



U.S. Food and Drug Administration

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FDA'S SAFE USE INITIATIVE

*Collaborating to
Reduce Preventable Harm from
Medications*



U.S. Department of Health and Human Services
Food and Drug Administration

November 4, 2009

ADDRESSING NSAID SAFE USE: *Primum non nocere*

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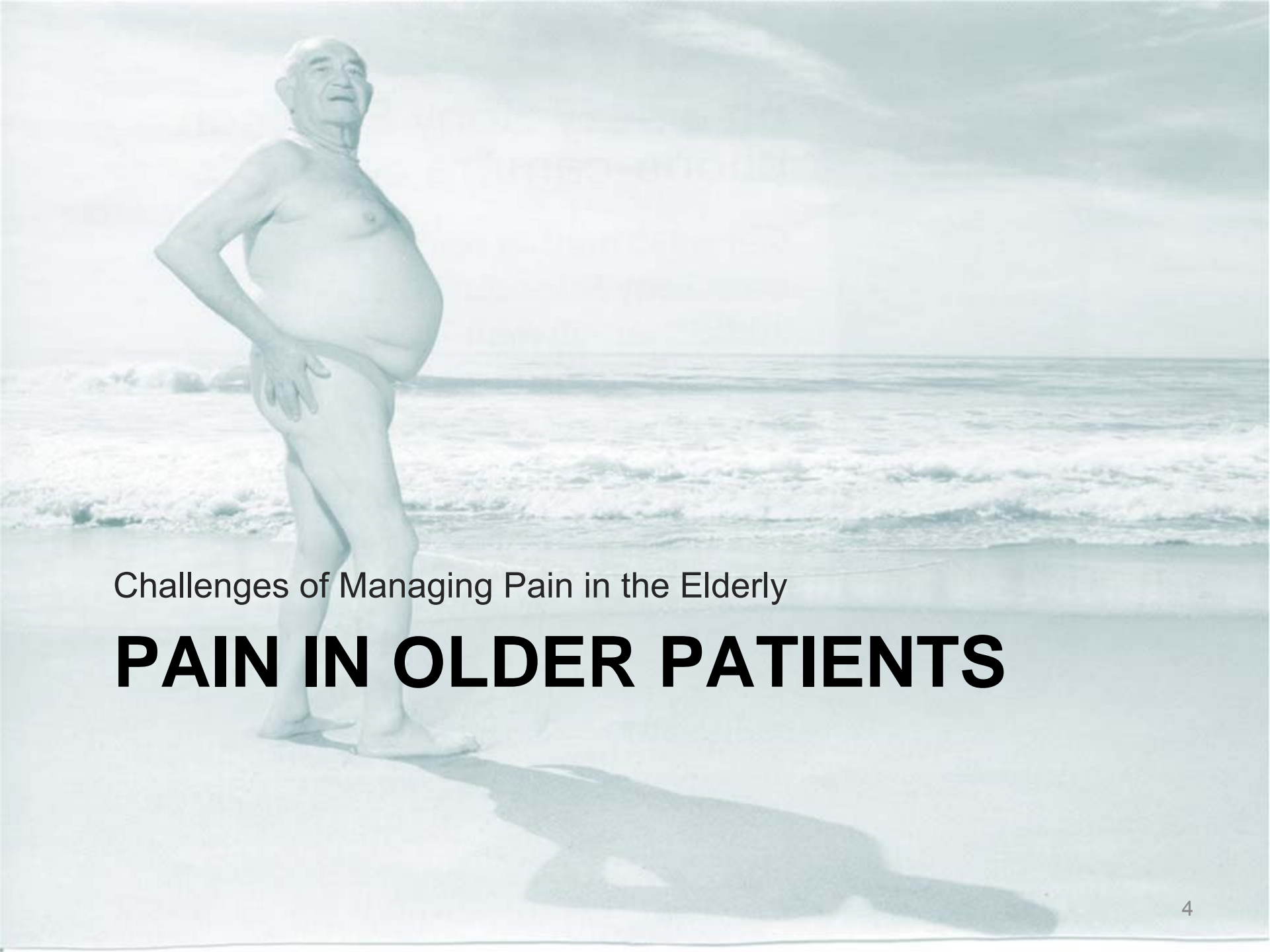
Association of Chronic Pain Patients



Definition of Pain

- Defined as an unpleasant sensory or emotional experience associated with actual or potential tissue damage or described in terms of such damage
- The World Health Organization (WHO) has stated that pain is one of the most underestimated healthcare problems in the world...
- Several international health authorities, including the WHO, and the International Association for the Study of Pain (IASP), have promoted the idea that adequate pain management is a fundamental human right, based on legal and bioethical rationale





Challenges of Managing Pain in the Elderly

PAIN IN OLDER PATIENTS

Pain Prevalence

- A US study of 1000 community-dwelling seniors (mean age 75.3 ± 6.7 years) found 74% reported pain in past 30 days
 - 52% had daily pain
 - 26% reported “agonizing pain”
- Analgesic use in this study was correlated with pain frequency and severity
- 28% in this study reported pain but took no analgesics

Most Geriatric Patients Have at Least One Comorbid Condition

- 82% of Medicare beneficiaries have ≥ 1 chronic disorder and 24% have ≥ 4 chronic disorders Hypertension 41%
- Arthritis (diagnosed) 49%
- Heart disease 31%
- Obesity 27%
- Any cancer 22%
- Diabetes 18%
- Sinusitis 15%

Factors that Complicate Pain Management in Older Adults

- Polypharmacy
 - Rate: 9% to 39% of geriatric population
 - 81% take ≥ 1 prescription drug
 - 29 % take ≥ 5 prescription drugs
 - 42% take ≥ 1 OTC drug
 - 49% take ≥ 1 supplement

Guideline Gap

- Preventing Medication Errors, Rule #5 states that patients should receive care based on best-available scientific knowledge
- Best practice recommendations have failed to translate to the care of geriatric pain patients

2008 OLYMPICS: SWIMMING

To the naked eye, it appeared that Cavie

"HE GOT HIM,"

Bowman, said.

But. . . . No!

TIPPING POINT

In the 100-meter Cavie fight in all points and then Bowman made the mistake of taking his head too early. For complete details of how these photos were shot, including an interview with the photographer, go to SI.COM/OLYMPICS

SI.COM/OLYMPICS

GAPS in Pain Management Quality

Underuse

Overuse

Misuse

Results of Inadequate Analgesia

- Reduced quality of life
- Decreased appetite, poor nutrition
- Impaired sleep
- Mood disorders, particularly depression
- Diminished function
- Reduced cognitive performance
- Risk of disability, inability to perform ordinary activities
- May be a form of “elder abuse”!

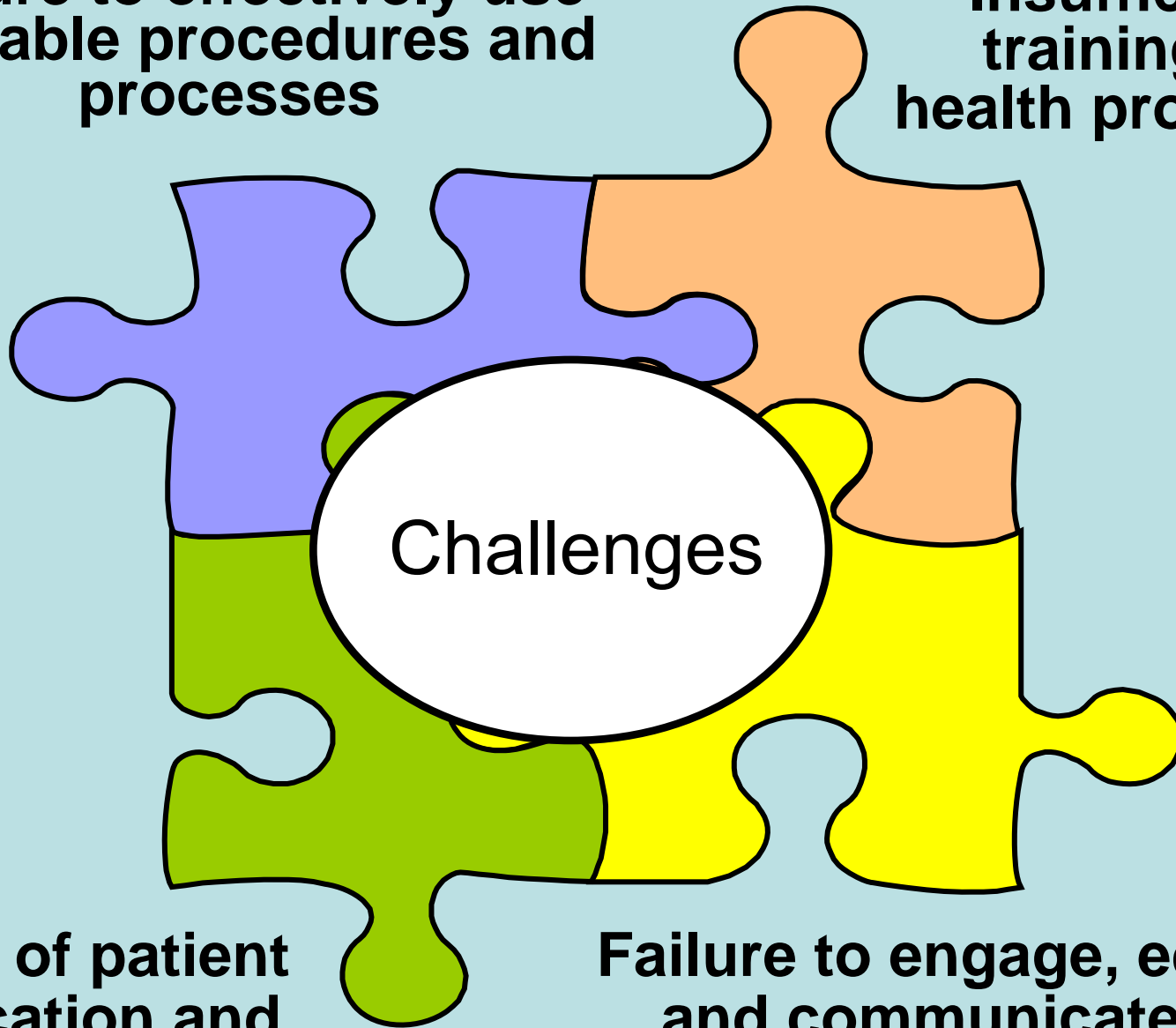
FDA Round Table

September 30, 2010

- Experts in geriatrics, pain management and medication safety
- Represented many parts of healthcare
 - academia, government, health care plans, consumer advocacy
- Discussed challenges to optimal use of pain medications in older adults
- Task: Identify area(s) of focus for safe use activities

**Failure to effectively use
available procedures and
processes**

**Insufficient
training of
health providers**



**Lack of patient
education and
awareness**

**Failure to engage, educate,
and communicate with
relevant stakeholders**



Challenges in Managing Pain in the Elderly

Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs

- Mainstay of chronic pain management
 - No stigma, no concern re: addiction
 - Widely available
- Significant dose-related, age related risks:
 - CV, renal, hematologic, GI, other organ systems
- Older patients are at increased risk of AEs
 - Drug-induced adverse events may actually lead to adding more drugs - “The prescribing cascade”
- Older patients are more likely to take multiple medications that increase risk for serious drug-drug interactions

NSAID – Risks in Older Adults

- GI toxicity especially among ≥ 75 years; similar to risk of patients with peptic ulcer
- 1.7 x more likely to require antihypertensive therapy vs. younger patients
- 10 fold increase in risk of falls
 - Suspicion that CNS effects are the cause
 - Falls also linked with CNS agents, diuretics, and hypnotics

Stillman MJ, Stillman MT. choosing nonselective NSAIDs and selective COX-2 inhibitors in the elderly. *Geriatrics*. 2007; 62:26-34

Walker, PC, Alrawi A, Mitchell JF et al Medication use as a risk factor for falls among hospitalized elderly patients. *Am J Health Syst Pharm*. 2005 Dec 1;62(23):2495-9.

Hageman, J, van den Bernt, BJ, Duysens J van Limbood J. NSAIDs and the risk of accidental falls in the elderly: a systematic review. *Drug Saf*. 2009;32(6):489-98.

Should Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) be Prescribed to the Older Adult?

Robert L. Barkin,^{1,2} Mihail Beckerman,³ Steven L. Blum,³ Frank M. Clark,⁴ Eun-Kyu Koh⁴
and Dickson S. Wu³

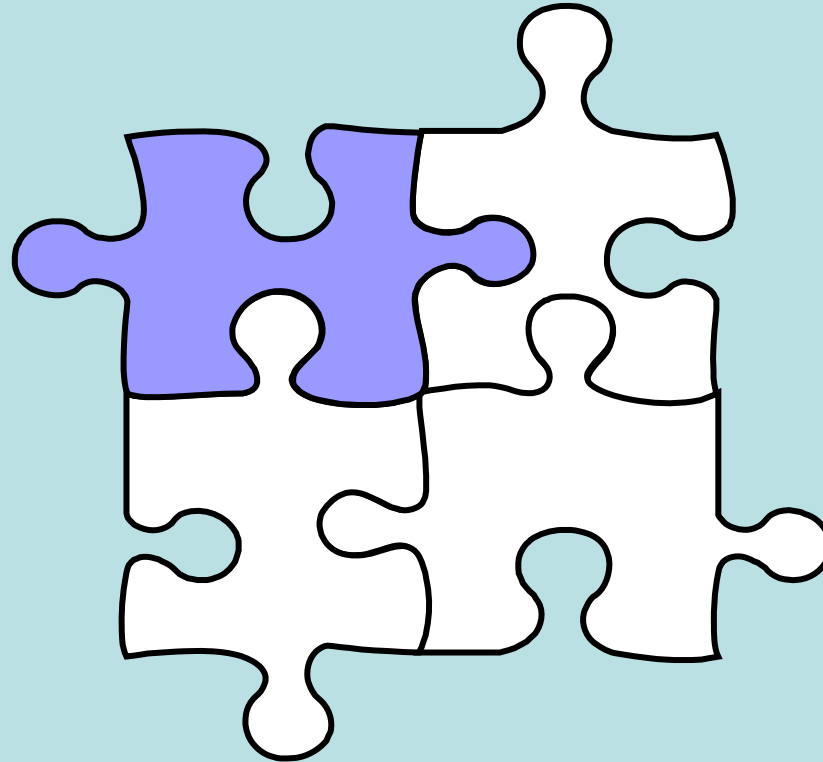
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4 North Shore University Health System Pain Center, Evanston Hospital, Evanston, Illinois, USA

Addressing the Challenges



**Effectively use
existing processes and procedures**

Effectively use existing processes and procedures

- Prescribing decisions: key considerations:
 - Efficacy of the agent in older patients
 - Likelihood of adverse drug events
 - Appropriate dose, formulation, delivery
 - Ability to monitor for adverse events
 - Other drugs the patient is taking
- Take time to discuss harm/benefit with patient

Table 1. Prescribing nonsteroidal anti-inflammatory drugs (NSAIDs) in older adults: general considerations

- Before prescribing an NSAID, clinicians should take a thorough medical history that includes all co-morbidities, medications (including over-the-counter and herbal medications) and alcohol and tobacco use
- Before beginning therapy, patients should have tests for renal function, hepatic enzymes, platelets, and complete blood count
 - Contraindications for NSAIDs include heart failure, creatinine clearance $< 50 \text{ mL} \cdot \text{min}$, hyponatraemia, hypovolaemia, nephrotic syndrome and liver failure with ascites
- After initiation of NSAID therapy, patients should be evaluated every 2–4 weeks for the first three or four visits
- NSAIDs should be administered at the lowest effective therapeutic dose
 - Brief episodic NSAID therapy is preferable to long-term NSAID therapy
 - NSAIDs with a short half-life may pose less risk of gastrointestinal bleeding than those with a longer half-life
 - Topical NSAIDs are an option for patients with pain in superficial joints
 - Tramadol or tramadol-paracetamol (acetaminophen) is an alternative to stronger opioids when central analgesia is required and NSAIDs are contraindicated
- Patients receiving NSAIDs should consult a physician before taking additional prescribed or over-the-counter analgesics

Revised AGS Guidelines

- Recently updated American Geriatrics Society (AGS) Management Guidelines for older patients with persistent pain recommend that:
- NSAIDs and COX-2 inhibitors should be considered *rarely*, and with *extreme caution*

SPECIAL ARTICLE

Pharmacological Management of Persistent Pain in Older Persons

American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons

Pain is a complex phenomenon caused by noxious sensory stimuli or neuropathological mechanisms. An individual's memories, expectations, and emotions modify the experience of pain.¹ Persistent pain, by definition, continues for a prolonged period of time and may or may not be associated with a well-defined disease process. In the medical literature, the terms "persistent pain" and "chronic pain" are often used interchangeably, but the newer term, "persistent pain," is preferred, because it is not associated with the negative attitudes and stereotypes that clinicians and patients often associate with the "chronic pain" label.^{1,2} In the definition of persistent pain, authors have used various durations of painful sensation, including pain longer than 3 months, 6 months, or more. Some reports make the assumption that patients with certain diagnoses, such as postherpetic neuralgia, low back pain, or cancer-related pain, must also experience persistent pain. In the final analysis, readers must evaluate new additions to the medical literature carefully and consider how these sometimes arbitrary definitions apply to each clinical situation and individual patient.

Demographers, insurers, and employers have defined older persons as aged 65 and older. By age 75, many persons exhibit some frailty and chronic illness, with many having multiple chronic illnesses. In the population aged 75 and older, morbidity, mortality, and social problems increase rapidly, resulting in substantial strains on the healthcare system and social safety net.^{3,4} The American Geriatrics Society (AGS) Panel on Pharmacological Management of Persistent Pain in Older Persons focused its attention on this older frail population in preparing this update.

Persistent pain commonly affects older people⁵⁻⁷ and is most frequently associated with musculoskeletal disorders, such as degenerative spine conditions and arthritis. Night-time leg pain (stemming from muscle cramps, restless legs, or other conditions) and pain from claudication are also

common. As many as 80% of older persons diagnosed with cancer experience pain during the course of their illness,⁸ and pain that occurs as a consequence of cancer treatment is increasingly recognized as a form of persistent pain.⁹ The distress of cancer pain creates an obligation for clinicians to provide effective pain management, particularly near the end of life. Persistent pain is also frequently encountered in nursing homes. Many nursing home residents have multiple complaints and numerous potential sources of pain.^{10,11} Neuralgia secondary to diseases such as diabetes mellitus, infections such as herpes zoster, peripheral vascular disease, and trauma, including surgery, amputation, and other nerve injuries, is somewhat less frequent.

Persistent pain or its inadequate treatment is associated with a number of adverse outcomes in older people, including functional impairment, falls, slow rehabilitation, mood changes (depression and anxiety), decreased socialization, sleep and appetite disturbance, and greater healthcare use and costs.¹² Although appropriate treatment can reduce these adverse events, the treatments themselves may incur their own risks and morbidities. Persistent pain can also be as distressing for the caregiver as for the patient. Caregiver strain and negative caregiver attitudes can substantially affect the patient's experience of pain and should be evaluated and discussed during the clinical encounter, if present.

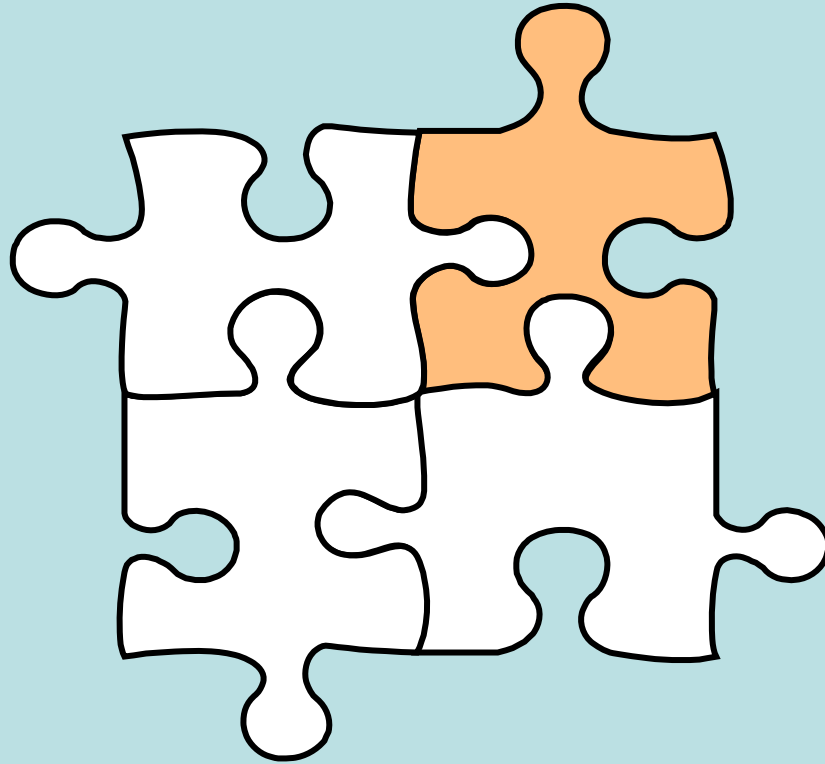
Guideline Development Process and Methods

The American Geriatrics Society (AGS) provided the first Clinical Practice Guideline on management of chronic pain in older persons in 1998.¹³ This landmark publication became a call to arms for improving pain management, quality of life, and quality of care for older patients. In 2002, the publication was revised to include new pharmacological and other strategies for improving patient care, as well as new information on the assessment of pain in patients with cognitive impairment.¹² The focus of these efforts has been to provide education and guidance to primary care clinicians, researchers, and other health professionals as they encounter patients with persistent pain and its complications.

American Geriatrics Society, New York, New York.
AGS Panel on Pharmacological Management of Persistent Pain in Older Persons.

This is an update to the AGS Panel on the Pharmacological Management of Persistent Pain in Older Persons, published in 2002.

Addressing the Challenges



Health care provider education

Provider Education

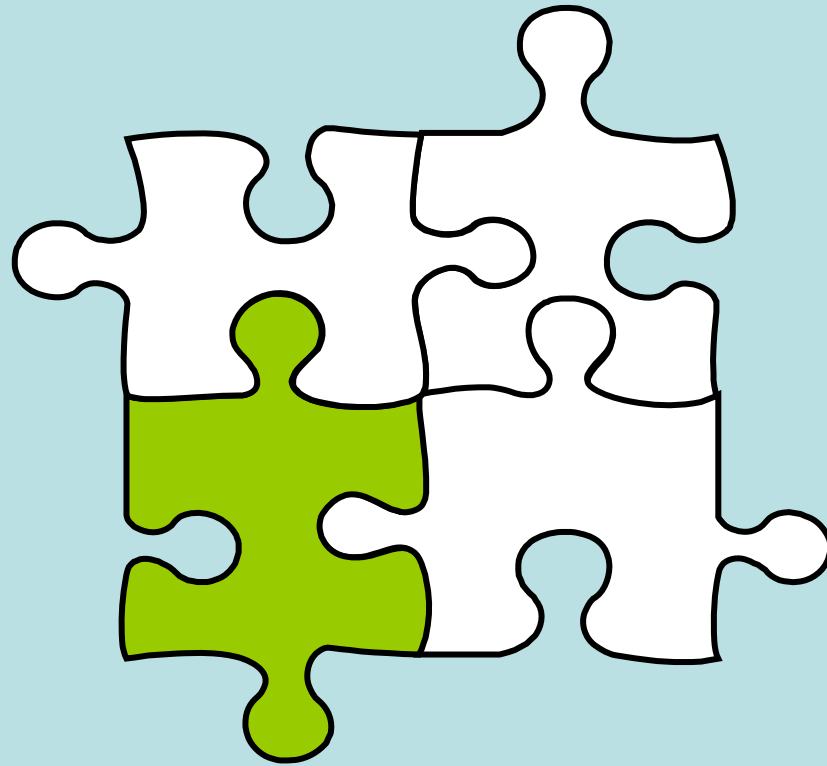
- Facts

- Geriatric pain patients typically present with multiple co-morbidities requiring treatment.
- Scarcity of published data relating to chronic pain in elderly
- Geriatric pain is often undertreated or not treated at all
- Increased specific training in analgesia, geriatric care is needed

- Drug interactions

- Exposure to potential drug-drug interactions is likely underestimated by prescribers
 - 26% rate of exposure in chronic low back pain population
 - 26.5% rate of exposure among general elderly population
- We need to reevaluate our approach to the treatment and management of pain in the elderly

Addressing the Challenges

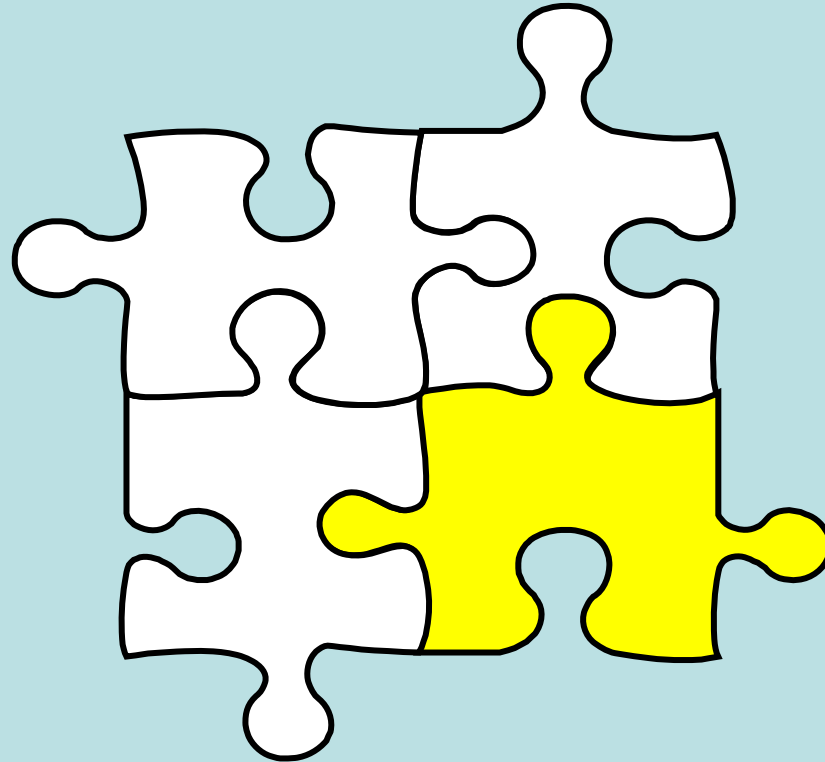


**Engage and educate patients
and caregivers**

Educate and Engage Patient/Caregiver

- The importance of analgesia
 - Acute to chronic pain transition
 - Risk of depression and mental health issues
 - Risk of impairment
- Importance of a complete medication history
 - Concurrent medications/supplements are rarely disclosed to physicians
 - May not be perceived as important
 - Encourage OTC/supplement disclosure

Addressing the Challenges



**Engage, educate, and communicate
with relevant stakeholders**

Engage Relevant Stakeholders

- Identify the variables and factors that influence a patient's perception of pain and attitudes about pain treatment
- Address how older adult patients receive health information
- Encourage and facilitate training of HCPs in treating pain in older adults
- Identify interventions that were shown to be successful
- More studies to address the effects of drugs in older individuals

IMPLEMENTATION

- Ignite
- Inspire
- Engage
- Excel
- Blue Sky approach towards implementation
- Organic growth
- Achievable realistic outcomes

Consensus Manuscript

BEACON: BEst prACtices Of safe NSAID use

- SUI Steering Committee to conduct a quantitative systematic review of the literature related to best practices for NSAID safe use.
- Provide critical insight into established safe use processes.

Principals of the Program

KISS Principle:

1. A Healthcare Provider and
Patient Orientated Approach

When it comes to NSAID use:

*Healthcare providers need to ask
about usage*

Patients need to take about usage

“Do ask, Do tell” policy

2. Web-based – medically edited
we site that provides product
centric listing of NSAID safety

3. Bee Safe E-learning modules for
patients and healthcare provides.





better records. better healthcare. better you

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SUPPORT TRIAL : Safe Use Pilot PrOgRam in The elderly

- Pilot program designed to assess baseline knowledge, Attitudes and Practices (KAP) related to safe use of NSAID's in the elderly
- Patient centric self reported medication use of NSAID's collected on portable propriety e-health card platform
- NSAID Utilization Information is inputted by the patient and monitored by Healthcare Provider (HCP)
- Program contains a modular based Safe Use NSAID educational program for patients and caregivers
- Tangible outcome measurements on utilization and K.A.P. related to NSAID's



NEMA Research Inc.

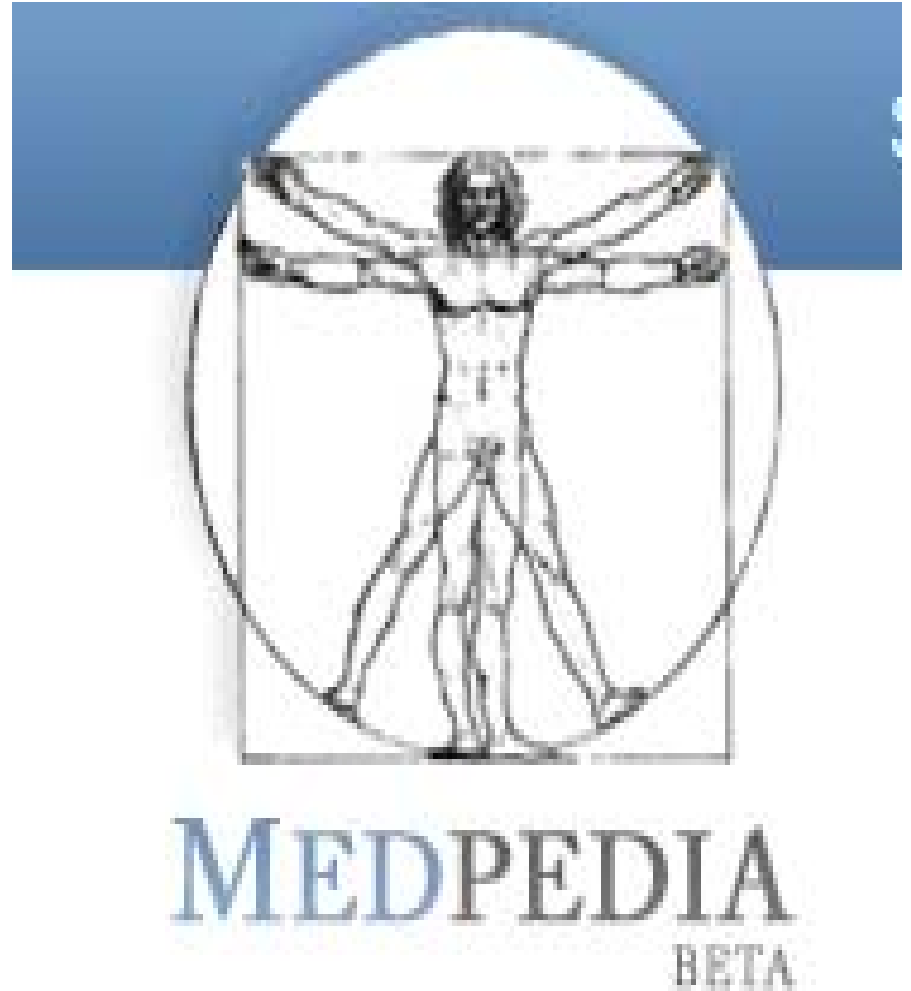
MEDPEDIA: SAFE USE INITIATIVE COMMUNITY AND ORGANIZATION

Medpedia is an open platform connecting people and information to advance medicine

Medpedia Editors are physicians and Ph.D.s in the biomedical field who have each had their credentials carefully checked and verified. They are responsible for writing, editing and overseeing the content on the medical encyclopedia portion of the Project.

Medpedia Organizations allow health-related associations, companies, hospitals, working groups, and organizations to network and communicate with each other.

Medpedia Communities allow people with common health interests to share information and communicate. Anyone may create a community of interest and anyone may join.



ACTION PLAN




Safe Use Initiative, through which FDA seeks to join in partnership and collaboration with relevant stakeholders to measurably reduce preventable harm from medications and improve patient health.

IMPLEMENTATION

Assuming there exists an openness to collaboration:

- How could or would you or your organization be able to contribute?
- What can you or your organization offer as a stakeholder?
- Who else do you think needs to be involved?



*“Greatness is not in where we stand, but in
what direction we are moving. “*

Oliver Wendell
Holmes



Thank you



OPEN DISCUSSION TIME

**SAFE
USE**

The logo consists of the words "SAFE" and "USE" in a bold, black, sans-serif font, stacked vertically. The letter "U" in "USE" is replaced by a stylized pill icon. The pill is white with a black outline and is filled with a solid red color, representing the lower half of the pill.