Today's webinar is:

Understanding Psychopharmacology Polypharmacy in Service Member and Veteran Populations

Oct. 25, 2012, 1-2:30 p.m. (EDT)

Moderator: CAPT Paul S. Hammer, MC, USN

Director, Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury

Presenter: Matthew J. Friedman, M.D., Ph.D.

Professor of Psychiatry, and Professor of Pharmacology and Toxicology, Geisel School of Medicine at Dartmouth Executive Director, Department of Veterans Affairs National Center for PTSD







Webinar Details

- The following continuing education (CE) and continuing medical education (CME) credit is approved for this activity:
 - 1.5 AMA PRA Category 1 Credits™
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 - 1.5 Nursing Contact Hours
 - 1.5 Social Work CE Hours
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Webinar Overview

Understanding Psychopharmacology Polypharmacy in Service Member and Veteran Populations

Health care providers treating service member and veteran populations with posttraumatic stress disorder, or PTSD, face a number of challenges. PTSD, itself, can be difficult to treat even when prescribed medications conform to the VA/DoD clinical practice guidelines. Furthermore, people with PTSD usually have at least one co-occurring disorder or problem that requires treatment in its own right. Most commonly these include depression, substance use disorders, traumatic brain injury, insomnia, pain, aggressive behavior or medical/surgical problems.

As a result, providers frequently interact with patients who have complex drug regimens for both physical and psychological health disorders. Prescribers need to carefully consider the implications of adding a new medication to a treatment regimen that may already include several pharmacological agents. They also need to consider discontinuing ineffective treatments that may only complicate clinical management.

Although sometimes it is necessary to prescribe a number of medications for complex patients, combinations of medications increase the occurrence of adverse drug interactions, medication misuse and medication non-compliance/adherence. Additionally, combinations of medications have been identified as a contributing factor of suicides and unintentional deaths.

Non-prescribing health care providers treating service member and veteran populations are in a unique position to identify risk of drug-drug interactions, monitor patients for adverse drug reactions, educate patients about polypharmacy and refer patients for further assessment. This webinar will:

- Review the rates of polypharmacy in service member and veteran populations with a special emphasis on psychopharmacological medications
- Identify factors leading to polypharmacy situations and the safety risks
- Describe the role of clinicians in working with patients who have complex drug regimens





Matthew J. Friedman, M.D., Ph.D.

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Executive Director, Department of Veterans Affairs National Center for PTSD







Required Disclosure

I have no relevant financial relationships, however, I do intend to discuss scientific evidence from clinical trials regarding the off-label use of medications not approved for the treatment of PTSD.

The following drug categories will be discussed today:

- Antidepressants
- Anti-adrenergic agents
- Anticonvulsants/Mood stabilizers
- Atypical antipsychotic agents
- Anxiolytics

Pharmacotherapy for Refractory PTSD

Matthew J. Friedman M.D., Ph.D.

Professor of Psychiatry, and Professor of Pharmacology and Toxicology Geisel School of Medicine at Dartmouth

Executive Director, Department of Veterans Affairs National Center for PTSD

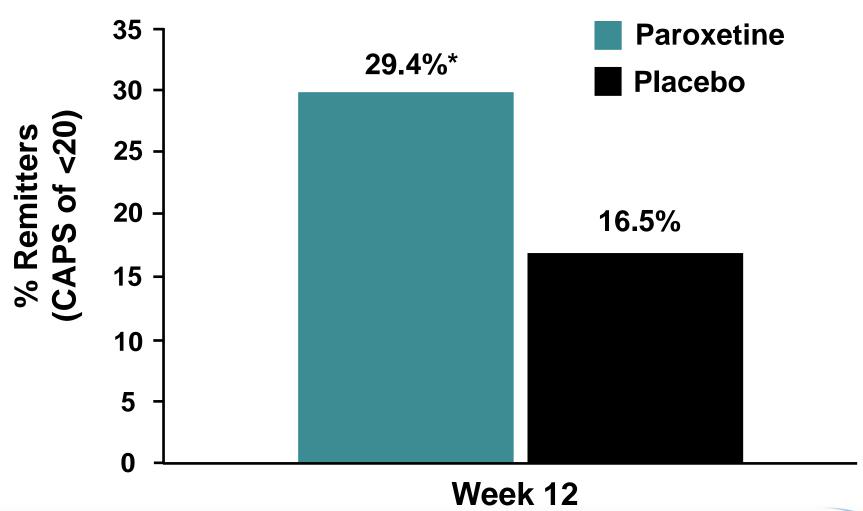
Strength of Recommendation from VA/DoD 2010 Guideline

Pharmacotherapy Interventions for Treatment of PTSD: Balance of Benefit and Harm

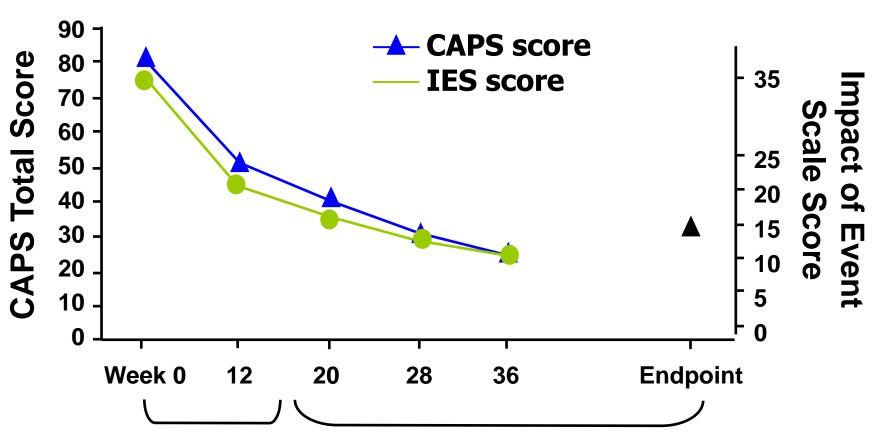
Strength of Recommendation Rating or (SR Rating): A, B, C, D or I

A (Strong Recommendation)	B (Fair Evidence)	C (No Recommendation)	D (Ineffective or Harmful)	I (Insufficient Evidence)
Significant Benefit	Some Benefit	Unknown	No Benefit	Unknown
 SSRIs–Fluoxetine, Sertraline and Paroxetine SNRIs–Venlafaxine 	 Mirtazapine Topiramate Prazosin (Use for sleep/nightmares) TCAs Nefazodone [Use caution] MAOIs (Phenelzine – attention to drugdrug and dietary interactions) 	■ Prazosin (For global PTSD)	 Benzodiazepines [Harm] Tiagabine Guanfacine Valproate Risperidone Citalopram 	 Olanzapine and Quetiapine Conventional Antipsychotics Buspirone Non-Benzodiazepine sedative/hypnotics Citalopram Bupropion Trazodone (Adjunctive) Gabapentin Lamotrigine Propranolol Clonidine

PTSD Remission Analysis



Sertraline Continuation Treatment in PTSD



Acute Phase Study Open-Label Continuation Study



Important Medication Developments

- Venlafaxine (SNRI)
 - At least as effective as SSRIs in civilian trials
- Prazosin (alpha₁ adrenergic antagonist)
 - Cooperative Study underway; effective in treating nightmares, allows improved sleep
- Augmentation with atypical antipsychotics
 - Negative Cooperative Study with Risperidone

Important Medication Developments

- Mirtazapine (alpha₂ agonist/5-HT blocker)
 - Positive Randomized Controlled Trials
- Nefazadone (SSRI + 5-HT₂ antagonist)
 - Very effective
 - Monitor LFTs because of hepatotoxicity
- Bupropion (blocks presynaptic NE/DA uptake)
 - No evidence for efficacy in PTSD

Important Medication Benefits

- Clonidine, Guanfacine (alpha₂ agonists)
 - Not shown to be effective
- Propranolol (beta adrenergic antagonist)
 - Has not proven to be an effective preventative agent, but reduces arousal
- Naltrexone (opiate antagonist)
 - Reduced drinking, but no direct benefit for PTSD
 - Compatible with SSRIs and TCAs

Antiepileptic Drugs in the Treatment of PTSD

- Antiepileptic drugs promising, but currently not approved for PTSD
- Positive RCTs with Topiramate
- Negative RCTs:
 - Divalproex
 - Tiagabine
 - An equivocal finding: Lamotrigine



Atypical Antipsychotics Not Recommended for Adjunctive Treatment of PTSD

- Four small positive trials:
 - Risperidone Three (mostly in Veterans)
 - Olanzapine
- One small negative trial:
 - Olanzapine
- One large negative multisite trial:
 - Risperidone; n=247

Benzodiazepine Basics

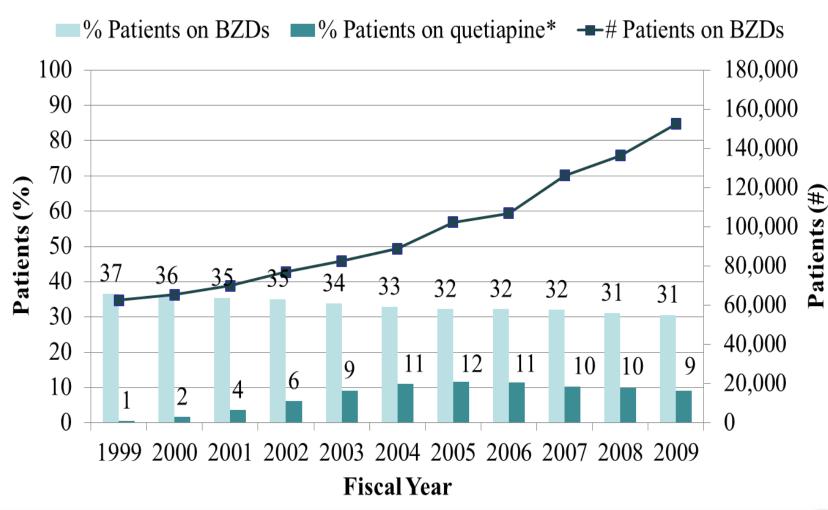
- Multiple RCTs demonstrate efficacy in anxiety disorders including:
 - Generalized Anxiety Disorder (GAD)
 - Panic Disorder (PD)
 - Social Anxiety Disorder (SAD)
- Effective treatments for short-term relief of anxiety symptoms or an "as-needed" basis
- Have a rapid onset of action, helps stabilize

Benzodiazepines – Not Indicated

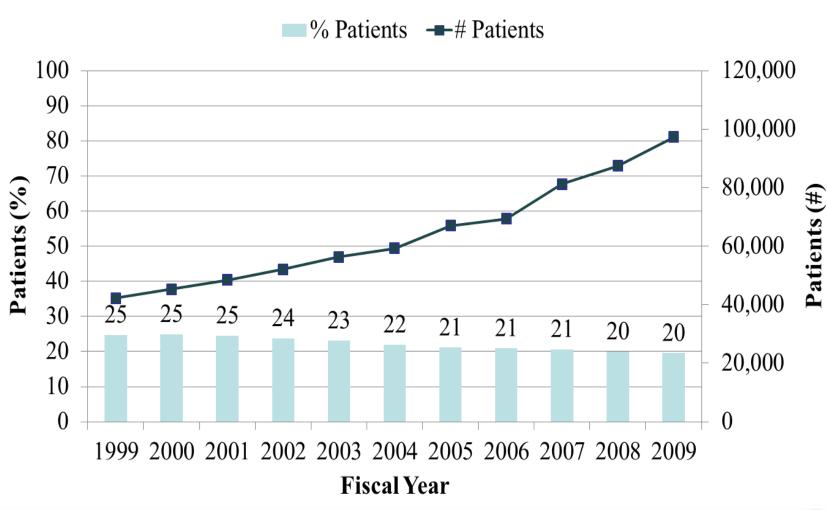
- There are concerns in prescribing benzodiazepines (BZDs) for PTSD anxietyrelated symptoms
 - Questionable beneficial effects will be short-lived
 - They may interfere with CBT treatment
 - Persistent withdrawal or craving exacerbates symptoms
 - May exacerbate coexisting substance use conditions
 - May exacerbate TBI-related cognitive impairment
 - May disinhibit aggressive behavior
 - BZDs use associated with suicidal behavior



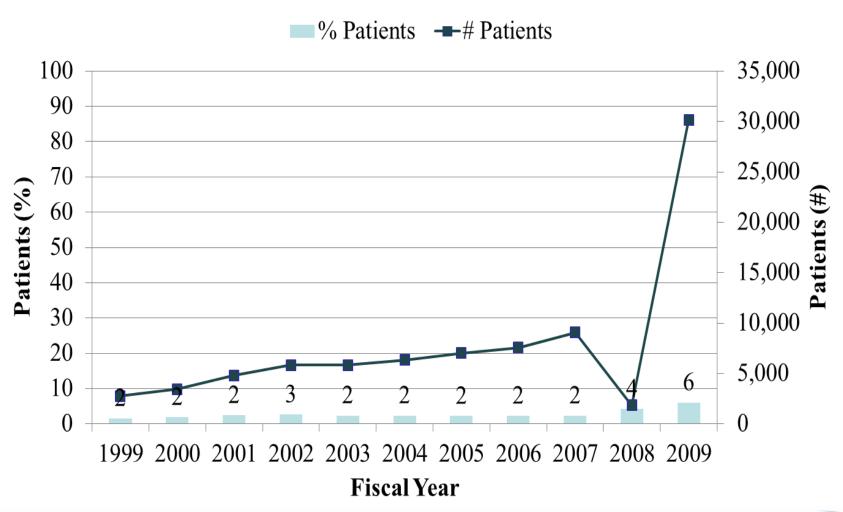
Benzodiazepines (BZDs)



Chronic Benzodiazepines*



Chronic Non-Benzodiazepine Hypnotics*



D-Cycloserine: PE Augmentation

- How it works
 - NMDA receptors enhanced
 - Mediates learning and memory
- Current research
 - Shown to be effective for other anxiety disorders
 - Faster extinction than exposure alone
 - Research with PTSD patients underway

PTSD Treatment Pharmocotherapy Balance = Benefit - Harm

SR	SUBS.	SOMEWHAT	UNKNOWN	NONE or HARM
Α	• SSRIs • SNRIs			
В		 Mirtazapine Topiramate Prazosin (Use for sleep /nightmares) TCAs Nefazodone [Use Caution] MAOIs (Phenelzine) 		
С			Prazosin (for global PTSD)	
D				 Benzodiazepines- [Harm] Risperidone Tiagabine Guanfacine Valproate

A = Strong Recommendation; B = Fair Evidence; C = No Recommendation; D = Ineffective or Harmful

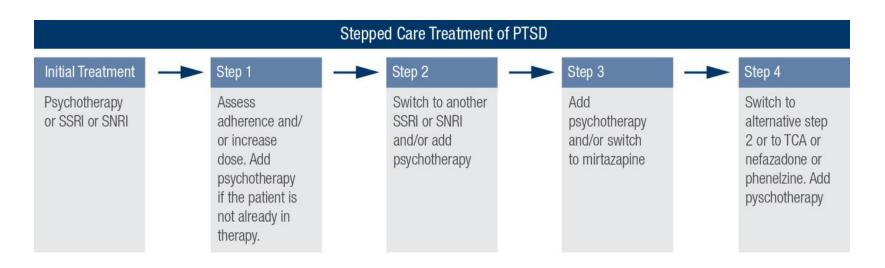
PTSD Treatment Pharmocotherapy Balance = Benefit - Harm

SR	SUBS.	SOMEWHAT	UNKNOWN	NONE or HARM
I			 Atypical antipsychotic (mono- & adjunctive therapy) Conventional antipsychotics Buspirone Non-benzodiazepine hypnotics Citalopram Bupropion Trazodone (adjunctive) Gabapentin Lamotrigine Propranolol Clonidine 	

I = Insufficient Evidence



Algorithm for Stepped Care Approach





Evidence for Augmentation

- As of yet, no RCTs comparing ET with pharmacotherapy. However, there have been two augmentation trials:
 - ET plus 10 weeks of Sertraline resulted in reduction in relapse and symptom reduction in patients who did not respond to Sertraline (Rothbaum, 2006)
 - Augmentation with Paroxetine for patients who partially responded to six ET sessions did not result in additional benefit (Simon, 2007)

PTSD Treatment Options

Psychotherapy

Exposure therapy Cognitive therapy **Anxiety management EMDR**

Pharmacotherapy

SSRIs/SNRIs Other antidepressants Mood stabilizers Atypical antipsychotics Antiadrenergic agents

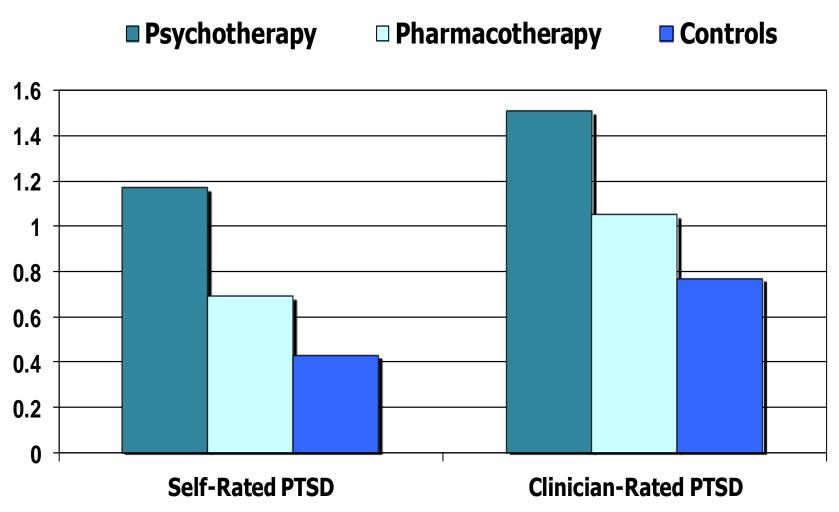


VA/DoD Clinical Practice Guidelines

- First Line Treatments: Psychotherapy
 - Cognitive-Behavioral Therapy
 - Cognitive Processing Therapy
 - Prolonged Exposure
 - Eye Movement Desensitization and Reprocessing
- Pharmacotherapy Treatments
 - Selective Serotonin Reuptake Inhibitors
 - Venlafaxine
 - Response rates to SSRIs, however, rarely exceed 60%
- Options for non-responders are needed



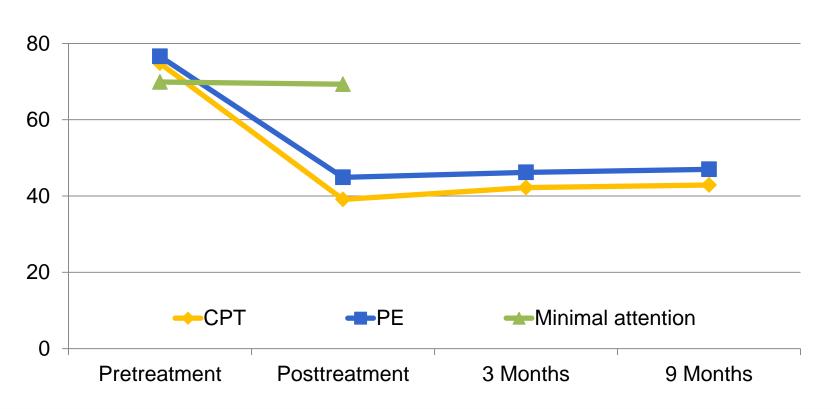
Meta-Analysis of PTSD Treatments



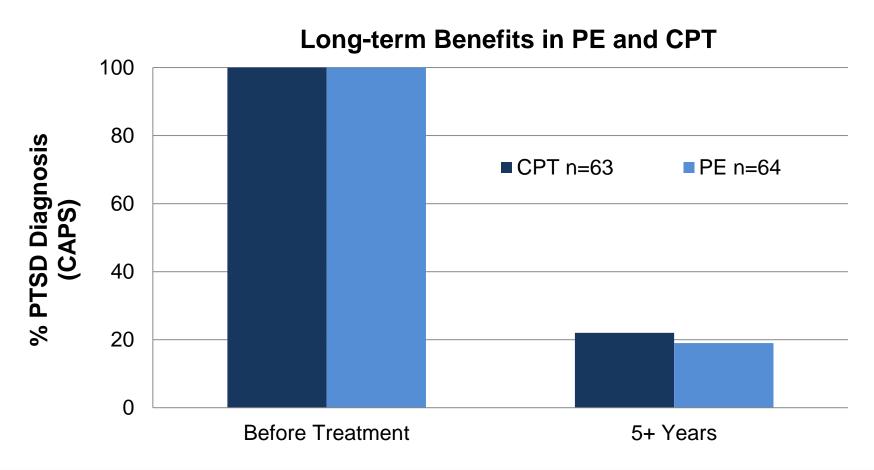


CAPS PTSD Scores in Women Treated with PE versus CPT

Comparable Effects of PE and CPT



PTSD Diagnosis Before Treatment and at 5+ Years in CPT and PE



CBT Instead of Medication

There is some emerging evidence that, given a choice, patients would rather have CBT than medication.



Key Questions About Treatment

- How should one choose among treatment modalities?
- What can one expect from treatment and how does one define realistic goals?
- How can one combine various treatment techniques?
- How does one approach complex clinical pictures and comorbid conditions?
- How long should a treatment be followed?
- How does one make sense of clinical difficulties and assess failure?

Criteria for Choosing Treatment for PTSD

- Expected efficacy for amelioration of PTSD severity
- Associated disorders and problems
- Difficulties, side effects, negative effects
- Acceptability and consent
- Cultural appropriateness
- Length, cost and availability of resources
- Legal, administrative and forensic implications
- Accessibility and acceptability to the family



Realistic Goals

- Remission is always the goal, unless proven otherwise
- Many chronic patients who have failed to respond to other therapies have benefited significantly from CBT or new medications
- If remission is not a realistic goal, maintenance of optimal function is the desired endpoint (e.g., recovery)

Combining Treatments

- Introduce treatments one at a time
 - Take into account: treatment efficacy, patient's choices and clinician's experience
- Conduct adequate clinical trial to determine effectiveness
- Discontinue if ineffective or intolerable side effects
- For partial response: introduce second treatment (prescription or CBT) without discontinuing first (e.g., Prazosin, atypicals, Mirtazapine)
- If response is adequate, try to discontinue first treatment
 - Try to eliminate all unnecessary medications

Polypharmacy

- The usual reason for polypharmacy is a partial response
- A clinical tendency is to add additional medications when one or more medications are only partially effective
- Because of compliance, side effects and drug interactions, one should always strive to eliminate ineffective medications whenever possible

Combined Treatments

- Combined treatments are common but data limited
 - Prolonged Exposure (PE) improved outcomes in partial responders to an SSRI
 - SSRI did not improve outcomes in partial responders to PE
 - D-cycloserine improved outcomes of PE in patients with anxiety disorders

Treating Comorbid Conditions

- Vast majority of patients will have >1 comorbid disorder
- Crises and urgent conditions must be treated first
 - Suicidal/homicidal behavior
 - Severe alcohol/chemical dependency
 - Incapacitating depression
 - Marital/family/vocational crisis

Management of Co-occurring Disorders

- Providers should screen/assess for medical disorders/symptoms, mental disorders and psychosocial problems that commonly co-exist with PTSD
 - Depression, other psychiatric disorders, substance use patterns (i.e., alcohol, nicotine, prescribed drugs and illicit drugs), TBI, chronic pain, sleep patterns, associated high-risk behaviors (e.g., HIV and hepatitis risk)

Management of Co-occurring Disorders

- Little evidence exists for treatment recommendations for co-occurring disorders and PTSD
- Strategy is to follow the other VA/DoD Guidelines for the co-occurring disorder
 - www.healthquality.va.gov

Management of Co-occurring Disorders – PTSD and SUD

- Recommendation is to offer coordinated treatment and concurrent care when possible
- Addiction-focused pharmacotherapy should be offered, when appropriate
- Several psychotherapy options in SUD guideline; preliminary evidence for PTSD CBT treatments
- Assess response to treatment and monitor biological indicators

Treating Comorbid Conditions

Few Randomized Clinical Trials:

- PTSD and SUD
 - Seeking safety Five RCTs
 - Sertraline One RCT
 - Naltrexone/Disulfiram One RCT
- PTSD and psychotic symptoms
 - Risperidone One RCT



Evidence-Informed Strategies for Comorbid Conditions

- PTSD and Depression or Anxiety
 - FIRST LINE: SSRI/SNRI -- good for both
 - Augment with Mirtazapine, TCA
 - Augment with Prazosin/atypicals (for depression)
- For co-occurring major depression, recommendation is to treat the PTSD and MDD which will typically improve (if severe, refer to specialty care)

Evidence-Informed Strategies for Comorbid Conditions

- PTSD and Hyperarousal/Dissociation/Aggression
 - SSRI/SNRI
 - Prazosin, Clonidine/Guanfacine, Propranolol
 - Benzodiazepines may disinhibit aggressive behavior

CPG Recommendations for Insomnia

- Behavior/Lifestyle Changes
 - Sleep hygiene
 - Less caffeine
 - Stop smoking
 - Aerobic exercise
- Psychotherapy (CBT-I)
- Medication

First, Make the Diagnosis

- Consider non-PTSD causes of insomnia
- First, screen for substance use disorders and depression
 - Alcohol
 - Nicotine
 - Stimulants
 - Major depression
- Refer to the VA/DoD CPG on SUD at www.healthqualityva.gov for the SUD and MDD guidelines and any of the other available CPG documents

Second, Primary Sleep Disorders

- Restless Legs (RL)
- Periodic Limb Movements of Sleep (PLMS)
- Obstructive Sleep Apnea (OSA)

Evidence-Informed Strategies for Comorbid Conditions

PTSD and Insomnia

- FIRST LINE: Prazosin
- Augment with Trazadone (i.e., Hydoxyzine or Diphenhydramine)
- Augment with SSRI/SNRI for co-occurring depression

Evidence-Informed Strategies for Comorbid Conditions

- PTSD and Psychotic/Hypervigilance
 - SSRI/SNRI and atypical antipsychotics
- PTSD and Bipolar Disorder
 - SSRI/SNRI and mood stabilizer

Treating Comorbid Conditions

PTSD and Cognitive Impairment (mTBI)

- Start low, go slow
- Avoid Anticholinergics
- Avoid Benzodiazepines
- Consider stimulants
- Consider CBT (for mTBI)

PTSD and TBI Three Important Medication Groups

- Dopaminergic Agonists
 - Amantadine and Memantine
 - Ropinirole and Pramipexole
- Anticholinesterase Inhibitors
 - Galantamine
 - Donezepil
 - Rivastigmine
- Stimulants
 - Methylphenidate
 - Dextroamphetamine
 - Amphetmine



Chronic Pain

PTSD



Migraine Headaches

Acute Migraine Treatment

- Triptans (Serotonin Agonists)
 - Faster-acting: Sumatriptan, Zolmitriptan, Rizatriptan, Almotriptan and Eletriptan
 - Slower-acting: Naratriptan and Frovatriptan
 - Synergy: Combination Triptan/NSAID (i.e., Sumatriptan/Naproxen Sodium)
- Ergots (Dihydroergotamine DHE)
 - Injection and nasal spray
 - Use in those who do not tolerate Triptans, failed
 Triptan therapy, or in those with prolonged attacks



Treatment Strategies for Back Pain

Exercise	Return to Activity	Medications	Other Interventions
Flexibility exercises	Return to activity	NSAIDS	Surgery
Range-of-motion exercises	Return to activity	Acetaminophen	Spinal cord stimulation
Aerobic exercises	Return to activity	Tramadol	Breathing techniques; Relaxation
Muscle strengthening exercises	Return to activity	Opioid analgesics	СВТ
	* Harder to rebuild after deconditioning	Antidepressants (primarily for patients with comorbid depression)	

Treatment Strategies for Neuropathic

Anticonvulsants	Opiates	Antidepressants	Other Meds	Interventions
Gabapentin 900-3,600mg/day	Methadone 5-100mg/day	Amitriptyline 25-200mg/day	Topical Capsaicin	Transcutaneous Electrical Nerve Stimulation (TENS)
Carbamazepine 600-1,200mg/day	Tramadol 50-400mg/day	Nortriptyline 25-150mg/day	Topical Lidocaine	Sympathetic Nerve Blocks
Valproic Acid 750-2,500mg/day Topiramate 100-200mg/day		Desipramine 25-200mg/day	Lidocaine patch 5% (max 3 patches in 12 hour period)	Hypnosis, biofeedback, relaxation training
Clonazepam 0.5-3mg/day		Venlafaxine XR 150-225mg/day		
Lamotrigine 200-400mg/day		Duloxetine 60-120mg/day		
Pregabalin 300-600mg/day				

Treatment Strategies for Tension Headaches

Abortive Treatments	Prophylactic Treatments	Other Treatments	
NSAIDS	TCAs (Amitriptyline, Nortriptyline)	Dental referral	
Acetaminophen	SSRIs	Stress management	
Aspirin	Venlafaxine	Biofeedback	
		Relaxation training	
		CBT	

Opioid Pain Management

- For patients with moderate to moderately severe pain
 - Oxycodone
 - Methadone
 - Hydrocodone
 - Fentanyl
 - Morphine
- Goal to provide sustained analgesia and improvements in sleep quality, adherence, quality of life
- Careful screening of patients being considered for long-term opioid therapy to identify patients who may have difficulties in managing opioids
- These patients should NOT be denied access to opioid therapy, but they
 do require focused monitoring; increased frequency and intensity
- During therapy prescribers MUST focus on the four A's:
 - Analgesia
 - Activities of daily living
 - Adverse effects (sedation, cognitive impairment, constipation)
 - Aberrant drug-related behaviors



Opioid Management for Chronic Pain Patients

- Clearly explain risks and benefits as part of informed consent process
- Dependence and tolerance are physiological responses to opioids
- Medication should not be abruptly stopped and must be tapered
- Withdrawal symptoms may occur
- Opioid agreement
- Adherence measures: urine drug screens as needed; pill counts
- Discuss treatment goals with patient -- expected degree of pain relief with treatment
- Provide enough medication needed until next evaluation
- Establish one provider, one pharmacy relationship
- Opioid therapy is a component of the overall treatment plan that should include:
 - Referral for physical and behavioral therapy
 - Life-style modifications
 - Consult specialists as needed



How long should a treatment be continued?

- Most published follow-up < 1 year
- Discontinuation of successful pharmacotherapy usually (but not always) followed by relapse
- Need to periodically assess necessity for continuing medication
- Since PTSD patients are vulnerable to relapse following complete remission, it would be good to investigate the utility of maintenance prophylaxis

How to Understand Treatment Resistance

- Inadequate dosage
- Side effects
- Drug interactions
- Poor compliance
- Adverse life events
- Ongoing or retraumatization
- Loss of social support

Reasons for Nonadherence

Intentional

- Choosing not to follow the prescribed treatment
- Choosing not to engage in treatment
- Choosing to avoid the side effect(s) of treatment

Nonintentional

- Forgetting the instruction(s) for treatment
- Confusion about the instructions for treatment
- Lack of finances to pay for treatment
- Deny the illness and thus, deny its treatment
- Fear of addiction and thus, reduce treatment
- Pressure from significant others; change treatment

PTSD and Nonadherence Risk

- Depression severity
- PTSD severity
- A sense of foreshortened future
- Feelings of detachment
- Avoiding reminders of the treatment event
- Cognitive deficits in memory and attention
- Desire to self-medicate

Key Concepts to Build Rapport

- Acknowledge readjustments after returning
- Recognize self-reliance and self-sufficiency
- Admire resilient temperament
- Question denial as a defense
- Combat stigma
- Explore ambivalences about treatment
- Establish hope for the future

Strategies to Enhance Adherence to Treatment

- Build rapport
- Reduce patient burden
- Discuss/Minimize side effects
- Show optimism about the treatment
- Engage patient in treatment decisions
- Respond to treatment related complaints or ambivalence
- Pay attention to anger or frustration towards patient whom is not adherent or is not improving in treatment

New Recommendations for the Management of Specific Symptoms

- Specific management of symptoms of sleep disturbance, chronic pain and anger is provided and aimed to assist primary care:
 - Initially use CBT to address sleep; consider Prazosin adjunctive pharmacotherapy for nightmares
 - Consider CBT to address pain; balance benefits of pain control with adverse medication effects
 - Explore for causes of anger; promote well-being and consider SSRI/SNRI; avoid Benzodiazepines

Implications of Recommendations

- In addition to specifics about treatment recommendations, important to advise clinicians on how to best use the guideline
- The move to integrated care models has several advantages including all issues addressed in one setting by multidisciplinary team
- In general, refer to specialty care if a patient with PTSD has comorbid mental disorders that are severe or unstable

Determination of Optimal Setting

- Consider local availability of necessary services (mental health, primary care, Vet Centers, others)
- Level of provider comfort and experience in treating psychiatric comorbidities
- Veteran-centered care -- patient preferences
- Need to maintain a coordinated continuum of care for chronic comorbidities
- Availability of resources and time in engaging in the necessary treatment(s)

Roles of Primary Care

- Routinely provide the following services for all patients with PTSD, especially those who are reluctant to seek specialty mental health care:
 - Continued discussion about specialty care
 - Address specific symptoms as reviewed in guidelines
 - PTSD-related education
 - Regular follow-up and monitoring of symptoms

Assessment in Primary Care

- Thorough assessment if
 - Presumed to have symptoms of PTSD
 - Positive for PTSD screen
- Consider using well-validated, self-administered symptom checklists (e.g., PCL)
 - Ensures systematic, standardized review of symptoms and trauma history exposure
 - Allows monitoring of treatment response and progress

Continuity of Care

- For patients referred to specialty care, important to preserve continuity of care by ensuring ongoing communication with the primary care provider
- Primary care providers should continue to be involved in treatment and provide a collaborative multidisciplinary treatment approach
- All PTSD patients should have a specific primary care provider assigned to coordinate overall health care

Conclusions and Challenges

- Promoting evidence-based treatment ultimately enhances and optimizes treatment outcomes
- Clearly, we have a ways to go to give providers tools that they can easily use
- Outcome measures will ensure that the guideline has a useful impact on practice and well-being
- Use the current gaps in knowledge as a map for future research/improvements

Thank You – Questions?



Question-and-Answer Session

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- We will respond to as many questions as time permits.

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