

Treating Chronic Pain Acutely: Not In Our Patient's Best Interest



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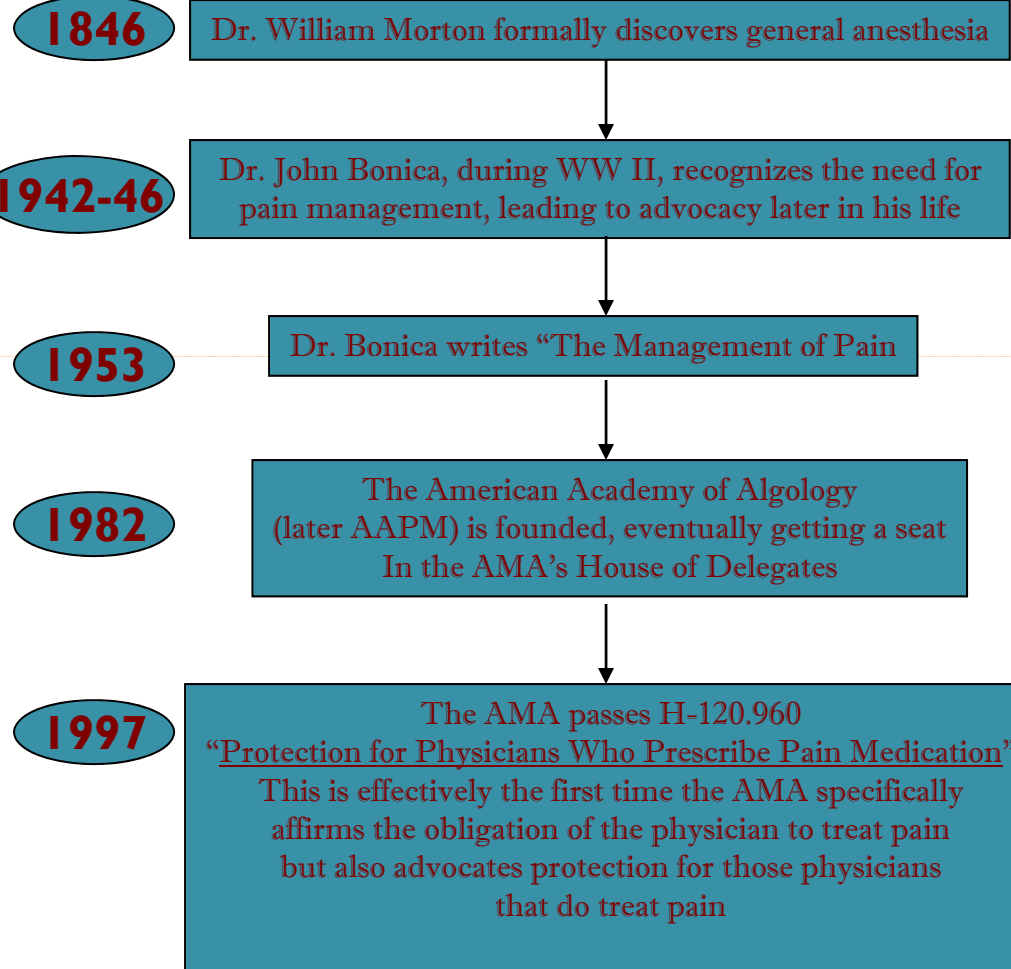
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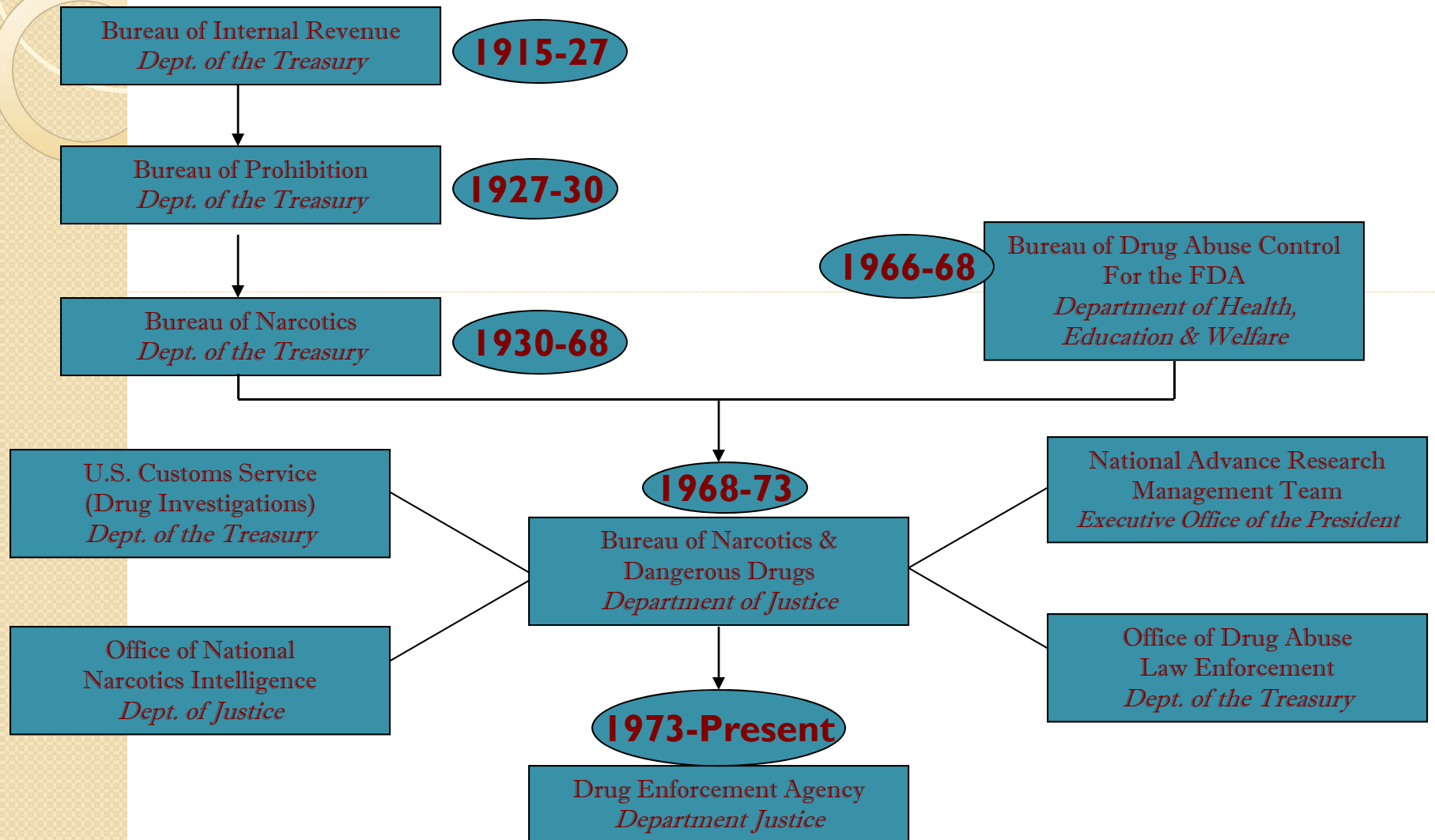
Objectives:

- Provide a brief overview of the evolution of modern pain medicine & society/law enforcement's response
- Discuss our obligation to treat chronic pain
- Address some of the unintended consequences
- Define commonly used terms
- Review the guidelines for Chronic Opioid Therapy (COT) as put forth by the AAPM
- Establish a rational strategy for chronic opioid prescribing
- Look at a few case studies

A Brief Medical Timeline



A Brief Regulatory Timeline



Federal Agent-at-Large
Elvis Presley
Bureau of Narcotics & Dangerous Drugs





*** | 1970 ***

The *Controlled Substances Act* replaced all the previous regulations and classified controlled substances in five categories:

- I. Substances that have no accepted medical use in the United States and have a high abuse potential (e.g.-heroin, L.S.D., etc.)
- II. Substances that have a high abuse potential with severe psychic or physical dependence liability but with an accepted medical use (e.g.-Dilaudid, Morphine, Ritalin, etc.)
- III. Substances that have an abuse potential less than those in Schedules I and II, and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs (e.g.-Tylenol #3, paregoric, Marinol, etc.)
- IV. Substances that have an abuse potential less than those in Schedules I, II and III (e.g.-Restoril, Darvocet, Ambien, etc.)
- V. Substances that have a relatively low potential for abuse (e.g.-Lyrica, Lomotil, Hycotuss, etc.)



*****1994*****

**The Uniform Controlled
Substances Act is proposed and
enacted by all 50 states**

In 2001 the US Drug Enforcement Agency and 21 Healthcare Organizations Issued and Unprecedented Joint Statement

- American Academy of Family Physicians
- American Academy of Hospice and Palliative Medicine
- American Academy of Pain Medicine
- American Alliance of Cancer Pain Initiatives
- American Cancer Society
- American Medical Association
- American Pain Foundation
- American Pain Society
- American Pharmaceutical Association
- American Society of Anesthesiologists
- American Society of Law, Medicine & Ethics
- American Society of Pain Management Nurses
- American Society of Regional Anesthesia and Pain Medicine
- Community-State Partnerships to Improve End-of-Life Care
- Drug Enforcement Administration
- Last Acts
- Midwest Bioethics Center
- National Academy of Elder Law Attorneys
- National Hospice and Palliative Care Organization
- Oncology Nursing Society
- Partnership for Caring, Inc.
- University of Wisconsin Pain & Policy Studies Group



A JOINT STATEMENT FROM 21 HEALTH ORGANIZATIONS AND THE DRUG ENFORCEMENT ADMINISTRATION

- Both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical.

SAMHSA

National Survey on Drug Use and Health

The NSDUH Report

June 19, 2008 - Non-medical Use of Pain Relievers in Sub-state Regions: 2004 to 2006

Misuse of prescription drugs is second only to marijuana as the nation's most prevalent drug problem, and the annual average number of people using pain relievers non-medically for the first time in the past 12 months has exceeded the number of new marijuana users since 2002.¹ Accordingly, misuse of prescription pain relievers has been cited as a growing public health problem.^{2,3} Data on geographic variation in the non-medical use of pain relievers (as well as other drugs) is important for developing targeted prevention and treatment programs.



Title 21

Code of Federal Regulations 1306.07-c

“This section is not intended to impose any limitations on a physician or authorized hospital staff ... to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts”

Chronic Pain!!!



A few brief definitions:



What is the definition of Chronic Pain???

Chronic pain is defined by the International Association for the Study of Pain as “pain that persists beyond normal tissue healing time, which is assumed to be three months.”

International Association for the Study of Pain. Classification of chronic pain: Descriptions of chronic pain syndromes and definitions of pain terms. Prepared by the International Association for the Study of Pain, Subcommittee on Taxonomy. Pain Suppl S1-S226, 1986



The FSMB defines addiction as:

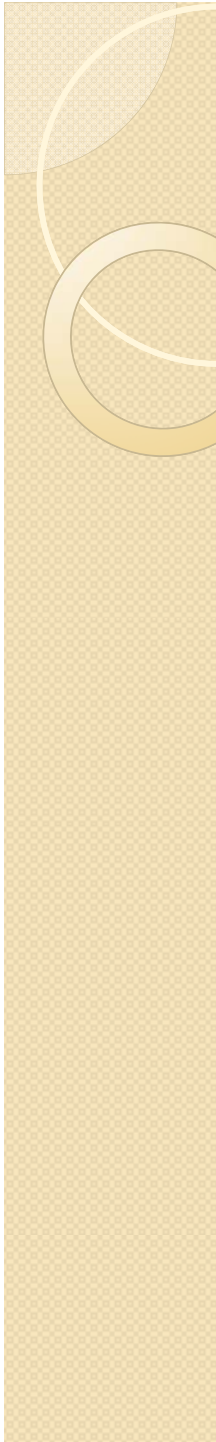
...a primary chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy for pain and are not the same as addiction.



PSEUDO-ADDICTION

Pattern of drug seeking behavior of pain patients receiving inadequate pain management that can be mistaken for addiction. Symptoms may include:

- Cravings and aberrant behavior
- Concerns about availability
- “Clock-watching”
- Unsanctioned dose escalation
- Resolves with reestablishing analgesia





**Now let's look at some recommendations
by the AAPM...**



Patient Selection and Risk Stratification

- Before initiating Chronic Opioid Therapy (COT, clinicians should conduct a history, physical examination and appropriate testing, including and assessment of risk of substance abuse, misuse, or addiction.
- Clinicians may consider a trial of COT as an option if CNCP is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh potential harms.
- A benefit-to-harm evaluation including a history, physical examination, and appropriate diagnostic testing, should be performed and documented before and on an ongoing basis during COT.

Universal Precautions in Pain Medicine

- Diagnosis with appropriate differential
- Psychological assessment with risk of addictive disorder
- Informed consent

- Treatment agreement (not a “contract”)
- Regular reassessment of pain level and functional level
- Regularly reassess the “Four A’s”:
 - Analgesia
 - Activity
 - Adverse reactions
 - Aberrant behaviors

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The Treatment Agreement:

- An agreement not a “contract”
- Clearly delineates the obligations and responsibilities of the patient and the practitioner
- At the outset makes the patient aware of the obligations a responsible practitioner will impose on patients receiving controlled substances which include, but are not limited to :
 1. **Random toxicology** screens to ensure compliance
 2. The use of **one pharmacy**
 3. **One physician** prescribing C.S.'es (no doctor shopping)
 4. Use of a **lock box and the patient responsible** for lost or stolen medications
 5. Clearly defines the already implied **consent to speak with the pharmacist** and other treating physicians but also to contact the authorities if illegality is suspected
 6. Bring in left-over medications for **pill counts**
 7. **Prescribing practices** (not outside of office hours, etc.)
 8. States the obvious, such as **no sharing, selling or trading** of medications
 9. Several are available, such as from the AAPM

Initiation and Titration of COT

- Clinicians and patients should regard initial treatment with opioids as a therapeutic trial to determine whether COT is appropriate
- Opioid selection, initial dosing and titration should be individualized according to the patient's health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms.



“There is insufficient evidence to recommend short-acting versus long-acting opioids, or as-needed versus around-the-clock dosing of opioids”



“Short-acting opioids are probably safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of inadvertent overdose.”

Why do practitioners have difficulty discussing Universal Precautions and COT Plans???

Many of us still view it as a moral failing or character defect.



Fear of the patient accusing us of suspecting them of drug abuse.



Fear of confrontation.



Time constraints.



Monitoring

- Clinicians should reassess patients on COT periodically and as warranted by changing circumstances. Monitoring should include documentation of pain intensity and level of functioning, assessment of progress toward achieving therapeutic goals, presence of adverse events, and adherence to prescribed therapies.
- In patient on COT who are at high risk or have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan of care.
- In patients not at high risk and not known to have engaged in aberrant drug-related behavior, clinicians should consider periodically obtaining urine drug screens or other information to confirm adherence to the COT plan of care.



High-Risk Patients

- Clinicians may consider COT for patients with CNCP and history of drug abuse, psychiatric issues, or serious aberrant drug related behaviors only if they are able to *implement more frequent and stringent* monitoring parameters. In such situations, clinicians should strongly consider consultation with a mental health or addiction specialist.
- Clinicians should evaluate patients with suspected aberrant drug-related behaviors for appropriateness of COT or *need for restructuring of therapy*, referral for assistance in management, or discontinuation of COT.



Dose Escalations, High-Dose Opioid Therapy, Opioid Rotation, and Indications for Discontinuation of Therapy

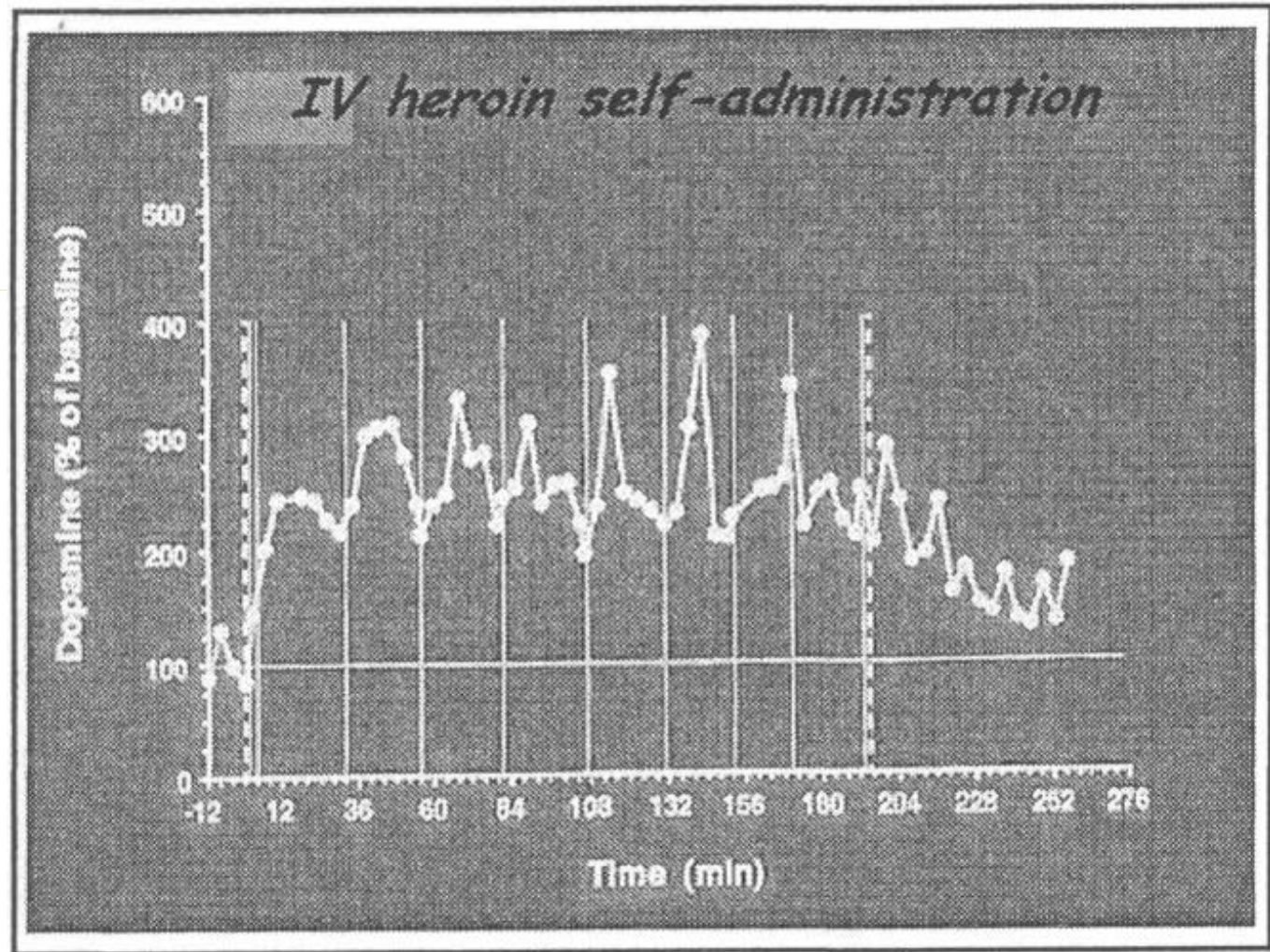
- When repeated dose escalations occur in patients on COT, clinicians should evaluate potential causes and reassess benefits relative to harms.
- In patients who require relatively high doses of opioids (>200mg daily of oral morphine), clinicians should evaluate for unique opioid-related adverse events, changes in health status, and adherence to the OCT treatment plan on an ongoing basis, and consider more frequent follow-up visits.
- Clinicians should consider opioid rotation when patients on COT experience intolerable adverse effects or adequate benefit despite dose increases. (weak evidence)
- Clinicians should taper or wean patients off of COT who engage in repeated aberrant drug-related behaviors of drug-abuse/diversion, experience no progress toward meeting therapeutic goals, or experience intolerable adverse effects.



A different take on the initiation and maintenance of controlled substances in COT

- When treating chronic hypertension, we do not tell the patient to wait until he has a headache and nose bleed before taking a short-acting anti-hypertensive.
- All pain waxes and wanes just as a patients BP fluctuates. Although most recommendations for COT initiation do not recommend a “follow-the-pain” pattern, they still recommend ~20-30% of the opioid load to be given as short-acting.
- I have found the use of short acting on a standing basis to be counter-productive and this is borne out in the animal model...

A different take on the initiation and maintenance of controlled substances in COT



Gardner, EL: What we have learned about addiction from animal models of drug self-administration. *American Journal on Addictions*, 2000; 9:285-313



Opioid Related Adverse Effects

Clinicians should anticipate, identify, and treat common opioid-associated adverse effects. These include:

- Constipation
- Nausea and/or vomiting
- Sedation or decrease/clouded mentation
- Some evidence to indicate hypogonadism
- Pruritus
- Respiratory depression occurs usually with high initial doses



Breakthrough Pain

In patients in around-the-clock COT with breakthrough pain, clinicians may consider as-needed opioids based upon an initial and ongoing analysis and therapeutic benefit versus risk. (weak recommendation)



Opioid Policies

Clinicians should be aware of federal and state laws, regulatory guidelines, and policy statements that govern the medical use of COT for CNCP.

Chou, et.al: Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*, Vol 10, No 2 (February), 2009: pp 113-130

When federal regulations differ from state regulations, it is safer to adhere to the more stringent of the two.

Closing Thoughts

- Both society and our own canon of ethics demand we treat chronic pain
- Society and law enforcement are demanding we be responsible in our prescribing
- Before prescribing COT for CNCP we must be circumspect in our approach, with adequate selection, prescribing and monitoring





Vignettes



Cheryl Ann D.

- A 46 year-old lady whom had undergone a post-traumatic ACDF at C3-4 in 1990. Subsequently the patient had a CESI with a right C7 nerve root trauma.

- The patient is referred by a fellow pain medicine specialist.
- The treating PM doctor left the practice and the referring doctor (PM) was not comfortable taking over the prescribing.

Cheryl Ann D.

Current Medications:

- Fentanyl TD Patch (2) 100mcg q48 hours (30/month)
- Fentanyl Lollipop (Actiq)
 - 1200mcg qid (120/month)
 - 1600mcg qid (120/month)
- Topiramate (2) 100mg bid
- Tizanidine 4mg (3) qhs
- Gabapentin 1800mg tid
- Duloxetine (Cymbalta) 60mg bid
- Lunesta 3mg qhs
- Special preparation Ketamine 10mg tid (90/month)



Cheryl Ann D.

Social history:

- The patient has a one-pack/28-year history tobacco use and is a recovering alcoholic with 12-years in recovery. She has a sponsor, home group and a commitment.
- Prior to 1990 she was a medical receptionist but has not worked since the injury.
- Although she reports the medication is working, her daily pain level is between 8 and 10 out of 10.

Side Effects:

- The patient has developed caries and is to undergo > \$5,000 of dental work.
- The patient's husband is concerned because his wife is emotionally unstable and will go from a crying fit to anger within seconds.



Cheryl Ann D.

Records Review and Precautions:

- Review of the patient's records and discussion with the referring doctor reveal no early refills, no aberrant behavior and appropriate urine screens
- History and Physical revealed an appropriate patient in obvious severe pain. No malingering is detected.
- Urine toxicology screening was consistent with the medications being taken.



Cheryl Ann D.

WWJD???

Cheryl Ann D.

Ultimate Disposition:

- **Medications**

- Fentanyl TD Patch (2) 100mcg q48 hours (30/month)
- Topiramate 25mg bid
- Opana immediate release 10mg up to bid (30/4-5 months)
- Savella 50mg bid
- Tizanidine 4mg 1-2 qhs

- **Social**

- The patient is currently working part-time as a law firm receptionist
- The husband comes in every four or five months and reports she is “a different person”

She was first consulted on June 4, 2007 and the last visit... October 7, 2010

Alison H.

History:

- A 30 year-old lady whom had been born with “femoral mal-alignment” with a total of six surgeries of the bilateral knees and one left ankle.
- She presents with chronic right knee and left ankle pain and has been diagnosed by the referring PM doctor with CRPS of the right lower extremity (specifically knee).
- I spoke with the referring doctor and she is being referred for evaluation for “something different”.
- She is currently on Roxicodone 15mg eleven pills per day and she continues to experience pain in the 8 to 10 out of 10 range in spite of stating she gets relief.



Alison H.

History:

- Review with the referring doctor and the medical records reveal no history of increased risk for addiction and no evidence of aberrant behavior.
- The patient had a Dorsal Column Stimulator in 2005 which was subsequently removed in 2007. She refuses an intrathecal pump.
- She has been tried on multiple long-acting narcotics with no relief.
- The patient is seen with her mother in attendance at her request. The mother is supportive and is only concerned with her daughter's pain, she reports no significant personality changes with the medications.



Alison H.

Social History:

- The patient denies tobacco use and rare alcohol intake.
 - She is self-employed as an artist with her own apartment.
-



Alison H.

Physical Examination:

- Decreased ROM right knee and left ankle secondary to pain
- Allodynia in the right lower extremity, primarily the knee region with mottled appearance of the skin but no change in temperature
- No evidence of illicit parenteral drug use



Alison H.

WWJD???



Alison H.

Disposition:

- I discussed with the patient and her mother the concept of opioid hyperalgesia.
- I broached the idea of a Suboxone induction to hopefully effect a “down-regulation” of the opioid receptors.
- I gave them the websites to investigate Suboxone but also for Buprenex to understand the use of buprenorphine in pain control.
- In mid-June the patient did an induction **for the diagnosis of chronic pain, not addiction.**

Alison H.

Disposition:

- Upon follow-up two days later and the patient states a 50% reduction in pain with a 20% increase in activity.
- She stated “I feel a lot clearer but a little tired from it.”
- She reported some mild nausea and stomach cramps for which she took Zofran but this was pre-morbid.

Alison H.

Current Status:

- The patient had done very well for three months but with increased activity she notes the medication is less effective but she does not wish to go back to oxycodone.
- The surgeon has recommended an extensive surgery on the left ankle necessitating a switch to a long-acting opioid.
- She was switched to Opana ER 20mg initially bid then after four days tid with excellent relief.
- At three months post-operative we will be considering a taper off all opioids, with or without Suboxone.

Deborah S.

History:

- The patient is a 51 year-old lady referred by the PM Nurse Practitioner for evaluation. She was diagnosed with CRPS ten-years ago involving the right lower extremity, specifically the knee and ankle. She was on Avinza 120mg qd, hydromorphone 8mg tid and amitriptyline 50mg qhs. She states that two-weeks prior she had suffered emotional distress and “over-medicated” herself. She reports she threw out all medications and went through withdrawal for five-days and then was put back on Embeda 30mg qid and sent to me for either adjustment of medications or detoxification. Unfortunately there was no opportunity for speaking with the referral source prior to or at the time of the consult.



Deborah S.

Social History:

- The patient denies tobacco use and states rare alcohol intake. She is employed as a N-P in a pre-surgical testing center. She denies any personal or family history of alcohol or drug abuse.

Physical Examination:

- No physical evidence of illicit drug use and the patient is not in opioid withdrawal as per the COW. Tenderness noted along the lateral right ankle and foot but otherwise unremarkable.



Deborah S.

Treatment Plan:

- I discussed at length with the patient the concept of pseudo-addiction, tolerance and physical dependence. I did not diagnose addiction with this presentation.
- We discussed the concept of a Suboxone induction to help detoxify her off all opioids and try an “opioid holiday”.
- The patient chose to do an induction and follow-up in one week.

One Week Follow-up:

- At follow-up the patient stated she was doing fine on Suboxone 8mg bid.



Deborah S.

Four Months Later:

- The patient presented to my office and was seen by my physician assistant. She had missed her previous appointments reporting that she did not like the stigma of being on Suboxone.
- She stopped it three months ago and went back to the referring NP and lied to get back on Avinza 60mg bid, she received sixty pills per month.
- She reports she was taking the pills four times a day and ran out a week ago.
- She is exhibiting mild opioid withdrawal but is emotionally distraught and tearful.



Deborah S.

WWJD???



Deborah S.

Disposition:

- The patient was asked to return with her husband in attendance.
- The husband stated he was unaware of any of these problems occurring except that she has been more stressed and emotional the past year.
- She was admonished that what she did was very dangerous. It was also explained to her that her career is at risk.
- A repeat induction was performed and the patient started IOP at a nearby facility.
- She is now coming up on three months clean and sober, is involved in a 12-step recovery program, continues IOP but is in step-down and states that she feels like she got her life back.



In Summary

- We have an obligation both morally and ethically to treat pain.
- We also have an obligation to minimize risk associated with the treatment we provide for pain.
- Universal Precautions and monitoring are essential to use as an early detection tool for the side –affect of addiction.
- When aberrant behavior is identified we have an obligation to give a patient what they need, not just what they want.



"I'M MARRIED, SO I'M AN EXPERT IN
PAIN MANAGEMENT."