Prescription Opioids:

Responding to the Crisis through Compliance and Other Measures

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KAISER PERMANENTE®

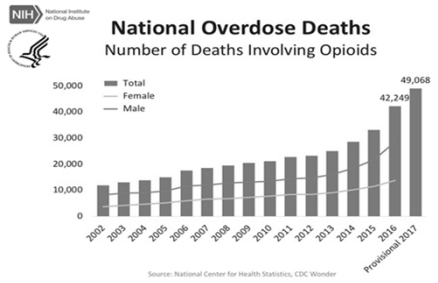
Agenda

- A Brief Overview of the Current Crisis
- A Provider's Perspective
- The Role of Compliance
- Investigation Case Study

"…about half of all prescriptions written fall outside of the 2016 CDC guidelines."

- Dr. Darshak Sanghavi, CMO, OptumLabs

Reference Link: https://www.washingtonpost.com/brand-studio/optum/working-to-end-the-epidemic/



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A Provider's Perspective

- Assessing a Patient's Risk of Use or Misuse of Opioids
  - Initial Evaluation and Assessment
    - Pain as a Vital Sign?
  - Opioid Treatment Agreements
  - Informed Consent
  - Regular Urine Drug Screening – Frequency depends on risk factors
  - Regular Assessments in Relation to Treatment Goals
  - Thorough Documentation in Electronic Health Record
- The Importance of Trust and Difficulties Establishing a Trusting Patient/Provider Relationship

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Integrated Pain Services

- Patients Benefit from Multi-Disciplinary Care
- Co-Morbidity is Common in Pain Patients
  - Collaboration Among Providers is Key
  - Coordinating Care between Family Medicine, Behavioral Health, Clinical Pharmacy, Pain Specialists, etc.
- Breaking Down Silos in Care Delivery
- Naloxone – A Life Saving Prescription

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Screening Tools for High Risk Patients

- What are They and How are They Used?
  - COMM – Current Opioid Misuse Measure
  - PHQ9/GAD7 – Depression/Anxiety
  - DAST -10 – Drug Abuse Screening Tool
  - PCS – Pain Catastrophizing Scale
  - ORT – Opioid Risk Tool
  - BPI – Brief Pain Inventory

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MME's and PDMP's

- **MME – Morphine Milligram Equivalents**
  - CDC.gov has a Calculating Tool to Assess MME Depending on the Type(s) of Opioids Prescribed
  - Any Dose >20 MME per day substantially increases risk for adverse events
  - 90 MME is an additional threshold to look for
- **PDMP – Prescription Drug Monitoring Program**
  - State Dependent and Limited, but Very Useful
  - In general, should be used along side other tools such as UDS, regular evaluations, physical examinations, specialist input
  - Limited to Provider and Pharmacy Use – Compliance Must Help Train Providers to Look for and Report Concerns

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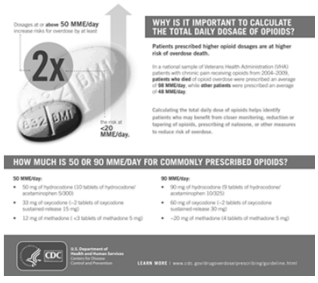

WHY IS IT IMPORTANT TO CALCULATE THE TOTAL DAILY DOSAGE OF OPIOIDS?

Patients prescribed higher opioid dosages are at higher risk of overdose death.

In a national sample of Veterans Health Administration (VHA) patients with chronic pain receiving opioids from 2004–2009, **patients who died** of opioid overdose were prescribed an average of **98 MME/day**, while **other patients** were prescribed an average of **48 MME/day**.

Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.

HOW MUCH IS 50 OR 90 MME/DAY FOR COMMONLY PRESCRIBED OPIOIDS?

50 MME/day:

- 10 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 30 mg of oxycodone (~2 tablets of oxycodone sustained-release 15 mg)
- 12 mg of methadone (~3 tablets of methadone 5 mg)

90 MME/day:

- 90 mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325)
- 60 mg of oxycodone (~2 tablets of oxycodone sustained-release 30 mg)
- ~20 mg of methadone (4 tablets of methadone 5 mg)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

HOW SHOULD THE TOTAL DAILY DOSE OF OPIOIDS BE CALCULATED?

1. **DETERMINE** the total daily amount of each opioid the patient takes.
2. **CONVERT** each to MMEs—multiply the dose for each opioid by the conversion factor. (see table)
3. **ADD** them together.

Calculating morphine milligram equivalents (MME)

OPIOID (taken in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
▲ 61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

CAUTION:

- Do not use the calculated dose in MMEs to determine dosage for converting one opioid to another—the new opioid should be lower to avoid unintentional overdose caused by incomplete cross-tolerance and individual differences in opioid pharmacokinetics. Consult the medication label.

USE EXTRA CAUTION:

- **Methadone:** the conversion factor increases at higher doses
- **Fentanyl:** dosed in mcg/hr instead of mg/day, and absorption is affected by heat and other factors

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Substance Use Disorder (SUD)

- SUD occurs when the recurrent use of alcohol and/or drugs causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school or home.
- According to the DSM-5, a diagnosis of SUD is based on evidence of impaired control, risky use, and pharmacological criteria.
- Principle Risk Factors for SUD
  - < 45 years old
  - Previous SUD and Family History
  - Non-Specific Pain, Back Pain, Headaches
  - Depression, PTSD, and/or Anxiety
  - High Dose Chronic Opioids - >90 MME
  - TROUP Study

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Symptoms of a SUD

- Strong desire for opioids
- Inability to control or reduce use
- Continued use despite interference with major obligations or social functioning
- Use of larger amounts over time/Development of tolerance
- Spending a great deal of time to obtain and use opioids
- Withdrawal symptoms that occur after stopping or reducing use ie (negative mood, nausea or vomiting, muscle aches, diarrhea, fever and insomnia

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Drug Seeking Behavior (DSB)

- **Potential Signs of DSB**
  - Unusual behavior in the waiting room or exam room
  - Unusual appearance - extremes of either slovenliness or being over-dressed
    - Obvious signs of use – Track marks, punctures, etc.
  - May show unusual knowledge of controlled substances and/or gives medical history with textbook symptoms **OR** gives evasive or vague answers to questions regarding medical history
  - Reluctant or unwilling to provide reference information
    - Usually has no regular doctor and often no health insurance;
  - Assertive and/or Combative Behavior
    - Will often request a specific controlled drug and is reluctant to try a different drug
  - Little or no interest in diagnosis - fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation
  - May exaggerate medical problems and/or simulate symptoms
  - May exhibit mood disturbances, suicidal thoughts, lack of impulse control, thought disorders, and/or sexual dysfunction

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DSB Continued…

- ***Modus Operandi Often Used by the Drug-Seeking Patient Include:***
  - Must be seen right away and wants an appointment toward end of office hours
  - Calls or comes in after regular hours
  - States he/she's traveling through town, visiting friends or relatives (not a permanent resident)
  - Contends to be a patient of a practitioner who is currently unavailable or will not give the name of a primary or reference physician
  - States that a prescription has been lost or stolen and needs replacing
  - Deceives the practitioner, such as by requesting refills more often than originally prescribed
  - Pressures the practitioner by eliciting sympathy or guilt or by direct threats
  - Utilizes a child or an elderly person when seeking methylphenidate or pain medication
  - High utilization of emergency departments – back room injections

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The Role of Compliance

- **Why is Compliance Involved in Trying to Deal with the Opioid Crisis?**
  - 1) **Ethics and Safety comes FIRST**
  - 2) Protecting the Organization and its Employees from Regulatory Liability and Litigation
  - 3) Protecting the Organization and its Employees from Reputational Liability

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Role of Compliance continued…

- Leveraging Compliance's Unique Role and Perspective (assuming you have a healthy, robust program…)
  - Executive Compliance Committees
  - Establish a Speak Up Culture
  - Effective, Responsive Reporting Tools
  - Stakeholder Engagement and Tactfully Wielding Your Influence
- Acknowledging the complexity and uniqueness of the opioid crisis

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Developing a Multi-Disciplinary Approach

To Begin: Enlist your Stakeholders

- Risk, Quality, and Patient Safety
- Legal
- Care Delivery and Providers
- Human Resources
- Pharmacy Benefit Manager(s) (Claims Data)
- Pharmacy Operations
- Network and Provider Contracting
- Membership Administration
- Health Information/Medical Records
- Data Analytics

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Supporting Care Delivery

- Providing trusted reporting paths for providers – Compliance Hotline, Direct Outreach
- **Aligning the right incentives**
- Analytics and Data – Acceptable Usage under Regulatory Framework – HIPAA and Part 2
- Addressing overdoses with Health Information Exchange data
- How do we identify patients at a high risk for adverse outcomes?
- Provider safety – dealing with difficult patient population

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Understanding HIPAA – Providers Need Guidance

- Understand Acceptable Use and Disclosure Rules
- Treatment, Payment, and Health Care Operations
- Empowering the Providers through Guidance and Reference Materials

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Data from Health Information Exchange

- Identify Overdoses via Emergency Dept. Admissions
- Data Analytics can help extract the appropriate information
- Provides opportunity for intervention
- Target Population for Naloxone

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42 CFR Part 2

- Regulations Govern Privacy of Substance Abuse Treatment Records
- Seek Authorization to Share Information Aggressively for Treatment Purposes, but Be Careful Not to Coerce
- Confidentiality concerns are legitimate, but in today's environment should be treated similarly to other medical information – HIPAA
- May impede effectiveness of treatment and care delivery due to creation of silos and lack of ability to share information
- Creates risk for medication interactions – Methadone, Suboxone, etc.

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Investigation Case Study

- Identified a prescription for Subsys® that raised suspicion and prompted a deeper look
- Additional data mining of Pharmacy Benefit Manager showed a population of members receiving unusually large amounts of opioids, including Subsys® and Actiq®
- Patients were receiving large quantities Oxycontin®, Oxycodone, Morphine, Clonazepam, Adderall®, etc.
- Prescriptions were being written by a non-KP doctor and nurse practitioners within a single, outside practice
- Providers specialize in Pain Management

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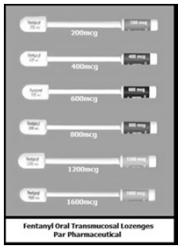
Actiq® is fentanyl citrate in lozenge form – for treating breakthrough cancer pain only
Subsys® is fentanyl sublingual spray – for treating breakthrough cancer pain only



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Investigation Evidence and Resources

- Propublica Outlier - https://projects.propublica.org/checkup/

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Additional Evidence and Resources

- CMS Open Payments Identified -
  - Approximately $100,000 over past 4 years from Pharmaceutical Companies

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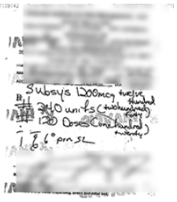
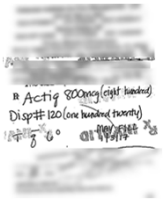
Pharmacy Benefit Manager Data

- Request Hardcopies of Suspect Prescriptions





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Investigating Medical Records and Documentation

- Requested Outside Records from the Provider
  - Ensure Provider Contracts Stipulate Production of Records for Quality, Compliance, Safety Review
- 19 Sets of Records were requested
- 8 Incomplete Sets of Records were provided after multiple follow-ups
  - No Documentation of Urine Drug Screens
  - 3 Patients were receiving Subsys or Actiq without a cancer diagnosis
  - Documentation was not detailed and appeared to be copied and pasted from one visit to the next
- PDMP showed that patients were receiving controlled substances from other providers

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Patient Name	Age	Diagnosis	Flags	Avg. Daily MED 2017
Patient 1	31	N/A	Oxycontin, Oxycodone, Alprazolam, Clonazepam	213
Patient 2	51	N/A	Oxycontin, Oxycodone, metaxolone, cyclobenzaprine	450
Patient 3	55	N/A	Morphine	576
Patient 4	55	N/A	Oxycontin and Oxycodone	487
Patient 5	51	N/A	Morphine, Alprazolam and Clonazepam	405
Patient 6	48	N/A	Subsys, Oxycontin, Clonazepam	N/A
Patient 7	40	Chronic Pain	Oycontin and Oxycodone	385
Patient 8	40	N/A	Actiq, Add, and Clonazepam	837
Patient 9	38	back pain,	Fent patch and Morphine	310
Patient 10	38	N/A	Actiq, Fent patch	705
Patient 11	42	Shoulder Pain, Migraine	Oxycontin, Oxycodone, clonazepam	353
Patient 12	55	Sleep Apnea	Morphine	780
Patient 13	43	Migraine/HA	Morphine and Clonazepam	453
Patient 14	50	No Cancer	Subsys, Oxycontin, Clon	1512
Patient 15	61	N/A	Oxycodone and Oxycontin	767
Patient 16	58	N/A	Morphine, Fiorinal	402
Patient 17	59	N/A	Methadone, oxycodone, yrica	315
Patient 18	37	N/A	Oxycodone and Oxycontin	225
Patient 19	56	N/A	Morphine and Oxucodone	293

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Date	Q	Product Name	Sig	MED	G
7/14/2017	90	OXYCONTIN 80 MG T12A	1T Q8H	10800	C
7/14/2017	120	SUBSYS 1200 (600 X 2) MCG	1200mcg Q6h prn	25920	F
7/11/2017	120	CLONAZEPAM 1 MG TABS			C
6/13/2017	120	CLONAZEPAM 1 MG TABS			C
6/12/2017	90	OXYCONTIN 80 MG T12A	1T Q8H	10800	C
6/12/2017	240	SUBSYS 1200 (600 X 2) MCG	1200mcg Q6h prn	51840	F
5/17/2017	90	OXYCODONE HCL ER 80 MG	1T Q8H	10800	C
5/9/2017	240	SUBSYS 600 MCG LIQD		25920	F
4/12/2017	120	CLONAZEPAM 1 MG TABS			C
4/12/2017	240	SUBSYS 600 MCG LIQD		25920	F
4/11/2017	90	OXYCODONE HCL ER 80 MG	1T Q8H	10800	C
3/14/2017	90	OXYCODONE HCL ER 80 MG	1T Q8H	10800	C
3/14/2017	240	SUBSYS 600 MCG LIQD		25920	F
3/10/2017	120	CLONAZEPAM 1 MG TABS			C
2/16/2017	90	OXYCODONE HCL ER 80 MG	1T Q8H	10800	C
2/13/2017	120	CLONAZEPAM 1 MG TABS			C
2/13/2017	240	SUBSYS 1200 (600 X 2) MCG	1200mcg Q6h prn	51840	F

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Investigation After Data Collection and Managing the Fallout

- Engage Medical Group Leadership and Legal Early and Often
- Peer Review – Ensure expertise in Chronic Pain on Review Panel
  - Pain Providers often look like outliers when they may not be
- Outside Medical Expert Review
- Plan of Action after Peer Review is Completed
  - Transitioning patient care to other providers is very difficult and sensitive
- Contract Termination
- Reporting to Key Stakeholders
  - NBI MEDIC, PBM, PLATO, Pharmacy Boards, Board of Medicine, Law Enforcement

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THANK YOU!

- Questions???

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