The Scourge of the Opioid Epidemic: Risks to Policyholders, Patients & Public

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I. THE OPIOID CRISIS
**The Data**

- Between 1991-2011 the number of opioid prescriptions tripled
- In 2012, 259 million prescriptions for opioid pain meds were written – enough for every adult in the US to have a bottle
- In 12 states more opiates are prescribed than people residing there
The Data

• In 2013, an estimated 1.9M persons abused or were dependent on prescription opioid pain medication

• CDC reports a 200% increase in opiate overdose deaths from 2000 – 2014

• In past decade, as death rates for heart disease and cancer have declined, death rate associated with opioid pain meds has increased substantially

Source: CDC and other references available
The Practices

• Prescribers not sufficiently educated in current pain management treatment strategies

• Prescribers report concern about opioid misuse, and find treating patients with chronic pain to be stressful
Common Misperceptions

– That opioid therapy is appropriate for chronic non-cancer pain
– Dose related toxicities can be avoided by slow upward titration
– Tramadol is not an opioid
Prescribing Habits

• Length of initial prescription and dosage are associated with increased risk of extended use

• “Clinical inertia” – once patients are started on a medication, physicians less likely to question the need for it and will continue to prescribe
Societal Impact

- Pervasive – touches every segment of society
- Loss of jobs, homes, education, families, lives
Societal Impact

• Surgeon General reports addiction costs $400B/year
• ↑ drug-related arrests
• ↑ numbers of children in protective custody due to parental drug abuse
• Access to treatment (medical & counselling) is limited, especially in rural areas
Trends to Watch

• Increased use of Fentanyl and carfentanil (elephant tranquilizer – 100x potency of Fentanyl)
• Increase in opioid-related ER visits and inpatient stays
• Hospitals developing dedicated units for substance abuse detox
• ↑ need for OP housing and community services to assist addiction treatment
II. STRATEGIES
Government - Agencies

(July 2012) FDA’s Opioid Action Plan

FDA Issued Extended-Release and Long-Acting Opioid Analgesic REMS

All ER/LA opioid companies to provide medications guides, CMEs for prescribers and Patient Counseling Documents

(Feb. 2016) approved Narcan nasal spray
States

- Prescription Drug Monitoring Programs (PDMPs) – effective tool to collect prescribing & dispensing data on Controlled Substances and drugs of abuse. (www.pdmpassist.org)

- Restrictive Opioid Rx’ing Laws – limits on quantity to be prescribed / dispensed - particularly on initial script; shorten time to fill scripts; require patient counseling
• Intended for PCP & Internists treating adult patients w/chronic pain in outpatient setting

• Not intended to address prescribing:
  – For patients in active cancer treatment, paliative care of end-of-life care
  – In children or adolescents
  – ER departments or dentists
  – Acute care settings
  – Sickle cell patients
Guidelines address:

1. When to initiate or continue opioids for chronic pain;
2. Opioid selection, dosage, duration, follow up and discontinuation; and
3. Assessing risk and addressing harms of opioid use
Guidelines intended to:

1. Improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain;

2. Improve the safety and effectiveness of pain treatment; and

3. Reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose and death.
12 “Recommendations” grouped into 3 areas:

1. Determining when to initiate or continue opioids for chronic pain;
2. Opioid selection, dosage, duration, follow up and discontinuation; and
3. Assessing risks and addressing harms of opioid use.
Themes of the Recommendations

• Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain
• If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate
• Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety
• When initiating opioid therapy for chronic pain, prescribe immediate-release opioids instead of extended-release/long-acting opioids
Themes of the Recommendations

• Start opioids at the lowest effective dose; take care when increasing dosage to >50MME/day and avoid increasing dosage to >90MME/day
• Evaluate patients after 1 to 4 weeks of starting opioid therapy or before increasing the dose
• Re-evaluate risk/benefit of opioid therapy every 3 months or more frequently

●Educate ● Inform ● Assess●
Push Back on Guidelines

• Will make it harder for patients with chronic pain to get treatment
• Pharmaceutical companies believe guidelines are inherently biased
• “Too little too late”

Roadmap for a malpractice suit
Medical Profession

Misconceptions with TJC’s Pain Standards: do they push doctors to prescribe opioids?

Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (July 2013)
Task Force to Reduce Opioid Abuse

(June 2016) adopted new policies:

• Encourage co-prescribing of Naloxone to patients at risk
• Promote access to non-opioid/non-pharma tx
• Delink reimbursement and patient pain scores
(July 2012) Citizens Petition to FDA urged labeling changes to ER opioids
- Establish maximum daily dose and maximum duration of use
- Remove “moderate pain” as an indication for opioid use in non-cancer pain

“Long-term safety & effectiveness of managing CNCP with opioids has not been established”
Opioid Safety Initiative (launched 2013)

- Education Strategies
- Expanded options for pain management therapy
- Risk mitigation – track 4 opioid safety indicators: metrics, online dashboard, predictive modeling of risk, audit opioid prescribing
- Addiction treatments (inpatient, outpatient, Suboxone, residential)
VA System: Results (2013 – 2016)

• ↓ 25% number of veterans dispensed an opioid each quarter
• ↓ 47% patients receiving opioids & benzodiazepines
• ↓ 36% patients receiving daily opioid > 100 morphine-mg equivalents

Source: Gellad WF, “Addressing the Opioid Epidemic in the US: Lessons Learned From the Dept. of Vet Affairs, JAMA Int Med, pub. online March 13, 2017 (E1-E2)
Insurance Companies


Anthem Inc. & Cigna Corp. have agreed to end pre-authorization for medication-assisted treatment (MAT) for opioid abuse.

MAT (buprenorphine & naloxone) is a safe & affordable therapy for recovering from opioid abuse.

MAT doctors must be trained and approved to administer MAT therapy.
Court System

- Drug Courts, Veteran Treatment Courts
- Diversion & Sentencing Options
- Impact on Domestic Relations, Family Court dockets
- (Aug. 2016) first ever Regional Judicial Opioid Summit (9 Midwest states)
- Provide substance abuse tx in prisons
- Expanded crime labs; staffing & technology

• Regulates the manufacture, importation, possession, use and distribution of controlled substances

• Wholesale distributors have duty to report “suspicious orders” (unusual size or frequency) to authorities (21 CFR § 1301.74)
Congress

21st Century Cures Act
(Pub.L. 114-255; signed Dec. 13, 2016)

- Provides $1B in grants to states for opioid prevention and treatment programs

Comprehensive Addiction and Recovery Act of 2016
(Pub.L. 114-198; signed July 22, 2016)

- First federal addiction legislation in 40 years; addresses prevention, treatment, recovery, law enforcement, criminal justice reform and overdose reversal
March 28, 2017: Senator Claire McCaskill (D-MO) announced probe of business practices of Purdue, J&J, Insys, Mylan and Depomed

- Requesting information on sales, marketing and education strategies used to promote opioid use, including marketing plans, quotas for sales reps
III. LITIGATION
Claims Against Providers

Themes:
- Patients are addicts; doctors must be in control
- Doctors have a duty
- “This is a doctor problem”

Theories:
- Inadequate history – medical, pharma, family, social, psych
- Inadequate physical exams
- Rx not needed – too much, too potent, too long
Claims Against Providers

Claims:

- Failure to refer to pain mgmt. specialist, or to ER

Evidence:

- Script & pill counts, MME/day totals, PDMP access records, contracts & consent forms, physician records

Verdicts:

- $17.6M verdict against PCP & SLU Clinic (July 2016)
Claims Against Pharmacies

Failure to:
• Detect diversion drug misuse, properly label & fill Rx, detect contra-indicated meds

Duty to:
• Counsel/warn patient, warn prescriber ("learned intermediary"), monitor PDMP
• Use due care in filling prescriptions
State and Municipal Litigation

**Plaintiffs:** City of Chicago, City of Everett, Wash., two W. Va. Counties, (April 2017) others

**Defendants:** Drug wholesalers, manufacturers, pharmacies

(Feb. 2017) Motley Rice LLC firm announced new Public Client Practice, representing cities & counties fighting health care & consumer fraud
State and Municipal Litigation

Claims
(Chicago) Overselling opioids to treat chronic pain; overstating benefits; (Everett) Purdue failed to report diversion & illegal sales of OxyContin; (W. Va.) false advertising, false claims, insurance fraud, conspiracy to defraud, unjust enrichment, consumer fraud

Damages
False claims for opioid scripts submitted to City’s health plan; recovery costs of dealing with epidemic
Enforcement actions for breach of CSA

• (Jan. 2017) McKesson Corp to pay a record $150M, suspend sales from distribution centers in 4 states, and hire an independent monitor to assess compliance with 5 year CIA to settle allegations of failure to report “suspicious” drug orders, including opioids 2008-2013.

• (Jan. 2017) Costco Wholesale pays $11.75M to settle claims that pharmacies lacked proper controls & filled invalid scripts for CS.

• (April 2017) Mallinckrodt, large manufacturer of oxycodone, settles DEA investigation of its opioid distribution practices in Florida for $35M.

• Other recent CSA settlements with Cardinal Health, AmeriSource Bergen, and Miami-Luken
Prosecutions

Health Care Fraud

(Feb. 2017) Insys Therapeutics, Inc. sales mgr. indicted for approving scheme of kickbacks to doctors to increase prescriptions of Subsys, a spray version of fentanyl

(Jan. 2017) Four other Insys execs, including former CEO, plead not guilty

(Jan. 2017) New Hampshire AG filed action against Insys for violating State Consumer Protection Act
Health Care Fraud

(Feb. 2017) Alabama pain mgmt. doctor plead guilty to illegal prescribing & HC fraud; sentenced to 15 years

- Wrote >400 opioid scripts/day
- Highest prescriber of Schedule II controlled substances in nation
- Ordered unnecessary UDS = 80% of his claims to Medicare ($9.5M)
Health Care Fraud

(May 2007) Purdue Pharm and executives pled guilty to misleading regulators, doctors and patients about OxyContin’s addiction risk.

Subsequent multi-state settlement of civil suits and Consent Judgment in which Purdue agreed to protect against diversion of OxyContin.
Malpractice v. Murder

(Oct. 2015) – California physician convicted of second-degree murder in OD deaths of three patients
(The People v. Hsiu-Ying Tseng, Superior Ct. L.A. Cty)

- (Feb. 2016) sentenced 30 years to life
- Prosecutors said first time physician convicted of murder in US for recklessly prescribing drugs
Source: Superior Court of the State of California, Cty of Los Angeles (CNBC)
IV. RISK MANAGEMENT & MITIGATION
CDC Checklist for Prescribing Opiates for Chronic Pain

When CONSIDERING long-term opioid therapy

If RENEWING without patient visit

When REASSESSING at return visit

The Standard of Care for Prescribing Opiates
Clinical Clues: What to Watch For

- Refusing to consent to obtain prior records or communicate with previous physicians
- Reluctance to undergo comprehensive history, physical exam, drug screening or diagnostic testing
- Requesting specific drugs by name/dosage
- Professing multiple allergies to recommendation medications
Clinical Clues: What to Watch For

• Resisting non-pharmaceutical treatment options

• Other suspicious behavior
  – Repeatedly losing a prescription
  – Requesting a dose escalation
  – Calling/visiting the physician’s associates
  – Noncompliance with prescription instructions
  – Unreasonable demands for pain medications

Patients at Risk for Opioid-Induced Respiratory Depression

• Patients with sleep apnea/snoring
• Patients who are morbidly obese
• Patients who are very young
• Patients who are very old
• Patients who are very ill
• Patients who are opioid naïve & smokers
• Patients concurrently taking CNS & respiratory depressants
“Best” Practices

Be Prepared to Treat

• Training and education of prescribers (M.D.s, D.O.s, APRNs, PAs) and staff
• Know the CDC guidelines
• Participate in and follow REMS Medication Guide & Prescription Education for ER/LA opioids
• Follow state licensing board rules
• Adhere to state & federal controlled substances laws & rules
“Best” Practices

• Clinical care:
  – review prior records
  – check PDMP database
  – thorough initial eval & workup: Hx; PE; diagnostic tests & utilize screening tools (NIDA test models, UDS)
  – maintain proper charts & document encounters to justify/explain prescribing decisions
“Best” Practices

– proactive medication mgmt: watch for daily drug ranges, limits on MME, avoid dangerous drug combinations, co-preserve Naloxone;
– schedule regular reassessments at appropriate intervals (1-4 weeks)
– know when & how to discontinue opioid therapy
“Best” Practices

Consent & Contracts
- obtain informed consent
- utilize opioid treatment contracts
- provide ongoing patient education and resources

Consult
- communicate with other healthcare providers & pharmacies then confer w/ colleagues
- refer patients to pain mgmt. specialists

Encourage safe practices regarding sharing, storage & disposal of opioids

EMR: program alerts and clinical decision tools to guide prescribing
Offer Complementary Pain Relief

Accupuncture – back pain, knee osteoarthritis
Massage – neck pain, back pain
Relaxation techniques – HA, migraines, fibromyalgia
Spinal/Osteopathic manipulation – back pain
Yoga – back pain
Tai chi – osteoarthritis of knee, fibromyalgia

Source: Abbasi J, JAMA Dec. 13, 2016; 316(22): 2343-2344
Offer Other Non-Opioid Treatment Strategies

• NSAIDS, topical gels
• Nerve blocks
• Behavioral therapies
• Steroid injections
• Add Fentanyl to routine drug screening panels (use in hospital ERs and inpatient)
V. RESOURCES

A bibliography of reference and source documents for The Opioid Epidemic: Risks to Policyholders, Patients & Public is available at today’s conference.

Also available upon request:
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