Pain Management and Safe Prescribing

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Why are we here today?

Today:
An “Epidemic of Opioid Overdoses in the United States and in Ohio?”


Number of Deaths from Motor Vehicle Traffic, Suicide and Unintentional Drug Poisonings by Year in Ohio 1999 – 2008

Contributing Factors to Rising Fatal Drug Death Rates
In Ohio:

Over 931,000 adult and 231,000 children with chronic malignant and non-malignant pain

Ohio Compassionate Care Task Force, 2004

The Provider’s Dilemma:

“Twin serpents in the Caduceus”

- Undertreated Pain and related costs:
  - Nationally 100 million Americans with chronic pain at a cost of >635 billion dollars
  
  IOM Report on Pain - 2011

- Opioid Abuse and related costs
  - Nationally > 6 million Americans abusing opioids at a cost of 70 billion per year

Money Magazine

THE CHALLENGE: How to prevent abuse and diversion and still safely treat the over 1 million Ohioans who live with chronic pain

As the gatekeepers of prescription medications physicians are being charged with fighting on two fronts: combating pain while defending against misuse of opioid medications!

Is Pharmaco Vigilance more than we can ask of Physicians??
Examining the data more closely:

- Review of death certificates: majority of opioid related deaths involve other substances - marijuana, cocaine, alcohol
- Chronic pain patients not the ones dying from opioid overdoses
- Millions of opioid doses are reaching the wrong hands!!

“Review of death certificates: majority of opioid related deaths involve other substances - marijuana, cocaine, alcohol. Chronic pain patients are not the ones dying from opioid overdoses. Millions of opioid doses are reaching the wrong hands.”

Fish, P8

Institute of Medicine Report – June, 2011

- Treating pain is a moral imperative
- Improved efforts to prevent pain are needed
- Increased research/education on pain is needed
- A biopsychosocial model of pain management improves outcomes
- A transformation is needed in our cultural view of pain

Treating Pain – A Moral Imperative

- Eighty percent of patients presenting for health care have pain
- Undertreated acute pain may become chronic, disabling pain: complex regional pain syndrome
- Under treatment of pain can lead to alcohol and substance abuse; isolation, depression, and institutionalization in the elderly

Two imperatives:

- To treat pain in a manner that is safe and effective for the patient
- To understand and implement Ohio’s regulatory oversight in order to protect our prescriptive rights

“Physicians need training and experience in pain management if issues of access and under-treatment are going to be addressed.”

National Pain Care Policy Act of 2009 Incorporated into the Obama Healthcare Reform Bill

The real issue for prescribers in Ohio’s Pain Epidemic is not whether or not to treat pain but how!
Today’s Discussion

Regulatory Oversight in Ohio
Safe and Effective Pain Management

CDC Guidelines: Epidemic: Responding to America’s Prescription Drug Abuse Crisis
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3htm?cid=6101a3w
Specifically address the concern of access to care for patients and the need to address the significant concern and expense of untreated pain

These serve as guidepost for the states – they are specifically Guidelines and not Laws

Ohio Automated Rx Regulatory System: OARxRS
Ohio Revised Code – 4729.75-4729.84
- Tool for prescribers, pharmacists to identify and prevent abuse and addiction
- Tool for law enforcement to deter diversion
- Pharmacists must enter data electronically weekly
- Reported drugs: schedule CII, CIII, CIV, V, Carisoprodol (Soma)& tramadol (Ultram)

CDC Guidelines

Epidemic: Responding to America’s Prescription Drug Abuse Crisis,
The Administration’s plan for addressing prescription drug abuse released in April 2011: four components:
- education,
- tracking and monitoring
- proper medication disposal,
- enforcement.

OARxRS

Who can access OARxRS?
- Pharmacist – own customer only
- Physician – current patient only
- Physician’s non licensed designee (HB93)
- Individual – own report
- Licensing boards – own licensee
- Law enforcement - only as part of a certified active investigation of suspected diversion, abuse or drug trafficking
OARxRS: HB 93 expanded use

- Physician’s designee may obtain data
- Physician dispensing reported drugs from office must enter data into OARRS
- Restricted dosage units furnished per month by prescriber
- Physician dispensing of reported drugs limited to a 72 hour emergency supply

HB 93 April 2012 expanded use of OARRS:

- Wholesalers must enter all sales
- Penalties for abuse/misuse of OARRS
- Licensing boards must develop rules governing the use of OARRS by their licensees OSMA, OSBP, etc
- Coroners must report deaths

HB 93 April 2012 expanded required use of OARRS: Medical Board Rule

4731-11-11

Mandated OSMA to develop rules for when physicians must access OARRS:
1. If patient exhibiting signs of drug abuse or addiction
2. Treatment of patient with reported drugs >12wks
3. At least annually if using reported drugs 12wks or more per year

Signs of abuse or addiction:

- Patient with unexpected drug screen
- Forging/adulterating script
- Stealing/borrowing meds
- History of illegal drug use/conviction

Signs of Abuse/Misuse –Mandate OARRS Check:

- Selling drugs
- Increasing the dose without permission
- Multiple prescribers identified/suspected
- Family member, friend or other professional raises issue of patient abuse/misuse

“Red Flags” – Suggested to check OARxRS but not mandated:

- History of chemical abuse/addiction
- Patient appears sedated/impaired in office
- Loosing scripts or requesting early refills
- ED visits for refills
- Sharing drugs
- Requesting drugs by name???
OARxRS

- The report is privileged health information (HIPPA), not a public record, not evidence
- You may not share the information with other professionals unless they use the same chart
- You may show the patient the data but not give it to them
- You must keep OARRS report in non reproducing part of chart
- You may not use OARRS to screen employees or potential employees

Exemptions:

Prescribers of patients with a terminal illness

OARxRS is meant to be and is a useful tool in pain management!

OARRS can be a useful tool for initial or ongoing patient assessment

OARRS is just one more piece of the clinical assessment; it does not replace your medical judgment

Ohio Automated Rx Regulatory System: OARxRS

In 2011:
Ohio Population approximately 11 million
Scripts in OARRS: 46.9 million
# of patients in OARRS: 5.7 million

Time to get report: 98% within 23 seconds
5% 5 mins - 3 hrs reports available 24/7
Lag time of 1-10 days from dispensing of medication until report available

Signing up for OARxRS

Google OARxRS
Home page – “Register”
- registration takes about 15 minutes

More information – Questions??
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Ohio’s Intractable (Chronic) Pain Law

Chapter 4731-21 Drug treatment of intractable pain
- Effective date: November 11, 1998
- Changed to “Chronic” in HB 93
- Currently under review with expected new rules to be developed by the Governor’s Cabinet Opioid Action Team
- Hotly debated issue: will recommendations of the team be “guidelines” or “rules”? – Should vs. Shall!
**Ohio’s Intractable (Chronic) Pain Law**

Current “Shalls” in the law:
- Initial evaluation documented in the record
- Medical diagnosis established
- Individualized treatment plan formulated and documented
- Appropriate consultation
- Signed consent to treatment and agreement to conditions of prescribing

**Governor’s Opioid Action Team**

Ohio Emergency and Acute Care Facility Prescribing Guidelines: Opioids and Other Controlled Substances (OOCs)
- These are guidelines, not rules: should and not shall
- Developed to assist ED physicians who are struggling to deal with the impact of chronic pain patients on the ED, as well as the ever present drug diverter and abuser

**Ohio Emergency and Acute Care Facility Prescribing Guidelines: OOCs**

- OOCs for pain will be prescribed only after evaluation of patient and risk of addiction
- OOCs should be given P.O., not IM/IV
- No Rx if patient seen within the last month or had Rx from another prescriber within last month for the same problem

- Meperidine (Demerol) use discouraged
- ED clinicians will not routinely provide replacement scripts for OOCs that were lost, stolen or destroyed
- Replacement doses of Suboxone, Subutex, or methadone will not be given for patients in treatment programs
Ohio Emergency and Acute Care Facility
Prescribing Guidelines: OOCS

- Long acting or controlled release formulations such as oxycodone SR, fentanyl patches, and methadone will not be routinely provided.

Ohio Emergency and Acute Care Facility
Prescribing Guidelines: OOCS

Prior to deciding whether or not to treat with an OOCS, the ED clinician or the facility:
- Should access OARRS
- Check a photo ID or photograph patient for the chart
- Reserve the right to perform a drug screen

Ohio Emergency and Acute Care Facility
Prescribing Guidelines: OOCS

- ED clinicians should consider contacting the physician who routinely prescribes for the patient
- Request a Palliative Care or pain consult, or other appropriate subspecialty service
- Perform case management on patients repeatedly seen in ED

Ohio Emergency and Acute Care Facility
Prescribing Guidelines: OOCS

- Limit the Rx of OOCS to a 3-day supply except in unusual circumstances
- Discharge instructions to patients given an OOCS Rx should include information on addiction risk, dangers of misuse, appropriate storage/disposal of OOCS

Ohio Emergency and Acute Care Facility
Prescribing Guidelines: OOCS

- ED and other facilities should maintain a list of clinics that provide primary care services and pain management
- ED and other facilities should display signage that reflects these prescribing guidelines and states the facility position regarding the prescribing of opioids and other controlled substances
Ohio Emergency and Acute Care Facility Prescribing Guidelines

Endorsed by:
- OOA
- OSMA
- OHO
- Ohio Pharmacists Association
- Ohio Chapter of the American College of Emergency Physicians
- Ohio Association of Health Plans
- Ohio Association of Physician Assistants
- Ohio BWC

8 Steps to Safe and Successful Pain Management

- Step 1: Reframing the discussion – realistic expectations
- Step 2: Utilizing a biopsychosocial model of pain management vs. the biomedical model
- Step 3: Evaluation of the pain patient
- Step 4: Evaluation of the pain

Steps for Successful Pain Management

- Step 5: Multimodal pain management
- Step 6: Initiating opioid therapy when needed
- Step 7: Monitoring ongoing opioid therapy
- Step 8: Celebrate Success!

Extracted in part from Scott Fish: Responsible Opioid Prescribing

Step 1: Set Realistic Expectations

- A good outcome is achieved if the patient’s pain is reduced by 30 points on a 100 point scale, or by 2-3/10
- Success should be measured in terms of improvement in lifestyle and function
- Set realistic expectations from the start: what is it that the patient would like to do that pain is preventing? Take mini steps toward achieving goal

Step 2: Utilize a Biopsychosocial Model vs a Biomedical Model of Pain Management

What does this mean?

Treat the patient instead of the pain!

When evaluating patients do so in terms of the affects of the pain on lifestyle, function, productivity: ask the patient:

“How does this pain affect you – What can’t you do that you want to do? What can’t you do that you need to do?”
Assess the “meaning of the pain” to the patient:

- Secondary gain or alienation from family, work or society may be hindering patient’s response to treatment
- Patients living with pain have depression that is chemically medicated – depression is a proven biologic outcome of chronic pain - address openly with the patient!
- Assure the patient that you don’t think the pain is “all in his head”, but that addressing depression will be part of treatment plan

Assess sleep, activity, sexual response in relation to the pain; fatigue will increase pain, pain is worse at night

- Actualize patients’ personal satisfaction in their ability to manage their pain’s psychosocial implications: reward gains in function and activity
- Utilize interdisciplinary case management as early as possible: pain psychologists, PT, OT, vocational counselors

Tools for assessing pain in terms of function and lifestyle:

- Pain / disability index
- Sickness Impact Scale

Documentation of improvement in function and activity as a result of using opioids justifies their use for reviewers

Step 3: Evaluation of the Chronic Pain Patient

- Requires time to evaluate the patient as well as the pain and to build a trusting relationship
- Requires utilizing staff and assessment tools when appropriate to evaluate the patient and the patient’s appropriateness for treatment

Patient Assessment

- One out of every ten patients with no history of addiction is at risk for opioid addiction
- Genetic incidence similar to prevalence for alcohol addiction
- Educate patients and families about genetic risk (use handouts from ODADAS) and take a history of family addictions

Tools to assess risk for addiction

- SBIRT
- Opioid Risk Tool (ORT)
- D.I.R.E. Score: patient selection for chronic opioid use
- CAGE-AID – alcohol assessment tool adapted to include drugs
- SOAPP-R – SODQ
Patient Assessment

Use OARxRS

Mandated Use:
1. If patient exhibiting signs of drug abuse or addiction
2. Treatment of patient with reported drugs >12wks
3. At least annually if using reported drugs >12wks

“Red Flags”: optional use of OARxRS

- OARxRS can be a useful tool for initial or ongoing patient assessment
- Document the use of tools in your medical record – may be mandated in state guidelines
- Patients with terminal illness/illness that may become terminal are exempted from OARxRS

Step 4: Pain Assessment

- In order to manage pain, the prescriber must be able to determine the anatomical origins of the pain; somatic, visceral, neuropathic
- Detailed history and listening to your patient’s descriptors of the pain will reveal its anatomical origin

Mnemonic for Pain Assessment

- P – palliating/precipitating
- Q – quality of the pain
- R – region/radiation
- S – severity
- T – temporal relationships
- U – impact of the pain on you

Physical examination of the patient: never prescribe an opioid for a patient without documenting a physical exam

4731-21-02, O.A.C.

Patients with chronic pain will have more than one type of pain –

Ability to control pain depends on choosing the correct medication for each type of pain the patient describes
Anatomical Origins of Pain

- Somatic pain
- Visceral pain
- Neuropathic pain
- Complex neuronal pain

Anatomical Origins of Pain: What is Chronic pain??

Complex Neuronal Pain – Chronic pain

- When patients live with pain, the brain’s response to the pain changes d/t changes in neurotransmitters and neuroreceptors
- Down regulation of Mu receptors (opioid receptors) up regulation of Delta, P, NMDA receptors (neuropathic receptors)
- Therefore, in chronic pain, patients are less receptive to opioids and more receptive to neuropathic pain medications

Complex Neuronal Pain

- Primary neuronal death
- Loss of myelin sheath
- Central sensitization
- Changes in neurotransmitters, neuroreceptors
  - Opioid receptor down-regulation
  - Increased importance of NMDA receptors, glutamate

Acute vs Chronic Pain

- Acute pain is very easy to localize and describe
- Up regulation of the sympathetic nervous system leads to physiologic response of the body that can be measured: increase in BP, pulse, respirations, anxiety
- In chronic pain: less response of the SNS
- Pain descriptors become more vague and pain more diffuse, patients use neuropathic pain descriptors and have flat affects

Step 4: Develop a treatment plan

- Use a biopsychosocial model of pain management: integrative (integrative) medicine
- Select appropriate medications that address the patients multifaceted pain
- Emphasize achievable goals directed at function that are taken in “baby steps”
- The sooner, in the course of the illness, the function is addressed and the patient increases activity, the more likely the treatment will be successful

Develop a Treatment Plan

- Discuss the plan with the patient/family
- Emphasize lifestyle
- Set the rules – consider a pain contract/patient agreement, informed consent?
- When you see a patient in acute pain, get the patient moving as quickly as possible!
Step 5: Utilize Multimodal Pain Management

- Physicians often equate pain management with opioids or interventions by pain specialists.
- Good pain management is “multimodal” and can be accomplished in the office of the attending physician.

Multimodal Medication Therapy

- Pure opioids, weak opioids and Adjuvant medications chosen to address the specific aspects of the patients “total pain” including psychosocial aspects of the pain (depression, sleep, anxiety)
- Initially treat without an opioid if possible, or with limited quantities of opioids

Analgesic Classes

- Non opioids
- Weak opioids
- Pure opioids
- Adjuvants

What are Adjuvants in pain management?

- Adjuvants may be analgesics themselves, or medications not commonly considered to be analgesics, such as anticonvulsants, anxiolytics, and antidepressants
- Enhance or augment the main analgesic
- Reduce the total opioid load if an opioid is needed
- Address different aspects of the patient’s total pain

Adjuvant Medications...

**NSAIDs:**
- Examples: Naproxen, Motrin, Celebrex, Toradol
  *relieves bone, muscle, or joint pain
* often better than Morphine for bone pain

**Antidepressants:**
- Tricyclics – Examples: Elavil, Doxepin
  * increases endorphins
  * helps neuropathic pain
  * may provide appetite stimulation, mood elevation
- SSRIs – Examples: Paxil, Prozac, Zoloft
  * improve sleep, mood appetite
  * have not been shown to help neuropathic pain
- SNRI – Example: duloxetine (Cymbalta), venlafaxine

**Topical Agents:**
- capsaicin, lidocaine patch, EMLA

**Anticonvulsants:**
- Examples: Tegretol, Dilantin, Neurontin
  * relieves neuropathic pain

**Steroids:**
- Examples: Decadron, Prednisone
  * reduces swelling in brain or visceral lesion
  * improves appetite
  * may improve mood
  * relieves neuropathic pain
  * serves as an anti-inflammatory if NSAIDs are contraindicated to reduce joint or bone pain

**Antianxiety Medications:**
- Examples: Ativan, Xanax, Haldol
  * treats agitation, restlessness, extremely helpful in dyspnea, COPD, terminal delirium
  * important adjuvant in controlling pain of all etiologies
Adjuvant Medications…

GABA Agonists
* Baclofen

NMDA Antagonists
* Dextromethorphan, ketamine

Scopolamine: Patch or SQ, Levain PO, Atropine PO or SQ
* treats terminal secretions, relieves death rattle, may help stomach, colic spasms
* motion induced nausea, dizziness

Bisphosphates, Macalcin, Arida, Zometa
* bone pain
* treat hypercalcemia

Alpha 2-adrenergic agonists:
* Clonidine

Neuroleptics
* olanzapine
* Haloperidol
* mirtazapine

Muscle Relaxants – Flexeril, Baclofen

The Concept of Total Pain
Tumor – 60% of pain directly related to tumor
19-28% of pain is secondary to side effects of treatment

End Stage Cardiac Disease

Total Pain in Cardiac Disease

Pain from debilitation, malnutrition (bedsores)
Radiation
Surgery

Pre-existing Pain
Brain Mets
Vesical Mets
Bone Mets

Total Pain in Oncology

Pain from debilitation, malnutrition (bedsores)

Total Pain in COPD

Pain in COPD is a combination of the pathophysiology of the primary process and the multiple common co-morbidities

Chronic Obstructive Pulmonary Disease

Chronic anxiety, depression
Wasting, cachexia, Chronic debilitation, bedsores
Osteoporosis
Venous insufficiency

WHO 3-step Ladder

1 mild
ASA
Acetaminophen
NSAIDS

3 moderate
A/Codeine
A/Hydrocodone
A/Oxycodone
A.Dihydrocodeine
Tramadol

7 severe
Morphine
Hydromorphone
Methadone
Levorphanol
Fentanyl
Oxycodone
Adjuvants
Treatment of Acute Pain

- Failure to treat acute pain preemptively can lead to development of chronic pain such as complex regional pain (RSD)
- Plan for successful management rather than reacting to failed treatment!

Treatment of Acute Pain Case Study

Case scenario: middle aged patient with ankle pain comes in the office on a crutch after an injury playing basketball. Patient rates his pain as a “6/10.” No history of opioid use or drug/alcohol abuse.

Treatment of Acute Pain – case study:

- Screen for abuse potential using appropriate tools
- Check OARxRS if any “Red Flags” or just because “who can tell!”
- Physical exam is compatible with the history; 2nd degree ankle sprain

Treatment of Acute Pain

- Goal of treatment is to reduce the pain to the point that patient can remain functional and able to say that he can move about comfortably with minimal pain and is able to sleep through the night
- One recipe: Naproxen 500mg 2xday p.o RTC for 10 days, hydrocodone 5/500 Tab 1 q4hrs prn p.o. for severe pain breakthrough – dispense 16 pills gabapentin 200mg qhs p.o to address the neuropathic component of the pain ...

Treatment of Acute Pain

- Patient advised to call you ASAP if not meeting the expectations/goals described above
- See patient back in the office in one week - prescribe very few if any opioids and start PT/OT – set goals for return to activity

Treatment of Acute pain

This is “multimodal” because instead of using only the opioid/acetaminophen combination you are also using an anti-inflammatory for the somatic pain and gabapentin for the neuropathic component of the pain. You are scheduling the naproxen and using the hydrocodone/acet prn so that you are giving both RTC continuous relief but sparing the opioid use.
Treatment of Chronic Non Malignant Pain

Case scenario: Beth has chronic pancreatitis and a pancreatic pseudo cyst. She has had repeated surgeries and has abdominal adhesions. Beth is also diabetic and has significant peripheral neuropathy. She is frequently hospitalized, losing weight, depressed and sleeps poorly. Beth sees several specialists but looks to you to manage her pain.

Treatment of Chronic Pain

Does Beth qualify as having “intractable pain” under the guidelines of Ohio SHB 187, “The Intractable Pain Law”?

Does Beth have pathology that could result in a terminal condition?

If so, then you and Beth are excluded from the regulatory scrutiny of pain contracts, urine screens, pill counts.

Treatment of Chronic Pain

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Treatment of Chronic Pain

One multimodal recipe for Beth:
- Beth has been on oxyIR 10 mg 6xday for several months, now her pain is worse and she wakes up at night with leg pain and numbness.
- Convert the oxy IR to oxycodone SR, 20mg 2x day; and continue the oxycodone IR for “break thru pain” every 2-4 hours prn.
- Start gabapentin for the neuropathic pain in her legs starting with 100mg 3xday, gradually titrate to comfort by increasing the dose in tolerated increments until acceptable relief of neuropathy pain is achieved, taking into consideration Beth’s GFR.
- SRNI for neuropathic pain and depression and sleep
- Anticholangeric for bowel spasms

Use of the gabapentin will not only help the diabetic neuropathy, it will also potentiate the effect of the opioid and address the “complex neuronal pain” which develops when pain becomes chronic.

Use of the adjuvants reduces the total mgs of opioid needed to provide comfort.

Step 6: Initiating opioid therapy for Chronic pain when necessary

Criteria: goals without opioids have been disappointing, reason to believe they are indicated (pathology involved, physical exam, pt’s need for relief in order to obtain function)

Assessment of patient, screening indicates patient is appropriate candidate for opioid therapy

A pain contract, patient agreement, consent to treat as appropriate are in place and documented.
Initiating opioid therapy for chronic pain

- Pretreatment urine screening if appropriate is complete and documented
- Educate the patient about the possible side effects of opioids and how to manage: sedation, confusion, itching, nausea, hypogonadism, secondary osteoporosis
- Initiate a “trial period” with set goals and expectations of the patient’s function
- Establish a plan to taper and d/c opioids when appropriate

Initiating Opioid therapy

- Discuss safe storage of medications and review concerns about diversion in the household by friends and relatives
- Discuss safe disposal of unused medications – office handout on these subjects

Step 7: Monitoring ongoing Opioid Therapy

- Utilize “Universal Precautions for Pain”
- Monitoring plan is in place and initiated prior to start of therapy
- Comply with established and evolving state and federal regulations
- Comply with OARxRs
- Document monitoring, compliance on part of patient, improvement in function, achievement in goals especially work related

Monitoring ongoing therapy

- Continue all integrative medicine as appropriate
- Continue to use a biopsychosocial model of patient and family management
- Positive reinforcement of patients improved coping and lifestyle skills

Step 8: Celebrate Success!!

- Document the improvement in terms of sleep, function, ADLs, independence in the elderly
- Taper and d/c opioids as patient’s overall condition and coping skills improve
- Positive feed back to patient, family and staff
- Have ODADAS send you handouts, signs for office and update info regularly

Safe and effective pain management

- Trust your real patients, and if you don’t, don’t treat
- Help your real patients who have substance use problems
- Success is improvement in function/productivity
- Use adjuvants to treat complex pain
- Prescribe opioids in appropriate quantities and address issues of diversion/drug disposal with patients.
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