Evaluation of Stepped CAre for Chronic Pain (ESCAPE) in Iraq/Afghanistan Veterans Trial

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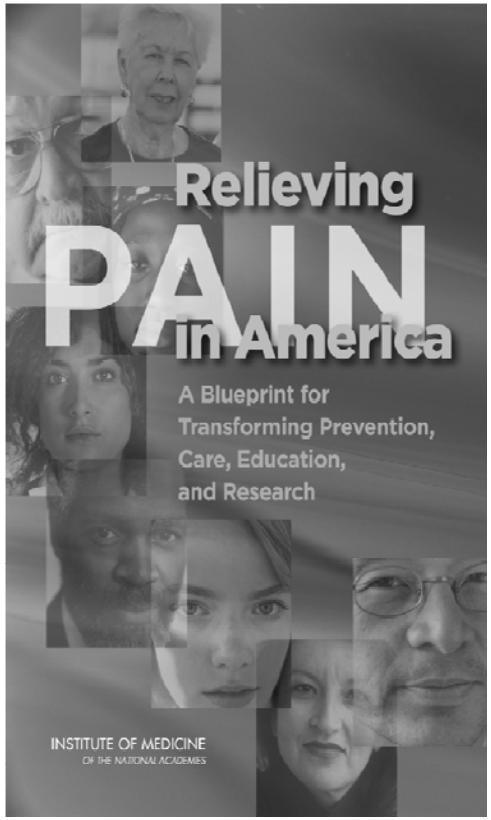
Pain: A public health problem

- **Affects > 100 million in US**
- **Reduces quality of life**
- **Costs $560–$635 billion/ yr**



Pain: A critical problem among Veterans

- **Most symptom reported in PGW vets** (Kroenke et al., 1998)
- **50% of Veterans in primary care report chronic pain** (Kerns et al., 2003; Clark, 2002)
- **Prevalence as high as 75% in female Veterans** (Haskell et al., 2006)

Pain among OEF/OIF Vets

- **One of most frequent presenting concerns among OEF/OIF vets** (Kalra et al., 2008)
- **43% & 47% of OEF/OIF veterans reported persistent pain** (Clark, 2004; Gironda et al., 2006)
- **Few intervention studies to address chronic pain**

Gap in the literature

- **Best outcomes in multidisciplinary pain clinics**
  - **But not widely available**
- **Evidence for effective individual treatments: Modest improvement**
- **Need for combined interventions to improve effect**

Long-term goal

- To test the effectiveness of multi-modal, multi-

- To determine best combinations of non-pharmacological and pharmacological treatments for chronic pain

- Applied in VA primary care settings

Study Objective

- **To determine if <u>a stepped-care intervention</u> reduces/improves:**
  - **Pain-related disability and pain severity**
  - **Secondary outcomes**
- **In OEF/OIF veterans with chronic musculoskeletal pain**

What is a Stepped-Care Intervention?

- **Starting with lower intensity, less costly treatments (Step 1)**
- **"Stepping up" to more intensive, costly, or complex treatments**
  - **"poor responders"**
  - **Low Back Pain (Von Korff), PGW Syndrome (Engel)**

ESCAPE Conceptual Model

Table 1. Conceptual model for ESCAPE trial			
Care Intensity	**Targeted Participants**	**Intervention**	**Objectives**
Step 1 (2 parts)	OIF/OEF veterans with disabling musculoskeletal pain	Analgesics coupled w/ self-management strategies	Reduce pain intensity Encourage activity Provide education
Step 2	Veterans with persistent pain and disability at 12 weeks	Cognitive behavioral therapy	Identify difficulties Identify negative thoughts Reframe thoughts Enhance coping

Primary Hypotheses

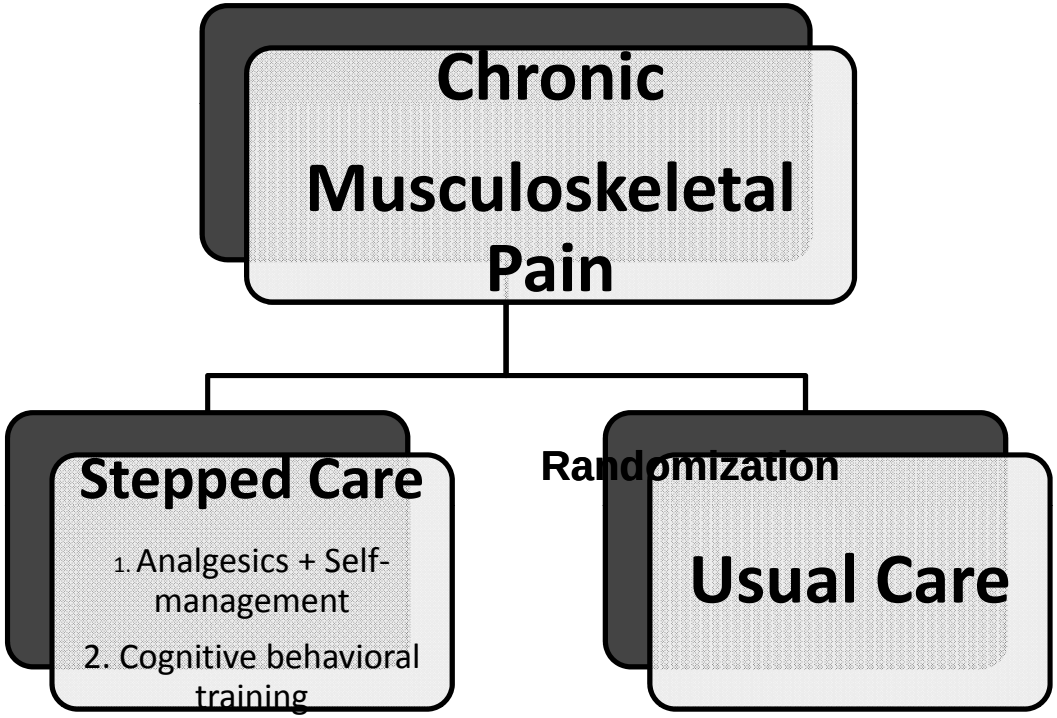
- **Stepped care is more effective than usual care in reducing:**
  - **pain-related disability**
  - **Interference with activities**
  - **pain severity**

Secondary Hypotheses

- **Stepped care is more effective than usual care in reducing <u>psychological distress</u>**

- **And improving <u>secondary outcomes:</u>**
  - **Health-related quality of life**
  - **Self-efficacy to manage pain**
  - **Negative pain beliefs and coping**

Study Design



- **Assessments**
  - **Baseline**
  - **3 months**
  - **6 months**
  - **9 months**

Study Sites

- **At Roudebush VA Medical Center**
  - **5 primary care clinics**
  - **1 post-deployment clinic**

ESCAPE Eligibility Criteria

- **OEF/OIF veterans**
- **Chronic musculoskeletal pain (> 3 months)**
  - **Low back, cervical spine, or extremities (shoulder, hip, knee)**
  - **Moderate functional impairment defined as Roland Disability Score ≥ 7**

ESCAPE Eligibility Criteria

- **Exclusions**:
  - Active suicidal ideation
  - Current alcohol/substance dependence
  - Prior surgery for pain or surgery pending
  - Pain-related disability claim under adjudication
  - Severe cognitive impairment
  - Bipolar or substance disorder/Schizophrenia

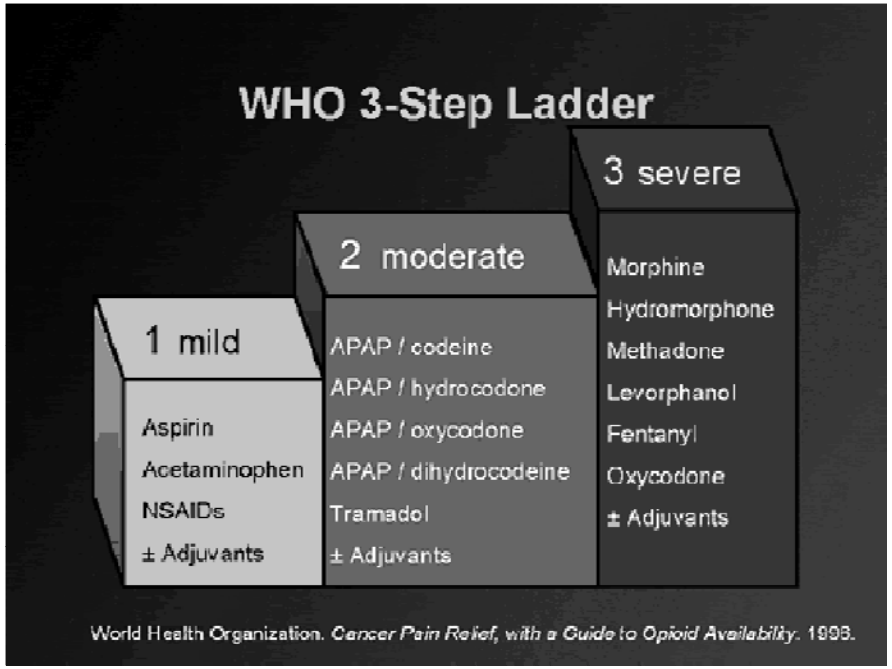
Randomization and Blinding

- Randomized 1:1 to stepped-care or usual care (control) arms
- Lists computer generated
- Assignments supplied in sealed opaque envelopes
- Baseline and follow-up assessments conducted by research assistant blinded to treatment arm

Stepped-Care Intervention: Step 1 (12 weeks)

- Analgesic management (WHO Ladder)
  - Evidence based algorithm
  - Optimize simple analgesics
  - Introduce co-analgesics
  - Address opioid regimen

WHO Analgesic Ladder



Analgesic Algorithm: Non-opioids

Step	Analgesic
Step 1	• Acetaminophen • Naproxen
Step 2	• Ibuprofen • Meloxicam • Etodolac • Diclofenac • Salsalate
Step 3	• Cyclobenzaprine • Gabapentin • Tramadol • Capsaicin
Step 4	• Nortriptyline • Amitriptyline

Analgesic Algorithm: Opioids

Step	Analgesic
Step 5	• Hydrocodone/acetaminophen • Oxycodone/acetaminophen
Step 6	• Morphine SR • Morphine IR • Methadone

Stepped-Care Intervention: Step 1

- Pain Self-Management Program (Damush, Lorig)
  - Pain education
  - Physical Activity (return to normal activities)
  - Alternative thinking (goal setting)
  - Working with health care providers
  - Stress management (e.g. deep breathing)

Stepped-Care Intervention: Step 2 (12 weeks)

- Brief cognitive-behavioral training
  - Cognitive behavioral therapy-based
  - Treatment manual modeled after Lysaker and Davis's VA Vocational Rehab Program (Davis, 2005; Lysaker, 2005)
  - 6 sessions delivered via phone

Treatment Details

- All aspects of stepped-care delivered by nurse case manager
- Weekly case management meetings
- Regular contacts with participants to
  - Monitor pain/disability
  - Assess response to treatment
  - Assess side effects
  - Query desire for treatment change
  - Introduce self-management strategies

Usual Care: Control Group

- Treatment-as-usual
- Recommended to seek treatment advice
- No other attempts to provide treatment
  - Unless psychiatric emergency e.g. suicidal ideation)

Design: Summary

- **RCT:** Stepped-care vs. usual care
- **Sample:** OEF/OIF Vets w/ chronic musculoskeletal pain
- **Pain location:** Spine (lumbar or cervical) or extremity
- **Site:** 5 VA primary care and post-deployment clinics
- **Outcome assessments:** Baseline, 3, 6, and 9 months

Primary Outcomes

- **Pain related disability**
  - **Roland Morris Disability Scale (24-items)**

    Validated in back pain **(Roland & Morris, 1983)**
  - **Validated in other pain conditions**
  - **0 (no disability) to 24 (severe disability)**

Primary Outcomes

- **Pain Interference**
  - 7-item BPI Interference Scale (BPI) (Cleeland (1990)
    0 (no interference) to 10 (severe interference)
  - Items summed and averaged

- **Pain Severity**
  - Grade Chronic Pain Scale (CGPS) (Von Korff, Dworkin, & Le, 1990)
  - 0 (no pain) to 100 (severe)

Brief Pain Inventory

INTERFERENCE

How has pain interfered with your

- General activity
- Mood
- Walking ability
- Work
- Relationships
- Sleep
- Enjoyment of life

Secondary Outcomes

- **Psychological distress**
  - **Depression (PHQ-9)**
  - **Anxiety (GAD-7)**
  - **PTSD (PCL-17)**
- **Health-related quality of Life**
  - **SF-36 domains**
- **Pain beliefs and cognitions**
  - **Pain catastrophizing**
  - **Centrality of pain**

Other Measures

- Demographics
- Military history
- Medical comorbidity
- Pain treatments
- Work function
- Pain beliefs/cognitions
- Alcohol use
- Somatization
- Stressors
- Cognitive function
- Social support
- Deployment exposure
- Physical activity

Analysis

- **Intention-to-treat method**
- **Assessed change (baseline to 9 month) between stepped-care and usual care**
- **Last-observation carried forward imputation and "complete case"**

Power and Sample size

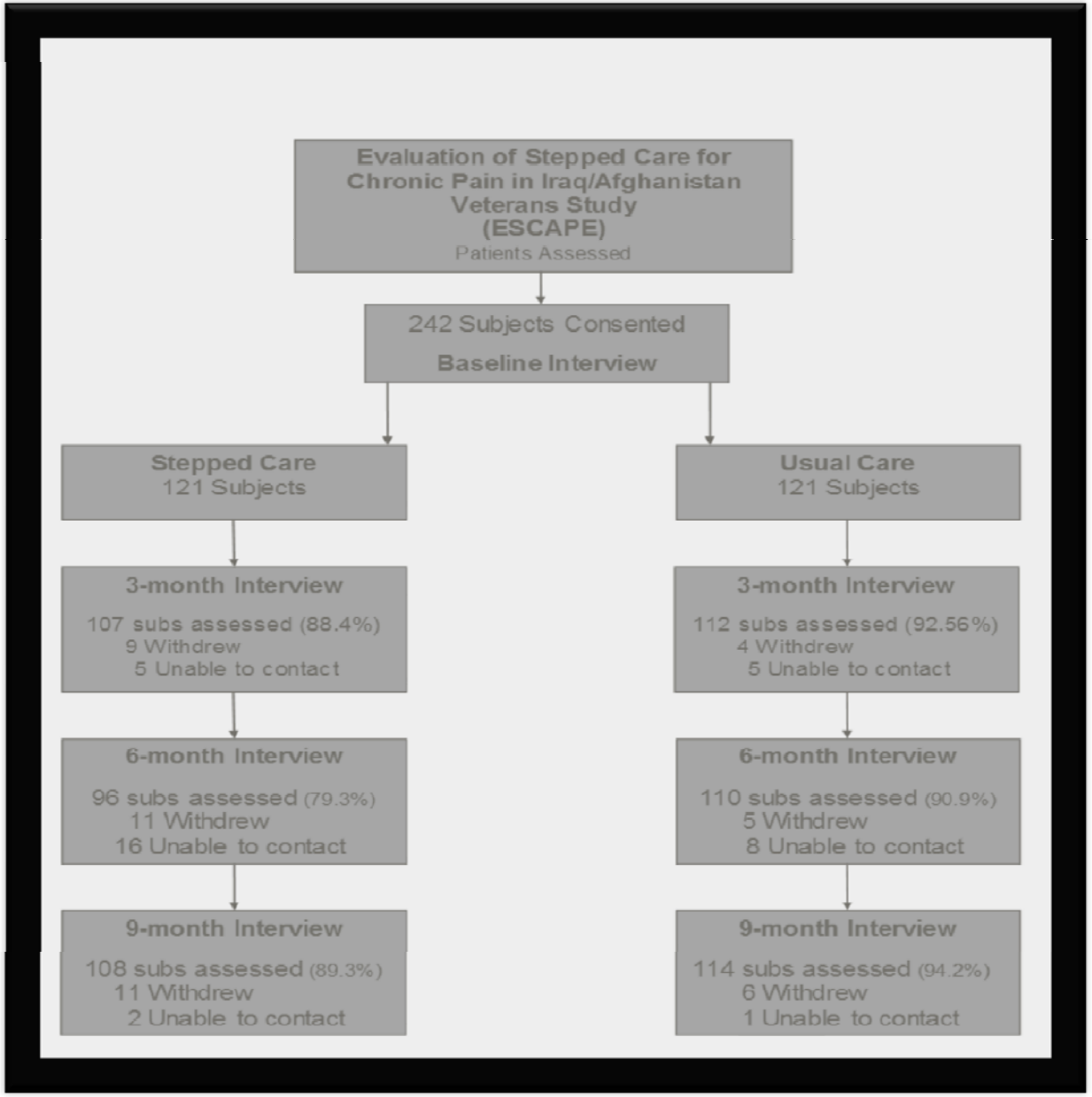
- To detect a stepped care treatment effect size of 0.4

- Need 100 patients per group
  - alpha = .05 (two-tailed)
  - beta = .20 (power = 80%)
  - Estimated > 15% attrition
  - Goal of 120 per treatment arm

Recruitment

- **December 2007 to June 2011**
- **Follow-up concluded in April 2012**

ESCAPE Participant Flow


Evaluation of Stepped Care for Chronic Pain in Iraq/Afghanistan Veterans Study (ESCAPE)
Patients Assessed
242 Subjects Consented
Baseline Interview
Stepped Care
121 Subjects
Usual Care
121 Subjects
3-month Interview
107 subs assessed (88.4%)
9 Withdrew
5 Unable to contact
3-month Interview
112 subs assessed (92.56%)
4 Withdrew
5 Unable to contact
6-month Interview
96 subs assessed (79.3%)
11 Withdrew
16 Unable to contact
6-month Interview
110 subs assessed (90.9%)
5 Withdrew
8 Unable to contact
9-month Interview
108 subs assessed (89.3%)
11 Withdrew
2 Unable to contact
9-month Interview
114 subs assessed (94.2%)
6 Withdrew
1 Unable to contact

Sample characteristics (*n*=241)

- **Mean age:** 36.7(10.2)
- **Sex:** 88.4% men
- **Married:** 54.4%
- **Race:**
  - 76.8 % White
  - 12.9% Black
- **Employment status**
  - 73.3% employed/student
- **Income**
  - 36.5% comfortable
    18.7% NOT enough

- **Military branch**
  - Army - 66.4%
- **Deployment**
  - Iraq- 74.9%
  - Afghanistan - 8.8%
- **Duty:**
  - Retired/discharged – 64.6%
- **Pain location:**
  - Back pain - 57.3%
  - Knee – 21.6%
  - Neck – 7.5%
  - Shoulder – 7.1%
  - Hip – 6.6%

Baseline Analgesics

Class	Stepped-care	Usual care
NSAIDs	69 (57.0)	69 (57.5)
Anti-depressants	45 (37.2)	50 (41.7)
Opioids	42 (34.7)	38 (31.7)
Muscle relaxants	37 (30.6)	20 (16.7)
Acetaminophen	20 (16.5)	17 (14.2)
Anti-convulsants	20 (16.5)	17 (14.2)

Baseline "Current" Treatments

Class	Stepped-care N = 121	Usual care N = 120
Pain Clinic, n (%)	7 (5.8)	12 (10.0)
Mental health, n (%)	54 (44.6)	57 (47.5)
Physical therapy	9 (7.4)	12 (10.0)

Baseline Pain Measures

Measure	Stepped-care Mean (SD)	Usual care Mean (SD)	P-value
Roland Disability	14.0 (4.3)	13.7 (4.7)	0.62
BPI-Interference	5.3 (2.1)	5.4 (2.4)	0.86
GCPS Pain Severity	67.3 (12.1)	65.1 (15.2)	0.22

Baseline Psychological Measures

Measure	Stepped-care Mean (SD)	Usual care Mean (SD)	P-value
PHQ-9 Depression	11.1 (6.2)	11.3 (5.6)	0.73
PCL-PTSD	27.6 (19.2)	25.2 (19.7)	0.33
GAD-7 Anxiety	8.9 (5.3)	8.7 (5.2)	0.68

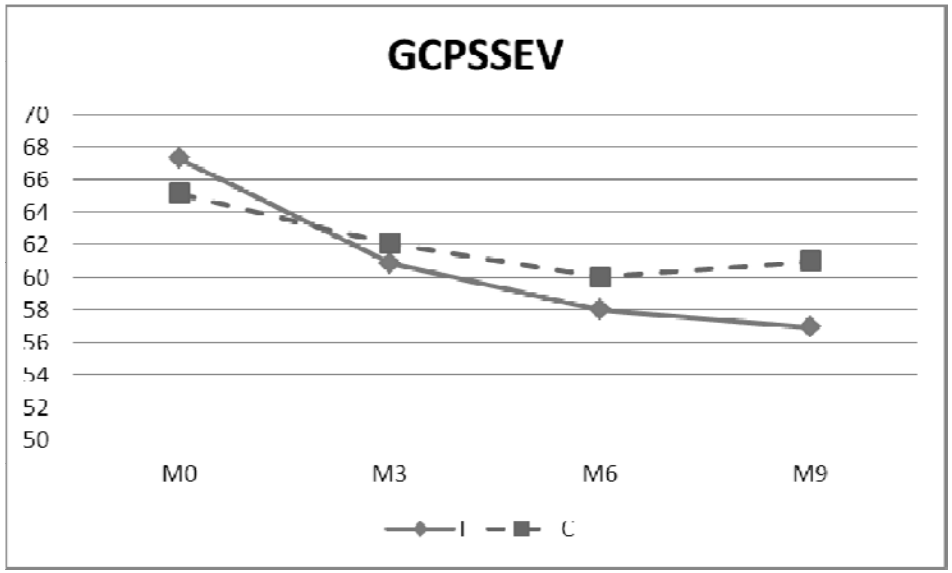
Between group difference (BL to 9 months): Pain Disability

Measure	Stepped-care Mean (SD)	Usual care Mean (SD)	P-value
Baseline Roland Disability	14.0 (4.3)	13.7 (4.7)	0.62
9-month Roland	10.6 (6.3)	12.1 (6.4)	0.075
Change	-3.4 (12.1)	-1.6 (5.1)	.0063

Between group difference (BL to 9 months): Pain Interference

Measure	Stepped-care Mean (SD)	Usual care Mean (SD)	P-value
Baseline BPI Interference	5.3 (2.1)	5.4 (2.4)	0.86
9-month BPI	3.8 (2.6)	4.5 (2.7)	0.031
Change	-1.6 (2.3)	-0.86 (2.2)	0.017

Between group difference (BL to 9 months): Pain Severity



Secondary outcomes: Analyses pending

Study Findings

- OEF/OIF Veterans have received several pain treatments
- Moderate comorbid psychological symptoms
- A stepped care intervention reduced:
  - Pain-related disability
  - Pain interference with activities
  - Pain severity

Discussion

- **SCAMP Trial** **(Kroenke, 2009)**
  - **Targeted depression and pain in primary care**
  - **Anti-depressants combined w/ pain self-management program**
    - **Substantial improvement in depression**
    - **Moderate reductions in pain severity and disability**

Discussion

- **Collaborative intervention for chronic pain** (Dobscha, 2009)
  - **2-session clinician education program**

    Patient assessment, education and activation
  - **Facilitation of specialty care**
  - **feedback and recommendations to clinicians**

- **Modest improvements in pain and depression**

Summary

- **One of first intervention studies for OEF/OIF veterans with chronic musculoskeletal pain**

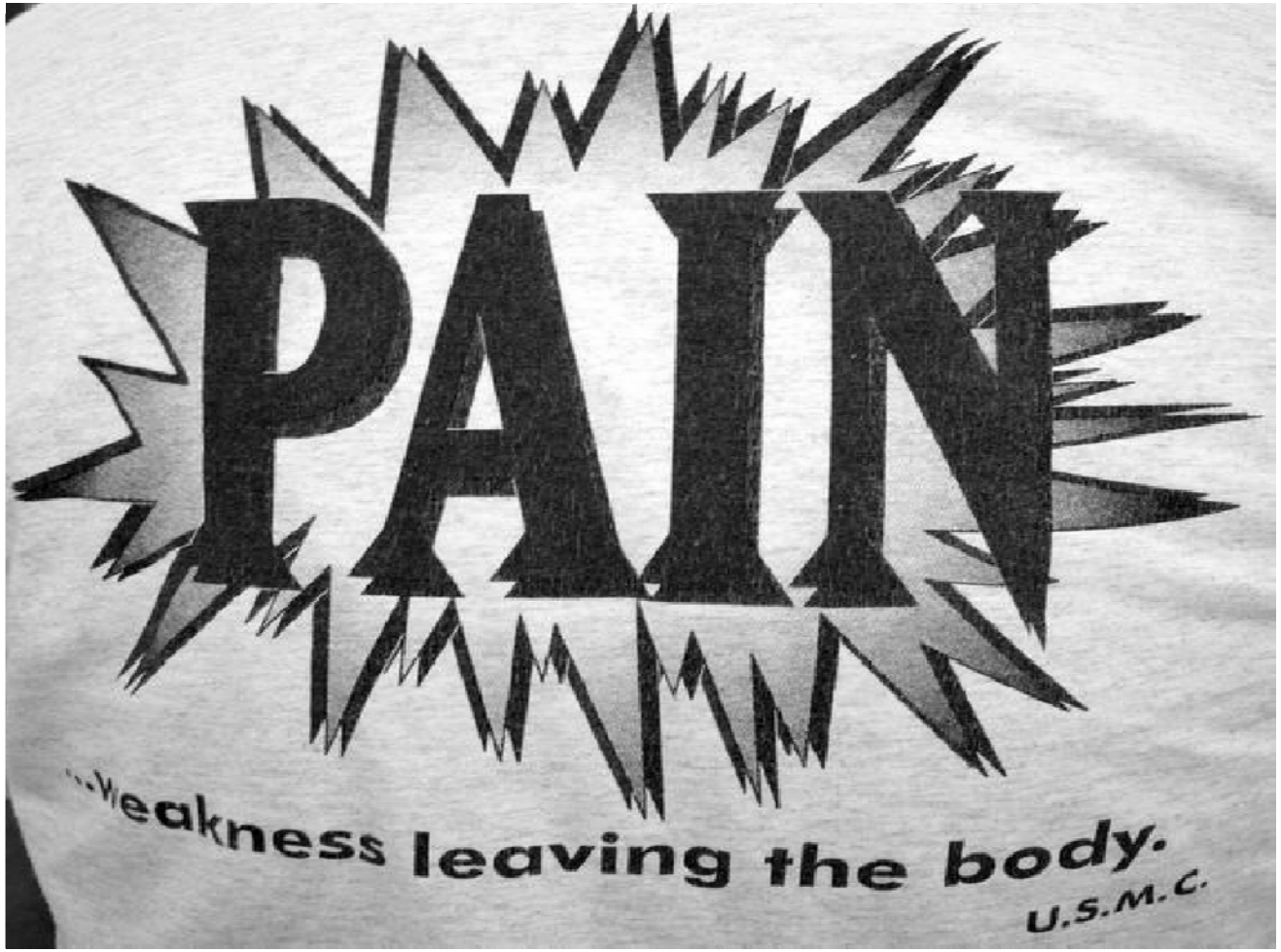
- **Intervention that included analgesics coupled with self-management strategies and cognitive behavioral therapy in context of nurse care management:**
  - **Moderate improvements in pain outcomes**

Conclusions

- Multimodal strategies needed to improve pain

- Given frequent comorbid psychological symptoms, need to treat concurrently for even better outcomes

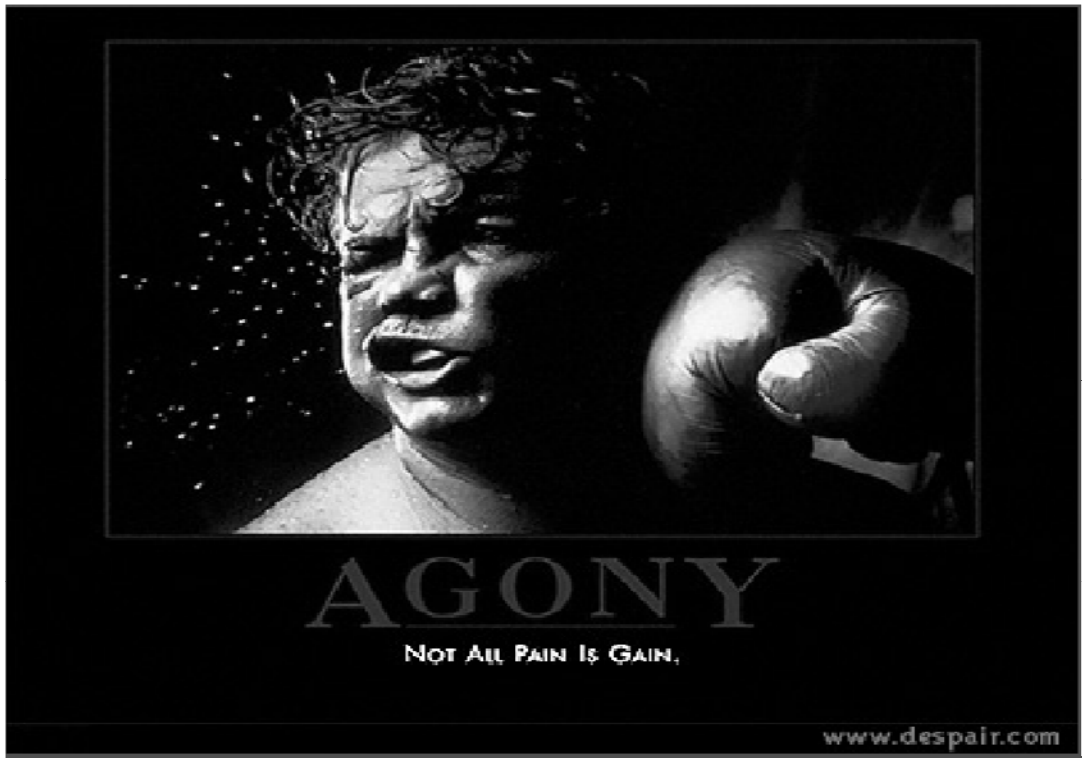
Unique Challenges in Caring for these Veterans



ESCAPE STUDY TEAM

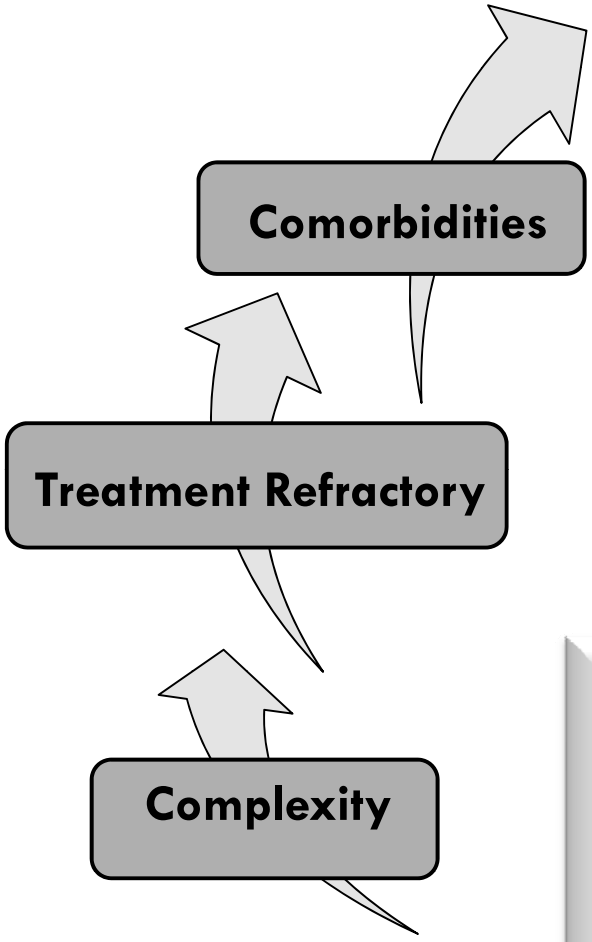
- Dennis Ang
- Jeff Barnd
- Teresa Damush
- Louanne Davis
- Amanda Gerwig
- Carol Kempf
- Kurt Kroenke
- Marianne Matthias
- Laura Myers
- Samantha Outcalt
- Christy Sargent
- Arlene Schmid
- Jingwei Wu
- Zhangsheng Yu

QUESTIONS?



Thank you for attending

VA Stepped Pain Care



RISK

STEP 3

Tertiary Interdisciplinary Pain Centers
Advanced diagnostics & interventions
CARF accredited pain rehabilitation

STEP 2

Secondary Consultation
Pain Medicine
Rehabilitation Medicine
Behavioral Pain Management
Multidisciplinary Pain Clinics
SUD Programs
Mental Health Programs

STEP 1

Patient Aligned Clinical Team (PACT)
Routine screening for presence & intensity of pain
Comprehensive pain assessment
Management of common pain conditions
MH-PC Integration, OEF/OIF, & Post-Deployment Teams
Expanded care management
Opioid Renewal Clinics

Department of Veterans Affairs
PATIENT CARE SERVICES

Ineligibles

- 417 Subjects ineligible
- 97 Low or “0” Roland Morris
- 31 No Pain
- 31 Previous Back Surgery
- 33 Potential Drug/Acholol
- issue
- 61 Not OEF/OIF Veteran
- 5 No longer seen at VA
- 8 Pain location ineligible
- 2 Pregnant
- 3 Schizophrenia
- 1 No phone
- 108 Not interested but eligible
- 37 Scheduled but did not show