Module 1: Overview of Office-Based Treatment of Substance Use Disorders

Learning Goals

Overview of integrating Office-Based Treatment of Substance Use Disorders into your practice

- Screening, Brief Intervention, Referral and Treatment (SBIRT): What is it and how can it improve medical care and reduce costs?
- A review of the basics of substance abuse treatment that can be accomplished in primary care and other office-based settings (e.g.: Psychiatry, Infectious Disease, Pain Medicine)
- An overview of pharmacotherapy for substance use disorders that can be undertaken in office-based settings

What is SBIRT?

- SBIRT is a comprehensive, integrated, public health approach to the delivery of early intervention and treatment services for persons with substance use disorders, as well as those who are at risk of developing these disorders. Primary care centers, hospital emergency rooms, trauma centers, office-based practices and other community settings provide opportunities for early intervention with at-risk substance users before more severe consequences occur.

What is SBIRT?

- SBIRT is an initial intervention that includes clinician screening of patients for hazardous substance use. Affirmative answers are to be followed with brief intervention aimed at offering advice on cutting back/stopping substance use and increasing motivation to do so. Those with more serious problems are referred to specialty substance abuse treatment.

Why Do We Need SBIRT?

Problem Substance Use is Highly Prevalent in Americans

Risky Drinking	23%
Illicit Drug Use	8%
Substance Abuse or Dependence	10%
Alcohol	7%
Illicit Drugs	3%

SAMHSA, National Survey on Drug Use and Health, 2008

SBIRT Components

- Screening quickly assesses the severity of substance use and identifies the appropriate level of treatment.
- Brief intervention focuses on increasing insight and awareness regarding substance use and motivation toward behavioral change.
- Referral to treatment provides those identified as needing more extensive treatment with access to specialty care.

Is SBIRT Effective?

- SBIRT research has shown that large numbers of individuals at risk of developing serious alcohol or other drug problems may be identified through primary care screening.

Is SBIRT Effective?

Interventions such as SBIRT have been found to:

- Decrease the frequency and severity of drug and alcohol use
- Reduce the risk of trauma
- Increase the percentage of patients who enter specialized substance abuse treatment
- Be associated with
  - fewer hospital days
  - fewer emergency department visits
  - net-cost savings to the health care system from these interventions

What are the Benefits of Screening and Brief Intervention?

- Strong evidence for the effectiveness of brief interventions with alcohol and tobacco use, growing support for use with other substances.
- Minimal amount of time needed to conduct brief interventions.
- Low-cost/cost-effective. For each dollar spent, it has been estimated that $2–$4 (per person) have been saved in terms of health costs and costs related to workforce productivity.

Gentilello, et al., 2005; Fleming, 2002

How to Rapidly Screen for Alcohol Problems

- Evidence for SBIRT is strongest in tobacco use and alcohol use. Research supports the use of a single question screener.
- NIAAA Single Question with high sensitivity & specificity:
  - In the past year, how many times have you had (4 for women, 5 for men) or more drinks in one day?
  - 84% sensitive, 78% specific for hazardous drinking
  - 88% sensitive, 67% specific for current AUD

Dawson et al. 2010

Why a Single Question Screener?

- Time constraints in busy medical settings
- Physician preference
- Multiple studies show high sensitivity, specificity for high risk drinking and alcohol use disorders (AUDs)
  - Specificity > sensitivity
  - Women>men
- Limitations:
  - Screener questions identified from a larger survey
  - Not done in primary care population
- Single question is not diagnostic; meant to prompt further questions

How to Screen for Alcohol Problems

- If the NIAAA single question screener is positive:
  - Assess frequency/quantity of drinking.
  - Assess negative impact/functional impairment
  - Offer advice for cutting back or stopping using a “brief intervention” model
  - Consider pharmacotherapy
  - If evidence of DSM-IV alcohol dependence refer to substance abuse treatment facility

What Pharmacotherapies Can Physicians in Office-Based Settings Use to Treat Substance Use Disorders (SUDs)?

SUD Pharmacotherapies: General Considerations

- Tobacco: Relapse Prevention-Yes, for office-based/outpatient practice
- Alcohol
  - Acute withdrawal (usually done inpatient)
  - Relapse Prevention-Yes, for office-based/outpatient practice
- Opiates
  - Acute withdrawal (often done inpatient, but can be outpatient procedure)
  - Relapse Prevention-Yes, for office-based/outpatient practice

SUD Pharmacotherapies: General Considerations

- Cocaine/Stimulants
  - No FDA approved medications for withdrawal symptoms or relapse prevention

When to Consider Pharmacotherapy

Consider Precipitant To Treatment And Severity of Medical/Psychiatric/Psychosocial Problems

- Family
- Employment
- Financial
- Medical
- Legal
- Psychiatric comorbidity *(including risk for harm to self or others)*
- Relapse Potential

- The higher the acuity or severity; the greater the need for use of medication treatment (if there is an appropriate medication intervention available)

When to Consider Pharmacotherapy

- Most FDA approved medications for SUDs can be used in outpatient settings
- Exception: Methadone maintenance therapy: can only be used for treatment of opioid addiction in licensed narcotic treatment programs

Cigarette Smoking

FDA approved:

- Nicotine Substitution (Agonist Therapy)
  - Nicotine polacrilex gum
  - Transdermal nicotine patch
  - Nicotine nasal spray
- **Bupropion** (approved for treatment of depression and smoking cessation)
- **Varenicline** (nicotine partial agonist)

Cigarette Smoking

- **Nicotine gum**
  - Reduces nicotine withdrawal: anger/irritability, depression, anxiety, decreased concentration
  - Effect on craving is minimal
  - 2 or 4 mg gum
  - Use 4 mg dose for heavy smokers >25 cigarettes daily
  - Dosing: 1 piece/hr better than prn for craving

    50-90% nicotine release depending on chewing rate
  - Absorbed through buccal mucosa
  - Peak concentrations in 15-30 min (compared to 1-2 min for cigarette smoking)
  - Avoid acidic foods/beverages: e.g.: coffee, juices, soda as these decrease absorption of nicotine

Cigarette Smoking

- **Nicotine gum**

  - Length of treatment is 4-6 weeks
  - Quit rates using gum are 8-10% with M.D. advice
  - Increases to up to 29% when combined with behavioral treatment

(see U.S. Public Health Service: A clinical practice guideline for treating tobacco use and dependence: A US public health service report. J Am Med Assoc 2000; 283:3244–3254)

Cigarette Smoking

- **Transdermal nicotine patch**
  - 16 h patch delivers 15 mg nicotine
  - 24 h patch delivers 21-22 mg nicotine
  - Peak levels 6-10 h after application
  - Dosing: 8-12 weeks
  - Side effects: local irritation, mild gastric, sleep disturbances
  - End of treatment smoking cessation: 18-77%
  - 6 month abstinence rates: 22-42%
  - Can use patch and gum together

Cigarette Smoking

- **Nicotine nasal spray**
  - Rapid delivery system of 1 mg nicotine
  - Peak nicotine blood level in 10 minutes
  - Rapid relief of withdrawal and craving
  - Associated with greater sense of control
  - Side effects: throat irritation, coughing, sneezing, lacrimation
  - Self-taper over 12 weeks
  - Use in those who fail nicotine gum and/or patch

Cigarette Smoking

- **Bupropion**
  - Dopaminergic/noradrenergic
  - Dose: 300 mg sustained release
  - Quit after 7-14 days of treatment
  - Adverse events: dry mouth, insomnia, stimulation
  - Do not use in patients with history of seizures or bulimia
  - Can supplement with gum or patch

Cigarette Smoking

- **Varenicline**
  - Partial agonist binds to nicotinic receptor
  - Does not fully activate receptor
  - Modulates receptor activity in the absence of nicotine reducing craving and withdrawal
  - Twice daily oral medication to be started 1 week before quit date (.5 mg/d x 3; .5 BID x 3; 1 mg BID)
  - Length of Treatment: 12 weeks
  - Monitor for depression/suicidal thinking
  - No abuse liability

Maintenance Medications To Prevent Relapse To Alcohol Use (FDA approved)

- Disulfiram
- Naltrexone (oral and injectable)
- Acamprosate

Pharmacotherapy of Alcohol Dependence: Naltrexone

- **Oral Naltrexone Hydrochloride**
  - FDA approved dose: 50 mg per day
  - Some have used 100 mg daily with rationale that naltrexone has been effective for heroin addiction at doses of 100mg-100mg-150 mg q Monday, Wednesday, and Friday; so an effective plasma concentration can be obtained even if some doses are missed; unclear if this extends to alcohol use disorders

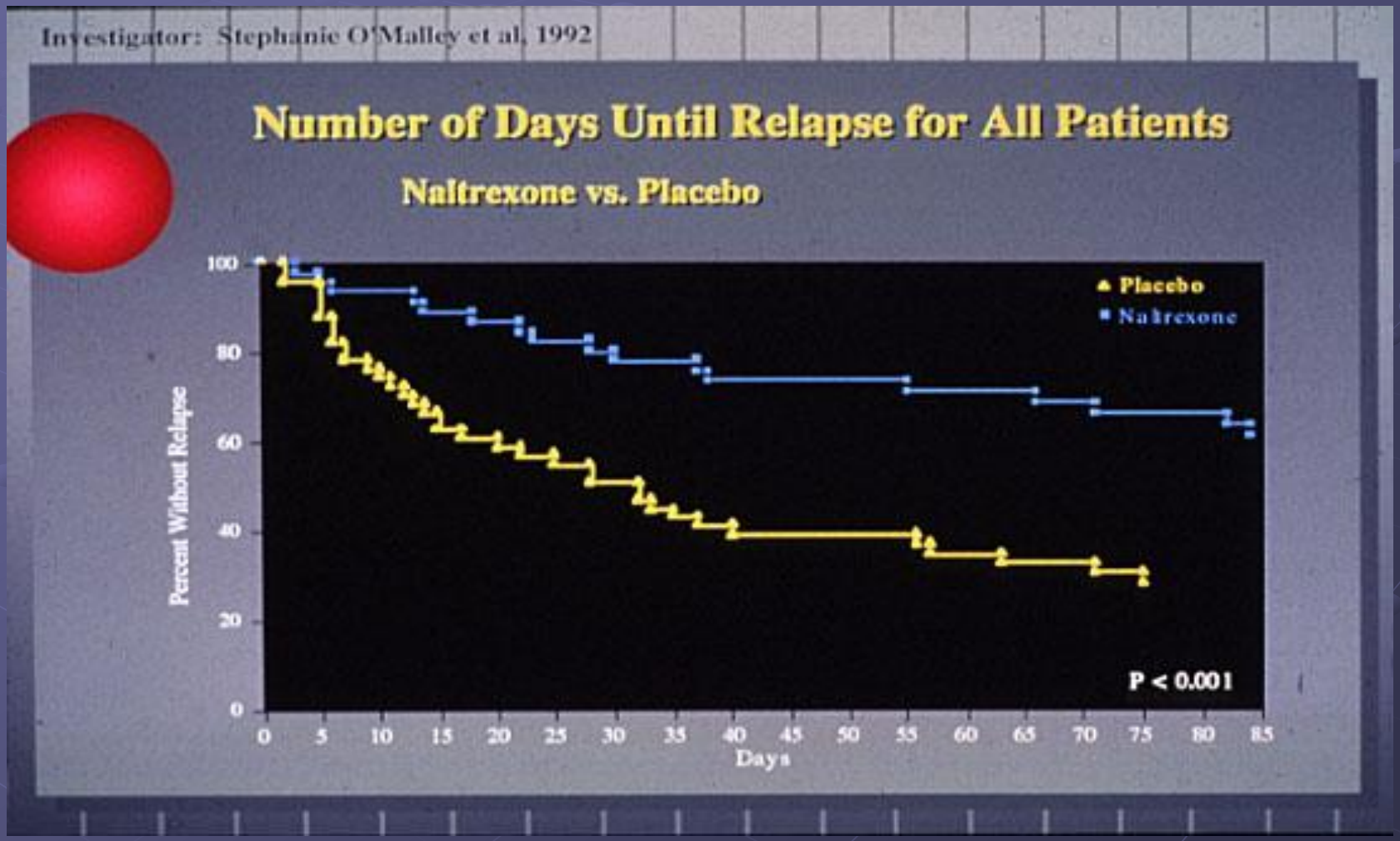
Pharmacotherapy of Alcohol Dependence: Naltrexone

Extended-Release Injectable Naltrexone

(Garbutt et al, JAMA 2005)

- 1 injection per month/ 380 mg
- Advantages: once a month injection can be done in clinician's office
- Better adherence with once monthly dosing

Naltrexone Delays the Onset of Relapse to Alcohol



Relapse defined as: ≥ 5/≥4 men/women drinks at one sitting

Naltrexone: How does it work?

- **Potent inhibitor at mu opioid receptors**
  - may explain reduction in relapse/craving
  - because endogenous opioids are involved in the reinforcing (pleasurable) effects of alcohol and possibly craving

Naltrexone Safety

- Common AEs: nausea/headache
- Can cause hepatocellular injury in very high doses (e.g. 5-10 times higher than normal)
- Contraindicated in acute hepatitis or liver failure
- Check liver function before, q1 month for 3 months, then q 3 months (this recommendation comes from the VA/DoD guidelines for naltrexone use)

VA/DoD CPG SUDs, www.oqp.med.va.gov/cpg/SUD/SUD_Vase.htm

Naltrexone Safety

- Contraindicated if patient needs opioid analgesia
- Ibuprofen, acetominophen, or other non-steroidal anti-inflammatory agents may be associated with GI or hepatic adverse events and patients should be followed for use of these medications and side effects

VA/DoD CPG SUDs, www.oqp.med.va.gov/cpg/SUD/SUD_Vase.htm

Other Alcohol Treatments: Disulfiram

- Disulfiram: inhibits alcohol metabolism; buildup of acetaldehyde causes noxious reaction if alcohol consumed
- Standard clinical dose 250/d (dose needs vary)
- Contraindicated: psychosis, significant liver disease, esophageal varices, pregnancy, impulsivity

(Barth et al., 2010)

Other Alcohol Treatments: Acamprosate

Acamprosate: Mechanism: Stabilizes glutamatergic neurotransmission altered during withdrawal (Littleton 1995);

- Anticraving, reduced protracted withdrawal
- No abuse liability, hypnotic, muscle relaxant, or anxiolytic properties
- Dose: 2 g daily (2-333 mg pills three times/d)
- Contraindicated: significant renal disease (creatinine clearance <70 ml/min)

How to Select a Medication

- Disulfiram: when the patient is committed to no further drinking; heavy consequences of relapse
- Naltrexone: for the patient who wants to cut back or get help for craving
- Acamprosate: naltrexone doesn’t work, patient needs opioid analgesia; disulfiram not an option

Pharmacotherapies for Opiate Addiction

- Methadone (Can't use outside of a registered narcotic treatment program)
- Buprenorphine
- Naltrexone

Why Would Physicians in Outpatient Settings Need to Know about Treating Opiate Addiction?

- Increasing use of opioids to treat chronic pain
- Rate of addiction and misuse may be underestimated; recent literature estimates: 4-26% have OUD; of those without OUD 10% misuse

Balantyne et al., 2003, Fleming et al. 2007, Banta-Green et al. 2009, Boscarino et al. 2010

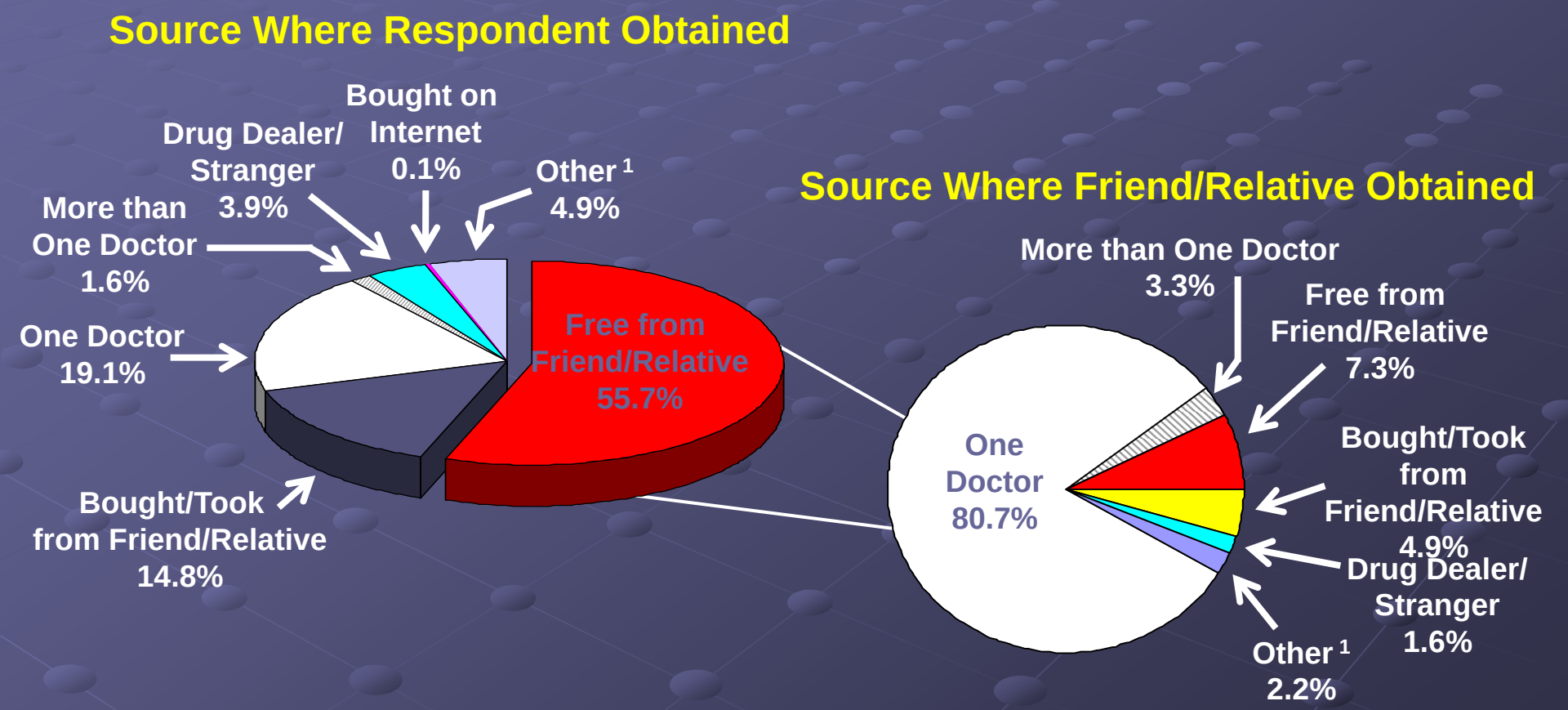
Rates of Prescription Pain Medication Abuse

- Nonmedical use of prescription pain medications (2009):
  - Prior month misuse: 5.2 million ≥ 12 y
  - 4.6% of those aged 18-25
  - Prescription pain medication misuse now second only to marijuana
  - In 2006, deaths involving opioid analgesics was 1.63 times the number involving cocaine and 5.88 times the number involving heroin.

Source: NSDUH, 2006, 2009, http://www.cdc.gov/HomeandRecreationalSafety/pdf/poision-issue-brief.pdf

Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older:

NSDUH 2006



Note: Totals may not sum to 100% because of rounding or because suppressed estimates are not shown.

[1] The Other category includes the sources: "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

A Common Dilemma in Medicine

- **Model Policy for the Use of Controlled Substances for the Treatment of Pain***
  - Pain management integral to medical practice
  - Opioids may be necessary
  - Physicians will not be sanctioned for prescribing opioids for legitimate medical purposes
  - Undertreatment of pain will be considered a deviation from the standard of care
  - Use of opioids for purposes other than analgesia threaten individuals and society
  - Physicians have a responsibility to minimize abuse and diversion

*Federation of State Medical Boards, 2003

A Common Dilemma in Medicine

- Message is that it's ok to use opioids to treat pain
- But don't give these medications to addicts
- Can be very difficult in current medical system where large numbers of patients must be seen in very short visits

Opioids for Pain Management

- Chronic opioids for non-malignant pain presents many potential problems:
  - Lack of evidence for efficacy, particularly with high dose opioid therapy
  - Syndrome of rebound pain/hyperalgesic states produced by opioid use
  - Withdrawal syndromes masquerading as "pain"

Balantyne et al., 2003

Opioids for Pain Management

- Opioid adverse events: QT prolongation, Torsades de Pointes
- Rate of addiction with chronic opioid use may be underestimated (e.g.: some published articles report as few as 1% of chronic pain patients receiving opioids vs. 10% rate of SUDs for general population)
- Note: the estimates for risk of addiction are increasing as more research findings are being reported

Balantyne et al., 2003

What's the Best Path?

- Good Practice in this area would include:

  - Thorough history and physical examination; get old medical records; query previous treatments and responses/check the Prescription Monitoring Program for patient's controlled substance prescriptions and prescribers if available in your state

  - Speak with family/S.O. if available

    Undertake as much of a diagnostic work-up as possible (given that some chronic pain syndromes have no identifiable lesion)

What's the Best Path?

- Good Practice in this area would include:

  - Provide adequate treatment of acute or chronic pain associated with diagnosed condition/lesion (e.g. metastatic cancer)
  - Consider non-opioid options (especially in those with substance abuse history)
  - Consider Risk/Benefit of chronic opioid therapy
  - Reassess frequently and modify treatment plan as indicated
  - Document thoroughly

If You Decide that Opioid Therapy for Chronic Pain is Indicated for Your Patient

- Treatment Agreement (now considered a standard of care)
- Specifies the limits of how you will prescribe medications and expectations for patient; this will help you to be able to transfer the patient to another treatment modality if the patient's needs exceed what you are able to provide in office-based treatment; the agreement will help the patient to be able to quickly be referred to a more intensive level of care if needed

(http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf)

If You Decide that Opioid Therapy for Chronic Pain is Indicated for Your Patient

- **Check urine drug screen initially and periodically:**
  - Illicit drug use highly correlated with opioid abuse/addiction
  - Can also use to confirm use of the drug you're prescribing
  - Point of Service (POS) (in office testing with immediate results) vs. Clinical Lab (will include GC/MS confirmation, but much more expensive than POS and delay in getting results)
  - Random Pill Counts (can be done by office staff to check patient's use of medication)

If You Decide that Opioid Therapy for Chronic Pain is Indicated for Your Patient

- **Undertake Periodic Reviews:**
  - Evidence of analgesia
  - Treat side effects
  - Enhanced social/employment functioning
  - Overall improved quality of life
- **Seek Consultation When Needed**
  - Addiction specialist
  - Psychiatrist (co-occurring mental illness is common)
  - Pain specialists

Approaching Patient with Aberrant Medication-Taking Behavior

- Take non-judgmental stance
- Use open-ended questions
- State your concerns about the behavior
    - Is the patient more focused on specific opioid or pain relief? (patient focus on specific opioid may indicate misuse of the drug)

Passik SD, Kirsh KL. J Supportive Oncology, 2005.

Approaching Patient with Aberrant Medication-Taking Behavior

- Approach as if they have a relative contraindication to controlled drugs (if not absolute contraindication)
- Take pressure off yourself by referring to clinic policies

Passik SD, Kirsh KL. J Supportive Oncology, 2005

What to do if Your Patient Develops a Substance Use Disorder with Prescribed Opioids

- Therapeutic Options if Patient is to continue treatment for opioid dependence in office-based setting:
- Initial treatment will include a combination of medication treatment plus psychosocial/ psychotherapeutic interventions:

  - Option 1: Inpatient for medical withdrawal followed by:
  - Residential or intensive outpatient treatment
  - Individual/Group Drug Counseling

What to do if Your Patient Develops a Substance Use Disorder with Prescribed Opioids

- Option 2: Medications to prevent relapse: (Can be prescribed from outpatient medical settings):
  - Naltrexone (can only be used following medical withdrawal)
  - Buprenorphine
- Option 3: Some patients may be better suited for methadone maintenance (especially if ongoing opioid analgesia needed but this can only occur in a licensed narcotic treatment program)
  - Know the options in your community

Naltrexone

- **Naltrexone (opioid antagonist therapy)**
  - Block effects of a dose of opiate (Walsh et al.1996)
  - Prevents impulsive use of drug
  - Relapse rates high (90%) following detoxification with no medication treatment Dose (oral): 50 mg daily, 100 mg every 2 days,150 mg every third day
  - Injectable naltrexone for opioid dependence now FDA-approved; once a month injection
  - Who gets naltrexone?
    - Highly motivated
    - Does not want agonist/controlled substance
    - Some employment requirements

Office-Based Opioid Dependence Maintenance Therapy

- **Buprenorphine**
  - Newer opioid maintenance therapy
  - Mu opioid receptor partial agonist
  - High affinity for opioid receptors; slow to dissociate
  - Dosing usually daily, but every other day or three times weekly also used successfully
  - Less effect than full opioid agonists on respiration or cardiovascular responses at higher doses; safer in overdose
  - Mild withdrawal
  - Physicians need special certification to prescribe

(McNicholas L, 2004)

Why is All of This Important?

- Drug and alcohol use disorders affect approximately 10-15% of the American population
- Screening and early intervention = prevention!
- Substance use disorders are chronic, relapsing diseases that are likely to recur
- Effective pharmacotherapies are available and can be implemented in primary care
- Substance abuse can negatively impact other illnesses present in the patient (e.g.: alcoholic cardiomyopathy, COPD, HIV/AIDS, HCV, other ID)
- May masquerade as an illness that the patient does not have (e.g.: HTN, seizure d/o, mental disorders)
- Can contribute to non-adherence to prescribed regimens, toxicities due to drug interactions

References

- 2006 National Survey on Drug Use and Health: National Findings," SAMHSA, September 2007.
- Office of National Drug Control Policy (ONDCP) www.ondcp.gov
- Anton RF, Miller WR, Lonnabaugh R, Hosking JD, Youngblood M, COMBINE Study Research Group. Combined pharmacotherapies and behavioral interventions for alcohol dependence (The Combine Study) examination of posttreatment drinking outcomes. J Stud Alcohol Drugs. 2008 69:5-13.
- Anton RF, O'Malley SS, Ciraulo DA, Cisler RA, Couper D, Donovan DM, Gastfriend, Hosking JD, Johnson BA, LoCastro JS, Longbaugh R, Mason BJ, Mattson ME, Miller WR, Pettinati HM, Randall CL, Swift R, Weiss RD, Williams LD, Sweben J, COMBINE Study Research Group. Combined pharmacotherapies and behavioral interventions for alcohol dependence: the COMBINE study: a randomized controlled trial. JAMA. 2006 May 3;295(17):2003-17.

References

- Barth KS, Malcolm RJ. Disulfiram: an old therapeutic with new applications. CNS Neurol Disord Drug Targets 2010;9:5-12
- Banta-Green, et al. Drug and Alcohol Dependence 104: 34-42, 2009.
- Banta-Green, et al. Drug and Alcohol Dependence 104: 43-49, 2009.
- Boscarino JA, et al. Addiction 105: 1776-1782, 2010
- Dawson DA, Pulay AJ, Grant BF: A comparison of two single-item screeners for hazardous drinking and alcohol use disorder. Alcoholism: Clin Exp Res 34: 1-11, 2010.
- Garbutt JC, Kranzler HR, O'Malley SS, Gastfriend DR, Pettinati HM, Silverman BL, Loewy JW, Ehrich EW: Efficacy and tolerability of long-acting injectable naltrexone for alcohol dependence: a randomized controlled trial. JAMA 2005; 293: 1617-1625.

References

- Gentilello LM, Ebel BE, Wickizer TM, Salkever DS, Rivara FP. Alcohol interventions for trauma patients treatment in emergency departments and hospitals: a cost benefit analysis. Annals of Surgery 2005, 241:541-550.
- Fishbain DA, Rosomoff HL, Rosomoff RS: Drug abuse, dependence, and addiction in chronic pain patients. Clin J Pain. 1992; 8:77-85.
- Fleming MF, Mundt MP, French MT, Manwell LB, Stauffacher EA, Barry KL. Brief physician advice for problem drinkers: long-term efficacy and benefit-cost analysis. Alcoholism: Clinical and Experimental Research 2002; 26: 36-43.

References

- Fuller RD, Willford WO, Lee KK, Derman R: Veterans Administration cooperative study of disulfiram in the treatment of alcoholism: study design and methodological considerations. Control Clin Trials. 1984 Sep;5(3):263-73
- Maxwell, J.C. 2006. Trends in the abuse of prescription drugs. Gulf Coast Addiction Technology Transfer Center, 1-14.
- McNicholas, L. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction: A treatment improvement protocol (TIP 40). Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, 2004.

References

- O'Malley SS, Jaffe AJ, Chang G, Schottenfeld RS, Meyer RE, Rounsaville B: Naltrexone and coping skills therapy for alcohol dependence. Arch Gen Psychiatry 49: 881-887, 1992.
- Paterick TJ, Carson GV, Allen MC, Paterick TE: Medical informed consent: general considerations for physicians. Mayo Clinic Proc, 2008 83:313-9.
- Passik SD, Kirsh KL. Managing pain in patients with aberrant drug-taking behaviors. J Supportive Oncology, 2005; 3:83-6.
- Paulozzi, L.J., Budnitz, D.S., Xi, Y, 2006. Increasing deaths from opioid analgesics in the United States. Pharmacoepidemiology and Drug Safety 15, 613-7.
- Prochaska JJ, Fromont SC, Banys P, Eisendrath SJ, Horowitz MJ, Jacobs MH, Hall SM: Addressing nicotine dependence in psychodynamic psychotherapy: perspectives from residency training. Acad Psychiatry 31: 8-14, 2007.

References

- SAMHSA, National Survey on Drug Use and Health, 2008, 2009
- Smith PC, Schmidt SM, Allensworth-Davies D, etal. Primary care validation of a single question alcohol screening test. J Gen Int Med 24: 783-788, 2009.
- U.S. Public Health Service: A clinical practice guideline for treating tobacco use and dependence: A US public health service report. The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives. J Am Med Assoc 2000; 283:3244–3254
- VA/DoD CPG SUDs, www.oqp.med.va.gov/cpg/SUD/SUD_Vase.htm
- Walsh SL, Sullivan JT, Preston KL, Garner JE, Begelow GE: Effects of naltrexone on response to intravenous cocaine hydromorphone, and their combination in humans. J Pharmacol Exp Ther 1996; 279-524-528.