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EDITORIAL

New opioid prescribing guidelines released in the US: what impact will they have in the care of older patients with persistent pain?

A focus on older adults and the use of opioid treatment for persistent pain is warranted given the high prevalence of pain and its impact in later life, as well as the substantial prevalence of opioid treatment in older adults. Almost half of all adults over age 65 daily experience persistent and debilitating pain due to multiple causes[1], including degenerative arthritis, spinal stenosis, and nerve damage (e.g. post-herpetic and diabetes). Persistent pain is associated with substantial disability in this age group, characterized by reducd mobility, activity avoidance, increased risk of falls, and psychosocial morbidity, including depression, anxiety, and social isolation. Pain relief constitutes one of the most commonly endorsed goals of older adults and a large body of evidence now demonstrates that advanced age is a risk factor for under-treatment of pain[2]. Possibly in response to this finding, US providers are prescribing opioids to older adults in record numbers. One large study examined prescribing patterns from 1999 to 2010 in the US and found that almost one in ten older patients received an opioid prescription[3]. In 2015, as many as 30% of Medicare Part D enrollees received an opioid prescription suggesting that opioid prescribing continues to increase in this age group[4].

Parallel to the dramatic increase in medical prescriptions of opioids (POs), which has occurred over the past two decades in the US, non-medical and misuse of POs has also strongly increased. Although an increase in prescribing strong opioids has also taken place in most EU countries over the past 15 years, the total number of prescriptions and PO-related mortality rates remain far lower than in the US[5]. The public health consequences of the opioid epidemic in the US have been profound to include record numbers of unintentional overdoses as well as overdose-related deaths (more than 165,000 over a 16 year period)[6].

In an effort to address the opioid epidemic, the Centers for Disease Control and Prevention (CDC) recently released a guideline for prescribing opioids for chronic pain[7]. The recommendations focus on the treatment of patients with chronic non-cancer pain (hereafter referred to as persistent pain) as opposed to those receiving active cancer treatment or palliative/end-of-life care. The guideline presents recommendations to help providers: (1) determine when to initiate opioids and guidance regarding the selection and dosing of opioids; (2) establish whether treatment benefits are occurring and decide whether to continue opioid therapy; and (3) conduct risk assessments and address harm that occurs as a consequence of opioid use. In this editorial, we review elements of the CDC guidelines that we believe could have positive or negative consequences when providing care to older adults with persistent pain. We also speculate about the implications of implementing the guidelines from a geriatric medicine perspective.

In the sections below, we examine several of the CDC guidelines, highlighting their positive and problematic elements. We also raise questions about what impact implementing the guidelines could have on the care of older adults with persistent pain (Table 1). Readers are strongly encouraged to review all 12 recommendations that are part of the guideline[3].

Determining when to initiate or continue opioids for chronic pain

CDC Recommendation 1: "Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain"

This recommendation is problematic from a geriatric medicine perspective for several reasons. Non-opioid therapies such as NSAIDs (which would likely be the treatment most clinicians prescribe as alternative therapy) have well established risks that increase significantly with age[8] and they should be used with extreme caution in older adults given their significant cardiovascular, gastrointestinal, and renal risks[9]. Moreover, this recommendation conflicts with current guidelines promulgated by the American Geriatrics Society[10] and the British Pain Society/British Geriatrics Society (BGS)[11]. Both guidelines, which are specific to the management of persistent pain in older persons, recommend minimizing NSAID use even in the short term. Given the conflict, which guideline should clinicians follow in the care of older adults with persistent pain? In addition, many NSAIDs are available as over-the-counter formulations and older patients may not consider their use to be dangerous and may not mention them to their physicians[8]. Paracetamol (acetaminophen) is another non-opioid therapy whose use will likely increase if the CDC guidelines are widely implemented. However, paracetamol is an extremely weak analgesic. Many reports are emerging that it is ineffective against common disorders that disproportionately affect older adults[12]. Greater use of paracetamol will likely increase the proportion of older adults whose pain remains undertreated. In addition, the long-term safety and efficacy of adjuvant agents (e.g. anticonvulsants, anti-depressants) advocated as part of the CDC guidelines have yet to be established.

The guideline further encourages the use of non-opioid therapies in large part because there is currently no evidence demonstrating the long-term efficacy of opioid treatment for

Table 1. Recommendations when implementing CDC guidelines in older adults.

CDC Recommendations	Comments
• Non-opioid pharmacotherapies are preferred for the treatment of persistent pain (CDC Recommendation 1).	• This recommendation will likely lead to increases in the number of NSAIDs (risk of cardiovascular, gastrointestinal and renal toxicities) and paracetamol prescriptions (risk of undertreated pain).
• Non-pharmacological therapies (i.e. physical activity, psychotherapy) are recommended for persistent pain (CDC Recommendation 1).	• Access to non-pharmacologic therapies is limited in many settings due to multiple barriers, (e.g. limited work force capacity to deliver these therapies, insurance plans that do not cover their costs).
• Clinicians should continue opioid therapy only if there is clinically meaningful improvement (i.e. 30% of greater score improvement on measures) of pain and function (CDC Recommendation 2).	• It could limit access to pain relief and opioids to many older adults. • A palliative (versus chronic disease) care approach is appropriate for many older adults where the chief goal is improving quality of life.
• Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy (CDC Recommendation 3).	• Disclosing the known benefits and risks of therapy constitute a key element of shared decision-making.
• When opioids are started, clinicians should prescribe the lowest effective dosage (CDC Recommendation 5).	• This recommendation is particularly appropriate in the care of older patients, given that age increases risk of side effects. • However clinicians should not be afraid to augment the dose of an opioid over time if treatment goals have not been met.
• Clinicians should evaluate benefits and harms with patients within 1–4 weeks of starting opioid therapy for chronic pain and after each dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently (CDC Recommendation 7).	• Many clinicians who prescribe long-term opioids for persistent pain agree that a subset of patients treated with opioid therapy is helped. • Tools to weigh formally the benefits and risks that may accrue from opioid use in older adults are lacking.
• Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms (CDC Recommendation 8).	• While this recommendation is prudent, advanced age appears to be a protective factor from the standpoint of opioid misuse/abuse and overdose.
• Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible (CDC Recommendation 11).	• This recommendation is particularly appropriate when treating persistent pain in later life, given the high prevalence of benzodiazepine use in older patients.

CDC: Centers for Disease Control and Prevention; NSAID: non steroidal anti-inflammatory drug.

persistent pain. But just because there is no data demonstrating the long-term value of opioids in patients with persistent pain does not mean there is no value. A lack of evidence does not mean evidence of no effect. Many clinicians who prescribe long-term opioids for persistent pain agree that a subset of patients treated with opioid therapy is helped[13]. What we currently lack is a way of identifying this sub-group of patients before embarking on opioid trials for the larger number of patients where side effects/harms occur leading to discontinuation of the therapy.

CDC Recommendation 1c: "If opioids are used, they should be combined with non-pharmacological therapy and non-opiod pharmacologic therapy, as appropriate"

There is substantial evidence to support this recommendation in patients of all ages[9–11]. While we strongly support this recommendation, it is important to note that many health systems are not adequately equipped to deliver non-pharmacologic (e.g. behavioral and exercise) therapies. In addition, many insurers do not cover their costs or only partially cover the costs. Finally, limited access to these therapies remains a problem given the dearth of healthcare providers who are currently trained to deliver non-pharmacologic therapies such as cognitive–behavioral therapy, meditation, relaxation, etc.

CDC Recommendation 2: "Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety"

The CDC defines "clinically meaningful improvement" as a 30% improvement in patient scores on standardized measures of both pain intensity and function. While a focus on ensuring that both pain and function improve with opioid treatment seems reasonable, many older adults have conditions (e.g. advanced arthritis, spinal stenosis, post-stroke pain) where a meaningful improvement in function is unlikely to occur. We believe that the requirement for a 30% improvement or greater threshold "sets the bar too high" for many older patients. What if an older patient's pain score improves by 30% but her (or his) function does not? It is important to remember the dictum "*cum grano salis*" which translates roughly into doing something wisely. While we can aspire to both reduce pain and improve function these goals should be determined on a case-by-case basis when treating older patients. An important aging issue is recognizing that a palliative care approach is both appropriate and necessary when treating pain in many older adults, particularly those with advanced age, frailty, or both.

In these cases, mitigating pain to improve quality of life is an appropriate goal on its own as corresponding improvements in function are not likely to be achieved. Strict adherence to this recommendation, i.e. the requirement that both pain and function level improves by at least 30%, will result in many older adults losing access to opioid therapy.

Opioid selection, dosage, duration, follow-up, and discontinuation

CDC Recommendation 3: "Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy"

We fully agree with this recommendation as disclosing the known benefits and risks of therapy constitutes a key element of shared decision-making and is important to do irrespective of patient age. This process requires that a careful assessment of the benefits and harms of non-opioid treatments be undertaken as well. Such discussions might alter the risk/benefit ratio of a given treatment, and alter the decision about whether to initiate a trial of an opioid medication, i.e. in a 90 year old female patient with congestive heart failure and renal insufficiency the risks of short-term NSAIDs may well outweigh the risks of a trial of an opioid therapy. This tailored approach should be the cornerstone for the safe, effective use of pharmacological agents to manage persistent pain in older adults[14].

Notably, when establishing a clinically meaningful benefit from analgesic therapy in older adults, clinicians typically lack the tools to weigh formally the benefits and risks that may accrue. In the future, this gap should be the focus of future research and corresponding consensus statements, that help clinicians to carry out this important task.

CDC Recommendation 5: "When opioids are started, clinicians should prescribe the lowest effective dosage"

This recommendation is appropriate in the care of older patients, given that age increases risk for deleterious side effects[9]. Prescribing the lowest effective dose of a given opioid should decrease the risk of untoward effects when treating this population of patients. On the other hand, clinicians should not be afraid to augment the dose of opioid therapy over time if treatment goals have not been achieved and the patient is tolerating the treatment.

A multi-disciplinary approach to pain management and establishing a mutual partnership between patient and practitioner can both help to maintain low doses of opioids thereby reducing the risks of adverse effects in patients who are prescribed opioid over long periods of time.

Assessing risk and addressing harms of opioid use

CDC Recommendation 8: "Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms"

Risk factors for opioid-related harm include a history of mental health conditions, a substance use disorder and prior overdose attempts. While this recommendation is prudent, it is important for clinicians to remember that advanced age appears to be a protective factor from the standpoint of opioid misuse/abuse and overdose[15].

CDC Recommendation 11: "Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible"

This recommendation is particularly appropriate when treating persistent pain in older patients, given the high prevalence of benzodiazepine use. One estimate reveals that as many as one in 10 women aged 65 and above take benzodiazepines[16].

Summary

The CDC guidelines are a response to the opioid epidemic, which has had devastating consequences on the health and lives of millions of individuals in the US. While many of the recommendations are appropriate for patients of all ages, several should be employed with caution when caring for older patients with persistent pain. Implementation of Recommendation 1 will likely lead to wide-scale increases in the number of 1) NSAID prescriptions, which will have negative health consequences for large numbers of older adults in the form of cardiovascular, gastrointestinal and renal toxicities, and 2) paracetamol prescriptions, which will likely lead to increases in the number of older patients with undertreated pain. Furthermore, recommending that clinicians prescribe non-pharmacologic therapies is appropriate but problematic. Most healthcare providers are not currently trained to deliver or have ready access to these types of therapies in their communities. In addition, many insurers do not cover their costs further exacerbating access to this type of treatment. Requiring that patients experience clinically meaningful improvement in both pain and function will mean that large numbers of older adults (whose pain is being managed palliatively) will not continue to have access to opioid therapy. Finally, while clinicians should remain alert for signs of possible opioid abuse/misuse, it is important to remember that rates of misuse/abuse are lower in older patients. However, this protective effect may not be present in aging baby boomers. We are faced with balancing the need to relieve pain and its consequences when inadequately treated, i.e. suffering, disability, and diminished quality of life, with the significant morbidity and mortality that has occurred through widespread opioid use in treating patients with persistent pain. The struggle to achieve balance between these two outcomes involves not only

patients, providers, and health systems, but the communities they inhabit.

Opinions differ as to whether the CDC guidelines will, if implemented broadly, help us to achieve this balance. Only time will tell. We hope that the US experience with the guidelines provides important lessons and leads to the development and implementation of policies and strategies in EU countries (in particular Northern EU countries and the UK, where rates of opioid prescriptions are higher) that mitigate against the onset of a European opioid epidemic.

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