June 15, 2018

Ms. Alicia Richmond Scott
Designated Federal Officer, Pain Management Best Practices Inter-Agency Task Force
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Great Hall
200 Independence Avenue SW,
Washington, DC 20201

Dear Ms. Scott,

The American Society of Hematology (ASH) appreciates the opportunity to submit comments to the U.S. Department of Health and Human Services’ Pain Management Best Practices Inter-Agency Task Force. The Society encourages the Taskforce to consider the implications of pain in special populations, including patients with hematologic conditions, as the group develops recommendations for best practices for pain management.

ASH represents approximately 17,000 physicians, scientists, and medical trainees committed to the study of blood and treatment of blood-related diseases. ASH members include clinicians who specialize in treating children and adults with hematologic disorders and researchers who investigate the causes of disease and potential new treatments and therapies.

ASH recognizes that the opioid epidemic in the United States is a public health emergency that requires immediate attention. As our nation continues to address this epidemic, the Society wants to promote cautious, thoughtful, consideration in order to avoid unintended consequences for patients with chronic diseases. ASH recently released the attached Statement on Opioid Use in Patients with Hematologic Diseases and Disorders. The Society is concerned about potential adverse effects that policy changes could have on the administration of necessary and appropriate pain medicine for patients with hematologic conditions, such as sickle cell disease (SCD), blood cancers, and other bleeding disorders. The Society supports a public health approach that improves the way opioids are prescribed and reduces misuse and overdose, yet safeguards access to these drugs for acute and chronic pain treatment for individuals with certain clinical conditions. Patients, including those with the hematologic diseases, such as sickle cell disease (SCD), blood cancers, and bleeding disorders, who rely on opioids to treat their debilitating pain, should have opioids prescribed safely with proper follow-up. Additional research focused on acute and chronic pain in individuals with hematologic conditions, as well as research into new health care delivery strategies, is critical to ensure that patients with pain receive timely, state of the art pain management. ASH encourages the Taskforce to consider the provisions outlined in the attached statement as the group develops pain-related policies and/or recommendations.

Thank you for the opportunity to provide these comments. We welcome any discussion on this issue. If you have any questions or require further clarification, please contact Stephanie Kaplan, ASH Senior Manager, Government Relations and Public Health at skaplan@hematology.org or 202-292-0263.

Sincerely,

Alexis Thompson, MD, MPH
President
ASH Statement on Opioid Use in Patients with Hematologic Diseases and Disorders

The American Society of Hematology (ASH) represents approximately 17,000 physicians, scientists, and medical trainees committed to the study of blood and treatment of blood-related diseases. ASH members include clinicians who specialize in treating children and adults with hematologic disorders and researchers who investigate the causes of disease and potential new treatments and therapies.

According to the Centers for Disease Control and Prevention, overdoses from prescription opioids in the United States have contributed to the 15-year increase in opioid overdose deaths and nearly half of all opioid overdose deaths involve a prescription opioid. The Society is alarmed about the opioid crisis; however, is concerned about potential adverse effects that policy changes could have on the administration of necessary and appropriate pain medicine for patients with hematologic conditions such as sickle cell disease (SCD), blood cancers, and other bleeding disorders.

Background

Pain in Sickle Cell Disease

Recurrent severe acute painful crises and chronic daily pain are the most common complications of SCD. Severe acute painful crises often require treatment in the hospital emergency department. In addition, many patients manage both their acute pain and chronic pain at home. Adequate management of acute and chronic pain associated with SCD is an ongoing challenge both for patients and the clinicians responsible for their care. A 2014 report by the National Heart, Lung, and Blood Institute (Evidence Based Management of Sickle Cell Disease: Expert Panel Report, 2014) that provides guidance on the management of acute and chronic SCD-associated pain, acknowledges that acute painful crises are the most common complication of SCD and this pain can be excruciating. Chronic pain from a variety of causes including avascular necrosis (death of bone tissues due to a lack of blood supply), leg ulcers, and other neuropathic pain, is also prevalent. Opioids may be the only option to provide relief and allow patients to function.

The clinical complexities associated with pain management for people living with SCD have been a focus of ASH’s own multifaceted SCD initiative. The Society’s effort seeks to ensure that all patients are able to access quality care for SCD, especially in areas of the country that lack providers with the comprehensive knowledge and expertise to care for people with SCD.

ASH is developing education and training modules for hematologists and other health care providers to ensure the proper care for individuals with SCD. The Society is also drafting new evidence-based clinical practice guidelines to inform the management of acute and chronic pain for individuals with SCD. Our goal in these efforts is to increase the use of evidence-based practices for acute and chronic pain management for the patients we serve.

Pain in Blood Cancers

Pain is also a common and undertreated symptom in patients with cancer, affecting patients in active treatment as well as those with terminal disease. Opioids are commonly prescribed to patients with leukemias, lymphomas, myeloma, and myeloproliferative neoplasms. Survey studies of patients with myelodysplastic syndromes (MDS) suggest that bone pain is a relatively common occurrence. Pain is a common symptom during and/or after induction chemotherapy in patients with acute myeloid leukemia. Pain is also seen in patients with various other types of leukemias due to the effect of the cancer cells destroying bone, cancer cells growing dramatically and placing pressure upon the bone marrow, and the growth of tumors within the spleen, liver and lymph glands. Patients with lymphoma may develop metastatic tumors to the bone where they can cause intense, unremitting pain, or may cause pain...
through the compression of nerves by rapidly growing tumor masses. More than 90% of patients with myeloma develop lytic bone disease which causes chronic pain and fractures.

Recommendations from multiple organizations including the World Health Organization, the National Comprehensive Cancer Network, and the European Society for Medical Oncology support the use of opioids as a treatment option in patients with cancer.

*Pain in Other Hematologic Disorders*

Patients with bleeding and clotting disorders can develop severe pain requiring short term and long-term use of opioids. Joint bleeding is the major clinical manifestation of hemophilia. Patients of all ages can suffer painful joint bleeds requiring opioids, while a third of adults with hemophilia have chronic pain often requiring opioid use due to chronic disease of the joints. Cryoglobulinemia, a hematologic disorder that causes a presence of abnormal proteins in the blood, can occasionally cause very painful skin lesions and require opioids to reduce pain. Severe post-thrombotic syndrome (PTS) is a chronic complication of deep venous thrombosis (DVT); more than one-third of patients with DVT will develop PTS, and five to ten percent of patients will develop severe PTS, which may manifest with ulcerations that can be painful and warrant chronic opioids.

*ASH Policy*

ASH recognizes that the opioid epidemic in the United States is a public health emergency that requires immediate attention. At the same time, ASH urges caution as policy makers propose changes to opioid prescribing that might result in unintended consequences. Patients with hematologic diseases often experience debilitating pain as a result of their disease, for which opioid medications may be the only effective treatment option.

The Society supports a public health approach that improves the way opioids are prescribed and reduces misuse and overdose yet safeguards access to these drugs for acute and chronic pain treatment for individuals with certain clinical conditions. The management of chronic pain is a multifactorial problem that requires a team effort including psychologic and social support to enhance functional long-term outcomes. Patients, including those with hematologic diseases such as SCD, blood cancers, and bleeding disorders who rely on opioids to treat their debilitating pain, should have opioids prescribed safely with proper follow-up. Medical specialty societies can play an important role in educating and training their members. ASH is committed to developing evidence-based clinical practice guidelines and professional education activities in pain management.

Every patient should have access to the approved evidence-based treatments for their disease and associated symptoms as recommended by their physician. Patients should not suffer from a lack of recognition of their pain nor should they have to suffer unnecessary delays in obtaining access to appropriate medications for which there is no effective substitute. Patients should be treated accordingly based on the type of therapy recommended and/or the most appropriate delivery mechanism in consultation with their physician and in coordination with other members of their health care team. Additional research focused on acute and chronic pain in individuals with hematologic conditions, as well as research into new health care delivery strategies is critical to ensure that patients with pain receive timely, state of the art pain management. Barriers and physician disincentives regarding the management of pain in hematologic conditions must be avoided.