SESSION OBJECTIVES

- be cognizant that all persons have the right to have access to high quality and effective pain management
- be informed of the current concerns of the FDA and the DEA related to drugs used to treat pain
- review strategies to minimize risks of opioid therapy in the management of chronic pain in primary care
- Understand the principles of “double effect”

A Focus On …..

- moderate to severe acute and persistent (chronic) pain
- in middle aged and older adults
- at physicians’ office practice, hospitals and skilled nursing facilities (SNFs)
- main stay of pharmacotherapy: opioid treatment

Ethical and Legal Aspects of Pain Management

- opioid analgesics are the most effective method of treatment of many types of severe pain
- laws and regulations governing the illicit use of opioids have as their primary objective the prevention of drug diversion and patient addiction
- *primum non nocere* (first do no harm) (Hippocratic Oath)

Pain and the Courts

- patients have a constitutional right to effective pain relief (1997 concurring opinion of the US Supreme Court)
- patient’s suffering from pain associated with terminal cancer was unnecessary and caused by defendant’s failure to meet the standard of care for the management of pain.

1. N Engl J Med 1997; 337:1234-6
Barriers to Effective Pain Relief

• failure of clinicians (physicians, nurses, PAs, NPs) to recognize pain relief as a priority in patient care
• insufficient knowledge among clinicians on pain assessment and management
• clinicians’ fear of regulatory scrutiny of opioid prescribing (and dispensing) practices
• failure of health care institutions to hold clinicians accountable for pain relief

“THE SUPPORT STUDY”

1990's: 2 year prospective study 4000+ hospitalized patients

• 50% of conscious patients who died in hospital, family members reported moderate to severe pain at least half the time
• specially trained nurse…. “to encourage attention to pain control…. no improvement …in level of pain”


CHRONIC PAIN IN U.S. SNFs PAST AND PRESENT

1990’s: 40-85% residents suffer from chronic pain
2009: Residents who have moderate to severe pain:
   National average 4.5% (19.4% SNF)
   OK average 6.8% (22.1% SNF)
   One facility 4.2% (12.7% SNF)

PAIN MANAGEMENT A BALANCING ACT

Ethical Imperatives
Health Care Jurisprudence
Relieve suffering
Optimize Health
Law
Regulations

Principle of “Double Effect”

• justifies the use of medications or other therapies in terminal patients to relieve (severe) symptoms such as __________, even though such use may lead to unintentional/hastened death due to side effects of the therapy

ANY THERAPY THAT HAS A “DOUBLE EFFECT” IS:

• ethically permissible if
  1) the action is not morally wrong
  2) the good effect must be the intended one (“intent”)
  3) the adverse effect is not the means by which the good effect is obtained
  4) the good effect outweighs the bad effect

**Common Issues Clinicians Face and Ethical Dilemmas**

- long-term prescribing of a controlled substance for pain control
- balancing therapeutic and potentially adverse outcome(s)
- potential drug diversion
- re-emergence of substance abuse

**The Regulatory Environment**

**FDA:** determines medication efficacy and safety, including its potential for abuse

**DEA:** enforces laws regulating the manufacture, distribution, dispensing and record-keeping requirements for controlled substances

**DEA Categories of Potentially Abusable Drugs**

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Abuse Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No approved medical indication i.e. heroin</td>
</tr>
<tr>
<td>II</td>
<td>Opioids, amphetamines</td>
</tr>
<tr>
<td>III</td>
<td>Mixed opioids, tramadol, THC</td>
</tr>
<tr>
<td>IV</td>
<td>Benzodiazepines, modafinil, barbiturates, propoxyphene</td>
</tr>
<tr>
<td>V</td>
<td>Pregabalin, diphenoxylate</td>
</tr>
</tbody>
</table>

Source: U.S. Controlled Substances Act

**Toward Improved Public Policy: Medical Availability**

- Empowering medical practitioners to provide opioids in the course of professional practice.
- Allowing them to prescribe, dispense, and administer according to the individual medical needs of patients.
- Ensuring that a sufficient supply of opioids is available to meet medical demand.

**Toward Improved Public Policy: Balanced With Drug Control**

- When misused, opioids pose a threat to society.
- Clinicians must recognize that a system of controls is necessary to prevent abuse and diversion. Although the system of controls is not intended to interfere with legitimate medical uses, they are necessary to protect the public health and should be understood and supported by the clinical community.
- Minimizing risk of abuse and diversion during the treatment of individual patients is part of the essential skill set needed for the safe and effective clinical use of opioid drugs.
The Principles of Balance

• Adapted from: http://www.medsch.wisc.edu/painpolicy/index.htm

Pain and Policy Studies Group at the University of Wisconsin Comprehensive Cancer Center.

Federation of State Medical Boards: Guidelines on Safe Opioid Prescribing

1. effective patient evaluation
2. create an appropriate treatment plan
3. obtain informed consent and agreements
4. periodically review the course of pain management
5. refer as necessary for additional evaluation and treatment
6. keep accurate and complete documentation
7. comply with applicable federal and state regulations related to use of controlled substances

+ BALANCE VIGILANCE WITH COMPASSION

Adapted from: Responsible Opioid Prescribing
A Physician’s Guide
Scott M. Fishman MD
Federation of State Medical Boards, 2007
Waterford Life Sciences 202-299-0600

FDA and Opioid Risk Evaluation and Mitigation Strategy (REMS)

| Goal                                      | mandated safety program to mitigate health and safety risks associated with opioids 1
|                                           | 24 marketed opioids included; 2 schedule II medication (CII) |
| Assumption                                | intentional and unintentional overdoses due to prescribers |
| Mandatory education                       | abuse, misuse, diversion  
|                                           | Demonstration of competency  
|                                           | May require: use of standardized opioid patient agreement and patient registry |

1. FDA Amendment Act: http://tinyurl.com/qty64a
2. www.medscape.com/newsarticle/588058

FDA Focuses on Drugs and Liver Damage

Concern:
- drug induced liver failure (404 in 2005); (½ due to acetaminophen)2
- small safety margin APAP between max recommended dose and toxicity


FDA Adds Stronger Warnings to Propoxyphene

Concern:
- reports of fatal overdoses; majority associated with ingestion of multiple drugs
- cardiotoxicity; sedation, confusion (especially in older patients)

FDA 2009 Action Warning on “unapproved” prescription opioids

Concern: many immediate release opioids never underwent efficacy and safety drug trials

Response: AAHPM and the Hospice Care Coalition: joint letter to the FDA

DEA: not recognize nurses in LTCFs as “agents of the prescriber”

Position Statement: “Since no legal agency relationship exists between the LTCF nurse and the physicians, the (currently) widely used system is not in compliance with legal requirement”

Proposed Solution: “It is suggested the nurse contact the provider pharmacy, and the pharmacist then contact the physician”.

Assumption: “Residents of LTCFs are visited infrequently by their physicians”. “Chart order (for an opioid) do not meet the definition of a valid prescription”.

CMS State Operations Manual

F tag 425: requires the SNF/NF to provide routine and emergency medication in order to meet the needs of each resident

F tag 329: quality of care (includes pain management)

The Solution?

Amend appropriate Section(s) of the Controlled Substances Act (CSA)

OHCA SoonerCare SBIRT Services

Screening, Brief Intervention and Referral to Treatment

Procedure Codes 99408 ($28.07) and 99409 ($55.04)

Based on the Primary Care MEDICAL HOME

Go to: http://sbirt.samhsa.gov/index.htm

Summary and Questions

Open Discussion