Navigating the Appropriate Use of Opioids for Acute and Chronic Pain in 2022

David R. Neff, DO

Two Age-old Competing Public Health Problems

Opioid Related Deaths and the Need to Appropriately Treat Pain

- ~5700 BC – First Documented Use of Opium in Iberia and the Italian peninsula
  - Eased pain, induced sleep, controlled symptoms like cough and diarrhea
  - It also created euphoria and engendered recreational use
- 400 BC – 1500's -- Opium was broadly used for medical, recreational and religious purposes by many Mediterranean and Middle East cultures
  - Valued by Hippocrates
- 1683 – The British East India Tea Company started trading opium with tea to balance deficits
- Early 1800's – morphine and codeine were isolated from opium
- 1840's - 1850's – The Opium Wars Were Fought Largely Between China and the United Kingdom (along with France) when China was overrun with addiction
- 1860's – Morphine and opium were often mixed with wine and spices to treat pain during the Civil War
- 1874 – Heroin (diamorphine) was synthetized
- 1900's – Nearly 150 synthetic opioids were developed to find a better medication to better control pain without causing addiction
  - To date, none have been found while more potent agents were becoming available
- 1914 – Addictions had become so prevalent that the Harrison Narcotics Tax Act was the First US Law Passed to Control Addictive Substances including Opium, Heroin & Cocaine with several legislative updates
- 1914 - 1970's – The need for better pain therapies increased with advancing lifespans and the number of industrial, automobile and war related injuries along with more acquired diseases such as cancer and autoimmune diseases
- 1980 – Porter and Jick (NEJM Vol 2) – "Addiction Rare in Patients Treated with Narcotics"
- 1996 – OxyContin Approved by the FDA
- 1997 – The Food and Drug Modernization Act (FDAMA) was passed to better cope with advancement of technological, trade and public health complexities
- 2000 – Pain Declared as the 5th Vital Sign Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), no "upper limit"
- 2000's -- Overdosed Deaths Being Identified with Increase Prescription Rates
- 2011 – Opioid Prescriptions Peaked as Opioid Deaths Increased
- 2013 – Heroin Deaths Increased and Illicit Fentanyl Arises as Prescription Rates Fall
- 2015 – Fentanyl-related Deaths Begin to Outpace Heroin and Prescription Opioid Deaths
- 2016 – CDC Chronic Pain Guidelines Emerge and Inadvertently Became the Yardstick For Regulators as Chronic Pain Patients Begin to Lose Access to Care
- 2021-22 – Opioid Deaths Reach an all-time high largely driven by illicit fentanyl, prescription opioids drop to 2000 prescribing levels and over ½ of chronic pain patients cannot get access to care

The Ongoing Conundrum in 2022

- **Fentanyl-Related Deaths Reach an All-time High**
- **The Number of "Pain Refugees" Who Truly Need Relief Has Grown Due to Restrictive Access to Care**

PAIN REEXAMINED

The New York Times

Good News: Opioid Prescribing Fell. The Bad? Pain Patients Suffer, Doctors Say.

Doctors and insurers are using federal guidelines as cover to turn away patients, experts tell the C.D.C. and Congress.

CDC Clarifies its Opioid Prescription Guideline

Laura Mills
Researcher

HARPER'S MAGAZINE

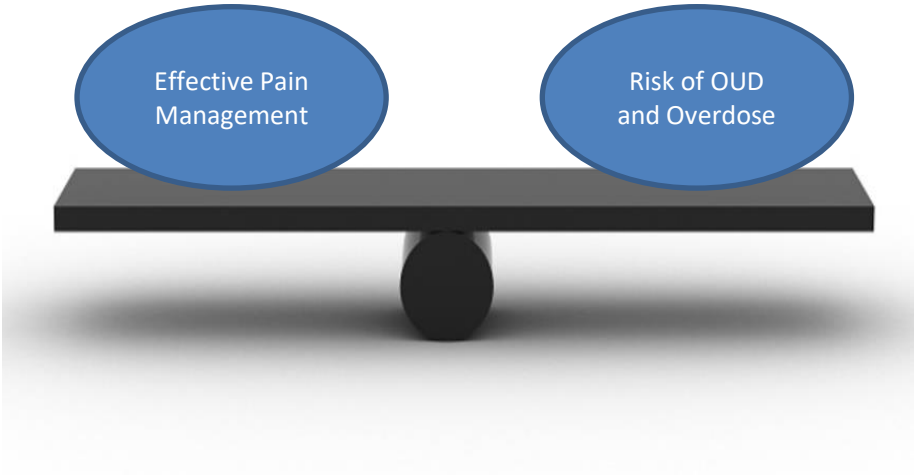
[Report]

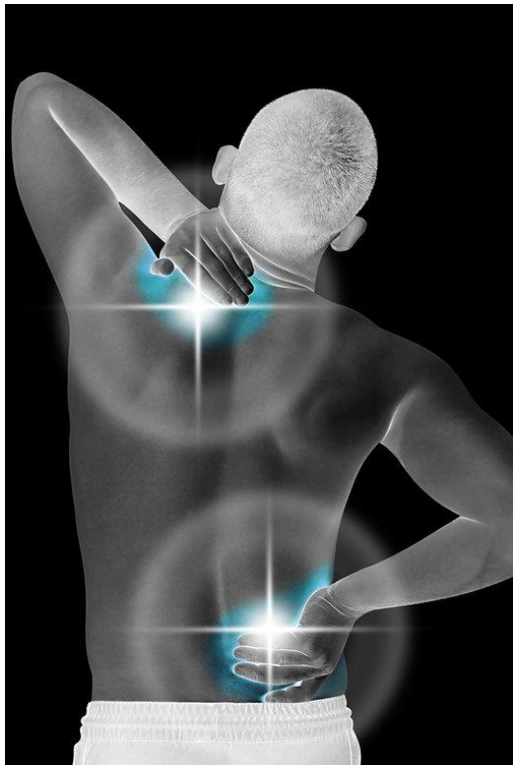
The Pain Refugees

The forgotten victims of America's opioid crisis

by Brian Goldstone

Goal: Help the Provider to Balance Effective Pain Management While Mitigating Overdose Risk





National Center for Health Statistics

NVSS Vital Statistics Rapid Release

Provisional Drug Overdose Death Counts

The Overdose Landscape for 2022: U.S.

Based on data available for analysis on: May 01, 2022

Figure 1a. 12 Month-ending Provisional Counts of Drug Overdose Deaths: United States

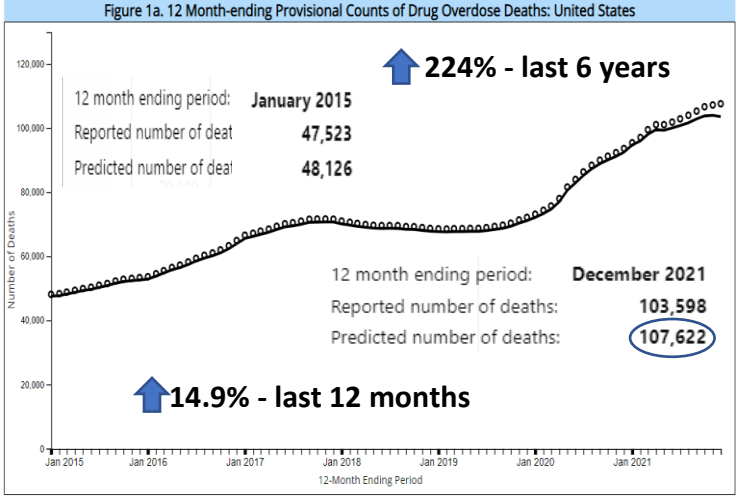
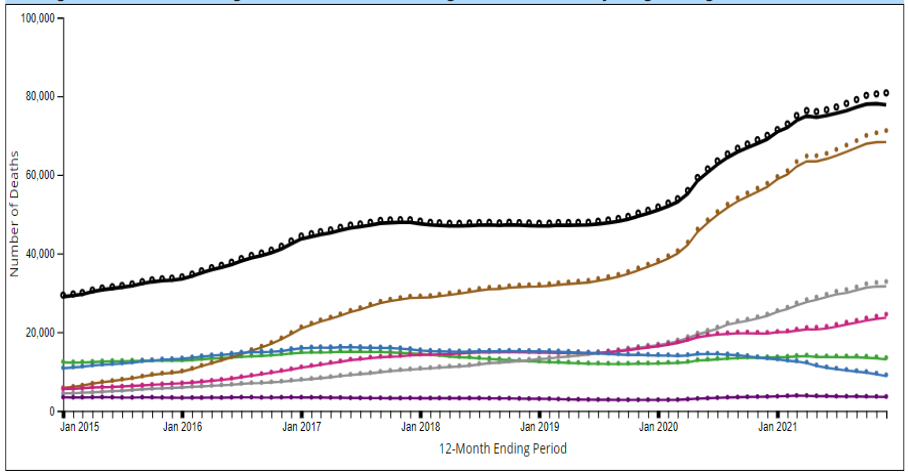


Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



12 months-ending Dec 2021 (Predicted)

All opioids 80,816

Fentanyl-Related 71,238

Amphetamines 32,856
Cocaine 24,538

Prescription Opioids 13,503
Heroin 9,137
Methadone 3,612

Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov) Accessed 5/14/2022

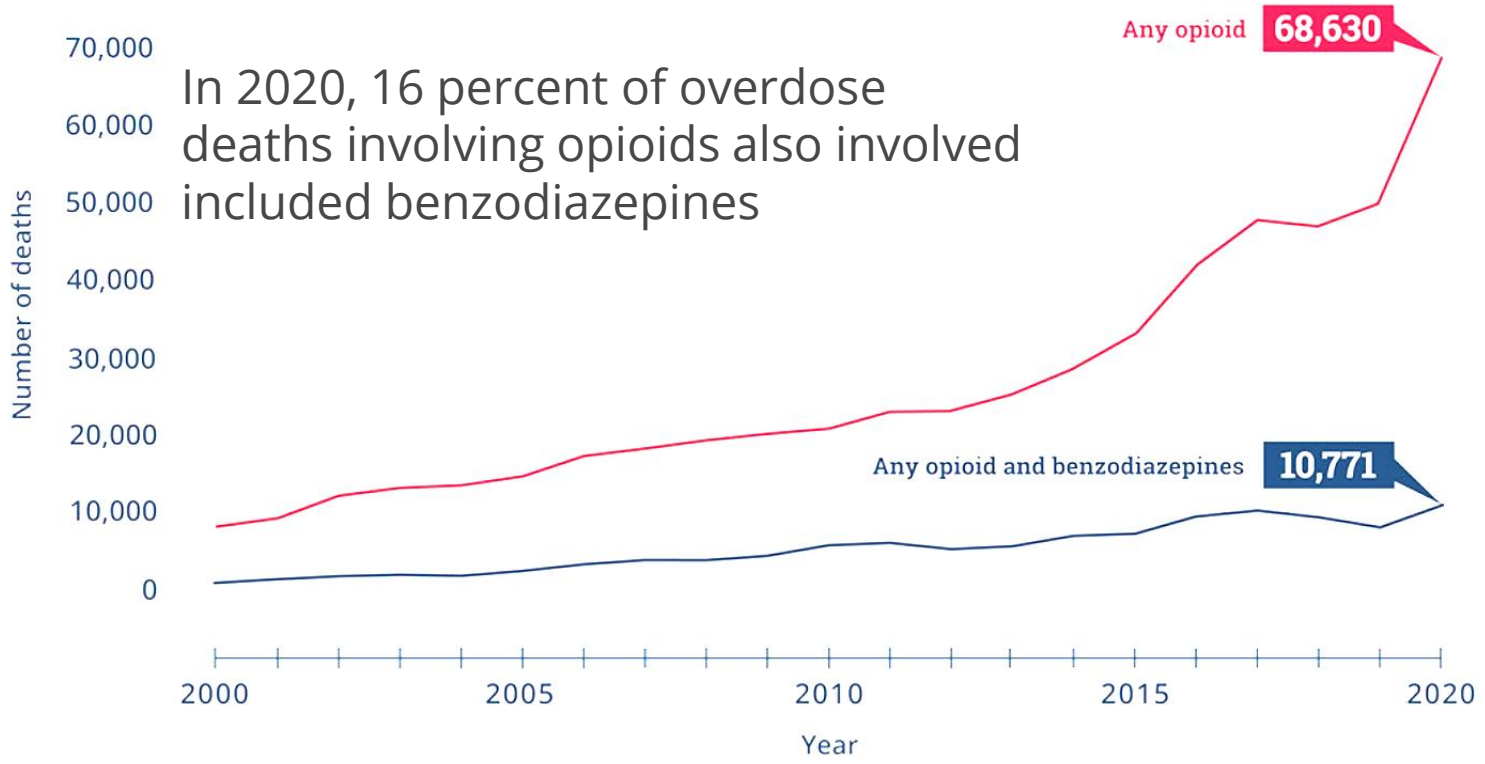
The Need to Provide Adequate Pain Management Services is Confounded by the Unchecked Number Deaths Related to Illicitly Manufactured Fentanyl (including Counterfeit Laced Pills) and Stimulants

Counterfeit Oxycodone Tablet Containing Fentanyl

Source: Santa Clara, California Department of Health

National Overdose Deaths Involving Any Opioid, by Benzodiazepine* Involvement,

All Ages, 2000 – 2020



*Among deaths with drug overdose as the underlying cause, the benzodiazepine category was determined by the T402.4 ICD-10 multiple cause of death code; the any opioid category was determined by the T40.0-T40.4, T40.6 ICD-10 codes.

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 2000–2020 on CDC WONDER Online Database, released 12/2021.

National Center for Health Statistics

NVSS Vital Statistics Rapid Release

Provisional Drug Overdose Death Counts

The Overdose Landscape for 2022: Michigan

Based on data available for analysis on: May 01, 2022

Figure 1a. 12 Month-ending Provisional Counts of Drug Overdose Deaths: Michigan

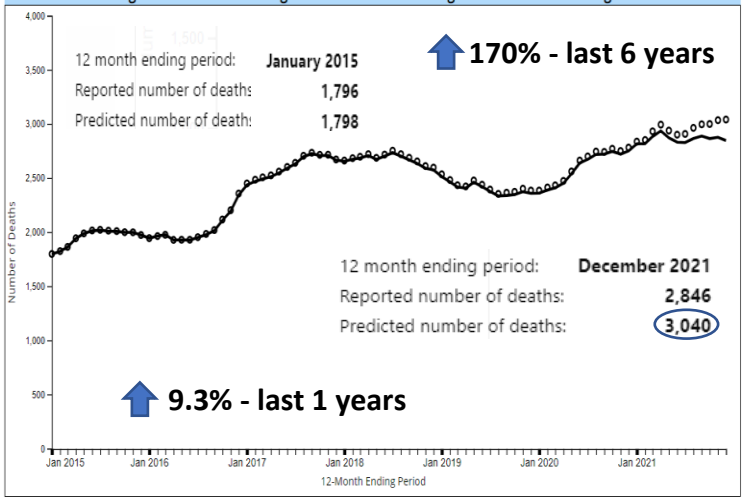
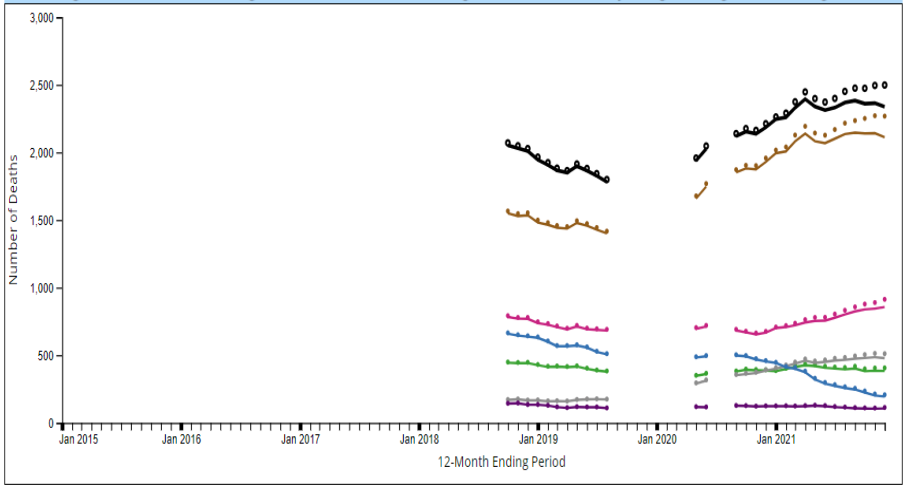


Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: Michigan



12 months-ending Dec 2021 (Predicted)

All opioids 2,498

Fentanyl Related 2,268

Cocaine 913

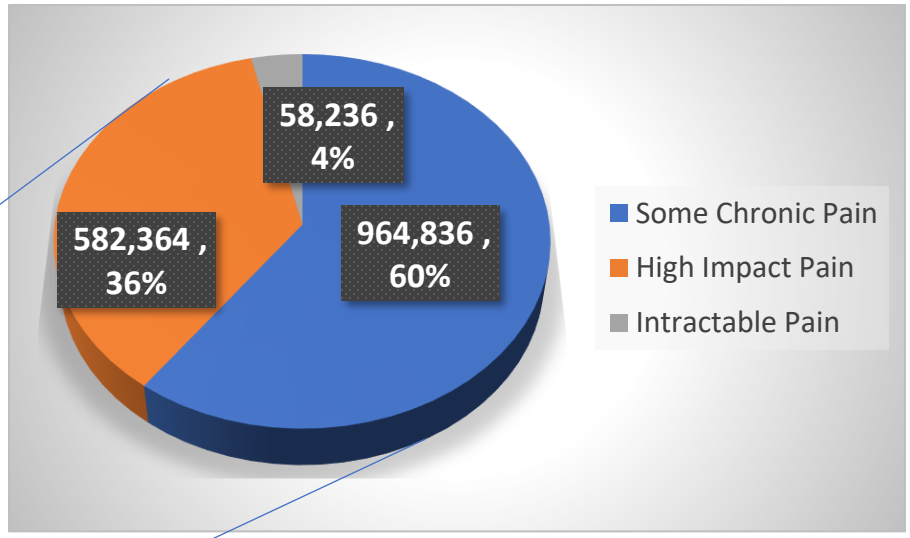
Amphetamines 478
Prescription Opioids 406
Heroin 207
Methadone 113

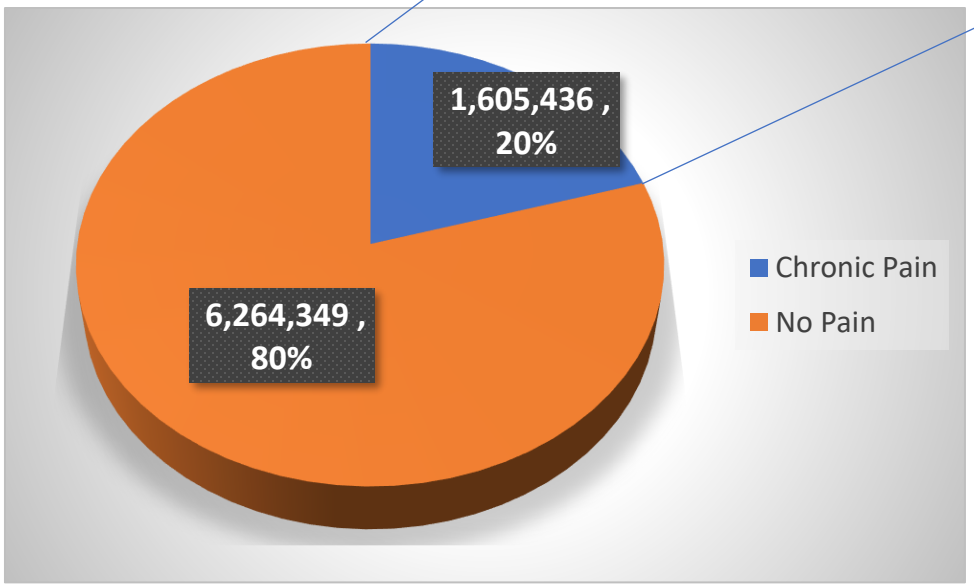
Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov) Accessed 5/14/2022

The Magnitude of Chronic Pain in Michigan Adult Residents Aged ≥18

(Best Estimate of NCHS 2020 Data Brief Extrapolated to the 2020 US Census Estimates for MI Residents)

- About 20% of all Michigan adults have chronic pain
- Chronic pain can occur with severe acquired illness
  - Cancer
  - Infection
  - Chronic Autoimmune and inflammatory disorders
- Long-term permanent injury
  - Auto
  - Work
  - Military Service
  - Sports Injuries
  - Slips and Falls
- Certain genetic disorders

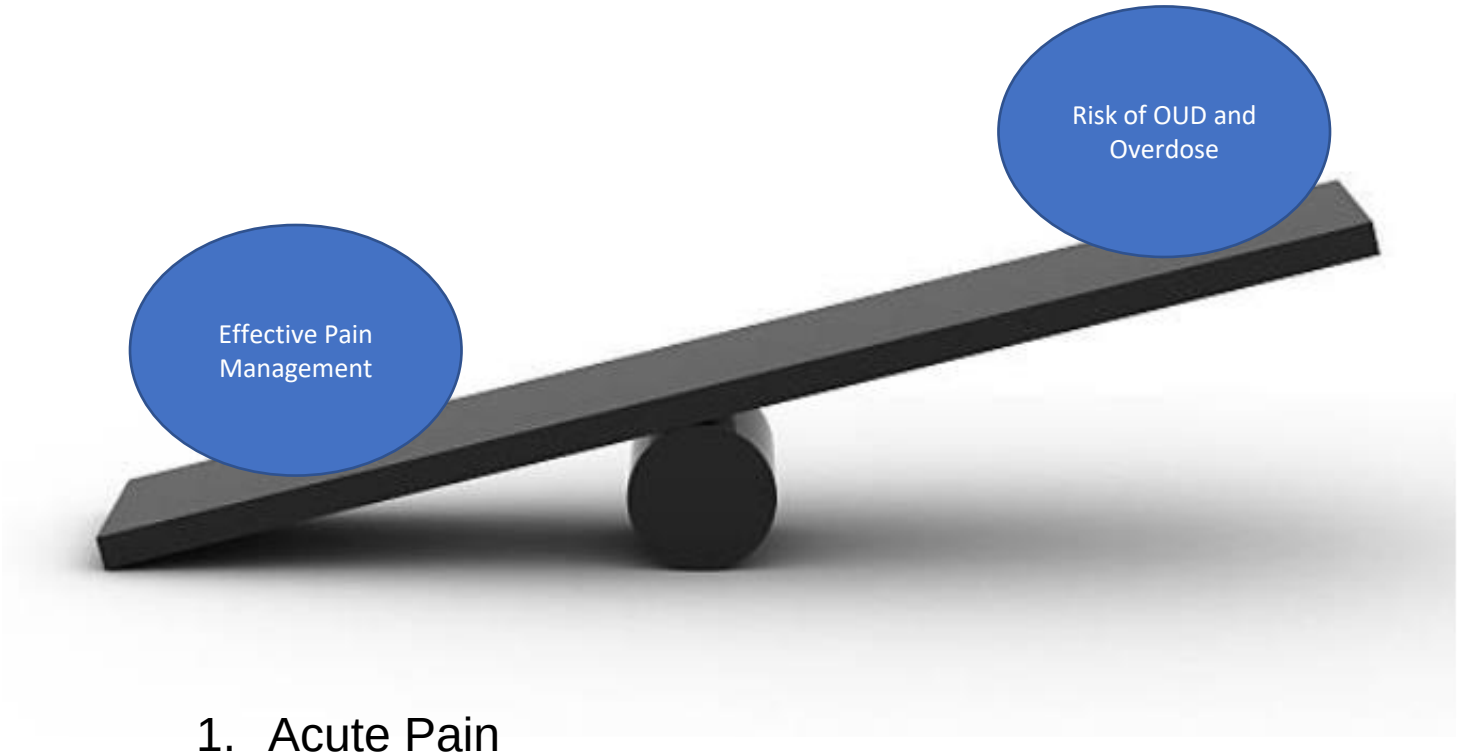




- Up to 60,000 (~4%) of the adult MI population has **Intractable Pain (IP)** which is a moderate to severe, constant pain that is typically relentless and debilitating, not curable by any known means, causes suffering, and leads to a house-bound or bed-bound state and possibly to premature death
- Intractable Pain patients cannot get access to care
- Abandoning the intractable pain patient challenges medical ethics, professional duty, the public health code and perhaps more

NCHS Data Brief ■ No. 390 ■ November 2020

When The Need for Effective Pain Management May Outweigh Risk In 4 Pain Types



1. Acute Pain
2. Chronic Pain
3. High Impact Chronic Pain
4. Intractable Pain That Is Otherwise Untreatable

Acute Pain

- Acute pain is defined as self-limited discomfort that typically lasts from a few moments to several weeks but less than 3 to 6 months.
- It can relate to soft tissue or skeletal damage, and may be categorized as spontaneous or post-traumatic, with the trauma planned (surgical) or unplanned (accidental).
- As the injured tissues heal, acute pain gradually resolves.

- Pain can vary in severity from mild to severe.
- Some therapies, such as opioids, are reserved for more severe pain.
- However, even if pain is severe, it is important to recognize that not all acute pain requires opioid therapy.

Severity	Examples
Spontaneous/trauma	
Mild	Sinus headache, soreness after yard work, superficial laceration
Moderate	Sprain, strain, simple bone fracture, deep laceration
Severe	Motor vehicle accident, burn, traumatic amputation

Planned/elective	
Mild	Immunization, catheter placement, phlebotomy, superficial biopsy, simple dental extractions
Moderate	Same-day surgery (arthroscopy, multiple dental extractions/ wisdom teeth, laparoscopy, podiatric procedures)
Severe	Arthroplasty, spinal, colorectal, open abdominal surgery requiring hospital stay

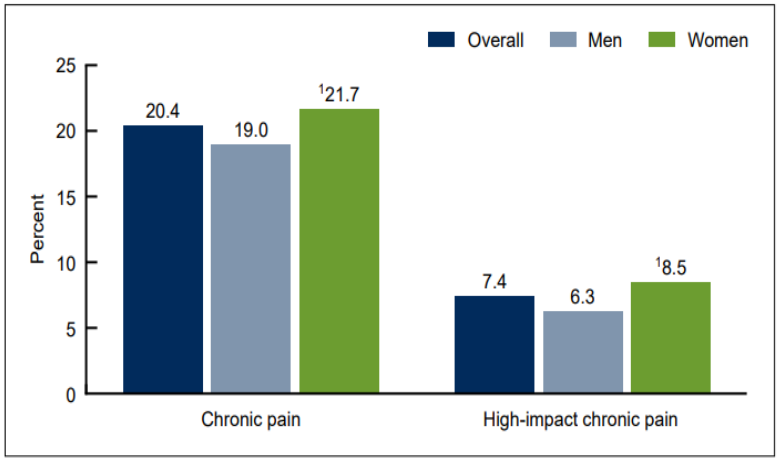
Medical Management of Acute Pain (practicalpainmanagement.com) – Accessed 4/30/22

Chronic and High Impact Pain

1. Chronic pain is based on responses of “most days” or “every day” to the survey question
2. High-impact chronic pain is based on responses of “frequently limits life or work activities”

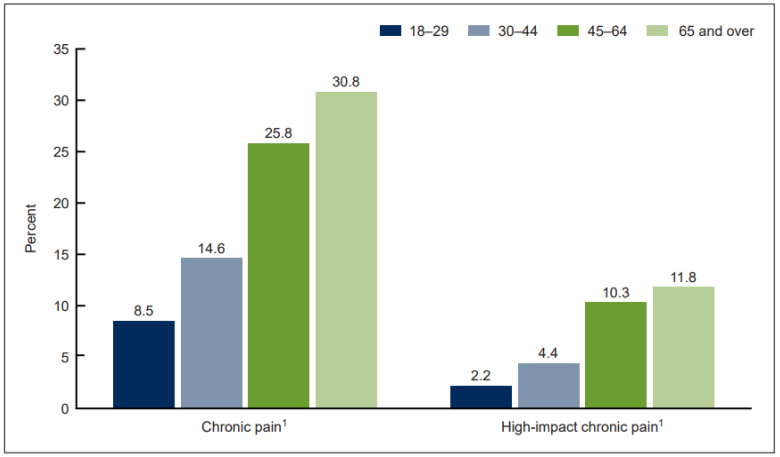
Overall and By Gender

Figure 1. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, overall and by sex: United States, 2019



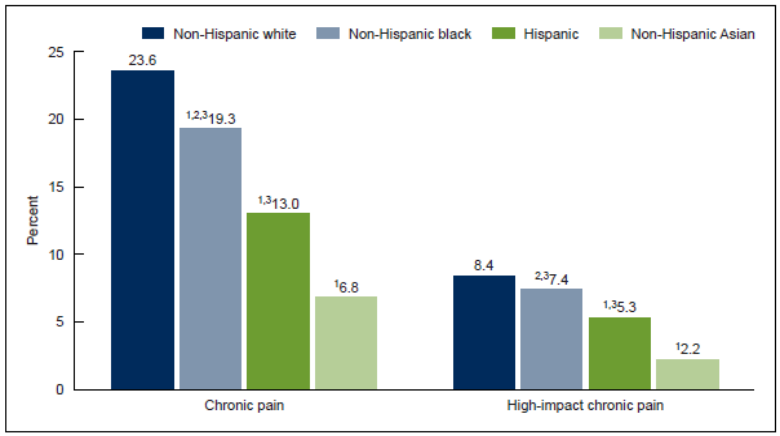
Age

Figure 2. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by age group: United States, 2019



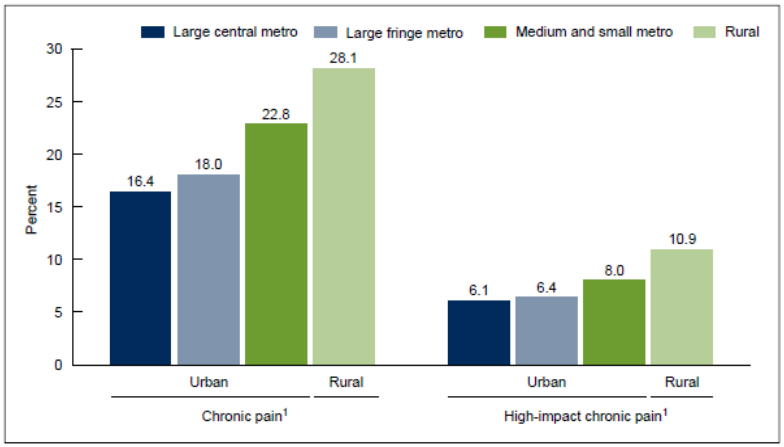
Ethnicity

Figure 3. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by race and Hispanic origin: United States, 2019



Locale

Figure 4. Percentage of adults aged 18 and over with chronic pain and high-impact chronic pain in the past 3 months, by urbanization level: United States, 2019



Intractable Pain (IP)

- IP is defined as “pain that is excruciating, constant, incurable, and of such severity that it dominates virtually every conscious moment, produces mental and physical debilitation and may produce a desire to commit suicide for the sole purpose of stopping the pain”

Common Characteristics of Intractable Pain

Pain reduces sleep and food intake
Bed-, chair-, or house-bound in the absence of opioid treatment
Depression, attention deficit, confusion, and suicide tendencies
Underlying cause is incurable, non-removable, and fails to respond to customary pain therapies
Elevated blood pressure and pulse rate
Serum adrenal hormone and immune abnormalities

Palliative Care is Commonly Required

- It is often characterized as one having “cancer quality” pain but “not dying of cancer”
- IP patients often systematically fail the usual treatments for acute and chronic pain including anti-inflammatory, mild opioid and non-opioid analgesics, antidepressants, muscle relaxants, and anti-seizure medications.
- They also don’t respond well to corticosteroid injections in and around the spinal column or peripheral nerves.
- Physical therapy, exercise, and psychological interventions have usually been of little or no avail because the pain is so profoundly uncontrolled that participation in these therapies is not possible.
- Chronic Opioid Therapy (COT) may be required
- This treatment should be regarded as end-stage or last resort due to its expense and inherent complications.

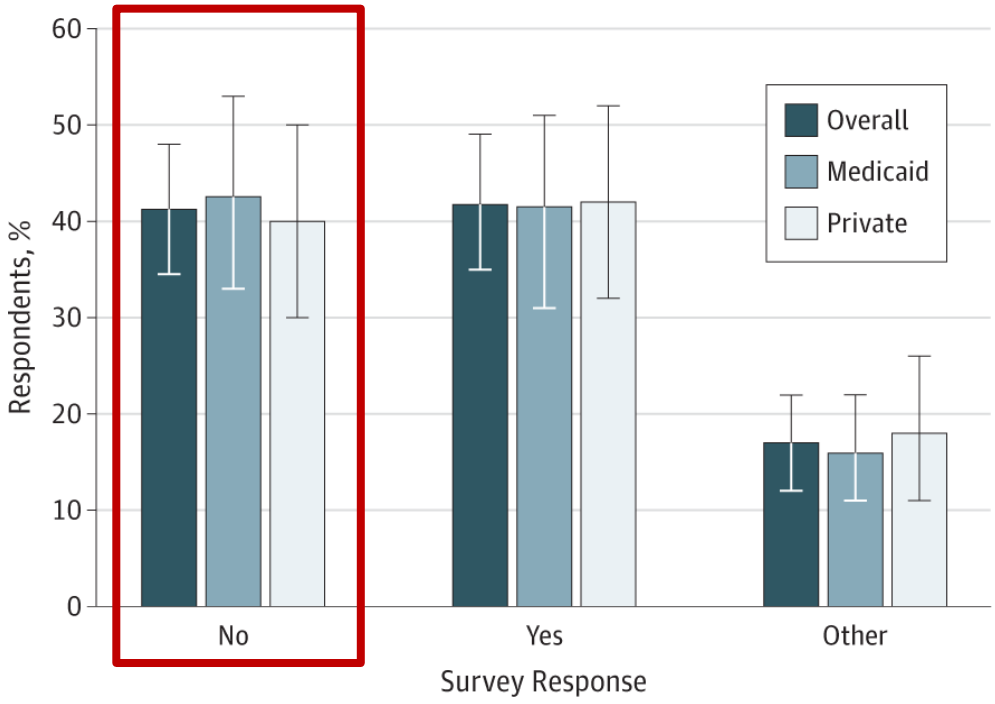
Common Causes of Intractable Pain

Admitted to Treatment	% Patients
Degenerative spinal disease post-surgery	32%
Degenerative spinal disease non-operable	22%
Fibromyalgia	15%
Migraine-vascular headache	8%
Neuropathies	6%
Congenital skeletal disease	5%
Headache-post trauma	3%
Reflex sympathetic dystrophy	3%
Osteoporosis	2%
Systemic lupus erythematosus	2%
Abdominal adhesions	1%
Interstitial cystitis	1%
Total	100%

What is Intractable Pain and How Does it Differ From Chronic Pain (practicalpainmanagement.com) – Accessed 4/30/22

“Legacy” Chronic Pain Patients Cannot Find Appropriate Access to Primary Care

- 41% of clinics won’t accept new pain patients on opioids
- Providers are reluctant to “inherit” the “legacy” patient due to regulatory constraints
- These patients may require long-term opioid use
- They are typically tolerant and dependent on opioids and would go into withdrawal if they were abruptly discontinued
- Most due not misuse opioids and exhibit addictive behaviors
- These patients typically have “cancer quality pain” without dying of cancer and are being treated palliatively.
- By some definitions – they have a “dual diagnosis” of “chronic pain disorder” and “opioid use disorder”
- There is potential for subsequent harm is high if abandoned.



Lagisetty, et al. *JAMA Netw Open.* 2019

Many Pain Clinics Also Have Restrictive Acceptance Policies

Roughly half (48%) of pain clinics did not accept Medicaid

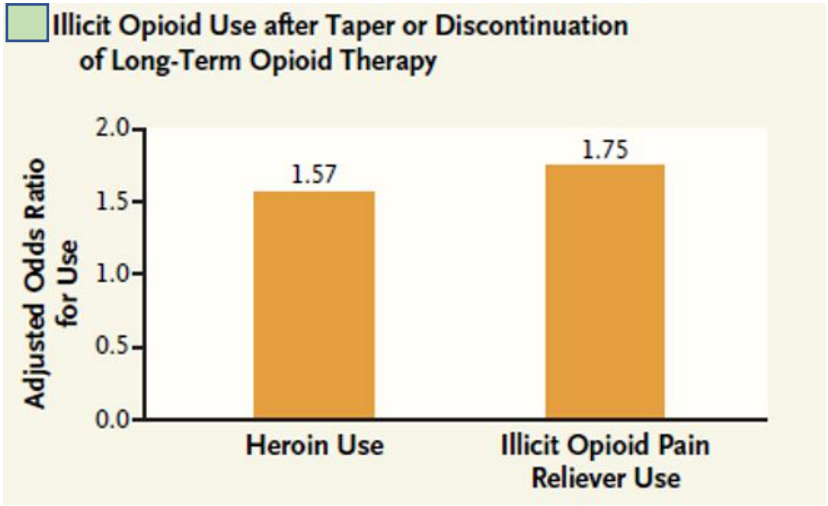
Over half (51%) required a referral before accepting new patients

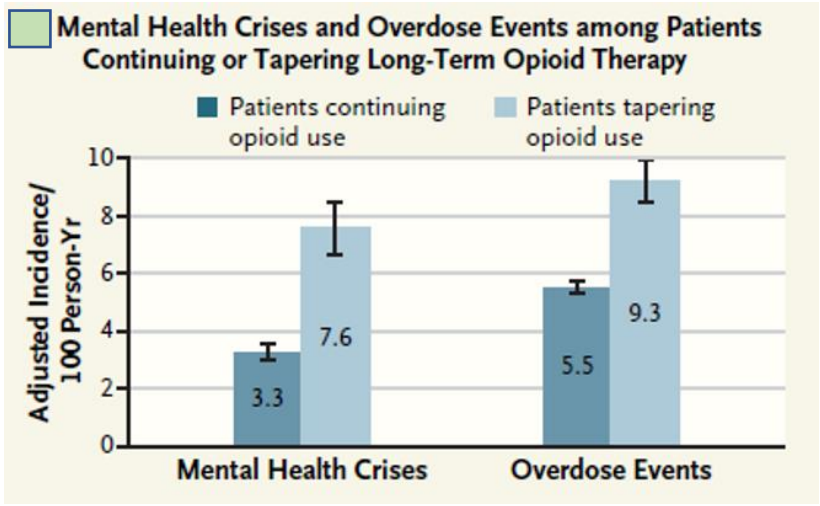
An additional 23% required a referral based on insurance type

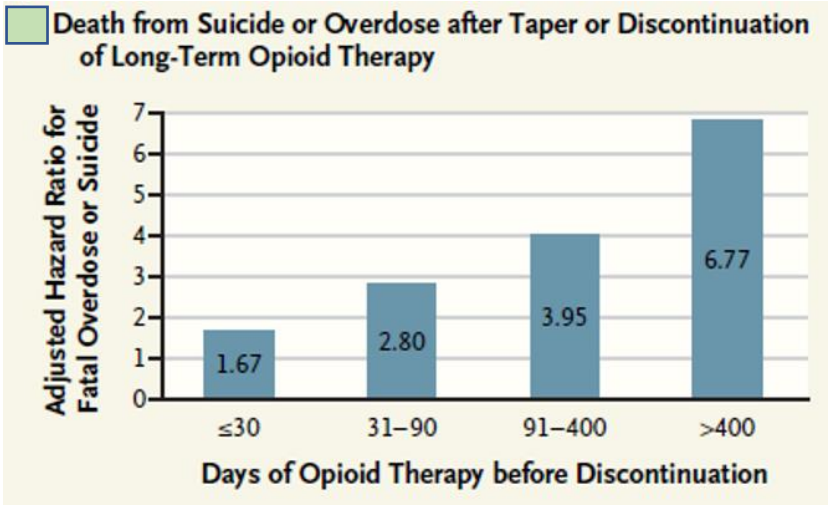
Lagisetty et al. *JGIM.* 2020.

With Loss of Access, "Legacy" Pain Patients Have Become "Pain Refugees" and Are Now Facing Harm

Phillip O. Coffin, M.D., and Antje M. Barreveld, M.D.







Patients whose medications were inappropriately tapered or stopped were:

- 1.75 x more likely to use illicitly obtained Rx's (including counterfeits which may be laced with fentanyl)
- 1.57 x more likely to use heroin (with or without fentanyl)
- 2.3 x more likely to experience a mental health crisis
- 1.69 x more likely to have an overdose event
- At increasingly greater risk for overdose or suicide the longer they have been on long term opioid therapy

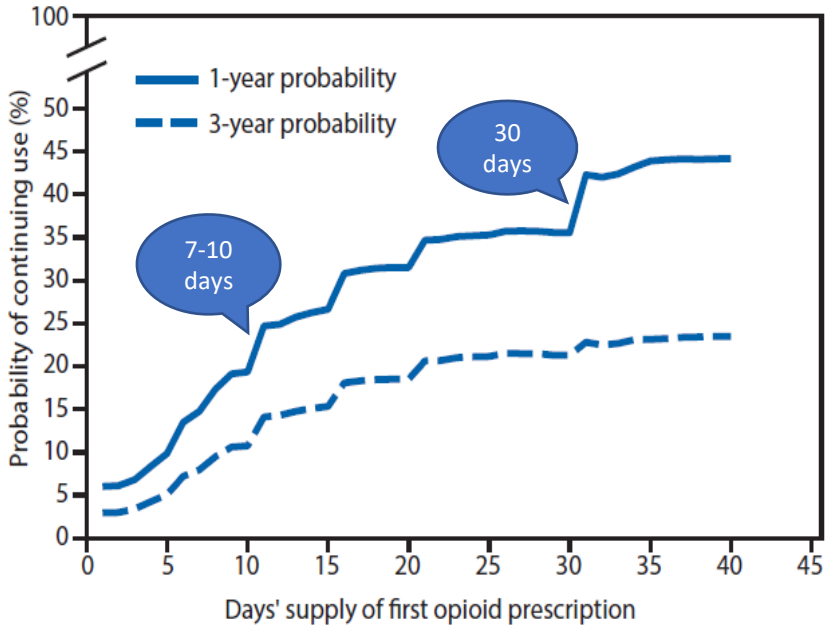
Primary Barriers to Pain Care

Lagisetty, et al.

When Risk Begins to Outweigh Benefit

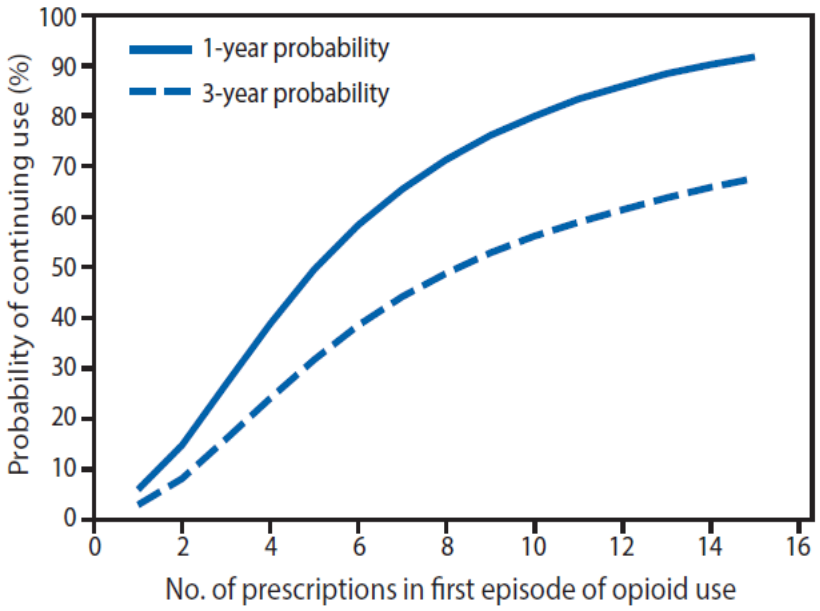
The Downside to Using Opioids Beyond 7-10 Days For Acute Pain: The Risk for Continued Opioid Use Goes Up with Days Supply and Number of Prescriptions in the First Episode of Care

FIGURE 1. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of days' supply* of the first opioid prescription — United States, 2006–2015



* Days' supply of the first prescription is expressed in days (1–40) in 1-day increments. If a patient had multiple prescriptions on the first day, the prescription with the longest days' supply was considered the first prescription.

FIGURE 2. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of prescriptions* in the first episode of opioid use — United States, 2006–2015

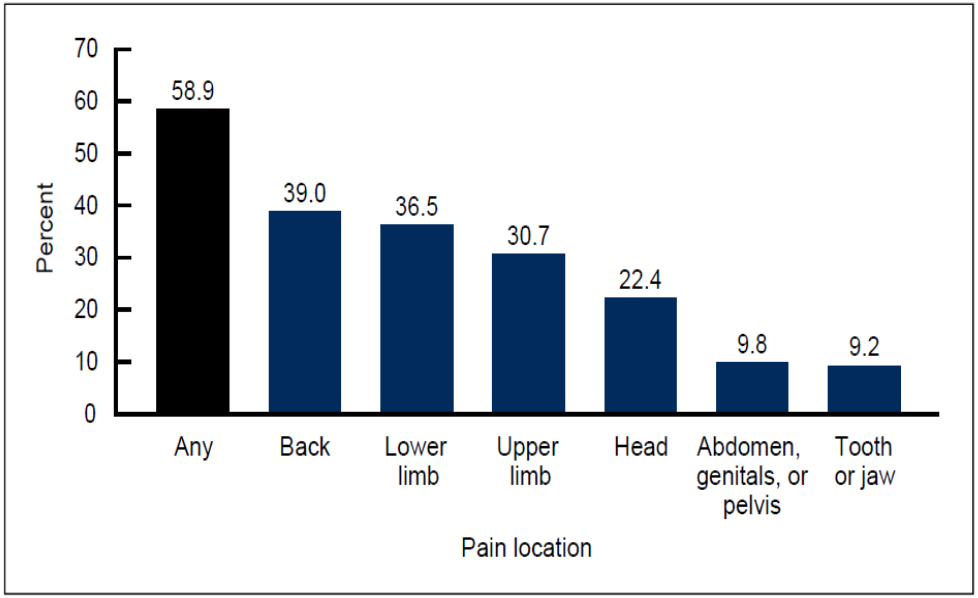


* Number of prescriptions is expressed as 1–15, in increments of one prescription.

The Percentage of Adults Aged 18 and Over With Any Pain By Body Region and Rate of Prescription Opioid Use and Opioid Use in Chronic Pain

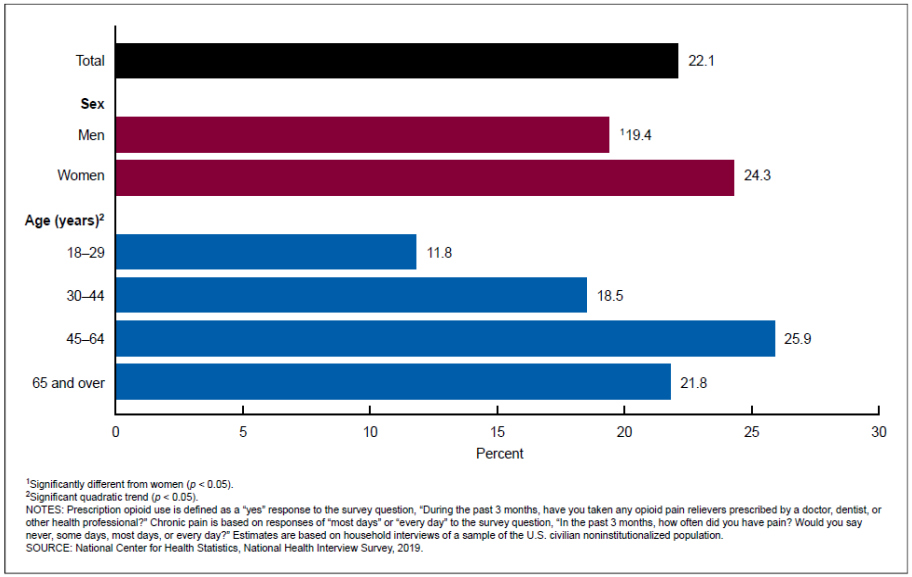
3 in 5 Have Adults Have Experienced Pain Within 3 Months of Being Asked

Figure 1. Percentage of adults aged 18 and over with any pain and pain by body region in the past 3 months: United States, 2019



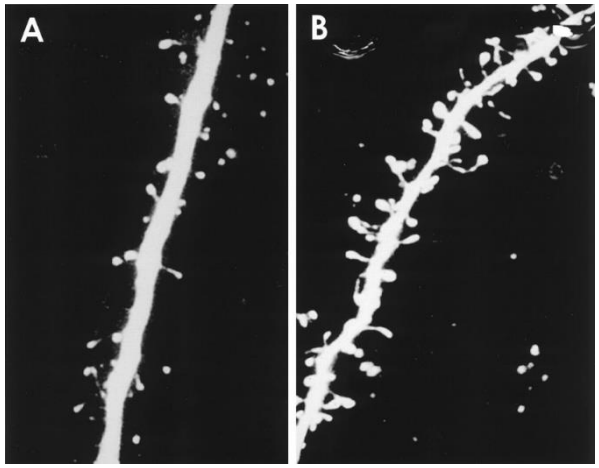
~1 in 5 Patients with Chronic Pain Have Used an Opioid Within 3 Months of Being Asked

Figure 1. Percentage of adults with chronic pain who used prescription opioids in the past 3 months, overall and by sex and age group: United States, 2019



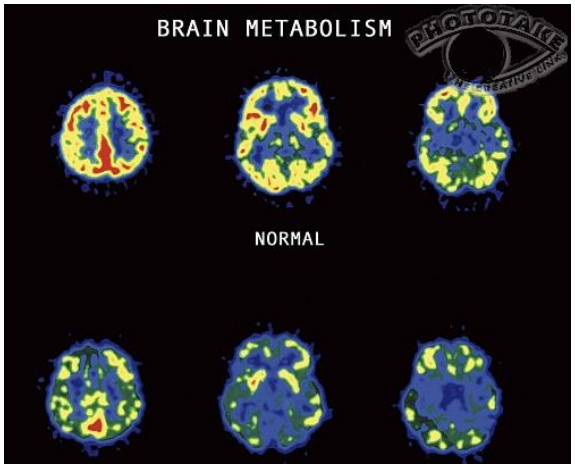
[1]Significantly different from women ($p < 0.05$).
[2]Significant quadratic trend ($p < 0.05$).
NOTES: Prescription opioid use is defined as a "yes" response to the survey question, "During the past 3 months, have you taken any opioid pain relievers prescribed by a doctor, dentist, or other health professional?" Chronic pain is based on responses of "most days" or "every day" to the survey question, "In the past 3 months, how often did you have pain? Would you say never, some days, most days, or every day?" Estimates are based on household interviews of a sample of the U.S. civilian noninstitutionalized population.
SOURCE: National Center for Health Statistics, National Health Interview Survey, 2019.

The Biological Basis of Tolerance & Dependence Leading to Addiction: A Neurodegenerative and Neurocognitive Disorder From Prolonged Exposure of External Chemicals on the Brain



Loss of Neural Dendrites (Prolonged Drug Exposure)

Normal Dendrites



Loss of Brain Function Including the Frontal Lobe

Biological and Social Consequences of Ongoing Tolerance, Dependence and Addictive Behavior

- Prolonged exposure leading to downregulated epigenetic control of nerve cell structure and function (decreased neurotransmitters, receptors and structural proteins)
- The brain can no longer synthesize these molecules and requires exogenous source of these molecules until cells can resume synthesizing them
- Loss of self control and executive function, ie, judgement
- Inability to calculate risk versus benefit
- Possible severe, uncontrollable drug seeking to satisfy craving and avert withdrawal symptoms when opioids are rapidly discontinued
- Loss of Family, Job and Shelter
- Petty Theft Leading to Larger Crimes, Arrest and Incarceration
- Accidental overdose, cardiorespiratory arrest, brain injury and death

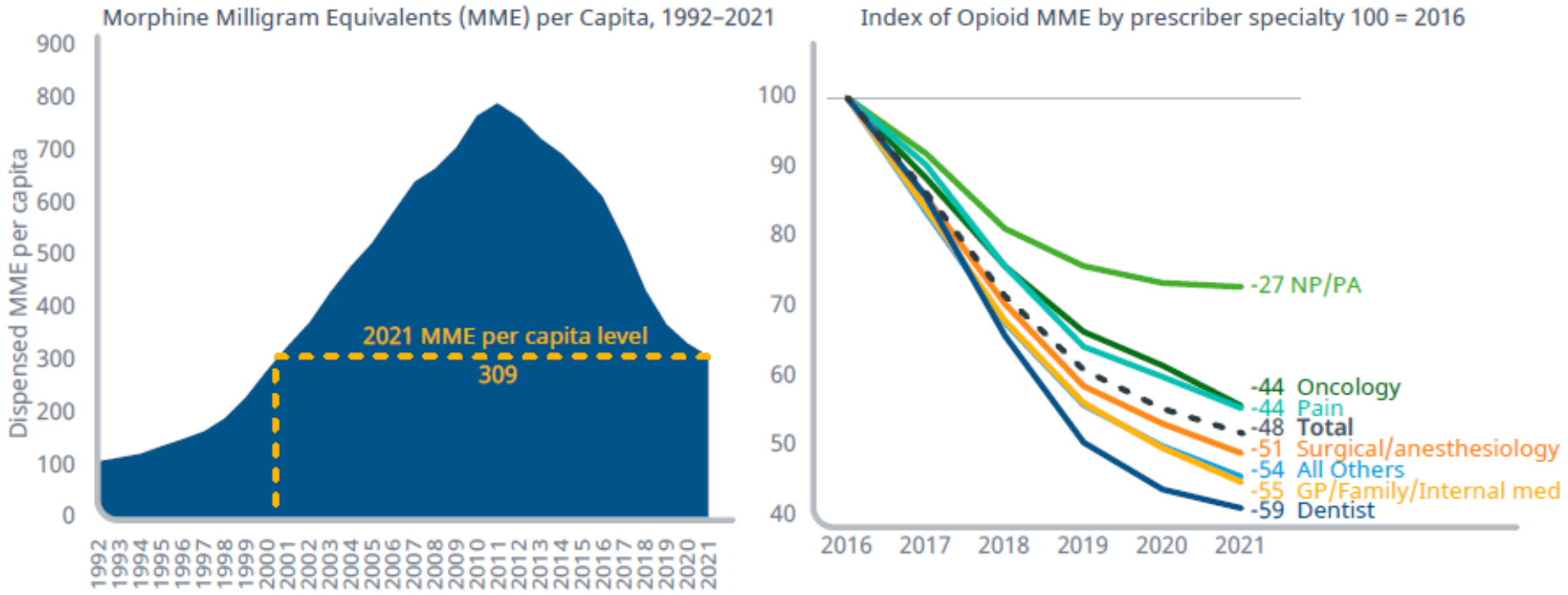
NOTE: A person's health is determined by their genes and the environment they live in. Epigenetics is the study of functional, and sometimes inherited, changes in the regulation of gene activity and expression that are not dependent on gene sequence.

The Good News – Prescriptions are Down and Most Patients Don't Misuse Opioids

The Good News -

Per capita prescription opioid use continues to decline to levels seen in 2000, with varying decreases across specialties

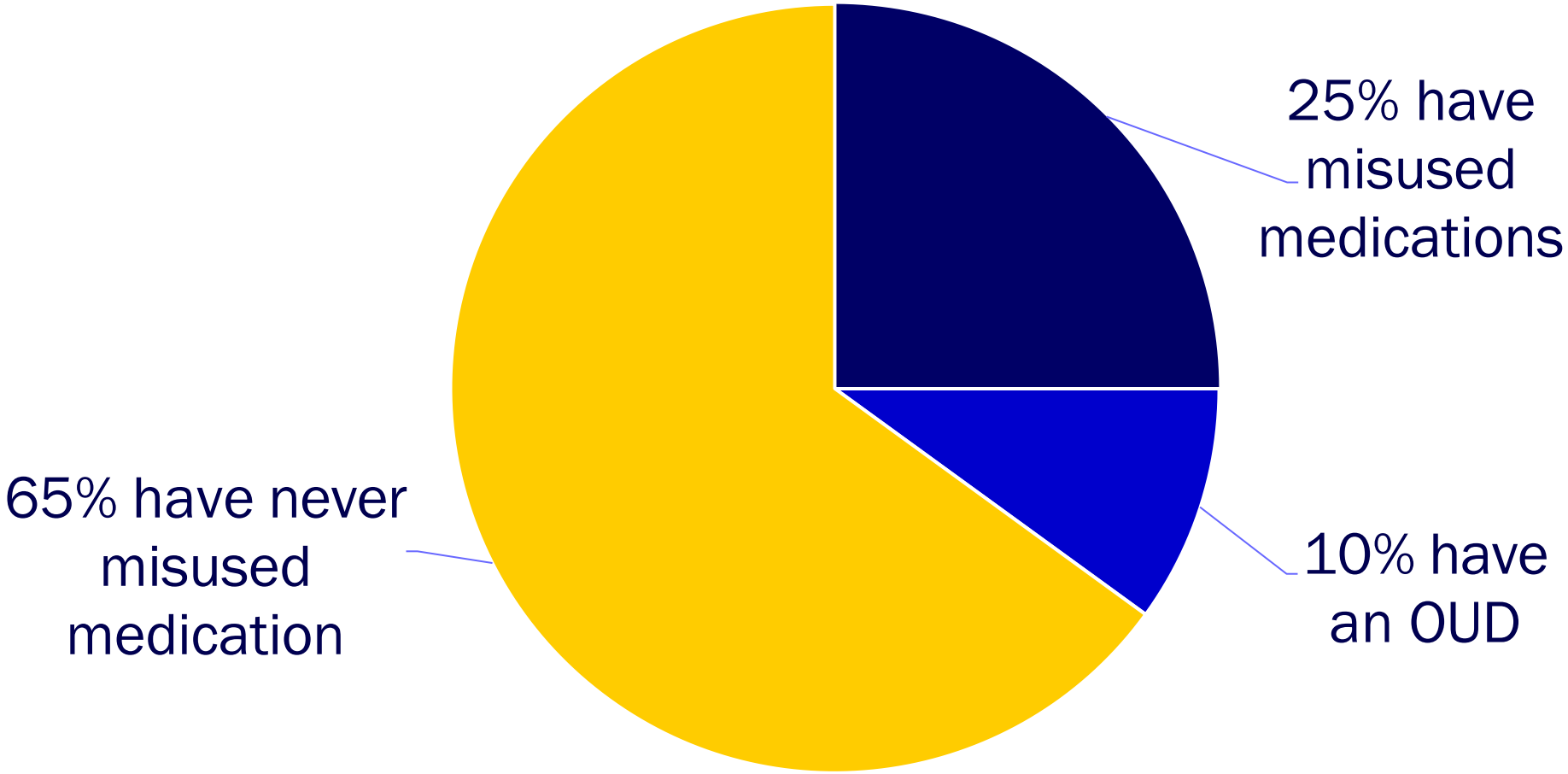
Exhibit 14: Prescription opioid use overall and by prescriber specialty



Source: IQVIA Xponent, Feb 2022; IQVIA National Prescription Audit, IQVIA Institute, Mar 2022.

The Good News - Most Chronic Pain Patients Don't Misuse Opioids

Of chronic pain patients prescribed opioids

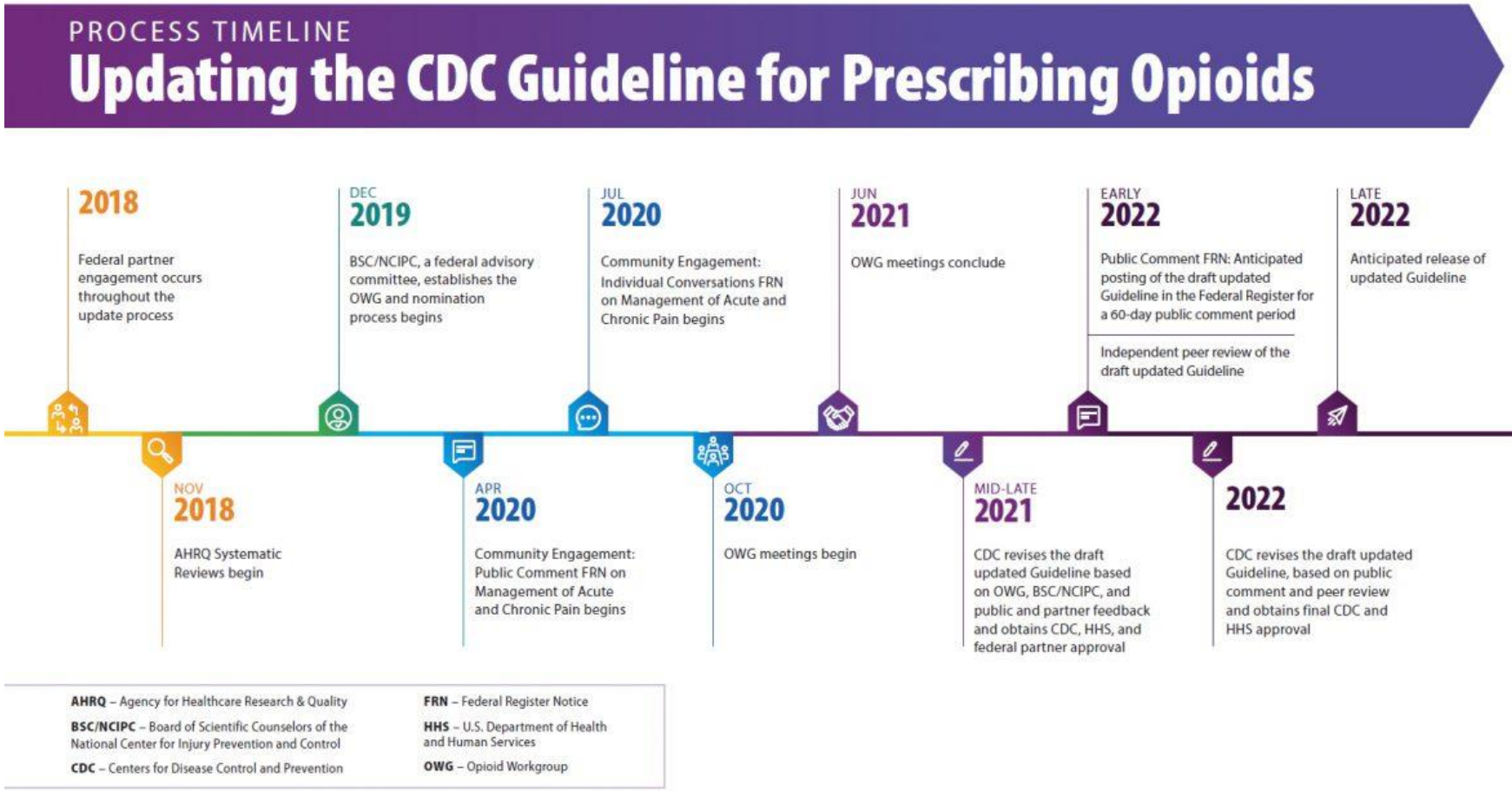


Frank, et al. Annals of Int Med, 2017

What Does the Draft 2022 CDC Pain Guideline Say About the 2016 Guideline?

2022 CDC Guidelines

When Policy is a Problem - The USDHHS, FDA and CDC Have Cited Multiple Examples of Misinterpretation, Misapplication and Potential Misuse of the 2016 Guidelines by Legislators, Regulators, Law Enforcement, Health Systems and Payers That Require Overarching Reassessment and Updating



Process for Updating the Opioid Prescribing Guideline | CDC's Response to the Opioid Overdose Epidemic | CDC – Accessed 4/30/2022

CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022

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Summary

This clinical practice guideline is

- **A clinical tool to improve communication between clinicians and patients and empower them to make informed, person-centered decisions related to pain care together**
- **Intended for primary care clinicians and other clinicians providing pain care for outpatients aged ≥18 years old with:**
  - acute pain (duration <1 month);
  - subacute pain (duration of 1-3 months); or
  - chronic pain (duration of >3 months)
- **Intended to be flexible to enable person-centered decision-making, taking into account an individual's expected health outcomes and well-being.**

This clinical practice guideline is not

- **A replacement for clinical judgment or individualized, person-centered care**
- **Intended to be applied as inflexible standards of care across patients, and/or patient populations by healthcare professionals, health systems, pharmacies, third-party payers, or governmental jurisdictions or to lead to the rapid tapering or discontinuation of opioids for patients**
- **A law, regulation, and/or policy that dictates clinical practice or a substitute for FDA-approved labeling**
- **Applicable to the following types of pain treatment:**
  - sickle cell disease-related pain
  - cancer pain
  - palliative care
  - end-of-life care

CDC-2022-0024-0002_content.pdf (uspainfoundation.org) (Accessed 4/30/22)

CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022

Summary

1. **For all patients with acute, subacute, or chronic pain**
   - Initiate the lowest opioid dose to achieve expected effects
   - For opioid naïve patients, start with immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids
   - Use extreme caution when prescribing opioids, benzodiazepines and other sedating substances concurrently
     - consider whether benefits outweigh risks
     - Taper cautiously to a less risky dose or discontinue
   - Check the state prescription drug monitoring program (PDMP) also known as the Michigan Automated Prescription Service (MAPS), to determine whether the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose
     - When initiating therapy
     - Periodically when continuing
   - Consider toxicology testing to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances
   - Offer naloxone and other overdose mitigation strategies when risk factors for opioid overdose are present
2. **For acute pain, consider initiating opioid therapy only if benefits are anticipated to outweigh risks to the patient**
   - Nonopioid therapies are effective for many common types of acute pain
   - prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids

CDC-2022-0024-0002_content.pdf (uspainfoundation.org) (Accessed 4/30/22)

CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022

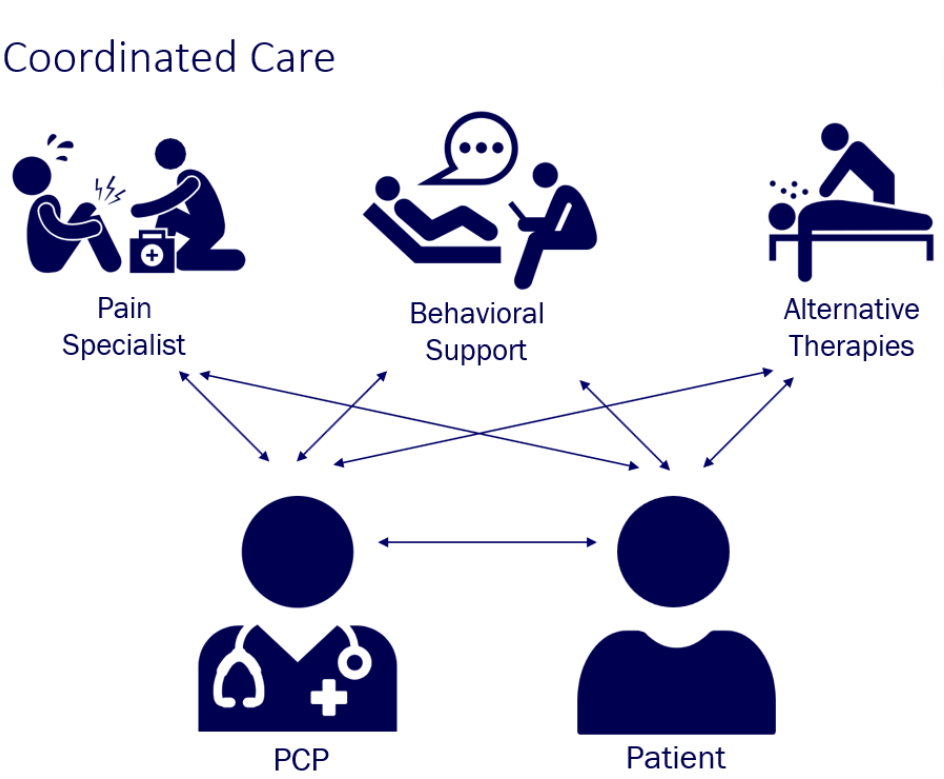
Summary

3. **For subacute and chronic pain, consider initiating opioid therapy only if expected benefits for pain and function are anticipated to outweigh risks to the patient**
   - Work with patients to establish treatment goals for pain and function
   - Nonopioid therapies are preferred
   - Discuss the known risks and realistic benefits of opioid therapy
   - Consider how opioid therapy will be discontinued when benefits do not outweigh risks
   - If opioids are continued
     - use caution when prescribing opioids at any dosage
     - avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients
     - re-evaluate benefits and risks after starting opioid therapy or when escalating dose
     - Initially at 1 to 4 weeks
     - Then every 3 months (or more frequently as indicated)
4. **Carefully weigh benefits and risks for patients already receiving higher opioid dosages**
   - Do not abruptly discontinue opioid therapy unless there are indications of a life-threatening issue, such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech)
   - Exercise care when reducing or continuing opioid dosage
   - Work closely with patients to optimize other therapies
   - Gradually taper to lower dosages if risks outweigh benefits of continued opioid therapy
   - Taper and discontinue opioids if warranted based on the individual clinical circumstances of the patient
5. **Offer medication assisted therapy (MAT) for patients without pain and exhibiting opioid used disorder (OUD)**

CDC-2022-0024-0002_content.pdf (uspainfoundation.org) (Accessed 4/30/22)

How can acute and chronic pain be better treated in 2022?

Coordinated Care



Medications

+

Behavioral Health Approaches

+

Restorative Therapies

+

Complementary and Integrative Health

+

Interventional Approaches

=

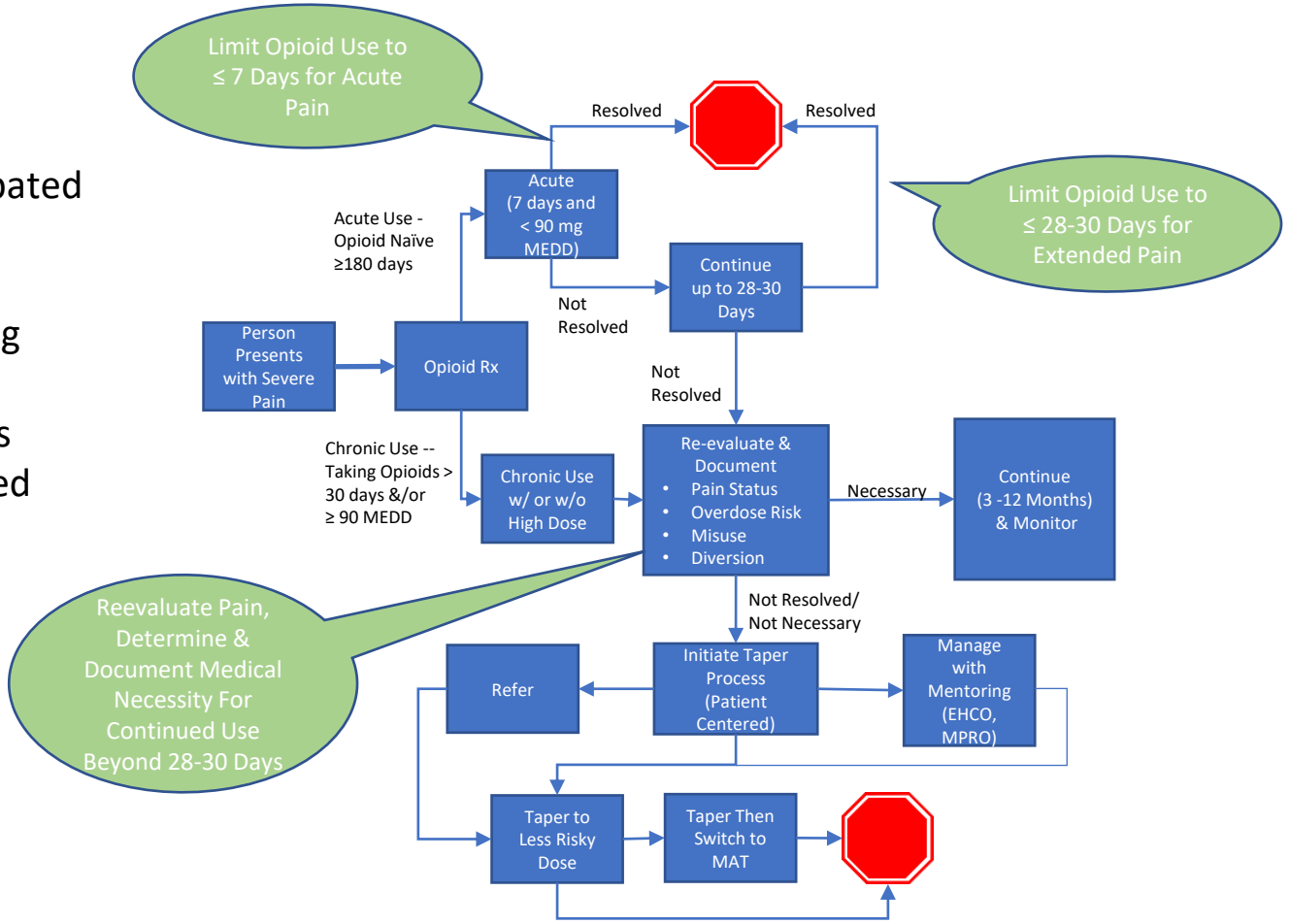
Effective Multimodal Treatment

U.S. Department of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force Report. 2019.

Utilize a Systematic Approach to Reducing Unnecessary Opioid Prescription Use, Misuse and Diversion

Recommendations

1. Assess Severity and Anticipated Duration of Pain
2. Assess Overdose Risk
3. Limit Initial Dose & Ongoing Duration
4. Securely Store Medications
5. Promote Disposal of Unused Doses



Reserve Opioids for Severe Acute Pain

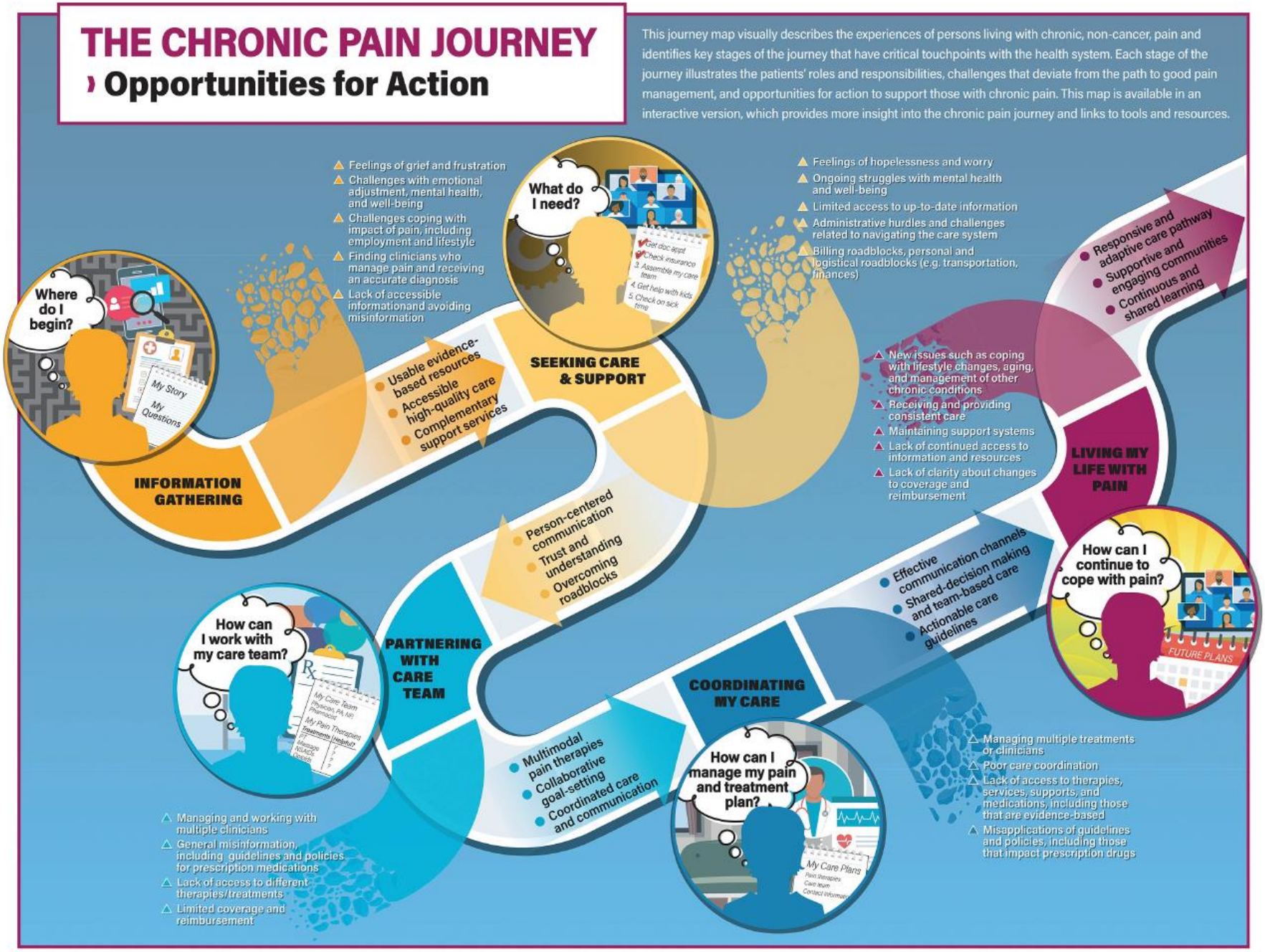
Severity	Examples	Treatment	Opioids Needed?
Spontaneous/trauma			
Mild	Sinus headache, soreness after yard work, superficial laceration	RICE, OTC analgesics	No
Moderate	Sprain, strain, simple bone fracture, deep laceration	Simple outpatient surgical procedure, NSAIDs, acetaminophen, RICE	No
Severe	Motor vehicle accident, burn, traumatic amputation	Surgery, hospitalization, possible intensive care, multimodal analgesics	Yes

Severity	Examples	Treatment	Opioids Needed?
Planned/elective			
Mild	Immunization, catheter placement, phlebotomy, superficial biopsy, simple dental extractions	Ice, Buzzy, lidocaine/ EMLA	No
Moderate	Same-day surgery (arthroscopy, multiple dental extractions/ wisdom teeth, laparoscopy, podiatric procedures)	NSAIDs, acetaminophen	Not likely, at most 6-8 tabs of opioid/ acetaminophen combination
Severe	Arthroplasty, spinal, colorectal, open abdominal surgery requiring hospital stay	Multimodal analgesics	Yes

EMLA, lidocaine/prilocaine; **NSAIDs**, nonsteroidal anti-inflammatory drugs; **OTC**, over the counter

Medical Management of Acute Pain (practicalpainmanagement.com) – Accessed 4/30/22

Be the Guide On the Patient's Journey to Adequate Care



[Chronic Pain Journey Map - National Academy of Medicine (nam.edu)](#) – Accessed 5/9/22

Don’t Ignore or Abandon Inherited “Legacy” Pain Patients Already on Opioids

Inherited Patients Taking Opioids for Chronic Pain — Considerations for Primary Care

Phillip O. Coffin, M.D., and Antje M. Barreveld, M.D.

Steps in Caring for Patients with Chronic Pain Who Have Received Long-Term Opioid Therapy from a Previous Clinician.

1. **Review the case with the former clinician if possible.** Try to develop a treatment plan that slowly adjusts to your style of management while avoiding a radical divergence from the previous plan of care.
2. **Consider providing a therapeutic bridge for the patient until a plan of care is determined, given the risks associated with stopping opioid therapy.** Abruptly tapering or stopping opioid therapy can be dangerous for multiple reasons. Opioids may be crucial for the patient’s condition (e.g., sickle-cell disease), and the patient may be at risk for other harms when opioids are tapered or discontinued (see figure).
3. **Develop a patient-centered care plan.** If a taper is needed, empower the patient to make decisions, including which medications to taper first and how fast. Successful tapers may take years.
4. **Assess the patient for opioid use disorder and start discussing medication options right away.** Patients may find it challenging to accept an opioid use disorder diagnosis; give them time.
5. **Document opioid stewardship and the rationale for the treatment plan.** Investigations into opioid prescribing are often based on insufficient documentation.

Help Prevent Opioid Overdose

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Edward W. Campion, M.D., *Editor*

Prevention of Opioid Overdose

Kavita M. Babu, M.D., Jeffrey Brent, M.D., Ph.D.,
and David N. Juurlink, M.D., Ph.D.

Every Opioid-related Death Represents a Missed Opportunity for Prevention

Distinct prescriber strategies for overdose prevention in three groups of patients:

1. Those who have not received previous opioid therapy
2. Those receiving long-term opioid therapy (legacy patients)
3. Those with an opioid use disorder

1. Reduce Overdose Risk in Initial Opioid Therapy

Table 1. Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD).*

Question	Points for Positive Response
In the past 6 mo, has the patient had a health care visit (outpatient, inpatient, or emergency department) involving any of the following health conditions?†	
Substance use disorder (abuse or dependence), including alcohol, amphetamines, antidepressants, cannabis, cocaine, hallucinogens, opioids, and sedatives	25
Bipolar disorder or schizophrenia	10
Stroke or other cerebrovascular disease	9
Kidney disease with clinically significant renal impairment	8
Heart failure	7
Nonmalignant pancreatic disease (e.g., acute or chronic pancreatitis)	7
Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)	5
Recurrent headache (e.g., migraine)	5
Does the patient use any of the following substances?	
Fentanyl	13
Morphine	11
Methadone	10
Hydromorphone	7
Does the patient use an extended-release or long-acting formulation of any prescription opioid?‡	5
Prescription benzodiazepine (e.g., diazepam, alprazolam)	9
Prescription antidepressant (e.g., fluoxetine, citalopram, venlafaxine, amitriptyline)	8
Is the patient's current maximum prescribed daily morphine-equivalent dose ≥100 mg for all opioids used on a regular basis?	7
Total possible score	**146**

Recommendations

1. Assess Overdose Risk
2. Limit Initial Dose & Duration
3. Securely Store Medications
4. Promote Disposal of Unused Doses

Table 2. Risk Classes and Predicted Probability of Serious Opioid-Induced Respiratory Depression during the Next 6 Months.*

Risk Class	RIOSORD Score	Average Predicted Probability	Actual Observed Incidence
		percent	
1	<5	1.9	2.1
2	5–7	4.8	5.4
3	8–9	6.8	6.3
4	10–17	15.1	14.2
5	18–25	29.8	32.2
6	26–41	55.1	58.8
7	≥42	83.4	82.4

* Data are from the study by Zedler et al.[17] The study resulted in a model for scoring of the risk of opioid-induced respiratory depression with a C-statistic of 0.90.

2. Reduce Overdose Risk in Patient Using Long-Term Opioid Therapy For Years or Decades (Legacy Patients)

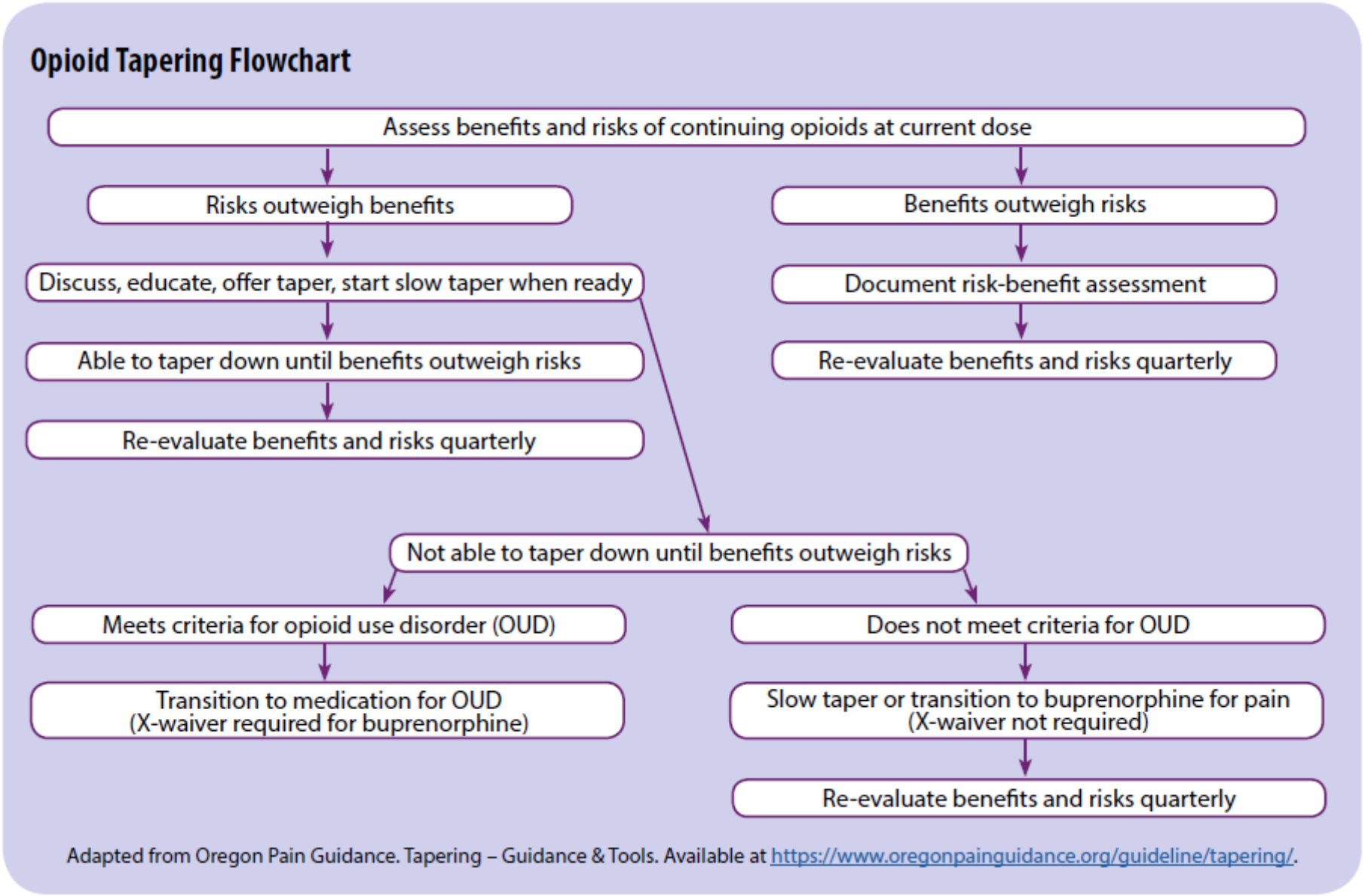
Recommendations

1. Assess Overdose Risk
2. Avoid Dose Escalation
3. Avoid Sudden Disruption of Long-term Chronic Opioid Therapy
4. Minimize Use For Other Sedating Medications, particularly benzodiazepines
5. Monitor for Evidence of Opioid Use Disorder
6. Consider Tapering or Switching to buprenorphine or other Medication Assisted Therapy (MAT)
7. Offer Naloxone

Table 3. Tapering Strategies and Rotation to Buprenorphine for Patients Receiving Opioids for Chronic Pain.*

Process	Tapering	Rotation to Buprenorphine
Indication	Patient requests dose reduction, no clinically significant improvement in pain or function despite opioid treatment, >90 mg MED or lower dose in conjunction with benzodiazepine or other sedating medication, having opioid-related adverse events, nonadherence to treatment plan, medical conditions conferring increased risk of overdose	Patient requests transition to buprenorphine, no clinically significant improvement in pain or function despite opioid treatment, concern that opioid-induced hyperalgesia is contributing to pain, nonadherence to treatment plan, medical conditions conferring increased risk of overdose, coexisting chronic pain and opioid use disorder
Strategy	Option A: If the patient is receiving multiple opioids, consolidate and switch all opioids to one new, extended-release oral opioid; decrease the dose to account for incomplete cross-tolerance Option B: If the patient is receiving multiple opioids, ask which opioid the patient would feel more comfortable tapering first	Patients must abstain from opioid agonists for at least 8 to 12 hr (best accomplished overnight) and be in mild-to-moderate withdrawal (a score of ≥8 on the Clinical Opiate Withdrawal Scale)†
Speed	Rapid taper: Reduce dose by 5 to 10% every 2 to 4 wk; continue taper over weeks to months Slow taper: Reduce dose by 2 to 10% every 4 to 8 wk with pauses in taper, as needed; continue taper over months to years	Once a patient is having mild-to-moderate withdrawal, administer 2 to 4 mg of sublingual buprenorphine or buprenorphine plus naloxone. If patient has no unacceptable side effects, administer an additional 4–8 mg sublingually at 1–2 hr, followed by adjustment according to response up to 32 mg daily in divided doses

When Using Chronic Opioids –
Consider a Taper or Switch to Buprenorphine If and When Possible



Adapted from Oregon Pain Guidance. Tapering – Guidance & Tools. Available at https://www.oregonpainguidance.org/guideline/tapering/.

3. Reduce Overdose Risk in Opioid Use Disorder

Recommendations

1. Assess Overdose Risk
2. Switch to Medication Assisted Therapy (MAT)
3. Co-prescribe Naloxone
4. Expand Access to Care
5. Care for Patients After Overdose
6. Use Harm Reduction Strategies

Table 4. Medications for the Treatment of Opioid Use Disorder.*

Drug	Pharmacology	Route of Administration	Typical Daily Dose Range	Comments
Buprenorphine	Partial opioid-receptor agonist	Oral, sublingual, transdermal, intramuscular	For opioid use disorder: sublingual 8 to 24 mg once daily or intramuscular 100–300 mg; for chronic pain: sublingual 4 to 32 mg in divided doses	In the U.S., a waiver is required to prescribe buprenorphine for opioid use disorder (8 hr of online or in-person training for physicians; 24 hr for advanced practice providers); absent a waiver, can be administered (but not prescribed) for opioid use disorder on an emergency basis for up to 72 hr Buprenorphine is often coformulated with naloxone to deter diversion for injection use (naloxone is inactive orally) Buprenorphine should only be initiated once symptoms of mild-to-moderate withdrawal are present (score of ≥8 on the Clinical Opiate Withdrawal Scale) Adherence to therapy associated with marked reduction in mortality
Methadone	Full opioid-receptor agonist; NMDA-receptor antagonist	Oral	Varies; often 40 to 120 mg per day	In the U.S., methadone must be administered by an opioid treatment program when used for opioid use disorder; does not require abstinence before initiation Long elimination half-life; initial dose escalation should proceed cautiously; multiple drug–drug interactions; dose-dependent increase in QT interval Adherence to therapy associated with marked reduction in mortality
Naltrexone	Opioid-receptor antagonist	Oral, intramuscular	Oral, 50 mg daily; intramuscular (gluteal), 380 mg every 4 wk	Prolonged abstinence (≥7 days) is required before initiation Little evidence of mortality benefit relative to methadone and buprenorphine As compared with standard care at discharge from incarceration, decreased number of overdose events

* NMDA denotes *N*-methyl-D-aspartate.

Document Well By Using a Tool Kit

Identify and Treat the Pain Source (Starting with a Good History & Physical)

Patient Instructions: Please fill out both sides of this questionnaire as completely as possible.

1. HISTORY OF THE PAIN

YES

► *Do you believe the pain is due to:*

☐ a car accident
- date: ____/____/____
- time: ____:____ a.m. / p.m.

☐ a work-related injury
- date: ____/____/____
- time: ____:____ a.m. / p.m.

☐ physical trauma *(examples: a fall, a fight, sports injury, etc.)*
- type : _____
- date: ____/____/____
- time: ____:____ a.m. / p.m.

☐ other: _____
- date: ____/____/____
- time: ____:____ a.m. / p.m.

☐ unknown cause

► *How long have you had this pain?*

☐ hours — how many? _____
☐ days — how many? _____
☐ weeks — how many? _____
☐ months — how many? _____

► *Did the pain appear:*

☐ suddenly
☐ gradually

► *Right now, is the pain:*

☐ better
☐ worse
☐ unchanged

2. LOCATION AND INTENSITY OF PAIN

► *The most intense pain is located:* _____.

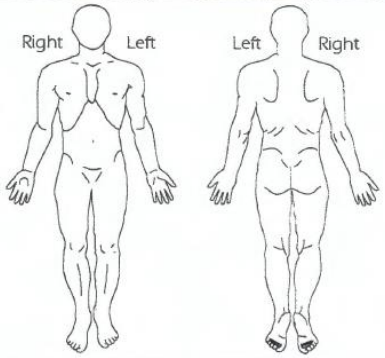
► *On the diagrams to the right:*
- mark an X or a series of X's where you feel pain.
- shade the areas where you have numbness.
- use arrows to point to where the pain radiates or travels to.

► *Has the pain changed in its location?*

_____
_____
_____

► *On the scale below, mark an X where it best describes the intensity of your pain:*

0 1 2 3 4 5 6 7 8 9 10
No Pain — Moderate Pain — Worst Possible Pain



3. DESCRIPTION OF THE PAIN

YES

► *Is the pain:*

☐ continuous *(no relief)*
☐ intermittent *(periods of relief)*
- amount of time **pain** usually lasts: _____
- amount of time **relief** usually lasts: _____

☐ other _____

► *Would you describe the pain as:*

☐ sharp, stabbing
☐ dull, aching
☐ throbbing
☐ burning like a hot poker
☐ steady, persistent
☐ waxing and waning
☐ feeling like a tight band
☐ easy to pinpoint
☐ difficult to pinpoint
☐ other _____

► *Does pain occur:*

☐ upon awakening
☐ in the morning
☐ in the afternoon
☐ in the evening
☐ 2-3 hours after falling asleep
☐ any time day or night
☐ only on weekends
☐ only at work
☐ only at home
☐ other _____

→

4. DO YOU ALSO HAVE:

YES

☐ runny, bloodshot eyes
☐ blurred or double vision
☐ nasal congestion/runny nose
☐ high blood pressure
☐ muscle weakness
☐ numbness in arms or hands
☐ numbness in legs or feet
☐ felt a "sudden snap"
☐ felt a "tearing" sensation
☐ muscle aches and pains
☐ joint pains
☐ morning joint stiffness
☐ fever
☐ abdominal pain
☐ nausea or vomiting
☐ diarrhea
☐ constipation
☐ bloody stools
☐ frequent or burning urination
☐ sudden loss of urine
☐ inability to urinate
☐ bloody urine
☐ weight gain or loss
☐ depression
☐ other: _____

► *Female patients only:*

☐ vaginal discharge
☐ heavy menstrual bleeding
☐ bleeding between periods
☐ pelvic infection
☐ ovarian cysts
☐ uterine fibroids
☐ painful intercourse
☐ hot flashes
☐ other: _____

► *Male patients only:*

☐ prostate trouble
☐ restricted or painful urination
☐ interrupted sleep to urinate
☐ swollen or painful testicles
☐ penis discharge
☐ other: _____

5. PREVIOUS MEDICAL WORKUP INCLUDES:

YES

☐ seeing other doctors name(s): _____
_____
_____
☐ skull x-rays
☐ neck x-rays
☐ lumbar and pelvis x-rays
☐ EEG/brain wave study
☐ CT scan
☐ brain scan
☐ MRI
☐ Evoked potentials
☐ EMG
☐ blood work
☐ other: _____

6. DOES ANY BLOOD RELATIVE HAVE A HISTORY OF:

YES

☐ arthritis
☐ diabetes
☐ aortic aneurysm
☐ cerebral aneurysm
☐ migraines
☐ high blood pressure
☐ stroke
☐ brain tumor
☐ spinal cord tumor
☐ poor leg circulation
☐ disk problems
☐ spinal stenosis
☐ multiple sclerosis (MS)
☐ muscular dystrophy
☐ arteriovenous malformation
☐ Lou Gehrig's disease
☐ other neurological disease: _____

7. IS THE PAIN MADE WORSE OR BETTER BY:

FEELS WORSE	FEELS BETTER		FEELS WORSE	FEELS BETTER		FEELS WORSE	FEELS BETTER	
☐	☐	inactivity or sleep	☐	☐	lifting _____ lbs.	☐	☐	menstrual periods
☐	☐	mild activity	☐	☐	carrying _____ lbs.	☐	☐	massage
☐	☐	exercising or stretching	☐	☐	stooping	☐	☐	heat
☐	☐	heavy work	☐	☐	twisting	☐	☐	trying to forget about it
☐	☐	climbing stairs	☐	☐	reaching overhead	☐	☐	spinal manipulation
☐	☐	walking	☐	☐	coughing/sneezing	☐	☐	spinal injections (blocks)
☐	☐	standing	☐	☐	sudden movement	☐	☐	physical therapy
☐	☐	sitting	☐	☐	other movement: _____	☐	☐	surgery
☐	☐	car riding				☐	☐	other: _____
☐	☐	straining at stool	☐	☐	touching a certain point: _____	☐	☐	other: _____
☐	☐	reclining or lying down						*Medications:*
☐	☐	lying on a firm bed or on the floor	☐	☐	sexual intercourse	☐	☐	_____
			☐	☐	drinking alcohol	☐	☐	_____
☐	☐	lying on one side	☐	☐	emotional tension	☐	☐	_____
☐	☐	getting up from bed	☐	☐	fatigue	☐	☐	_____
☐	☐	bending forward	☐	☐	changes in weather	☐	☐	_____

Assess for Opioid Use Disorder (DSM-5 Criteria)

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the following, occurring within a 12-month period:

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain, use, or recover from the effects of opioids.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
10. Tolerance, as defined by either of the following:
    a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect, or
    b. Markedly diminished effect with continued use of the same amount of an opioid.
    Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.
11. Withdrawal, as manifested by either of the following:
    a. The characteristic opioid withdrawal syndrome, or
    b. Opioids (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.
    Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

Mild: Presence of 2-3 symptoms

Moderate: Presence of 4-5 symptoms

Severe: Presence of 6 or more symptoms

Assess Risk for Overdose

Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)		
Question	Points for Positive Response	Actual Response
In the past 6 mo, has the patient had a health care visit (outpatient, inpatient, or emergency department) involving any of the following health conditions		
Substance use disorder (abuse or dependence), including alcohol, amphetamines, antidepressants, cannabis, cocaine, hallucino- gens, opioids, and sedatives	25	
Bipolar disorder or schizophrenia	10	
Stroke or other cerebrovascular disease	9	
Kidney disease with clinically significant renal impairment	8	
Heart failure	7	
Nonmalignant pancreatic disease (e.g., acute or chronic pancreatitis)	7	
Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)	5	
Recurrent headache (e.g., migraine)	5	
Does the patient use any of the following substances?		
Fentanyl	13	
Morphine	11	
Methadone	10	
Hydromorphone	7	
Does the patient use an extended-release or long-acting formulation of any prescription opioid?	5	
Prescription benzodiazepine (e.g., diazepam, alprazolam)	9	
Prescription antidepressant (e.g., fluoxetine, citalopram, venlafaxine, amitriptyline)	8	
Is the patient's current maximum prescribed daily morphine- equivalent dose ≥100 mg for all opioids used on a regular basis?	7	
Total possible score	**146**	

Risk Classes and Predicted Probability of Serious Opioid-Induced Respiratory Depression during the Next 6 Months.			
Risk Class	RIOSORD Score	Average Predicted Probability (Percent)	Actual Observed Incidence (Percent)
1	<5	1.9	2.1
2	5–7	4.8	5.4
3	8–9	6.8	6.3
4	10–17	15.1	14.2
5	18–25	29.8	32.2
6	26–41	55.1	58.8
7	≥42	83.4	82.4

Confirm Medical Necessity and Appropriateness of Care

Name: _____ DOB___/____/___

DIRE Score: Patient Selection for Chronic Opioid Analgesia

For each factor, rate the patient's score from 1-3 based on the explanations in the right-hand column

SCORE	FACTOR	EXPLANATION
	DIAGNOSIS	1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, non-specific back pain. 2 = Slowly progressive condition concordant with moderate pain, or fixed condition with moderate objective findings. Examples: failed back surgery syndrome, back pain with moderate degenerative changes, neuropathic pain. 3 = Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis.
	INTRACTABILITY	1 = Few therapies have been tried and the patient takes a passive role in his/her pain management process. 2 = Most customary treatments have been tried but the patient is not fully engaged in the pain management process, or barriers prevent (insurance, transportation, medical illness). 3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate response.
	RISK	(**R** = Total of **P+C+R+S** below)
	Psychological	1 = Serious personality dysfunction or mental illness interfering with care. Example: personality disorder, severe affective disorder, significant personality issues. 2 = Personality or mental health interferes moderately. Example: depression or anxiety disorder. 3 = Good communication with clinic. No significant personality dysfunction or mental illness.
	Chemical Health	1 = Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse. 2 = Chemical coper (uses medications to cope with stress) or history of chemical dependence (CD) in remission. 3 = No CD history. Not drug-focused or chemically reliant.
	Reliability	1 = History of numerous problems: medication misuse, missed appointments, rarely follows through. 2 = Occasional difficulties with compliance, but generally reliable. 3 = Highly reliable patient with meds, appointments & treatment.
	Social Support	1 = Life in chaos. Little family support and few close relationships. Loss of most normal life roles. 2 = Reduction in some relationships and life roles. 3 = Supportive family/close relationships. Involved in work or school and no social isolation.
	EFFICACY SCORE	1 = Poor function or minimal pain relief despite moderate to high doses. 2 = Moderate benefit with function improved in several ways (or insufficient info - hasn't tried opioid yet or very low doses or too short of a trial). 3 = Good improvement in pain and function and quality of life with stable doses over time.

_____ **Total score= D + I + R + E**

Score 7-13: Not a suitable candidate for long-term opioid analgesia

Score 14-21: May be a good candidate for long-term opioid analgesia

NOTES

A DIRE Score of :513 indicates that the patient may not be suited to long-term opioid pain management. Used with permission by Miles J. Belgrade, MD |

Create a Multi-modal Chronic Pain Management Plan

Chronic Pain Management Plan

Patient Name: _____ Date: _____

DOB: _____

Disease(s)/Condition(s) Causing Pain:

#	Disease/Condition	ICD-10 Code(s)
1		
2		
3		
4		
5		

Pain Management Goals

What are your goals as the result of treatment? What activities did you stop because of pain? As a result of pain management, I want to be able to:

1.) _____
2.) _____
3.) _____

My current pain level is (1-10): _____

My goal for pain management is to reduce my pain to (1-10): _____

Which of these treatments or strategies might help you meet your goals?

□ Specialty Consultation

- □ Orthopedic/General Surgery: _____
- □ Neurology: _____
- □ PM&R_____
  - □ Physical therapy_____
  - □ Occupational therapy_____
- □ Osteopathic Manipulative Therapy: _____
- □ Chiropractic: _____
- □ Pain specialty clinic: _____
- □ Pulmonary Sleep apnea: _____
- □ Addiction: _____
- □ Behavior Therapy/Psychiatry: _____
  - □ Cognitive behavioral therapies focused on pain management
  - □ Training in meditation and relaxation
  - □ Therapy or counseling to treat depression, anxiety, or other mental health condition(s)
  - □ Attend support group or pain classes: _____

□ Medications

- □ Non-opioid pain medication (such as anti-inflammatory medications or acetaminophen): _____
- □ Medications to treat coexisting behavioral disorders
- □ Adjuvants: _____
- □ Opioid pain medication: _____
- □ Other: _____

□ Sleep: _____

□ Integrative medicine

- □ Acupuncture
- □ Hypnosis
- □ Biofeedback
- □ Other: _____

□ Self-care (Home therapies):

- □ Ice/heat therapies
- □ Exercise
  - □ Aquatic
  - □ Aerobic
  - □ Strength building
  - □ Stretching
- □ Quit tobacco use
- □ Quit alcohol use
- □ Quit caffeine use
- □ Quit Cannabinoid use
- □ Manage weight
- □ Practice meditation, yoga or relaxation
- □ Improve sleep habits
- □ Other: _____

Signatures:

Patient or Parent/Guardian: _____

Date: _____

Mature Minor Patient:

_____

Date: _____

Provider: _____

Date: _____

Confirm the Need for Palliative Care or Hospice Care

Chronic Pain Management & Palliative Care Certification Form

Patient Information

Patient Name:		Telephone #:	
Date of Birth:		Fax #:	
Address:		Cellphone #:	
City, STATE, Zip:		Email:	

Primary Diagnoses (relating to persistent intractable pain)

Certication Criteria

	Palliative Care Criteria
☐ YES ☐ NO	The underlying disease is protracted with an unpredictable outcome and/or is uncurable
☐ YES ☐ NO	Pain is persistent and intractable despite using non-opioid therapies that have been maximized and reached maximal therapeutic benefit
☐ YES ☐ NO	Symptomatic pain treatment has a good probability to improve functionality and existing quality of life
☐ YES ☐ NO	Anticipated benefit exceeds potential risk for overdose and/or diversion
☐ YES ☐ NO	Pain management is a component of all aspects of palliative care including management of other treatable conditions and symptoms

Certification

I have performed a comprehensive and detailed examination for_____ and have developed a collaborative palliative care plan.

I have determined that this person has intractable pain and satisfied the criteria for Palliative Care Status. Support documentation is included in the patient's medical record with this certification.

I, hereby, certify this pain management and palliative care plan is medically necessary. This plan will be recertified annually or sooner if there is substantive change beforehand.

PROVIDER

Signature of Provider: _____Date: ___/___/___

Provider Name Printed:_____

PATIENT

By signing below, and I hereby agree to all terms and conditions set forth under this certification document and accompanying treatment agreement.

Signature of Patient: _____Date: ___/___/___

Patient Name Printed:_____

Obtain Meaningful Informed Consent

Practice Name
Street, City, State, Zip
Phone (xxx) xxx-xxxx • Fax (xxx) xxxx

Sample Controlled Medication Management Agreement and Informed Consent

Patient Name:
DOB:
Provider:
Facility:
Date:

#	Controlled Medication	Dose	Quantity	Directions	New Start	Refill	Switch
1							
2							
3							
4							
5							

The terms "I", "my" and "you" in this document refer to the patient. Where the patient is under age 18, or an adult for whom a guardian is signing the Agreement, the terms "I", "my" and "you" refer to the patient and to his or her parent or guardian.

This document lists commitments I will make before beginning one or more of these medications or continue them, if already being taken. I have received and have read the following patient education:

- ☐ Opioids *(Opioid Medication for Chronic Pain Fact Sheet)*
- ☐ Stimulants *(Stimulant Medicine for ADHD fact sheet)*
- ☐ Benzodiazepines, Sedatives, Hypnotics and Sleeping Pills *(Sedatives and Sleeping Pills: Understanding the Risks fact sheets)*
- ☐ *Gabapentin (Gabapentin Fact Sheet)*
- ☐ Others (*Describe*) _____

1. I will work with my provider(s) in a collaborative manner to develop an accurate and balanced diagnosis and treatment plan that considers both benefits and risks.
    a. My provider(s) and staff will treat me with dignity and respect throughout the course of my care and I will do the same when interacting the them.
2. I have discussed the medication(s) and had the chance to ask questions about the medications being prescribed with my provider(s).
    a. all my questions have been answered in a way I understand.
3. I will engage in all activities to continue my ongoing therapy
    a. I will schedule and keep all necessary appointments
    b. I will tell my provider(s) about all of my prescribed and over the counter (OTC) medications, including vitamins, supplements, medicinal herbs
    c. I understand and will follow all my provider's instructions about my medication(s), including instructions about refills
    d. I will not crush, chew, extract, mix or otherwise manipulate the formulation of my medication(s)
    e. I will take this medication only as directed and will not use other prescription drugs that have not been prescribed for me, alcohol, and/or other potentially addictive substances without discussing it with my provider.
    f. I will attend and participate fully in any ongoing assessments, education, and treatment programs as recommended by my provider(s) as part of my total treatment plan.
    g. I will actively participate in therapies that complement this medication to help manage my condition including counselling, stress reduction, exercise, proper diet and use of non-controlled medications.
    h. I will cooperate with drug screening and pill counts whenever requested.
4. I acknowledge that I might develop tolerance, dependence, addiction or other serious and potentially life-threatening conditions when taken improperly, either individually or in combination with other controlled medications or addictive substances.
    a. My treatment plan may require close monitoring, including consultation with other treating provider(s) and expert(s) who can evaluate medical necessity for using this medication and determining signs of tolerance, dependence or addictive behavior requiring a different approach in my therapy.
    b. I will work with my providers to regularly assess my condition to determine medical necessity to start or continue the prescribed medication over time
    c. If no longer necessary to use, I will work with my provider(s) to taper or discontinue controlled substances based on ongoing medical necessity, clinical effectiveness and the risk of potential overdose or misuse. (An example of a taper plan is enclosed below)
    d. If taken for prolonged periods of time, I understand that reducing/tapering my controlled substance usage may take weeks or even months to complete
    e. I recognize that I may require Medication Assisted Treatment (MAT) if I cannot accomplish a taper without ongoing craving or withdrawal symptoms
5. I will refrain from taking actions that could endanger myself or the public.
    a. I will not drive or operate dangerous equipment while under the influence of controlled substances that may reduce my coordination, judgment, or whenever my medication makes me feel impaired in any way (including whenever I feel tired, dizzy, mentally foggy or unsteady).
    b. I will be responsible for my medication and will securely store it (i.e., in a lock box) to avoid theft or improper use by others, including children
    c. I understand that my provider may not prematurely refill lost or stolen medication(s).
    d. I will not sell, share or trade my medication(s).
    e. I will return all unused controlled substances to an approved collection site as soon as they are no longer needed for the condition being treated.
6. I understand that insurers and regulatory authorities have the right to review my records when taking controlled substances.
    a. I understand that my medical and insurance claims records may be reviewed by an independent review team to evaluate my ongoing opioid and controlled substance usage.
    b. the Michigan Department of Licensing and Regulatory Affairs (LARA) maintains and makes available a database of my controlled drug prescriptions to all medical providers providing my care.
7. I acknowledge that unwillingness or inability to work collaboratively with my provider(s) and adhere to this agreement may result in discharge from the provider's care
    a. Any action on my part that may be threating to safety of your provider(s) and their staff may be subject to subsequent action
8. I acknowledge that my provider and I have reviewed the following information (in accordance with State Law):
    a. A controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse.
    b. The risks of substance use disorder and overdose associated with the controlled substances containing an opioid, benzodiazepine, other sedatives and hypnotics, stimulants and/or alcohol.
    c. Individuals with mental illness and substance use disorders may have an increased risk of addiction to a controlled substance.
    d. Mixing opioids with benzodiazepines, alcohol, muscle relaxers, or any other drug that may depress the central nervous system can cause serious health risks, including death or disability.
    e. For a female who is pregnant or is of reproductive age, the heightened risk of short and long-term effects of opioids and other substances, including but not limited to neonatal abstinence syndrome.
    f. Any other information necessary for patients to use the drug safely and effectively as found in the patient counseling information section of the labeling for the controlled substance.
    g. Safe storage and disposal of opioids has shown to reduce injury and death in family members.
    h. Proper disposal of expired, unused or unwanted controlled substances may be done through community take-back programs, local pharmacies, or local law enforcement agencies. Information on where to return your prescription drugs can be found at http://www.michigan.gov/deqdrugdisposal.
    i. It is a felony to illegally deliver, distribute or share a controlled substance without a prescription properly issued by a licensed health care prescriber.
9. I acknowledge the potential benefits and risks of the controlled medications as described by my provider along with the responsibility of properly managing my medication as stated above.
10. For OPIOID USE ONLY, I understand that there are inherent risks for using opioids that are associated with increasing doses and when used in combination with other drugs. Naloxone, also known as Narcan, is an antidote that can reverse overdose of opioids by blocking their sedating effects that may slow down breathing and lead to cardiopulmonary arrest. Narcan can be helpful to reverse over sedation and may be lifesaving when too much opioid is taken be myself or others. I acknowledge that Naloxone has been offered by prescription from my provider and is also available by request at participating pharmacies under standing orders of the Chief Medical Executive for the State of Michigan. Additional information regarding Naloxone and it's proper use can be found at https://www.michigan.gov/opioids/0,9238,7-377--480835--,00.html.

My signature confirms that I have had an opportunity to ask questions about this agreement, and that I understand and agree to all the statements above. I have been given a copy of this Agreement and agree to keep the copy for my future reference.

Patient or Patient Guardian (print)	Patient or Patient Guardian Signature	Date
Patient Name (Optional - If Present with Guardian)	Patient Signature	Date
Provider Name (print)	Provider Signature	Date

This form is provided for educational and informational purposes only. It is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting this form and applying it to the circumstances of their individual patients and practice arrangements. The information provided in this form is provided "as is" with no guarantee as to its accuracy or completeness. Consider seeking legal evaluation before utilizing.

Implement a Taper Plan Whenever Practicable

Name: _____ **DOB**___/____/___

Opioid and/or Benzodiazepine Tapering Plan Agreement

The purpose of this document is to develop a specific tapering plan with a timeline for discontinuation or reaching a taper "target dose".

We will work with you to develop a plan that is safe, effective and will minimize any symptoms that may be associated with tapering. Enclosed is a sample of a tapering schedule that can be used to help keep everyone apprised.

Taper Schedule

Visit	Date	Medication	Taper Frequency (# weeks)	Single Dose	Dose Frequency	Total Daily Dose	Total Dose/Day	Quantities Needed
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

We will allow for gradual dose reductions and will reassess regularly and adjust accordingly.

Sign and Date below:

Patient or Patient's Representative (required):

_____ Date: _____

Mature Minor Patient:

_____ Date: _____

Physician Signature or Provider:

_____ Date: _____

Summary

1. We must continue to effectively treat pain but still mitigate overdose risk
2. We cannot abandon the “pain refugee” because many will go to the street
3. We must increase access to care for both Substance Use Disorders and Pain Management Services
4. We must help diminish supply and demand for illicit opioids and stimulants through community-based initiatives
5. We as Health Care Professionals are well positioned to help lead the way

Questions