Safer Opioid Prescribing: Pain Management, Supportive Care & Addiction

Friday, May 5, 2017
7:30am – 11:30am
The Grandview
176 Rinaldi Blvd
Poughkeepsie, NY
Please be sure to fill out your conference evaluation here:

https://www.surveymonkey.com/r/Paineval17
Safer Opioid Prescribing: Pain Management, Supportive care and Addiction

Program Schedule

7:30am – 8:00am – REGISTRATION & CONTINENTAL BREAKFAST

8:00am – 8:05am – Welcome/Opening Remarks –

8:05am – 8:35am  State and Federal Requirements for Prescribing Controlled Substances
- Michael Fania, BD Pharm, PharmD, Medicaid Safety/ Regulatory Compliance Officer, Vassar Brothers Medical Center- Pharmacy Services

8:35am – 9:05am – Supportive Care: End of Life Management
- Ruchira Chandra, MD, Supportive Care Medicine, Vassar Brothers Medical Center; Medical Director of Hudson Valley Hospice

9:05am – 10:00am - Prevention, Screening & Signs of Addiction: Strategies to Reduce Pain in Patients with Substance Abuse Disorders
- Andrew Kolodny, MD, Executive Director, Physicians for Responsible Opioid Prescribing; Co Director of Opioid Policy Research at the Heller School for Social Policy & Management, Brandeis University

10:00am – 10:30 – BREAK

10:30pm – 11:30pm – Pain Management: Chronic & Acute Pain
- Edward Michna, MD, JD, Director of Pain Trials Center, Assistant Professor of Anesthesia at Harvard Medical School, Anesthesiologist at Brigham and Womens Hospital in Chestnut Hill, MA,
Safe Opioid Prescribing: Pain Management, Supportive care and Addiction

General Information

Learning Objectives:
• Discuss the impact of federal and state laws and regulations pertaining to the prescription, distribution, and administration of controlled substances.
• Initiate and modify an appropriate treatment plan involving controlled substances.
• Employ key diagnostic and treatment techniques for the management of pain.
• Address common clinical challenges in the management of acute and chronic pain.
• Promote appropriate and safe opioid usage in patients.
• Recognize and assess patient risk factors that contribute to prescription drug misuse and abuse
• Integrate assessment and management tools to mitigate drug misuse and monitor effective patient adherence to drug Regimens.
• Discover individual perspectives about end of life issues.
• Discuss the basic principles of pain assessment and management at the end of life
• Identify expectations of healthcare professional by patient and families at the end of life.

Outcome Objective: Heightened the awareness of opioid misuse and learn more appropriate ways to manage pain in acute, chronic and the end of life.

Accreditation
Vassar Brothers Continuing Medical Education is accredited by the Medical Society of the State of New York to provide continuing medical education for physicians.

AMA Credit Designation
Vassar Brothers Continuing Medical Education designates this live education activity for a maximum of 3.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nursing Accreditation
3.0 CME = 3.0 Contact Hours
http://www.nursecredentialing.org/RenewalRequirements.aspx

AAPA Accreditation
AAPA accepts certificates of participation for educational activities certified for Category 1 from AOACCME, Prescribed Credit from AAFP, and AMA PRA Category 1 Credit(s)™ from organizations accredited by ACCME or a recognized state medical society. Physician assistants may receive a maximum 3.0 of Category 1 Credit for completing this program.

Americans with Disabilities Act
We encourage participation by all individuals. If you have a disability, advance notification of any special needs will help us to better serve you. Please notify us of your needs in advance of the program. Thank you.

Vassar Brothers Medical Center
Acknowledgements
Special thanks to:

- Vassar Brothers Medical Center for sponsoring this event
- The Faculty giving these talks
- Staff of Vassar Brothers CME
- The Grandview

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No commercial funding has been accepted for the activity.

Upcoming CME Teaching Days
2017 Oncology Teaching Day
May 24, 2017 | 11:30am-5:45pm

22nd Annual GI Teaching Day
September 20, 2017 | 8am-3pm

7th Annual Breast Cancer Symposium
October 5, 2017 | 11:30am-5pm followed by dinner

47th Annual Cardiology Teaching Day
October 18, 2017 | 7:30am-4pm

5th Annual Orthopedic Education Day
November 3, 2017 | 7:30am-4pm

Trauma Education Day
November 15, 2017 | 7:00am-4:30pm

For more information call 845.483.6013.
TTY for the hearing impaired 800.421.1220.
Register online at http://cmetracker.net/HQ/Catalog.
Safer Opioid Prescribing: Pain Management Supportive, Care and Addiction

Online Resources

During the conference, the full digital syllabus will be available on the conference webpage: http://vbmclibguides.com/2017Pain.

You can view and take notes on this PDF syllabus on your mobile device through the free Adobe Reader app downloadable at http://www.adobe.com/products/reader-mobile.html.

Keep up-to-date on what other Vassar Brothers CME activities are offered on our website: http://vbmclibguides.com/CME.

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Need research or information? Check out the Health Quest Knowledge Resources website: infoDispensary at http://vbmclibguides.com.

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Vassar Brothers Medical Center
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healthquest.org/VBMC
State and Federal Requirements for Prescribing Controlled Substances
State And Federal Requirements for Prescribing Controlled Substances

Michael Fania, BS Pharm, PharmD
Medication Safety/Regulatory Compliance Officer
Vassar Brothers Medical Center-Pharmacy Services

May 5, 2017

Federal Regulations

- The Federal Regulations - enacted to establish a system of controls;

1. To prevent
   - Abuse
   - Trafficking
   - Diversion

2. Ensure availability of Controlled Substances (CSs) for medical and scientific purposes
   - Should be accessible to all patients who need them, including for the relief of pain

https://www.deadiversion.usdoj.gov/drugreg/index.html
American Society of Addiction Medicine http://www.asam.org/pain-and-addiction
The Principles of Lawful Prescribing of CSs

- A lawful prescription for a Controlled Substance
  - Each separate prescription is issued for a legitimate medical purpose
    Must be written for a specific patient
  - By an individual practitioner acting in the usual course of professional practice

- DEA Registration is required to write a Controlled Substance prescription
  - Initial Registration is varies 28 to 39 months, then must be renewed every 3 years (36 months).
  - NOTE: Significant change to DEA Registration renewal process-effective January 1, 2017, no more grace period and only one renewal notice will be sent approx. 65 days before the expiration date.

- To administer or dispense directly (but not prescribe) narcotic drugs to a narcotic-dependent person for “detoxification” or “maintenance treatment,” a physician MUST have a separate registration with the DEA as an opioid treatment program (OTP).

https://www.deadiversion.usdoj.gov/drugmg/index.html

Scheduling of Controlled Substances

Schedule I - Cannot be prescribed
  - High potential for abuse and lack safety data
Schedule II - High potential for abuse
  - and may lead to severe physical or psychological dependence
Schedule III - Less abuse potential than Schedule II
  - high risk for psychological dependence and low to moderate risk of physical dependence
Schedule IV - Low abuse potential relative to Schedule III

Schedule V - Low abuse potential relative to Schedule IV

Federal vs. State Regulations

Healthcare professionals must comply with both State and Federal laws and regulations that govern prescribing scheduled CSs.

When Federal laws or regulations differ from State laws or regulations, the more stringent rule applies.

Federal vs. State Regulations

- **Length of time a Schedule II CS prescription is valid**
  - Federal Regulations: No limit
  - State specific - New York State: Must be filled within 30 days

- **Amount or duration of a Schedule (II-V)**
  - Federal Regulations: No limit
  - State specific - New York State: 30 day supply limit

- **Refills of a prescription**
  - Prescriptions for Schedule II CSs can not be refilled.
  - Same for Federal and State

Prescriptions for Schedule III-IV CSs can not be dispensed after 6 months from date of issue, or refilled more than 5 times.

Rules for refilling Schedule V CSs are not established by federal law, and the authorized number of refills depends on the professional judgment of the prescriber and the pharmacist

- **PRN orders for CSs are limited to 72 hours for inpatients and must be renewed within 72 hours in New York State.**

[https://www.deadiversion.usdoj.gov/](https://www.deadiversion.usdoj.gov/)

*New York State Department of Health/Bureau of Narcotics Enforcement*
Federal vs State Regulations

- The Controlled Substances Act and Drug Enforcement Administration regulations contain no specific limits on the number of days worth of a Schedule II controlled substance that a physician may authorize per prescription.

- New York State Legislation Enacted to Limit Initial Opioid Prescribing to a 7 Day Supply for Acute Pain – effective July 22, 2016

Requirements of CS Prescription

- Same for both Federal and State
  - Prescriptions for CSs must be dated as of, and signed on, the day when issued
    - Must never post date a prescription
  - Must include full name and address of patient, drug name, dosage form, strength, quantity, and directions for use

- Must include the name, address, registration number of Practitioner

https://www.deadiversion.usdoj.gov/
New York State Department of Health/Bureau of Narcotics Enforcement
Drug Overdose Deaths

In 2010, there were 38,329 drug overdose deaths in the USA

57.7% (22,134) involved pharmaceuticals;
- Opioids - 75.2% (16,651)
- Benzodiazepines - 29.4% (6497)
- Antidepressants - 17.6% (3889)
- Antiepileptic and Antiparkinsonism – 7.8% (1717)

New York State – Just under 800 deaths involving Opioid Analgesics or 4.8% in 2010

Electronic Prescriptions for Controlled Substances

- Effective June 1, 2010 the CFR was revised to:
  - Provide practitioners with the option of writing prescriptions for CSs electronically
  - Addition to, not a replacement of, existing rules
  - Permit pharmacies to receive, dispense, and archive these electronic prescriptions
  - Provide pharmacies, hospitals, and practitioners with the ability to use modern technology for CS prescriptions while maintaining the closed system of controls on CSs

- A practitioner may sign and transmit e-prescriptions if all of the following requirements are met:
  - Must comply with all other requirements for issuing CS prescriptions
  - Must use an application that meets specific requirements (in Part 1311)
  - Must comply with requirements for electronic orders and prescriptions (in Part 1311)

New York State Electronic Prescriptions for Controlled Substances – mandated much later
Practitioner Responsibilities for Electronic Prescriptions

- Rapid reporting of identified breaches
- Same responsibilities when issuing e-prescriptions for CSs as when issuing a paper or oral prescription
  - Including issuing prescriptions only for a legitimate medical purpose and in the usual course of professional practice
- The prescription must conform in all essential respects to the law and regulation

21 CFR 1311.102
https://www.deadiversion.usdoj.gov/
New York State Department of Health/Bureau of Narcotics Enforcement

New York’s Prescription Drug Reform Act - Legislation

The “I-STOP” law took effect on August 27, 2013

Part A: I-STOP (Internet System to Track Over-Prescribing)
Part B: Electronic Prescribing
Part C: Controlled Substance Schedule Changes
Part D: Work group
Part E: Safe Disposal Program

New York State Department of Health/Bureau of Narcotics Enforcement
Legislation

This law:

- Overhauled New York’s Prescription Monitoring Program (PMP);
- Required practitioners consult the PMP before prescribing;
- Required dispensing data be reported in real time;
- Required electronic prescribing;
- Placed hydrocodone on C-II and tramadol on C-IV; and
- Created a workgroup to advice the Department of Health

Duty to Consult PMP Registry

Practitioners must consider their patient’s information presented in the PMP Registry prior to prescribing or dispensing any controlled substance listed in Schedule II, III, or IV.

The data considered by the practitioner must be obtained from the PMP Registry no more than 24 hours before the prescription is issued.

Prescribers may utilize a designee to obtain the information for them, but may not designate the actual review of the data.
Exceptions

- Practitioner administering a Controlled Substance.
- Prescribed for use with an institutional dispenser:
  - Does not include;
    - Discharge
    - Therapeutic leave
    - Other off-premise use
- Prescribed within an ED attached to a general hospital:
  - Limited to a 5 day supply
- Hospice

Exceptions

Technology failures of PMP or practitioner’s hardware;
- Practitioner must take reasonable steps to correct the technological failure or limitation.
- If consulting the PMP Registry would result in a patient’s inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient.
- If it is not reasonable to access the PMP, no other practitioner/designee may access for the practitioner, AND the quantity prescribed is 5 days or less;
  - All 3 elements must be satisfied, to meet this exception
  - Merely writing for a 5 day prescription does not relieve a practitioner from having to check the PMP.
Changes to Schedules – New York State

Effective February 23, 2013

- All products containing hydrocodone were placed on Schedule II
- Tramadol was placed on Schedule IV

Changes in Prescribing Behavior

Comparison of opioid prescribing during the year prior to mandated PMP use and year post implementation:

- 8.72% decrease in total CS prescriptions
- 10.4% decrease in patients with a prescription
- 10.3% decrease in quantity dispensed
- Largest decrease in prescriptions was codeine S (24%)
- Increases in prescriptions for fentanyl (3.5%), morphine (2.2%)

Hydrocodone
- 17.7% decrease in prescriptions
- 16.3% decrease in patients with a prescription
- 16.4% decrease in total doses dispensed

Oxycodone
- 0.2% increase in prescriptions
- 1.6% increase in patients with a prescription
- 2.98% decrease in total doses dispensed

Buprenorphine
- 11.3% increase in buprenorphine prescriptions
- 10.9% increase inpatients receiving a buprenorphine injection
Electronic Prescribing of Controlled Substances

Effective March 27, 2013, regulations allowed electronic prescribing of controlled Substances (EPCS) in New York

Electronic prescribing of controlled and non-controlled substances

– Mandatory effective date for all practitioners was supposed to be March 27, 2015
– On March 13, 2015, Governor Andrew M. Cuomo and the New York State Legislature amended the Public Health Law and the Education Law to extend the implementation date for mandatory electronic prescribing to March 27, 2016

• Prescribers must use an application that has satisfied DEA’s security requirements

EPCS Exceptions

• Veterinarians
• Technological or electrical failures
• The prescriber reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and would impact patient’s medical condition (up to 5 day supply).
• Issued by the practitioner to be dispensed out New York State
• Practitioners who have received a waiver from the Department of Health
Waivers

- Practitioners may apply for a waiver for the electronic prescription requirement for controlled substances

- Waivers are granted upon proper showing of economic hardship, technological limitations outside of the practitioner’s control or other exceptional circumstances

- By statute, waivers are good for one year, after which a practitioner may apply for a renewal

Blanket Waivers

Two blanket waivers of the Electronic Prescribing requirements have been issued by the Commissioner of the NY State Department of Health, for certain exceptional circumstances in which Electronic Prescribing cannot be performed due to limitations in software functionality.

- The first letter to all Practitioners and Pharmacists was dated March 16, 2016, went into effect on March 27, 2016, and ran through March 26, 2017.
- The second letter was dated March 2, 2017, went into effect March 26, 2017, and shall be effective through March 25, 2018.
- The recent letter also acknowledged that, while many Nursing Home/Residential Health Care facilities have adopted electronic prescribing, there remains some facilities in which Electronic Prescribing may not be available due to technological or economic issues or other exceptional circumstances, including a heavy reliance upon oral communications with the prescriber and pharmacy. They will continue to receive a blanket waiver, which also went into effective on March 26, 2017, but only through October 31, 2017.
- These blanket waivers do not affect other general waivers that the DOH has issued to a practitioner upon request.
Additional Resources


- New York Chapter of the American College of Physicians website. [https://www.nyacp.org/i4a/pages/index.cfm?pageid=1](https://www.nyacp.org/i4a/pages/index.cfm?pageid=1)

Contact Information

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Supportive Care: End of Life Management

Ruchira Chandra, MD

Supportive Care Medicine, Vassar Brothers Medical Center; Medical Director of Hudson Valley Hospice

Vassar Brothers Medical Center
PALLIATIVE and END OF LIFE CARE

Ruchira Chandra, MD

Vassar Brothers Medical Center

PALLIATIVE CARE

• Whole person care for patients all ages who are experiencing a debilitating chronic or life threatening illness. The primary goal of palliative care is to prevent and relieve suffering—including pain and other distressing symptom
  • May be given with curative treatments
  • Does not have a time constraint, and should be offered at diagnosis of debilitating illnesses.

• Hospice care is a service delivery system that provides palliative and end of life care for terminally ill patients.
  • Is a Medicare part A benefit (most private insurers and Medicaid also provide) and requires a possible 6 month or less life expectancy

Vassar Brothers Medical Center
Palliative Care Information ACT

Effective February 9, 2011, Chapter 331 of the Laws of 2010 (commonly known as the Palliative Care Information Act) amends the Public Health Law by adding section 2997-c:

- Public Health Law section 2997-c requires the “attending health care practitioner” to offer to provide patients with a terminal illness with information and counseling regarding palliative care and end-of-life options appropriate to the patient, including:
  - Prognosis;
  - Range of options appropriate to the patient;
  - Risks and benefits of various options
  - Patient’s “legal rights to comprehensive pain and symptom management at the end of life.
  - If the attending health care practitioner is “not willing to provide the patient with information and counseling,” he/she must "arrange for another physician or nurse practitioner to do so," or must "refer or transfer the patient to another physician or nurse practitioner.
  - When the patient lacks medical decision-making capacity, the information and counseling must be provided to the person who has authority to make health care decisions for the patient.

Palliative Care Access ACT

- Effective September 2011, PHL Section 2997-d requires that hospitals, nursing homes, home care agencies, special needs assisted living residencies, and enhanced assisted living residencies, provide access to information and counseling regarding options for palliative care appropriate to patients with life limiting conditions and illnesses (or their surrogates)

- These providers and residencies must also facilitate access to appropriate palliative care consultation and services, including associated pain management consultation and services
Advance Directives

• Health Care Proxy
  • Legal document that appoints a health care agent to make medical decisions in the event the patient is unable
• Living Will
  • Document that outlines medical procedures that patients do or do not want in the event of a terminal, irreversible condition
  • Not a legal document—but gives family members and health care providers clear and convincing evidence of patient preferences
• Power of Attorney
  • Non medical document designating a person to make financial decisions
• Non Hospital DNR
  • Legally recognized statewide form for patients not in hospital or nursing homes
• Medical Orders for Life Sustaining Treatment (MOLST)
  • NYS Authorized form for hospital and non hospital DNR and DNI orders
  • Form is also beneficial for specific medical orders regarding comfort care measures, tube feeding, IV fluids, IV antibiotics and Do Not Hospitalize.

So, who should have a MOLST?

• Patient with a chronic or new debilitating condition with a poor prognosis
• Patient has specific preferences regarding medical interventions
• All long term patients at SNF and assisted living facilities
• Physician would not be surprised if the patient died in the next 1 year
• Decreasing functionality, weakness, weight loss and several hospitalizations in the last year
When to approach palliative care?

- It is never too soon to introduce palliative care
- Most physicians overestimate the survival times for their patients: especially if they have had a long relationship
- 2010 study showed that patients with advanced lung cancer who were referred to palliative care at diagnosis
  - Had improved quality of life scores
  - Less depression
  - Survival improved from 8.9 months to 11.6 months
  - Aggressive care was reduced at the end of life

How to approach Palliative Care

- Find a private area-minimize distractions
- Find out the patient’s understanding
- Ask for permission prior to introducing new information
- Clearly explain the information in simple terminology (no medical jargon)
- Ask patient to repeat the information
- Be empathetic and listen
- Try to find out the patient’s goals: cure, symptom management, next big birthday; and address each one
- If asked about prognosis:
  - Acknowledge uncertainty
  - Give ranges (remember we tend to overestimate!)
Summary of NHPCO Guidelines of Determining Prognosis

**General**

A life-limiting condition with evidence of either disease progression and/or impaired nutritional status indicated by involuntary weight loss greater than 10% of body weight in past 6 months. Serum albumin 2.5 is a helpful but not necessary factor. The goal of treatment is relief of symptoms, not cure. These are guidelines not rules.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Primary Factors</th>
<th>Secondary Factors</th>
</tr>
</thead>
</table>
| Heart Disease | • Symptoms of recurrent heart failure or angina at rest, discomfort with any activity (HYHA class IV)  
                • Patient already optimally treated with diuretics and vasodilators (ie, ACE inhibitors) | • Ejection fraction $< 20\%$  
                • Symptomatic arrhythmias  
                • History of cardiac arrest and CPR  
                • Unexplained syncope  
                • Embolic CVA of cardiac origin  
                • HIV disease                                      |
### Pulmonary Disease

**Primary Factors**
- Disabling dyspnea at rest
- Progressive pulmonary disease (increasing emergency department visits or hospitalizations for pulmonary infections and/or respiratory failure)
- Hypoxemia at rest on supplemental O₂
  - $pO_2 \leq 55$ mm Hg on supplemental O₂
  - $O_2$ sat $\leq 88\%$ on supplemental O₂
- Hypocapnia: $pCO_2 \geq 50$ mm Hg

**Secondary Factors**
- FEV1 after bronchodilator <30%
- Decreasing FEV1 on serial testing by $>40$ml per year
- Weight loss $>10\%$ body weight in 6 months
- Resting tachycardia $>100$/min
- Cor pulmonale or right heart failure due to advanced pulmonary disease

### Dementia

**Primary Factors**
- Severity of dementia > FAST: Stage 7-C:
  - Unable to walk, dress, or bathe without assistance
  - Urinary and fecal incontinence
  - Unable to speak more than 6 different intelligible words per day
- Sever comorbid condition within past 6 months:
  - Aspiration pneumonia
  - Pyelonephritis
  - Septicemia
  - Multiple, progressive stage 3 to 4 decubiti
- Fever after antibiotics
- Unable to maintain fluid/caloric intake to sustain life
- If feeding tube in place
  - Weight loss $>10\%$ in 6 months
  - Serum albumin $< 2.5$ g/dL
### NHPCO Prognosis Guidelines Cont.

#### HIV Disease

**Primary Factors**
- CD4+ < 25 cells/mcL or viral load > 100,000 copies/mL
- Karnofsky ≥ 50%
- One of the following:
  - CNS lymphoma
  - Progressive multifocal leukoencephalopathy
  - Advanced dementia
  - Cryptosporidiosis
  - Wasting > 33%
  - Toxoplasmosis
  - Visceral Kaposi’s sarcoma, no Rx
  - MAC bacteremia, no Rx
  - Renal failure, no dialysis

**Secondary Factors**
- Forgoing antiretroviral and prophylactic drug Rx
- Chronic, persistent diarrhea for 1 year
- Albumin <2.5 g/dL
- Age > 50 years
- CHF, NYHA Class IV
- Active substance abuse

#### Liver Disease

**Primary Factors**
- End-stage cirrhosis; not a candidate for liver transplant
- PT > 5 seconds over control or INR > 1.5 and serum albumin < 2.5 g/dL
- At least one of the following:
  - Ascites despite treatment
  - Spontaneous peritonitis
  - Hepatorenal syndrome
  - Hepatic encephalopathy
  - Recurrent variceal bleed

**Secondary Factors**
- Progressive malnutrition
- Muscle wasting
- Continued Alcoholism
- Primary liver cancer
- Positive HBsAg
### NHPCO Prognosis Guidelines Cont.

#### Renal Disease

**Primary Factors**
- Chronic renal failure; coming off or not a candidate for dialysis
- Creatinine clearance < 10cc/min (for diabetics < 15cc/min) and serum creatinine > 8.0mg/dL (for diabetics > 6.0mg/dL)
- Signs and symptoms associated with renal failure:
  - Uremia: nausea, Pruritus, confusion, or restlessness
  - Oliguria: output< 400cc/24 hours
  - Intractable hyperkalemia: serum K>7.0
  - Uremic Pericarditis
  - Hepatorenal syndrome
  - Intractable fluid overload

**Secondary Factors**
- Mechanical ventilation
- Malignancy, other organ system
- Chronic lung disease
- Advanced cardiac or liver disease
- Sepsis
- Immunosuppression, HIV
- Cachexia or albumin <3.5 g/dL
- Age> 75 years
- Platelets <25,000
- Gastrointestinal bleed
- Disseminated intravascular coagulation

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#### Stroke and Coma

**Primary Factors**
- Acute phase following CVA:
  - Coma or persistent vegetation state> 3 days
  - Any four of the following on day 3 of coma:
    - Abnormal brain stem response
    - Absent verbal response
    - Absent withdrawal to pain
    - Serum creatine >1.5 mg/dL
  - Unable to maintain fluid/caloric intake to sustain life
- Chronic phase of CVA; any one of the following:
  - Age>70 years
  - Post stroke dementia: FAST score>7
  - Karnovsky< 50%
  - Poor nutritional status; see above

**Secondary Factors**
- Aspiration pneumonia
- Upper urinary tract infection (eg. Pyelonephritis)
- Sepsis
- Progressive refractory stage 3 or 4 decubiti
- Fever after antibiotics
NHPCO Prognosis Guidelines Cont.

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<thead>
<tr>
<th>Disease</th>
<th>Primary Factors</th>
<th>Primary Factors Cont.</th>
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<tbody>
<tr>
<td>Amyotrophic lateral sclerosis (ALS)</td>
<td>• Critically impaired ventilatory capacity indicated by</td>
<td>• Rapid progression and life-threatening complications such as</td>
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<tr>
<td></td>
<td>• Vital capacity&lt;30% of predicted</td>
<td>• Aspiration pneumonia</td>
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<td>• Significant dyspnea at rest</td>
<td>• Upper urinary infection (ie, pyelonephritis)</td>
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<td>• Requires O₂ at rest</td>
<td>• Sepsis</td>
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<td>• Declines intubation, tracheostomy, mechanical ventilation</td>
<td>• Multiple, progressive stage 3 or 4 decubiti</td>
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<td></td>
<td>OR</td>
<td>• Fever recurrent after antibiotics</td>
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<td>• Rapid Progression and critical nutritional impairment indicated by</td>
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<td></td>
<td>• Oral intake of nutrients or fluids insufficient to sustain life</td>
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<td></td>
<td>• Continued weight loss</td>
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<td>• Dehydration or hypovolemia</td>
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End of Life Care

- When death is imminent
- May last hours to weeks
- Comfort Care
  - Discontinuing medical treatments that
    - Will not improve quality of life
    - Will increase burden or have worsening side effects
  - Eliminate unnecessary medications and treatments
    - Such as cholesterol meds, dementia meds, DVT prophylaxis, anti diabetic meds, vitamins, lab work, antibiotics
2 Roads to Death

THE USUAL ROAD
- Normal
- Sleepy
- Lethargic
- Obtunded
- Semicomatose
- Comatose
- Death

THE DIFFICULT ROAD
- Confused
- Tremulous
- Hallucinations
- Mumbling
- Delirium
- Myoclonic
- Jerks
- Seizures

The Actively Dying Patient

- Pain and Dyspnea
  - Opioids: morphine is first choice
    - Opioid naive: oral morphine (SL) 2.5-5mg Q2-4hrs prn or IV/SQ morphine 1-2mg Q2-4hrs prn
    - Opioid tolerant: oral morphine (SL) 5-10mg Q2-4hrs prn or IV/SQ morphine 2-5mg Q2-4hrs prn or continuous infusion with prn boluses
    - Fentanyl patches may become ineffective due to weight loss and need to careful if fevers/broken skin
  - Anxiolytics: Ativan IV or PO(SL)
    - Can be used as adjuvant pain relief or for dyspnea related to anxiety
    - Start with either 0.25-0.5mg PO or 0.25-0.5mg IV Q6hrs prn in naïve pts
  - Avoid BIPAP or NRB as they are uncomfortable and will no longer add benefit.
    - Even O2 is causing prolongation.
    - Medication titration and fan on face can be helpful for air hunger
Actively dying patient con’t

• Nausea and Vomiting
  • 60% cancer patients may report some nausea
  • 90% can be controlled
  • Pathophysiology
    • Cerebral cortex-anxiety, intracranial pressure
    • Vestibular-motion sickness, inner ear disease
    • Chemoreceptor trigger zone (4th ventricle)
      • Uremia, medication, hypercalcemia
    • Gastric- obstruction, intestinal distention or compression

• Pharmacologic agents for nausea and vomiting
  • Cerebral cortex
    • Tumor/intracranial pressure- dexamethasone
    • Anxiety- Ativan,
    • Uncontrolled pain- opioids, adjuvancts
  • Vestibular
    • Vertigo-meclezine
    • Middle ear infection-antibiotics
    • Motion sickness-scopolamine, dimenhydrinate
  • Chemoreceptor trigger zone
    • Medications- discontinue or decrease doses (common drugs: digoxin, chemotherapy, antibiotics, opioids, NSAIDS and Iron)
    • Metabolic-haldol, prochlorperazine, chlorpromazine
    • Hypercalcemia- hydration and pamidronate, dexamethasone
  • Gastric
    • Obstruction:
      • constipation- laxatives, enema, manual disimpaction, methylnaltrexone / naloxegol
      • Tumor infiltration/bowel obstruction- metoclopramide ( only for incomplete), octreotide 100-200mg 4 times daily for large volume emesis
• Other Agents:

  • Serotonin 5HT3 receptor antagonists
    • Odansetron, granisetron- mostly effective for postoperative or chemo related nausea/vomiting
  • Antihistamines
    • Benadryl, phenargan and atarax- effective for vestibular and gut receptor mediated nausea/vomiting
  • Combinations often effective for intractable symptoms
    • ABHR (ativan, benadryl, haldol and reglan)
    • Ativan, haldol, steroid

The Actively Dying Patient

• Stop IV fluids
  • Gently offer food and fluids by mouth for comfort and pleasure
  • Not eating/drinking are a natural part of the dying process
  • Artificial nutrition or hydration can cause burden (abdominal pain, vomiting, edema, pleural effusions, dyspnea)

• Limit or discontinue vital signs: often times unreliable predictors

• Secretion management: often times more distressing to family than patient
  • Atropine gtts given SL: 3-4 gtts Q3hrs prn
  • Hycosamine
  • Scopolamine patch 1 patch Q72hrs
  • Glycopyrolate: 6mcg/kg
  • Avoid suctioning
The Actively Dying Patient (continued)

- Terminal restlessness/delirium
  - Signs and symptoms: skin mottling, cool extremities, mouth breathing with hyperextended neck, respiratory pattern changes, calling out for dead family, talking about taking a trip, periods of somnolence
  - Could be either due to disease process (renal failure, hypoxia, brain mets), medications or both
  - Try to eliminate other causes of distress: pain, new decubitus, positioning, functioning catheter etc
  - Create a peaceful environment
  - Pharmacologic:
    - halol 0.5-1mg PO every 12hrs ATC with additional doses Q4-6hrs prn for breakthrough
    - Benzodiazapines: ativan 1-2mg SL or IV every hr until calm for severe symptoms or Q3-4 hrs prn for moderate symptoms
    - Midazolam or propofol: terminal sedation

Non Pharmacologic interventions

- Social work and pastoral care
- Continue to support and educate family
  - Breathing pattern changes, continued state of not eating/drinking
- Encourage speaking with and touching patient even if they can not respond
- Music therapy
Resources

- Supportive care medicine at Vassar
  - Inpatient consults for goals of care discussions and symptom management
  - Outpatient consults

- Hudson Valley Hospice
  - For patients that may have a 6-month life expectancy or less
  - Additional support at home

References
Responding to the Opioid Crisis: Preventing and Treating Opioid Use Disorders

Andrew Kolodny, MD
Executive Director, Physicians for Responsible Opioid Prescribing, Co-Director, Opioid Policy Research Collaborative, Heller School for Social Policy and Management, Brandeis University
Responding to the Opioid Crisis: 
*Preventing and treating opioid use disorders*

Andrew Kolodny, M.D.  
*Executive Director, Physicians for Responsible Opioid Prescribing*  
*Co-Director, Opioid Policy Research Collaborative, Heller School for Social Policy and Management, Brandeis University*

Conflict of Interests

*I have no relevant financial relationships to disclose.*
Opium

Overdose Deaths Involving Opioids, United States, 2000-2015

11
10
9
8
7
6
5
4
3
2
1
0

Deaths per 100,000 population

Any Opioid
Commonly Prescribed Opioids (natural & semi-synthetic opioids and Methadone)
Heroin
Other Synthetic Opioids (e.g., fentanyl, tramadol)

Heroin treatment admissions: 2003-2013

Death rates from overdoses of heroin or prescription opioid pain relievers (OPRs), by age group

SOURCE: CDC. Increases in Heroin Overdose Deaths — 28 States, 2010 to 2012
MMWR. 2014, 63:849-854
Non-heroin opioid treatment admissions: 2013

All-cause mortality, ages 45–54 for US White non-Hispanics (USW), US Hispanics (USH)

France (FRA), Germany (GER), the United Kingdom (UK), Canada (CAN), Australia (AUS), and Sweden (SWE).

Mortality by cause, white non-Hispanics ages 45–54


Unintentional overdose deaths involving opioid analgesics parallel per capita sales of opioid analgesics in morphine equivalents by year, U.S., 1997-2007

Source: National Vital Statistics System, multiple cause of death dataset, and DEA ARCOS

* 2007 opioid sales figure is preliminary.
Rates of Opioid Sales, OD Deaths, and Treatment, 1999–2010

CDC. MMWR 2011

New York Consumption of Oxycodone
1980 - 2006

Sources: U.S. Dept of Justice, Drug Enforcement Administration, Office of Diversion Control
New York Consumption of Hydrocodone 1980 - 2006

Source: U.S. Dept of Justice, Drug Enforcement Administration, Office of Diversion Control

Dollars Spent Marketing OxyContin (1996-2001)

Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales

Absolute dollars in millions

Source: United States General Accounting Office: Dec. 2003, "OxyContin Abuse and Diversion and Efforts to Address the Problem."
Industry-funded “educational” messages

- Physicians are needlessly allowing patients to suffer because of “opiophobia.”
- Opioid addiction is rare in pain patients.
- Opioids can be easily discontinued.
- Opioids are safe and effective for chronic pain.

Industry-funded organizations campaigned for greater use of opioids

- Pain Patient Groups
- Professional Societies
- The Joint Commission
- The Federation of State Medical Boards
"The risk of addiction is much less than 1%"


Cited 824 times (Google Scholar)
“The risks for chronic opioid therapy for some chronic conditions such as headache, fibromyalgia, and chronic low back pain likely outweigh the benefits.”
The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop

Roger Chou, MD; Judith A. Turner, PhD; Emily B. Devine, PharmD, PhD, MBA; Ryan N. Hansen, PharmD, PhD; Sean D. Sullivan, PhD; Ian Blazina, MPH; Tracy Dana, MLS; Christina Bougatsos, MPH; and Richard A. Deyo, MD, MPH

Background: Increases in prescriptions of opioid medications for chronic pain have been accompanied by increases in opioid overdoses, abuse, and other harms and uncertainty about long-term effectiveness.

Purpose: To evaluate evidence on the effectiveness and harms of long-term (>3 months) opioid therapy for chronic pain in adults.

Data Sources: MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, PsycINFO, and CINAHL (January 2008 through August 2014); relevant studies from a prior review; reference lists; and ClinicalTrials.gov.

Study Selection: Randomized trials and observational studies that involved adults with chronic pain who were prescribed long-term opioid therapy and that evaluated opioid therapy versus placebo, no opioid, or nonopioid therapy; different opioid dosing strategies; or risk mitigation strategies.

Data Extraction: Dual extraction and quality assessment.

Data Synthesis: No study of opioid therapy versus no opioid therapy evaluated long-term (>1 year) outcomes related to pain, function, quality of life, opioid abuse, or addiction. Good-and-fair-quality observational studies suggest that opioid therapy for chronic pain is associated with increased risk for overdose, opioid abuse, fractures, myocardial infarction, and markers of sexual dysfunction, although there are few studies for each of these outcomes; for some harms, higher doses are associated with increased risk. Evidence on the effectiveness and harms of different opioid dosing and risk mitigation strategies is limited.

Limitations: Non-English-language articles were excluded, meta-analysis could not be done, and publication bias could not be assessed. No placebo-controlled trials met inclusion criteria; evidence was lacking for many comparisons and outcomes, and observational studies were limited in their ability to address potential confounding.

Conclusion: Evidence is insufficient to determine the effectiveness of long-term opioid therapy for improving chronic pain and function. Evidence supports a dose-dependent risk for serious harms.

Primary Funding Source: Agency for Healthcare Research and Quality.

Ann Intern Med. 2015;162:276-286. doi:10.7326/M14-2559 www.annals.org For author affiliations, see end of text. This article was published online first at www.annals.org on 13 January 2015.
"The science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits."

VA/DoD Clinical Practice Guidelines
Management of Opioid Therapy (OT) for Chronic Pain (2017)

“We recommend against initiation of long-term opioid therapy for chronic pain.”
Controlling the epidemic: 
* A Three-pronged Approach

- **Prevent** new cases of opioid addiction.
- **Treat** people who are already addicted.
- **Reduce supply** from pill mills and the black-market.

*For comparisons with data for 1989 and later years, data in the bottom (red) line for 1987–1988 were modified to account for ICD-10 codes instead of ICD-9 codes.*
Buprenorphine Experience in France

- Introduced in the mid 90s
- 79% decline in OD deaths in 6 years
- Use of mono product (not formulated with naloxone) associated with diversion and injection use


Barriers to Buprenorphine

- Ideological
- Federally imposed patient caps
- Federally imposed ban on NP and PA prescribing – ban lifted in 2017
- Limited integration of addiction treatment in primary care
- Limited integration of addiction treatment in specialty pain care
Heroin treatment admissions with planned medication-assisted opioid therapy 2003-2013

Q: What about methadone maintenance?

A: Strong evidence supporting effectiveness. Consider in severe OUD patients who fail buprenorphine and/or require more structure.
Q: What about Vivitrol (ER naltrexone)?

A: May only be useful for a small subset of patients. May increase risk of OD.
High drop-out rate in unpublished Vivitrol registry trial

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td>403</td>
</tr>
<tr>
<td>Provided ≥ 1 post-baseline assessment</td>
<td>288 (71.5)</td>
</tr>
<tr>
<td>Discontinued after 3 months</td>
<td>134 (33.3)</td>
</tr>
<tr>
<td>Discontinued after 6 months</td>
<td>97 (24.2)</td>
</tr>
<tr>
<td>Discontinued after 12 months</td>
<td>70 (17.4)</td>
</tr>
</tbody>
</table>

Source: Unpublished Vivitrol registry data provided by Alkermes

More than 90% of Vivitrol registry patients failed treatment

<table>
<thead>
<tr>
<th>Reasons for Discontinuation</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lost to follow up</td>
<td>199 (49.4)</td>
</tr>
<tr>
<td>Withdrawal by Patient</td>
<td>60 (14.9)</td>
</tr>
<tr>
<td>Study Terminated by Sponsor</td>
<td>30 (7.4)</td>
</tr>
<tr>
<td><strong>Patient feels treatment goal met</strong></td>
<td>22 (5.5)</td>
</tr>
<tr>
<td>Other</td>
<td>21 (5.2)</td>
</tr>
<tr>
<td>Physician intended planned course of treatment met</td>
<td>12 (3)</td>
</tr>
<tr>
<td>Insurance loss or loss of coverage for Vivitrol</td>
<td>11 (2.7)</td>
</tr>
<tr>
<td>Lack of efficacy by Patient</td>
<td>10 (2.5)</td>
</tr>
<tr>
<td>Noncompliance</td>
<td>10 (2.5)</td>
</tr>
<tr>
<td>Incarcerated</td>
<td>9 (2.2)</td>
</tr>
<tr>
<td>Relocated</td>
<td>9 (2.2)</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>5 (1.2)*</td>
</tr>
<tr>
<td>Time constraints</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>Withdrawal symptoms or re-entered detox</td>
<td>2 (0.5)</td>
</tr>
</tbody>
</table>

*3 ODs- 21, 55, 115 days post last dose; 1 drowning-28 days post last dose; 1 suicide 34 days post last dose

Source: Unpublished Vivitrol registry data provided by Alkermes
Naltrexone use increases morphine sensitivity

Summary

- The U.S. is in the midst of a severe epidemic of opioid addiction

- To bring the epidemic to an end:
  - We must prevent new cases of opioid addiction
  - We must ensure access to treatment for people already addicted

Pain Management: Chronic & Acute Pain

Edward Michna, MD, JD
Director of Pain Trials Center, Assistant Professor of Anesthesia at Harvard Medical School, Anesthesiologist at Brigham and Womens Hospital in Chestnut Hill, MA,
Rational Opioid Prescribing in Current Regulatory Environment for Both Acute and Chronic Pain

Edward Michna MD, JD
Brigham & Women’s Hospital
Harvard Medical School
Director, Pain Trial Center

Conflict of Interest

Currently None
Opioids in Clinical Practice

Opioids for Pain

“It may surprise you to hear that, actually, morphine is the best medicine.”
Scope of the Problem

“Pharm Parties”
New Users of Illicit Substances

N=67,500 people surveyed

Number of Estimated New Users (Thousands)

- Pain Relievers: 2193
- Marijuana: 2114
- Tranquilizers: 1286
- Cocaine: 877
- Stimulants: 872
- Ecstasy: 647
- Sedatives: 615
- LSD: 247
- Heroin: 243
- PCP: 106
- Inhalants: 77

Elderly Misuse and Abuse

- More than 40 people over age 60 were caught selling prescription pain medications in Kentucky 2004-2006
- 87 y/o woman recently arrested and imprisoned for reselling her prescription medications for cash
What We Know

- Source of medications frequently friends and family up to 70%
- A lot of what ends up on street comes from legal prescriptions
- There has been over prescribing of medications
- Some patients benefit from chronic opioids but many do not
- Patient with Psychological comorbidities do less well on opioids/ on higher doses

What We Do Not Know

- Much more than we know
- What rates of patients exposed during acute pain evolve into misuse and abuse
- Any difference between opioids and formulations that may effect this progression
- What screening and tools have an effect on outcomes
- Incidence of overuse and abuse in chronic pain patients
What We Do Not Know

- What effect does urine screens have on outcomes
- What are the secondary unintended consequences of regulation and laws
- Do these actions actually have an impact on addiction as a disease and death rates
- Squeezing balloon phenomenon

General Approach to Pain Treatment
Individualization of Care

How Do We Approach Patient in Chronic or Acute Pain

- Acuity of pain
- Disease state
- Patient’s individual needs and preferences
- When possible start with conservative approach
- Consider interventional therapy
- Avoid algorithmic approaches
How Do We Approach Patient in Chronic Pain

- Need to educate patient as to reasonable expectations
- Not all pain is treated with opioids
- A multi-discipline multi-therapeutic approach has best results
- Goal is increased function, decreased pain, and better quality of life

Chronic Pain Experience and Opioid Misuse and Abuse
Opioids Safe and Effective Alternative to Surgery Etc.


Chronic use of opioid analgesics in non-malignant pain: report of 38 cases.

Portenoy RK, Foley KM.

Abstract

Thirty-eight patients maintained on opioid analgesics for non-malignant pain were retrospectively evaluated to determine the indications, course, safety and efficacy of this therapy.

FOUR A’S of Pain Treatment Outcomes

- Analgesia
- Activities of Daily Living
- Adverse effects
- Aberrant drug taking

Passik & Weinrib 1998
Universal Precautions
Gourlay & Heit 2005
- Parallel between infectious disease and chronic pain management
- Apply a minimum level of caution to all patients
- Asking questions and assessing risk

BWH Approach

Original Article

Predicting Aberrant Drug Behavior in Patients Treated for Chronic Pain: Importance of Abuse History

Eduard Michna, MD, JD, Edgar L. Ron, MD, Wilfred L. Hynes, MD, Srdjan S. Nedeljkovic, MD, Sharonah Sowmuth, MD, David Juntaza, MD, Diane Paleonbi, RN, and Robert N. Jamison, PhD
Pain Management Center, Brigham and Women’s Hospital, Boston, Massachusetts, USA
BWH Approach

Urine Toxicology Screening Among Chronic Pain Patients on Opioid Therapy: Frequency and Predictability of Abnormal Findings

Edward Michna, MD, JD,* Robert N. Jamison, PhD, † Loc-Duyen Pham, BS,* Edgar L. Ross, MD,* David Janfaza, MD,* Srdjan S. Nedeljkovic, MD,* Sanjeev Narang, MD,* Diane Patonshi, RN,* and Ajay D. Wasan, MD, MS,* ‡

Research papers
Substance misuse treatment for high-risk chronic pain patients on opioid therapy: A randomized trial

Robert N. Jamison* ₢, Edgar L. Ross†, Edward Michna*, Li Q. Chen*, Caroline Holcomb*, Ajay D. Wasan* ₢*

* Pain Management Center, Department of Anesthesiology, Perioperative and Pain Medicine, Brigham and Women’s Hospital, Harvard Medical School, Boston, MA, USA
* Department of Psychiatry, Brigham and Women’s Hospital, Harvard Medical School, Boston, MA, USA

PAIN® 150 (2010) 390–400
SCREENING TOOLS SOAPP

- Easy to understand and use
- Risk assessment in patients who are candidates for chronic opioid therapy
  - Only validated in chronic pain patients
- Most patients are truthful
- Cut off set low deliberately for detection
- Patients classified into high, medium or low
- 24 questions
- Patient is asked to answer each question on a scale of 0(never) – 4 (often)

BWH Approach To Mitigate Risk of Misuse

- Universal precautions
- Direct Communication with PCP’s
- Risk assessment
- Modification of RX based on Risk
- Urine drug screens
- Psychological screening and treatment
- Prescription monitoring program
- Opioid treatment agreements and trilateral agreements
NALOXONE

Available through state programs, pharmacy programs and prescription

Who should be given prescription

High risk of overdose intended and unintended

Patients on higher doses

Patients on other medications that increase risk

Patients and family members need training
SAFE STORAGE

- Patients need to be educated
- Do not place meds in bathroom cabinet, on tables nightstands, unlocked purses, kitchen drawers, etc.
- Locked cabinet, drawer, or safe

SAFE DISPOSAL

- Take back programs
- Environmental issues with flushing down toilet EPA website
- Place in container water, flour, coffee grounds, cat litter
BWH Approach To Mitigate Risk of Misuse

- Universal precautions
- Direct Communication with PCP’s
- Risk assessment
- Modification of RX based on Risk
- Urine drug screens
- Psychological screening and treatment
- Prescription monitoring program
- Opioid treatment agreements and trilateral agreements

Incidences of Chronic Pain After Surgery

Why Am I Having So Much Pain After My Back Surgery?
Incidence of Chronic Pain After Surgery

- 10-15%
- Gender
- Psychosocial factors
- Preexisting pain
- Type of surgery
- Risk of nerve injury
- Severity of Post-op pain

Incidence of Post-Operative Patients on Chronic Opioids

- Clark; BMJ: Patients opioid naïve before surgery 3% on opioids after 90 days. Highest for thoracic, young, depression, psych vulnerable, and stressed
- Sun: JAMA Int Med: 0.5% of 11 surgeries on opioids 1 yr post. Highest in knee surgery. Other risks, elderly, male, taking antidepressants, abusers of drugs
Incidence of Post-Operative Patients on Chronic Opioids

- Clarke: JAMA Surgery After 1yr only 0.4% of opioid Naïve patients on opioids. Highest in lung resection patients. Patients were 66y/o and higher

Current Surgical Practice Issues

- Failure to inform or give unrealistic expectation for pain control
- Failure to even ask about past dependence issues
- My surgery was successful everything looks good
- Failure to work as a team when issues of post-op pain continue
Role Patient Surveys (HCAHPS) May Play in Overuse of Opioids Peri-Operatively

Argued by some that to obtain better satisfaction scores, opioid Rxing encouraged as easy response

Pain Pract: Van Dijk: Relation between pain scores and their desire for additional opioids.

Only when patients scored 8 or above did a majority express a need for opioids

Some guidelines encourage medication at 4

We Treat Patients Not Numbers
### Risk Mitigation Strategies Acute Pain: Tailoring Opioid Therapy and Reduce Societal Risk

- Set realistic patient expectations pre-op
- Risk assess patients
- Especially with high risk procedures
- Follow closely minimize opioid exposure period
- Use technology like phone apps to better follow patients and reduce cost
- Better use of adjuvants and non opioid approaches

### Current Medical legal, and Regulatory Issues and the Effect on Opioid prescribers

- Federal and state responses
- Pharmacy and pharmacist responses
- Negligent monitoring and over zealous actions
- Criminals
- Opioids and driving.
- Guidelines: Their usefulness and dangers.
- Under-treatment of pain.
- Inappropriate opioid prescribing
Federal Response

- Multiple bills before congress
- Office of National Drug Control Policy
- FDA actions
- CDC guidelines

ONDCP

- Prescriber education
- Legislative proposal to amend CSA
- Enhanced prescription monitoring plans
- More take back programs
- Stepped up DEA enforcement against “Pill Mills”
FDA

- REMS
- Encouraging abuse deterrent product development
- Vicodin rescheduling

Abuse –Deterrent Formulations
Abuse deterrent Products

- Addresses small part of problem
- What is direct benefit to patient
- Allows medication to be marketed
- Unclear what the overall effect on public health issues of opioid addiction
Rescheduling Unintended Consequences

- In some states some prescribers limited to Schedule 3
- Access to appropriate care limited
- Limited options for alternative Schedule 3 medications

Classification in Schedule 2 Does Not Prevent Abuse
CDC Guidelines

- Intended for Primary Care Provider
- Excludes Cancer related pain and end of life care
- Goal is benefits outweigh risks
- Establish goals and discontinue if not effective
- Need for informed consent
- Recommend starting with short acting opioids

CDC guidelines

- Recommend Rxing lowest effective dose
- Reassess benefit and risk at 50mg MS equivalent
- Avoid doses greater than 90 mg MS equivalent
- For acute pain use lowest effective dose
- Rxing for greater than 7 days rarely needed
CDC Guidelines

- Evaluate risk benefit after 1-4 weeks
- Before initiating and periodically during therapy evaluate risk and incorporate risk mitigation strategies
- Naloxone Rx in higher risk and dose patients
- Review Hx and PMP prior to Rxing
- Should use urine drug testing prior and periodically during therapy

CDC Guidelines

- Avoid concurrent Benzodiazepine Rxing
- Offer help to those that develop over use disorders
Insurance Companies

- More aggressive in evaluating physicians
- Pain practices are under review because of higher utilization and growing costs
- Peer review
- Stacked with anti-opioid physicians: emergency medicine, addiction medicine, critical pain physicians
- Loss of privileges triggers state medical board investigation
- Many criminal cases started with insurance review

Walgreens Actions in Response to DEA Fines

- Required Pharmacists to take additional steps to verify opioid Rx’s
- Diagnosis, ICD 9, expected length of therapy, previous therapies tried and failed
- Indiana Pharm Tech released internal document “Secret Checklist”
- 4 mandatory steps
Opiophobia

Current Views of Primary Care on Prescribing Opioids

- More and more practices refusing to write for schedule 2 opioids
- Referrals to specialty groups to care for patients
- Too much time and little compensation
- Unsure of what is expected from them
- Unaware of evolving standards of care
State Responses

- Ohio
- New York
- Florida
- Washington

State Legal Restrictions and Prescription Opioid Use among Disabled Adults

- Recent NEJM: Meara, Horwitz et al.
- Looked at associations between prescription opioids and state controlled substances laws
- Between 2006 and 2012: 81 new laws
- Conclusion: No association between opioid outcomes and specific laws
- Laws not associated with reductions in hazardous use or overdose
Complying with practice guidelines does not necessarily establish that there was no negligence was committed.

Just as proof of non-compliance should not establish negligence per se.

But it can be highly persuasive evidence in a court of law.
Secondary Unintended Consequences

- All regulations produce them
- Important to be aware of potential ones
- Need to monitor these effects and try to address prior as well as during implementation
- We already see issues occurring as to access to care for medical issues that may require opioids for effective therapy
- Insurance companies cover based on guidelines
Secondary Unintended Consequences

- Make hurdles too high less likely prescribers will write for opioids
- Education has to be effective and for all physicians and practitioners
- California requirements and lack of effect
Requirements May Produce Conflict and Misunderstanding in Physician – Patient relationship

Patient Perceptions

Why do the pharmacy staff treat me like a drug addict when I'm getting my meds. Seriously, I have ADHD and without them I can't study.
Negligent Monitoring of Opioid Use

Error in Monitoring

- Recent lawsuit filed against a pharmacist
- A women in her 30’s brought a prescription for an opioid to a pharmacy
- The pharmacist tried to call physician to verify but the physician was not available
- Unknown why the pharmacist suspected a fraudulent prescription
Error In Monitoring

- The pharmacist had the patient arrested suspecting a non valid prescription
- It turned out the patient was a cancer patient and the prescription was valid

Case of Wrongful Discharge

- Patient with chronic post-laminectomy back pain
- Followed by defendant primary care physician for 5 years.
- Oxycontin and Percocet and Neurontin
- Defendant never monitored with urine screens
- Physician became increasingly concerned so implemented urine drug testing
Case of Wrongful Discharge

- Used immunochemistry test
- Negative for Oxycodone
- Confronted patient
- Discharge patient refused to prescribe
- Patient went through withdrawal
- No other physicians would prescribe because of record of negative urine
- Patient sued had urine retested GC/MS
- Positive for oxycodone
- Case settled $300,000

Under Prescribing of Opioids
Estate of Henry James v. Hillhaven Corp

- 75 year old with metastatic prostate cancer is admitted to a nursing home
- Metastasis to lumbar sacral spine and left femur
- Physician orders prn morphine 150 mg q3-4hours
- Nursing supervisor concludes patient is addicted to morphine

Estate of Henry James v. Hillhaven Corp

- Nurse substitutes mild tranquilizer for the prescribed morphine without physician order
- Of the 23 days spent in the facility the patient received little or no morphine
- Following the patient's death the family sued the nursing supervisor and the facility
Estate of Henry James v. Hillhaven Corp.

- Nursing director testified that she never heard of such high doses for pain
- She had seen much sicker patients in more pain on less morphine
- Jury awarded $7.5 million
- An additional $7.5 million in punitive damages
- Case settled for less

Bergman v. Chin & Eden Medical Center

Doctor guilty of elder abuse for undertreating pain

A California court ruling could spur physicians to become more knowledgeable about the best way to treat their patients’ pain.

Tanya Albert

Physicians might want to get up to speed on the latest pain management techniques available now that a

Continued on page 4
Opioids and Driving

Most published studies demonstrate no significant psychomotor and cognitive impairment of patients under stable long term opioid therapy.

The recommendations to patients have been that they can drive if on stable doses and if they ever feel sedated not to drive.
Vasa vs. Compass Medical et al

- Recent Massachusetts case filed against primary care physicians for wrongful death
- Case claims the physicians failure to warn patient not to drive while on pain medication
- Patient is a 77 year old female with multiple medical conditions including breast cancer, CHF, HTN.
- While in the parking lot of hospital
- She drove car into building killing radiologist and another individual

Vasa vs. Compass Medical

- Police stated she stepped on gas pedal instead of brake
- Initially she denied that prescriptions affected her driving and never had a reaction to the medications currently taking
- During her deposition for a suit filed against her she said she repeatedly complained to her doctors she was lightheaded and dizzy sometimes while driving
Vasa vs. Compass Medical

During the deposition she was adamant the doctors never informed her she should not operate a motor vehicle.

Patient was sentenced to 18 months of probation after pleading guilty to motor vehicle homicide, and settled the civil suit.

New legal territory holding doctors libel to 3rd parties for failure to warn of side effects of medications

Vasa vs. Compass Medical

Attorney's now advising doctors to tell patients not to drive

Ability to drive is an important marker in measurement of quality of life

Economic impact, ability to work

Inability to drive impact on psych
Driving & Opioids Recommendations

- Needs to be personal assessment
- If sedated do not drive
- If sick or changing medical condition do not drive
- Use of concurrent psychoactive may need to limit driving
- Need written documentation of warnings

Failure To Warn of Side Effects

ARE YOU ADDICTED TO YOUR PRESCRIPTION MEDICATION?

If you or someone you know has taken either of the following medications and become addicted or dependant, you may have legal rights:

OXYCONTIN
STADOLNS

To protect your legal rights, call
1-800-438-3285
HUGO & POLLACK, LLP.
www.hugoandpollack.com
Side Effects of Opioids

- As part of informed consent, you must warn patients of side effects of any medication.
- Must warn of addiction potential, tolerance, constipation, and physical dependence.
- Potential for mental status changes.
- Warn not to drive until on stable dose with known effect on the patient.

Side Effects of Opioids

- Must also tell the patient that they might not achieve an adequate level of pain control with these medications.
- The physician has the right if they feel opioids are not effective or causing significant side effects to titrate the patient off them.
- Not all pain = opioids.
Negligence Cases for Inappropriate Prescribing

- Growing in number
- Usually involving Oxycodone and high dosage units
- Lack of screening
- Ignoring critical facts
- No effort to uncover history
- Poor decision making
- Poor documentation

Importance of Communication

- Important to communicate with prior treating physicians
- Not everything written in medical notes
- Mass. requires specialists to notify primary care prior to writing
- Continue to communicate during treatment
- Documentation so can communicate your thoughts as to treatment
Summary

- If possible use non-opioid treatment
- Multi-modal approach is best
- Use evidenced based approach
- Individualize care

Set The Right Expectations
Close Scrutiny

Horse Out of the Barn
Opioids and Pain

It's ALL about ME! (or is it?)
Pain Management Care is Individualized

Sir William Osler

“ It is more important to know what type of person has a disease than to know the disease a person has.”