



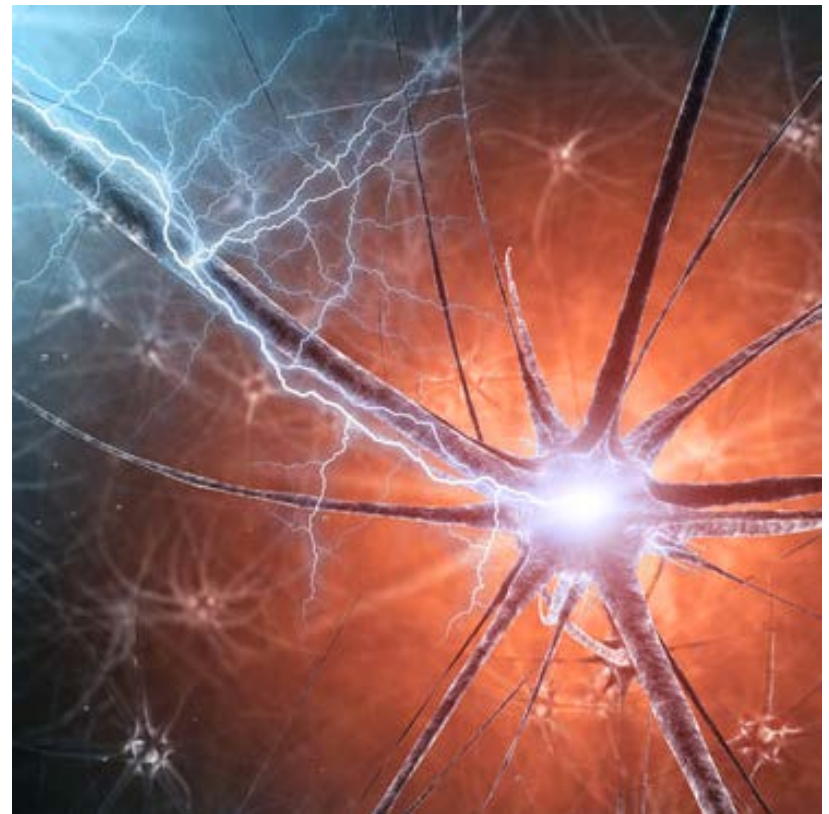
Exempted Codeine Products: Perceptions, principles, & optimizing practice

CPhM Education Session
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OF MANITOBA



Presenter Disclosure

- **Faculty:** **Jamie Falk**

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 - **Other:** None

A few perspectives on exempted codeine products

➔ “...kind of useless”

*- Ross Tsuyuki, editor of the CPJ & professor
of pharmacy and medicine (U of A)*

➔ “... safe and effective for treatment of
mild to moderate pain”

- Johnson & Johnson

Objectives

- After attending this part of the presentation, participants will be able to:
 1. Assess the appropriateness of a patient's request to self-medicate for a recognized medical or dental reason
 2. Examine the appropriate use of opioids in chronic pain
 3. Evaluate a patient's addiction potential
 4. Summarize prevention tactics for diversion of exempted codeine preparations in primary care

Practice Direction:

Exempted Codeine Preparations



- 2.3 A licensed pharmacist shall only prescribe an Exempted Codeine Preparation for a patient whom they have seen and assessed in person. The pharmacist's assessment of the patient shall include, but is not limited to the following:
- 2.3.1 Signs and symptoms of the condition to be treated
 - 2.3.2 Length and severity of present symptoms
 - 2.3.3 Laboratory or other test results (if applicable)
 - 2.3.4 Medical history
 - 2.3.5 Allergies and/or sensitivities
 - 2.3.6 Current medications (must include a review of the patient's DPIN profile)
 - 2.3.7 Extent and results of previous treatment for the current condition
 - 2.3.8 Pregnancy and lactation status (if applicable)
 - 2.3.9 Abuse risk**
- 2.4 A licensed pharmacist shall only prescribe an Exempted Codeine Preparation when it is in the patient's best interest, having considered the risks and benefits to the patient and other relevant factors specific to the patient's care.
- 2.5 A licensed pharmacist shall issue a prescription only after advising the patient with the therapeutic alternatives and providing adequate information so the patient can make an informed decision.




Practice Direction

Prescribing

Documentation: A licensed pharmacist who issues a prescription must make and retain a record of:

- 2.9.1 The name and address of the patient
- 2.9.2 The date of birth of the patient
- 2.9.3 The name of the drug/device prescribed
- 2.9.4 The strength, if applicable, and quantity of the medication
- 2.9.5 The directions for use
- 2.9.6 The number of refills
- 2.9.7 the name of the licensed pharmacist issuing the prescription
- 2.9.8 the date of the prescription
- 2.9.9 the treatment goal, diagnosis or clinical indication for issuing the prescription
- 2.9.10 the rationale for the prescribing decision
- 2.9.11 the follow up plan
- 2.9.12 other health professionals notified



➤ “Particularly striking to the panel was the realization that evidence is insufficient for every clinical decision that a provider needs to make about the use of opioids for chronic pain...”

➤ *NIH Position Paper on the Role of Opioids in CNCP (Ann Intern Med 2015)*

So, how do we deal with this?

Opioids: One of many tools



But they are usually blunt and may be dangerous

What about OTC codeine products?

➤ Chronic pain:

➤ **Statement of the obvious:** if there's poor evidence support for the use of prescription-strength opioids, we can reasonably apply this to weaker opioid regimens as well

➤ Acute pain:



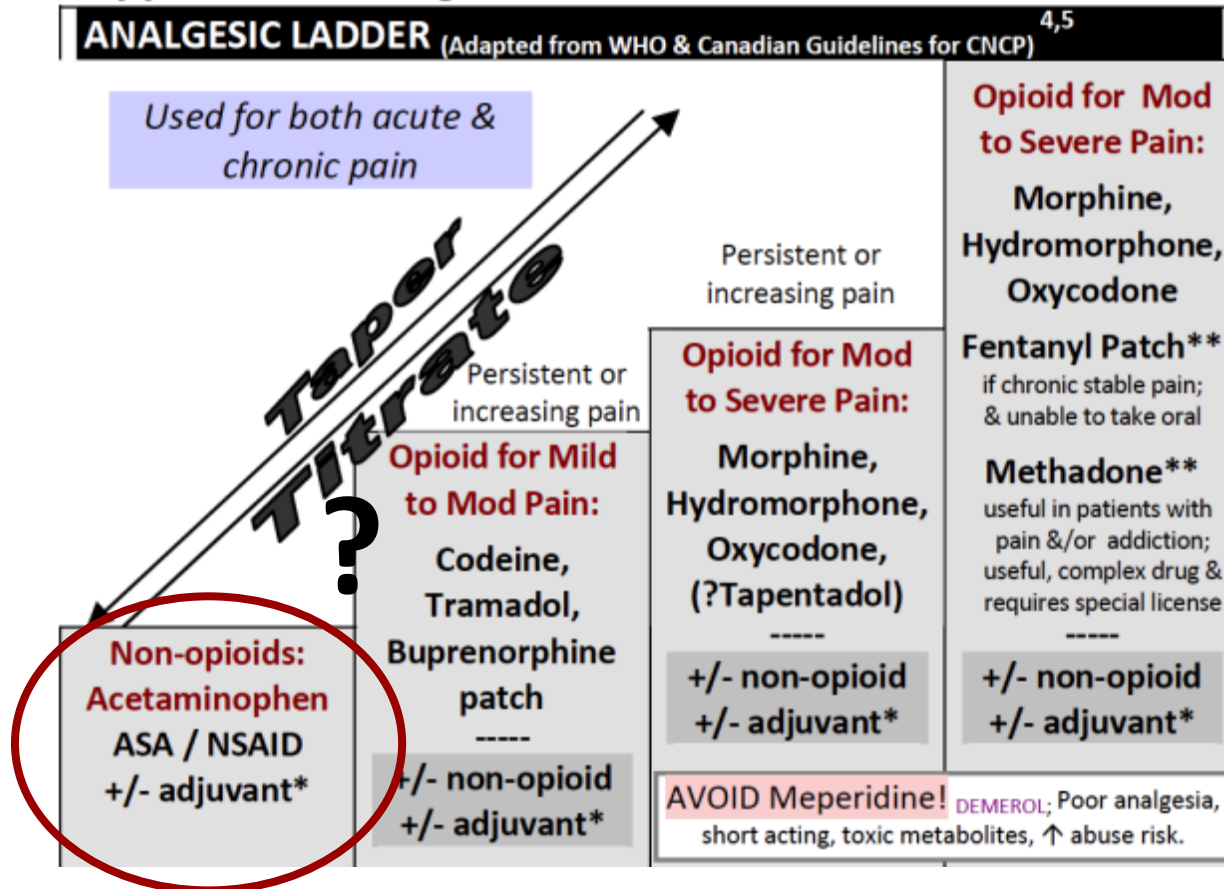
Non-prescription (OTC) oral analgesics for acute pain - an overview of Cochrane reviews (Review)

evidence). The lowest (best) NNT values were for combinations of ibuprofen plus paracetamol, with NNT values below 2. Analgesics with values close to 2 included fast acting formulations of ibuprofen 200 mg and 400 mg, ibuprofen 200 mg plus caffeine 100 mg, and diclofenac potassium 50 mg. Combinations of ibuprofen plus paracetamol had success rates of almost 70%, with dipyron 500 mg, fast acting ibuprofen formulations 200 mg and 400 mg, ibuprofen 200 mg plus caffeine 100 mg, and diclofenac potassium 50 mg having success rates above 50%. Paracetamol and aspirin at various doses had NNT values of 3 or above, and success rates of 11% to 43%. We found no information on many of the commonly available low dose codeine combinations.

Contemporized WHO pain ladder

Approach to Drug Tx in Pain

ANALGESIC LADDER ^{4,5} (Adapted from WHO & Canadian Guidelines for CNCP)



The caveat...

Generally recommended codeine dose for acute pain: 15-60mg q4-6h

To reach those doses with OTC codeine products →→

more ACETAMINOPHEN & CAFFEINE

- T1 X 2 tabs = T2 + 300mg more acetaminophen + 15mg more caffeine per dose --- **OK**
- T1 X 4 tabs = T3 + 900mg more acetaminophen + 45mg more caffeine per dose --- less OK/not OK

***Not to mention additional pill burden

An early bottom line (based on theory, safety concerns, & an absence of solid evidence):

➔ Use of OTC codeine products for acute pain might be appropriate if non-opioid options are contraindicated or have not been effective or tolerated

➔ **e.g.???**

➔ Use of OTC codeine products for chronic pain may be an appropriate approach in a **VERY SMALL SUBSET** of patients

How do we decide who those appropriate cases are?

In the absence of clear direction...

Getting back to the basics

→→→ Practice evolution

Back to the basics...

1. Nothing happens in isolation
 - i.e. pain is not an isolated disease
2. Be prepared
 - i.e. what happens upfront is essential
3. Use all the resources around you
 - i.e. pharmacological & non-pharmacological approaches

- 
1. Nothing happens in isolation:
Pain is not an isolated disease


Definitions

“**Acute pain** is a symptom that plays a functional role in body defenses and resolves with tissue recovery.

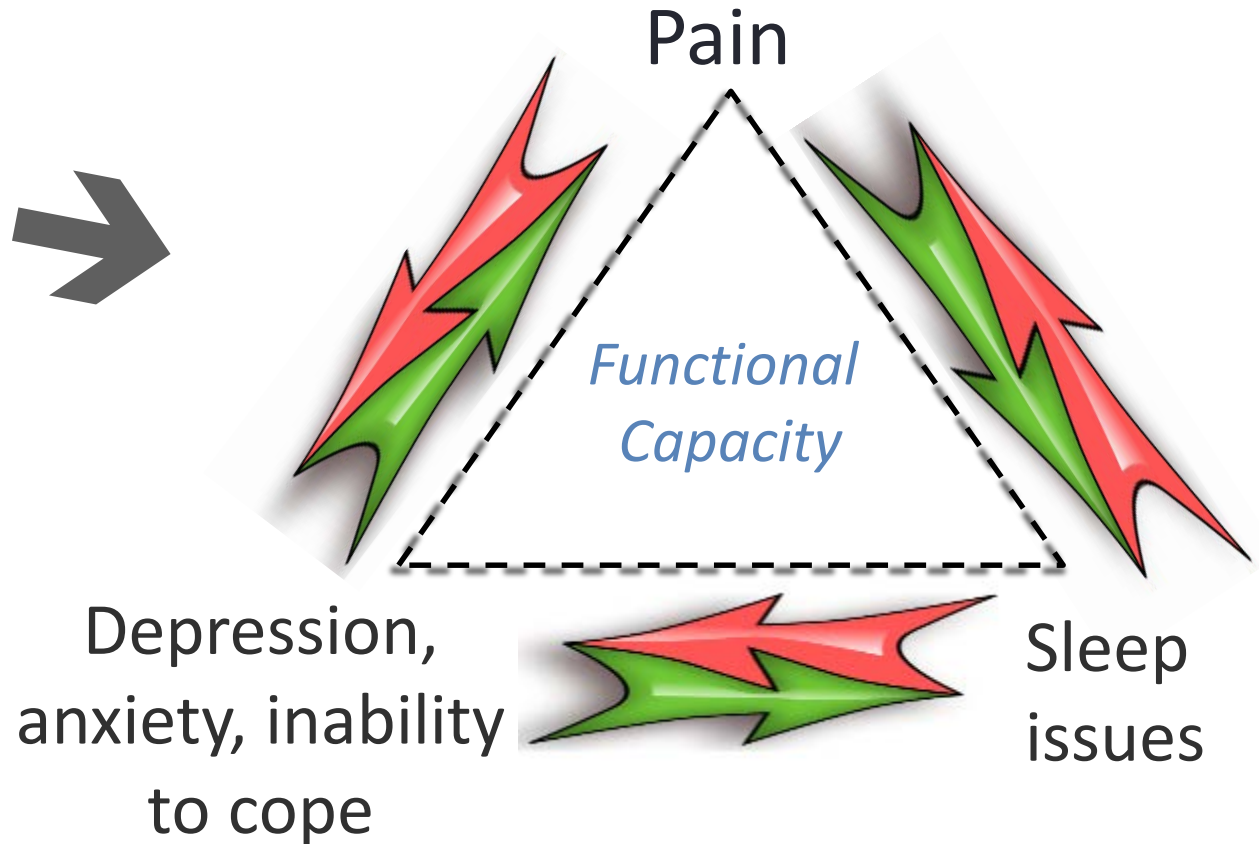
...**chronic pain**^{usually} has no such functional role, does not resolve with tissue recovery, and can be a **primary diagnosis**. Chronic pain involves complex CNS signaling that can be **amplified by stressors**...

...a **biopsychosocial condition** that requires a comprehensive, **multidisciplinary approach**”

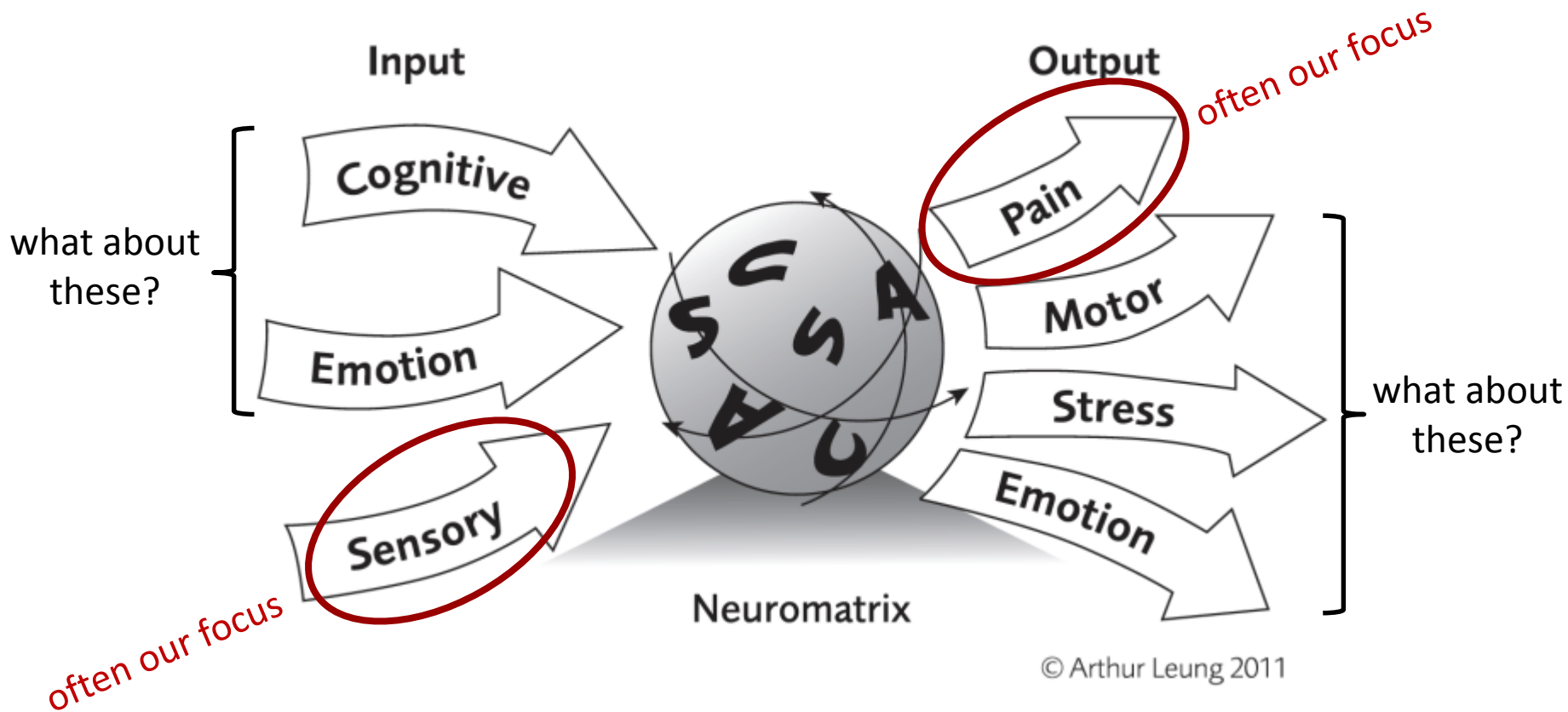
Acute vs. Chronic pain

Characteristic	Acute Pain 	Chronic Pain
Relief of Pain	Highly desirable	Highly desirable
Dependence and tolerance to medication	Unusual	Common
Psychological component	Usually not present	Often a major problem
Organic cause	Common	May not be present
Environmental/family issues	Small	Significant
Insomnia	Unusual	Common component
Treatment goal	Cure	Functionality
Depression	Uncommon	Common

Impact of Chronic Pain



The Pain Experience



“A biopsychosocial condition”



2. Be prepared:

What happens upfront is essential

a) Assessment

*CURRENT
STATE*

- Description of pain
- Function

*BEST
PREDICTION*

- Individual's risk of side effects
 - Considering age, comorbidities, and past experiences
- Individual's risk of abuse/diversion

Pain Assessment

➤ PQRST mnemonic

➤ **P: provokes, precipitates**

➤ What brings it on and what takes it away?

➤ **Q: quality**

➤ In the patient's own words (prompt only if necessary – e.g. dull, sharp, stabbing, burning, etc.)

➤ **R: radiation, referral**

➤ Does the pain move to another spot?

➤ Are there other symptoms associated with the pain (e.g. nausea, shortness of breath)

➤ **S: severity**

➤ How does the patient rate the pain?

➤ **T: timing**

➤ When did the pain start?

➤ Has it occurred before?

➤ Is it constant or does it come and go?



Pain Severity Scales



UNBEARABLE

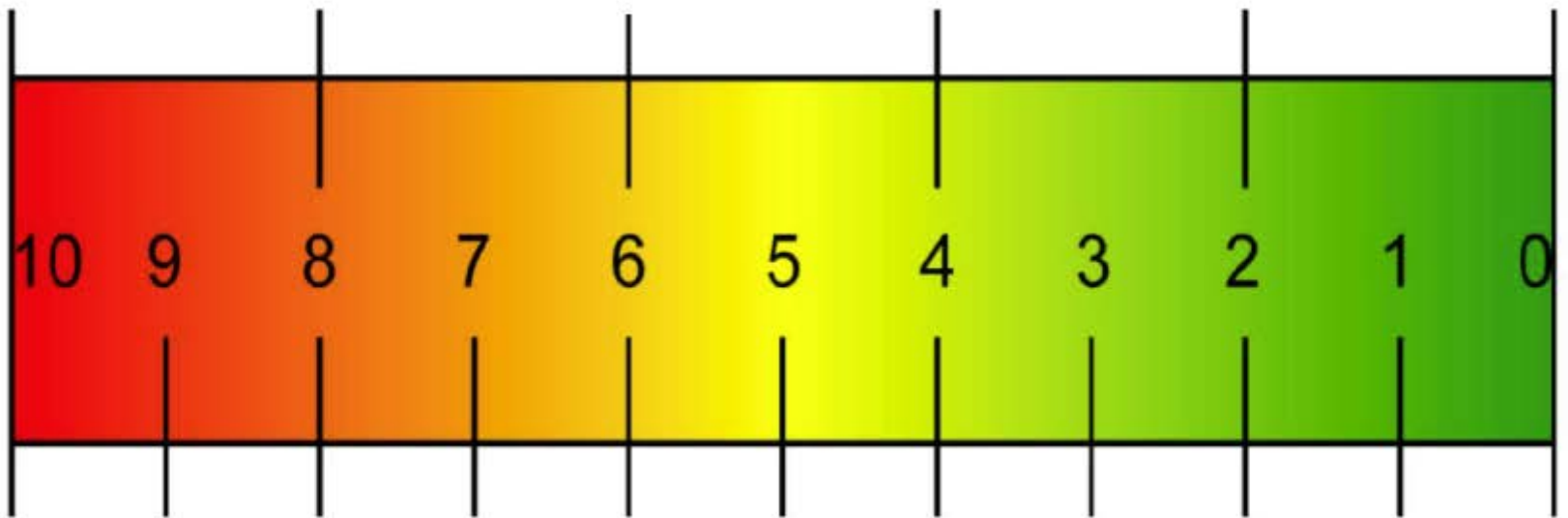
SEVERE

MODERATE

MILD

SLIGHT

NO PAIN



Pain Severity

- If you roll your ankle, what degree of pain severity have you experienced?
- If you have “bone-on-bone” knee osteoarthritis, what degree of pain severity do you experience?
- If you suffer from chronic low back pain, what degree of pain severity do you experience?
- If you had a pain score of 2/10, would you use a pain reliever?
- If you had a pain score of 5/10, would you use a pain reliever?
- If you had a pain score of 8/10, would you use a pain reliever?
- Would your answer change depending on what you had to do that day?

Subjectivity

Stoicism

Intensity of Chronic Pain — The Wrong Metric?

Jane C. Ballantyne, M.D., and Mark D. Sullivan, M.D., Ph.D.

NEJM 2015;373:2098-99

***i.e.** Is a reduction in pain intensity the right goal for the treatment of chronic pain (or rather, is it the improvement of the pain experience)?*

- “For many patients, especially those who have become dependent on opioids, maintaining low pain scores requires continuous or escalating doses of opioids at the expense of worsening function and QoL.”
- “Over time, pain intensity becomes linked less with nociception and more with emotional and psychosocial factors. Suffering may be related as much to the meaning of pain as to its intensity”
- “Persistent helplessness and hopelessness may be the root causes of suffering for patients with chronic pain yet be reflected in a report of high pain intensity”

Pain 2017, Aug 21 (same authors):

“When we use exogenous opioids chronically and continuously, we sacrifice normal healthy motivational behaviors, socialization, and coping.”

MORE IMPORTANT questions: Pain Severity → **FUNCTION**

- How does the patient look and mobilize?
- Are they able to perform valued activities?
- Are they dysphoric and/or irritable?
- How are they sleeping?
- Do they feel well enough to socialize?

Brief Pain Inventory

Brief Pain Inventory

1. Throughout our lives, most of us have had pain from tiredness or aches (like toothaches). Have you had pain other than these every day?

Yes No

2. On the diagram, shade in the areas where you feel pain.



3. Please rate your pain by marking the box beside the number that best describes how often you have pain in the last 24 hours.

0 1 2 3 4 5
No Pain

4. Please rate your pain by marking the box beside the number that best describes how much pain you have in the last 24 hours.

0 1 2 3 4 5
No Pain

5. Please rate your pain by marking the box beside the number that best describes how much pain you have in the last 24 hours.

0 1 2 3 4 5
No Pain

6. Please rate your pain by marking the box beside the number that best describes how much pain you have in the last 24 hours.

0 1 2 3 4 5
No Pain

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity
0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

B. Mood
0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

C. Walking Ability
0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

D. Normal Work (includes both work outside the home and housework)
0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

E. Relations with other people
0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

F. Sleep
0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

G. Enjoyment of life
0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

100% Complete Relief

10 Completely Interferes

10 Completely Interferes

10 Completely Interferes

10 Completely Interferes

10 Completely Interferes

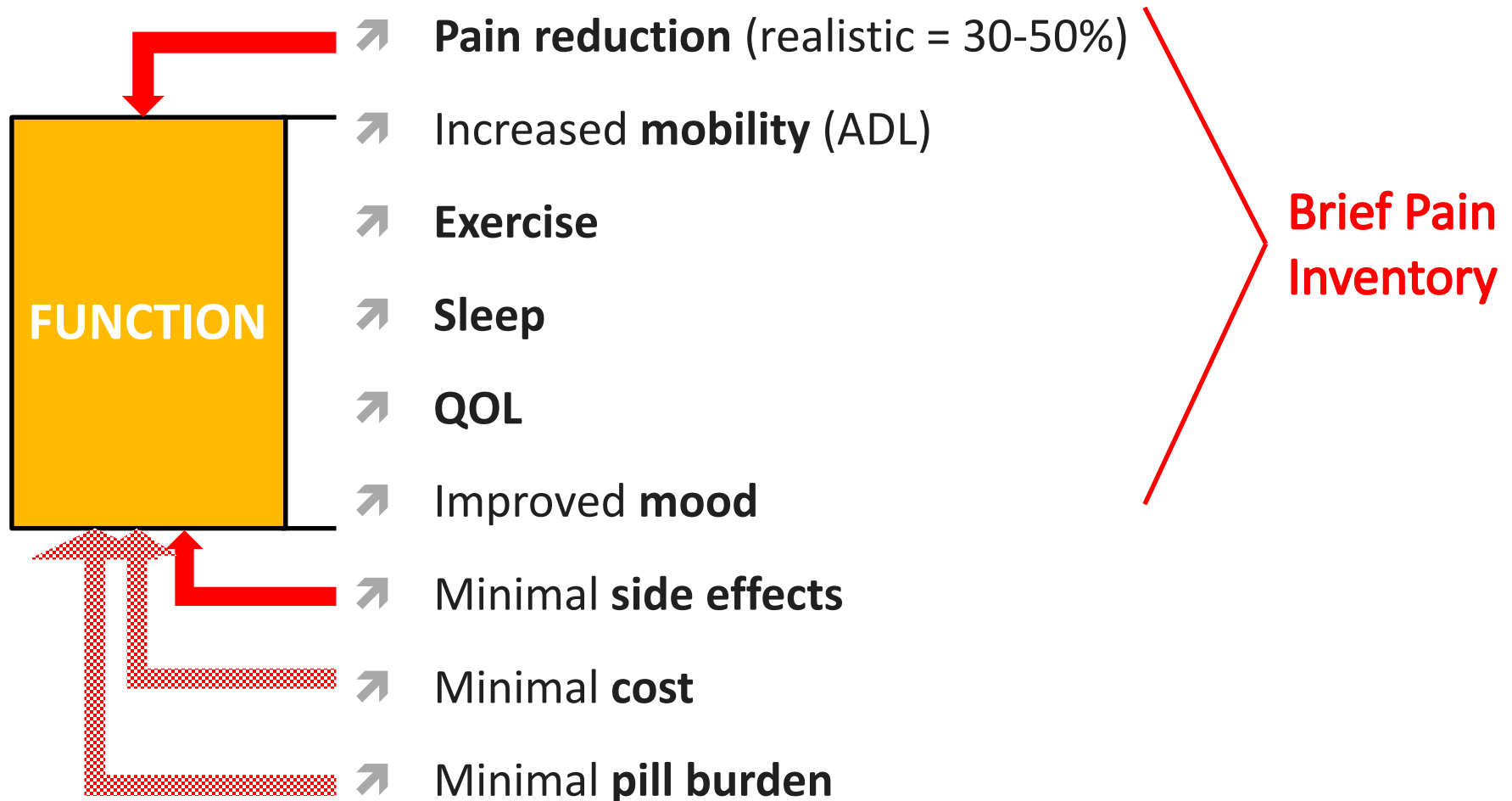
b) Information sharing

Are you speaking the same language ?

Iron out/avoid early misconceptions

- The natural history and expected course of the pain condition
- Establish goals & expectations...
 - of treatment & the therapeutic relationship
 - yours and theirs (are they realistic?)
- Potential benefits of treatment (best estimates)
- Potential harms of treatment (best estimates)

Goals of therapy



Now, how do we get there?



Need to look
closely at:



Patient
factors
(past & present)

+

Evidence
for effect



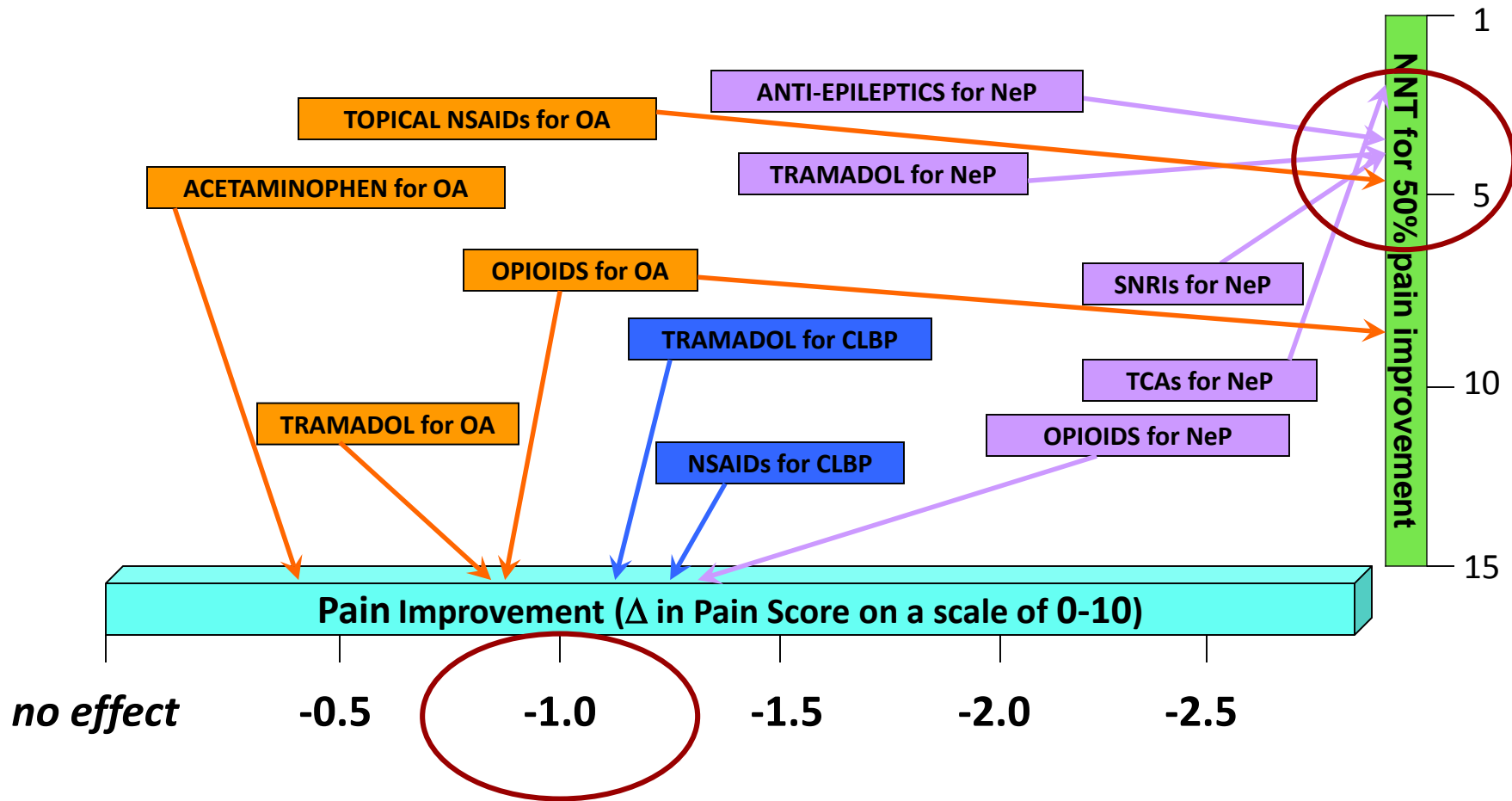
3. Use all the resources around you:
Pharm and non-pharm approaches

Pharmacological Treatment of CNCP : (

- **“Overall, currently available treatments provide modest improvements in pain and minimum improvements in physical and emotional functioning. The quality of evidence is mediocre and has not improved substantially during the past decade.”**

Turk, et al. *Lancet*. 2011 Jun 25;377(9784):2226-35

ANALGESIC COMPARISONS FOR CHRONIC NON-CANCER PAIN

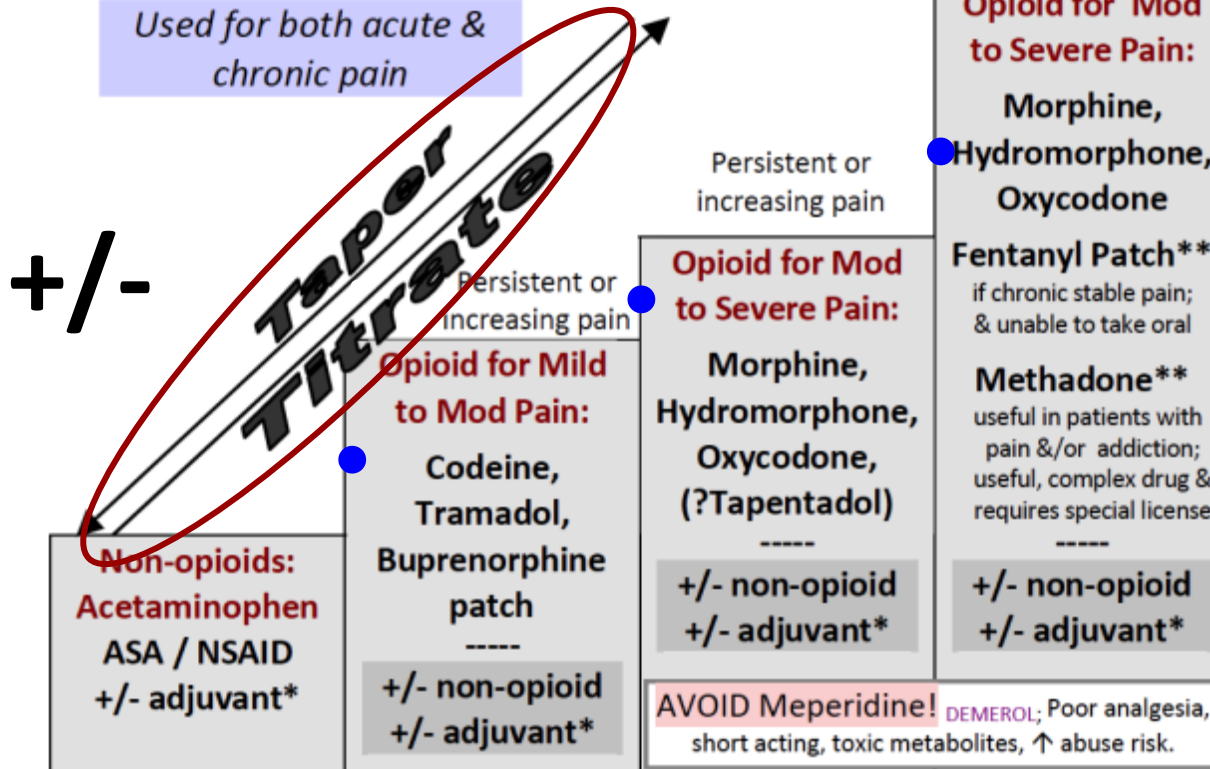


WHO ladder contemporized: the multipronged approach

Approach to Drug Tx in Pain

ANALGESIC LADDER ^{4,5} (Adapted from WHO & Canadian Guidelines for CNCP)

Used for both acute & chronic pain



education

+

non-pharmacological

Non-pharmacological approaches



- Heat and/or cold
- Physiotherapy
- Massage
- Chiropractic
- Acupuncture
- Counseling, CBT
- Exercise
- Music
- Yoga



acute &
chronic

chronic

***Likelihood of
benefit
dependent on
type of pain
being treated**

Multimodal Care

- ➔ “...encompasses behavioral, physical, and integrated medical approaches. It is not titrated to pain intensity but has a primary goal of reducing pain-related distress, disability, and suffering. When it does that successfully, a reduction in pain intensity might follow — or acceptance might make the intensity of pain less important to a person’s functioning and quality of life.”

Role of the pharmacist:

- Ensure safe and effective medication use
- Move patients away from a drug-centric approach to pain management
- Collaborate with others to reinforce positive approaches



How would you respond?

➤ Case 1

Mr. Smith, 35 years old, is taking Tylenol #1 for low back pain which occurs once every 2 months or so. His pain is presently debilitating, but when he uses T1s for 3-4 days (8-10 tabs/day), he can function reasonably well until the episode resolves. He has some constipation when he uses them, but knows it is short-lived. He picks up a bottle of 100 every 3 months or so.

➤ Case 3

Mr. Brown, 35 years old, is taking Tylenol #1 for chronic low back pain. He has been using them for 6 months and has escalated his dose from 4/day to 8/day to 12/day and now is asking for a bottle of 100 q1w.

➤ Case 2

Mr. Jones, 35 years old, is taking Tylenol #1 for chronic low back pain. He uses 4/day and has consistently done this for a few years. On occasional bad days (every few weeks), he will take 6-8/day. His use allows him to get to work every day at his construction company. On your advice, he has a warm bath at the end of the day to prevent having to use T1s after work. He picks up a bottle of 100 about every 3 weeks.

➤ Case 4

Mrs. White, 35 years old, is taking Tylenol #1 for headaches. She takes 3 tabs every morning plus another 3 tabs 2-3 X/day. She reports that she has headaches everyday, but T1s take the edge off the pain. If she doesn't use T1s, she can't get through a day.

The 6 A's of Opioid Therapy

- 1) Analgesia
- 2) Activity
- 3) Adverse effects
- 4) Affect
- 5) Accurate records
- 6) Aberrant behaviour/Abuse risk

How is your
patient's
picture shaping
up?

Analgesia & Activity: e.g. Chronic Low Back Pain



Cochrane review (2013): n= 15 trials, 5540 patients, duration = 4-12 wks

➤ Strong opioids vs. placebo:

- NNT ($\geq 30\%$ pain relief) = 6
- NNT ($\geq 50\%$ pain relief) = 7
- Disability effect size = -0.26 (small)

➤ Strong opioid vs. TCA (n=56):

- No difference in pain or disability outcomes

➤ Tramadol vs. placebo:

- Pain intensity effect size = -0.55 (mod)
- Disability effect size = -0.18 (small)

➤ Tramadol vs. celecoxib (n=1598)

- NNT ($\geq 30\%$ pain relief) = 9 (for celecoxib)

Bottom line: very rarely would a patient with CLBP gain benefit from OTC codeine doses

Authors' conclusions

There is some evidence (*very low to moderate quality*) for short-term efficacy (for both pain and function) of opioids to treat CLBP compared to placebo. The very few trials that compared opioids to non-steroidal anti-inflammatory drugs (NSAIDs) or antidepressants did not show any differences regarding pain and function. The initiation of a trial of opioids for long-term management should be done with extreme caution, especially after a comprehensive assessment of potential risks. There are no placebo-RCTs supporting the effectiveness and safety of long-term opioid therapy for treatment of CLBP.



What about Mr. Smith/Jones?

Abuse & Diversion Risk

- ❑ DPIN check +/- a phone call to your peer(s)
- ❑ What else are they asking for?
- ❑ What else is on their prescription profile?
- ❑ Other signs of current or future abuse?
- ❑ Utilize an Opioid Risk assessment Tool?

- ❑ Provide Small fills
 - ❑ How often?
- ❑ Discourage prn use → Why?
 - A reactive behaviour
 - Prevents development of active coping mechanisms and use of distractors

Assessing abuse risk...

IF we're
thinking
about using
opioids:

Now, what do we do
with this? → dependent
on patient, relationship,
comfort level, etc.

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, or Bipolar, Schizophrenia	[]	2	2
Depression	[]	1	1
Total		—	—
Total Score Risk Category: Low Risk: 0 to 3 Moderate Risk: 4 to 7 High Risk: 8 and above			



Opioid Adverse Events

➔ “Short term” (i.e. they may go away):

➔ Most common & bothersome: nausea (28%), sedation (24%), dizziness (18%), cognitive impairment (<10%)

* 80% of patients will have ≥ 1 side effect

➔ “Long-term”:

➔ Constipation (26%)

➔ Dependence, tolerance, addiction

➔ With daily opioid use, can develop in days or weeks.

➔ Dental problems(?), hypogonadism

➔ **How often do we tell this to our patients up front?**

➔ Unintentional overdose

Important:
We shouldn't sacrifice
function for pain
reduction

STOPPING SIGNS

3. Clinical Features of Opioid Use Disorder (OUD)⁸

Indicator	Examples
Altering the route of delivery	<ul style="list-style-type: none">• Injecting, biting or crushing oral formulations
Accessing opioids from other sources	<ul style="list-style-type: none">• Taking the drug from friends or relatives• Purchasing the drug from the 'street'• Double-doctoring
Unsanctioned use	<ul style="list-style-type: none">• Multiple unauthorized dose escalations• Binge use rather than scheduled use
Drug seeking	<ul style="list-style-type: none">• Recurrent prescription losses• Aggressive complaining about the need for higher doses• Harassing medical office staff for faxed scripts or 'fit-in' appointments• Nothing else 'works'
Repeated withdrawal symptoms	<ul style="list-style-type: none">• Marked dysphoria, myalgia, GI symptoms, cravings
Accompanying conditions	<ul style="list-style-type: none">• Currently addicted to alcohol, cocaine, cannabis, or other drugs• Underlying mood or anxiety disorders are not responsive to treatment
Social features	<ul style="list-style-type: none">• Deteriorating or poor social function• Concern expressed by family members
Views on the opioid medication	<ul style="list-style-type: none">• Sometimes acknowledges being addicted• Strong resistance to tapering or switching opioids• May admit to mood-leveling effect• May acknowledge distressing withdrawal symptoms



* https://thewellhealth.ca/wp-content/uploads/2017/09/CEP_OpioidManager2017.pdf

How would you respond? Back to Cases 3 & 4...

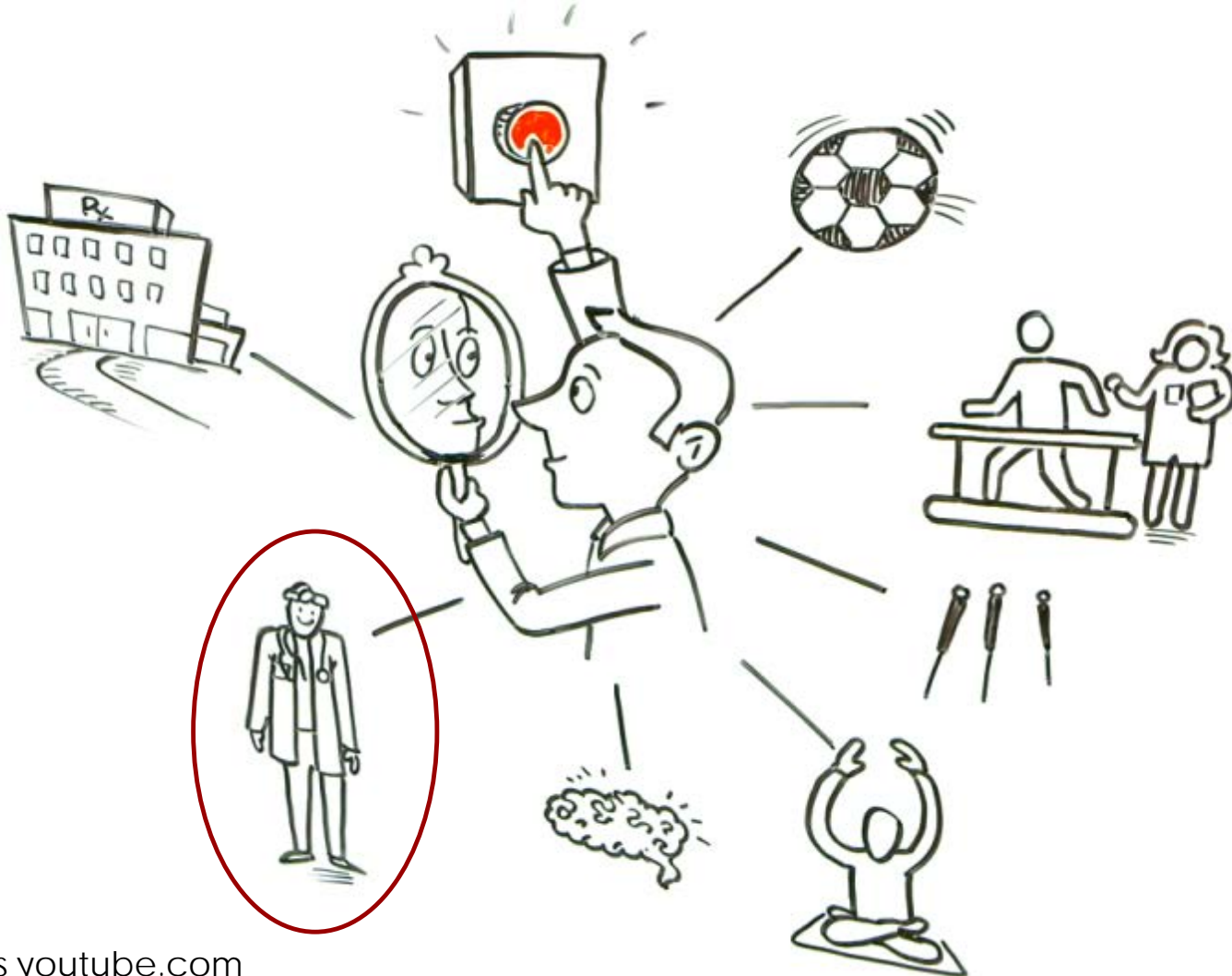
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➤ Case 4

Mrs. White, 35 years old, is taking Tylenol #1 for daily headaches. She takes 3 tabs every morning and 3 tabs an additional 2-3 X/day after that. She reports that she has headaches everyday, but T1s take the edge off the pain. If she doesn't use T1s, she can't get through a day.

Hitting the Reset Button



Opioid Tapering

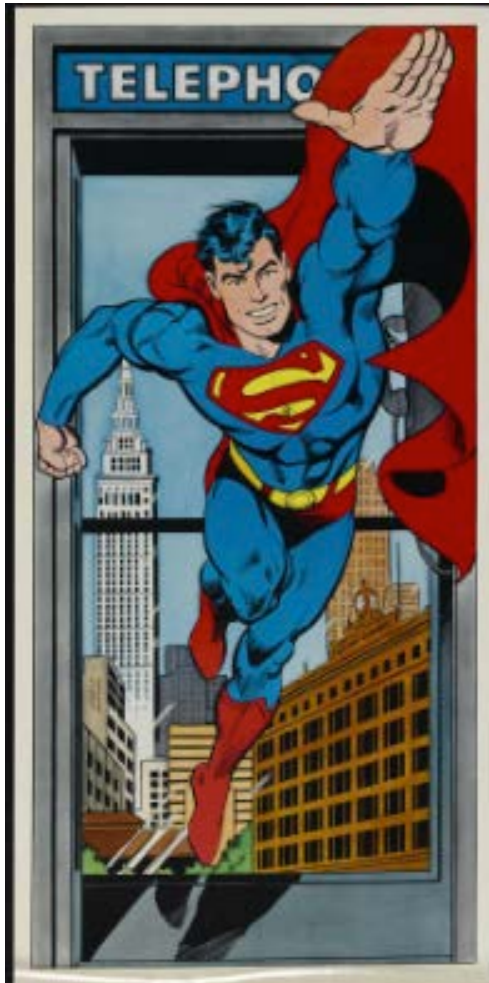
1. Educate on **why** (the purpose)
2. Educate on **what** you are doing (the physiological principles)
3. Educate on **how** (the process)
4. Emphasize that the process should go in **one direction**, even if it takes awhile



Basic follow-up checklist

- Established Goals: have they been accomplished?
- Re-educate: understanding pain condition and expectations of benefit and harm are essential
- Non-drug modalities: are they being pursued?
- Recovery & disposal: inquire if codeine no longer used
- Document: what is the specific plan for the future?

It's time to suit up



- ➔ Due to our:
1. Expertise
 2. Positioning at key points in the health care system...

Pharmacists have tremendous potential to:

1. Take our place as a key player in the multimodal model of pain management
2. Promote and initiate effective pain management
3. Significantly minimize exempted codeine product use

Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

Part A: Executive Summary and Background
Part B: Recommendations for Practice



Centre for Effective Practice

Morbidity and Mortality Weekly Report (*MMWR*)

[CDC](#) > [MMWR](#)

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

Early Release / March 15, 2016 / 65



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Questions ?



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