• This presentation refers to several commercial products that are relevant to the topic discussed. These products are referred to as examples only. The US Army, Army Medical Command, Army Public Health Center, and Surety Medicine Division make no endorsement of any commercial products.

• The content presented is that of the presenter, and does not represent an official position of The US Army, Army Medical Command, Army Public Health Center, or Surety Medicine Division.
OBJECTIVE

• Given an employee prescribed opioid pain medication for the treatment of acute or chronic intermittent pain syndromes,
  • Briefly review the nuances of Surety Medicine and the Personnel Reliability Program
  • Understand the implications for return to work, given the July 2014 ACOEM Practice Guidelines for Opioids and Safety - Sensitive Work
  • Discuss impacts and potential approaches to various levels of site requirements
OUTLINE

• Intro info
• Case 1 and poll questions
• Historical perspective and background
• ACOEM Baltimore Conference 2015 Session 310 Prescription Drugs and Safety for Transportation Workers
• Opioid pharmacology examples
• ACOEM Practice Guidelines – Opioids and Safety Sensitive Work
• BGCAPP definitions and examples
• Various State Rx databases and access
CASE 1

• 50 y.o. male general construction laborer / maintenance (with mechanical engineering degree) in the Unescorted Access Program daily performing safety sensitive duties such as erecting / climbing scaffolds, utilizing power tools, spotter for scissor lifts, driving site motorized vehicles such as scissor lifts, booms, etc.

• EVENT - slipped and twisted without fall in a yellow “porta-john"

• Seen and evaluated in clinic by paramedic and managed as first aid – mild low back strain unchanged (1 out of 10 with a little stiffness as only difference) from pre-existing history and managed by pain management specialist on a monthly basis
POLL QUESTION #1

• On f/u the next day from the first-aid an “up-referral” to APRN occurs
  • Paramedic noted a nonspecific report from a coworker that the employee has a history of “something is wrong with that guy”
• What is the most appropriate course of action from the nurse practitioner (APRN)
  A. Turf back to medic, with no change in back issue - don’t bother me
  B. NP see employee with limited discussion / exam and no further f/u
  C. NP see employee with appropriate exam and request more information such as meds list and pertinent outside provider documentation of previous injury
  D. NP refer up to physician without evaluation
• What is the most appropriate course of action from the nurse practitioner (NP)

A. Turf back to medic, with no change in back issue don’t bother me

B. NP see employee with limited discussion / exam and no further f/u

C. NP see employee with appropriate exam and request more information such as meds list and pertinent outside provider documentation of previous injury

D. NP refer up to provider without evaluation
CASE 1 (continued)

• PMHx
  – Low back pain with 6 yr history (he thinks due to herniated disc L3) without issues during the day
  – Arthroscopies bilateral knees with missing ACL on right
  – Appendicitis / appendectomy age 17
  – Amoxicillin causes rash

• PE
  – Essentially unremarkable exam except for some subjective tightness to left lower back on direct questioning but minimal with distraction
APRN FINDINGS ON FURTHER EVALUATION

• Current Meds
  – Oxycodone 30 mg TID to QID, usually takes at least TID but also not uncommonly QID, time frames from 1800 to 0300
  – Methadone 10 mg TID to QID, time frames from 1800 to 0300
  – Diazepam 10 mg QD or BID
  – Ambien® (zolpidem) 10 mg Q HS
  – Employee statement - my physician said I could take these up to 4 hours before work, and who are you to say different?
POLL QUESTION #2

• Based on findings, which is the most appropriate course of action:

A. Well, his Doc is the specialist, follow his Doc’s orders of no meds 4 hours before duty

B. Follow 8 hours guideline since there is historical precedence in spite of what his specialist states

C. Restrict from all SSD until 90% bio - eliminated, discuss issue with employee and make self available to specialist for discussion, provide employee and specialist with ACOEM position paper, notify supervisor and management of recommended limitations / PDI

D. Find appropriate research resources to write a paper regarding how in the world the employee is able to function on such a regimen
POLL QUESTION #2 - ANSWER

• Based on findings, which is the most appropriate course of action:

A. Well, his Doc is the specialist, follow his Doc’s orders of no meds 4 hours before duty

B. Follow 8 hours guideline since there is historical precedence in spite of what his specialist states

C. Restrict from all SSD until 90% bio - eliminated, discuss issue with employee and make self available to specialist for discussion, provide employee and specialist with ACOEM position paper, notify supervisor and management of recommended limitations / PDI

D. Find appropriate research resources to write a paper regarding how in the world the employee is able to function on such a regimen
CONSULT FORM AND RECORDS RECEIVED REVEAL:

• No Kidding!
  – Specific consult re: Meds and safety sensitive duties / limitations
  – Specialist Response:
    • Cleared for SSD
      • “These medications should not be taken within 4 hours of the employee reporting for duty or while the employee is on duty.”
    – Roughly 6 year history of variations building up to this current regimen
    – Side note – when not being directly engaged by the provider the employee likes to quickly slip into a cat nap
Brief Overview of Surety and PRP:
Surety Medicine - Introduction

• Specialized component of the Army OH Program

• Highly visible and routinely inspected
  
  • SAV, SMR, DAIG, DoDIG, CDC, EPA, state equivalent EPA, and on and on and on ……

• Requires specialized training
  
  • Surety medicine is a subspecialty of OM/OH, which is a subspecialty of PM, which is a subspecialty field in Medicine.

• Surety materials include special chemical warfare and novel threat agents, biologic select agents and toxins, and nuclear/radiological materials
Background and Definitions - Surety Medicine

• Surety Medicine encompasses all of the activities and programs performed by medical organizations and personnel in support of those populations, organizations, facilities, Commands/leaders who execute surety missions. Medical includes:

• OM/PM duties

• Emergency medical response and preparedness

• Medical support to Personnel Reliability Programs (PRP)

• Training and education

• Community outreach
Local MTF and EMS

• Provide direct emergent care and OH services to personnel in surety/PRP and those who aren’t
  • Heavy administrative burden
  • Unique training requirements for providers
    • MCBC, TCTC, FCBC, HM-CBRNE/HICS
    • MRO, DOT, CAOHC, NIOSH
    • ACLS, ATLS, ABLS, PALS…
  • Staffing is regulated and augmented for those clinics with surety support responsibilities
    • May include care for some contract vendor personnel on reimbursable basis
• N/B/C Accident/Incident Response and Assistance
  • Highly visible and routinely exercised
  • Frequently includes MOAs for external support
Personnel Reliability Program

• Purpose - ensure worker reliability/suitability
• Common sense system
• Many rules
• Considers health, attitude, behavior, performance
• Privilege not a right
• Highly visible and inspectable
• Separate from OH but related
Reliability - Qualify Factors

• Emotional stability
• Mental alertness
• Technical proficiency
• Dependability
• Flexibility
• Good social adjustment
• Trustworthy
• Sound judgment under stress
Potentially Disqualifying Information

• PDI is any information regarding, but not limited to, a person’s physical, mental, emotional status, conduct or character, on and off duty, which may cast doubt about an individual’s ability or reliability to perform chemical duties
Regulatory Basis of Surety Medicine

- DoD 5210.42-R Nuclear Weapons PRP Regulation
- AR 50-1 Biological Surety
- AR 50-5 Nuclear Surety
- AR 50-6 Chemical Surety
- AR 385-10 Army Safety Program
- AR 40-5 Preventive Medicine
- AR 40-66 Medical Records Administration
- AR 40-400 Patient Administration
- DA PAM 40-11 Preventive Medicine
- DA PAM 40-8 OH and Nerve Agents
- DA PAM 40-173 OH and Vesicant Agents
- DA PAM 385-61 Toxic Chemical Agent Safety Standards
- DA Directive Memorandum -
  - Interim Guidance on OH for Nerve and Mustard Agents
  - Chemical Accident/Incident Response and Assistance
  - Guidance for Individuals in Biological or Chemical PRP
- HQDA EXORD 151-09 Implementation of SEC-ARMY/DAIG Recommendations
- MEDCOM Regulation 50-X Surety Programs (draft in force by memo)
- MEDCOM Regulation 40-55 OH for Biological Select Agents and Toxins
- OTSG MEDCOM Policy MEMO 13-024, Privileging for surety programs
- MEDCOM CG MEMO Medical Support to Chem/Nuc Surety
- All applicable CFR and State Regulations
HISTORICALLY:

• Conflicting authority recommendations
  
    
    • “Clinicians should counsel patients on chronic opioid therapy about transient or lasting cognitive impairment that may affect driving and work safety. Patients should be counseled not to drive or engage in potentially dangerous activities when impaired or if they describe or demonstrate signs of impairment.”
    
    • “In the absence of signs or symptoms of impairment, there is no evidence that patients maintained on stable doses of chronic opioid therapy should be restricted from driving.”
HISTORICALLY: (continued)

• G 3/5/7 Army Medical Guidance for Reliability Program Reporting
  – “does not take his medication within 8 hours of reporting for his work activities,” class 3 medications

• Longstanding recommendations against the use of opioids in safety sensitive work in transportation sector

• Led to various physicians' discretions as noted in above case
COMMON RESPONSES

• I’m not impaired! I’ve been taking "Lortab 10®" (hydrocodone bitartrate) TID for years and I have never had an issue
• Who are you to say I’m impaired
• I don’t feel impaired
• I’ve never had an accident
• Why are you out to get me
• I was able to take these meds and work at my last location
• Why are you jeopardizing my livelihood
Current Ongoing Opioid Crisis & Surety/Workplace Implications
• John P. Holland
  – Explosion of pain meds usage since 1990s with relaxed restrictions
  • 1994 to 2003
    – All opioid use generally **up 402%**; immediate - release **up 265 to 899%** and sustained - release methadone **up 1,214%**
    – Heroin deaths increased 12% while Rx opioid deaths up 91%
    – Opioids most widely prescribed class of medications in US
    – Research to validate skills and abilities with SSMs on board
      » Standard Deviation of Lateral Position (ICADTS) compares category 3 drugs such as tramadol or alprazolam (e.g., Xanax®) to an equivalent blood alcohol concentration of >0.08% with gross impairment of driving performance, and potentially dangerous
• Diaz
  – We are in an epidemic of Rx drug abuse – amphetamines, barbiturates, benzodiazepines, opioids with effects and restrictions where most are restricted based on transportation recommendations

• Hegman
  – “The combination of physician promotion, industry marketing and regulatory activities appears to have inadvertently launched the greatest reported iatrogenic and advocagenic epidemic of fatalities in U.S. history” MMWR 1/13/12; 61(01):10-13
  – 12 epidemiological studies in which 11/12 have elevated risks of motor vehicle crash, a 29% to 190% increased risk for both strong and weak opioids
OPIOID – PHARMACOLOGY

• Hydrocodone / APAP
  – Peak Plasma (Medscape)
    • 10 to 20 minutes
    – T_{1/2}
    • 3.3 to 4.4 hours
    – 3.3 - T_{1/2}
    • 10 to 14 hours max

– Side effects (top few, dose - dependent)
  • Hallucinations
  • Dependence with prolonged use
  • Confusion
  • Dizziness
  • Drowsiness
  • Fatigue
  • Dysphoria
  • Euphoria
  • …
OPIOID – PHARMACOLOGY (continued)

• Methadone  
  (ISMP Canada Methadone: Not your typical narcotic! ISMP Canada Safety Bulletin 2003;3(12):1-
  2)

  – Peak Plasma
    • 1 to 7.5 hours
    – $T_{1/2}$
      • intolerant - about 59 hours
      • tolerant - about 24 hours
    – 3.3-$T_{1/2}$
      • 194 hours for intolerant
      • 79 hours for tolerant

  – Side Effects (top few, dose dependent)
    • Agitation
    • Dizziness
    • Dysphoria
    • Euphoria
    • Faintness
    • Mental clouding or depression
    • Nervousness
    • …
BENZODIAZEPINES - PHARMACOLOGY

• Clonazepam (e.g., Klonopin®) (Medscape)
  - Peak Plasma
    • 1 to 4 hours
    • 5 to 7 days steady state
    - $T_{1/2}$
      • 17 to 60 hours
    - 3.3 - $T_{1/2}$
    - 56 o 198 hours max
  - Side Effects (top few, dose dependent)
    • Somnolence
    • Abnormal Coordination
    • Ataxia
    • Depression
    • Dizziness
    • Fatigue
    • Memory impairment
    • …
• Alprazolam (e.g., Xanax®) (Medscape)
  - Peak Plasma
    - 1 to 2 hours immediate release
    - 9 hours extended release
    - \( T_{1/2} \)
      - 11 hours immediate release
      - 13 hours extended release
      - 21 hours obese
    - 3.3-\( T_{1/2} \)
      - 36 hours (immediate release) max
      - 69 hours (obese) max
  - Side Effects (top few, dose dependent)
    - Drowsiness
    - Depression
    - Impaired coordination
    - Fatigue
    - Memory impairment
    - Cognitive disorders
    - ...
WHY REVIEW / REVISE GUIDELINES

• Significant rise in opioids use as noted above
• Time to update opioid guidelines from the third edition
• Provide health care providers evidence - based guidance
ACOEM PRACTICE GUIDELINES:
OPIOIDS AND SAFETY - SENSITIVE WORK

Results:

• Acute or chronic opioid use is not recommended for patients who perform safety-sensitive jobs. These jobs include operating motor vehicles, other modes of transportation, forklift driving, overhead crane operation, heavy equipment operation and tasks involving high levels of cognitive function and judgment.

Conclusions:

• Quality evidence consistently demonstrates increased risk of vehicle crashes and is recommended as the surrogate for other safety sensitive work tasks.
ACOEM GUIDELINES – KEY POINTS

• Acute or chronic opioid use
  – Not recommended for patients who perform safety-sensitive jobs
  – Jobs include
    • Operating motor vehicles, other modes of transportation, forklift driving, overhead crane operation, heavy equipment operation, sharps work (e.g., knives, box cutters, needles), work with injury risks (e.g., heights) and tasks involving high levels of cognitive function and judgment.

• The rating level is "C"
  – Confidence in the recommendation is moderate

• Panel agreement with this guideline recommendation is 100%

• By definition all PRP enrollees are in safety-sensitive positions
Among those treated with opioids (including tramadol)

- Sufficient time after the last dose is recommended to eliminate approximately 90% of the drug and active metabolites from their system

- Caution is also warranted for those consuming other depressant medications such as benzodiazepines and sedating antihistamines

- Quality evidence consistently demonstrates increased risk of vehicle crashes and is recommended as the surrogate for other safety sensitive work tasks
ACOEM GUIDELINES – KEY POINTS (continued)

• Harms include
  – Potential preclusion of someone from working who is theoretically not at risk

• Benefits include
  – Potential reductions in accidents and injury risks to self, public and coworkers

• No validated method to demonstrate an individual’s safety while consuming opioids
ACOEM GUIDELINES – KEY POINTS (continued)

• The literature is
  – Routinely monitored
  – Formally searched
  – At least annually for evidence that would overturn this guidance

• Guideline is planned to be updated at least every three years or more frequently should evidence require it
Any good legal precedence or definition?

A **safety-sensitive position or function** means any job position or work-related function or job task designated as such by the employer, which through the nature of the activity could be dangerous (unsafe, hazardous, can cause harm) to the physical well-being of or jeopardize the security of the employee, co-workers, customers or the general public through a lapse in attention or judgment.

SSD/L GUIDELINES

• These positions/functions consist of but not limited to:
  – Use of dangerous tools / equipment in the performance of their essential job duties
  – Performance of job duties at heights
  – Operation of a motor vehicle in the course of their essential job duties
  – Operating other modes of transportation as well as forklift driving, overhead crane operation, heavy equipment operation
  – Sharps work (i.e. knives, box cutters, needles)
  – Essential job duty tasks which require high levels of cognitive function and judgment (PRP)
EXAMPLES FROM THE STATE OF CONNECTICUT OF DESIGNATED HIGH - RISK OR SAFETY - SENSITIVE POSITIONS, WORK - RELATED FUNCTIONS, OR JOB TASK DESIGNATIONS:

(http://www.ctdol.state.ct.us/wgwkstnd/highrisk.htm)

- EXAMPLES
- ALS technicians
- Assistant Plant Operators
- Beta Field Engineer
- Compressed gas branch managers
- Chemist and chemist manager of hazardous waste materials
- Coax splicer
- Clinical assistant
- Clinicians (social workers, therapists, psychologists)
- Deburrier
- Director of Operations (EMS)
- EMT
- Expediter
- Flagman
- Foreman
- HVAC service technician
- Inventory assistant team leader
- IV nurse
- Lab technician
- LPN
- Location manager
- Maintenance supervisor
- Nurse Practitioner
- Paramedic
- Physician
- Physician Assistant
- Yard laborer
Case 2

- 53 y.o. male systems engineer with +80% field work (remainder is systems design)

- Referred to medical early 2015 by management after RTW from short term disability (first of year). Referral based on significant decline in performance such that he is now only reading SOPs for typographical issues and has been accommodated by management to an office position only.

- HPI / PMHx (pertinent):
  - Chronic pelvic pain syndrome, longstanding since 21 years of age; stable until about 2011
    - Controlled with pain medication until end of 2014 when pain control became unstable contributor to short term disability
    - Significant increase in medications since November
  - Depression and 6 week confinement during short term disability period end of 2014

- PE
  - Non - contributory
Poll Question #3

• Based on findings, which is the most appropriate course of action:
  
  – No worries, everyone who mouth pipettes VX nerve agent is living on the edge
  
  – Ask about pain control – meds, dosing, frequency, etc. and further historical evaluation with release of records, and return to work without limitations
  
  – Ask about pain control – meds, dosing, frequency, etc. and further historical evaluation with release of records, with return to work with limitations of no SSD noted above, to include no essential job duty tasks which require high levels of cognitive function and judgment as determined by management
  
  – Realize this is a hopeless case, immediately dismiss employee with prompt phone call recommendations to management of immediate termination
Poll Question #3 – Answer

• Based on findings, which is the most appropriate course of action:
  – No worries, everyone who mouth pipettes VX nerve agent is living on the edge
  – Ask about pain control – meds, dosing, frequency, etc. and further historical evaluation with release of records, and return to work without limitations

  – Ask about pain control – meds, dosing, frequency, etc. and further historical evaluation with pertinent release of records, with return to work with limitations of no SSD noted above, to include no essential job duty tasks which require high levels of cognitive function and judgment as determined by management

  – Realize this is a hopeless case, immediately dismiss employee with prompt phone call recommendations to management of immediate termination
CASE 2 (continued)

• **NOW WHAT?**

• Receive and review detailed job description, with consultation with supervisor/management etc and safety as needed

• Initiate safety sensitive recommended limitations and Submit Employee Duty Status Report (EDSR) to management

• Supply ACOEM Practice Guideline
  – Employee
  – Employee’s physician
CASE 2

• **NOW WHAT?** *(continued)*

• Request release of records
  – From employee’s PCP or treating provider, any additional info pertinent to issue

• Submit consult request to provider detailing issues bulleted below, and in essence, in the provider’s professional opinion - is the employee capable of safely performing duties with respect to his job description and PPE requirements
  – ACOEM Guidelines
  – Specific employee medications
  – Specific employee safety sensitive duties and required PPE

• Provider(s) are available for consult; discuss alternatives to treatment
CASE 2 (continued)

• Current Meds
  – Percocet® (oxycodone / acetaminophen) 10 mg QID for breakthrough pain
  – OxyContin® (oxycodone) 20 mg BID for constant control
  – Ativan® (lorazepam) unknown dose up to TID
  – Ambien® (zolpidem) unknown dose PRN but in reality almost every night for sleep
  – Prilosec® (omeprazole) for heart burn
  – Senokot® (sennoside) for constipation from opioids
  – Abilify® (aripiprazole) 5 mg for depression

• Pain pattern and medication use has significantly increased over the last 6 to 8 months with extensive workup by specialists, without any findings

• REST OF THE STORY
One Approach - Management Discussion

• Above data presented to all partners of the JV to include project and upper management as well as HR

• Data included
  – ACOEM paper
  – Legal definition
  – State of Connecticut’s DoL list of safety - sensitive positions
  – SSD/L recommendations
    • Mirrors ACOEM paper and surrogates
  – Process to evaluate and medically manage cases
  – Awareness of ADAAA and preceding legal agreements

• Management agreement for site and institution of accommodations with approach details below
OPIOID AND SSD/L EVALUATION PROCESS (general)

- Receive and review detailed job description with consultation with management and safety as needed
- Evaluate and document
  - Pathology necessitating scheduled medication usage
  - Type and dose
  - Utilization of non-pharmacologic therapies
  - Realistic treatment goals
  - Expected resolution
  - Concurrent neurocognitive meds
  - Appropriate reassessments
- Initiate safety sensitive recommended limitations
- Submit Employee Duty Status Report (EDSR) to appropriate management with SSL recommendations
- Supply ACOEM Practice Guideline, Fitness For Duty Policy, Pertinent Regulations
  - Employee
  - Employee's physician
  - Encourage non-opioid therapies and discussion regarding realistic treatment goals and risks of chronic opioid use as well as close f/u and appropriate reassessments
EVALUATION PROCESS - Acute < 4 months

- Appropriate immediate SSD/L
  - Not to be taken at work
  - SSL mandatory 3.3 half lives before SSD (chart of most common)
    - Very short course (tooth extraction)
    - PRN (shoulder, back, whatever pain)
    - 2 week course or longer (pre or post-op)
- F/U 2 weeks and monthly out to 4 months (provider discretion) or sooner PRN
  - Monitor for stabilization of the condition/treatment and effects from neurocognitive meds
- Initial f/u evaluation
  - May request records specific to issue to evaluate progress, plan, etc (complexity, lack of insight)
- EDSR will read
  - If SSD called out on Job Description: specify specific duties and include - “The employee should not perform any work-related function or job task which through the nature of the activity could be dangerous (unsafe, hazardous, can cause harm) to the physical well-being of the employee, co-workers, etc. through a lapse in attention or judgment.”
  - If not then use that in quotes alone Initial f/u evaluation
- Any unstable condition/treatment regimen will remain in acute process until stable
EVALUATION PROCESS - Chronic > 4 months

• Reevaluate SSD/L based on condition and response to medications
  • Not to be taken at work
  • SSL 8 hours before SSD (Regulatory Guidance)
  • Limitations on EDSR will read
    • If SSD called out on Job Description: specify specific duties and include - “The employee should not perform any work-related function or job task which through the nature of the activity could be dangerous (unsafe, hazardous, can cause harm) to the physical well-being of the employee, co-workers, etc. through a lapse in attention or judgment.”
    • Continue to observe for stabilization of the condition/treatment and effects from neurocognitive meds
  • 6 month f/u evaluation and every six months thereafter (increasing opioid use) or sooner PRN
    • Request pharmacy logs and pertinent medical records for reevaluation and compliance, changes, etc
    • Benzodiazepine’s follow same approach
  • Medical conditions becoming unstable revert back to acute process
REFERENCES:

• 4123-17-58 Drug-free safety program (DFSP) and comparable program. http://codes.ohio.gov/oac/4123-17-58

• List of occupations designated as high-risk or safety-sensitive by the Labor Commissioner of the State of Connecticut. http://www.ctdol.state.ct.us/wgwkstnd/highrisk.htm


• Guidance for Individuals Performing Biological Personnel Reliability Program (BPRP) and/or Chemical Personnel Reliability Program (CPRP) Duties Regarding What Medical Information Should Be Reported to the Competent Medical Authority (CMA)

• Diaz, Hegman, and Holland: ACOEM Baltimore Conference 2015 Session 310 Prescription Drugs and Safety for Transportation Workers
QUESTIONS

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