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Family Doctor

A JOURNAL OF THE NEW YORK STATE ACADEMY OF FAMILY PHYSICIANS

FEATURE ARTICLES:

- Optimizing your Management of Chronic Pain: A Holistic Approach to Evidence-based Pain Management and Opioid Deprescribing
- Overcoming Barriers to Treatment of Opioid Use Disorder in Primary Care
- Alcohol Withdrawal in my Office – Yes!
- Emerging Evidence of the Role of Cannabis in Chronic Pain Management and Opioid Use Disorder

New York State Academy of Family Physicians

Focus:

Pain Management & Opioid Update

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[1]U.S. Department of Agriculture Economic Research Service. Household Food Security in the United States in 2015

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New York State Academy of Family Physicians
16 Sage Estate, Suite 202
Albany, New York 12204
www.nysafp.org
Phone: 518-489-8945
Fax: 518-888-7648

Letters to the Editor, comments or articles can be submitted by mail, fax or email to journaleditor@nysafp.org

Editor: Penny Ruhm, MS

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From the Executive Vice President

By Vito Grasso, MPA, CAE

Health care is already a major issue in the 2020 presidential election. Democratic candidates are trying to differentiate themselves in proposing various forms of reforms along a limited spectrum encompassing minor tinkering with the Affordable Care Act to wholesale single payer. The President's health care plan is still focused on reversing the ACA, which equates to preserving a system that has already failed.

While the national debate about health care system reform has been elevated because of the upcoming election, the facts have not actually changed much. Millions of people still do not have coverage. Health care costs continue to rise as do premiums, co-pays and deductibles. Costs have increasingly been shifted to consumers and waste remains high and growing. Also, as we learn of more new and different therapies on the horizon, particularly treatments for genetically caused conditions, we do not seem prepared to absorb the much higher costs of new genetic based treatments and technology. If we fail to accommodate introduction of emerging therapies into clinical application because they are so costly, then we are delaying if not foregoing the opportunity to advance quality and improve outcomes for millions of people who could benefit from new advancements in medical science.

Too much of the debate about health care reform has centered around costs and the role of government. Both are inherent issues in the single payer debate.

Containing costs will always be a priority regardless of whether a company is for-profit or not-for-profit. No company can exist for long if it continually loses money and no company can significantly improve if it does not have capital to invest in new technology and growth. Profit creates capital for investment. Socialism is the bogey man used by those who wish to preserve the insurance model in the face of growing support for a single payer system, but the insurance model has not allowed providers, physicians in particular, to create capital within their practices to invest in expansion, management innovation or new therapies.

Health care is certainly different from other commodities traded in our economy. Our Congress of Delegates adopted a resolution years ago establishing that health is a human right and that access to health care is essential to actualize that right. The AAFP COD also adopted the same policy. If we truly believe health is a human right then we need a system of paying for health care that is based on assuring that everyone has access to care, that care provided is continually the best which current science can accommodate and that we pay for the delivery system through a mechanism which spreads that cost equitably throughout our entire society.

The best mechanism for achieving this type of system is a public benefit corporation whether it is exclusively operated by government or is designed to accommodate a partnership between government and the private sector. The most important element should be that our health care system operates in the best interests of consumers and not for the pecuniary benefit of private interests. Private interest, particularly the legitimate need of businesses to realize profits, is not a motivating force for the delivery of vital health care to a widely diverse population with significant differences in ability to pay. In a multi-payer system with numerous companies competing for market share and focused on making more money than they spend, it is unrealistic to expect a payment system that is consistent, transparent and which can equitably spread the cost of heath care among everyone.

Additionally, profit motivated companies cannot implement payment systems that account for the significant costs of addressing social determinants of health. These are matters which have traditionally not been addressed through health insurance. Only a public interest focused system can begin to account for social determinants of health in allocating resources to support a system of care that also affords assistance in preventing the conditions that can adversely affect health.

It is unlikely the results of the 2020 elections will produce a clear pathway for health care reform. Our system of governance and our economy are simply too complicated to accommodate the large scale changes necessary to make health care more accessible and more affordable. We should, however, know after the results are in whether we will have four more years of chaos and decline or a different perspective on how to proceed with actual reform.

President's Post
By Barbara Keber, MD, FAAFP

This issue is dedicated to the opioid epidemic and related topics. Opioids are a national as well as a local concern. Family medicine has always been on the forefront of treating individuals with addiction. We have many family physicians in NYS who have received training to prescribe medication for patients trying to recover from opioid addiction. At our last COD this past June, the Congress passed several resolutions addressing this significant problem in our state. One resolution requested that our Board of Directors reach out to the family medicine residency programs within our state to encourage the training of our residents in medication assisted treatment (MAT), with waiver training for the use of buprenorphine treatment being the major training for residents. I include this here as one way to encourage and request that all residency training programs within NYS provide this training for their residents prior to graduation.

Other resolutions which passed this year related to the opioid epidemic include the partnering of county chapters with their local departments of health to work on including family physicians on local and state-level committees to address this issue and contribute to programs being developed throughout New York. Another resolution requires the NYSAFP to provide best practice information on our website regarding the use of naloxone for reduction in opioid overdose deaths. Lastly, another resolution that passed will work with NYS to allow for NP and PA physician extenders to receive training and provide MAT for larger numbers of patients, increasing access for patients who need this treatment.

Our Winter Weekend program will have offered both buprenorphine waiver training as well as other CME presentations related to the opioid epidemic in an effort to educate attending physicians, residents, and students as well as nurse practitioners and physician assistants on this important information.

The opioid epidemic provides an opportunity for family doctors to provide care to a group of patients who otherwise might not be treated for their addiction. The dedication of this journal edition to the issues surrounding opioid use and pain management shows the importance of addressing this critical issue for our Academy.

Your NYSAFP will continue to work to improve access and treatment for opioid addiction within the state. We thank those who provide this care for their work with this vulnerable population and continue to work to develop additional programs and education related to this important topic.

The staff and Board of Directors of your NYSAFP wishes everyone a happy and healthy new year!

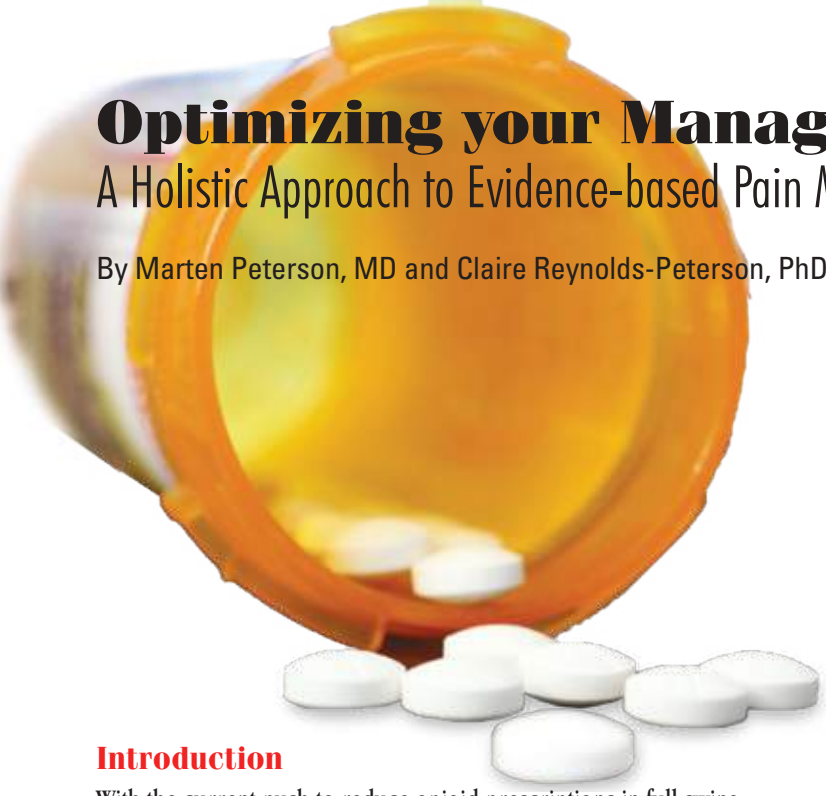
Barbara Keber MD, FAAFP
President NYSAFP 2019-2020

Opioids are a national as well as a local concern. Family medicine has always been on the forefront of treating individuals with addiction.

Optimizing your Management of Chronic Pain:

A Holistic Approach to Evidence-based Pain Management and Opioid Deprescribing

By Marten Peterson, MD and Claire Reynolds-Peterson, PhD



Introduction

With the current push to reduce opioid prescriptions in full swing, family physicians and their offices bear the task of putting an end to long term opioid use. Ample evidence exists to show that chronic pain is better controlled with non-opioid management, but unfortunately little evidence exists to guide office-based policy and patient discussion. The majority of evidence focuses on rule-making for preventing misuse of opioids which is important, but is minimizing the complexity of managing pain in the primary care setting.

Physicians have many different motives for deprescribing opioids, however patients are often unsympathetic to our plight. Threats of stiffening regulations, and 'new office policies' may contribute to the overall conversation, but the motivation for reducing opioid use must primarily focus on the interest of the patient, not the provider. Providers and patients should have a shared goal of improving pain and function, rather than solely reducing opioids. Thankfully, the nation-wide spotlight on the opioid epidemic is providing troves of research on effective methods of controlling pain by non-opioid means. Many well publicized studies, opinions, and focused guidelines exist on the topic,[1-4] but high impact journals such as JAMA, NEJM, and even AFP have yet to publish a thorough review or practice guideline on implementing opioid-sparing chronic pain management for general outpatient practice.

Neurobiology Behind Pain and Opioid Use

Any primary care provider can tell you that not all pain is the same. And likewise, it is important to understand the basics of pain physiology in order to effectively treat it. It is important to consider the primary pain driver and any modifying drivers. For example: osteoarthritis of the knee may be the primary pain driver causing nociceptive pain, but inactivity, deranged gait, anxiety, and opioid induced hyperalgesia modify and complicate the picture. Treatment of this patient's pain will require addressing all of those factors. Opioids may help with the acute nociceptive pain, but they do little to address those other sources of pain and distress.

Chronic opioids are horrible at treating chronic pain. All opioid prescribers should feel comfortable saying this. You can base the statement on your own anecdotal evidence, or you can point to the abundance of supporting scientific literature. Opioids drastically affect the beautifully complex neuronal system for processing of pain and emotions in our brains. Under normal circumstances, potentially harmful stimuli are detected by peripheral neurons and relayed to the brain where they can be interpreted, potentially (but not always) as pain.[5] This system has evolved to prevent and reduce injury. Pain signals to the brain are differentially modulated through the regulation of synaptic strength,[6,7] and suppression of nociceptor neuron firing via endogenous opioids and GABA.[8,9]

Opioid treatment works by overloading the nociceptive suppression system to inhibit the processing of pain. This is extremely effective short term. Long term, however, opioid treatment has well-documented failings both in terms of pain management and side effects. Treatment with opioids leads to tolerance, necessitating higher dosages to maintain a similar level of perceived pain control. Unfortunately, scaling up the dose of opioid treatment leads to opioid induced hyperalgesia (OIH), the symptoms of which were first published by physicians in the 1800s.[10,11] Many factors influence the development of tolerance and OIH, which have been extensively studied and thoroughly reviewed elsewhere.[12,13] At the simplest level, bombarding the brain with opioids causes a negative feedback loop that reduces the number of opioid receptors present on the neuronal cell surface, and desensitizes the remaining receptors.[14]

The negative feedback of high opioid tone in the brain also leads to activation of many stress response pathways, releasing pro-inflammatory compounds and ultimately causes brain-wide structural changes and decreased endogenous endorphins.[14,15] In addition to modulating pain, the natural opioid system is a strong modulator of social behavior. A damaged opioid system is associated with decreased human relatedness and painful social dysphoria.[16] The blunted or labile affect of some of your chronic pain patients could be from worsening mental health conditions, but it could also be from these opioid-related neurologic derangements. One of the most challenging (and satisfying) aspects of treating chronic pain is stopping exogenous opioids and watching the body recover its ability to self-modulate pain and other emotional stressors. Success is measured in weeks, months, and years.

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Repairing these endogenous opioid systems is a slow process, but evidence shows that the process can be sped up by increasing physical activity and increasing social interactions.[16-18]

Case: Tammy is a 48- year old women who has been your patient for about 1 year. She has low back pain from a work-related fall that occurred 8 years ago. She is also a smoker and struggles with depression. During your initial few visits, you were managing acute concerns and resuming her previous prescription regimen. Today she comes in for an acute cough and complains of excruciating upper back pain in addition to her usual low back pain. She typically takes oxycodone-APAP 10-325mg four times a day. Dependence to opioids is apparent, but you also suspect that her pain will be better cared for with non-opioid therapies.

When Should you have the "Opioids are Horrible at Treating Chronic Pain" Discussion?

So now we have new information showing that opioids are not so great for treating chronic pain, but when should you introduce this idea to your patients? The CDC and other groups have suggested you keep an eye out for the following opportunities:

- Patient requests taper or expresses safety concerns
- Increasing tolerance and dependence, necessitating increased dose and frequency
- CNS side effects such as confusion, sedation, falls, or car accidents
- Evolving or ambiguous pain complaints with no clear source
- Signs of substance use disorder, or 'living pill-to-pill'
- Any acute pain that is turning into chronic pain

Case: You and Tammy have been following your office protocol for chronic opioid prescribing without any irregular behavior. Your concern for misuse is not high, but her pain is rather ambiguous and she is obviously physically and psychologically dependent on them. She is consistent in her complaint of low back pain, but at every visit she complains of new pain at other locations. It seems that every visit is a new emergency. You address her cough symptoms, and explain that the increased back pain is likely related to the cough and should be expected to resolve soon. You reluctantly write for a few extra oxycodone tablets to get through the next few days. You also offer to see her for an appointment dedicated to pain management, which she promptly accepts.

Preparing for Changing Someone's Pain Management Regimen:

Deprescribing opioids for the sake of improved pain control necessitates some basic history taking. A pain history should focus on three key components:

1) Identifying the original pain driver and all of the modifying drivers
2) Pain severity with function as the metric, and
3) History of previously trialed therapies

This history can be elicited during the interview, but a patient questionnaire can help focus the conversation. A questionnaire is especially helpful for 'inherited' patients on long-term opioids, or those who tend to be a bit tangential in the exam room. Another benefit of a questionnaire is that the section inquiring about trialed therapies provides a visual representation of the numerous therapies available for treating pain (of which opioids are just one little box). "https://tinyurl.com/painquest" is a link to a PDF of my questionnaire. When inquiring about pain severity, a common, brief, validated tool is the PEG scale:[19] for the past week- what has your average pain level been? – how has pain interfered with your **enjoyment** of life? – how has **pain** interfered with your **general** activity? This is also incorporated into my patient questionnaire.

Case: At the next visit your nurse hands Tammy a pain questionnaire and you give her a few extra minutes before entering the room. You see that she has completed about half of the form. She indicates that her back is still her primary concern, and that her left popliteal region has been bothering her for about 1 week. She completed the therapies section: She has tried PT at the time of the injury along with Tylenol, ibuprofen, and the current oxycodone-APAP. She did not complete the PEG scale, so you perform that during your interview.

Evidence on how to Opioid Deprescribe:

Existing evidence on opioid deprescribing is generally focused on opioid use disorder (which points to opioid maintenance therapy rather than detox/abstinence). When the patient and provider have a goal of getting off all opioids, then a slow taper is the standard advice given by experts. Only about 25% of the previous day's dose is necessary to prevent florid withdrawal, but a much slower taper is typically preferred over a period of weeks or months.[20] The CDC recommends a dose reduction of 10% per month for patients with opioid exposure greater than 1 year.[2] If receiving multiple forms of opioids, then the extended release or long acting forms should be tapered first as they have the greatest overdose risk.[2,21] Patients should be warned about the risk for accidental overdose if they stop the taper and resort back to their previous higher dose.

Family physicians should be alert for substance use disorders and other underlying mental health diseases. If either of those diagnoses were missed prior to opioid tapering, then they will likely manifest during the tapering process. For patients who fail outpatient tapering attempts or for those at significant risk of overdose, opioid maintenance therapy or inpatient programs should be considered. If referring to a specialist, ensure that the patient understands that this is not punishment (even if they broke your office's controlled substances "contract"). Emphasize that the pain or addiction service is the safest and best care you can offer at this time, and that you plan to continue caring for them as their family doctor in coordination with the specialists.

Any patient undergoing an opioid taper should receive frequent encouragement. They may appreciate reminders that while the process is slow, improved pain and function can be expected after the initial hurdle. Ultimately, the taper should be patient directed, unless serious concern for misuse or harm exists. The provider should be prepared to take a pause from the taper schedule when the patient requests, and adding additional pain management therapies will be needed.

Case: You ask her if she thinks her current meds are treating her pain well. She initially suggests that her pain was well controlled before on oxycodone, but believes that she simply needs a higher dose now. A conversation ensues around the implications of increasing opioid use. You remind her she is only 48- years old and ask her if she intends to be on opioids for the rest of her life. The conversation continues and ultimately she is interested in slowly tapering opioids and trying some non-opioid therapies. In addition to deciding on a tapering schedule over the next few months, the two of you decide for her to start counseling, to begin an oral NSAID, a topical analgesic, begin trazadone for depression and pain-related insomnia, and for a referral to see the spine surgeon who she initially saw 8 years ago. You schedule quick check-up appointments for every 2 weeks to tweak the regimen, and she leaves excited to begin all these new therapies.

Non-opioid Therapies for Pain Management:

While making changes to a patient's pain regimen, the physician should be sure to revisit the original diagnosis. It is often beneficial to the clinician and patient to formulate a diagnosis other than "pain of …" It's too easy to treat 'pain' with a 'pain pill' and overlook other treatments. While evaluating the patient's primary pain driver, ensure that all appropriate treatment options and specialist referrals have been pursued. If surgery was involved in the past, then perhaps a follow-up appointment should be made to ensure no complications or hardware failures have occurred.

Thankfully, there are numerous treatment methods for chronic pain when no disease specific cure exists. The quality of patient oriented evidence varies greatly, but ultimately the uniqueness of every patient's pain necessitates an individualized treatment plan anyway. Trialing therapies can be time-consuming, but the frequent follow-up is often appreciated by patients in severe pain. There are many approaches to attack chronic pain, and I find it difficult to remember them all on the spot. So, I have several tables that I like to use as cheat sheets during discussions and brainstorming with patients. Combining two or more non-opioid analgesics has been shown to be more effective than single therapy regimens, while also reducing adverse effects.[22] No patient is identical, but it seems that patients benefit most when utilizing options in each of the following groups: Psychosocial, Oral analgesic, Non-oral analgesic, and Adjunctive therapies for any unique conditions or co-morbid concerns that may be present.

Psychosocial

As discussed above, the opioid system modulates social interactions in addition to pain. Increasing social experiences can speed up the recovery process. As such, providing psychosocial support may be the most effective therapy we can offer patients struggling with chronic pain. Cognitive behavioral therapy (CBT) has a lot of evidence showing its efficacy in improving pain, but virtually all forms of psychosocial support have some evidence of efficacy, including talk therapy, meditation, religious/spiritual care, and even hypnosis.[23] Tele-psych and mobile phone app-based therapies such as 'Insight Timer' are also great options. Do not be afraid to introduce distressed patients to psychosocial support for concerns about possibly offending them. Individuals in significant pain and stress are often very receptive to the idea of meeting with a counselor, even if they have no other psychiatric diagnoses. My usual statement is: "Most patients struggling with pain appreciate having someone they can talk things through with. Even if you don't need regular sessions now, it's nice to have someone you're familiar with and can go to if things get worse."

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Oral Analgesics

Acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) remain the mainstay of oral analgesics. There is strong evidence for their efficacy and relative safety.[1] The table below outlines a variety of options with some patient oriented information. It's important to remind patients that not all NSAIDs are the same. If you reach the maximum dose of one with no effect on pain, try another from a different drug class. Using a first-day loading dose of the maximum daily dose (MDD), then returning to a safer maintenance dose is another method useful for patients who like to quickly claim treatment failure.

Drug name	Common adult doses	Effectiveness*	Tolerability and Safety concerns†	Price‡
Central Acting Analgesics				
Acetaminophen (APAP)	650mg q4hr 1000mg q6hr MDD: 3,000mg Frequent doses may be of benefit to patients used to frequent opioid doses	No anti-inflammatory effects. Less effective than NSAIDs.	Well tolerated, GI upset most common. Box Warning: Accidental overdose and death often due to dosing errors, especially with multiple acetaminophen containing products. Hepatotoxicity and nephrotoxicity at doses >MDD. Reduce dose for hepatic impairment, contraindicated for severe hepatic impairment.	$8
Common to considerations for all of the NSAIDs below: 1) US Boxed warning for cardiovascular thrombotic events (except for aspirin). Avoid if history of CABG. 2) US Boxed warning for GI ulceration and bleeds. GI risks increase for gastric bypass patients and heavy alcohol users. Common side effects of GI upset can be mediated by taking with food or water. If enteric or slow release formulations are available, they can help with GI upset, but will delay pain relief and will not decrease GI ulceration risk. Adding misoprostol or a proton pump inhibitor, and prophylactically testing for H. Pylori has been shown to reduce ulceration risk.[24] 3) Regularly monitor GFR and LFTs. Risks vs benefits should be considered for all renally and hepatically impaired patients. There is kidney disease risk for high cumulative doses.[25] Avoid NSAID use if GFR <30 or if severe hepatic impairment. 4) Use caution for cross-reactivity amongst NSAIDs for anaphylactic or asthma reactions.				
Salicylic Acids				
Aspirin (ASA)	425-650mg q4-6hr MDD: 4,000mg		General NSAID concerns above. CNS disturbances and tinnitus at high doses. Caution during start for asthma patients. Antiplatelet effect increases risk for clinically significant bleeds.	$6
Diflunisal	1,000mg once then 500mg q8-12hr MDD: 1,500mg	Similar to APAP or ASA w/ slower onset & longer duration.	General NSAID concerns above. No antiplatelet effect like ASA, GI bleeds rare. Common SE: Headaches. Caution during start for asthma patients.	$200
Salsalate	500mg q6hr 1000mg q12hr MDD: 3,000mg		General NSAID concerns described above. No antiplatelet effect like ASA, GI bleeds rare. Caution during start for asthma patients.	$150
Propionic Acid				
Ibuprofen (IBU)	200-400mg q4-6hr MDD: 2,400mg	200mg is similar to ASA and APAP. **400mg is similar to APAP/ Codeine.**	General NSAID concerns described above. Lower bleeding risk compared to other NSAIDs. Common SE: Drop in hemoglobin, Edema.	$8
Ketoprofen	25-50mg q6hr 75mg q8hr 200mg ER daily MDD: 300mg	Superior to ASA and IBU. **50mg is superior to APAP/ Codeine.**	General NSAID concerns described above.	$150 $200 (ER)
Naproxen [Rx]	250mg q6hr 500mg q12hr 750-1000mg ER daily MDD: 1,000mg	Superior to ASA.	General NSAID concerns described above. Common SE: Edema, Hemolysis, Tinnitus.	$8
Naproxen sodium [OTC]	220mg q8-12hr MDD: 660mg	This form has faster onset, better for acute pain.	General NSAID concerns described above. Common SE: Edema, Hemolysis, Tinnitus.	$6

Phenylacetic Acid				
Diclofenac potassium	100mg once then 50mg q8-12hr 75mg q12hr 100mg ER daily MDD: 200m	Similar to ASA, longer duration.	General NSAID concerns described above. Lower bleeding risk compared to other NSAIDs. Common SE: Edema, Tinnitus.	$100
Ketorolac [PO]	10mg q4-6hr for 5 days or less MDD: 40mg	Likely superior to IBU or Naproxen.	General NSAID concerns described above. US Boxed warning: Bleeding. Highest bleeding risk of all NSAIDs. Common SE: Headache. Acute use only, 5 days max.	$40 (5day)
Ketorolac [IM]	**<65yrs**: 30mg q6hr MDD: 120mg **>65yrs**: 15mg q6hr MDD: 60mg	**Similar to 12mg of IM Morphine w/ longer duration.**	General NSAID concerns described above. US Boxed warning: Bleeding. Highest bleeding risk of all NSAIDs. US Boxed warning: No injection if allergic to other NSAIDs. Common SE: Headache, Tinnitus.	$30+
Indoleacetic Acid				
Etodolac	200-400mg q6-8hr 400-1000mg ER daily MDD: 1,00mg	Superior to ASA and IBU. **Nearly as Cox-2 selective as celecoxib.**	General NSAID concerns described above. Full effect seen in 1-2wks.	$100 $100 (ER)
Oxicam				
Meloxicam	5-15mg caps daily MDD: 15mg	Cox-2>Cox-1 at low dose.	General NSAID concerns described above. Pretty high bleeding risk compared to other NSAIDs. Oral disintegrating tablets (ODT) are available.	$6
Cox-2 inhibitor				
Celecoxib	400mg once then 200mg q12hr MDD: 400mg	Inferior to high dose IBU or naproxen.	General NSAID concerns described above. Lowest bleeding risk of all NSAIDs. Higher thrombosis risk. Avoid if MI risk or history of heart failure. Historic concern for sulfa cross-reactivity, but anaphylaxis extremely unlikely with nonantibiotic sulfonamides.	$300

MDD= Maximum daily dose; OTC= over-the-counter; SE= Side effects
* This information primarily came from http://medicalletter.org/TML-article-1540a, which goes into greater depth.
† This information primarily came from the above resource and Lexicomp database.
‡ These prices are estimates of the retail cost for a 30 day supply. Many coupons are available. Data from GoodRx.com

Non-Oral Therapies

Another key aspect of treating chronic pain is the use of non-oral analgesics and pain management techniques that can be performed in the PCP office or with referrals to specialists.

Topicals	
Lidocaine patch or gel Diclofenac gel Capsaicin (BenGay) Menthol/salicylate (IcyHot) Lidocaine/Menthol] (IcyHot Lidocaine) Heat or Ice Therapy	Topicals are great PRN medications. Diclofenac is an NSAID, but the systemic absorption is minimal. It's important that patients understand that these topicals are not applied like hand lotion, they require a larger amount and must be rubbed into the skin for several minutes. Many of these can be received over the counter, but patients should be advised that stronger doses can be prescribed if desired. It's important to also explain that all of these medicated creams have different mechanisms of action, so they should try different ones to see which works best for them.
Physical- Exercise	
PACED physical activity Physical Therapy Yoga, Water aerobics Tia Chi	Exercise increases natural opioids and endorphins (that the Rx opioids have destroyed). This does take time… don't expect a 'runner's high.' Careful exercise is essential for the long-term recovery and maintenance of range-of-motion for any joint pain.[26] Weight loss will also help with many weight bearing joints.
Physical- Manipulation	
Osteopathic Manipulation Chiropractor Massage Acupuncture	Manipulation-based therapies have varying strengths of evidence for various pathologies, but are generally low risk. Insurance companies are slowly improving coverage of these therapies in order to avoid opioid use.
Interventional	
Steroid joint injections Hyaluronic acid injections TENS nerve stimulator Implanted nerve stimulator Regional nerve blocks Nerve ablation	A surprising amount of my patients are not aware that family doctors can perform joint injections. Extra 'specialists' may or may not be appreciated by patients, so it's worth the conversation to see if they would like a referral.
Smoking Cessation	
Nicotine is a stimulant that will actually provide a few minutes of pain relief, but it is a known source of chronic pain. Long term tobacco use decreases your overall pain tolerance, and is directly associated with joint, spine, and abdominal pain.	
Medical Marijuana	
In 2018 NYS DOH enacted rules to streamline the process for patients to obtain medical marijuana certification for pain. "Opioid Replacement" is now a qualifying condition, which can be used by marijuana prescribers for any conditions which could otherwise be treated with opioids. Additionally, the regulation change allows for more rapid access to marijuana by allowing patients and care-givers to use printed temporary registry ID cards while waiting for their permanent card in the mail.[27]	

Adjunctive Therapies

There are many medications that are less effective than those in the oral analgesics table, but are still commonly used for treating chronic pain and as adjunctive therapies for common comorbid conditions.

Drugs	Comorbid conditions, Comments
TCAs Amitriptyline Imipramine HCl Nortriptyline	Neuropathic pain, Anxiety/depression, Insomnia, Headaches. Caution for antimuscarinic SE, especially in elderly.
SNRIs Venlafaxine Duloxetine	Neuropathic pain, Anxiety/Depression. Common SE of decreased libido and impotence is not ideal if trying to increase social interactions or treat anxiety/depression.
Other Antidepressants Bupropion Trazodone	Depression, Smoking cessation, ADHD, Fatigue. XL form taken once in morning avoids stimulating effect at night. Insomnia, Depression. Sedating effect helps for pain or anxiety related insomnia.
Antiepileptics Gabapentin Pregabalin Carbamazepine	Neuropathic pain, Restless legs, Insomnia. **Caution**: Increased risk of death if combined w/ high dose opioids. Has CNS SE and abuse/mis-use potential. Peripheral neuropathy, Trigem neuralgia.

Anxiolytics/Sympatholytics Propranolol Clonidine Prazosin	Pain associated w/ anxiety, PTSD or panic-type symptoms, insomnia. Caution: Cardiovascular effects, careful tapering up, and do not stop abruptly.
Muscle relaxers Cyclobenzaprine Methocarbamol Carisoprodol Tizanidine	Most helpful for acute pain with spasmodic component. Sedating effects may be a benefit if taken at night. Caution if combined with other CNS depressants.

Managing Withdrawal Symptoms

Opioid withdrawal symptoms are unlikely to occur if following a slow taper. The primary solution to withdrawal is to take a pause in the opioid taper, or reconsider buprenorphine for opioid maintenance therapy and pain control. However, if continued opioid taper/detox is desired then the below medications are commonly used for the symptoms. Opioid withdrawal is safe compared to alcohol or benzodiazepine withdrawal, but the symptoms can last up to two weeks depending on the opioid and level of dependence. The patient should be thoroughly counseled about the process and risks, and should be offered specialty addiction support.

Situation	Rx	Comments
Insomnia + Anxiety	Clonidine, 0.1mg up to tid	Caution for BP, do not stop abruptly.
Insomnia + Depression	Trazodone, 100-300mg at night	Response is variable, warn about priapism.
Insomnia or Restless legs	Gabapentin, 600mg at night	Caution for CNS effects.
Gut cramping or diarrhea	Hyoscyamine, 0.125mg SL PRN	
Breakthrough Nausea +/- Anxiety	Olanzapine, 5mg up to tid	Short-term use for nausea. Long-term use for psych Dx.
Nicotine addiction or Depression or ADHD symptoms	Bupropion XL 450mg in morning	Build up as tolerated 150-300-450mg, takes weeks to see effect, often useful for long term use after opioid detox.

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Marten Peterson, MD *is a resident at the Champlain Valley Physicians Hospital Family Medicine Residency Program in Plattsburgh, NY. He also sees patients at the Hudson Headwaters Champlain Family Health Clinic in Champlain, NY. He is a graduate of the SUNY Upstate Rural Medicine Education program in Syracuse, NY, where he also received extra training in managing pain and addiction.*

Claire Reynolds-Peterson, PhD *is a research affiliate with the New York State Department of Health. She is a graduate of The Pennsylvania State University Biochemistry, Microbiology, and Molecular Biology program. Her research expertise include neurobiology and neurodevelopmental disorders.*

VIEW ONE

A MILLION REASONS

By Umara Saleem, MD

One

I was listening to the radio playing Lady Gaga's song – "Million Reasons." She sang, "you're giving me a million reasons...a million reasons to quit…I just need one good one to stay." Made me reflect on my experiences with challenging patients regarding their experiences with buprenorphine treatment, the rewards of going through the process with them, and the inspiring achievements they were able to make onwards.

In a time of increasing physician burnout, one story of positive change can be a reason – the "why" you show up to work the next morning.

"My older sister died from a heroin overdose. I found her in her car, she died in my arms. I'm raising her kids. I got scared of what could happen to me. That's why I'm here."

"I'm living in the woods, I can't stay in that DSS housing... they got dealers there and I'm trying to keep clean."

"I was so high that when my 9-month-old daughter died in her crib [of SIDS], I didn't even know until hours later. I want to have a baby again- I know I need this medication to 'keep me straight'."

"I have 5 kids and I'm fighting to keep custody of them, that's why I need this medication. It's the only thing that keeps me off the streets."

"I'm a lesbian but have had 5 abortions from when I traded sex for drugs. My body was the only thing I had to offer. I haven't had to do that since I've been getting Suboxone from a doctor."

"The painkillers were the only memory of me being happy- that's why I relapse sometimes. But I'm so proud of where I am today. My body feels clean, and I think I can have a life like normal person [education, family, friends, career]."

Patient stories are the most awe-inspiring part of my job. Having grown up with a disciplined upbringing, I couldn't even imagine the lives my patients had for even one day, with more crises in one week than I've had in my entire life. Seeing the insurmountable challenges they've had to overcome to lead "clean lives" as they called it, made my medical career trajectory look like a joke in comparison.

I feel privileged to have been part of a residency program that incorporated our behavioral health department with trained family medicine attending physicians in medication assisted treatment. We even had our own proactive local celebrity "medical champion"

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VIEW TWO

STRENGTH OF MIND

By Christine Pendergast

Two

When I was 11 years old, my friend and I thought it was fun to steal Miller Lite beer pony bottles from her parent's mini-fridge on the weekends and get drunk. That was the early start of my addiction.

In 8th grade I had my hip pinned due to slipped capital femoral epiphysis (SCFE). The following year the other hip required surgery. After the healing period, the pins from both hips were removed. That was the early start of arthritis.

When I was 16 years old, I got my first job at a pizza shop. Most of the people working there were a lot older than I was. That is when my drinking got out of control. I also started smoking marijuana and snorting cocaine. Then I got a job at a hospital where I made more money, which allowed me to move out on my own where I could hide my use, which continued to escalate.

Fast forward to my early twenties when hip x-rays revealed that the arthritis was getting to the point of requiring total hip replacement. Since I was very young for this procedure I was given opiates in order to put off surgery for as long as possible. The opiates helped the pain, but my tolerance increased and eventually became an addiction. I doctor shopped and was able to keep a steady flow of opiates coming in. This continued for a few years while I healed from the first surgery and underwent total hip replacement on the opposite side.

Eventually, there was no longer a medical reason to continue being prescribed opiates. My mental health got very bad after I found my husband deceased in bed one morning as a complication of his renal disease. I lost my job after failing employer recommended inpatient rehab. Over the next few years I was out of work and in and out of the hospital for depression and suicide attempts, and spent about a year in Rochester Psychiatric Center. During this period, I underwent bilateral hip revision surgery with the same cycle of opiate abuse. I started and failed about 3-4 outpatient rehabs.

In 2013, an MRI of my back showed that surgery for degenerative disc disease would be beneficial. The opiate addiction cycle started again. Three weeks after this surgery I underwent emergency surgery as a spacer had dislodged from the initial surgery. After two additional back surgeries and a neck surgery within a two- year period, I had a rod in my back and an out of control opiate addiction. This is when recognition of the opiate epidemic began and I-STOP monitoring began. My opiates were promptly cut off.

In June 2015, I was severely depressed, in a great amount of pain and no longer able to obtain opiates. I stole firearms from a family member, planning to commit suicide. Fortunately, they had safety

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physician. We got our annual buprenorphine training (Narcan training as well) and had an integrated program that centered around offering Suboxone to patients, and dedicated faculty that spent time teaching residents the intricacies of interpreting tests and working to establish trust with patients who didn't have many examples of stability in their lives. Some attendings were strict on how many "dirty [mixed in with other unprescribed drugs/substances] urines" or missed mental health therapy appointments were allowed for a patient to continue getting their prescriptions. These transgressions could be reasons for dismissing the patient from the practice and transitioning them into hands of more active behavioral health/ higher level of care facilities when the patient agreed.

Others were more lenient, allowing refills even when the patient was sharing on the street. The idea being that users diverting the medicated sublingual films were dispensing Suboxone versus more lethal options like heroin into our local intravenous drug abuser's bloodstreams. One attending simply said we weren't cutting off a female patient from our practice after a few missed appointments and "inappropriate urine screens" so she wouldn't have to resort to using her body to get Suboxone on the streets.

We also saw patients who had already detoxed themselves on Suboxone they got illegally off the streets. I had a few patients tell me how they used to cheat their oral drug screens at their methadone clinics; what the drug recipe was to get "high" even when on methadone; and how a few wanted to be on buprenorphine as there wasn't as much leeway with that on an outpatient basis versus how they had been unstable and "cheating" on methadone. And of course, we treated soon- to-be mothers that wanted to try a medication that wouldn't have as many risks of neonatal abstinence syndrome. Or they wanted to try breastfeeding and had some encouragement after years of feeling as if their bodies were "unclean" from years of active drug abuse.

<u>So what makes a good medication assisted program?</u>

-An integrated practice with behavioral health and faculty support to promote continuous learning and discussion of patient treatment so one couldn't get too judgmental or burned out by patients.

- Having the ability to consult with an addiction medicine fellowship program or graduate.
- Having a Suboxone committee as was in my residency – outpatient office – which allowed monthly discussions on patient care and progress with a multifactorial and integrated team.
- Having continuous education centered around practice delivery – the benefits of an academic program.
- Having primary care physicians taking the lead.

<u>What makes a good MAT trained clinician?</u>

Being open minded. As my residency advisor would say, "Be that person that offers unconditional positive regard towards a patient and really understand the challenges that patients face on every level- social, personal, physical, and financial." Many of these patients have lost everything to their previous life of addiction and had nothing to start with.

Where I trained in Kingston, NY, patients had to walk everywhere as we didn't have a good public transportation system. I had patients walk more than an hour for an appointment with me, so I forgave them when they were more than 15-20 minutes late and saw them anyway. Some would travel from different counties as our office was the only place accepting new patients for buprenorphine treatment for multiple miles. The waitlist at other limited local programs was greater than 3 months.

Once you have them enrolled with you to start treatment, challenge them to address the other medical issues in their life so they have a chance to be the whole healthy person they desire to be. That is the beauty of primary care – you have the knowledge and training to do that. It's your specialty.

I recall on my first rotation of OB/GYN, we had to call in Dr. Harvey – our medical champion – for a patient that was on Subutex and was delivering her 4th child. The nurses weren't sure what we could give her for pain management. They wanted Dr. Harvey there as he was the PCP and expert on peri- and post- partum management of this expectant mother and our only local expert in this field. I remember him walking in confidently but hurriedly onto the busy floor, sitting down, logging into the computer then looking directly at me to ask philosophically: "What do you call a woman on Suboxone?" I looked at him with some unspoken, judgmental answers in my eyes thinking back to this patient's rambunctious borderline personality, how she had been struggling with addiction in this pregnancy even on Subutex, and how CPS was going to be involved as they had been involved in every pregnancy beforehand. "A good mother" he said in a matter- of- fact, strong voice. I was surprised. I thought like many of the staff there that day, that he too might comment about the patient's personal life choices and lifestyle. Later as I got to know more about her and her struggles, I was able to better understand what he had initially told me.

After he moved away, she chose me as her PCP, remembering the openness and connection we had over her delivery. That's what I remembered when I had to advocate for her with my supervising faculty, to keep giving her a chance, understanding the very challenging and unstable life circumstances that drove her to relapse at times. What seemed to us as simple, were for her difficult lifestyle choices that she had to overcome every day to keep required mental health and medical appointments. When I saw her last, she was pregnant with her 6th child and wanting to enroll in the program again. We gave her a chance even while knowing she would probably be more appropriate for higher level of care. She lost the pregnancy attributing it to her abusive partner, but we had her continue

successfully on Suboxone, as her resolve to be a good mother to her 5 children superseded all the other difficulties she continued to face in her life.

You may have a lot of questions and hesitations on the road to educating yourself on medication assisted treatment. At the heart of this journey is the patient with wounds and shortcomings like all of us, but also with incredible inner strength to enroll him/herself. You will experience this journey with your patient along with learning the science behind this treatment. You will be the light for them. As one of the MAT training experts said, "Opioid use disorder is like hypertension. Sometimes you have ups and downs, and patients can relapse, not take medications, and have life impact them. But there they are at the doctors' visits with you, putting a lot of trust in a relationship where they don't want to be viewed with a colored [judgmental or even unexperienced] lens you may be using to view them. Having appreciated personal challenges in your own life opens you up to understanding the crushing waves that roll towards patients."

Be that rock on the beach they can sit upon to get respite from the only 'abusive, rejecting, or built on principles of exchange world' they may have known. They may see the sunrise of remission based on the foundation of support you can build for them. As the sun cycles up and down, you'll encounter the ups and downs on this journey with your patient. This begins the potential to have a deeply rewarding journey that you can share with them as a trained medical provider. Be the power in the one against the million reasons the patient resolves to change. Moreover, you can help create and support the domino effect of a million reasons why they should stay [enrolled].

Umara Saleem, MD *is family medicine physician that practices in Kingston, NY. She completed her residency in full spectrum family medicine from the Mid-Hudson Family Medicine Residency Program. Dr. Saleem is interested in academic and narrative medicine, pediatrics, immigrant health, and substance abuse treatment. She loves volunteering in her local community and spending time with her family.*

view two, continued *(Strength of Mind)*

locks so my plan ultimately failed. The firearms were returned and I was subsequently arrested for felony grand larceny and taken to jail.

As part of my probation, the judge ordered mandatory mental health treatment. With the help of my therapist, I admitted my addiction and began outpatient drug treatment. I was unaware of buprenorphine until I told my therapist that I didn't want to continue living with the pain that had resulted from so many surgeries. I began buprenorphine in April 2017. Once I found a schedule to divide my dose throughout the day, my pain was under control.

Once my pain was under control and I was no longer using illegal substances, I slowly started to participate in drug treatment which consisted of group therapy in a dual diagnosis program beginning twice a week, completion of two elective groups, meetings with my drug counselor, a relapse prevention group and random drug screening. I was determined to complete treatment rather than the other option, which was returning to jail. I put a lot of effort into mental health therapy over the next three years.

Although it was a difficult decision for me to go on MAT, I honestly believe that it saved my life. I obtained my peer counseling certificate while working at a crisis respite house, and used my drug abuse and mental health history to try and instill hope and support to individuals that were struggling themselves. It is encouraging to feel as though you have made a difference even if it is just for one person.

I have not been admitted to a psychiatric hospital in over two years. My pain is now under control with the help of buprenorphine. My health has improved dramatically and I have lost over 100 pounds. In taking better care of myself I haven't had an asthma attack, or needed an iron transfusion in more than one year.

Family and friend relationships have been a more challenging part of my recovery. I chose to give up "friends" that continued to use. I have not had contact with my mother in a year and rarely speak with my siblings. I don't know if my family will ever trust me again or believe that I am on the right path.

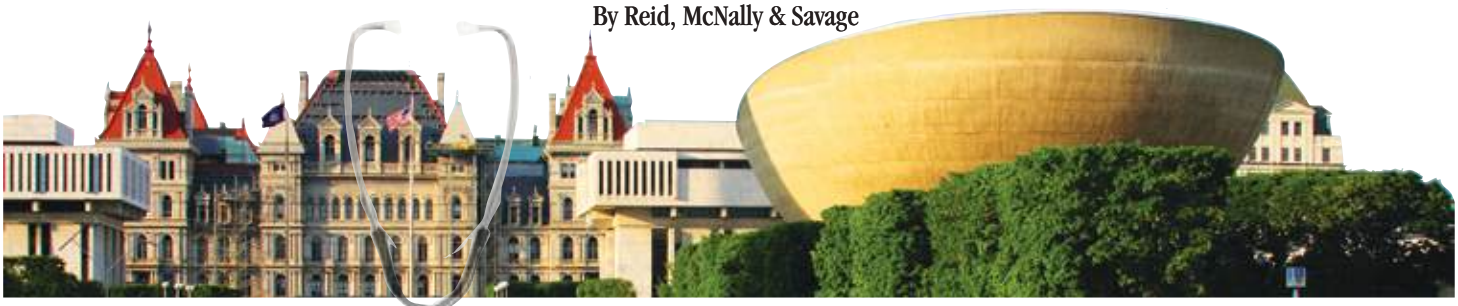
After being clean for two years, I relapsed this October. Fortunately, I was able to get back on track the following day with the help of the doctors at the clinic. I am very thankful for their support and encouragement. I had to re-frame my thinking from getting clean in order to get my family back to getting clean for myself. I also realized how important it is to have a therapist for support and a sponsor so I now have those two things in place.

I'm sure that I would not have gotten this far without MAT to help with the cravings and pain. This treatment has allowed me to work through mental health issues. I am now content with being a part of this universe. I hope that I can be an example and inspire others that MAT can be a tool in getting your life back.

Christine Pendergast *is from Rochester, NY. She worked as a medical secretary for over 20 years and more recently as a peer counselor. In her free time Christine enjoys listening to music, writing poetry, baking, and cuddling with Zoie, her cat.*

Albany Report

By Reid, McNally & Savage



As the New York State Academy of Family Physicians prepares its winter edition of the journal for print and members prepare for the new year, the focus in Albany is on the dismal fiscal situation of the State.

Below is a summary of recent information released by the State Division of Budget regarding the Medicaid budget gap and broader structural budget deficit facing NYS. Also included is an update on the status of legislation passed by both houses during the 2019 which relate to opioid addiction, prevention and treatment and a summary of the recent and upcoming legislative hearings on this important topic.

State Division of Budget Released FY 2019-20 Mid-Year Update to Financial Plan

On November 22, 2019, the State Division of Budget (DOB) released its mid-year update for the current fiscal year 2019-20. According to DOB, general fund (GF) budget gaps are currently estimated to be $6.1 billion in FY 2020-21, $7.5 billion in FY 2021-22, and $8.5 billion in FY 2022-23. The stated rationale for these gaps is an increase in minimum wage costs for health care providers, which is funded entirely outside of the Medicaid global spending cap and not subject to the indexed spending limit. The increased minimum wage costs are entirely offset in FY 2020 and partly offset in subsequent years by savings in other areas.

In addition to these GF budget gaps, the Medicaid global spending cap has a structural imbalance. Absent savings measures, DOB estimates that state-share Medicaid spending subject to the global cap would exceed the indexed growth amount by $4.0 billion in the current fiscal year, $3.1 billion in FY 2020-21, $3.5 billion in FY 2021-22, and $3.9 billion in FY 2022-23. According to DOB, factors that are placing upward pressure on state-share Medicaid spending (which includes spending under and outside the global cap) include but are not limited to: reimbursement to providers for the cost of the increase in the minimum wage; the phase-out of enhanced federal funding; increased enrollment in Medicaid; costs in managed long-term care; and payments to financially distressed hospitals.

For the current fiscal year, DOB is developing a savings plan (the "FY 2019-20 savings plan") intended to maintain a balanced GF and working with the Department of Health (DOH) to avoid, to the extent practicable, piercing the Medicaid global Cap. At a minimum, the FY 2020 savings plan is expected to consist of a permanent adjustment to the timing of certain health care payments, consistent with contractual terms and past practice, and a range of cost containment measures. Savings may include across the board reductions in rates paid to providers and health plans, reductions in discretionary payments, and other actions that can be executed administratively in the current fiscal year.

The Governor's 2020-21 Executive Budget will be released in mid to late January 2020 and is expected to outline the specific elements of the current year's savings plan (impacting the last quarter of the fiscal year) and the proposals that will be advanced to eliminate the GF budget gap, including the Medicaid global cap imbalance, in the next fiscal year (2020-21).

What this may mean for NYSAFP Members & Health Care Services?

We are concerned that DOB will begin imposing delayed Medicaid payments to providers in the near future and also release a proposal for across-the-board and other spending cuts to Medicaid providers and other health programs in the Governor's January budget. Such cuts may be retroactive to the last quarter of the current fiscal year (January-March 2020).

Unfortunately, the Governor's office and DOB have a significant amount of administrative authority and leeway to impose cuts and delays without needing special legislative approval, which will make this very challenging to fight or prevent. However, we are working with NYSAFP leadership and members to make it clear to policy makers that cutting safety net and primary care providers who focus on prevention and low cost care to prevent costlier services is penny-wise and pound foolish and should not be an option.

Legislation Passed by Both Houses Related to Opioid Use/Prevention

Good Samaritan Protections Opioid Antagonists (S6361 Carlucci/A7277 Rosenthal)
Adds good samaritan protections to the list of required information that is on the card that comes with opioid antagonists. This bill passed both houses and was signed into law by Governor Cuomo November 20th, Chapter 504 of the laws of 2019.

Death Certificates, Opioid Use (S1668 Brooks/A4195 Jean-Pierre)
Current public health law requires that where a death is caused by an opioid overdose, such information shall be indicated on the death certificate. This bill requires that the specific opioid that caused the death of the decedent be included, if known to the person completing the death certificate. This bill passed both houses and was signed into law by Governor Cuomo November 5th, Chapter 443 of the laws of 2019.

Medication Assisted Treatment for Substance Use Disorders (S5935A, Harkham/ A7246B, Rosenthal L)
Expands access to medication assisted treatment for individuals with substance use disorders by allowing individuals under Medicaid the ability to access whichever MAT medication is most beneficial to them and their needs, without utilization control, prior authorization, or lifetime limits. This bill passed both houses and has not yet been delivered to the Governor.

Report on Outcomes of the State's Response to the Opioid Epidemic (S4650, Sanders/ A1068, Rosenthal L)
Requires OASAS to provide a report to the Senate President, Assembly Speaker, Chairs of the Alcohol and Drug Abuse Committees and the Chairs of the Ways & Means and Finance Committees regarding the status and outcomes of initiatives put in place in response to the heroin and opioid epidemic. Such report would begin July 1, 2019 and be required quarterly. It would include information on the number of individuals enrolled in the initiatives, the number of individuals who completed a treatment program, the number of individuals discharged from a treatment program, and the age, sex and other relevant regional data about the population served and outcomes and effectiveness of the programs. The initiatives to be reported on include opioid treatment programs, crisis detox programs, 24/7 open access centers, adolescent clubhouses, family navigator programs, peer engagement specialists, recovery outreach centers, regional addiction resource centers and the state implementation of the federal opioid state targeted response initiatives. This bill passed both houses and was signed into law by Governor Cuomo November 20th, Chapter 493 of the laws of 2019.

Mental Illness and Chemical Dependence Initiative (S3200A, Parker/A2758A, Ortiz)
Requires the Commissioner of OMH, in conjunction with the Commissioner of OASAS and the Director of the Division of Veterans Services to create a public education initiative designed to eliminate stigma and misinformation about mental illness and substance use among military service members. This bill passed both houses and was signed into law by Governor Cuomo October 18th Chapter 378 of the laws of 2019.

Renaming OASAS (S6591, Harckham/ A7347, Rosenthal L)
Renames the Office of Alcoholism and Substance Abuse Services to the Office of Addiction Services and Supports and requires all references to the Office in law be changed accordingly. This bill passed both houses and was signed into law by Governor Cuomo September 13th, Chapter 281 of the laws of 2019.

Chapter Amendment to Mental Health and Substance Use Disorder Parity Report (S4356, Ortt/ A6186A, Gunther)
Enacts a chapter amendment to a law passed in 2018 creating Mental Health and Substance Use Disorder Parity Reports to change the frequency of the required reports submitted by insurers from annually to every two years. Also it requires the reports to be posted on the Department of Financial Services website. This bill passed both houses and was signed into law by Governor Cuomo August 29th, Chapter 207 of the laws of 2019.

PA for Certain SUD Treatment Medications (S4808, Harckham/ A2904, Quart)
Prohibits commercial insurance policies from requiring prior authorization (PA) for certain medications (initial and renewal prescriptions for buprenorphine and long-acting injectable naltrexone) used in the treatment of substance use disorders. This bill passed both houses but has not yet been delivered to the Governor.

Legislative Hearings on Opioids

In August-November 2019, the Joint Senate Task Force on Opioids, Addiction & Overdose Prevention held hearings around the state regarding strategies for reducing overdoses, improving individual and community health, and addressing the harmful consequences of drug use. The Task Force is led by the Chairs of the Senate Committees on Alcoholism and Substance Abuse; Mental Health; and Health-Senator Harckham, Carlucci and Rivera, along with nine other Senate colleagues who serve on the Task Force.

In addition, on December 17th, the Assembly Committee on Alcoholism and Drug Abuse and its Chair, Assembly member Rosenthal held a hearing in Manhattan regarding substance use disorder services and barriers to accessing those services.

Following these hearings, we expect to see proposals introduced, possibly a package of bills, based on feedback and recommendations received to be considered in 2020 as part of the State's continued efforts to address the opioid epidemic impacting so many residents. We will continue to closely monitor and keep NYSAFP updated on new developments and opportunities for participation in this ongoing effort.

All of us at Reid, McNally & Savage wish you a happy new year and we look forward to continuing to work with the leadership and members of NYSAFP in 2020.

The Family Doctor's Role in Chronic Pain Management among Reproductive-aged and Pregnant Women:
A Unique Opportunity for Generational Change

By Sarah A. Abdelsayed, MD; Tildabeth Doscher, MD, MPH and Richard D. Blondell, MD

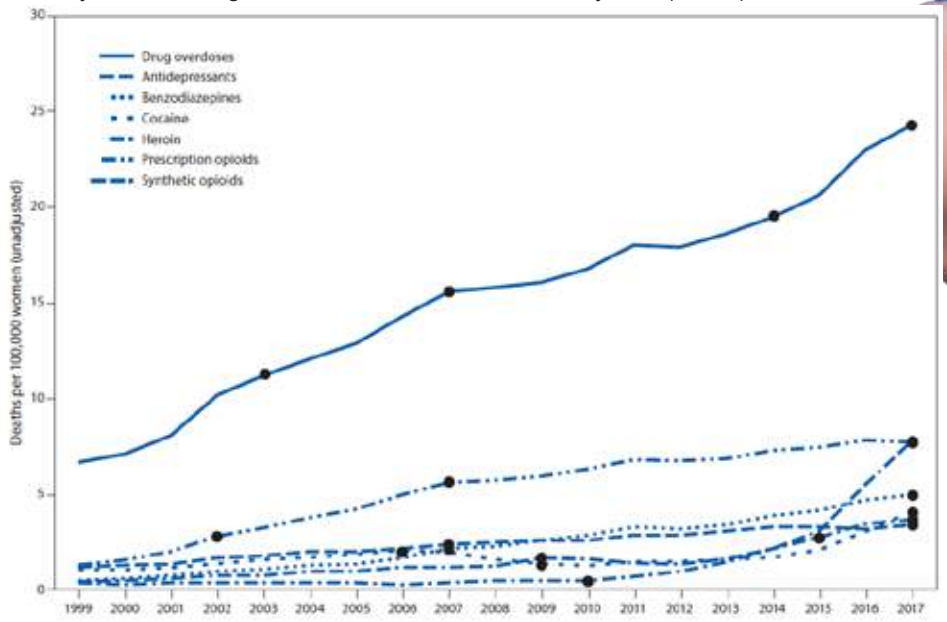
Introduction

Pregnant women are a unique population affected by the opioid epidemic, as their chronic disease carries generational impacts when left untreated. While the intersection of chronic pain and opioid use disorder is not well understood in the general population, the added complexity of pregnancy makes this group more vulnerable to lack of access to care and poor treatment of their disease. Family doctors offer continuity and a long-term relationship to these women, and potentially their children, when effectively managing their pain, addiction, and reproductive health. This review article summarizes the evidence-based guidelines for screening for opioid use disorder during pregnancy and its management in the setting of chronic pain. Multimodality pain management during all stages of pregnancy and the post-partum period is reviewed. Alongside these clinical recommendations, barriers and facilitators to care are discussed to illustrate the necessity of a multifaceted biopsychosocial approach to this epidemic.

Background

The opioid epidemic does not discriminate and has taken a severe toll on a diverse group of patients. Within this group is a particularly vulnerable population with a unique set of needs – reproductive-aged and pregnant women. Given that the largest percentage increases in overdose deaths were among women ages 45-54 years and 55-64 years, the CDC aimed to develop prevention strategies by further evaluating women aged 30-64 years during 1999-2017.[1] Results showed the unadjusted drug overdose death rate increased 260% during this time.[1] **Figure 1** from the Morbidity and Mortality Weekly Report illustrates the largest increases in overdose death rates, which were among the following drug classes: synthetic opioids (1,643%), heroin (915%), and benzodiazepines (830%).

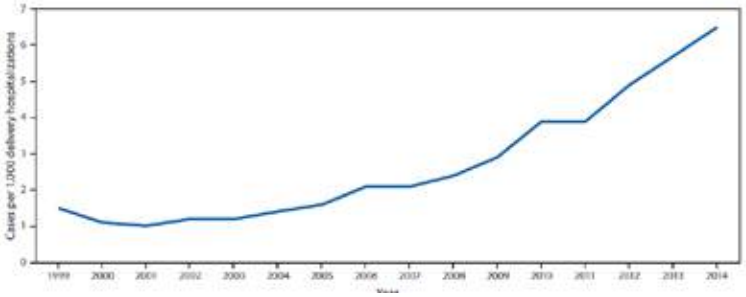
Figure 1. Drug overdose deaths (unadjusted) per 100,000 women aged 30-64 years, by involved drug class – National Vital Statistics System (NVSS), 1999-2017



Source: CDC MMWR, January 11, 2019

This opioid use among reproductive-aged women often continues in pregnancy and increases the risk of poor maternal and neonatal outcomes, including lack of prenatal care, miscarriage, preterm labor, and neonatal abstinence syndrome (NAS). As seen in **Figure 2**, the rates of opioid use disorder at delivery hospitalizations increased 333% during 1999-2014.[2] The national rate increased from 1.5 cases per 1,000 delivery hospitalizations to 6.5, and the New York state rate increased from 1.6 cases per 1,000 delivery hospitalizations to 4.9.[2] This rise in adverse maternal and neonatal outcomes has proven to require a complex prevention and treatment approach to reduce the public health burden.

Figure 2. National prevalence of opioid use disorder per 1,000 delivery hospitalizations – National Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), United States, 1999-2014



Source: CDC MMWR, August 10,2018

Prevention: Screening, Brief Intervention, Referral to Treatment (SBIRT)

Screening, brief intervention, and referral to treatment (SBIRT) offers an evidence-based framework for prevention of substance use and/or its progression. The first step to ensuring pregnant women with OUD receive needed treatment is to screen for the disease. Substance use is common among reproductive-aged women, with 55% using alcohol, 23% cigarettes, and 10% illicit drugs.[3] In addition, unintended pregnancy is more common (86%) in opioid-dependent women compared to the general population (30-50%).[4] These factors highlight the importance of screening in primary care. Multiple organizations including USPSTF, ACOG, AAP, and CDC recommend universal screening for substance use in pregnant women. It is recommended to use both urine toxicology along with a screening questionnaire at the initial prenatal visit. Validated screening tools available are T-ACE, TWEAK, and the 4Ps (see **Table 1**.)[3] The authors strongly encourage use of 4Ps as the questions screen for any substance use, reduce stigma by asking the patient if others around them use substances, and potentially lead to further questioning for a wider population that will screen positive; in comparison, the T-ACE and TWEAK instruments screen only for alcohol use and are specific for screening physical dependence symptoms.

Table 1. Validated screening instruments available for use among pregnant women

Instrument	Questions
T-ACE	
Tolerance	How many drinks does it take to make you feel high?
Annoyance	Have people annoyed you by criticizing your drinking?
Cut Down	Have you felt you ought to cut down on your drinking?
Eye Opener	Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?
TWEAK	
Tolerance	How many drinks can you hold?
Worried	Have close friends or relatives worried or complained about your drinking in the past year?
Eye Opener	Doyou sometimes take a drink in the morning when you first get up?
Amnesia	Has a friend or family member ever told you about things you said or did while you were drinking that you could not remember?
K/Cut Down	Do you sometimes feel the need to cut down on your drinking?
4Ps	
Parents	Did either of your parents have a problem with alcohol or drugs?
Partner	Does your partner have a problem with alcohol or drugs?
Past	Have you ever drunk beer, wine, or liquor?
Pregnancy	In the month before you knew you were pregnant, how many cigarettes did you smoke? In the month before you knew you were pregnant: How many beers did you drink? How much wine did you drink? How much liquor did you drink?

continued on page 24

For those women screening positive for substance use, a brief intervention using motivational interviewing techniques is delivered. Motivational interviewing was developed by Drs. William R. Miller and Stephen Rollnick for alcohol use disorder; since its development, family doctors are trained to also apply the techniques to other chronic disease such as diabetes mellitus, obesity, and depression. While multiple tools are available to organize the brief intervention format, the spirit of motivational interviewing is key. When using motivational interviewing in practice, family doctors increase trust in the patient-provider relationship as they help patients explore their own ambivalence and motivations for behavioral change.[5] Pregnant women in particular respond to providers embodying empathy and a nonjudgmental attitude. Patients who positively respond to the brief intervention and are motivated for treatment should be initiated on medication-assisted treatment and/or referred to an addiction treatment center.

Medication-Assisted Treatment

The gold standard of treatment for pregnant women with opioid dependence and OUD is opioid agonist medication-assisted treatment (MAT) with methadone or buprenorphine maintenance. The MOTHER trial (Maternal Opioid Treatment: Human Experimental Research) was a double-blind, double-dummy, flexible-dosing randomized controlled trial assessing neonatal outcomes in pregnant women with opioid dependence on methadone or buprenorphine treatment. The study showed that the two maternal medication treatment groups did not significantly differ in the percentage of neonates requiring NAS treatment and peak NAS score.[6] Neonates exposed to buprenorphine in utero, however, required 89% less morphine and had hospital stays 43% shorter than those exposed to methadone.[6] While rate of opioid use among the two groups was not significantly different, attrition was higher in mothers on methadone maintenance.[6] Therefore, it is recommended that family doctors discuss the risks and benefits of each option with their pregnant patients and be trained to offer office-based buprenorphine MAT or a referral to their local methadone maintenance treatment center.

Chronic Pain During Pregnancy

Pregnant women may find it difficult to access pain management care given the lack of evidence-based practice guidelines and training among specialists. When pain management specialists decline treating chronic pain during pregnancy, family physicians and obstetrics providers have an important role in adequately managing pregnant women's chronic pain. The most commonly prescribed opiate analgesics in pregnancy are codeine, fentanyl, hydrocodone, morphine, oxycodone, oxycontin, and tramadol.[7] The safety profiles of these medications are not well understood compared to methadone and buprenorphine as discussed above. In addition, medication-assisted treatment with methadone and buprenorphine treats both chronic pain and opioid use disorder whereas opioid analgesics can contribute to the development of OUD. Opioid-dependent women who do not meet criteria for OUD should be maintained on their chronic pain opioid regimen during pregnancy to avoid withdrawal and risk miscarriage.[7]

Family doctors should also discuss the risks and benefits of commonly used over-the-counter analgesics with reproductive-aged and pregnant women. Acetaminophen is the most widely used analgesic in pregnancy and was initially thought to be safest; however, most recent evidence has shown that the drug affects fetal brain development and can lead to poorer communication, language, and motor skills in exposed children.[8, 9] The benefits of aspirin outweigh its risks in the treatment of antiphospholipid syndrome and preeclampsia. Its use in chronic pain treatment carries significant risks of gastroschisis when used during the first trimester and maternal bleeding throughout. Its use for chronic pain management is therefore not recommended during pregnancy.[7] Nonsteroidal anti-inflammatory drugs (NSAIDs) are not recommended during the first trimester due to increased risk of spontaneous abortion, nor after 30 weeks gestational age due to increased risks of premature closure of the ductus arteriosus, persistent pulmonary hypertension, renal compromise, oligohydramnios, necrotizing enterocolitis, and intracranial hemorrhage.[7,10,11,12] These potentially adverse fetal outcomes emphasize the importance of discussing family planning with reproductive-aged women with chronic pain. Options include contraception and weaning off opioids prior to pregnancy.[7] Family doctors' scope of practice provides the continuity of care needed to address these issues during all stages of a woman's reproductive life.

Peripartum Anesthetic Management

Patients with chronic opioid dependence are at higher risk of hyperalgesia and allodynia, which may result in the incorrect label of "drug-seeking" behavior when in fact, they have a higher sensitivity to pain. Of note, medication-assisted treatment does not adequately provide labor analgesia.[13] Pain management for women undergoing vaginal delivery includes continuation of MAT with methadone or buprenorphine, initiation of epidural analgesia, and scheduled analgesics including acetaminophen and NSAIDs. The management of post-cesarean delivery pain is more complex, with options including the addition of systemic opioids with high affinity for μ-opioid receptors such as hydromorphone, use of patient controlled epidural analgesia (PCEA), and offering regional truncal block.[14]

Barriers and Facilitators to Care

Despite recent evidence-based guidelines for the treatment of opioid use disorder among pregnant women, the implementation of these practices has been hindered by barriers such as lack of access to

and coordination of quality services, lack of statewide provider awareness and experience with SBIRT and MAT prescribing, and financial stressors with MAT treatment and counseling coverage.[15] More importantly, a major barrier affecting patient outcomes is the stigmatization of mothers with substance use disorders. While efforts have been made to destigmatize the disease of addiction and improve collaborative care, further interventions are needed to address overarching issues facing these pregnant women such as lack of social services support, intergenerational poverty, and fear of losing custody of their children.[15]

Conclusion

Family doctors trained in SBIRT and MAT prescribing are equipped to care for the vulnerable population of pregnant women with opioid use disorder and chronic pain. This opportunity to provide continuity of care in a nonjudgmental and supportive environment translates into generational impacts for a family.

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Sarah A. Abdelsayed, MD *is a Clinical Assistant Professor at the University at Buffalo (UB) Department of Family Medicine. Her research interests include substance use disorders in pregnant and parenting women and improving addiction medicine training for family medicine residents.*

Tildabeth Doscher, MD, MPH *is a Clinical Assistant Professor at the UB Department of Family Medicine and is the Addiction Medicine Fellowship Director at UB. Dr. Doscher is leading an implementation research project to train primary care physicians to care for patients with substance use disorders.*

Richard D. Blondell, MD *is a Professor Emeritus at the UB Department of Family Medicine where he served as Vice Chair of Addiction Medicine until 2019. He is a nationally recognized expert on substance abuse and a pioneer in addiction medicine research. Dr. Blondell has numerous publications focusing on pregnant women with addiction and on chronic pain.*

THE UNDER UTILIZATION OF SLEEP MEDICINE FOR THE TREATMENT OF CHRONIC PAIN AND OPIOID USE

By Sandy Wang, MD, MPH; Sachiko Kaizuka, MD; Holly Ann Russell, MD, MS and Michael Mendoza, MD, MPH, MS, FAAFP

Chronic Pain and Opioid Use

For primary care providers, addressing chronic pain in the clinical setting has become common place, but its management remains complex. An NHIS study in 2016 reported almost 20.4% of US adults had chronic pain and 8% reported chronic pain limiting life or work activities on most days in the past 6 months.[1] Chronic pain remains one of the most common reasons why patients seek medical care, but its effects are widespread including restrictions on patients' mobility and daily activities, dependence on opioids and depression, and poor perceived health or reduced quality of life.[2-4] Chronic pain has become a public health concern, with negative consequences to individuals and their families and costs almost $560 billion a year in direct medical costs, lost productivity, and disability programs.[5]

Management has been challenging, as opioid analgesics are one of the most commonly prescribed medications in the US, with US pharmacies dispensing 245 million prescriptions for opioid pain medications in 2014.[6,7] However, with addictions and drug- over dose related deaths on the rise, many providers have begun to question the prescribing practices of opioid medications.[7] Physicians are reporting concerns of prescribing opioids safely, detecting abuse or emerging addiction, and discussing these issues comfortably with their patients.[8] Thus, it is important to prepare primary care physicians with multi-disciplinary methods in managing chronic pain, including training in non-pharmacologic treatments. This article intends to provide primary care physicians with alternative non pharmacologic treatments to address chronic pain, with a specific focus on sleep medicine.

Improved sleep hygiene and cognitive behavioral therapy for insomnia (CBT-i) have been shown to improve sleep quality and decrease symptoms of chronic pain.[9] Good sleep has been shown to improve outcomes and perceptions of chronic headache and musculoskeletal pain.[10] There is also evidence that "complementary" modalities such as acupressure, tai chi, yoga, acupuncture, and certain supplements have been effective in treating insomnia without creating significant side effects.[11] In this article, we will summarize the evidence- based approach to treating sleep disorders with a specific focus on patients with chronic pain and opioid use. We recommend that physicians utilize a multimodality approach including sleep hygiene, cognitive behavioral therapy, and complementary treatments in order to improve sleep quality, decrease chronic pain, and decrease opioid use in our patient population.

Pain, Sleeplessness, and Opioid Use

It is not surprising that pain itself can cause sleeplessness. A 2015 NSF poll showed that one- quarter of chronic pain sufferers reported poor or very poor quality of sleep. Individuals with pain had an average of 42 minutes of sleep debt weekly, with a positive correlation between the level of pain and the gap between the sleep they need and they actually obtain.[12] Only recently, has it been recognized that the relationship of pain and quality of sleep is bidirectional. Impaired sleep in itself, can cause hyperalgesia and exacerbate pain that further inhibits quality of sleep.[13] Many patients turn to opioid pain medications in an attempt to cope and break this cycle.[14] However, opioids also disrupt sleep architecture by blocking access to rapid eye movement sleep and to the deeper restorative stages of non REM sleep. Opioids interfere with levels of adenosine, an important neuromodulator that balances the homeostasis between sleep and wakefulness.[15] Research has shown that local administration of opioids in specific regions of the brain reproduced sleep disturbances, and when the opioids were blocked, sleep disturbances were prevented.[16] Patients and physicians then find themselves in a conundrum of treating the pain at the cost of worsened sleep, and thus, rather than introducing medications to treat the sleep problems, it may be worthwhile to investigate other non-pharmacological treatments.

Addressing Sleep Disruption in Clinic

It is important that sleep is regularly addressed in clinical visits. Many patients may seem surprised that their physician is asking about sleep, but physicians should explain that sleep health is important to one's overall wellbeing. Only a third of poor sleepers discuss their insomnia with a physician.[17] Almost a quarter of the population reported daytime sleepiness and insufficient sleep, and others reported sleep related difficulties including difficulty with finance, completing tasks, and at work.[18] Despite these findings, studies suggest that there is an under-diagnosis of sleep disorders by primary care physicians.[18]

Starting with open ended questions, such as "Tell me about your sleep" or "How do you think you sleep at night?" can be good ways to gauge a patient's perception of sleep and provide a basis to discussing sleep health. Physicians should then attempt to better understand the etiology of a patient's poor sleep by asking about total sleep time and sleep quality. Screening should include ruling out secondary causes of insomnia that can be medically treated and may include ordering a polysomnography to clarify the diagnosis.[19] Clinicians can also screen for other sleep disorders such as sleep apnea as there is a high possibility of multiple disorders that tend to cluster in one patient.[20] Targeting sleep disorders such as sleep apnea and insomnia have been shown to be cost effective and improves the quality of life for chronic sufferers.[21] Sleep medicine education for clinicians and patients, the availability of diagnostic modalities, and therapeutic facilities to treat disorders have been shown to reduce the socioeconomic implications of untreated sleep disorders.[22]

Screening for Psychological Causes

It is also important to screen for acute life stressors that may correspond with the acute phase of insomnia. Without addressing these early stressors, patients begin to also worry about the lack of sleep with consequences in daily work performance. Not all sleeplessness qualifies as insomnia, and it is important to reassure patients that occasional sleeplessness is acceptable when associated with transient stressors or hormonal changes. However, sleep has been medicalized over the years, causing people to react maladaptively to sleeplessness.[20] Coupled with misinformation and lack of resources of sleep, both the sleep environment and process of falling asleep begin to be associated with as a stressful process, evolving into persistent insomnia.[20]

By the time patients have developed insomnia, clinicians will realize that insomnia tends to present alongside with mood disorders such as depression, PTSD, ADHD, and generalized anxiety.[23, 24] It is important to screen for sleep problems early, because insomnia is a risk factor for development of depression, and is also associated with a worse outcome for already depressed patients.[25] Moreover, depressed patients tend to have negative thinking, such as catastrophizing, which is characterized by the lack of confidence and control in expectation of negative outcomes. This type of negative thinking is a maladaptive coping strategy that can intensify the experience of pain and depression.[26] There is a significant association between catastrophizing and depression,[27] and avoiding catastrophic thinking may result in lower levels of emotional distress and thus lower pain perception.[26]

Physicians can refer such patients to cognitive behavioral therapy (CBT-I) which has been shown to improve sleep as well as the perception of pain's interference on daily functioning.[9] While primary care physicians can refer patients to sleep specialists, there is data that show that adequate training in cognitive behavioral therapy involving stimulus control, relaxation, and sleep hygiene education delivered by primary physicians can produce significant benefits.[28, 29] We provide the following basic CBT type of therapies below.

Sleep Hygiene Tips

When asking about sleep hygiene, clinicians can ask about contents on patients' nightstand, which can reveal bedtime habits and disruptors such as bright lights, noisy technology, computers, work, stimulating materials, and even various foods and drinks. It is also important to ask about sources of "noise" which usually fall into 3 categories: body noise, mind noise, and environmental noise. Integrative medicinal recommendations for each type of category are summarized in Figure 1 below.

Figure 1

	Body Noise	Mind Noise	Environmental Noise
Examples	Medical conditions Medication induced Muscular tension Inadequate exercise Stimulant/sedatives	Anxiety/Worry Stress Over stimulation Marital/family/relationship tension	Excessive light exposure Inappropriate temperature of bedroom Uncomfortable bed Night time allergies Circadian rhythm disruption/Jet lag
Avoid	Avoid exercise less than 3-4 hrs. prior to sleep Avoid high glycemic foods that can disrupt energy rhythms Avoid stimulating substances such as caffeine Avoid alcohol use despite causing drowsiness	Avoid forcing sleep Avoid thoughts about tomorrow and indulge in the actual experience of sleep Avoid conflict with bed partners Avoid stressful activities prior to sleep	Avoid clock watching Avoid too bright light exposures prior to sleeping Avoid sleeping in brightly lit rooms Avoid temperatures >68 degrees Avoid overstimulating material
Consider	Regular exercise Gentle stretching, massage, and yoga prior to sleep Warm shower or bath to trigger drop in body temperature to promote sleep Good nutrition- consider anti-inflammatory diet and know side effects of all medications Consider short term supplements of valerian, hops, chamomile, jasmine, and lavender Address snoring, which can be clues to underlying medical issues	Make bedtime rituals a soothing process Laughter and positive thinking prior to sleep Journal thoughts to help deescalate and reframe challenging experiences Write down a to do list for worries and write plans for day ahead Engage in dream health	Maintain regular bed and rising times, Regulate stimulating activity times Obtain exposure to outdoor morning light after rising Simulate dusk by dimming household lights 1-2 hrs. prior to bedtime Sleep in total darkness throughout the night; use eye mask if necessary Choose natural and organic colors, neutralize odors and chemical exposures from floor, wall, and carpeting Consider houseplants, humidifier, or filtration Create a safe space with home security system, comforting images

**Summarized and modified from the Andrew Weill IM in Residency Sleep and Dream Health Module[20]*

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Supplements in Place of Sleep Disrupting Medicines

Along with addressing psychological and medical causes of insomnia, physicians can look for secondary causes of insomnia. Chronic pain patients often have other chronic complex medical problems. Patients with chronic medical problems often have fewer hours of sleep and less restorative sleep compared to healthier individuals and often report worse symptoms of the disorder.[30] Unfortunately, many of the medications used to combat these co-morbid conditions can disrupt sleep architecture and exacerbate underlying sleep disorders.[20] (Figure 2) Thus, it is important for clinicians to realize that very medicines that they are using to combat a medical problem can worsen or create sleep disturbances. In a patient with chronic pain and comorbidities, it is worthwhile to use clinical judgement in weighing the benefits and risks of medications and consider cessation or decreasing dosages of offending medications. For example, in an elderly patient with low ACSVD risk, it may not be necessary to continue statin therapy if poly pharmacy and sleep are major issues.[31, 32]

Figure 2

Alcohol	Corticosteroids	Pseudoephedrine
Antiarrhythmics	Diuretics	SSRIs
Antihistamines	Decongestants	Sedatives
Benzodiazepines	Estrogen	Statins
Bronchodilators	MAO inhibitors	Thyroid Hormones
Caffeine	Nicotine	TCAs
Carbidopa/Levodopa		

**Modified from List of Medications/Substances that can interfere w/ sleep from Andrew Weill IM in Residency[20]*

Some patients may ask about supplements or medicines to help with sleep. Knowing about alternative supplements is especially important, because as addressed above, opioids and many medications can disrupt sleep architecture, but patients may ask for more "natural" medications to take instead. The following supplements in Figure 3 have been well known and utilized in integrative medicine for the treatment of sleeplessness. Melatonin is commonly seen in the clinical practice, but knowing about the other 3 can give clinicians alternative options. It must be noted that melatonin has considerable person to person variability in bioavailability. That is, it is known for relatively poor absorption and depends highly on differences in hepatic processing, especially in older populations compared to young populations.[33] The therapeutic dose is 0.25-0.5 mg, despite pills coming in 3.0 mg pills, because the absorption can range from 10-56%;[34] some patients may report good outcomes at that dose, but if they don't absorb enough, it may be worthwhile to increase their OTC dose to the 5 mg pill. It is best to not exceed the 10 mg OTC pill.

Conclusions

Sleep medicine is an underutilized and under addressed topic in the primary care world. However, research and data have shown that sleep may be crucial in the complex treatment of chronic pain. By addressing sleeplessness, primary care physicians can better target underlying medical and psychological barriers to sleep hygiene. Good sleep has been shown to decrease the perception of pain and can impact the vicious cycle of sleeplessness, pain, and opioid use. We recommend a multi- disciplinary integrated medicine approach to the treatment of chronic pain, and believe that providing education on sleep hygiene, CBT-I, and complementary medicine will help alleviate the opioid crisis in our nation.

Figure 3

Supplement	Usage	Recommended therapeutic dosage
Melatonin	Avoid factors that suppress melatonin such as light exposure and meds such as beta blockers, caffeine, alcohol Initiating and maintaining sleep	0.25-0.5 mg, assuming 10-56% absorption in 3-5 mg tablets OTC[35] 0.05 mg/kg in children ages 6-12 1-2 hrs. before sleep[36]
Valerian (Valeriana officinalis)	Useful for chronic insomnia[37]	1-3 grams of crude root -or- 800-1200 mg of extract of 0.8-1.0% valerenic acid taken 30-60 mins prior to bedtime
Hops (Humulus lupulus)	Used in production of beer helpful for insomnia[38]	300-500 mg before bed in either capsule or tincture
5- HTP	Increases Serotonin production Used for antidepressant, sleep aid, treatment of fibromyalgia[39,40]	50-100 mg at 30-60 mins prior to bedtime but avoid >300 mg daily (can cause nausea)

**Modified and Adapted from Andrew Weill IM in Residency module on Sleep Medicine[20]*

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Sandy Wang, MD, MPH *is a family medicine resident at the University of Rochester Highland Family Medicine program. Her interests include integrative medicine, medical anthropology, and medical education.*

Sachiko Kaizuka, MD *is a board-certified family physician and also board-certified in integrative medicine (ABOIM) and board-eligible in medical acupuncture (ABMA). She practices and teaches integrative approach all aspects of health care but particularly to chronic pain.*

Holly Ann Russell, MD, MS *graduated from the University of Rochester School of Medicine and Dentistry with a distinction in community health and completed her residency in family medicine at Lancaster General. Dr. Russell is the co-director of the Substance Use Disorder Treatment Program at Highland Family Medicine. She is currently working on several projects improving the treatment of substance use disorders in primary care and another project studying the use of group medical visits to promote healthy behavior change. She is an Assistant Professor in the Department of Family Medicine and the Center for Community Health and Prevention at the University of Rochester.*

Michael Mendoza, MD, MPH, MS, FAAFP *is the Commissioner of Public Health for Monroe County, NY and Associate Professor in the Departments of Family Medicine, Public Health Sciences, and Nursing at the University of Rochester School of Medicine and Dentistry.*

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OVERCOMING BARRIERS TO TREATMENT OF OPIOID USE DISORDER IN PRIMARY CARE

By Elizabeth Loomis, MD; Andrew Hayes and Holly Ann Russell, MD

Few issues in primary care medicine have garnered as much public attention as the current opioid epidemic. While increased physician awareness and widened usage of prescription databases has helped curb prescription of opioid analgesics, the prevalence of opioid overdose deaths continues to worsen.[1] Medication-Assisted Treatment (MAT) for opioid use disorder (OUD) has shown clear mortality benefit as well as improved outcomes in pregnancy and decreased time spent in criminal behavior,[2-4] however analysis of insured patients has found that receipt of this potentially lifesaving medical therapy has not kept pace with increased identification and diagnosis of OUD.[5]

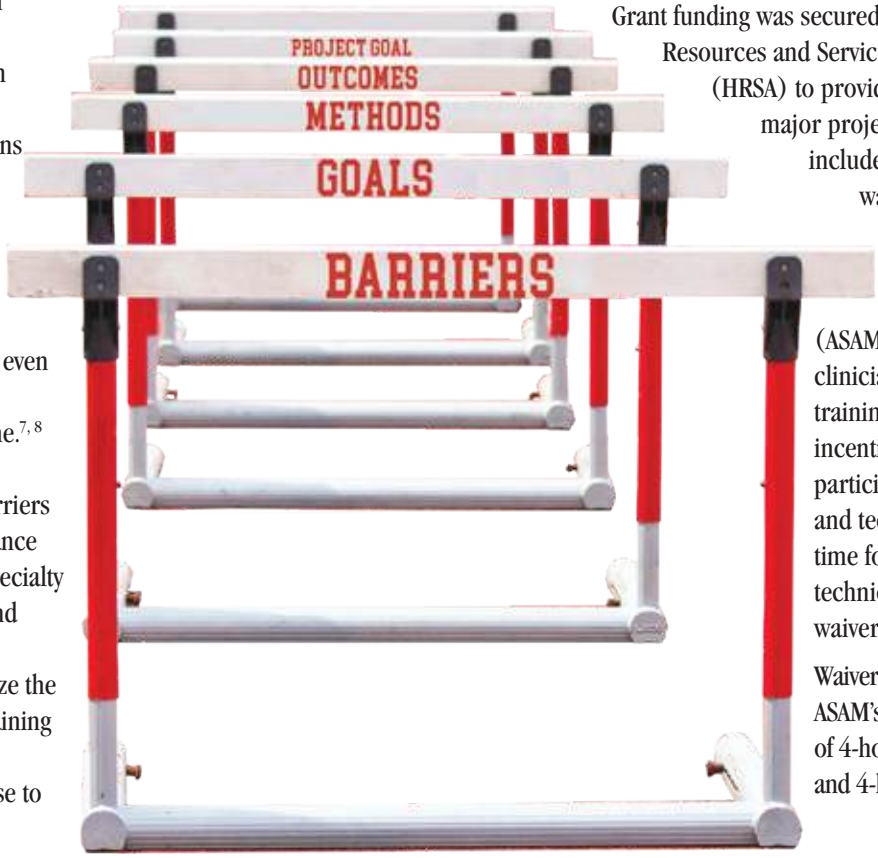
While primary care providers are experts in the treatment of other chronic diseases, they have yet to fully embrace treatment for the chronic disease of OUD with MAT options such as buprenorphine. One study polled 108 family physicians and found that 80% regularly saw patients with OUD and 73% felt it was their role to treat these patients. Only 10 % however, were buprenorphine providers.[6] The most commonly cited barrier to becoming a prescriber was a lack of training, both for the provider and for their staff.[6] The Drug Addiction Treatment Act of 2000 mandates that physicians who wish to prescribe buprenorphine first complete an 8- hour training course and apply for a waiver from the Drug Enforcement Agency (DEA). In addition to certification requirements, many doctors cite insecurity with treating these often complex patients as well as bias against addicted persons as reasons that they had not become buprenorphine providers.[6] These barriers contribute to the fact that up to 80% of those with OUD do not receive MAT and that 60% of rural counties do not even have a single provider with a DEA waiver to prescribe buprenorphine.[7, 8] Even clinicians with waivers often discontinue prescribing citing barriers including time constraints, resistance from practice partners, lack of specialty backup for complex problems, and attraction of drug users to their practice.[8] These findings emphasize the need for improved methods of training and clinical support in order to improve the primary care response to the OUD crisis.

Project Goal:

The overarching goal of this project was to improve access to high quality treatment for opioid use disorder with buprenorphine in the primary care setting. We planned to accomplish this through the following objectives:

- Increasing the number of primary care clinicians able and willing to prescribe buprenorphine
- Providing in-person technical assistance with a Credentialed Alcoholism and Substance Abuse Counselor (CASAC) consultation to ease set-up and implementation of OUD treatment in primary care
- Creating a community wide referral network to ease access for patients who need treatment in more intensive settings
- Increasing the number of local trainers who could teach buprenorphine waiver trainings
- Establishing treatment of OUD as an integral part of family medicine physician and nurse practitioner residency training at the University of Rochester

Methods:



Grant funding was secured through Health Resources and Services Administration (HRSA) to provide funding for the major project costs which included the price of the waiver trainings through the American Society of Addiction Medicine (ASAM), the time of the clinicians involved in the trainings, financial incentives for providers who participated in the training and technical support, and time for a CASAC to provide technical support to newly waivered clinicians.

Waiver trainings utilized ASAM's mixed training model of 4-hours of online training and 4-hours of live

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conference training. ASAM did not have a formal 'train- the- trainer' program in place for waiver trainings so a model was developed with consultation from local addiction medicine specialists to develop new providers who could teach the waiver trainings. Waiver training courses were limited by the size of the conference room (ranging from 30 to 50) and open to any interested clinician regardless of specialty or institution. All waiver training attendees were contacted by the program's CASAC after the training and offered follow up support including further clinician education, office staff education, and administrative protocols to establish buprenorphine treatment in the office.

Considering the cited barriers of time constraints and lack of practice partner support, we added information during the buprenorphine waiver trainings about our own successful experience providing buprenorphine in a primary care setting. We offered clinician and CASAC led educational sessions to office partners and staff to help overcome concerns about what treating patients with opioid use disorder looks like in practice. To overcome the barrier of lack of specialty back-up, we reached out to local chemical dependency treatment programs and were able to create a step-wise guide for how to manage relapse or complex patients, and provided direct phone numbers that primary care clinicians could use to easily access more intense chemical dependency programs if needed.

For resident education, all graduating physician and nurse practitioner residents in family medicine at the University of Rochester were required to take the buprenorphine waiver course as well as spend a minimum of 16 hours of clinical time working in patient care sessions devoted to buprenorphine treatment for opioid use disorder.

Outcomes:

From September to November 2018, three primary care trainee clinicians (2 MD and 1 DNP) received 6- hours of training from two addiction medicine experts in order to be able to teach the waiver course. Additionally, these three trainees attended the national conference for the American Society of Addiction Medicine to gain further experience in current topics in addiction medicine. The trainee clinicians co-taught one buprenorphine waiver course with the addiction medicine specialists and then taught 3 further courses independently. The DNP trainee additionally taught a full course aimed at advanced practice providers outside of the grant funded courses.

The initial goal of the program was to train 30 primary care clinicians in the management of opioid use disorder over the course of three buprenorphine waiver trainings including one in a neighboring rural community. Due to demand, a fourth training was added. In total 117 clinicians completed the waiver training course. Of these 117 clinicians, 36 were primary care residents and 5 were NP residents. CASAC office consultations were performed at 6 clinical sites. Of five physician residents that were trained who have already entered practice, 3 are providing buprenorphine as part of their practice. Assessing at 3 months after the last training, 45 MD clinicians had confirmed they received their buprenorphine waiver and 34 were actively prescribing.

Discussion:

In general, we found higher levels of interest in gaining further knowledge and tools in treating patients with opioid use disorder than anticipated. We believe that the increasing number of persons affected by OUD and increasing fatality of overdoses has motivated clinicians to consider providing treatment with buprenorphine. We also found that using inter-professional teams to overcome barriers can increase access to OUD treatment, and specifically the role of a CASAC was vital in the success of our program by providing office based support to newly waivered clinicians. For clinicians who do not already have a partnership with a CASAC, developing a relationship with intake personal at a local outpatient chemical dependency center could serve a similar role in providing level of care assessments and linkage to higher levels of care when needed.

Several barriers were identified and addressed by the program (Table 1). Customizing the waiver training for a primary care audience allowed our own clinical experience to reassure clinicians that providing treatment for OUD was sustainable and rewarding. We emphasized that patients with substance use disorder are already in primary care practices and that buprenorphine offers an evidence-based treatment for a chronic disease that many of their patients are already suffering from. Offering clinician to clinician support as well as guidelines for managing relapse and easy access to experts when a higher level of care is needed, helped to address the fear of lack of access to specialty backup. We also provided access to all of our note templates, care agreements and protocols for situations such as patient relapse. To access these materials go to https://drive.google.com/open?id=1U5rX9qFaeYQ_ab0xIadNe0Htj-iHjbUy or contact penny@nysafp.org for the link.

Importantly, we also identified office staff concerns about treating patients with opioid use disorder as an additional barrier. We addressed this by providing in-office staff education via our outreach CASAC, who helped diminish stigma around treating patients with OUD, educated staff on appropriate language as well as decreased fears around attracting persons with addiction to a practice.

We found it was helpful to provide free courses at a variety of times and locations including a more rural area to encourage participation. Our 'train- the- trainer' model will ensure that new course instructors are available to provide these trainings on an ongoing basis. Additionally, we also created multiple teaching presentations around opioid use disorder as well as required waiver training for our own residents to assure a future of well-rounded clinicians ready to respond to the opioid overdose crisis. To access these materials go to https://drive.google.com/open?id=1U5rX9qFaeYQ_ab0xIadNe0Htj-iHjbUy or contact penny@nysafp.org for the link.

Overall, we found that primary care clinicians wanted to know more about treatment for opioid use disorder and were willing to invest time in doing so after some basic barriers were overcome.

Table 1: Barriers Identified During Training

Key Characteristics	
Gaining Acceptance:	• Leadership, including department chairs and administrative leaders, must be openly supportive • Education should be provided around treatment of OUD with buprenorphine to all clinical and administrative staff with question and answer opportunities to help overcome bias and allay concerns • Consultations with experts, such as CASACs, to office administration can address the impact of buprenorphine treatment on routine patient care as well as budget
Additional resources provided:	• Shared intake paperwork, agreement of responsibilities ('patient contract') and electronic health record templates from our well established program • CASAC and clinician consultations with office managers to set up clinical and administrative work-flows that would be appropriate for each individual office • Reviewed setting up and maintaining a patient registry for possible DEA audit at clinical training program with clinicians available for further consultation • Support from experienced clinicians available via email, electronic health record communications, and telephone
CASAC or clinician consultation components:	• Important considerations for the consultation • What time is best to meet with the practice? Consider lunch presentations or during team meeting. • Who is the audience? Information for support staff may be different then for administration or clinical partners. • In what area is the practice located? Identify local supports for each office. • How will prescribing look at this practice? Larger practices could consider dedicated session to OUD compared to smaller practices that may only see a few patients.
Specific barriers or misconceptions encountered across practices that were addressed in consultations:	• Stigma around addiction • Concerns around the specialized DEA numbers and possible DEA audits • Concerns with urine screening procedures to verify adherence to treatment • Concerns on how to implement MAT in different types of setting (i.e. rural areas with less resources) • Concerns around other substance use (especially marijuana)

Endnotes

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Elizabeth Loomis, MD *graduated from the University of Rochester School of Medicine and Dentistry with a distinction in community health and completed her residency in family medicine at Lancaster General as a fellowship in academic medicine. Dr. Loomis codirects the Substance Use Disorder Treatment Program at Highland Family Medicine as well as the Centering Pregnancy Program. Her publications and research interests are primarily focused on the education of family clinicians in maternal-child health and substance use disorders.*

Andrew Hayes *is a 4th year medical student at Renaissance School of Medicine at Stony Brook University. He plans on pursuing primary care as a career with interest in treatment of substance use disorders, global health, and integrative patient care.*

Holly Ann Russell, MD, MS *graduated from the University of Rochester School of Medicine and Dentistry with a distinction in community health and completed her residency in family medicine at Lancaster General. Dr. Russell is the co-director of the Substance Use Disorder Treatment Program at Highland Family Medicine. She is currently working on several projects improving the treatment of substance use disorders in primary care and another project studying the use of group medical visits to promote healthy behavior change. She is an Assistant Professor in the Department of Family Medicine and the Center for Community Health and Prevention at the University of Rochester.*

HIV: What Family Medicine Clinicians Need to Know

By Scott Hartman, MD, FAAFP and Kristin E. Smith, DNP, FNP-C, AAHIVS

STATE OF THE EPIDEMIC

The first cases of Acquired Immune Deficiency Syndrome (AIDS) were reported in June 1981. Whereas in the early 1980s most AIDS cases occurred among whites, cases among persons of color increased steadily and by 1996, more cases occurred among black individuals than any other ethnic or racial population.[1] Cases among persons of Hispanic, Asians/Pacific Islander, and American indigenous populations continue to increase. Despite all the money, research and public education campaigns, the incidence of new cases of human immunodeficiency virus infection (HIV) has held steady over the last 10 years.[1]

In 2017, most new diagnoses of HIV infection (83%) were attributed to male-male sexual contact, while 9% were attributed to heterosexual contact, and 4% to both injection drug use and male-male sexual contact.[2] Among females 13 years and older, 12% of all new diagnoses were attributed to injection drug use and 87% to heterosexual contact.[2] Of note, transgender women and men who are sexually active potentially exhibit increased risk of HIV acquisition, with transgender women experiencing especially high risk. The CDC estimates that about one fourth of transgender women, and 56% of African American transgender women, are living with HIV infection.[5]

About 8700 women living with HIV give birth annually in the US,[4] with the potential for mother-to-child transmission. Incidence of perinatally-acquired HIV infection peaked in the US in 1992 and declined greatly after implementation of routine antenatal screening and use of medications and precautions to prevent transmission.[3, 4]

Studies indicate that 15% of persons living with HIV are unaware of their diagnosis, and persons unaware of their infection are responsible for 40% of HIV transmission nationally.[1, 2]

SCREENING AND LINKAGE TO CARE

USPSTF

The USPSTF assigns screening for HIV for ages 15-65, for younger or older if at risk and for pregnant women an A-rating.[6] Current CDC guidelines recommend testing for HIV infection with an antigen/antibody immunoassay approved by the U.S. Food and Drug Administration that detects HIV-1 and HIV-2 antibodies and the HIV-1 p24 antigen, with supplemental testing after a reactive assay to differentiate between HIV-1 and HIV-2 antibodies.[7] If supplemental testing for HIV-1/HIV-2 antibodies is nonreactive or indeterminate (or if acute HIV infection or recent exposure is suspected/reported), an HIV-1 nucleic acid test is recommended to differentiate acute HIV-1 infection from a false-positive test result.[7] Antigen/antibody tests for HIV offer high sensitivity and specificity, and results are available in two days or less. Rapid antigen/antibody tests also exist,[7] but any positive results should be confirmed. Pregnant women presenting in labor with unknown HIV status should be screened with a rapid HIV test.[7]

Clinicians' education must include: 1) the latest recommendations on routine HIV screening, 2) implementation of fourth-generation testing, 3) targeted use of preexposure prophylaxis (PrEP) for high risk adults without HIV, 4) treatment as prevention to lower community viral loads, 5) treatment guidelines on single fixed-dose combination antiretroviral therapy (cART).

The most important evidence-based message focuses on early treatment as an integral part of community-based prevention.[8] Adherence to cART, even for early HIV infection, prevents disease progression through control of HIV, contributing to lower community viral loads and reduced risk of transmission.

INITIATING HIV CARE

Dramatic changes have occurred in the treatment of HIV over the past 20+ years. As shown in **Figure 1**, 1998 guidelines universally recommended against treatment for individuals with CD4 cell counts greater than 500 cells/mm.[3] During the 1990s, and even into the early 2000s, the only agreement across multiple guidelines was to start treatment when CD4 cell count decreased to <200 cells/mm.[3, 9] A CD4 cell count of <200 cells/mm^3 results in a diagnosis of AIDS and places the patient at a much higher risk for opportunistic infections. Unfortunately, despite U.S. guideline agreement starting in 2012 supporting initiation of care at all CD4 cell counts, widespread acceptance and uptake has not occurred. In vulnerable populations we still observe low rates of prescribing, thus placing them at high risk for opportunistic infections.[10]

With newer, easier treatment regimens and minimal to no side effects or toxicities, beginning treatment early is far more feasible for patients.[11] Adverse effects of ART regimens of course still persist, but now occur far less frequently. Adverse effects may include cardiovascular disease, renal tubular acidosis, and decreased bone density; the frequency of these complications are minimized by selecting regimens individualized to patient risk factors.[8] Robust evidence demonstrates several key benefits of early treatment. These benefits impact the individual patient as well as public health by improving immunologic function and decreasing rates of HIV transmission.

Maintenance of Immunologic Function

The goals of HIV therapy as outlined by the U.S. Antiretroviral Therapy Guidelines[11] include:

- Reduce viral load as much as possible for as long as possible
- Restore or preserve the immune system
- Reduce sickness and death due to HIV
- Prolong the duration and quality of life
- Prevent HIV transmission

An NA-ACCORD Study compared mortality outcomes in deferred ART initiation to either initiation at CD4 cell counts of a) 500+, and b) 351-500.[11] At the time of this study group A would not have qualified for treatment based on WHO/European guidelines, and U.S. guidelines only recommended to consider treatment; group B would have qualified based on U.S. guidelines, with consideration given by European guidelines.[9] Researchers found deferring ART increased risk of death by 69% compared to those who began therapy in the 351-500 CD4 cell count, and the risk of death was increased by 94%, compared to those who began therapy with a CD4+ count ≥500.[11] USPSTF published an article in JAMA citing numerous other studies demonstrating similar impact of early ART on decreasing all-cause mortality.[6]

In addition to early initiation's benefits on mortality, it also has been shown to decrease time to virologic suppression and enable patients to maintain higher CD4 cell counts; it might also decrease HIV reservoir size and allow for better HIV control even in situations where ART is interrupted.[12]

Decreasing HIV Transmission

To truly end AIDS by the end of 2020 in NYS, we need to decrease transmission of HIV. Linkage and retention of patients in care is key. Providing an HIV positive partner with treatment and maintaining virologic suppression for 3-6 months has been shown in multiple studies to lead to a patient being unable to transmit the HIV virus.[8, 13, 14]

A systematic review of 12 reviews and 11 studies found no transmission with ART plus consecutive evidence of virologic suppression (i.e., VL <200 copies/mL) measured 4-6 months apart, regardless of condom use or non-use.[13] The PARTNERS I study (548 heterosexual and 340 gay couples) and PARTNERS II study (serodiscordant MSM (men who have sex with men) couples reporting condomless intercourse, with no PEP/PrEP) also demonstrated no linked transmissions when the HIV positive partner had a HIV-1 RNA <200 copies per mL.[14] In these studies, when HIV seroconversions occurred, a phylogenetic analysis was completed comparing HIV-1 *pol* and *env* sequencing to determine if the transmission was linked to the HIV-positive partner (versus a partner outside of the relationship) and of the 15 seroconversions over 7 years and a reported 76,088 acts of condomless anal intercourse, none of those serologic conversions were a phylogenetic match to the original partner.[14] **This research had led to a commonly seen concept of U=U, in other words, undetectable equals untransmissible, thus making the linkage and retention of HIV+ patients in care not only valuable for the individual patient, but also a public health imperative.**

Rapid Start of Antiretroviral Therapy (ART)

The U.S. Antiretroviral Therapy Guidelines recommend "Treatment is recommended for all people living with HIV, regardless of CD4 count", however WHO data updated 08/02/2019 show that only 67% of people living in the Americas, and 62% globally are receiving ART.[15] Based on the evidence presented above, for most individuals, rapid start of ART is indicated. In the U.S., uninsured/underinsured patients may access The AIDS Drug Assistance Program (ADAP), which can quickly approve patients for ART treatment coverage and allow rapid ART initiation.

Rapid start of ART may include: a) treatment the day of diagnosis (without waiting for resistance test results), b) the start of treatment with discordant test results in the setting of symptoms and risk factors highly suspicious of acute HIV infection, or c) the start of treatment in patients re-engaging in care.[12] Despite International AIDS Society USA 2018 guidelines, rapid start may not always be feasible depending on practice setting. Most primary care clinicians do not work in settings with the recommended adequate services, staffing, and expertise.[8] We do not suggest that all primary care clinicians begin ART regimens, but rather counsel patients on benefits and assist in rapid linkage to care.

PREP (PREEXPOSURE PROPHYLAXIS)

PrEP for prevention of sexual transmission of HIV consists of a combination of continual delivery of counseling on behavioral risk reduction, techniques for medication adherence, easy access to condoms, monitoring of pregnancy status, STI screening and treatment, **and strict adherence to once-daily oral combination therapy of 200 mg emtricitabine/300 mg tenofovir disoproxil fumarate (Truvada).** In October 2019, the FDA approved a second option for PrEP, 200 mg emtricitabine/25 mg tenofovir alafenamide (Descovy). This drug, approved ONLY in MSM and transwomen as effective, has not yet been established in those who have receptive vaginal intercourse. This new option is particularly appealing as the pro-drug tenofovir alafenamide (TAF), has up to a 90% decreased serum concentration when compared to tenofovir disoproxil fumarate (TDF), while maintaining high tissue concentration. The lower serum concentration results in lower risk of toxicities (i.e., kidney and bone) and continued use with a creatinine clearance >30, compared to >60 with TDF.[16,17]

Consistent use of condoms can decrease the risk of HIV acquisition by 80%, but sexually active adolescents and adults do not consistently utilize this mode of prevention, necessitating other evidence based approaches. HIV specialists and STI clinics often prescribe PrEP, but primary care clinicians can integrate this mode of prevention into their practices with relatively few barriers.

The CDC recommends PrEP be offered to people whose ongoing practices put them at substantial risk for HIV acquisition, and PrEP medication should be taken daily regardless of frequency of risk-associated practices (such as injection drug use, unprotected sex).[18] Randomized trials demonstrate a 90% reduction in new HIV infections in high-risk populations with PrEP. Almost all patients who acquired HIV in the trials were not taking PrEP as prescribed.[19, 20] Infection with HIV virus containing viral mutations conferring tenofovir/emtricitabine resistance is rare among the few people who have become HIV-positive after utilizing PrEP. Individuals with resistance mutations had actually converted to HIV-positive pre-PrEP, but had been screened with tests that could not detect very recent infection.[20]

continued on page 36

Table 1 includes a list of individuals at risk who can benefit from PrEP per CDC guidelines. Before initiating PrEP, normal renal function should be documented, as well as a few other key tests. The patient must be documented to be HIV-negative, ideally with an antigen-antibody (4th generation) test or HIV RNA test, and without symptoms of acute HIV infection.[21, 22] Hepatitis B (HBV) surface antigen, surface antibody and core antibody must be tested because both medications in the PrEP combination show activity against HBV. For patients with HBV infection, experts propose a theoretic concern that starting/stopping PrEP may lead to flares of HBV.[21] Baseline hepatitis C virus testing is also recommended if patients meet general criteria for screening.

Table 1: Patients to whom PrEP Should be Offered

Sexually active, HIV negative adults regardless of gender, who in the past 6 months report: 2 or more sexual partners Inconsistent or absent condom use 1 or more HIV-positive sexual partners Any diagnosis of chlamydia, gonorrhea or syphilis Engagement in commercial sex work
Sexually active, HIV-negative women who report, in the past 6 months, sexual contact with a male partner who injects drugs or has sex with men
HIV-negative adults who have ever injected drugs, and in the past 6 months report: Injecting drugs not prescribed for them Shared needles or injection equipment Engagement in behaviors that place them at significant risk for sexual HIV exposure
Any HIV-negative person with an HIV-positive sexual partner that is considering pregnancy

Table 2 describes initial and follow-up laboratory monitoring (and other recommended services) in detail for patients taking a PrEP regimen. Contact penny@nysafp.org for a fact sheet on PrEP that can be used for clinician and/or patient information.

Table 2: Monitoring and services before and during PrEP)

Before Prescribing PrEP Document negative HIV testing Confirm no signs/symptoms of acute HIV infection Evaluate creatinine clearance - must be > 60 mL/min Evaluate hepatitis B infection and vaccination status Screen for hepatitis C
Follow-up visits every 3 months HIV testing every 3 months Assess renal function 3 months after initiation then every 6 months Screen for STIs regularly - potentially every 6 months Provide oral and rectal STI testing for patients engaging in anal sex Pregnancy test every 3 months for patients with a uterus
Additional services at follow-up visits Medication adherence counseling, adverse effect assessment Behavioral support for risk reduction Assess need for substance use treatment and safe injection services

CDC PrEP 2019, Stekler 2016

NPEP (NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS)

Identifying persons in need of PEP or PrEP requires frequent evaluation of risk factors, as a person's risks will change over time; in high risk populations this will require frequent testing.[8] Post-exposure prophylaxis (nPEP) should be considered for patients with a high risk exposure (e.g., vagina, rectum, eye, mouth, mucous membrane, nonintact skin, or percutaneous contact) with blood or body fluids (e.g., semen, vaginal/rectal secretions, breast milk), if the source of the exposure is either known to be HIV positive (particularly if not on treatment) or HIV status is unknown.

In giving consideration to risk, it is important to consider disproportionately affected populations, including those who are incarcerated, in which HIV prevalence is 5%, compared to <1% in the general population. High risk sexual behaviors and drug use co-occur in prison settings.[22] Even though a patient may have been prescribed PEP/PrEP prior to entering into a prison system, they may have had treatment interruptions, increasing their HIV exposure risk.

Any patients having received nPEP, or who has tested positive for an STI or Hepatitis C infections should prompt a clinician to consider and discuss with their patients a seamless transition to PrEP.[8]

Testing should be carried out prior to starting a PEP regimen, however PEP initiation should not be delayed if testing cannot be immediately provided. PEP testing is summarized in ***Table 3***. The most common regimen for PEP in adults and adolescents ≥13 years of age with a creatinine clearance greater than 60 is tenofovir disoproxil fumarate/emtricitabine (TDF 300 mg/FTC 200 mg) once daily PLUS either dolutegravir 50 mg daily OR raltegravir 400 mg twice daily.[24] Currently raltegravir and dolutegravir can be prescribed to pregnant women.[25] Patients with creatinine clearance less than 60 require an alternative regimen (e.g., ZDV + 3TC + RAL).

Table 3: Recommended Testing Before, During, After PEP

Baseline	4-6 weeks	3 months	6 months
HIV Ag/ Ab test	HIV Ag/ Ab test	HIV Ag/ Ab test	HIV Ag/ Ab test
Serum Creatinine[1]	Serum Creatinine		
AST/ALT[1]	AST/ALT		
GC/CT/RPR	GC/CT/RPR		
Pregnancy test	Pregnancy test		

[1]*For regimens containing TDF/FTC, RAL, or DTG*

FUTURE DIRECTIONS

Primary care clinicians play an important role in preventing HIV. It could be argued that two-thirds of the components of Governor Cuomo's initiative to End AIDS by 2020 fall squarely on the shoulders of the primary care clinician. This initiative was introduced in 2014, proposing that to end AIDS we must:

A. Identify persons with HIV who remain undiagnosed.

B. Link and retain persons diagnosed with HIV to health care and initiate antiretroviral therapy to maximize viral suppression.

C. Facilitate access to PrEP and nPEP.

It is well within our domain to identify persons who are undiagnosed and link them to care with HIV specialists (who may be primary care clinicians certified in HIV care). We should do this by offering HIV testing liberally according to guidelines.[26] Rapid linkage to care is vital for optimization of patient outcomes. In addition to identifying these patients, when we are truly engaging in these conversations with our patients this also affords us the opportunity to identify patients who would greatly benefit from nonoccupational post-exposure prophylaxis (nPEP). Alternatively, clinicians may identify a patient with ongoing risks, and after receiving a negative HIV test, the patient can be prescribed PrEP.

In order to battle this epidemic, from the sociopolitical perspective, sustained prevention programs focusing on MSM (especially racial/ethnic groups of low socioeconomic status), women, and injection drug users are imperative.

In September 2017, the New York State Department of Health became the first state health department in the United States to sign on to the Prevention Access Campaign's Undetectable equals Untransmittable (U=U) Consensus Statement.[27] The framework of U=U offers the opportunity to dismantle HIV stigma and discrimination. It emphasizes the critical importance of antiretroviral therapy, as well as engagement in health care for people living with HIV.

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Endnotes continued on page 56.

Scott Hartman, MD, FAAFP *currently serves as Chair of the NYSAFP Public Health Commission and practices at University of Rochester Medical Center. He completed an HIV medicine fellowship at Cook County Hospital in Chicago and is a certified HIV Specialist with the American Academy of HIV Medicine.*

Kristin E. Smith, DNP, FNP-C, AAHIVS *currently serves as the Director of the Family Nurse Practitioner (NP) Residency Program at Highland Family Medicine. Prior to transitioning to her current role she served as the Clinical Director of the Opioid Overdose Prevention Program and a staff clinician at an HIV clinic. She is certified as an American Academy of HIV Medicine Specialist.*

Figure 1: When to start HAART among asymptomatic HIV + patients according to guidelines: 1998 to 2012.

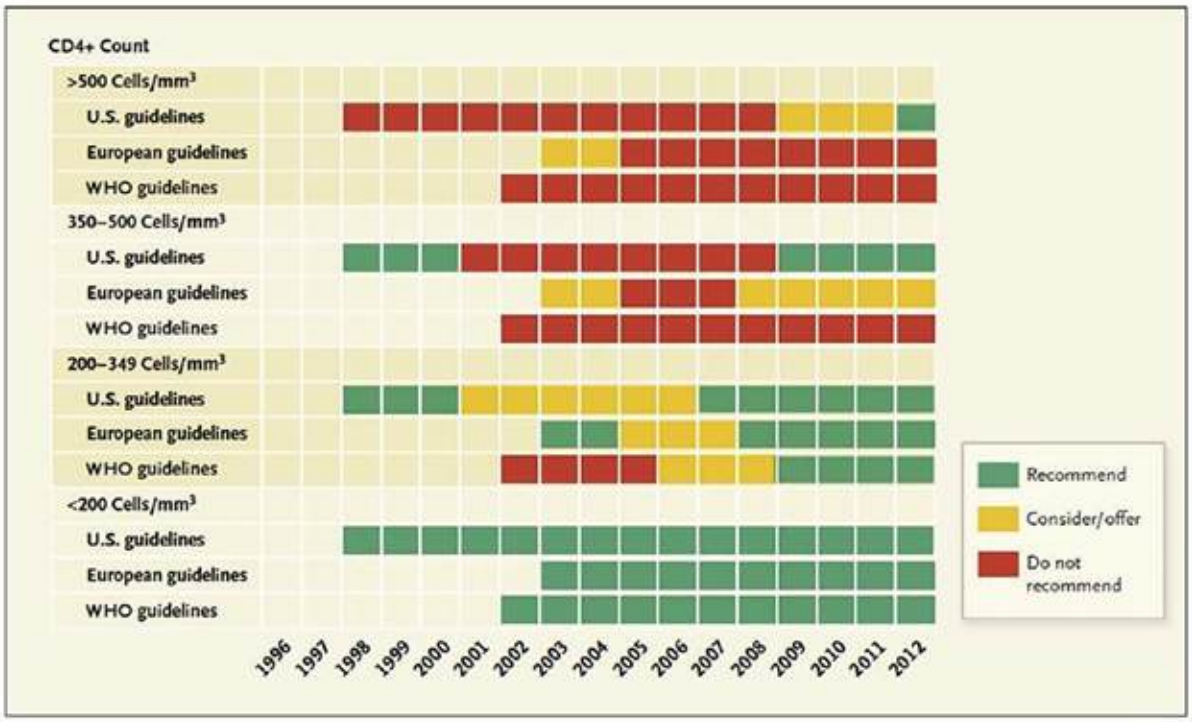

Table reprinted with permission. Franco, RA, Saag, MS.

Harm Reduction: From Education to Practice

By Leah Miller-Lloyd; BahiaZoe Wahba; Jasmine Landry; Deborah Steinberg; Kara Burke, MPH and Jose David, MD

Over the past three years, 22 first- and second-year medical students from Albany Medical College (AMC) have stepped away from their lectures and flashcards to volunteer each month with people who use drugs, providing thousands of clean syringes and supplies and learning from staff and clients alike. Project Safe Point is an organization that runs a mobile syringe access service in New York's Capital District. The mobile sites provide sterile injecting supplies (needles, cookers, cotton, water, tourniquets), the opioid-reversal agent naloxone, sharps disposal containers, and smoking supplies. Clients can also receive human immunodeficiency virus (HIV) and hepatitis C virus (HCV) testing, access to medical care, social services such as transportation, and guidance for safe injection strategies.

Volunteering with Project Safe Point as part of AMC's service learning curriculum has given students the chance to interact in a meaningful way with a patient population often marginalized in medical settings. Students have been able to learn techniques for openly and non-judgmentally talking to people about their drug use and provide effective counseling about strategies to reduce harm associated with their use. As one student put it, "Getting a chance to meet face to face with substance users – meet them where they're at – it's an exceptional experience and one that you don't get often in your preclinical years. Working with Project Safe Point enabled me to engage in social justice built on a belief in, and respect for, the rights of people who use drugs." Through Project Safe Point, medical students are empowered with the foundational skills needed to work effectively with patients who actively use drugs. Sometimes in health care, patients with current or past substance use are labelled "difficult," which can result from providers' lack of addiction education or positive experiences working with this population. Here we aim to highlight the importance of harm reduction and addiction medicine education throughout medical school, residency, and beyond.

History and Effectiveness of Harm Reduction Strategies

Harm reduction is an approach to patients who use drugs, rather than a specific protocol. It includes policies, programs, practices, and forms of advocacy that aim to minimize negative outcomes for people who use drugs.

The first syringe exchange was developed by people who used drugs in the Netherlands in 1984 in response to a hepatitis B epidemic. The burden of infectious disease, especially HIV and HCV, is substantial among people who inject drugs (PWID). An estimated 10% of HIV infection is transmitted via IV drug use; however, this statistic is extremely variable, with some regions as high as 80% HIV transmission among PWID.[1] Harm reduction practices like syringe access programs and opioid substitution programs have repeatedly been shown to decrease rates of overdose and HIV and HCV transmission. One important meta-analysis showed that patients enrolled in methadone maintenance programs have a 54% reduction in HIV infection,[2] while PWID participating in SAPs have over 50% reduction in HIV and HCV infection.[3] Notably, when syringe access programs are discontinued, incidence of HIV among PWID increases drastically, in one study from 0.5% to nearly 50%.[4-6] As mentioned previously, harm reduction services like Project Safe Point also improve access to HIV and HCV testing, condoms, naloxone, and many other social services.[7] Given the wealth of literature surrounding the benefits of these interventions, of which syringe access programs require the lowest cost to implement,[8] these programs have sprouted throughout the United States, even where they are not legalized.

The Family Doctor's Role in Harm Reduction

Family physicians are in a unique position to provide comprehensive, compassionate care for patients who use drugs.[9] Building longitudinal relationships creates a positive space in healthcare for marginalized patients, and there is a lot we can do as providers for these patients. Patient-centered care for people who use drugs includes educating patients on harm reduction strategies, prescribing medication treatment, connecting patients with appropriate resources, and caring for the patients' other medical and socioemotional concerns. While many family doctors may not have personal experience with drug use, we can still counsel patients on safer use just as we counsel patients on inhaler management and weight loss. This counseling includes strategies such as using only sterile syringes, avoiding sharing equipment (cookers, filters/cottons, pipes, etc.), cleaning the skin with alcohol before injection, avoiding use of broken pipes, and not using alone.

Overdose prevention. First and foremost, any patient who uses opioids (prescription or non-prescription), or other drugs, should have access to naloxone for opioid overdose. Naloxone is a high affinity opioid receptor antagonist that will rapidly reverse an opioid overdose and induce withdrawal. People may require multiple doses, especially if they used large quantity or high potency opioids (e.g. fentanyl). Samples of cocaine, meth-amphetamines, and counterfeit pills have all been found to be contaminated with fentanyl in New York,[10] which suggests that even patients who don't use opioids may be at risk of an opioid overdose. Providers should prescribe naloxone for patients using illicit or prescription opioids.[10] Importantly, patients should educate family members or friends about signs of opioid overdose (respiratory depression and unresponsiveness) and how to administer naloxone. Intramuscular, intranasal, and auto-injection naloxone are equally effective at reversing overdose, though patients and insurers may have a preferred formulation.

Sterile supply access. Many health risks associated with injecting drugs can be avoided by using a new, sterile syringe for every injection.

Using new syringes reduces damage from dull needles and reduces infection transmission. Physicians in New York, as well as 47 other states, can prescribe syringes to patients who inject drugs.[11] Providers should also be aware of local syringe access programs (NASEN.org), which are often an excellent source of sterile supplies, naloxone, social services, education, and community.

Infectious disease screening, prevention, and treatment. The U.S. Preventative Services Task Force recommends annual screening for HIV and hepatitis C for people who use drugs. Patients should be screened for STDs, and may benefit from HIV pre-exposure prophylaxis (PrEP) if they have shared supplies within the past 6 months or have high-risk sexual practices. All patients who inject drugs should be vaccinated against hepatitis A and B, as well as tetanus. Patients with other risk factors for community-acquired pneumonia, such as heavy alcohol use or cigarette smoking, should receive the 23-valent pneumococcal vaccine.[11] The CDC encourages hepatitis C treatment in the primary care setting for all patients excluding those with decompensated cirrhosis, and there are many resources supporting family doctors training to do so.[12]

Educating patients about risks and prevention techniques. Appropriate counseling for patients who use drugs should also include teaching patients what signs and symptoms to be alert for. Some symptoms, such as early skin and soft tissue infections, may be able to be managed in an outpatient setting. However, symptoms of systemic infection, including fever, hypotension, tachycardia, or tachypnea should prompt patients to seek care at an emergency department. People who inject drugs are at increased risk of cellulitis and soft tissue infections, endocarditis, community-acquired pneumonia, tuberculosis, myocarditis, and osteomyelitis, among other infections.[11] Thus, physicians should have a higher index of suspicion for systemic infection and educate patients about risks and prevention techniques.

Providing medications for opioid use disorder. Finally, many patients with opioid use disorder (OUD) benefit from medication, including buprenorphine, methadone, or naltrexone. Methadone is a long-acting full opioid agonist with good efficacy and tolerability. However, it can only be prescribed for OUD at specific methadone maintenance programs. Buprenorphine is a partial opioid agonist that has been shown to lower risk of overdose, reduce infection transmission, and is associated with decreased opioid use and increased treatment retention. Buprenorphine has a good safety profile, can be used in pregnant patients, and can be prescribed from an outpatient setting in up to 90-day supplies. Any licensed physician can prescribe buprenorphine after obtaining a Drug Addiction Treatment Act of 2000 (DATA) waiver and registering with the Drug Enforcement Administration.[13] Naltrexone is an opioid receptor antagonist that can be prescribed in outpatient settings for treatment of alcohol use disorder and off-label for treatment of OUD. Patients must be abstinent from all opioids for 7-14 days before induction, forcing them to endure extended withdrawal. Specifically, injectable extended-release naltrexone in conjunction with psychosocial treatment has shown efficacy in decreasing opioid use and reducing cravings.[14]

Addiction Medicine and Harm Reduction in Medical Education

While there is much that family physicians can do to help people who actively use drugs, only one-fifth of general practitioners feel prepared to simply screen for substance use disorders; even fewer feel prepared to intervene or discuss treatment.[15] In parallel, almost all family medicine program directors expect their graduates to be able to provide brief interventions for substance use disorder, but only one-quarter of programs have required addiction medicine curriculum, and less than half have an optional addiction medicine elective.[16] The same pattern is seen in family medicine clerkships, where 86% of clerkship coordinators feel it is important to offer opioid overdose prevention education, while only one-quarter of family medicine clerkships include the topic in their curriculum.[17]

To address this gap in training, the American Society of Addiction Medicine has co-sponsored the Medication Access and Training Expansion (MATE) Act which would require medical schools to include education on how to prevent, identify, treat, and manage patients with SUD. This change is expected to standardize addiction medicine education and remove the need for additional training to obtain the DATA waiver after graduation. Training medical students how to have informed conversations about drug use will produce more compassionate and informed physicians, regardless of future career plans. While some medical schools are increasing training in addiction medicine to ensure all students have certification for the DATA waiver prior to graduation, no such programs have been implemented in New York State, despite the continued rise in overdose deaths.[17] With an ever-increasing death count, our country cannot wait any longer for medical practitioners and educators to catch up to what public health research has been showing for decades: harm reduction strategies work, and medical professionals need to be trained in them.

Through our partnership with Project Safe Point, medical students have been able to serve a population often pushed to the outskirts of healthcare and they are learning practical ways of addressing their health needs through a harm reduction lens. As overdose deaths continue to rise in New York state, it is imperative that medical students and physicians incorporate evidence-based harm reduction strategies into their education and practice. As family physicians provide comprehensive and longitudinal care, we hope these harm reduction strategies will not only create a more open and caring clinical environment for patients, but also lead to better health outcomes and fewer preventable deaths.

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Leah Miller-Lloyd *is a fourth year medical student at Albany Medical College interested in family medicine/psychiatry. She is a co-founder of the Project Safepoint service learning program and has worked in harm reduction prior to attending medical school.*

BahiaZoe Wahba *is a fourth year medical student at Albany Medical College interested in internal medicine. She is a co-founder of the Project Safepoint service learning program.*

Jasmine Landry *is a third year medical student at Albany Medical Center. In addition to leading the Project Safepoint service learning program, she has done research on medical student perceptions of people who use drugs.*

Deborah Steinberg *is a second year medical student with an interest in addiction medicine who has been instrumental in continuing the Project Safepoint service learning program.*

Kara Burke, MPH *is the Director for Community Engagement in the Division of Community Outreach and Medical Education. She works on projects related to patient empowerment and medical education. She received her MPH from University of Albany with a concentration in social behavior and community health.*

Jose David, MD *is a family medicine trained physician who works as an addiction specialist in Albany, New York. Outside of his work in the community he is also involved in medical student mentorship and education.*

Upcoming Events

2020

March 15-16
Winter Cluster and Lobby Day
Albany, NY

May 16
Downstate Regional Family Medicine Conference*
NYU Winthrop Hospital, Mineloa

June 13-14
Congress of Delegates
The Desmond, Albany

2021

Jan 21-24
Winter Weekend
Saratoga Springs, NY

***Downstate Regional Family Medicine Conference**

CME conference with resident & student tracks

Date: May 16, 2020

Place: NYU Winthrop Hospital, Mineola

Topics include: LGBTQ+, Diabetes, Health Maintenance & Women of Reproductive Age, POCUS, Everything about Contraception, Stop the Bleed

More information at www.nysafp.org

Acupuncture for Chronic Pain:

Access Barriers and Implementation Strategies at a Community Health Center

By Anup Bhandiwad, MD, MS; Arya Nielsen, PhD; Hyowoun Jyung, MD; Mirta Milanes, MPH and Raymond Teets, MD

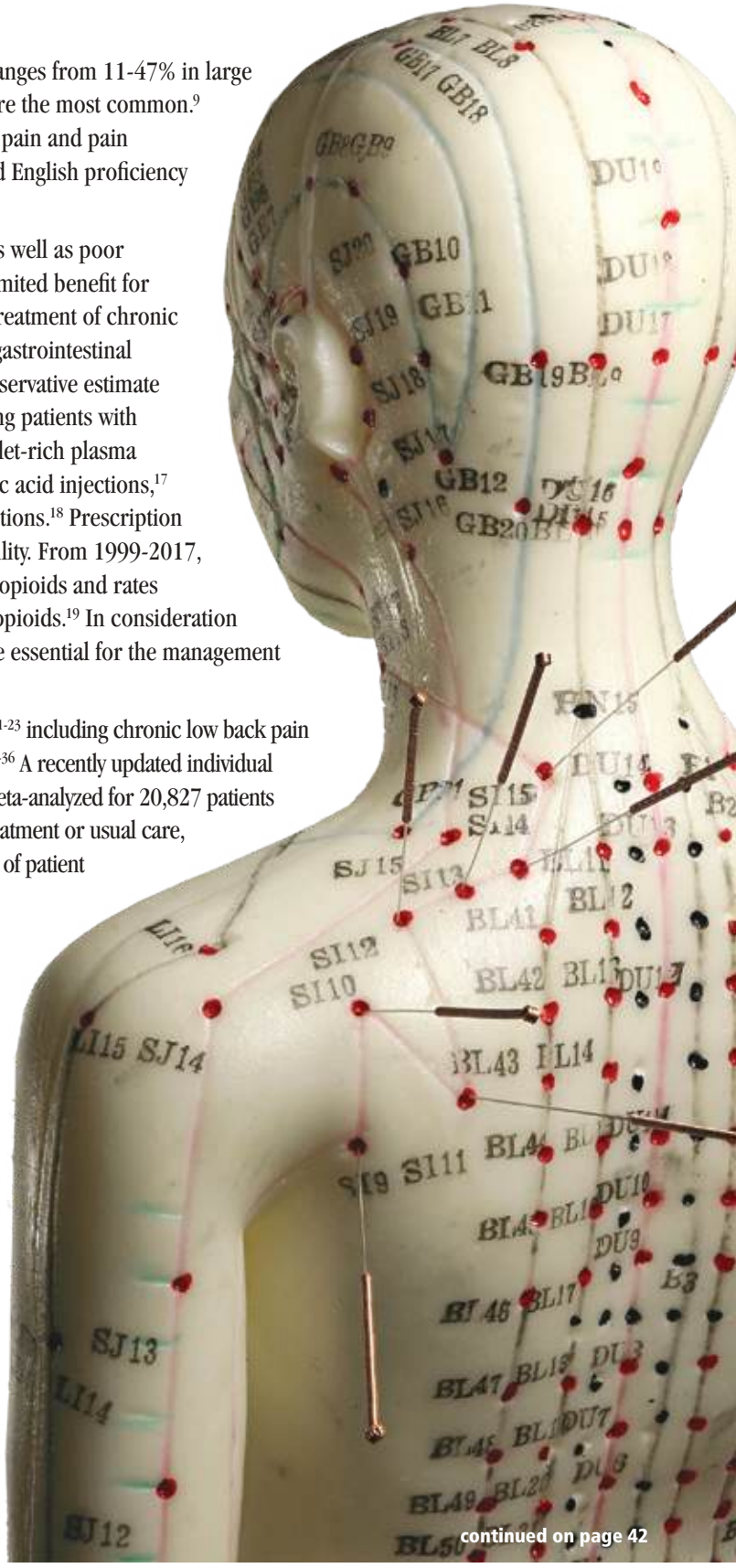
Background

The prevalence of chronic pain conditions in the adult U.S. population ranges from 11-47% in large surveys.[1-8] Low back and neck pain, osteoarthritis (OA), and headache are the most common.[9] Underserved and ethnically diverse populations are especially at risk for pain and pain undertreatment,[5,10-12] and these disparities are compounded when limited English proficiency impacts communication.[10]

Among the challenges in treating chronic pain are adverse effect risks, as well as poor outcomes with current pharmacological methods. Acetaminophen has limited benefit for knee OA per Cochrane review[13] and limited quality evidence overall for treatment of chronic pain.[14] Non-steroidal anti-inflammatory drugs risk harms with potential gastrointestinal bleeding, renal impairment, and cardiovascular risks.[12,15] In 1999, a conservative estimate showed 107,000 hospitalizations and 16,500 NSAID-related deaths among patients with rheumatoid arthritis or osteoarthritis every year in the USA.[16] While platelet-rich plasma injection therapy may provide benefit in knee OA compared to hyaluronic acid injections,[17] there is growing concern for tissue degradation with corticosteroid injections.[18] Prescription opioids are known to have a high adverse risk profile and addiction liability. From 1999-2017, there were nearly 400,000 drug overdoses in the United States involving opioids and rates continued to increase through 2017, including 47,600 deaths involving opioids.[19] In consideration of all of these concerns, safe and effective nonpharmacologic options are essential for the management of chronic pain in primary care practice.[12,20]

Acupuncture therapy is effective in the treatment of chronic pain conditions,[21-23] including chronic low back pain (cLBP),[24-27] neck pain,[27-29] shoulder pain and knee pain from osteoarthritis.[30-36] A recently updated individual patient data meta-analysis (2018), where original trial data was able to be meta-analyzed for 20,827 patients with chronic pain, found acupuncture to be significantly better than sham treatment or usual care, with only a 15% loss in treatment effect at one year.[30,37] Moreover, an analysis of patient characteristics for the same data cohort –whether age, gender, chronic pain duration, severity of pain at baseline or psychological distress moderated the effect of acupuncture treatment –found severity of pain at baseline was the only moderator of effect. That is, patients with more severe pain at baseline improved more from acupuncture treatment than those with lower levels of pain, compared to sham control or non-acupuncture control.[38]

Acupuncture therapy is supported or recommended as part of comprehensive pain care by the U.S. Agency for Healthcare Research and Quality,[39] the U.S Food and Drug Administration[40] and the Joint Commission.[41,42] The National Institutes for Health recommends acupuncture for cLBP and knee OA pain.[43] The American Academy of Family Physicians endorsed the American College of Physicians Guidelines recommending acupuncture as one first option for acute, subacute and cLBP.[44] An observational retrospective claims-based study supports conservative nonpharmacologic options wherein initial visits to chiropractors, physical therapists or acupuncturists for new onset LBP substantially decreased early and long-term use of opioids.[45] Likewise, active military service members who were able to access non-pharmacologic options, including acupuncture, for chronic pain, had reduced risk of long-term adverse outcomes.[46]



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However, there remain significant access barriers to evidence-based guidelines recommendations, generally.[47] Hence, 'dissemination and implementation' have become a focused effort by the NIH.[48] For access to acupuncture care there is ongoing discussion on implementation strategies in primary care and family practice settings.[49-51] This article will describe three separate implementation efforts at our community health center, highlighting utilization, successes and ongoing barriers.

Models of Care

In New York State, acupuncture can only be provided by either licensed acupuncturists (LAcs) or physicians certified in acupuncture (CAcs). Most states, including New York, require LAcs to complete an approved three-year program (1905-4,050 hours) for an entry level clinical master's degree and pass the national board exam[52] (Table 1 below - NCCAOM Practitioners). In 38 states, physicians may practice acupuncture without acupuncture specific training. Twelve states including New York, require a course of acupuncture specific training (up to 300 hours) for physicians to be 'certified'[53] (Table 1). Effective acupuncture care can be provided in an individual patient/provider setting or in a group setting in a facility's common room space.[54]

Table 1: Acupuncture Resources for New York State

New York State Office of the Professions Licensing for Acupuncturists: http://www.op.nysed.gov/prof/acu/acupunlic.htm
Finding NCCAOM Practitioners: https://www.nccaom.org/find-a-practitioner-directory/ (National Certification Commission for Acupuncture and Oriental Medicine)
New York State Office of the Professions Certification for Physicians: http://www.op.nysed.gov/acupuncert.htm
American Academy of Medical Acupuncture: https://www.medicalacupuncture.org/For-Physicians/Education/Ongoing-Courses-Colleges-and-AcupunctureSchools

Institute for Family Health (IFH) Initiatives:

The Institute for Family Health is one of the largest community health centers in New York State, serving over 115,000 patients annually at 31 locations with acupuncture services currently provided at two of the locations via primary care physician referrals. As a Federal Qualified Health Center (FQHC), IFH has significant numbers of patients covered by Medicaid (41.5% in 2018) and Medicare (11.1% in 2018), as well as some patients without insurance (12.68% in 2018). One-third of our patient population self-identifies as Black/African American and 35.7% as Hispanic/Latino.

Over the last two years, IFH has had 4 CAcs physicians providing acupuncture. Secondly, our organization has developed a collaboration with an accredited program, the Pacific College of Oriental Medicine (PCOM), where supervised acupuncture students provide care at our community health center. Thirdly, LAcs are providing care in a group setting within a feasibility trial evaluating group acupuncture and yoga therapy for chronic pain.

Methods

A retrospective chart review in our electronic medical record, EpicCare®, was conducted to identify the total number of patients seen, number of visits, demographics and insurance mix from the date range November 27, 2017 until November 11, 2019 for acupuncture care provided by CACs and supervised PCOM students. REDCAP data was obtained from the ongoing prospective clinical trial evaluating group acupuncture and yoga therapy from the start of the study until November 11, 2019 (just over 10 months) was collected.

Results/Discussion

The establishment of implementation initiatives to offer acupuncture therapy in our community health center has given providers a much needed, evidence-based option to treat chronic pain. Over approximately two years, 469 patients received 1597 visits for acupuncture treatment. Moreover, 56% of these patients either had Medicaid (49.5%) or were uninsured/self-pay (6.6%) (Table 2). Comparing our community health center patient population within New York City for 2018 with the patients who received acupuncture revealed comparable demographics amongst Black/African American (33.3% vs 33.6%) and slightly lower rates amongst Hispanic/Latino (35.7% vs 32.6%). Increased utilization of acupuncture was seen within our Medicaid (41.5% vs 49.6%) and Medicare (11.1% vs 21.1%) population, although lower rates were seen within our uninsured/self-pay population (12.7% vs 6.6%). With underserved and ethnically diverse populations especially at risk for pain and pain undertreatment,[10] this data suggests access is being provided without undue barriers and that acupuncture is an acceptable, utilized mode of treatment for our underserved patients.

Table 2: Patients, Visits and Insurance Information

	Number of Patients	Total Visits	Average Visit per Patient	Private Insurance		Medicaid/ Managed Medicaid		Medicare/ Managed Medicare		Uninsured/ Self Pay	
				Total	%	Total	%	Total	%	Total	%
PCOM	48	388	8.1	5	10.4%	28	58.3%	13	27.1%	9	18.8%
Physician Acupuncture	400	1081	2.7	106	26.5%	188	47.0%	84	21.0%	21	5.3%
GAPYOGA	22	129	5.9	2	9.1%	17	77.3%	2	9.1%	1	4.5%
Total	**470**	**1598**	**3.4**	**113**	**24.0%**	**233**	**49.6%**	**99**	**21.1%**	**31**	**6.6%**

Given that the barriers for access to acupuncture also include establishing credentialing standards and intra-cultural communication, we undertook the following implementation steps (Table 3):

Table 3: Steps for Acupuncture Implementation

1.	A credentialing process to establish qualifying physicians to have acupuncture added to their scope, and to credential LAcs within our institution. Work with human resources staff to establish credentialing that complied with New York State law regulating acupuncture practice.
2.	Considering the relative "cost" of patient care rooms at FQHCs, offer acupuncture services at times when fewer clinicians were providing primary care, e.g., evenings. Larger conference rooms were used for group acupuncture care. Group acupuncture requires a community space and storage for the equipment needed to deliver group care but allows for more flexibility in providing acupuncture to patients that doesn't burden individual patient care rooms.
3.	Recognizing that patients may find acupuncture services more acceptable in their medical care space, provide acupuncture services in the primary care setting.
4.	Provide in-service briefings on the evidence for acupuncture therapy and the background for providing this service in primary care settings
5.	Enlist the aid of IT to create documentation templates in the EMR (EpicCare® in our case) to comply with state law on documentation of acupuncture as part of the medical record, to facilitate communication among our acupuncture and medical providers and normalize acupuncture as an important aspect of care.
6.	Streamline referral for acupuncture care – with in-house services, we were able to process all referrals internally, with minimal burden on our referring providers.

Barriers still remain regarding implementation of acupuncture. Space and provider availability continue to limit access for our increasing demand, noted by our long waitlist for acupuncture services. Wide variation exists for insurance coverage for acupuncture therapy and among all payers for low back pain. A recent study found low likelihood of coverage mentioned for acupuncture (20%; 9 of 45 plans) and most plans explicitly did not cover it (67%; 30 of 45 plans).[55] Inter-professional difficulties also persist, where medical providers may be unaware of the current evidence for acupuncture therapy, and not understand the language and philosophy of this therapy which might, in turn, impact appropriate referrals. Still, our programs are highly accepted within our system by both staff and patients, and the demand by patients and referring providers to access the options we have created continually exceeds our capacity.

Conclusion

It is essential to continue to develop alternative options for safe and effective pain relief. Given the prevalence of chronic conditions and limitations with pharmacological methods, particularly the risks of opioids, acupuncture therapy can provide a safe, effective treatment option. Establishing creative, directed solutions regarding space, credentialing, documenting and primary care provider education can increase patient access to acupuncture therapy. Our FQHC has worked through these barriers to provide evidence-based, safe and effective options for chronic pain.

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***Anup Bhandiwad, MD, MS**, is currently an integrative medicine fellow at the Institute for Family Health in New York City and a board-certified family medicine physician having recently completed his residency at Mount Sinai Hospital in New York. His interests include underserved integrative medicine, access to care, mindfulness and culturally competent primary care.*

***Arya Nielsen, PhD**, is an associate clinical professor at the Icahn School of Medicine, Department of Family Medicine & Community Health. She is a board certified acupuncturist for over 40 years, inaugural board member and chair of the New York State Board for Acupuncture. Her research focus includes acupuncture therapy and evidence-based nonpharmacologic therapies for acute and chronic pain as well as facilitation of access in underserved communities.*

***Hyowoun Jyung, MD**, is an assistant professor at the Icahn School of Medicine, Department of Family Medicine & Community Health. She is a board certified family medicine physician with integrative medicine training and is certified in acupuncture in New York State.*

***Mirta Milanes, MPH**, is Clinical Research Coordinator for the Department of Family Medicine & Community Health at the Icahn School of Medicine at Mount Sinai, operated by the Institute for Family Health. In this role she hopes to expand access to integrative services to medically underserved communities. She is also the current program coordinator for the Integrative Medicine Fellowship and Interprofessional Program in Integrative Healthcare.*

***Raymond Teets, MD**, is faculty and Director of Integrative Medicine at the Mount Sinai Downtown Residency in Urban Family Medicine and Assistant Professor at the Icahn School of Medicine at Mount Sinai. He is an elected member of the Board of Directors for the Academic Consortium for Integrative Medicine and Health, representing the Icahn School of Medicine at Mount Sinai. Dr. Teets is the director of the Integrative Medicine in Residency (IMR) program.*

Lessons Learned from Taking Over Chronic Pain Management with Opioids from Other Clinicians

By Sachiko Kaizuka, MD; Gale Johnsen, MSN, PhD, FNP-C; Yoshiko Tamura, MD; Traci Salter, RN-BC, MS, FNP-BC; B. Wade Turnipseed, MS, LMFT and Arthi Chawla, MD

Introduction

Chronic pain is prevalent, affecting approximately 20 % of US adult population.[1] Due to the well-documented risks of chronic opioid treatment (COT) and the opioid overdose epidemic, and given primary care providers (PCP) prescribe the majority of opioids[2] the Center for Disease Control and Prevention released guidelines for COT for chronic, non-cancer pain for primary care providers in 2016.[3] The prescribing patterns are variable geographically and even within the same practice[4-6], and adherence to the guidelines is variable.[7] The guidelines place significant burden on PCPs. Managing chronic pain may contribute to burnout and stress in primary care settings, where clinicians often feel pressured and frustrated when caring for patients with chronic pain.[8]

Inheriting patients from a departing clinician within or from outside of a practice is a special scenario that many clinicians encounter in continuity practices.[9] However, there is little literature about best practice guidelines in terms of how to systematically approach this issue. This is especially true when dealing with a large number of new patients on COT.

A team-based approach to improving opioid management in primary care, "Six Building Blocks," has been studied with existing patients[10,11] and endorsed by Agency for Healthcare Research and Quality (AHRQ).[12] The authors describe the process of taking over new patients on COT and review each in comparison with the recommended building blocks. This article will conclude by adding suggestions to the Building Blocks to apply to these difficult clinical situations.

Six Building Blocks

A survey of 30 primary care practices across the United States, selected for their use of team-based workforce innovations, identified 6 attributes or practices that are important for clinics to improve COT prescribing. These 6 Building Blocks are now endorsed and promoted by AHRQ[12,13] to support PCP offices with management of patients on COT. These building blocks are (1) leadership support and developing consensus among clinicians about following the CDC guidelines; (2) standardization of policies/patient agreements/workflows; (3) patient registries to proactively track and monitor patient care; (4) planned, patient-centered visits; (5) identifying resources for complex patients; and (6) measurement of progress toward achieving clinic objectives. Other studies show similar, multi-component approaches are effective in improving guidance-concordant care.[14,15]

Examples

Four different practices of COT transition are described here, to illustrate the common themes and how small interventions can make differences. The first three practices experienced challenges initially; and recovered later on; the last case went smoothly. To respect the privacy of practices and clinicians, identifying information has been changed.

Common Background for all the Practices

Multi-clinician primary care clinics in New York State, with beloved and respected senior clinicians practicing for many years deciding to retire. However, retirement revealed that all the retiring clinicians had a high number of patients on COT above 90 morphine milligram equivalents (MME) per day and co-prescribing of benzodiazepines (BZD) in the practice. The practices had policies for controlled substances and patient agreements. However, it was left to the individual clinicians whether to perform various components such as urine testing, renewing or discussing the patient agreements, and prescribing naloxone to high-risk patients, and tapering of high doses. The number of these patients needing regular appointments exceeded the availability of the retiring clinicians. Hence, there were multiple patients with gaps in care such as regular urine tests, controlled substance agreements, and naloxone prescription. The general consensus among clinicians, including the leadership, was to adhere to the office policies, aligned with the CDC

guidelines. Pain clinics were available but at another location and not easily accessible. Medication-assisted treatment (MAT) with buprenorphine and behavioral health services for patients with mental health co-morbidities were available in the community.

Typical Patient

A 54- year old female patient with depression, anxiety, obesity, nicotine dependence, asthma, low back pain from past motor vehicle accidents, fibromyalgia and migraine headache, on long-acting oxycodone 80 mg twice a day, immediate-release oxycodone 30 mg four times a day, and alprazolam 1mg three times a day, in addition to other medications for asthma and an anti-depressant. She has not had naltrexone prescribed, has not signed a controlled substance agreement, and her last urine screening test was over two years ago. She is not receiving behavioral therapy as she says it "didn't work." She has never been to any local pain clinic. She is disabled and is not working and is under constant financial and social stress due to her daughter with substance use disorder and having to care for her grandchildren. The retiring clinician tried to reduce her opioid dose but she "did not do well" per chart review. She frequently calls the office the day when she runs out of her controlled substance prescriptions, sometimes demanding them done right away at the reception of the office.

Practice # 1

The retiring clinician tried to refer his COT patients to other practices, but other community practices did not have the capacity. The clinicians inheriting these patients were junior and fairly new to the practice and not used to management of COT. They experienced significant emotional distress from unpleasant interactions with anxious, worried or angry patients, to the point all of these clinicians eventually left the practice within several months. The staff were also emotionally stressed about interacting with these patients.

The practice's new leader recruited a team made up of the remaining clinicians and staff to address the transition. The goal of the new committee of providers was to reach consensus about how to manage these patients as a team, eventually hiring a nurse to be a liaison who would manage COT, tapering, addressing patients' concerns, check in with patients regularly, and troubleshoot. The process is ongoing but both the clinicians and the staff feel supported by one another and feel they are working as a team.

Practice # 2

There was some time between the senior clinician's retirement and the arrival of the new clinician who would inherit these patients. The existing clinicians renewed internal consensus, standardized the checklist for these patients in their electronic medical record, created the new workflow involving the nurses, medical assistants, and secretaries, to adhere to the office policy. They tried to improve the adherence to regular urine tests, documenting patient agreements, and scheduling regular appointments, while they bridged these patients' care. Tapering of the patient with high dose COT was left to the new clinician.

By the time the new clinician started practicing, many of these patients were "caught up" on urines, agreements, and appointment intervals. However, from working with a large number of the patients on high dose COT, the new clinician also experienced burnout, reduced his work to part time, and eventually resigned the practice within a year.

Practice #3

A new clinician to the practice inherited most of these patients without being informed about the type of patients the clinician was going to inherit. The new clinician immediately experienced "push back," anger and complaints from these patients, as the new clinician tried to endorse urine tests, controlled substance agreements, and naltrexone prescriptions for patients at high risk for respiratory suppression, which were all in the office policy. This caused significant distress to this new clinician to the point of considering resignation.

When the senior leader in the practice became aware of this situation, the more challenging patients were reassigned to other clinicians in the practice. Together this new clinician and the other clinicians in the practice started discussing the process as work for the whole team, rather than solely for this individual clinician. They openly discussed the consensus of following the office policy, support for one another, and the workflow at the staff meetings. As a result, the new clinician felt supported and was able to continue to practice.

Practice #4

Before the retirement, the transition of the COT patient was discussed among the leadership, retiring clinician, and the remaining clinicians. The leader announced the assignment of the highest dose patients to existing clinicians across the practice before the actual retirement. The retiring clinician, recognizing the importance of this new approach to COT, was supportive of the consensus of the remaining clinicians and staff about improving adherence to the office policy. The retiring clinician also worked on closing the gaps in care as much as possible before leaving.

Adherence to the office policy on urine tests, controlled substance agreements, and prescribing naloxone was straightforward for these patients as all were clearly documented in the policy and agreements. The clinicians repeatedly reiterated their agreement about adherence to policy and mutual support, and their pledge to work as a team. When junior clinicians were uncertain, more senior clinicians gave advice and supported decision-making.

The more challenging issues included the actual tapering process, how to change the patients' mindset from medications and procedures as

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the only solutions for chronic pain to a multi-dimensional, biopsychosocial approach, and how to address the non-standard indications of COT, such as for migraine headache, fibromyalgia and other non-specific musculoskeletal pain, as well as axial neck and low back pain, even when the dose of COT is less than 90 MME a day.

Discussion and Pearls

For the System

In each of these transitions, the 4 practices achieved all the "Six Building Blocks" including (1) leadership support, (2) standardized policies/patient agreements, (3) patient registries, and (4) planned, patient-centered visits, which included pre-visit huddling to identify gaps in care and conduct visits with more emphasis on function rather than just pain scale, (5) identified resources for complex patients; and (6) measured progress toward achieving clinic objectives. Many of the studied offices in the "Six Building Blocks" study actually used only 2 to 3 of them.[13]

Given that they met the criteria for all Building Blocks and most of the transitions still had challenges, we postulated there are other factors that are important to address in the transition of the COT patients. While large, systematic studies are needed, we identified the following characteristics that contribute to success:

1. The leadership identified the potential "pain points" early on, discussed the anticipated challenges and did some troubleshooting before the actual changes, similar to disaster preparedness.
2. The clinicians and the leadership discussed the transition as the work of the whole practice, rather than the few individual clinicians' responsibility.
3. The clinical team continued to meet, share concerns or problems, discussed solutions, and continued this process throughout the transition, to adjust to the new situations and address clinician/staff concerns.
4. The high-dose COT patients were not assigned to one or two clinicians, which would have been too stressful, as in practices 1-3.
5. A multi-component support system was developed which included the nurse liaison, nurses and medical assistants to proactively collect urine samples and prepare the patients for a controlled substance agreement renewal if noted during the huddle; this seemed to improve the adherence rate. Depending solely on the clinician for these necessary components of success is known to produce suboptimal outcomes in any quality improvement projects.
6. The clinicians taking over the high-dose COT patients were informed of upcoming changes so they could discuss the plan with their colleagues. When we are prepared, we can handle challenges, particularly when we have team support. Without fair warning, it can be challenging, as if we are in it alone.
7. When the retiring clinicians started the process of closing the gaps (urine, agreements, naltrexone) by either preparing the patients for tapering in the near future, or even better, starting the taper, it had a very positive effect, as there was minimal discrepancy between the clinicians. When retiring clinicians openly disagree with the care of the remaining clinicians and try to refer the patients out, returning patients were not sure who to trust, making the transition difficult.
8. Attention to the emotional burden on the clinicians taking care of a large number of these COT patients is crucial so we avoid losing clinicians to burnout. With frequent check-in with the clinicians, explicit support from the leadership, emphasis on a team-based approach, the new clinicians did not have to take this solely on themselves. Inheriting patients from a long-term clinician is challenging enough, and adding the stress of changing the provided care, particularly on COT, can create a significant level of confusion to the patients, and self-doubt and/or frustration in the new (or early-career) clinicians. Whenever possible, we propose avoiding assignment of a large number of these patients to a few number of clinicians, especially in their early careers.
9. Family clinicians tend to work alone and try to take care of everything by themselves. However, sharing the experiences with colleagues can be very liberating, and reassuring to know we are not alone, and that we share similar frustrations. This can lead to discussions about how to resolve some of the glitches. Team-based care presents the opportunity to provide patients with a "united front" regarding boundaries or specific rules about COT, decreasing the chance of splitting behaviors. A team approach can also help reduce the emotional burn out, improve morale and the sense of autonomy of the clinicians and staff. As more patients are now adherent with the CDC guidelines and office policies, there is less anxiety about covering for other clinicians for fear of having to authorize refills that are beyond what a clinician is comfortable with.
10. Early-career and more senior clinicians communicated frequently to check in and for mentoring regarding questions or challenging situations.
11. In the most successful transitions, the patients and new clinicians had early, open discussions about expectations and potential outcomes of care. In some cases, however, this resulted in patients being discharged for aberrant behaviors and disrespectful interactions with staff.

For Individual Clinicians

"Put on your oxygen mask first," as we cannot help others when we ourselves are in distress. When the necessary changes are getting stressful for the clinician and the patient, speak up early and ask for help.

Make this a team project; do not do the work alone. Discuss the practice consensus with your colleagues and leadership so you do not second-guess yourself when the patients do not like you for trying to provide appropriate and safe care.

For Residents

When taking on patients from graduating residents – similar pearls apply, but we recommend residency administration and clinical team leaders providing more help. Education about how to set healthy boundaries helps residents practice standard of care. It may be helpful to mandate the residents' patients on COT be caught up on policy adherence (urine etc.) before graduation. Start the appropriate discussion for tapering (or start the actual taper) before graduation so there is no discrepancy between two residents. Mandating the clinical summaries of the patients on COT (and other controlled substances) can help the new residents grasp the gestalt of each patient and more easily take over the care. As residents are not in the clinic very often, patients could go for months without being properly evaluated and reassessed for the conditions requiring COT. Sharing care with clinicians who are in the office more can also improve the regular appointment intervals and policy adherence.

For Leadership

- Start preparing early.
- Discuss and approach the transition as a team and create a workflow that does not depend only on clinicians.
- Inform the new clinicians of anticipated challenges and promote team discussion.
- Have alignment between departing and inheriting clinicians, pay attention to the clinician/staff wellbeing throughout the process, and make flexible adjustments as possible.

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Sachiko Kaizuka, MD *is Assistant Professor of Family Medicine at Highland Family Medicine in Rochester, NY. Dr. Kaizuka is a board-certified family physician and also board-certified in integrative medicine (ABOIM) and board-eligible in medical acupuncture (ABMA). She teaches an integrative approach in all aspects of health care but particularly to chronic pain. She is also a wellness representative of the family medicine department for the URMC Wellness committee, and a clinical suite leader at Highland Family Medicine, leading the recent transition of long-term clinicians.*

Gale Johnsen, MSN, PhD, FNP-C *is a family nurse practitioner with extensive experience in rural primary integrative care. She has taught primary and geriatric care curriculum in the graduate schools of University of New England, University of Southern Maine, St. Joseph's College and Simmons College, and currently works at a federally qualified rural health clinic in Maine, focusing on medication assisted treatment and recovery for patients living with substance use disorder.*

Yoshiko Tamura, MD *is a board-certified internist and pediatrician. She practices in a health-system owned family medicine practice with another med-peds physician, family medicine physicians, and advanced practice providers. Her clinical interests include health maintenance and vaccine management along the spectrum of life, chronic conditions, the impact of social factors and mental health on physical health, and travel medicine.*

Traci Salter, RN-BC, MS, FNP-BC *is an experienced nurse practitioner at Highland Family Medicine in Rochester, NY with prior experiences in pain medicine and board certified in pain management by the American Nurses Credentialing Center (ANCC). Since joining the department, she has been instrumental in the improvement of the guideline-concordant clinical care of our clinic, educating the faculty and residents, and in the transition of care of the clinical team.*

B. Wade Turnipseed, MS, LMFT *is a licensed marriage and family therapist providing patient care, as well as providing guidance on interpersonal relationships within the clinical team at Highland Family Medicine. He currently serves as Vice Chair of the controlled substance committee of the family medicine department and has been supportive of the transitions and improvement of adherence to the guidelines. His clinical interests include chronic illness (including chronic pain) and its impact on the family system, medically-unexplained symptoms, and medical family therapy.*

Arthi Chawla, MD *is a board-certified family physician and senior instructor of family medicine at Highland Family Medicine. She completed a faculty development fellowship and has been instrumental in the cultural changes of the clinical suite. She is also in charge of group visits at the family medicine department.*

Emerging Evidence of the Role of Cannabis in Chronic Pain Management and Opioid Use Disorder Treatment

By Joseph V. Mure MD, FAAFP and Michael Lillis LMHC-P

With the opioid epidemic at an all-time high many family health physicians may find their chronic pain patients looking to trade in their opioid prescriptions for a medical cannabis card. Although the New York State Department of Health allows medicinal cannabis to treat chronic pain and opioid use disorder, the efficacy of medical cannabis is not fully proven. Furthermore, with federal regulations halting a majority of prospective medical cannabis research, and with those struggling with opioid use facing risks of relapse and overdose, it is important for family physicians to know how cannabis may impact their patients' treatment. In this article, we review emerging evidence that suggest medical cannabis may be effective when used to minimize opioid medication for chronic pain patients while analyzing how medical cannabis may compound concerns in those suffering from opioid use disorders and may be a dangerous response to the opioid epidemic. Subsequently, we stress areas for continued research and discuss concerns family physicians and patients may have in utilizing medical cannabis as an alternate form of treatment for chronic pain or opioid use disorder.

The debate on utilizing medical cannabis as an effective way to treat both chronic pain and opioid use disorders has been ongoing amongst New York State physicians. On December 1, 2016, NYSDOH announced chronic pain as a qualifying condition for medical cannabis; opioid use was added as a qualifying condition on June 18, 2017, and by July 12, 2018, medical cannabis could be utilized as any form of opioid replacement. While The National Academies of Sciences, Engineering, and Medicine found good- to-fair quality evidence in support of utilizing cannabis for a modest effect on chronic pain in adults, they also found that there was no current evidence to support or refute the use of cannabis in maintaining abstinence for those with substance use disorders. There have been numerous research articles examining the interrelation of cannabinoid receptors and mu opioid receptors that suggest cannabis could be a novel therapy for opioid use disorders[1], however, these studies may obfuscate the dangers associated with utilizing medical cannabis to treat high-risk opioid addiction.

In order to understand the complex nature of how opioids interact with cannabinoids it helps to first understand the endocannabinoid system. The endocannabinoid system is an endogenous pain-processing system composed of cannabinoid receptors CB1 and CB2 as well as the endocannabinoid ligands anandamide (AEA) and 2-arachidonoylglycerol (2-AG). In addition to AEA and 2-AG, synthetic cannabinoids, and phytocannabinoids – or plant based cannabinoids including THC (tetrahydrocannabinol), CBD (Cannabidiol), CBN (cannabinol), CBG (cannabigerol), etc. – also bind to the CB1 and CB2 receptors.

These receptors are the major reason for the interaction between cannabinoids and opioids. Cannabinoid and opioid receptors have similar transduction pathways and both express in regions of the brain involved in antinociception. CB1 receptors were found to co-localize with mu-opioid receptors in the spinal cord at the first synaptic contact for peripheral nociceptive afferent neurons.[6,] CB2 receptors can indirectly stimulate mu- opioid receptors located in primary afferent pathways. A study in the mu- opioid receptors in rat spinal cords found anatomical evidence for presynaptic and postsynaptic localization of cannabinoid receptors in the spinal dorsal horn.[7] From laboratory animal testing to pharmacological studies, research suggests a synergistic interaction between cannabinoid and opioid receptors. All this research points towards the idea that in addition to having their own analgesic effect, cannabinoids could work synergistically to enhance opioid analgesia. Further research has found that certain phytocannabinoids (specifically THC) enhance the potency of opioids in animal models and that the analgesic effect of this phytocannabinoid is mediated through delta and kappa opioid receptors.

What this Means for Chronic Pain Management, the Opioid Epidemic, and why it Matters to NYS Family Physicians

By understanding these systems, we can see how cannabinoids could work to treat pain in similar ways as opioids. Chronic pain patients now have the option of reducing their opioid dosage and utilizing a form of medical cannabis in combination with a low dose opioid to maximize the opioid analgesic response. Another option is to forgo the opioid and manage pain solely on the analgesic response of the cannabis. When The National Academies of Sciences, Engineering, and Medicine conducted their investigation into cannabis, they evaluated five systematic reviews on whether cannabis was effective in the reduction of chronic pain. They found these five systematic reviews were all consistent in suggesting cannabinoids had a modest effect on pain and that the evidence supporting this finding was of "good-to fair quality."[2] Their investigation concluded that there is substantial evidence that cannabis is an effective treatment in chronic pain in adults.[2] The National Academies' publication specifically references a recent Michigan medical cannabis study that found chronic pain patients had a 64 percent reduction in opioid use while on medical cannabis. New York State takes a much more pharmaceutical and physician centered approach to medical cannabis than states like Michigan. In many states, medical cannabis patients have access to all parts of the cannabis plant and are left to make their own decisions on what type of cannabis and how to consume it. In New York State, medical cannabis patients are advised to take a specific ratio of THC to CBD which is administered in either a capsule, tincture, or vape pen. New York State is home to one of the largest

physician directed medical cannabis clinics in the country, DENT Neurologic Institute. Researchers at DENT have been tracking patients' opioid use and, in different studies, have found between a 30-50% reduction in opioid use.[3] However, opioid reduction while treating chronic pain does not equate utilizing medical cannabis as an alternate form of medication assisted treatment to treat patients struggling with opioid use disorder or opioid addiction.

Family physicians in New York State have the resources and ability to assist patients in managing chronic pain and reducing opioids through the use of medical cannabis. Unfortunately, a misperception of how cannabis works has led to potential dangers in treating patients that struggle with opioid addiction. A 2019 study from Stanford School of Medicine shows that while 2014 data suggested opioid deaths decreased by 21% in states with legalized medical cannabis, recent rates show this mortality has reversed to now show a 23% increase in overdoses in states with medicinal cannabis. Now, these trends are correlational but it does draw attention to the paucity of research in this area. NYS family physicians need to be especially cognizant of this due to NYS laws on medical cannabis; when the NYSDOH listed opioid use as a qualifying condition, it cited this now out of date research on opioid overdose deaths decreasing in medical cannabis states in 2014.[1] While, in theory, an individual using opioid medication as prescribed would be able to decrease a prescription opioid with use of medical cannabis, the same cannot be said of those addicted to illicit opioids with a high risk of overdose. The synergistic effects of opioids allow for less prescription opioids to treat the same level of pain. Unfortunately, due to this synergistic effect, if an individual addicted to an illicit opiate such as heroin were put on medical cannabis, they would need less heroin to achieve the same desired effect. While some might view this as a good thing, individuals addicted to opioids, especially those in early stages of change, may struggle to set that extra heroin aside. What is really happening is an increased risk of overdose. While there is very limited research in this area, there is a trend of patients struggling with opioid use disorder reporting an "increased high" when abusing both opioids and cannabis.

While many studies show medical cannabis could reduce opioid use in those individuals struggling with chronic pain, utilizing medical cannabis for individuals struggling with opioid addiction may be further placing them at an increased risk of overdose. Family physicians should be cautious in recommending medical cannabis for patients struggling with opioid use disorder. Given the nature of cannabis as a schedule I drug, many publications regarding its efficacy tend to be prospective, based in anecdotal evidence, or might not be peer reviewed. While the NYSDOH approved opioid use statement says that medical cannabis "greatly reduces the chances of dependence and eliminates the risk of fatal overdose compared to opioid-based medications" there is good reason to call that into question. For those struggling most in the opioid crisis, the synergistic effects between cannabis and opioids might lead to an increased rate of overdose and further worsen the opioid epidemic due to an ignorance of what we are recommending to our patients.

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Joseph V. Mure, MD, FAAFP *is an addiction medicine and family medicine physician in private practice as well as the Medical Director for Horizon Health Services Terrace House, an alcohol and drug treatment acute detox and residential rehabilitation center in Buffalo, NY. He is a Clinical Assistant Professor at the Jacobs School of Medicine and Biomedical Sciences in the department of family medicine and addiction medicine.*

Michael Lillis, LMHC-P *is a clinical mental health counselor with provisional license who has spent the past two years working at as a counselor in an inpatient substance use program with Horizon Health Services. Michael also works as a research assistant at Dent Neurologic Institute and is currently studying for licensure and board certification and is applying for PhD programs in counseling psychology.*

Collaborative Community Approach to

By Rubayat Qadeer, MD, AAHIVS

The opioid epidemic has killed more Americans over the last few years than gun violence – death rates are even higher than those due to HIV at the height of the AIDS epidemic.[1] While in recent years our public health response has improved, communities around the country are still in the throes of the opioid crisis.

My first glimpse into the epidemic was during residency training in rural Southwestern Pennsylvania. Cambria County has had increasingly high drug overdose death rates, and in 2017 had the highest mortality rate from overdoses of all counties in the state.[2] I saw firsthand the powerful role family physicians' play in addressing this epidemic. As an intern, our program director encouraged us to dispense naloxone widely, not only on hospital discharge to patients admitted for an opioid overdose, but also at visits to our health center by patients, families, or community members who were worried they would find an unresponsive family member or friend.

While doing an elective rotation at the Highlands Health free medical clinic, I advocated for a syringe exchange program to provide access to clean needles. There was initial resistance to these measures from unlikely sources that included nurses, emergency responders, and local police. However, over the course of the next few years, these "radical" ideas that our program had been championing became the standard of care, and were accepted as potential lifesaving measures by key stakeholders in the local community. This advocacy effort culminated in my last few months of residency, when I was an initial member of the Cambria County Drug Coalition, a collaborative effort to address the opioid epidemic by mobilizing local community advocates, policy makers, educators, law enforcement, and healthcare workers. Since then, despite the continued high overdose death rate, there has been a better public health response. I have no doubt that these measures, many of which were spearheaded by our residency program, have contributed significantly to this improved outlook.

One of the most moving encounters I had occurred in the middle of intern year, when I saw a patient after his urine test came back positive for amphetamines. EJ had been a heavy heroin user for about five years before he got help. It started when he was given approximately one hundred oxycodone tablets after breaking his wrist in an accident, and it spiraled out of control from there. Once he discovered buprenorphine therapy he managed to stabilize his life. He was back in school, getting his master's degree in social work and planning to start a family. Overall, he was doing well. His previous doctor had retired, and I had only been seeing him as a patient for a couple of months at that point. I was still unsure of the "correct" way to approach the situation that early on in my career, but I thought the best thing to do would be to bring it up in a quiet and nonthreatening way. I was still learning the basics of trauma informed care, but I could see him tense up and get defensive when I said the urine was positive for amphetamines. He was adamant that he had not used any illicit substances and could not figure out why the test came back positive. We tried to figure out if anything could have tainted his urine sample. Based on this conversation, he realized he had been taking supplements prior to working out every day, unaware that ingredients in these supplements could potentially interfere with the accuracy of urine drug testing. I told him that he should just stop taking them for now and we would follow up on the issue at his next visit. He conveyed surprise as he got up to shake my hand, and said, "You're the first doctor that didn't automatically accuse me of using." I was dumbfounded, thinking that I had not done anything special...I just trusted him and gave him the benefit of the doubt. It dawned on me that this minimal bit of respect was something that many patients with opioid use disorder often do not receive, not just from the healthcare system, but their own family and friends. That powerful moment of connection, centered around basic human dignity, is something that I often still think about.

Since completing residency, I have returned home to New York City. I currently work in the South Bronx, which, if considered as its own state, would have had an overdose rate in 2017 surpassed only by West Virginia.[3] The opioid problem is not new to this community. However, it is not discussed in the same way as in the "opioid belt" in rural parts of the country, because of the socioeconomic demographics of the Bronx. While NYC is rightfully known as a progressive haven when it comes to harm reduction, there continues to be stigma related to substance use in communities like the South Bronx. Furthermore, patients and families have limited access to naloxone at local pharmacies, as previously detailed by news outlets like the New York Times – despite the fact that NYC has standing orders in place to increase access of naloxone at pharmacies. It has been well documented that people have had difficulty obtaining naloxone from Bronx pharmacies in an appropriate and timely manner.[4]

Community stakeholders have also been divided on some harm reduction measures, as there continues to be pushback for building new treatment facilities in some communities where the epidemic has hit the hardest. There is also political momentum building against safe injection facilities, which have been proven to help reduce overdose deaths in other settings.[5] On the flip side, allowing clinics to register as an Opioid Overdose Prevention Program (OOPP) and decreasing barriers for primary care physicians to prescribe buprenorphine are strategies that could significantly prevent avoidable opioid-related deaths.

The effects of cultural stigma regarding opioid use, especially in minority communities, is something that resonates with my work in the

Bronx. Stigma is associated with personal feelings of guilt and limited family and community support. This can undermine individuals' abilities to remain substance free, as shown by the experience of JW, a young Latinx woman struggling with "on and off" heroin use who has been in my care for the past couple of years. She developed opioid use disorder by virtue of heroin always being around – in her neighborhoods, in the parties she went to, in the corners she walked by day to day. She had been attending a methadone clinic for the past year but going there on a daily basis and being regularly triggered by seeing heavy opiate users in withdrawal was becoming increasingly difficult for her. I transitioned her to buprenorphine, and she went through a period of about six months where she was off any opiates, and was doing well as a teacher's assistant in photography. Then during one visit, she walked in and burst into tears. "Dr. Qadeer," she told me, "I messed up." She told me she had a relapse, revealing that she been hiding her buprenorphine treatment from her husband because he did not approve, as he also had a history of opioid use disorder but had "gotten clean without using other drugs," as he told her. He had been pushing for her to get off methadone and did not realize she was coming to her primary care clinic for another avenue of medication assisted treatment (MAT). JW did not feel like she could utilize any of the support options around her, like the substance use counseling services, because her husband knew most of the people that either worked there or would attend. She felt incredible guilt just taking buprenorphine even though she recognized that it was helping her maintain some normalcy in her life. Taking buprenorphine proved to be too challenging for her though, and she has gone back to a methadone clinic as she acknowledged the need for a more regimented and structured treatment system. Her husband is slightly more supportive of her being in treatment now as well. I still check in with her as her primary care physician and she knows the door is always open if she ever wants to try MAT again in our clinic in the future. As primary care physicians treating opioid use disorder, we can recognize and acknowledge that patients will often have a turbulent journey to recovery that may entail several relapses along the way.

As someone who has worked in both rural and urban settings, it is clear that there is a lot of common ground among communities across the nation affected by the opioid epidemic. It is also understandable that community responses to the epidemic can be complicated and fractured, as harm reduction and treatment measures are not always embraced. Prior to graduating from residency, I sat in the audience at a town hall hosted by one of Johnstown's local news organizations, and was struck by how the experts that they had on stage included a district attorney, police chief, and even someone who was representing the White House, but no one from our local hospital was included on the panel, even though my medical director, who had been a strong champion for harm reduction efforts at the time, was sitting in the audience right next to me. We listened to a mother talk later on in the session about how she didn't approve of buprenorphine because it "killed her son", but no one was able to address her comment from a medical perspective.

In the Bronx, our district attorney is against opening a safe injection facility due to concerns of legality, even though there is evidence in other states and other countries regarding effectiveness for such measures.[6] Some people in our Bronx community also worry about finding more used needles in public spaces if there was an increase in access to needle-exchange services.

These experiences have crystalized the crucial role family physicians can have in addressing something as difficult and complex as the opioid crisis, whether it is in an urban, suburban, or rural setting. Understandably, from the outside looking in, harm reduction principles can seem counterintuitive to those not directly affected by the epidemic. However, effective strategies are available. Not only can we prescribe buprenorphine in our clinics or improve access to naloxone to prevent overdose deaths, family physicians have the ability to be community advocates for patients with substance use issues, a historically underserved medical population, as well as their families. We should be part of a coalition of community stakeholders who are addressing this deadly epidemic, and as beacons for the communities we serve, we are uniquely qualified to be leaders in this fight.

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Rubayat "Ricky" Qadeer, MD, AAHIVS *is currently a family physician in the South Bronx for Montefiore Medical Center and the Children's Health Fund, and is a clinical instructor at Albert Einstein College of Medicine. He graduated from DLP-Conemaugh Memorial Family Medicine in Johnstown, PA in 2017. He is an advocate for marginalized populations including families experiencing homelessness, people living with HIV, substance use populations, and immigrant families. He also serves as a mentor for underrepresented students seeking careers in medicine.*

Alcohol Withdrawal in my Office... Yes!

By Camille Bergeron-Parent, MD

In the last years, the opioid epidemic has caught a lot of medical and media attention. Organizations throughout the country have launched national campaigns on overdose prevention, safe injection sites, and other harm reduction strategies. While this is necessary work, let us not forget that a well established and widely popular substance is still the third cause of preventable death in the US. With an estimated 88,000 deaths in 2017 and 86.3% of Americans adults reporting drinking in their lifetime, alcohol is the most socially accepted addictive substance.[1]

We celebrate life achievements with alcohol; we drink when we are sad; there is always an excuse to crack open a bottle of beer or unscrew a bottle of wine. I left Canada to train as an addiction medicine fellow in New York City, and I must say I was stunned when I entered a pharmacy and saw that they were selling beer.

"Big Alcohol" – consisting of producers, distributors, retailers, and marketers of alcohol products – has made a great work at making us forget how harmful drinking is for our health. The public is generally aware of the harms caused by junk food or by cigarette smoke, but for alcohol, the "average" drinker is still portraited as a trendy and hip consumer. Like Big Tobacco, Big Alcohol uses effective marketing strategies to attract a younger clientele; colorful packaging and flavors are everywhere. Despite it being pictured as inoffensive, the NSDUH survey of 2017 reported 14.1 million adults with a diagnostic of Alcohol Use Disorder (AUD).[2] That is equivalent to 5.7 % of the American population age 18 and older.

It is Tuesday morning; you are doing your regular family practice clinic. The schedule is fully booked, as always. Before entering the next room, you review your patient's chart. Mr. X has alcohol use disorder (AUD). He scheduled an appointment because he will begin a rehabilitation program where he needs to be sober. You enter the room and notice that sweat is pearling on his forehead, and he appears anxious. Will you send him to the hospital to complete a "detoxification"?

Patients experiencing alcohol withdrawal can present in many health care settings in need of treatment. Indeed, what is called "detox" is no longer restricted to the inpatient unit. Non-traditional environments need to be prepared to evaluate, support and treat safely in the acute setting, and offer continuity of care to those patients.

Evaluation

When evaluating someone for medically supervised alcohol withdrawal in the office, providers should do a thorough examination. The first question we need to answer is, "Is this patient a candidate for outpatient alcohol withdrawal?" In other words, is he at risk of complicated alcohol withdrawal syndrome (AWS)? We define complicated AWS as the presence of withdrawal hallucinosis, seizures, and delirium tremens. Up to 90% of alcohol withdrawal will not progress beyond mild to moderate symptoms,[3] but for people at risk, if unrecognized, withdrawal can result in substantial morbidity. These patients need to be referred to a medical facility.

These questions can help guide the interview:

- *Confirmation of alcohol use disorder diagnosis?*
- *Duration of disorder?*
- *When was your last drink?*
- *How many drinks per day, and days per week?*
- *History of withdrawal seizure or delirium tremens*
- *Medical complications related to alcohol?*
- *Number of prior supervised withdrawal episodes?*

Questions to ask to Distinguish True Seizures, Delirium Tremens and Blackouts

Sign/Symptom	Example of question
Seizures	Has a healthcare professional told you that you've had a seizure in the past? Were you awake during the seizure? If they answer yes, it was probably not a seizure. Have you had consequences of having a seizure, e.g. driver's license removed, medication, neurologist visit?
Blackouts	Are there any periods of time while you were drinking that you don't remember? Have you ever woken up after consuming alcohol without remembering how you got to the place you were at?
Delirium Tremens	Have you ever been in the ICU or hospitalized for withdrawal? When do you remember experiencing hallucinations – after you stopped drinking or while you were drinking?

The "Prediction of Alcohol Withdrawal Severity Scale" (PAWSS – Table 1) is the first validated tool for the prediction of severe AWS and can help in the early identification of patients at risk. A score of less than four (< 4) is needed to proceed with an outpatient withdrawal. Absolute contraindications also need to be ruled out (see Table 2). In the presence of these conditions, patients should undergo the therapy in an inpatient setting.

Table 1:

Prediction of Alcohol Withdrawal Severity Scale (PAWSS)

Maldonado et al., 2014

Part A: Threshold Criteria: (1 point either)

1. Have you consumed any amount of alcohol (i.e., been drinking) within the last 30 days?

   OR did the patient have a "+" BAL upon admission? ____

   IF the answer to either is YES, proceed with test:

Part B: Based on patient interview: (1 point each)

2. Have you ever experienced previous episodes of alcohol withdrawal? ____
3. Have you ever experienced alcohol withdrawal seizures? ____
4. Have you ever experienced delirium tremens or DT's? ____
5. Have you ever undergone of alcohol rehabilitation treatment? ____

   (i.e., in-patient or out-patient treatment programs or AA attendance)
6. Have you ever experienced blackouts? ____
7. Have you combined alcohol with other "downers" like benzodiazepines or barbiturates during the last 90 days? ____
8. Have you combined alcohol with any other substance of abuse during the last 90 days? ____

Part C: Based on clinical evidence: (1 point each)

9. Was the patient's blood alcohol level (BAL) on presentation > 200? ____
10. Is there evidence of increased autonomic activity?

    (e.g., HR > 120 bpm, tremor, sweating, agitation, nausea) ____

Total Score: ____

Notes: Maximum score = 10. This instrument is intended as a SCREENING TOOL. The greater the number of positive findings, the higher the risk for the development of alcohol withdrawal syndromes. A score of ≥ 4 suggests HIGH RISK for moderate to severe AWS; prophylaxis and/or treatment may be indicated.

Completing the Clinical Institute Withdrawal Assessment-A Revised (CIWA-Ar commonly referred to as the CIWA) provides an efficient and validated evaluation of the severity of the withdrawal experienced by the patient. CIWA, a 10-item scale, should not be used as a diagnostic tool; the diagnosis of alcohol withdrawal is based on the clinical setting. The rest of the physical exam should focus on identifying signs of complications from alcohol (e.g., nystagmus, gait instability). Laboratory investigations and imaging can complement the assessment by giving us more information on alcohol consumption, liver damage, and other factors helpful for the subsequent follow-up.

Laboratory Investigations	Others Depending on Comorbid Conditions
Complete blood count Blood glucose Electrolytes Magnesium Calcium Phosphorus Liver Enzymes Urine drug screen Pregnancy test Alcohol levels	Chest X-ray Electrocardiogram Viral Hepatitis Immunodeficiency virus

Our patient denies any history of seizures or complicated withdrawal. His last drink was 2 days ago. He scores 4 on the PAWSS and 8 on the CIWA.

Treatment

When initiating an outpatient withdrawal, providers should discuss the need for a safe and supportive home environment; patients may need to take time off from work or other obligations. Regular check-ins, by phone or in person, are necessary in the first five days, where patients are still at risk of developing symptoms from the withdrawal state. In clinical settings, that could mean having nursing involved in the care of the patient and providing the patient with a phone number and/or email address to reach the team more easily. Transportation is often an issue, and we should ensure that they have a means of transportation to and from clinic. If possible, starting the treatment at the beginning of the week allows better access to medical support.

Benzodiazepines can be used to treat alcohol withdrawal – their pharmacological cross-tolerance with alcohol results in a similar effect on the GABA receptor. Alcohol creates its effects by binding to the GABA receptors in the brain and mimicking the effect of the GABA neurotransmitter. Usually, the brain is balanced between the inhibitory effects of GABA and the excitatory effects of glutamate on NMDA receptors. If chronically ingested over the years, alcohol forces the brain to adapt. GABA activity is suppressed by desensitizing the receptors, while NMDA receptors become more sensitive to glutamate. If alcohol intake is stopped abruptly, there is a relative deficiency in GABA and an increase in glutamate activity. These effects lead to overstimulation and excitability of the brain, which is expressed by increased psychomotor activity, anxiety, and a higher risk of seizures.

By targeting the GABA receptors, benzodiazepines help restore the balance and treat the symptoms.

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While hospitals are more and more adhering to a symptom-triggered approach, in the outpatient setting, benzodiazepines should be cautiously prescribed; a short-course fixed-dose taper regimen. Supportive care with pain reliever (acetaminophen), anti-emetics and anti-diarrheal can be used alone for patients who experience very minimal symptoms. In case of mild withdrawal (CIWA-Ar <10) providers can use non-benzodiazepines medications like gabapentin or clonidine. Gabapentin is particularly interesting because it has demonstrated efficacy at treating insomnia and anxiety symptoms as well as reducing mild to moderate withdrawal symptoms. Patients can start it during acute withdrawal and adjust the dose for relapse prevention. In withdrawal, 300 mg TID regular with additional doses for breakthrough symptoms can be prescribed on day one and tapered up or down depending on patient's response to treatment for a total of five days. Thereafter, the target dose for relapse prevention is 600 mg three times daily.

Benzodiazepines can put people at risk of overdose when taken at higher dose than prescribed or with other depressants like alcohol or opioids. They are contraindicated in patients with respiratory insufficiency, hepatic disease and sleep apnea. Safe use, signs of overdose and side effects should also be discussed with the patient and the family. To reduce the risk associated with benzodiazepines, prescribers can consider prescribing them as daily dispensed doses or asking a family member to administer.

When choosing a type of benzodiazepine, even if trials have shown they have similar efficacy, providers need to consider specific characteristics like half-life and onset of action. Because they show steadier blood levels, molecules with a longer half-life, like diazepam, are better at preventing seizures and are preferred. On the other hand, they might be riskier in elderly patients. Indeed, active metabolites accumulate and can cause sedation to which sicker and older patients are more susceptible. Time of onset can also be relevant if a rapid control of the symptoms is needed. Shorter-acting molecules, such as lorazepam or oxazepam, are the preferred choice for patients who have hepatic dysfunction, delirium dementia, or for patients with chronic pulmonary disease. A prescription for thiamine (100 mg daily) is used to lower the risk of Wernicke encephalopathy, and folic acid (1 mg daily) can be added for likely malnutrition. See Table 3 for examples of benzodiazepines regimens.

Mr. X presents with mild withdrawal symptoms (CIWA<10). From the discussion, you also learn that he lives with his wife, who does not drink and is a great support. He denies any history of pulmonary disease of hepatic disease. Benzodiazepines or gabapentin could be an option. You make the prescription and plan for him to come back the next day. You give him a phone number to call in case of emergency.

A successful medical withdrawal is not enough for treating AUD. It should never be used as a standalone therapy. Providers should organize for follow-up and continuity of care with their patients before even starting the outpatient regimen. People with AUD should be offered pharmacologic and nonpharmacologic therapies for relapse prevention. Medications, counseling and support groups combined with comprehensive primary care and psychosocial interventions are needed with these patients. In 2017, the NSDUH survey showed that only 6.5 percent of adults who had AUD in the past year received treatment.[4] Can you imagine if we had the same rate of treatment for other chronic conditions like diabetes or hypertension?

There are three FDA approved medications for the treatment of AUD; naltrexone (ReVia or Vivitrol), acamprosate (Campral), and disulfiram (Antabuse). In 2015, a review by the Agency for Healthcare Research and Quality (AHRQ) included 135 studies of treatment of AUD in ambulatory settings. They found moderate evidence for the use of naltrexone and acamprosate and insufficient evidence to support the use of disulfiram.[5]

Naltrexone and acamprosate are two medications that appear to be more effective at maintaining abstinence if patients are already abstinent from alcohol at the time of treatment initiation. Naltrexone is the first-line medication and can be prescribed while patients are still drinking. It exists as an oral and as an injectable formulation. It acts as an opioid antagonist and blocks the pleasurable effects of alcohol mediated by the endogenous opioid receptor system. A systematic review in 2014 found that naltrexone increased abstinence rates (NNT = 20) and decreased heavy drinking (NNT = 12).[6] It is usually well-tolerated, but side effects include nausea, headache and dizziness. If taken concurrently with opioids or opioid agonist therapy like buprenorphine or methadone, it can cause severe opioid withdrawal. Liver failure is another contraindication to naltrexone.

Acamprosate is thought to restore the brain balance by interacting with GABA and with glutamate at the NMDA receptor. The same systematic review showed that acamprosate could reduce the return to any drinking with a number needed to treat of 9 (NNT=9).[5] Safe for patients with liver disease, acamprosate is contraindicated in cases of renal failure. Its three times per day dosage makes it less practical from an adherence view point compared with naltrexone. Finally, the use of disulfiram causes unpleasant symptoms when alcohol is ingested by blocking alcohol metabolism which results in accumulation of acetaldehyde. It could be considered if patients are highly motivated, committed to abstinence and willing to have a family member dispense the medication to them to increase adherence rates.

Your patient does not have contraindications to either naltrexone nor acamprosate. You choose to start him on 50 mg daily of naltrexone. Using one of your smartphone applications, you help him find a fellowship meeting close to his home and encourage him to attend regularly.

Conclusion

Most patients presenting with alcohol withdrawal in the office can be managed in an ambulatory setting, but recognizing severe cases and patients at risk of complications is essential. Medical withdrawal should never be a standalone treatment for AUD, and maintenance of abstinence requires a multidisciplinary and patient-centered approach. While there is a need for improvement in recognizing and accessing therapy for AUD, we should keep in mind our roles as advocates on the public health scenes.

Table 2:

Contraindications to Outpatient Treatment of Alcohol Withdrawal Syndrome
Abnormal laboratory results
Absence of a support network
Acute illness
High risk of delirium tremens
History of a withdrawal seizure
Long-term intake of large amounts of alcohol
Poorly controlled chronic medical conditions (e.g., diabetes mellitus, chronic obstructive pulmonary disease, congestive heart failure)
Serious psychiatric conditions (e.g., suicidal ideation, psychosis)
Severe alcohol withdrawal symptoms
Urine drug screen positive for other substances

Muncie HL, Yasinian Y, Oge' L. Outpatient management of alcohol withdrawal syndrome. Table 2. Contraindications to Outpatient Treatment of Alcohol Withdrawal Syndrome, Am Fam Physician. 2013 Nov 1;88(9):589–95.

Table 3: Examples of Benzodiazepines Regimens

	Symptom-triggered	Fixed-dose tapered
Short acting	5-day Lorazepam Day 1: 2 mg q6 h PRN Days 2: 2 mg q6h PRN Day 3: 1 mg q8h PRN Day 4-5: 1 mg q 12h PRN	5-day Lorazepam Day1: 2 mg QID Day 2: 2 mg TID Day 3: 1 mg TID Day 4: 1 mg BID Day 5 1 mg HS
Long-acting	5-day with Diazepam Day 1: 10 mg q4h PRN Day 2-3: 10 mg q6h PRN Day 4-5: 10 mg q12h PRN	5-day with Diazepam Day 1: 10 mg QID Day 2: 10 mg TID Day 3: 10 mg BID Days 4 and 5: 10 mg HS

Muncie HL, Yasinian Y, Oge' L. Outpatient management of alcohol withdrawal syndrome. Table 4. Fixed and Symptom-Triggered Dosing for Oral Alcohol Withdrawal Medications Am Fam Physician. 2013 Nov 1;88(9):589–95.

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***Camille Bergeron-Parent, MD**, obtained her medical degree from the University of Montreal in Canada and completed her residency training in family medicine at McGill University Health Center Hospitals, mainly working in a small community clinic. She moved to New York to complete a fellowship in addiction medicine at the Institute for Family Health where she cares for patients with all kinds of addictions.*

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