Opioid and Pain Management Best Practices Series

Technology for Opioid Risk Assessment, Naloxone Access, and Urine Screening

Webinar
March 10, 2022, 12pm-1pm ET
IPRO
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Welcome!

- Today's session is being recorded
- Everyone is muted for this session – please use the Chat feature for questions and comments. Select to send to "everyone". We'll have a Q&A session at the end of the presentation
- Please introduce yourself (name, organization & role, location) using the Chat feature
- Slides and the recording will be posted on our website

Objectives

- Examine the importance of opioid risk assessment, naloxone access and urine assessment for patients who are prescribed opioids
- Demonstrate free evidence-based software for opioid management: ORAtel, Naloxotel and Urintel
- Suggest workflow for software use and share user experiences from different care settings
- Share other free, evidence-based, opioid harm reduction technology resources

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- **The deadline to complete the evaluations is March 24.** If you have any questions or issues, please contact Lisa Capobianco at CPA: lcapobianco@ctpharmacists.org.

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IPRO Overview: What We Do

- Medicare beneficiary healthcare quality improvement
- Medicare Quality Innovation Network - Quality Improvement Organization (QIN-QIO) since 1st Scope of Work in 1989
- Medicare Hospital Quality Improvement Contractor (HQIC) serving 270 hospitals

Selected Contracts	Geographic Scope
QIN-QIO	NY, CT, DC, DE, MA, MD, ME, NH, NJ, OH, RI, VT
HQIC	NY, OH, NJ, KY, MI, MN, WI, PA, ME, MA, DE, MD

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Hosts

Anne Myrka, BS Pharm, MAT
Sr. Director Drug Safety
IPRO QIN-QIO/HQIC

Lynn Wilson
Senior Quality Improvement Specialist

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Guest Speaker

Jeffrey Fudin, B.S., Pharm.D., FCCP, FASHP, FFSMB
President, REMITIGATE THERAPEUTICS
Clinical Pharmacy Specialist (WOC), Stratton VA Medical Center

Adjunct Affiliations:
Albany College of Pharmacy & Health Sciences, Albany NY
Western New England University College of Pharmacy, Springfield MA

Opioid and Pain Management Best Practices: Technology for Opioid Risk Assessment, Naloxone Access, and Urine Screening

www.paindr.com | www.remitigate.com

Learning Objectives

1. Explain the importance of opioid risk assessment, naloxone access and urine assessment for patients who are prescribed opioids
2. Demonstrate free evidence-based software for opioid management: ORAtel, Naloxotel and Urintel
3. Suggest workflow for software use and share user experiences from different care settings

Disclosures

Affiliation	Role/Activities
Abbott Laboratories	Lecture, non-speakers' bureau
AcelRx Pharmaceuticals	Acute perioperative pain (speakers bureau, consulting, advisory boards)
BioDelivery Sciences International	Collaborative publications, consulting, advisory boards
Collegium Pharmaceutical	Educational studio recording
GlaxoSmithKline (GSK)	Collaborative non-paid poster presentations
Hisamitsu America Inc	Advisory Board
Hikma Pharmaceuticals	Advisory Board
Lilly Pharmaceuticals	Meeting registration support (ASHP 2021) for poster presentation
Scilex Pharmaceuticals	Collaborative non-paid publications
Salix Pharmaceuticals	Speakers' bureau, consultant, advisory boards
Torrent Pharmaceuticals	Lecture, non-speakers' bureau
Remitigate, LLC	President/Owner, sole proprietor LLC: Consulting, Writing, Lecturing, Expert Witness, Ownership of open access apps

Validated tools on which apps are based…

BACKGROUND

Naloxotel and ORAtel

ASSESSING RISK OF OIRD

RIOSORD
Risk Index for Serious Prescription Opioid-Induced Respiratory Depression

- 2-major studies (linear regression multivariate analysis)
  - VA population (17 questions/115 highest possible score)
  - General population (16 questions/146 highest possible score)

1. Zedler, Barbara, et al. "Development of a Risk Index for Serious Prescription Opioid-Induced Respiratory Depression or Overdose in Veterans' Health Administration Patients." Pain Medicine 16.8 (2015): 1566-1579.
2. Nadpara P, Joyce A, Murrelle L, Carroll NW, Carroll NV, Barnard M, Zedler B. Risk factors for serious prescription opioid-induced respiratory depression or overdose: Comparison of commercially insured and Veterans Health Affairs populations. Pain Medicine. 2017; In press.
3. Zedler B, Saunders W, Joyce A, Vick C, Murrelle L. Validation of a screening risk index for serious prescription opioid-induced respiratory depression or overdose in a U.S. commercial health plan claims database. Pain Medicine. 2017; In press.

VA Population Design (17 questions/115 highest possible score)

- Case control analysis
- 8,987 veteran patients included
- 10 controls assigned to each veteran included
- Variables were selected for the risk index model
  - Based on logistics regression modeling
- Each variable was assigned a point value
- Point values added up to scores
  - Scores were then defined by predicted probability

Zedler, Barbara, et al. (2015): 1566-1579.

Question	Points for Yes Response
In the past 6 months, has the patient had a healthcare visit (outpatient, inpatient or ED) involving any of the following health conditions?[†]	
Opioid dependence?[‡]	15
Chronic hepatitis or cirrhosis?	9
Bipolar disorder or schizophrenia?	7
Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)?	5
Chronic kidney disease with clinically significant renal impairment?	5
An active traumatic injury, excluding burns (e.g., fracture, dislocation, contusion, laceration, wound)?	4
Sleep apnea?	3
Does the patient consume:	
An extended-release or long-acting (ER/LA) formulation of any prescription opioid?[§] (*e.g., OxyContin, Oramorph-SR, methadone, fentanyl patch*)	9
Methadone? (*Methadone is a long-acting opioid so also check "**ER/LA formulation**" [9 points]*)	9
Oxycodone? (*If it has an ER/LA formulation [e.g., OxyContin] also check "**ER/LA formulation**" [9 points]*)	3
A prescription antidepressant? (*e.g., fluoxetine, citalopram, venlafaxine, amitriptyline*)	7
A prescription benzodiazepine? (*e.g., diazepam, alprazolam*)	4
Is the patient's current maximum prescribed opioid dose[#]:	
≥100 mg morphine equivalents per day?	16
50–<100 mg morphine equivalents per day?	9
20–<50 mg morphine equivalents per day?	5
In the past 6 months, has the patient:	
Had one or more emergency department (ED) visits?	11
Been hospitalized for one or more days?	8
Total point score (maximum 115)	

VA Population Results

Zedler, Barbara, et al. (2015): 1566-1579.

VA Population Results

Risk Class	Risk Index Score (Points)	All Patients ($n = 8,987$), n (%)	Overdose or Serious Opioid-Induced Respiratory Depression (All patients, $n = 8,987$)	
			Average Predicted Probability (95% CI)	Observed Incidence
1	0–24	7,133 (79.4)	0.03 (0.03, 0.03)	0.03
2	25–32	780 (8.7)	0.14 (0.14, 0.15)	0.14
3	33–37	306 (4.5)	0.24 (0.24, 0.24)	0.23
4	38–42	238 (2.7)	0.34 (0.34, 0.35)	0.37
5	43–46	133 (1.5)	0.46 (0.45, 0.46)	0.51
6	47–49	77 (0.9)	0.55 (0.54, 0.55)	0.55
7	50–54	101 (1.1)	0.64 (0.64, 0.65)	0.60
8	55–59	87 (1.0)	0.76 (0.75, 0.76)	0.79
9	60–66	73 (0.8)	0.85 (0.84, 0.85)	0.75
10	≥67	59 (0.7)	0.94 (0.93, 0.95)	0.86
Model performance				
C-statistic = 0.88				
Hosmer–Lemeshow goodness-of-fit statistic = 10.8 ($P > 0.05$)				

Zedler, Barbara, et al. (2015): 1566-1579.

Non-VA Population (16 questions/146 highest possible score)

- Retrospective case-control study of 18,365,497 patients
- IMS PharMetrics Plus integrated commercial health plan opioid claims in the U.S.
- 7,234 patients experience OSORD
- OSORD found to be associated with:
  - ER/LA opioid formulations
  - Daily morphine equivalence dose
  - Interacting medications
  - ED visits and hospital admissions
  - Coexisting health conditions

90% predictability

OSORD = Overdose or Serious Opioid-induced Respiratory Depression

Zedler, Barbara K., et al. "Validation of a Screening Risk Index for Serious Prescription Opioid-Induced Respiratory Depression or Overdose in a US Commercial Health Plan Claims Database." Pain medicine (Malden, Mass.) (2017).

General Population Results

- Retrospective case-control study of 18,365,497 patients IMS
- PharMetrics Plus integrated commercial health plan opioid claims in the U.S.
- 7,234 patients experience OSORD
- OSORD found to be associated with:
  - ER/LA opioid formulations
  - Daily morphine equivalence dose
  - Interacting medications
  - ED visits and hospital admissions
  - Coexisting health conditions

- Zedler B, Saunders W, Joyce A, Vick C, Murrelle L. Validation of a screening risk index for serious prescription opioid-induced respiratory depression or overdose in a U.S. commercial health plan claims database. Pain Medicine. 2017; In press.
- Nadpara P, Joyce A, Murrelle L, Carroll NW, Carroll NV, Barnard M, Zedler B. Risk factors for serious prescription opioid-induced respiratory depression or overdose: Comparison of commercially insured and Veterans Health Affairs populations. Pain Medicine. 2017; In press.

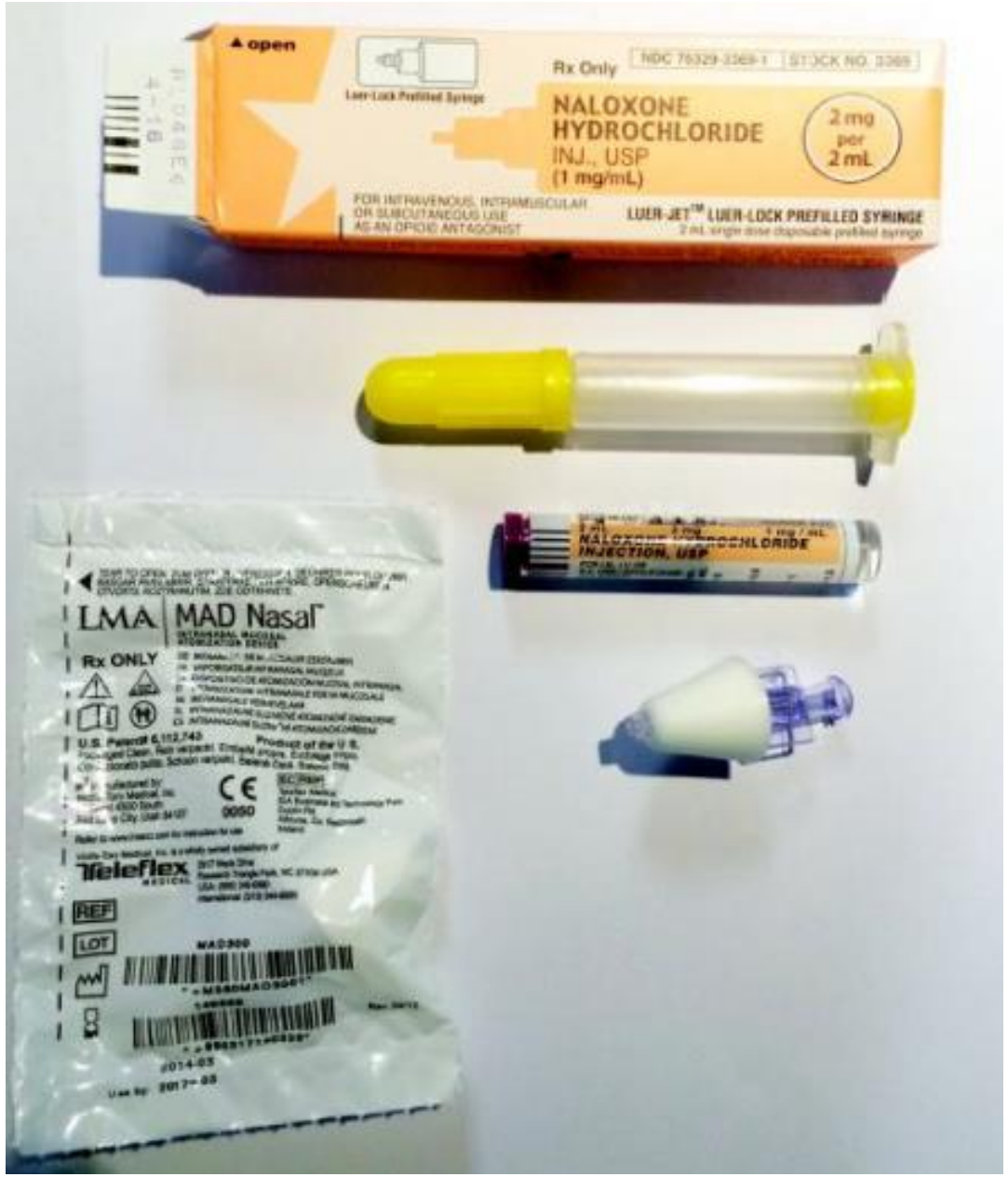
Question*	Points for "yes" response
In the past 6 months, has the patient had a health care visit (outpatient, inpatient, or ED) involving any of the following health conditions?†	
• Substance use disorder (abuse or dependence)? (This includes alcohol, amphetamines, antidepressants, cannabis, cocaine, hallucinogens, opioids, and sedatives/anxiolytics)	25
• Bipolar disorder or schizophrenia?	10
• Stroke or other cerebrovascular disease?	9
• Kidney disease with clinically significant renal impairment?	8
• Heart failure?	7
• Nonmalignant pancreatic disease (e.g., acute or chronic pancreatitis)?	7
• Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)?	5
• Recurrent headache (e.g., migraine)?	5
Does the patient consume:	
• Fentanyl?	13
• Morphine?	11
• Methadone?	10
• Hydromorphone?	7
• An extended-release or long-acting formulation of any prescription opioid?‡	5
• A prescription benzodiazepine?	9
• A prescription antidepressant?	8
Is the patient's current maximum prescribed opioid dose ≥100 mg morphine equivalents per day? (Include all prescription opioids consumed on a regular basis)	7
Total point score (maximum = 146)	

Antidepressant or Benzodiazepine = Higher Risk than Opioids >100 mg MEDD

Zedler B, Saunders W, Joyce A, Vick C, Murrelle L. Validation of a screening risk index for serious prescription opioid-induced respiratory depression or overdose in a U.S. commercial health plan claims database. Pain Medicine. 2017; In press.

Naloxone Choices

- Naloxone rescue kit (injectable verses “intranasal”)
- Commercial FDA Approved Intranasal – various strengths
- Naloxone Auto-injector (no longer available in US)



Intranasal (IN) Naloxone Rescue Kit

Edwards ET, Edwards ES, Davis E, Mulcare M, Wiklund M, Kelley G. Comparative usability study of a novel auto-injector and an intranasal system for naloxone delivery. Pain and therapy. 2015 Jun;4(1):89-105.

3 Steps to Help Reverse Opioid Overdose

Using [redacted] Nasal Spray involves 3 simple steps.

1 **PEEL** back the package to remove the device.	**2** **PLACE** the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.	**3** **PRESS** the plunger firmly to release the dose into the patient's nose.

Source: Data on file. Adapt Pharma.

FDA Approved In-Home Naloxone

Naloxone HCl for injection Auto-injector

(FDA approved in 2014)

Intranasal naloxone

(FDA approved 11/18/2015)

Naloxone Kits and Naloxone Autoinjectors Recommendations for Issuing Naloxone Kits and Naloxone Autoinjectors for the VA Overdose Education and Naloxone Distribution (OEND) Program. VA Pharmacy Benefits Management Services. October 2015. www.pbm.va.gov/PBM/clinicalguidance/clinicalrecommendations/Naloxone_Kits_and_Autoinjector_Recommendations_for_Use_Rev_Oct_2015.pdf. Accessed February 17, 2016.

Validated Opioid Risk Tool / 5-Question Questionnaire

Validation

185 new patients in one pain clinic took the self-administered Opioid Risk Tool (ORT) measuring. All patients were monitored for aberrant behaviors for 12 months after their initial visits.

Questions/Items

1. personal and family history of substance abuse
2. age
3. history of preadolescent sexual abuse
4. certain psychological diseases
5. Patients received scores of 0–3 (low risk), 4–7 (moderate risk), or ≥8 (high risk), indicating the probability of their displaying opioid-related aberrant behaviors.

Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. Pain medicine. 2005 Nov 1;6(6):432-42.

ORT Results

Results

1. Low risk, 17 out of 18 (94.4%) did not display an aberrant behavior
2. High risk, 40 out of 44 (90.9%) did display an aberrant behavior
3. The ORT displayed excellent discrimination for both the male (c = 0.82) and the female (c = 0.85) prognostic models

1. Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. Pain medicine. 2005 Nov 1;6(6):432-42.
2. Cheatle MD, Compton PA, Dhingra L, Wasser TE, O'Brien CP. Development of the revised opioid risk tool to predict opioid use disorder in patients with chronic nonmalignant pain. The journal of pain. 2019 Jul 1;20(7):842-51.

Naloxotel

https://www.remitigate.com/access/page/naloxotel

ORAtel

https://www.remitigate.com/access/page/oratel

Urine Drug Testing (UDT) Rationale

- Guidelines recommend UDT as standard of care when prescribing chronic opioid therapy, especially for CNCP
- Helps to ensure compliance and mitigate risk
  - Detects presence of illicit substances
  - Detects absence of prescribed medication
- Helps to justify continual prescriptions
- Supports clinician decision to discontinue controlled substance medication

1. Rosano, T.G., Wood, M., Hooten, W.M., Rumberger, J.M., Fudin, J. and Argoff, C.E., 2021. Application and Clinical Value of Definitive Drug Monitoring in Pain Management and Addiction Medicine. Pain Medicine.
2. Argoff, C.E., Alford, D.P., Fudin, J., Adler, J.A., Bair, M.J., Dart, R.C., Gandolfi, R., McCarberg, B.H., Stanos, S.P., Gudin, J.A. and Polomano, R.C., 2018. Rational urine drug monitoring in patients receiving opioids for chronic pain: consensus recommendations. Pain Medicine, 19(1), pp.97-117.

Urine Drug Testing (UDT) Rationale

- Supports justification for closer monitoring (more frequent visits / lab monitoring)
- Supports behavior modification and referral to psychologist

Potential Pitfalls

- Patient reliability to report compliance, use and misuse is dubious and often poor
- Behavior alone is unreliable for identifying patients at risk non-compliance, abuse, misuse, and diversion

1. Rosano, T.G., Wood, M., Hooten, W.M., Rumberger, J.M., Fudin, J. and Argoff, C.E., 2021. Application and Clinical Value of Definitive Drug Monitoring in Pain Management and Addiction Medicine. Pain Medicine.
2. Argoff, C.E., Alford, D.P., Fudin, J., Adler, J.A., Bair, M.J., Dart, R.C., Gandolfi, R., McCarberg, B.H., Stanos, S.P., Gudin, J.A. and Polomano, R.C., 2018. Rational urine drug monitoring in patients receiving opioids for chronic pain: consensus recommendations. Pain Medicine, 19(1), pp.97-117.

Types of Urine Drug Testing

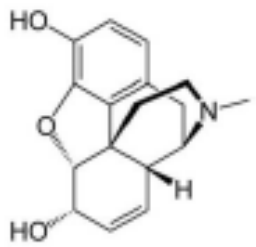
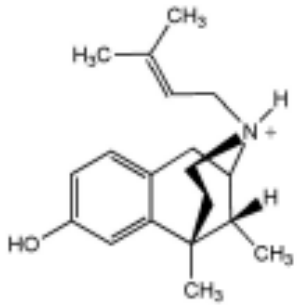
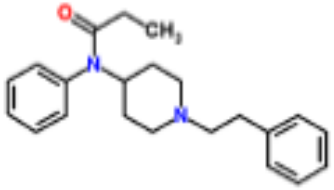
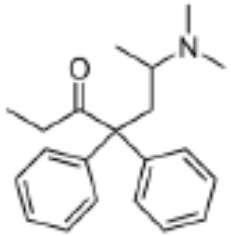
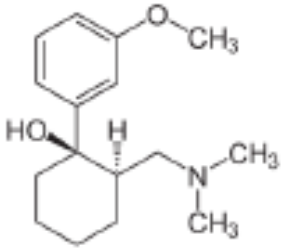
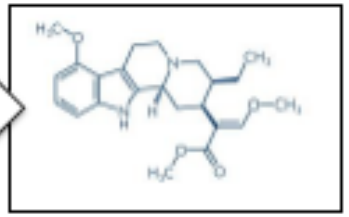
Immune Assay (IA)

- In office or send out
- Inexpensive
- Results are quick (minutes)
- Helps for initial detection
- False negatives/positives
- False patient accusations
- Easier for pts to manipulate low sensitivity, esp w/ synthetics
- Presence/absence of RX class only
- No option for synthetics, designer drugs, and unique natural products

Chromatography

- Usually send-out
- More expensive
- 24 hours to 1 week (per lab)
- Final result
- Definitive testing
- Justifies RX decisions
- 99.999 percent reliability high senstivity
- Presence/absence of RX metabolites
- Custom option for synthetics, designer drugs, and unique natural products

Chemical Classes of Opioids

PHENANTHRENES	BENZOMORPHANS	PHENYLPIPERIDINES	DIPHENYLHEPTANES	PHENYLPROPYL AMINES
				
MORPHINE	PENTAZOCINE	FENTANYL	METHADONE	TRAMADOL
Buprenorphine* Butorphanol* Codeine Dextromethorphan* Dihydrocodeine Heroin (diacetyl-morphine) Hydrocodone* Hydromorphone* Levorphanol* Methylnaltrexone** Morphine (Opium, conc) Nalbuphine* Naloxone* Naloxegol* Naltrexone** Oxycodone* Oxymorphone*	Pentazocine	Alfentanil Fentanyl Remifentanil Sufentanil Meperidine Diphenoxylate[a] Loperamide[a] **Fentalogues** **Illicit Fentanyl Analogues** Furanyl fentanyl Acetyl fentanyl Fluoro-fentanyl Carfentanil Others[b]	Methadone Propoxyphene Mitragynine (Kratom)	Tapentadol Tramadol 
CROSS-SENSITIVITY RISK				
PROBABLE	POSSIBLE	LOW RISK	LOW RISK	LOW RISK

*Agents lacking the 6-OH group of morphine, possibly decreases cross-tolerability within the phenanthrene group
**6-position is substituted with a ketone group and tolerability is similar to hydroxylation

With permission, Dr. Jeffrey Fudin. Available at:
https://paindr.com/wp-content/uploads/2020/11/Opioid-Structural-Classes-Figure_-updated-2020Nov.pdf

Urintel

https://www.remitigate.com/access/page/urintel

Opioid and Benzodiazepine Metabolites plus Validity Testing

Lab Value Resources

Table 5. SAMHSA Criteria for Validity Testing of a Urine Specimen[3,64]

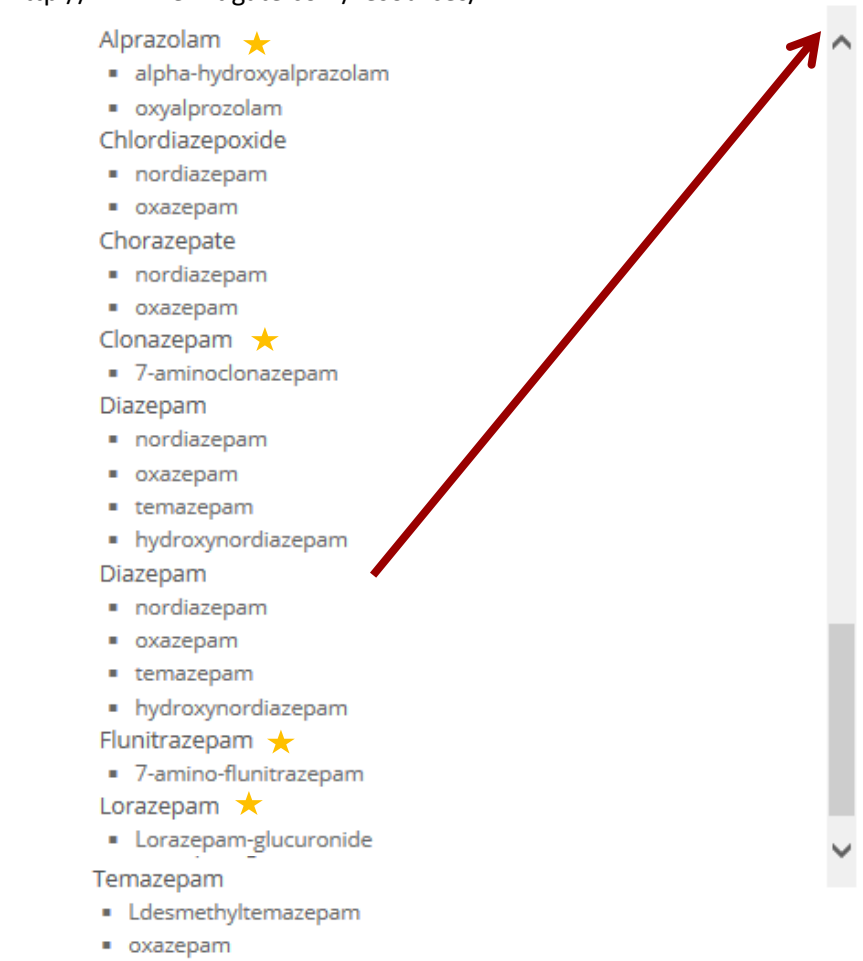
Urine specimen is reported as:	When:
Dilute	Creatinine concentration ≥2 mg/dL, but <20 mg/dL, & specific gravity* >1.001, but <1.003
Substituted	Creatinine concentration <2 mg/dL & specific gravity* ≤1.001 or >1.020
Adulterated	pH† <3 or ≥11, nitrite concentration ≥500 µg/mL; chromium (VI) concentration ≥50 µg/mL; presence of a halogen (eg, from bleach, iodine, fluoride), glutaraldehyde, pyridine, surfactant

*Using refractometry; †using a pH meter

1. Hammett-Stabler CA, Webster LR. A Clinical Guide to Urine Drug Testing. An educational activity designed for primary care physicians, family physicians, and pain physicians.
2. Clinical Drug Testing in Primary Care, Technical Assistance Publication Series TAP 32. SAMHSA

Opioid and Benzodiazepine Metabolites

http://www.remitigate.com/resources/



Opioids and Benzodiazepine Metabolites

(continued from previous slide)

Buprenorphine
- Norbuprenorphine

Codeine
- Morphine
- Norcodeine
- Normorphine
- Hydrocodone
- Codeine 6-glucuronide

Fentanyl (Transdermal, Transbuccal, Transmucosal, Sublingual)
- Norfentanyl
- 4-N-(N-propionylanilino) piperidine
- 4-N-(Nhydroxypropionylanilino) piperidine
- 1-(2-phenethyl)-4-N-(Nhydroxypropionylanilino) piperidine

Hydrocodone
- Hydromorphone
- Norcodeine
- 6-beta-hydrocodol
- 6-alphahydrocodol
- 6-beta-hydromorphol
- 6-alpha-hydromorphol
- norhydrocodone

Heroin
- 6-acetylmorphine
- Morphine
- Morphine-3-glucuronide
- Normorphine
- 6-acetylmorphine 3-glucuronide
- Normorphine glucuronide

Hydromorphone
- Hydromorphone-3-glucuronide
- Hydromorphone-3-glucoside
- Dihydroisomorphine-6-glucuronide
- Dihydroisomorphine-6-glucoside
- Dihydroisomorphine
- Dihrydromorphine

Levorphanol
- 3-glucuronide

Meperidine
- Normeperidine
- meperidinic acid
- normeperidinic acid

Methadone
- EDDP (2-ethyl-1,5-dimethyl-3,-3-diphenylpyrrolinium)
- EMDP (2-ethyl-5-methyl-3,3-diphenylpyraline)

Morphine
- Morphine-3-glucuronide
- Morphine-6-glucuronide
- Normorphine
- 7,8-dihydromorphinone
- codeine (minor)
- hydromorphone (minor)

Morphine/Naltrexone (Embeda)
- Morphine-3-glucuronide
- Morphine-6-glucuronide
- Normorphine
- 7,8-dihydromorphinone
- codeine (minor)
- 6-beta-naltrexol
- hydromorphone (minor)

Oxycodone
- Noroxycodone
- Oxymorphone
- Oxycodyl
- Oxymorphol
- Noroxycodyl

Oxymorphone
- Oxyorphone-3-glucuronide
- 6-OH-oxymorphone

Tapentadol
- Tapentadol-O-glucoronide

Addressing Unexpected Results

- False or Unexpected Positive
  - Discuss findings with patient
    - Confirm false positive (as a true negative) to support and document patient's integrity and compliance
  - Confirm unexpected positive to justify
    - ADT products, and or other RX adjustments (partial agonist, partial agonist/antagonist, etc.)
    - substance abuse counseling
    - Alternative and other behavior health intervention
- False Negative
  - Confirm false negative (as a true positive) to support and document patient's integrity and compliance

Reisfield GM,Goldberger, BA, Bertholf RL. False-positive and false-negative test results in clinical urine drug testing. Bioanalysis 2009. 1(5): 937-52.

Thank you Dr. Fudin!

Opioid and Substance Use Disorder Treatment Apps

reSET and reSET-O

reSET

reSET

- reSET is indicated as a 12-week (90 day) prescription-only treatment for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse
- Intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older, who are currently enrolled in outpatient treatment under the supervision of a clinician

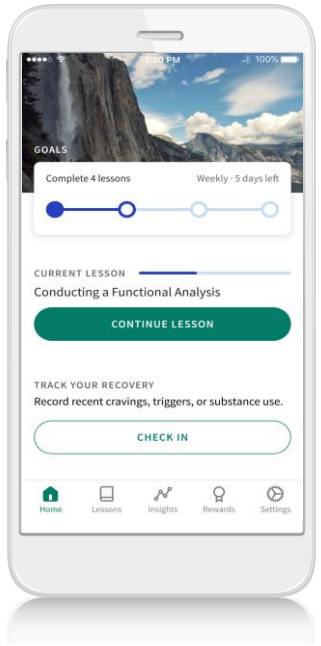
https://www.resetforrecovery.com/overcoming-addiction/

reSET-O

reSET-O

- reSET-O prescription digital therapeutic is a 12-week (84 day) software application intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician
- reSET-O is indicated as a prescription-only digital therapeutic

Introducing reSET and reSET-O. Digital recovery companions* for your patients.



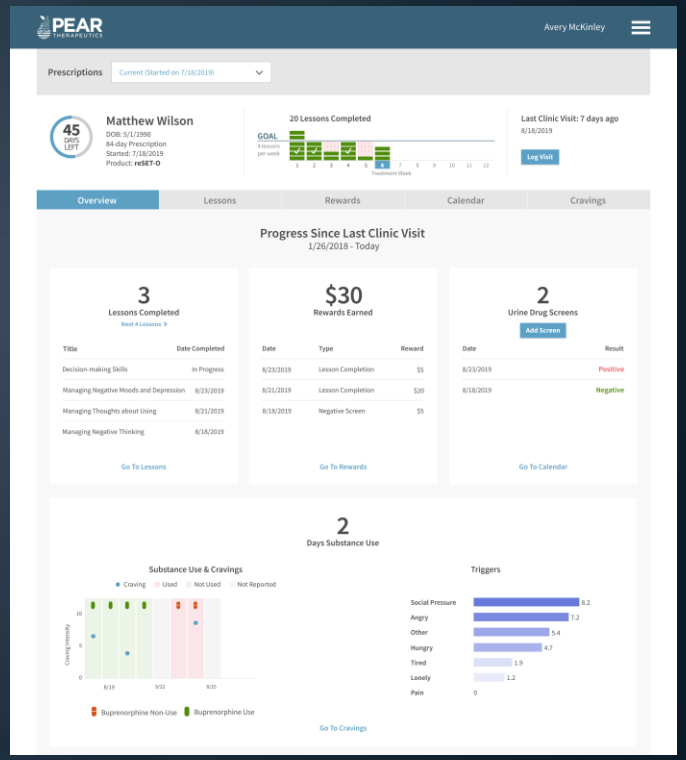
First-of-their-kind prescription digital therapeutics (PDTs)[1,2]:

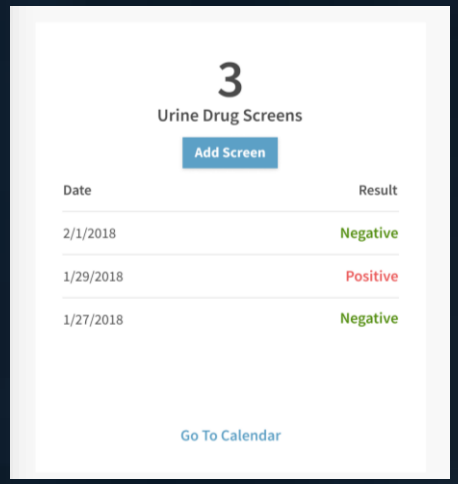
- FDA authorized
- Evidence-based treatment for substance use disorder (SUD) and opioid use disorder (OUD) accessible on a smartphone or tablet†
- Cognitive behavioral therapy lessons, fluency training to help patients remember what they've learned, and contingency management using rewards like gift cards

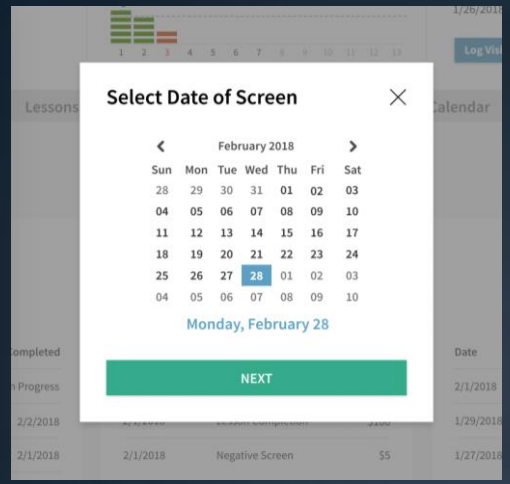
*SUD and OUD are chronic conditions, and permanent recovery is uncertain. reSET and reSET-O may help to retain patients in treatment.
†reSET is indicated for SUD and reSET-O is indicated for OUD.

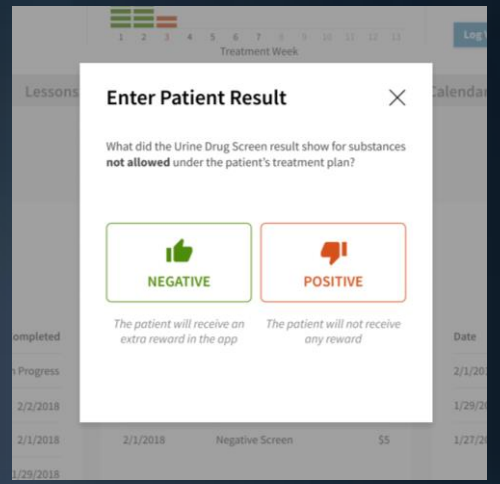
References: 1. reSET Clinician Directions for Use. Pear Therapeutics, Inc. 2020. **2.** reSET-O Clinician Directions for Use. Pear Therapeutics, Inc. 2020.

Pear.MD Clinician Dashboard allows for real-time monitoring* of patients.









*Monitoring usage, lesson progress, triggers, and cravings for informed patient conversations. Real-time requires patient on internet connection.

Not a real patient. For demo purposes only.

reSET® and reSET-O®: Clinically Validated Treatments for SUD and OUD

In a 12-week randomized clinical study of reSET®

>2x
ABSTINENCE[1]

In a secondary analysis of patients whose primary substance of abuse was not opioids, adding reSET to outpatient treatment as usual (TAU) more than doubled abstinence rates during the last 4 weeks of the 12-week trial:

- **17.6% with TAU (n=193) vs. 40.3% with rTAU* + reSET (n=206); P=.0004**

+13%
RETENTION[2]

In a secondary analysis of patients whose primary addiction was not opioids, adding reSET to outpatient treatment as usual (TAU) significantly improved retention rates compared to TAU alone at the end of the 12-week trial:

- **63.2% with TAU (n=193) vs. 76.2% with rTAU* + reSET (n=206); P=.0042**

In a 12-week randomized clinical study of reSET-O®

+14%
RETENTION[3]

Adding reSET-O to outpatient TAU using buprenorphine increased retention of patients with OUD 14% at the end of the 12-week trial:

- **68.4% with TAU (n=79) vs. 82.4% with TAU + reSET-O (n=91); P=.0224**

*rTAU: reduced treatment as usual in which 2 hours of face-to-face therapy each week was replaced with use of a desktop-based Therapeutic Education System, which has equivalent content to reSET.
1. reSET Clinician Directions for Use. Pear Therapeutics, Inc. 2020. reSET is a clinically validated treatment for SUD. 2. Pear Therapeutics Data on File. 2021. 3. reSET-O Clinician Directions for Use. Pear Therapeutics, Inc. 2020. reSET-O is a clinically validated treatment for OUD.

Please see Indications for Use and Important Safety Information for reSET, reSET-O, and Somryst at the end of this presentation.

PEAR THERAPEUTICS

reSET-O® May Provide Value for Patients and Health Systems[1]

Inpatient stays* **-62%** + Emergency visits **-20%** + Surgical procedures **-22%** + Case management services **8.2%** = **~$2,150** in cost reductions, six months following reSET-O treatment initiation

Pear cannot provide any assurance that organizations will experience similar cost savings. reSET-O has not been shown to impact patient and health systems cost in prospective, randomized clinical trials.

* Includes intensive care unit (ICU) stays: Four ICU stays were observed in the pre-treatment period vs none post-treatment initiation

1. Velez FF, et al. Real-world reduction in healthcare resource utilization following treatment of opioid use disorder with reSET-O, a novel prescription digital therapeutic. *Expert Rev*. 2021.

CONTINUE

Please see Indications for Use and Important Safety Information for reSET, reSET-O, and Somryst at the end of this presentation.

PEAR THERAPEUTICS

Opioid & Pain Management Best Practice Provider Self-Assessment Opportunity

- **An important focus of our work is spreading strategies for implementing opioid and pain management best practices.**
  - We are opening up our self-assessment to new initiative participants. If you've completed this assessment in the past, you do not need to complete this version
- ***Who should complete this self-assessment?***
  - **For hospitals:** Usually, the Director of Pharmacy, a Clinical Pharmacist or the lead of an opioid committee/workgroup
  - **For other facilities:** Opioid committee, workgroup, or Director of Nursing or Quality
- ***What do I get after completing the assessment?***
  - After completing the initial assessment, you will receive aggregate results by care setting. We'll be collecting quarterly updates to identify improvement areas we can help you with, capture new best practice strategies, and share ongoing aggregate results with you
- ***What if I already responded to it?***
  - You might have received this same opportunity from your quality improvement point of contact. If you responded to the assessment, you do not need to complete it again. Thank you for completing it!

Complete the Assessment

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Chat In

Improvement is a Team Support

Please use the chat feature to share questions, ideas, success strategies, and/or lessons learned

More Questions?

Dr. Fudin: https://paindr.com/

Anne Myrka: amyrka@ipro.org

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Leaving in Action

Tips for success:

- Access these tools from the IPRO QIN-QIO Resource : https://qi-library.ipro.org/
- Small steps of change: for example, start implementing the new process on one unit for two weeks, then evaluate and adjust as needed
- Reach out to our IPRO QIN-QIO team with questions or needs

Let Us Know More…

Your feedback is critically important and will help guide us as we prepare future small Talks and other educational events.

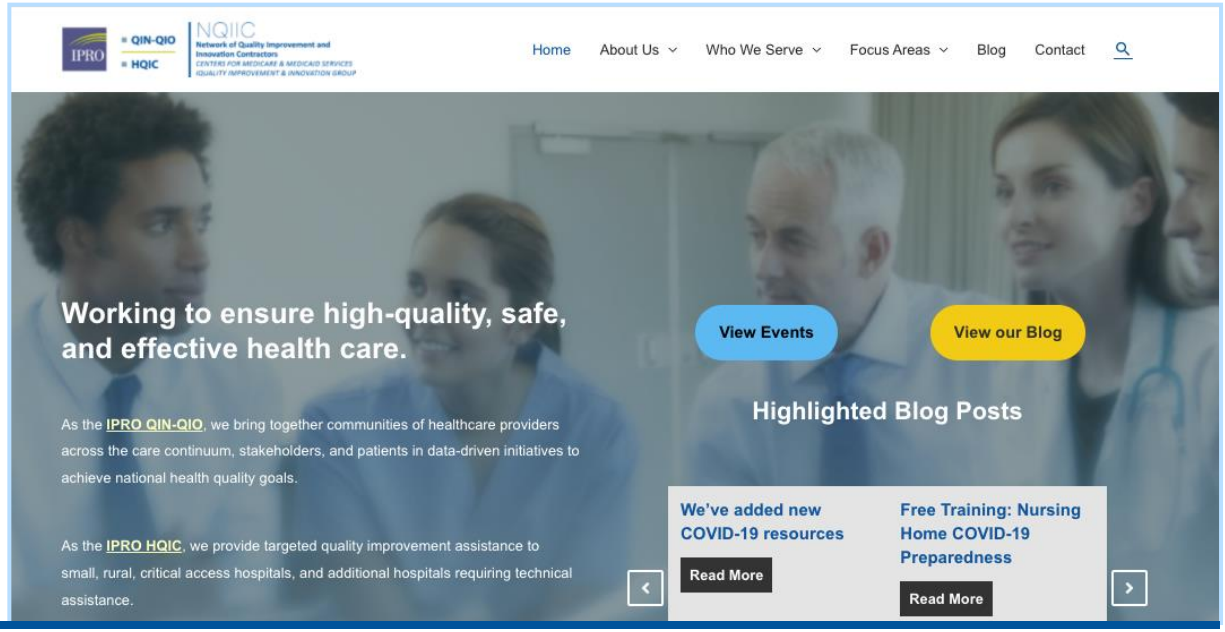
Please take just a few minutes to complete our session evaluation after the webinar.

Thank You

Thank you for your continued partnership and commitment to quality improvement.

Learn More & Stay Connected

https://qi.ipro.org/



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