WISAM Newsletter: Teleconference Minutes
February 23, 2017

Moderator: Aleksandra Zgierska (WISAM President; Madison)

Present: Dr. Aleksandra Zgierska (President), Dr. Matthew Felgus (President-Elect), Dr. Nameeta Dookeran (Chair, Educational Committee), Dr. Subhadeep Barman (Member, Educational Committee), Dr. William Gaertner (Member, Educational Committee), Dr. Joseph Blustein, Dr. Dan Sessler, Dr. Blaise Vitale, Dr. Gayl Hamilton; Dr. Robert Sedlacek, Dr. Ying Wong, John Weitekamp, RPh Matt Mabie, RPh, Randi Stouffer, PharmD.

Main topics addressed at tonight's teleconference:

Pharmacy Society of Wisconsin

Hometown Pharmacy

1. Naloxone pricing related issues

According to the CDC and Wisconsin Medical Examining Board guidelines, naloxone should be recommended to patients with opioid addiction and those treated with opioids who are at higher risk for overdose (due to: a) therapy with higher dose of opioids (≥50 morphine-equivalents/day); b) history of overdose; c) concurrent use of opioids and benzodiazepines or other sedating medications; c) diagnosis of an alcohol/drug use disorder; d) risk for returning to a high-dose use of opioids after a period of non-use, e.g., after release/discharge from monitored settings).

Unfortunately, recently, mirroring the increased demand for and use / prescribing of naloxone, its prices, especially for certain preparations, dramatically increased, bringing concerns for "egregious price hikes for profit." The ASAM, with Dr. Zgierska involved in this initiative, is working on putting forward a policy calling for the accountability of pharmaceutical companies when price hikes are noted (best BEFORE they are implemented) and condemning "for profit" approach to life-saving medications.

Currently, there are 3 major types of naloxone preparations available on the market: autoinjector (Evzio®); injectable; and nasal spray.

Autoinjector (Evzio®): The price of Evzio® rose recently from ~$600 to $4,500; even if the patient does not pay the full price (due to insurance coverage; rebates / coupons put forward by the company), this pricing makes this medication unaffordable. It usually requires a prior authorization (if it's even covered). Although its delivery (autoinjector – similar to epinephrine

autoinjector system) is very convenient for patients / first responders, **due to its cost, it is NOT a recommended first line medication** when prescribing naloxone.

Injectable naloxone: It comes in a package of 10 vials, which are usually sold together, as one package. Although the price per vial is lower, when purchasing as the whole "box," it's comparable to the nasal spray current pricing. It is not convenient for patients / rescuers to use, as the naloxone liquid has to be first drawn from the vial, before injecting. This limits its utility.

Nasal spray naloxone: The recommended and well-covered naloxone preparation is nasal spray (Narcan®, 4 mg/dose); it comes as a two-dose package. In terms of coverage / cost, here are some examples: Medicaid covers it with a $0-3 copayment; Care Wisconsin does not require copayments ($0 cost to the patient); commercial plans may require a ~$35 copayment. When purchasing out of pocket, the price typically does not exceed $150 for the two-pack, and is likely to be coming down.

New naloxone products: Some companies started manufacturing naloxone preparations that contain 2mg naloxone per dose; the general consensus among clinicians and first responders is that this is not optimal dosing, as the patient often requires more than one dose of 4 mg naloxone!

Proxy vs. "usual" prescribing of naloxone: The Wisconsin law and regulations allow the pharmacists (from the pharmacies that agreed to it) to administer naloxone to anybody who is asking for it under so-called "proxy prescribing" – a standing order from the physician leading our state's public health. The majority of pharmacies in Wisconsin are cooperating, so that, for example, a family member can go get naloxone even when the intent is to administer it to the family member.

Although "proxy prescribing" is very convenient (ie, patient / person does not need a prescription from their clinician) and represents a great advancement in how we approach a prevention of overdose, there are some caveats related to this practice. When the medication is picked up with the intent to be used for somebody else than the individual who is requesting it, then the pharmacist is not allowed to bill the insurance of that "other person." Therefore, if this is clear that naloxone is for somebody else, then there is no insurance coverage for it; with the current pricing of naloxone, it can make it unaffordable for many. However, many pharmacists implement a "do not ask, do not tell" policy so that they bill the insurance (under the proxy prescribing) of a person who is asking for naloxone, without asking further questions (for whom it is intended).

It is worth mentioning that patients / family members can receive naloxone for free, along with the training on how to use it, some counseling, help with linking to resources and putting in touch with "peer coaches" through the AIDS Resource Center of Wisconsin (http://www.arcw.org) – a great resource for patients and families!

Take home points about naloxone prescribing:

- Favor prescribing of the nasal spray as it is currently the best option.
- It is best to provide a prescription (to ensure that it is covered by the patient's insurance), however, sending a patient to the pharmacy to simply request naloxone is also possible under the proxy prescribing rule; the latter option depends on whether a given pharmacy "signed up" for the proxy prescribing, and coverage for depends on whether they use "do

not ask, do not tell" policy… (if the patient asks for it, then it is covered; if the family member asks for it, then it may not be covered…).
- Pharmacies often (so far) do not stock naloxone so patients may need to come in to pick up the following day.
- Recommend the AIDS Resource Center of Wisconsin a great resource for patients and families – they dispense naloxone for free…

2. Long-Acting Injectable Naltrexone (Vivitrol®) for Opioid Addiction

Vivitrol® can be prescribed and administered by any clinician with prescribing privileges, including primary care clinicians. No additional certification / training is required (this is different than for buprenorphine, prescribing of which requires a special training / waiver).

Vivitrol® can also be administered by a Pharmacist, when ordered by a clinician. This is a relatively new option, which can broaden access to this medication. Currently, HomeTown Pharmacy (represented at the tele-conference by Matt Mabie) is administering Vivitrol® (see below), and Medicine Shoppe (Monona Drive, Monona, WI) is gearing toward it.

With a valid prescription from the prescriber (who would have to perform due diligence in ensuring that the patient is ready / suitable for Vivitrol®), a patient could present to the pharmacy and have the injectable naltrexone administered by the pharmacist. Unfortunately, Medicaid is not covering the injection fee when administered by the pharmacist; in spite of that, to contribute toward improving opioid addiction-related outcomes in Wisconsin, many pharmacists are interested in doing it.

Hometown Pharmacy will be implementing and evaluating a collaboration with Alay Health company from Milwaukee who provides tele-medicine services, including counseling (www.AlayHealthTeam.org) that seems to be getting coverage from many insurers.

The patient will be able to either be referred for a Vivitrol® shot by his/her provider or be able to "seen" in a private assessment room (part of the pharmacy) by the tele-medicine clinician; point-of-care urine drug screen would be a part of the assessment process. The tele-medicine clinician would advise about the suitability for Vivitrol® and, if appropriate, provide counseling and prescribe Vivitrol® to be administered by the pharmacist.

As of now, the following Hometown Pharmacy locations are able and comfortable giving Vivitrol®: Waupaca, Beaver Dam, Oregon, Brodhead, Janesville, Sun Prairie, Fitchburg, Cottage Grove, Deforest, McFarland, Randolph, Poynette, Pardeeville, Rio, West Bend, Oshkosh, and Neenah. By the end of March, it is likely that all 48 locations will be able to handle it. It is best to check on the website: www.hometownpharmacywi.com, where they can search for locations nearest to them, to confirm if a given pharmacy is offering Vivitrol® administration and/or has tele-medicine addiction services.

Practice standards related to Vivitrol® treatment, especially its initiation: Clinicians seem to vary in how they approach the Vivitrol® therapy, especially the procedures leading to its initiation. Vivitrol® can be prescribed / utilized in primary care and specialty settings, and initiated on outpatient basis. The PCSS has issued a set of recommendations for Vivitrol® therapy initiation and management (**attached**); however, many clinicians across Wisconsin have slightly different patterns of practice that seem to be especially suitable for the outpatient primary care.

During the prior teleconference in January 2017, and this was echoed during this teleconference, several members voiced concerns about different practices used for the initiation of injectable naltrexone. Many of the clinician-members of WISAM often first start the therapy with oral naltrexone to take at home (ie, 12.5mg as the first test dose; if well tolerated, repeat in 2-3 hours; if well tolerated, take the remaining 25 mg in 2-3 hours, then 50mg daily until the scheduled Vivitrol® shot; if not well-tolerated, wait until the next day with the subsequent dose). It was felt that for patients using heroin, a minimum of 3-5 days should have elapsed (or at least until the patient has completed withdrawal) prior to initiation of naltrexone and this period is longer (10-14 days) for longer acting opioids such as buprenorphine or methadone (though some members discussed techniques to initiate naltrexone sooner).

Many clinicians start with oral naltrexone before administering it IM to ensure that naltrexone is well-tolerated before we a depo preparation is injected. The patient is counseled to start oral naltrexone at home. When to start naltrexone (the minimum number of days after the last opioid use), depends on the type of opioid they used. If they "cheat" and start too soon, and have some precipitated withdrawal (which, of note, is not too bad with 12.5mg dose – see below), they experience all these symptoms at home…

It is also to use naltrexone to "speed up" the process of opioid withdrawal; starting with very low doses (PO or SC) can precipitate some withdrawal but it is typically not overwhelming, especially with appropriate up-front counseling and anti-withdrawal medications. Some clinicians suggested using a very-low-dose naltrexone – this approach requires a compounding pharmacy. Hoey Apothecary (Cottage Grove Rd; http://www.hoeyrx.com/) can compound naltrexone and, of note, has been promoting a low-dose naltrexone as a treatment for a variety of ailments, including chronic pain. Many do not prescribe a compounded very-low-dose version; it is cheaper to use Revia® (eight- or fourth- of a 50 mg tablet) than to prescribe a compound medication or administer a SC naloxone challenge.

This process before the Vivitrol® administration is typically supplemented with anti-withdrawal medications as needed; they usually do NOT include benzos.

Drs. Zgierska, Barman, Dookeran, Sessler, Stouffer and Hall (Ted Hall agreed to do it during the prior tele-conference) will work on the summary of recommendations for Vivitrol® therapy management that are applicable to primary and specialty care and to pharmacy-provided Vivitrol® administration in Wisconsin.

Reminder: register for the ePDMP

All prescribers need to register for the new Wisconsin ePDMP at https://pdmp.wi.gov/. Beginning April 1, 2017, it will be mandatory for all prescribers to query the ePDMP prior to issuing a prescription for any controlled substance except under the following circumstances: (2015 Wisconsin Act 266):

a. The patient is receiving hospice care, as defined in s. 50.94 (1) (a).
b. The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.
c. The monitored prescription drug is lawfully administered to the patient.

d. Due to emergency, it is not possible for the practitioner to review the patient's records under the program before the practitioner issues a prescription order for the patient.
e. The practitioner is unable to review the patient's records under the program because the digital platform for the program is not operational or due to other technological failure if the practitioner reports that failure to the board.

New addiction treatment programs in Madison

New (upcoming) federally-licensed opioid addiction treatment program
A new federally-licensed treatment program will be opening soon (likely in March 2017) offering methadone, buprenorphine and naltrexone for opioid addiction. It will be located in Madison (third "methadone" program in town) in the location of the former Madison Health Services on E Washington Ave, with Dr. Blustein as the Medical Director. Clinicians will be able to refer patients for a full-spectrum care or for injectable naltrexone administration.

New, private buprenorphine/family medicine clinic in Madison
Recently, Dr. Gayl Hamilton (former medical director of one of the local methadone/buprenorphine maintenance programs) opened a private buprenorphine / family medicine clinic in Madison (info: www.facebook.com/TheArtOfMedicineNaturally, 2317 International Ln., Suite 120, Madison, WI 53704, (608) 720-1500).

Meeting adjourned at 8:02 PM.

The next WISAM Teleconference will occur on Thursday, March 23, 2017, 7-8 PM.

Please let Cindy Burzinski, WISAM's Executive Administrator, know if you have suggestions for topics to discuss at the upcoming teleconferences or to consider for the 2017 Annual Conference, or if there are any errors in the current document: Cindy.Burzinski@fammed.wisc.edu

IMPORTANT REMINDERS

Please remember to **renew your ASAM / WISAM membership** or consider becoming a member (open to all clinicians). More details can be found at: http://www.asam.org/membership

Please mark your calendars for the **ASAM's 48th Annual Conference** on April 6-9, 2017 in New Orleans (http://www.asam.org/education/live-online-cme/the-asam-annual-conference).
The WISAM meeting at this conference will be held on Friday, Apr 7, 1-2 PM.

Please mark your calendars for the **WISAM 2017 Annual Conference** on September 14-16, 2017 at the Pyle Center, Madison, WI (Thu and Fri: variety of educational topics and workshops; Sat: buprenorphine / Probuphine® training).

RESOURCES
TO ENHANCE CLINICAL CARE RELATED TO ADDICTION MEDICINE

FREE CSAM Webinars
These live webinars are FREE for all clinicians (4th Fri of the month, 12-1 PM PST). Current series of 12 monthly webinars is designed to support the implementation of Medication Assisted Treatment (MAT) in primary care. In general, CSAM (California Society of Addiction Medicine) offers great resources, available at: http://cme.csam-asam.org/content/buprenorphine-resources#overlay-context=courses

FREE Provider's Clinical Support System (PCSS) for Medication-Assisted Treatments (PCSS-MAT: http://pcssmat.org) and Opioid Prescribing (PCSS-O: http://pcss-o.org): excellent free resource, funded by a grant from SAMHSA; it offers free webinars available "real-time" or via the archived library. One can sign up for regular news emails from them.

FREE David Mee-Lee's monthly Tips and Topics, sent via email (one needs to sign-up to it), it is an excellent resource:
dmeelee@changecompanies.net
http://www.changecompanies.net

FREE Join Together Daily News is a news service from the Partnership for Drug-Free Kids that provides daily or breaking news on the top substance abuse and addiction news that impacts our work, life and community. It also provides original reporting and/or commentary features published every Wednesday by influential thought leaders in the addiction field or staff.
http://www.drugfree.org/join-together/

PAID The Carlat Report: Addiction Medicine (however, it appears to be a paid resource, ~$109/year); a link to the copy of the recent report is attached so that you can get a flavor of what it is: http://carlataddictiontreatment.com/sites/default/files/CATR_May2016.pdf

The National Academy of Sciences (IOM) Recent Report on Cannabis

"*The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*" was published in Jan 2017; free copy is available for a limited time at the following web site:
https://www.nap.edu/login.php?record_id=24625&page=https%3A%2F%2Fwww.nap.edu%2Fdownload%2F24625.

a. The report's tone is generally favorable toward use of cannabis as medicine despite not-so-convincing evidence on some of the recommendations.
b. The report is surprisingly sparse on discussing potential adverse effects of cannabis and cannabinoids (in general).
c. The report makes recommendations regarding the need for more research.
d. Provides should familiarize themselves with the report as patients (and other professionals) are likely to ask questions about this issue.

e. It’s worth remembering that marijuana use is illegal in Wisconsin; professional societies, including the ASAM/WISAM, overall do not endorse its use (as a plant) for medicinal purposes due to lack of convincing evidence for effectiveness, while, at the same time, presence of evidence for harms, including addiction (as outlined in a recent ASAM’s white paper on this topic); cannabis produces sedating effects, which can potentiate sedating effects of other substances, eg, opioids.