Medication Assisted Treatment:

The Who, What, Why, and Where of MAT

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June 21, 2016

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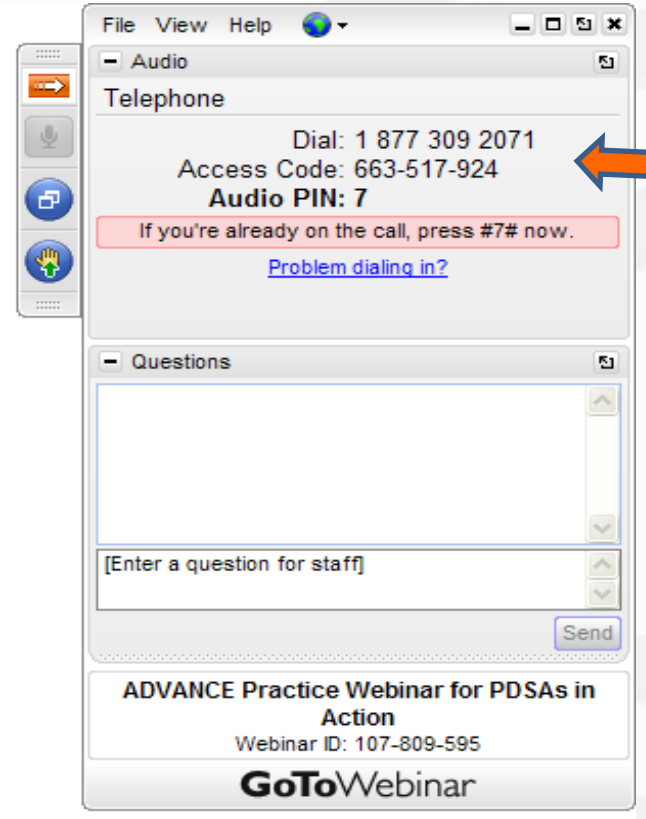

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Conflict of Interest

All presenters have signed a conflict of interest form and have declared that there is no conflict of interest and nothing to disclose for this presentation.

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Objective

- The objective of this webinar is to discuss establishing a Medication Assisted Treatment program in a primary care setting

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Medication Assisted Treatment: Buprenorphine-Naloxone

A Primer for Primary Care Providers

Thomas A. Bertolli, MD, MPH

June 21, 2016

The Opioid Epidemic

- The opioid epidemic crosses all socio-demographics

- One of our fundamental responsibilities is to treat that pain, but also "do no harm."

- In the 1990's, pain was considered the "5th vital sign" along with BP, Pulse, RR and Temperature. Assessment, documentation and treatment of pain were pushed to the forefront of patient care and pain management became a large determinant of patient satisfaction.

The Opioid Epidemic: Opium Use Historically

- Ironically, the current issues with opioids are likely the product of efforts to improve patient care.
- Opium
  - From poppy seeds
  - Was first used around 1500 BC for the treatment of pain and insomnia
  - First used around the turn of the 19th century to treat pain and addiction (morphine)
  - Seven decades later, heroin was synthesized from morphine and was marketed by Bayer for cough and respiratory illnesses as both tuberculosis and pneumonia were major health issues then

The Opioid Epidemic: 21st Century

- Non-medical use of prescription opioids , i.e. diversion, actually decreased between 2003 and 2013 but the prevalence of prescription use disorders, frequency of use and opioid mortality increased.
- In 2010, enough opioids were sold in the United States for every adult to receive 5 mg of hydrocodone every four hours for one month.
- Each day in 2016, 44 people die from an overdose of prescription opioid and this number outpaces deaths from motor vehicle accidents by 50%.
- However, when used appropriately for acute trauma and injury, cancer and end if life care, opioids can help people tremendously.

The Opioid Epidemic: Alternative Treatments

- There are other modalities of care that are healthier, safer and can ease pain:
  - Physical therapy
  - Acupuncture
  - Chiropractic care
  - Yoga
  - Massage
  - Meditation
  - Cognitive behavioral therapy
  - Biofeedback
  - Exercise and diet
  - Medications such as non steroidal anti-inflammatories, seizure meds, gabapentin, naltrexone, methadone and buprenorphine-naloxone

Methadone vs Buprenorphine-Naloxone

Methadone

- Full agonist
- Long half life(8-59 hours)
- No ceiling effect

Buprenorphine-Naloxone

- Partial agonist
- Long half life(24-60 hours)
- Ceiling effect

My Clinical Experience With Buprenorphine-Naloxone

- X license since 2011
- Managed 90-100 patients in a community health center in conjunction with a team that included a nurse case manager and a drug and alcohol counselor
- Now continue to offer it to those who have chronic pain, are overusing or addicted
- Clinical example

Food, Water and Dopamine

- What dopamine tells us about opioid addiction.
- What's normal?
- The science behind craving
- Raising dopamine levels
- The numbers

Definition of Addiction

Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Addiction characterized by:

- Inability to consistently abstain
- Impairment in behavioral control
- Craving
- Diminished recognition of significant problems
- A dysfunctional emotional response

Dependency vs Addiction: An important distinction

Physical Dependence

- The body relies on an external source of opioids to prevent withdrawal.
- Can resolve with slow taper.
- Normally, endogenous opioids (i.e. endorphins) can be produced to prevent withdrawal but as tolerance increases, the bodies ability to to maintain this equilibrium is exceeded and the body becomes dependent on the external source.

Addiction

- Is abnormal and classified as a disease.
- A primary condition manifesting as uncontrollable cravings, inability to control drug use, compulsive drug use and use despite doing harm to self or others. There is no addiction w/o cravings.

Dependency vs Addiction

Physical Dependence

- Many substances such as caffeine, nicotine and sugar, can cause physical dependence.
- Physical dependence to opioids is normal and expected and a distraction from the real problem: addiction
- Confusion because addiction is sometimes called dependence as well

Addiction

- Cravings are rooted in altered brain biology. Recovery is the process of reversing, to the extent possible, these brain changes. Accomplished through therapy and replacing addictive behaviors with healthy alternates.
- Addiction is called opioid dependence, substance dependence and opioid use disorder. Simply calling it dependence leads to confusion.

Who is Appropriate for Buprenorphine-Naloxone

- Chronic pain patients (both midlevel and MD's can dispense without "X" license if pain is the Dx)
- Positive DSM V(score of 2 or greater) (criteria to follow)
- Positive DAST for opioids(score of 6 or greater) (criteria to follow)
- SAMHSA(substance abuse and mental health services administration) guidelines: one year history of opioid use disorder prior to use of methadone
- Clinical basis w/o strict criteria
- Hope for effectiveness in 2/3 of patients for whom it is given

Opioid Use Disorder Criteria:

A minimum of 2-3 criteria is required for a mild substance use disorder diagnosis, while 4-5 is moderate, and 6-7 is severe (APA, 2013). Opioid Use Disorder is specified instead of Substance Use Disorder, if opioids are the drug of abuse. Note: A printable checklist version is linked below

1. Taking the opioid in larger amounts and for longer than intended
2. Wanting to cut down or quit but not being able to do it
3. Spending a lot of time obtaining the opioid
4. Craving or a strong desire to use opioids
5. Repeatedly unable to carry out major obligations at work, school, or home due to opioid use
6. Continued use despite persistent or recurring social or interpersonal problems caused or made worse by opioid use
7. Stopping or reducing important social, occupational, or recreational activities due to opioid use
8. Recurrent use of opioids in physically hazardous situations
9. Consistent use of opioids despite acknowledgment of persistent or recurrent physical or psychological difficulties from using opioids
10. *Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount. (Does not apply for diminished effect when used appropriately under medical supervision)
11. *Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal (Does not apply when used appropriately under medical supervision)

DAST-10

Introduction

The Drug Abuse Screening Test (DAST-10) is a 10-item brief screening tool that can be administered by a clinician or self-administered. Each question requires a yes or no response, and the tool can be completed in less than 8 minutes. This tool assesses drug use, not including alcohol or tobacco use, in the past 12 months.

DAST-10 Questionnaire

I'm going to read you a list of questions concerning information about your potential involvement with drugs, excluding alcohol and tobacco, during the past 12 months.

When the words "drug abuse" are used, they mean the use of prescribed or over-the-counter medications/drugs in excess of the directions and any non-medical use of drugs. The various classes of drugs may include: cannabis (e.g., marijuana, hash), solvents, tranquilizers (e.g., Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., LSD) or narcotics (e.g., heroin). Remember that the questions do not include alcohol or tobacco.

If you have difficulty with a statement, then choose the response that is mostly right.
You may choose to answer or not answer any of the questions in this section.

These questions refer to the past 12 months.	**No**	**Yes**
1. Have you used drugs other than those required for medical reasons?	0	1
2. Do you abuse more than one drug at a time?	0	1
3. Are you always able to stop using drugs when you want to? (If never use drugs, answer "Yes."	0	1
4. Have you had "blackouts" or "flashbacks" as a result of drug use?	0	1
5. Do you ever feel bad or guilty about your drug use? If never use drugs, choose "No."	0	1
6. Does your spouse (or parents) ever complain about your involvement with drugs?	0	1
7. Have you neglected your family because of your use of drugs?	0	1
8. Have you engaged in illegal activities in order to obtain drugs?	0	1
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	0	1
10. Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding, etc.)?	0	1

Interpreting the DAST 10

In these statements, the term "drug abuse" refers to the use of medications at a level that exceeds the instructions, and/or any non-medical use of drugs. Patients receive 1 point for every "yes" answer with the exception of question #3, for which a "no" answer receives 1 point. DAST-10 Score Degree of Problems Related to Drug Abuse Suggested Action.

DAST-10 Score	Degree of Problems Related to Drug Abuse	Suggested Action
0	No problems reported	None at this time
1–2	Low level	Monitor, re-assess at a later date
3–5	Moderate level	Further investigation
6–8	Substantial level	Intensive assessment
9–10	Severe level	Intensive assessment

Skinner, H. A. (1982). The Drug Abuse Screening Test. *Addictive Behavior*, 7(4),363–371.

What is Buprenorphine-Naloxone? Why does it work? Or not…

- Combination of buprenorphine, a partial μ-opioid agonist displaying high affinity for and slow dissociation from the μ-opioid receptor and naloxone, an opioid antagonist
- Buprenorphine: greater affinity for opioid receptor, effective pain med w/o euphoria; need for mild to moderate withdrawal or precipitates withdrawal
- Naloxone/Naltrexone: antagonists

Forms of Buprenorphine-Naloxone

Forms:

- film(2/.5, 4/1, 8/2, 12/3 mg bid);
- tablet(2/.5, 8/2mg bid);
- patch(bup only: 5, 7.5, 10, 15, 20 mcg q 7 days);
- buccal film(bup only: 75, 150, 300, 450, 600, 750, 900 mcg bid)

Before the First Dose

- Work flow in primary care and team approach
- Comprehensive screening
- Urine drug screen every visit: point of care vs send out
- Benefit of the doubt: addiction is a disease
- Wean down from high dose methadone
- Once decision is made , pick date, write prescription or have supply in office

Before the First Dose

- Informed Consent: patient agrees to plan
- Behavioral health referral, Cognitive Behavioral Therapy, 12 step
- Contingency management: concept of "tools in your belt" to deal with cravings, temptations, situations

Buprenorphine-Naloxone Induction

- Conversion table/morphine equivalent dose
- Clinical Opioid Withdrawal Scale (COWS)

Buprenorphine-Naloxone Induction

- Standard: first dose(in office) when flipping from full agonist opioids.
- UDS negative for opioids or in mild to moderate withdrawal on COWS
- Can give up to 8/2 Buprenorphine-Naloxone if urine drug screen (UDS) negative based on historic intake(see conversion table)
- If positive UDS for opioids but in withdrawal, start with 2/.5 to 4/1 mg
- Observe in office and treat with up to 24/6 to abate withdrawal

Buprenorphine- Naloxone Induction

- Typical flip: detox or weaning from full agonist
- 24-72 hours of no opioids
- Use Clonidine, Promethazine and Ondansetron to treat withdrawal
- Start buprenorphine-naloxone, usually up to 16/4 mg divided BID–QID
- Clinically found that patients used to dosing frequently need QID dosing of buprenorphine-naloxone. Based on slow dissociation from receptor, BID is adequate

Buprenorphine-Naloxone Induction

- Other Induction: Butrans and Fentanyl bridge to buprenorphine-naloxone
- Used for patients who can't tolerate even 24 hours of withdrawal as these drugs peak slowly
- Butrans: Place 5 mcg patch. It takes 36 hours to peak. Remove after 36-48 hours and give 4/1-8/2 mg of buprenorphine-naloxone.
- Can also use clonidine/promethazine/ondansetron for withdrawal

Buprenorphine- Naloxone Induction

- Fentanyl Bridge: place morphine equivalent patch on skin
- Patient returns in 72 hours. Remove patch, wash skin with soapy water
- Give 2/.5 mg of buprenorphine-naloxone, watch for 30 minutes. If no withdrawal, send home to take first full dose upon subjective signs of withdrawal. If withdrawal, can give up to 8/2 mg of buprenorphine-naloxone

Conversion table other drugs equivalent to suboxone

#Pain Killer Equivalent Doses (Oral)
1.2mg.....Buprenorphine (Bupe)
200mg.....Codeine (Tylenol 2, 3, 4, etc)
30-60mg.....Diacetylmorphine (Heroin) (orally it = morphine, IV/IM/insuffilated it's 2x as strong)
100mg.....Dihydrocodeine
30mg.....Hydrocodone (Vicodin, Lorcet, etc)
7.5mg.....Hydromorphone (Dilaudid)
4mg.....Levorphanol (Dromoran)
300mg.....Meperidine (Demerol)
10-20mg.....Methadone
30-60mg.....Morphine
20mg.....Oxycodone (Oxycontin, Percocet)
10mg.....Oxymorphone (Numorphan)
200-300mg.....Propoxyphene (Darvocet)
150mg.....Tramadol (Ultram, Ultracet)

Clinical Opiate Withdrawal Scale (COWS)

Flowsheet for measuring symptoms over a period of time during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal.
For example: If heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

Patient Name: _____ Date: _____

Buprenorphine Induction: _____

Enter scores at time zero, 30 minutes after first dose, 2 hours after first dose, etc.	Times of Observation:			
Resting Pulse Rate: Record Beats per Minute Measured after patient is sitting or lying for one minute 0 = pulse rate 80 or below 1 = pulse rate 81-100 • 2 = pulse rate 101-120 • 4 = pulse rate greater than 120				
Sweating: Over Past 1/2 Hour not Accounted for by Room Temperature or Patient Activity 0 = no report of chills or flushing 1 = subjective report of chills or flushing 2 = flushed or observable moistness on face • 3 = beads of sweat on brow or face • 4 = sweat streaming off face				
Restlessness Observation During Assessment 0 = able to sit still 1 = reports difficulty sitting still, but is able to do so • 3 = frequent shifting or extraneous movements of legs/arms • 5 = Unable to sit still for more than a few seconds				
Pupil Size 0 = pupils pinned or normal size for room light 1 = pupils possibly larger than normal for room light • 2 = pupils moderately dilated • 5 = pupils so dilated that only the rim of the iris is visible				
Bone or Joint Aches if Patient was Having Pain Previously, only the Additional Component Attributed to Opiate Withdrawal is Scored 0 = not present 1 = mild diffuse discomfort • 2 = patient reports severe diffuse aching of joints/muscles • 4 = patient is rubbing joints or muscles and is unable to sit still because of discomfort				
Runny Nose or Tearing Not Accounted for by Cold Symptoms or Allergies 0 = not present 1 = nasal stuffiness or unusually moist eyes • 2 = nose running or tearing • 4 = nose constantly running or tears streaming down cheeks				
GI Upset: Over Last 1/2 Hour 0 = no GI symptoms 1 = stomach cramps 2 = nausea or loose stool • 3 = vomiting or diarrhea • 5 = multiple episodes of diarrhea or vomiting				
Tremor Observation of Outstretched Hands 0 = no tremor 1 = tremor can be felt, but not observed • 2 = slight tremor observable • 4 = gross tremor or muscle twitching				
Yawning Observation During Assessment 0 = no yawning 1 = yawning once or twice during assessment • 2 = yawning three or more times during assessment • 4 = yawning several times/minute				
Anxiety or Irritability 0 = none 1 = patient reports increasing irritability or anxiousness • 2 = patient obviously irritable/anxious • 4 = patient so irritable or anxious that participation in the assessment is difficult				
Gooseflesh Skin 0 = skin is smooth 3 = piloerection of skin can be felt or hairs standing up on arms • 5 = prominent piloerection				
Score: 5-12 = Mild 13-24 = Moderate 25-36 = Moderately Severe More than 36 = Severe Withdrawal	Total score			
	Observer's initials			

The National Alliance of Advocates for Buprenorphine Treatment
PO Box 333 • Farmington, CT 06034 • MakeContact@naabt.org
naabt.org

*Source: Wesson et al. 1999.

5M 11/11

Monitoring

- Short term: follow closely for diversion and use of other drugs, alcohol and strict no benzo policy.
- What to do about THC?
- 3 strikes and you're out(sometimes)
- See everyone weekly once or twice, then monthly X 6 months, every other month from 6-12 months and q 3 months after a year
- Compliance: no diversion, clean urine drug screen, on time and makes it to all appointments and groups
- Being firm but fair and compassionate is important. Expect slip ups.

Monitoring

- Long term: 18 months to 2 years for neuronal stabilization
- Weaning: patient driven with encouragement
- Behavioral health groups if at all possible and individually for the long term
- Long term abstinence of 70% is very successful

Documentation and Regulatory Requirements

- SAMHSA DATA(Drug Addiction Treatment Act) 2000 waiver: must have an "X" license, which requires an 8 hour online course to qualify.
- Keep an active list of all patients past and present
- DEA oversight
- A minority of offices are visited annually, a majority are in compliance or have minor record keeping problems

Documentation and Record Keeping Requirements

In case of a DEA audit you may be asked to present the following :

- Documentation of your waiver to prescribe
- Treatment logs
- Documentation of prescriptions given
- Dispensing practices if you are dispensing from your office

Writing Prescriptions for Buprenorphine-Naloxone

- No special guidelines ; should have "X" DEA number on the prescription
- Can be refilled up to 5 times, like any Schedule III drug(limit initial amounts)
- If Rx is for an off label use, i.e., not for opioid dependence, no "X" number should be on the prescription.
- The patient is considered under your care for the duration of the last prescription issued

Clinical Support Team

- **A Case Manager-** Usually an LVN or RN who does the intake, schedules, fields questions, deals with issues that come up between appointments and prepares the "huddle," done before all group visits.
- **A Behavioral Health therapist-** Ideally, this team member has drug and alcohol training, sees patients prior to acceptance in the program and then in ongoing, mandatory f/u either individually and/or in a group setting.
- **A Prescribing Medical Provider-** Must be an MD/DO with "X" waiver if diagnosis is opioid dependence/addiction.
- **Other patients** who are or have struggled with addiction issues and can lend support in a group setting

The Model of Care

- Intake done over the phone as the case manager can't bill
- Patient is seen by behavioral health to determine psychological readiness(30 min)
- Patient is seen by Medical Provider at a different appt. to gather history, do exam, order appropriate labs, explain buprenorphine-naloxone, prescribe withdrawal meds (30 minutes)
- Approved patient is then appointed for induction.

The Model of Care

- Patient seen individually one week after Induction: evaluate buprenorphine-naloxone dose, cravings, side effects, slip ups (15 minute appointment)
- Patient seen 2 weeks after induction in a group visit with behavioral counselor.

The Model of Care

- If patient is stable after 2 visits and urine drug screen appropriate, visits go to monthly X 6 months, every other month from 6-12 months and then every 3 months thereafter(all 15 minute visits)
- If slip ups occur, then more frequent visits occur
- 3 strikes and you are out for at least 6 months with referral to alcohol and other drug program, or another, more intensive, drug treatment program

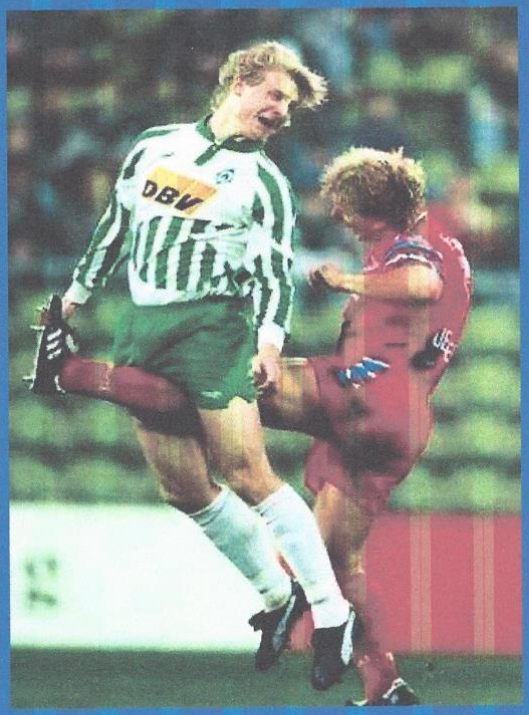
The Financial Case

- Many short visits can be billed with two up front longer appointments: behavioral health and MD/DO
- If more frequent visits needed once in the program, they are scheduled for 15 minutes
- Maximize group visits
- DATA 2000 "X" license waiver: 8 hour online course , $200 fee. Partnership has a PCP QIP measure for x-license providers who are taking new patients

What's In It For The Team?

- Personal Satisfaction:
  - For the patient
  - For the team- Helping patients acquire the tools to change behavior and transition to healthy choices rather than back to opioids is one of the most satisfying aspects of this work.

Conclusion

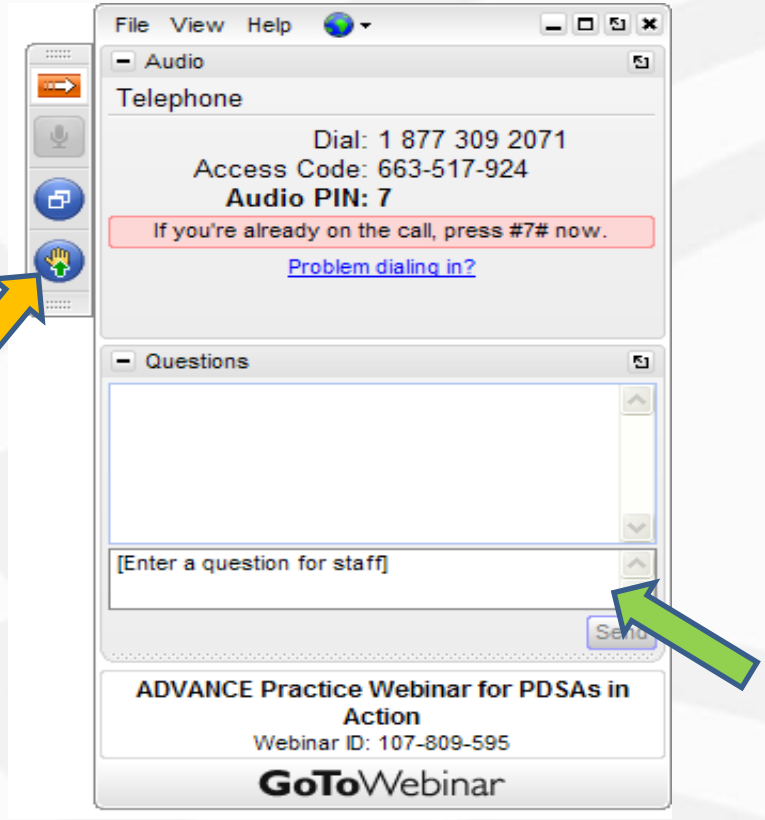


Albert Schweitzer stated “Pain is a more terrible lord of mankind than even death itself.”

Questions?

If you have a question or would like to share your comments, please

- Type your question in the “question” box, or
- Click the “raise your hand” icon



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PHC Resources

PHC Website:

http://www.partnershiphp.org/Providers/HealthServices/Pages/Managing-Pain-Safely.aspx

Member Resources:

http://www.partnershiphp.org/Members/Medi-Cal/Pages/ManagingPainSafely-MemberResources.aspx

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Want to Talk More?

Question and Answer Office Hours

Tuesday June 28, 2016

Noon-12:30pm

Call-In: 1-866-951-1151; 9879782

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Thank You!

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