Appendix A

Davis MedicalCenter
812 Gorman Avenue • Elkins, WV 26241 • 304.636.3300 • Fax 304.637.3435 • davishealthsystem.org

Voluntary Non-Opioid Directive (VNOD)

PATIENT'S LAST NAME	PATIENT'S FIRST NAME	DATE OF BIRTH (MM/DD/YY)
STREET OR RESIDENTIAL ADDRESS		
CITY	STATE	ZIP CODE (5 or 9 digits)
LAST NAME OF GUARDIAN OR HEALTH CARE AGENT (If Applicable)		
FIRST NAME OF GUARDIAN OR HEALTH CARE AGENT	MIDDLE NAME OR INITIAL	

PATIENT/GUARDIAN/HEALTH CARE AGENT STATEMENT (SIGNATURE AND DATE REQUIRED)

I hereby certify that I am refusing at my own insistence the offer or administration of any opioid medications including in an emergency situation where I am unable to speak for myself. I understand the risks and benefits of my refusal, and hereby release the health care provider(s) or emergency medical service, its administration and personnel, from any responsibility for all consequences, which may result by my abstinence under these circumstances. I further certify my understanding that I may effectively revoke this certification at any time orally or in writing.

I hereby direct that health care provider(s) or emergency medical service(s), their administration and personnel, comply with the West Virginia Senate Bill 273 and guidance with regard to the above named patient.

_____ _____

Signature of Patient/Guardian/Health Care Agent Date / Time

SIGNATURE AND DATE (ALWAYS REQUIRED)

I am a health care practitioner for the above named patient. I verify that the above named patient has a current and valid Voluntary Non-Opioid Directive (VNOD) issued on _____.

_____ _____

Signature of Heath Care Practitioner Date / Time

_____ _____

Printed Name of Health Care Practitioner Telephone Number of Health Care Practitioner

_____ _____

Effective Date of OD Certification Address of Health Care Practitioner

First Copy: To be kept by patient.
Second Copy: To be kept in patient's permanent medical record.
If the person completing this form is currently enrolled in substance treatment, appropriate consents must comply with HIPAA and 42 CFR Part 2.

Appendix B

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CONTROLLED SUBSTANCE AGREEMENT

I, _____, understand that in order to receive care for the treatment of pain or the use of controlled medications, I agree to and will comply with the following:

A. MENTAL HEALTH AND/OR PAIN MANAGEMENT CONSULTANT: A mental health assessment and/or continuing psychological therapy may be required. If I am currently involved in mental health therapy, or if I enter such therapy, I will authorize my mental health practitioner to exchange unrestricted information regarding my condition and treatment with the undersigned physician.

B. USE OF MEDICATIONS: I will take all medications as prescribed. I will speak with the undersigned physician before making any change in either the dose or frequency of my medications. There will be no early refills of controlled medications without prior authorization. Narcotic pain medications must all be obtained from the same pharmacy each time (any exception must be approved by the undersigned physician). I will abstain from alcohol use.

C. SEEKING PRESCRIPTIONS: I will neither seek nor fill prescriptions for any controlled medication from any other health care provider unless authorized by the undersigned physician. I will not harass or repeatedly speak with the pharmacist about refills, which may be early. I will not call the physician after hours about my controlled substance prescription refills.

D. MEDICAL RECORDS RELEASES: I will inform all of my health care providers that I receive pain management and will maintain an unrestricted and current medical records release on file.

E. DRUG SCREENING: I will participate in drug screening as a part of my treatment plan. I understand that drug screening may be conducted at least every 12 months and may be required more frequently at the discretion of the undersigned physician. Screening may include urinalysis, blood testing or pill counts. I agree to pay all costs associated with drug testing not covered by my insurance. Refusal to submit to screening at the time specified may result in termination of services.

F. ILLEGAL AND NON-PRESCRIBED DRUG USE: I understand that the use any controlled medication not prescribed by the undersigned physician may result in termination of care. I authorize the practice to cooperate fully with any city, state or federal law enforcement agency, including this state's Board of Pharmacy, in the investigation of any possible misuse, sale, or other diversion of controlled medicines. I authorize the practice to provide a copy of this Agreement to my pharmacy. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations. I also understand that the use of any illegal substance, including marijuana, may result in termination of care.

G. LOST OR STOLEN MEDICATIONS: I agree to safeguard all medications prescribed by the undersigned physician and understand that lost or damaged medications will not be replaced.

H. PRESCRIPTIONS WHILE TRAVELING: The practice may provide prescriptions for up to 90 days when patients are traveling out of state. Patients will have to arrange for shipment of controlled substances by their pharmacy at their own expense. Patients who will be out of state longer than 90 days need to arrange for health care at their travel destinations.

I. DRIVING & OPERATING EQUIPMENT: many medications can cause drowsiness and/or a very relaxed state of mind causing operation of equipment or vehicles to be dangerous. I agree to refrain from driving or operating dangerous equipment for 72 hours after any change in medication dosage and whenever I feel drowsy.

J. OTHER RESTRICTIONS AND/OR CONSIDERATIONS:

K. TERMINATION: I will no longer be eligible for care if I am in possession of illicit drugs or substances, trafficking in controlled or illegal substances, intoxicated or if arrested for DUI. If I alter my prescription in any way, sell or share my medications, I will no longer be eligible for care.

I UNDERSTAND AND AGREE TO THE CONDITIONS OF CARE DESCRIBED ABOVE AND WILL COMPLY WITH THEM. ALL OF MY QUESTIONS ABOUT THE TERMS OF THIS AGREEMENT HAVE BEEN ANSWERED TO MY SATISFACTION. FAILURE TO COMPLY WITH ANY OF THE TERMS OF THIS AGREEMENT MAY RESULT IN IMMEDIATE TERMINATION OF SERVICE.

_____ _____

Patient Signature Date / Time

_____ _____

Medical Care Provider Signature Date / Time

Contract was reviewed on 05/01/2018.

Appendix C

Clinical Decision Making in Pain Management

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are:

heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are:

Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are:

Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are:

Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are:

cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin

Licensing Requirements

Physicians and Physician Assistants must complete three hours of drug diversion training every two years to maintain licensure. This can be done either online or in person.

Nurse practioners must complete 3 hours of drug diversion training upon receiving their license, then one hour yearly thereafter. There are links to online and face to face courses on the WV Board of Nursing website.

Legal Issues

Any practioner who fails to register with the WV Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database shall be subject to an administrative penalty of $1000 by the licensing board of his or her licensure. (per chapter 60A article 9 of the WV Controlled Substances Act)

A physician is not subject to disciplinary sanctions by a licensing board or criminal punishment by the state for prescribing, administering, or dispensing pain relieving controlled substances for the purpose of alleviating or controlling pain if:
a. in the case of a dying patient experiencing pain, the physician practices in accordance with an accepted guideline and works to relieve the dying patient's pain and promote the dignity and autonomy of the dying patient.
b. the case of a patient who is not dying and is experiencing pain, the physician works to relieve the pain within acceptable guidelines. (per WV Management of Pain Act section 30 article 3A-2)

A provider can be disciplined if he/she:
a. fails to maintain complete, accurate, and current records documenting the physical exam and medical history of the patient and basis for clinical diagnosis and treatment plan
b. writes a fictitious or false prescription for a controlled substance
c. prescribes, administers, or dispenses a controlled substance in violation of the provisions of the federal Comprehensive Drug Abuse Prevention and Control act of 1970 d. diverts controlled substances prescribed for a patient to the physician's own personal use. (per the WV Management of Pain Act section 30 article 3A-3)

Chronic Pain

Definition:

Pain that typically lasts greater than three months or past the time of normal tissue healing.

Types of Pain:

Nociceptive: Caused by stimuli that threaten or provoke actual tissue damage.

Primarily involves nonnarcotic and opioid analgesia. Tylenol is typically recommended as 1st line for OA and chronic low back pain. However, it is less effective than NSAIDS and has potential for hepatic toxicity at doses more than 3-4 g/day.

Alternative 1st line is NSAIDS for mild-moderate chronic low back pain and OA.

Opioids only considered for patients who have persistent pain despite conservative therapy with low addiction risk, no contraindications.

Neuropathic: Results from damage or pathology within the nervous system – can be central or peripheral.

Establish a diagnosis whenever possible and treat the underlying problem.

Initial treatment is antidepressants (tricyclic or dual reuptake SNRIs), Gabapentin, or Lyrica with adjunctive topical therapy for localized pain.

Combination therapy is often required.

Caveats:

The guidelines herein are intended for patients over 18 with chronic pain outside of palliative, cancer, or end of life pain.

Use of opioid pain medication in pre-high school graduates is highly discouraged as this is associated with a 33% increase in the risk of later opioid misuse.

Keep in mind that the CDC found that evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy though evidence suggests risk for serious harms that appears to be dose dependent.

Evidence suggested that long-term opioid therapy is associated with an increased risk for an opioid abuse or dependence diagnosis.

Factors associated with increased risk for misuse include history of substance abuse disorder, younger age, major depression, and use of psychotropic meds.

Recent opioid use was associated with an increased risk for any overdose events and serious overdose events versus nonuse.

Opioid therapy prescribed for acute pain is associated with greater likelihood of long-term use.

Patients who received early opioids had an increased likelihood of receiving five or more opioid prescriptions 3—730 days following onset that increased with greater early exposure.

Effectiveness of Non-opioid therapies:

Cognitive Behavioral Therapy – small positive effects on disability and catastrophic thinking.

Exercise therapy is evidenced to help reduce pain and improve function in low back pain and OA of the knee and hip, and improve physical function, fibromyalgia symptoms, and well-being in fibromyalgia.

Multimodal therapies can help reduce pain more than singular therapies.

Analgesics, antidepressants, and anticonvulsants have also had evidence of benefit.

Guidelines for use:

Initial evaluation

Non-pharmacological therapy and non-opioid therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacological therapy and non-opioid pharmacologic therapy as appropriate.

Non-opioid therapy consists of cognitive behavioral therapy, NSAIDS, acetaminophen, exercise therapy, psychological therapy, arthrocentesis, injections, anticonvulsants, antidepressants, physical therapy, occupational therapy, acupuncture, massage therapy, osteopathic manipulation, chronic pain management program, counseling, music therapy, aromatherapy, and chiropractic services.

Before beginning opioids, clinicians should establish treatment goals including realistic goals for pain and function and should discuss how opioid therapy should be discontinued if benefits no longer outweigh the risks. Therapy should be continued only if there is clinically meaningful improvement in pain and function. Clinicians need to determine how effectiveness will be evaluated and should establish treatment goals with patients. These goals should involve both improvements in pain relief and in physical, emotional, and social function. Depression scales and PEG scales should be done prior to and during treatment.

During Therapy

Before and during therapy, the practitioner should explain the expected benefits, but that resolution of pain is unlikely; goal should be improved function despite ongoing pain; advise about serious adverse effects and side effects; discuss vehicle operation; discuss risk of respiratory depression and death at higher doses; review risk increases when taken with benzodiazepines; discuss risks to household members; discuss periodic reassessment; discuss and use the PMDP; address cognitive issues, address bowel habits, constipation.

Methadone accounts for 1/3 of opioid related overdose deaths despite representing <2% of opioid prescriptions in the U.S.

Concurrent use of narcotics and benzodiazepines put patients at greater risk for potentially fatal overdose. Concurrent use has been evidenced in 31-61% of fatal overdoses. This risk is greater for patients with sleep apnea or other causes of sleep disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders.

Patients who do not experience clinically meaningful pain relief early in treatment (within one month) are unlikely to experience pain relief with longer-term use.

Initiation of opioids with an ER/LA versus immediate-release opioids for titrating patients was associated with a greater risk for non-fatal overdose with the risk being greater in the first two weeks after initiation of treatment.

No data exists for the rapidity of dose adjustment.

Little consistency or reliability to the real world was found with risk assessment instruments.

The indication for switching to ER/LA opioids is for daily management of pain severe enough to require around-the-clock, long-term opioid treatment in patients for whom other treatment options are ineffective, not tolerated, or would otherwise be inadequate to provide sufficient management of pain.

Time scheduled opioid use was associated with substantially higher average daily opioid dosage than as needed medications.

Clinicians should carefully assess any patient receiving ≥ 50 morphine mg equivalents (MME)/day and should avoid increasing dosage to ≥ 90 MME/day. If increasing the dose above 50MME/day, clinicians should assess whether opioid treatment goals are being met. If prescription is greater than 50MME, clinicians should implement additional precautions including increased frequency of follow up and offering naloxone and overdose education to patients and their household members. If increasing >90MME/day, it is suggested that the clinician consult with a pain medicine specialist for guidance.

Acute Pain

When using opioids for acute pain, clinicians should use the lowest effective dose and prescribe for only 3-7 days.

Evaluate the benefits and harms with patients within 1-4 weeks of initiation and at least every 3 months thereafter.

Tapering off of opioids

Tapers reducing weekly dosage by 10-50% of the original dosing have been recommended as have rapid tapers over 2-3 weeks in the case of a severe adverse event such as an overdose.

The current recommendation is approximately 10% per week with the realization that this can take months.

Working together with mental health is suggested for psychosocial support for anxiety related to the taper.

Special circumstances

Over 65- monitor often.

Patients with substance use disorder – use PMDP data and drug testing as well as the Drug Abuse Screening Test and the Alcohol use Disorders Test.

Prior overdose – discontinue use if possible.

PMDP

Use when starting opioid therapy and every three months thereafter.

Should be reviewed for both prescribed medication as well as other medications, also use to determine the MME the patient is receiving.

Monitor for benzodiazepines – clinicians should avoid prescribing both whenever possible.

Discuss safety concerns with other physicians prescribing for the patient.

Urine Drug Testing

Upon start of medication and at least annually to assess for prescribed medications as well as other medications.

A positive opiates assay detects morphine, which may denote morphine, codeine, or heroin, but does not detect synthetics such as fentanyl or methadone and may not detect semi-synthetics such as oxycodone – the test needs to be specific.

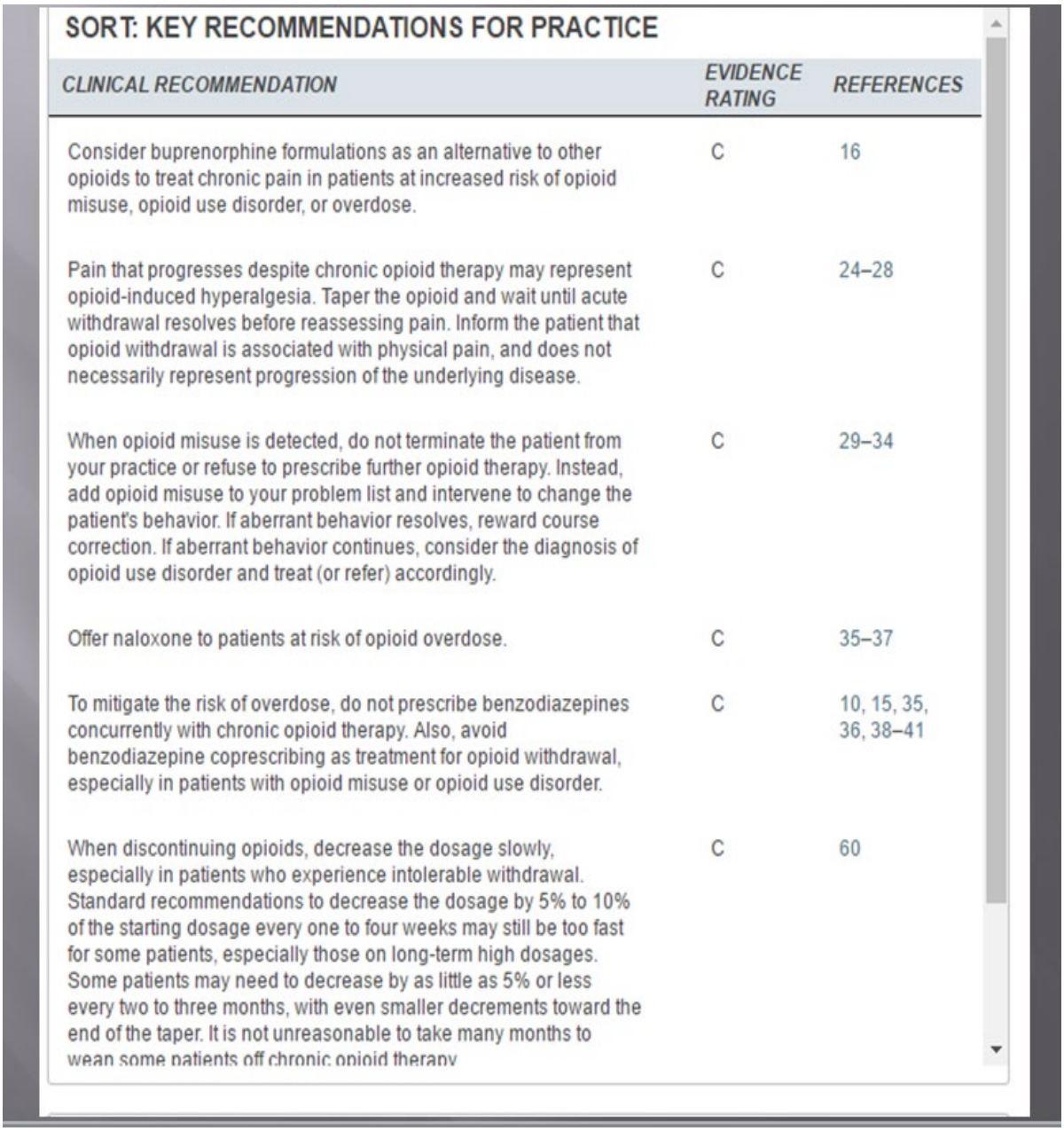
Abuse

Clinicians should offer or arrange evidence based treatment for patients that become addicted. This can be done with buprenorphine, methadone, or naloxone combined with psychology intervention.

Naloxone

WV Board of Pharmacy has made pharmacists and interns capable of dispensing without a prescription. When dispensing, they are required to counsel to the proper administration of the medication, the importance of contacting EMS and the risk of failing to do so. They are also required to provide educational materials including the 1-844-HELP-4-WV line and a copy of the "I Have Narcan" trifold available at www.wvoems.org.

AAFP Guidelines



SORT: KEY RECOMMENDATIONS FOR PRACTICE

CLINICAL RECOMMENDATION	EVIDENCE RATING	REFERENCES
Consider buprenorphine formulations as an alternative to other opioids to treat chronic pain in patients at increased risk of opioid misuse, opioid use disorder, or overdose.	C	16
Pain that progresses despite chronic opioid therapy may represent opioid-induced hyperalgesia. Taper the opioid and wait until acute withdrawal resolves before reassessing pain. Inform the patient that opioid withdrawal is associated with physical pain, and does not necessarily represent progression of the underlying disease.	C	24–28
When opioid misuse is detected, do not terminate the patient from your practice or refuse to prescribe further opioid therapy. Instead, add opioid misuse to your problem list and intervene to change the patient's behavior. If aberrant behavior resolves, reward course correction. If aberrant behavior continues, consider the diagnosis of opioid use disorder and treat (or refer) accordingly.	C	29–34
Offer naloxone to patients at risk of opioid overdose.	C	35–37
To mitigate the risk of overdose, do not prescribe benzodiazepines concurrently with chronic opioid therapy. Also, avoid benzodiazepine coprescribing as treatment for opioid withdrawal, especially in patients with opioid misuse or opioid use disorder.	C	10, 15, 35, 36, 38–41
When discontinuing opioids, decrease the dosage slowly, especially in patients who experience intolerable withdrawal. Standard recommendations to decrease the dosage by 5% to 10% of the starting dosage every one to four weeks may still be too fast for some patients, especially those on long-term high dosages. Some patients may need to decrease by as little as 5% or less every two to three months, with even smaller decrements toward the end of the taper. It is not unreasonable to take many months to wean some patients off chronic opioid therapy.	C	60

View/Print Table

BEST PRACTICES IN PAIN MANAGEMENT: RECOMMENDATIONS FROM THE CHOOSING WISELY CAMPAIGN

RECOMMENDATION	*SPONSORING ORGANIZATION*
Do not prescribe opioid analgesics as first-line therapy to treat chronic noncancer pain.	American Society of Anesthesiologists
Do not prescribe opioid analgesics as long-term therapy to treat chronic noncancer pain until the risks are considered and discussed with the patient.	American Society of Anesthesiologists
Do not prescribe opioids for treatment of chronic or acute pain for workers who perform safety-sensitive jobs, such as operating motor vehicles, forklifts, cranes, or other heavy equipment.	American College of Occupational and Environmental Medicine

Source: For more information on the Choosing Wisely Campaign, see http://www.choosingwisely.org. For supporting citations and to search Choosing Wisely recommendations relevant to primary care, see http://www.aafp.org/afp/recommendations/search.htm.

Information on Non-Narcotic Analgesia

Tylenol:

MOA is uncertain.

Liver toxicity can occur even at therapeutic levels.

Recommending 3-3.25mg/day max and avoid in heavy drinkers.

NSAIDS

Exert synergy when paired with opioids.

AGS recommends against use when possible despite this being recommended by several other societies as a first line treatment.

Cox-2 has fewer GI side effects than NSAIDS, but doses above 200mg/day are associated with increased cardiac risk.

Nephrotoxicity, edema, ATN, interfere with cardio protective effects of ASA, CHF exacerbations, HTN, prothrombotic, hepatic toxicity, inability to concentrate are all potential side effects.

Anticonvulsants

Gabapentin, pregabalin, carbamazepine are the only ones approved that have good studies for pain.

Gabapentin (up to 3600mg/day div tid) and pregabalin (up to 600mg/day div tid) have proven efficacy for neuropathic pain.

Pregabalin also approved and studied in central neuropathic pain and fibromyalgia.

Carbamazepine is treatment of choice for trigeminal neuralgia, though not effective for other pain.

Antidepressants – Tricyclic Antidepressants

Have independent analgesic effects as well as ability to relieve depressive symptoms associated with pain.

Potentiate the endogenous opioid system.

Can take 6-8 weeks at the highest dose tolerated to see effect, though onset of analgesia can be seen in one week.

Amitryptyline has most anticholinergic effect and desipramine has the least. Nortriptyline is also low.

Sleep induction occurs 1-3 hours after ingestion.

If patient gets a "hangover", take earlier in the evening.

Educate on anticholinergic side effects.

Relatively contraindicated in patients with severe cardiac disease – particularly conduction issues – obtain a pre-treatment EKG.

Desipramine and nortriptyline can be used safely in older patients, but starting dose should be reduced by ½.

Antidepressants SSRI/SNRI

Duloxetine and venlafaxine have been studied in peripheral neuropathy and milnacipran has been studied in fibromyalgia.

Venlafaxine is for peripheral neuropathy.

Duloxetine is for peripheral neuropathy, fibromyalgia, chronic low back pain, and OA – up to a 30% reduction in pain.

SSRIS only pain relief studies may be related to helping with the depression associated with pain.

Topicals

Lidocaine – topical patch shows efficacy and tolerability in patients with post-herpetic pain and allodynia.

Capsaicin – 0.025 and 0.075 percent cream. Used in post-herpetic neuralgia, HIV, neuropathy, and diabetic neuropathy. Must be applied 3-4 times a day for 6-8 weeks for optimal pain relief. Also comes as a patch, but must be applied under clinical supervision.

NSAIDS – weak studies for anything but acute pain.

Botox used in severe post-herpetic neuralgia.

Benzodiazepines/Cannabis

Use of benzodiazepines was associated with greater pain severity, prescription of higher doses of opioids, substance use, and greater mental health comorbidities.

Several cannabis trials had positive results for chronic pain, but the long-term effects are not known and it is not currently legal in this state.

Non-pharmacologic therapies

Behavioral medicine – CBT, biofeedback, relaxation, psychotherapy

Aerobic exercise

Acupuncture

PT/OT

Chiropractic/OMT

Ultrasound

Electric neuromodulation – TENS, spinal cord stim

Thermal applications

Interventional – ablative, Botox, nerve blocks, trigger points, epidural steroids

Surgical

Summary

In our current environment, we are now pain specialists. Narcotics are not a 'never' proposition, and are certainly the only option for some patients, but our prescribing practices must be evidence based. The federal and state boards have established guidelines and it is the goal of our population health team to make sure we are all apprised of these changes as they occur.