PCSS MAT TRAINING
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For Medication Assisted Treatment

Models of Buprenorphine Induction

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System Requirements

- In order to complete this online module you will need Adobe Reader. To install for free click the link below:
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Target Audience

- The overarching goal of PCSS-MAT is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.

- The target audience for the current module should have basic familiarity with the general process of BUP induction as covered by the standardized, designated 8-hour training programs.

Educational Objectives

- At the conclusion of this activity participants should be able to:
  - List barriers reported by physicians to initiating buprenorphine (BUP) in an office setting
  - Determine the goals of induction
  - Identify different clinical models of BUP induction and associated evidence
  - List the pros/cons of the various models of BUP induction

Induction Goals

- Initiate effective BUP dosing
  - Reduce withdrawal
  - Reduce cravings
  - Stop non-rx opioid use
- Avoid adverse effects
- Establish care structure
  - Sets the tone regarding structure, follow-up, and monitoring
  - Helps establish patient rapport, develop therapeutic alliance

Induction Challenge

- Barrier for inexperienced MD adoption[1-4]
- Concern related to:
  - Precipitated withdrawal transitioning from full -> partial mu agonist
  - Logistics of office induction: time/resources for assessment & monitoring response to initial doses
  - Economics
  - Guideline ambiguity: variable dosing/timing recs
  - Patient-specific factors: e.g., clinical stability

[1] Kissin 2006; [2]Gunderson 2006; [3]Egan 2010; [4]Netherland 2009

Patient Induction Concerns

- Withdrawal symptoms
- Travel for office induction
  - Rural: long distances potentially burdensome
  - Disenfranchised: limited transportation access
  - Driving discouraged after medication initiation. Unclear if driving ability is impaired by opioid withdrawal prior to visit.
  - Anonymity: potentially compromised if pt is in withdrawal in the office or if needs to access a ride
- Patient perspectives data are needed

This Lecture Covers

- 3 models of induction for office practice
  - General in-office approach: the standard approach recommended in CSAT, TIP 40 & 8-hr courses
  - Specialty approach (non-Opioid Treatment Program (OTP)): Could this facilitate induction for some patients/practices?
  - Unobserved “home” approach: patient self-initiated often with clinician phone support

General In-Office Induction

- National guidelines (CSAT, TIP 40, 2004)
  - Withdrawal: should be mild – moderate, but no specific recommendations regarding measurement cut-offs
  - Abstinence timing: varies based on opioid duration of action
    - 12 - 24 hr short-acting
    - 24+ hr methadone
  - Dose: 2 – 4mg initial BUP dose, 8mg maximum on Day #1
  - Monitor: 2+ hours, assessing treatment response

General In-Office Induction

- Updated PCSS guidance[1]
  - Measure withdrawal, several scales available such as:
    - Clinical Opioid Withdrawal Scale (COWS 12–16 is mild/moderate and appears sufficient to avoid precipitated withdrawal[2])
  - Hours of abstinence since last full mu opioid use
    - 12-16 short-acting, 17-24 intermediate-acting, 30-48 methadone
  - BUP dose: 2 – 4mg initial, 16mg max day #1
  - Monitor: 1+ hours
  - Follow-up: phone + visit in 3 – 4 days

[1] Cassadonte, 2013; [2] Nielsen,2014

Clinical Opioid Withdrawal Scale (COWS)

- 11 item scale, max 48 points
  - Includes both objective and subjective items
    - Pulse
    - Diaphoresis
    - Tremor
    - Pupils dilated
    - Yawning
    - Runny nose/tearing
    - GI upset
    - Restlessness
    - Bone/joint ache
    - Anxiety
    - Gooseflesh
  - Objective withdrawal signs help establish physical dependence
  - Serial scales for treatment response assessment

Wesson, 2003
Available at: http://www.naabt.org/documents/cows_induction_flow_sheet.pdf

In-Office Induction Effectiveness

- Few studies specifically assess induction outcome
  - 83% treatment retention after a 2 week induction phase in a primary care study[1]
  - Variable precipitated withdrawal[2-4]
    - 10% in a 1˚ care/specialist clinic[3]
      - 6+ hr heroin abstinence minimum prior to induction
    - None in residential program[5]
    - Mean COWS prior to induction: 8
      - 1/3 ancillary withdrawal medication use

[1] Fiellin 2006; [2]Gibson 2003; [3]Lintzeris 2002; [4]Whitley 2010; [5]Collins2007

General In-Office Induction

- Summary
  - Variation in abstinence & dosing recommendations may pose a clinical challenge
  - Withdrawal scale cutoffs are useful to guide induction
  - Time requirement is potentially burdensome
  - Complication rate is generally low

This Lecture Covers

- 3 models of induction for office practice
  - **General in-office approach**
  - Specialty approach (non-OTP)
  - Unobserved “home” approach

Specialty Induction Approaches

- Two specialized induction approaches will be reviewed:
  - Outpatient Buprenorphine Treatment Program[1]
    - Established 2003 with a goal as an induction center
    - Induction data were collected early after program inception
- General Medical Hospital Induction Study[2]
  - Examined induction vs. detoxification on a medical ward
  - Coupled with outpatient primary care maintenance linkage

[1] Gunderson, 2009; [2] Liebschutz,2014

Buprenorphine Program of Columbia University

- Outpatient psych practice established 2003
- Staffing
  - MD - 2 addiction specialists
  - Clinical psychologist
  - RN
  - Administrator
- Self-pay with insurance reimbursement

Clinical Procedures

- Pre-induction visit
  - Clinical assessment by MD/psychologist
  - Procedural review (changed 3 months after program start)

Abstinence: Initial

- 12 hr short-acting
- 24 hr long/methadone

~ 3 Months Later

- 16 hr short-acting
- 24 hr long-acting
- 36 hr methadone

  - Ancillary withdrawal medication available at the program
    - Clonidine
    - NSAIDs
    - Ondansetron

Induction Visit Procedures

- COWS on arrival and serially
  - General target score 5-12 prior to starting BUP
  - After the first 3 months of experience, began to require > 1 objective sign and raised the pre-dose COWS target to >7
  - Discharge after the COWS decreased to < 4
- Dosing
  - 2-4mg q1-2 hr (BUP/NX or BUP) started at program
  - Take home meds + instructions/phone #s
  - Max 16mg Day 1
  - Initial Rx/stored on site > dispensed (Requires locked storage and detailed documentation)
- Ancillary withdrawal meds taken prn before or after initiation

Induction Effectiveness Study

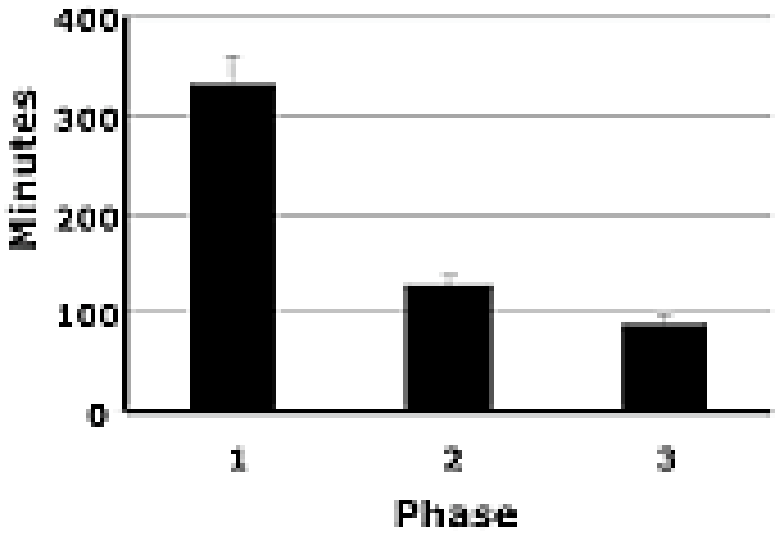
- Chart review[1] for the first 41 patients examined:
  - Temporal process of induction
    - Time until first BUUP dose given
    - Time unit withdrawal was relieved
    - Total time at clinic
  - Procedures associated with efficiency
  - Withdrawal level and BUP dosing
  - Hypothesis: ↑efficiency over phases
    - Each phase included ~13-14 patients over a 2-3 month period after the program opened

[1] Gunderson, 2011 (Supported by NIDA DA020000)

Patient Characteristics (n=41)

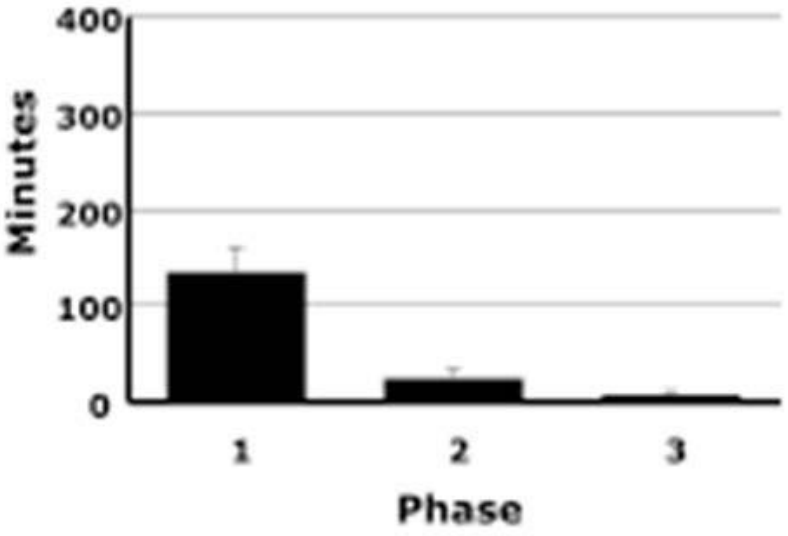
Age (mean)	41 yr
Sex (Male)	59%
Race (White)	78%
Employed	56%
Insured	83%
Psychiatric d/o	68%
Primary opioid, past mo. daily Heroin Rx opioid (non-methadone) Methadone	 41% 41% 22%
Prior buprenorphine	5%

Total Time at the Clinic



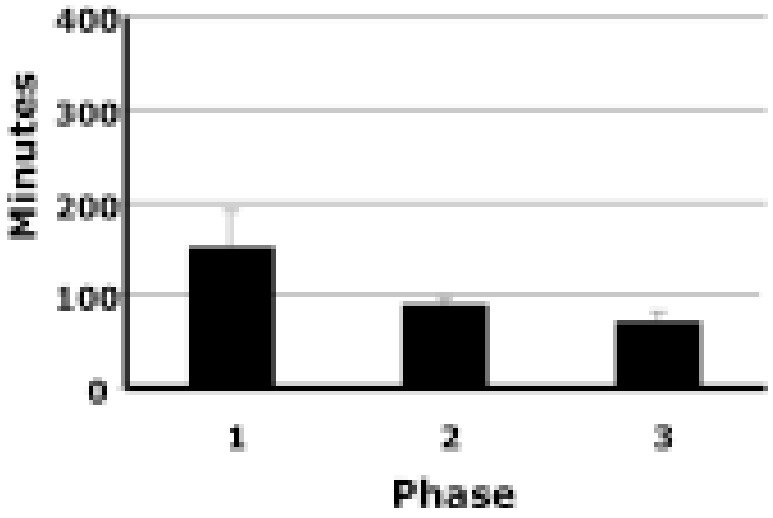
- Efficiency improved across the phases
  - Time may pose less of a practical burden for office induction as experience is gained
  - Several factors may have influenced efficiency

Time Delay Until Initial Dose



- The delay until the initial dose was longer for Phase 1
  - May have related to change in recommended pre-BUP abstinence with patients from later phases arriving in more withdrawal
  - Means COWS on arrival: 6 for Phase 1, 10 for Phases 2 & 3

Time Until Withdrawal Relief



- The time until withdrawal relief was longer for Phase 1
  - Might have related to initial BUP dose size and pre-dose ancillary withdrawal medication use (depicted next slide)
  - COWS immediately before the initial dose did not differ by Phase (mean score = 10)

Medication Dosing

Buprenorphine Dosing (mean mg)	Phase 1	2	3
Initial dose	2*	3	3
Total at program	9	7	6
Total Day #1 (includes at program + take home)	13	11	14
Ancillary withdrawal medication use (%)			
Pre-induction	7*	31	57
Post-induction	20% overall (NS)		

*p<.05; NS = non-significant difference between groups

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Procedural Considerations

- Factors that may facilitate induction[1]
  - Longer abstinence before BUP initiation (16h, 24h, 36h for short-acting opioids, long-acting formulations, and methadone, respectively)
  - COWS 8-10 with objective signs appears adequate, though 12 might be preferable based on a clinical trial[2]
  - Ancillary withdrawal meds could be considered
- Day 1 max 16mg was well tolerated
- Efficiency improves with experience, potentially could translate to other office settings

[1] Gunderson, 2011; [2] Liebschutz,2014

Hospital-Based Induction

- General Medication Hospital Induction Study[1]
  - Objective: Examine effectiveness of buprenorphine treatment initiation during a 5-day medical hospitalization
  - Design: Randomized clinical trial comparing 1) hospital-based buprenorphine induction with linkage to outpatient primary care after discharge for opioid agonist treatment (OAT) vs. 2) hospital detoxification
  - Main outcome measures:
    - Entry and sustained buprenorphine maintenance at 1, 3, & 6 months
    - Prior 30-day use of illicit opioids (self-report)

[1] Liebschutz, 2014

Hospital-Based Induction

- Invention
  - Day 1: Induction with buprenorphine/naloxone 2/0.5, max QID, for both treatment groups
  - Day 2 - 5:
    - Detoxification Group: BUP 8mg > 6mg > 4mg > 2mg (Days 2-5, respectively)
    - Linkage Group: BUP 12mg on Day 2, 16mg on Days 3-5 with research staff facilitated linkage to hospital-associated primary care buprenorphine OAT

[1] Liebschutz, 2014

Patient Characteristics (n=139)

Age (mean)	41 yr
Sex (Male)	71%
Race (White)	43%
Baseline illicit opioid use (past 30d), mean days	21
Baseline past month prescription opioid agonist treatment	41%

- The intervention groups did not differ significantly regarding demographics, baseline frequency of opioid use or opioid agonist treatment

Hospital-Based Induction

- Results[1]
  - Buprenorphine OAT entry was significantly more likely in the hospital-based induction and linkage group compared to the hospital detoxification group (72% vs. 12%, $p < .001$).
  - At 6 months, 17% of linkage vs. 3% detox patients were receiving buprenorphine OAT (p=.007)
  - Linkage patients reported less past 30d illicit opioid use at the 6 month interview

[1] Liebschutz, 2014

Specialty Induction Approaches

- Potential Specialty Induction Approach Limitations
  - Accessibility: dedicated outpatient and inpatient induction programs are of limited availability
  - Cost: the cost of such approaches may be prohibitive for patients and may not be cost-effective relative to outpatient induction
  - Resources: the staffing and other resources required for outpatient program induction and inpatient induction with linkage may be a barrier for approach adoption

This Lecture Covers

- 3 models of induction for office practice
  - **General in-office approach**
  - **Specialty approach (non-OTP)**
  - Unobserved “home” approach

Unobserved “Home” Induction

- PCSS Guidance (2013)[1]
  - Experienced clinicians (and patients) probably better suited for unobserved approach than inexperienced
  - Provide written instructions about withdrawal assessment, dose timing and amount
  - Maintain and document phone contact
  - Follow-up visit within 2 days
  - Overall supporting level of evidence: Low/Moderate, though many unobserved inductions likely performed without adverse effects

[1] Cassadonte, 2009 (Updated 2013 by M. Sullivan)

Implementation

- ~40% Massachusetts prescribers utilize unobserved induction at least some of the time[1]
- >1100 patients in U.S. published reports[2-8]
  - Procedures appear generally c/w PCSS guidance[9]
  - Adoption appears more widespread in academic primary care clinics
  - Most data are prospective or retrospective cohort
  - Only 1 published RCT, a pilot study described as follow

[1] Walley 2008; [2]Alford 2007 ; [3]Lee 2009; [4]Gunderson 2010; [5]Stohler 2010; [6]Soeffing 2009, [7]Mintzer 2007; [8]Lee 2014, [9]Cassadonte 2009; [10]Gunderson & Fiellin 2010

Clinical Procedures

- Adapted from a NIDA-funded pilot study1
  - Pre-visit phone
  - Initial visit
    - Patient assessment
    - Procedural review
    - Decision making discussed
    - Patient handouts reviewed

[1]Gunderson, 2010 (Supported by NIDA DA020000)

Clinical Procedures – Initial Visit

- Patient assessment
  - Establish diagnosis
  - Use pattern (type/amount/duration/route)
  - Document physiological dependence
  - Co-morbidity
  - Goals and motivation
  - UDS/Rx monitoring program

Clinical Procedures – Initial Visit

- Procedural review with patient
  - Abstinence timing: 16, 24 36+ hrs for transition form short/long-acting opioids, and methadone, respectively
    - Withdrawal toleration vs. precipitated withdrawal risk reduction
  - Subjective Opioid Withdrawal Scale (SOWS)[1]
    - 16 items, 0-4 scale, ≥17 (mild) prior to initiation
  - Bup dosing: target the minimally effective dose*
  - Consider ancillary withdrawal medication but not standardized

[1] Handelsman 1987

Clinical Procedures – Initial Visit

- Procedural review, continued
  - Safety
    - Interaction risks, avoiding driving, safe storage
  - Precipitated withdrawal avoidance: review abstinence recommendations
  - Follow-up plan
    - Phone contact the day of induction and on subsequent days
    - Visit in 3-7 days

Clinical Procedures – Initial Visit

- Patient handouts: review when/how to start
  - SOWS ≥17 (higher if possible) as a goal before dosing
  - Bup dosing
    - 1-2 mg to start, then q2hr prn
    - Max 8 mg day #1 (16 mg maximum ok'd by phone)
  - Day #2
    - Total day #1 in the morning (can split BID)
    - 2 mg q2hr prn, mx 16 mg (24 maximum ok's by phone)

Unobserved Induction Outcome Data Summary

- Effectiveness: 1 wk success ~70%[1-2] defined as being in treatment, on Bup, and free of withdrawal
- Safe: AE's appear generally mild/infrequent[1-4]
  - 1-5% precipitated withdrawal
  - 5-20% prolonged withdrawal
- Increased risk of AE's appears to occur with[1-3]
  - Methadone transfers
  - Bup inexperience
  - Procedural non-adherence

[1]Lee 2008; [2]Gunderson 2010; [3]Whitley 2010; [4]Doolittle 2011

Observed vs. Unobserved

Potential factors to consider	Observed	Unobserved
Effective and tolerability	+++	+(+)
Establish treatment structure	+++	-
Development of therapeutic alliance	++	-/+
Confirm baseline withdrawal (and presence of physiologic dependence	+++	-/+*
Convenience/preference ▪ MD ▪ Patient	 -/+ -/+	 +++ ++
Resources/cost	--	+
Co-morbidity	-/+	-/+

* Note: pt's can present for evaluation in mild withdrawal but start Bup out of the office

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Summary

- Induction is challenging aspect of treatment
- Hopefully practice-based evidence from different induction approaches will help improve induction efficiency, implementation, and effectiveness
- Several models of induction are available for initiating buprenorphine treatment, including observed and unobserved “home” approaches
- Pros/cons of the various models of induction should be considered by clinicians, patients, and policy makers

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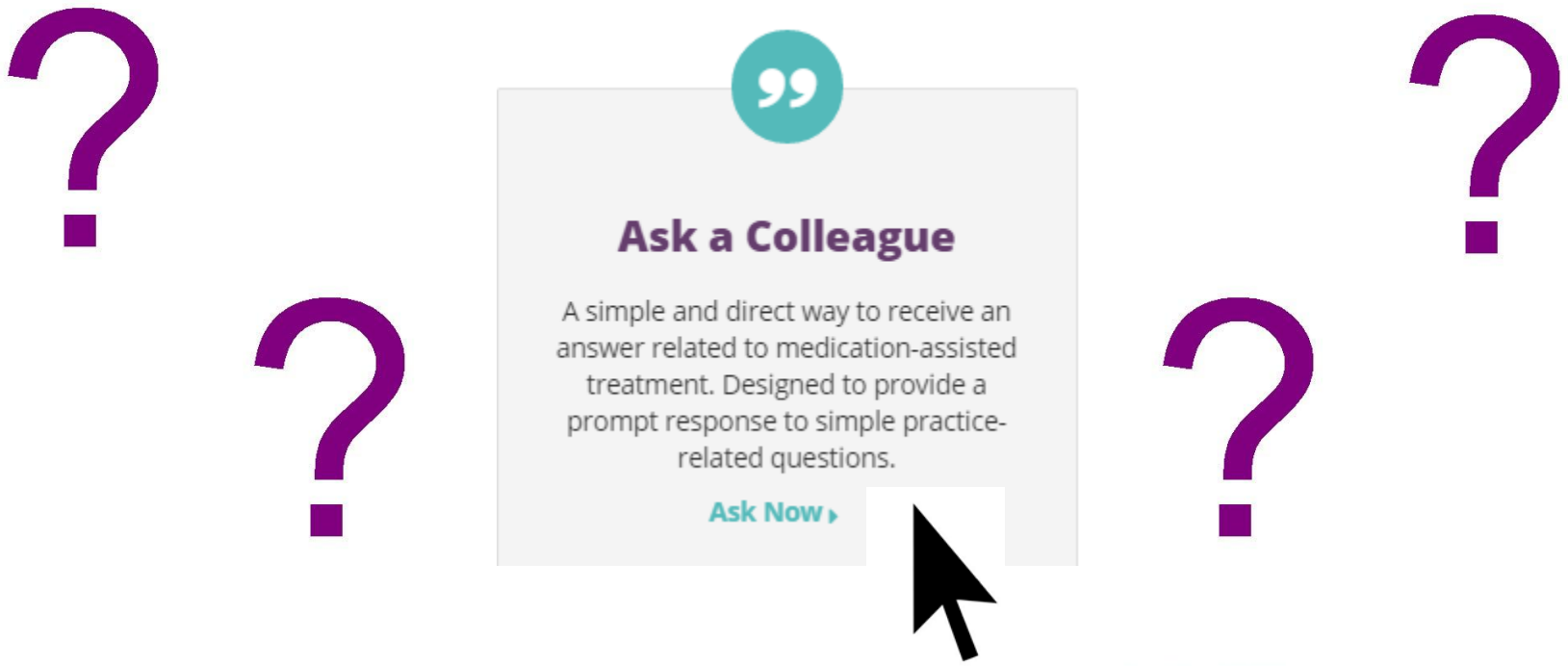

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