MAT TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM
For Medication Assisted Treatment

Models of Buprenorphine Induction

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- Date of Release December 16, 2014
- Date of Expiration December 16, 2017

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]Collins 2007

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

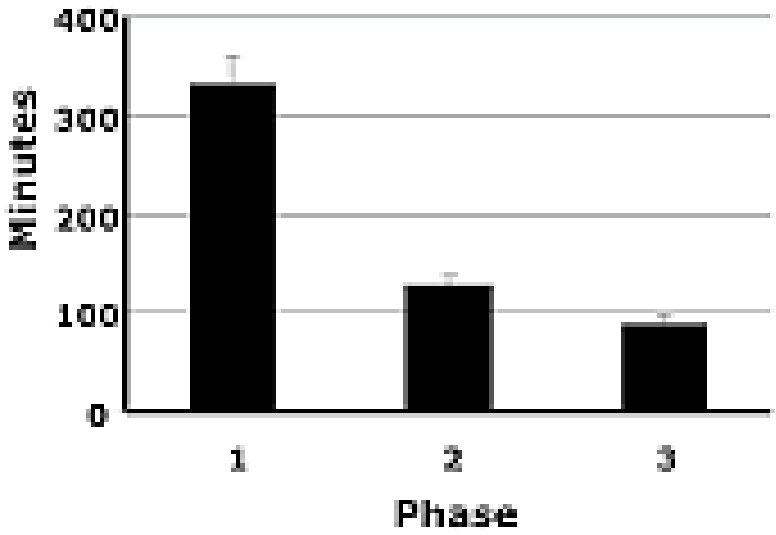
- Chart review[1] for the first 41 patients examined:
  - Temporal process of induction
    - Time until first BUUP dose given
    - Time unit withdrawal was relieved
    - Total time at clinic
  - Procedures associated with efficiency
  - Withdrawal level and BUP dosing
  - Hypothesis: ↑efficiency over 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)

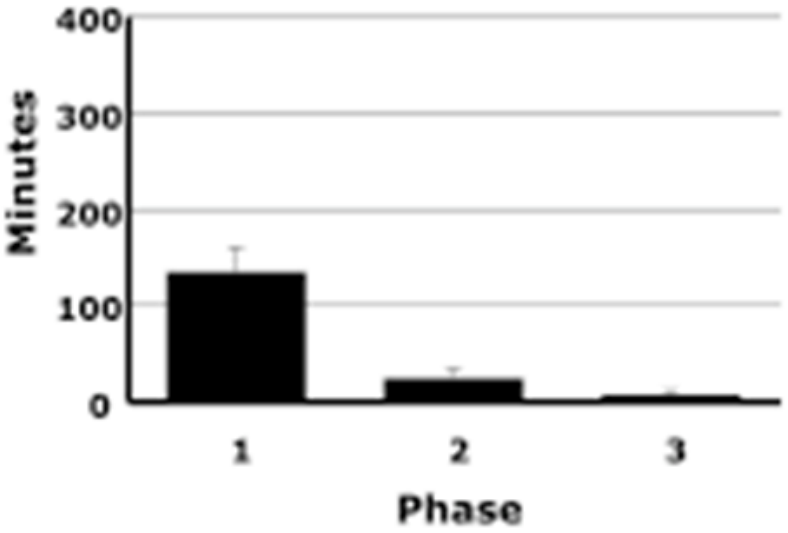
Age (mean)	41 yr
Sex (Male)	59%
Race (White)	78%
Employed	56%
Insured	83%
Psychiatric d/o	68%
Primary opioid, past mo. daily Heroin Rx opioid (non-methadone) Methadone	 41% 41% 22%
Prior buprenorphine	5%

Total Time at the Clinic



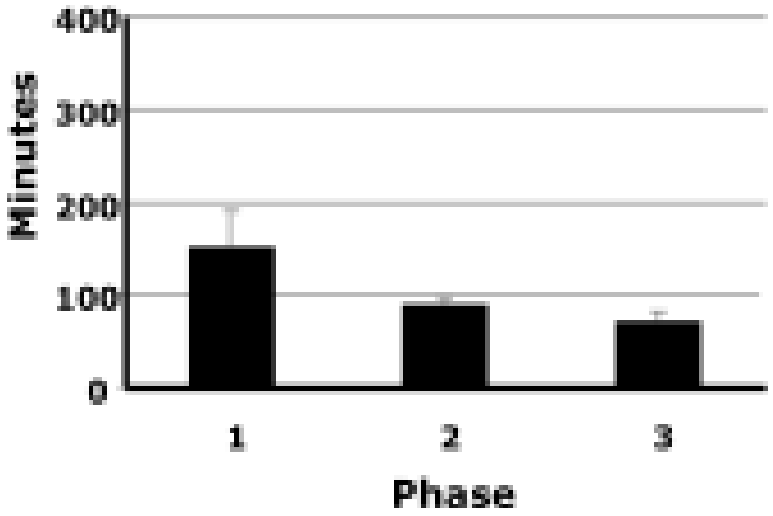
- Efficiency improved across the phases
  - Time may pose less of a practical burden for office induction as experience is gained
  - Several factors may have influenced efficiency

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

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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Funding for this initiative was made possible (in part) by Providers' Clinical Support System for Medication Assisted Treatment (5U79TI024697) from SAMHSA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

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