American Society of Anesthesiologists®

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October 4, 2013

Howard K. Koh, M.D., M.P.H.
Assistant Secretary for Health
Department of Health and Human Services
Office of Disease Prevention and Health Promotion
1101 Wootton Parkway, Ste LL100
Rockville, MD 20852

Attn: Draft National ADE Action Plan

Dear Dr. Koh:

On behalf of over 50,000 members of the American Society of Anesthesiologists (ASA), I am writing in support of further development and refinement of the HHS National Action Plan for Adverse Drug Event Prevention. ASA appreciates the challenges ahead for expanding the Action Plan and offers its recommendations in these areas: 1) pain medicine and opioid use; 2) development of quality measures related to adverse drug events; and 3) use of Perioperative Surgical Home. ASA applauds the initiative of HHS in developing a National Action Plan to reduce adverse drug events; however, the document should include clear-cut recommendations and action items designed to proactively reduce adverse drug events (ADEs).

Pain Medicine and Opioid Use

ASA strongly believes that access to opioids must be balanced with efforts to reduce the misuse, abuse, and diversion of these medications, particularly those obtained through prescriptions. In June 2011, the Institute of Medicine released *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, finding that at least 100 million U.S. adults suffer from common chronic pain conditions. Given the prevalence of chronic pain, the National Action Plan should prioritize initiatives that will minimize prescription drug abuse while ensuring patient access to the medications they need.

Prescription Drug Monitoring Programs

One of the most effective approaches to reducing diversion is the development of real-time, state-based, prescription drug monitoring programs (PDMPs) that can interface with each other. PDMPs are important clinical tools that allow physicians to make a more informed decision about whether or not to prescribe controlled substances. ASA, therefore, continues to reiterate our strong support for funding and implementation of the National All Schedules Prescription Electronic Reporting (NASPER) Act. NASPER's public health focus provides the appropriate framework for state-based PDMPs. While there is a legitimate social need for law enforcement to identify "pill mills" that promote opioid abuse, physicians' support of PDMPs depends on continued assurance that law enforcement will not subject them to unwarranted "fishing expeditions."

Opioid Conversion Labeling
Use of equianalgesic opioid conversion tables, intended for safe conversion between opioid products, has resulted in prescribing errors, serious adverse events, and deaths. On July 29, 2013, ASA testified at a FDA public workshop on clinical development programs for opioid conversion and recommended a staged approach for opioid conversion labeling:

1. Labels should identify which conversions have sufficient evidence to make a conservative dose ratio recommendation for the initiation of a new opioid. The table should produce conversion ratios that are conservative enough that an additional automatic reduction in the calculated equianalgesic dose is not required and excludes opioids from standardized conversion scales that have known significant variability in bioavailability such as buprenorphine or methadone. For those medications that do not have sufficient evidence, no ratio can be listed until appropriate relative potency studies are performed.[1]
2. Federal funding sources should be used to develop comparative potency research studies in the chronic pain population that are opioid naïve in sufficient numbers to determine age, sex and directionality differences, at a minimum. The research studies should use a reference standard of oral morphine, report responses at peak effect and at stable state, the time to peak effect and stable state, and develop high, low and mean conversion ratios.
3. Federal funding sources should be used to repeat these studies in opioid tolerant chronic pain patients to address the effects of prior opioid exposure.

In the formal comments, ASA also recommended that the research findings and development of opioid conversion tables be communicated through peer-reviewed publications. In addition, opioid conversion tables should be available in print form and in electronic form, including web-based, tablet-based, and smartphone-based applications.

REMS for extended-release and long-acting (ER/LA) opioids
To help reduce opioid-related ADEs, ASA strongly supports the REMS for ER/LA opioids, and particularly the inclusion of voluntary continuing education programs at no cost to physicians. However, ASA believes that any program meant to address the abuse, misuse, or diversion of opioids should cover all opioid classes to avoid the unintended consequences of shifting problems from one group of drugs to another and reducing the number of physicians available to prescribe necessary pain medications**.** We encourage the FDA to apply the ER/LA REMS to all opioids, including transmucosal immediate release fentanyl (TIRF) products. We also urge the FDA, as part of its Action Plan, to review the effectiveness of ER/LA REMS, its impact on patient access, individual practitioners, and the healthcare delivery system, and whether it creates a spike in the misuse or abuse of other drugs.

Multimodal Pain Care

[1] While not stated in our testimony, ASA further believes that this determination should be clearly highlighted in conversion tables to help educate health care professionals of the need for caution with these agents.

ASA strongly advocates, based on current evidence, that multimodal interventions should be used to care for patients with chronic pain. Multimodal interventions complement other strategies included in the National Action Plan to reduce ADEs. According to ASA's Practice Guidelines for Chronic Pain Management,

> Multimodal interventions should be part of a treatment strategy for patients with chronic pain. The Task Force recognizes that a patient's pain and health status may change over time, necessitating reevaluations and changes in treatment. Therefore, a long-term approach that includes periodic follow-up evaluations should be developed and implemented as part of the overall treatment strategy. The goal of treatment should be to effectively reduce pain while improving function and reducing psychosocial suffering. When available, multidisciplinary programs may be used.[2]

ASA also believes that opioids should not be prescribed as first-line therapy to treat chronic non-cancer pain. Physicians should consider non-drug treatments such as behavioral and physical therapies prior to prescribing opioids. Physicians should also employ non-opioid analgesics both before and in combination with opioids when possible to improve pain relief and reduce total opioid dose requirements. If opioids are appropriate, physicians should consider using a Patient-Prescriber agreement and avoid co-prescribing opioids and benzodiazepines or methadone unless the physician is aware of their risks.

Patient Access to Naloxone

ASA sees the importance in patient access to naloxone to reduce the incidence of ADEs, especially opioid overdose fatalities. Prior to prescribing naloxone, it is imperative that physicians educate patients, as well as the patients' caregiver(s), about naloxone. Education should include: recognizing an opioid overdose; proper administration of naloxone; the importance of calling 911 immediately after administering naloxone; effectively administering rescue breathing; and information on the shelf life of naloxone. ASA recognizes that the side effects of naloxone, such as negative pressure pulmonary edema or extreme high blood pressure, can be severe. However, naloxone is a patient safety tool, and these side effects are treatable and preferable to an opioid-related death or severe end-organ injuries that may result from an opioid-related ADE.

Pain Research

Federal funding of pain research is inadequate to address the enormity of the public health burden related to chronic pain. Opioid-related adverse events reflect, in part, the lack of alternate therapies for this condition. The Interagency Pain Research Coordinating Committee, based at the National Institutes of Health, will summarize advances in pain research supported or conducted by federal agencies and identify gaps in pain research. That analysis should inform priorities for future research efforts, which should be supported with adequate federal funding to fill these key gaps.

[2] American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology 2010; 112(4):810-33.

One key research gap is the long-term efficacy of opioids for chronic pain. Fundamental questions bearing upon the benefit-to-risk ratio of opioids and other treatments for chronic non-cancer pain must be resolved, including the percentages of patients of various ages and genders who will become tolerant, dependent upon, or addicted to opioids during long-term therapy. This effort must be accomplished in a comprehensive fashion, accommodating individual variability and the diversity of our nation's population, and supplementing results from randomized controlled trials with outcomes data on treatment effectiveness in everyday settings of care.

Development of Quality Measures Related to Adverse Drug Events

ASA sees an opportunity to align quality measures aimed at patient safety, care coordination, and effective clinical care emerging from this discussion on ADEs. Federal as well as multiple state and private health insurance programs measure the care an anesthesiologist provides patients on a daily basis. Oftentimes, quality programs and specific measurements are not aligned from one agency or insurance program to the other. ASA encourages HHS to provide resources and funding to groups to develop, test and benchmark PQRS measures related to reducing ADEs. ASA also asks that the Action Plan emphasize the development of team-based measures with shared accountability into its prevention, surveillance, and research agendas. As is currently the case, the vast majority of quality measures fail to contemplate the totality of care a patient receives. Developing measures that encompass a wider view of the patient's medication use, interactions with physicians, and care received will allow physicians to develop clear benchmarks regarding appropriate drug use and practice.

Use of Transfer of Care (TOC) Measures

To effectively reduce post-procedure ADEs, the Action Plan must encourage the adoption of TOC quality measures that emphasize patient safety and care coordination when a patient is transferred from one care setting to the next. The peri-procedure setting often involves communication between various health care providers of differing specialties and requires the transfer of multiple types of information (surgical, medical, and anesthetic). Transitions of care remain vulnerable to poor communication between medical providers, often exposing patients to a greater likelihood of ADEs.

In addition, a patient's care should not abruptly end when discharged from a hospital or surgical center. Effectively transitioning the patient back to the home setting is an important part of any episode of care, and the physician must proactively take responsibility. Medical professionals must ensure that the appropriate drug information is given and that patient medical conditions and medication histories are not only communicated to the rest of the patient's care team but also properly explained to the patient and/or the patient's caregiver. In these circumstances, it is exceedingly important that those persons responsible for administering medication safely understand appropriate dosage, and the risks of not following the prescribed drug plan. Effective transfer of care is as important for pain management as it is for management of other serious medical conditions, which is where much of the focus has been to date.

Use of Perioperative Surgical Home

ASA has consistently advocated that a physician-led, coordinated care team is essential to managing a patient's medication use and preventing adverse drug events in hospitals and ambulatory care settings. In addition to the surgical procedure, surgical patients require

preoperative testing and preparation, anesthesia, specialized nursing care, postoperative recovery and rehabilitation. Perioperative care accounts for about 60% of hospital expenditures. Although generally safe, perioperative patients are at risk for bleeding, infection, blocked blood vessels, or thromboembolism, and other hospital-acquired conditions. Patients who are managed by multiple physicians have a significantly increased risk for ADEs from miscommunication and misinformation. Anesthesiologists can play a central role in reducing adverse events that result from unintended drug interactions for patients taking anticoagulants, diabetes agents, or opioids.

The surgical home concept would more actively integrate anesthesiologists into the patient continuum by increasing their involvement in all parts of the perioperative period from pre-operative assessment, intra-operative stabilization and safeguarding of all body systems and vital organs to post-operative optimization and pain relief. By coordinating the services provided by other health care professionals in the perioperative period, the anesthesiologist participates in a patient-centered process that ensures greater patient safety, care coordination between medical professionals, and better patient outcomes after surgery.

By vesting responsibility in a single entity, such as a perioperative surgical home or a medical home, the total care a patient received will be measureable and easily applied to quality improvement initiatives. This allows for the coordinating physician to be aware of a patient's medication use and allows the physician to contemplate the potential risk for ADEs. The Action Plan should encourage regulatory and financial support for surgical homes to be developed and measured for their impact on reducing ADEs and improving patient outcomes.

ASA thanks HHS for the opportunity to comment on the National Action Plan. We share your commitment to reducing and eliminating unnecessary ADEs. We welcome the opportunity to actively participate in improving the National Action Plan. For questions, or to schedule a meeting, please contact Maureen Amos, Director of Quality and Regulatory Affairs, at (202) 289-2222 or m.amos@asahq.org.

Sincerely,

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President
American Society of Anesthesiologists