Safe Opioid Prescribing

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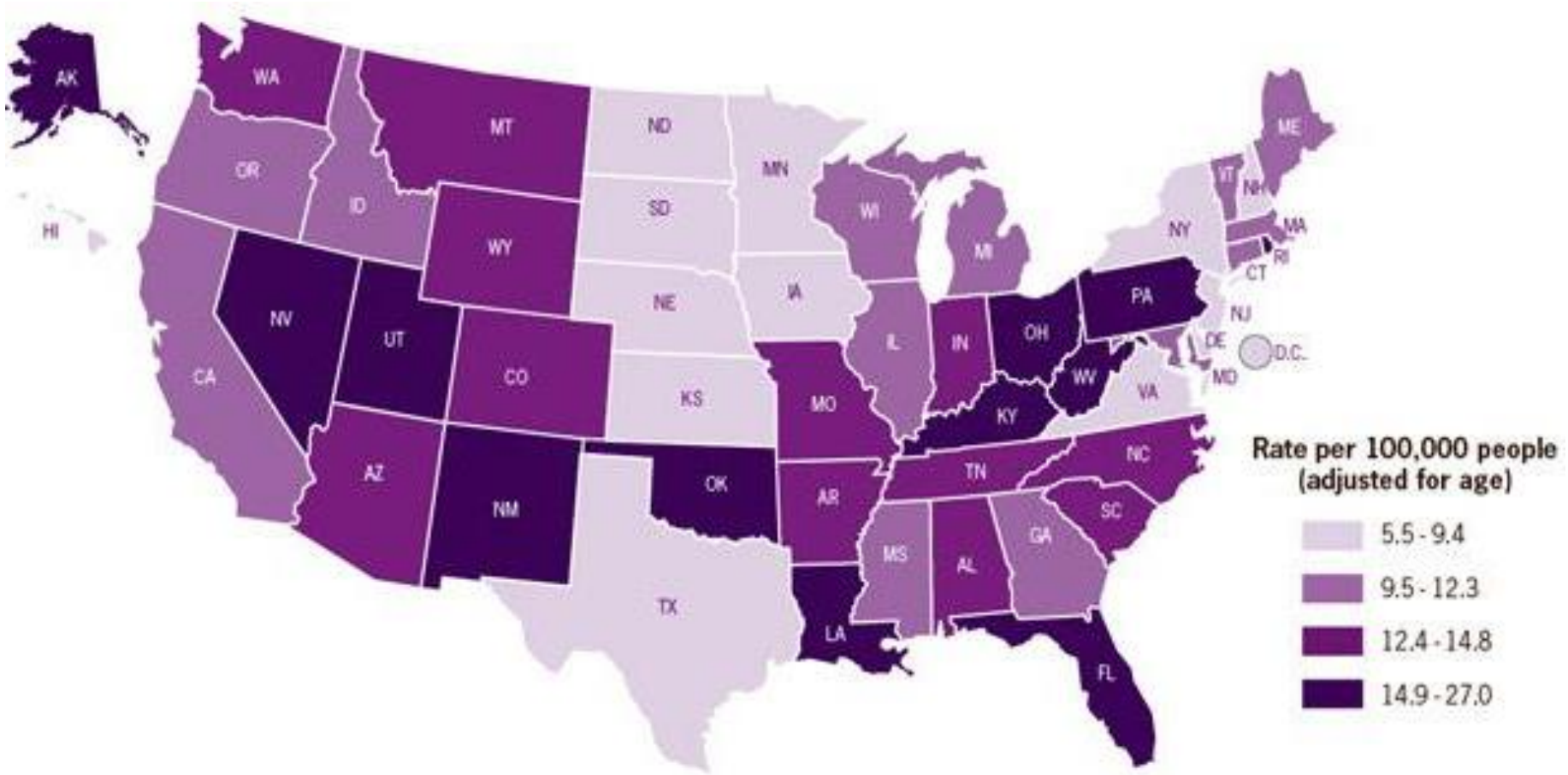
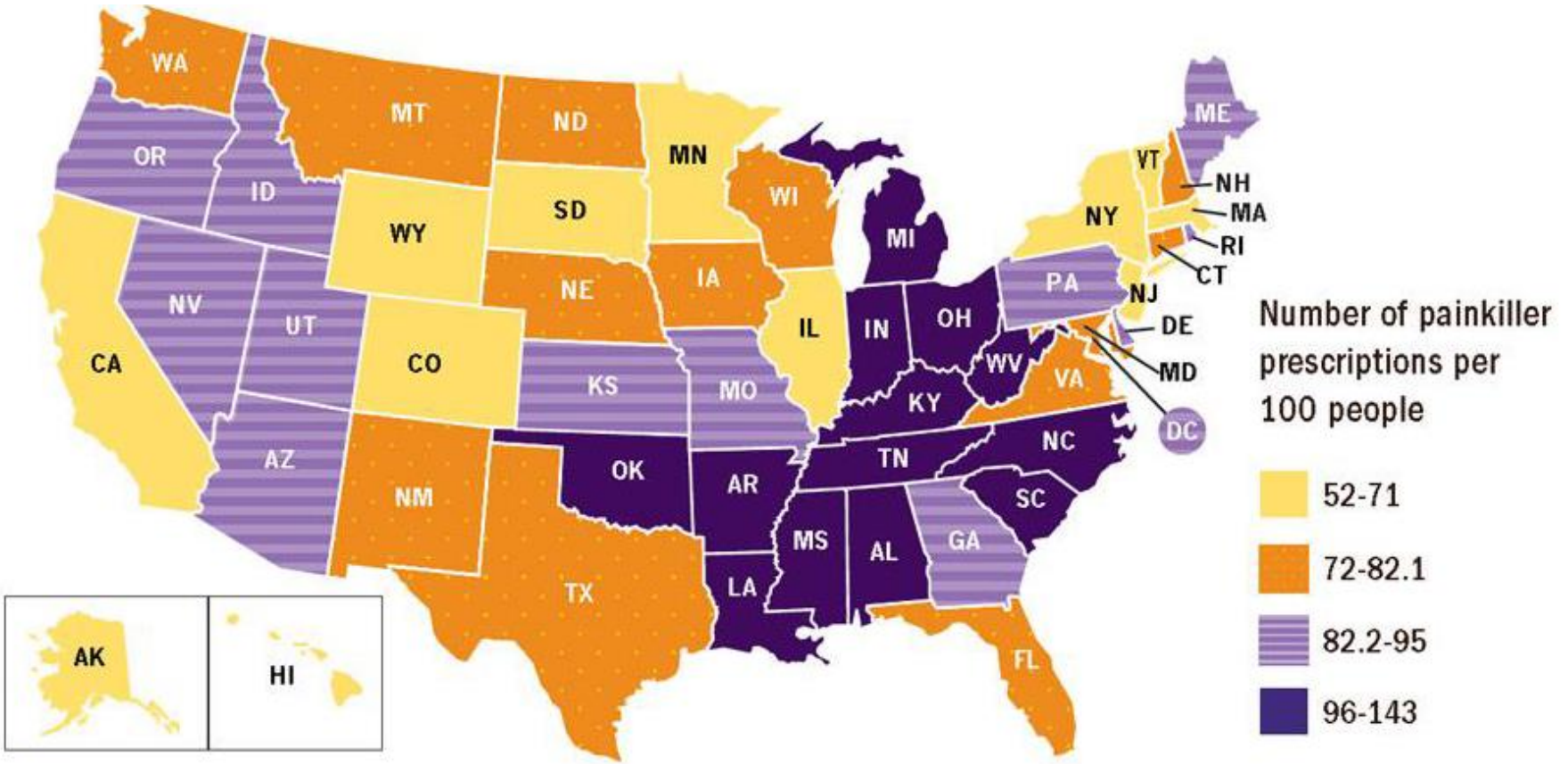
Learning Objectives

- Implement risk assessment tools when prescribing chronic opioid therapy (COT)
- Utilize SCRIPTS (PMP)
- Approach to therapy initiation, titration, rotation, and discontinuation
- Monitoring tools such as drug testing
- Patient education
- Identify specific drug differences among ER/LA opioids

Overdose Death Rates (2008)



Opioid Prescribing by State (2012)



SOURCE: IMS, National Prescription Audit (NPA™), 2012.

COT in Pain Management

- Commonly prescribed
  - Limited evidence supports use for non-cancer pain
- COT goals
  - Improve overall quality of life
  - Improve activity tolerance and physical function
  - Decrease pain intensity
- Among the most abused medications
  - Opioids, benzodiazepines, stimulants
- Significant risk from misuse and drug interaction

COT Risks

- Side effects
- Drug interactions
- Tolerance
- Physical Dependency
- Inadvertent exposure, especially children
- Misuse / abuse
- Addiction
- Diversion by patient or family / household
- Respiratory Depression
- Overdose and Death

Opioid Side Effects / Management Options

Nausea and vomiting	**Anti-emetics** **Opioid Rotation**
Sedation	**Lower dose (if possible);** **Add nonsedating co-analgesic** **Add stimulant or attention enhancer**
Constipation	**Stool softeners, osmotics, diet changes** **Relistor, Amitiza, Movantik**
Itching	**Antihistamines (low efficacy), A / A rotation**
Endocrine dysfunction **Reduced libido** **Loss of menstrual period**	**Endocrine monitoring** **Testosterone replacement** **Endocrine consultation**
Edema and sweating	**Opioid Rotation**
Dizziness	**Antivertigo agents**
Confusion	**Lower dose, rotate opioid**

Opioid Interactions

- **CNS depressants**
  - alcohol, sedatives, hypnotics, tranquilizers, TCAs, MAOIs
  - respiratory depression, hypotension, profound sedation, or coma, serotonin syndrome
- **Partial agonists, agonist/antagonist analgesics**
  - buprenorphine, pentazocine, nalbuphine, butorphanol
  - May reduce analgesic effect or precipitate withdrawal symptoms
- **Skeletal muscle relaxants**
  - Increased respiratory depression
- **Anticholinergic agents**
  - Increased risk of urinary retention and severe constipation, which may lead to paralytic ileus

Other Interactions

Medication	Methadone	Buprenorphine
AZT	Increase in AZT concentrations; possible AZT toxicity	None
Lopinavir/Ritonavir	Opiate **withdrawal** may occur	None
Rifampin	Opiate **withdrawal** may occur	Opiate **withdrawal** may occur
Fluconazole	**Increased methadone** plasma concentrations	
Ciprofloxacin	**Increased methadone** plasma concentrations	
Sertraline	None	None
Duloxetine	Potentially **increases duloxetine** exposure	
Dextromethorphan	Associated with delirium	
Aripiprazole	None	None
Carbamazepine	Opiate **withdrawal** may occur	Not studied
Methylphenidate	None	None
Diphenhydramine	May have synergistic depressant effect	

Risk Factors for RD/OD

- Generally preceded by sedation and decreased respiratory rate
- Risk factors for Respiratory Depression
  - OSA, morbid obesity, snoring
  - Age (>60)
  - CNS depressant polypharmacy
  - Cardiopulmonary disease, organ failure
  - Smoking
  - Post-Surgery – upper abdominal and thoracic

Aberrant Use Definitions

- **Misuse** - using a medication in a manner other than as specifically directed by a healthcare professional
  - Self titration due to poor pain control or anxiety
- **Abuse** – deliberate nonmedical use
  - Crushing, snorting, injecting
  - Diversion (buying/selling/stealing)

- Both contribute to opioid-related deaths

Definitions (continued)

- **Tolerance** - adaptive state after drug exposure, increased dose required for clinical effect
  - Alone, does not indicate addiction
- **Dependency** – physiological adaptation wherein discontinuation or reversal of drug causes withdrawal syndrome
  - Occurs in all patients on sufficient doses over time
  - Alone is not indicative of addiction
- **Addiction** – primary, chronic, neurobiological disease with genetic, environmental, and psychosocial elements
  - One or more of the following
    - Impaired control over use, compulsive use, continued use despite harm, craving

Opioid Tolerance

- According to the FDA, a patient is considered opioid tolerant if they are taking, **for one week or longer**, at least:
  - Morphine (po) – 60 mg/day
  - Hydrocodone – 60 mg/day
  - Oxycodone – 30 mg/day
  - Fentanyl (td) – 25 mcg/h
  - Hydromorphone - 8 mg/day
  - Oxymorphone – 25 mg/ day

Risk Factors for Misuse/Abuse

- Personal history of substance abuse
  - Prescription drugs > illicit drugs > EtOH
- Family History of substance abuse
- Age 16 – 45
- Psychiatric Comorbidity
  - BPAD, ADHD, GAD, MDD, personality d/o
- Preadolescent sexual abuse in women

Risk Stratification Tools

- Use prior to opioid initiation
- Opioid Risk Tool (ORT)
  - www.partnersagainstpain.com
- Screener and Opioid Assessment for Patients with Pain (SOAPP)
  - www.painEDU.org

Opioid Risk Tool (ORT)

CATEGORY	RISK FACTOR	FEMALE	MALE
Family History of Substance Abuse	Alcohol Illegal Drugs Prescription Drugs	1 2 4	3 3 4
Personal History of Substance Abuse	Alcohol Illegal Drugs Prescription Drugs	3 4 5	3 4 5
Age	Age 16-45 years	1	1
History of Preadolescent Sexual Abuse		3	0
Psychological Disease	ADHD, OCD,BPAD, Schizophrenia Depression	2 1	2 1
Total Risk Score			

Total Score Risk Category

Low Risk 0–3 **Moderate Risk 4–7** **High Risk ≥8**

Opioid Risk Tool (ORT)

- Low Risk
  - No past or current substance abuse
  - Noncontributory family history
  - Psychologically stable
- Moderate Risk
  - History of substance abuse, long-term recovery
  - Concerning family history
  - Comorbid psychiatric condition
- High Risk
  - Active Substance abuse / addiction
  - Major untreated / unstable psychiatric condition
  - Significant risk to self and prescriber

COT Initiation

- Step 1: Take a history
  - Pain / Symptom history
    - Onset, character, duration, severity, relieving/exacerbating factors
    - Prior workup, diagnoses, tests, treatments, surgeries
    - Substance use history, family substance use history
      - Parental addiction is the #1 risk factor for patient addiction
    - Psychiatric History
    - Work History / Disability

COT Initiation

- Physical Exam
  - Multi-organ system
    - Musculoskeletal, neurological
    - Waddell signs
      - ***Tenderness*** not related to a particular skeletal or neuromuscular structure; may be either superficial or nonanatomic.
      - *Superficial* – The skin in the lumbar region is tender to light pinch over a wide area not associated with the distribution of the posterior primary ramus.
      - *Nonanatomic* – Deep tenderness, which is not localized to one structure, is felt over a wide area and often extends to the thoracic spine, sacrum or pelvis.

PE: Waddell Signs (contd)

- ***Simulation Tests -*** These tests give the patient the impression that a particular examination is being carried out when in fact it is not.

- *Axial Loading* – Low back pain is reported when the examiner presses down on the top of the patient's head

- *Rotation* – Back pain is reported when the shoulders an pelvis are passively rotated in the same plane as the patient stands relaxed with the feet together

PE: Waddell Signs (contd)

- ***Distraction Test*** - A positive physical finding is demonstrated in the routine manner, and this finding is then checked while the patient's attention is distracted; a nonorganic component may be present if the finding disappears when the patient is distracted.

- *Straight Leg Raising* – The examiner lifts the patient's foot as when testing the plantar reflex in the sitting position; a nonorganic component may be present if the leg is lifted higher than when tested in the supine position.

PE: Waddell Signs (contd)

- ***Regional Disturbances*** - Dysfunction (eg, sensory, motor) involving a widespread region of body parts in a manner that cannot be explained based on anatomy; care must be taken to distinguish from multiple nerve root involvement.
  - *Weakness* – Demonstrated on testing by a partial cogwheel "giving way" of many muscle groups that cannot be explained on a localized neurological basis.
  - *Sensory* – Include diminished sensation to light touch, pinprick or other neurological tests fitting a "stocking" rather than a dermatomal pattern.

PE: Waddell Signs (contd)

- ***Overreaction*** (pain behaviors) - May take the form of disproportional verbalization, facial expression, muscle tension and tremor, collapsing, or sweating; judgments should be made with caution, minimizing the examiner's own emotional reaction.

COT Initiation

- Prior to initiation, discuss/document:
  - Goals of therapy
    - Moderate pain reduction - 30-50%
    - Objective functional goals
  - Risks and Benefits
    - Dependency is not a risk, it is a virtual absolute
    - Side effects, drug / EtOH interactions
    - Impairment – work, driving
    - Risk stratification, potential for aberrancy
  - Start Low and Go Slow

Drug Initiation

- Start low-potency, short-acting, PRN
  - ER/LA formulations are inappropriate for COT initiation and most should only be considered for opioid tolerant patients.
- Follow-up frequently with patients
  - 1-2 weeks until stable
    - Fewer pills dispensed, fewer to discard if ineffective or side effects preclude use
    - Monitor compliance and effectiveness

Controlled Substance Agreement

- Informed consent + treatment “contract”
  - Risks/benefits/alternatives to COT
  - Outlines prescriber expectations of patient
    - Single pharmacy / single prescriber
    - Patient accountability to safeguard medication
      - No refills for lost/stolen/destroyed medication
      - Keep out of reach of children, elderly, etc
    - No selling or sharing of medication with others
    - Take ONLY as prescribed, no self-titration
      - No early refills or nights, weekends, holidays
    - Consent to toxicology testing and pill-counts
    - Refills are contingent upon keeping scheduled appointments
    - Refill requests and appointment rescheduling: 3 days notice
    - 24 hour wait time for Rx refills
    - Privacy waved in the event of law enforcement involvement
    - Therapy may be discontinued at any time for misuse, lack of efficacy, risk > benefit, noncompliance with terms.

Opioid Management / Monitoring

- The 4 A's
  - Analgesia
    - Numerical or Subjective
  - Activity level
    - Work duties, exercise, domestic chores, leisure
  - Adverse reactions / effects
    - Side effects, affect / personality, family dynamics
  - Aberrant behaviors
    - Misuse/Abuse/Diversion

Other Monitoring Tools

- Current Opioid Misuse Measure (COMM)
  - 17 questions of issues over last 30 days
  - 0 = Never, 4 = Very Often
    - Thinking, memory, task completion
    - Obsessive thoughts, anger, anxiety, self-harm
    - Misuse, diversion, drug seeking, ER visits
- NPV for opioid misuse = 0.95%
  - www.painEDU.org

Drug Testing

- Saliva, Urine and Blood
  - Urine Point of Care cups, GCMS confirmation
    - POC has substantial false (-) and (+)
    - GCMS is very accurate
  - Saliva testing
    - Takes about 5 minutes to saturate swab
    - No POC, may be more convenient or low-risk patients
  - For POC(+) results, consider waiting for confirmation before making major management decisions
  - Know your metabolites for proper interpretation
    - Codeine to Morphine, OC to OM, HC to HM
    - Parent drug vs metabolite presence, detection window

Prescription Monitoring Program

- SCRIPTS
  - South Carolina Reporting & Identification Prescription Tracking System
  - Created in 2006 (H.3803), started 2008
  - Exclusions
    - Inpatient pharmacies
    - 48 hour supply dispensed from hospital ER
    - Dispensings to long-term care facility residents
    - Five day supply (or 31 days of phenobarb) by a vet
    - FEDERAL DISPENSERS
      - **VA / military base pharmacies**
      - **Methadone clinics**

SCRIPTS Sample Report

Health Information
Designs Inc.

South Carolina DHEC
Query Report

Date: 03/24/15
Page#: 1

Patient Rx History Report

BROWN BETTY

Search Criteria: Last Name [redacted] and First Name [redacted] and D.O.B. = '[redacted]' and Request Period = '03/24/14' to '03/24/15' - 2 out of 2 Recipient(s) Selected.

Fill Date	Product, Str, Form	Qty	Days	Pt ID	Prescriber	Written	RX#	N/R*	Pharm
02/24/2015	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218	[redacted]	01/16/2015	0403439	N	BR5386669
02/22/2015	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		11/24/2014	0386331	R	BR5386669
01/26/2015	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		01/16/2015	0397976	N	BR5386669
01/23/2015	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		11/24/2014	0386331	R	BR5386669
01/14/2015	HYDROCODON-ACETAMINOPHEN 5-325	40.000	4	00067218		01/14/2015	0396030	N	BR5386669
12/29/2014	HYDROCODON-ACETAMINOPHEN 5-325	40.000	5	00067218		12/29/2014	0392902	N	BR5386669
12/27/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		12/18/2014	0392563	N	BR5386669
12/24/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		11/24/2014	0386331	R	BR5386669
11/29/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		10/29/2014	0386825	N	BR5386669
11/25/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		11/24/2014	0386331	N	BR5386669
10/30/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		10/29/2014	0381753	N	BR5386669
10/27/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		09/26/2014	0369434	R	BR5386669
10/21/2014	TRAMADOL HCL 50 MG TABLET	120.000	30	00067218		10/21/2014	0379939	N	BR5386669
09/26/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		08/20/2014	0369439	R	BR5386669
09/26/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		08/26/2014	0369434	R	BR5386669
08/27/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		08/20/2014	0369439	N	BR5386669
08/27/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		08/26/2014	0369434	N	BR5386669
07/27/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		06/27/2014	0359165	R	BR5386669
07/27/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		03/25/2014	0343118	R	BR5386669
06/27/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		06/27/2014	0359165	N	BR5386669
06/26/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		03/25/2014	0343118	R	BR5386669
05/28/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		04/30/2014	0354177	N	BR5386669
05/27/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		03/25/2014	0343118	R	BR5386669
04/28/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		03/18/2014	0343119	R	BR5386669
04/28/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		03/25/2014	0343118	R	BR5386669
03/29/2014	HYDROCODON-ACETAMINOPH 7.5-325	60.000	30	00067218		03/18/2014	0343119	N	BR5386669
03/29/2014	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00067218		03/25/2014	0343118	N	BR5386669

*N/R N=New R=Refill

Prescribers for prescriptions listed

[redacted] [redacted] ER INTERNAL MEDICINE ASSOCIATES, 12 BARNETTE DRIVE, SUMTER SC 29150
ED TO OFFICIAL STATE DUTIES ONLY, DEPARTMENT OF CORRECTIONS, 4444 BROAD RIVER ROAD, COLUMBIA S
920 SECOND LOOP ROAD, FLORENCE SC 29501
CAROLINA COMPREHENSIVE HEALTH NETWORK, 4920 ALBEMARLE ROAD, CHARLOTTE NC 28205
; 595 W. WESMARK BLVD, SUMTER SC 29150
JR.; FIRSTCHOICE HEALTHCARE, PC, 1920 2ND LOOP ROAD, FLORENCE SC 29501

Pharmacies that dispensed prescriptions listed

BR5386669 RITE AID PHARMACY #11577; 375 PINEWOOD ROAD, SUMTER SC 29150,

Report Disclaimers:

The Report is based on the search criteria and the data provided by the dispensing entities. For more information about any prescription, please contact the dispenser or the prescriber.
This Report contains confidential information, including patient identifiers, and is not a public record. The information should not be provided to any other persons or entity.

Prescription Monitoring Program

- 2014
  - S.840 – signed by Gov Haley 6/6/14
    - Daily data submission from dispensers
    - Delegate authorization
      - Individual supervised by authorized prescriber or pharm
    - Criminal penalty for delegate use violations
      - Felony – fine < $10k, or prison < 10 years
    - Disciplinary board action for practitioner violations
    - 2 hr prescribing CME per biannual license period
    - Mandatory use was REMOVED from the bill

PDAP Council

- Gov Haley executive order 3/14/2014
  - In response to SCOIG 5/2013 outlining the growing Rx drug abuse problem in SC and the lack of statewide strategy
- 10 members
  - SLED, DHEC, LLR, DHHS, DAODAS, Solicitor's Office
  - Boards of Medical Examiners, Nursing, Pharmacy, Dentistry
  - Physician advisors in pain management, emergency medicine, family practice

PDAP Council – Joint PM Guide

- MANDATORY PMP UTILIZATION per Joint Revised Pain Management Guidelines
- MED 80 > 3 months = RED FLAG
  - Re-establish informed consent, review functional status including daily activities, analgesia, aberrant behavior and adverse effects as it relates to progress toward treatment objectives established at the onset of opioid therapy; consult SCRIPTS to verify compliance; re-establish office visit intervals' review frequency of drug screens; and review and execute a new treatment agreement. Relevant information from SCRIPTS should become part of the patient's medial record.
  - Avoid dose escalation without attention to risks and alternatives
  - Complete eradication of pain is not an attainable goal
    - "**Reasonable level of discomfort" is the best clinical outcome a patient may receive**

PDAP Council – Joint PM Guide

- Pain management in the ER
  - Utilize SCRIPTS
  - Consult with patient's opioid prescriber
  - Rx for chronic pain is only rarely indicated in the ER and should limited to supply sufficient for patient to see primary provider
  - No replacement Rx for lost/stolen/destroyed
  - ER/LA opioid should not be routinely Rx
  - Acute pain Rx should rarely exceed 5 days
    - Use SCRIPTS
    - Screen for substance abuse prior to Rx when appropriate

Opioids -Titrate, Rotate, Convert?

- Opioid management frequently requires dose or drug changes to balance efficacy, tolerability, compliance and risk
  - Short vs Long-Acting opioids
  - Abuse Deterrent Formulations (cost / benefit)
  - Breakthrough pain
  - QHS dosing (sleep apnea)
  - Limited formulary options for CMS, Tricare
  - Poor evidence-based management data

Drug Diversion – Warning Signs

- Suspicious History
  - Patient referred already taking controlled substances, especially opioid/relaxer/sed
    - Vicosomaxanax / Percosomaxanax
  - Soft diagnosis based on symptoms
    - COT often contraindicated in FMS, IBS, chronic daily headache, interstitial cystitis, chronic pelvic pain
  - Multiple doctors / prescribers
  - The Out-of-Towner
  - Limited / unobtainable old records from referring doc
  - Old, tattered, suspicious records (ash tray smell)
  - Request for specific drug

Drug Diversion – Warning Signs

- Suspicious Physical Exam
  - Normal exam, exaggerated exam, Waddell
  - Symptoms out of proportion to objective findings
    - Severe weakness with normal reflexes
    - Severe numbness with normal Babinski
  - Poor Dentition (meth mouth)
  - Arm scars (skin popping / track marks)
  - Red eyes / nares
  - Smoke smell, “Legalize It” T-shirt, etc.

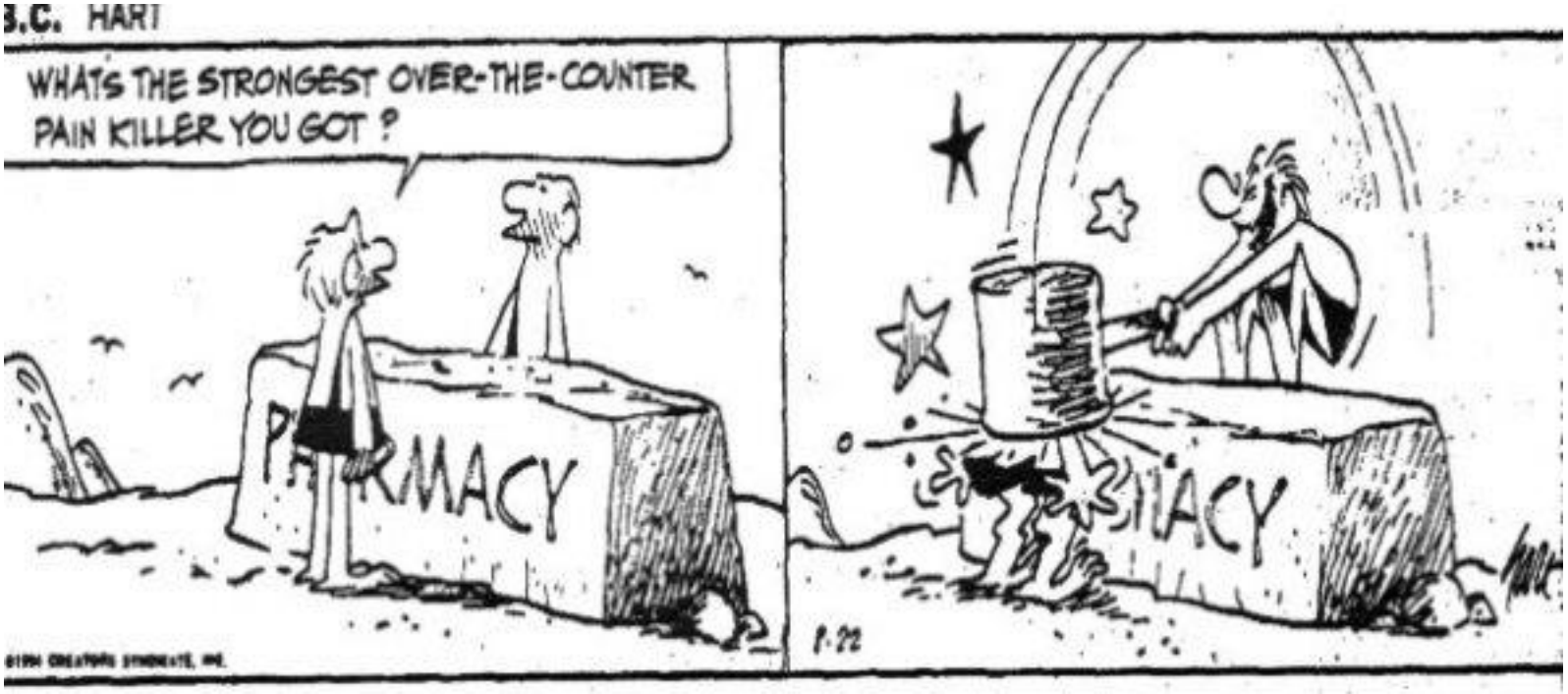
COT Discontinuation

- Reasons
  - Lack of objective improvement in physical, functional, and psychosocial activities
  - Compliance issues
  - Intolerance
- Discontinuation of COT is not patient abandonment but should NOT mark the end of treatment through other modalities or referral to specialists (pain, addiction)
- Structured wean is often safe and effective
  - Reduce dose 30-50% every 3-5 days, >14 days rarely necessary
  - Increased pain is most common complaint
  - Opioid W/D is NOT associated with DT
  - Rapid discontinuation is NOT life threatening
  - Consider inpatient detox and outpatient recovery program

Further Information

- ER/LA REMS program (3 hours CME)
  - In depth instruction on long-acting opioid prescribing / management
- Bibliography
  - Lots of links to cited documents and online resources for further reading

Questions?


B.C. HART
WHAT'S THE STRONGEST OVER-THE-COUNTER PAIN KILLER YOU GOT ?
PHARMACY
PHARMACY