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A MEDICARE LEARNING NETWORK® (MLN) EVENT

National Partnership to Improve Dementia Care in Nursing Homes & Quality Assurance and Performance Improvement (QAPI)

September 18, 2018

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Learning Network®

Acronyms in this Presentation

- AHCA - American Health Care Association
- AMDA - The Society for Post-Acute and Long-Term Care Medicine
- C-I through C-V - Controlled Substance Schedules I-V
- CFR - Code of Federal Regulations
- CMS - Centers for Medicare & Medicaid Services
- LTCF - Long-Term Care Facility
- PA/LTC - Post-Acute and Long-Term Care
- SNF - Skilled Nursing Facility

Agenda

CMS Perspective on Opioid Use	Dr. Shari Ling, CMS
Opioid Use in Post-Acute and Long-Term Care	Dr. Karl Steinberg, Mariner Health Care
The Impact of Opioid Use on Persons Living with Dementia	Dr. Abraham Brody, Hartford Institute for Geriatric Nursing, New York University, James J Peters Bronx VAMC GRECC
National Partnership to Improve Dementia Care in Nursing Homes	Michele Laughman, CMS

Opioid Use in Post-Acute and Long-Term Care

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Agenda

- Briefly review the history, benefits, and harms of opioids and the opioid crisis
- Discuss opioid use in Skilled Nursing Facilities (SNFs) in the context of the opioid crisis
- Recognize regulatory concerns around opioid prescribing and administration in Post-Acute and Long-Term Care (PA/LTC)
- Emphasize the importance of treating pain in SNF residents, keeping residents' rights and person-centered care in the forefront when weighing treatment options

Brief Opioid History

- Derived from opium poppy (*Papaver somniferum*)
- Natural components include morphine and codeine
- Recognized for their analgesic and euphorigenic properties from ancient times
- Tolerance, dependence, addiction potential also identified centuries ago
- Very useful in the field of medicine
  - Excellent for treatment of dyspnea and unlikely to cause respiratory depression in therapeutic doses
    - More dangerous when combined with benzodiazepines
  - Also useful and often prescribed for cough, diarrhea
  - Side effects include constipation, nausea, somnolence, pruritus
    - Saunders: “The hand that writes the opiate prescription should also write the laxative”

Brief Opioid History

- Perennial search for safer, less addictive modified or synthetic alternatives (e.g., heroin, pentazocine, methadone)
  - Has not really been a success, but some very potent agents have been developed (e.g., fentanyl)
- Controlled Substances Act of 1970
  - The most potent legal opioids (fentanyl, morphine, oxycodone, others) are C-II, cannot be phoned in and cannot be refilled
  - Only codeine combinations, tramadol, mixed agonist/antagonists, antidiarrheals not C-II
    - Note that buprenorphine (including Subutex/Suboxone), nalbuphine, others are C-III
  - Heroin and illicit fentanyl derivatives are Schedule I (no legally recognized use in U.S.)

Brief Opioid History

Pendulum of prescribing

- 1980s: Standard practice: generally reserve use for severe post-op or trauma pain, terminal cancer
- 1990s: More relaxed prescribing, pain as the Fifth Vital Sign, advent of pain specialists
- 2000s: Even more relaxed, many new opioid formulations became available
- 2010s: Recognition of opioid epidemic has rapidly returned us to highly restricted use
  - Some facilities are refusing to admit residents who are on opioids, especially with a history of addiction—or those on maintenance therapy (e.g., buprenorphine or methadone).
  - But in 2014, over 200 million opioid prescriptions were filled by US pharmacies
  - Mostly for acute pain (<3 weeks) but 10 million patients were receiving chronic opioid prescriptions
  - Many are being diverted
  - New opioid formulations with deterrents (not a new concept)
  - Numerous recent laws and regulations passed with respect to opioid prescribing, including limits on duration (e.g., 1 week), dosages (e.g., 90 mg morphine equivalents [Morphine Milligram Equivalent])
  - Also limits on opioid production—has resulted in shortages in hospitals and local pharmacies

The Opioid Crisis

- With wider availability of prescription opioids in the last 20 years, use increased
  - Patients were kept on opioids long-term for chronic pain [note: not very effective or evidence-based]
  - Abuse/misuse/addiction also increased
- But they are killing more people than auto accidents, AIDS at their peak—predicted 50,000 in 2018
- “Traditional” opioid addiction was heroin, historically very expensive (>$100/day) and associated with criminal activity to support habit
  - Methadone clinics
  - Heroin maintenance used in England
- Combination of factors drove opioid crisis
  - Largesse in prescribing by pain specialists and others
  - Larger supply of illicit opioids, also less expensive and more accessible to “average” and younger users
  - Different kinds of “marketing” also de-stigmatized opioid use and abuse—both traditional pharmaceutical companies and illegal drug traffickers
  - Now laced with super-potent fentanyl derivatives—some are 100x stronger than morphine
    - Much higher risk of overdose
  - Excellent article in lay press: http://nymag.com/daily/intelligencer/2018/02/americas-opioid-epidemic.html

Opioids in Skilled Nursing Facilities

- With wider availability of prescription opioids in the last 20 years, use increased substantially
- Chronic pain is very common in PA/LTC residents due to arthritis, many other conditions
  - Acetaminophen is a good first choice, should be given routinely up to 3 grams daily
  - Relative contraindications to other types of agents (e.g., nonsteroidal anti-inflammatories)
  - 2012 data: 1 in 7 nursing home residents on **chronic** opioid therapy—but most of them continue to report moderate to severe pain (Minimum Data Set data)
  - No good data to support the efficacy of opioids for chronic nonmalignant pain
- Many residents come from hospital on opioids—some never go off them
  - Patients who take prescription opioids for 3+ weeks often wind up on them long-term
  - May be worthwhile to request a stop date for opioids when treating short-term pain

Opioids in Skilled Nursing Facilities

- Most guidelines recommend routine, around-the-clock dosing of opioids for patients who will predictably have pain
  - Preferably long-acting agents without a rapid rise in serum levels, which can be reinforcing
  - Helps keep pain levels lower, because it takes higher dosages to treat breakthrough pain than to prevent severe pain from occurring.
  - In postoperative or post-trauma pain, routine opioids should be tapered rather than discontinued “cold turkey” as the painful condition improves
- Adjuvant medications can be very helpful to potentiate analgesic effects of opioids (or replace them)
  - Specific medications for neuropathic pain
  - Psychostimulants
  - Antidepressants
  - Corticosteroids (e.g., dexamethasone, prednisone)
  - Topical meds (capsaicin, diclofenac, lidocaine)
  - Many others including some compounded medications
- Nonpharmacologic measures: Cognitive Behavioral Therapy, modalities, massage, acupuncture, manipulation, many others—with varying evidence base; Physical activity generally improves pain

Opioids in Skilled Nursing Facilities

- Drug Enforcement Administration, nurse-as-agent controversy, tightened requirements for dispensing pharmacies to fill controlled substance prescriptions
  - 2012: large settlement for improper dispensing of medications “without valid prescription”
  - Since then, controlled substance prescriptions have required written prescription or verbal OK from prescriber to pharmacist for emergency fills—SNF nurse no longer able to authorize (without explicit “contract” between prescriber and nurse)
  - Some states have even more restrictive laws/regulations
  - This has caused delays in residents receiving needed pain medication
  - Even applies to dispensing from E-kits
- Facsimile prescriptions for C-II OK in Long-term Care Facility (LTCF), “original” does not have to be sent
- E-prescribing will probably become more prevalent in next few years; state laws vary
- Acceptable to order up to a 60-day supply of C-II medication in LTCF pharmacy (under federal law)
  - LTCF Pharmacy can do partial fills
- Acceptable to order up to 120 days’ supply (including refills) valid up to 6 months of C-III to C-V
  - Oral prescription is OK, no written prescription is required
- Pharmacies are tending to dispense shorter durations
  - Important to get reordered before resident runs out of opioid on med cart

Opioids in Skilled Nursing Facilities

- Controlled substances cannot be returned to pharmacy or transferred to any other patient, must be destroyed
  - Instances of diversion related to non-destruction of SNF controlled substances have been identified
  - Robust processes for counting/inventory and destruction of unused medications are a best practice
- Hydrocodone products became C-II in 2014, making it more difficult to prescribe—leaving acetaminophen/codeine and tramadol as “easier” agents to order
- In proposed rule for 2016 revision of 42CFR§483 (Requirements of Participation), opioids were to be considered a psychotropic medication
  - This was removed in the Final Rule at the urging of The Society for Post-Acute and Long-Term Care Medicine (AMDA), American Health Care Association (AHCA), LeadingAge, and others

Opioids in Skilled Nursing Facilities

Relevant F Tags

- F757 (old F329), Unnecessary Drugs (and F756, “irregularities”) 483.45(c)(d)(e)
  - Excessive dose, including duplicative drugs—if multiple opioids or analgesics used, document why
  - Excessive duration
  - Without adequate monitoring
  - Without adequate indications for use
  - In the presence of adverse consequences “which indicate the dose should be reduced or discontinued”
- F697 (Quality of Care: Pain Management) 483.25(k)
  - Based on the comprehensive assessment of a resident, the facility must ensure that residents receive the treatment and care in accordance with professional standards of practice, the comprehensive care plan, and the resident’s choices, related to pain management.
- Best practice: Specific care plan for opioid use, including realistic goals (not usually pain level = 0)
  - Obviously, need care plan for pain
  - Monitoring pre-and post-dose pain levels for effectiveness (don’t just document “improved”)
  - Use pain scales appropriate to the individual resident

Key Points/Summary

- Opioids are still the most effective pain reliever available, as they have been for millennia
- Opioid crisis is real and must be addressed by our society
- Opioid “crisis” probably doesn’t exist in nursing homes, but we can do better with our processes
- When appropriate: taper, use adjuvants, consider other analgesics, non-pharmacologic measures
- Constraints on opioid prescribing do not apply to hospice enrollees
  - There is no ceiling for pure opioid agonists; patients may require 1000+ mg of morphine daily because of tolerance
- Order ongoing opioids in plenty of time before resident runs out
- Have naloxone on hand for potential overdose situations
- Use caution when prescribing/administering opioids with benzodiazepines, respiratory depression

Key Points/Summary

- For residents with potential addiction issues, consider usual measures (check Prescription Drug Monitoring Program, observed administration, use of abuse-deterrent formulations, long-acting rather than short-acting formulations, use of buprenorphine and/or methadone to treat pain)
- Treat addiction like any other disease, not a character defect
- Have strict policies about destruction of unused medications
- Be vigilant for diversion of opioids and unusual behavior by nursing staff
- Be realistic in goals of pain management, and create realistic expectations for residents/families
- Always consider pain as a cause of behavioral disturbances in residents with cognitive deficits

Resources

- Pain management in the geriatric population, including nursing guidelines: https://geriatricpain.org/
- AMDA – The Society for Post-Acute and Long-Term Care Medicine, Clinical Practice Guideline (Pain) https://paltc.org/product-store/pain-management-cpg-pocket-guide
- Pain as a “moving target” https://www.caringfortheages.com/article/S1526-4114(17)30496-1/pdf
- Opioid Abuse in Chronic Pain https://www.nejm.org/doi/full/10.1056/NEJMra1507771
- Excellent history and review of opioids and the opioid crisis from the lay press: http://nymag.com/daily/intelligencer/2018/02/americas-opioid-epidemic.html
- Prevalence of chronic opioid use in nursing homes: https://www.ncbi.nlm.nih.gov/pubmed/28940193

The Impact of Opioid Use on Persons Living with Dementia

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Researcher and Nurse Practitioner, James J Peters Bronx VAMC GRECC

Significance

Prevalence of chronic pain increases with age

- 50% of community-dwelling older adults have some form of pain
- At least 35%-61% of nursing home residents have some form of pain

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Significance

More than 80% of older adults have chronic medical conditions typically associated with pain.

These conditions include:

- Rheumatoid or Osteoarthritis
- Gout
- Pressure Ulcers
- Cancer
- Post-Herpetic Neuralgia (From shingles)
- Back Pain
- Vertebral Fractures (From osteoporosis)
- Diabetic Neuropathy

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Adverse Effects

Pain can have significant effects on how older adults live.

Some consequences include:

- Depression
- Sleep disturbances
- Agitation
- Loss of function
- Withdrawal or decreased socialization
- Caregiver burden, depression, and burnout
- Increased health care utilization and costs

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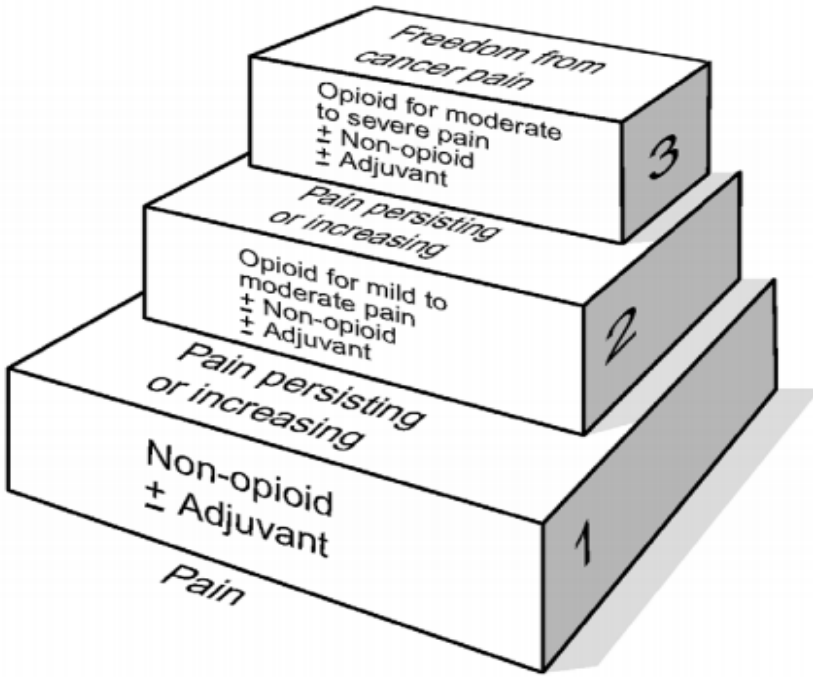
Using Opioids or Pain

We used to believe in the stepwise World Health Organization Ladder:

- Non-opioid
- Opioid
- Strong opioid



Problem is:

- IT WASN'T BASED ON EVIDENCE
- IT WAS FOCUSED ON CANCER PAIN

We now know it is not equally applicable to other conditions.

Original Investigation

March 6, 2018

Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain

The SPACE Randomized Clinical Trial

Erin E. Krebs, MD, MPH[1,2]; Amy Gravely, MA[1]; Sean Nugent, BA[1]; et al

» Author Affiliations | Article Information

JAMA. 2018;319(9):872-882. doi:10.1001/jama.2018.0899

Key Points

Question For patients with moderate to severe chronic back pain or hip or knee osteoarthritis pain despite analgesic use, does opioid medication compared with nonopioid medication result in better pain-related function?

Findings In this randomized clinical trial that included 240 patients, the use of opioid vs nonopioid medication therapy did not result in significantly better pain-related function over 12 months (3.4 vs 3.3 points on an 11-point scale at 12 months, respectively).

Meaning This study does not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.

What we Know

- Opioids are non-superior in:
  - Lower back pain
  - Osteoarthritis
- Opioids have limited efficacy in neuropathic pain
- No strong evidence that opioids reduce agitation in persons with dementia
- Opioids increase the risk of falls

What we know

- Pain **IS** associated with disinhibition and irritability, and better pain control reduces these symptoms
- Opioids only very modestly reduce the use of benzodiazepines and antipsychotics
- Opioids do not likely have long-term effects on cognition
- Opioids do not cause psychosis in most persons with dementia
- Long-acting opioids are inappropriately prescribed in persons with dementia in nursing homes:
  - Leads to higher rates of sedation/somnolence, and overdose

What we know

Opioids have significant side effects

- Nausea/Vomiting
- Constipation
- Drowsiness
- Short-term Cognitive Effects
- Respiratory Depression

What does this mean?

- Opioids are NOT appropriate for use in some of the more typical painful conditions in older adults
- Older adults who are opiate-naïve should NOT be placed on long-acting opioids like fentanyl patches which have a black box warning specifically for this
- Opioids should not be used to replace antipsychotics and sedative/hypnotics

What does this mean?

- Opioids are appropriate for use in the following conditions where there is moderate to severe pain not controlled by other modalities:
  - Cancer Pain
  - Acute pain caused by injury (hip fracture, broken ribs, vertebral compression fractures) for TIME LIMITED periods
  - New pressure injuries (e.g. ulcers)
  - Severe flares of chronic conditions
  - Dyspnea caused by severe chronic obstructive pulmonary disease or congestive heart failure
  - Terminal agitation or tachypnea
- Otherwise effectively assess residents and attempt to use other modalities of pain control

Barriers to Assessment

- Older adults are reluctant to report pain
- Older adults use different terminology
- Fear of addiction to analgesics
- Cognitive impairment further prevents report
- Clinician knowledge and attitudes
- Caregiver perception, fear, and attitudes

Assessing Pain in Older Adults

Usual assessment questions still apply:

- Intensity
- Onset
- Duration
- Frequency
- Location
- Radiation
- Character
- Precipitating Factors
- Aggravating Factors
- Alleviating Factors

HOWEVER

How the questions are asked change!

Assessing Pain in Older Adults

- So ask other questions:
  - Are you having any difficulty getting out of bed in the morning?
  - Are you having any difficulty walking or moving?
  - Do you have any discomfort, soreness, achiness?
  - Are you having any of “the arthritis” or “the gout”

- THEN if they answer yes, ask the typical questions (severity, intensity, location, etc…)

Pain Scales in the Elderly

No Cognitive/Mild Dementia

- Use a mixed scale with Numeric Rating Scale, Verbal Descriptor, Faces Pain Scale
- Persons with dementia and older adults in general have significant preferential differences that affect pain reporting

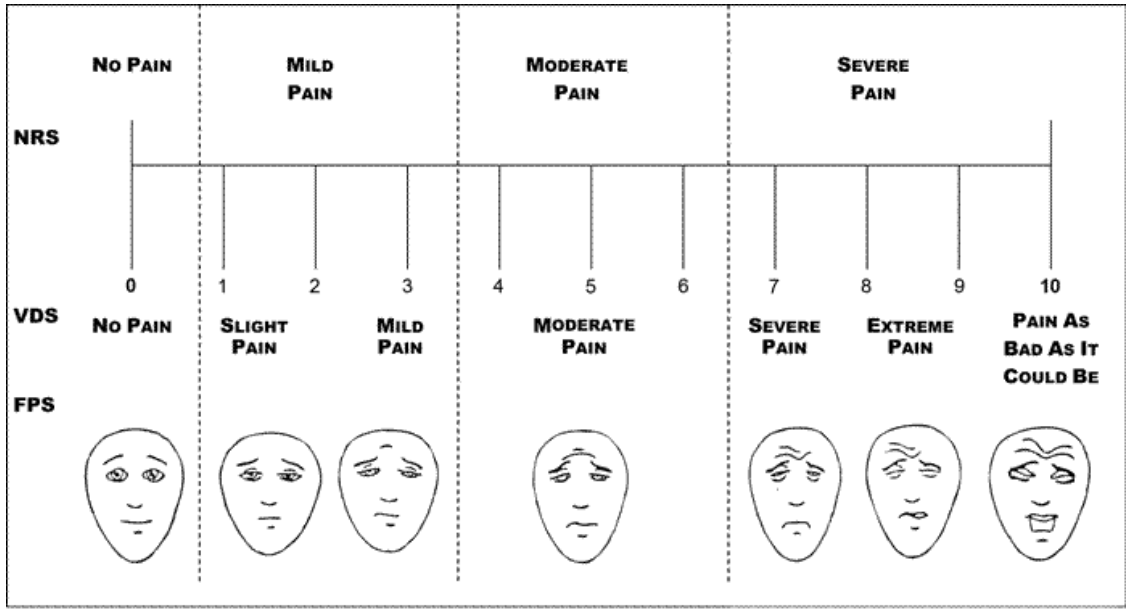


Figure.
Numeric Rating Scale (NRS), Verbal Descriptor Scale (VDS), and Faces Pain Scale (FPS). *Source* (FPS): Bieri D, Reeve RA, Champion GD, Addicoat L, Ziegler JB. The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: Development, initial validation, and preliminary investigation for ratio scale properties. Pain. 1990;41(2):139–50. [PMID: 2367140] Used with permission.

Pain Assessment Tool for Moderate to Severe Dementia Patients

Pain Assessment in Advanced Dementia (PAINAD) Scale

Items*	0	1	2	Score
Breathing independent of vocalization	Normal	Occasional labored breathing. Short period of hyperventilation.	Noisy labored breathing. Long period of hyperventilation. Cheyne-Stokes respirations.	
Negative vocalization	None	Occasional moan or groan. Low-level speech with a negative or disapproving quality.	Repeated troubled calling out. Loud moaning or groaning. Crying.	
Facial expression	Smiling or inexpressive	Sad. Frightened. Frown.	Facial grimacing.	
Body language	Relaxed	Tense. Distressed pacing. Fidgeting.	Rigid. Fists clenched. Knees pulled up. Pulling or pushing away. Striking out.	
Consolability	No need to console	Distracted or reassured by voice or touch.	Unable to console, distract or reassure.	
			Total**	

The PAIN-AD tool that examines breathing, vocalization, facial expression, body language, consolability is one example of a non-verbal tool.

Considerations for Treating Pain

- Monitor for relief from analgesics, assess at each visit
- Educate patient/staff about assessing pain, and taking breakthrough medication prior to pain becomes really bad
- Monitor for medication side effects
- Encourage non-pharmacologic treatment
- Encourage use of acetaminophen scheduled 1000mg 3x daily (2gm maximum in End Stage Liver Disease)
- Nonsteroidal Anti-inflammatory Drugs and celecoxib only for time-limited periods (6 weeks maximum)
- Encourage activity and exercise
- Thoroughly document findings

Resources

- **Hartford Institute for Geriatric Nursing**
  - https://www.hign.org
- **Aliviado**
  - https://www.aliviado.org
- **Geriatric Pain**
  - https://www.geriatricpain.org
- **AMDA Opioids Page**
  - https://paltc.org/topic/opioids

National Partnership Updates

Michele Laughman, CMS

Question & Answer Session

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