Institute for Healthcare Improvement

Advancing the Safety of Acute Pain Management

Report of an Expert Panel Convened by the Institute for Healthcare Improvement

AN IHI RESOURCE

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The opioid epidemic is now widely recognized as a major public health crisis. In 2016 alone, more than 63,000 Americans died due to a drug overdose, 42,000 due to an overdose of prescription opioids or illicit opioids such as heroin, fentanyl, and fentanyl derivatives. More than one in five people aged 12 and older have used prescription drugs, including opioids, for nonmedical reasons or for reasons other than their intended use at least once in their lifetimes. In 2016, opioid overdose deaths increased across all age groups, racial and ethnic groups, and regions in the United States.

In addition to being a public health crisis, the opioid epidemic is a major patient safety and financial crisis that has negative consequences for patients, health professionals, health care organizations, and our society. Although there are many underlying causes of the epidemic, several are direct consequences of medical care, such as over-prescribing practices. Of the prescriptions written for the majority of patients who do not become chronic users, up to 80 percent of pills remain unused. These drugs are at risk for diversion, future misuse by the patient, use by family members, and accidental ingestion.

Poor management of acute pain is a substantial patient safety issue. Undertreatment can lead to physiologic stress from continuing pain, and poorly managed postoperative pain increases the risk of complications and a longer rehabilitation period. Overuse of opioids for acute pain has been a key driver in the current opioid crisis.

Opioid prescription rates have decreased in recent years yet remain high compared with historical levels. Too often organization-wide agreement on opioid prescribing and management is lacking, and frontline clinicians who enforce limits that may upset patients may not be supported sufficiently by leadership. Coordination, prioritization, strategy alignment, and buy-in at all levels of the organization are often insufficient. An expert panel convened by the Institute for Healthcare Improvement (IHI) found that a multitude of factors have led to the less-than-optimal state of acute pain management. These include societal and clinicians' perceptions about pain and a lack of coordination between different clinical practice guidelines, among other factors.

Advancing toward ideal acute pain management involves a two-part paradigm shift for an organization. First, rather than focusing narrowly on reducing the use of opioids, clinicians and leaders can focus on a broader aim: providing comfortable, safe care for patients with acute pain. Second, rather than setting the expectation that pain will be completely eliminated, clinicians can work with patients to co-create pain management goals in the broader context of their functioning, quality of life, and health status.

In addition to this paradigm shift, advancing the safety of acute pain management requires four foundational elements. Just as a tent requires all of its poles to work properly, delivering safe acute pain management requires that certain elements must be in place. They are:

- A common vision of acute pain management as a patient safety priority
- Comprehensive education, training, and evaluation of effectiveness of training
- Patient- and family-centered acute pain assessment, management, and monitoring
- Effective systems of care

Once these foundational elements have been established, it is important for organizations to determine what other elements are needed. Every organization's "tent" will require slightly different elements to support its poles.

Each organization also has a unique constellation of weaknesses that can thwart the achievement of the ideal state as well as assets that can be leveraged to achieve it. Examples of weaknesses include competing priorities, issues with information technology, limited resources, and lack of a safety culture. Health care safety leaders can work with others to discover weaknesses, identify ways to address them, leverage their assets, and engage leaders and staff in improvement methodologies to achieve positive change.

Building an effective, safe acute pain management strategy is a complex endeavor, especially when stakeholders within a health care organization are following different strategies. Suggested steps for a health care safety leader implementing a safe acute pain management program include:

Step 1. Understand your role.

Step 2. Gather information and data.

Step 3. Obtain organizational commitment.

Step 4. Convene a multidisciplinary working group.

Step 5. Conduct an organizational assessment.

Step 6. Prioritize activities.

Step 7. Develop an implementation plan.

Step 8. Select metrics and identify a measurement strategy.

Step 9. Execute the plan and continue improvement activities.

Providing comprehensive, holistic, safe care for patients with acute pain while minimizing unnecessary use of opioids is a challenging goal. A key tactic is using alternatives to opioids because the best way to reduce opioid misuse and opioid-related complications is to avoid prescribing opioids in the first place.

Although there are many key stakeholders whose engagement is needed to advance safe acute pain management, health care safety leaders play a unique and essential role. These leaders can advance patient safety by bridging the various clinical and operational units within their organization to create a coordinated, enterprise-wide strategy for safe acute pain management; by fostering the engagement of leadership; and by supporting a strong safety culture.

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About This Report

Acute pain management is a complex patient care issue. In an effort to create a practical, useful guide that will foster real change, this report was created with a specific focus: safety and quality issues related to acute pain management and the role of health care safety leaders in improving patient care and preventing opioid-related harm.

In most organizations, the champions of safety in acute pain management will be patient safety, quality, or risk officers, anesthesia professionals, pain service leaders, or other clinicians who have responsibility for or particular interest and expertise in acute pain management. In some organizations, the champion will be the director of an opioid stewardship program. Patient safety champions have a variety of titles and include both formal and informal leaders. **In this report we use the term "health care safety leaders" when referring to all of these health professionals.** Although health care safety leaders are the primary intended audience for this report, organizational leaders, policymakers, patients and families, and frontline clinicians may find this resource to be beneficial and educational.

Health care safety leaders play an essential role in acute pain management safety. These leaders can serve as a bridge for the development of coordinated acute pain management policies and practices across their organization. They also can support the safety culture of the organization and encourage the buy-in of staff and leaders, both of which are essential to acute pain management safety.

Many organizations have developed recommendations to address the opioid epidemic. This resource specifically and uniquely addresses acute pain management as a patient safety issue. It provides health care safety leaders in hospitals, emergency departments (EDs), urgent care clinics, outpatient surgery facilities, and other acute care settings with specific action steps to improve the safety of acute pain management in their organizations.

The purpose of this guide is to help health care safety leaders:

- Empower their role in advancing safe acute pain management practices in their organizations
- Elevate acute pain management as a key safety priority in their organizations
- Effectively serve as a bridge for consistent best practice across their organizations
- Design and implement pain management safety standards and programs
- Identify and apply relevant innovations in organization-wide approaches to acute pain management
- Measure and evaluate the effectiveness of interventions for managing acute pain
- Sustain gains through continuous improvement activities

To expedite improved safety for the majority of patients, this report focuses on safety for patients with acute pain. It does not cover chronic pain treatment, care in outpatient settings, opioid use disorder (OUD), comparisons of specific marketed therapies, or recommendations for addressing issues related to payment, electronic health records (EHRs), or the informed consent process, which may be addressed by other policies and programs within health care organizations.

Future work might focus on outpatient settings or on groups for whom more nuanced approaches to acute pain management are needed, such as patients who:

- Are pediatric or elderly*
- Are pregnant
- Have cancer or require palliative care
- Have a primary behavioral health diagnosis
- Have a history of opioid abuse or addiction, including patients on medication for addiction treatment (MAT)
- Are receiving chronic, stable opioid therapy (e.g., for recurrent sickle cell disease)
- Are cared for in skilled nursing or long-term acute care facilities
- Are receiving worker's compensation benefits for acute pain related to their worker's compensation claim
- Are military personnel or emergency first responders

*Although much of the learning in this document applies to all populations, this report specifically focuses on acute pain management in adults aged 18 to 65, recognizing that differences in pain intensity occur with age and that nuanced care may be required for children and adults older than 65 years of age. An extremely important population for additional work is adolescents, whose social environment and developmental stage puts them at risk for opioid misuse. Research has shown that adolescents who receive a legitimate prescription for an opioid during high school have a risk of opioid misuse as young adults that is 33 percent higher than in adolescents who do not receive prescription opioids.[1]

Acute Pain Management: A Critical Patient Safety Issue

The opioid epidemic is now widely recognized as a major public health crisis. In 2016 alone, more than 63,000 Americans died due to drug overdose, 42,000 of these due to an overdose of either prescription opioids or illicit opioids such as heroin, fentanyl, and fentanyl derivatives.[2] Among individuals under age 50, drug overdose is now the leading cause of mortality.[3-4] Opioid overdose deaths have been identified as a key contributor to the declines in life expectancy observed recently in the US.[5] The National Center for Health Statistics has estimated that in 2018 more than 71,000 people will die from an overdose of drugs, including opioids.[6]

However, opioid misuse is not the only patient care issue in acute pain management. Other patient safety issues also exist. Multimodal treatment is underutilized, and clinicians and patients alike often focus narrowly on pain intensity rather than considering functioning and quality of life as well. Non-opioid alternatives are not considered and used as often as would be ideal. Patients and families are not educated proactively about pain, pain treatments, and associated risks.

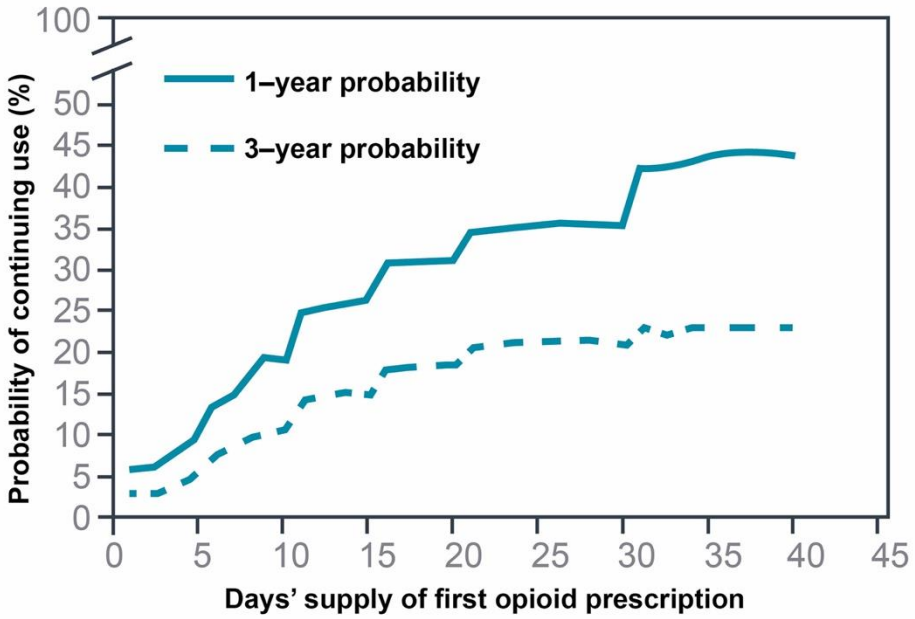
The Rise in Opioid Use and Opioid-Associated Mortality

Although there are many underlying causes of the opioid epidemic, several are direct consequences of medical care, such as over-prescribing practices. In the 1990s, opioid prescribing rates began to increase due to a constellation of factors, including emerging concern about the undertreatment of chronic pain and an increase in availability and marketing of prescription opioids.[7] Prescribing rates have since declined — yet still remain higher than at historical levels — about three times higher than the 1999 rates.[8, 9] Prescription opioids are involved in more than 40 percent of opioid overdose deaths, which equates to 46 Americans dying each day from overdoses that involve a prescription opioid.[10]

Researchers estimate that more than one in five people aged 12 and older have used prescription drugs (opioids, central nervous system stimulants, or central nervous system depressants) for nonmedical reasons or for reasons other than their intended use at least once in their lifetimes.[11] A meta-analysis of 38 studies found rates of opioid misuse among patients prescribed opioids averaged between 21 percent and 29 percent, although the analysis was limited in that demographic information about participants was not provided with all studies.[12] The same study found rates of addiction averaging between 8 percent and 12 percent.

More recent analysis showed that the probability of persistent or continued opioid use among people who received an opioid prescription was 6 percent at one year and 3 percent at 3 years.[13] In addition, the likelihood of continuation was associated with the number of days' supply of the first prescription for opioids (see Figure 1).

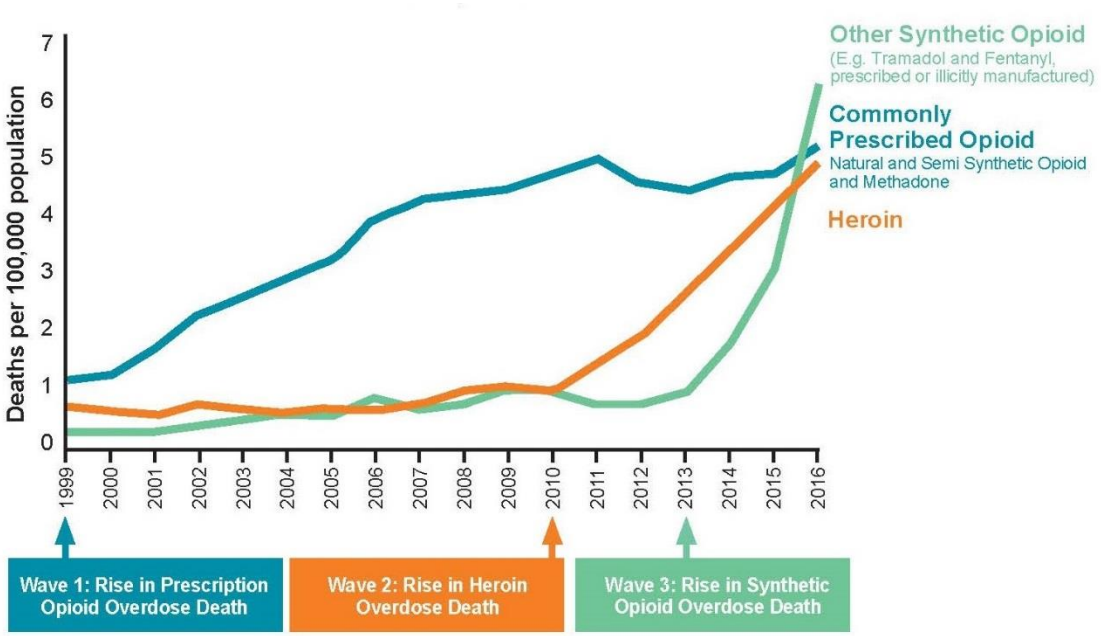
Figure 1. One- and Three-Year Probabilities of Continued Opioid Use among Opioid-Naïve Patients, by Number of Days' Supply of the First Opioid Prescription, United States, 2006–2015



Source: Adapted from Shah A, Hayes CJ, Martin BC. Characteristics of initial prescription episodes and likelihood of long-term opioid use — United States, 2006–2015. *MMWR Morbidity and Mortality Weekly Report*. March 17, 2017;66:265-269.

The epidemic of opioid-related deaths has been defined as having three waves: the rise of prescription opioid deaths, increase in heroin-related deaths, and increases in deaths attributed to synthetic opioids (see Figure 2). As noted previously, in recent years opioid prescribing has declined. However, overdose rates have continued to climb.[10]

Figure 2. Three Waves of the Rise in Opioid Overdose Deaths



Source: Opioid overdose deaths. Centers for Disease Control and Prevention website. https://www.cdc.gov/drugoverdose/epidemic/index.html

Acute Pain Management: Definition of Terms
For the purpose of this report, terms have been defined as described below.

Abuse: The repeated use of illegal drugs or the inappropriate use of legal drugs to produce pleasure, alleviate stress, and/or alter or avoid reality[14]

Acute pain: The physiologic response and experience to noxious stimuli that can become pathologic, is normally sudden in onset, is time limited, and motivates behaviors to avoid actual or potential tissue injuries[15]

Addiction: A chronic, relapsing disease characterized by compulsive drug-seeking and use despite negative consequences and by long-lasting changes in the brain[14]

Bridge clinic: Facility that provides temporary care for patients who need treatment for opioid use disorder or support transitioning off opioids; may be referred to by other names in different locales

Buprenorphine: A medication approved by the U.S. Food and Drug Administration in October 2002 for the treatment of opioid addiction[14]

Cancer pain: Pain related to cancer, either to the disease itself or to cancer treatment; may be continuous or intermittent[16]

Chronic pain: Pain that lasts 3 months or more and can be caused by a disease or condition, injury, medical treatment, inflammation, or an unknown reason[17]

Chronic pain with acute needs: An acute increase in pain intensity, which may reflect either an increased intensity of chronic pain or separate acute pain condition; also referred to as "acute on chronic" pain

Dependence: A physiological state that can occur with regular drug use and results in withdrawal symptoms when drug use is abruptly discontinued[14]

Drug diversion: A medical and legal concept involving the transfer of any legally prescribed controlled substance from the person for whom it was prescribed to another person for any illicit use[18]

Health care organization: An entity that delivers health care services, such as a hospital, health system, or free-standing surgical center

Medication for addiction treatment (MAT): Treatment for opioid use disorder combining the use of medications (methadone, buprenorphine, or naltrexone) with counseling and behavioral therapies; also referred to as medication-assisted treatment[17]

Methadone: A long-acting synthetic opioid medication that is effective in treating pain and opioid addiction[14]

Misuse: Taking a medication in a manner or dose other than prescribed; taking someone else's prescription, even if for a legitimate medical complaint such as pain; or taking a medication to feel euphoria (i.e., to get high); also referred to as the nonmedical use of prescription drugs[19]

Morphine milligram equivalents (MME): The amount of milligrams of morphine an opioid dose is equal to when prescribed; used to calculate the total amount of opioids, accounting for differences in opioid drug type and strength[17]

Multimodal pain management: The concurrent use of separate therapeutic interventions with different mechanisms of action within one discipline aimed at different pain mechanisms[20]

Naloxone: Drug that can be used to reverse the respiratory depression of an opioid overdose victim when administered immediately[21]

Non-opioid option: A pain treatment that is not an opioid; examples include medications such as non-steroidal anti-inflammatory drugs, acetaminophen, and select anticonvulsants and antidepressants and nonpharmacologic treatments such as ice or massage; also referred to as non-opioid medications, non-opioid analgesics, or first-line pain medications[22]

Opioid (or opiate): A controlled substance most often prescribed for the management of pain; natural or synthetic chemical similar to morphine that works by mimicking the actions of pain-relieving chemicals produced in the body[14]

Opioid-related adverse drug event (ORADE): A negative effect associated with opioid use; examples include pruritus, dizziness, nausea, vomiting, sedation, oxygen desaturation, delirium, hypotension, and death[23]

Opioid-related adverse respiratory event (ORARE): Respiratory depression associated with opioid use; the cause of the majority of deaths due to opioid overdose[21]

Opioid use disorder (OUD): A problematic pattern of opioid use that causes significant impairment or distress; the diagnosis is based on specific criteria such as unsuccessful efforts to cut down or control use or use resulting in social problems and a failure to fulfill obligations at

work, school, or home, among other criteria; also referred to as opioid abuse or dependence or opioid addiction[17]

Overdose: Injury to the body that occurs when a drug is taken in excessive amounts; can be fatal or nonfatal[17]

Pain: Unpleasant sensory and emotional experience associated with actual or potential tissue damage[20]

Pain assessment: A multidimensional observational evaluation of a patients' experience of pain[24]

Persistent or chronic opioid use: Continuous use of opioids; operational definitions vary regarding the duration (e.g., 6 weeks, 90 days)[25, 26]

Prescription drug abuse: The use of a medication by someone other than for whom it is prescribed, in ways or amounts other than intended by a doctor, or for the experience or feeling it causes[14]

Substance use disorder (SUD): The recurrent use of alcohol and/or drugs that causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home[27]

Synthetic opioids: A class of drugs that are designed to provide pain relief, mimicking naturally occurring opioids such as codeine and morphine; synthetic opioids like tramadol and fentanyl tend to be highly potent[28]

Tolerance: A condition in which higher doses of a drug are required to produce the same effect achieved during initial use, which often leads to dependence[14]

Withdrawal: Symptoms that occur after regular use of a drug has been abruptly reduced or stopped; severity depends on the type of drug, the dosage, and how long and how frequently it has been taken[14]

In addition to contributing to the risk of overdose and death, prescription opioid misuse is linked to subsequent heroin use. Nearly 80 percent of heroin users initially abused prescription opioids.[29, 30] Research suggests that prescription opioid abuse increases the risk of heroin use by a factor of 40.[31]

Fentanyl use, including synthetic fentanyl and its derivatives, has increased substantially in recent years, as have overdoses and deaths due to these agents.[32] It is estimated that deaths due to fentanyl derivatives, which are relatively inexpensive to produce, increased between 2013 and 2016 by more than 500 percent.[33] In the 12 months from December 2016 to November 2017, the number of overdose deaths that involved synthetic opioids was higher than the total number of all opioid overdose deaths in 2013, which is when deaths due to synthetic opioids began to rise.[32] These deaths are driven in part by the addition of fentanyl and its derivatives to other drugs, such as heroin, oxycodone, and cocaine.

Consequences of Opioid Misuse

The opioid epidemic is a major patient safety crisis that has negative consequences for society, patients, and health care organizations. The financial costs of the opioid epidemic to society are staggering. It has been estimated that the economic burden related to prescription opioid abuse alone totaled more than $78 billion dollars in 2013, more than one-third of which was due to increased costs related to health care and treatment of opioid use disorder (OUD).[34] The total economic cost of the opioid crisis was estimated to have risen to more than $500 billion in 2015.[35]

Opioids are associated with a number of adverse events that directly affect patients, in addition to addiction, overdose, and death. These include serious complications such as sedation and respiratory depression, as well as side effects such as constipation, nausea, physical dependence, and impaired recovery from injury or surgery.[36] According to a 2017 meta-analysis, 16 percent to 29 percent of patients report experiencing an opioid-induced adverse effect.[37] In a survey of surgeon leaders, 87 percent reported that their patients experienced opioid-related adverse effects.[38] Research has shown that patients with FDA-defined opioid tolerance have significantly longer hospital lengths of stay and higher rates of readmission than patients without tolerance.[39] In addition, withdrawal from opioids causes significant physical and psychological effects, including anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, tremor, and tachycardia.[40] The risk also extends to infectious disease. The incidence of injection-related infectious diseases, such as HIV infection and hepatitis C, has steeply increased in recent years.[41]

Certain populations are at higher risk for adverse events with opioids. The majority of overdose deaths related to opioids occur among people age 25 to 55.[35] In addition, some studies have shown that female gender, white race, lower family incomes, and being uninsured or unemployed are associated with greater risk for prescription opioid misuse and addiction.[42, 43] A number of factors underlie these differential risks. Bias in prescribing explains a portion of the racial disparities: minorities are less likely to be prescribed opioids.[44] Women are more likely than men to have chronic pain, to be given opioids for pain, and to use opioids for a longer duration than men.[45]

Although certain populations are at higher risk for addiction and overdose, it is difficult to accurately predict which individual patients will develop addiction or experience an overdose. Opioid addiction is an "equal opportunity offender." In 2016, opioid overdose deaths increased across all age groups, racial and ethnic groups, and regions in the country.[10]

Similarly, it is difficult to predict which individual patients in the hospital setting will develop life-threatening complications related to acute pain therapies because of the variability of risk associated with patients' co-morbidities and with different medical interventions.[46, 47]

The opioid crisis also represents an operations and finance problem for health care organizations, with substantial direct and indirect costs. A strong business case exists for improving the safety of acute pain management. Health care organizations that implement effective acute pain management strategies can minimize the many financial consequences associated with inadequate pain management and poor opioid stewardship. These consequences include:

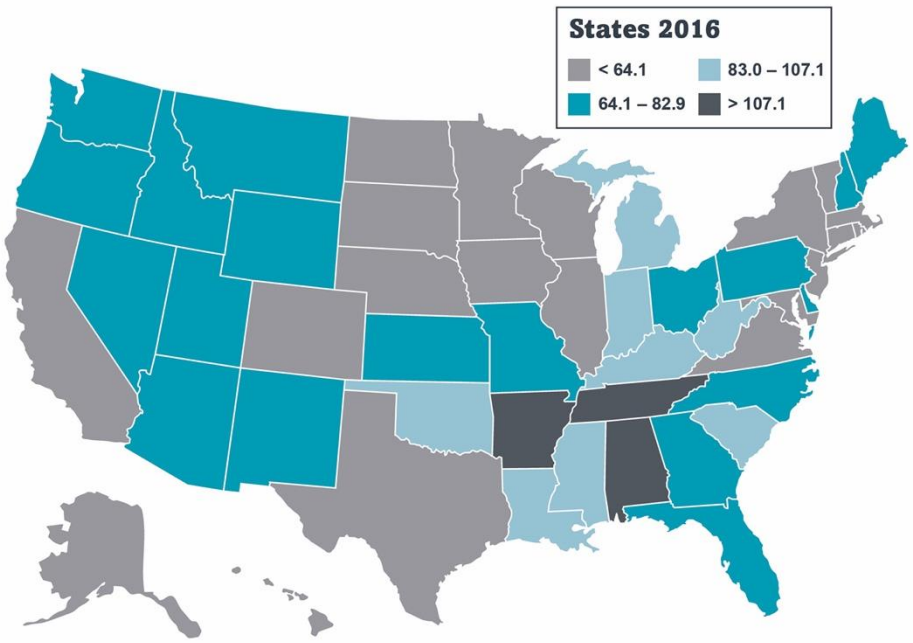
- Increased length of stay (LOS),[39, 48] potentially leading to decreased bed capacity (One urban academic medical center estimated that a 10 percent reduction in the LOS of patients with OUD would create space for an additional 32 inpatient stays per year.[49])
- Increased number of ED visits[50]
- Increased risk of readmission[48]

- Substantially higher costs associated with admission for infectious complications of OUD, such as bacteremia, epidural abscess, and endocarditis (e.g., $107,000 per hospitalization for OUD with associated infection versus $28,000 per hospitalization for OUD without infection in 2012)[51]
- Possibly an increased risk of malpractice claims (In an analysis of 10,000 medical malpractice claims, opioids were the most common drug cited in claims related to medication.[52])

A Patient Safety Crisis

A key driver of the opioid epidemic is over-prescribing by clinicians — a harm directly caused by medical treatment, the basic definition of harm. Prescription rates show great variation by geographic location, suggesting that prescribing patterns are not always reflective of patient needs, as shown in Figure 3.[53, 54]

Figure 3. US State Prescribing Rates, 2016



Source: US State Prescribing Rates, 2016. Centers for Disease Control and Prevention website. https://www.cdc.gov/drugoverdose/maps/rxstate2016.html

Over-prescribing increases the risk of addiction and diversion.[37, 55] Researchers estimate that between 3 and 10 percent of opioid-naïve patients become chronic users.[56, 57] Research has demonstrated that the risk of opioid misuse among opioid-naïve patients increases significantly with each refill and week of opioid prescription.[58] Research has also shown that of the prescriptions written for the majority of patients who do not become chronic users, up to 80 percent of pills remain unused.[56] Unused pills that are not secured create the potential for diversion, future misuse by the patient, use by family members, and accidental ingestion by children. These harms are all direct complications of medical care.

However, the patient safety issues related to the management of acute pain comprise more than overuse of opioids. Undertreatment can lead to physiologic stress from continuing pain, including profound effects on the endocrine system.[59] Research has demonstrated that poorly managed postoperative pain increases the risk of complications and a longer rehabilitation period.[60] In addition, acute postoperative pain intensity has been associated with the development of persistent postsurgical pain.[61] Research suggests that early intervention in certain cases, for example after traumatic amputation injury, reduces the risk of chronic pain.[62] The conversion of acute to chronic pain, or "chronification" of pain, is an area of ongoing research.[63, 64, 65]

Addressing the opioid crisis must be part of a larger endeavor: improving acute pain management. Otherwise, unforeseen consequences may develop, and ultimately patients may suffer additional harm. For example, although multimodal analgesic therapies appear to have important advantages compared with opioids for the management of acute pain, they also carry risks, and clinicians and researchers must continue to monitor adverse effects of these treatments.[66]

The opioid epidemic is an important patient safety issue that has a substantial impact on general public health, health care organizations, work force safety, and finance. It is a public health crisis, a patient safety crisis, and, for health care organizations, an operations and finance crisis. The opioid epidemic presents an opportunity to improve patient care by reducing the use of these drugs and also addressing essential gaps in care. Advancing safe acute pain management requires a system-wide, coordinated, integrated acute pain management strategy.

Acute Pain Management: Where We Are and Where We Strive to Be

Many clinical practice guidelines exist, and states have enacted a variety of regulations and initiatives to improve opioid prescribing.[67] Of note, the guidelines developed by the Centers for Disease Control and Prevention focus on safe management of *chronic* pain.[40] The National Academies of Medicine is currently working to develop guidelines specifically related to the management of acute pain.[68] The degree to which practice guidelines are adopted and consistently implemented is not yet known.

Some clinicians have chosen to avoid prescribing opioids at all, which can leave patients who have formerly received opioids to navigate the transition off prescription opioids with little guidance, potentially leading to undertreated pain or use of illicit opioids.[69] Currently, in most states across the country, there is a resource gap between the number of clinicians who are certified to provide MAT for opioid use disorder and the number of people with OUD.[70] Too often organization-wide agreement on opioid prescribing and management is lacking, and frontline clinicians who set limits that may upset patients are not sufficiently supported by leadership. Coordination, prioritization, strategy alignment, and commitment at all levels of the organization are often insufficient.

Contributing Factors

According to our expert panel, a multitude of factors have led to the less-than-optimal current state of acute pain management. These factors include:

- Misperceptions about pain: For example, the belief that being completely pain-free is a reasonable goal or tracking pain intensity in isolation of other patient needs, such as functional improvement
- Lack of a patient-centered orientation: For example, failure to effectively engage patients in their care (e.g., through use of tools such as care plans and standardized decision aids)
- Insufficient patient education: For example, failure to clearly identify opioids when they are prescribed and delineate the risks and benefits of use
- Competing guidelines and best practices: Specifically, challenges related to the use of different guidelines and best practices for pain management and opioid stewardship by different specialties
- Competing priorities: For example, reimbursement models that cause time pressure and limit time available for complex conversations
- Lack of safety culture: An organizational culture that does not support learning from errors
- Issues with information technology (IT): For example, lack of integration of prescription drug monitoring programs (PDMP) with electronic health records (EHRs)
- Lack of resources and training: For example, limited access to pain management specialists in some settings
- Issues related to measurement and data: For example, the lack of measurement consistency within systems and across the country
- Issues with systems and care coordination: For example, institutional, financial, and educational barriers to accessing and using nonpharmacologic modalities

(For a detailed list of factors, see Appendix A.)

Existing Strengths and Resources for Advancing Patient Safety

Our expert panel recognized that the work to advance patient safety in acute pain management can build on a foundation of existing strengths and resources.

Clinical practice guidelines: Professional practice guidelines are widely available. Clinical guidelines, policy statements, and expert reports about acute pain management and the use of opioids have been developed by regulatory groups, accrediting bodies, and professional groups. Guidelines have been published by Centers for Disease Control and Prevention, The Joint Commission, National Quality Forum, National Academy of Medicine, American Hospital Association, American College of Surgeons, and many other organizations.

Examples include:

- American Hospital Association: *Stem the Tide: Addressing the Opioid Epidemic*[71]
- American College of Surgeons: Optimal Perioperative Management of the Geriatric Surgical Patient: Best Practice Guidelines[72]
- National Quality Forum: *National Quality Partners Playbook: Opioid Stewardship*[73]
- Food and Drug Administration: *Guidelines on Safe Disposal of Medicines*[74]

While the availability of these practice guidelines is essential, optimal acute pain management and opioid stewardship require an appreciation of the nuances of the various specialty guidelines and an overarching strategy that ensures that the guidelines complement rather than contradict each other.

At first blush, it might seem prudent to create a single national guideline for all acute pain management and opioid prescribing. However, while a coordinated effort is essential, separate guidelines and protocols are necessary for different clinical specialties and to meet the unique needs of various patient populations. Keeping up to date and merging the various recommendations to create an effective strategy can be challenging and time-consuming for individual health professionals and for health care organizations.

Safety culture: The critical importance of a culture of safety is more widely recognized than in the past. Developing a safety culture promotes behaviors that improve patient safety, such as reporting of errors. Without a strong safety culture, the ability of an organization to authentically prioritize challenges and effectively implement protocols to improve the safety of pain management is likely to be limited. (For more information on building a safety culture, see *Leading a Culture of Safety: A Blueprint for Success.*[75])

Improvement science: Fostering change in a positive direction is challenging, whether at the clinical unit level or organization-wide. Today, tools and strategies are available to help ensure that implemented changes move patient care toward sustainable improvement. An important strength on which to build is the accumulated knowledge of improvement science, including systems thinking, awareness of human factors, improvement skills, and systemic improvement models such as the *Model for Improvement*.[76]

Alternatives to opioids: More alternatives to opioids exist today than in the past. Optimizing the use of both non-opioid analgesics and nonpharmacologic therapies provides effective options that avoid the initiation of opioids. A simple way to reduce opioid-associated consequences is increasing the use of alternatives. For more information, see the description of the St. Joseph's University Medical Center's Alternatives to Opioids (ALTO®) Program[77] and the clinician training materials from the Colorado ALTO Project.[78] For a list of evidence-based, non-opioid pharmacologic and nonpharmacologic options for pain management, see *Joint Commission's Quick Safety 44*.[79]

Prescription drug monitoring programs: The development of prescription drug monitoring programs (PDMPs) began in 1939, although 70 percent of PDMPs were enacted after 2000.[80] Current PDMPs use an electronic database to track prescription of opioids and other controlled substances within a state. PDMPs provide health authorities with timely information about prescribing and patient behaviors that in turn can help inform clinical practice and improve prescribing practices.

Examples of best practice initiatives: Another important strength on which to build are the existing examples of successful initiatives to address issues in acute pain management, in particular, effective stewardship of opioids. These efforts can be studied, modified as necessary, and shared for use across the country. See Appendix B for a few examples of the many existing best practice initiatives.

Understanding the existing gaps and strengths in current acute pain management helps inform both the vision of the ideal state and the strategy for achieving it. The next section describes what that ideal state might look like.

Acute Pain Management: Aiming for Safe Optimal Care

Every year patients experience the adverse consequences of poor acute pain management, including the overuse of opioids — consequences that are serious and include an increased risk of complications, longer hospitalizations, OUD, and death. In addition, people who never enter the health care system are at risk due to drug diversion and accidental poisoning. For these reasons, acute pain management is an urgent patient safety issue. Health care organizations can help mitigate this crisis by developing an effective strategy to reduce the harms Americans are experiencing due to current pain management practices.

Overarching Goals

What are the goals of safe acute pain management? At the highest level, there are two: to provide appropriate and effective acute pain management and to decrease the risk of harm due to opioids and other treatment. More specific goals include:

- Reduce suffering related to acute pain and ensure alignment with patients' needs
- Enable early return to daily life activities and functional capabilities
- Decrease the use of opioids by increasing use of non-opioid pharmacologic and nonpharmacologic pain management options
- Reduce the risk of future addiction
- Reduce the risk of complications and other adverse effects of opioids
- Minimize the development of chronic pain

The Ideal State

In *Leading a Culture of Safety: A Blueprint for Success,*[75] the first recommendation for leadership is to set a compelling vision for safety. Addressing the national opioid crisis requires a national vision and action plan, as well as an organizational plan. It is important for leaders and staff at each individual hospital and health system to create a vision for the ideal state and make a commitment to advancing acute pain management at their organization.

Establishing a vision of the ideal state galvanizes positive change and gives everyone in the organization a common vision for the ultimate aim of improvement.

Attributes of an ideal state of acute pain management are described below.

Influence of a safety culture

- Executive leaders and board members make decisions and distribute resources to prioritize safe acute pain management throughout the organization.
- Staff are confident that they have full leadership support when making evidence-based decisions about acute pain management, including those that may conflict with patient expectations.
- Clinicians with outlier prescribing patterns and pharmacists with outlier dispensing patterns receive support and coaching to improve.

System processes

- A coordinated strategy informs prescribing, treatment, monitoring, referrals, and communication across the entire organization and into the community.
- Specialty-specific practice guidelines and, where appropriate, prescribing protocols are consistently used within relevant clinical units.
- Guidelines, prescribing protocols, order sets, and specific care plans prioritize the prevention of drug diversion.
- An on-site acute pain service is fully staffed, ready to provide expert consultation for clinicians across the organization, and clinicians are aware of the process for accessing consultations. (For smaller hospitals or rural settings, one or more clinicians acting as acute pain champions is an alternative.)
- Prescribing patterns and other relevant metrics are tracked at the organizational, department, and clinical unit level.
- Staff display competency in assessing pain; effectively communicate with patients about realistic expectations, pain, and opioid use; set limits where needed regarding prescribing opioids; and appropriately treat or refer patients with OUD.

Workflow processes

- Workflow processes have been streamlined (e.g., the PDMP system has been integrated into the electronic health record).
- Clinicians complete a comprehensive, holistic, person-centered assessment of pain.
- Patients receive effective, person-centered, holistic management of acute pain with minimal risk of harm, including OUD.

How can an organization move toward this ideal? What essential components are required to successfully build and maintain an ideal acute pain management ecosystem? The following section provides a framework to guide organizations in every phase of program advancement.

The Journey Toward Safe Acute Pain Management

Moving from the current to the ideal state is a journey of many steps. Success on this journey requires a paradigm shift and four foundational elements.

Paradigm Shift

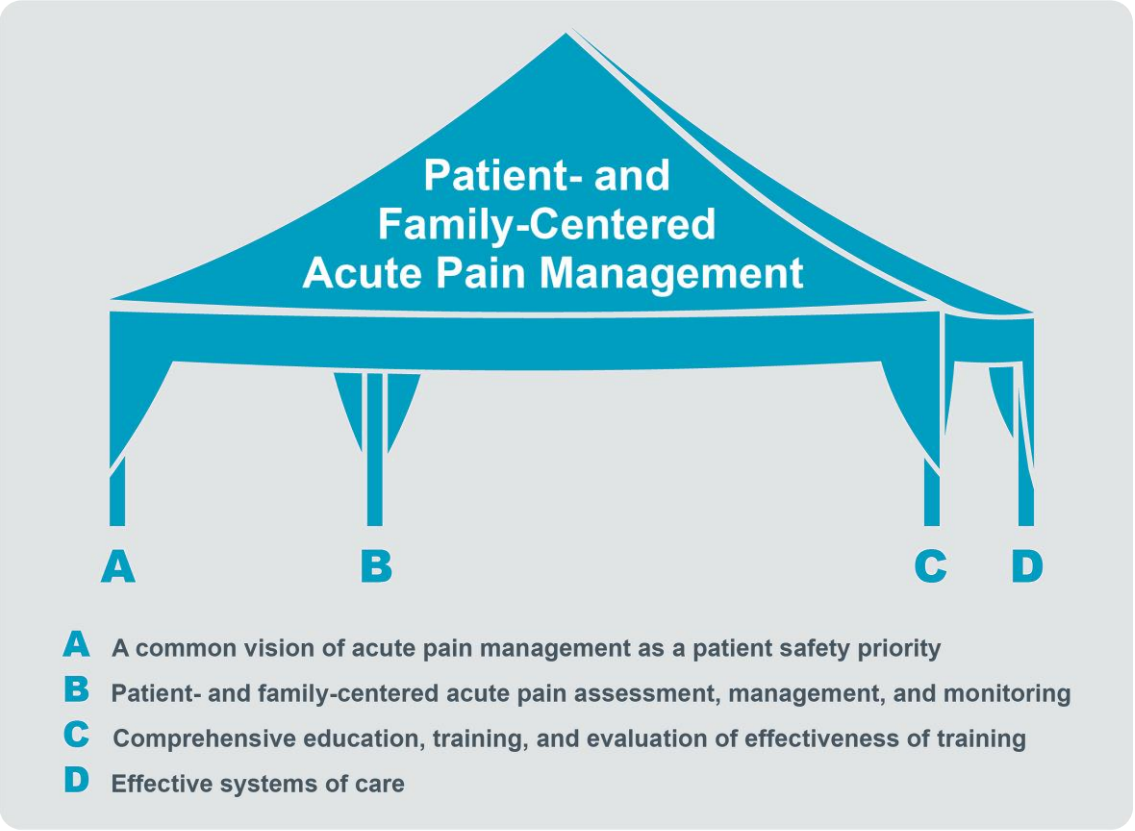
Truly advancing the safety of acute pain management will require a two-part paradigm shift. First, rather than focusing narrowly on reducing the use of opioids, clinicians and leaders can focus on a broader aim: providing comfortable, safe care for patients with acute pain. This approach includes using opioids only when clearly indicated *and* providing comprehensive, effective pain management. Second, rather than setting the expectation that pain will be completely eliminated, clinicians can work with patients to co-create pain management goals in the broader context of their functioning, quality of life, and health status.

Foundational Elements

Creating a successful acute pain management process requires several foundational elements. Just as a tent requires all of its poles to be in place to work properly, safe acute pain management requires all of these foundational elements to be in place in order to provide an overarching framework for safe care of acute pain (see Figure 4).

To build these elements, each organization will determine its unique requirements, based on the needs of local patient populations, existing prescribing patterns, availability of acute pain specialists, and other factors. A critical role of health care safety leaders is ensuring that the foundational elements within their organization are structurally sound.

Figure 4. Tent Poles: The Foundational Elements of Patient-Centered Safe Acute Pain Management



These are the four foundational elements:

A. A common vision of acute pain management as a patient safety priority. Safe acute pain management requires coordination and consistency at every level of the organization.

In a successful program, leaders and board members are informed and fully engaged, ensure that the safety of patients with acute pain is a priority, and ensure that organizational resources and programs are available to guarantee safety and reduce the inappropriate use of opioids.

It is also important for leaders to engage and work with stakeholder groups in the communities they serve, including first responders, local government, public health departments, community-based groups, and patient advocacy groups. Calculating and articulating the business case for optimizing care of the patient with acute pain can help leaders and board members see the importance of allocating resources toward acute pain management. (For more information on building the business case, see the upcoming section, Action Steps for Health Care Leaders.)

B. Patient- and family-centered pain assessment, management, and monitoring. Optimal and safe acute pain management benefits from a patient- and family-centered approach. While an overarching strategy and consistent policies for acute pain management are essential, it is important for treatment to be tailored to the individual patient, and for processes to be in place that engage patients in their care. For example, it is best if the care plan includes the patient's functional goals and preferences, and does not strictly rely on a rating of the single dimension of pain. Social determinants of health are also helpful considerations in a well-designed care plan.[81]

It is essential for clinicians to practice shared decision making, engage in an effective informed consent process with patients and families, and provide evidence-based educational resources and guidance for those in their care. Clinicians can provide extra support for patient populations at highest risk of harm from acute pain therapies (e.g., middle-aged women for prescription opioids). Moving beyond the individual patient, it is helpful for the organization to collaborate with their communities and related services to improve the safety of care for patients with acute pain and minimize the risk of adverse consequences related to opioid use.

C. Comprehensive education, training, and evaluation of effectiveness of training. Misperceptions about pain, pain treatment, and opioids, among both patients and health care professionals contribute to the opioid crisis. It is essential to establish that the goal of acute pain management is not necessarily elimination of pain, but rather maximizing emotional and physical functioning and comfort. Both patients and families and health care professionals can benefit from education about these topics.

An essential step is ensuring that patients and families have the information they need prior to any planned procedures or treatments. It is important for conversations about post-surgical pain management to occur during the preoperative evaluation, not in the moments before surgery. Clinicians can provide national or local statistics to set realistic expectations about pain and addiction. For example, they can say, "Most of my patients find that X days of prescription pain killer is adequate after this procedure," or "Studies have shown that after X days of taking a prescription opioid, Y percentage of people become addicted. After Z days, there is a sharp uptick in the number of people who develop addiction." Patients can then be told explicitly that most patients do not use all of their prescribed pills and that it is best to safely dispose of any remaining pills.

A key step in advancing safe acute pain management is building the capacity of the workforce to provide comprehensive care for patients with acute pain. It is critical for staff to receive ongoing education, as well as training on specific competencies, such as accurate and comprehensive assessment of pain, navigation of health records to identify past pain or pain management issues, and goal setting with patients prior to surgery. In a successful program, staff are able to assess current opioid use and the appropriateness of continued use. Staff are also trained in avoiding cultural bias and promoting equity in health.

D. Effective systems of care. Certain systems must be in place for an organization to execute a safe acute pain management strategy. If these are lacking or insufficient, effective leaders set priorities to address these deficiencies. First, these leaders attend to any infrastructure issues related to standardized practices, workflow, workload, electronic health records, reporting systems, population health databases, interoperability of health information technology, and other processes and resources that affect multiple clinical and operational units. Second, organizations create structures (e.g., committees), processes, and procedures for safe acute pain management and communication plans and tools to improve care coordination. Third, organizations engage in continuous improvement, using data in a feedback loop to inform future changes.

Communication is a critical aspect of an effective acute pain management strategy. Communicating with patients and families about pain management and safety may be challenging. Patients who are concerned about postoperative pain may become anxious or upset if they learn they will receive lower doses and prescriptions for smaller quantities of opioids than they expected. Patients who have a pain management or opioid use agreement with their primary care provider may object if they are seen in the ED and their request for opioids is denied. It is

critical for staff to communicate effectively in these types of clinical situations — with the support of supervisors, managers, and leaders.

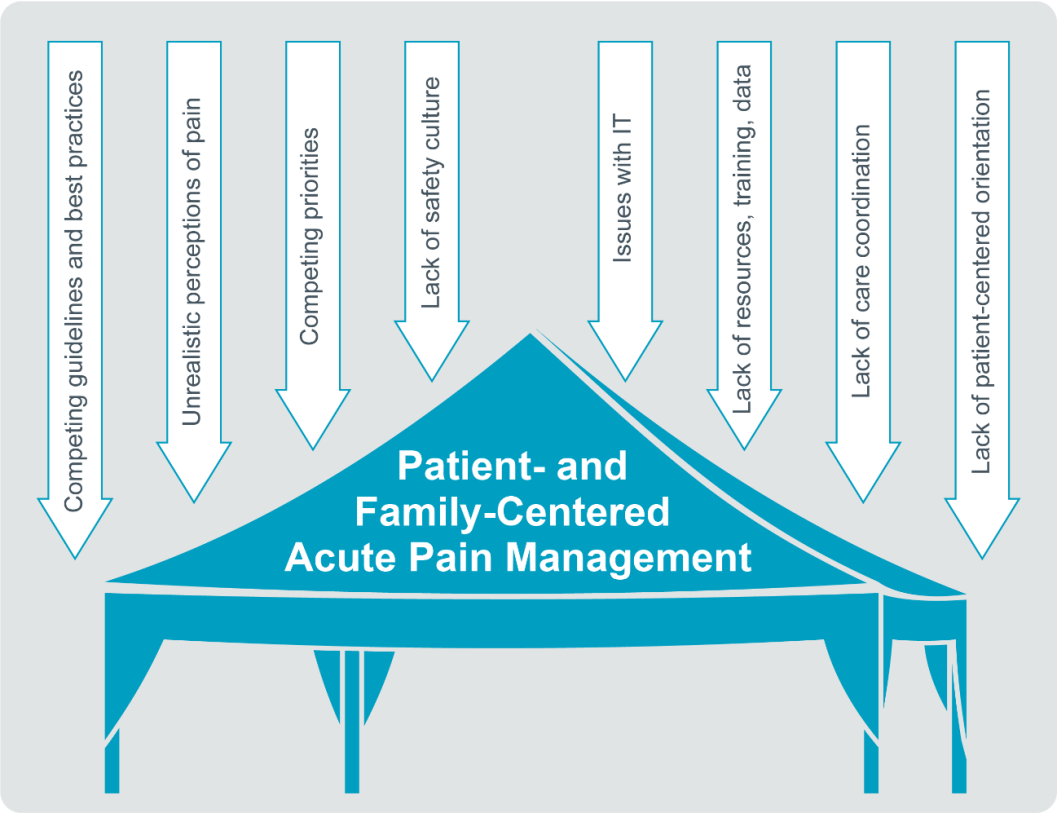
Equally important is for organizations to develop a means for communicating relevant information about acute pain management to patients, family, and staff. In this way, organizations can effectively share data, best practices, and updates about acute pain management across all clinical and operational units, including primary care settings. Finally, it is advantageous for IT systems to communicate information about patients' pain management needs and opioid use reliably and in a way that efficiently fits in the clinical workflow.

A fully implemented acute pain management program has all four foundational elements securely in place and has addressed existing barriers to the optimal state.

Barriers to the Ideal State

A number of factors can impede developing and maintaining safe acute pain management strategies or programs across an organization (see Figure 5). These are many of the same issues in acute pain management that are described in Appendix A. These barriers may place undue stress on the foundational elements of safe acute pain management and adversely affect patient care.

Figure 5. Factors That Impede Safe Acute Pain Management



Each organization has a unique constellation of gaps and weaknesses that exert stress and can thwart the achievement of the ideal state. Health care safety leaders can work with others to identify the gaps and weaknesses that are hindering improvement at their organization, identify ways to address them, and engage leaders and staff in improvement methodologies to achieve positive change.

Action Steps for Health Care Safety Leaders

Building an effective, safe acute pain management strategy is a complex endeavor, especially when stakeholders within a health care organization are using different care practices. Health care safety leaders are ideally situated to bridge these differences, creating a consistent strategy and practices across the organization, yet supporting specialty-specific modifications where appropriate.

Steps for Implementation

The following section provides suggested steps for implementation that will build or strengthen the foundational elements described earlier. The steps and the way they are implemented will likely require tailoring to suit the needs of your specific hospital or health system. (See the Case Study at the end of this document for a description of how a fictional health care safety leader approaches implementation of a comprehensive acute pain management strategy in her community hospital.)

Step 1: Understand Your Role

Recognize the degree of power you exert within the structure of your organization. As a safe pain management champion, will you be the pilot, the co-pilot, or a passenger on the plane? Based on this awareness, you will either drive the action steps that follow or work with others, such as an executive sponsor, to drive these steps.

- Assess whether existing organizational structures support safe acute pain management.
    - Assess your organizational chart, identify reporting relationships and existing accountability.
    - Identify potential gaps in reporting relationships and accountability.
- Identify clinicians with expertise in pain management to serve as acute pain champions.

Step 2: Gather Information and Data

Begin gathering pertinent information that you will need to share with leadership and later with a multidisciplinary working group. This information will also be important for building a business case as part of Step 3.

- Gather the following:
    - National data on opioid prescribing, complications, and other relevant clinical data
    - Organizational data related to opioid use
    - Accreditation requirements related to opioid stewardship
    - Local, state, and national regulations and requirements related to opioid prescribing, storage, and stewardship
- Review and assess current protocols, policies, standard operating procedures, and best practices used throughout the organization related to safe acute pain management and opioid stewardship.

- Assess existing organizational goals, principles, and mission for alignment with best practices and overall strategy for safe acute pain management and opioid stewardship. Review the history of pain management at your organization and the outcome of any previous improvement efforts in pain management.

Step 3: Obtain Organizational Commitment

It is crucial to obtain the commitment and support of top leaders and board members to optimize pain care and reduce use of unnecessary opioids.

- Develop the business case for opioid safety and safe acute pain management.[82]
- Consider the cost-related consequences listed in the previous section on building the business case. Recognize that a large portion of potentially averted costs is avoiding expensive hospitalizations for the complications of OUD, such as endocarditis and osteomyelitis, which require weeks of antibiotic therapy.
- Consult with risk management personnel or organizational counsel regarding litigation risk related to inappropriate pain care and unnecessary opioid administration.
- Request that leadership write a commitment letter pledging to prioritize safe acute pain management and develop and implement organization-wide training on optimizing safe care of patients with acute pain.
- Develop a compact regarding acute pain management between leaders, staff, and clinicians. (See the example in the Tools and Resources section and in *Leading a Culture of Safety: A Blueprint for Success.*[75])

Step 4: Convene a Multidisciplinary Working Group

- Convene a multidisciplinary working group to spearhead the efforts to improve the safety of acute pain management. The selection of members should be based on organizational culture and clinical workflow. It is important to have at least one representative from each of the following groups: safety leaders, patient and family advisory council members, physicians, nurses, pharmacists, executive leaders, and clinical experts in pain management. (See Appendix C for a comprehensive list of leaders and health care professionals that you might include.)
- Develop a statement regarding conflicts of interest and ensure that all members of the committee are in compliance with existing rules related to documentation of income from pharmaceutical companies and other industries.
- Provide the group with available national data on opioid prescribing, complications, and other relevant data, from Step 2.

Step 5. Conduct an Organizational Assessment

- Provide the group with the data and information you gathered in Step 2.
- As part of the working group, assess the culture of your organization with respect to supporting safe pain management. (See the Cultural Assessment Tool in the Tools and Resources section of this document.)
- As a group, complete the worksheet, Tent Poles: The Foundational Elements of Patient-Centered Safe Acute Pain Management (in the Tools and Resources section), and assess the strengths and weaknesses of your organization for each foundational element.
- As a group, complete the worksheet, Barriers to Safe Acute Pain Management (in the Tools and Resources section), and discuss existing barriers in your organization. Brainstorm potential solutions to overcome the barriers.
- As a group, assess the information technology structure within your organization. (See the Information Technology Assessment tool in the Tools and Resources section.)

Step 6: Prioritize Activities

The priorities of the working group may have been mandated by leadership; however, often there are specific aims within larger organizational goals that require that the group focus initially on certain activities. Based on the information gathered through the organizational assessments, determine which goals and objectives are "must-do" and which are "nice-to-do." (See Appendix D for a rubric the working group can use to identify and prioritize potential opportunities for improving acute pain safety in your organization.)

Step 7: Develop an Implementation Plan

As part of the working group, develop a process plan for implementing a safe pain management program.

- Identify and prioritize the gaps in your organization's current approach to acute pain management.
- Obtain consensus on the gaps that the group will address first.
- Select a quality improvement model. The best approach will depend on the metrics that will be tracked and the organization's stage in the implementation journey. Quality improvement models include the Model for Improvement, Lean, Six Sigma, and others. When limited resources are an issue, using the Model for Improvement may be most effective.
- Select tools to use with the improvement model (e.g., driver diagram, A3 process, fishbone diagram). A driver diagram is a visual display of a group's theory about what contributes to the achievement of a project aim. It captures improvement goals, as well as primary and secondary drivers, which help the team identify specific change ideas to test. For more information, see the driver diagram for reducing opioid use on page 11 of *Addressing the Opioid Crisis in the United States*.[53] For general information about driver diagrams, see *QI Essentials Toolkit: Driver Diagram*[83] and *How Do You Use a Driver Diagram*[84] on the IHI website.

Encourage the development of a learning health care system. For more information on the learning health care system, see the Agency for Healthcare Research and Quality's *Learning Health Systems*[85] and National Academy of Medicine's *The Learning Healthcare System*.[86]

Step 8. Select Metrics and Identify a Measurement Strategy

As part of the working group, identify the metrics that will be tracked and the individual who will be responsible for gathering and tracking the data. Consider the selection of metrics carefully; they must be easy for all clinicians to use, clinically relevant, and a reliable reflection of improvement. (See Appendix E for metrics to consider.) For more information, see the recommendations and resources on measurement on the IHI website.[87]

- Create a dashboard of metrics that aligns with the organization's approach to implementation and adheres to accreditation standards and state law. Include a selection of operational, process, and outcome metrics.
- As the group selects metrics, keep these tips in mind:
    - Involve frontline health care professionals in selecting metrics.
    - Invite members of your patient and family advisory council (PFAC) to join the discussion and help select metrics that matter to patients.
    - Metrics should relate to your aim of increasing safety and better managing pain, not simply reducing utilization of opioids.[88]
    - Whenever possible, select validated metrics.
    - Optimal metrics will change over time as the acute pain management strategy is implemented and higher levels of safety are achieved.
    - Use a combination of metrics to ensure a comprehensive view of acute pain management and opioid stewardship, including outcomes measures, process measures, and balancing measures. For example, measure opioid prescribing rates and also the use of non-opioid medications and nonpharmacologic approaches.
    - Begin with metrics to identify variation between service lines and prescribers in a given clinical unit. Identifying high prescribing outliers can help shift prescribing patterns.

Step 9: Execute the Plan and Continue Improvement Activities

Execute the plan, monitor progress, provide feedback, and communicate regularly with leaders, staff, and health care professionals. Share lessons learned and celebrate successes.

- Build upon activities.
- Continue to assess and expand programming.
- Identify and share successes and areas for improvement within the organization, in the community, and nationally.
- Spread safe pain management practices, including the use of a comprehensive pain assessment with other organizations.

Taking these steps will launch your organization on its way to advancing the safety of acute pain management. To sustain the gains your organization has achieved, make sure leaders, patients, and clinicians remain engaged in continuous improvement activities. Be sure to celebrate your successes!

Conclusion

Safe and effective acute pain management is complex. Providing comprehensive holistic care while minimizing the unnecessary use of opioids is a more complicated goal than simply reducing the use of opioids, but it is an approach that is more likely to improve the safety of acute pain management. Health care organizations need to prioritize safe acute pain management and opioid stewardship, effectively coordinate an integrated strategy across all clinical and operational units, and communicate a consistent approach and messaging. Key gaps in the current landscape are limited resources, lack of coordination, and failure to develop an integrated pain management strategy across the organization.

Although there are many key stakeholders whose engagement is needed to advance safe acute pain management, health care safety leaders play a unique and essential role in connecting disparate, uncoordinated efforts within their organizations. Health care safety leaders can advance patient safety by bridging the various clinical and operational units within their organization, by fostering the engagement of leadership, and by supporting a strong safety culture to create a coordinated, enterprise-wide strategy for safe acute pain management.

Appendix A: Factors that Contribute to Issues in Acute Pain Management

Misperceptions about Pain

- Societal belief that being completely pain-free is a reasonable goal and that patients can expect the elimination of all pain
- Societal desire for an easy solution to pain (Some cultures are less quick to resort to medication. See the opinion piece in *The New York Times* as an example.[89])
- Failure to view pain management from a holistic (i.e., biopsychosocial) perspective
- Use of traditional pain scales that assess pain intensity in isolation of total patient care needs and lack of focus on functional goals for recovery
- Clinician recommendations for patients to "stay ahead of the pain" with an expectation of zero pain
- Focus on OUD as a behavioral or social problem, without understanding that OUD may originate from a pain management issue (e.g., inadequate pain control, focus on pain not function, use of opioids first)
- Clinician attitudes related to pain, opioids, stigma, and patient expectations

Lack of Patient-Centered Orientation

- Failure to include family members or primary caretakers in conversations about pain management
- Lack of a designated medication safety manager
- Not effectively engaging patients in their care (e.g., through use of tools such as care plans and standardized decision aids) and not defining success in collaboration with patients (i.e., functional goals)
- Failure to incorporate patient-specific medication indications in the prescribing process[90]
- Lack of continuity of care and coordination between providers from the patient's perspective (e.g., lack of consistency between post-operative staff and floor staff in care plans and patient education)
- Failure to clearly communicate to patients and families which health professional is the primary contact for the pain management plan
- Reactive rather than proactive approach to pain (e.g., failing to educate patients and co-create a care plan prior to planned procedures)

Insufficient Patient Education

- Failure to build greater resiliency in patients by providing information that is relevant and meaningful to them up front and addressing fear of the unknown
- Failure to educate patients about expectations and opioid alternatives and to clearly identify opioids when they are prescribed and delineate the risks and benefits of use
- Challenges related to limited patient literacy and understanding of the potential consequences of opioid use
- Failure to use teach-back systems to clarify patient and family understanding of the patient's care plan for pain
- Not communicating realistic expectations for pain, as well as goals for comfort and recovery
- Failure of the current consent process to establish a realistic understanding of pain

Competing Guidelines and Best Practices

- Challenges related to the use of different guidelines and best practices for pain management and opioid stewardship by different specialties and the need to balance specialty practices and standardization
- Lack of awareness that a single, detailed set of guidelines will not work for all specialties (i.e., no "one size fits all")
- Lack of care coordination regarding the use of guidelines and best practices
- Lack of time and productivity pressures leading clinicians to provide prescriptions without a detailed conversation, a comprehensive assessment, and co-production of a pain management plan

Competing Priorities

- Health care safety leaders with short-term focus due to competing priorities
- Leaders who focus on short-term, singular objectives rather than a long-term, more comprehensive approach that optimizes multiple objectives
- Reimbursement models causing time pressure, specifically, insufficient time for needed complex conversations
- Lack of support for nonpharmacologic options (e.g., massage)
- Clinicians and protocols "hardwired" to automatically prescribe opioids
- Leadership and health care safety leaders not viewing safe acute pain management as a top priority in their organization
- Lack of administration support for clinicians (e.g., when patients complain about best practices related to opioid use)
- Focus on patient satisfaction scores related to pain
- Lack of organizational will to implement a comprehensive acute pain management strategy

Lack of Safety Culture

- Lack of a blame-free environment with accountability to support learning from errors
- Staff concerns about negative repercussions of reporting errors or misuse of opioids
- Moral distress among clinicians and executives about decisions that impact acute pain management

Issues with Information Technology (IT)

- Gaps and problems with electronic health records (EHR) (e.g., lack of interoperability, standardization, and safeguards to accurately track and communicate the patient's pain medication use and history)
- EHR workarounds
- Lack of integration of prescription drug monitoring programs (PDMP) with EHRs to streamline use of PDMP within daily work flow
- Lack of interstate sharing of data from PDMP
- Lack of interoperability for pharmacies
- Failure to leverage the potential of information technology

Lack of Resources and Training

- Clinicians' lack of education about opioids, opioid misuse, and the risks associated with opioid use
- In some settings, limited access to pain management specialists; in others, lack of clinician awareness that consultative services exist
- Clinicians' lack of skills and ability to accurately and effectively assess pain and develop comprehensive, multimodal, holistic care plans
- Lack of awareness of patients' prior periods of opioid use
- Lack of recognition that even brief opioid use can lead to addiction
- Lack of interdisciplinary training in communication and in safe acute pain management
- Clinician's lack of experience in a coaching role
- Lack of awareness of clinicians and health care safety leaders about existing tools and resources or lack of time to access and use them
- Lack of awareness of opioid alternatives

Issues Related to Measurement and Data

- Lack of measurement consistency within systems and across the country
- Lack of metrics or benchmarks within the organization, as well as state and national benchmarks
- Lack of feedback to prescribers from leaders about prescribing patterns and other relevant data

Issues with Systems and Care Coordination

- Institutional, financial, and educational barriers to accessing and using nonpharmacologic modalities
- Variability of regulations and standards across states and lack of awareness of current requirements
- Lack of coordination across specialties and clinical units regarding best practices, including coordination with the larger community (e.g., with community pharmacies regarding dispensing practices)
- Lack of care coordination for individual patients (e.g., a designated professional to ensure care is patient-centered and coordinated among specialists)
- Care that is not patient-centered, resulting in more opioid prescriptions (e.g., automatically prescribing opioids after surgery, even if the opioid is not needed or desired by patient)
- Lack of communication when providers move between settings
- Organizational structure and culture that interferes with high-performing, interprofessional care teams[91] and fails to support best practices

Issues Related to Opioid Disposal

- Lack of clear instructions about disposal of opioids and other medications
- Lack of facilities that accept medications for disposal

Appendix B: Examples of Best Practice Initiatives

Best Practice Initiative	Description	Resources for More Information
Expanding use of alternatives to opioids	A comprehensive plan to reduce administration of opioids by ED clinicians; pilot sites reduced opioid prescriptions by 82 percent while increasing patient satisfaction;[92] program expanded to other hospital-based specialties	St. Joseph's University Medical Center's Alternatives to Opioids (ALTO®) Program The Colorado ALTO Project
Developing an acute pain service	A group within the organization with expertise in the management of acute pain to educate clinicians and provide consultation when needed	Kerns RD, Philip EJ, Lee AW, Rosenberger PH. Implementation of the Veterans Health Administration National Pain Management Strategy. Translational Behavioral Medicine. 2011;1(4):635-643. Upp J, Kent M, Tighe PJ. The evolution and practice of acute pain medicine. Pain Medicine. 2013;14(1):124-144 Le-Wendling L, Glick W, Tighe P. Goals and Objectives to Optimize the Value of an Acute Pain Service in Perioperative Pain Management. *Techniques in Orthopaedics*. 2017;32(4): 200-208. Abstract Link.
Creating an awareness campaign	A campaign launched with the goal of educating clinicians and patients about prescription drug abuse and overuse	Be Rx Safe campaign in Michigan American College of Surgeons: Safe Pain Control Opioid Abuse and Surgery campaign
Developing an opioid guardianship program	A formal, organization-wide program to holistically address opioid prescribing and use	Weiner SG, Price CN, Atalay AJ, Harry EM, Pabo EA, Patel R, et al. A health system-wide initiative to decrease opioid-related morbidity and mortality. *Joint Commission Journal of Quality and Patient Safety.* 2018. Aug 28. pii: S1553-7250(18)30088-6. Abstract Link
Using assessments to identify patients at high risk for OUD	Algorithm to distinguish patients at low, medium, and high risk for OUD	Sharma M, Lee C, Kantorovich S, Tedtaotao M, Smith GA, Brenton A. Validation study of a predictive algorithm to evaluate opioid use disorder in a primary care setting. Health Services Research and Managerial Epidemiology. 2017. NIDA Quick Screen: questions about illicit prescription drug use during past year and lifetime NIDA Modified-ASSIST: questions about nonmedical use of prescription drugs during the past year and lifetime DAST-10 (Drug Abuse Screening Test): 10-item self-report instrument SISAP (Screening Instrument for Substance Abuse Potential): 5-item clinician administered instrument to identify patients with chronic pain at higher risk for substance abuse ORT (Opioid Risk Tool): 5-item checklist completed by the clinician that predicts future aberrant drug-related behaviors SOAPP-R (Screener and Opioid Assessment for Patients with Pain-Revised): 24-item self-administered tool to predict aberrant drug-related behaviors in chronic pain patients DIRE (Diagnosis, Intractability, Risk, and Efficacy): a clinician-administered rating scale to predict suitability for long-term opioid treatment of non-cancer pain

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Best Practice Initiative	Description	Resources for More Information
Using assessments to identify patients at high risk for OUD	Algorithm to distinguish patients at low, medium, and high risk for OUD	COMM (Current Opioid Misuse Measure): 17-item questionnaire to identify chronic pain patients who are currently misusing their prescribed opioids Office of Inspector General: Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose
Developing a perioperative optimization program	A multidisciplinary collaboration that provides clinical assessment and management prior to surgery, including acute pain management	Walters TL, Mariano ER, Clark JD. Perioperative surgical home and the integral role of pain medicine. *Pain Medicine.* 2015;16(9):1666-1672. American College of Surgeons: Optimal Perioperative Management of the Geriatric Surgical Patient: Best Practice Guidelines
Using enhanced recovery after surgery (ERAS) protocols	Multimodal perioperative care pathways designed to accelerate recovery after surgical procedures by reducing the stress response and maintaining organ function at presurgical levels	For example, Clinical Practice Guidelines for Enhanced Recovery After Colon and Rectal Surgery From the American Society of Colon and Rectal Surgeons and Society of American Gastrointestinal and Endoscopic Surgeons
Creating a peer recovery specialist program	Program that trains people with a personal experience of substance use disorder and recovery to support the recovery of others	Tennessee Department of Mental Health and Substance Abuse Services Certified Peer Recovery Specialist Program
Using a multimodal pain assessment	Assessment that measures pain in a holistic context (e.g., function, sleep, mood, stress, pain)	Veterans' Administration Defense and Veterans Pain Rating Scale (DVPRS) The Pain Intensity, Enjoyment of Life, General Activity (PEG) Brief Pain Measure The Pain Assessment Screening Tool and Outcomes Registry (PASTOR), a chronic pain survey tool created by the Defense and Veterans Center for Integrative Pain Management, incorporates demographics, DVPRS measures, Patient-Reported Outcomes Measurement Information System (PROMIS) measures, an anatomical map for locating pain, and military-specific pain related questions The Stanford Collaborative Health Outcomes and Information Registry (CHOIR), an interactive tool for gathering information from patients about chronic pain For additional context, see the NIH PROMIS measures and the Quality of Recovery 40 Scale.
Using procedure-specific guidance	A guideline for postsurgical opioid prescribing tailored to the specific procedure	Johns Hopkins Center for Opioid Research and Education

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Best Practice Initiative	Description	Resources for More Information
Developing an academic detailing program	Guide for training clinical pharmacy specialists in academic detailing to promote evidence-based treatments by clinicians	Veterans Administration Academic Detailing Implementation Guide
Establishing a protocol for the care of patients with OUD undergoing surgery	Suggestions to consider when developing a protocol	For example: Harrison TK, Kornfeld H, Aggarwal AK, Lembke A. Perioperative considerations for the patient with opioid use disorder on buprenorphine, methadone, or naltrexone maintenance therapy. *Anesthesiology Clinics.* 2018;36(3):345-359.

Appendix C: Possible Members of Multidisciplinary Working Group

The selection of members should be based on your organization's culture and clinical workflow.

Health care safety leaders (Safety, Quality, Risk)

Patient and Family Advisory Council members

Health care professionals:

- Emergency physicians
- Emergency department nurses
- Hospital-based physicians (i.e., "hospitalists")
- Surgeons, especially neurosurgeons and general, oral, orthopedic, and trauma surgeons
- Perioperative nurses
- Floor nurses
- Primary care physicians
- Pain specialists
- Addiction specialists
- Social workers
- Psychiatrists
- Psychologists
- Advanced practice providers in primary care, ED, and surgery
- Dentists
- Providers of acupuncture, massage, physical therapy, behavioral health, exercise therapy, and chiropractic care
- Hospital-based pharmacists
- Community pharmacists

Executives:

- Chair of Anesthesia (or designee)
- Chair of Emergency Medicine (or designee)
- Chair of Internal Medicine (or designee)
- Chair of Psychiatry (or designee)
- Chair of Surgery (or designee)
- Chief Medical Officer
- Chief Nursing Officer
- Chief Information Officer

Director of Graduate Medical Education or Designated Institutional Official (if applicable)

Director of Pain Management Services

Director of Primary or Ambulatory Care

Director of Behavioral Health Services

Pharmacy Director

Medical Director

Community Services representatives

Appendix D: Rubric for Identifying and Prioritizing Opportunities for Improving Acute Pain Safety

	Starter	Intermediate	Comprehensive
A common vision of acute pain management as a patient safety priority	• Conduct an organizational assessment related to safe acute pain management and opioid stewardship. • Adapt national solutions for local requirements • Identify areas for organizational improvement • Ensure patient and family engagement in all efforts to promote pain management and opioid stewardship.	• Empower clinicians to use their judgment about safe action in their interactions with patients who are upset about best practices ○ Develop a protocol for setting realistic expectations about pain/pain management ○ Ensure comprehensive education of patients and families about multimodal pain treatment ○ Consider designating a medication safety manager ○ Develop a standard de-escalation protocol for interacting with upset patients ○ Develop scripts for use in different scenarios (e.g., patient requesting intravenous hydromorphone) ○ Be pre-emptive about best practices (e.g., post pain management policies and advise patients about policies prior to procedures) ○ Ensure medication lists are updated ○ Develop resources for educating patients about herbal and over-the-counter options for pain management ○ Consider the use of pain management contracts with patients ○ Use root cause analyses[93] to investigate the underlying drivers of patients' negative responses to best practices (e.g., Is there miscommunication, failure to set expectations, or inconsistent messaging?) • Ensure that organizational leaders are aware of and consistently supporting protocols, policies and procedures • Use a balanced set of metrics to assess acute pain management safety across the organization	• Promote community and regional support for safe, effective acute pain management and opioid safety. • Engage and work with stakeholder groups, including first responders, local government, public health departments, community-based groups, and patient advocacy groups.
Patient- and family-centered pain assessment, management, and monitoring	• Develop a comprehensive pain assessment and management plan ○ Create a process for accurately, comprehensively, and continually assessing patient pain	• Work with community groups to establish access sites for safe disposal of unused opioids • Provide consistent, standardized messaging to patients about pain management at the time of initial care for injuries and prior to procedures. Messaging should include: ○ Expected experience post-procedure, including degree and timing of movement, length of stay, and pain level	• Continue and expand formal patient and family engagement activities, for example, identifying a family member as a designated medication safety manager who, along with the patient, is part of the care team

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	Starter	Intermediate	Comprehensive
	○ Continually monitor and update process plan ○ Co-create management plans with patients ○ Create a script for presurgery conversation between patient (or primary caregiver) and surgeon or nurse	○ Education on safe, effective acute pain management ○ Goal setting ○ Explanation of the shared decision making approach ○ How to be fully informed about their care and engaged co-producers of their care plan	• Develop and distribute patient education and self-management tools • Work with PFAC members to develop a program that matches patients with members who have had a similar surgical procedure, managing pain effectively
Comprehensive education, training, and evaluation of effectiveness of training.	• Train clinicians to conduct multidimensional pain assessments, co-produce care plans, and manage care management plans over time; test the proficiency of individual clinicians, clinical units, and the organization as a whole.	• Ensure a mechanism for just-in-time leadership support for clinicians (i.e., a leader or pain management representative, such as the director of pain management, director of opioid stewardship, chief medical officer, or a member of the pain management team, medical board, or pharmacy and therapeutics committee, who is available for back up)	• Use health care simulation to practice conversations between patients and clinicians. • Develop training videos for effective communication between patients and providers.
Effective systems of care	• Create a process for referrals to and communication with the pain management service or acute pain champions; ensure clinicians are aware of the process • Develop a "bridge clinic"* (for smaller organizations, this may be a capability or service that is part of an existing department or clinical unit) • Integrate the PDMP into the workflow	• Consider and utilize relevant resources to assist clinicians with identification of specific patients who may benefit from MAT or other interventions. Example: https://www.samhsa.gov/medication-assisted-treatment • Reduce variation by using standardized protocols and order sets • Increase the use of EHR standardized order sets • Review pop-up warnings in EHR; monitor the proportion that are ignored • Develop and share best practice advisories with clinicians (e.g., on high-dose opioid prescribing) • Develop standard recommendations for post-operative pain management • Encourage electronic prescribing of controlled substances if permitted locally • Implement best practices for disposal of unused drugs to prevent diversion • Assess procedure-specific local prescription patterns for a given diagnosis or procedure where feasible (e.g., track MME) • Develop universal monitoring for inpatient safety • Refer patients with chronic pain who develop acute pain for consultation with a pain management service • Implement EHR standardization and evidence-based care plans to provide decision support and consistent information for patients	• Promote and develop data-driven solutions to offer safer acute pain management ○ Develop a data warehouse with tools and analytic support to extract data for metrics related to acute pain management ○ Track key metrics in dashboards ○ Analyze PDMP reports to prioritize needs for intervention

*Bridge clinics provide temporary care for patients who need treatment for OUD or support transitioning off opioids; they may be referred to by other names in different locales.

Appendix E: Examples of Metrics for Advancing the Safety of Acute Pain Management

Operational Metrics*	Process Metrics	Outcome Metrics
• ED length of stay • ED wait time • ED bed/bay turnover time • Post-anesthesia care unit (PACU) length of stay • PACU turnover time • 30-day readmission rate • Inpatient length of stay • Employee injury rate (EIR) • Employee days away restricted or transferred (DART)	• New opioid prescription written per 1,000 patients • Morphine milligram equivalents (MME) prescribed across hospital and per unit/clinician • Number of pills prescribed after specific surgeries • Number of days' supply prescribed after specific surgeries • Percent of patients readmitted for pain management • Percent of patients receiving multimodal analgesia • Percent of patients receiving Narcan during hospital stay • Percent of eligible patients receiving local/regional anesthesia • Percent of patients receiving opioid refills following surgery (without referral to pain management consultant) • Unplanned ED visits for pain management • Unplanned postoperative admissions for pain management • Utilization of a screening tool for risk assessment • Percent of patients receiving medication for addiction treatment (MAT) • Percent of cases in which non-opioid options were tried first (with certain exceptions such as trauma) • Prescriber opioid prescription rate by specialty** • Number of incidents of high-risk coprescribing (e.g., opioids and benzodiazepines) • Percentage of postsurgical prescriptions for which the number of pills prescribed is consistent with adopted standards (For example, see standards set by Washington State.[94])	• Annual number of fatal overdoses per patient population or "covered lives" • Annual number of nonfatal overdoses per patient population or "covered lives" • Prevalence of OUD per 1,000 person-years • Percent of patients experiencing opioid-related adverse drug events (ORADE), such as opioid-related adverse respiratory events (ORARE) requiring naloxone administration **Outcome Metric Sets** • PROMIS measures • Metrics related to function (ambulation, sleep, delirium, ileus, nausea, vomiting, pruritus, urinary retention) • VA approved metrics • National Quality Forum metrics

*Alternatively, select metrics relevant to a specific service line.

** Based on patient panel size for primary care providers or number of discharges for emergency physicians

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Tools and Resources

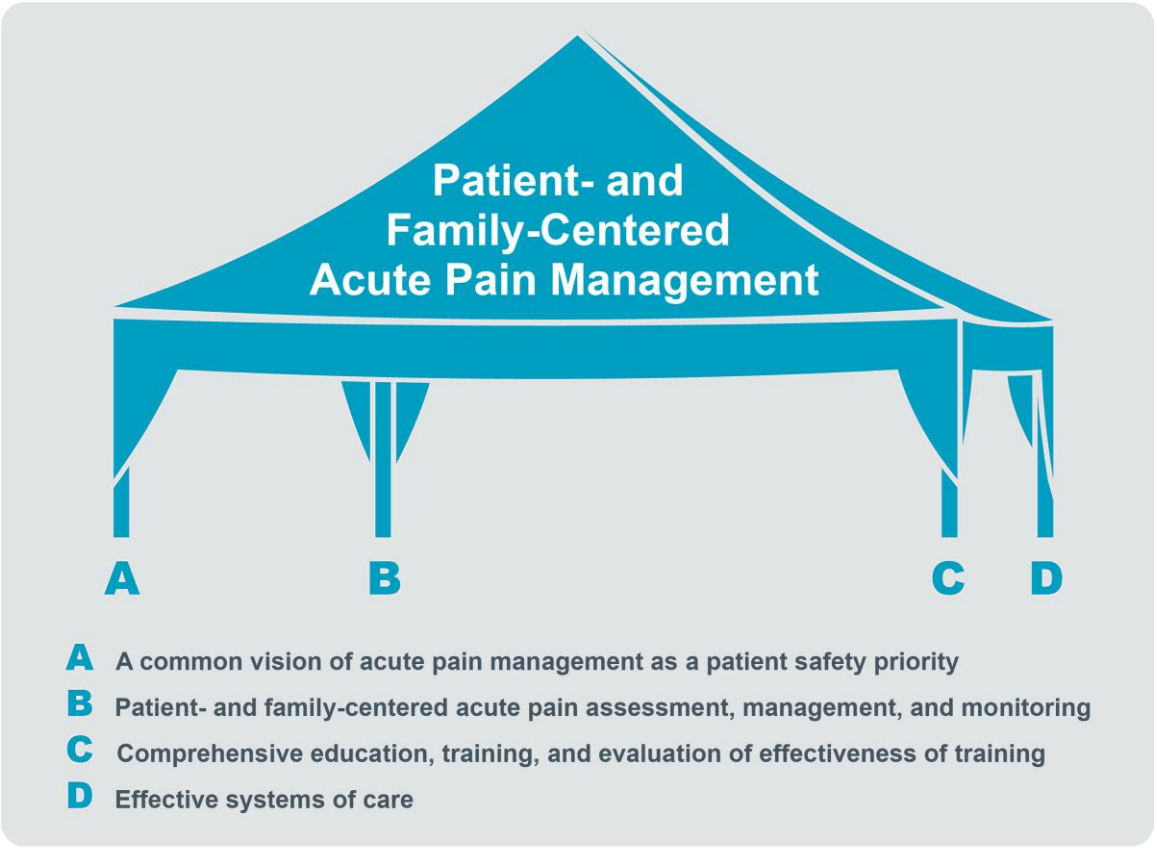
Pain Management Organizational Compact

Leadership	Clinicians and Staff
Make pain management/opioid safety a priority for your organization.	Understand the impacts of opioid prescribing.
Review regularly the dashboard of metrics that aligns with the organization's approach to implementation and adheres to accreditation standards and state law.	Review regularly the dashboard of metrics that aligns with the organization's approach to implementation and adheres to accreditation standards and state law.
Prioritize safe acute care pain management.	Participate in efforts to improve opioid safety.
Support the development and implementation of organization-wide training on optimizing safe care of patients with acute pain.	Participate in data collection efforts.
Recognize that a large portion of potentially averted costs is avoiding expensive hospitalizations for the complications of opioid use disorder (OUD), such as endocarditis and osteomyelitis, which require weeks of antibiotic therapy.	Communicate concerns with acute pain champions or senior leaders.
Include patients and families in system design, development, and processes, and in highlighting exemplary practices.	Collaborate and communicate with patients and families.
Provide clinicians and staff with the support needed to implement improvement efforts.	Ask for the support needed to implement recommended improvement efforts.
Listen to clinician and staff concerns about acute pain management stewardship.	Listen to your concerns about acute pain management stewardship
Support clinicians and staff with efforts to encourage multimodal approaches to pain management.	Support organizational efforts to improve multimodal approaches to pain management.
Become informed about best practices and standards related to acute pain management and safety.	Become informed about best practices and standards related to acute pain management and safety.
Support efforts to balance analgesic efficacy with safety concerns.	Consider patient safety first when making decisions about choices for analgesia.

Cultural Assessment Worksheet

YES	NO		If no, please rate priority level (1 low priority – 5 high priority)
		The organization has a strategy for safe acute pain management.	
		The organization's goals, principles, and mission are aligned with developing an acute pain management program.	
		There is an expectation that the goal of acute pain management is not necessarily elimination of pain, but rather maximizing emotional and physical functioning and comfort, while providing the safest possible care.	
		There is an existing and strong culture of safety within the organization.	
		There are policies on opioid prescribing, storage, disposal, and stewardship.	
		There are standard operating procedures and protocols on file for safe pain management.	
		There are documented best practices for opioid stewardship.	
		Policies, protocols, procedures, and best practices are made easily available to clinicians.	
		Policies, protocols, procedures, and best practices are shared with patients and families.	
		Complex conversations with patients about expectations regarding pain and pain management are encouraged and supported.	
		Pain management processes are in place to engage patients in their care.	
		Clinicians are encouraged to practice shared decision making.	
		Resources are available to assist patients and clinicians in effective shared decision making about safe acute pain management.	
		Resources are available for educating patients about safe pain management.	
		Resources are available for ongoing education and training of clinicians about safe acute pain management.	
		Mechanisms are in place to consistently measure and track opioid prescribing data.	
		Mechanisms are in place to communicate data to senior leadership.	
		Senior leadership consistently reviews data related to opioid prescribing.	

Tent Poles: The Foundational Elements of Patient-Centered Safe Acute Pain Management



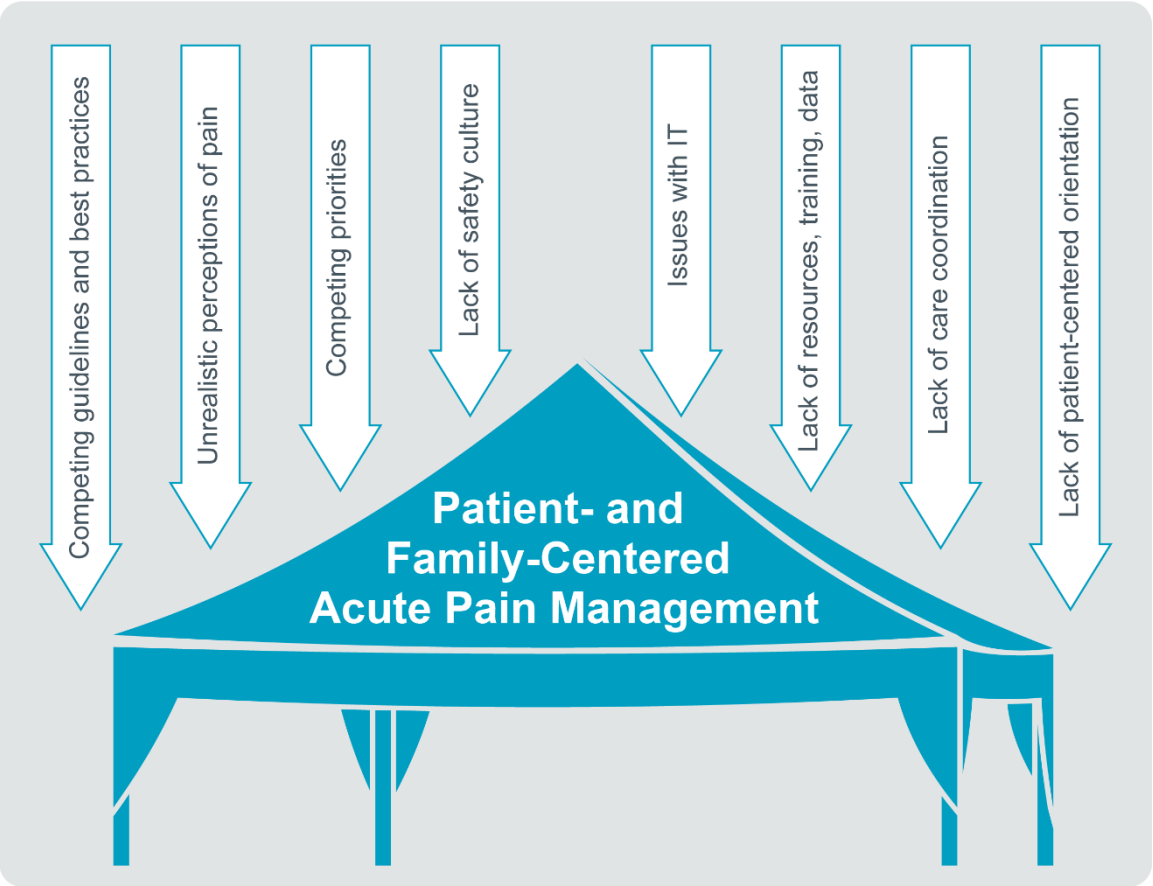
What organizational goals, principles, or aspects of your mission are aligned with and support these foundational elements?

Are any of these tent poles weak or lacking support?

Are there poles that are particularly strong? How might you draw on those strengths?

Identify and discuss with your team the organizational strengths and weaknesses related to supporting and sustaining these tent poles.

Factors that Impede Safe Acute Pain Management



These are factors that weigh down your tent (and the structural integrity of your organization). These factors put stress on the foundation and ultimately impact the care provided to your patients. As the safety leader, and as the bridge to better and safer coordinated efforts to patient safety, work with your team to understand which of these stressors are putting your organization at risk.

What additional elements related to pain safety are weighing down your organization?

Information Technology Assessment

YES	NO		If no, please rate priority level 1–5 (1 low priority – 5 high priority)
		The Prescription Drug Monitoring Program (PDMP) system is integrated into the electronic health record (EHR).	
		The use of standardized EHR order sets are encouraged or required.	
		Data has been gathered about ignored pop-up warnings.	
		Standard IT-related recommendations have been documented and shared across the organization.	
		Electronic health record workarounds have been explored and identified.	
		Mechanisms are in place for interstate sharing of data from PDMP system.	
		Mechanisms are in place for interoperability with pharmacies.	
		Electronic standardization and safeguards to accurately track and communicate patients' pain medication use and history are in place.	
		There is an automated alert system within the EHR that monitors cumulative morphine daily dose and alerts clinicians and staff if present dosage thresholds have been breached.	
		Prescriber dashboards are available that illustrate acute pain management metrics to inform physician practice.	

Checklist for Presurgery Conversation Between Patient (or Primary Caregiver) and Surgeon or Nurse

- ☐ Explain to the patient that this is the time to discuss what will happen post surgery.
- ☐ Explain to patients how they will feel when they wake up from the anesthesia, who will be there to help them, what will be done, and how long they will remain in the recovery room.
- ☐ Discuss with patients if they will receive opioids, how they will be administered and for how long. Discuss any safety monitoring that will go on while the patient is receiving opioids.
- ☐ Discuss the long-term plan for pain management, the risks and benefits of opioids (including serious side effects and addiction), and how the patient will be monitored for safety.
- ☐ Discuss with patients any choices they can make at this point about pain management for the first 48 hours after surgery. Provide patients with enough information, including your recommendations, so that they can make appropriate decisions.
- ☐ Explain the expected trajectory of recovery/pain over the first 48 hours to the patient. Explain the multimodal options for pain management and which functions (breathing exercises, sitting up, walking, physical therapy, etc.) the patient can expect to begin within that period of time.
- ☐ Discuss with patients any choices they can make about pain management for the first week or month after surgery. Provide patients with enough information, including your recommendations, so that they can make appropriate decisions.
- ☐ Discuss the patient's priorities/goals regarding function (returning to work in x number of days, walking up stairs, traveling, playing a sport, etc.).
- ☐ Depending on the patient's goals and personal preferences, develop a postsurgery plan to achieve the patient's goals that may include:
    - Massage, acupuncture, aromatherapy, etc.
    - Physical and/or occupational therapy
    - Yoga, exercise, walking, etc.
- ☐ Provide surgery-specific tips to reduce pain (for example, placing pillows under the arms to reduce pressure).
- ☐ Discuss non-opioid medications, including Tylenol (acetaminophen) and NSAIDS (non-steroidal anti-inflammatory drugs), which include medications such as ibuprofen and naproxen as well as other non-opioid medications and topical agents that can be applied for pain relief.
- ☐ Discuss if the patient can expect to return to 100 percent of the function he or she had prior to surgery. If that isn't possible, discuss the long-term prognosis.
- ☐ Discuss who will coordinate the patient's care post surgery.
- ☐ Make sure to ask the patient if he or she has other questions.

Script for Presurgery Conversation Between Patient (or Primary Caregiver) and Surgeon or Nurse

Dr/Nurse: Hi, how are you feeling about your upcoming surgery?

Patient: Pretty good, ready to have it behind me!

Dr/Nurse: That is completely understandable! We are meeting today to make sure your surgery and recovery goes as smoothly as possible. So today, would it be ok if we spend a few minutes discussing what will happen post surgery, including your recovery?

Patient: That would be great!

Dr/Nurse: Post surgery, you will wake up in a recovery room. I would expect that you would be there for anywhere from 45 minutes to one and one-half hours. A nurse will be there to assess your level of discomfort and manage your pain.

We have prescribed _____, which will be administered through your IV for the first 24 hours. This medication is an opioid, so I want to be sure you are comfortable with that. I believe that you will need it initially as your body recovers from the surgery. We can adjust the medication to make sure you receive an effective dose that is the least amount necessary.

My expectation is that you will have some discomfort in the first 24 hours, but we will work together to make sure you are comfortable enough to rest and get sleep that will aid in your recovery. In addition, we will get you to sit up and walk a little — with assistance.

You may have heard some negative things about opioids. Opioids are very effective for short-term relief of pain. Opioids have some serious side effects, such as impairing your ability to take a deep breath, constipation, and, if taken for longer periods of time, opioid dependence and even addiction. We will monitor your heart rate, breathing, and sedation levels, and also give you a medicine to help prevent constipation when you are prescribed opioids. Because of these side effects, we use the lowest dose of opioid necessary to help you control your pain for the shortest possible amount of time. You completed a preoperative assessment, which indicates you are at low risk for complications from opioids, including breathing problems and addiction. So just know we will use the lowest dose possible, monitor you carefully post surgery for side effects, give you medicine to help prevent side effects, and also try to discontinue the opioid as soon as possible.

Do you have any questions or concerns thus far with the plan?

Patient: I'm comfortable with that plan. What would happen after the first 24 hours?

Dr/Nurse: After 24 hours we would switch to an opioid by mouth or Norco [a combination of opioid and non-opioid medication] every 4 hours as needed. Depending on your pain, we can try Advil or Tylenol instead of Norco. If you end up having to take Norco for pain, the goal would be for you to be on the Norco for only the second 24–36 hours. Most patients find their pain is controlled with only Advil or Tylenol or nothing at all at this point.

Many patients are able to successfully make that transition to non-opioid medications before they leave the hospital. Some require no medication at all for pain. We will help you manage your pain

with what we call a multimodal approach, meaning several techniques will be used at the same time. In your case, you may be offered a variety of medications and you will have the option to select other pain control options, including aromatherapy, acupuncture, heat, ice, and relaxation therapy. We have many different safe and effective options for pain control as alternatives to taking medicines. Because each patient is unique and the options we give you for no-medicine pain relief have a low risk of serious side effects, your care team will work with you to customize a pain control plan. How does this sound so far?

Patient: I think it sounds fine. Does this plan get scheduled in advance? What if the medication is not enough or is more than I need?

Dr/Nurse: Here is a copy of your anticipated pain management plan. After your operation, your designated nurse contact will help you manage your pain and maximize your recovery. You will be able to communicate any changes you want in the plan on a daily basis with your nurse. The nurse will contact me if you have any questions or requests that need my attention.

Right now, after 24 hours on IV pain medicine we are planning to give you Norco for your first dose of oral pain medicine. Then we will switch to a non-opioid pain reliever such as Tylenol. You can still have one Norco every 4 hours (up to 6 tablets every 24 hours). In between this you can select up to 6 other pain management modalities from the list of safe pain management options. We have selected three for you already. The first is ice every two hours (on for 30 minutes), the relaxation-feedback exercises, and the walking. We will ask you for feedback on how this is working for you and make changes to help keep you comfortable. How does this sound?

Patient: This sounds really good. I like that I have some control over my pain. It makes me feel like I have a choice.

Dr./Nurse: Exactly! That is important to us as well. If you have any questions that should come up after this visit, please feel free to call my office. Here is my number and the detailed directions about how to get to the hospital and floor where you will check in on the date of your surgery.

Next, I'd like to discuss your goals for your recovery. What would you like to set as goals?

Patient: At home, I would like to go for a walk every day. Would I be able to shower or cook? I'd like to go back to work in two weeks if possible.

Dr/Nurse: You will have some limitations for the first few weeks. No shower for 5 days while the incision is healing. I would encourage you to walk every day — even in the hospital. Don't lift anything heavy or even over one pound, so let others cook for you in the first week. You should be able to return to work after two weeks.

Get as much sleep as you can. After the first week, which should be spent resting, you can begin the arm exercises that we will provide you at your doctor's visit, a week after surgery, and you can discuss the next steps. If your recovery is on track your surgeon will likely clear you to return to work.

Patient: Do you expect that I will be able to recover 100 percent?

Dr/Nurse: You may be slightly limited in your arm movement, but I anticipate a 95–98 percent recovery.

Next I would like to discuss who will help coordinate your care after surgery.

My office will schedule you to see your primary care physician, who will make sure that you are doing well after your surgery and will give you a general postoperative check-up to make sure you are doing well. You will also be scheduled with a physical therapist, who will develop a treatment schedule for you. You will see me two weeks after your surgery, at which time I will remove your sutures, and if all is going well, sign your approval to return to work. How does this sound?

Patient: That sounds great. Thanks for explaining this to me.

Dr./Nurse: Of course. Are there any other questions you have?

Patient: Because of my atrial fibrillation, I see a cardiologist regularly. Who will coordinate my medications and pain management?

Dr/Nurse: We at the hospital will contact Dr. Smith and make sure that you have a well-coordinated plan. How does this sound to you?

Patient: That sounds great. I really trust my cardiologist and am pleased to hear you will be coordinating with him.

Dr/Nurse: I work with Dr. Smith a lot and he is a really great physician. He is always a great help in helping his patients have a successful and safe surgery. Are there any other questions you have?

Patient: No, I think you have answered all my questions. Thank you!

Dr/Nurse: Thank you and I will see you next at the hospital.

Case Study: Initiating a Safe Acute Pain Management Strategy at General Memorial Hospital

Note: *The following case study is a fictional representation of how a health care organization might go about using the recommendations and tools in this document to develop and implement a safe acute pain management strategy. Data and project details are illustrative and meant to be referenced only as examples.*

Roberta Snow, RN, MSN, is the safety and quality officer at General Memorial, a 400-bed community hospital in a small city in the Midwest. She worked in the post-anesthesia care unit (PACU) for 12 years, then as the infection control officer for 5 years, before accepting her current position 6 years ago. Roberta's responsibilities include quality and safety monitoring and initiatives, compliance, patient experience, and infection control. She has eight direct reports, including a process improvement team of two people.

On a Tuesday morning in July, Roberta is informed by the CMO that the board received a complaint about a recent stay in the PACU. Her presence is requested at the weekly executive quality meeting that afternoon.

At the meeting, the chief executive officer (CEO) reads the complaint, a letter from the wife of a patient.

> "My husband Dan struggled with drug addiction in his twenties. He has been drug-free for 15 years now and is active in Narcotics Anonymous. As part of his recovery, he completely avoids prescription painkillers and sedatives. Last week, he had surgery to repair a knee injury caused by a fall from a ladder. After the fall, he tried to manage the pain with just ibuprofen and ice, but was not able to sleep. Before surgery, Dan told Dr. Smith, the orthopedic surgeon, that he didn't want any opioids. However, in the recovery room, the doctors and nurses offered him Dilaudid four times (he kept saying no). When Dan asked for something in addition to the ibuprofen for the pain, he was given a hospital glove with some ice in it.
>
> When we left the hospital a few hours later, the doctor gave him a prescription for Percocet. What I didn't realize was that after another day of unbearable pain, Dan filled the prescription. He has contacted his sponsor and has stopped using the Percocet, but nothing is guaranteed. I can't believe that your hospital put his recovery and his life in jeopardy.
>
> This never should have happened. We're lucky that he has a support system and is getting the treatment he needs now. Many patients don't have that support, and the outcome could have been much worse. I'm angry that my husband was in pain for days and that his recovery from addiction was put at risk. I want to make sure this doesn't happen to other patients. Why was his only choice pain or opioids?"

The CEO concludes, "This is something we need to address. We can't give the impression that we're encouraging opioid use. Why wasn't he offered something else? We're lucky this outcome wasn't worse. I want to fix this before we wind up in the news for killing a patient."

The chief medical officer (CMO) nods and looks to Roberta. "We need to better understand our use of opioids — and make sure we are using best practices. The safety of our patients is central to all that we do in this organization, yet we continue to struggle to put the patient first. Roberta, we want you to take the lead on this."

Back at her office after the meeting, Roberta frowns, thinking, "Where am I supposed to begin with this? Opioid use impacts every service line in the hospital. This is completely overwhelming. I can't do this alone." Roberta spends some time that evening looking online for resources that might be helpful. She finds the IHI document titled, "Advancing the Safety of Acute Pain Management." After a thorough read, Roberta feels encouraged to ask for the help she needs and begins taking the steps along the journey toward safer, patient-centered pain management.

Step 1: Understand Your Role

Roberta asks the CMO for an executive sponsor. The CMO takes on this role. Roberta realizes that the initiative will be more effective with a clinical lead who has expertise in pain management. She asks the emergency department chief, who has taken an active interest in opioid stewardship, to take on this role. Roberta sets a time for the three of them to meet to discuss and clarify their roles and the steps that will take place over the course of the next 6 to 24 months. She wants to be certain that everyone is in agreement regarding roles and responsibilities as they continue this work. Having the support of these leaders reinforces Roberta's confidence that the organization is ready to begin this work.

Step 2: Gather Information and Data

Next, Roberta gathers information and data, both national and hospital-specific, on opioid prescribing, use of opioid alternatives, and regulations related to opioid prescribing, storage, disposal, and stewardship in the acute care setting. She reviews the current protocols and procedures related to opioid prescribing, storage, disposal, and stewardship used in the various service lines across the organization. She interviews an anesthesiologist who has worked at the hospital for 30 years about the history of improvement work in pain management in the past.

Roberta realizes that while the organization has recently implemented new protocols, many staff are not aware of these protocols or where to access them. Roberta initiates the Root Cause Analyses and Action (RCA²) protocol related to the concern expressed in the letter from the patient's wife to gain insight and develop a strong action plan to mitigate future risk. Roberta meets again with the CMO and the clinical lead to discuss the gaps she has identified between best practices, state and national requirements, and organizational practice. They begin to plan their next steps for creating commitment across the organization.

Step 3: Obtain Organizational Commitment

Roberta presents her findings at an executive quality meeting and at a board meeting. At the meetings, she begins by emphasizing that quality and safety are a key priority for their organization, as clearly stated in the hospital's mission and vision statements. She shares the Pain Management Organizational Compact (see example in the Tools and Resources section), which outlines the accountability of leaders, staff, and clinicians. While giving these presentations and having these conversations with senior leaders, Roberta highlights the foundational elements that will need to be built to foster the development of a successful pain management initiative.

These foundational elements are:

- A common vision of acute pain management as a patient safety priority
- Patient- and family-centered acute pain assessment, management, and monitoring
- Comprehensive education, training, and evaluation of effectiveness of training
- Effective systems of care

The leadership team accepts Roberta's plan. Following these meetings, she develops a commitment letter and distributes it to the executive team and the hospital board members. The letter gives the working group the authority to execute the safe acute pain management initiative within the organization, outlines the key service lines that will be involved, and includes a budget listing the resources that will be made available.

These resources include:

- IT support
- Dedicated time of a project manager
- Access to data
- Funds to cover FTE/clinical time for Roberta and her team
- Resources in the form of funds and administrative support to develop a multidisciplinary committee that includes patient and family representatives

Step 4: Convene a Multidisciplinary Working Group

Roberta convenes a working group that consists of a pharmacist, an ED nurse, the ED chair, a member of the hospital's Patient and Family Advisory Council, a hospital-based internist who has expertise in acute pain management, a PACU nurse, and a physical therapist. Roberta shares the information gathered previously and the presentation developed for the executive leaders in an effort to ensure the commitment of members of the working group.

Once the group members are fully engaged, they develop a charter for their work and agree to meet for three hours for an initial meeting, then for one hour each month. Each member of the working group signs a statement regarding conflicts of interest that ensures that all members of the committee are in compliance with existing rules related to documentation of income from pharmaceutical companies and other industry sources.

Step 5. Conduct an Organizational Assessment

To get a sense of the current state of acute pain management, over the next month, the group completes the Cultural Assessment Tool, the Tent Poles worksheet, the Barriers to Safe Acute Pain Management, and the Information Technology Assessment Tool. (See Case Study Figures 1–4.) The working group seeks input from various departments, including clinical, operational, and administrative, before completing the assessments together as a group.

Step 6: Prioritize Activities

As the group reviews the information on the worksheets, several gaps and weaknesses become evident. Several members of the working group attend a meeting of the Patient and Family Advisory Council to get their feedback on the accuracy of the working group's assessment and prioritization of future activities. Next, they use the Rubric for Identifying and Prioritizing Opportunities for Improving Acute Pain Safety (Appendix D) to identify the highest priority opportunities and prioritize future activities. Roberta and the ED chair, the clinical lead, present their findings and priority list to senior leaders and gain consensus on next steps.

Step 7: Develop an Implementation Plan

At the next meeting of the working group, members decide to use the Model for Improvement as a quality improvement model and a driver diagram as their primary improvement tools. They decide to begin their work with a specific acute inpatient population: patients undergoing scheduled surgical procedures. Over the next several weeks, the group creates a driver diagram. (See Case Study Figure 5.) They develop an aim statement: *"By December 31, 80% of our planned surgical patients will receive safe pain management pathways of care."*

Step 8. Select metrics and identify a measurement strategy.

Based on their understanding of the drivers and their aims, the group decides to create a dashboard of six key metrics that they will track. Recognizing that she will need to report to leadership, Roberta volunteers to gather the related data and create monthly reports on the dashboard metrics.

The six metrics they select for the dashboard are:

1. Number of patients undergoing surgical procedures with documented use of standardized pain management per month (numerator) over total number of patients undergoing scheduled surgical procedures per month (denominator)
2. Prescriber opioid prescription rate by specialty per month
3. Average post-anesthesia care unit (PACU) length of stay per month
4. Percent of inpatients experiencing opioid-related adverse drug events (ORADE) per month
5. Unplanned ED visits for pain management per month
6. Percentage of postsurgical prescriptions per month for which the number of pills prescribed is consistent with adopted standards

Step 9: Execute the Plan and Continue Improvement Activities

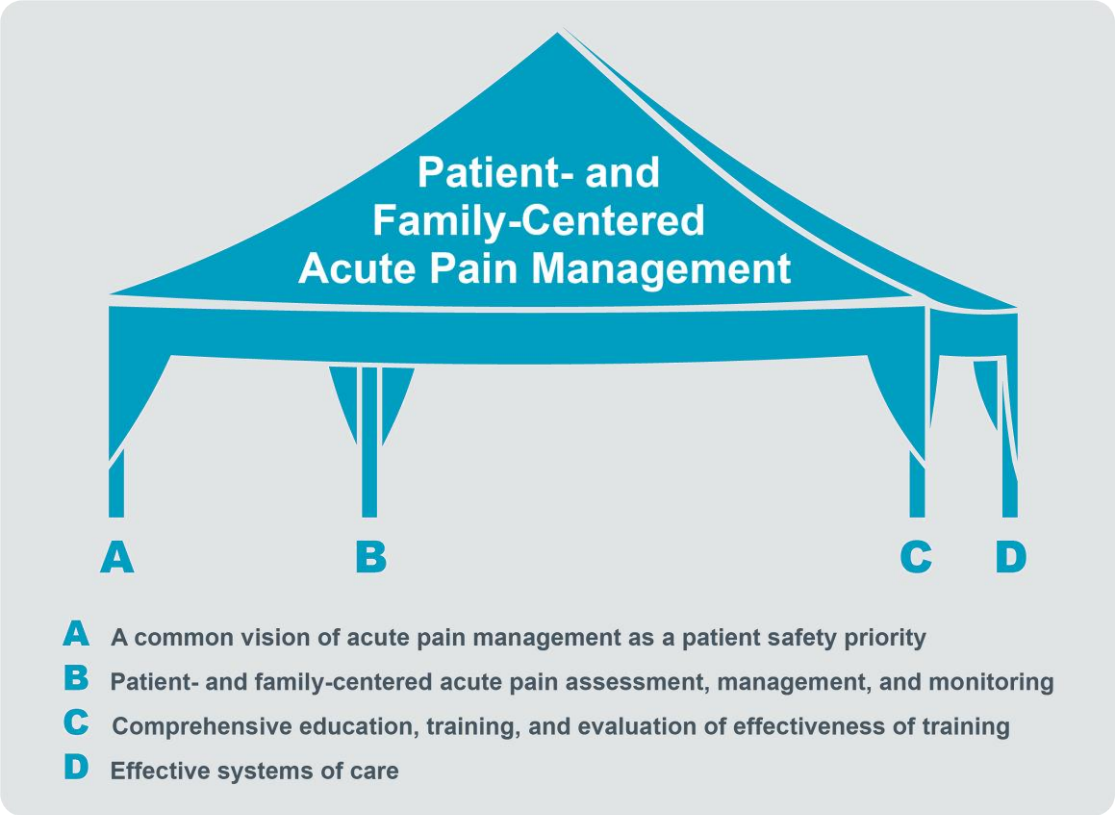
The working group, with assistance and support from their executive sponsor, begin testing their change ideas. The team kicks off with a series of lunch-and-learn events on hospital standards and protocols. Based on the simulation script provided in Advancing the Safety of Acute Pain Management, two members of the committee (the ED nurse and the PFAC representative) develop a script for clinicians on how to effectively communicate safe pain management. They also develop a training video and plan to share it at future lunch-and-learn events. (See video.) Each month Roberta collects data on the dashboard metrics and shares the data with the group. She also reports these data to the executive sponsor, who shares them at the monthly executive operations meeting. Every quarter Roberta and the project champion attend the executive quality meeting, where they describe the current state of the initiative, highlight improvements, and list barriers for which the working group needs executive support.

As their pain management program advances, the working group completes the Cultural Assessment quarterly to identify existing gaps and returns to the Rubric for Identifying and Prioritizing Opportunities for Improving Acute Pain Safety to select the next areas of focus. Roberta and the clinical lead work with the hospital's communication department to share lessons learned and successes with all clinical staff and all clinical units across the organization.

Figure 1. Cultural Assessment Worksheet: General Memorial Hospital

YES	NO		If no, please rate priority level 1–5 (1 low priority – 5 high priority)
	√	The organization has a strategy for safe acute pain management.	5
	√	The organization's goals, principles, and mission are aligned with developing an acute pain management program.	4
	√	There is an expectation that the goal of acute pain management is not necessarily elimination of pain, but rather maximizing emotional and physical functioning and comfort, while providing the safest possible care.	3
√		There is an existing and strong culture of safety within the organization.	
√		There are policies on opioid prescribing, storage, disposal, and stewardship.	
	√	There are standard operating procedures and protocols for safe pain management.	4
√		There are documented best practices for opioid stewardship.	
	√	Policies, protocols, procedures, and best practices are made available to clinicians.	5
	√	Policies, protocols, procedures, and best practices are shared with patients/families.	4
	√	Complex conversations with patients about expectations regarding pain and pain management are encouraged and supported.	4
	√	Pain management processes are in place to engage patients in their care.	3
√		Clinicians are encouraged to practice shared decision making.	
	√	Resources are available to assist patients and clinicians in effective shared decision making about safe acute pain management.	3
√		Resources are available for educating patients about safe pain management.	
√		Resources are available for ongoing education and training of clinicians about safe acute pain management.	
√		Mechanisms are in place to consistently measure and track opioid prescribing data.	
√		Mechanisms are in place to communicate data to senior leadership.	
√		Senior leadership consistently reviews data related to opioid prescribing.	

Figure 2. Tent Poles Worksheet: General Memorial Hospital



What organizational goals, principles, or aspects of your mission are aligned with and support these foundational elements?

Patient centered orientation, quality of care, community engagement

Are any of these tent poles weak or lacking support?

A, C, and D are weak. B is now strong but was not in the past.

Are there poles that are particularly strong? How might you draw on those strengths?

A strong pole is mobilizing the hospital around the common vision, set by leadership, with the heightened awareness of pain management as a patient safety priority. We have a strong patient and family advisory council (PFAC) and could work closely with the council to identify opportunities for improvement.

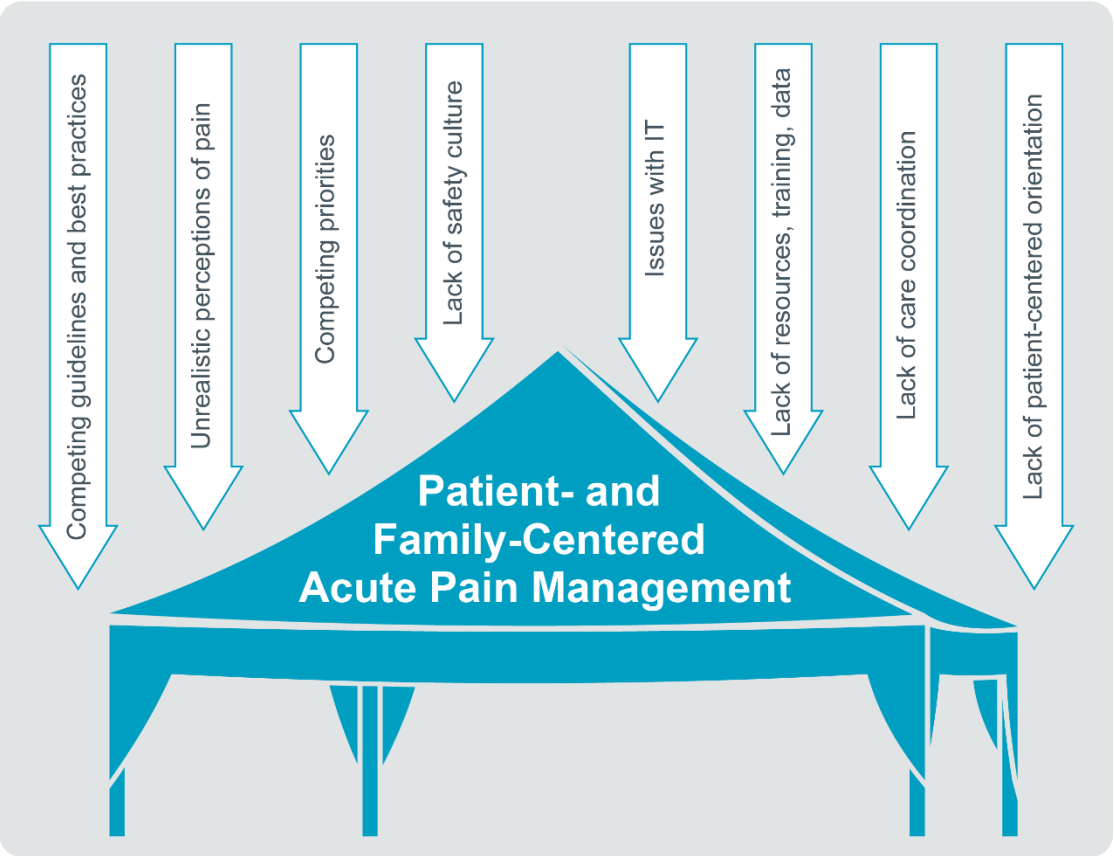
Identify and discuss with your team the organizational strengths and weaknesses related to supporting and sustaining these tent poles.

The hospital leaders and board have clearly made safe pain management a key priority area. However, the coordination and communication across the hospital is not consistent. We do not have an overarching consistent strategy that shapes pain management across all clinical units and service lines. Protocols exist, but not all clinicians are familiar with them or know where to access them.

The training available for clinicians is very limited. In conversations with clinicians, we heard that they know it is a nationwide problem, but they are not clear about what is expected of them. We also heard that clinicians are not comfortable saying no to patients and would like training in how to effectively communicate about safe pain management.

The PFAC noted that pre-op conversations were lacking any discussion about safe pain management. Most could not recall ever hearing the word "opioid" used in pre-op or post-op conversations with care providers and suggested that communication between the care provider and the patient and family could be improved.

Figure 3. Factors that Impede Safe Acute Pain Management Worksheet: General Memorial Hospital



These are factors that weight down your tent (and the structural integrity of your organization). These factors put stress on the foundation and ultimately impact the care provided to your patients. As the safety leader, and as the bridge to better and safer coordinated efforts to patient safety, work with your team to understand which of these stressors are putting your organization at risk.

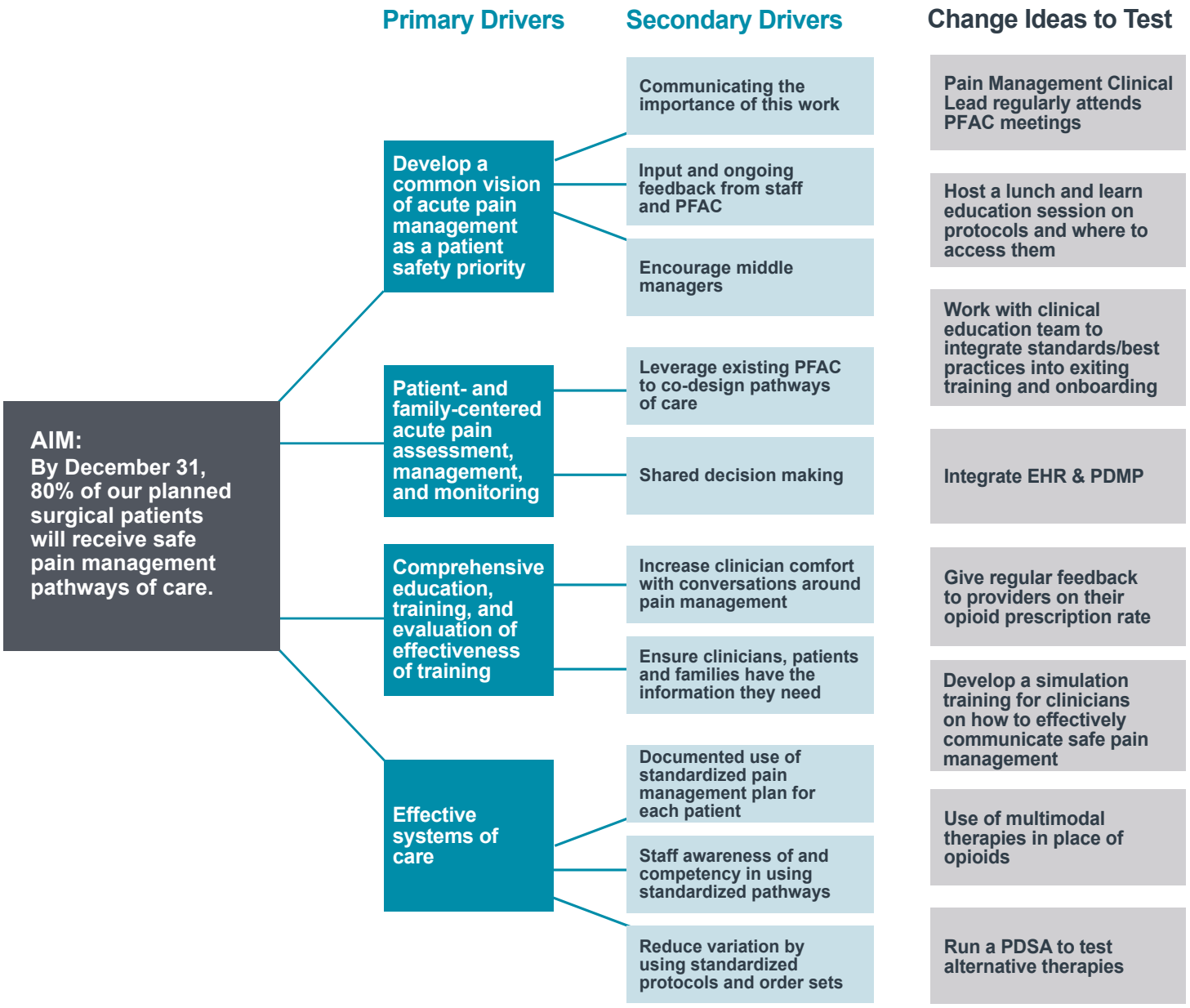
What additional elements relating to safe pain management are weighing down your organization?

Protocols are not made easily accessible; communication with patients during pre-op is lacking; lack of dedicated training of staff; competing priorities; new EHR 12 mos. ago; PFAC; EHR and PDMP not integrated.

Figure 4. Information Technology Assessment: General Memorial Hospital

YES	NO		If no, please rate priority level 1–5 (1 low priority – 5 high priority)
	√	The Prescription Drug Monitoring Program (PDMP) system is integrated into the electronic health record (EHR).	5
√		The use of standardized EHR order sets are encouraged or required.	
	√	Data has been gathered about ignored pop-up warnings.	3
√		Standard IT-related recommendations have been documented and shared across the organization.	
	√	Electronic health record workarounds have been explored and identified.	4
	√	Mechanisms are in place for interstate sharing of data from PDMP system.	3
	√	Mechanisms are in place for interoperability with pharmacies.	4
√		Electronic standardization and safeguards to accurately track and communicate patients' pain medication use and history are in place.	
	√	There is an automated alert system within the EHR that monitors cumulative morphine daily dose and alerts clinicians and staff if present dosage thresholds have been breached.	5
	√	Prescriber dashboards are available that illustrate acute pain management metrics to inform physician practice.	5

Figure 5. Driver Diagram: General Memorial Hospital



MEASURES

1) Number of patients undergoing surgical procedures with documented use of standardized pain management per month (numerator) over total number of patients undergoing scheduled surgical procedures per month (denominator)
2) Prescriber opioid prescription rate by specialty per month
3) Average post-anesthesia care unit (PACU) length of stay per month
4) Percent of inpatients experiencing opioid-related adverse drug events (ORADE) per month
5) Unplanned ED visits for pain management per month
6) Percentage of postsurgical prescriptions per month for which the number of pills prescribed is consistent with adopted standards