon initiation
  - Avoid in opioid-naïve patients
- Not used PRN
- Reserved Cancer pain or palliative care
- Controversial for chronic pain

Opioid Equivalence Chart

Opioid	IV (mg)	PO (mg)	Duration of action
Codeine	130	200	3-4h
Tramadol	---	50-100	3-7h
Hydrocodone	---	30	3-5h
Morphine	10	30	3-4h
Oxycodone	---	20	3-5h
Hydromorphone	1.5	7.5	2-3h
Fentanyl	0.1 (100mcg)	---	1–3h

All opioids are considered equipotent at these doses
Can use to convert between opioids

Opioid Conversion

Determine the 24hr total dose of current opioid

Calculate the equianalgesic dose for "new" opioid using chart

Reduce the dose by 25-50% to allow for incomplete cross-tolerance between opioids (if pain was adequately controlled)

Divide the total daily dose of new opioid by number of doses given per day

During the first 24hrs, titrate up if pain still present

Recommended to convert to MORPHINE EQUIVALENT DOSE first (MED)

Keep in mind: All conversions are ESTIMATES (not exact)

NCCN Guidelines. Adult Cancer Pain. V.I. 2016

Discontinuing Opioids

Ideal

- Success of therapy + Quick cessation
- Patient returns to normal daily function

Less ideal

- Failure of therapy (use alternatives)
- Intolerable side effects (opioid rotation)
- Discuss withdrawal symptoms and agree on exit strategy (scheduled taper)

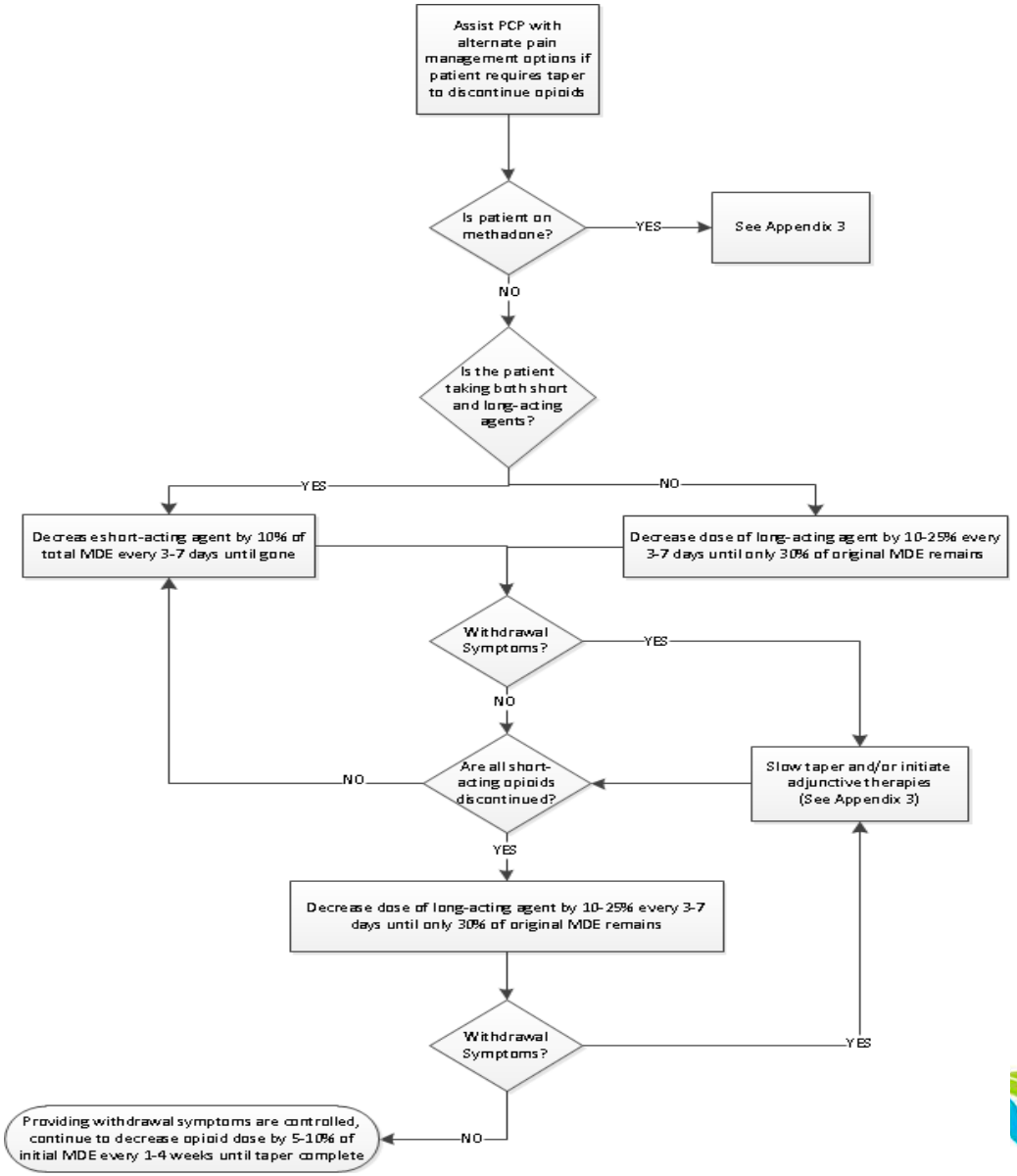
Not ideal at all

- Opioid hyperalgesia
- Development of opioid use disorder

Worse case

- Overdose
- Death

Clinical Pharmacy Opioid Taper Algorithm



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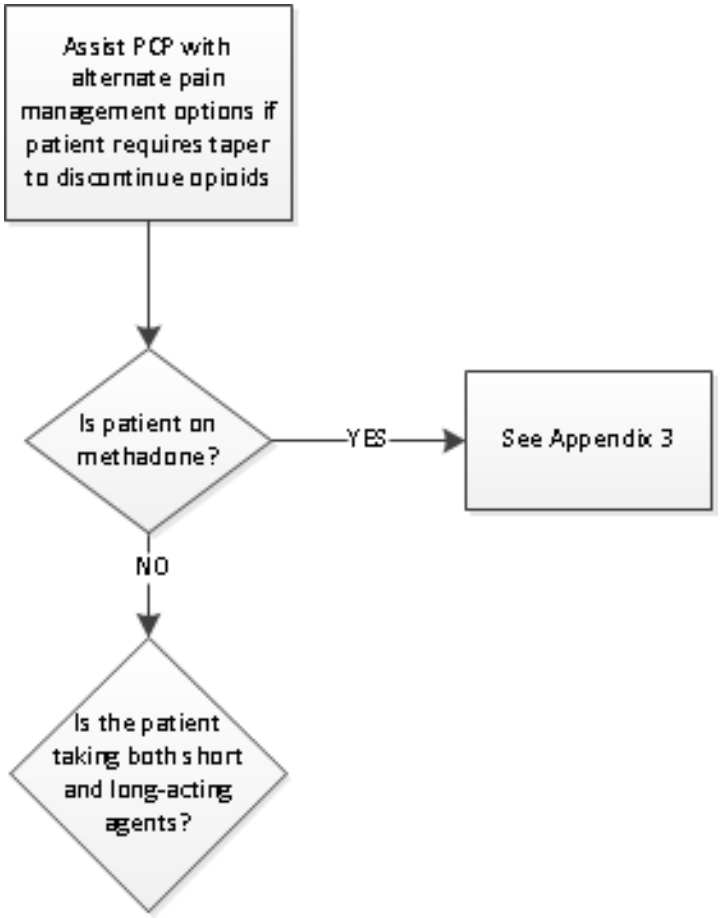
Clinical Pharmacy Opioid Taper Algorithm



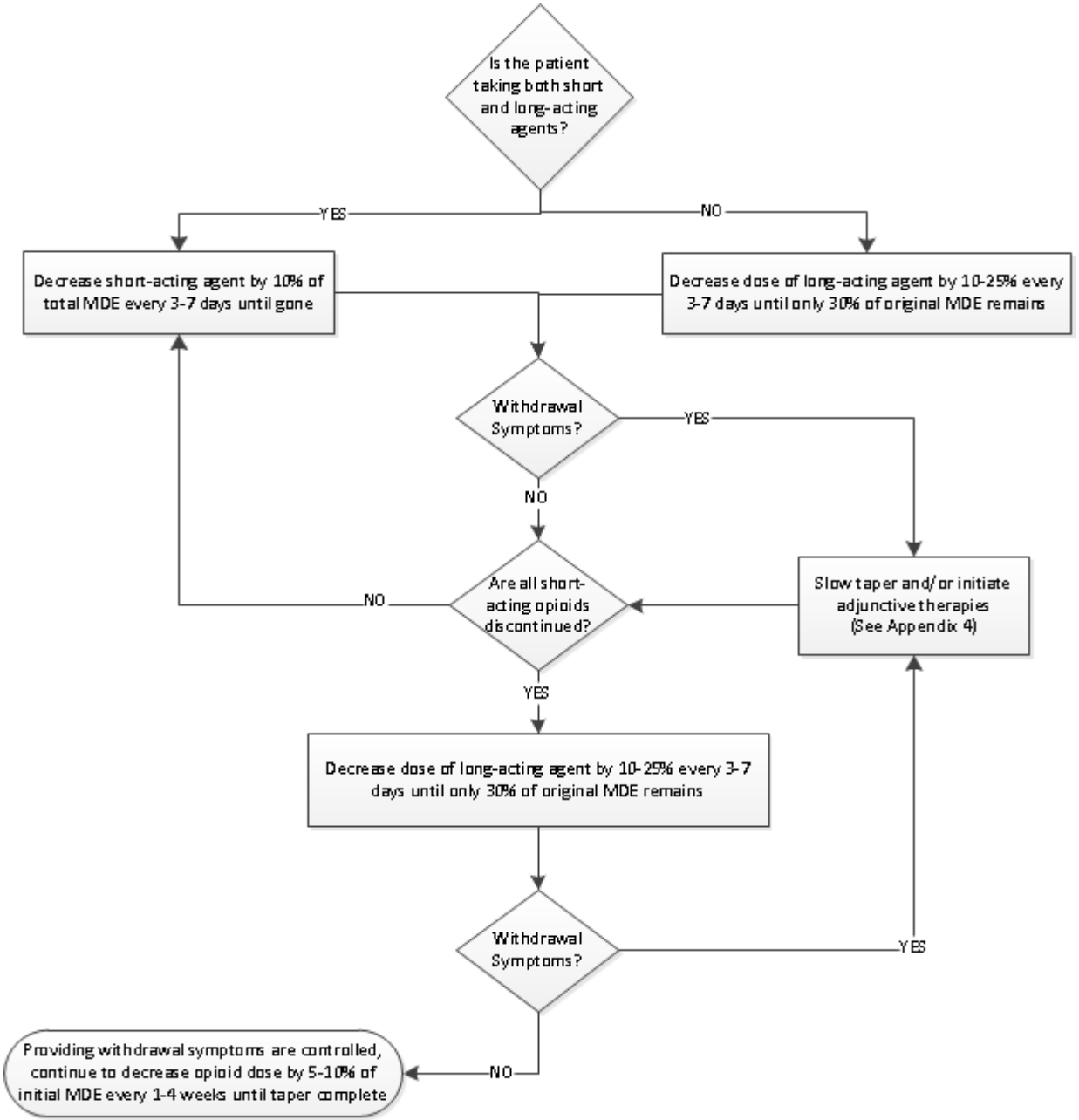
APPENDIX 3 : Tapering Methadone (in the setting of chronic, non-cancer pain)

Suggested Steps for Tapering Methadone:
1.Decrease dose by 20-50% per day until you reach 30mg/day.

2.Then decrease by 5mg/day every 3-5 days to 10mg/day.

3.Then decrease by 2.5mg/day every 3-5 days.

Clinical Pharmacy Opioid Taper Algorithm



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Appendix 2: Morphine Equianalgesic Dose Chart and Calculator

APPENDIX 2
Morphine Equianalgesic Dose Chart and Calculator

Medication	Equi-analgesic doses	Route of Admin	Half-life (hours)	Duration of analgesic effect (hours)	Comments (IR = Immediate Release) (SR= Sustained Release) (ER = Extended Release)
Fentanyl patch£	12.5 mcg/hr*	Transdermal		48-72**	
Levorphanol	4 mg	Oral	11-16	4-8	
Hydromorphone	7.5 mg	Oral	2-3	3-6	IR, SR or ER forms have same equianalgesic potency
Oxymorphone	15 mg	Oral	7-9	4-6	IR and ER forms have same equianalgesic potency
Oxycodone	20 mg	Oral	2-3	3-6	IR and SR forms have same equianalgesic potency
Morphine	30 mg	Oral	2-3	3-6	IR, SR or ER forms have same equianalgesic potency
Hydrocodone	30 mg	Oral	3-4	4-8	
Tramadol (IR)	300mg	Oral	6-9	3-11	
Codeine	200 mg	Oral	2-4	4-6	
Meperidine	300mg	Oral	2.5-4	2-4	

Essentia Health
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Taper Conversion Link

http:www.hca.wa.gov/medicaid/pharmacy/documents/taperschedule.xls

Initial Total Dose

Opioid Type	Baseline Opioid	Current mg/Day	Current MED/Day	% of Total MED
Short Acting	Hydrocodone (Lortab, Vicodin, Zydone, Lorcet)	15	15	20.00%
Long Acting	Oxycodone (OxyContin, Oxycodone ER)	40	60	80.00%
	Total Morphine Equianalgesic Dose		75	

First taper Short Acting Narcotics (Hydrocodone) q week if > 10% of total MED if combined with a long acting opioid.

Week	Day	Total mg/day: dosage schedule	MED of Short Acting Opioid	Week	Day	Total mg/day: dosage schedule	MED of Short Acting Opioid
1	1-7	10	10	6	36-42	0	0
2	8-14	5	5	7	43-49	0	0
3	15-21	0	0	8	50-56	0	0
4	22-28	0	0	9	57-63	0	0
5	29-35	0	0	10	64-70	0	

Then taper long acting narcotics (Oxycodone) weekly by 10% reduction from Initial Total Dose until down to 30% of the initial dose (milligrams). Then, taper by 10% of the remaining 30% of the initial taper (milligrams).

Week	Date	Total mg/day: dosage schedule	MED of Long Acting Opioid	Week	Date	Total mg/day: dosage schedule	MED of Long Acting Opioid	Week	Date	Total mg/day: dosage schedule	MED of Long Acting Opioid
1		35	52.5	7		5	7.5	13			
2		30	45	8		0		14			
3		25	37.5	9				15			
4		20	30	10				16			
5		15	22.5	11				17			
6		10	15	12							

Opioid Withdrawal Symptom Management

- **Opioid withdrawal symptoms <u>should not</u> be treated with opioids or benzodiazepines**
- **First step to management of withdrawal symptoms = SLOW THE TAPER**

Opioid doses of 25-50% of the usual dose will generally prevent severe withdrawal symptoms.

- If needed, adjunctive therapy options:
  - Clonidine 0.1mg PO two to three times daily as needed for hypertension, nausea, cramps, diaphoresis, tachycardia
  - Trazodone 25-50 mg PO at bedtime as needed for insomnia
  - Diphenhydramine 25-50 mg PO every four hours as needed for insomnia, restlessness
  - Ibuprofen 200-400 mg PO every eight hours as needed for muscle aches
  - Acetaminophen 500-1000 mg PO every six hours as needed for muscle aches; do not exceed 4000 mg / 24 hours
  - Loperamide 2 mg PO after each loose stool; do not exceed 16 mg/day

Side Effects of Opioid Use

Short-Term

- Constipation
- Itching
- Nausea & Vomiting
- Respiratory Depression
- Sedation
- QT Prolongation

Long-Term

- Hyperalgesia
- Fractures and falls
- Opioid Use Disorder

The Controversy of Opioids for Chronic Pain

Opioids have not produced the desired outcome for chronic pain

- Can worsen pain (hyperalgesia) and function

Long-term opioid use has NOT been validated in trials

- Most studies only go up to 6 weeks

Escalated doses in chronic pain

- Doses 50-100MED increases mortality 9 fold

Extensive evidence shows the possible harms of opioids

- Abuse, dependence, overdose, side effects, hyperalgesia

Opioids controlling pain is no longer the ultimate goal

- Substantial risk vs. uncertain benefits

There is ~100% agreement that the medical profession has become overly opioid-centric for chronic pain

Speaking of Dose Escalation…

New Opioid Formulations

2013: Zohydro® ER

- Hydrocodone ER 10,15,20,30,40, 50mg ER (BID)
- Can be crushed

2015: Hysingla® ER

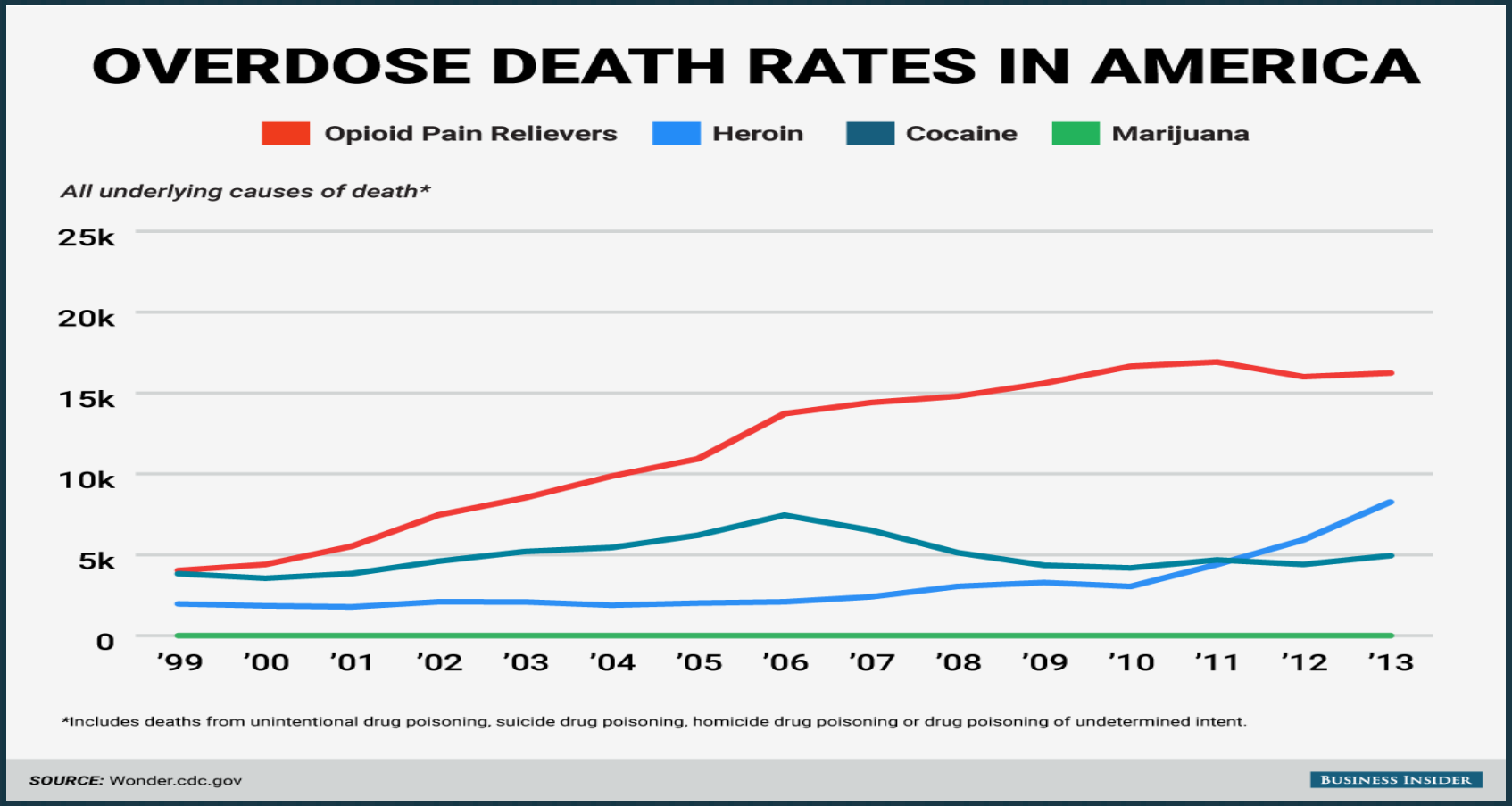
- Hydrocodone ER 20,30,40,60,80,100,120mg ER (once daily)!
- Abuse deterrent formulation

2014: Targiniq® ER

- Oxycodone 40mg + naloxone ER (BID)
- Abuse deterrent formulation

Are we going in the wrong direction?

Mortality from Drug Overdoses



Remember JCAHO mandated pain as the 5th vital sign in 1999?

Increasing prescribing and misleading marketing of opioids for chronic pain

http://www.huffingtonpost.com/2014/02/21/america-heroin-charts_n_4817130.html

How to Recognize an Opioid Overdose

Heavy nodding, snoring, snorting

↓

Unresponsiveness, shallow breathing, skin changes

↓

Fatal overdose

Up to 3 hours (progression not instantaneous)

Miosis

Opioids can cause:

- Constriction of the pupil (appears pinpointed)
- Opposite of mydriasis (dilation of pupil)
- Note: nicotine and cholinergic agents can also cause miosis

Responding to an Overdose

Check for Response

- Shake, Shout, Sternal Rub (grind knuckles into chest bone)

Call 911

- Report overdose
- Time & Location

Administer Naloxone

Resuscitation

- If not breathing, chest compressions (rescue breaths if properly trained)

What is Naloxone?

First approved as Narcan in 1971

- 80% was used for heroin overdoses

Reverses opioid effects

- Effective for 30-90mins

Can cause sudden withdrawal (unpleasant)

- Agitation, hypertension, violent behavior, fever, sweating

Safe and effective

- Not addictive

Pure opioid antagonist at the opioid receptors

- Inserting glue into a door lock
- Does not prevent deaths caused by other drugs
  - Benzodiazepines
  - Alcohol
  - Cocaine

What is Naloxone?

Indication

- Known or suspected overdose of opioids
  - Natural or Synthetic
- Reversal of opioid activity
  - Respiratory depression
  - Itchiness, Nausea

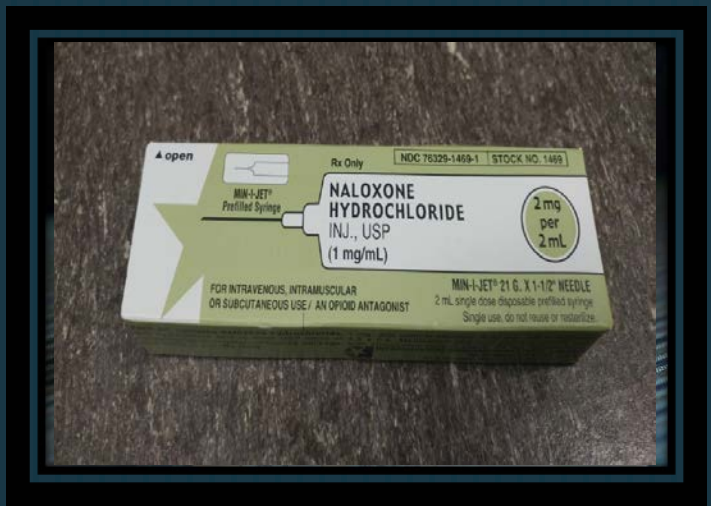
How supplied

- Injection (IV or IM or SQ)
  - 0.4ml=0.4mg x 1 (repeat dose every 2-3 minutes or increase to 2mg if inadequate response)
- Auto-injector
  - 1 dose (0.4mg) IM or SQ x 1 (may repeat every 2-3 minutes)
- Intranasal
  - 4mg x 1 (repeat dose every 2-3 minutes)

Lower doses recommended to prevent sudden opioid withdrawal

Naloxone

IV or IM or Intranasally



Evzio – Auto Injector

Q4

What happens if you administer Naloxone to a person NOT using opioids?

A. Withdrawal
B. Sedation
C. Pain Relief
D. Nothing

Naloxone Prices

Naloxone Product	Manufacturer	Previous price per year	Current Price (2016)
Injectable • 0.4mg/ml vial	Mylan	$23.72 (2014)	$23.72
Auto-Injector (Evzio) • 2 pack pre-filled	Kaleo	$690 (2014)	$4500
Nasal spray • Single use	Adapt	$150 (2015)	$150

Gupta R, Shah N, Ross J. The rising price of naloxone. Dec. 2016. NEJM 375;23. 2213-15

Naloxone kits

- Advising clinicians to co-prescribe with long-term or high dose opioid use

Q5

Which of the following is a recommended route of administration for Naloxone?

A. Intramuscular
B. Intravenous
C. Intranasal
D. Subcutaneous
E. All of the above are recommended routes

Stocking Naloxone

Pharmacies

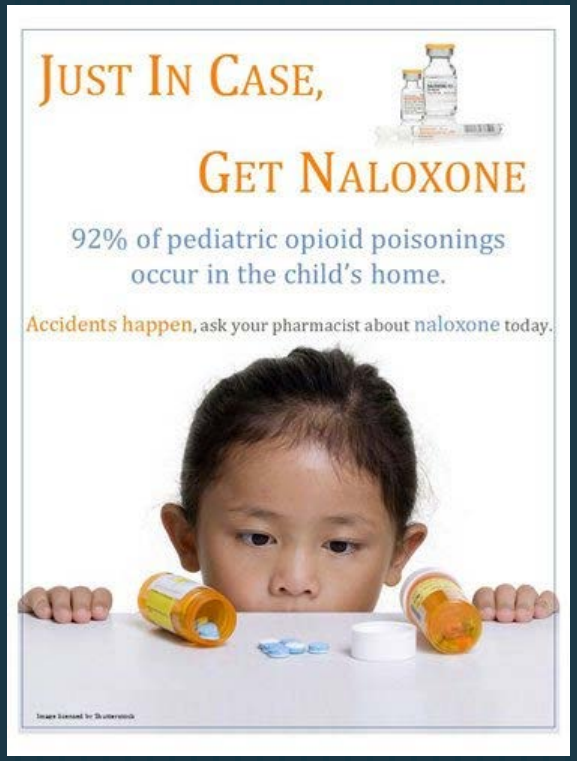
CVS, Walgreens, Meijer, Family Fare

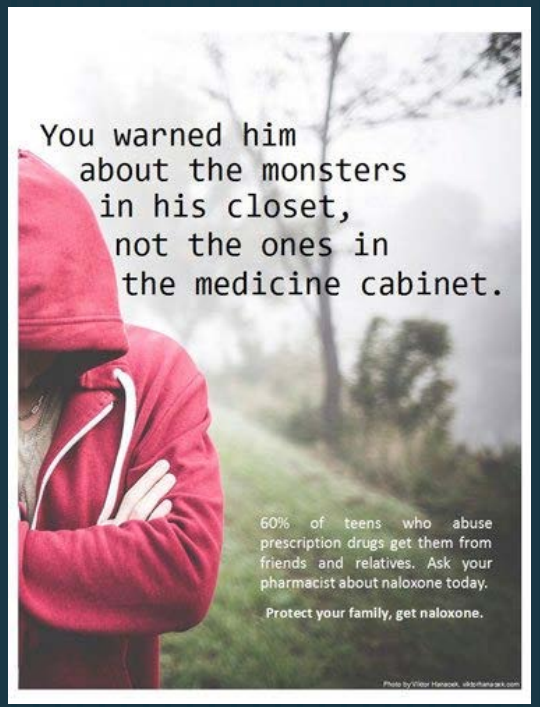
More than half of US states currently with access on shelves

Considered a “standing” order in most approved states, including Michigan

Conclusions

- Pain is the #1 reason to seek medical attention
- Assess pain, establish realistic goals, and form a plan before starting treatment
- Using a multi-modal approach is highly recommended
- Opioids are useful for severe acute and cancer pain
- Recognizing overdoses is important when prescribing opioids





https://neuroethicscanada.wordpress.com/tag/dsm/

https://www.bmc.org/research/maximizing-opioid-safety-naloxone-moon-study/moon-study-opioid-safety-and-naloxone-public/2016-winners

CDC 2016 – Opioids for Chronic Pain

1

- Non-pharmacologic therapy and non-opioid therapy are preferred for chronic pain
- Only consider opioids if expected benefits for both pain and function outweigh the risks
- If used, should be combined with non-pharm + non-opioid therapy

2

- Before starting opioid therapy for chronic pain, providers should establish treatment goals (realistic) and consider how therapy will be discontinued

3

- Before starting opioid therapy, providers should discuss known risks and realistic benefits

CDC 2016 – Opioids for Chronic Pain

4	• Prescribe immediate-release opioids instead of extended release
5	• Use the lowest effective dosage • Precautions when increasing dosage to >50MED per day • Avoid >90MED per day
6	• If initiating for acute pain, 3 days or less will often suffice • More than 7 days rarely needed
7	• Evaluate benefits and harms within 4 weeks of starting opioids and then every 3 months. • Reduce or discontinue if benefits do not outweigh the harm (decrease by 10% per week)

CDC 2016 – Opioids for Chronic Pain

8	• Evaluate other risk factors for harm • History of overdoses, substance abuse) • Offer naloxone if necessary
9	• Review patient's history of controlled substance prescriptions using state prescription drug monitoring programs
10	• Use urine drug testing before and at least annually to screen for other controlled and illicit drugs
11	• Avoid using opioids with benzodiazepines whenever possible
12	• Offer or arrange buprenorphine or methadone with behavioral therapies for patients with opioid use disorder

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016