WHERE IT’S AT:
LEVELS OF CARE FOR INDUCTION OF MAT

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CONTINUUM - The ASAM Criteria Decision Engine, ASAM
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Disclosure Information

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Options/Stock: Alkermes; Intent Solutions
Consultant Fees: BioCorRx, Indivior, Kaleo, Purdue, RCA, IBM Watson/Truven Health Analytics, Rand Corp., US WorldMeds
Where It’s At:
Levels of Care for MAT Induction

9:00-10:15 Agenda & Scientific Rationale
10:15-10:30 Break
10:30-11:15 Induction Protocols
11:15-12:00 Service Needs for Different Protocols
12:00-1:00 Lunch
1:00-2:15 ASAM Criteria & Level Specifications
2:15-2:30 Break
2:30-3:15 Decision Logic for LOC Selection
3:15-4:00 Optimizing Real-time Decision Making
4:00 Discussion & Conclusions
Purpose of the Workshop

- Evidence-based Medication in Addiction Treatment (MAT) must start somewhere
- It turns out that can be anywhere
- The patient’s needs must be thoroughly understood
- Treatment services must meet all acute needs
- The ASAM Criteria assessment dimensions and service specifications provide a valuable framework for structuring successful initiation of MAT and longitudinal recovery
Objectives:

As a result of this workshop, participants will be able to:

- Identify and utilize the 6 Dimensions of assessment for effective patient induction onto MAT
- Structure Clinical Services to meet patient MAT induction needs according to the ASAM Criteria
- Implement the placement, prescribing, dosing, dispensing and monitoring necessary for effective MAT induction in opioid use disorder (OUD).
Norway Study: XR-NTX vs. BUP/NAL
(Tannum et al. JAMA Psychiatry 2017)

QUESTION: Is XR-NTX as effective as BUP/NAL for heroin-OUD?

DESIGN: 12-week, multicenter, outpatient, open-label RCT at 5 urban addiction clinics in Norway with 232 adults from outpatient addiction clinics & detoxification units.

INTERVENTIONS: Randomization to either daily flex-dose BUP/NAL, 4 to 24mg/d, or XR-NTX 380mg IM every 4th week for 12 weeks.

SAMPLE: 159 participants, mean age 36 years, 27.7% women.

80 randomized to XR-NTX and 79 to BUP/NAL; 66.0% completed.
Retention in Treatment

![Graph showing cumulative retention over days since randomization for two groups: Extended-release naltrexone group and Buprenorphine-naloxone group.](image)
Patient Satisfaction with Treatment

- **Extended-release naltrexone group**
- **Buprenorphine-naloxone group**

Satisfaction With Treatment vs. Weeks
Norway Study: XR-NTX vs. BUP/NAL
(Tannum et al. JAMA Psychiatry 2017)

RESULTS:
Retention:
XR-NTX non-inferior to BUP/NAL: 69.3 vs. 63.7 days

Opioid (–) Urines:
XR-NTX non-inferior to BUP/NAL: 90% vs. 80% (p<.001)

CONCLUSIONS:
XR-NTX was effective as BUP/NAL for short-term abstinence from heroin & other illicit substances
Norway Study: XR-NTX vs. BUP/NAL
(Tannum et al. JAMA Psychiatry 2017)

159 Randomized

80 Randomized to receive extended-release naltrexone
71 Received extended-release naltrexone as randomized
  9 Did not receive extended-release naltrexone
  5 Dropped out
  3 Failed detoxification
  1 Developed acute illness

79 Randomized to receive buprenorphine-naloxone
72 Received buprenorphine-naloxone as randomized
  7 Did not receive buprenorphine-naloxone
  1 Dropped out
  6 Never received study drug

15 Lost to follow-up
11 Dropped out
  4 Discontinued owing to adverse effects

56 Completed 12 weeks of extended-release naltrexone

23 Lost to follow-up
17 Dropped out
  6 Discontinued owing to adverse effects

49 Completed 12 weeks of buprenorphine-naloxone
Induction into XR-NTX treatment required full detox to a greater extent than into the BUP/NAL.

The Norwegian detox guidelines turned out to be insufficient.

Detox frequently produced WD adverse effects on induction of XR-NTX and, to some extent, BUP/NAL.

The study therefore changed its detox strategy in the 1st year in accordance with the literature.

These changes reduced new adverse events from induction.
**NIDA XBOT Study** (Lee et al., Lancet 2017)

**QUESTION:** How do XR-NTX vs. BUP-NAL differ in relapse rates?

**METHODS:**
24 week, open-label, comparative effectiveness RCT, at 8 US inpatient services with outpatient follow-up. Participants were ≥18 years with DSM-5 OUD, & used non-Rxed opioids in the past 30 days.

**INTERVENTION:** Vivitrol vs. Suboxone SL film

**OUTCOME:**
Opioid relapse-free survival: Relapse was 4 consecutive weeks of any non-study opioid use by urine or self-report, or 7 consecutive days of self-reported use
NIDA XBOT Study  (Lee et al., Lancet 2017)

XR-NTX Induction Process

• Detox & LOS were not protocol-derived; varied by site.

Detox Options:

• **Opioid-free**: No opioids; clonidine/comfort meds (2 sites)
• **Short Stay**: 3–5 day methadone taper (4 sites)
• 3–14 day BUP taper (2 sites)

• Before XR-NTX induction, patients had to:
  • complete detox (≥3 days from last opioid)
  • have opioid-negative urine
  • have a negative Naloxone Challenge Test
    (= no/minimal opioid WD after naloxone ≥0.4 mg IM/SQ/IV)
NIDA XBOT Study (Lee et al., Lancet 2017)

570 randomly assigned

283 randomly assigned to XR-NTX treatment
  Randomisation timing status: <3 days vs. ≥3 d
  107 early randomisation group: 53% completed
  176 late randomisation group: 84% completed
  Induction status
  204 induced to XR-NTX treatment
  79 induction failures: 39%

287 randomly assigned to BUP-NX treatment
  Randomisation timing status
  110 early randomisation group
  177 late randomisation group
  Induction status
  270 induced to BUP-NX treatment
  17 induction failures: 6%

XR-NTX induction success varied by site:
  · Short Stay, methadone-taper unit: 52%
  · Opioid-free extended-stay site: 95%

No difference in induction or relapse for either medication in men vs. women
Opioid Craving VAS self-report, range 0–100

- Per-protocol BUP-NX (n=270)
- Per-protocol XR-NTX (n=204)

*p=0.0012 at wk 7

p=NS at wk 24
NIDA XBOT Study (Lee et al., Lancet 2017)

Retention in All Randomized Patients (N = 570)

Retention in All Inducted Patients (N = 474)
<table>
<thead>
<tr>
<th></th>
<th>XR-NTX group (n=283)</th>
<th>BUP-NX group (n=287)</th>
<th>Treatment effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inducted to study medication</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intention-to-treat group</td>
<td>204 (72%)</td>
<td>270 (94%)</td>
<td>OR 0.16, 95% CI 0.09–0.28; p&lt;0.0001</td>
</tr>
<tr>
<td>Per-protocol group</td>
<td>106/204 (52%)</td>
<td>150/270 (56%)</td>
<td>OR 0.87, 95% CI 0.60–1.25; p=0.44</td>
</tr>
<tr>
<td><strong>Opioid relapse, weeks 3–24</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Intention-to-treat group</td>
<td>185 (65%)</td>
<td>163 (57%)</td>
<td>OR 1.44, 95% CI 1.02–2.01; p=0.036</td>
</tr>
<tr>
<td>Per-protocol group</td>
<td>106/204 (52%)</td>
<td>150/270 (56%)</td>
<td>OR 0.87, 95% CI 0.60–1.25; p=0.44</td>
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<tr>
<td><strong>Relapse-free-survival (weeks), range 3–24</strong></td>
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<tr>
<td>Intention-to-treat group</td>
<td>8.4 (3.0–23.4)</td>
<td>14.4 (5.1–23.4)</td>
<td>HR 1.36, 95% CI 1.10–1.68; p=0.0040</td>
</tr>
<tr>
<td>Per-protocol group</td>
<td>20.4 (5.4–23.4)</td>
<td>15.2 (5.7–23.4)</td>
<td>HR 0.92, 95% CI 0.71–1.18; p=0.49</td>
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<tr>
<td><strong>Total number of weekly opioid-negative urine samples, range 0–24</strong></td>
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<td></td>
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<tr>
<td>Intention-to-treat group</td>
<td>4 (0–19)</td>
<td>10 (3–20)</td>
<td>p&lt;0.0001</td>
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<tr>
<td>Per-protocol group</td>
<td>13 (3–21)</td>
<td>11 (3–20)</td>
<td>p=0.81</td>
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<tr>
<td><strong>Total number of self-reported opioid-abstinent days, range 0–144</strong></td>
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<tr>
<td>Intention-to-treat group</td>
<td>39 (1–144)</td>
<td>81 (16–144)</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Per-protocol group</td>
<td>123 (18–144)</td>
<td>87 (20–144)</td>
<td>p=0.67</td>
</tr>
</tbody>
</table>

Data are n (%), n/N (%), or median (IQR). XR-NTX=extended-release naltrexone. BUP-NX=buprenorphine-naloxone. OR=odds ratio. HR=hazard ratio.
# NIDA XBOT Study

(Chinese text)

## OVERDOSE EVENTS

<table>
<thead>
<tr>
<th></th>
<th>XR-NTX (N=283)</th>
<th>BUP/NAL (N=287)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants with one or more overdose event (all)<strong>†</strong></td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Participants with one or more overdose event (per protocol)<strong>‡</strong></td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Number of overdose events (all)<strong>§</strong></td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td>Number of overdose events (per protocol)</td>
<td>10</td>
<td>9</td>
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</table>

## Fatal overdose events

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<tr>
<th></th>
<th>XR-NTX (N=283)</th>
<th>BUP/NAL (N=287)</th>
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</thead>
<tbody>
<tr>
<td>Number of fatal overdose events (all)</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Number of fatal overdose events (per protocol)</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

**†p=0.14** (Fisher’s exact). **‡p=0.31** (Fisher’s exact).

§ 4 participants reported >1 OD. 3 of the 4 were randomly assigned to XR-NTX (2 were induction failures, 1 successfully inducted); each reported 2 ODs. One of the 4 was assigned to BUP/NAL (successfully inducted) & reported 3 ODs. None of these 9 overdoses were fatal.
NIDA XBOT Study (Lee et al., Lancet 2017)

FINDINGS (n=570): XR-NTX (n=283) vs. BUP-NAL (n=287)

• Fewer initiated XR-NTX 72% vs. BUP-NX 94%; p<0.0001
  Overall (intention-to-treat population, n=570)
  24 week relapse events: XR-NTX 65% vs. BUP-NX 57%

• Almost all of the difference was due to early relapse in 89% of XR-NTX induction failures

• Among successfully inducted participants (n=474), 24 week relapse events were similar.

• Self-reported opioid craving was initially less with XR-NTX (p=0.0012), then converged by week 24 (p=0.20)
Aside from mild-to-moderate XR-NTX injection site reactions, adverse events did not differ between groups.

5 fatal ODs occurred (2 XR-NTX; 3 BUP-NAL).

Most ODs occurred at times quite distal to the last dose or, for participants who were not inducted, distal to detox.

Thus, it is difficult to attribute an association between study med & overdose.

**CONCLUSION:**

- More difficult to initiate XR-NTX
- But once initiated, both meds were equally safe & effective
- Need to focus on induction
Opioids

- **Morphine**
- **Codeine** - also called opiates
- **Diacetylmorphine (Heroin)**
- **Hydrocodone (Vicodin)**
- **Oxycodone (Oxycontin)**
- **Oxymorphone (Opana)**
- **Hydromorphone (Dilaudid)**
- **Buprenorphine**
- **Methadone**

Naturally occurring opioids

Semi-synthetic opioids

Long-acting opioids
Brain Structure:
Two Regions – Cortex & Limbic

Cortex
Role:
- Decision making
- Thinking
- Reasoning
- Learning

Limbic Region
Role:
- Basic Drives
- Experience of Reward, Euphoria

Interventions
- Psychosocial Therapies
- 12 Step Programs
- Monitoring

Interventions
- Agonist Medications
- Antagonist Medications

Reward/Motivation ("Go" signals) & Inhibitory Control ("No Go") are disrupted & must be addressed in prevention & treatment.
Healthy Opioid Receptor Activity

**Dopamine**
- Eating when hungry
- Drinking when thirsty
- Rewards survival behavior

**Endorphins**
- Pain relief
- Stress relief
- Emotional bonding


Opioid Agonists & Partial Agonists

Agonists
- Opioid analgesics
- Illicit opioid (e.g., heroin)
- Methadone
- Activates opioid receptors
- Excess dopamine release

Partial Agonists
- Buprenorphine
- Same as agonists, but ceiling effect
Opioid Antagonist

- Naltrexone
- Blocks opioid receptor
- Preferentially binds to the opioid receptors
- Displaces opioids
Brain Reward: Clinical Pharmacology

- Ventral Tegmental Area
- Nucleus Accumbens
- GABA (Dopamine)
- Opioid Peptides
- Arcuate Nucleus
Brain Reward: Clinical Pharmacology

**Ventral Tegmental Area**

**Dopamine**

**Arcuate Nucleus**

GABA (Dopamine)

Nucleus Accumbens

Opioid Peptides

Naltrexone
Neurotransmitter Mediators of OUD: Positive AND Negative Reinforcement

- β-endorphin
- Dopamine Circuits
- GABA System
- GLU Glutamate AMPA
- 5-HT Serotonin
- Other?
  - NE
  - CRF

CRF = corticotrophin releasing factor
AMPA = amino-3-hydroxy-5-methylisoxazole-4-propionic acid
GABA = gamma amino butyric acid
NE = norepinephrine

Reward & Positive Reinforcement

- Pain: brain’s natural signal to protect the body
- Proper goal of pain medicine: alleviate *but not eliminate* pain
- Exceeding pain alleviation – risks euphoria
- Euphoria = reward
- Repeated reward → positive reinforcement
- The “Go” System
Withdrawal & Negative Reinforcement

- Opioid drugs all wear off after a while
- When excessive opioid doses wear off, the brain is in **withdrawal**
- Withdrawal is an uncomfortable, even painful state even worse than the pain preceding the medicine
- This negative effect → wanting to keep taking opioids, known as negative reinforcement
- Disrupted ability of inhibitory control damages the “No Go” system
Neurobiology of Opioid Use Disorder

- Opioids: at substantia nigra & VTA interneurons, rapidly & briefly bind MOP-r, GABAergic inhibition of DA neurons

- **Dopaminergic Reward:** Initial positive reinforcement; later, regulatory changes via mRNA or protein/peptides

- **Recurrent withdrawal** negatively reinforces recurrent use, via regulatory changes that persist for weeks/months

- **Negative Reinforcement:** mediated via
  - Upregulation of the KOP-r/dynorphin system (may underlie aversion, dysphoria/anhedonia, and depression-like or anxiety-like states)
  - Stress-responsive brain areas via the hypothalamo-pituitary-adrenal (HPA) axis

(Kreek et al., J Clin Investigation 2012)
A Biopsychosocial Disorder: Treatment + Chemistry

Medications (All FDA-approved Agents)

Behavioral Therapies (Including Contingency Management*)

Medical Detoxification Services

Recovery Support Services

*Sanctions: measured, prompt, scientifically sound

NIDA
The Phases of Treatment

- **Withdrawal Management** – Medical Detoxification
- **Post-Withdrawal Anti-Craving Medication** – stabilizing brain chemistry
- **Counseling** – for the real *work* of recovery
  - Accept the disease
  - Know one’s vulnerabilities
  - Anticipate risk factors
  - Insulate from re-encountering the drug of abuse, even under stress
  - Master new coping behaviors
  - Construct healthy relationships
  - Find purpose in life/spiritual grounding
Goals of Anti-Opioid Pharmacotherapy

- **Withdrawal Management** alone: *inadequate care*
- **Early recovery protection**: period of highest risk for OD
  - Death rates upon prison release = 12-100x that of general population
  - Harm reduction, e.g., from HIV and HEP C transmission
- **Anti-craving**: stabilize urges/impulses to use long enough to permit counseling effects to take hold
- **Stress Response Normalization**: OUD disrupts ACTH/Cortisol
- **Extinction**: of both positive and negative cue response
- **Biological Stabilization**: Eating, diurnal cycle, sexual function, capacity for self-care / activities of daily living / treatment retention, general healthcare, relationship bonding
- **NOT Recovery**: Disease acceptance, coping skills, rehab
Summary: Scientific Rationale

1. MAT options are all effective. After induction: equally so
2. Induction of MAT, particularly XR-NTX is a challenge
3. OUD involves multiple brain receptors & circuits
4. BOTH positive & negative reinforcement must be managed
5. Therefore, induction treatment must address:
   - Biology
     – brain chemistry, including multiple systems
   - Psychology & Sociology
     – including motivation, impulsivity & social structure
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Levels of Care for MAT Induction

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Buprenorphine: Initiation

- Patient arrives in MILD opioid withdrawal (e.g., COWS 6-12)
- Sublingual/buccal administration necessitates being kept in the mouth for a long period of time for appropriate absorption
- BUP/naloxone 2-4mg initial dose SL, observed
  BUP/naloxone buccal film: same doses as with SL tabs
- Reassess at 30-60 min; 2-4mg SL PRN, observed
- Next day – morning dose is sum of initial day’s dose(s) with increases, usually up to 8mg SL by end of day
  Provide total day’s dose, for each of the next 2 – 7 days
- Days 2-7, maintain in-person or phone contact each day, titrate up as needed for stability, up to 16mg SL per day
- Home-based induction is recommended only if the patient or prescribing physician is experienced with the use of BUP
At 24 weeks, overall, 59% remained in treatment.

**FIGURE 1.** Program retention time by week 1 opiate test.
Clinical Opioid Withdrawal Score

1. Resting pulse rate: ______BPM
   - 0 80 or below
   - 1 81–100
   - 2 101–120
   - 4 >120

2. Sweating: over past half hour
   - 0 None
   - 1 Subjective chills or flushing
   - 2 Flushed or moisture on face
   - 3 Beads of sweat on brow or face
   - 4 Sweat streaming off face

3. Restlessness: during assessment
   - 0 Able to sit still
   - 1 Reports difficulty sitting still
   - 3 Frequent movements
   - 5 Unable to sit still >few seconds

4. Pupil size
   - 0 Pupils pinned or normal size
   - 1 Possibly larger than normal
   - 2 Pupils moderately dilated
   - 5 Dilated; only rim of iris visible

5. Bone or joint aches: (due to WD)
   - 0 None
   - 1 Mild diffuse discomfort
   - 2 Severe diffuse joint/muscle ache
   - 4 Rubbing joints/muscles

6. Runny nose or tearing: not from cold
   - 0 None
   - 1 Stuffiness or unusually moist eyes
   - 2 Nose running or tearing
   - 4 Constant nose running or tearing
Clinical Opioid Withdrawal Score

7. GI upset: over last half hour
   ▪ 0 No GI symptoms
   ▪ 1 Stomach cramps
   ▪ 2 Nausea or loose stool
   ▪ 3 Vomiting or diarrhea
   ▪ 5 Episodes of diarrhea or vomiting

8. Tremor: observe outstretched hands
   ▪ 0 No tremor
   ▪ 1 Tremor felt, but not observed
   ▪ 2 Slight tremor observable
   ▪ 4 Gross tremor or muscle twitching

9. Yawning: during assessment
   ▪ 0 No yawning
   ▪ 1 Yawning 1-2x during assessment
   ▪ 2 Yawning ≥3X during assessment
   ▪ 4 Yawning several times/minute

10. Anxiety or irritability
    ▪ 0 None
    ▪ 1 Fells increasingly irritable/anxious
    ▪ 2 Patient obviously irritable, anxious
    ▪ 4 Difficult participating in assessment

11. Gooseflesh skin
    ▪ 0 Skin is smooth
    ▪ 3 Arm hair standing up
    ▪ 5 Prominent piloerection

Total: sum of all 11 items
   ▪ 5–12=Mild; 13–24=Moderate;
   ▪ 25–36=Mod. severe; >36=Severe

(Adapted from Wesson et al., 1999)
XR-NTX: Induction – How To Start?

- There is no single proven method, however, success has been found with Inpatient AND Outpatient approaches

- Success = No precipitated withdrawal AND >50% of patients retained through 1\textsuperscript{st} XR-NTX injection

- KEY: Close contact & attention to the patient’s changing needs

- Setting expectations, providing support AND structure
Withdrawal is commonly compared to the flu
- Aches, pains, insomnia, nausea, anergia
- Anxiety, irritability, dysphoria, anhedonia

**Aggressive** symptomatic treatment helps
- Insomnia: zolpidem, trazodone, quetiapine
- GI distress: H2 blockers
- Anxiety/hyperarousal: clonazepam, clonidine

Most symptoms remit in 2-4 weeks
- Prolonged symptoms are rare & likely represent additional psychopathology
Improving NTX-PO Effectiveness

- Development of novel methods of detoxification
  - Clonidine became available to treat withdrawal (Gold et al., 1978)
  - Rapid Detox: detoxification was accelerated by administering antagonist and emerging symptoms are treated with clonidine (Riordan & Kleber 1980)
  - General anesthesia and an Ultra-Rapid Detox (1 day detox) was introduced (Loimer 1988)
  - Buprenorphine was introduced as a step-down from methadone during detoxification (Kosten et al., 1992)

- Using antagonists during detox became an opportunity to start naltrexone as a relapse prevention agent: Rapid Naltrexone Induction (Brewer)

- Work continued on improving adherence to oral preparations using tailored behavioral therapy

- Several long-acting preparations of naltrexone become available to deal with compliance issue
VIVITROL (extended-release naltrexone; XR-NTX)

- VIVITROL is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL.
  - Patients should not be actively drinking at the time of initial VIVITROL administration.

- VIVITROL is indicated for prevention of relapse to opioid dependence, following opioid detoxification.
  - Opioid-dependent patients, including those being treated for alcohol dependence, **must be opioid-free for a minimum of 7–10 days** before starting VIVITROL treatment.

- Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support.

- VIVITROL has a boxed warning related to hepatotoxicity.
WD Severity: Untreated vs. Treated
Balancing the Intensity & Duration of Withdrawal

- Untreated Heroin
- Antagonist + Symptomatic
- Symptomatic Only
- Agonist-Assisted
VIVITROL Pharmacokinetics
Mean Steady-State NTX Concentration

*Predicted concentrations based on rapid achievement of steady state and literature evidence

Plasma concentrations do not necessarily correlate with clinical efficacy.
E Krupitsky\textsuperscript{1}, EV Nunes\textsuperscript{2}, W Ling\textsuperscript{3}, A Illeperuma\textsuperscript{4}, DR Gastfriend\textsuperscript{4}, BL Silverman\textsuperscript{4}

\textsuperscript{1} Bekhterev Research Psychoneurological Institute, St Petersburg State Pavlov Medical University, St Petersburg, Russia
\textsuperscript{2} New York State Psychiatric Institute and Department of Psychiatry, Columbia University, New York, NY, USA
\textsuperscript{3} Department of Psychiatry and Biobehavioral Sciences, University of California Los Angeles, Los Angeles, CA, USA
\textsuperscript{4} Alkermes, Inc., Waltham, MA

**Funding**: Alkermes Inc.

**Objective**: To assess the efficacy, safety and patient-reported outcomes of an injectable, once monthly extended-release formulation of the opioid antagonist naltrexone for the treatment of patients with opioid dependence after detoxification
Secondary Endpoint: Treatment Retention

Placebo - Median days of treatment = 96

VIVITROL - Median days of treatment = 168

Log-rank $P = 0.0042$ (adjusted)

Secondary Endpoint: Craving

- Baseline craving scores: VIVITROL=18; Placebo=22
- VIVITROL patients had a 50% reduction from baseline in VAS-craving vs. no change for placebo

Rapid XR-NTX Induction - 2012
Columbia Protocol – In- OR Outpatient

- Patients who start naltrexone right after detoxification commonly experience a “flu-like” sign and symptoms
  - somatic complaints: insomnia, GI distress, hyperalgesia, anergia
  - anxiety, irritability, dysphoria, anhedonia
  - severity may be lower if naltrexone is started 10-14 days after completion of detoxification (but many relapse by then)

- Partially alleviated with aggressive symptomatic treatment,
  - Insomnia (v. frequent, often severe): zolpidem, trazodone, quetiapine
  - GI distress: H2 blockers
  - Anxiety/hyperarousal: clonazepam, clonidine

- Most of these symptoms remit by 2-4 weeks
  - true prolonged symptoms are rare and likely reflect additional psychopathology

- Persistent/protracted withdrawal vs. acute effects of naltrexone (?)
  - Possibility that naltrexone acts initially as an inverse agonist
# Rapid XR-NTX Induction - 2014

Columbia Protocol – In- OR Outpatient

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
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<tr>
<td>Buprenorphine</td>
<td>admission</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>50 mg po</td>
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<td></td>
<td></td>
<td></td>
<td>380 mg im</td>
</tr>
<tr>
<td>Naltrexone</td>
<td></td>
<td></td>
<td>3 mg</td>
<td>6 mg</td>
<td>25 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supportive medications</td>
<td></td>
<td>clonidine 0.1-0.2 mg qid, clonazepam 0.5-1.0 mg qid, toradol, ranitidine, zolpidem, trazodone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Rapid XR-NTX Induction - 2014
Columbia Protocol – In- OR Outpatient

Toradol (Ketorolac): Start parenterally, then move to PO
IV: 30 mg as single dose or 30 mg q6hr; not to exceed 120 mg/day
IM: 60 mg as single dose or 30 mg q6hr; not to exceed 120 mg/day
PO: 20 mg once after IV or IM therapy, THEN 10 mg q4-6hr; not to exceed 40 mg/day

Ranitidine (Zantac): 150 mg BID
Zolpidem (Ambien): 5-10 mg HS
Patients abstain from opioids for \( \leq 12 \) hours (e.g., Sun. afternoon)

Mon. AM, BUP begins with adjunctive meds PRN withdrawal

Clinic is daily, M-F during induction, for 1-3 hours for monitoring

Assess patient on arrival, 1 hr post meds, & before leaving clinic

Patient gets daily from nurse/physician:

- Medical Assessment
- Medication Management
- Study meds & take-home meds

Patients also receive weekly therapy sessions
• **Day 1**: If COWS score $\geq 6 \rightarrow$ BUP 2 mg
  
  If tolerated, add 2-4 mg in the clinic
  Plus 2 mg dose at home that evening

• **Days 3, 4, & 5**: NTX-PO, in split doses if 1st daily dose tolerated
  
  Adjust depending on the clinical situation

• **Day 5**: XR-NTX IM, usually 1 hour after total of NTX-PO 25 mg

• Ancillary meds are standing doses during days 2-5

• Start ancillary doses PRN the night prior to the 1st BUP dose and for 2 weeks after the XR-NTX injection
Rapid XR-NTX Induction - 2017
Columbia Protocol – In- OR Outpatient

<table>
<thead>
<tr>
<th>Study Day</th>
<th>BUP</th>
<th>NTX</th>
<th>Clonidine&lt;sup&gt;a,b&lt;/sup&gt;</th>
<th>Clonazepam&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Prochlorperazine&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Zolpidem&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Trazodone&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td></td>
<td></td>
<td>0.1 qid</td>
<td>0.5 qid</td>
<td>10 qHS</td>
<td>100 qHS</td>
<td></td>
</tr>
<tr>
<td>Day 3</td>
<td>1 + 2</td>
<td>0.1 qid</td>
<td>0.5 qid</td>
<td>10 bid</td>
<td>10 qHS</td>
<td>100 qHS</td>
<td></td>
</tr>
<tr>
<td>Day 4</td>
<td>3 + 3</td>
<td>0.1 qid</td>
<td>0.5 qid</td>
<td>10 bid</td>
<td>10 qHS</td>
<td>100 qHS</td>
<td></td>
</tr>
<tr>
<td>Day 5</td>
<td>6 + 6 + 12</td>
<td>0.1 qid</td>
<td>0.5 qid</td>
<td>10 bid</td>
<td>10 qHS</td>
<td>100 qHS</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> clonidine is held if SBP<100

<sup>b</sup> add’l adjunctive meds <i>as needed</i> the evening prior to 1<sup>st</sup> BUP dose & 2 wks after XR-NTX
Rapid XR-NTX Induction - 2017
Columbia Protocol – In- OR Outpatient

- 57% retention overall
- 78% retention among prescription opioid users
Where It’s At:
Levels of Care for MAT Induction

9:00-10:15  Agenda & Scientific Rationale
10:15-10:30  Break
10:30-11:15  Induction Protocols
11:15-12:00  Service Needs for Different Protocols
12:00-1:00  Lunch
1:00-2:15  ASAM Criteria & Level Specifications
2:15-2:30  Break
2:30-3:15  Decision Logic for LOC Selection
3:15-4:00  Optimizing Real-time Decision Making
4:00  Discussion & Conclusions
Choosing Withdrawal Management Setting Based on Drug Use Severity Alone

- Based on biological/pharmacological parameters:
  - Amount (e.g., number of bags, total mg per day)
  - Frequency (times per day – reflects reinforcement)
  - Duration (< 1 year – number of years)
  - Route of administration (PO, XR, IN, IV)
    - Reflects: Speed of onset
# Rapid XR-NTX Induction Algorithm

## Columbia Protocol – In- OR Outpatient

<table>
<thead>
<tr>
<th>Severity (physical dependence/anticipated withdrawal)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NONE</strong></td>
<td><strong>MILD</strong></td>
</tr>
<tr>
<td>Already abstinent (completed bup taper and has abstained for 7-10 days, exiting controlled environment)</td>
<td>H: 1-2 bags/day; OXY: &lt;50mg/day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Setting</th>
<th>Outpatient</th>
<th>Outpatient or partial hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine Dose</td>
<td>None</td>
<td>None or 4mg, day 1</td>
</tr>
<tr>
<td>Clonidine</td>
<td>None</td>
<td>0.1-0.2 mg TID to QID</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>None</td>
<td>0.5 mg BID</td>
</tr>
<tr>
<td>Ancillary medications</td>
<td>None</td>
<td>Sleep, pain (e.g. NSAID)</td>
</tr>
<tr>
<td>Hydration</td>
<td>Routine</td>
<td>Aggressive oral hydration (e.g., sports drinks)</td>
</tr>
<tr>
<td>Time to first NTX dose</td>
<td>Day 1</td>
<td>Day 3</td>
</tr>
<tr>
<td>Initial oral NTX dose</td>
<td>25-50 mg</td>
<td>12.5 mg QD</td>
</tr>
<tr>
<td>Time to Vivitrol injection</td>
<td>Days 1-2</td>
<td>Day 4; (or Day 5-6 after titrating oral naltrexone to 25-50mg QD)</td>
</tr>
</tbody>
</table>
# Rapid XR-NTX Induction Algorithm

**Columbia Protocol – In- OR Outpatient**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Severity (physical dependence/anticipated withdrawal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MODERATE</td>
</tr>
<tr>
<td></td>
<td>H: 3-6 bags/day; OXY (50-100mg/day); following short-term methadone or buprenorphine taper</td>
</tr>
<tr>
<td></td>
<td>SEVERE</td>
</tr>
<tr>
<td></td>
<td>&gt; 6 bags/day; illicit methadone; severe prescription opioid use (&gt;100 mg/day); significant medical problems</td>
</tr>
<tr>
<td>Partial hospital with inpatient backup</td>
<td>Inpatient or partial hospital with inpatient backup</td>
</tr>
<tr>
<td>4-8 mg, day 1 or 2</td>
<td>8 mg, day 1 or 2, or &gt;8 mg as needed</td>
</tr>
<tr>
<td>0.2 mg (TID to QID)</td>
<td>0.2-0.3 mg QID</td>
</tr>
<tr>
<td>1.0-2.0 mg (TID to QID)</td>
<td>1.0-2.0 mg QID</td>
</tr>
<tr>
<td>Sleep, pain, GI distress</td>
<td>Sleep, pain, GI distress</td>
</tr>
<tr>
<td>Aggressive oral hydration</td>
<td>Aggressive oral or IV hydration</td>
</tr>
<tr>
<td>Days 3-4</td>
<td>Day 4-5 (later if needed)</td>
</tr>
<tr>
<td>6 mg BID</td>
<td>3-6 mg QD-BID</td>
</tr>
<tr>
<td>Days 4-5; or days 5-7 after titrating oral naltrexone to 25-50 mg QD</td>
<td>Day 5-6; (or Day 6-7 after titrating oral naltrexone to 25-50mg QD)</td>
</tr>
</tbody>
</table>
Choosing Withdrawal Management Setting Based on Drug Use Severity Alone

- Based on biological/pharmacological parameters:
  - Amount (e.g., number of bags, total mg per day)
  - Frequency (times per day – reflects reinforcement)
  - Duration (< 1 year – number of years)
  - Route of administration (PO, XR, IN, IV)
    - Reflects: Speed of onset

- Does not account for:
  - Motivation/reward/socialization, e.g., ritualization
  - Impulsivity, e.g., craving, cue reactivity, distractability
  - Environment, e.g., supports, structural order/chaos
XR-NTX Induction Process

• Detox & LOS were not protocol-derived; varied by site.

Detox Options:

• **Opioid-free**: No opioids; clonidine/comfort meds (2 sites)
• **Short Stay**: 3–5 day methadone taper (4 sites)
• 3–14 day BUP taper (2 sites)

• Before XR-NTX induction, patients had to:
  • complete detox (≥3 days from last opioid)
  • have opioid-negative urine
  • have a negative Naloxone Challenge Test
    (= no/minimal opioid WD after naloxone ≥0.4 mg IM/SQ/IV)
xr-ntx induction success varied by site:
- short stay, methadone-taper unit: 52%
- opioid-free extended-stay site: 95%

no difference in induction or relapse for either medication in men vs. women
Primary Goal of Withdrawal Management

- **Goal:** Maximize the likelihood of continuing into the psychosocial rehabilitation of addiction

- **Challenge:** Premature termination of treatment is a significant problem

- **Facilitator:** The likelihood of continuing is much greater if psychosocial rehabilitation services are initiated *simultaneously* with WM services
  - Delay increases the likelihood of treatment drop-out
Level of Care Decisions

- Two major guidelines:

1. Conserve scarce resources by using lowest intensity level of care in which effective treatment can be delivered

2. There is evidence of poorer treatment outcome if level of care intensity is either too high or too low
XR-NTX in Opioid Dependence in the Inpatient Rehabilitation Setting

DL Leslie PhD\textsuperscript{1}, W Milchak LCSW\textsuperscript{1}, DR Gastfriend MD\textsuperscript{2}, P Herschman PhD\textsuperscript{3}, EO Bixler PhD\textsuperscript{1}, RE Meyer, MD\textsuperscript{1}

\textsuperscript{1}Penn State U/Hershey Medical Center, \textsuperscript{2}Alkermes Inc, \textsuperscript{3}CRC Health Group Inc

**Funding:** Research services agreement from Alkermes Inc. to Penn State University

**Objective:** A naturalistic study of patient characteristics, feasibility & hospital course of opioid dependent patients post-detox, in the midst of residential rehabilitation treated with (or without) once-monthly XR-NTX
XR-NTX in Rehab: Data Sources

- Administrative records from 3 inpatient CRC rehabs in PA
- CRC is the largest U.S. provider of specialized behavioral healthcare, treating >30,000 individuals daily
- Electronic records characterized 7,687 opioid dependent detox/rehab inpatients in terms of demography, diagnosis, payer & hospital course.
- The largest site provided data on how many patients attended their 1st post-discharge visit by day 10.
- 3 Groups were compared, with groups 2 & 3 as controls:
  - 1: **Injected** – with at least 1 XR-NTX
  - 2: **Not Injected** – but wanted & was prescribed XR-NTX
  - 3: **Not Prescribed** – neither offered nor prescribed XR-NTX
# XR-NTX in Rehab: Results

## Baseline Characteristic

| Baseline Characteristic | Injected  
| N = 168 | Not injected  
| N = 430 | Not Rx’ed  
| N = 7089 | P-values |
|------------------------|---------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                        | N | % | N | % | N | % | 1 v. 2 | 1 v. 3 | 2 v. 3 | All |
| **Age (Mean ± SD)**    | 29.6 ± 8.2 | 28.3 ± 8.2 | 29.7 ± 9.1 | 0.086 | 0.824 | <0.001 | <0.001 | 0.001 | <0.001 |
| **Gender**             |                  |               |              | 0.838 | <0.001 | <0.001 | <0.001 | 0.001 | <0.001 |
| Male                   | 84 | 50.0% | 219 | 50.9% | 4,549 | 64.2% |               |               |               |     |
| Female                 | 84 | 50.0% | 211 | 49.1% | 2,540 | 35.8% |               |               |               |     |
| **Race**               |                  |               |              | 0.812 | 0.954 | 0.092 |               |     |
| White                  | 158 | 94.1% | 393 | 91.4% | 6,298 | 88.8% |               |     |
| Black                  | 4  | 2.2%  | 17  | 4.0%  | 271  | 3.8%  |               |     |
| Hispanic               | 4  | 2.4%  | 7   | 1.6%  | 202  | 2.9%  |               |     |
| Other                  | 2  | 1.2%  | 13  | 3.0%  | 318  | 4.5%  |               |     |
| **Primary payer type** |                  |               |              |     |     |     |               |     |
| Commercial insurance   | 22 | 13.1% | 114 | 26.5% | 1589 | 22.4% | <0.001 | 0.004 | 0.049 | 0.498 |
| Medicaid               | 142 | 84.5% | 306 | 71.2% | 5191 | 73.2% | 0.001 | 0.001 | 0.349 | 0.002 |
| Special Payor          | 1  | 0.6%  | 4   | 0.9%  | 105  | 1.5%  | -     | 0.521 | 0.353 | 0.423 |
| Missing                | 3  | 1.8%  | 6   | 1.4%  | 204  | 2.9%  | 0.716 | 0.635 | 0.070 | 0.141 |
XR-NTX in Rehab: Results

![Bar charts showing the results of XR-NTX in rehab. The charts compare injected vs. not injected and not prescribed vs. prescribed. The p-values are highlighted with asterisks (* for p<0.05, ** for p<0.01 vs XR-NTX).](image-url)

- **AMA**:Injected vs Not injected
- **Treatment Complete**: Injected vs Not injected
- **Attended Post-discharge visit**: Injected vs Not injected
- **Length of Stay (Days)**: Injected vs Not injected

p<.001 vs XR-NTX
XR-NTX in Rehab: Conclusions

• **Limitations**: Retrospective data (from PA), possible cohort differences, lack of clinical info, & short-term temporal focus.

• **Strengths**: Data reflect real world clinical experience, both commercial insurance & Medicaid populations; cohorts similar in BL demographic, clinical & payer characteristics; consistent findings across 3 sites.

**Conclusions**

1. XR-NTX patients were significantly less likely to leave AMA, more likely to complete rehab, have longer LOS & greater entry to continuing care.

2. Women: as likely as men to receive XR-NTX; Race did not appear to be a factor in treatment selection.

3. XR-NTX can be successfully administered to opioid dependent patients after detox & before discharge from inpatient rehab.
Advances in Treatment Matching

Modality Matching:
many studies, e.g., Project MATCH – but few findings
(Gastfriend & McLellan, Med Clin NA, 1997)

Placement Matching:
Multiple studies; ASAM model – consistent signals
(Gastfriend, Addiction Treatment Matching, Haworth Press, 2004)

Support:
• NIDA: Validation - R01-DA08781 & K24-DA00427
• NIAAA: ASAM Software - SBIR grant R44-AA12004
• CSAT: Access to Recovery Initiative - grant 270-02-7120
• Belgian National Fund for Scientific Research
• Belgian American Educational Foundation
• Central Norway Health Trust /Rusbehandling Midt-Norge
• SAMHSA: Open Behavioral Health IT Architecture Program
# ASAM Principles of Placement Matching

**ASAM Guiding Principles**

<table>
<thead>
<tr>
<th><strong>Assessment.</strong></th>
<th>Move from one-dimensional to a multidimensional assessment.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Approach.</strong></td>
<td>Shift from program driven to clinically driven &amp; outcomes-driven; focus on outcomes; interdisciplinary team approach.</td>
</tr>
<tr>
<td><strong>Terms of Treatment.</strong></td>
<td>Move away from using “treatment failure” as an admission prerequisite; clarify “medical necessity”; engage with “informed consent.”</td>
</tr>
<tr>
<td><strong>Length of Service.</strong></td>
<td>Move from fixed length to variable length depending on client needs.</td>
</tr>
<tr>
<td><strong>Continuum.</strong></td>
<td>Move from limited levels of care to a broad, flexible continuum of care.</td>
</tr>
<tr>
<td><strong>Population.</strong></td>
<td>Identify adult- and adolescent-specific needs.</td>
</tr>
<tr>
<td><strong>Goals &amp; Roles.</strong></td>
<td>Clarify treatment goals and the physician’s role.</td>
</tr>
</tbody>
</table>
ASAM Patient Placement Criteria

1. Outpatient
2. Intensive Outpatient
3. Medically Monitored Intensive Inpatient
4. Medically Managed Intensive Inpatient

DIMENSIONS
1. Intoxication Withdrawal
2. Biomedical
3. Emotional Behavioral
4. Treatment Acceptance/Resistance
5. Relapse Potential
6. Recovery Environment

Decision Rules
Using Multidimensional Assessment to Determine WM Level of Care

- **Step 1:** Determine patient’s needs for Dimension 1, Withdrawal Potential

- **Step 2:** Determine patient’s needs in Dimensions 2 to 6

- **Step 3:** Use decision rules to match patient’s final needs & strengths to appropriate Level of Care and Setting
**Summary: Services for Different Protocols**

- Studies: Setting/duration *dramatically* affect induction success
- Biological/Pharmacologic parameters are important criteria
  - Can guide choice of medication, dose, duration & setting
  - BUT – may be seriously insufficient for fully understanding the patient
- Motivation, Impulsivity & Environment – also impact service needs
- High intensity setting: Can yield efficient long-term benefit
- Goal in choosing services: To optimize intensity-to-need balance
Where It’s At:
Levels of Care for MAT Induction

9:00-10:15  Agenda & Scientific Rationale
10:15-10:30  Break
10:30-11:15  Induction Protocols
11:15-12:00  Service Needs for Different Protocols
12:00-1:00  Lunch
1:00-2:15  ASAM Criteria & Level Specifications
2:15-2:30  Break
2:30-3:15  Decision Logic for LOC Selection
3:15-4:00  Optimizing Real-time Decision Making
4:00  Discussion & Conclusions
Developing an Industry Standard

1980s: 40-50 criteria sets differing on assessment, placement, length of stay

1990: Development of Cleveland Circle Criteria & National Association of Addiction Treatment Providers’ (NAATP) Patient Placement Criteria

1991: NAATP & ASAM collaborate to create Patient Placement Criteria (PPC) for the Treatment of Psychoactive SUDs

1996: ASAM PPC-2

2001: ASAM PPC-2R

2013: ASAM Treatment Criteria for Addictive, Substance-Related & Co-Occurring Conditions

2013 ASAM Criteria references updates from DSM-5, includes a new definition for ‘addiction’, moves away from PPC to considering levels of care across a continuum
ASAM Text: Hundreds of Decision Rules
To place patients in the least intensive & restrictive care
that meets the patient’s multi-dimensional needs and affords optimal treatment outcome

www.ASAMcriteria.org

www.haworthpress.com

www.ASAMcriteria.org
Introduction to the ASAM Criteria

- SUD benefits should be designed to support the care continuum
  - The ASAM Criteria offers a model service continuum
  - Recovery supports are also necessary
# ASAM Placement Criteria

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Levels:</th>
<th>Outpatient</th>
<th>Opioid Treatment Program</th>
<th>Day Treatment</th>
<th>Partial Hosp.</th>
<th>Residential Rehabilitation</th>
<th>Hospital (Medically Managed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 1</td>
<td></td>
<td>OTP</td>
<td>2.1, 2.5</td>
<td>3.1, 3.3, 3.5, 3.7</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Sub-levels:

- **Intox/WD**
  - Withdrawal Management (L-1, 2, 3.2, 3.7, 4)

- **Biomedical**
  - Biomedical Enhanced (L-3.7)
  - Co-Occurring Disorders

- **Emot'l/Behav'l**
  - Capable (L-2, 3)
  - Co-Occurring Disorders

- **Readiness**
  - Enhanced (L-2, 3)

- **Relapse Potential**

- **Environment**

---

*ASAM Placement Criteria*
ASAM’s LOC Specs: Example

An individualized treatment plan,
which includes problem formulation
and articulation of short-term, measurable treatment goals
and activities designed to achieve those goals.

The plan is developed in collaboration with the patient
and reflects the patient's personal goals,
while considering the capabilities and resources available
to achieve the patient's personal goals.
ASAM’s Level Of Care (LOC) Specifications: Six Domains

1. **Setting**: Structural component(s)
2. **Support Systems**: Services & provider entities
3. **Staff**: The care team, credentials & specific roles
4. **Therapies**: The types of care being delivered
5. **Assessment**: For initial & ongoing treatment planning process
6. **Documentation**: The process of care communication
The Phases of Treatment

• **Withdrawal Management** – Medical Detoxification
• Post-Withdrawal **Anti-Craving Medication**
  – stabilizing brain chemistry
• **Counseling** – for the real **work** of recovery
  – Accept the disease
  – Know one’s vulnerabilities
  – Anticipate risk factors
  – Insulate from re-encountering the drug of abuse, even under stress
  – Master new coping behaviors
  – Construct healthy relationships
  – Find purpose in life/spiritual grounding
The Stages of Change Model of Recovery

- Precontemplation
- Contemplation
- Preparation
- Action
- Maintenance

Withdrawal Phase Patient
Need for Withdrawal Management (WM) Services

- People with SUDs have good treatment outcomes
- Problem: Not enough people with SUD enter treatment
- Onset of withdrawal symptoms presents a unique opportunity to engage individuals with SUD in the treatment system

<table>
<thead>
<tr>
<th>Withdrawal Management (WM) Levels of Care</th>
<th>Residential / Inpatient Services</th>
<th>Medically Managed Intensive Inpatient WM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3.2 Medically Monitored Intensive Inpatient WM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.7 Medically Monitored Intensive Inpatient WM</td>
</tr>
</tbody>
</table>

IAP | Medicaid Innovation Accelerator Program
Defining Treatment Terms

• Clinically Managed:
  – Appropriate for individuals with emotional, behavioral cognitive, readiness to change, relapse, recovery environment concerns
  – Services are directed by non-physician addiction specialists

• Medically Managed:
  – Appropriate for individuals requiring daily medical care and 24-hour nursing
  – Diagnostic and treatment services are directly provided and/or managed by an appropriately trained and licensed physician
Identifying the Appropriate Level of Care: Ambulatory Withdrawal Management

• Level 1-WM: Ambulatory WM Without Extended On-Site Management
  – Ex. Physician’s office, home healthcare agency
• Level 2-WM: Ambulatory WM With Extended On-Site Management
  – Ex. Partial hospitalization facility

Reasons for Preferring Outpatient Levels of Care:

• More accessible
• Simultaneous provision of psychosocial services is more feasible
• Continuity of care is more easily preserved as patients are “stepped down” to less intensive levels of care
Identifying the Appropriate Level of Care: Residential/Inpatient

- Level 3.2-WM: Clinically Managed Residential WM
  - Ex. Social setting WM facility
- Level 3.7-WM: Medically Monitored Inpatient WM
  - Ex. Free standing WM facility, within specialty unit of an acute care general/psychiatric hospital, addiction rehab facility
- Level 4-WM: Medically Managed Intensive Inpatient WM
  - Ex. Acute care general/psychiatric hospital

Higher intensity residential and inpatient levels of WM may not be the most appropriate level of care...
# ASAM Placement Criteria

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intoxication/Withdrawal</td>
<td>no risk</td>
<td>minimal</td>
<td>some risk medical</td>
<td>severe risk</td>
</tr>
<tr>
<td>Medical Complications</td>
<td>no risk</td>
<td>manageable</td>
<td>monitoring</td>
<td>24-hr acute med. care</td>
</tr>
<tr>
<td>Psych/Behavior Complications</td>
<td>no risk</td>
<td>mild severity</td>
<td>moderate</td>
<td>24-hr psych. &amp; addiction Tx required</td>
</tr>
<tr>
<td>Readiness For Change</td>
<td>cooperative</td>
<td>cooperative but requires structure</td>
<td>high resist., needs 24-hr motivating</td>
<td></td>
</tr>
<tr>
<td>Relapse Potential</td>
<td>maintains abstinence</td>
<td>more symptoms, needs close monitoring</td>
<td>unable to control use in outpt care</td>
<td></td>
</tr>
<tr>
<td>Recovery Environment</td>
<td>supportive</td>
<td>less support, w/ structure</td>
<td>can cope</td>
<td>danger to recovery, logistical incapacity for outpt</td>
</tr>
</tbody>
</table>
MGH-Harvard ASAM Criteria Validity Study
Gastfriend, et al.  Supported by NIDA grants # R01-DA08781 & K24-DA00427

• Randomized controlled trial (RCT) in 3 Cities in Eastern MA
• Tested matched v. mismatched assignments with PPC-1
• Compared Levels II (IOP) & III (Residential)
• Outcomes: No-show to step-down care
• Balanced for gender, ethnicity (N=700)
• Used computerized algorithm; blinded raters, patients & treaters
  ▪ Based on instruments with known reliability
  ▪ B.A. level interviewers
    achieved inter-rater reliability of 0.77 (ICC)
Under-Matching Worsens No Shows

From Inpatient Detox to Residential Rehab or Day Treatment: All patients, High Frequency Cocaine Users and Heroin Users

- All Patients (N=700)
  - Mis-matched: ~25% worse
  - Matched: ~25% worse
  - p≤.019

- Cocaine (N=183)
  - Mis-matched: ~100% worse
  - Matched: ~100% worse
  - p≤.001

- Heroin (N=279)
  - Mis-matched: ~300% worse
  - Matched: ~300% worse
  - p≤.001
Patient Assessment & Early Intervention Services

David R Gastfriend, MD DFASAM
Chief Architect, CONTINUUM
– The ASAM Criteria Decision Engine
American Society of Addiction Medicine
Vice President, Washington Circle Group
<table>
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</thead>
<tbody>
<tr>
<td>4: Medically Managed</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3: Residential</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2: Intensive Outpatient</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>1: Outpatient</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

**Level 2**
Evidence for ASAM Matching

Validity

- Face validity, inter-rater validity and concurrent validity

Predictive Validity

- ASAM matching: superior in: no-show rates, global improvement, drug use, step-down, hospital utilization
- Overall and with heroin, cocaine, comorbid populations
- For undermatching and overmatching
- In multiple systems, pay models (block grant, Medicaid, VA)
- In multiple cultures/languages (MA, NYC, Belgium, Norway)
- At multiple time frames: immediate, 30-day, 90-day, 1 year

Feasibility

- Good patient and provider adoption
- Streamlined for repeated use across the CONTINUUM
"Thank you for doing this screening with me today. I'd like to spend about 10 minutes with you now, asking you just a few questions to get a rough sense of the best place to start your care. When you arrive there, they will conduct a more detailed assessment and discuss with you whether you should start treatment there or at a place that offers a more intensive or less intensive level of treatment. Is that OK?"
1809808
Religion: Protestant  Ethnicity: Caucasian

"How strong is your desire to use any drug right now?"

"Have your addiction symptoms increased recently? How...? (Ask about any items below not mentioned by the patient) Have you had more craving, risk behaviors, more frequent use, increased amount of substance or have you used a more rapid route of administration?"

"Do you feel you are likely to continue using or, if not using, that you are in danger of relapsing? How soon...? Do you feel at risk, even if you have had some treatment previously?"

"Do you have any concerns about pursuing treatment...? Would anything possibly hold you back, such as money, insurance, schedule, attending groups, having to take medicines, drug tests, or drinking or drug-using friends?"
Example Patient Assessment - Triage

Patient: L-3Prg Gastfriend
Interviewer: gastfriend@gmail.com

Admission Date: 12/4/2016 3:21 PM
Assessment Begun: 12/4/2016 3:21 PM
Assessment Ended: 12/4/2016 3:26 PM

20) Would ambulation/mobility problems impede attending No treatment?

21) Will daily routine keep patient occupied most days AND No free from problematic alcohol or drug(s)?

Comments:

FINAL SCORING & PROVISIONAL RECOMMENDATION

This patient has met the provisional requirements for Level 3 - Residential/Inpatient Services, Opioid Treatment Services (Pregnancy).

QUALIFIERS - SUBLEVELS OF CARE

This patient also shows signs of Withdrawal Management.

Note:

1. L-0.5, L-1, L-2 and L-4 in this Triage Tool are fully specified, whereas L-3 has specifications but can also be selected as a default, when none of the other LOCs are specified. This is to assure adequate services for the initial evaluation site, where additional detail will become known in the full CONTINUUM(TM) assessment.

2. L-OTS is not one LOC but includes: OTP (Methadone Maintenance Program), OBOT (Office-Based Buprenorphine Treatment) and XRNTX (Extended-Release Naltrexone). IN PREGNANCY: Patient should be sent to either OTP, or if unavailable, OBOT. Otherwise, the choice between OTP, OBOT & XR-NTX should be by patient choice. L-OTS can be combined with any other LOC; therefore, if L-OTS is recommended in addition to L-3 or L-4, the patient should proceed to a L-3 or L-4 site for full evaluation.

3. If L-4 is recommended, consider ambulance transport, e.g., if patient is frankly psychotic, acutely suicidal, or acutely medically ill.
Category of final disposition (i.e., where the patient is actually being sent to treatment):

Level 3.7 - Medically Monitored Intensive Inpatient Treatment

Reason for final disposition (i.e., where the patient is actually being sent, different from Recommended)

Clinician disagrees with ASAM Criteria recommendation

- Not applicable (patient agrees) / or No Answer
- Final disposition is, or is expected to be, same as recommended by ASAM Criteria
- Different treatment selected due to patient choice
- Recommended program is unavailable in geographic region
- Lack of physical access (e.g. transportation, mobility)
- Conflict with job / family responsibilities
- Patient lacks insurance
- Patient has insurance but insurance will not approve recommended treatment
- Program available but lacks opening or wait list too long
- Program available but rejects patient due to patient characteristic(s), e.g. attitude, behavior, clinical presentation
- Court or other mandated treatment is different or blocks PPC-2R recommendation
- Patient rejects any treatment at this time
- Patient eloped

Clinician disagrees with ASAM Criteria recommendation

- Not known

NOTE: This provisional recommendation is made by the individual provider (including FEi Systems) assessing the patient, and is not intended to guarantee availability of treatment. Users may need to check with local treatment facilities, as there are many clinical tools that determine the best course of treatment, which may be available in a variety of levels and modalities of care.

Comments:

This is a Demo Site do not enter any actual PHI.
Partial Hospitalization & Clinically Managed Low Intensity Services

David Gastfriend, MD
Chief Architect, CONTINUUM – The ASAM Criteria Decision Engine
American Society of Addiction Medicine
Vice President, Washington Circle Group
ASAM Levels of Care

- **Focus:** Levels 2.5 and 3.1

---

**Levels 0 - 4**

- **0**
  - Early Intervention
  - Outpatient Services

- **1**
  - OTS
  - Opioid Treatment Services

- **2**
  - Intensive Outpatient Services
  - Partial Hospitalization Services

- **3**
  - Clinically Managed Low-Intensity Res. Services
  - Clinically Managed High-Intensity Res. Services

- **4**
  - Medically Monitored Intensive Inpatient Services
Level of Care for MAT Support

- Based on the ASAM Criteria decision rules
- **Level 3-WM Withdrawal Management (WM) Inpatient Care**
  Severe withdrawal, with med/psych issues & unlikely to complete
- **Level 2-WM Intensive Outpatient (IOP) Care**
  Moderate, needing daytime support & supervision, But with a supportive evening/night environment
- **Level 1-WM Outpatient Care**
  Mild withdrawal and stability across all 6 dimensions
- **Level OTS Opioid Treatment Services**
  Need for daily opioid agonist meds, plus counseling For severe, unstable addiction & chaotic life environment
# Level 2.5 – Partial Hospitalization

<table>
<thead>
<tr>
<th>Setting: Structured outpatient setting</th>
<th>With direct access to psych, medical, lab services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Interdisciplinary teams with MH cross-training, qualified practitioners must provide medical, psych, psychiatric, lab, toxicology and emergency services</td>
<td></td>
</tr>
<tr>
<td>Treatment A support system for all medical &amp; behavioral health needs with psych &amp; other medical consult available within 8 hours by phone or 48 hours in person</td>
<td></td>
</tr>
<tr>
<td>Goal: Individual/group counseling, educational groups, occupational therapy, psychotherapy, MAT, enhancement &amp; engagement strategies, motivational interviewing</td>
<td></td>
</tr>
</tbody>
</table>
Patient Selection

Patient Assessment: organize with ASAM Criteria dimensions

- Acute Intoxication and/or Withdrawal Potential
- Biomedical Conditions and Complications
- Emotional, Behavioral, or Cognitive Conditions and Complications
- Readiness to Change
- Relapse, Continued Use, or Continued Problem Potential
- Recovery/Living Environment
Adult Admission Criteria for Level 2.5
*This webinar only presents a high-level overview of admissions criteria

Basic Requirements

• If any biomedical or emotional, psychological or cognitive conditions, these are severe enough to distract from treatment or require medical monitoring/management
• If any emotional, behavioral or cognitive conditions, these prevent stability over a 48-hour period or risk endangerment

And 1 or more of the following:

• Requires structured therapy to promote progress (e.g., previous treatment failures or impulse control issues)
• SUD symptoms are intensifying or there is a high likelihood of relapse w/o structured therapeutic services
• Continued exposure to non-supportive living/working environment hinders recovery
Level 2.5: Partial Hospitalization Services

Description

- Structured intensive outpatient settings (e.g., partial hospitalization programs) with ~20 or more hours of clinically intensive programming each week provide a support system for all medical and behavioral health needs
- Co-occurring capable vs. co-occurring enhanced

Staffing

- Interdisciplinary teams with cross-training in mental health
- Qualified practitioners who can provide medical, psychological, psychiatric, lab, toxicology, and emergency services
Level 2.5: Partial Hospitalization Services

Services

- Skilled treatment services including:
  - 1:1 and group counseling, medication management, educational groups, occupational therapy, family therapy, motivational enhancement

- Consultation/referral access:
  - Medical, psychological, psychiatric, lab, toxicology within 8 hours via telephone or 48 hours in-person
  - Emergency services w/in 24 hours via telephone 7 days/week
  - Direct affiliation with other levels of care
Where It’s At:
Levels of Care for MAT Induction

9:00-10:15  Agenda & Scientific Rationale
10:15-10:30  Break
10:30-11:15  Induction Protocols
11:15-12:00  Service Needs for Different Protocols
12:00-1:00  Lunch
1:00-2:15  ASAM Criteria & Level Specifications
2:15-2:30  Break
2:30-3:15  Decision Logic for LOC Selection
3:15-4:00  Optimizing Real-time Decision Making
4:00  Discussion & Conclusions
ASAM PPC Decision Rules – Mr. D.

- Mr. D. is a 41 y/o MWM unemployed carpenter, referred by his wife, a nurse, who, after a recent relapse, will soon throw him out if he continues his daily 6-pack habit and Percocet.

- His history includes no prior withdrawal symptoms, but + major depression with suicidal ideation, intermittent prescribed opiates for low back injury, & alcoholism in his father.

- He would now accept treatment, including abstinence from any opiates, restarting his antidepressant, & attending some AA meetings.
ASAM PPC Decision Rules – Mr. D.

Level 2

1 - Outpatient

2 - Day Tx

3 - Med Mon

4 - Med Mgd

DIMENSION

1 2 3 4 5 6
WD Bio Psy Mot Rel Env

LEVEL OF CARE
### Example of WM Assessment & Matching: Opioid Use Disorder

<table>
<thead>
<tr>
<th>Step 1: Dimension 1 Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assessment:</strong> Patient has nausea, diarrhea, body aches, is anxious, restless and irritable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2: Adjust Risk Based on Multidimensional Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assessment:</strong> Patient had debilitating symptoms during previous withdrawal, now has low level of commitment to treatment w/ questionable cooperation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 3: Match Final Risk w/ Level of Care &amp; Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two possible levels:</td>
</tr>
<tr>
<td>2-WM: Ambulatory WM w/ extended on-site monitoring</td>
</tr>
<tr>
<td>3.7-WM: Medically monitored inpatient WM</td>
</tr>
</tbody>
</table>
"Thank you for doing this screening with me today. I’d like to spend about 10 minutes with you now, asking you just a few questions to get a rough sense of the best place to start your care. When you arrive there, they will conduct a more detailed assessment and discuss with you whether you should start treatment there or at a place that offers a more intensive or less intensive level of treatment. Is that OK?"

"Are you asking for help with a substance use problem that is either alcohol or drugs? Is this for yourself or someone else?"

"Which substances are you having problems with that you would like help with?" [Select all that are mentioned.]

- Not answered (patient does not acknowledge use problem)
- Tobacco or other nicotine-containing products (inhalants)
- Alcohol
- Marijuana or cannabis
- Heroin
- Methadone or buprenorphine or Suboxone®, even if prescribed for opioid use disorder
- Opioid or narcotics other than heroin, methadone
- Cocaine
- Stimulants other than cocaine (e.g., amphetamines)
- Barbiturates
- Non-barbiturate sleeping pills, anti-anxiety pills, some benzodiazepines (e.g., Ativan, Xanax, Ambien), even if prescribed
- Solvents or inhalants
- PCP & other hallucinogens
- Any other drug of abuse (e.g., high-dose caffeine, street painkillers)
- No history of alcohol or any other drugs used
"Based on your experience, would you need a detox to stop using?"

"Have you needed inpatient detox in the past?"

[If doesn't know:] "What happens when you stop drinking/using?"

[If hasn't stopped:] "What do you think your withdrawal would be like - would you feel sick if you tried?"

Reference for determining withdrawal:
If using multiple substances, answer based on greatest risk.
NOTE: Alcohol/barbiturate/benzodiazipine withdrawal can be life-threatening. Opioids can be difficult to withdraw from (although less life-threatening).

0-No withdrawal, no risk of severe withdrawal (neither intoxicated nor showing any withdrawal symptoms and no history of needing withdrawal treatment);

1-At least mild withdrawal OR evidence of imminent withdrawal AND minimal risk of a severe withdrawal syndrome AND can be safely managed at Level 1-WM (has or has had withdrawal symptoms such as mild anxiety, tremor, or mild insomnia but is not intoxicated, is cognitively clear and can eat adequately without vomiting or severe diarrhea);

2-Withdrawal OR evidence of imminent withdrawal AND moderate risk of severe withdrawal outside a program setting, but is free of severe physical and psychiatric complications AND would safely respond to several hours of monitoring, medication and treatment (has symptoms such as difficulty controlling anxiety, overt tremor, or mild difficulty sleeping or eating or mild diarrhea, but without history of DTs or withdrawal seizures, is cognitively clear and can focus on discussing problems without distraction by symptoms)
Level 2- WM (has or has had withdrawal symptoms such as mild anxiety, tremor, or mild insomnia but is not intoxicated, is cognitively clear and can eat adequately without vomiting or severe diarrhea)

2- Withdrawal OR evidence of imminent withdrawal AND moderate risk of severe withdrawal outside a program setting, but is free of severe physical and psychiatric complications AND would safely respond to several hours of monitoring, medication and treatment (has symptoms such as difficulty controlling anxiety, overt tremor, or mild difficulty sleeping or eating or mild diarrhea, but without history of DTs or withdrawal seizures, is cognitively clear and can focus on discussing problems without distraction by symptoms)

3- Withdrawal OR evidence of imminent withdrawal AND no risk of severe withdrawal syndrome AND moderate withdrawal is safely manageable at Level 3.2-WM (has symptoms such as mild anxiety, tremor, and mild insomnia, is cognitively clear and eats adequately without vomiting or serious diarrhea, but still some intoxication evident or extent of withdrawal severity is not well established, requiring more than 6-8 hours of monitoring to determine full extent of withdrawal needs)

4-Severe withdrawal OR evidence of imminent severe withdrawal which is manageable at Level 3.7-WM (has or has had problems such as the following: noticeable tremor of both limbs and torso, high distractibility due to anxiety, cognitive symptoms such as confusion or sensory illusions, vomiting or persistent diarrhea, need for medication to manage DTs or seizures, or resting systolic blood pressure above 130 or heart rate above 90)

5-Severe withdrawal OR imminent severe withdrawal (has or has had problems such as the following: severe or breakthrough DTs, seizure disorder, serious cardiac problems, malnutrition or need for IV rehydration or overt cognitive impairment or hallucinations)

9- Not answered OR don’t know
"Do you have any medical problems these days?"

- None
- Neurological, seizures or fits
- Ophthalmologic, eye
- Ear/nose/throat
- Dental, teeth, gums
- Cardiovascular (heart, circulation, heart attack)
- Pulmonary, lung, asthma
- Digestive, stomach, bowel, liver, pancreas, diah
- Urinary, bladder
- Reproductive, (If male: prostate; If female: gyn periods)
- Skin
- Musculoskeletal
- Immune/rheumatologic
- Endocrine (hormones/glands)
- Malignancy, cancer
- Other

"Are any of these problems serious?" [List all mentioned items from Q7.]

"How serious are they?"

"Are you under the care of a healthcare provider? What treatment is being recommended and provided?"

"Do you think you need to be in a hospital?"

- Acute life-threatening health crisis requiring emergency room or hospital
  (vomiting blood, active seizure) 9
- Severe health problems & may require urgent care or physician's change in medical plan at any time; non-life threatening but needs to be assessed 8
- Other health problems 7
"How serious are they?"

"Are you under the care of a healthcare provider? What treatment is being recommended?"

"Do you think you need to be in a hospital?"

| Acute life-threatening health crisis requiring emergency room or hospital (vomiting blood, active seizure) | 9 |
| Severe health problems & may require urgent care or physician’s change in medical plan at any time; non-life threatening but needs to be assessed immediately (e.g., jaundice) | 8 |
| Considerable problems & may need nursing care during day, evening & nights (e.g. chronic pancreatitis) | 7 |
| Moderate problems require close outpatient follow-up (e.g. diabetes. patient needs regular healthcare visit(s) but not urgently) | 6 |
| Minimal health issues (i.e., backache, dental disease) | 5 |
| No medical (i.e. non-substance) problems | 4 |

"Are you pregnant?" [If NO, score 0 & skip to Q10]

[If YES:] "Does the pregnancy involve any high risk? Is there any unstable problem that might require monitoring, such as bleeding, leaking amniotic fluid (‘water breaking’), contractions, or an unstable fetal heartbeat?"
Dimension 3 - Emotional, Behavioral, or Cognitive Conditions and Complications

"Are you having any psychological or emotional problems, of any kind? Can you please describe the symptoms you have?"

"What are these problems like for you?" (Choose the closest category/ies that may fit the patient’s description. Choose all that seem potentially appropriate.)

- None
- Symptoms of:
  - Anxiety Disorder
  - Panic Disorder
  - Agoraphobia
  - Post Traumatic Stress Disorder
  - Social Phobia
  - Obsessive-Compulsive Disorder
  - Eating Disorder
  - Depressive Disorder
  - Mania or Bipolar Disorder
  - Schizophrenia, Psychotic or Thought Disorder
  - Personality Disorder (e.g., Borderline, Paranoid, Antisocial, etc.)
  - Other
  - Not Answered

"Are you having trouble understanding, concentrating, or remembering things? How serious is this problem for you?"

[If Yes] "Are these problems mostly when you are using, OR coming off of your alcohol or drug(s) OR not related to them?"

"Are you having hallucinations, that is, seeing, hearing, smelling or feeling things that were not there? How serious is this problem for you?"

[If Yes] "Are these problems mostly when you are using, OR coming off of your alcohol or drug(s) OR not related to them?"
Dimension 6 - Recovery/Living Environment

- "Are you involved in any court or legal/criminal conviction requirement that requires you to be in a residential or inpatient program or halfway house?"

- "Do you have a safe place to live, where you can stay and begin treatment? Can you consistently attend a daily or weekly outpatient program if this is offered to you?"

- "Would you have transportation available to a treatment program? What kind of transportation could you use and how often would it be available to you? Will this be safe for you?"

- "Do you have any problems with walking or getting around that would make it difficult to attend treatment? For example needing a cane, scooter, or difficulty climbing stairs or walking commuter distances."

- "Do you have a daily routine that keeps you occupied most days and can be free from the substances that you are trying to stop or decrease using?"

  [If asked:] Daily routine = job, school, providing child care and Most days = weekdays.

Comments:
Addiction Treatment History

Have you had any previous treatment for alcohol or other drug use problems? [Drug only]

How many times in your life have you been treated for drug use problems? 

Counting the times in your life you have been treated for drug use problems, how many of these were withdrawal management only? 

Have you usually left withdrawal management before you were advised to, in the past? [Yes No]

After withdrawal management, have you usually entered continued treatment? [Yes No]

How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days (include attending N.A., A.A., etc.)? 

In the past 90 days, have you relapsed after being discharged from, or dropping out of, another treatment program? What type? (If the patient has relapsed, what was the highest level of care that the patient failed in past 90 days?) 

Have you just successfully completed (or are you just about to complete) a treatment program? What type? (If yes, what was the Level of Care?)
### Additional Addiction and Treatment Items

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which substance is the major problem?</td>
<td>Heroin</td>
</tr>
<tr>
<td>How long was your last period of voluntary abstinence from this major substance? (Select 0, if never abstinent)</td>
<td>Years: 0 Months: 0</td>
</tr>
<tr>
<td>How many times have you overdosed on drugs or alcohol?</td>
<td>10</td>
</tr>
<tr>
<td>Have you had a substance (alcohol and/or drug) overdose in the past 24 hours?</td>
<td>No</td>
</tr>
<tr>
<td>Imagine yourself in the environment in which you previously used drugs and/or alcohol. If you were living in this environment today, what is the likelihood that you would use?</td>
<td>0 (Not at all)</td>
</tr>
<tr>
<td>Rate how strong your urges are for a drug and/or alcohol when something in the environment reminds you of it.</td>
<td>0 (Not at all)</td>
</tr>
<tr>
<td>How strong is your desire to use any drug right now?</td>
<td>0 (Not at all)</td>
</tr>
<tr>
<td>Have your addiction symptoms increased recently? How...? (Ask about any items below not mentioned by the patient) Have you had more craving, risk behaviors, more frequent use, increased amount of substance or have you used a more rapid route of administration?</td>
<td>No</td>
</tr>
<tr>
<td>Do you feel you are likely to continue using or, if not using, that you are in danger of relapsing? How soon...? Do you feel at risk, even if you have had some treatment previously?</td>
<td>Increased use or more acute route of administration than before</td>
</tr>
</tbody>
</table>
"How strong is your desire to use any drug right now?"

"Have your addiction symptoms increased recently? How...? (Ask about any items below not mentioned by the patient) Have you had more craving, risk behaviors, more frequent use, increased amount of substance or have you used a more rapid route of administration?"

"Do you feel you are likely to continue using or, if not using, that you are in danger of relapsing? How soon...? Do you feel at risk, even if you have had some treatment previously?"

"Do you have any concerns about pursuing treatment...? Would anything possibly hold you back, such as money, insurance, schedule, attending groups, having to take medicines, drug tests, or drinking or drug-using friends?"

Options:
- No; has been fully participating in all recommended treatments
- No; open to fully participating in any recommended treatments
- Passive or some hesitations
- Resists important components
- Rejecting or obstructs plan with many contingencies
<table>
<thead>
<tr>
<th>Question</th>
<th>Rating Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Have you been emotionally abused during the past 30 days?&quot;</td>
<td>Not at all, Slightly, Moderately, Considerably, Extremely</td>
</tr>
<tr>
<td>&quot;Have you been physically abused during the past 30 days?&quot;</td>
<td>Not at all, Slightly, Moderately, Considerably, Extremely</td>
</tr>
<tr>
<td>&quot;Have you been sexually abused during the past 30 days?&quot;</td>
<td>Not at all, Slightly, Moderately, Considerably, Extremely</td>
</tr>
<tr>
<td>&quot;Who is the person (or persons) with whom you have had contact during the past 4 months and who has been most important to you?&quot;</td>
<td></td>
</tr>
<tr>
<td>&quot;Have you recently neglected/abused family members?&quot;</td>
<td>Not at all, Slightly, Moderately, Considerably, Extremely</td>
</tr>
<tr>
<td>&quot;How much help will this person (or these persons) need to assist in your treatment and recovery and how likely is it that he/she/they&quot;</td>
<td></td>
</tr>
</tbody>
</table>
Trouble with your attitude or holding onto relationships with others?

In your lifetime?
- 0: Not at all
- 1: Slightly
- 2: Moderately
- 3: Considerably
- 4: Extremely

Serious thoughts of suicide, i.e. that you would be better off dead, or wanting to hurt yourself?

In your lifetime?
- 0: Not at all
- 1: Slightly
- 2: Moderately
- 3: Considerably
- 4: Extremely

Thoughts of how you might hurt yourself?

In your lifetime?
- 0: Not at all
- 1: Slightly
- 2: Moderately
- 3: Considerably
- 4: Extremely

Attempted suicide?

In your lifetime?
- 0: Not at all
- 1: Slightly
- 2: Moderately
- 3: Considerably
- 4: Extremely
Psychosocial Therapy/Support

- Brief interventions
- Motivational Enhancement Therapy
- 12-step programs
- Cognitive-Behavioral Therapy
- Cue exposure therapy
- Behavioral Couples Therapy
- Recovery Support Services: Coaches, Wrap-Around Services
- Contingency Management
Motivational Interviewing

A counseling style based on the following assumptions:

- Ambivalence about substance use change is normal and a motivational obstacle.
- Direct argument & aggressive confrontation may increase client defensiveness & reduce the likelihood of behavioral change.
- Ambivalence can be resolved by working with intrinsic motivations & values.
- The alliance between provider & client is a collaborative partnership to which you each bring important expertise.
- An empathic, supportive, yet directive, counseling style provides conditions under which change can occur.
Motivational Interviewing

1. Express empathy through reflective listening.

2. Develop discrepancy between clients' goals or values and their current behavior.

3. Avoid argument and direct confrontation.

4. Adjust to client resistance rather than opposing it directly. Roll with resistance, side with the negative ambivalence, reframe

5. Support self-efficacy and optimism.
Motivational Enhancement Therapy

- Aims to evoke rapid, internally motivated change, rather than guide patient stepwise through recovery process.
- After assessment, 2 to 4 sessions (1:1)
- 1: Feedback, stimulate discussion & self-motivational statements. Use MI to build motivation & a change plan, with coping strategies for high-risk situations.
- 2-4: Monitor change, review strategies, boost commitment.
- Effective for alcohol, MJ, (with CBT); mixed for other drugs. More effective for treatment engagement than for cessation.
Patient Engagement

- Use a Motivational Interviewing (MI) model of assessment and psychoeducation,
- Advise patients of their options,
- Discuss relative success rates of MAT vs. non-MAT care
- Review the treatment burdens
  - Initial withdrawal management
  - Tapering upon cessation
  - Length of treatment
  - Side effects
  - Contraindications, cautions & warnings
<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>1. OUTPT</th>
<th>2. INTENSIVE OUTPT</th>
<th>3. MED MON INPT</th>
<th>4. MED MGD INPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intoxication/Withdrawal</td>
<td>no risk</td>
<td>minimal</td>
<td>some risk medical</td>
<td>severe risk</td>
</tr>
<tr>
<td>Medical Complications</td>
<td>no risk</td>
<td>manageable</td>
<td>monitoring required</td>
<td>24-hr acute med. care</td>
</tr>
<tr>
<td>Psych/Behav Complications</td>
<td>no risk</td>
<td>mild severity</td>
<td>moderate</td>
<td>24-hr psych. &amp; addiction Tx required</td>
</tr>
<tr>
<td>Readiness For Change</td>
<td>cooperative</td>
<td>high resist., needs 24-hr motivating</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>but requires structure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapse Potential</td>
<td>maintains abstinence</td>
<td>more symptoms, needs close monitoring</td>
<td>unable to control use in outpt care</td>
<td></td>
</tr>
<tr>
<td>Recovery Environment</td>
<td>supportive</td>
<td>less support, w/ structure</td>
<td>can cope</td>
<td>danger to recovery, logistical incapacity for outpt</td>
</tr>
</tbody>
</table>
## Induction LOC Logic

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Level 1 WM</th>
<th>Level 2 WM</th>
<th>Level 3.2 WM</th>
<th>Level 3.7 WM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Intoxication</td>
<td>Mild</td>
<td>Mild-Mod</td>
<td>Mild-Mod</td>
<td>Mod-Severe</td>
</tr>
<tr>
<td>Withdrawal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Biomedical</td>
<td>Stable</td>
<td>Stable-Mild</td>
<td>Stable</td>
<td>Mild-Mod</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Emotional</td>
<td>Stable</td>
<td>Stable-Mild</td>
<td>Stable</td>
<td>Mild-Mod</td>
</tr>
<tr>
<td>Behavioral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Relapse</td>
<td>Low Risk</td>
<td>Low-Mod Risk</td>
<td>Mod Risk</td>
<td>Mod-Hi Risk</td>
</tr>
<tr>
<td>Potential</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Environment</td>
<td>Supportive</td>
<td>Low Structure</td>
<td>Unsupportive</td>
<td>Unsupportive</td>
</tr>
</tbody>
</table>
Where It’s At:
Levels of Care for MAT Induction

9:00-10:15  Agenda & Scientific Rationale
10:15-10:30  Break
10:30-11:15  Induction Protocols
11:15-12:00  Service Needs for Different Protocols
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1:00-2:15  ASAM Criteria & Level Specifications
2:15-2:30  Break
2:30-3:15  Decision Logic for LOC Selection
3:15-4:00  Optimizing Real-time Decision Making
4:00  Discussion & Conclusions
From Screening to Prescribing

- In medicine, patients accept a majority of treatment recommendations made by their physician.
- In addiction, <50% of eligibles actually get MAT.
- The largest cause of drop-off: is lack of readiness for detox or definitive treatment, due to the motivational disruption of addictive disease.
- This problem is followed by culture obstacles in the treatment environment.
- Patient failure to engage is commonly due to:
  - Delays: insurance, wait-lists, detox (w/XR-NTX)
  - Stigma
  - Motivational impact of the disease
Patient Engagement

Medical Management

- Evidence-based, brief counseling model to reinforce:
  - Adherence
  - Counseling participation
  - Mutual-help group activity
  - Recovery

(COMBINE Project, 2004)
Medical Management

- Follow patient throughout withdrawal, with assessment, support, & direct advice for stabilization.
- Appeal to patients’ common sense & reasoning ability, in relation to the goal of achieving a good treatment start.
- In expressing concern for patients, be nonjudgmental. Also be friendly, supportive, & optimistic about recovery. Acknowledge discomfort & praise endurance & steps taken towards persevering.
Medical Management: Initial Session

- Review intake evaluation results
- Present diagnostic information and set treatment goals
- Provide medication information
- Develop Medication Adherence Plan – individualize it
- Discuss counseling & mutual-support group participation
- Seek patient’s questions, concerns, expectations
- Summarize Initial Session & address patient’s concerns
- 40-60 min
Medical Management: Follow-Up Session

- Check Medical Status & Meds Safety & Adherence
- Status check, incl. drug tests
  - “What was your goal?”, “How did you do?”
  - Avoid disapproval/disappointment –“What went well?”
  - “What didn’t? What were the circumstances?”
  - Don’t signal that s/he will not attain recovery, rather, note any positives & where more/new efforts may help
- Troubleshoot Outcomes, e.g., revisit motivating reasons
- Make Recommendations:
  - Add PRNs, Treatment Components, Escalate Level of Care
- 15-25 min
Supportive Other/Family Engagement

- Early identification
- Obtaining consent to involve & be in contact
- With one or more supportive others
- Both initially & throughout follow-up
- Reinforce availability, safety & retention
- If appropriate, involve in monitoring induction dosing & PRNs
- If needed, determine suitability for home management of meds
Counsel the Patient Regarding…

- Mood effects: Anxiety, Depression
- Cognitive effects: Slowing, dizziness: initially, avoid driving
- Naltrexone “Flu” and nausea - tend to be mild, for a few days
- Note prior daily reinforcement on short-acting opioids, & even on methadone & less so, buprenorphine
- Notifying prescriber in case of pregnancy/breast-feeding
Counseling For MAT Induction: What?

- What is the Clinical Risk/Benefit?
- What Detox Approach Should I Go Through?
- What is the Time Frame?
- What is the Patient Role?
- What are the Side Effects?
Counseling During MAT Induction: HOW?

- Explore the Patient’s Perceptions
- How Is Hydration, Sleep, Appetite, Energy?
- How Is Craving Changing?
- “Pulling Off the Band-aid”: Slowly or All-At-Once
- How to Cope? Accepting Neediness, Taking Comfort Measures
- Light Activity/Exercise is Acceptable & May Be Helpful
Counseling During MAT Induction: HOW?

- Anticipate & recognize discomfort
- Foster Self-Efficacy: You can do it!
- Setbacks & Contingencies
- How Long Should Induction & Comfort Meds Be Continued?
- Talk to Significant Others
MAT Induction Program Best Practices

- MAT Adherence Champion – responsible for ongoing adherence monitoring for all patients undergoing induction
  - Medication Access – get support from sales reps for med availability/reimbursement
  - MAT Patient Tracking System – call patient (& Supportive Other) if late or no-shows
- Referral Affiliation Agreements – for continuity of care
- Have alternative plans ready, just in case:
  - Change in Level of Care (escalation)
  - Buprenorphine
  - Methadone
Recovery Support Services

- Recovery support services:
  - Can be provided throughout the SUD care continuum
  - Are non-clinical services that support individuals and families throughout the recovery process
  - Are an integral part of a recovery-oriented approach
- Example services include, but aren’t limited to:
  - Alcohol and drug free social activities
  - Aftercare services
  - Case management services
  - Child care
  - Employment and education services
  - Housing supports
  - Individual services coordination
  - Information and referral
  - Peer supports
  - Recovery coaching
  - Relapse prevention
  - Self help and support groups
  - Transportation to and from treatment
# Recovery Support Services

<table>
<thead>
<tr>
<th>Type of Support</th>
<th>Description</th>
<th>Peer Support Service Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional</td>
<td>Demonstrate empathy, caring, or concern to bolster person’s self-esteem and confidence.</td>
<td>Peer mentoring Peer-led support groups</td>
</tr>
<tr>
<td>Informational</td>
<td>Share knowledge and information and/or provide life or vocational skills training.</td>
<td>Parenting class Job readiness training Wellness seminar</td>
</tr>
<tr>
<td>Instrumental</td>
<td>Provide concrete assistance to help others accomplish tasks.</td>
<td>Child care Transportation Help accessing community health &amp; social services</td>
</tr>
<tr>
<td>Affiliational</td>
<td>Facilitate contacts with other people to promote learning of social and recreational skills, create community, and acquire a sense of belonging.</td>
<td>Recovery centers Sports league participation Alcohol- &amp; drug-free socialization opportunities</td>
</tr>
</tbody>
</table>
Recovery Support Team Agreement

- We understand how important recovery is to you and how difficult it can be. This agreement lists some of the most important things you can do for your recovery. It is to be signed by you and at least other person who you can count on to support your recovery.

- Patient Agreement:  I, _________________, agree that …

- I will make my recovery the #1 priority in my life and be active in my recovery program for at least one year and one month.

- I will work to abstain from all mood-altering substances and report to members of my Recovery Support Team any increase in craving, worsening of urges, or plans I might have to drink or use any unprescribed substances.

- I will promptly let all members of my Recovery Support Team know if I drink or use any unprescribed substances.

- I promise to keep whatever agreements I make with my Recovery Support Team, including the treatment schedule described below. If for any reason I don’t keep some part of this agreement, I will re-schedule quickly so that my recovery is not disrupted.
Recovery Support Team Agreement

- I will provide **accurate information** to members of my Recovery Support Team. I will not let embarrassment or false pride keep me talking about difficulties I may be having. Even if it is difficult for me I will be honest about how I am doing with my recovery.

- I will report to members of my Recovery Support Team any significant return of symptoms such as: a) drinking, b) drug use, c) urges to drink or use drugs, d) uncomfortable moods, or e) other disturbing physical or emotional symptoms.

- I can be contacted by [ ] telephone [ ] email [ ] mail and/or [ ] in person by members of my Recovery Support Team including qualified members of their staff. I understand that these contacts will respect my confidentiality and that my privacy will be respected at all times.

- I will discuss any plans I have to end treatment with my physician and other members of my Recovery Support Team before dropping out of treatment.

_________________________          ________________________________
Patient Signature                       Support Person/Phone#
Treatment Program Best Practices

- **Support from Current MAT Patients** – may volunteer to provide first-hand accounts to prospective and newly initiated MAT patients.

- **MAT Groups** – Provide educational and emotional support, excellent for patients considering MAT

- **Telephone Support** – Enhances persistence with MAT and counseling engagement

- **Ongoing Clinical Self-report Surveys** – e.g., BAM - Brief Addiction Monitor, to clarify to patient his/her own risks AND protections and to objectively guide psychosocial support/counseling
Be Vigilant For Risks

- MAT blockade testing & override attempts
- Seeking prescribed opioids (either excessive agonist MAT doses or analgesics) to divert them for income – despite MAT
- Not adhering to prescribed regimens
- Returning late for refills
- Premature discontinuation.
- Address risks proactively: advise patient, supportive others, providers; monitor attendance & drug tests; communicate among addiction/medical/justice teams in timely fashion; re-assess & modify plan/ escalate as needed, over & above MAT
Adverse Events

- Side effects can occur with any medication
- AEs fall into basic categories:
  - Serious Adverse Events (SAEs) – rare, but need to anticipate them; may require ED
  - Routinely advise patients to expect common, mild to moderate side effects
- Of greatest concern early; mentoring helps
  - With experience, these become less frequent
- Vivitrol precipitated opioid withdrawal: not a side effect but is an adverse event due to inadequate withdrawal.
- Phone mentors to report these episodes, so they can help improve success with detox and induction.
Drug-Drug Interactions

- Few with the current MAT options, but require prospective awareness/monitoring
- Precipitated opioid withdrawal
  - not a side effect, an adverse event from incomplete WM
  - worse than Cold Turkey withdrawal
  - avoiding this is the goal of effective MAT Induction

FINAL WORDS OF WISDOM...

- Encourage patient to call
- Call the patient to check-in
- REVISE THE PLAN, including escalating Level if needed
Summary: Optimizing in Real-Time

- 50% success rates – *are still not that successful!*
- Patients vary widely, both objectively & subjectively
- Decision logic for MAT induction placement is but an aid
- So...encourage patients & supportive others to call
- Call patients to check-in – DAILY is not too often
- Review med-taking, doses, timetable, symptom progress
- Bring the patient back in, whenever uncertain
- REVISE THE PLAN, *including escalating Level if needed*
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Conclusions: MAT Induction Levels of Care

- Induction protocols are improving
- BUT, Induction success is highly dependent on proper LOC
- Patients’ needs dictate the services required
- ASAM Dimensions & LOC specifications are tools for describing both needs & services
- CONTINUUM’s decision engine is evidence-based for patient engagement & treatment
- Advise patients of optimal approach, offer patient choice, but keep close watch, and if needed, REVISE THE PLAN, including escalating Level of Care
REFERENCES

• ASAM Criteria. Mee-Lee D, Editor. American Society of Addiction Medicine, 2013
• Lee J, et al. Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): A multicentre, open-label, randomised controlled trial Lancet 2017. Published online November 14, 2017
• Wesson DR, Ling W. Clinical Opiate Withdrawal Scale (COWS). J Psychoact Drugs 2011; 23: 253-259