

Prudent Opioid-sparing Therapies: An Evidence-based, Strategic Approach

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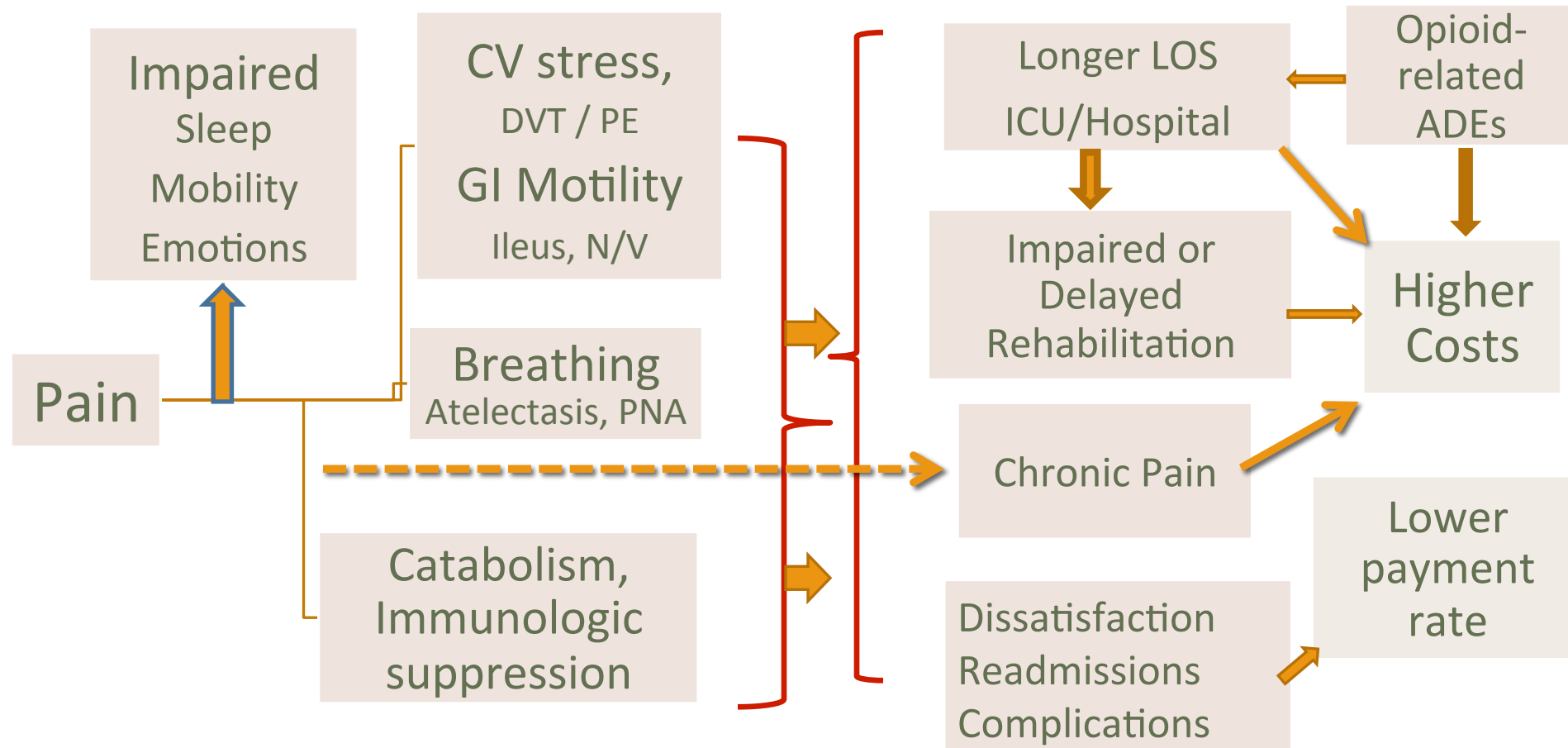
4/5/17

Pain: a Universal Experience



A teleological adaptive response

Complications & Costs Linked to Poorly Controlled Pain



Harmful Effects of Chronic Pain

CNS remodeling with 5-10% gray matter loss

- Reversible with better pain control

Long-term exposure to potential dangerous drugs

Health care expenditures average \$10,000/pt./yr.

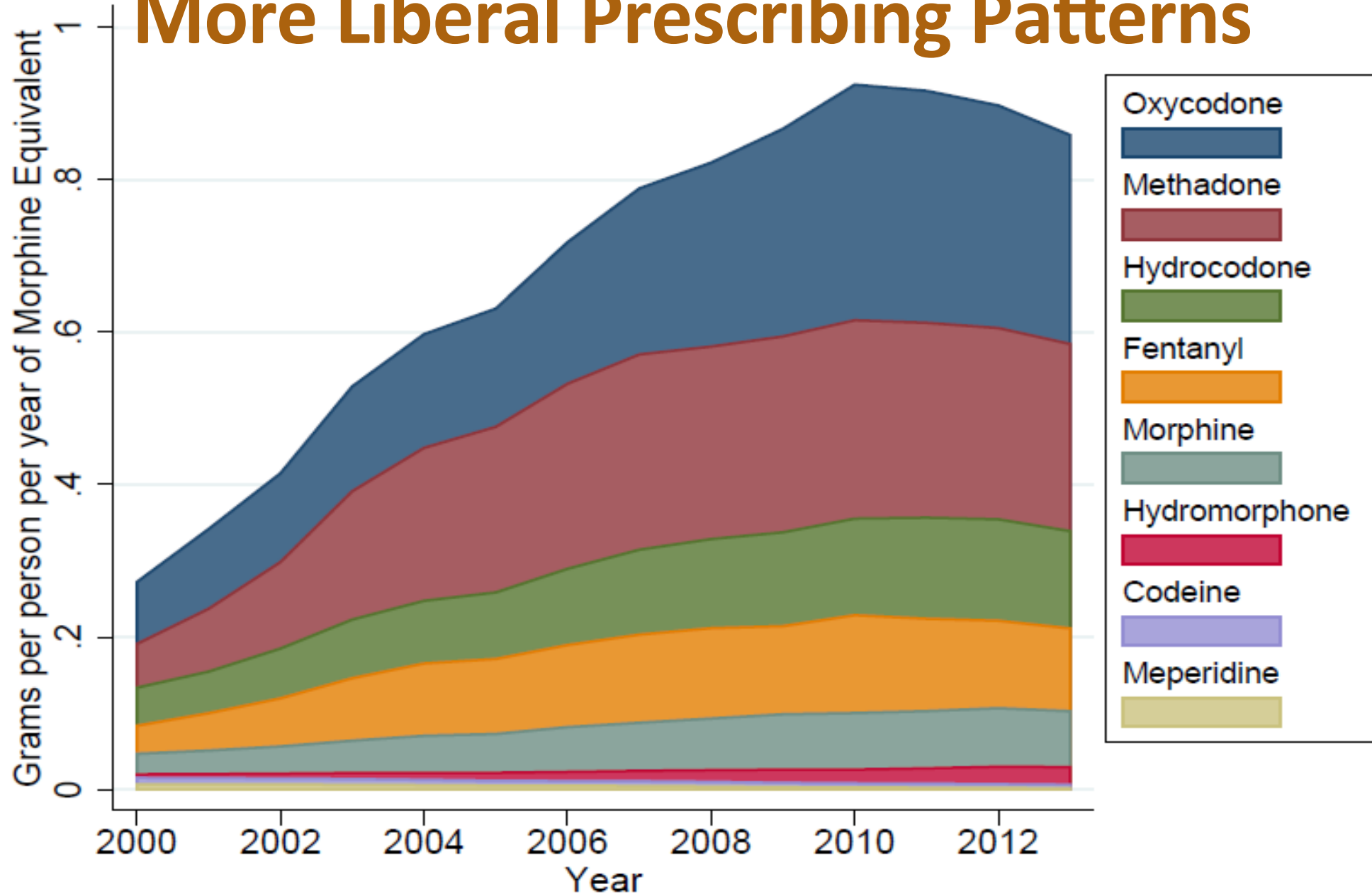
50% increase in all-cause mortality within 10 years

- Three times higher with severe pain

Chronic pain is a common reason for:

- Seeking health care,
- Specialist consultation
- Risk of developing depression

More Liberal Prescribing Patterns



2 Major Public Health Crises

Chronic Pain

126 million > 3 mo.

- 25 million daily
- 23 million disabling

Leading burden of disease (WHO)

- Lower back & neck pain
 - Afflicts 900 million
 - 95 Million YLD

\$635 Billion / year

- Healthcare & disability

Addiction (SUD)

- 20 Million with SUD
- 2 Million with OUD
 - 600,000 Heroin users

Overdose Deaths ⁽²⁰¹⁴⁾

- 88,000 alcohol
- 47,000 (all drugs)
 - 28,647 Any opioid
 - 11,346 Rx opioids
 - 10,574 Heroin
 - 6,727 Synthetics

\$400 billion/ year

- Crime, health, disability & social services

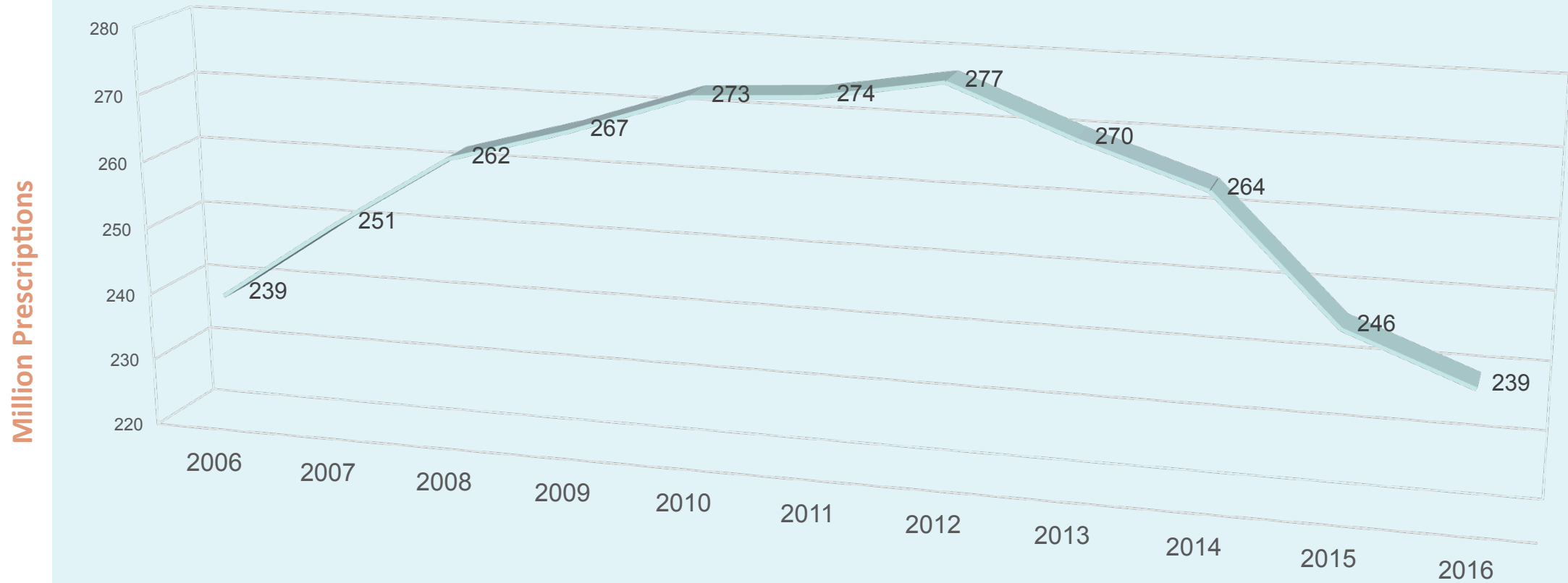
U.S. DHHS, Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report* Washington, DC: HHS, November 2016.

Nahin RL. Estimates of pain prevalence and severity in adults: United States, 2012. *J Pain*. 2015 Aug;16(8):769-80.

IOM 2011. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education & Research*. Washington DC: National Academies Press

Disease & Injury Incidence and Prevalence Collaborators (2016). Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016 Oct 8;388(10053):1545-1602.

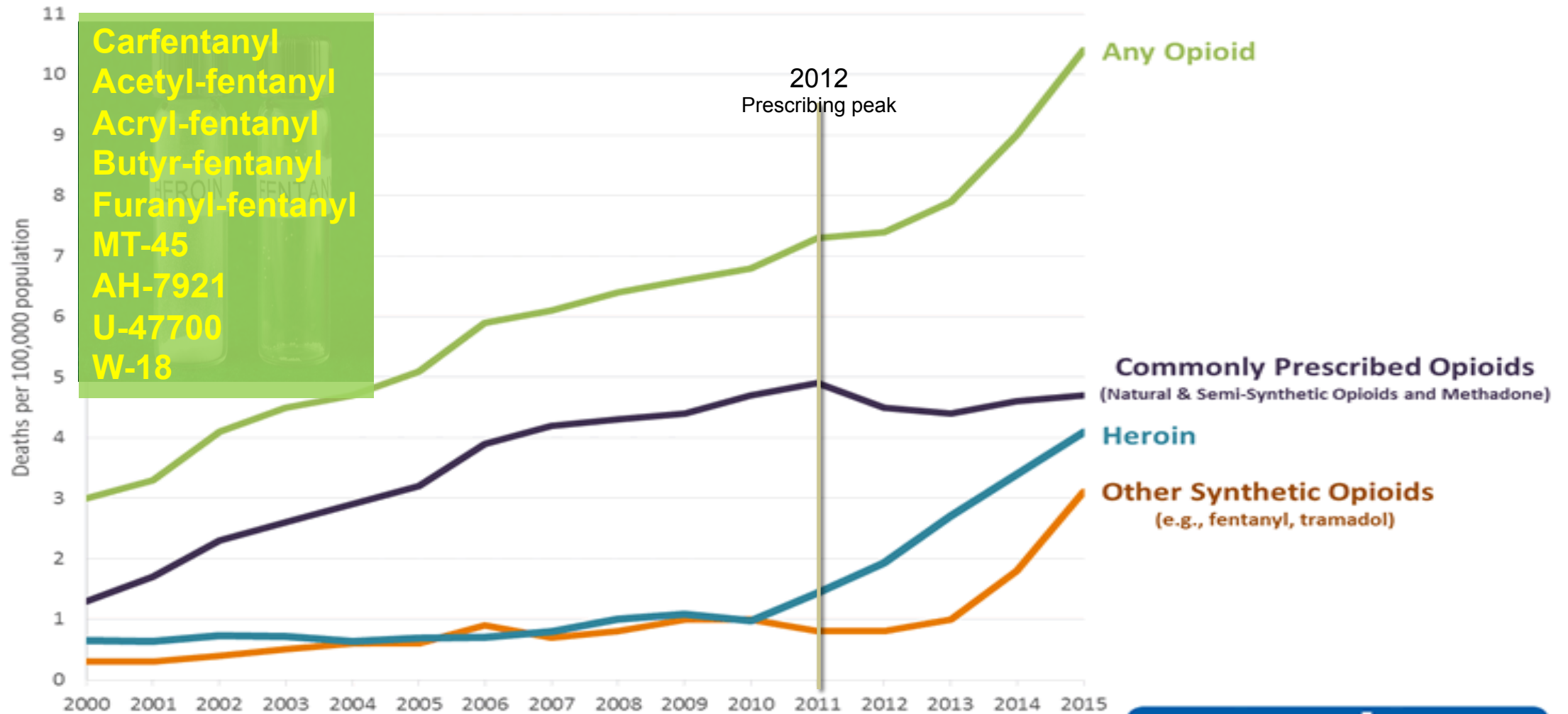
Opioid Prescriptions 2006 - 2016



Since 2012, 13% reduction in opioid prescriptions (at lower dose and lower pill counts)

[Decrease IR = 13% ER = 11%]

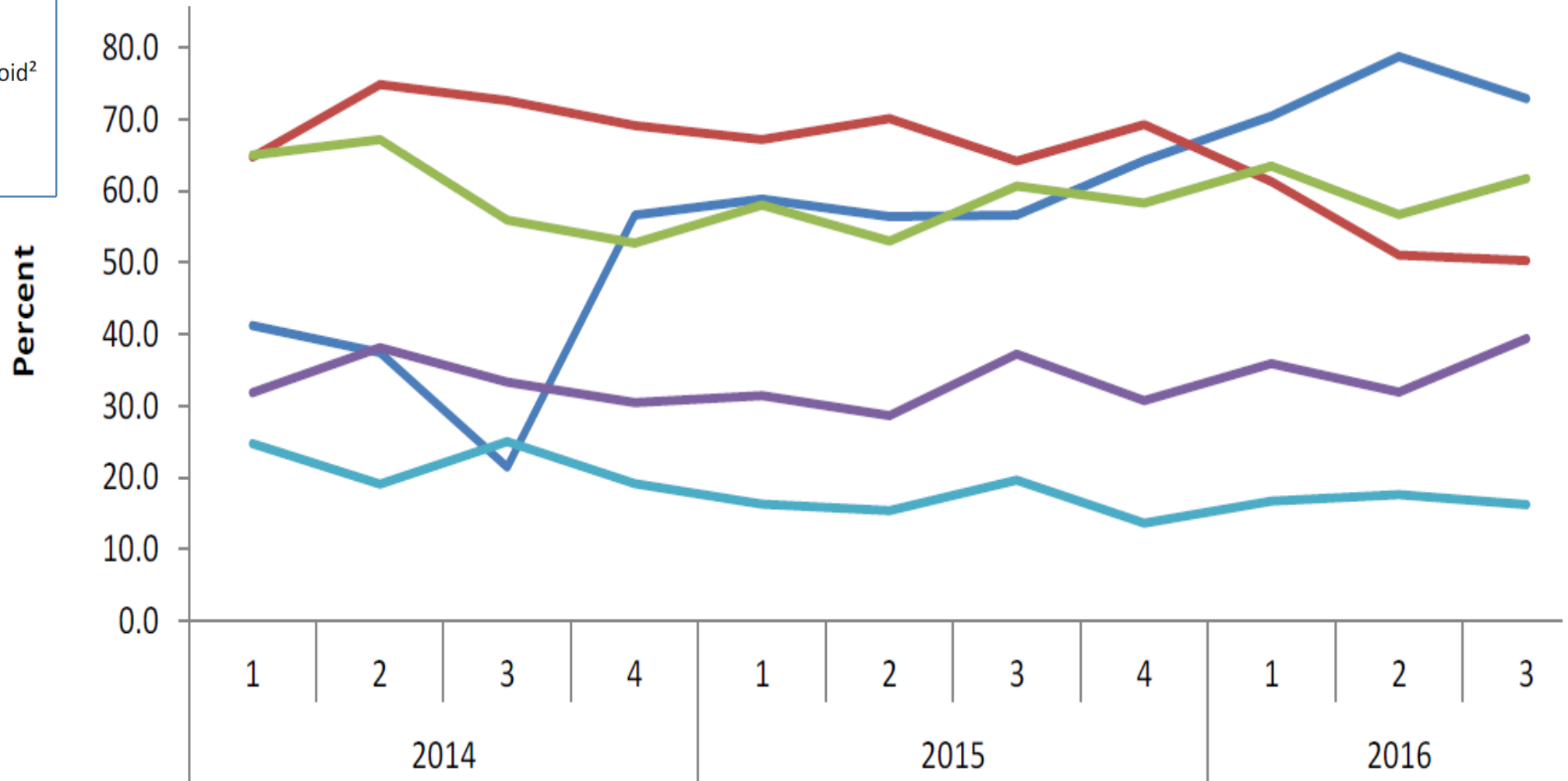
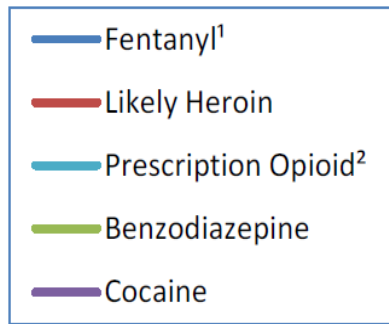
Overdose Deaths Involving Opioids, United States, 2000-2015



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. <https://wonder.cdc.gov/>.

www.cdc.gov
Your Source for Credible Health Information

Percent of Opioid Deaths with Specific Drugs Present MA: 2014-2016



1. 75% have illicit Fentanyl¹; 50% have heroin in system at time of death
2. 8% have been prescribed an opioid in past month

Nonmedical Opioid Use

Nonmedical use is highly problematic

- Using drug in a way other than prescribed
 - Unsupervised use for different problem
 - Prevent pain, insomnia, anxiety, different pain
 - Seeking pleasure, euphoria, “high”
 - Different dose, different dosing interval
 - Manipulation to change route of administration
 - Drug not prescribed
- 40-81% self-medicate for pain
- 80% of heroin users started with nonmedical OUD

Compton WM, Jones CM, Baldwin GT. Relationship between Nonmedical Prescription-Opioid Use and Heroin Use. *N Engl J Med*. 2016 Jan 14;374(2):154-63.

Alford DP, German JS, Samet JH, et al. Primary care patients with drug use report chronic pain and self-medicate with alcohol and other drugs. *J Gen Intern Med*, 2016;31(5):486-91.

Lynch, M. Nonmedical use of prescription opioids: What is the real problem? *Pain Res Manag*. 2013 Mar-Apr; 18(2): 67–68.

Existing Know-how: Pain Relieving Strategies

Stepped approach

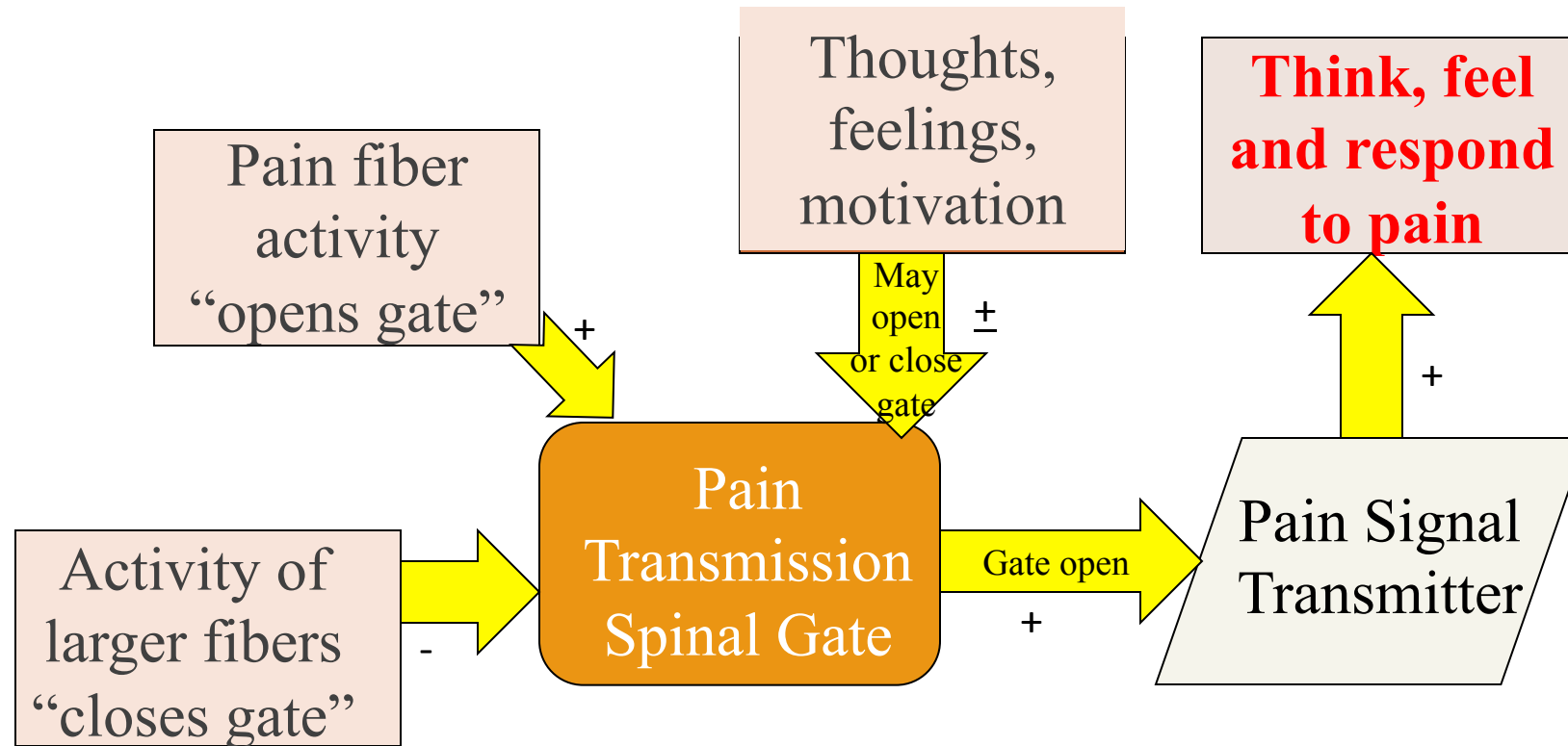
Pre-emptive approaches

Multimodal treatments

- Address multiple physical pathways
- Address psychosocial aspects
- Consider active & passive approach

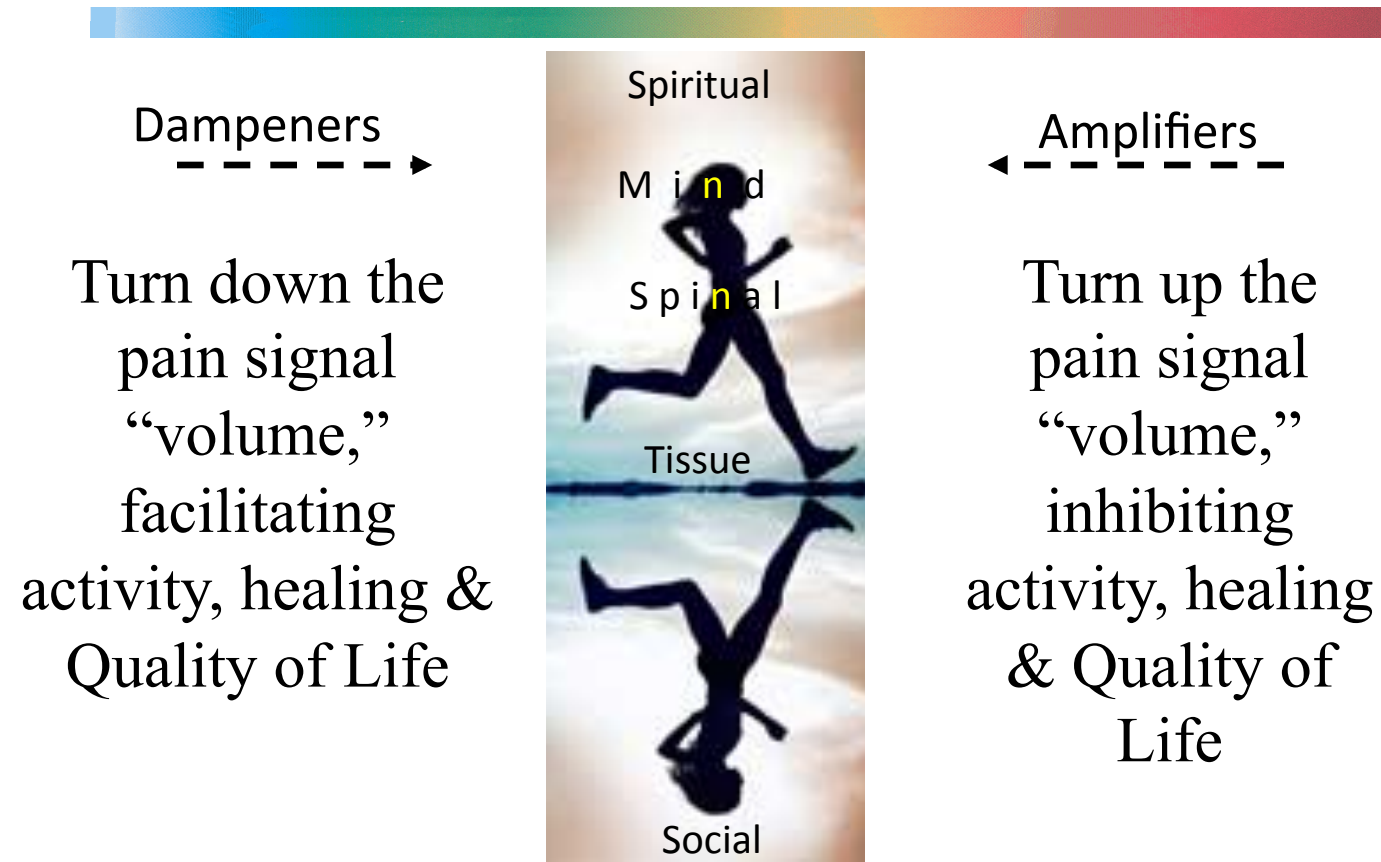
Gate Control Theory of Pain

How can a “shot” hurt worse than being shot?



Addresses simple acute pain physiology; not complex chronic pain

Gain Control Model of Pain



Gain Control: Tissue Level

Dampeners



- Stop tissue damage
- Homeostasis
 - Good circulation/O₂
 - Good nutrition
 - Activity/rest balance
 - Adequate sleep
- Positional support
- Muscle relaxation
- Low stress / eustress



Amplifiers*



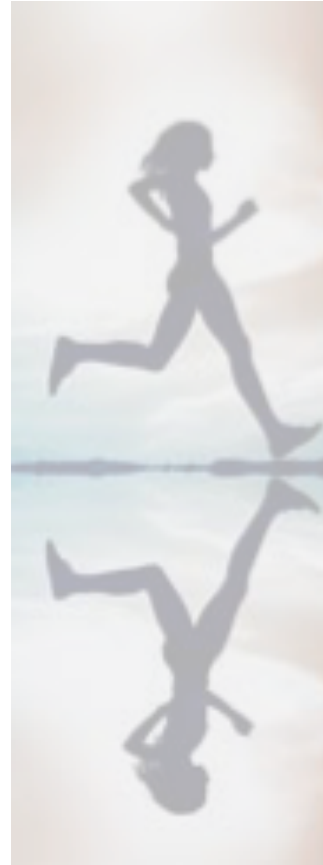
- Ongoing tissue damage
- Inflammation/infection
 - TNF- α , IL^{1 β , 6}, Ca⁺⁺
 - CGRP, Substance P
- Electrolyte imbalance
- Environmental extremes
- Hypoxia
- Muscle tension / spasm
- Sleep deprivation

*Partial list

Gain Control: Mind Level

Dampeners

- Emotional stability
- Feel loved
- Self efficacy, optimistic
- Acceptance
- Realistic beliefs and expectations
- Mental distraction
- Pain & stress coping



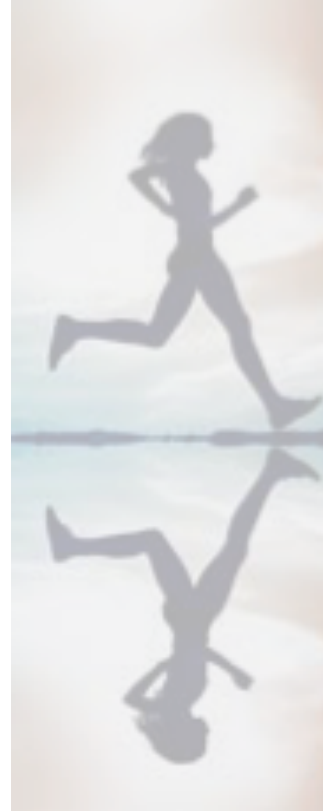
Amplifiers

- Emotional distress
 - Anxiety, fear, depression...
 - High or prolonged stress
- Unhelpful thoughts
 - Catastrophizing
 - Self doubts
 - Helplessness, hopelessness

Gain Control: Social & Spiritual Level

Dampeners

- Socially engaged
- Essence unchanged
- Meaningful, pleasurable activities pursued
- Sense of purpose / Faith
- Sense of connection
- Effective communication
- Work, volunteering
- Energy flow balanced



Amplifiers

- Spiritual distress
- Lost connections
- Dire meaning
- Suffering
- Energy imbalance
- Socially isolated
- Relationship/role conflict
- Over-dependency
- Dysfunctional coping

Best Practices per Guidelines

Comprehensive assessment of pain & its impact

- Risk assessment of short-term/long term effects

Pre-emptive, multimodal analgesia (not opioid-only)

Educate patients for realistic expectations

- Need to balance benefits and potential risks
- Laws affecting opioid prescribing, dispensing, use & disposal

Benefits of learning & using non-drug relief methods

Need for vigilant monitoring

Ongoing risk-benefit analysis to continue therapy

Optimal Pain Management

Care is individualized

- Common language/terms
- Mutually agreed goals
- Treatment based on assessment & reassessment

Care is collaborative:

- Interdisciplinary in conjunction with patient & family

Pain assessment is consistent

- Across different shifts, disciplines and settings

Systematic reassessment & interventions evaluated

- Findings & plan are well documented
- Assessment parameters, goals, outcome

Realistic Comfort/Function Goal

Eliminate or control cause of pain

Analgesics provide partial, temporary relief

- 50% < pain considered “good” for acute / cancer pain
- 30% < pain considered “good” for chronic pain

Balance desire for pain reduction with:

- Improved functioning (self care, participate in therapy)
- Avoidance of drug-related adverse effects
- Developing nondrug skills to better cope with pain

Goals should be SMART*, both daily & long-term

* SMART = Specific, Measurable, Attainable, Relevant & Time-bound

Strategies Differ based on Pain Type

Acute, Transient Pain

- Pre-emptive ~ intermittent if mild/episodic
- Pain reduction > 50%
- Prevent, monitor, treat side effects
- Optimum functioning for healing

Persistent Pain (chronic disease model)

- Realistic pain reduction expectation (30%)
- Functioning, self-management & coping despite pain
- Emotional stability and QOL

Pain at the end of life

Best Practice Guidelines

Assess pain & mental health/SUD risk

Treat with analgesics & adjuvant

- Base on prior experience / pharmacology
 - Requires regular dosing for opioid dependent
 - Limit dose escalation (<200mg/day) & concurrent Benzodiazepine
 - Avoid problem-prone drugs
- Anticipate, recognize & treat side effects

Monitor closely, tailor to responses

Attend to psychosocial concerns & aberrant behaviors

Nondrug, interventional/specialty care prn

E.R.A.S. Protocols

Preoperative preparation

- Nutrition, Exercise
- Learn non-drug pain management approaches
- Taper opioid to lowest tolerated dose if applicable

Initiate Perioperative Multimodal Approaches

- Local Anesthetics, Acetaminophen, Coxib or NSAID, Ketamine &/or gabapentinoid
- Carbohydrate loading up to 2 hours prior to induction; optimize fluid balance
- PONV prophylaxis (e.g., corticosteroids, scopolamine, ondansetron, 5HT-3)

Scheduled non-opioid ATC (until 7 days post-op) + non-drug comfort measures

- Opioid prn, oral route ASAP
- Early mobilization & gut wake-up
- Avoid sedatives, treat side effects
- Patient / Family education

Best Practices Chronic Opioid Therapy

Risk stratified care

- Informed consent & treatment agreements
- Frequent re-evaluation, including adherence
 - e.g. Urine drug screens, pill counts, State monitoring
- Base on prior experience / pharmacology
 - Requires regular dosing for opioid dependent
 - Limit dose ($\leq 200\text{mg/day}$) & duration of opioid Rx (as possible)
- Anticipate, recognize & treat side effects

Tailor to bio-psychosocial needs/responses

Nondrug, interventional/specialty care prn

Multi-modal therapy balances concerns by selecting:

A combination of different interventions to treat pain (drug & nondrug)

Use low doses of different drug classes for combined and synergistic effects to:

- Target different mechanisms of pain
- Lower amplifiers of pain and side effects
- Lower end-organ toxicity



Multimodal Therapy

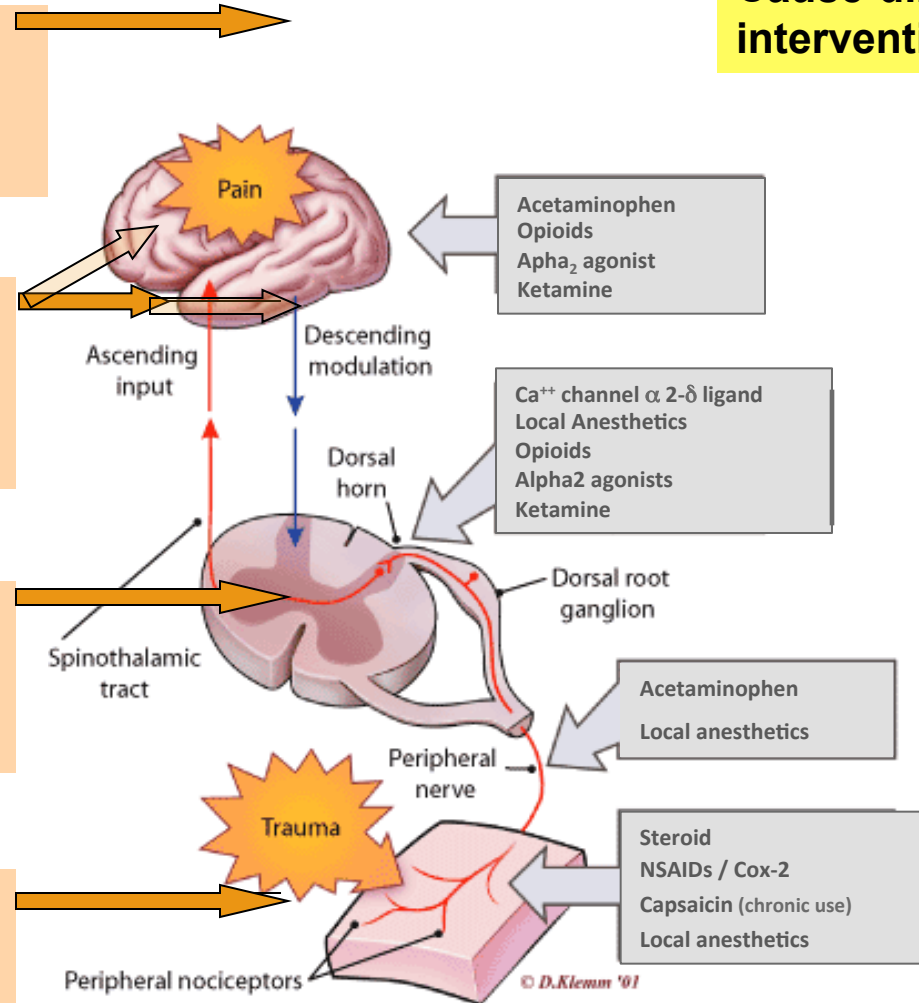
Cause-directed interventions

Therapeutic communication/use of self, prayer, rituals, pet therapy, support groups, Complementary Integrative

Coping strategies, relaxation/imagery; patient/family education & counseling music, distraction, cut fear, anxiety, sad

Reduce extraneous stimuli; stimulation (proximal, distal, contra-lateral), positional alignment, physical therapy, graded activity

Heat, cold, position, orthotics, exercise, massage, wound support, TENS, compression, rehabilitation



Acetaminophen (APAP)

- First-line analgesic for older adults
 - Especially mild - moderate musculoskeletal pain¹
- Less effective than NSAIDs for inflammatory pain
- Ineffective for chronic low back pain and arthritis²
- Inadvertent exposure common
 - Co-ingredient in many common OTC drugs
 - (fever, cough/cold, headache, etc)
 - Co-analgesic in many pain relievers
 - Dose caps implemented by FDA helped

1. AGS. (2009). Pharmacological management of persistent pain in older persons. *JAGS*, 57(8), 1331-1346.

2. Felson D. (2015) Paracetamol is ineffective for spinal pain and knee and hip osteoarthritis. *Evid Based Med*. 20(6):205

NSAIDs Help But May Be Toxic

#1 prescribed drug class in world

Effective for many pains; & synergistic with acetaminophen

Causes 3300 deaths; 41,000 hospitalizations/yr¹

Ibuprofen or Celecoxib ~ have best efficacy & GI safety²

- Diclofenac sodium & naproxen (doubles) risk
- Piroxicam, indomethacin, ketorolac >4X GI risk

Can worsen hypertension, CHF, renal disease

- Naproxen (880mg/d) or low dose (200mg/d) celecoxib best²

With cancer ~mask fever or predispose to bleeding

1. Scarpignato, et al. International NSAID Consensus Group. Safe prescribing of non-steroidal anti-inflammatory drugs. BMC Med. 2015 Mar 19;13:55

2. Nissen et al. Cardiovascular Safety of Celecoxib, Naproxen, or Ibuprofen for Arthritis *N Engl J Med*. 2016 29;375(26):2519-29.

Better choice non-opioids

Drug (Daily Max)	Recommended Starting Dose	Comments
Acetaminophen (3,000-4,000mg)	500-1000mg q4-6h	↓ 50-75% with liver co-morbidity
Celecoxib (200mg)	100-200mg daily	Gastroprotection if ASA used
Naproxen (1,500mg)	250mg q8-12h	500mg load. Less cardiotoxic, more GI effects (protect).
Ibuprofen (3,200mg)	400-600mg tid	Avoid w/ cardioprotective ASA. Takes a week for best effect. Gastroprotection \geq 1800mg/d
Nabumetone (2Gm)	500-750mg q8h	1Gm Load. Long half life; little platelet effect. Less GI effects
Salsalate (2Gm)	1-1.5Gm q12h	Dosed once or twice daily. Takes 3-4 days for best effect

Topical NSAIDs

Higher concentration @ target tissue

Lower concentration distant areas

High level patient acceptance

Better when pain is localized

Less GI & CV side effects than oral

- More likely in patients with Hx GI side effects
- Dry skin in 25% of patients

Safe NSAID Use: Longer-Term

Avoid long-term use with risk factors

- Over age 70
- Co-morbid GI, renal, hypertension, cardiac, hepatic states
- Drug-drug interactions (e.g. NSAIDs, Steroids, anticoagulants)

Gastroprotection with PPIs (e.g. omeprazole)

Warn patient about hidden OTC sources of Non-opioids

- Especially Acetaminophen, (not a true NSAID)
 - No more than 2 Gm Acetaminophen/day with liver risk
 - No more than 4 Gm Acetaminophen/day with liver risk

Limit duration of indomethecin or ketorolac

Baseline & periodic monitoring of risk/complications

- GI, Renal, Blood counts, BP, skin, cognition

Opioid Starting Doses*

(in opioid naïve patients)**

Drug	Oral	Parenteral	Comment
Morphine	15mg	2.5 - 5mg	Women tend to need higher doses for same effect. Avoid with renal dysfunction (M3G).
Oxycodone	7.5mg	NA	Oxycodone has longer duration than morphine. CYP 2D6 & 3A4
Hydrocodone	10mg	NA	Watch co-analgesic dose. CYP 2D6 & 3A4 metabolism, drugs or food may affect response
Hydromorphone	2mg	0.5mg	Significantly more potent than morphine with quick onset and shorter duration of action
Tramadol	50mg	NA	Lowers seizure threshold. 200-400mg/day maximum. Risk of serotonin syndrome

* Doses not equipotent ** Start with 25-50% lower dose in older adult

Opioid titration/tapering

Based on frequent re-assessments (4-A's)

- Analgesia, Activity, Adverse effects, Aberrancy

Change dose based on response

- 10% when small adjustment needed
- 25% when expedient adjustment needed
- 50% when rapid adjustment needed

Titrate/taper bolus doses can be incrementally

Adjust the dosing interval

Adjust continuous infusions daily if used

Patient is Opioids Tolerant if,

Take at least 1 of the following daily for > 1 week

- 60mg oral morphine/day
 - 20mg IV Morphine per day
- 25mcg/hr TD Fentanyl
 - 600mcg IV Fentanyl/day
- 30mg oral oxycodone /day
- 8mg oral hydromorphone/day
 - 1.6mg IV Hydromorphone (Dilaudid)/day
- 25mg oral oxymorphone (Opana) /day
 - 2.5mg IV Oxymorphone/day
- Equianalgesic dose of other opioid

Medical Marijuana

Legal in 28 States and Washington DC

- 16 States allow Cannabidiol (CBD) for medical use
- 7 States and Washington DC permit recreational use

Research appears to support

- CBD effective against neuropathic/chronic pain and seizures
- THC reduces nausea/vomiting and improves appetite
- Cannabis helps MS spasticity; Tourette's; PTSD
- CBD low SEB; THC high SEB

Potential Harms

- Unintentional injury (MVC), COPD, Testicular germ cell tumor, pediatric OD
- Learning, memory, performance-related impairment
- Psychosis, schizophrenia (especially with use < age 18), worsens bipolar disorder

Schedule I

National Academies of Science, Engineering, and Medicine.

[The health effects of cannabis and cannabinoids: the current state of evidence and recommendation for research.](#) (2017) Washington, DC: The

Approaches to refractory pain

Relative success in treating Neuropathic Pain / NNT

Opioids	NNT = 2.7
Gabapentin/Pregabalin	NNT = 3.2
TCA / SSNRI	NNT = 4
Lidoderm 5%	NNT = 4.4
Capsaicin	NNT = 5.3

Anticonvulsants (Neuropathic Pain)

Gabapentin commonly used

- Favorable safety profile & positive RCTs in PHN/PDN
- Usual effective dose: 1200–3600 mg/d ~ higher

Pregabalin equally effective, better tolerated

Analgesic effects established for other AEDs

- Phenytoin, Carbamazepine, Valproate,
- Oxcarbazepine (Trileptal), Lamotrigine (Lamictal)

Limited experience with other drugs

CNS depressant effect

Renal dosing adjustments as indicated

Antidepressants

Best evidence: 3⁰ amine TCAs (eg, amitriptyline)

2⁰ amine TCAs (desipramine, nortriptyline) similar <SE

SSNRIs growing evidence of efficacy

- Duloxetine (Cymbalta), Venlafaxine (Effexor), Savella (milnacipran)

Atypical antidepressants ~ tried

- Trazodone (Desyrel), Bupropion (Wellbutrin)

SSRI ~help underlying mood disorder (not pain)

- Paroxetine (Paxil), Fluoxetine (Prozac)

Local Anesthetic: Lidocaine

Topical

- EMLA
- LMX
- J-Tip
- Lidocaine 5% patch
- Skin reaction most common problem

IV Lidocaine for neuropathic pain

- Loading dose/bolus dose by Pain Service
- 1 mg/kg/hr to 4 mg/kg/hr titration for effect
- Monitor for neurologic and CV side effects

Capsaicin

Topical OTC version (0.25 – 0.075%)

Qutenza 8%

- Applied for ≤ 1 hour (up to 3 patches)
 - Very painful so area needs to be anesthetized
 - Monitoring and analgesia needed before and after application
 - Apply Cleansing Gel for a minute, then wipe dry
 - Skin will be sensitive for a few days to heat.
 - Approved for post-herpetic neuralgia (intact skin)

Better choice adjuvants

Drug (Daily Max)	Recommended <i>Starting</i> Dose	Comments
Gabapentin (3,600mg/d)	100-300mg HS	Titrate q3-7 days. Renal dosing. Effect 2 weeks @ top dose
Prebatalin (600mg)	75mg BID	Titrate q3-7 days. Renal dosing. Seizure risk sudden withdrawal
Nortriptyline (150mg)	10-25mg HS	Risk for anticholinergic side effects (less than amitriptyline)
Duloxetine (60-120mg/d)	20-30mg Daily	Titrate weekly. Less toxic than TCS. Drug interactions, suicide
Tizanidine (32Gm)	2mg q6h	Titrate Q1-4 days. Sedation & hypotension effects ~ drug interaction. Taper

Cause Directed Adjuncts

Muscle relaxants

- Tizanidine (Zanaflex)
- Botulinum Toxin type A (BOTOX, Myobloc)
- Antispasmodics
 - For Smooth Muscle (e.g. GI / GU spasms)
 - For Skeletal Muscle (e.g. Baclofen [Lioresal])

Caffeine

Serotonin receptor agonist

Teach Patients

Medication ~ necessary but alone is insufficient

Use the right drug for right discomforts in right way

- Analgesics: lowest dose, shortest time
- Adjuvants, Give adequate trial

Avoid interactions;

- 1 prescriber – 1 pharmacy
- Know foods, drugs, herbs, alcohol that can interact <http://healthtools.aarp.org/drug-interaction>

With opioids

- Always use opioid sparing methods to limit adverse effects
- Always be concerned about safe storage, safe use, safe disposal
- Never sell or give opioids to another person

Rx Opioid Disposal

New “Disposal Act” expands ways for patients to dispose of unwanted/expired opioids

Decreases amount of opioids introduced into the environment, particularly into water

Collection receptacles

Call DEA Registration Call Center at **1-800-882-9539** to find a local collection receptacle



Mail-back packages

Obtained from authorized collectors



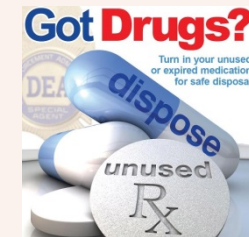
Local take-back events

- Conducted by Federal, State, tribal, or local law enforcement
- Partnering w/ community groups

Voluntarily maintained by:

- Law enforcement
- Authorized collectors, including:
 - Manufacturer
 - Distributer
 - Reverse distributor
 - Retail or hospital/clinic pharmacy
 - Including long-term care facilities

DEA National Prescription Drug Take-Back Days



Spectrum of Pain Relief Options



Spectrum of Pain Relief Options:

Self-initiated or "Low-tech" Approaches	Treatment Targets (& common medications)	Professional-initiated or "High-tech" Approaches
	Immediate Area of Pain:	
Massage, rubbing Moist heat Application ice Positioning Braces, orthotics, compression Remove source, cause of pain	Medications: NSAIDs Treat cause (e.g. headache) Capsaicin or menthol cream Local Anesthetics	Physical Therapy (modalities) Electric stimulation (TENS) Specialize massage techniques Trigger Point Injections Low level Laser therapy Surgery
	Region of Pain & Spinal level	
Reduce local irritation Contra-lateral stimulation Proximal/distal stimulation	Medications: Opioids Anticonvulsant (gabapentin) Antidepressants Reduce nerve inflammation Muscle relaxers (tizanidine)	Nerve Blocks (sensory, autonomic) Cryotherapy, Radiofrequency Prolotherapy (sugar injected in tendons) Peripheral Nerve Stimulation Spinal Cord Stimulation Epidural / spinal analgesia Physical manipulation, traction
	Whole Body	
Diet, nutritional supplements Exercise, pacing activities Herbal or Aroma Therapy, Breathing techniques Yoga, Tai Chi		Acupuncture, Acupressure Work Hardening Functional Restoration Multidisciplinary Rehabilitation
	Brain or Mind-Body Focused	
Relaxation, imagery, hypnosis Knowledge about condition Music, distraction Journal writing Change thinking, attitudes Reduce fear, anxiety, stress Reduce sadness, helplessness	Medications Opioids, Anticonvulsants Antidepressants Other co analgesics	Biofeedback training Counseling Electroconvulsive therapy Deep-Brain Stimulation Cognitive-Behavioral Therapy
	Spiritual or Energy-Focused	
Prayer, meditation Self-reflection, re: life / pain Meaningful rituals Energy work (e.g. TT, reiki)		Spiritual Healing Magnetic Therapy Homeopathic remedies
	Social Interaction-focused	
Improved communication Volunteering Problem solving Support groups Pet Therapy		Family therapy Functional restoration Vocational training Psychosocial Counseling

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Self-initiated or “Low-tech” Approaches	Treatment Targets (& common medications)	Professional-initiated or “High-tech” Approaches
	Whole Body	
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Developed by Paul Arnstein at MGH pmarnstein@partners.org
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General Domains of CIM

∞ Natural Products

- Herbs (botanicals), vitamins and minerals, and probiotics.

∞ Mind and Body Practices

- Chiropractic, Physical Therapy; and osteopathic manipulation,
- Yoga, & meditation,
- Massage therapies (most popular mind / body practices)
- Energy Therapies

∞ Traditional healers,

- Ayurvedic medicine, traditional Chinese medicine,
- Homeopathy, and naturopathy

Most patients will need more than one tool to relieve pain

Pharmacological and non-drug methods

Active and passive (1 + 1 = 3)

Simultaneously targeting the:

- Body
- Mind
- Spirit
- Social interactions

Treat Known amplifiers

We Must Work Together to Stop the Pendulum Swing Away from Effective Pain Control!



Thank you for your Commitment to Effective Pain Care