Recognizing & Treating Opioid Dependence in your Clinic

Abdulhassan Saad M.D.
Beaumont Hospital

www.saadmd.com

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Medical Clinic

DISCLOSURE

Dr. Saad is compensated by ALKERMES, Inc. for periodic speaking engagements discussing Vivitrol® and other M.A.T. options.

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GOALS

1. Identify patients in clinical setting with an opioid use disorder
2. Provide treatment options once diagnosed
3. Properly manage Medication Assisted Treatment in outpatient setting

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Self Assessment Questions

1) Name one screening tool used to better diagnose/treat opioid use disorder.

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Self Assessment Questions

2) Name the three types of medications prescribed for treatment of opioid use disorder.

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Self Assessment Questions

3) Name two strategies used to successfully monitor patients on Medication Assisted Treatment.

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Overview

- Epidemiology
- Primary Care stats
- Identifying use disorder
- Mechanism of Action
- Treatment options

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Epidemiology

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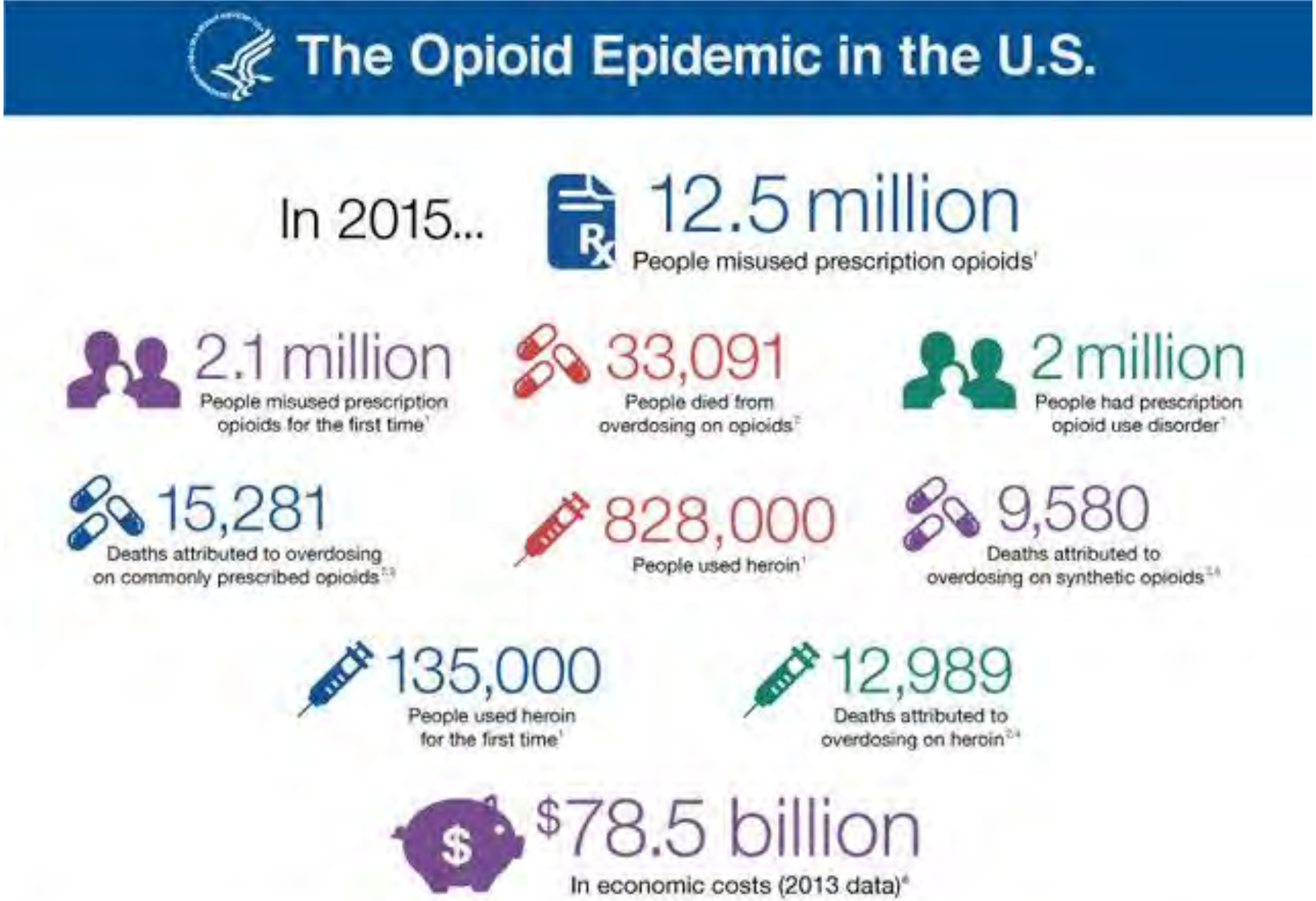
The Opioid Epidemic in the U.S.



Sources: [1] 2015 National Survey on Drug Use and Health (SAMHSA). [2] MMWR. 2016; 65(50-51):1445–1452 (CDC). [3] Prescription Overdose Data (CDC). [4] Heroin Overdose Data (CDC). [5] Synthetic Opioid Data (CDC). [6] The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Florence CS, Zhou C, Luo F, Xu L. Med Care. 2016 Oct;54(10):901-6.

More than 63,000 Americans died from a drug overdose in 2016.

See the full report to see the rates by state.

@CDCInjury

www.cdc.gov

Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least 1 other drug.

Most used at least **3** other drugs.

Heroin is a highly addictive opioid drug with a high risk of overdose and **death** for users.

People who are addicted to...

ALCOHOL

are

2x

MARIJUANA

are

3x

COCAINE

are

15x

Rx OPIOID PAINKILLERS

are

40x

...more likely to be addicted to heroin.

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.

Primary Care Stats

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Around

40%

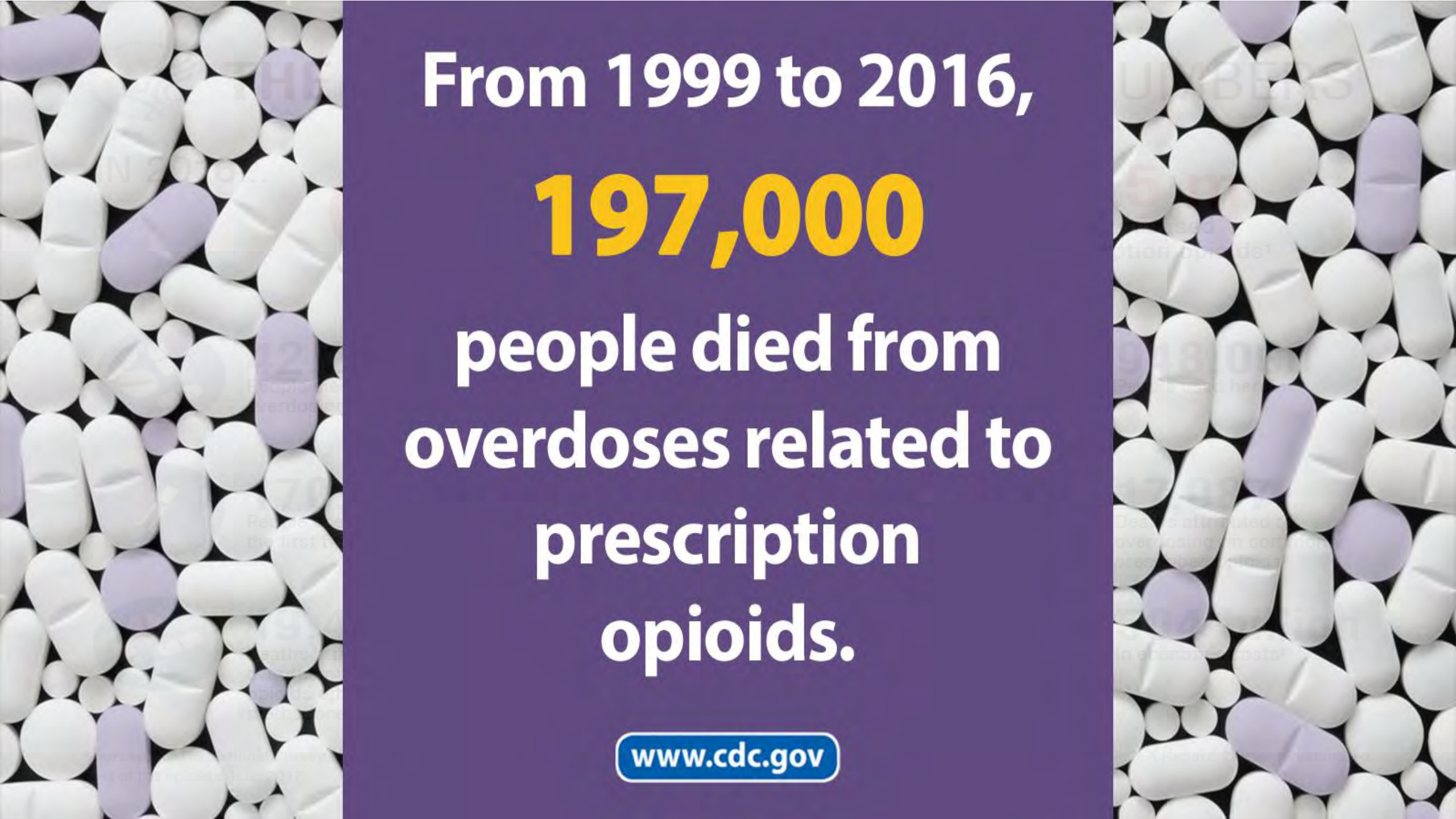
of all opioid overdose deaths involve a **prescription opioid**.

As many as

1 in 4

PEOPLE

receiving prescription opioids long term in a primary care setting struggles with **addiction**.


From 1999 to 2016,
197,000
people died from overdoses related to prescription opioids.
www.cdc.gov

Identifying patients with opioid use disorder

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Signs of a potential opioid use disorder

- Self-reported risk factors (ORT)
- Opioid withdrawal symptoms (COWS)
- Recent opioid emergency or overdose
- Opioid seeking or diversion behavior (MAPS,UDS)

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Tools

- Opioid Risk Tool (ORT)
- Objective Opiate Withdrawal Scale (OOWS)
- Clinical Opiate Withdrawal Scale (COWS)
- Michigan Automated Prescription System (MAPS)
- Urine Drug Screen (UDS)

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Opioid Risk Tool (ORT)

Mark each box that applies:		Female	Male
1	Family history of substance abuse		
	Alcohol	☐ 1	☐ 3
	Illegal drugs	☐ 2	☐ 3
	Prescription drugs	☐ 4	☐ 4
2	Personal history of substance abuse		
	Alcohol	☐ 3	☐ 3
	Illegal drugs	☐ 4	☐ 4
	Prescription drugs	☐ 5	☐ 5
3	Age (mark box if between 16-45 years)	☐ 1	☐ 1
4	History of preadolescent sexual abuse	☐ 3	☐ 0
5	Psychological disease		
	ADD, OCD, bipolar, schizophrenia	☐ 2	☐ 2
	Depression	☐ 1	☐ 1
	Scoring totals:	_____	_____

Administration

- On initial visit
- Prior to opioid therapy

Scoring

- 0-3: low risk (6%)
- 4-7: moderate risk (28%)
- ≥ 8: high risk (> 90%)

Webster, et al. Pain Med. 2005;6:432.

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MAPS and Urine Drug Testing (UDS) why?

- Confirm compliance to a treatment plan
- Rule out other substances of abuse (poly-substance abuse)
- Uncover potential contraindications
- Combat diversion
- Protect prescribers and pharmacists from fraud

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MAPS

Support: 844-364-4767

C W , 38M

Narx Report | Resources

Date: 10/18/2018

Print Report Download CSV

[redacted]

Risk Indicators

NARX SCORES

Narcotic	Sedative	Stimulant
470	220	000

OVERDOSE RISK SCORE

680

(Range 000-999)

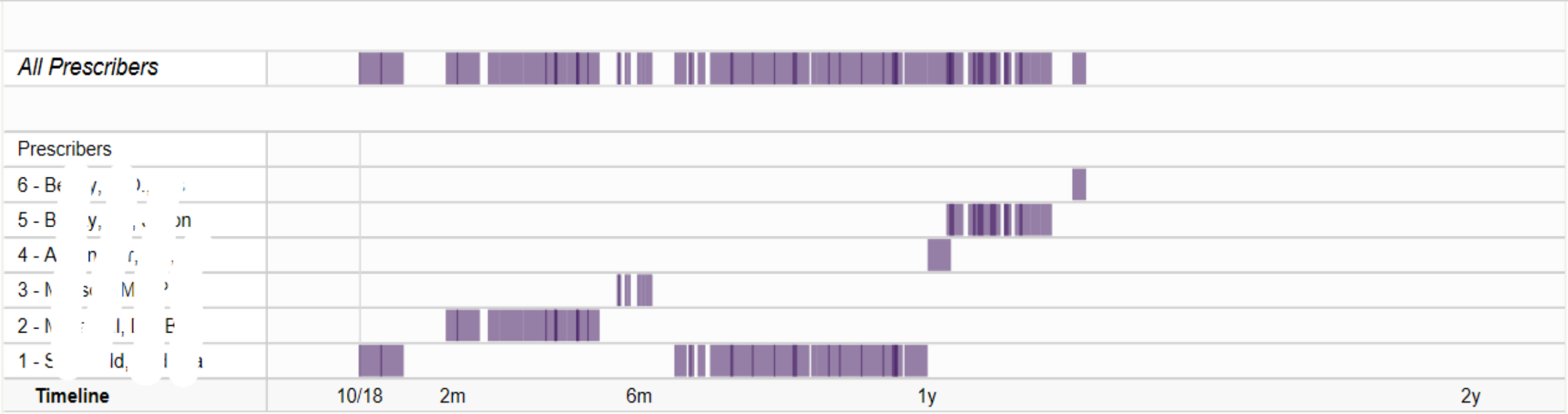
ADDITIONAL RISK INDICATORS (3)

- >= 4 opioid or sedative dispensing pharmacies in any 90 day period in the last 2 years
- >= 5 opioid or sedative providers in any year in the last 2 years
- > 100 MME total and 40 MME/day average

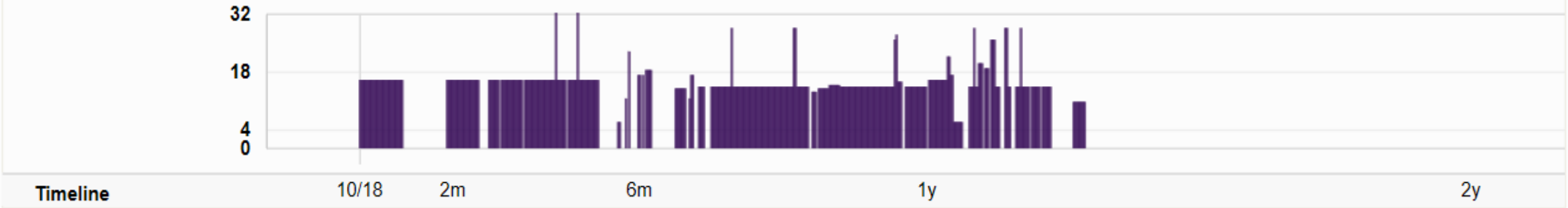
Explanation and Guidance

Explanation and Guidance

Explanation and Guidance



Buprenorphine mg



*Per CDC guidance, the MME conversion factors prescribed or provided as part of the medication-assisted treatment for opioid use disorder should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain. Buprenorphine products have no agreed upon morphine equivalency, and as partial opioid agonists, are not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids. MME = morphine milligram equivalents. LME = Lorazepam milligram equivalents. mg = dose in milligrams.

Summary

Summary
Total Prescriptions: 56
Total Prescribers: 6
Total Pharmacies: 8

Narcotics* (excluding buprenorphine):
Current Qty: 0
Current MME/day: 0.00
30 Day Avg MME/day: 0.00

Sedatives*
Current Qty: 0
Current LME/day: 0.00
30 Day Avg LME/day: 0.00

Buprenorphine*
Current Qty: 0
Current mg/day: 16.00
30 Day Avg mg/day: 16.00

Rx Data

PRESCRIPTIONS

Total Prescriptions: **56**
Total Private Pay: **8**

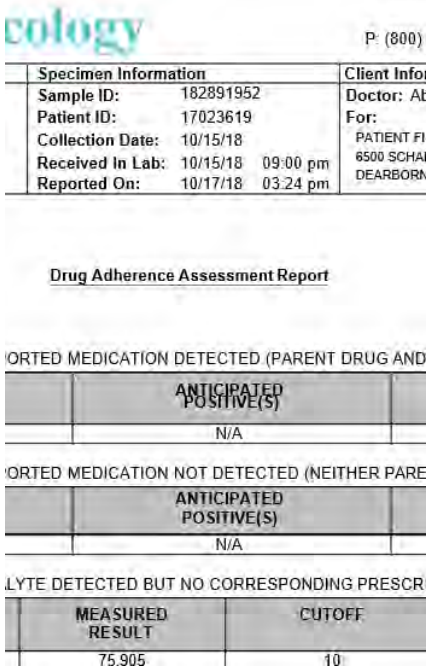
Fill Date	ID	Written	Drug	Qty	Days	Prescriber	Rx #	Pharmacy	Refill	Daily Dose *	Pymt Type	PMP
10/04/2018	3	10/04/2018	BUPRENORPHIN-NALOXON 8-2 MG SL	28	14	AE	14	N	0	16.00 mg	Medicaid	MI
09/20/2018	3	09/20/2018	BUPRENORPHIN-NALOXON 8-2 MG SL	28	14	AE	1	N	0	16.00 mg	Medicaid	MI
08/16/2018	3	08/16/2018	SUBOXONE 8 MG-2 MG SL FILM	14	7	BF	00	W	0	16.00 mg	Medicaid	MI
08/02/2018	4	08/01/2018	SUBOXONE 8 MG-2 MG SL FILM	28	14	BF	11	R	0	16.00 mg	Medicaid	MI
07/20/2018	4	07/20/2018	BUPRENORP-NALOX 8-2 MG SL FILM	14	7	BF	05	R	0	16.00 mg	Medicaid	MI
07/05/2018	4	07/05/2018	BUPRENORP-NALOX 8-2 MG SL FILM	28	14	B	0	RI	0	16.00 mg	Medicaid	MI
06/20/2018	4	06/20/2018	SUBOXONE 8 MG-2 MG SL FILM	28	14	BF	0	R	0	16.00 mg	Medicaid	MI
06/14/2018	4	06/13/2018	SUBOXONE 8 MG-2 MG SL FILM	12	6	BI	059	R	1	16.00 mg	Medicaid	MI
06/13/2018	4	06/13/2018	SUBOXONE 8 MG-2 MG SL FILM	2	1	BI	059	RI	0	16.00 mg	Comm Ins	MI

Urine Drug Testing (UDS)

Point of Care Testing- *Subjective*
immediate results

Chromatography – *Objective*

Discrete data results in a few days



cology P: (800)

Specimen Information			Client Info
Sample ID:	182891952		Doctor: Ab
Patient ID:	17023619		For:
Collection Date:	10/15/18		PATIENT FI
Received In Lab:	10/15/18	09:00 pm	6500 SCHA
Reported On:	10/17/18	03:24 pm	DEARBORN

Drug Adherence Assessment Report

ORTED MEDICATION DETECTED (PARENT DRUG AND

	ANTICIPATED POSITIVE(S)	
	N/A	

ORTED MEDICATION NOT DETECTED (NEITHER PARE

	ANTICIPATED POSITIVE(S)	
	N/A	

LYTE DETECTED BUT NO CORRESPONDING PRESCR

MEASURED RESULT	CUTOFF
75.905	10

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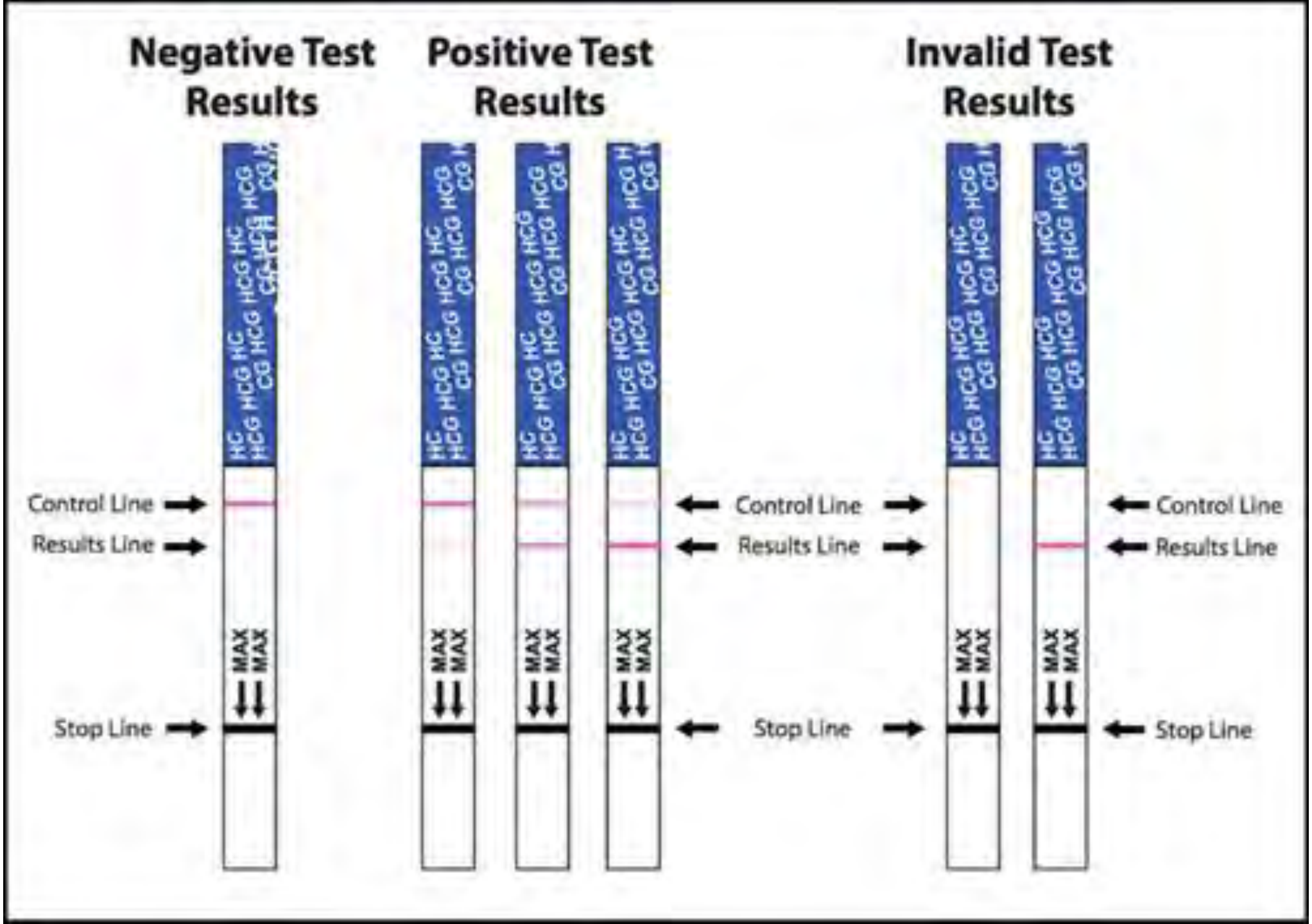
Negative Test Results
Positive Test Results
Invalid Test Results
Control Line
Results Line
Stop Line
HC HCG HCG HC CG HCG HCG
MAX MAX

Final

Prime Toxicology, LLC
28266 Franklin Rd, Suite B
Southfield, MI 48034
P: (800) 901-9077 F: (800) 980-4077

Patient Information	Specimen Information		Client Information
Name:	**Sample ID:** 182891952		**Doctor:** Abdulhassan Saad
Birth:	**Patient ID:**		**For:**
Gender: F	**Collection Date:** 10/15/18		PATIENT FIRST MEDICAL CLINIC
	Received In Lab: 10/15/18	09:00 pm	6500 SCHAEFER
Phone:	**Reported On:** 10/17/18	03:24 pm	DEARBORN, MI 48126

Drug Adherence Assessment Report

Benzodiazepines							
2-Hydroxyethylflurazepam	Negative		20	ng/mL	5 - 7 days		Consistent
Cocaine							
Benzoylecgonine	Negative		50	ng/mL	1 - 2 days	Y	Consistent
Buprenorphine Panel							
Buprenorphine	Positive	75.905	10	ng/mL	1 - 3 days		Inconsistent
Norbuprenorphine	Positive	607.678	20	ng/mL	2 - 4 days		Inconsistent
Fentanyl							
Fentanyl	Negative		10	ng/mL	1 - 3 days		Consistent
Norfentanyl	Negative		10	ng/mL	1 - 3 days		Consistent
Heroin							
6-MAM	Negative		10	ng/mL	1 - 2 days	Y	Consistent
Methadone							
EDDP	Negative		20	ng/mL	1 - 14 days*		Consistent
Methadone	Negative		20	ng/mL	1 - 14 days*		Consistent
Methylenedioxyamphetamines							
MDMA	Negative		20	ng/mL	1 - 2 days	Y	Consistent

Fentanyl						
Fentanyl	Negative	10	ng/mL	1 - 3 days		Consistent
Norfentanyl	Negative	10	ng/mL	1 - 3 days		Consistent
Heroin						
6-MAM	Negative	10	ng/mL	1 - 2 days	Y	Consistent
Methadone						
EDDP	Negative	20	ng/mL	1 - 14 days*		Consistent
Methadone	Negative	20	ng/mL	1 - 14 days*		Consistent
Methylenedioxyamphetamines						
MDMA	Negative	20	ng/mL	1 - 2 days	Y	Consistent
MDEA	Negative	20	ng/mL	1 - 2 days	Y	Consistent
MDA	Negative	50	ng/mL	2 - 4 days	Y	Consistent
Methylphenidate						
Ritalinic Acid	Negative	20	ng/mL	1 day		Consistent
Muscle Relaxant						
Meprobamate	Negative	50	ng/mL	2 - 4 days		Consistent
Opiates						
Morphine	Negative	20	ng/mL	1 - 3 days		Consistent
Codeine	Negative	20	ng/mL	1 - 3 days		Consistent
Hydrocodone	Negative	20	ng/mL	1 - 3 days		Consistent
Hydromorphone	Negative	20	ng/mL	1 - 3 days		Consistent
Opiods						
Meperidine	Negative	20	ng/mL	1 - 3 days		Consistent
Normeperidine	Negative	20	ng/mL	1 - 3 days		Consistent
Oxycodone						
Oxymorphone	Negative	20	ng/mL	1 - 3 days		Consistent
Oxycodone	Negative	20	ng/mL	1 - 3 days		Consistent
Phencyclidine (PCP)						
PCP	Negative	10	ng/mL	4 - 6 days	Y	Consistent
Propoxyphene						
Propoxyphene	Negative	20	ng/mL	1 - 7 days		Consistent
Tapentadol						
Tapentadol	Negative	20	ng/mL	1 - 3 days		Consistent

Reported On: 10/17/18 03:24 pm By: RC

Other possible signs of an abuse problem

- ER/Admission report with overdose diagnosis
- Patient reports meds lost or stolen
- Patient is asking for early refills
- Patient asking for a brand name analgesic
- Patient reporting withdrawal-like symptoms

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Withdrawal symptoms

DURATION and SEVERITY of Opioid withdrawal symptoms can depend on many variables such as:

- Patient age
- Opioid type / half life
- Severity of opioid dependency(Quantity)
- Duration of dependency (Time)

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Withdrawal symptoms

- Agitation, Anxiety
- Nausea, Pain
- Insomnia, Restlessness
- Fatigue, Chills, Sweats
- Overdose: Non-responsive/Respiratory Distress (emergency)

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Mechanism of Action

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Receptors

- 3 main type of receptors= MU – μ, DELTA – δ, KAPPA – κ,
- MU (μ) is the most important with respect to exerting euphoric effects, analgesic effects, overdose and withdrawal
- Important effects: respiratory depression, miosis, euphoria, decreased GI motility, hypotension, itchiness and bradycardia

Receptor binding action

1) **Full Agonists**

   bind and exert the full effects possible at that receptor;

   Heroin, Codeine, Fentanyl, Hydrocodone

- bind the receptor completely – how long they bind [dissociation rate], and how fast + strongly they bind [affinity] need to be considered

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Receptor binding action

2) Partial Agonists:

bind but do not exert full effects at that receptor; ***Buprenorphine***

- How strongly they bind [receptor affinity] , and how much an effect they have [receptor efficacy/intrinsic activity] need to be considered
- They are DOSE DEPENDENT, meaning the higher the dose, the greater the partial agonist effect. May even become an antagonist

Receptor binding action

3) Antagonists

bind at receptors but do not activate effects at that receptor: ***Naloxone and Naltrexone***

- Prevent agonists from exerting their effects by competitively binding the receptor (Blocking action)
- Not Inverse agonists

Medication Assisted Treatment Options

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Patient Type Considerations

1. Fully engaged in recovery? (Best results)
2. Participating due to threat of adverse situation? (significant other, or legal ramifications of non-compliance)
3. M.A.T. – Appropriate medication selection for the individual's medical situation and current mindset.
4. Pregnancy? Coordinate care with OB and PCP?

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Methadone

(agonist)

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METHADONE

- Part of a licensed (LARA) comprehensive treatment program including therapy and counseling.
- Prescribing Dr. must be licensed as a controlled substance treatment program prescriber. (LARA)
- By law, methadone treatment for substance abuse can only be dispensed through an opioid treatment program (OTP) certified by SAMHSA.

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WHAT IS METHADONE

A narcotic painkiller medication that is used to treat heroin addiction.

It's a opioid.

It's used to lessen withdrawal symptoms.

The effects last about 6 hours after a single dose.

It can be highly addictive.

Methadone is invented by German doctors during world war 2 , and entered united States in 2002 to treat extreme pain .

Methadone is available under brand names : methadose and dolophine

Methadone is μ-receptor agonist and releases neurotransmitters

This reduce cravings for opioids , not induce intoxication , reduce the euphoria effects of opioids

Methadone Maintenance Therapy for Opioid Addiction

- In the early 1960s, it was discovered that when taken daily at an appropriate maintenance dose, methadone benefited patients experiencing withdrawal from other opioids, including morphine and heroin.
- Strict criteria are in place for persons to be admitted to MMT. These may include a history of at least six months' daily opioid use, positive urine screening for opioids, and the presence of active withdrawal symptoms.
- During the first 30 to 60 days, when daily attendance is required, the proper methadone maintenance dose is determined. Participants are monitored regularly with urine drug screening.

Methadone Maintenance Therapy for Opioid Addiction

- Methadone is **longer acting (24 to 36 hours) than most other opioids. For example, heroin, which is short acting (three to six hours)**, is often injected several times a day while, in MMT, methadone is administered only once a day.
- Tolerance to methadone develops slowly, so clients can be maintained in MMT indefinitely.
- A variety of studies have found that MMT is associated with a reduction in the use of other opioids, mortality, injection drug-related risk behaviors, high-risk behavior associated with the transmission of HIV and other sexually transmitted diseases, criminal activity.

METHADONE

- EKG all potential patients, screening for QT wave prolongation
- Induction max is 30mg / day
- Patient is off opioids and entering withdrawal phase prior to induction
- Complete medication review / and laboratory workup recommended

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Buprenorphine

(partial agonist)

zubsolv® sublingual tablets
(buprenorphine and naloxone) C

Suboxone
(buprenorphine HCl/naloxone HCl dihydrate) C

Bunavail® buccal film
(buprenorphine and naloxone) C

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BUPRENORPHINE

- Under the Drug Addiction Treatment Act of 2000 (DATA 2000), qualified U.S. physicians can offer buprenorphine for opioid dependency in various settings, including in an office, community hospital, health department, or correctional facility.
- physicians must qualify for a physician waiver, which includes completing required buprenorphine training.
- Physicians can also request a patient limit increase from the initial 30 patients to 100 and then after one year to 275.

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Suboxone: the Best of Both Worlds?

Suboxone is the combination of Buprenorphine and Naloxone

Buprenorphine

- Partial opioid AGONIST
- Can mimic some of heroin's effects
- Can satisfy heroin cravings
- No euphoric "high"
- Less habit-forming than full opioid agonists such as heroin or methadone
- Less respiratory depression compared to methadone

Suboxone

- Can satisfy heroin cravings
- No euphoric "high"
- Less habit-forming than full opioid agonists such as heroin or methadone
- Less respiratory depression compared to methadone
- Low risk of overdose

Naloxone

- Opioid ANTAGONIST
- Blocks heroin's actions
- Eliminates risk of opioid overdose

Day 1

An induction dosage of up to 8 mg/2 mg SUBOXONE Film is recommended.

– Clinicians should start with an initial dose of 2 mg/ 0.5 mg or 4 mg/1 mg buprenorphine/naloxone and may titrate upwards in 2 or 4 mg increments of buprenorphine, at approximately 2-hour intervals, under supervision, to 8 mg/2 mg buprenorphine/naloxone based on the control of acute withdrawal symptoms

Day 2

A single daily dose of up to 16 mg/4 mg SUBOXONE Film is recommended.

– Medication should be prescribed in consideration of the frequency of visits. Provision of multiple refills is not advised early in treatment or without appropriate patient follow-up visits

– It is recommended that an adequate maintenance dose, titrated to clinical effectiveness, be achieved as rapidly as possible. In some studies, a too-gradual induction over several days led to a high rate of drop-out of buprenorphine patients during the induction period

- **Induction day 1 and day 2**

Maintenance phase of opioid dependence treatment

The dosage of SUBOXONE Film from Day 3 onwards should be progressively adjusted in increments/decrements of 2 mg/0.5 mg or 4 mg/1 mg buprenorphine/naloxone to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms.

After treatment induction and stabilization, the maintenance dose of SUBOXONE Film is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient and clinical response.

The recommended target dosage of SUBOXONE Film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose. Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage.

Patient considerations

Patients dependent on methadone or long-acting opioid products

- Buprenorphine monotherapy is recommended in patients taking long-acting opioids when used according to approved administration instructions
- Following induction, the patient may then be transitioned to once-daily SUBOXONE Film

Patients dependent on heroin or other short-acting opioid products

- Patients dependent on heroin or short-acting opioid products may be inducted with either SUBOXONE Film or with sublingual buprenorphine monotherapy
- The first dose of SUBOXONE Film or buprenorphine should be administered when objective signs of moderate opioid withdrawal appear, and not less than 6 hours after the patient last used an opioid

Naltrexone

(antagonist)

Vivitrol®
(naltrexone for extended-release injectable suspension)

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- Naltrexone is the generic name for the medication in the Vivitrol® injection, and Revia® tablets
- Covered by Michigan Medicaid and Medicare
- No special training, licenses or certifications
- For private insurance or cash-pay, company offers co-pay assistance up to $ 500 per month

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Vivitrol®

Vivitrol is an extended release injectable given once a month for Alcohol and Opioid dependence.

What are the Benefits of Vivitrol Treatment?

- Vivitrol is non-addictive
- It does not create a "high"
- Easier than daily oral medications
- Successful for both alcohol and opioids
- Effective for relapse prevention

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Facts for NALTREXONE

- Blocks opiate receptors (Mu), as an Antagonist.
- Can be used in both alcohol and opiate dependent patients
- Vivitrol; Once monthly, time released injection to prevent relapse
- Works best in combination with therapy and support agencies (AA, NA, etc.)
- The treatment is recommended for 24 months

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The risk of opioid overdose with VIVITROL® or Revia®

One serious side effect of VIVITROL, Revia or other abstinence plans is the risk of opioid overdose. Relapse, using opioids, even in amounts that were tolerated before VIVITROL treatment, or abstinence can lead to accidental overdose, serious injury, coma, or death.

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Thank You!

Abdulhassan Saad M.D.

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.csaadmdom

(313)584-7900

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