Pain Management

A Systems Approach to Improving Quality and Safety

Joint Commission Resources

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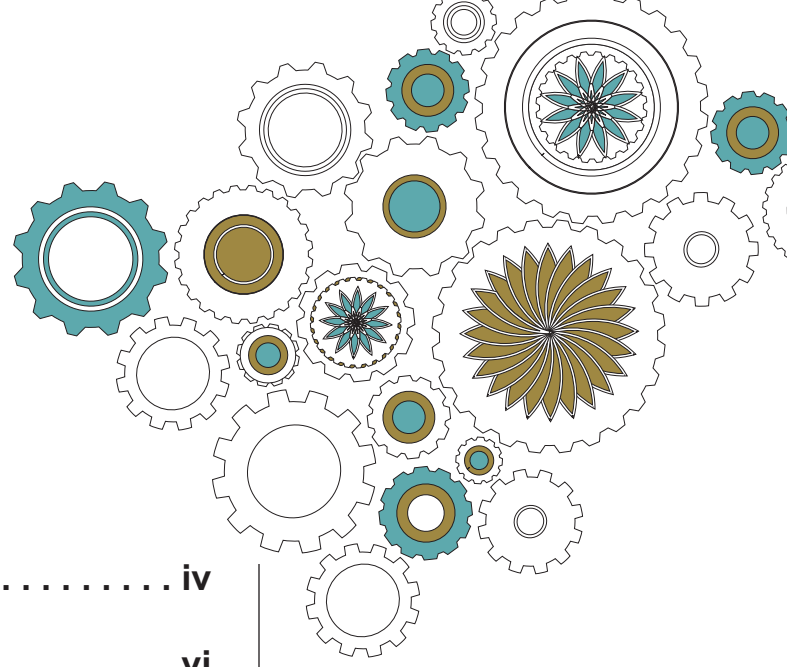

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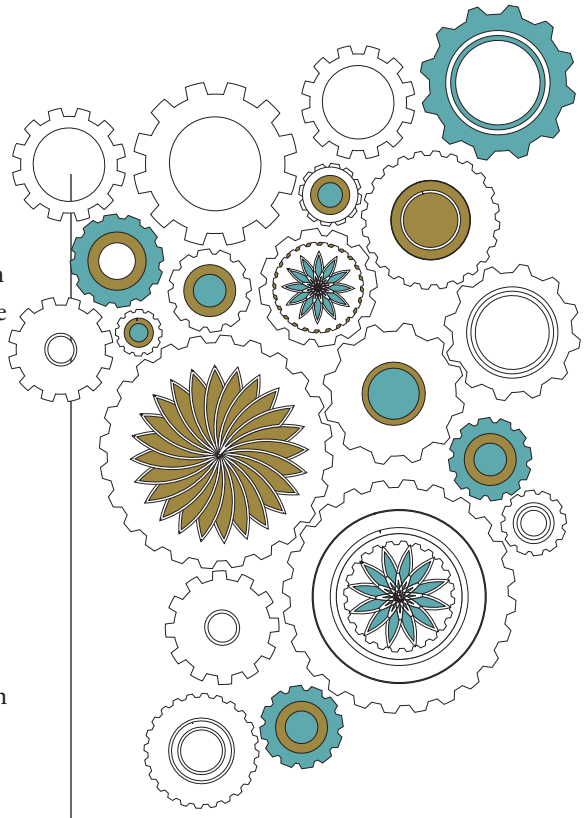
Preface

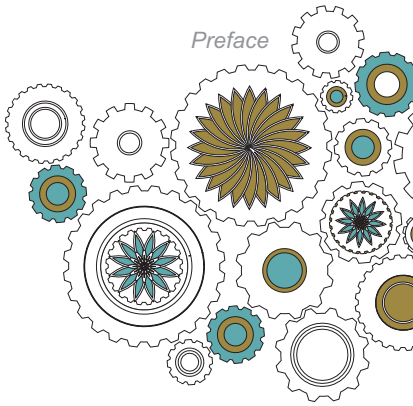
Nanne M. Finis, R.N., M.S.



Pain affects more Americans than diabetes, heart disease, and cancer combined. Management of pain is a challenge demanding the attention of health care teams, individual professionals, and structured systems and processes. Pain is both a symptom (acute) and a disease (chronic) that is often given inadequate consideration, despite the fact that it can result in suffering, loss of work time, unplanned readmissions, poor patient and family satisfaction, and slow recovery from illness and surgical procedures.

During the past two decades, a great deal of effort has focused on the science of managing pain. The clinical therapies of pain management, the expansion of palliative care and symptom management, and The Joint Commission's requirements for pain assessment and reassessment have transformed practice. The unfortunate news is that although these advances and requirements exist, breakdowns in patient care processes and care delivery continue to mean that patients are suffering needless pain.
Leaders of health care organizations and health care systems often assume that the pain of their patients is well managed. However, effective pain management within our complex health care system does not happen as a matter of course; it requires knowledge of pain assessment and management, prevention strategies, documentation systems, and care coordination across individual care practitioners, diverse care teams, and patient care units. Dedicated effort to coordinate the prevention and management of this symptom requires nothing less than a systemwide approach and leaders who specifically provide clear direction and vision to minimize patients' experience of pain. As part of an initiative to examine the steps necessary to such a systemwide approach, we have observed several top-performing organizations that have implemented successful improvement actions to minimize patient pain. We have incorporated findings that result from critically analyzed events where health care systems most often fail in their management of pain. Finally, we have compiled practical tools and techniques that can help an organization to assess its current state and implement improvement and change initiatives with simple "next steps" to ensure that it is managing the pain of its patients.

Minimizing pain and suffering demands coordinated efforts in each unique organization. We are hopeful that our tools and self-study materials will aid and propel



your organizational efforts to redesign the pain management processes. We suggest that clinical leaders use the following tools, which can help guide discussions among senior leaders, provide directional strategies, and facilitate improvements.

Collectively, these four modules constitute a call to action and provide script to make such action optimally effective. Health care leaders must now examine their respective organizations' pain management systems and structures for delivering services. Ultimately, the goal is to effectively coordinate and deliver therapy in accordance with evidence-based practices and principles, contributing to effective and safe care, exemplary outcomes, and improved efficiency in resource utilization. Our joint aim and duty is to reduce unnecessary suffering by patients in our care.

Acknowledgments

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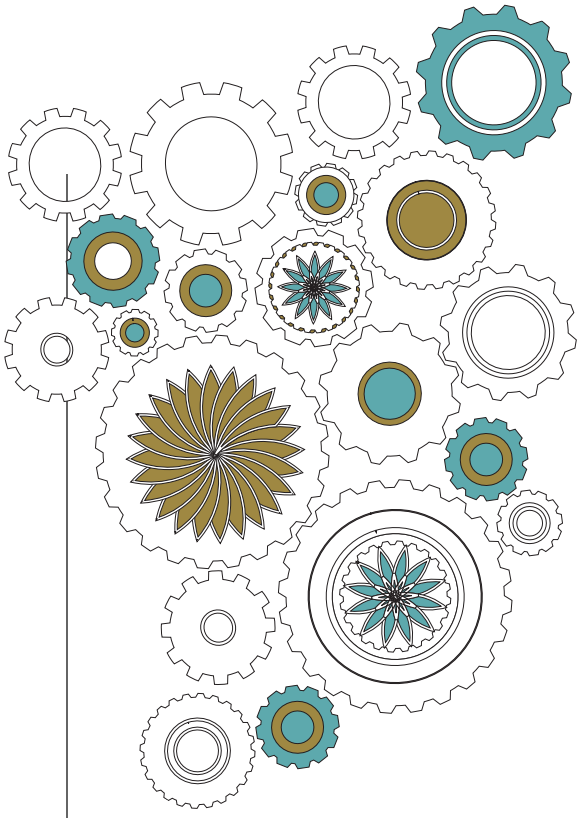

Module 1

Make the Case

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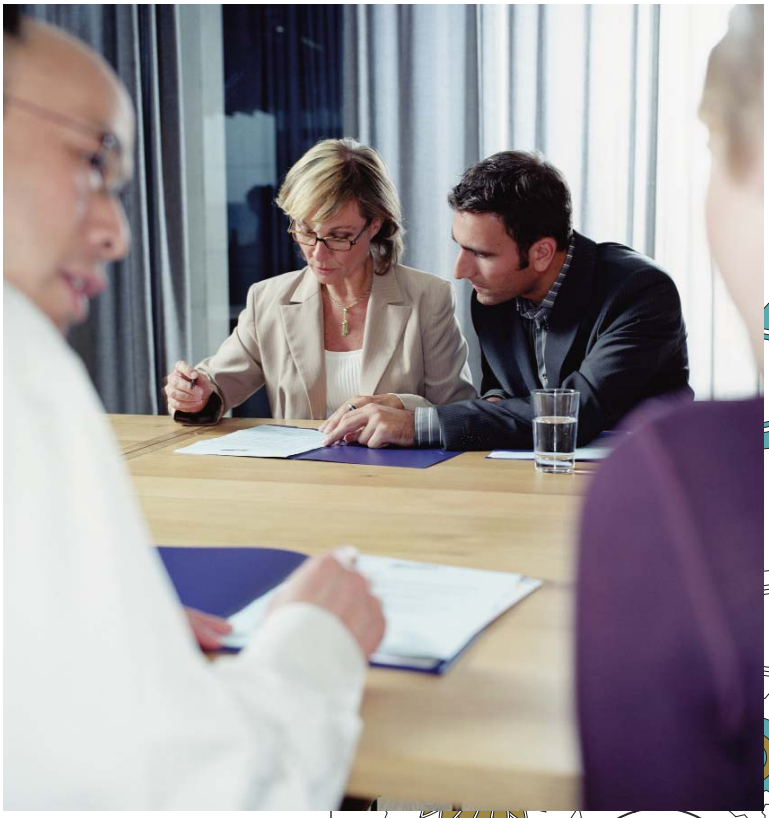


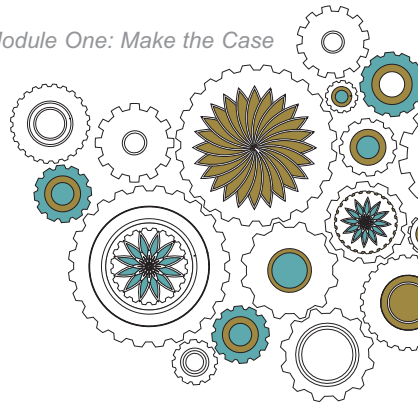
How to Use This Module

If you are reading this guide, then you know that pain management is a complex health care challenge requiring systemwide assessment and organizationwide support. It is imperative that prior to working with the tools provided here, you and your improvement team gain committed support from senior leadership in your organization. This first module makes the case for assessing and improving your organization's pain management system, and it can be used to convince senior leadership that your organization needs to begin now. This module describes the pain imperative and provides an overview of the project, including the need to determine the current state of pain management in an organization. Modules 2, 3, and 4 provide a practical guide to applying tools and techniques to assist an organization in assessing its current state related to pain management. These tools and techniques identify organizational strengths as well as risk points that assist with the prioritization of needs addressed by a newly designed pain management program.

Core Objectives for This Module

Core objectives for this module include the following:

- Engage your organization in understanding the value and high priority of meeting current standards for pain control.
- Crosswalk the tangible challenges of pain management to the specific needs of your organization.
- Identify the potential for external review of a health care organization to assess the following:
  - Gaps in the existing pain management program
  - Opportunities to continuously improve organizational pain management efforts using a performance improvement approach
- Describe the eight components of an effective pain management program.
- Use a case study to facilitate your organization's understanding of specific needs in the areas described in this module.
- Consult the Module 1 Next Steps.



The Complex Challenges of Pain Management

From multiple perspectives, pain management is a complex health care challenge. In light of substantial industry changes under way regarding organizational reputation, value-based care models, and accountability, pain management has important organizational implications for health care organization executives. On the front lines of care, clinical providers are treating patients with comorbidities, managing transitions across the continuum of care, administering complex analgesic regimens, and contending with inadequate patient medication histories. Caregivers may also be faced with time constraints that prevent thorough assessments and appropriate interventions, as well as regulatory requirements for careful documentation. At the crux of all of these challenges is the need to meet each individual's pain needs and expectations.

Patients may encounter many providers whose overlapping roles in managing pain are confusing, at worst leading to over- or undertreatment of pain. Alternatively, patients may experience a *lack* of providers effectively managing pain across care settings. Indeed, communication and appropriate handoffs among providers within an organization and in the broader community, as well, present an organization with tremendous opportunities for improving continuity of therapies and medications designed to meet the unique diverse needs of each patient in pain.

Furthermore, real business needs with economic ramifications now require an assessment of the current pain services in organizations. Value-based purchasing, patient satisfaction scores, and reports from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey are all changing how services are evaluated and publically reported (*see* Sidebar 1.1).

Leveraging existing knowledge about pain control can substantially benefit organizations by improving business outcomes for value-based purchasing, satisfaction, and HCAHPS survey scores.

The Changing Landscape of Pain Management

There have been many advances in the clinical management of pain in recent years, particularly in management techniques such as pharmacology and in the emerging recognition of pain management as a clinical specialty. Examples are regional anesthesia interventions, such as placing peripheral catheters for local anesthesia infusion, and nondrug cognitive–behavioral techniques, such as complementary medicine. Despite important advances, the diverse pain management needs of individual patients transcend the continuum of care, challenging communication and handoff systems both in an organization and in the broader community beyond the organization (*see* Sidebar 1.2).

Sidebar 1-1. The HCAHPS Survey

The Centers for Medicare & Medicaid Services has created the HCAHPS survey. This standardized survey instrument and data collection methodology can be used for measuring a patient's perspective on his or her health care. The survey has three core objectives:

1. Produce comparable data on patients' perspectives on care to enable objective and meaningful comparisons among health care organizations.
2. By reporting publicly, create incentives for health care organizations to improve quality of care.
3. By reporting publicly, enhance public accountability in health care through increased transparency.

Ideally, the process of effectively managing pain could exemplify a model of community service coordination, through which all providers collaborate to provide patient-centered care. When a patient enters a health care system, that system's clinical resources are challenged to accurately assess that patient's current pain needs and available therapies. Complex transitions for each patient across the care continuum present potential gaps in attending to patient pain, and similar challenges continue to arise outside the health care system, where the patient's pain can persist.

Each day, patients transition from the acute care setting to the community setting. Pain management has become increasingly sophisticated, with advances in pharmacology and the use of complex analgesic devices (including epidurals and peripheral catheters) and regimens. Patients on these complex new analgesic regimens (including opioids) are discharged into the community and followed by their primary care physicians, thereby posing challenges for care providers in the community who may not be educated or who may not feel comfortable about these newer techniques. This invariably affects the continuity of treatment and follow-up. Thus, communication handoffs among practitioners within a setting and between settings require increasingly thorough and comprehensive information.

These complex relationships within and outside the health care setting can cause confusion about who is responsible for the various components of a patient's pain management. Such ambiguity has tremendous potential to compromise the quality of patient care and impact the financial balance sheet of an organization (to say nothing of the financial health of the community in which the organization is situated) and may contribute to the following:

- Worsening of comorbid conditions
- Additional emergency room visits
- Unplanned readmissions

Thus, we are clearly presented with significant process improvement opportunities for health care organizations, aligned with current market forces and incentives for improved care coordination and outcomes.

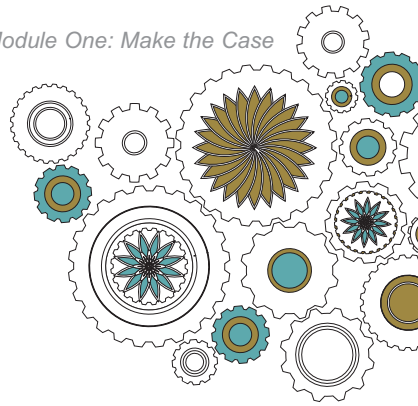
The Business Case for Pain Management

In addition to the impact of pain management on quality of care, there are wide-reaching economic reasons to focus on improving the delivery of pain services. One study found that 1.5% of same-day surgery (SDS) patients were readmitted within 30 days for pain-related complaints, accounting for more than one-third of the total SDS readmissions in the study and an estimated cost of over $4,000 per readmission.[1] Market forces such as

Sidebar 1-2.
Pain Management Beyond the Health Care Organization System

Communication and handoff systems transcend the health care organization, extending into broader community contexts such as the following:

- Patient-centered medical homes
- Community clinics
- Home care facilities
- Long term care facilities
- Primary physician offices
- Patient homes



value-based purchasing of health care will elevate the importance of managing patients' pain in order to prevent unnecessary readmissions (*see* Sidebar 1.3).

Globally, patients with persistent pain symptoms have an impact on employer benefit costs and productivity. Estimates for the annual U.S. cost of chronic pain, including its negative effect on workforce productivity, reportedly range from $40 billion to $220 billion.[2] One study estimates that in the United States, as much as $70 billion per year is attributed to lost ("absenteeism") or reduced effectiveness due to workers' pain.[3]

The cost of medications continues to grow, as does the cost of the complex analgesic drugs prescribed for many patients. A 2008 International Medicine Studies (IMS) study says $8.2 billion was spent in the United States for prescription pain medications.[2]

Data from 12 months, ending in March 2007, indicate that between $2 billion and $6 billion was spent on over-the-counter analgesics.[2] There are also substantial costs associated with alternative therapies. There can be no doubt that the financial burden of managing patients' pain presents a forceful ethical, economic, and even political argument for optimal pain management across the continuum of care.

The Prevalence of Pain

Pain is an unpleasant sensory and emotional experience caused by actual or potential tissue injury. Acute pain is pain that comes on quickly and can be severe but lasts a relatively short time. Chronic pain is persistent or intermittent pain lasting at least three months. Acute postsurgical pain, particularly when poorly controlled, may become chronic pain.[4] The American Pain Foundation reports that pain affects more Americans than diabetes, heart disease, and cancer combined. In one U.S. study, 76.5 million people reported having experienced pain in the immediate past month of being surveyed, and 4.2 million reported pain lasting longer than three months.[5] According to another study, more than 50 million Americans experience chronic pain.[6] It is estimated that every year, 40 million Americans undergo surgery and suffer from inadequate postoperative pain control.[7]

These and related studies contribute to the mounting case for an urgent review of the current state of pain management. We must close gaps in pain control services and improve the quality of pain management for all patients. Health care organization leaders should be mindful that in this age of health care reform, it is a competitive advantage to be in the forefront of pain control, which has already impacted business models and best practices.

Consequences of Unrelieved Pain

Unrelieved pain results in a host of adverse consequences (*see* Sidebar 1.4). The physiological effects include poor sleep, reduced mobility with subsequent loss of strength, immune impairment leading to increased susceptibility to infection and cancer recurrence, and the development of changes in the nervous system that lead to chronic pain

Sidebar 1-3.
The Centers for Medicare & Medicaid Services (CMS) and Agency for Healthcare Research and Quality (AHRQ) Team Up to Assess Patient Pain

As a purchaser, CMS will be seeking health care value for patients, which might include the active management and improvement of pain outcomes, as seen in the HCAHPS survey scores. In the summer of 2002, the CMS asked the AHRQ to develop an instrument to measure patient perceptions of care. The measurements were to be used to publicly report hospital performance (based on patient perceptions of quality of care), and this public reporting instrument would do the following:

- Provide consumers with information that might be helpful in choosing a health care organization.
- Complement rather than compete with quality improvement instruments already being used by health care organizations.
- Include 27 questions (stand-alone or embedded in an existing discharge survey) about recent hospital stays.
- Ask patients to rate the frequency of events during their care, using the scale "never," "sometimes," "usually," "always."
- Organize information under the following headings: Your Care from Nurses, Your Care from Doctors, The Health Care Environment, Your Experiences in the Health Care Organization, When You Left the Health Care Organization, Overall Rating of the Health Care Organization, and About You.

Survey questions are to be reported in the following areas:

- Communication with Doctors
- Communication with Nurses
- Responsiveness of Staff
- Pain Control
- Communication About Medicines
- Cleanliness of Health Care Organization Environment
- Quietness of Health Care Organization Environment
- Discharge Information
- Overall Health Care Organization Rating
- Likelihood to Recommend the Healthcare Organization

For more information, visit the AHRQ Web site, at https://www.cahps.ahrq.gov/content/products/HOSP/PROD_HOSP_Intro.asp.

syndromes. The psychological and social effects include depression, anxiety, poor concentration, and impaired relationships with others, along with caregiver distress as loved ones witness pain. The implications for health care globally from unrelieved pain include unplanned or unnecessary readmissions, longer stays, additional resources for diagnosis and treatment, and increases in outpatient visits. Unrelieved pain impairs the functional status of patients, leading to a downhill spiral of disability and increased health care costs.

The Pain Imperative and Its Challenges

Considering the need for effective management of pain and the business needs for efficient and effective pain management, we truly are faced with an imperative to review and redesign an integrative, systematic approach to

Sidebar 1-4.
Consequences of Unrelieved Pain

Unrelieved pain can result in the following:

- Poor sleep
- Reduced mobility
- Immune impairment/susceptibility to disease
- Chronic pain
- Depression
- Anxiety
- Poor concentration
- Impaired relationships
- Unplanned readmission
- Unnecessary readmission
- Longer stays
- Increased outpatient visits

pain management at the individual institution level (*see* Sidebar 1.5).

There are many challenges to reviewing and redesigning a comprehensive approach to managing pain. For example, although a patient's chief complaint might be pain, pain is a symptom. We may well call this the first challenge. After all, patients are admitted under a diagnosis-related group, not a symptom; therefore, the ability to quantify the specific scope of pain as the presenting complaint is difficult. This administrative constraint also makes tracking patients readmitted for pain a difficult task for data-gathering purposes.

A second challenge involves an organization's competing priorities. A pain management program may very well compete for limited resources with quality and safety imperatives. For example, major emphasis has been placed on the effective management of core measures. The challenge is to objectively and effectively weigh these competing priorities and advise senior leaders of the organizational benefits associated with assigning a high priority to excellence in meaningful pain management. The management of an effective pain management program aligns with the quality and safety mission of any health care organization.

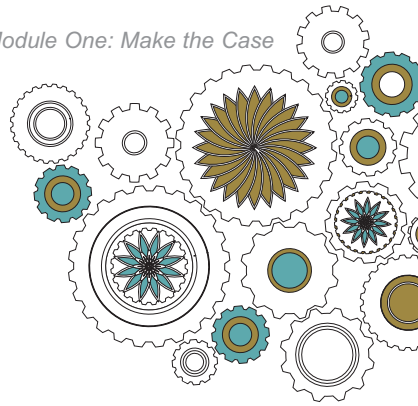
The third challenge is confusion regarding who or which service is responsible for the management of patient pain, both acute and chronic. Confusion regarding how a patient's pain will be well managed at all times and by whom stands in contrast to many other aspects of care; for example, the substantial work to develop protocols for critical test reporting has clarified and thereby improved that component of care. Perhaps this confusion arises most frequently between medical staff from anesthesia and surgery, but with advanced practitioner roles at the bedside, there are potentially many caregivers and providers in the mix. Roles and responsibilities can overlap or suffer from ineffective communication and clinical information handoffs. Patients may be confused due to postoperative cognitive impairment and staff may fail to indicate who is charged with managing their pain. Staff and nurses who are continuously at the bedside with patients may not always have clear and available protocols regarding accountability and resources for effective pain needs. In a teaching facility, house staff may have many knowledge gaps regarding the diagnosis and treatment of patient pain.

Patients may also seek nonpharmacologic methods of pain relief to supplement or substitute for pharmacologic ones. Some of these methods are provided in health care organization settings as part of a pain management system. Examples include physical therapy, hot or cold applications, music therapy, acupuncture, visualization, and relaxation techniques. Patients may seek these alternative resources independent of—and sometimes

Sidebar 1-5.
Challenges to Redesigning and Defining a Pain Management Program

Challenges to designing and defining a pain management program may include the following:

- Variation among clinicians' practice and education
- Practitioner fears of loss of licensure
- Incomplete assessment information
- Bias in caregiver interpretations of patients' pain responses
- Sophisticated pain medications
- Complex comorbidities
- An interdisciplinary care approach
- Continuity between settings



unbeknownst to—the clinical team, adding to the complexity of assessing each patient's therapies.

All these challenges—as well as challenges unique to an individual organization—must be considered in the assessment of the current pain management programs in an organization. Furthermore, we can consider these challenges to be indicators of what merits re-assessment and redesign in providing effective pain management interventions.

Pain, Fear, and Subjectivity

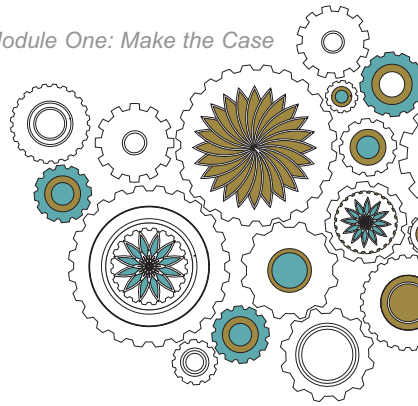
Clinical staff assisting with pain management can impose various concepts and preconceived notions on the pain management process as they attempt to discern a patient's pain needs. For example, various (and potentially conflicting) pain scales are available to define a patient's pain intensity, but the uniqueness of each patient's pain tolerance is rarely documented, nor is the human factor error potential of the professional assessing pain.

As we learned during site visits described later in this module, in some instances, clinicians fear that prescribing opioids will jeopardize their own licenses. Concerns about either over- or undermedicating for pain can add to the liability of practice patterns. Varying educational preparation to effectively understand, assess, and manage a patient's pain can also contribute to clinicians' reluctance to address patient pain. In addition, clinicians report staffing issues associated with a lack of resources and time to adequately assess and respond to an individual patient's needs. In some instances, it is easier to give pain medication than to address emotional concerns or to reposition a bedridden inpatient as a means of addressing pain.

A patient's ability to self-report his or her own symptoms requires the use of both objective and descriptive words (for example, "I have a throbbing pain on the left side of my forehead that occurs constantly when I am standing"). However, there are often subjective and emotional comments about and descriptions of pain, which may be difficult for a clinical team to understand in a clinical context. A patient's description can be interpreted with various meanings and, hence, addressed with various treatment options. The increasing recreational use of drugs (such as opioids and other narcotics) adds complexity to the assessment and treatment of patients in pain. Recreational drug use or of treating patients with addictive disease using opioids can further complicate treatment plans and create situations that place patients at risk. Finally, factors that promote a patient's transition from acute pain to chronic pain are not fully defined.

The Quality Improvement Approach to Pain Management

The quality improvement approach is aimed at the improvement of pain management services to address and, when possible, reduce the complexities just described. Equally important is the return on investment (ROI) opportunity that requires metrics and



associated measures of quality. This analysis is important to support improving the delivery of care, increasing transparency, and supporting appropriate payment for services.

Health care organizations should consider a number of key pain-related issues, including the following:

- **Public reporting of quality and safety metrics.** Such metrics increasingly guide value-based purchasing. Each health care organization strives to maintain its market share. Poor performance on such measures could lead to eroding market share.
- **The effect of staff satisfaction on retention and costs of hiring and orientation.** A solid pain management program can enhance staff satisfaction. The Agency for Healthcare Research and Quality (AHRQ) survey is one tool organizations can use to document a need to improve staff confidence in patient experience and safety as an institutional priority. Staff satisfaction also supports nurse excellence in patient care and accreditation opportunities such as achieving Magnet status.
- **Cost reductions related to redesign of a pain management program.** The following are the most obvious direct cost reductions related to redesigning a pain management program:
  - Reduction in medication drug costs
  - Reduction in "never events" (*see* Sidebar 1.6)
  - Prevention of extended lengths of stay
  - Reduced readmissions
  - Reduced ED visits
- **Indirect cost reductions related to redesign of a pain management program.** A health care organization can expect to experience indirect cost reductions such as the following:
  - Reduced malpractice claims
  - Compliance with government-mandated programs emphasis and outcomes that align with value-based purchasing requirements

Sidebar 1-6. Never Events

The term *never event* was first introduced in 2001 by Ken Kizer, M.D., former CEO of the National Quality Forum, in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur.

There is evidence of variability in readmission rates, of failure to provide close patient follow-up, and of inadequate communication among physicians and patients at the time of discharge. Collectively, this evidence has raised concerns that many readmissions may be preventable,[8] and it also makes a case for the future potential of financial penalties for health care organizations with high rates of readmission. CMS already withholds payment from health care organizations for the costs associated with treating preventable complications.

The HCAHPS survey is the first standardized and publicly reported national survey of patients' perspectives of their health care. Recently discharged patients are asked 27 questions about their recent stay. How the patient's pain is managed is one of the core questions. The intent is for these publically reported scores to allow fair and accurate comparisons across health care organizations.[9] The pain imperative is directly aligned with the improvement of pain management in health care organizations and across transitions of care. Pain management will be increasingly transparent in the HCAHPS reports.

Health care organizations also collect data for internal and external use in administrating patient satisfaction programs and, in some cases, staff and physician satisfaction. These data provide additional insights to evaluate current processes in the delivery (or lack) of pain management services.

Considering a patient's comfort with his or her pain management involves real fiscal implications. Health care organizations need to approach pain management with an assessment of the current state of pain management and the determination to reduce risk points.

In today's resource-constrained environment, health care leaders are appropriately insistent on assessing the financial implications associated with major initiatives. Just as with a routine capital or operating decision where a financial analysis occurs, pain management program effectiveness lends itself to similar financial discipline. Therefore, calculating ROI can provide quantifiable justification and credibility for the value associated with a robust pain management program; doing so reflects the evidence-based approach presented in this document (*see* Sidebar 1.7).

The Joint Commission Resources Customer Survey

Joint Commission Resources conducted a voice-of-the-customer survey in the fall of 2010 with all of its U.S. consultants. The purpose of the 14-question survey was to collect opinions regarding the current state of pain in all U.S. health care patients (*see* Sidebar 1.8).

The top three challenges to an effective pain management program were identified as resistance to collaborative and interdisciplinary approaches, limitations on necessary resources such as staff and budget, and lack of measurement instruments to document the state of practice (*see* Sidebar 1.9).

The Joint Commission has had a long-standing commitment to effective pain management, as evidenced by its standards for pain management and many of its publications.

The Pain Management Mission and Vision

Following the Joint Commission Resources survey and after gathering input from leaders in pain control and from current review of the literature, pain team consultants arrived at the following mission and vision statement:

Sidebar 1-7. Return on Investment (ROI)

An ROI should focus on the financial gain associated with the commitment of quantifiable resources to an initiative. In the case of determining the ROI of a pain management program, we are referring to the following incremental input costs:

- **Dedicated or fractional labor invested in the initiative.** This would include staff members such as a pain management coordinator or a program medical director.
- **Staff training costs.** These costs may include costs of related pain management medication administration practices.
- **Costs associated with documentation or supplies associated with pain management.** Such supplies might include color-coded OR caps, interventional therapies such as music, and so on.

In respect to incremental output, an institution should consider the following in an ROI calculation:

- **Revenue benefit** associated with pay-for-performance or value-based purchasing, and
- **Supply savings** resulting from more appropriate utilization of alternate therapies, less utilization of pain medication, and utilization of less costly pain medications.

Such a direct cost ratio of money gained or lost (whether realized or unrealized) on an investment expressed as a percentage results in heightened accountability for financial outcomes. It also provides for an objective financial expectation prior to embarking on such a program.

Mission: Joint Commission Resources and a panel of national pain and leadership experts come together to provide a systems approach to assessing the quality of pain management across a sample of U.S. health care organizations in an effort to highlight and prioritize system risk points that create challenges and opportunities to target systematic improvements for pain management programs.

Vision: To develop a systematic approach that enables an assessment of pain management programs in order to offer models for safe and comprehensive pain care across the patient care continuum.

At the outset, JCR consultants identified the following core values for such models:

- **Patient driven for patient safety.** Patient involvement is necessary.
- **Solutions that are unique, transferrable, and sustainable.** Systems of all configurations must benefit.
- **Interdisciplinary collaboration.** Everyone's role is important and necessary.
- **Continuum of care focus.** The settings are all locations that provide pain service to patients.
- **ROI documented through measurement.** Objective results will sustain the effort.
- **Valued-added processes.** Safe, affordable care should be provided to alleviate unnecessary suffering of patients.

The clarity of the mission, vision, and core values align with the interests and expertise of the advisory panel of experts. (*See* the Appendix for their biographical information.)

Throughout the process, each member on the advisory panel holds various roles and responsibilities. Collectively, they provide direction on the sites selected for visits and provided resources and references to complement the project mission and vision. In addition, their depth of experience, both clinically and in senior leadership roles, provides affirmation, direction, and confirmation of the mission, vision, and goals.

Sidebar 1-8.
Key Themes from the Joint Commission Resources Survey on the Current State of Pain

In the 14-question survey that Joint Commission Resources conducted with all U.S. consultants, respondents indicated that pain was not well managed across the continuum of care. They also said that nurses and physicians could benefit from education and performance improvement tools. The survey identified the following challenges:

- Fear of addiction
- Lack of planning across transitions of care
- Lack of coordination among providers
- Actual practice patterns versus documented action
- Nurses in general not having adequate knowledge of pain medications
- Nurses' opinions about chronic pain influencing the care they provide
- Short length of stay for inpatients, meaning that there is little time available to effectively assess pain needs and address them
- Ineffectiveness of some physicians in managing pain
- Physicians' variable receptiveness to additional education on pain management
- Physician challenges including time management, lack of expertise, and lack of clarity about who is responsible for pain management

Sidebar 1-9.
The Top Three Challenges to Effective Pain Management

In a survey conducted by Joint Commission Resources in the fall of 2010, respondents identified three areas in which they faced the greatest challenges to achieving effective pain management programs:

- Resistance to collaborative, interdisciplinary approaches
- Limitations on necessary resources (such as staff and budget)
- Lack of measurement instruments

The Joint Commission Resources Site Visit Process

Joint Commission Resources consultants visited each site in an effort to understand each organization's current system for pain management. Each site was asked to complete various documents prior to the visit, thereby allowing the consultants to begin the assessment before the actual visit. While on site, consultants used the performance improvement tools described in Modules 2 and 3 with an interdisciplinary team and leadership from the site. Interviews, system pain tracers, SWOT (strengths, weaknesses, opportunities, and threats) analysis, document reviews, and group discussions were components of each site visit. At the conclusion of each visit, the site received detailed information on its current state. It also received a gap analysis to guide decisions regarding subsequent priorities for pain management improvements.

The collaborative effort at each site was overwhelmingly positive. Each organization validated the need to use a systems approach to assess, design, and measure the effectiveness of pain management.

The pain management project used the performance improvement framework while visiting the following sites:

Duke University Hospital, Durham, NC

University of Miami Hospital, Miami, FL

University of Wisconsin Hospital and Clinics, Madison, WI

St. Joseph's BayCare Health System, Tampa, FL

St. Peter's Health Care Services, Albany, NY

The consultants observed many creative pain management and safety practices during the site visits. Many sites use evidence-based practice interventions. For a list of best practices, *see* Sidebar 1.10.

Joint Commission Resources Lessons Learned

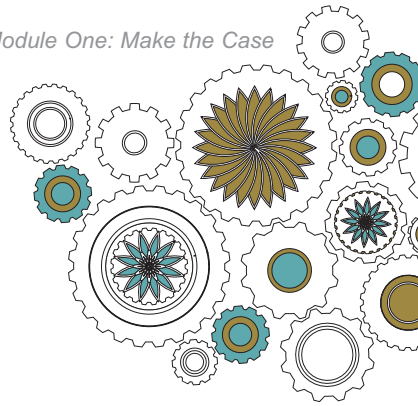
The Joint Commission Resources consultants identified key lessons learned from the review of the site visits, including the following:

- The decentralized existence of providers of pain services contributes to confusion regarding who is accountable for managing the patient's pain. This accountability is diffuse among anesthesiologists, surgeons, staff nurses, and other health care professionals. Patients experience confusion in integrating advice from various providers with diverse opinions on pain treatment interventions that are presented in an uncoordinated manner. Clarity of roles and responsibilities is needed.
- Patients frequently present with increased complexities in diagnosis, numerous comorbidities, and existing complex medication regimens. These complexities often are not known before a patient is admitted. Patients also enter via emergency services, often compromising the collection of complete and accurate history information. This dynamic creates patient safety issues and practitioner concerns.
- Providers express fear related to over- or underadministration of pain medication, particularly opioids, and question their own competence in pain management. They describe concern about finding the time needed to properly assess and understand the pain control needs of their patients. They raise questions about liability and ethical issues related to practice. More information is necessary to alleviate such concerns.
- It is not uncommon to find practitioners focusing more on documenting a patient's pain intensity on an objective scale than on being attentive to actually intervening to relieve the pain.
- Physicians and staff have a wide variety of knowledge, skills, and interest in managing pain.
- Clinical education updates are necessary for managing patients' pain-related needs.

Sidebar 1-10.
Best Practices Gleaned from Site Visits

Evidence-based practice interventions used at site-visit organizations include the following:

- The use of color as a safety practice was impressive. For example, the operating room of one organization switches the patient's head cap to one of a different color to indicate completion of the time-out at the transition from preoperative care to the operating room.
- Unit-based nurse pain champions attended to pain-specific needs.
- Each site had acute pain services primarily serving inpatients with acute postoperative pain.
- All sites showed appreciation for and compliance with the pain standards.
- Each site recognized education and competencies as being important, but not all sites had the capacity to prepare and teach relevant pain content to their staff.
- A few sites had pharmacy involvement in bedside pain rounds. All these sites displayed respect and appreciation for the depth of pharmacy involvement.
- One site described its chronic pain clinic and used it as an extended resource beyond acute care.
- A variety of communication techniques were used to keep all staff updated on advances in pain management.
- Some of the education resources were designed to be available 24/7 in electronic form.
- All sites found measurement requirements challenging and were hopeful that some vendors would offer products or services to address their needs to extract data electronically from the medical record.



- Communication among health care providers, patients, and community practitioners leaves considerable room for improvement. This includes both oral and written communication. New systems are needed to apply technology that quickly and reliably connects all care providers.
- Many caregivers are frustrated that patients often use a drug before trying a simpler nonpharmacologic intervention, such as repositioning. Some sites have done a better job than other at using nonpharmacologic methods for pain relief.
- The issues of labor demands and time management continue to challenge organizations. Staff must often manually audit medical records to gather data. Information technology systems need to be optimized to quantify and qualify the data needs of patients with pain. Clinical resources and information technology support need to partner in solving this issue.
- Organizations need to strive for continuous improvement of pain management, and they need to use quality tools to analyze data.

Components of Building or Expanding a Pain Treatment Service

National pain advisors and the Joint Commission Resources consultants reviewed the literature and the site data, themes, and lessons learned described earlier in this module. Their review and discussion led to the identification of eight components that are appropriate for a systematic approach to pain treatment services. These eight components are the foundation for building or expanding an organized pain service (*see* Sidebar 1.11).

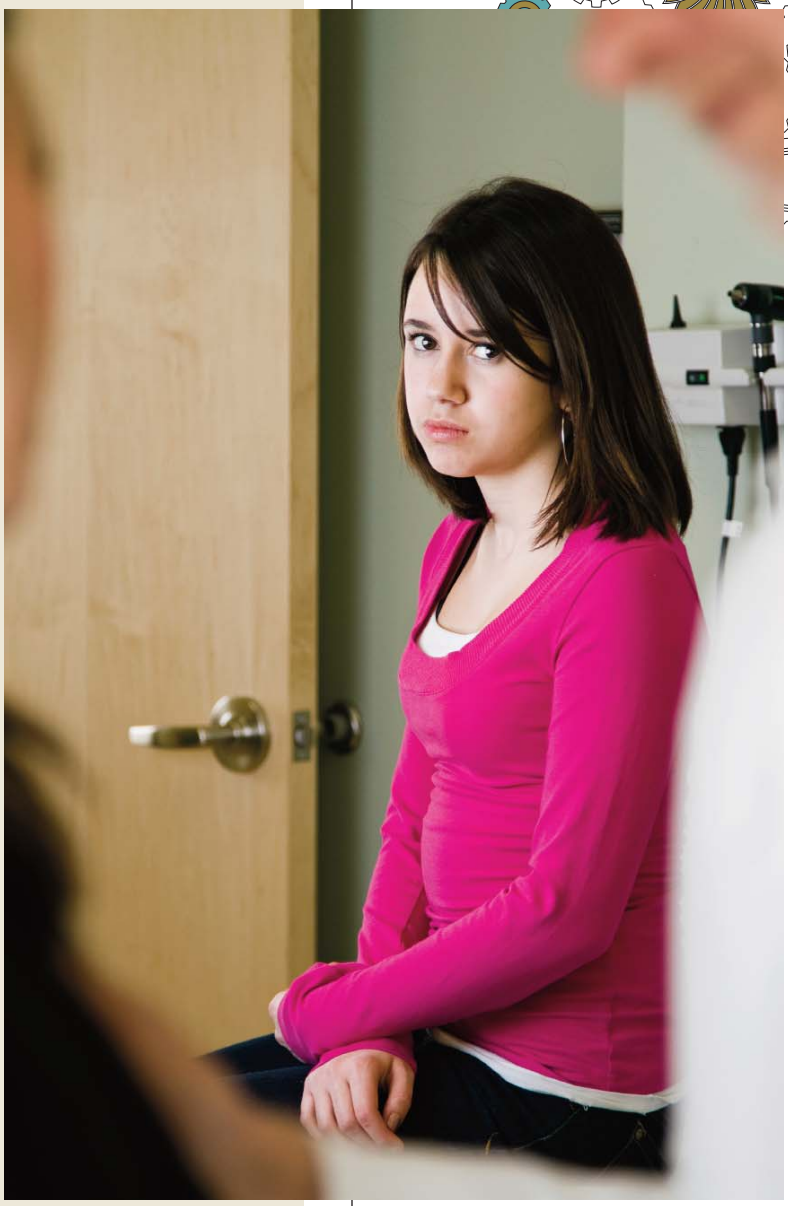
Sidebar 1-11.
The Eight Critical Components

These eight critical components are necessary for building and/or expanding a systemic pain service:

Component #1	Use of National Pain Standards
Component #2	Commitment of a Senior Leader Champion
Component #3	Consistent Oversight of a Pain Project Manager
Component #4	Collaboration of the Interdisciplinary Team
Component #5	Provision of Systematic Performance Improvement Methodology
Component #6	Provision of a Pain Management Infrastructure
Component #7	Promotion of the Patient's Continuous Learning
Component #8	Transition of Care for all Stakeholders

Case Scenario

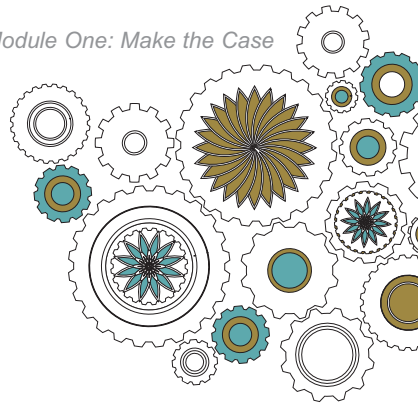
This case scenario illustrates how one organization designed a systematic approach to managing pain. Each module of this guide details the tools and resources the organization used to design its approach and improvements.



A patient with acute abdominal pain was admitted to the local hospital from her primary care physician's (PCP's) office. She had recently been diagnosed and treated for a localized cancer. Her three-month course of chemotherapy had been completed two months previously, and based on her oncologist's assessment, her cancer was in remission. A thorough history and physical revealed that the patient was on a complex analgesic regimen. Because of the patient's physical and psychological symptoms, the situation proved to be challenging and time-consuming for the clinical team. The assessment and treatment plans needed to incorporate the patient's complex analgesic regimen and medication needs.

In the weeks before this patient presented for evaluation, the organization had observed that the documentation of pain could be improved. A task force was formed to review current practices and search the literature for guidance on best practices. An initial rushed action plan resulted in the premature design of a policy based on anticipated peak effect of interventions (for example, 15 to 30 minutes after a parenteral medication and one hour after oral medication or a nonpharmacologic intervention). The new policy was implemented. Longitudinal policy compliance data on more than 100,000 pain reassessment episodes revealed no evidence that the new policy requirement for documentation had affected patient safety or outcomes.

An alarming trend began and was detected from the added documentation burden placed on nursing staff: Documentation of interventions (apart from the medication administration record) became less frequent. Nurses found that the frequently timed reassessments interrupted workflow, and they began to avoid documenting interventions, which resulted in reduced reassessment entries. They ultimately became noncompliant within the new policy and had concerns specific to safe, effective, and efficient pain management. Senior leaders became aware of and involved in the need to investigate the management and



documentation of patients' pain assessments and reassessments in the organization.

The business case senior leaders identified included the following critical outcome components:

a. Clinical quality and patient safety were potentially compromised.
b. Ongoing and consistent assessment of pain based on the policy was not effective.
c. Maintenance of a safe, effective, and efficient pain management system is necessary.
d. Organization-wide compliance with Joint Commission accreditation requirements is essential.
e. Patient, staff, and physician satisfaction in the management of patients' pain is important in order to achieve the desired results.

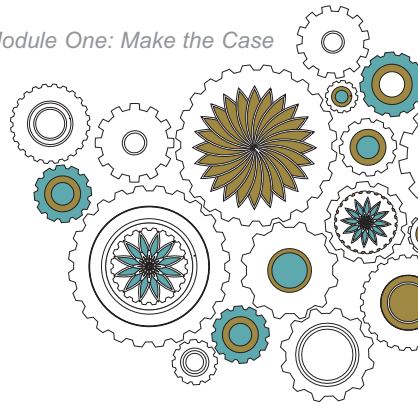
Senior leaders decided to initiate a performance improvement project team under the direction of the senior clinical nurse specialist for pain. (Please continue to read more in the Module 2 case scenario.)

Next Steps:

1. Complete the checklist for Module 1.
2. Proceed to Module 2.

Checklist

- ❑ Review the global business dynamic and begin to consider the business dynamic in your state, community, and health care organization. Look for similarities and differences with the site findings. What are the business opportunities in your organization to benefit from a robust pain management program?
- ❑ Are there obvious challenges to managing pain systematically in your organization? What are the challenges?
- ❑ Consider the CMS expectation for readmission rates and reimbursement. Do you have opportunities for improvement? What are those opportunities?
- ❑ What leading practices for safe pain management are currently being applied in your organization?
- ❑ The lessons learned have applicability in any organization. Do any particular lessons learned apply to your health care organization? Identify the lessons that are applicable to your site.



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Module 2

Define and Measure

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How to Use This Module

By now, you have completed Module 1. You learned about the importance of several factors related to an organization's pain management program: the current state of the organization's business case priorities, key challenges, and the importance of adopting a systems approach to the provision of care. You also learned about the eight critical components of a successful pain management program:

1. Use of national pain standards
2. Commitment of a senior leader champion
3. Consistent oversight by a pain project manager
4. Collaboration of the interdisciplinary team
5. Provision of systematic performance improvement methodology
6. Provision of a pain management infrastructure
7. Promotion of continuous learning for the patient and family
8. Transition of care for all stakeholders

This module will guide you through developing a team to assess your organization's current pain management process. This is a crucial step, as performance improvement (PI) tools will improve the systems approach only if gaps and shortcomings in the current process are correctly identified. Specifically, this module addresses the first five components of the eight critical components of a successful pain management program.

Component #1	Use of National Pain Standards
Component #2	Commitment of a Senior Leader Champion
Component #3	Consistent Oversight of a Pain Project Manager
Component #4	Collaboration of the Interdisciplinary Team
Component #5	Provision of Systematic Performance Improvement Methodology
Component #6	Provision of a Pain Management Infrastructure
Component #7	Promotion of the Patient's Continuous Learning
Component #8	Transition of Care for all Stakeholders

Core Objectives for This Module

Core objectives for this module include the following:

- Describe the first five key components of an effective pain management system.
- Perform a systemwide assessment of your organization's pain management processes across multiple transitions of patient care.
- Perform a pain system tracer (*see* Sidebar 2.1).
- Develop a high-level process map specific to how pain is managed in your organization.
- Define potential PI opportunities, based on the current state analysis and write a team-based project charter.
- Establish an interdisciplinary pain management PI team.
- Read and understand a case study specific to establishing priorities for pain management improvement.
- Consult the Module 2 Next Steps.

Critical Component 1: Use of National Pain Standards

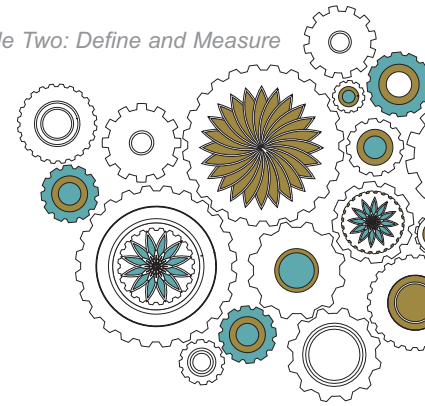
The first critical component of a successful pain management system is an organization's use of both national evidence-based clinical practice guidelines and The Joint Commission's pain standards. It is not our intent to focus on the clinical management of individual patients and the various treatments for acute and chronic pain. Rather, our aim is to facilitate your access to pain standards of care and evidence-based standards, practice guidelines, core references, key Web sites, publications, and other literature by professional organizations, as well as evidence-based practices relevant to effective pain management.

An organization may be tempted to focus on published literature alone, instead of first assessing its current state strengths, limitations, and gaps specific to effective pain management. When best practice protocols are introduced within broken systems, the clinicians and leaders are often disappointed that a so-called best practice is not sustainable. Systems that are "broken" require unique and individualized solutions that can be generated only through the use of a systematic organizational assessment and application of the eight critical components of a pain initiative.

The Joint Commission standards specific to patients and their pain were developed in response to credible documentation of inadequate pain care in the United States and evidence of the importance of developing standardized processes to pain assessment and treatment. The standards were established as a framework to guide efforts for making pain management an essential and integral part of patient care. The pain standards were among the first of The Joint Commission's evidence-based standards. Although reaction

Sidebar 2-1. Tracer Methodology

Tracer methodology is an integral part of The Joint Commission's on-site survey process. Tracer methodology helps organizations identify and assess priority focus areas, identify opportunities to observe patient care, and identify opportunities to interview physicians and other non-nursing personnel. Please refer to the Appendix for more information and a practical tracer example.



to these standards has been varied, since their creation, they have had substantial impact nationally. Some of The Joint Commission standards require that certain aspects of care be documented. The process of documenting and standardizing processes begins to place focus and accountability on caregivers to manage pain. Pain management advocates have enthusiastically embraced the standards because they address documented impediments in the health care system, including the following:

1. The failure to assess pain appropriately
2. The need to ensure that pain is addressed as patients move from one care setting to another
3. The failure to make patients aware of their right to and the benefits of effective pain control

There have, however, been some problems regarding implementation and misinterpretation of the standards. For example, in some cases, caregivers take too literally the analogy of pain as "the fifth vital sign" and treat patients' pain ratings rather than the pain itself. In addition, caregivers may selectively overemphasize access to opioids as the foundation for compliance with stringent medication orders.

It is important to note that The Joint Commission standards do the following:

- Support and reinforce clinical practice guidelines
- Provide a framework to guide organizations
- Stimulate ongoing performance monitoring

An organization's initial assessment of its pain-related systems will enable it to operationalize standards in a manner appropriate to the particular settings, patient populations, and resources.

Critical Component 2: Commitment of a Senior Leader Champion

Because there are many competing strategic priorities in health care organizations and because pain management requires organizational resources and interdisciplinary care delivery models, it is important to establish an executive sponsor who understands the need for effective pain management and the key roles of organizational program development and outcomes measurement specific to pain management.

PI projects align strategically with the mission and vision of a health care organization. Therefore, it is critical to the success of a project to have a designated executive sponsor serve as an advocate for the pain management PI team. It is also important that key roles for pain management PI systems be clearly defined and that appropriate individuals be appointed to them (*see* Sidebar 2.2).

The Executive Sponsor

The executive sponsor is a senior leader who sponsors the overall pain initiative and who may be the CEO or COO or is a senior leader who reports to them. The sponsor

Sidebar 2-2. Key Roles for Pain Management PI Systems

Role	Description
Executive sponsor	A senior leader who sponsors the overall pain initiative, for example a Chief Nurse Executive (CNE), and who reports to the Chief Executive Officer (CEO) or Chief Operating Officer (COO).
Pain project champion	A middle- or senior-level leader who sponsors a specific pain project, ensuring that resources are available and that cross-functional issues are resolved.
Pain project manager	An individual who is responsible for implementing PI pain projects, communicating with the senior leader champion, setting agendas, facilitating the use of PI tools, and providing oversight for project phases.
Interdisciplinary pain team members	Professionals who bring relevant experience or expertise to the management of patients in pain and who work together to provide a pain management system that is safe, effective, and efficient.
Pain resource nurse	A designated nurse in each work area who functions as a peer resource for pain management issues.
Process owner	A professional who is responsible for the business process that is the target of a PI project. For instance, if the pain team implements a change in pain management in the emergency department (ED), the process owner may be the ED director who provides oversight to the change process and is responsible for sustaining the improvement when the project is over.

sanctions the initiation of the PI pain projects and delegates the leadership of the pain initiatives to a senior leader pain champion.

The Senior Leader Pain Project Champion

Sometimes the executive sponsor must designate a champion to seek additional resources for the team, remove unexpected barriers to the project, and enable the celebration of team success. The pain project champion may need to assist with the identification of the physician referral base so that the team can design the patient discharge and pain management follow-up process in an organized and efficient manner that benefits both referring physicians and their patients. The pain project champion may facilitate the understanding of the needs and satisfaction of referral physicians to help the pain project establish an organizationwide process for streamlining pain-related information to primary care physicians (PCPs) in the future.

The champion for a pain management process also communicates the improvement vision, determines the appropriate scope for pain management projects, selects appropriate interdisciplinary team members, advocates for the need for future change, helps to manage that change, and allocates available resources to the team, as necessary. Senior leaders who understand and have a commitment to using PI methodology also support the pain team's need to investigate systemwide root causes that promote error-prone processes and subsequent medical errors.

The pain project champion ensures that the quality improvement reporting relationship of the interdisciplinary pain management team is aligned with quality, safety, and risk reduction functions of the institution. For instance, a PI steering committee may exist in the institution, but the pain management project's work and quality improvement (QI) data may not be discussed within that forum if it is not seen as a strategic priority.

Dr. Mark Chassin and Dr. Jerod Loeb from The Joint Commission emphasize three requirements for achieving high reliability (in other words, consistent performance at high levels of safety over long periods of time) within health care organizations[1]:

1. Leadership must make a commitment to the goal of high reliability.
2. The organizational culture supporting error reduction and high reliability must be fully implemented.
3. The organization must adopt the tools of robust process improvement.

Sidebar 2-3. Sample Pain Team Agenda

Date and time:
Meeting purpose:
Team members present:
Team members not present:
Agenda:

1. Review of team ground rules
2. Team expectations, mission, and vision
3. Pain team updates
   - Policies and procedures
   - Leadership updates
   - Structure outcomes
   - Unit-based measurement review
   - Performance improvements: process and outcome results
4. Organization scorecard review
5. Status reports (action plan)
6. New challenges and opportunities
7. Next steps

In order to initiate the work of the pain team, the sponsor and pain project champion sanction the project charters that are created by the pain team, ensure that systematic PI methods are used, and facilitate the team's progress through the various PI phases of the project.

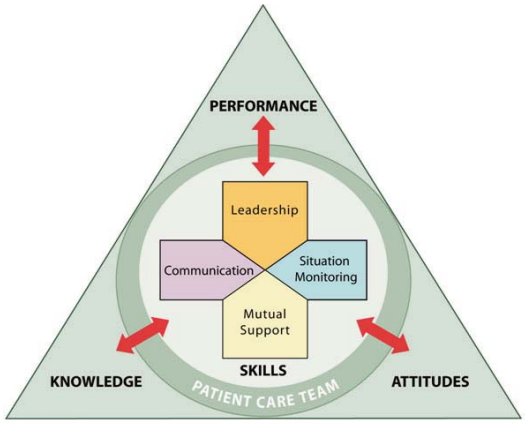
Critical Component 3: Consistent Oversight by a Pain Project Manager

Project managers who are committed to using PI methodology will come to understand the global nature of pain management within the organization, what the current state is, and what potential gaps may exist. They must possess the individual drive and passion to get all team members on board and sustain their motivation for pursuing continuous improvement opportunities related to pain management.

The pain project manager communicates with the pain champion, sets agendas for team meetings, facilitates the use of PI tools and techniques for change management, provides oversight for the project phases and deliverables, delegates project tasks to team members, and facilitates interdisciplinary collaboration across the system. (For a sample pain team meeting agenda, *see* Sidebar 2.3.) The project manager may or may not be a clinician but must be someone who understands the mission and vision for the program and who can facilitate positive dynamics among all team members.

The capacity of the project manager to understand project management, group dynamics, facilitation techniques, objectivity, PI tools and techniques, and overall positive framing is critical to the success of the project. The project manager maintains established meeting structure, uses established ground rules for group focus, and keeps the team energized and committed to the process. (*See* "Project Leader Facilitation Guide" in the Appendix for more information.)

Figure 2-1. The TeamSTEPPS Logo



The program manager may use Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS), an evidence-based teamwork system designed for health care professionals. The Department of Defense's Patient Safety Program and the Agency for Healthcare Research and Quality (AHRQ) collaborated to develop TeamSTEPPS. The primary goals of TeamSTEPPS are to produce highly effective medical teams, increase team member awareness of roles and responsibilities, resolve conflicts, improve information sharing, and eliminate barriers to quality and safety. (For more information, *see* http://teamSTEPPS.ahrq.gov and Figure 2.1.)

Critical Component 4: Collaboration of the Interdisciplinary Team

Many disciplines are involved in the care of patients who are in pain. Depending on the types of patients your organization serves, you may have nurses, hospitalists, PCPs, surgeons, anesthesiologists, pharmacists, social workers, chaplains, physical and occupational therapists, wound care specialists, case managers, rehabilitation staff, and many more serving patients who are in pain. In order to have an effective and successful pain program consisting of strong medical leadership and consistency in using individualized care plans, a physician champion for pain is critical for success.

The role of the pain project champion may be filled by a primary care physicians (PCP) or specialized physician who directs the care, treatment, and activities of the focused patient population and who also has a passion for evidence-based medicine. Engaging physicians as leaders in a pain management improvement project is critical to the success or failure of efforts. Establishing a collaborative relationship between physician and nonphysician team members is also essential to ensure clear communication pathways, mutual trust, and respect for the work that needs to be done for patients and families. A lead physician champion should be a member of the pain team; this person should participate when able and stay informed and involved with the team's activities.

Your health care organization may have chosen to use unit-based pain nurses who are responsible for providing oversight for the specific patients they serve in their work unit. Although education is essential for progress, education alone rarely results in

behavior changes. Educational programs must not only address the learning needs of practicing clinicians but also reinforce implementation of newly acquired information.

A pain resource nurse (PRN) training program provides a model for combining information transfer with sustained care. The intent of a PRN program is to train a select group of staff nurses on each inpatient nursing unit to function as a peer resource for ongoing pain management issues. PRNs function as role models in pain assessment and management, interface with staff at the unit level to solve pain management problems, disseminate new information about pain management, and function as change agents.[1]

Nurses in particular have a unique role and opportunity to impact the way pain is managed in an organization. Nurses use evidence-based practices that consider the following three factors:

- Available evidence of all forms (history, physical, etc.)
- Clinical judgment and expertise
- Patient and family values and preferences

Regardless of the roles represented on an interdisciplinary pain team, it is important to apply proven group process methodology, including establishing mutual trust and respect. Doing so promotes safe, efficient, and effective communication within the team's work environment (*see* Sidebar 2.4).

Sidebar 2-4. The Interdisciplinary Team

Key members of the interdisciplinary team may include the following:

- Pharmacists
- Nurses
- Hospitalists
- PCPs
- Surgeons
- Anesthesiologists
- Social workers
- Chaplains
- Physical and occupational therapists
- Complementary pain therapists
- Case managers
- Rehabilitation staff

Critical Component 5: Provision of Systematic PI Methodology

Before beginning a pain management project, it is important for a pain team to understand what is to be addressed. Organizations often come to the table with preconceived notions of what is wrong with current processes, only to find out that what they believe to be the problem is actually not the root cause. A team may apply solutions that are not directed at root causes, that are, therefore not effective. For instance, a team may believe that all units in the health care organization follow the identical postoperative pain management process, but after building a high-level process map and completing a system tracer, the team may discover that each surgical unit has a different process in place.

PI Methodologies

It is not our intent to prescribe the type of PI methods you should use. However, we do promote using a systematic PI methodology as a critical component of establishing a safe, effective, and efficient pain management system within an organization. Some

commonly used PI methods are PDCA/PDSA (plan, do, check/study, act) cycle (also called the Deming cycle), Lean Sigma (which targets elimination of waste), or Six Sigma (which involves the steps define, measure, analyze, improve, and control). Each of these PI methods, if used correctly, applies a systematic process to move a team from problem definition to planning and measurement, using data collection plans, applying solution-generation methods to target root causes, and implementing a postlaunch control or monitoring plan. Each method has the potential to achieve the desired results for a project. We have been taught traditionally in health care to see a problem and immediately "fix it," but we are now challenged with the need to step back and define the problem through the eyes of the patient, family, and stakeholders and to facilitate a systematic process for sustainability and high reliability of the improved system of care.

Sidebar 2-5. The PDCA/PDSA Cycle

PLAN: Plan ahead for change. Analyze and predict the results.

DO: Execute the plan, taking small steps in controlled circumstances.

CHECK (or STUDY): Check or study the results.

ACT: Take action to standardize or improve the process.

The PDCA/PDSA Cycle

The PDCA cycle (also known as PDSA cycle and the Deming cycle) is a continuous QI model consisting of a logical sequence of four repetitive steps for continuous improvement and learning: plan, do, check (or study) and act (*see* Sidebar 2.5).

Lean methods, originating from the Toyota Production System (TPS), have been used to eliminate errors and waste in system processes. As shown in Sidebar 2.6, the DOWNTIME acronym is used to remember the different types of Lean waste. Lean tools are available in the Appendix.

Sidebar 2-6. Types of Lean Waste

D—Defects
O—Overproduction
W—Wait time delays
N—Non-value-added process steps
T—Transportation waste
I—Inventory waste
M—Motion waste
E—Employee underutilization

Six Sigma, on the other hand, is a PI methodology that enables a team to not only eliminate waste in a process but also define the problem and associated metrics, analyze the root cause variables, and—by generating solutions targeting root causes—reduce or eliminate variation in a given process. Six Sigma's PI phases include the following: Define, Measure, Analyze, Improve, and Control (DMAIC). These phases move a team through a systematic process from defining a problem's root causes to generating solutions and ultimate sustainability and monitoring for solutions.

Regardless of the PI methods used, using a systematic PI methodology will guide a team through a series of PI steps that will enable focused and directed solutions targeting root causes. As a team moves through the PI phases, it must determine possible measurements or metrics so that it can understand the baseline performance of the organization's system as well as the improvements that have been made.

The Donabedian Structure

Donabedian's structure, process, and outcome model (*see* Figure 2.2) has long served as a unifying framework for examining health care services and assessing patient outcomes.[2,3] This model proposes that each of the three components—structure, process and outcome–has direct influence on the subsequent component, as shown by the arrows in the model.

Figure 2.3 provides an example of structure, process, and outcome metrics for pain management systems.

Teams that are collecting data related to outcome metrics often have limited data on process metrics, which leads to confusion about why our patients' outcomes are not improving. A primary tenet of PI is to examine and better understand the processes of care in order to identify targets for improvement that can lead to better outcomes. A key lesson for institutions is that if they do not address structural and process-related system variables, then the system may very well remain broken.

After a team has determined what type of PI methodology it will use, it can begin in the planning phase of the PDCA (PDSA) cycle or the define phase of DMAIC to identify and describe the current state of the issue or concern relative to pain management.

Defining the Current State

A team can use the following PI tools to define the current state:

1. SWOT analysis for organizational self-assessment
2. A system tracer
3. A high-level process map
4. A project charter for senior leadership sanctioning of the project

SWOT Analysis

SWOT analysis is a strategic planning method used to evaluate the strengths, weaknesses, opportunities, and threats (or barriers) involved in a project or process. Conducting internal and external assessments—including analysis of the organizational environment—is critical to performing a SWOT analysis.

Figure 2-2.
The Donabedian Model of Patient Safety[4,5]

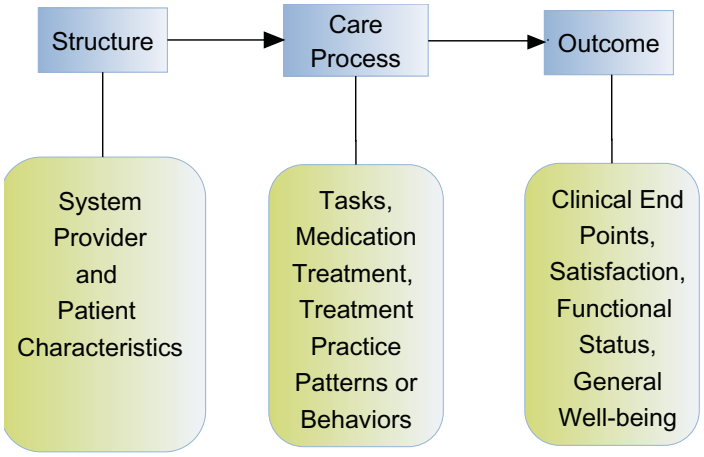


Figure 2-3.
Examples of Donabedian Structure, Process, and Outcome Metrics

Pain Structure Metrics	Pain Process Metrics	Pain Outcome Metrics
Interdisciplinary pain care PI team	Use of complex analgesic regimens	Patient satisfaction
Educational programs for interdisciplinary staff	Pharmacy delivery time	Functional status
Complementary therapy resources	Nursing documentation of pain assessment/ reassessment	Individual pain goal accomplishment
Access to specialty referral sources	Information flow across the medical record	Pain intensity ratings or amount of pain relief

Care providers with clinical backgrounds can have difficulty acknowledging the business dimension of health care, but that dimension is what sustains the enterprise. Addressing the business dimension requires the application of specific business management principles and collecting voice-of-the-customer information from patients, their families, referring physicians, care providers (including physicians, nurses, pharmacists, and physical therapists), and other internal and external stakeholders across a patient's continuum of care.

It is important to understand the voices of an organization's many customers and stakeholders prior to performing a system tracer for pain and developing a high-level process map. As we have discussed, clinicians often attempt problem-solving methods before they listen to and assimilate the many voices of customers and stakeholders; when they do so, they are likely to provide solutions where patients and their families do not perceive problems and they may miss issues that are, in fact, important to these participants in health care processes.

Figure 2.4 provides a one-page form that a team can use to conduct a SWOT assessment. The following list provides tips for ensuring effective SWOT feedback from internal and external stakeholders:

1. The SWOT assessment can be mailed or e-mailed to defined customers, staff, and stakeholders.
2. Individual feedback is recommended over group consensus responses to solicit diverse opinions, thoughts, and feelings of group members.
3. Patient and family surveys postdischarge can provide feedback specific to satisfaction with care processes.
4. Anonymity of the tool encourages freely voiced and honest feedback.
5. It can be helpful to preserve confidentiality by not asking for names on the tool response form.
6. The team facilitator should synthesize the responses for the pain team's review.
7. A SWOT analysis may bring to light potential issues and problems that can be explicitly included in team projects.

The SWOT analysis is the initial organizational assessment and risk analysis of current perceptions of stakeholders in the process. To ensure the success of a pain management process, a team should solicit perceptions from patients, families, and individuals

Figure 2-4.
SWOT Assessment Form

Joint Commission Resources, Inc.
SWOT Analysis: Systems Assessment of Pain Management Processes

Please respond to each of the following questions from your personal perspective.

1. Describe the strengths of your pain management program:

2. Describe the weaknesses or limitations of your present pain management program:

3. List specific opportunities that you feel would improve your pain management program and related services:

4. List any barriers or threats to successful improvement for the opportunities identified in item 3:

5. Indicate your professional discipline (surgeon, anesthesiologist, nursing, and so on) and how many years you have been a part of the pain program.

Figure 2-5. Sample SWOT Analysis for Pain: Structure and Content

PRESENT	FUTURE
Strengths: • Pain intensity assessments • Nursing leadership • Pain orientation class • Dedicated pain pharmacist • Integrative and complementary therapies	**Opportunities:** • Appoint a pain management specialist • Establish unit-based pain resource nurses • Provide evidence-based education/Web-based learning to all disciplines
Weaknesses: • Lack of physician provider pain education • Pain management often limited to medications only • Limited provider referral resources • Lack of specialty pain team resources	**Threats:** • Time • Resource availability • Leadership commitment/support • Strategic priorities • Information systems

representing all involved disciplines, including surgery, anesthesia, nursing, medicine, pharmacy, support services, the chronic pain clinic, addiction rehabilitation services, complementary therapies, and the primary care providers in the various community settings.

Once the SWOT analysis has been collated and the results reported to the team, the team should prepare to "walk the walk" within the organization by performing a system tracer for pain. The facilitator can point out during review of the SWOT analysis that the strengths and weaknesses represent perceptions of the current state, and the opportunities and threats represent perceptions of the future state. As the team begins to identify gaps in the current system, both the weaknesses and opportunities can generate a wealth of information and discussion (*see* Figure 2.5).

System Tracers

A system tracer is an essential component of The Joint Commission's on-site accreditation survey. It serves as a PI tool to visualize and document the current state of specific PI issues and concerns in the organization. *See* Sidebar 2.7 for a system tracer example. *See* Appendix for a sample laboratory tracer.

High-Level Process Maps

For good reason, health care providers are taught to diagnose and treat problems. While this approach is appropriate for clinical care, health care providers often approach system-related issues with little or no information about how failures or errors at the start of the process affect outcomes at the end of the process.

Sidebar 2-7. System Tracer Example

Scenario

Joint Commission Resources consultants conducted a pain management system tracer in a 450-bed hospital. They started the session by meeting with the senior leaders, pain management committee, QI staff, risk management, and surgical staff representatives from across the continuum. They provided basic information about the purpose of the visit and shared educational information about PI methodology and Lean wastes found in health care organizations (*see* Sidebar 2.6).

Team members introduced themselves and described their roles specific to pain management in the organization. This was a very helpful way to establish relationships prior to tracing the various systems in the health care organization. The group also discussed the various types of meetings and communication methods used across the pain management continuum.

The consultants asked the representatives to identify their greatest concerns related to the management of patients in acute or chronic pain and also asked them to identify any data that were currently being collected. They explained that they monitored for pain assessment, reassessment, and intensity ratings and that this monitoring was a main focus for the existing pain committee. Team members described how they worked with staff regarding identification of and interventions for maintaining compliance with documentation of pain ratings and also how difficult it was to manage the chronic pain patients in the organization during inpatient stays such as for surgeries.

The consultants next shared their findings from the SWOT analysis that had been performed confidentially prior to the site visit. The team members validated that while they were very proud of the work they had accomplished in pain management over the past several years, they fully understood that there was room for improvement.
After the formal meeting and review, instead of tracing an individual patient, the consultants chose to trace the management of pain across the surgical continuum, from the outpatient setting, to preanesthesia testing, to preop holding, to the operating room (by interviewing anesthesia staff), and to the postanesthesia care unit (PACU) and surgical floors. In each area, the consultants inquired about the process used to manage pain, reviewed assessment tools, and asked staff what they felt was working well and what issues and/or barriers were obstacles to providing safe, effective, and efficient pain management for patients. The consultants documented each care process and the key tasks associated with each process in each of the surgical areas. Where best practices were already in use, examples of them were highlighted, as were opportunities for improvement.

Sample Tracer Questions

Questions for the Pain Committee and Senior Leaders

- How do you obtain relevant, up-to-date information regarding pain management?
- How do you disseminate this information to other staff at all levels?
- What are the greatest pain-related risks facing your organization?
- What are you doing to diminish the risks and impact on outcomes of care?
- How do you monitor compliance with the requirements of pain standards?
- How do you intervene when you observe noncompliance?
- How do you collect and analyze data that may help reveal risky or problematic trends and patterns?
- What is your involvement on the committee?
- Why were you selected to be on this committee?
- What data are being studied?
- How are data communicated to you?
- Do you compare and benchmark your data and outcomes with others?
  - Describe this process.
  - How do you compare?
- What improvements have you implemented?
  - Have they been effective?
  - How do you know?
- How are staff performing regarding safe, effective, and efficient pain management?
  - Is improvement sustained, and is it sustainable?
  - How do you know?

(continued)

Sidebar 2-7. System Tracer Example, *continued*

Questions for the Clinicians Across the Continuum

- Do you have a pain management protocol or process?
- How do you monitor for continuity of care?
- How do you monitor for compliance with protocols?
- How do you know whether patients and families are engaged in decisions about pain treatment?
- Do you intervene if you believe the relevant guidelines are not being complied with? How?
- How do you educate patients and families?
- How do you document this education?
- Do you have an electronic medical record (EMR), or do you rely on paper charts?
- How does your pain management information flow across your EMR or paper charts?
- What types of integrative or complementary and alternative medicine techniques do you use to manage pain?
- What are your resources and levels of support for patients and their families?
- What would you like to see change?

Working with systems of care delivery requires leaders and practitioners to see *patterns,* not just single events, and to look beyond the immediate symptoms to fix the *root causes* of problems. A root cause is defined as an initiating step in a causal chain that leads to a particular outcome or effect of interest. The root cause is the target for an intervention that might alter performance and prevent an undesirable outcome, such as a medication error resulting in oversedation of a patient. For instance, in looking at a postoperative medication administration process, a nurse may detect an error in the administration of a medication in the post-anesthesia care unit (PACU), when the failure or error actually occurred much earlier in the process, in the preoperative suite. In this case, an error in the process for ordering medication in the preoperative area would be considered the root cause.

In many cases, solutions that are implemented at the beginning of a process can prevent potential errors throughout the process from becoming actual errors. For instance, fixing or verifying a handwritten documentation order at the start of a process can eliminate an error due to illegible handwriting at the end of the process.

The act of creating a process map provides a shared understanding among those involved in creating the map of what the actual steps of the process are and what the goals or outputs of the process need to be. It is also helpful before the map is created if the team has a general understanding of how to identify root causes and risk points.

Process maps do the following:

- Help staff visualize more than the tasks within a single process or group of steps they regularly perform, by framing each task as a component of the whole system.
- Link material and information flows, allowing staff to identify communication lines and target them to avoid potential errors related to handing off patients and relevant

information from one care unit to another.
- Provide a common language or a standard method, thereby helping to clarify inconsistencies in a policy or a practice by regularly employing the same agreed-upon terms, labels, or names for the steps in a process.
- Facilitate planning for problem solving.
- Uncover steps that waste time, reduce energy, and affect efficiency. A process map may, for example, uncover the fact that an organization is using different patient information forms that are redundant and can be merged into a single standardized form.

Creating a High-Level Process Flow Map

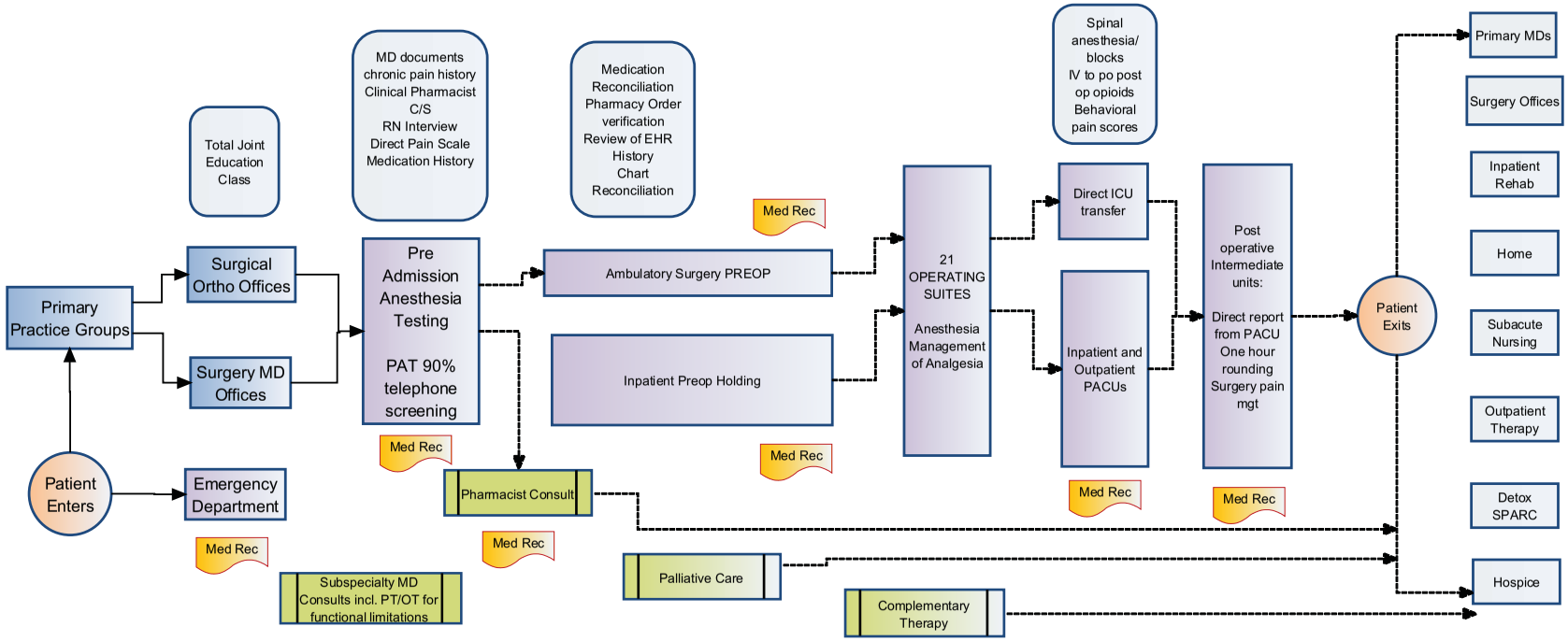
The process of *creating* a high-level process flow map is just as important as the map itself. Creating a map may clarify some of the following:
- How work is actually performed
- Whether staff work together or in separate functional groups (sometimes referred to as "silos" or "swim lanes")
- The work requirements of different team members
- The sequence followed in the care process
- Whether the needs of the customers are being met (For instance, if a medication is ordered and there is a 1.5-hour delay before the patient receives it, the process clearly shows that the needs of the customer—that is, the patient—for timely treatment are not being met.)

In most cases, a process map begins with the identification of a customer need and documents the flow of information and activities to achieve that need and satisfy the customer's expectations.

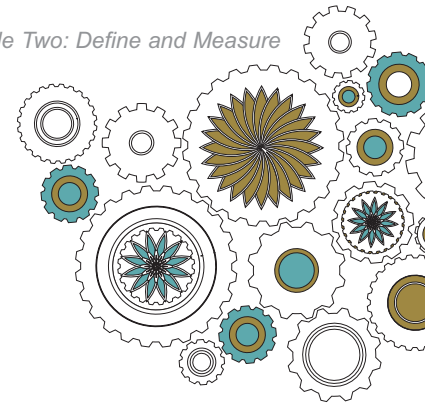
The power and value of the process flow map as a tool is that it can often demonstrate inconsistencies in practice, wasteful steps in a process, sources of staff frustration, lack of adherence to recommended practices, and barriers to compliance with processes and opportunities for sustainable improvement solutions. Clarity about the process emerges as staff share their understanding about what happens in each step. The interdisciplinary team works together to place the system tracer findings on the high-level map. After it creates the map, the team can step back and identify what is working, what is not working, and whether there are gaps specific to the eight critical components of a safe, effective, and efficient pain management system.

Figure 2.6 shows an example process map from a national site visit. Instead of tracing a specific patient's experience, the team that created this map actually traced the pain management system across the surgical practice arena. Because the consultants "walked the process" and talked to staff in each work area, they discovered many inconsistencies in practice. This was an opportunity for interdisciplinary staff to validate the many strengths and potential limitations and gaps in the existing processes. While the team learned many key lessons for the team, one of the most eye-opening gaps it found was

Figure 2-6. An Example of a High-Level Process Map



* The patient entry and exit is depicted as circles in pink, medication reconciliation is amber, patient flow with nursing is violet, preadmission and postdischarge stakeholders and pain assessments and treatments are light blue, and the pain resource consultations are in green.



that preadmission and postdischarge stakeholders reported frequent communication breakdowns with the health care organization related to the transition of care at the time of patient handoff. (We will discuss critical component 8, transition of care for all stakeholders, in Module 3.)

Positive outcomes of process mapping include the following:

- Visual display of the steps in a complex process. This promotes team and staff understanding and facilitates communication within the team and with those not close to the process.
- Objective review of what happens. For example, how does what happens on a midweek day shift differ from what happens on nights and weekends?
- Validation of the input of point-of-service staff (those who provide direct patient care) who have expert knowledge of the 24/7 process
- Design of focused pilot testing of changes in the process, as defined by the team
- Team involvement and enthusiasm
- Better understanding of the process and its boundaries, such as where the process begins and ends. For example, the team may focus on when the patient enters the preoperative screening unit or preoperative holding and when the patient is transferred to the operating room.
- Role clarification. Everyone is more aware of their roles in the mission to improve high-quality, safe patient care and how their efforts contribute to the overall objectives of the process.
- Use of the process map in training new employees, identifying areas that need improvement, and creating interfaces between the hospital-based process and processes of the supplier or customer.
- A resource for marketing high-quality services. If a process map documents seamless and efficient process flow for a patient entering the pain management system, the organization can use that information to market its services (for example, via pain satisfaction HCAHPS scores).
- An overview of the whole system that conveys the complexity of the system
- An instant impression of the system that addresses questions such as the following:
  - Is the process well organized? Do its steps flow in logical sequence?
  - Are the movements and activities clear? Does the team understand where the handoffs occur?
  - How are patients transferred between different points in the system?
  - What are the flow and handoff communications in the process?
- A basis for writing policies and procedures based on the process

The Functional Flow Map/Swim Lanes Diagram

One specific type of high-level process map is called a functional flow map, or swim lanes diagram. A swim lanes diagram allows a team to see what each separate discipline or pain management resource is doing. Using such a map is helpful when those involved are working within individual silos. In this situation, the patient and family see the big picture of whether the individuals in the silos work together. The swim lanes diagram shown in

Figure 2-7. An Example of a Swim Lanes Diagram

As you can see, there are many functional roles, and each one operates well within its functional swim lane, but the various roles have integration opportunities for improvement.

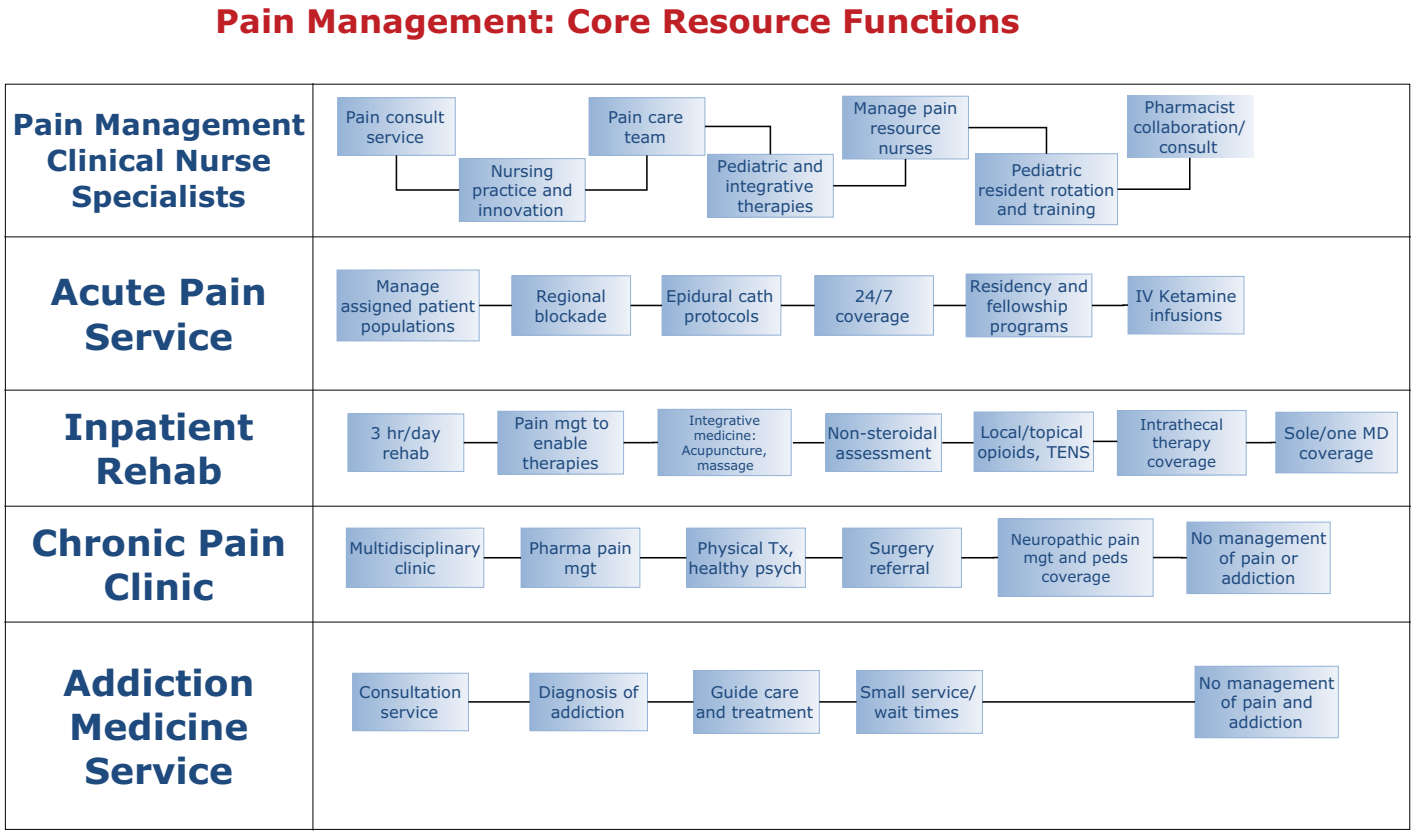


Figure 2.7 was created in a hospital site whose pain control leaders are nationally regarded. Although the organization exemplifies best practices in pain management strategies and research, by using this diagram, it discovered ways the interdisciplinary staff could better communicate and coordinate their care and services to patients across the continuum of care. Figure 2.7 is an example of how a team can illustrate and describe the many functional requirements within the pain management system.

Please refer to the handout "How to Build a High-Level Process Map" for detailed instruction.

The Project Charter

The final tool used in the planning or define phase of a PI project is the project charter. The charter includes a one-page executive overview of the problem or issue being addressed, the mission and aim of the project, a list of team members who will begin to work together, the patient and organizational benefits and business case, and the time

Sidebar 2-8. Sample Pain Improvement Project Charter

Project Charter: Pain Management — Start Date: July 20XX

Problem/Goal Statement:

Leadership Signoff / Sanction:_____

Stakeholders:

Why is this project important?

Describe the patient benefit:

What will the project achieve?

Describe the organizational benefit:

What is the business case? (ROI)

Project Metrics:

Team Members:

Stage	Target Date	Actual Date
Define		
Measure		
Analyze		
Improve		
Control		

line for PI phase resolution. Many might think that the project charter should be written first, before work begins. However, the charter should be written later, in the define phase, because the problem statement, aim, and project members should not be fully determined until after the problem has been accurately defined and the project is well scoped. Scoping a project is important because it prevents a team from trying to solve all potential system issues at once. Creating and then initiating projects one at a time allows a team to focus on the true root causes of a given process as opposed to the root causes of the overall system. The project charter can be a tool for acquiring leadership sanctioning of the project and can be used as a "tollgate" review—a means to check that work is still on target—after each phase of the PDCA cycle or DMAIC so that senior leaders and champions are updated consistently and the team is sanctioned to keep moving forward. After an organization ensures that its project is appropriately scoped, is manageable, and can be completed within a predetermined amount of time, it can select interdisciplinary team members who will serve on the project team. If the team decides to scope a pain improvement project within surgical services, for example, it will be critically important for staff from surgical services to serve on the PI project team (*see* Sidebar 2.8: Sample Pain Improvement Project Charter).

Case Scenario

This case scenario is a continuation of the scenario in Module 1 and illustrates how one organization designed a systematic approach to managing pain.

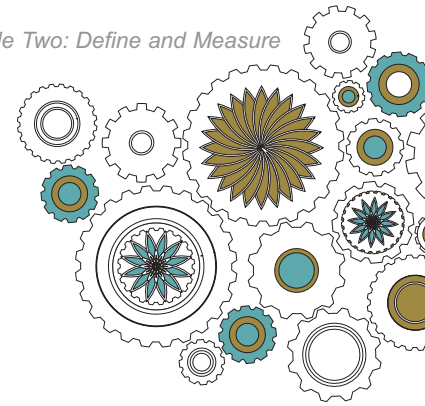
Determine the Current State

Before the team members rushed to solutions, they knew that they needed to define the current state of its process and to benchmark pain reassessments and documentation against those of other organizations. The champion of the pain management program brought compliance data to the administrative policy and nursing leadership groups. A number of stakeholders were present at these meetings, including senior leaders, physician and nurse members of the acute pain service, physical therapy staff, pharmacy staff, medical staff, QI staff, risk management staff, and clinical staff representatives from across the continuum of care, including the primary care physicians. Group discussions ensued to formulate shared goals and outcome parameters for patient safety and accreditation requirements and to assess the transition of care handoffs and potential breakdowns in the system.

A task force was appointed to more closely examine root causes for documentation barriers. It invited 18 key nursing, anesthesia, surgery, and pharmacy personnel from adult and pediatric medical, surgical, and intensive care units and the emergency department to participate. Members included bedside staff nurses, certified nurse assistants, nurse managers, the nursing directors of practice innovation and quality, and the hospital and pharmacy Joint Commission compliance officers. The team broke up into smaller work units and completed the following PI tools:

- A pain system tracer to understand current state
- A high-level process map to visualize the current state
- The project charter (including mission, vision, business case, team members, and time line)
- A swim lanes diagram to visualize the interdisciplinary roles and communication handoffs

Team facilitators set ground rules, managed group dynamics, and achieved results-oriented work. In addition, the team contacted a number of peer hospitals



to obtain details about alternative methods to improve pain reassessment documentation. It also reviewed national pain standards and protocols. The pain committee and nursing practice and administrative policy committees identified the pros and cons of various alternatives. The task force recognized four criteria as being essential in the construction and approval of any policy modifications:

1. Policy language must be compliant with The Joint Commission standards.
2. Nursing practice required by policy language must be practical and possible to achieve.
3. Practice (compliance with policy) must be measureable.
4. The policy must be unlikely to impede the safety and efficacy of pain management.

Process Flow

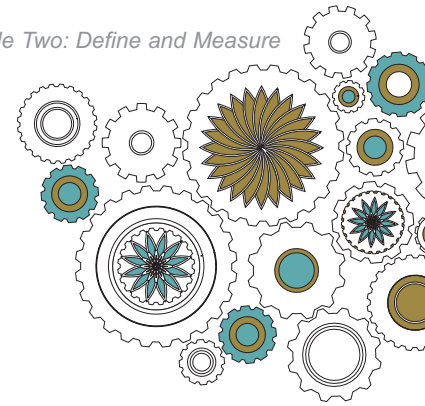
The task force traced the pain management system from the outpatient area through the admission to surgical services to a general care unit. The tracer continuum looked specifically at all processes from patient admission through patient discharge. In each area, the task force examined the process by which pain was reassessed following interventions, reviewed tools, and encouraged staff to share what was working well and what issues or barriers were impeding documentation. The group identified key risk points and agreed that a "critical few" variables warranted further study:

1. Transition failures between IV and oral routes of analgesia
2. Errors in patient-controlled analgesia pump programming
3. High variation in process for analgesic dosing adjustments
4. Staff inability to manage analgesic side effects

Task force members and clinical staff agreed that pain reassessment is more than a single event and occurs in an ongoing manner. The EMR included space to document a comprehensive reassessment, including pain relief, side effects, impact on function, and patient satisfaction. However, the original policy did not focus on the practical interventions specific to safe, effective, and efficient pain management for patients. For example, repositioning a patient prior to administration of an opioid might be the first treatment of choice for a patient.

The collaborative organizationwide pain committee now understood the current state and how its practice compared to the practices of peer institutions. As a result of the system tracer, team members were able to view the high-level process and potential risk points and barriers within the system that could affect patient quality and safety.

The team proceeded to address issues and barriers and the subsequent solutions generated by targeting root causes. (Please continue to read more in the Module 3 case scenario.)



Next Steps:

1. Complete the checklist for Module 2.
2. Proceed to Module 3.

Checklist

- ❑ Review national pain standards and protocols.
- ❑ Identify a senior leader champion.
- ❑ Choose a project manager.
- ❑ Complete a SWOT analysis.
- ❑ Complete a high-level process map.
- ❑ Identify potential risk points on the high-level map and scope your potential project.
- ❑ Ascertain project team membership and the collaborative and interdisciplinary structure to be used for pain management work.

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Module 3

Analyze and Improve

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How to Use This Module

By now, you have completed Module 2. Mindful of your organization's specific needs and resources (including its current pain management program), your team has discussed and reviewed national pain standards and protocols, identified an executive sponsor and project champion, chosen a project manager, reviewed the need for a collaborative interdisciplinary pain team, selected potential team members, and affirmed the use of a systematic performance improvement (PI) methodology.

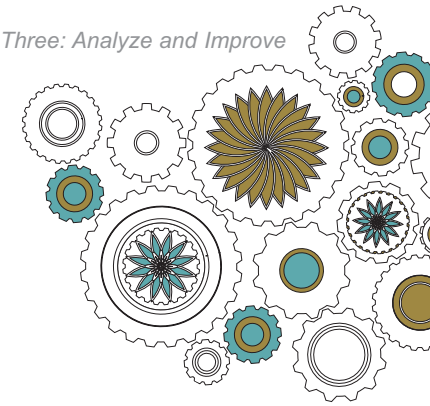
You learned about the following tools in Module 2:

- SWOT analysis
- Pain system tracer
- High-level process map and/or the swim lanes diagram
- Project charter

Using these PI tools enables you to define multiple projects, prioritize them, and begin to redesign your pain management system. The next step is to determine available and/or needed metrics for the measurement of the current state of your pain management system.

This module focuses on the final three of the eight critical components for establishing a safe, effective, and efficient pain management system within a health care organization and community:

Component #1	Use of National Pain Standards
Component #2	Commitment of a Senior Leader Champion
Component #3	Consistent Oversight of a Pain Project Manager
Component #4	Collaboration of the Interdisciplinary Team
Component #5	Provision of Systematic Performance Improvement Methodology
Component #6	Provision of a Pain Management Infrastructure
Component #7	Promotion of the Patient's Continuous Learning
Component #8	Transition of Care for all Stakeholders



Core Objectives for This Module

Along with being able to describe the final three components of an effective pain management system, upon completion of this module you will also be able to:

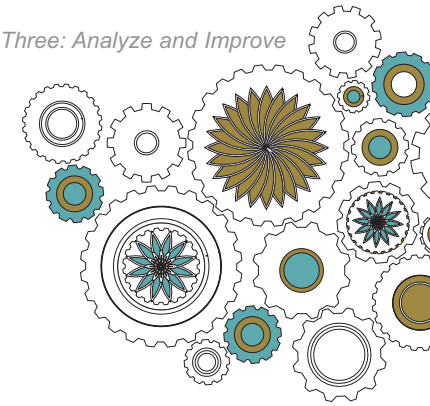
- Use your SWOT assessment and high-level process map of the current state to identify organizational gaps specific to the management of patients' pain.
- Develop a cause-and-effect diagram that highlights variables that may impact the effectiveness of your organization's pain management system.
- Complete a failure mode and effects analysis (FMEA) of key patient-centered variables that affect pain management.
- Create a future vision and potential design for the ideal state of pain management in your institution.
- Develop a measurement system to assess the impact of changes made from the current state of pain management in your organization toward the ideal state.
- Generate solutions for effective management of pain across transitions of care.
- Read and understand a case study specific to analyzing and improving pain management systems.
- Consult the Module 3 Next Steps.

Critical Component 6: Provision of a Pain Management Infrastructure

The sixth critical component of a successful pain management system is an organization's ability to build infrastructure that will support safe, effective, and efficient pain management systems and processes. This means that the organization must have determined that the management of a patient's pain is a strategic priority and therefore will consistently maintain resource support to systematically improve performance. An interdisciplinary pain team needs reporting and resource support provided by an identified executive champion.

The pain team establishes a set of structure, process, and outcome metrics that will be monitored at least quarterly through the organization's PI oversight committee or executive leadership's quality improvement process. As discussed in Modules 1 and 2, specific organizational policies and procedures that align with evidence-based practices need to be in place and accessible for all disciplines. Process-related tools assist the clinicians in their assessment, management, and documentation of the patients' pain, as well as education of patients and stakeholders to facilitate these processes.

Across U.S. health care organizations, a variety of educational methods are used to ascertain care provider competencies related to safe, effective, and efficient pain management. Up-to-date policies, protocols, and pain management methods that cross the continuum of care are core components of a well-built infrastructure. Education alone does not ensure competency. However, new staff and physician orientation, along with updates as needed throughout the year and/or annual updates help ensure competency. Requiring competency-based education as part of the annual performance review is one method to ensure awareness and adoption of new practice standards and controls.



A major challenge in health care today is putting into place systems that deliver clear and reliable information—or that provide a systematic flow of information—particularly in handoffs that may be verbal or electronic. The pain management system analysis, specifically through the SWOT analysis and the high-level process mapping exercise, includes assessing the degree to which all disciplines have access to the medical record, generate information to communicate, and carry out individualized care plans across the many transitions both internal and external to the organization. As described in the following section, information handoff issues need to be analyzed and addressed using gap analysis.

Critical Component 7: Promotion of the Patient's Continuous Learning

Providing information to patients about what to expect during hospitalization can decrease anxiety and even decrease the requirement for postoperative analgesia. Patient education in nonpharmacologic methods of pain control is also helpful for patients whose cognitive function allows them to apply those methods. Most procedures conducted in health care are likely to result in some acute pain. Thus, expectations of a pain rating of "0" at every moment may be unrealistic. For all patients, including those with acute or chronic pain or a mixture of both, maintenance and improvement in function must be balanced against the potentially adverse effects of pharmacologic therapies.

Nonpharmacologic strategies may be beneficial, as may physical measures such as heat or cold, music therapy, or cognitive–behavioral techniques such as positive reframing. Unfortunately, some instinctive coping strategies may be harmful. For example, it is not uncommon for people to significantly reduce activity due to fear of worsening the underlying condition. Education and coaching are crucial interventions to help patients achieve targeted levels of mobilization as they recover from illness or surgery.

Standardized educational material gives patients information about assessment strategies, management techniques, expected outcomes with time frames, and assistance with goal setting. Optimally, these tools would be specific to the surgery or intervention delivered for each patient, although a generic tool could be individualized to each patient's condition and experience. Nurse educators with expertise in pain management (described in Module 2 as pain resource nurses) could collaborate with other specialties to develop such materials and be responsible for educating bedside clinicians in their use.

Critical Component 8: Transitions of Care for All Stakeholders

Because effective pain control depends on the work of many disciplines, interdisciplinary care and collaboration are essential. Communication can be enhanced through shared documentation (where nurses, physicians, pharmacists, and others provide input to paper or electronic charts in areas that are visible to all), bedside

rounds that incorporate the medical team along with the nurse caring for that patient, and interdisciplinary team rounds that include physicians, nurses, pharmacists, discharge planners, and others. Specific team-based strategies can be used to assess, manage, and solicit individual goals from each patient in order to provide for his or her unique needs.

Poorly executed transitions in care place patients' health and well-being at risk, and they often result in avoidable and costly readmissions. Maintaining continuity in a patient's medical care is especially critical following discharge. Gaps in planning for this transition, failures in communication, and delays in scheduling postdischarge care all contribute to readmissions. A well-planned and smooth transition out of the health care organization can significantly improve a patient's quality of life and also allow nurses, physicians, and other clinical caregivers to provide the kind of excellent care patients deserve and desire. (*See* Sidebar 3.1 and http://www.ihi.org for more information on improving care transitions.)

If your team has not done so already, we recommend that you revisit your voice-of-the-customer and pain system SWOT analysis to ascertain whether you have gathered the necessary information from your customers regarding prehospital and postdischarge transfers of information.

In addition, when your team creates the high-level process map, its members can identify all the risk points during handoffs to determine whether there are current-state gaps in the process. A swim lanes diagram is a practical high-level map that highlights how each interdisciplinary team member functions within his or her respective swim lane and how he or she hands off information across lanes to different interdisciplinary staff.

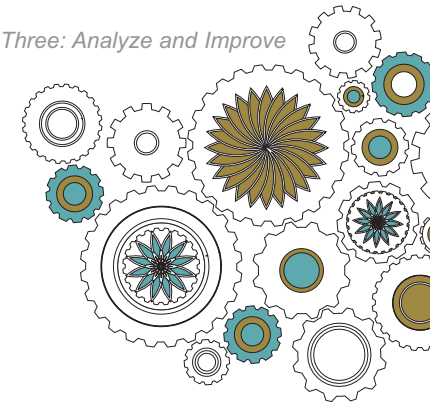
Unfortunately, health care PI efforts have traditionally been focused within the boundaries of the health care organization. In other words, improvement projects have limited their attention from patient admission through discharge. It is now clear that we must do more to ensure safe, effective, and efficient pain control across the continuum of care.

The more we know about our patients *prior* to admission, the better able we are to plan and to communicate their needs during their stay as well as upon discharge and the more likely our chances of providing safe, effective, and efficient care across the *patient's* continuum. In addition, the more we know about the barriers patients face after admission, the better able we are to prevent these obstacles to good pain control.

Sidebar 3-1. Care Transitions

"A care transition is a team sport, and yet all too often we don't know who our teammates are, or how they can help."
—Eric A. Coleman, MD, MPH

The term *care transitions* refers to patients' movement between health care practitioners and settings as their condition and care needs change during the course of a chronic or acute illness. For example, in the course of an acute exacerbation of pain during a flare-up of an underlying medical condition, a patient might receive care from a primary care physician (PCP) or specialist in an outpatient setting and then transition to a physician and nursing team during an inpatient admission before moving on to yet another care team at a skilled rehab facility. Finally, the patient would return home, where he or she might receive care from a visiting nurse and potentially be assisted by a home health aide. Each of these shifts between care providers and settings is defined as a care transition.



You now have the tools you need to analyze the many aspects of your organization's processes that affect multiple transitions of care, including the following:

- Prehospital pain management
- Interhospital transitions and handoffs
- Specialty pain resources/collaboration
- Posthospital pain management
- Relationships with referral agencies
- Patient and family education and perceptions
- Communication flow with PCPs

The following are some of the common challenges to sustaining effective pain care outside the health care organization environment:

- Insufficient payment for (or other restrictions on) medications by third-party payers
- Difficulty finding specialized physical or occupational therapists with expertise in pain
- Difficulty finding practitioners to prescribe medications that may be specific to the needs of the patient
- Assisting patients and families who are unlikely to be aware of the range of resources that are available to them

During the pain initiative site visits, the consultants guided each site's pain improvement team to complete a systems tracer and then participated in a high-level map creation session. During that time, each site's team realized what worked well for pain management in their organization and what did not.

Gap Analysis Using a Cause-and-Effect Diagram

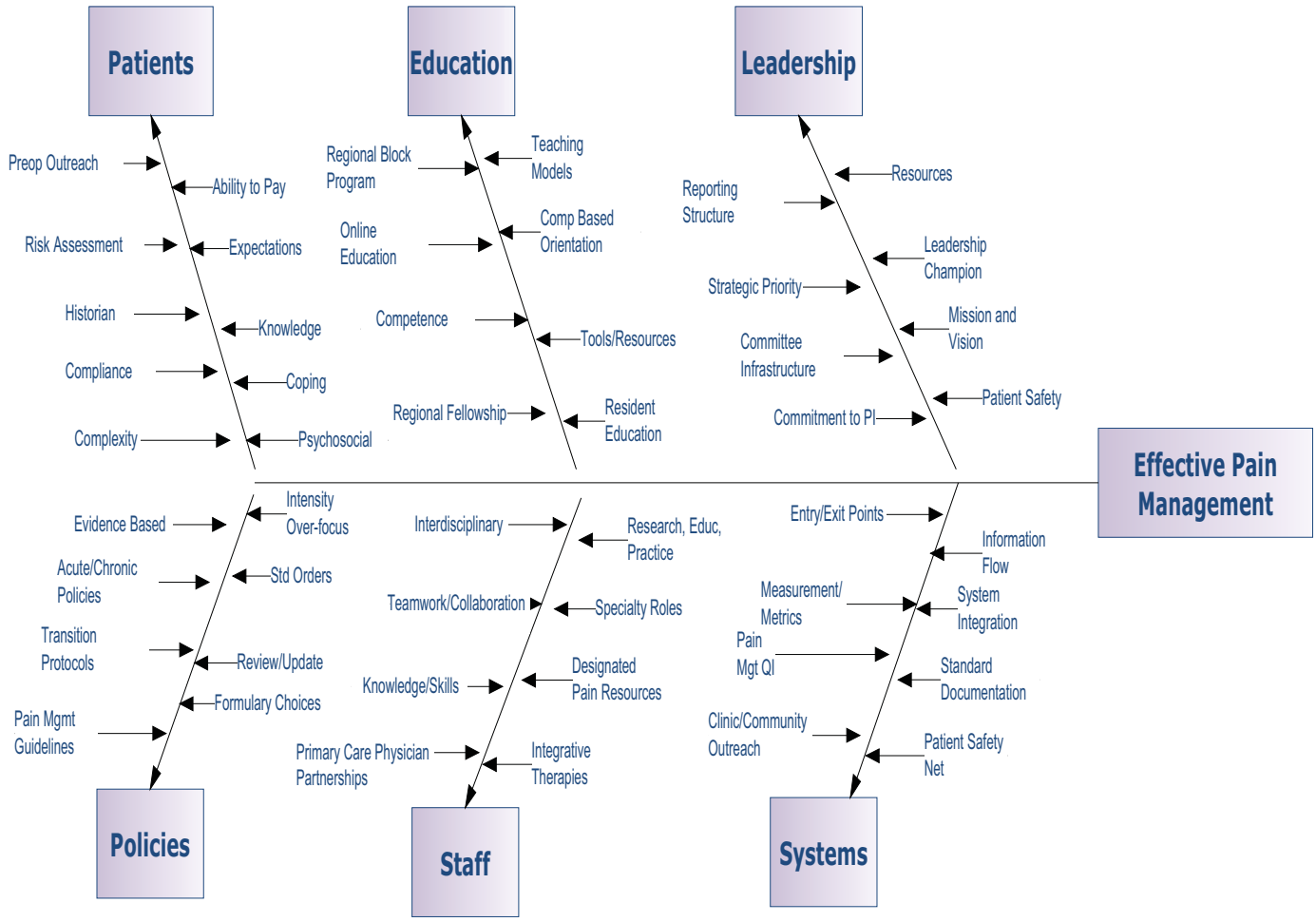
After a high-level process has been mapped, the PI team will scrutinize each process step to identify and discuss potential defects. A process tool that has traditionally been used to highlight potential causes is known as the cause-and-effect diagram. The cause-and-effect diagram is also known as the fishbone diagram because it is drawn to resemble the skeleton of a fish, with the main causal categories drawn as "bones" attached to the spine of the fish (*see* Figure 3.1).

Each PI team involved in the five site visits determined that the causative factors fell into six categories, represented as the main bones on a fishbone diagram:

1. Patients
2. Education
3. Leadership
4. Policies
5. Staff/faculty
6. Systems

During the cause-and-effect session at each site, team members were taught to think about the causative variables *(x)* that have an impact on or affect an outcome *(y)*. Each

Figure 3-1. Cause-and-Effect Diagram: Effective Pain Management

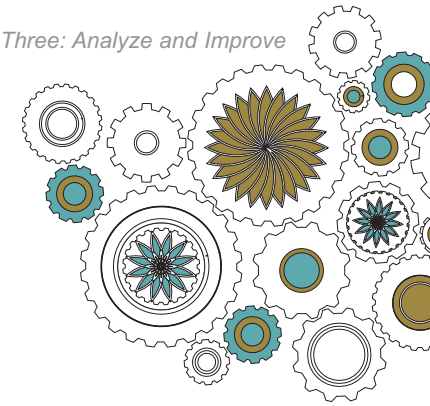


team generated a list of variables *(x's)* within each of these categories that they believed have an impact on effective pain management *(y)*.

To further describe this, information displayed in a fishbone diagram can be developed into a mathematical formula that expresses the outcome as a function of a group of variables. The outcome *Y* is equal to the *function (f)* of many *x* variables:

$Y = f(x^1, x^1, x^3...)$

Some *x* variables include education, leadership support, and resources; the outcome *Y* variable is the team's ability to establish an effective pain management system. In the system tracer in Module 2 and in the discussion specific to interdisciplinary collaboration and handoff failures, the *(x)* variables in the Staff bone of the cause-and-



effect diagram (interdisciplinary teamwork and collaboration) were highlighted as potential targets for the team's attention. While the $Y = f(x)$ formula may at first appear confusing, it was very helpful for each site visit team to understand and clearly differentiate those variables that not only *did* impact effective and efficient pain management, but it also gave them a framework to identify *ALL potential* variables without getting defensive with one another.

The cause-and-effect diagram is an excellent PI tool that enables teams to anticipate as many potential failures as possible, so that when they begin to generate solutions and redesign their current state process, they can be assured that the highlighted prioritized variables can be addressed and potential failures can be eliminated. Bear in mind that a number of potential projects may be uncovered during the creation of a cause-and-effect diagram. Before jumping to solutions, a team needs to prioritize the "critical few" variables to work on first.

To successfully build a cause-and-effect diagram, a PI team should do the following:

- Be sure everyone agrees before beginning that safe and effective pain management is the desired effect.
- Consider possible causes within each bone in the fishbone diagram.
- Use sticky notes and individual documentation of *x* variables to enable 100% participation and a quick and easy way to display the variables on a flip chart.
- Pursue each line of causality back to its root cause.
- Consider which root causes are most likely to merit further investigation.
- Discuss each variable on each bone that may positively or negatively affect safe and effective pain management.

Project Scoping

After the primary focus area of a project has been identified, the team performs scoping—breaking down the focus area into the many specific processes, subdivisions of the process, and/or segments that drive the performance of the focus area. Scoping can uncover multiple potential processes requiring improvement.

Scoping ensures that the team is concentrating on the best opportunity for improvement. A project has a greater possibility of success if the scoping session includes understanding where the critical benefits may be found. Scoping also helps to set clear parameters and determine what is in scope and out of scope for a particular project, what resources and skills will be required, and a time frame for completion.

A team can scope a project to define the boundaries of each single project instead of trying to solve the world's problems in one step. For example, a team may decide that three critical gaps exist:

1. Lack of an interdisciplinary collaborative pain team
2. Lack of an executive pain champion in the health care organization
3. Transition handoff failures between medicine, surgery, acute pain service, and nursing staff

In this example, variables 1 and 2 may be projects that are scoped specifically for the health care organization and medical executive leadership of the organization. Variable 3 might be a project to be scoped around all levels of staff, from patient admission through handoff to the community PCP within a designated patient population. A team can use the 5 Whys tool to ensure that each variable is specific to the root cause identified (*see* Sidebar 3.2).

Gap Analysis

In addition to examining variables to ascertain root causes, a team can also generate a list of gaps or deficiencies in practices, processes, and outcomes that may need to be addressed and measured prior to designing the ideal state for the new processes and pain system (*see* Table 3.1).

The Measurement System and Potential Metrics

A team needs to think about how to measure the overall impact of a project. Before the process is pilot tested, the team should ensure that baseline and current state data are available for later comparison of the pre- and posttest design of the new pain management system. Recall that in Module 2, we discussed the Donabedian structure, process, and outcome model. Structures influence processes, which influence outcomes. By reviewing this model, a team can begin to think about what data are available and what data now must be acquired.

A pain team certainly does not want to generate more work for the interdisciplinary staff to collect data. A team needs to think creatively and seek resources to capture structure, process, and outcome data from existing processes.

If a team enters a project without fully understanding the data from the current state, there will be no foundation or baseline for assessing the overall improvements. Instead, the team will bring knowledge, skills, and perceptions based on impressions rather than data that define the causative variables in a process. The process and outcome metrics should be collected in a simple and direct fashion at the beginning of the project so that these data can shape the team's framing of reality early on.

Sidebar 3-2. The 5 Whys Tool

A team can use the 5 Whys tool to ensure that each variable is specific to the root cause. It is not always necessary to ask why five times, but in some cases it may be necessary to ask why more than five times. Here's an example of using the 5 Whys tool on the variable "gaps in interdisciplinary":

1. Why does (a lack of) interdisciplinary collaboration have a negative impact on effective pain management in this organization?
   - Because safe and effective pain management requires interdisciplinary care. Pain resource personnel currently operate within their own swim lanes and patient populations, with limited cross-communication or planning.
   - Safe and effective pain management requires interdisciplinary care.
2. Why do staff and faculty managing patients' pain work within their own territories?
   - Because care is organized around tasks or phases of care, such that surgery and medicine have little opportunity or structure to support collaborative planning.
3. Why do physicians have little opportunity or structure to support collaborative planning?
   - Because the organization does not have a physician champion for pain management at this time and has not ever had an interdisciplinary pain orientation education program that standardizes pain care, treatment, resources, and collaborative activities.

This example needed to ask only three why questions to arrive at potential root causes. Asking why up to five times almost always enables the visualization of a root cause. When the root causes are established, the solutions often become evident.

Table 3-1. Sample Gap Analysis

Strategic Variable	Measurement	Current Standing	Deficiency	Action Plan
Interdisciplinary pain team	Present/absent	Does not exist	Lack of collaborative pain management practice	Create an interdisciplinary pain team
Pain assessment and reassessment documentation	% compliance, by unit	80%	20%	Initiate a PI project
Required educational resources	Compliance rates by discipline	MD 20%, Nursing 80%	80%, 20%	Restate requirements to practice and manage accountability
Access to specialty referral	15-minute turnaround time—phone call	Turnaround time averages 1.5 hours	1.25 hours	Initiate a PI project to determine root cause
Individual pain goal	Daily shift assessment present/absent	Noncompliance with individual pain goal policy	50%	Initiate PI project that includes stakeholders, patient, and family

Based on a gap analysis, a team can determine what measurements currently exist and how current and accurate these data are. In health care, retrospective data are often used to monitor performance. For example, if patient satisfaction data are three months old, how might the team decipher and understand what variables caused the negative outcomes? The team should not analyze historical data without concurrently monitoring it. Because of this, the next step for the team will be to create a simple, streamlined data collection plan that will be used to analyze current state performance of the program.

The Data Collection Plan

Gathering informative data as the foundation for measurement and ongoing improvement is a crucial step. A data collection plan does the following:

- Ensures that everyone has a clear understanding and definition of the data to be collected
- Stipulates who will collect which data
- Assigns accountability for how and when the data will be collected

A team may choose to analyze programmatic data for one week in 30 patients who have pain. Because the PI process is not a research study, a team should keep data gathering

simple but robust enough to understand the current state. By using accurate and timely data, a team can prioritize root causes that have been analyzed and generate sustainable solutions.

The Ideal State Process: What Will Your Pain System Look Like?

A pain team needs to develop a future state vision and an ideal state process for safe, effective, and efficient pain management across transitions of care.

By now, the pain team should have a solid appreciation of what works in the current state and what does not. It should have identified cause-and-effect variables, and it should understand potential gaps in the system. Based on the analysis of root cause variables, the team can begin to brainstorm solutions that will allow a smooth transition from the current state to the future state, and it can prepare to pilot test the new process.

A team needs to design a new process map, as discussed in Module 2, to prevent and eliminate as many care gaps and failure modes as possible. Even though the team may believe that all care gaps and potential failures have been eliminated, it is often helpful to simulate the new process to identify failure modes, just in case.

Interdisciplinary team communication and design of the new process are critical for success in pain management strategies and subsequent patient outcomes. It is desirable for communication to occur between the chronic pain service and preoperative testing area to identify patients entering for surgery with a history of ongoing opioid use, in an effort to help adjust opioid doses accordingly. Also, early referral of patients to the chronic pain service is important for patients who appear to have developed persistent pain postoperatively (that is, when pain intensity is not subsiding as it should).

Figure 3.2 shows an example of a team's ideal state diagram, which the team should test for potential failures. An interdisciplinary pain team can start with this sample ideal state diagram and integrate its unique organizational needs in its own version of the diagram.

Each health care organization must align best practice opportunities with its own unique needs. Many aspects of safe and effective pain care can be viewed both as the translation of best practices into daily clinical care and the avoidance of failures such as intervals of preventable severe pain or undesirable side effects. Therefore, a preemptive analysis of possible failure modes complements the construction of an ideal state.

FMEA

A number of general failure modes have been identified in health services research. When designing new processes such as a process to improve pain control, it is important to double-check for potential failures related to the new system.

Figure 3-2. Ideal State Diagram

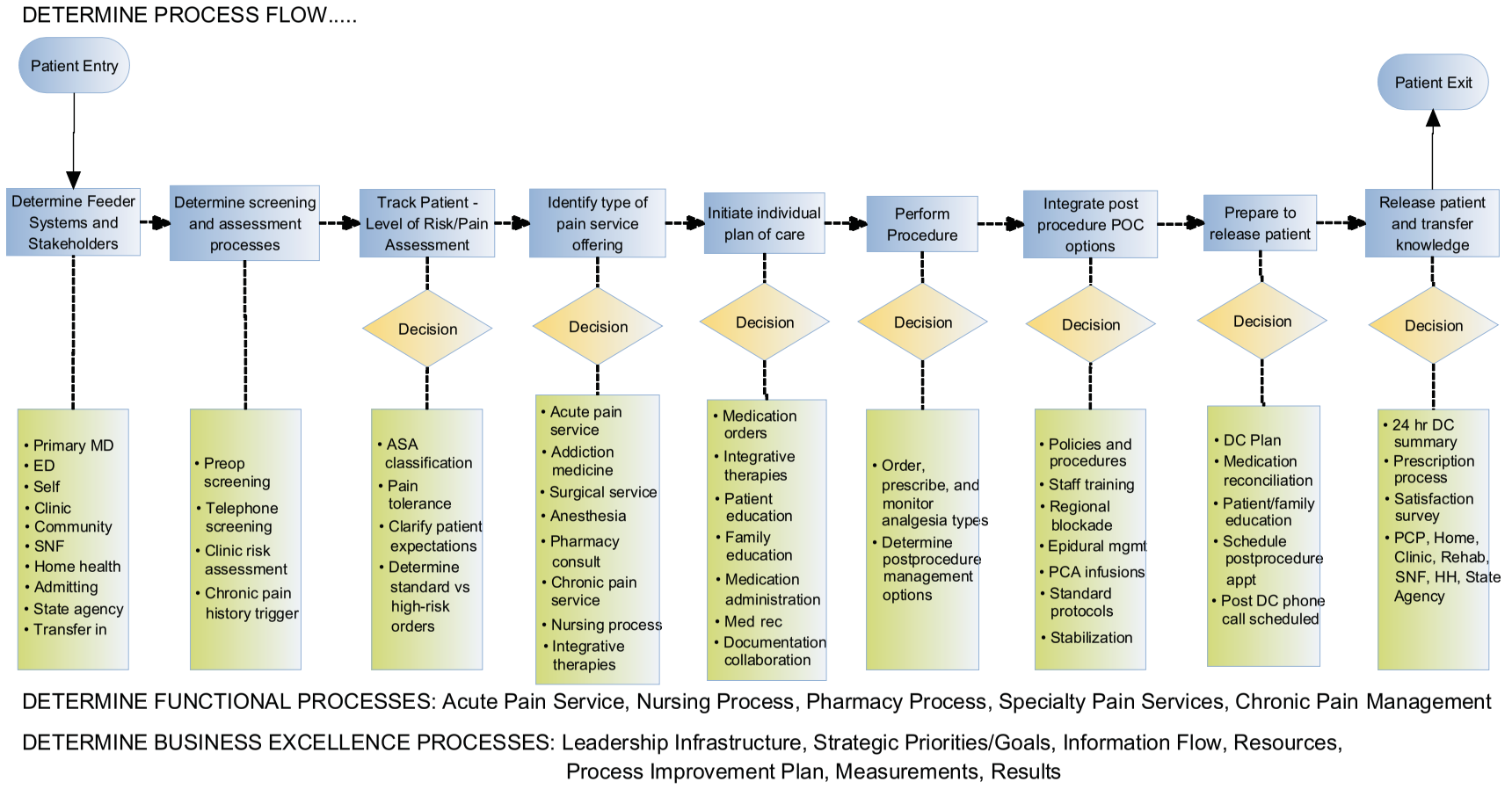


Table 3-2. Health Care Failure Modes[1]

Failure Type	Examples: Pain Management Failures
Omission failures	Not using age or language-specific pain assessment tools Failure to assess response to pain management treatment options
Excessive repetition	Repeating medication doses without using complementary therapy/alternatives
Wrong sequence	Misreading or misunderstanding physician orders
Early or late execution	Failure to manage pain therapies in a timely way
Incorrect identification/selection	Not checking for compatible medications or prescribing opioids, for instance, for a patient with pulmonary disease
Incorrect information	Incorrect route and/or setting for a PCA pump[2]

We will address pilot testing in Module 4, but at this point a team should think about the new pain system design and consider potential problems (*see* Table 3.2).

Based on a team's review of the ideal state model it has created, the team should use FMEA to double-check for failures before pilot testing the new design. The use of HEALTH care FMEA is an easy and efficient way to generate potential failures. A team needs to review each process task or function and ask the following questions:

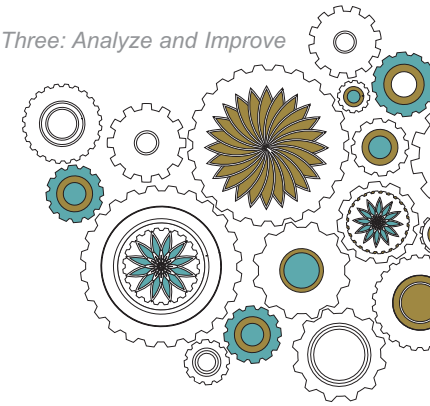
1. What process or subprocess is prone to be excessively repeated?
2. What process or subprocess is prone to occur in the wrong sequence?
3. What process or subprocess is prone to occur either too early or too late?

The team should consider asking and answering these questions for each health care failure mode the team has listed.

Based on the analysis of health care failure modes and the in-depth discussion that occurs throughout that analysis, a team generates a list of potential failures that it needs to prevent prior to pilot testing the new or modified process of pain control.

List of Potential Failure Modes:

1. Omission of physician order for discontinuation of epidural analgesic regimen
2. Excessive repetition of epidural checks that wake the sleeping patient
3. Incorrect transcription of verbal orders, resulting in medication errors
4. Incorrect hookup of tubing, resulting in epidural pain medicine being given by IV or IV medicine being given by epidural

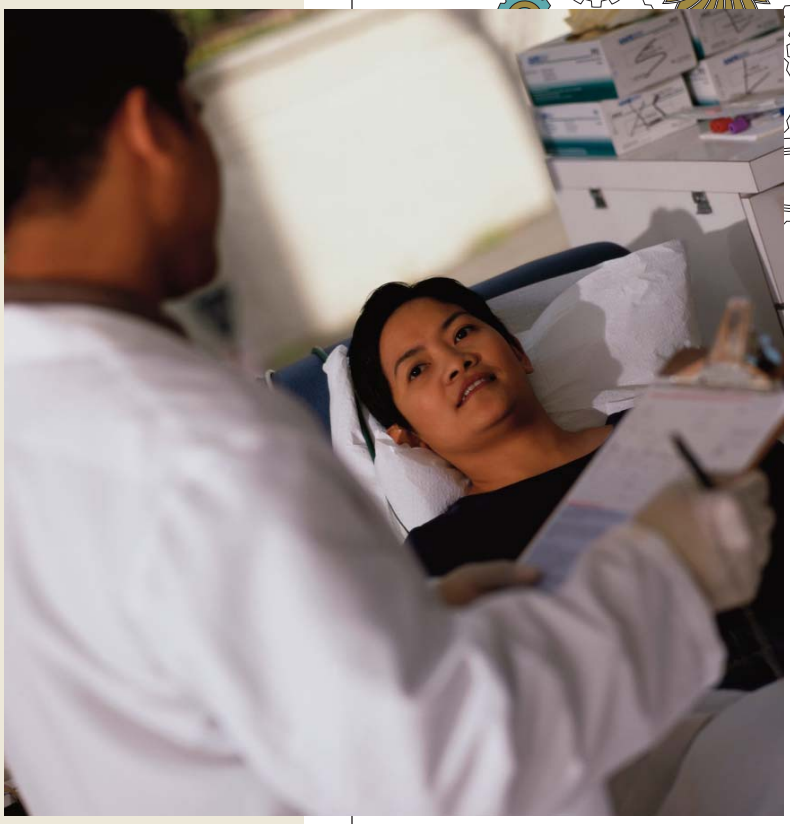


Health care organizations have been taught to perform FMEA after root cause analysis and after sentinel events occur. However, in this module, we focus on using FMEA to do the following:

1. Design a new process
2. Test the new process for potential failures
3. Eliminate potential failures prior to pilot testing the new design, thereby preventing errors

Case Scenario

This case scenario is a continuation of the scenario in Module 2 that illustrates how one organization designed a systematic approach to managing pain.



In Module 2, the team identified key risk points and agreed that the following "critical few" variables warranted further study:

1. Transition failures between IV and oral routes of analgesia
2. Errors in patient-controlled analgesia pump programming
3. High variation in process for analgesic dosing adjustments
4. Staff inability to manage analgesic side effects

The team realizes that while it has a variety of key variables to study, it does not know what the root cause variables are. For example, why do transition failures occur between IV and oral routes of analgesia? And why are clinicians unable to assess, document, and manage pain medications, side effects, and overall functional impact? The team uses the 5 Whys tool to drill down into each key variable and determine its root cause.

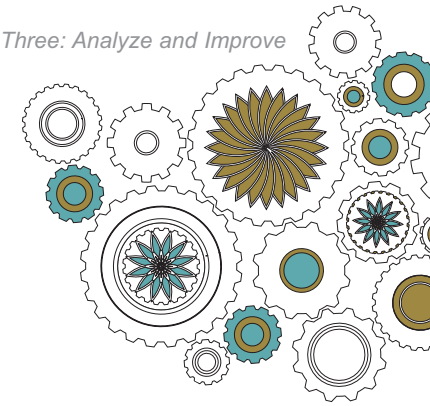
Determining the Root Causes

The team found that its bottom-line root cause is that there is no standardized practical and organizationwide policy for documenting patients' self-assessment of pain ratings, assessment of pain symptoms, and the functional impact of these symptoms.

The team decides to create a standardized clinical practice protocol that aligns with evidence-based best practice and takes into consideration organizational needs and resources.

Using the best available evidence and task force member feedback, the team emphasized the importance of distinguishing between the practice of reassessment and the process of documentation:

- The reassessment of pain is ongoing and not simply a one-time event. Each patient's response to pain interventions is reassessed in a manner appropriate to the route and method of pain control for that individual patient. Depending on the situation, reassessments and their frequency include pain relief, side effects such as sedation, impact on function, and patient satisfaction with treatment.



- Documentation of the ongoing reassessments of each inpatient receiving pain treatment is performed by a registered nurse at least three times within 24 hours, approximately 8 hours apart. Reassessments typically occur more frequently than every 8 hours (e.g., at the time of anticipated peak effect) but the documentation of patient responses can be less frequent. This documentation might occur at times of shift handoff, transfer to another unit, or change in therapy, and should summarize the interim treatments and responses. In other words, any inpatient receiving either nonpharmacologic or pharmacologic treatment, whether a scheduled or an as-needed opioid for either acute or chronic pain, should have a summary reassessment documented at least three times within 24 hours. This definition is based on a policy created by the site visit organization and does not define Joint Commission policy. Other organizations may select alternate language and protocols.

All internal stakeholders reviewed the new policy and incorporated it into administrative policy, with interdisciplinary and senior leadership support and commitment to change. The team then communicated the policy across the continuum of care. The work of this team was critical to enabling a formal infrastructure within the organization in the management of a systematic approach to safe, effective, and efficient pain management.

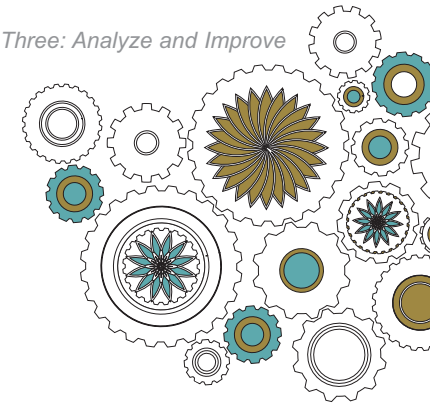
Implementation

Many interdisciplinary staff on all shifts across 23 inpatient units as well as the emergency department were affected by this policy change. The team devised an extensive communication and education plan to inform staff of the final new requirements using e-mail, nursing orientation and continuing education forums, and unit-based peer champions (pain resource nurses).

The implementation plan included nursing grand rounds and clinical rounds by clinical nurse specialists (CNSs) to interact directly with nursing staff about any implementation questions. Nursing shift supervisors, managers, and CNSs used a form of bedside coaching. Distinct from telling or simply directing the new changes, coaching and mentoring is used as a means of interacting with staff in a way that aligns goals and supports their adaptation for a dynamic health care environment.

PI Monitoring

The interdisciplinary team worked with staff from the nursing quality council and information systems departments to develop a more efficient electronic performance measure and reporting strategy. This involved a number of changes to the electronic medical record and the design and construction of an electronic report. The project team focused on the building of structure, process, and outcome metrics. The collection of data moved from being a manual, nursing-intensive process to an automated one that captured critical data.



Next Steps:

1. Complete the checklist for Module 3.
2. Proceed to Module 4.

Checklist

- ❏ Determine infrastructure needs and solutions.
- ❏ Individualize pain management plan of care review.
- ❏ Document all stakeholders, pre-, during, and posthospitalization.
- ❏ Perform gap analysis.
- ❏ Prepare a cause-and-effect diagram.
- ❏ Conduct FMEA to prioritize failure modes.
- ❏ Select potential metrics and incorporate them into the measurement system.
- ❏ Sketch out the ideal state.
- ❏ Review the case scenario.
- ❏ Complete the Module 3 checklist.

References:

1. Joint Commission on Accreditation of Healthcare Organizations: *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction.* Oakbrook Terrace, IL: Joint Commission Resources, 2002.
2. Godfrey A.B., Clapp T.G., Nakajo T., Seastrunk C.S.: Application of Healthcare-Focused Error Proofing: Principles and Solution Directions for Reducing Human Errors. *Proceedings of ASQ World Conference on Quality and Improvement,* Seattle, May 2005.

Module 4

Launch and Control

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Daniel B. Carr, M.D.

How to Use This Module

The performance improvement (PI) processes completed in the previous modules have prepared your organization to focus on its high-priority needs. The use of the process map has illuminated what currently happens to patients in pain, and the swim lanes diagram identifies the roles in the interdisciplinary team. The cause-and-effect diagram assembles key insights based on interdisciplinary team thinking. Your pain team is using three "W" questions: What? Who? and When? Your data and findings are conveyed clearly by the various visual templates. Your team reviewed the data it obtained at your site and crosswalked it against the eight critical components for building a new or expanding an existing pain service:

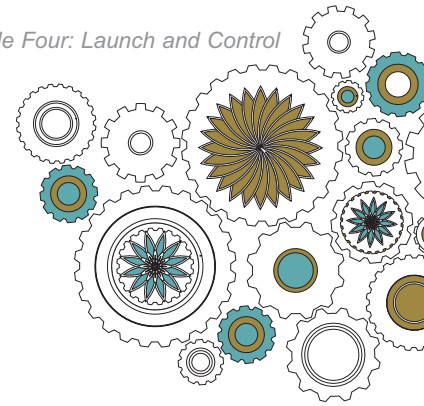
1. Use of national pain standards
2. Commitment of a senior leader champion
3. Consistent oversight by a pain project manager
4. Collaboration of the interdisciplinary team
5. Provision of systematic performance improvement methodology
6. Provision of a pain management infrastructure
7. Promotion of continuous learning for the patient and family
8. Transition of care for all stakeholders

Together, these steps have prepared you to launch and control the new pain management process.

Core Objectives for Module 4

Completion of Module 4 will enable your team to do the following:

- Pilot test its new pain management process.
- Create a deployment plan to set the new process into place smoothly.
- Develop communication strategies that provide information vertically and horizontally to all stakeholders in the health care organization, at ambulatory sites, and with community physicians and other clinicians.
- Plan celebrations to honor and showcase the team and its accomplishments.
- Share lessons learned.
- Reinforce the performance improvement framework to improve and sustain change.



Pilot Testing

Designing or redesigning a pain management program requires a pilot test. The pilot test provides an opportunity to try the new initiatives, identify the effects of any changes, and make necessary adjustments before full implementation.[1] Depending on the magnitude of a change, more than one pilot may be needed.

An interdisciplinary team creates the parameters for a pilot, mindful of the need to test changes in selected areas and situations before implementing change across the entire continuum of care. An initial step is to select the site(s) where the pilot will occur before it is rolled out to the full continuum of care. For example, if a surgical patient is participating in the pilot, the team should consider history and observations specific to preadmission at the time of admission, postoperatively, at discharge, and postdischarge. Keeping narrow the focus of a pilot increases the clarity of its findings.[2] A narrow focus provides those conducting the pilot with better control of variables; fewer variables allow for clearer analysis and understanding. For example, a team might focus on only one surgeon performing the same operative procedure for all pilot patients, and perhaps include only patients who have a primary care physician.

Measurement of baseline data before the pilot is essential for objective documentation and understanding of the change achieved during the pilot. The start and stop dates of the pilot provide additional boundaries for comparing results. Another basis for comparison of the effects of the pilot might be to implement it only for selected procedures.

After the pilot, the team should review the findings and identify conclusions. It should create a list of accomplishments and challenges that highlights what works and what needs to be revised. It is important to report the process and outcome measures when describing the findings from the pilot.[1] A team should revise elements as needed and should determine whether a subsequent pilot is required. If the team decides it does not need another pilot, it can prepare a deployment plan to launch the new or revised process more broadly across the organization and the continuum of care.

The Deployment Plan

A deployment plan is a step-by-step description of how an implementation will occur or a roadmap showing what must happen in the final stage of a project to translate it into practice. It should provide details about what will be done by whom and when.[1,2] A deployment plan clearly identifies the sequence of activities needed to implement and sustain effective change. It also defines the major activities that upper-level management and change agents must ensure take place within the organization.[1,2]

A deployment plan incorporates and aligns the work completed in Modules 2 and 3 in order to achieve the pain management deliverables in the new future state. The plan includes, where relevant, system support information, an issues-tracking process, and

Sidebar 4-1. Sample Framework for a Deployment Plan[5]

What? Changes	How? Actions	Who? People	When? Start	When? Complete	Measure? Results
People (new pain resource nurse)					
Process					
Equipment (new patient-controlled analgesia [PCA] pumps)					
Materials					
Environment/location					
Replicate					

clear roles and responsibilities for all involved before, during, and after implementation. The plan begins in the define phase and continues throughout the project life cycle.

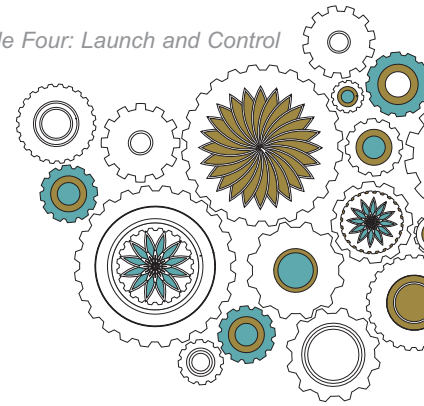
The project manager typically prepares the initial draft of the deployment plan, but its development is a team effort. Process changes are introduced carefully in an organization in order to give employees and physicians time to adapt. The plan describes each action at each location, identifying all work steps and who does each one. This detail is needed to explain the changes to others who are less closely involved in the process. The team should survey and interview patients in order to include the patient voice in the plan.[1,3] The team should also include return on investment (ROI) measures in the plan to provide a roadmap for all stakeholders to understand, support, and sustain the changes.[4] (*See* Sidebar 4.1 for an example of a framework for a deployment plan.)

Once a change is fully integrated into operations, efforts to sustain the change can begin.[6] There are four key requirements for achieving sustainability:

1. The key processes must be described in explicit detail.
2. The process owners must be clearly identified.
3. Sufficient resources, personnel, equipment, and budget must be allocated.
4. Education and communication strategies must be planned.

Monitoring and Sustaining the Gains

A monitoring plan should be a part of a long-range plan to maintain the changes identified in a deployment plan. The purpose of writing a monitoring plan is to prevent slipping back into the old familiar patterns of managing pain. Once aspects of the



process have been defined in detail, the options to sustain the plan must be discussed. Typical sustainability options include the following.

- The process owner assumes responsibility for continuous monitoring. The process owner is the individual who will logically take the handoff from the project manager, and this person's daily work involves responsibility for maintaining the new process.
- The team establishes a consistent monitoring technique such as a dashboard for pain metrics and then carries out the following steps to roll up those data to the organization's balanced scorecard (via HCAHPS metric scores):
  - Include pain competency behaviors in employee performance reviews
  - Consider whether compensation of a broad group of those involved should align with the changes
  - Incentivize people responsible for leading the change
  - Regularly convene senior leaders to review pain outcomes data
  - Schedule walking rounds by senior leaders to implement and support the pain initiatives
  - Celebrate milestones and achievements (as described later in this module)

The sustainability phase lasts until the goals are met, including the financial goals and ROI measures. Sustaining the results often requires a change in institutional culture to develop self-disciplined people who take purposeful action with consistency of purpose.[7] Successfully elevating expectations for self-discipline and consistency of action require that employees, including clinicians, be knowledgeable about the change and the reasons for the change.

There are many options for keeping clinicians and employees informed about changes in the institutional pain management process. A communication plan can ensure that needed information is delivered in a timely and creative manner to achieve understanding and support for changes. Drawing the most benefit from teaching moments that arise requires a preplanned approach involving clear messages for all.

Communicating the performance improvement findings and the progression toward an ideal state to all involved in pain management must occur throughout all phases of this project. Sidebar 4.2 provides a guide for communicating pain management process changes.

A team can work with public relations staff to tap into their skills and experience in knowing how to effectively communicate specific messages to targeted audiences. Their skills can be extremely valuable in developing key themes related to pain management and reinforcing them over time.

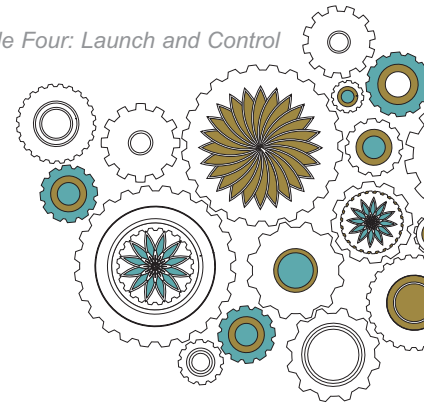
While developing a communication plan, a team should be aware of techniques that help learners embrace new information and change. Consider the following ideas when

Sidebar 4-2. Communicating Pain Management Process Changes

What	When	Content
Module 1: Make the Case	At the beginning	Describe the patient, clinical, and business benefits of a pain management program/approach. Provide an overview of the quality improvement approach and the challenges it must face in the context of pain control.
Module 2: Define and Measure	At conclusion of Module 2	Use a project charter, a process map, and SWOT analysis.
Module 3: Analyze and Improve	At conclusion of Module 3	Use a cause-and-effect diagram to illustrate the gaps; describe the new process.
Module 4: Launch and Control	At conclusion of Module 4	Describe the pilot test; discuss the deployment plan highlights. Determine the monitoring plan.
Results: Use the updated project charter and add pre and post data with target completion dates	A particular number of days after implementation	Report the process measures and outcome measures.
Share articles/references	Ongoing	Pain management interest stories
Share plans to monitor/sustain changes	Ongoing	

planning your communication strategies, and keep in mind that using multiple approaches is best for reinforcing the messages:

- Use narrative based on the patient experience to bring patients' pain needs to life. Pain management scenarios with clinical details resonate with clinical learners. This approach draws on the human instinct to relieve suffering. Such presentations may be used as a vehicle to describe current and future states to convey how and why the events portrayed will be different. Grand rounds may be one venue for these presentations.
- Grab the attention of the organization. Consider using content from Module 1 to help the organization understand the pain relief imperative. Appeal to the clinical and management leaders in the organization as well as to care providers. Use formal committee structures, such as medical executive committees and quality improvement committees, to report progress on the pain management program.
- Don Wetmore, a motivational speaker, suggests the following retention numbers[1]:
  - People remember 10% of what they read
  - People remember 20% of what they hear
  - People remember 35% of what they see
  - People remember 50% of what they read, hear, and see
  - People remember 70% of what they say
  - People remember 90% of what they do



In other words, multiple messaging modalities that recruit behavioral and psychomotor learning activities enhance adoption and retention of new skills. When available, a learning lab environment for pain management training may be effective.[1]

- Messages need to be clear and goals achievable. Moving from simple to complex will allow learning to progress in a stepwise manner.
- Facts and honesty support the transparency that organizations strive to model. Pain data (including patient satisfaction) and honest summaries are compelling and will get attention and promote the desired results.
- The promotion of a change can best be communicated if the change is acted through. The practical need to experience a change before implementing it directly promotes the change.

Regardless of the specific choices for initial communication of change related to pain, it is important to refresh the communication periodically. The continuous improvement philosophy helps avoid complacency. Updating the interim results and outcomes of a new pain process provides a model of the continuous improvement process for everyone in the organization. An organization should encourage comments and invite suggestions.[8] A pain team should stretch its communication strategies and share relevant data transparently across the continuum of care, including providers caring for patients in the community. Advocating for the pain needs of patients systematically conveys thoroughness and effectiveness of care. Communication between providers across settings aligns with continuity of care needs and patient satisfaction, both of which have the potential to affect the market share of organizations.

Celebrating Successes

Communicating and sustaining change can be reinforced by celebrating the results.[9] Celebrations build confidence and pride in individuals, teams, and entire organizations.[1] Health care is a very serious business and profession. Celebrations are energizing and invigorating. Recognition of accomplishments and progress within the health care delivery system supports continuous improvement and ongoing growth. Consider the following suggestions for celebrations[1]:

- Because people are the most important resource in health care, celebrations should honor specific people as well as the teams of which they are part.
- Celebrating milestones is important. Doing so reinforces the steady advance of quality.
- It is important to be specific in providing the reason(s) that recognition was earned; doing so will have a great impact on the community as well as those being recognized.
- The amount and type of recognition should be appropriate for the behavior and outcomes being celebrated.
- Senior leadership and medical staff, like other employees, need positive reinforcement for their support and contributions.
- Various means can be used for recognition: awards, project story boards, written commendations, certificates, perks, formal and informal efforts, newsletter articles, emails, acknowledgement in meetings, and so on.

- Recording a celebration with video or audio commemorates the milestone achieved and the clinicians/employees involved.
- Using a journal or blog enables an organization to record creative progress details.
- Screen savers with images of special performers can be used to recognize and honor them.
- Asking people what is important to them evokes many suggestions about how and what to celebrate.

Working through all these modules and documenting the findings at each stage will naturally generate a list of lessons learned. It is important to compile a list of lessons learned about what has been effective and what has not.[1] This list can serve as the basis for reflection on the lessons and sharing their content insofar as it is relevant to the deployment and communication needs of the change (*see* Table 4.1).

Such documentation allows chronological tracking of important lessons that add value to the understanding of the continuous improvement work on pain. The identification of interim lessons learned can serve as a standing agenda item for pain team meetings to which all team members can contribute.

Regarding the capture of lessons learned in the redesign process, one author has proposed five factors that affect the speed and success of adoption of a quality improvement framework (*see* Sidebar 4.3).[2]

Sidebar 4-3.
Five Factors Affecting the Speed and Success of a Quality Improvement

- Can a trial test (pilot) be easily conducted?
- Is the change difficult to understand?
- Compared to current practice, what value-added change does the change offer?
- Is the change compatible with the organization's environment and culture?
- How easy is it for leaders and opinion makers to view the benefits of the change?

A review of these questions can provide insights into an organization's capacity to launch and control.

Site Visit Feedback

The five health care organizations in the national pain initiative reported on their progress, post-visit, no longer than four months following the initial consultant site visit. The post-visit questions, along with highlights of the sites' responses, are as follows:

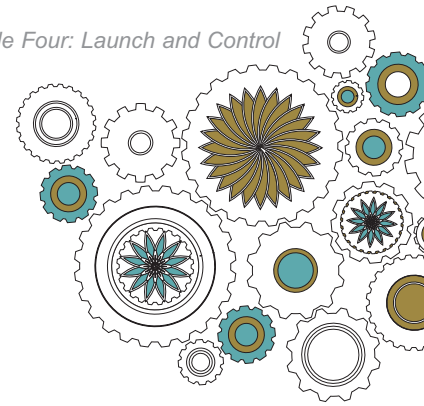
1. **What priorities or system opportunities did the pain team identify in the gap analysis? Explain how your organization addressed them. (For example, if lack of education was perceived as a priority, you may have developed an orientation program.)**
   - One site identified five priorities for improvement:
     - To ensure appropriate, safe, and timely pain management, the inventories and functioning of PCA devices, epidural infusion pumps, and oximeters were reviewed. Required equipment is now available and functional.
     - Processes were established to improve patient safety. For example, order forms now use standardized drug concentrations; hard limits on highest and lowest infusion rates are programmed on all pumps used for pain control; the pharmacy does not process orders provided in any format other than on the

Table 4-1. Reflecting On and Sharing Lessons

Date	Module Topic	Effective Action/Steps	Ineffective Action/Steps

standard pain relief order forms; and policies for pain are now cross-referenced across departments for consistency.

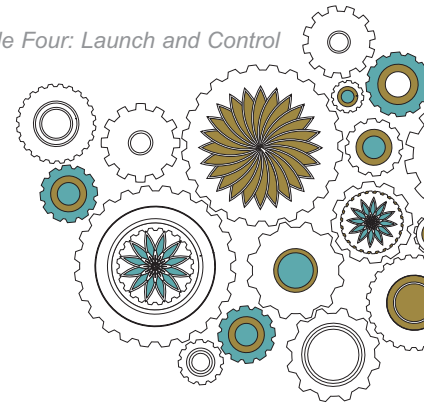
- Education programs are provided for orientation, nurse residency programs, the pain resource nurse program, and both physician and pharmacist education are regularly reviewed and revised, as needed.
- Evidence-based tools are used. For example, the organization is now using literature, surveys of community hospitals, standards of practice for PCA and epidurals, and the Critical Care Pain Observation Tool (CCPOT).
- Documentation opportunities have arisen with new flow sheets and policies.



- Another site identified four opportunities:
  - Providers at multiple pain management sites need to collaborate.
  - Standards regarding handoffs and transitions of care are lacking and must be strengthened or developed and then implemented.
  - Efforts must be made to address the wide variety of information technology systems that do not speak to each other.
  - The process map needs to be finalized to convey the total system view.
- Collectively, the sites indicated the following priorities:
  - Developing a process for clinicians to ask questions and/or relay concerns
  - Competency-based pain education is needed for all clinicians
- Sites also identified other needs as they redesigned their pain programs:
  - Identifying an executive sponsor
  - Restructuring reporting relationships for pain personnel
  - Realigning the pain program with the strategic goals and performance improvement framework for the entire system
  - Enhancing the electronic medical record
  - Reviewing chronic pain services available in the continuum of care
- A community hospital reported the following:
  - The need for education, toolkits, and resources for pain management
  - Unit-based/service-line pain resource nurses
  - Pain management orders for new admissions from the emergency department
  - Sanctioning of a pain management task force

2. **What have been the most significant challenges to implementing the improvements?**
   - Lack of structure for discussion and resource sharing across services
   - Struggle to define a metric for ROI and identify appropriate resources for the business model
   - Competition with other organizational priorities
   - Difficult procurement process for purchasing and problematic budget and capital planning cycle
   - Scheduling training so that it does not compete with clinical care needs of patients
   - Lack of time
   - Selection of an interdisciplinary pain team
   - Finding a dedicated interdisciplinary pain consulting service
3. **What were the strengths you identified in your organization's pain management system, and how have you expanded them or used them as a basis for moving forward?**

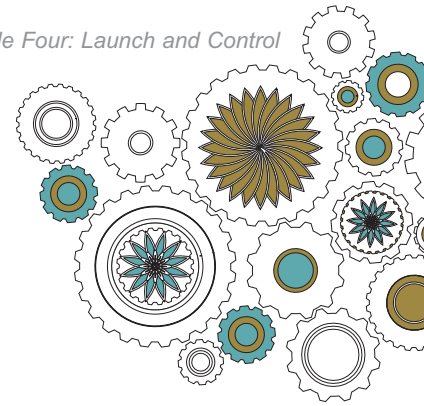
   Some of the following existed already, and others were in the new design plan:
   - Unit-based pain champions, including pharmacists
   - Physician champion volunteering during the redesign process
   - Healing touch program
   - Steady increase in referrals to the pain service
   - Support for outpatient clinic pain interventions
   - Financial support



- Full compliance with Joint Commission pain standards
- A learning center
- An interdisciplinary approach
- Patient identification of their own pain goals
- Integrated therapies such as TV, music, Wii, and massage
- Resources available to clinicians 24/7
- Evidenced-based practices and clinical guidelines
- Order sets and assessment flow sheets
- Six Sigma classes at one organization

4. **What additional needs does your organization have in order to continue its commitment to improving pain management?**
   - An advisory panel of high-level leaders
   - Filling of clinical vacancies
   - A physician champion
   - A model for the transition of care across the continuum
   - Various methods of pain relief measures
   - Ongoing education
   - Identification of performance measures
   - Continued leadership support
   - Continued collaboration and motivation with national pain practices
   - Creation of an annual plan
   - Sanctioning of a pain management resource service
   - Engagement of the community
5. **What three activities of the Joint Commission Resources consultant site visit were most helpful?**
   - The presence of outside consultants quickly organizing, collating, analyzing, and presenting concrete, specific site data; participation of high-level leaders; and new insights gained
   - The use of the pain tracer survey method, which has improved communication between disciplines
   - PowerPoint tools using specific site data in a process map, SWOT analysis, and a cause-and-effect diagram, which provided greater understanding of current state; sharing feedback on leading practices; appreciation for the business opportunities
6. **What could be different, in terms of support from Joint Commission Resources?**
   - A more specific site visit agenda and schedule
   - A full narrative summary in addition to the PowerPoint presentation
   - Identification of data elements for measurement
   - Periodic webinars and networking opportunities for pain clinicians
   - Earlier contract review
   - More time with the final presentation and recommendations
   - A broadened tracer that includes medical patients

The sites' feedback after the consultant visits reveals both similarities and differences between organizations. Each organization was unique in its capabilities, yet all are



committed to the need for improvement in their pain management services. The consultants learned from each site visit. The goal of this project is to share these findings and needs with other health care organizations.

Summary

When launching a new process, it is important to keep startup simple and flexible, using performance improvement tools to aid in the analysis and design of pain management services. The eight critical components identified from the site visits serve as the foundation for building a safe and efficient pain service:

Component #1	Use of National Pain Standards
Component #2	Commitment of a Senior Leader Champion
Component #3	Consistent Oversight of a Pain Project Manager
Component #4	Collaboration of the Interdisciplinary Team
Component #5	Provision of Systematic Performance Improvement Methodology
Component #6	Provision of a Pain Management Infrastructure
Component #7	Promotion of the Patient's Continuous Learning
Component #8	Transition of Care for All Stakeholders

These eight critical components are essential aspects of every pain service redesign model. Besides these components, additional and valuable lessons will no doubt arise from both internal experiences and external sources during the redesign process. They can help reach beyond familiar boundaries and raise organizations to new heights. Communication needs to be continuous. Messages need to be packaged using various strategies. The entire continuum of care needs to be engaged in a redesign. Measurement and milestones contribute to the communication of messages. A team should focus on results using structure, process, and outcome measures. These measures can be displayed before and after a change. Their completion culminates in celebration of the people and their accomplishments.

Case Scenario

This case scenario is a continuation of the scenario in Module 3 that illustrates how one organization designed a systematic approach to managing pain.

Modules 1 through 3 describe an organization's PI approach to pain management that resulted in improved patient satisfaction ratings and compliance with assessment/reassessment documentation. This project demonstrated that the use of systematic and analytic PI tools can yield improvements that go beyond their well-known fiscal and operational applications.

The team was able to start small and pilot test the new policy design on one unit to assess the operational feasibility of the policy, determine patient- and staff-related impact, and quantify the success of the policy through monitoring.

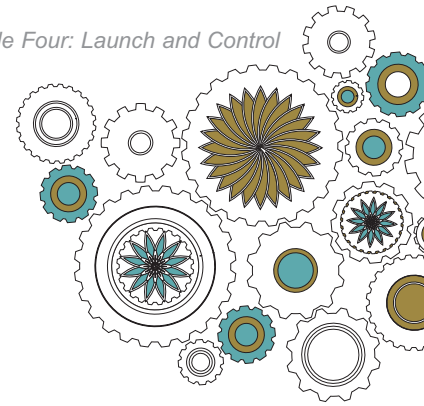
The deployment plan was successful. The organization held a celebration to honor the pain team. The team's data were displayed on a storyboard and presented at both physician grand rounds and the directors' meeting. The team created a sustainability plan describing what would be done, who would do what, and when the target action steps would be completed. Clear roles and responsibilities were apparent.

The patient referred to in Module 1 has now experienced a safe, effective, and efficient pain management process. Thanks to interdisciplinary teamwork, patient safety has been enhanced, clinical and patient satisfaction have both improved, and regulatory requirements have been met.

Lessons Learned

A number of important lessons were learned through this experience.

1. Documentation policies should not be designed at the expense of patient and nursing needs. When articulating policy, a health care organization should be careful to craft language that incorporates clinical practice realities rather than untested requirements that have been extrapolated from textbook ideals (for example, pharmacokinetics).
2. Rushing to solutions when deficits are uncovered often results in ineffective solutions that can have negative unintended consequences. Use of robust improvement processes may initially take more time but in the long term can save time and resources and produce positive results.
3. Caution is warranted when designing compliance measures. During failure



mode and effects analysis (FMEA), the organization determined that setting the bar too high for critical performance measures may itself be a root cause for failure. The constant negative feedback created by the difficulty of maintaining daily performance above an arbitrarily chosen 90% critical threshold can deflate staff morale and may also result in unintended negative consequences (such as avoidance of documentation).

4. Communication and follow-up with all stakeholders, including physicians, pharmacists, social workers, pastoral care, nursing managers, nursing directors, nursing councils, staff nurses, and other leaders in the organization as well as external stakeholders are essential.
5. Information system support is essential to help quantify and monitor continuous improvement efforts.

This four-module case scenario is a realistic example of how teams can use PI methodology for sustainable and realistic change within a system.
We recognize and appreciate the contributions and actual experience of the University of Wisconsin Hospital, Madison.

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Appendix/Toolkit

About the Tools

The tools and handouts in this appendix should be used in conjunction with the text of the preceding four modules. As you and your team read through each module, you will find links to these tools in discussions and analysis that will guide you to assess and design your organization's pain management strategies.

Appendix/Toolkit Contents

- Pain Expert Biographies
- *Acute Post-Surgical Pain Management: A Critical Appraisal of Current Practice*, Rathmell et al.
- The Pain Summit Survey
- Form for Assigning Key Roles
- Key Roles for Pain Management
- Sample Pain Team Agenda
- Defining Lean Waste and Potential Failure Modes
- Practical Tracer Example: The Laboratory Tracer
- Instructions for Developing a High Level Process Map and Swim Lane Diagram
- Project Charter: Pain Management
- University of Wisconsin Health Center Core Competency Worksheet
- University of Wisconsin Health Center Health Facts: What You Should Know About Pain Management (a tool for patients, their families and caretakers)

Daniel B. Carr, M.D.

Daniel B. Carr, M.D., is the Saltonstall Professor of Pain Research in the departments of anesthesia and medicine at Tufts-New England Medical Center. He also serves as vice chairman for research of Tufts-New England Medical Center's department of anesthesia, and medical director of its pain management program.

A graduate of Columbia College and Columbia University, Carr trained in internal medicine at Columbia-Presbyterian Medical Center and later at the Massachusetts General Hospital, where he continued his training in internal medicine, endocrinology and anesthesiology. He is a diplomat of the American Boards of Internal Medicine and Anesthesiology and the American Board of Pain Medicine, and holds the Certificate of Added Qualification in Pain Management from the American Board of Anesthesiology.

Carr is known internationally for his contributions to pain research, including:

• Co-chairinganddraftingmajorportionsof theAgencyforHealthCarePolicyand Research *Clinical Practice Guidelines on Acute and Cancer Pain Management*;

• Preparing related scholarly publications, such as meta-analyses of pain therapies;

• Serving as principal technical consultant for the Agency for Healthcare Research and Quality's evidence reports on cancer pain; and

•Serving in leadership roles in developing comprehensive multidisciplinary pain treatment centers (and their accredited fellowship programs) at the Massachusetts General Hospital and Tufts-New England Medical Center.

Carr is the editor-in-chief of the International Association for the Study of Pain's didactic publication for front-line clinicians, *Pain: Clinical Updates;* lead editor for pain trials in the Cochrane collaborative review group on Pain, Palliative and Supportive Care; and an editorial board member of several pain-related journals.

J. Robert Clapp, Jr., F.A.C.H.E.

Senior Vice President for Hospital Affairs, Rush University Medical Center and Executive Director, Rush University Hospitals

As Senior Vice President for Hospital Affairs at Rush University Medical Center and Executive Director of Rush University Hospitals, Mr. Clapp has responsibility for the institution's hospitals division, joint ventures and clinical business subsidiaries. In addition to Rush University Hospital, his scope includes the campus based Rush Children's Hospital and Johnston R Bowman Health Center for inpatient geriatric and rehabilitative medicine. System facilities Rush Oak Park Hospital, Health Delivery Management Home Infusion, Circle Imaging and the Rush Surgery Center are also within his portfolio. Mr. Clapp is an Assistant Professor in the Rush University Health Systems Management graduate program. He has lectured and published extensively on health care topics both domestic and international.

Prior to his position with Rush, Mr. Clapp served ten years as a senior executive with Duke University Health System and Medical Center in Durham, NC. During his tenure at Duke, Mr. Clapp held positions as Associate Vice Chancellor in the Medical Center & School, and as Chief Operating Officer of Duke University Hospital.

The initial phase of Mr. Clapp's career was in the for-profit setting, including hospital Chief Operating Officer and Chief Executive Officer positions with Tenet Healthcare Corporation. As part of his tenure with Tenet he was based in Singapore, providing executive management of Tenet's operations and business development for all of Asia as Vice President, Asia region. This included hospitals in Singapore, Malaysia, and others under development in Thailand, Indonesia and India, as well as related regional healthcare businesses. In 1994, Singapore operations received *International Organization for Standardization (ISO) Certification*, the first healthcare system in Asia to receive this internationally recognized process improvement and quality accreditation. Mount Elizabeth Health System, a Tenet subsidiary in Asia was also selected by *Far Eastern Economic Review* as one of Asia's top 5 companies in Singapore in 1994.

Mr. Clapp earned a Graduate Fellowship in Health Administration from Duke University; a Master of Health Services Administration from George Washington University; and a Bachelor of Science in Business and Economics from the University of North Carolina, Greensboro. At Rush, he received the 2010 Rush University Health Systems Management Program *Distinguished Faculty Award*, and the 2009 Rush *Medical Staff Ambassador Award*.

Due to his extensive work in institutional diversity and inclusion, The Chicago Chapter of the National Association of Health Services Executives (NAHSE) recognized Mr. Clapp with its 2010 President's Award, and The Ohio State University Health Systems Management Program recognized him with its 2010 *Champion of Diversity Award.* At Rush, in 2009 the institution named (in perpetuity) its annual award for institutional leadership in the advancement of diversity, the *J. Robert Clapp Jr. Diversity Award.* He is also the recipient of the 2004 Duke University Hospital *Cornerstone Award* for work in diversity.

Debra B. Gordon R.N.-B.C., D.N.P., AC.N.S.-B.C., F.A.A.N.

Debra Gordon is a Senior Clinical Nurse Specialist at the University of Wisconsin Hospital and Clinics (UWHC) in Madison, and a Faculty Associate at the University of Wisconsin School of Nursing. She chairs the hospital's interdisciplinary pain management improvement group with responsibilities for program and policy development, education, and quality monitoring. Ms Gordon also directs and staffs the UWHC Inpatient Pain Management Consultation Service. She has lectured extensively and authored a number of publications on pain management. Deb has also been involved in a number of national and international projects focused on improving pain management including for the American Pain Society's (APS) Quality Improvement Guidelines, the Robert Wood Johnson (RWJ) funded Postoperative Pain Management Quality Improvement Project (POP), the Australian National Institute of Clinical Studies (NICS) evidence-practice gap project on managing acute and cancer pain in hospitalized patients, and the International "Pain-Out" Registry. She has served as a member of the American Nurses Credentialing Center's (ANCC) content expert panel on pain management and the American Medical Association's (AMA) Episodes and Costs of Care Low Back Pain Workgroup. Ms Gordon is active in a number of professional pain management societies, and has served as a Board member for both the Alliance of State Pain Initiatives (ASPI formerly AACPI), and the American Pain Society (APS). She is on the Board of Directors for the American Pain Foundation (APF) and is a Fellow in the American Academy of Nursing.

Judith A. Paice, Ph.D., R.N., F.A.A.N.

Judith Paice, PhD, RN is the Director of the Cancer Pain Program in the Division of Hematology-Oncology and a Research Professor of Medicine, Northwestern University; Feinberg School of Medicine. She is also a full member of the Robert H. Lurie Comprehensive Cancer Center. Dr. Paice served as President of the American Pain Society from 2006-2008 and is currently Secretary of the International Association for the Study of Pain. Much of Dr Paice's clinical work has been in the relief of pain associated with cancer and HIV disease. She has traveled within the People's Republic of China, Indonesia, Japan, Kenya, Korea, Taiwan, Tanzania, and Tajikistan to educate health care professionals regarding cancer pain relief and palliative care. Dr. Paice serves as Associate Editor of the *Journal of Pain*, and serves on the editorial board of the *Clinical Journal of Pain* and the *Journal of Pain and Symptom Management* and is the author of more than 150 scientific manuscripts. She was one of the original consultants in the End of Life Nursing Education Consortium (ELNEC) and has continued serving as a faculty member in this program.

Acute Post-Surgical Pain Management: A Critical Appraisal of Current Practice

James P. Rathmell, M.D., Christopher L. Wu, M.D.,
Raymond S. Sinatra, M.D., Ph.D., Jane C. Ballantyne, M.D., F.R.C.P.,
Brian Ginsberg, M.D., Debra B. Gordon, R.N., Spencer S. Liu, M.D.,
Frederick M. Perkins, M.D., Scott S. Reuben, M.D., Richard W. Rosenquist, M.D.,
and Eugene R. Viscusi, M.D.

The Acute Pain Summit 2005 was convened to critically examine the perceptions of physicians about current methods used to control postoperative pain and to compare those perceptions with the available scientific evidence. Clinicians with expertise in treatment of postsurgical pain were asked to evaluate 10 practice-based statements. The statements were written to reflect areas within the field of acute-pain management, where significant questions remain regarding everyday practice. Each statement made a specific claim about the usefulness of a specific therapy (eg, PCA or epidural analgesia) or the use of pain-control modalities in specific patient populations (eg, epidural analgesia after colon resection). Members of the American Society of Regional Anesthesia and Pain Medicine (ASRA) were asked, via a Web-based survey, to rate their degree of agreement with each of the 10 statements; 22.8% (n = 632) of members responded. In preparation for the pain summit, a panel member independently conducted a literature search and summarized the available evidence relevant to each statement. Summit participants convened in December 2005. The assigned panel member presented the available evidence, and workshop participants then assigned a category for the level of evidence and recommendation for each statement. All participants then voted about each statement by use of the same accept/reject scale used earlier by ASRA members. This manuscript details those opinions and presents a critical analysis of the existing evidence supporting new and emerging techniques used to control postsurgical pain. *Reg Anesth Pain Med 2006;31:1-42.*

Key Words: Acute postoperative pain, Patient-controlled analgesia, Regional analgesia, Epidural analgesia.

Fear of uncontrolled postsurgical pain is among the primary concerns of many patients about to undergo surgery. During the past 2 decades, new technologies to aid postoperative-pain control have gained widespread use, and formal acute-pain services have evolved in many institutions.[1] The use of microprocessor-driven, patient-controlled analgesia (PCA) devices has become routine, and the extension of epidural analgesia beyond the operating room to control pain in the postoperative period is now common. At the same time, our understanding of the pharmacology and clinical usefulness of spinal opioids has rapidly improved.[2] In more recent years, we have seen the emergence of continuous peripheral-nerve blocks as a promising new approach for improving pain control after a number of specific surgical procedures.[3] As these new technologies have achieved more common use, public awareness of pain management and expectations about pain treatment have risen. The medical community has worked toward a more uniform approach to assessment and treatment of pain through the preparation and dissemination of practice guidelines.[4]

As experts in perioperative medicine, we are called upon to make sense of these new technologies and guide the implementation of safe and effective practices in our own institutions for control of postsurgical pain. The Acute Pain Summit 2005 was convened to critically examine the perceptions

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of physicians in our field about current methods used to control postoperative pain and to compare those perceptions with the available scientific evidence. This manuscript details those opinions and presents a critical analysis of the existing evidence that supports new and emerging techniques used to control postsurgical pain.

Methods

A group of clinicians, chosen for their knowledge, expertise, and track records for meaningful research and publication in the field of perioperative pain control, was assembled via the Acute Pain Summit 2005 to evaluate 10 practice-based statements. This summit was supported by an unrestricted educational grant from the PriCara division of Ortho-McNeil, Inc. and executed by Consensus Medical Communications in collaboration with the American Society of Regional Anesthesia and Pain Medicine (ASRA). The statements were written by the leaders of the summit (Drs. Rathmell, Sinatra, and Wu) to reflect areas within the field of acute-pain management where significant questions remain regarding everyday practice when choices were made among various pain-control techniques. The statements are admittedly arbitrary and were chosen with the guidance of summit participants, but each statement makes a specific claim about the usefulness of various delivery methods (eg, PCA or epidural analgesia) or the use of pain-control modalities in specific patient populations (eg, epidural analgesia and return of bowel function after colon resection).

Members of ASRA, the majority of whom are closely involved with treating perioperative pain in their regular clinical practices, were then polled by use of the same 10 practice statements. An electronic survey was circulated to all members with working e-mail addresses. They were then directed to a Web site where they rated their degree of agreement or disagreement with each of the 10 statements (Appendix A). Overall, the response rate to the survey was 22.8%, with a total of 632 respondents.

Each of the 10 statements was assigned by the summit leaders (Drs. Rathmell, Sinatra, and Wu) to a specific participant, who independently carried out a detailed literature search and summarized the available evidence relevant to the statement. Each participant was responsible for independently conducting a detailed literature search regarding their assigned statement and summarizing the available scientific evidence. All authors queried the National Library of Medicine's MEDLINE database, the American College of Physicians Journal Club, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews in late November 2005. The specific literature search terms each participant used to gather the evidence are described in detail for each statement. All Acute Pain Summit 2005 participants convened December 2-4, 2005 in Fort Lauderdale, Florida and were assigned to 1 of 2 workshops that pertained to delivery methods or patient populations. Each panel member presented the available evidence regarding their statement to the workshop participants, and a detailed discussion of the evidence ensued. After that discussion, workshop participants were asked to assign a category for the level of evidence that supported or refuted the statement and assign a final category to the evidence (Table 1). After hearing a summary of the evidence, all summit participants then voted on their level of acceptance or rejection by use of the same scale employed earlier by ASRA members in the electronic survey (Table 1); the participants' opinions were compared with the ASRA poll for each statement in the sections that follow.

Statement 1

Use of intravenous (IV) PCA leads to improved patient outcomes when compared with nurse-administered parenteral opioids.

Rationale and Definition of Statement

The common perception is that use of IV PCA for the delivery of opioid analgesics produces improved outcomes when compared with nurse-administered parenteral opioids. IV-PCA devices have been in use for more than 25 years and have become widely accepted as the preferred means for delivering opioid analgesics for postoperative analgesia, as well as other acute-pain conditions. These devices allow the patient to self-administer an opioid analgesic on an as-needed basis within the parameters set by the ordering physician. In most settings, the readily available drug afforded by the PCA device has the potential to allow safe individualization of opioid analgesic dosing, improve pain control, and increase patient satisfaction.

Literature Search

Specific text words used in the literature search were "patient controlled analgesia and outcome" (348 articles), "nurse controlled analgesia and outcome" (21 articles), "nurse controlled analgesia and patient controlled analgesia" (16 articles), "nurse controlled analgesia" (22 articles), "patient controlled analgesia" (2816 articles), "patient controlled analgesia and meta-analysis" (17 articles), and "nurse

Table 1. Workshop Grading of Level of Evidence and Subgroup Support for Each Statement

Category	Level of evidence*
Ia	Evidence obtained from meta-analysis, including at least 1 large, randomized, controlled trial
Ib	Evidence obtained from meta-analysis, including at least 1 small, randomized, controlled trial or well-designed, large, randomized, controlled trial alone
II	Evidence obtained from well-designed cohort or case-controlled studies
III	Evidence obtained from case series, case reports, or flawed clinical trials
IV	Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees
V	Insufficient evidence to form an opinion
	Level of Subgroup support for statement
A	Good evidence to support the statement
B	Fair evidence to support the statement
C	Poor evidence to support the statement, but recommendations may be made on other grounds
D	Fair evidence to reject the statement
E	Good evidence to reject the statement

Summit panel (group at large) voting	Individual level of support
1	Accept recommendation completely
2	Accept recommendation with some reservations
3	Accept recommendation with major reservations
4	Reject recommendation with reservations
5	Reject recommendation completely

*Definitions for level of evidence were modified from those proposed by the Oxford Center for Evidence Based Medicine and available at http://www.cebm.net/levels_of_evidence.asp. The Acute Pain Summit 2005 participants modified the existing levels by dividing Level 1 evidence into 1a and 1b, as the group consensus was that a meta-analysis that contained at least 1 large, randomized, controlled trial was stronger than a single large, randomized trial alone or a meta-analysis composed only of a group of small trials.

controlled analgesia and meta-analysis" (0 articles). The reference lists of the meta-analyses were also reviewed for relevant articles. After careful review of the resulting articles, a total of 11 articles (9 randomized controlled trials and 2 meta-analyses) were felt to represent the wide variety of patients and surgical procedures studied and have the most direct relevance to the statement.

Evidence

Pettersson et al[5] examined the efficacy and amount of opioid delivered with PCA *v* nurse-controlled analgesia (NCA) after extubation in 48 patients after coronary artery bypass surgery (CABG).[5] The authors found that visual analog scores (VAS) did not differ on the day of surgery. On postoperative day 1, VAS scores were higher in the NCA group (VAS 3-4/10 *v* 2/10 in the PCA group, $P < .01$). The PCA group used more opioid analgesic than did the NCA group ($P < .01$). Additional oral analgesics were required in 50% of the NCA group *v* none in the PCA group. The side effects were equal in both groups. They concluded that PCA resulted in better pain treatment and increased use of opioids without an increase in side effects compared with NCA.

Boldt et al[6] assessed the degree of sedation, satisfaction, and pain for the first 3 postoperative days in 60 cardiac surgery patients with a comparison between standard therapy (intermittent bolus doses on demand or as determined by the staff nurse) and a PCA regimen. In addition, they examined vital capacity (VC) and forced expiratory volume in 1 second (FEV_1), cortisol, and troponin levels. Postoperative pain scores were significantly lower, and more opioid was used throughout the observation period in the PCA group. The VC and FEV_1 were significantly lower in the standard group than in the PCA group. Cortisol, troponin, and side effects were similar in both groups. The authors concluded that PCA improved pain relief and increased patient satisfaction after cardiac surgery when compared with standard nurse-based pain therapy.

Murphy et al[7] compared PCA to nurse-titrated, continuous IV opioid infusions in 200 patients undergoing major thoracic or abdominal surgery. The patients were examined for pain, level of sedation, nausea, presence of adverse effects, and cumulative opioid dose over 24 hours. They found no significant differences in the quality of analgesia, frequency, and severity of adverse effects or the cumulative dose of opioid. The authors concluded that nurse-controlled infusions are as effective as PCA and may be used as an alternative to PCA when it is unavailable or unsuitable.

Myles et al[8] compared PCA and a nurse-titrated continuous infusion of morphine in 72 patients after cardiac surgery. They examined pain and nausea scores 5, 20, 32, and 44 hours after surgery and serum cortisol levels 24 and 48 hours after surgery; they found no differences in pain or nausea scores, serum cortisol, morphine consumption, time to extubation, or discharge from the intensive care unit (ICU) between the 2 groups. A significant association was seen between pain and serum cortisol at 48 hours. The authors concluded that no benefit was obtained from routine PCA use in cardiac surgical patients. The differences in staffing time required with each technique were not evaluated in this study.

Gust et al[9] examined the effect of PCA on pulmonary complications in 120 patients for 72 hours after CABG. They examined 3 groups; PCA, PCA and non-

steroidal anti-inflammatory drugs (NSAIDS), and traditional NCA. They found that chest radiographic atelectasis and VAS scores were similar on the first and second days. On the third day, atelectasis scores were better in the PCA and PCA with NSAID groups, and VAS scores were higher in the NCA group. The authors concluded that PCA significantly decreases postoperative pulmonary atelectasis compared with NCA and produces a higher quality of analgesia.

Weldon et al[10] examined the uses of PCA, PCA with concurrent basal infusion, and NCA for 72 hours in 54 pediatric patients (ages 5 to 20 years) undergoing elective scoliosis surgery. The authors found no differences between the PCA and the PCA plus basal infusion groups with respect to morphine use, pain relief, side effects, or patient satisfaction. They found that nurses consistently underestimated their patients' pain and that children in the NCA group received less morphine per kilogram than those who self-administered their medication. The authors concluded that NCA is an acceptable alternative in the ICU setting for patients incapable of self-administering pain medication.

Forst et al[11] examined pain therapy after total-hip or knee arthroplasty in 42 patients who received either PCA or conventional demanded pain therapy. The authors found no significant differences in pain scores or side effects. The PCA group used twice as much opioid ($P < .001$). Patient satisfaction with the therapy was good in both groups but was significantly better in the PCA group ($P < .01$). The authors concluded that even when patients feel satisfied by the administered pain therapy, the majority are objectively treated below their individual subjective pain threshold.

Nitschke et al[12] examined whether PCA would achieve better pain control with fewer adverse effects than intramuscular (IM) analgesia in 92 patients undergoing major colon resection. They compared PCA morphine with IM morphine or IM ketorolac. Only 2 patients had adverse effects and they were receiving PCA morphine. More patients receiving IM ketorolac required alternative analgesia (32% IM ketorolac *v* 16% IM morphine and 0% PCA). The ketorolac group had a significantly shorter duration of ileus ($P < .01$), significantly lower pain scores ($P < .04$), and less postoperative confusion ($P < .03$) than the morphine groups. The ketorolac group had a significantly shorter duration of stay than either morphine group ($P < .01$), with no significant difference between the morphine groups. The patients preferred PCA to the other analgesic methods. The authors concluded that although ketorolac appears to provide a better postoperative course than either IM or PCA morphine, 18% of ketorolac patients required additional analgesia, with a strong preference for PCA.

Wheatley et al[13] examined hypoxemia and pain relief for 24 hours after upper abdominal surgery in 44 patients who received either IM or PCA analgesia with morphine. They found that 9 of 19 in the PCA group rated their pain control excellent *v* 2 of 20 in the IM group ($P < .05$). No significant difference was seen in the incidence of hypoxemia. Severe hypoxemia (SpO_2 <85% for more than 6 minutes) was seen in 3 IM patients and in 1 PCA patient. The authors concluded that PCA is not associated with an increased risk of severe hypoxemia compared with IM analgesia and that severe hypoxemia can occur in upper abdominal surgery patients with poor pain relief. However this study was too small to draw meaningful conclusions regarding the risk of hypoxemia.

Ballantyne et al[14] performed a meta-analysis that examined the initial randomized control trials (RCTs) in patients who received postoperative PCA. The meta-analysis included 15 RCTs with a total of 787 adult patients aged 16 to 65 years who were undergoing various operative procedures and who received either PCA or conventional analgesia for postoperative pain control. The authors extracted data on analgesic efficacy, analgesic use, patient satisfaction, length of hospital stay, and side effects. The meta-analysis found greater analgesic efficacy when PCA was used. A nonsignificant trend toward reduced analgesic use in PCA patients was observed. On the basis of an analysis of 3 studies that examined patient satisfaction with PCA *v* conventional analgesia, a mean difference of 42% occurred in the probability of satisfaction with PCA *v* conventional analgesia. A nonsignificant trend toward shortening length of stay with PCA use was seen. The authors concluded that patients obtain better pain relief with PCA, compared with those who use conventional analgesia, without an increase in side effects, and they strongly prefer PCA over conventional analgesia.

Walder et al[15] subsequently performed a meta-analysis that examined the efficacy and safety of PCA for acute postoperative pain. Included in their meta-analysis were 32 RCTs, with a total of 2,072 patients who received morphine (22), piritramide (3), nalbuphine (1), and tramadol (1). Three morphine trials and 1 meperidine trial demonstrated patient preference for PCA (89.7% *v* 65.8%). The combined data on pain intensity and relief and the need for rescue analgesics from morphine (8 trials), meperidine (1 trial), piritramide (1 trial), and nalbuphine (1 trial) all were in favor of PCA. In 2 morphine trials, pulmonary complications were less frequent in those who received PCA. The trials

demonstrated equivalence for cumulative opioid consumption, pain scores, duration of hospital stay, and opioid-related adverse events. The authors concluded that PCA with opioids, compared with conventional opioid administration, improves analgesia and decreases the risk of pulmonary complications; patients also prefer PCA over traditional NCA.

Grading of Evidence

On the basis of the evidence in these 9 RCTs and the 2 meta-analyses, the members of this workshop agreed that the nature of evidence available regarding this statement was Category Ia (evidence obtained from meta-analysis, including at least 1 large, randomized, controlled trial) (Table 1).

Level of Support for Statement

On the basis of the available evidence, 4 out of the 5 workshop participants agreed that their level of support was Category C (poor evidence to support the statement, but recommendations may be made on other grounds) and 1 participant voted for Category D (fair evidence to reject the statement) (Table 1). Workshop participants struggled with the term "improved patient outcomes," but agreed to define this term as any outcome that is seen as beneficial to the patient in the postoperative period. Across the majority of randomized trials and both meta-analyses, IV PCA improves postoperative pain relief and overall patient satisfaction with pain control after surgery. The effectiveness of IV PCA in improving other postoperative outcomes is variable.

In the group at large, 18% (2 of 11) of the summit participants voted "1" (accept completely), 45% (5 of 11) voted "2" (accept with some reservations), 18% (2 of 11) voted "3" (accept with major reservations), 18% (2 of 11) voted "4" (reject with reservations), and none voted "5" (reject completely) (Table 1). This result was compared with the vote of the ASRA membership survey of 57% for "1," 34% for "2," 4% for "3," 4% for "4," and 1% for "5" (Fig 1).

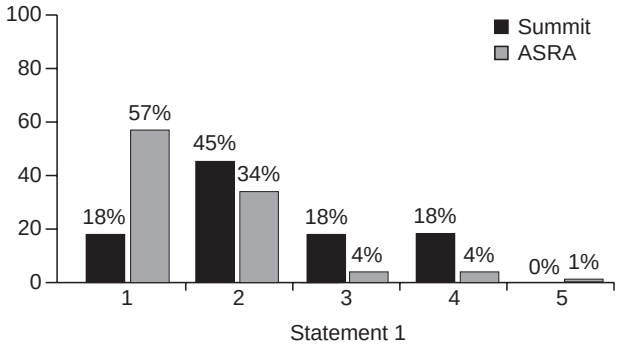

Fig 1. Voting comparison for Statement 1 (Use of IV PCA leads to improved patient outcomes when compared with nurse-administered parenteral opioids). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Discussion

On the basis of the available evidence, the most consistent difference relates to patient satisfaction and preference for PCA *v* NCA. This outcome may reflect satisfaction regarding the ability to maintain a degree of control during hospitalization, especially over something as individual as pain control. The value of self-determination is reflected in the wide variability of total opioid use by individuals undergoing the same surgical procedure. This variable cannot be predicted in advance in most cases and may cause some patients to be undertreated if a one-size-fits-all approach is used to order postoperative analgesics. The use of PCA does not appear to lead to improvement in other outcomes. However, the potential benefits outlined in some small studies include improved pulmonary function, provision for a wide variability in opioid dose, and reduced hospital stay.

The absence of clearly defined and widely accepted measures of patient outcomes limits comparisons between studies and makes accumulation of sufficient patient numbers to draw clear conclusions a challenge. The absence of improvements in areas such as side effects may reflect the drug itself and not the delivery system. The strong support for PCA is evident in the survey of the ASRA membership, and this support likely reflects the routine use of PCA for postoperative analgesia. It may also reflect the widespread acceptance of PCA as the standard of care. Given the relative equivalence of the 2 methods and the strong patient preference for IV PCA, the currently held opinion that favors PCA seems quite reasonable. Other issues regarding the inherent safety of PCA devices need to be resolved for the future but are not widely reported in the medical literature. Data regarding these problems are available in the Manufacturer and User Facility Device Experience (MAUDE) database, which outlines numerous adverse events related to PCA devices (see *Discussion* in Statement 5). These complications include overdose, drug switches, inaccurate drug delivery, and others. Improved devices capable of recognizing the drug, its concentration, and common dosing, in addition to improved delivery accu-

racy, may reduce device-related and human-related errors but may not make significant changes in most routine outcomes.

Future Directions

Future directions suggested by the workshop participants reflect weaknesses of the currently available data to support the widely held perception that PCA improves postoperative outcomes. Appropriately constructed studies that more closely reflect current practice with much larger numbers are required to provide a better picture of current PCA use and whether or not it truly improves outcomes as compared with NCA. In addition, use of validated patient-oriented (eg, patient satisfaction, quality of life, quality of recovery) and functional outcomes should be incorporated into these studies. Although large RCTs are ideal, larger population-based studies capable of identifying trends, complications, and outcomes are also needed. Such large observational studies would be ideal for characterizing the frequency and severity of PCA device–related problems. Current studies are too small to identify these outcomes with any accuracy, as their total numbers are small, even within the confines of a meta-analysis. As a result, many descriptions of unusual complications are based on case reports, small case series, or self-reported data to federal device registries that provide a numerator but no denominator.

Statement 2

Use of continuous peripheral analgesic techniques leads to improved patient outcomes.

Rationale and Definition of Statement

The use of continuous perineural analgesia is increasing in popularity for both hospitalized and ambulatory patients. These peripheral techniques offer the ability to provide effective focal analgesia and reduce the need for systemic opioid analgesics and are considered to have less risk of bleeding complications in anticoagulated patients.[3] However, performance of these techniques requires skill and a formal infrastructure for postoperative management and may increase anesthesia-related time. Thus, solid evidence of analgesic efficacy, reduced side effects, and, ideally, functional and long-term benefit would support making the required investment to routinely employ these techniques. For the purposes of this analysis, we were interested in prospective RCTs that compare continuous perineural analgesia to systemic opioids for postoperative analgesia. Thus, either sham perineural catheters, catheters infused with placebo, or no placebo were considered acceptable control groups. Specific outcomes extracted included postoperative pain, side effects (nausea/vomiting, sedation, pruritus, motor/sensory block), opioid use, and patient satisfaction compared with opioid analgesia.

Literature Search

A literature search for RCTs that compare continuous peripheral-nerve block with opioids for the management of postoperative pain yielded 788 articles by use of the terms "pain, postoperative" (13,752 articles) combined with "nerve block" (7,399 articles). The limitation of those results to only RCTs of humans and all adults (older than 18 years of age) yielded 236 articles. No language limitations were used. Each article's abstract was reviewed to determine if it included the use of continuous peripheral-nerve catheters for postoperative pain in one of the randomized groups and opioids (either oral or parenteral) in the other randomized group. This search identified 37 articles for further full-text review to determine if our analysis-inclusion criteria were met. A hand-search of the author's (Dr. Liu's) files and references from the original search results yielded an additional 7 articles for full-text review. Inclusion criteria were a clearly defined anesthetic technique (combined general anesthesia [GA]/regional, GA, peripheral-nerve block); randomized trial; adult patient population (older than 18 years of age); continuous peripheral-nerve block (or analgesia) used postoperatively (intrapleural catheters were deemed not to be classified as a peripheral-nerve catheter); and opioids administered for postoperative analgesia in groups who did not receive peripheral-nerve block. Exclusion criteria were no measurement of pain score that could be converted to VAS or no comparison of opioid to continuous peripheral-nerve block.

Evidence

Nineteen articles, related to studies that enrolled a total of 603 patients, were ultimately included in the meta-analysis.[3] Included articles came primarily from hospitals in Europe (58%) and North America (38%). More studies involved lower-extremity surgery (60%) than upper-extremity surgery (40%), and femoral nerve/lumbar plexus was the most common catheter location for analgesia (51%), followed by interscalene (35%). Randomized clinical trials that compared perineural catheters with opioids were very limited for other locations (13%).

Studies in the analysis included 11 with data obtained by intention to treat (all enrolled patients were included in the data analysis, with no treat-

ment failures), but only adequately functioning catheters were included in the remaining 8 studies. A total of 13 patients were withdrawn from the catheter group after randomization, and 7 were excluded from the opioid group in these 8 studies. Ten additional patients were withdrawn before randomization. Overall, 10 catheter-placement failures and 11 catheter dislodgements occurred; 2 patients in the catheter groups were excluded for other reasons, and a total of 5 patients in the opioid groups were withdrawn because of nausea and 2 were withdrawn for failure to complete surveys.

When all studies and observations were combined, the analysis revealed that perineural analgesia provided better postoperative analgesia compared with opioids ($P < .001$). This effect was seen for all time periods measured for both mean VAS (1.4 *v* 3, global mean) and maximum VAS (3 *v* 5.4) at 24 ($P < .001$), 48 ($P < .001$), and 72 (mean VAS only) ($P < .001$) hours postoperatively. When analyzed by catheter location, perineural analgesia provided superior analgesia to opioids ($P < .05$) for all locations and time periods.

No major complications were reported in any of the 19 studies. Twelve of the 19 studies (63%) reported at least one minor complication; sedation occurred most frequently overall. Motor block was the adverse effect most attributed to peripheral-nerve block (31% *v* 15%, $P < .001$), whereas nausea/vomiting (49% *v* 21%), sedation (52% *v* 27%), and pruritus (27% *v* 10%) all occurred more commonly with opioid analgesia ($P < .001$). Number needed to harm was calculated for nausea/vomiting, sedation, and pruritus with 4, 4, and 6 patients who received perineural analgesia expected to result in 1 fewer patient with nausea/vomiting, sedation, and pruritus, respectively, compared with opioid analgesia.

Four trials measured patient satisfaction on a VAS and demonstrated a higher composite mean VAS satisfaction for catheters 9.6 (n = 93) (95% CI 9.5-9.7) compared with opioids 7.1 (n = 90) (95% CI 6.9-7.2). Total opioid consumption for both groups for the duration of catheter use was calculated for 12 of the 19 studies. Seven studies either failed to document total opioid consumption for both groups or did not provide the data in a manner that could be converted for direct comparison. Total opioid consumption over 48 hours was significantly less ($P < .001$) with the use of perineural analgesia (20.8 mg morphine [n =165 patients; 95% CI 18.5-23.1]) compared with opioid analgesia (54.1 mg morphine [n = 174 patients; 95% CI 50.8-57.4]).

Grading of Evidence

On the basis of the evidence in these 19 RCTs, all members of this workshop agreed that the level of evidence available regarding this statement was Ia (evidence obtained from meta-analysis, including at least 1 large, randomized, controlled trial [Table 1]).

Level of Support for Statement

On the basis of the available evidence, the workshop members voted that their level of support was Category A (good evidence to support the statement) (Table 1). In the group at large, 73% (8 of 11) of the summit participants voted "1" (accept completely), and 27% (3 of 11) voted "2" (accept with some reservations) (Table 1). Reservations included the level of skill and clinical infrastructure required to achieve similar positive efficacy with perineural catheters, unknown incidences of serious complications, and the overall heterogeneity of the RCTs in the meta-analysis. This level of support was similar to results from the ASRA survey, but the ASRA survey reported a greater incidence (43%) of "2" (accept with some reservations) (Fig 2). This support may reflect a greater "real world" concern of previously mentioned reservations of level of required skill, clinical-management infrastructure, and potential complications.

Discussion

On the basis of our meta-analysis, continuous peripheral-analgesic techniques provide superior analgesia, reduce opioid consumption, and reduce opioid-related side effects (nausea/vomiting, seda-

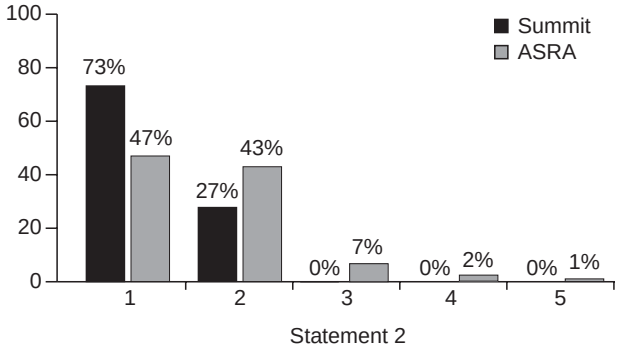

Fig 2. Voting comparison for Statement 2 (Use of continuous peripheral analgesic techniques leads to improved patient outcomes). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

tion, pruritus). However, several unresolved issues remain concerning the technique. Current subject numbers are insufficient to truly gauge the safety of techniques. General applicability of techniques is uncertain because of the required level of technical skill and infrastructure to manage these catheters, especially for outpatients. Current RCTs are relatively small and heterogeneous; thus, little can be concluded regarding optimal techniques, especially for individual surgical procedures. Finally, insufficient evidence is available to determine the ability of continuous peripheral-analgesic techniques to affect venue for recovery (inpatient *v* outpatient), duration of hospital stay, long-term functional outcome, or major morbidity. One small study examined the ability of continuous sciatic analgesia to allow conversion of inpatient foot surgery to outpatient surgery.[16] Although more patients in the perineural analgesia group were able to go home, the difference was not statistically significant. Two RCTs that examined total-knee replacement have noted shorter hospital stays with continuous femoral analgesia *v* IV PCA,[17,18] but both study protocols included inpatient physical rehabilitation and hospital stays that were quite long (16-45 days) compared with current data from the United States Hip and Knee Registry (4-day average hospital stay).[19] These same studies reported faster initial recovery of joint flexion with femoral-nerve analgesia, but no differences were noted by 3 months. Finally, no RCT has addressed effects on major morbidity or mortality.

Future Directions

An examination of the included studies for methodology found no consistency in analgesic regimen for either the opioid or peripheral-nerve catheter group. The opioid group included a variety of opioids, routes of administration (oral, parenteral), and frequency of administration, whereas the catheter group included different local anesthetics (bupivacaine and ropivacaine), concentrations (ranging from 0.125% to 0.5%), infusion rates and boluses, and catheter locations. Both groups also commonly had supplemental analgesics administered, including various NSAIDs. Further studies to determine the ideal local anesthetic, concentration, infusion rate, bolus dose, and additives for each catheter site and surgical location are still needed to determine the optimal use of continuous peripheral-nerve block. Large prospective surveys are needed to accurately determine the risk of complications with these techniques. Large RCTs are needed to evaluate potential effects on venue for recovery (inpatient *v* outpatient), duration of hospital stay, long-term functional outcome, and major morbidity.

Statement 3

The use of multimodal analgesia improves postoperative pain control and reduces analgesia-related adverse effects.

Rationale and Definition of Statement

The common perception is that combining two or more analgesic agents, an approach termed multimodal analgesia, may provide at least additive, if not synergistic, analgesia.[20] Another perception is that combining analgesic modalities with different mechanisms of action may reduce the use of individual analgesic agents and, thereby, decrease the incidence of side effects associated with each agent, particularly with the opioid analgesics.

The broad term "multimodal analgesia" is used to describe any combination of two or more analgesic modalities. Numerous permutations of analgesic agents and techniques are possible (some of which may not be routinely used in clinical practice on a global basis), which makes a meaningful comprehensive assessment particularly difficult. The available evidence for most multimodal regimens is scant; thus, to allow for a meaningful analysis, the statement focused on the examination of analgesic efficacy and side-effect profiles of the combination of nonspecific NSAIDs, cyclooxygenase-2 (COX-2) inhibitors, or acetaminophen in conjunction with IV PCA. The definition of "multimodal analgesia" in this case did not refer to the multimodal approach to patient convalescence, which also incorporates nonpharmacologic approaches. Our focused definition of "multimodal" examined whether the addition of these commonly used adjuvant agents would provide superior analgesia, while decreasing the incidence of opioid-related side effects and adverse events.

Literature Search

The literature search was conducted by use of the specific text words "nonsteroidal anti-inflammatory agents" or "NSAID," which yielded a total of 130,606 articles, and "acetaminophen," which yielded a total of 10,783 articles. These two searches were combined with the "OR" function for a total of 138,559 articles. This search was combined with "postoperative pain" (17,797) articles by use of the "AND" function and limited further by use of the English language and meta-analysis functions to yield a total of 26 articles, each of which was examined for relevance to the statement. The reference lists of these articles were also examined.

Evidence

A total of 5 articles were ultimately included in the analyses. Twenty-one of 26 articles were rejected because they did not examine postoperative pain, used only single-dose regimens, or evaluated pediatric patients. The first meta-analysis, which examined 22 randomized, controlled trials (2,307 subjects), attempted to assess the effect of NSAIDs on morphine-related adverse events.[21] The included studies compared the addition of an NSAID *v* placebo to standard IV PCA morphine for pain management after a range of operative procedures. The authors' analyses demonstrated that NSAIDs decreased the relative risk (RR) *v* placebo of postoperative nausea and vomiting (PONV) by 30% (RR = 0.70; 95% CI = 0.59-0.84) and of sedation by 29% (RR = 0.71; 95% CI = 0.54-0.95). NSAIDs did not reduce the risk of developing pruritus, urinary retention, or respiratory depression. Effects on pain were not assessed.

The second meta-analysis, which included 7 randomized, controlled trials (491 subjects), examined the effect of acetaminophen on morphine-related adverse events.[22] The studies compared the addition of acetaminophen *v* placebo to standard IV PCA morphine for pain control after major surgery. The authors' analyses suggested that use of acetaminophen decreased morphine use by approximately 20% (9 mg) over the first 24 hours after surgery (95% CI = −15 to −3 mg). The addition of acetaminophen did not reduce the risk of any opioid-related side effects. Although the effect of acetaminophen on postoperative pain was not quantitatively analyzed as a single-pooled estimate, the authors noted that only 2 of 6 studies found that use of acetaminophen improved pain scores when compared with placebo.

The most recent meta-analysis examined whether multimodal analgesia combined with a variety of agents provided any advantage when added to IV PCA morphine.[23] Included in their meta-analysis were 10 randomized controlled trials that examined the addition of acetaminophen, 14 that examined addition of the COX-2 inhibitors, and 33 that assessed the addition of an NSAID to standard IV PCA morphine for pain control after surgery. As in the previous reports, the comparison was between the additions of an analgesic agent (acetaminophen, COX-2 inhibitors, or NSAIDs) *v* placebo. The results suggested all of the analgesic agents studied provided an opioid-sparing effect; however, this decrease in opioid consumption did not consistently result in a decrease in opioid-related side effects or adverse events. Use of NSAIDs was associated with a significant decrease in the relative risks of PONV and sedation, similar to those seen in the previous meta-analysis.[21,23] However, use of acetaminophen or COX-2 inhibitors did not significantly decrease the risk of opioid-related adverse events compared with placebo. NSAIDs (multiple dose and infusion only), but not acetaminophen or single-dose NSAIDs, were associated with a statistically significant decrease in pain scores, but whether this decrease was clinically meaningful was not clear. The analgesic efficacy of COX-2 inhibitors was not assessed in this meta-analysis.

Finally, 2 systematic reviews were conducted of the analgesic efficacy of a COX-2 inhibitor compared with placebo in addition to a standard opioid analgesic regimen for postoperative pain control.[24,25] One systematic review examined the effect of preoperative COX-2 inhibitors on postoperative outcomes in 22 randomized trials (2,246 subjects).[24] Compared with placebo, preoperative administration of a COX-2 inhibitor reduced postoperative pain and analgesic consumption in 15 of 20 trials; however, no significant differences were seen between placebo and COX-2 inhibitors in the overall relative risk of PONV or incidence of PONV in 13 of 17 trials. The other systematic review was a meta-analysis of 9 trials (1,738 subjects) that examined patients' global evaluation of analgesia after IV parecoxib for postoperative pain.[25] Compared with placebo, subjects who received parecoxib, particularly the 40-mg dose, had a significantly superior analgesic outcome (ie, they more frequently rated their pain control as "good" or "excellent"), but here again, COX-2 inhibitors did not significantly decrease the risk of opioid-related adverse events compared with placebo.

Grading of Evidence

On the basis of the evidence in these 4 meta-analyses and 1 systematic review, all members of this workshop agreed that the level of the evidence available regarding this statement was Category Ia (evidence obtained from meta-analysis, including at least 1 large randomized, controlled clinical trial [Table 1]).

Level of Support for Statement

On the basis of the available evidence, discernable differences exist in analgesic and side-effect profiles for different agents. Thus, the level of support for this statement was assessed separately for postoperative pain control and reduction of analgesia-related adverse (opioid-related) effects by individual classes of agents (acetaminophen *v* COX-2 inhibitors *v* nonspecific NSAIDs). All of the mem-

bers of this workshop agreed on the level of support for each statement as follows.

With regard to the first part of the statement (*the use of multimodal analgesia [NSAID-based] improves postoperative pain control*), all members of this workshop agreed that the level of support was Category A (good evidence to support the statement) only for nonspecific NSAIDs (multidose or infusion) and COX-2 inhibitors. However, when acetaminophen and single-dose NSAIDs were considered, all members of this workshop agreed the level of support was Category E (good evidence to reject the statement) (Table 1).

With regard to the second part of the statement (*the use of multimodal analgesia [NSAID-based] reduces analgesia-related adverse [opioid-related] effects*), all members of this workshop agreed that the level of support was Category E (good evidence to reject the statement) for acetaminophen and COX-2 inhibitors only. For nonspecific NSAIDs, all members of this workshop agreed that the level of support was Category B (fair evidence to support the statement) (Table 1).

When voting on support of this statement, 73% (8 of 11) of the summit participants voted "2" (accept with some reservations) and 27% (3 of 11) voted "3" (accept with major reservations); none voted for "1" (accept completely), "4" (reject with reservations), or "5" (reject completely) (Table 1). This result was compared with the vote of the ASRA membership of 73% for "1," 23% for "2," 3% for "3," 0% for "4," and 1% for "5" (Fig 3).

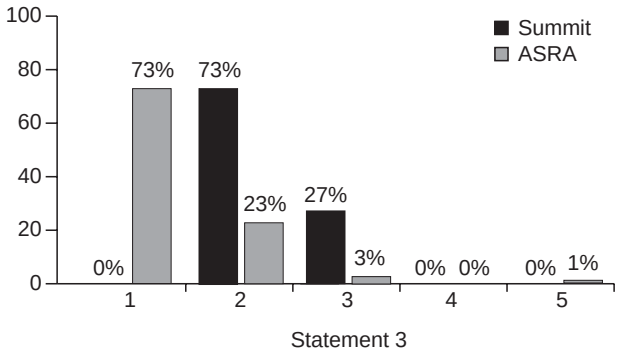

Fig 3. Voting comparison for Statement 3 (Use of multimodal analgesia improves postoperative pain control and reduces analgesia-related adverse effects). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Discussion

On the basis of the available evidence, it appears that multimodal analgesia (use of NSAIDs, COX-2 inhibitors, or acetaminophen in combination with IV PCA) does result in an opioid-sparing effect. However, this decrease in opioid consumption does not consistently translate into a decrease in opioid-related adverse events or side effects. The use of acetaminophen and COX-2 inhibitors does not appear to decrease the relative risk of opioid-related side effects (eg, PONV, sedation, pruritus, urinary retention) or adverse events (respiratory depression). Use of nonspecific NSAIDs does appear to decrease the relative risk of some opioid-related side effects (ie, PONV, sedation) but not others (ie, pruritus, urinary retention, respiratory depression). With regard to postoperative analgesia, addition of NSAIDs (multiple dose or infusion), but not acetaminophen or single-dose NSAIDs, produces a statistically significant decrease in postoperative-pain scores. Two systematic reviews seem to indicate that the addition of COX-2 inhibitors also provides superior postoperative analgesia; however, no quantitative analysis of the extent of this benefit was done.

This statement, like many of the statements included in the summit, is broad and can be interpreted in different ways. The interpretation of this statement depends on the particular definition assigned to specific words (eg, "multimodal" and "adverse effect") in the statement. Because available evidence was limited regarding other forms of multimodal analgesia, this analysis was limited to the combination of an NSAID, acetaminophen, or a COX-2 inhibitor with an opioid regimen for pain control after surgery. Indeed, ASRA members voted strongly in support of the statement, and this support likely reflects a strong bias toward the clinical impression that a multimodal analgesia regimen that includes regional anesthesia can improve clinical outcomes. In addition, the methodology used in some of the randomized controlled trials examined does not accurately reflect conditions in actual clinical practice (ie, they lack external validity). For instance, addition of a single-dose of NSAID did not provide superior analgesia compared to placebo; however, NSAIDs would more likely be used in multiple doses (which do provide superior analgesia *v* placebo) in the typical clinical setting.[23] Whether statistically significant reduction in weighted pain scores (approximately −1 on a scale of 0 to 10) for multiple doses or continuous infusion of NSAIDs would be clinically meaningful is also unclear.[23]

Finally, the intent of the statement was to address the effect of NSAIDs, COX-2 inhibitors, and acetaminophen on opioid-related side effects; however,

we did not discuss the possible increased relative risks of these treatments (severe bleeding: number needed to harm [NNH] = 59; renal failure in cardiac patients for COX-2 inhibitors: NNH = 73; and other serious adverse events [including death, myocardial infarction, sternal wound infection, and cardiac failure] for COX-2 inhibitors: NNH = 11).[23]

Future Directions

Future directions suggested by workshop participants reflect some of the limitations already discussed. The studies used to assess this statement may be considered "bimodal" therapy (IV PCA + one adjuvant). Appropriately constructed studies are needed to evaluate a more comprehensive multimodal approach (eg, combinations of regional-analgesic techniques, other adjuvant agents, and opioid analgesics). Future studies should be designed to reflect actual clinical practice (eg, use of a multiple rather than a single-dose NSAID regimen). Use of validated patient-oriented (eg, patient satisfaction, quality of life, quality of recovery) and functional outcomes should also be incorporated into these trials. Future trials should assess outcomes in not only the short term (days) but also a longer time frame (weeks to months).

Statement 4

Technology-related problems limit the safety and effectiveness of IV and epidural PCA.

Rationale and Definition of Statement

PCA was introduced as a method of closing the loop between patients in pain and their sources of analgesia. This technique allowed patients to deliver small, intermittent doses of opioids to provide analgesia and minimize the risks of sedation and respiratory depression. PCA devices come with intrinsic safety features, such as lockout intervals during which additional doses of medication cannot be delivered and 1-hour or 4-hour maximum allowable doses. Another factor critical to the safety of PCA is that the button should only be pressed by the patient, to avoid repeated dose administration if sedation ensues. PCA has improved pain control and patient satisfaction, but has this new technology introduced additional risks for patients?

Postoperative epidural analgesia was initially limited to the use of preservative-free epidural opioids given as a single bolus dose. Epidural infusions of different analgesic combinations have been given in the epidural space to provide prolonged analgesia, with reduced need for bolus injections. An infusion device is required to provide continuous epidural analgesia, and this feature is often combined with a patient-control function similar to IV PCA. Thus, a similar question arises concerning continuous epidural analgesia: Do the limitations of the technology add new risks for the pain patient?

PCA, via both IV and epidural routes, has involved the introduction of sophisticated technology into widespread use in a variety of settings. In this section, we assess whether the technological limits of current therapy reduce the safety or effectiveness of these techniques.

Literature Search

The specific text words used to carry out the literature search were "patient controlled analgesia," and they yielded a total of 2,863 articles, which when combined with "medication errors" yielded 30 articles. The combination of "patient controlled analgesia" and "technological failure" yielded 16 articles. No meta-analyses looked at technological failures; the majority of articles examined were case reports. Some of these references were not in traditional peer-reviewed journals but rather in reports from drug-safety monitoring groups. These references were identified from the reference lists of cited articles or by summit participants, and these databases are described along with the evidence below.

Evidence

MEDMARX is USP's (United States Pharmacopeia, Rockville, MD) interactive, anonymous, Internet-accessible system that allows self-reporting of medication errors and adverse drug reactions (available at https://www.medmarx.com/, accessed February 15, 2006). The most common errors involving PCA pumps as reported by MEDMARX were improper dose/quantity (38.9%), unauthorized/wrong drug (18.4%), and dose omission (17.6%). Opioids were the drugs most likely to be associated with medical injury. Forty-five percent of these opioid-related adverse events were attributed to misuse or malfunction of infusion devices.

MEDMARX uses the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Error Outcome Category Index (Table 2).[26] The average overall rate for errors of the types in categories E through I submitted to MEDMARX has been approximately 2%. However, when PCA pumps were involved, the chance for error leading to patient harm increases to 7% (a 3.5-fold increase).[27]

A recent observational study detailed 56 adverse events associated with use of PCA reported over a 1-year period in a tertiary referral hospital. Program-

ming errors accounted for 71% of PCA adverse events.[28] The majority (75%) of these errors resulted in overmedication, and 25% resulted in inadequate analgesia caused by undermedication. Another prospective observational study in a tertiary referral center demonstrated that in just over 2 years IV PCA was used in 3,758 patients and 14 critical events occurred (1:946 patients or 1:2,280 patient days).[29] They divided the problems into four categories: programming errors, machine tampering, doses administered by others, and poor clinical judgment by the prescribing physician (Table 3). Fifty percent of these adverse events were caused by programming errors, with one of the eight resulting in a serious consequence. A retrospective analysis of adverse events in a major teaching hospital in New Zealand found that 3 of 14 potentially life-threatening complications were caused by programming errors.[30]

The United States Food and Drug Administration (FDA) Center for Devices and Radiological Health maintains an Internet-based, self-report database; the Medical Device Reporting (MDR) database contains over 600,000 reports entered between 1984 and 1993. The MAUDE database contains reports from facilities, distributors, and manufacturers from as early as 1991 (available at http://www.fda.gov/cdrh/mdr/index.html, accessed February 15, 2006). The Safe Medical Devices Act of 1990 requires user facilities to report device-related deaths to the FDA and the device manufacturer and to report device-related serious injuries to the manufacturer or to the FDA if the manufacturer is not known. Analysis of the MDR database found programming errors that resulted in patients receiving 5-fold to 10-fold higher amounts of PCA medication than was intended. These errors resulted in 5 to 8 deaths, depending on the method used for counting total number of events (whether 3 of the same deaths were reported by 2 different individuals is unclear from the database). Utilizing this data, the author postulated that because only 1.2% to 7.7% of adverse events are usually reported, these 5 to 8 deaths out of the 22 million users of this PCA pump before March 2001 represent a death rate of 1 in 33,000 to 300,000.[31]

Table 2. NCC MERP Error Outcome Category Index

Category	Description
A	Circumstances or events that have the capacity to cause error
B	An error occurred but the error did not reach the patient
C	An error occurred that reached the patient but did not cause patient harm
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
G	An error occurred that may have contributed to or resulted in permanent patient harm
H	An error occurred that required intervention necessary to sustain life
I	An error occurred that may have contributed to or resulted in the patient's death

Table 3. Categories of Critical Events That Occurred with IV PCA in an Observational Study

Programming errors
Machine tampering
Doses administered by others
Poor clinical judgment by the prescribing physician

A review of the MAUDE database demonstrated that malfunction of the PCA device may cause patient harm.[32] During the 2-year period January 2001 to December 2003, 2,108 problems related to PCA pumps were reported. Seventy-nine percent of these events were caused by device-related problems; 61% were confirmed by the manufacturer. A host of other reports have appeared in the literature relating malfunctioning of the PCA devices and resultant delivery of excessive amounts of opioid (free flow of opioid caused by cracked syringes or poorly designed pumps and delivery systems).[33] Many of the currently available PCA pumps do not default to zero when programming delays occur. If a delay in entering a numeric value is detected or if the pump is turned off during programming, several commonly used PCA pumps default back to the value that was last entered rather than to zero.[34] Experts have recommended the PCA pump should default to "000," which would require the active selection of a value. Errors in PCA programming are also influenced by the pump design. Many available pumps incorporate software that is not intuitive or is often repetitive, tedious, and sometimes illogical.[35] In a recent prospective review of IV infusions on a single day in a tertiary referral center in 2003, 66.9% of 426 medication infusions had 1 or more errors.[36] Thirty-seven of these errors out of 389 deviations were rate related (9%) and 3 were caused by programming errors. The severity ratings of these errors required that 29 have increased monitoring and determined that 4 were likely to cause temporary harm, 1 was likely to result in increased hospitalization, and 3 could have produced permanent harm.

Unauthorized/wrong drug. Several case reports and advisories are about one of the safety fea-

tures of the PCA device being circumvented when the button is pushed by others. Family members and health professionals have administered doses for patients, by proxy, hoping to keep them comfortable. Ashburn et al[29] and Sidebotham et al[30] documented that 3 out of 14 PCA-related adverse events were caused by family members pushing the button while the patient slept. A report from the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) indicated that 15 of 460 PCA-related errors were caused by unauthorized people pushing the PCA button; 12 of 15 cases were attributed to family members, 2 to a nurse, and 1 to a pharmacist.[37]

Another type of error occurs because the opioids used in the PCA pumps have similar packaging with similar names: morphine and hydromorphone. These opioids, which often are not easy to differentiate from one another, are also available in higher concentrations, a potential source of error. For example, many devices allow entry in either mL or mg; if morphine at a concentration of 1 mg/mL is mistakenly replaced with hydromorphone 1 mg/mL and the pump is programmed to deliver a 1 mL dose, the result is a 5-fold overdose because of the potency differences of the drugs.[38]

Grading of Evidence

On the basis of the evidence in these case reports and epidemiologic surveys, all members of this workshop agreed that the level of evidence available regarding this statement was Category III (evidence obtained from case series, case reports, or flawed clinical trials) (Table 1).

Level of Support for Statement

Because of the paucity of data on technological issues and the similarity between pumps used to deliver IV PCA and epidural infusions, the same data were used to address the safety and effectiveness of both routes of delivery. On the basis of the available evidence, the workshop participants voted their level of support was Category B (fair evidence to support the statement) (Table 1). In the group at large, 27% (3 of 11) of the summit participants voted "1" (to accept the statement completely), 55% (6 of 11) voted "2" (to accept the statement with some reservations), and 18% (2 of 11) voted "4" (to reject the statement with reservations); none voted for "3" (accept with major reservations) or "5" (reject completely) (Table 1). This result was compared with the vote of the ASRA membership of 13% for "1," 34% for "2," 10% for "3," 32% for "4," and 11% for "5" (Fig 4).

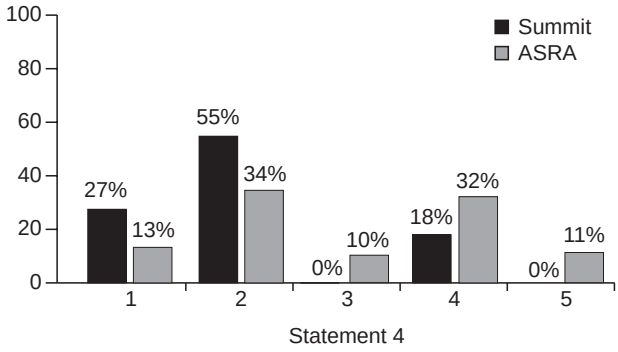

Fig 4. Voting comparison for Statement 4 (Technology-related problems limit the safety and effectiveness of IV and epidural PCA). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Discussion

Although currently used pain technology has improved patient satisfaction, the limited evidence indicates that the technology has been far from infallible. The majority of the members attending the summit recognized the limitations and safety concerns associated with our current technology; the most prominent concern is programming errors associated with infusion devices. The views of ASRA members who participated in the survey differed from those of the faculty at the summit, but the majority did accept that technology is problematic.

Future Directions

Many of the technological limitations to the use of PCA and epidural analgesia can be addressed by modifying existing technology. Redesigning the software of commercially available PCA pumps can reduce the number of human programming errors.[35] Smart pumps with preprogrammed hard and soft limits on the amount of analgesic that can be infused may reduce programming errors. However, a prospective review of infusion pumps only identified a small percentage of errors that would be reduced by employing this technology.[36] Another potential way to reduce programming errors would be to equip the PCA devices with bar-code readers that would prevent entry of the wrong drug or concentration; a number of devices that incorporate bar-code technology are now available. Other options include a patient-activated fentanyl transdermal system, a disposable, self-contained PCA device that has been demonstrated in controlled trials as

equivalent to standard IV PCA with morphine that eliminates the potential for human programming errors.

Statement 5

New and emerging therapies offer advantages over existing analgesic options for treating postoperative pain.

Rationale and Definition of Statement

Current data suggest that patients are likely to experience significant pain after surgery. Although recent pain initiatives and pain guidelines exist, statistics on pain after surgery have remained largely unchanged.[39] Under ideal conditions, available technologies may provide reasonable control of postoperative pain. However, these technologies have a number of problems that limit results. Invasive technologies that have indwelling catheters and external pumps are perceived to be cumbersome and labor intensive. Such pumps are also implicated in medication errors that lead to patient harm.[40] Additionally, mechanical delivery systems have an inherent failure rate related not only to the pump but also to the catheter and tubing. Consequently, patients may experience analgesic "gaps" or periods of unrelieved pain.[41]

New and emerging technologies may offer advantages over older technologies by reducing failure rate, improving safety, and eliminating analgesic gaps. Newer technologies may facilitate patient mobility, be compatible with anticoagulation protocols, and reduce burdens on health-care providers.

Two technologies meet the criteria of new and emerging techniques. Fentanyl HCl Patient Activated Transdermal Analgesia (PATS) (IONSYSTM; Ortho-McNeil, Raritan, NJ) is an iontophoretic needle-free, active-drug delivery system. Extended Release Epidural Morphine (DepoDur; Endo Pharmaceuticals, Chadds Ford, PA) is a liposomal morphine preparation for epidural administration that was recently approved by the FDA. Both technologies may address unmet needs associated with existing approaches to the treatment of postoperative pain.

Literature Search

Literature review included all published papers found on the MEDLINE database for the respective technologies. Because both technologies are new, available literature is rather limited and related to studies from the drug-approval process. Results of 6 well-designed RCTs are published—3 for each technology at this time.

Fentanyl HCl PATS

Fentanyl HCl PATS is a small, needle-free, self-contained delivery system about the size of a credit card that delivers small charged molecules by iontophoresis. The system is preprogrammed to deliver fentanyl (40 μg) over 10 minutes upon patient demand, up to 80 doses a day. The system deactivates after 24 hours of use, or 80 doses. The fentanyl HCL PATS was granted marketing authorization by the European Commission in January 2006; approval by the FDA is pending.

To date, 3 pivotal trials have been published, including an open-label comparison with a standard morphine IV-PCA protocol and 2 double-blind, placebo-controlled trials. These trials were intended to demonstrate safety and efficacy, not superiority to standard therapy.

Fentanyl HCl was compared with a standard morphine IV-PCA protocol in an open-label randomized study of 320 patients.[42] Patients reported similar global assessments of treatment success between the groups. Withdrawal because of inadequate pain control and last pain score were similar between the groups. The adverse-event profile was also similar between the groups and reflected typical opioid-related side effects.

Two additional studies compared fentanyl HCl PATS to an identical placebo system.[43,44] Both studies demonstrated superiority over placebo. Additionally, these trials also demonstrate a side-effect profile typical of opioids, with both fentanyl HCl PATS and morphine via IV PCA.

None of the trials published thus far were intended to examine potential benefits over standard therapy. Several studies presented as abstracts explore some of these issues. A resource-utilization study of IV PCA of 540 patients identified an average of 39 nursing interventions per patient, which suggests that standard IV PCA is complex and labor intensive.[45] Another abstract identified problems associated with IV-PCA pumps found in the MAUDE database.[32] Although these data showed 79.1% to be device-related, 6.5% were identified to be user errors, which suggests that operator error is a significant source of IV PCA–related problems. In a recent abstract that compared "ease of care" as rated by patients, nurses, and physical therapists with fentanyl HCl PATS *v* morphine IV PCA, Phillips[46] suggests that less-invasive technology may be preferable.

Extended-Release Epidural Morphine

Extended-release epidural morphine (EREM) exploits a lysosomal carrier (DepoFoam; SkyePharma, San Diego, CA), which consists of naturally occur-

ring lipids, that provides an extended period of drug release without the need for an indwelling epidural catheter. Three randomized, double-blind trials explore the safety and efficacy of EREM compared with placebo plus IV-PCA fentanyl or with standard epidural morphine in several surgical models.

EREM was compared with a placebo saline epidural with IV-PCA fentanyl in a hip arthroplasty study.[47] Patients who received placebo demonstrated a consistent need for supplemental fentanyl, whereas patients who received EREM had a significantly reduced need for rescue within 48 hours. Additionally, patients who received EREM demonstrated better control of pain during the 0 to 24-hour period after surgery. Adverse events were consistent with those expected with the use of any opioid analgesic. Up to 4% of patients required an opioid antagonist across all trials.[48] However, these trials were dose-finding studies, with some doses in excess of the approved doses. Also, the trials utilize opioid monotherapy, not opioid-sparing multimodal therapy, as practiced by most clinicians. Hence, these numbers may represent something of a "worst-case scenario" for respiratory depression. At recommended doses, all incidents of respiratory depression occurred by 16 hours. EREM was compared with standard epidural morphine for lower abdominal surgery.[49] Patients who received EREM demonstrated a reduction in supplemental fentanyl requirements over 48 hours. In a caesarean-delivery study, EREM was compared with standard epidural morphine.[50] Patients who received EREM demonstrated reduced need for analgesic supplement, better pain scores, and better functional ability over 48 hours.

Grading of Evidence

On the basis of these studies, members of this workshop agreed that the level of evidence available to support this statement was Category Ib (evidence from at least one well-designed, randomized, controlled trial) for both new technologies presented (Table 1).

Level of Support for Statement

On the basis of the available evidence, the level of support for this statement was assessed separately for each new technology. The results of 3 multicenter trials are published for each.

For both technologies, workshop members rated the level of support for this statement as Category C (poor evidence to support the statement but recommendations may be made on other grounds) (Table 1) but recognized that these trials were not designed to address the statement as written.

When the group at large voted on the support of this statement for fentanyl HCl PATS, none of the summit participants voted "1" (accept completely), 27% (3 of 11) voted "2" (accept with some reservations), 64% (7 of 11) voted "3" (accept with major reservations), 9% (1 of 11) voted "4" (reject with reservations), and none voted "5" (reject completely) (Table 1). This result was compared with the ASRA membership of 4% for "1," 29% for "2," 23% for "3," 14% for "4," and 6 % for "5" (Fig 5A). Of the ASRA participants, 24% had not heard of this technology.

When voting on the support of this statement for epidural extended-release liposomal morphine, none of the summit participants voted "1" (accept completely), 9% (1 of 11) voted "2" (accept with some reservations), 73% (8 of 11) voted "3" (accept with major reservations), 18% (2 of 11) voted "4" (reject with reservations), and none voted "5" (reject completely) (Table 1). This result was compared with the ASRA membership of 5% for "1," 35% for "2,"

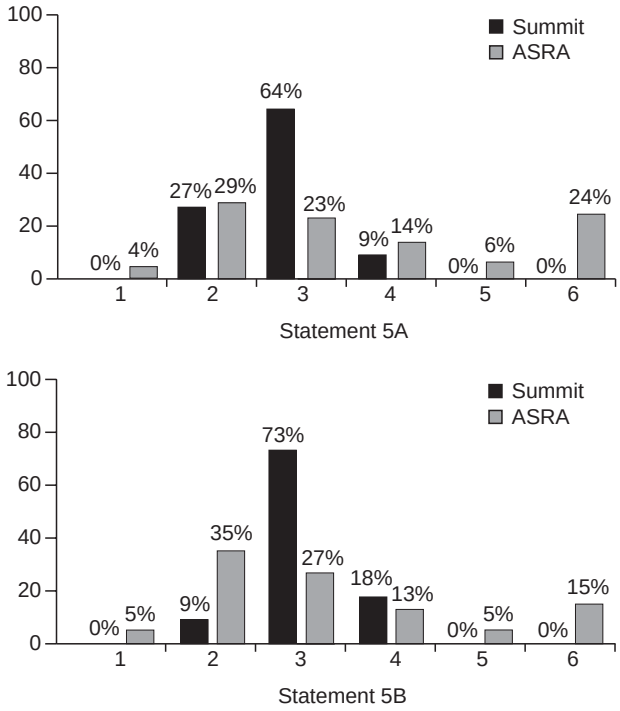

Fig 5. Voting comparison for Statement 5 (New and emerging therapies offer advantages over existing analgesic options for treating postoperative pain). (A) Iontopheretic transdermal fentanyl therapy. (B) Extended-release morphine therapy. Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

27% for "3," 13% for "4," and 5% for "5" (Fig 5B). Surprisingly, 15% of the ASRA participants had not heard of this already-approved technology.

Discussion

On the basis of the available evidence, the statement that new and emerging therapies offer advantages over existing therapies is not well supported. However, the purpose of these studies was not to demonstrate superiority, but rather to show safety and efficacy compared with standard therapy or placebo. This study is typical of studies designed for the drug-approval process. After approval, further studies are needed to evaluate potential advantages in a clinical setting.

Studies with fentanyl HCl PATS demonstrated analgesia with a preprogrammed system and without the need for an intravenous delivery of drug. Likewise, studies with EREM successfully demonstrate 48 hours of analgesic effect with a single dose, with a significant reduction in the need for supplemental analgesics during the first 48 hours after surgery.

Future Directions

Carefully designed future studies will be needed to explore and confirm these observations. Workshop participants recognized the limitations of the initial trials that are part of the drug-approval process. These studies are not intended to address advantages over existing therapy in most cases, but to establish the safety and efficacy of a novel technology. Hence, the level of support for the statement is not unexpected at this point or predictive of actual clinical advantage. Future studies should be designed to reflect actual clinical practice and evaluate complex comparisons to existing therapies. Also, validated instruments to address questions such as ease of use and burden of care must be used or created.

Statement 6

The creation and dissemination of acute-pain guidelines has improved postoperative-pain management.

Rationale and Definition of Statement

Clinical-practice guidelines (CPGs) are systematically developed statements meant to assist practitioners and their patients in making decisions about appropriate health care for specific clinical conditions. Originally designed as a tool to control costs of Medicaid and Medicare programs, CPGs are now commonly viewed as a means to introduce evidence into practice and make positive contributions to the quality and outcomes of care. Definitive reviews of CPGs in other areas of health care have demonstrated improvement in the quality of clinical decisions.[51-53] However, little is known about the impact of CPGs, specifically the American Society of Anesthesiologists (ASA) "Practice Guidelines for Acute Pain Management in the Perioperative Setting,"[4] on practice behaviors and patient outcomes. Developed in 1994 and updated in 2004, the ASA CPG currently serves as the most relevant guideline for individuals who manage perioperative pain.

Literature Search

Since the 1980s, CPGs have proliferated to number more than 1,000 documents approved through the National Guideline Clearinghouse (NGC).[54] A search of the NGC Web site (www.guideline.gov) by use of the words "acute pain management" generated 433 relevant guidelines, including the ASA acute-pain management CPG. A search for outcome studies of the ASA acute-pain guidelines by combining the text words "practice guideline" (PG) or "clinical guidelines" (CG), "pain," and "effectiveness" resulted in 26 abstracts, none of which addressed the ASA guidelines. A combination of only "practice guidelines" and "evaluation studies" identified 162 relevant abstracts that were further examined for relevance to the statement. Additionally, key citations were reviewed from a recent literature search performed and previously described for a revision of the American Pain Society quality-improvement recommendations.[55]

Evidence

We reviewed only investigations specific to pain-management CPGs and rigorous systematic reviews of guideline-evaluation studies. However, 1 study was included to allow a better understanding of the phenomenology of CPGs.[56] A total of 5 clinical studies and 2 systematic reviews on the effectiveness and efficiency of guideline dissemination and evaluation were included in our final analysis. The first clinical study reviewed is a prospective RCT of 26 medical oncologists in outpatient-clinic settings.[57] The primary objective was to compare a guideline-based cancer-pain algorithm to standard practice. Implementation of an algorithm-based cancer-pain management guideline that standardized analgesic drug choice and side-effect management demonstrated that guideline implementation could enhance pain outcomes. Patients randomized to the pain-algorithm group achieved a significant

reduction in usual pain intensity, when compared with standard practice ($P < .02$).

The second clinical study was the only reference found specific to acute postoperative-pain management. The outcomes of the national Post-Operative Pain Management Quality Improvement Project were described.[58] The intervention consisted of written resource materials, including the ASA acute-pain guidelines, accompanied by support services that included an e-mail listserve, a resource Web page, and assistance from project staff via telephone. Data regarding critical structures, processes (practice patterns), and patient outcomes were collected from 56 hospitals at baseline and at follow-up 12 to 18 months after implementation. Results revealed a significant increase in the presence of structural elements that are critical to improvement of pain management from baseline (45%) to follow-up (72%). Improvements in practice were significant, including documented use of pain-rating scales, decreased use of IM opioids, and increased use of nonpharmacologic strategies. Patient outcome data were collected, including pain intensity, pain interference with life activities, and overall satisfaction with pain management.[59] Patient-survey data revealed no change in these pain outcomes. The study was limited by voluntary reporting of data, emphasis of the project on changes in structure as opposed to treatment practices, and the short time frame from implementation to follow-up.

The third clinical study, a randomized controlled trial, examined implementation of the Dutch Low Back Pain Guideline for general practitioners and found small changes in patient management.[60] General practitioners in the intervention group (n = 21) received the Dutch pain guideline, a clinical practice workshop, scientific articles on low-back pain management, the guideline for occupational physicians, a tool for patient education, and a tool for reaching agreement on low-back care with physical therapists. The control group (n = 20) received no intervention. Guideline implementation resulted in fewer inappropriate follow-up referrals to physical therapy. However, no differences were noted in patient education, initial referral to physical therapy, or prescription of pain medicine.

The fourth and fifth clinical studies examined organizational predictors to CPG implementation success. Although not specific to pain management, both articles provide important context to understanding barriers to guideline development, dissemination, and evaluation. One study utilized qualitative open-ended interviews with 45 key physician, nursing, quality management, and administrative participants from 8 hospitals in the United States to identify factors that influence the success of efforts to increase beta-blocker use after acute myocardial infarction.[56] The interviews revealed 6 factors that can be used to classify efforts to adopt guideline recommendations. Four characteristics were found only in hospitals where practice improvement was seen and included shared goals for improvement, substantial administrative support, strong physician leadership that advocated change, and use of credible feedback data (Table 4). The other study examined adherence to 3 screening CPGs (depression, tobacco use, and alcohol use) and included 114 acute-care facilities and use of 3 large databases from the American Hospital Association and Veterans Administration.[61] Specific organizational factors were important: mission, capacity, professionalism, and patient-population characteristics were highly significant predictors that confirmed the importance of organizational context for guideline adherence (Table 5).

The 2 review articles included in our analysis provided further evidence of the complexity of examining outcomes of CPGs. A Cochrane review examined the effects of CPGs on nursing, midwifery, and allied health and found insufficient evidence to draw conclusions.[62] Eighteen studies that involved more than 467 health-care professionals were included in the review. Most used inadequate study methods. The authors suggest that knowledge of barriers and incentives to change drawn from observational studies, as well as available theories and models of the change process, should be utilized when implementing CPGs.[63] In the second systematic review analyzed, Grimshaw et al.[64] used MEDLINE, Healthstar, Cochrane Controlled Trial Register, EMBASE, SIGLE, and the specialized register of the Cochrane Effective Practice and Organisation of Care (EPOC) group to examine 235 studies that reported 309 comparisons of CPG-implementation strategies. Most interventions, including educational outreach, reminder systems, audit and feedback, use of local opinion leaders, and computerized information systems, were shown to be effective under some circumstances; however, none were effective under all circumstances. The observed effects both within and across implementation interventions were shown to be variable and at best relatively weak (mean 10%, range −1 to +34%).

Table 4. Factors Seen in Hospitals That Successfully Implemented Clinical-Practice Guidelines

Shared goals for improvement
Substantial administrative support
Strong physician leadership advocating change
Use of credible feedback data

Table 5. Hospital Organizational Characteristics That Influence CPG Adherence in a Large Multiinstitutional Sample That Involved Multiple Provider Practices

Mission	Council of Teaching Hospitals members *v* nonmembers; hospitals with approved residency training programs *v* those without
Capacity	Total beds set up and staffed, nonemergency outpatient visits, physician FTEs per 1,000 outpatient visits, organizational resources (created as a ratio of staff to patients by dividing FTEs by the average daily census), and inpatient occupancy
Professionalism	Proportion of all FTEs represented by registered nurses (RNs)
Patient population	Average number of conditions, race, age, and length of stay

Grading of Evidence

On the basis of the evidence of these 2 randomized trials, 1 qualitative study, 2 descriptive studies, and 2 systematic reviews, all members of this subsection of the workshop agreed that the level of evidence available regarding this statement was Category Ib (evidence obtained from at least 1 well-designed randomized, controlled trial) (Table 1).

Level of Support for Statement

Level of workshop support was Category C (poor evidence to support the statement, but recommendations may be made on other grounds) (Table 1). When the group at large voted on support of this statement, 55% (6 of 11) of the summit participants rejected the statement with reservations ("4"). None of the participants completely agreed ("1") or disagreed ("5") with the statement. Nine percent (1 of 11) accepted the statement with some reservation ("2"), and 36% (4 of 11) accepted with major reservation ("3") (Table 1). This result was compared with the vote of the ASRA membership of 37% for "1," 42% for "2," 11% for "3," 8% for "4," and 2% for "5" (Fig 6).

Discussion

Many believe that the creation and dissemination of evidence-based guidelines would lead to improvements in the quality and outcomes of care. Unfortunately, a paucity of evidence is available for acute-pain management guidelines and conclusions are difficult to draw from studies of guidelines in other areas of health care. To assume that simply making a CPG available through passive dissemination will result in its application by practitioners is naive.

Caution is advised because unintended negative outcomes can result from a misinterpretation of guideline recommendations or from inappropriate decisions made in the care of individuals with complex comorbidities whose care falls under overlapping and potentially conflicting guidelines.[65] For example, in 2001, JCAHO released pain assessment and management standards. Although the JCAHO standards are not CPGs, they directly reiterate recommendations of institutional responsibility provided in available evidence-based CPGs developed by groups such as the American Pain Society (APS) and the Agency for Healthcare Research and Quality (formerly the Agency for Healthcare Policy and Research). "Make Pain Visible" became a central theme in many settings, leading to the genesis of the now familiar "Pain As a Fifth Vital Sign" campaign. In response, many institutions implemented treatment policies guided by patient pain-intensity ratings indexed with a numerical scale. The Institute for Safe Medication Practices (ISMP) soon took notice that overaggressive pain management appeared to be linked to an alarming increase in oversedation and fatal respiratory-depression events.[66] In one setting alone, the incidence of opioid oversedation adverse-drug reactions per 100,000 inpatient hospital days increased from 11.0 before use of a numerical pain-treatment algorithm to 24.5 after implementation ($P < .001$).[67] In response to this confusion, and to support what was stated earlier (that the "fifth vital sign" slogan was never intended to mandate treatment of pain intensity as a fifth vital sign), that implementation model has been removed from all standards manuals.[68] The American Medical Association Council on Scientific

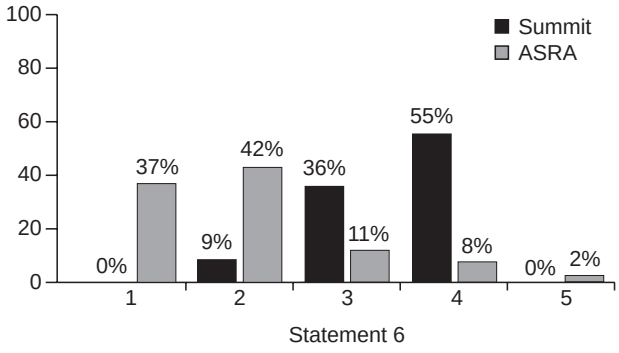

Fig 6. Voting comparison for Statement 6 (Creation and dissemination of acute-pain guidelines has improved postoperative-pain management). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Affairs (CSA) concluded that much of physicians' concerns regarding the JCAHO pain-management standards reflect a misunderstanding of the actual requirements of the standards.[69]

Confusion has persisted about the requirement of the JCAHO to specify PRN-range opioid orders for acute pain in institutional policies.[70] Statements on the JCAHO Web site implied that organizations could no longer use PRN-range orders for analgesic medications without specific implementation protocols. Again, institutions felt pressured to develop rigid, unsafe policies or protocols that would specify opioid doses on the basis of numeric pain-intensity ratings. The JCAHO has since clarified that their intent is not to dictate prescribing, but rather to assure patient safety. Range orders should be written in a way to assure that the physician who ordered the medication and the nurse who administers it has the same understanding of how the patient will be treated. The original intent of a CPG is to assist clinical decision making. An important lesson learned is that this original intent can be misconstrued during translation to practice and create a risk of diminished safety and quality of care.

Future Directions

Guideline implementation is a complex phenomenon and likely to be most successful when multifaceted interventions are used to introduce and implement the guideline, and strategies are based on an assessment of potential barriers. Rather than a specific type or number of intervention strategies, barriers and incentives to change in practice should be identified, categorized, and used to tailor interventions to facilitate desired changes.

When guidelines are promulgated, they should include an implementation and evaluation plan, developed by the implementer, that includes both qualitative and quantitative data. Evaluation studies should not be limited to expensive, sophisticated clinical trials. Measuring outcomes from any kind of practice guideline is in its infancy and much work is needed.

Statement 7

Poorly controlled postoperative pain leads to an increased likelihood of chronic pain.

Rationale and Definition of Statement

Over the past decade, a number of papers have concluded that more severe postoperative pain is a risk factor for the development of chronic pain after surgery.[71] This prospect raises the question of whether interventions that decrease acute postoperative pain can also decrease the incidence of chronic postoperative pain.

As discussed in a recent review,[71] we have defined acute postoperative pain as pain at the surgical site or sites during the 2 weeks immediately after the surgical procedure. Chronic postoperative pain is pain at the surgical site or sights longer than 3 months after the surgical procedure, and time zero is the most recent surgical procedure at the site of interest.[71] Pain must have been measured in the cohort in a consistent manner and the data must have been gathered systematically. Interventions to decrease acute postoperative pain, including the use of local anesthetics administered as regional or epidural anesthetics, or the use of adjuvant analgesics—such as anticonvulsants (eg, gabapentin), antidepressants (eg, venlafaxine), or NMDA inhibitors—to decrease acute pain or modify the incidence of chronic pain were examined. Because the surgical approach has a significant effect on acute pain, it was also examined. In most cases, the control population received opioids and NSAIDs for pain control; in some cases, the amount of opioid consumed was used as a surrogate measure for the acute-pain response to the operative procedure.

Literature Search

For the database search, the term "pain, postoperative" (8,121 articles) was combined with the text word "chronic pain" (4,728 articles) and they yielded 188 citations. These results were then limited to "English language" and "meta-analysis" and yielded 2 citations, neither of which were appropriate to the search by hand. The 188 articles were then limited to "English language" and "review" and yielded 44 citations whose abstracts were reviewed, and of which 15 had some pertinence to the literature search. The terms "hernia, inguinal" or "hernia" or text word "hernia" (10,442 articles), or the term "mastectomy" or word "mastectomy" (6,592 articles), or the term "thoracotomy" or word "thoracotomy" (5,958 articles) were combined (22,791 articles). The results were then combined with the 188 pain citations above and yielded 64 citations, which when limited to "English language" and "clinical trial," yielded 15 citations. Those abstracts were reviewed, and 14 were determined to have some pertinence. The full texts of the 29 citations identified by the database screen were read. Articles previously identified in a detailed literature search were also used.[71]

Evidence

A meta-analysis of the subject of acute-pain intensity and subsequent chronic pain does not exist.

A thorough review of the relation between acute-pain intensity and the development of chronic pain was done, and the authors conclude that increased acute-pain intensity is a predictor of chronic pain in conditions such as postherpetic neuralgia and low-back pain.[72] Whether generalizations can be made to all chronic pain after surgery is not clear. For this analysis, 3 specific surgical repairs were examined.

Chronic pain after inguinal hernia repair was of interest because of the high frequency of this surgery, with estimates of 500,000 to 700,000 operations a year in North America. Even if a small percentage of these patients were to develop chronic pain, a large number of people in the population would be affected. For inguinal hernia repair, 2 recent reviews are available, and both identify high levels of postoperative pain as a risk factor for chronic pain.[73,74] As noted in 1 review, the frequency of chronic pain varied from 0% to 53%, but only 6 studies had chronic pain as a specified endpoint, and in those studies, chronic pain was found in 15% to 53% of patients.[73] They concluded that approximately 10% of patients appear to have moderate to severe chronic pain after inguinal hernia repair. In addition to the intensity of acute postoperative pain, other predictive factors for chronic pain include: preoperative pain, female gender, surgery for a recurrent hernia, and open surgery (Table 6). A recent meta-analysis that compared laparoscopic hernia repair to open hernia repair found evidence that laparoscopic repair was associated with less acute and chronic pain.[75] Open-mesh hernia repair may also have less acute and chronic pain.[76]

After mastectomy, with or without axillary dissection, an estimated 30% or more of women experience some chronic surgery-related pain at 12 months.[71] A recent review concluded that the most frequent type of postmastectomy pain is neuropathic pain.[77] The intensity of acute pain is a predictor of chronic pain, as is the amount of opioid consumed in the period after surgery.[71,77] Additional risk factors for chronic pain include immediate adjuvant radiation therapy and surgery type.[71] Less invasive surgical approaches, such as sentinel-node biopsy, are associated with less acute and chronic pain. Sentinel-node biopsy is also associated with less intercostobrachial nerve dysfunction.[78] A number of recent studies have looked at the use of paravertebral local-anesthetic blocks or thoracic epidural local-anesthetic analgesia to reduce acute postoperative pain.[79-82] Long-term follow-up studies have not yet been published, but the prolonged decrease in pain after a preoperative paravertebral block may well be associated with less chronic pain.

Table 6. Predictive Factors for Chronic Pain after Surgery

Predictors of chronic pain after hernia surgery
Intensity of acute postoperative pain
Preoperative pain
Female gender
Surgery for recurrent hernia
Open surgery
Predictors of chronic pain after mastectomy
Intensity of acute postoperative pain
Amount of opioid consumed in the period after surgery
Immediate adjuvant radiation therapy
Axillary dissection (when compared with sentinel node biopsy)

After thoracotomy, the prevalence of chronic pain approaches 50% at 12 months.[71,83] More intense acute pain predicts chronic pain. Three studies document that use of continuous thoracic-epidural analgesia in the perioperative period is associated with a decreased prevalence of pain at 6 months.[84-86] Two of these studies compared preincisional epidural local anesthetics to postincisional dosing; both studies found less acute postoperative pain and less chronic pain with preincisional dosing. Continuous thoracic paravertebral block has been reported to achieve superior or equivalent postoperative analgesia when compared with epidural analgesia, but long-term follow-up studies on chronic-pain prevalence have not been published.[87,88] Thoracoscopic surgery appears to be associated with less acute and chronic pain.[71,89]

The use of adjuvant analgesics (eg, antiarrhythmics, anticonvulsants, antidepressants, and NMDA receptor blockers) to decrease acute pain and prevent chronic pain has not been well studied. Fassoulaki et al.[90] noted that either gabapentin or mexiletine decreased acute postoperative analgesic use after mastectomy, and burning pain at 3 months was decreased. Venlafaxine did not significantly alter either postoperative pain at rest or analgesic consumption after mastectomy, but pain with movement was decreased; at 6 months, the prevalence of pain was significantly less in the venlafaxine group.[91] Definitive studies on the use of perioperative NMDA blockers such as ketamine or dextromethorphan are lacking.

Grading of Evidence

On the basis of studies, members of this workshop agreed that the level of evidence available to support this statement was Category II (evidence obtained from well-designed cohort or case-controlled studies) (Table 1). Appropriately blinded randomized, controlled studies are lacking.

Level of Support for Statement

The workshop level of support was Category A (good evidence to support the statement) (Table 1). The literature supports the observation that more intense acute pain is a risk factor for chronic pain. Less-invasive surgical approaches, such as laparoscopic hernia repair, sentinel-node biopsy, and thoracoscopic chest surgery, appear to be associated with less acute and chronic pain. Use of local anesthetics via the epidural route is associated with a lower frequency of chronic pain after thoracotomy and with less acute pain. This approach is most effective if the epidural is dosed before skin incision and then analgesia is continued. Paravertebral block with local anesthetics has documented prolonged postoperative analgesia after breast surgery or thoracotomy, but long-term follow-up studies have not been published.

When the group at large voted on support of this statement, 82% (9 of 11) of the summit participants voted "2" (accept with some reservations); one vote was for "1" (accept completely), and one vote was for "3" (accept with major reservations); no votes were for "4" (reject with reservations) or "5" (reject completely) (Table 1). The ASRA membership voted 36% for "1," 37% for "2," 14% for "3," 10% for "4," and 3% for "5" (Fig 7).

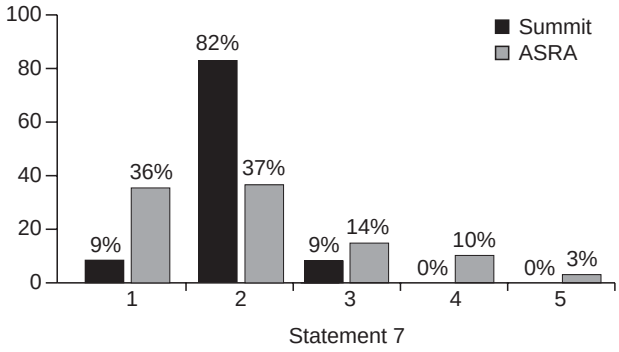

Fig 7. Voting comparison for Statement 7 (Poorly controlled postoperative pain leads to an increased likelihood of chronic pain). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Discussion

Chronic pain after surgery is a significant problem. Many patients report that pain interferes with daily activities after hernia surgery.[92,93] Functional impairment is also common after mastectomy and thoracotomy.[71] More intense acute postoperative pain, indicated by either higher pain scores or more opioid use or both, is a predictor of chronic pain. Interventions that decrease postoperative pain and opioid use, such as minimally invasive surgical procedures or effective local-anesthetic block, are associated with less chronic pain. Perioperative use of adjuvant analgesics may also decrease acute and chronic pain.

The statement "Poorly controlled postoperative pain leads to an increased likelihood of chronic pain" is broad, and it does not address why some patients have more acute pain than others. As worded, the statement also implies a causative link between poorly controlled postoperative pain and chronic pain, rather than an association between the two. Yet, the literature supports the observation that more intense acute pain is a risk factor, not a causative factor, for chronic pain. Indeed, those who experience more severe pain after surgery may well go on to develop chronic pain regardless of our best efforts to control their pain. For any individual patient, the appropriate perioperative pain management will depend on a number of factors other than the proposed surgery. Factors not addressed in this focused statement include management of preexisting pain at the operative site, patients with chronic pain at other sites, and psychosocial risk factors and their management. Also, individual differences in pain sensitivity do exist, which makes broad statements questionable as to the "best" management of a population of patients undergoing a specific surgical procedure.[94]

Future Directions

Future directions discussed by the summit participants reflect the problems of trying to prevent an adverse outcome that not everyone will experience. For the individuals who will not experience significant acute pain and are at low risk for chronic pain, adding medications and interventions offers little benefit and probably some risk. Can these low-risk individuals be identified prospectively? For individuals at high risk, which interventions will provide the most benefit? Prospective studies are needed to address numerous questions in this area.

Statement 8

Use of continuous postoperative epidural analgesia leads to improved patient outcomes when compared with parenteral opioids in patients with preexisting cardiovascular and pulmonary disease.

Rationale and Definition of Statement

During the 1980s, the use of epidural analgesia became a favored option for pain control after sur-

gery. Epidural analgesia had been used to provide analgesia for labor and childbirth, utilizing high-dose local anesthetics, and rendering the mothers either totally or partially paralyzed below the waist. It also had been used occasionally to provide postoperative analgesia, particularly after thoracic surgery, even though patients who received this treatment would not be able to ambulate and would need to remain in bed for the duration of the analgesic treatment. These practices changed after endogenous opioids and endogenous opioid receptors were identified in the 1970s, and experimentation began on the administration of opioids directly into the intrathecal or epidural space. The addition of an opioid to the epidural infusate was then found to produce excellent analgesia—subsequently named *selective spinal analgesia* because of the ability of spinally delivered opioids to bind selectively to spinal-cord receptors. The local anesthetic was then either not needed, or, as was subsequently found, could be used in combination with the opioid to provide additional analgesia, but at markedly lower doses than had been used previously. Epidural analgesia for postoperative pain immediately became popularized, and, at least anecdotally, patients were observed to do better—get out of bed sooner, cough without bracing, regain an appetite sooner, and generally appear less prostrate than they had under old treatment regimes. The question remained, however, whether this observed improvement could be substantiated with real data that confirmed an improvement in surgical outcome, and whether the improvement was attributable to superior pain relief alone, rather than to factors such as opioid sparing or sympathectomy. These questions have formed the basis of countless studies undertaken and published since the 1980s that attempted to clarify whether epidural analgesia improves surgical outcome.[95] The question is often focused on patients at risk, as is the present statement, because these patients are most likely to benefit from careful analgesic intervention.

The statement, as worded, produced some difficulty for the workshop members. First, "preexisting cardiovascular and pulmonary disease" is not defined as such in the literature and can only be assumed. The assumption was made either from the measure of general health status used in the trials (typically, ASA grading) or from the surgery itself (eg, cardiovascular disease is assumed to exist in patients undergoing vascular or cardiac surgery). Second, "improved patient outcomes" can be interpreted in many ways. Mortality and life-threatening morbidity have been the outcomes of interest for many investigators and reviewers, but the panel decided that for the present assessment and scoring, "outcomes" would encompass any outcome that might be beneficial to patients, including outcomes generally considered as minor morbidities, such as pain, bowel mobility, and ambulatory capacity.

Literature Search

The literature search was conducted with the subject headings "pain, postoperative" and "analgesia, epidural" and yielded 15,265 and 6,208 articles, respectively. Combining these terms with "OR" yielded 1,621 articles. Eight articles were identified when the search was limited to English language and meta-analysis, and 11 were identified when the search was limited to English language and multicenter study. Upon further review of the 19 meta-analyses and multicenter studies identified by the November 2005 search, only 4 meta-analyses and 1 multicenter study had been correctly identified. By use of hand searches and cross references from this and previous literature reviews, an additional 3 published meta-analyses and 4 published multicenter or large studies (>50 patients) were identified. A total of 6 meta-analyses and 5 large or multicenter studies were identified. All 6 of the meta-analyses[96-101] and 3 of the large studies that were RCTs[102-104] were considered for this review. Two multicenter studies were removed from consideration because of a lack of randomization. These studies also did not specify that their patients were "at risk," so it could not be assumed.[105,106]

Evidence

In 1987, Yeager et al.[107] published a small, randomized study that assessed surgical outcome in high-risk patients who received or did not receive epidural anesthesia and analgesia. Fifty-three patients were included in this study, and the results strongly favored the epidural treatment (reduction in mortality, $P = .04$, overall postoperative complication rate, $P = .002$, incidence of cardiovascular failure, $P = .007$ and incidence of major infectious complications, $P = .02$). Although the anesthesia community embraced these findings as validation for epidural analgesia and its ability to improve surgical outcome, several groups felt that anesthesia practice should not be driven by the results of such a small trial. Some set about conducting large, multicenter studies attempting to reproduce the findings of Yeager et al,[107] specifically in high-risk patients undergoing major procedures. Park et al[102] published their results of a 1,021-patient multicenter randomized trial in 2001. In contrast to Yeager et al,[107] these authors found no significant differences in mortality or rates of major (life-threatening) complica-

tions, except in the subset of patients undergoing abdominal aortic aneurysm (AAA) surgery. In AAA patients, the overall incidence of death and major complications was significantly lower in the epidural group (22% *v* 37%, $P < .01$), attributable to lower rates of respiratory failure ($P < .01$), new onset stroke ($P = .03$), new myocardial infarction ($P = .05$), and overall cardiovascular complications ($P = .03$). In 2002, Rigg et al[103] published results of an Australian multicenter randomized study that comprised 915 patients. They found no significant differences in mortality or major morbidity, except for a lower incidence of respiratory failure in the epidural group ($P < .02$). A later reanalysis of the Australian data, in which respiratory depression from the assessment of respiratory failure was removed, found no difference in respiratory failure overall but did find a small difference in the duration of postoperative ventilation ($P = .048$).[104] On the strength of these large RCTs, a claim that epidural anesthesia and analgesia reduces mortality can no longer be made (expect possibly in the case of AAA surgery), although the large RCTs do support an improvement in some potentially disastrous outcomes, most notably pulmonary outcomes.

Meta-analyses have tended to be more targeted than these large randomized trials. A 1998 meta-analysis by Ballantyne et al.[108] that specifically assessed pulmonary outcomes in relation to a number of analgesic interventions found that epidural analgesia with local anesthetic produced lower rates of hypoxia ($P = .047$), pulmonary infection (RR 0.36, $P < .001$), and pulmonary complications overall (RR 0.58, $P < .001$). A 2001 meta-analysis by Beattie et al.[98] that specifically assessed cardiac outcome, found a reduced incidence of myocardial infarction in patients who received epidural analgesia ($P = .049$). More recently, Liu et al.,[96] in a meta-analysis of trials that assessed epidural analgesia in patients undergoing coronary artery bypass grafting (CABG), found no differences in mortality or myocardial infarction but did find differences in rates of cardiac arrhythmias (odds ratio 0.52, $P = .03$), time to extubation (weighted mean difference −4.5 h, $P = .0005$), and pulmonary complications overall (odds ratio 0.41, $P < .00001$). Apart from these specific findings related to cardiac and pulmonary outcomes, the meta-analyses agree with the large RCTs in finding no differences in mortality or major morbidity attributable to perioperative epidural anesthesia and analgesia.[98,99,109] Superior analgesic efficacy, on the other hand, is overwhelmingly supported.[97,99-101,110]

Grading of Evidence

On the basis of the quantity of high-level evidence available to make the assessments regarding the present statement (7 meta-analyses and 3 large RCTs), the workshop unanimously agreed that the level of evidence was Category Ia (evidence obtained from meta-analysis, including at least 1 large randomized, controlled trial) (Table 1).

Level of Support for Statement

The consensus of the workshop, before considering of the evidence and before the vote, was that "improved patient outcome" should apply to all outcomes, regardless of whether the outcomes were likely to result in serious (life-threatening) morbidity or mortality. Accordingly, on the basis of the evidence that supported a beneficial effect of epidural anesthesia and analgesia in terms of some measures of cardiac and pulmonary function, and that overwhelmingly supported superior analgesic efficacy, the workshop level of support was unanimously agreed to be Category A (good evidence to support the statement) (Table 1). However, the workshop members also considered the strong evidence of no effect on major morbidity or mortality and agreed that had the statement specified improvement in major morbidity or mortality, their level of support would change to Category E (good evidence to reject the statement) (Table 1). Further, because the evidence on cardiac outcome supported an effect only on myocardial infarction and arrhythmias, with no improvement in cardiac failure or cardiac death, the level of support for overall cardiac morbidity, as distinct from general morbidity, would change to a Category D (fair evidence to reject the statement).

The workshop participants accepted that the existence of cardiovascular and pulmonary disease (as explicitly delineated in the statement) could only be presumed, either from a stated high risk by use of a broad measure of anesthesia or surgical risk (eg, ASA status),[102-104,107] or from the surgical procedure (cardiac,[96] intraabdominal,[101] or hip and knee replacement[99]). Several of the meta-analyses did not specify either high-risk surgery or high-risk patients,[97,98,108] and those that specifically selected high-risk patients (likely, but not necessarily, with cardiovascular or pulmonary disease), were predominantly the large RCTs. The fact that these patients were in a known high-risk category adds weight to the finding that major morbidity and mortality is not improved by epidural analgesia and anesthesia in the stated population.

In the group at large, 45% (5 of 11) of the summit participants voted "2" (accept with some reser-

vation), 27% (3 of 11) voted "1" (accept completely), and 27% (3 of 11) voted "3" (accept with major reservations). None of the summit participants voted to reject the statement ("4" or "5") (Table 1). The ASRA membership voted 43% for "1" and 45% for "2"; therefore, 88% voted to accept the statement either completely or with some reservations. Seven percent had major reservations about accepting the statement, and 5% rejected the statement (4% with reservation and 1% completely) (Fig 8).

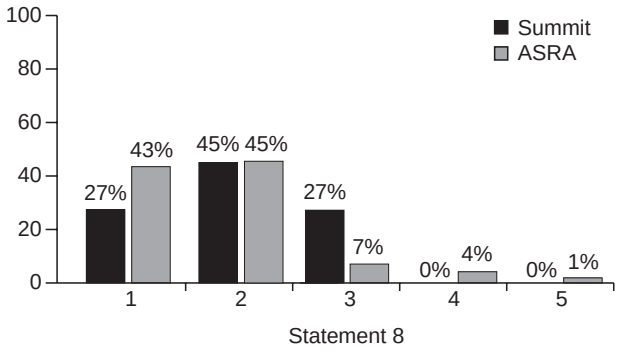

Fig 8. Voting comparison for Statement 8 (Use of continuous postoperative epidural analgesia leads to improved patient outcomes when compared with parenteral opioids in patients with preexisting cardiovascular and pulmonary disease). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Discussion

The statement concerns an area of pain practice that has been intensely studied in an effort to address the issue of whether perioperative epidural anesthesia and analgesia improve surgical outcome. For this reason, the evidence was rated at the highest level (Category Ia) (Table 1). Less clarity exists, however, on the assessment of level of support for this statement. The exact meaning of "improved patient outcome" was the first area of uncertainty. The panel decided to interpret this wording broadly, and, by use of a broad interpretation, voted unanimously for Category A (good evidence to support the statement). However, neither the summit participants nor the ASRA membership had the opportunity to arrive at a consensus on the meaning of "improved patient outcome," which probably explains the uncertainty in their voting. Only 27% of the summit participants and 43% of the ASRA membership accepted the statement without reservation, despite the strong level of evidence.

The second area of uncertainty is the specification that patients had "preexisting cardiovascular and pulmonary disease." As stated above, trials have not been conducted specifically in patients with cardiovascular and pulmonary disease, so the existence of these conditions can only be assumed from the stated high risk of the patients or the surgical procedures. As discussed under "Level of Support for Statement," the fact that the large RCTs provide strong evidence that perioperative epidural anesthesia and analgesia do not improve serious surgical morbidity or mortality in a population that is known to be at risk cannot be ignored. Because of the vagueness of the statement, the statement could as easily be judged strongly supported as strongly rejected on the basis solely of clarification of the statement (ie, all outcomes *v* specific outcomes; all patients *v* only patients with cardiovascular or pulmonary disease).

Future Directions

The summit participants discussed the need to refocus future trials on identifying rare but catastrophic outcomes of epidural catheterization, especially epidural hematoma, which seems increasingly prevalent, at least anecdotally. Pain relief aside, the most important benefits of neuraxial block are thought to be related to the sympathectomy (a local-anesthetic effect), which, in turn, improves blood flow and reduces coagulation, thrombosis, and thromboembolism. Yet modern thromboprophylaxis has surpassed neuraxial block in its capacity to protect against thromboembolism, and in addition, increases the risk of epidural bleeding and hematoma with subsequent spinal-cord or nerve-root compression. Thus, one major benefit is lost, and a significant risk factor is added. Also, as the present review shows, improvement in serious morbidity and mortality is no longer supported, even though epidural anesthesia and analgesia is seen to provide certain circumscribed benefits, including good analgesic efficacy. The present review helps provide a perspective on the state of the evidence that supports continuous postoperative epidural analgesia. Well-designed observational studies could be used to quantify rare but catastrophic outcomes, particularly those related to spinal-cord injury. Such studies could also be used to reassess rates of serious morbidity and mortality related to epidural analgesia, where differences may not be identified other than by very large (observational) studies. This work would contribute considerably to

the quest for well-founded risk:benefit analysis of an intervention for which the primary benefit is pain relief.

Statement 9

Opioid-sparing analgesic regimens result in an earlier return of bowel function after major abdominal surgery.

Rationale and Definition of Statement

Postoperative ileus, usually defined as a transient impairment in bowel motility for more than 3 days after surgery, is common after major abdominal surgery.[111] Ileus may be associated with nausea, vomiting, and stomach cramps and lead to significant abdominal discomfort, which contributes to delayed oral intake, immobilization, prolonged hospital stay, and increased medical expenditures.[112] The pathogenesis of postoperative ileus is multifactorial and includes activation of inhibitory reflexes, release of inflammatory mediators, and the presence of opioids (endogenous and exogenous).[112] Because opioids produce a dose-dependent inhibition of gastrointestinal motility,[113] opioid-sparing analgesic techniques can reasonably be assumed to result in an earlier return of bowel function.

The average duration of postoperative ileus after major abdominal surgery ranges from 0 to 24 hours in the small intestine, 24 to 48 hours in the stomach, and 48 to 72 hours in the colon.[111] The duration of ileus is related to the anatomic location of surgery and occurs after both intraperitoneal and extraperitoneal abdominal surgeries. Colonic surgery is associated with significant postoperative pain and the longest duration of postoperative ileus.[114] Because of the significant variability in the extent of surgical trauma, and the incidence of ileus after "major abdominal surgery," we chose to examine the evidence of opioid-sparing analgesic techniques on postoperative ileus after only colonic surgery.

Literature Search

The literature search was conducted by use of specific text words as follows. "Opioid" and "opioid sparing" were used and combined with the term "OR" (search 1: 93,949 articles). "Colectomy" and "colon" were used to search the database and combined with the term "OR" (n = 11,258). This search was combined with search 1 with the term "and" (n = 10). All final searches were limited by "human" and "clinical trials." After selection of the initial articles, the reference lists of all of the analyzed articles were checked for any additional studies.

Evidence

Few RCTs have examined the effect of opioid-sparing analgesic techniques on the incidence of postoperative ileus. A total of 7 articles were incorporated in our final analyses, which included 1 meta-analysis.[12,110,115-119] Opioid-sparing techniques were aimed at reducing the total doses of either parenteral or epidural opioid analgesics. Chen et al[115] examined the effect of adding ketorolac to intravenous morphine PCA on bowel function after colorectal surgery. This prospective, randomized, double-blind study was designed and adequately powered ($\alpha = 0.05$ and $\beta = 0.8$) to test the primary endpoint that the opioid-sparing effect of ketorolac in PCA morphine can shorten the duration of postoperative ileus by at least 1 day. A total of 79 consecutive patients undergoing elective colorectal resection were randomly allocated into 2 groups who received IV PCA morphine (1 mg/mL) or IV PCA morphine (1 mg/mL) plus ketorolac (1.2 mg/mL). The PCA was programmed to deliver a bolus of 2 mL with a 10-minute lockout interval without a continuous infusion for all patients. The PCA bolus dose was adjusted according to the patient's pain intensity at the time of each daily visit. Patients who received ketorolac demonstrated a 29% reduction in total morphine use for the duration of this study (approximately 6 days) and reported comparable pain scores. The time to first flatus as well as the time to first oral intake was not different between the 2 groups. The time [median (range)] to first bowel movement was significantly ($P < .05$) earlier in the ketorolac group, 1.5 (0.7 to 1.9) days *v* 1.7 (1.0 to 2.8) days in the morphine group. The authors concluded that the addition of ketorolac to PCA morphine has a "limited benefit in shortening the duration of bowel immobility" after colorectal surgery.

Albert and Talbott[116] evaluated the effects of PCA *v* IM morphine on the duration of postoperative ileus after colon surgery. This prospective, randomized, open-label study evaluated patients who received either PCA morphine (n = 32) or IM morphine (n = 30) for 72 hours after colon surgery. Patients assigned to PCA were administered 1 mg of morphine every 10 minutes, which was titrated up or down according to the patients' reported pain scores. Patients in the IM-morphine group were administered 5 to 12 mg of morphine every 3 to 4 hours on an as-needed basis. The specific postoperative day of ileus resolution, as assessed by passage of flatus or stool, as well as the total dose of morphine for the 3-day period, were recorded. This study revealed a significantly ($P < .05$) lower use of morphine [mean (range)] in the PCA group, 69.6 (3

to 133) mg *v* 92.2 (35 to 204) mg in the IM group. Patients in both groups reported similar pain scores. Despite this 25% reduction in 72-hour morphine use, the duration of ileus was not significantly different between the 2 groups. However, a power analysis was not performed for this clinical investigation, which makes the determination of whether these results are clinically meaningful difficult.

In a prospective RCT, Nitschke et al.[12] compared the effect of 3 analgesic regimens for 5 days in patients undergoing colon resection: PCA morphine (n = 31), IM morphine (n = 31), and IM ketorolac (n = 28). IM medications were administered on the basis of "pain scores and nurse's assessment," and PCA morphine doses were determined "individually for each patient" on the basis of weight and age. A basal-rate infusion was utilized for the first 2 postoperative days. Patients were assessed for resolution of postoperative ileus as determined by passage of first flatus. Unlike the previous study,[116] this study revealed significantly (P =.02) lower use of morphine (mean ± SE) in the IM-morphine group (105.9 ± 12.1 mg) compared with the PCA-morphine group (147.4 ± 11.0 mg). Despite this 28% reduction in 5-day morphine use, the duration of ileus was not significantly different between the 2 morphine groups. Similar to the study by Albert and Talbott,[116] the authors failed to perform a power analysis for this clinical investigation, which makes interpretation of the significance of these results difficult. Overall, patients assigned to the ketorolac group passed flatus 1 day earlier than in either of the 2 morphine groups (P = .006). Although ketorolac appears to be more advantageous, 43% declined participation in this study and requested PCA, 18% of patients assigned to ketorolac required additional analgesia, and 32% in the ketorolac group broke protocol and required alternative analgesia.

Several other interventions for postoperative analgesia have been examined after colon surgery. Results from a prospective RCT suggest that mechanical massage of the abdominal wall by use of an intermittent negative-pressure device for the first 7 postoperative days can reduce pain, analgesic use, and the duration of postoperative ileus.[117] The use of guided imagery with audiotapes for the first 6 postoperative days also reduced pain, opioid use, and duration of postoperative ileus.[118]

In addition to parenteral opioid-sparing techniques, other investigators have examined the effect of reducing epidural opioids on the duration of postoperative ileus after colon surgery. A systematic review of RCTs of epidural analgesia for abdominal surgery has concluded that the use of thoracic epidural block with local anesthetics decreases the duration of postoperative ileus compared with the systemic administration of opioid analgesics.[110] A meta-analysis of 5 studies with 261 patients revealed that epidural local anesthetics alone reduced postoperative ileus by 54 hours when compared with systemic opioid administration.[110] Although the addition of an opioid to an epidural local anesthetic may improve analgesic efficacy, the duration of postoperative ileus may be prolonged compared with epidural local anesthesia alone. A meta-analysis of RCTs revealed a 21-hour reduction in postoperative ileus when epidural local anesthetics were compared with epidural opioids and a 16-hour reduction when compared with epidural local anesthetic and opioid infusions.[110] The duration of ileus was similar with administration of epidural opioids compared with systemic opioids.[110]

Only 1 RCT has evaluated whether a reduction in epidural local anesthetic/opioid consumption can reduce the incidence of ileus. This prospective, double-blind, RCT evaluated the efficacy of administering dextromethorphan with thoracic epidural anesthesia and analgesia on bowel function after colonic surgery.[119] Epidural catheters were placed at the T6-12 interspaces, and a test dose of 1% lidocaine was used to confirm the location of the catheter. On arrival to the postanesthesia care unit, all patients were given a patient-controlled epidural analgesia (PCEA) pump and received an initial dose of 10 mL of PCEA solution that contained 0.2% ropivacaine and 0.1 mg/mL. These investigators concluded that the combination of preincisional dextromethorphan, intraoperative thoracic epidural anesthesia, and postoperative PCEA enhanced analgesia and facilitated earlier return of bowel function. Patients administered dextromethorphan required significantly ($P < .0001$) smaller amounts of PCEA (47.1 ± 4.4 mL) to achieve a similar level of analgesia during the first 72 hours compared with 87.9 ± 12.1 mL in the group not given dextromethorphan. This 46% reduction in epidural local anesthetic/opioid use resulted in a significantly ($P < .0001$) shorter time to first passage of flatus (40.8 ± 7.8 hours) compared with the general anesthesia group (66.5 ± 7.8 hours). No other studies to date have examined the effect of administering nonopioid analgesics in combination with epidural analgesics on the duration of ileus after colon surgery.

Grading of Evidence

On the basis of the evidence in these 7 articles,[12,110,115-119] all members of this workshop agreed the level of evidence regarding this statement was Category Ib (evidence obtained from at least 1 well-designed large, randomized, controlled trial) (Table 1).

Level of Support for Statement

On the basis of the available evidence, the overall level of support for this statement was Category C (poor evidence to support the statement, but recommendations may be made on other grounds) (Table 1). However, differences in opinion existed on the level of support for the statement within the subsection of the workshop, with 3 members voting Category C and 2 members voting Category E (good evidence to reject the statement).

In the group at large, 10% (1 of 11) of the summit participants voted "2" (accept with some reservations), 36% (4 of 11) voted "3" (accept with major reservations), 36% (4 of 11) voted "4" (reject with reservations), 18% (2 of 11) voted "5" (reject completely), and none voted "1" (accept completely) (Table 1). In comparison, the ASRA membership voted 50% for "1," 40% for "2," 7% for "3," 3% for "4," and 0% for "5" (Fig 9).

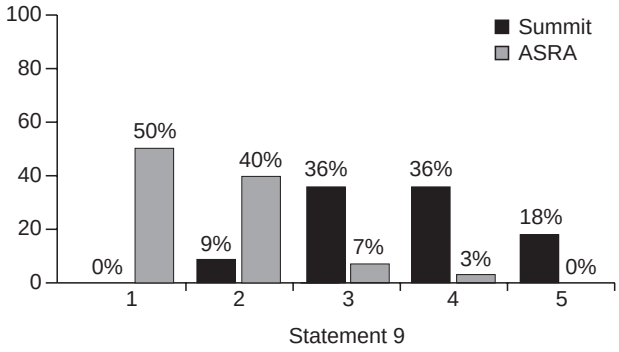

Fig 9. Voting comparison for Statement 9 (Opioid-sparing analgesic regimens result in an earlier return of bowel function after major abdominal surgery). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Discussion

On the basis of the limited data available, opioid-sparing analgesic regimens appear not to result in an earlier return of bowel function after colonic surgery. This outcome may result from the fact that postoperative ileus is influenced by multiple factors in addition to opioids, including the extent of surgical trauma, severity of postoperative pain, excessive hydration, immobilization, use of nasogastric tubes, and lack of enteral feeding.[111] Therefore, analgesic strategies designed to reduce only perioperative opioid use may not be effective in the reduction of the duration of postoperative ileus. Data from animal experiments reveal that the gastrointestinal tract is very sensitive to opioids, even at very low doses. The ratio between analgesic and constipating doses of morphine is approximately 4 to 1 (4 times more morphine is needed to obtain analgesic effect than to obtain slow gastrointestinal motility).[120] This gastrointestinal sensitivity to opioids is probably caused by relatively poor penetration of morphine into the brain, which may partly account for the severity of constipation in patients who receive opioids.[120] Further, repeated administration of opioids for pain relief may result in tolerance to these analgesics, but tolerance does not appear to extend to gastrointestinal motility and transit.[120] Endogenous opioids released after surgical injury may also play a role in the pathogenesis of postoperative ileus.[121] These opioids may not be affected by traditional "opioid-sparing" analgesic techniques after colonic surgery. For these reasons, simply reducing exogenous opioid use by 20% to 30% after traditional analgesic techniques may not be effective in promoting an earlier return of bowel function after major abdominal surgery.[12,115,116]

The methodology utilized in the RCTs that examined the role of parenteral opioid-sparing analgesic regimens on bowel function were limited and of poor quality and methodology. Postoperative ileus was considered a secondary endpoint in many studies, and they may have been insufficiently powered to make a definitive conclusion. Studies that evaluated the short-term (<72 hours) reduction in opioid use may not adequately assess the true incidence of postoperative ileus. Further, the definition of ileus and methods of assessment were either variable or not well defined. A correlation between some of the widely used clinical endpoints for resolution of ileus, including return of bowel sounds and passage of flatus and stool, as well as assessment of electrical activity of the colon, are still controversial.[111]

Surprisingly, only 1 published RCT to date has examined the opioid-sparing effect of the administration of an NSAID on bowel function after colon surgery.[115] NSAIDs may possess the ideal analgesic properties for abdominal surgeries because they not only reduce postoperative opioid use but also may increase gastrointestinal motility, probably by decreasing the synthesis of inhibitory prostaglandins.[122] Although this well-designed prospective, double-blind RCT demonstrated a 29% reduction in morphine use, no differences were evident in the time to first flatus or first intake of soft diet.[115] A statistical ($P < .05$), although not clinically significant, reduction occurred in the time to first bowel movement in the ketorolac group (1.5 days) compared with the morphine group (1.7 days). Perhaps

an even greater reduction in postoperative opioid use is necessary to result in a more significant earlier return of bowel function.

Evaluation of whether a reduction in epidural opioid use contributes to an earlier return of bowel function after abdominal surgery is more difficult because the beneficial effect of epidural analgesia on the duration of postoperative ileus is probably related to the local anesthetic. Epidural block with local anesthetics may improve bowel function after surgery by several mechanisms, including block of afferent and efferent inhibitory reflexes, efferent sympathetic block with concomitant increase in splanchnic blood flow, and anti-inflammatory effects after absorption of local anesthetics.[111] Therefore, the fact that virtually every RCT that examined epidural local anesthetics alone *v* parenteral opioids after colon surgery supports the findings of faster recovery from postoperative ileus with the former method of postoperative-pain management is not surprising.[110] The fact that the duration of ileus is similar with the administration of epidural opioids compared with systemic opioids[110] confirms that the pathogenesis of the reduction of postoperative ileus by epidural analgesia is probably mediated by local anesthetic block.[111] No RCTs have evaluated the effect of reduced epidural opioid use on bowel function after colon surgery. Only 1 RCT has examined the efficacy of combining a nonopioid analgesic with an epidural local anesthetic/opioid solution for colon surgery.[119] This study revealed an earlier return in bowel function with the addition of dextromethorphan to an epidural local anesthetic/opioid infusion in patients undergoing colonic surgery.[119] However, whether this improvement in bowel function was attributable to a reduction in epidural opioid use or to an interaction between dextromethorphan and the epidural local anesthetic is difficult to determine. Experimental evidence indicated that *N*-methyl-D-aspartate (NMDA) receptor antagonists may interact synergistically with local anesthetics.[123,124] Surprisingly, no RCTs have examined the effects of perioperative NSAID administration on epidural analgesia for colon surgery.

In contrast to the summit participants, ASRA members voted strongly in support of the statement, which reflects a strong perception that opioid-sparing regimens can result in an earlier return of bowel function after major abdominal surgery. This perception is likely the result of their interpretation of "opioid-sparing regimen" to mean epidural analgesia, where significant reduction in the duration of ileus has been demonstrated with local-anesthetic–containing infusions. In "less-invasive" abdominal surgery, such as abdominal hysterectomy, no correlation exists between the dose of morphine and the duration of ileus.[125] This finding may reflect the lower severity of pain and opioid use after abdominal hysterectomy when compared with colon surgery.

Future Directions

Because, as a single-modality treatment, opioid-sparing analgesic techniques by themselves are unlikely to significantly shorten the duration of postoperative ileus after colonic surgery, members of the workshop suggested that future studies are needed to evaluate a more comprehensive multimodal rehabilitation program for major abdominal surgery. As suggested by previous investigators[112,126-128] this program may include the use of minimally invasive surgery, thoracic epidural analgesia, avoidance of nasogastric tubes, early ambulation, and nutrition, in addition to opioid-sparing analgesic techniques. Further research is needed to examine the role of opioid-sparing analgesic techniques, including NSAIDs, in combination with either epidural or systemic analgesics on postoperative bowel function after major abdominal surgery.

Statement 10

Postoperative pain can be effectively controlled in patients with opioid tolerance.

Rationale and Definition of Statement

Perioperative management of acute pain in opioid-dependent patients often presents major clinical challenges. The majority of these individuals may be moderately to profoundly unresponsive to the therapeutic effects of opioid analgesics,[129-132] whereas a subset of patients may actually experience increased discomfort or hyperalgesia after opioid administration.[133,134]

Although many caregivers appreciate the implications of diminished opioid sensitivity and believe they can adequately manage these patients, others may not recognize or compensate for high-grade opioid tolerance.[129,131,135] Treatment options in this challenging situation include opioid-dose escalation, the use of neuraxial or neural block, and treatment with nonopioid analgesic adjuvants.[131,135-138] Nevertheless, the available evidence that effective management guidelines exist for providing optimal postsurgical analgesia in opioid-tolerant patients is limited. Thus, to allow for a meaningful analysis of the statement, we focused on textbook chapters, review articles, and pertinent case reports that examined this particular patient subset.

Literature Search

The literature search was conducted by use of the specific text words "postoperative pain and postsurgical pain" and yielded a total of 37,431 articles. Modifiers such as "opioid tolerance", or "opioid dependent" resulted in 159 articles. The search was initially focused by use of the descriptors "English language," "humans," "meta-analysis," and "randomized controlled trials"; however, no papers could be located. Expansion of the search to include review articles, case reports, and clinical papers yielded a total of 26 articles, each of which was examined for relevance to the statement. The reference lists of these articles were also examined.

Evidence

A total of 7 review articles and 11 clinical reports were ultimately included in this analysis. Several recommendations and patient-care guidelines were consistently mentioned in each review, including the importance of recognizing the opioid-tolerant patient, maintaining baseline opioid therapy, upward compensation in perioperative opioid dosing, the use of peripheral and central neural block, and administration of nonopioid analgesics (Table 7).[129-132,139,140] The reasons that underlie recent increases in the number of opioid-dependent patients were discussed in 4 of the reviews and included increased acceptance and prescription of opioid analgesics, concerns of analgesic undermedication, the favorable side-effect profiles of newer semisynthetic and sustained-release opioids, and morbidity associated with NSAIDs and COX-2 inhibitors (Table 8).[129,131,132,139] All of the reviews underscored the importance of patient identification. To help ensure optimal pain control, surgeons, anesthesiologists, and pain specialists need to identify opioid-dependent patients before surgical admission and develop a clear management strategy that employs liberal doses of opioid and nonopioid analgesics.[129,131,132,139,140] Clinicians should also recognize that a subset of patients may be polydrug dependent and often require alcohol, marijuana, or sizable doses of anxiolytics and other psychoactive drugs to help control pain or to provide emotional/psychological support.

Table 7. Guidelines for Effective Treatment of the Opioid-Tolerant Patient

Recognize the opioid-tolerant patient
Maintain baseline opioid therapy
Upward compensation in perioperative opioid dosing
Use of peripheral and central neural block
Administration of nonopioid analgesics

Table 8. Recent Trends That Indicate an Increased Prevalence of Opioid-Tolerant Patients Who Present for Surgery

Increased acceptance and prescription of opioid analgesics
Concerns of analgesic undermedication
Favorable side-effect profiles of newer semisynthetic and sustained-release opioids
Morbidity associated with NSAIDs and COX-2 inhibitors

Three clinical reviews stressed the importance of maintaining baseline analgesia. Patients should be instructed to take their usual dose of oral opioid on the morning of surgery. Because most sustained-release opioids provide 12 hours or more of analgesic effect, baseline requirements will generally be maintained during preoperative and intraoperative periods. Thereafter, baseline requirements may be provided orally or parenterally.[131,132,135]

With regard to the use of IV PCA, several recent reviews and clinical reports agreed that opioid-tolerant patients can effectively use such therapy as long as an adequate loading dose is provided, the incremental dose is increased in proportion to the degree of tolerance, and a basal infusion is provided.[129,131,132,136,141] Allowing substance abusers or recovering addicts to use IV PCA to control postoperative pain was initially considered controversial, as caregivers worried that self-administration might rekindle addictive behavior. More recent case reports indicate that along with oral methadone, IV PCA may be offered, provided pain intensity and opioid consumption are carefully assessed, and such therapy is supplemented with neural block and nonopioid analgesics.[132,135,136,140,141]

Several reviews and case reports advocated administration of nonopioid analgesics to reduce opioid-dose requirements and provide multimodal analgesia, although relatively few evaluations were performed in opioid-dependent patients.[131,132] Five reviews and case reports discussed the benefits of continuous neural block and neuraxial analgesia. Increased bolus doses and infusion concentrations were recommended to overcome spinal opioid-receptor down-regulation and improve analgesic efficacy, which underscores the observation that larger-than-average doses of neuraxial opioid are also required to attain adequate pain control in opioid-tolerant patients.[129,131,132,135,140] de Leon-Casasola and Lema[138,142] also recommend coadministration of local anesthetics and switching to an opioid such as sufentanil with high intrinsic binding and spinal potency.

Grading of Evidence

On the basis of the evidence in these reviews and clinical reports, members of this workshop agreed

that the level of evidence available regarding this statement was Category III (evidence obtained from a case series, case reports, or flawed clinical trials) (Table 1).

Level of Support for Statement

On the basis of available evidence, workshop members rated the level of support for this statement as Category C (poor evidence to support the statement, but recommendations may be made on other grounds) (Table 1). Reasonable, well-thought-out treatment guidelines appear to be available to optimize pain relief in opioid-dependent patients, although none has been critically tested.

In the at-large group, none of the summit participants voted "1" (accept completely), although 63% (7 of 11) voted "2" or "3," to accept the statement with some (4 of 11) or major (3 of 11) reservations, respectively. Forty-two percent (4 of 11) voted to reject either with reservations ("4") or completely ("5") (Table 1). This outcome contrasted to the vote of the ASRA membership, of whom 96% felt that evidence was sufficient to accept the statement, 36% accepting it completely ("1"). Only 4% of the ASRA respondents rejected the statement (Fig 10).

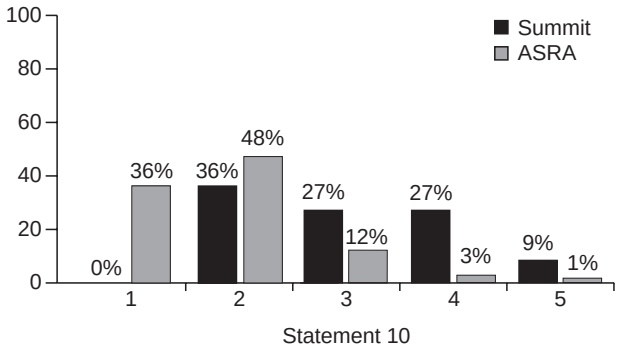

Fig 10. Voting comparison for Statement 10 (Postoperative pain can be effectively controlled in patients with opioid tolerance). Summit: 11 members of the Acute Pain Summit 2005 panel; ASRA: American Society of Regional Anesthesia and Pain Medicine members participating in Web-based survey. 1 = accept completely; 2 = accept with some reservations; 3 = accept with major reservations; 4 = reject with reservations; 5 = reject completely.

Discussion

On the basis of the available evidence, most opioid-tolerant patients can experience effective postsurgical analgesia, provided that critical treatment principles are followed. Differences in support for the statement "Postoperative pain can be effectively controlled in opioid-dependent patients" between the ASRA members and those attending the pain summit were striking, and, at first, difficult to understand. As was mentioned, many of those attending the summit felt that guidelines for patient management were anecdotal and observational and not from carefully controlled trials. Moreover, they recalled difficulties controlling pain in many highly tolerant patients. Problems included the fact that chronic pain and drug-seeking behaviors greatly influenced management of acute pain, the magnitude of opioid tolerance was difficult to assess, and many patients developed hyperalgesia after high-dose opioid administration. For these reasons, those summit participants disagreed with the ASRA respondents' perception that the statement could be accepted without reservations. Members of the summit group were, however, able to accept the statement with either minor or major reservations. Reservations included the fact that guidelines presented in several of the review articles can be followed closely, with care taken to avoid either opioid underdosing or potential for withdrawal, or overdosing and potential for hyperalgesia, yet pain control can remain poor. The fact that many ASRA members voted strongly in support of the statement may reflect a lack of experience with difficult, highly dependent patients. On the other hand, it could underscore the fact that this select group of caregivers routinely employs effective neural block in the majority of patients, thereby achieving effective analgesia while minimizing the need to administer anything other than baseline opioids.

The major issue raised by those attending the pain summit was the absolute lack of controlled data or any meta-analysis that demonstrated that adherence to published guidelines improves perioperative management and outcomes in opioid-dependent patients. With regard to epidural analgesia, no controlled trials have been performed to determine whether increased opioid dose, increased local-anesthetic concentration, or both are necessary to improve overall efficacy in opioid-dependent patients.[138,142]

Future Directions

Future directions suggested by summit participants reflect some of the limitations of relying on case reports that describe improvements in analgesic management, rather than on data collected from RCTs. Clinical trials that evaluate dose requirements after various surgical procedures in opioid-tolerant patients have yet to be performed. Studies are also needed to evaluate whether multimodal analgesic approaches, such as the perioperative use of methadone and ketamine to minimize opioid-dose escalation and development of opioid-

induced hyperalgesia will improve postsurgical outcomes.[137,143-145] Future trials should assess not only outcomes in the short-term (pain intensity, opioid consumption, treatment of side effects) but also events occurring over longer time frames (opioid dose de-escalation, opioid detoxification, return to work, etc.).

Conclusions

Many of the pain-treatment modalities we use daily have clear, scientific support for their usefulness in clinical practice. Through this critical appraisal, we can see the limitations of the existing evidence and confirm the areas in which benefit has been demonstrated. The use of PCA, continuous epidural analgesia, and continuous peripheral-nerve blocks clearly improve pain control and patient satisfaction in the postoperative period. However, improvement in other outcomes, particularly reductions in major morbidity or mortality, is less certain. A limited body of evidence that has emerged suggests technical weaknesses associated with use of PCA-infusion devices that limit their usefulness, increase expense, and lead to frequent safety concerns. Despite much rhetoric about combining multiple analgesic techniques to provide multimodal analgesia, only limited evidence suggests that this approach will improve pain control or perioperative outcomes. More studies are needed on new modalities to determine their place in therapy. Many practicing clinicians remain unfamiliar with these new modalities, and the published trials offer little guidance on how to use them in clinical practice.

Despite marked public interest and a number of national efforts to develop guidelines for acute-pain management, whether the appearance and dissemination of these guidelines have improved our ability to provide adequate postoperative pain control remains unclear. Experimental evidence points toward the need for better pain control, because current evidence indicates that poorly controlled acute pain may well increase the likelihood of chronic pain thereafter. Finally, the prevalence of opioid-tolerant patients presenting for major surgery is on the rise, and controlling pain in this population can be difficult. Limited evidence suggests that pain can be controlled in most of these patients, but widespread opinion is that adequate pain control may be difficult or impossible to achieve in some opioid-tolerant patients.

Examination of the disparities between the opinions of a large number of practicing clinicians and those of the summit participants after a detailed examination of the scientific evidence is interesting. Many of the disparities likely arose from each individual's interpretation of the statements. Despite our attempts to write discrete statements and avoid vague terminology, dual interpretations inevitably arose. The authors in each section have been careful to point out where these vagaries led to difficulties with their evidence-based analyses.

One theme about the types of evidence most likely to help guide rational use of pain therapy evolved from a number of our discussions. Although randomized, controlled trials are thought to be the "gold standard" to determine analgesic efficacy, even the largest trials are unlikely to examine more than several hundred patients. Randomized trials are unlikely to detect rare, but potentially catastrophic, outcomes. Thus, large-scale observational (cohort) studies would be especially valuable to determine the actual incidence of infrequent side effects and adverse reactions in the typical clinical setting, and future investigators should be encouraged to pursue this line of investigation.

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Appendix A: The Pain Summit Survey

Acute Post-Surgical Pain Field Survey

Please tell us about the role of acute postsurgical pain in your practice.

What percentage of patients in your practice expect to have mild to moderate acute pain after surgery?
☐ 0-25% ☐ 25-50% ☐ 50-75% ☐ 75-100%

What percentage of your patients would say postsurgical pain is their greatest fear when preparing for surgery?
☐ 0-25% ☐ 25-50% ☐ 50-75% ☐ 75-100%

What percentage of your patients with acute postsurgical pain would report having a quicker recovery if their pain needs were adequately treated?
☐ 0-25% ☐ 25-50% ☐ 50-75% ☐ 75-100%

How many acute postsurgical pain patients have you seen in your practice in the past 6 months?
☐ 0-10 ☐ 11-20 ☐ 21-30 ☐ 31-50 ☐ 50+

Grade your level of support for the following statements using the scale below

1 = Accept completely
2 = Accept with some reservations
3 = Accept with major reservations
4 = Reject with reservations
5 = Reject completely

STATEMENT 1: Use of intravenous PCA leads to improved patient outcomes when compared with nurse-administered parenteral opioids.
1 2 3 4 5

STATEMENT 2: Use of continuous regional analgesic techniques leads to improved patient outcomes.
1 2 3 4 5

STATEMENT 3: The use of multimodal analgesia improves postoperative pain control and reduces analgesia-related adverse effects.
1 2 3 4 5

STATEMENT 4: Technology-related problems limit the safety and effectiveness of IV and epidural PCA.
1 2 3 4 5

STATEMENT 5: New and emerging therapies offer advantages over existing analgesic options for treating postoperative pain (grade each therapy).

Iontopheretic transdermal fentanyl
1 2 3 4 5 ☐ Unfamiliar

Extended-release epidural morphine
1 2 3 4 5 ☐ Unfamiliar

STATEMENT 6: The creation and dissemination of acute-pain guidelines has improved postoperative-pain management.
1 2 3 4 5

STATEMENT 7: Poorly controlled postoperative pain leads to an increased likelihood of chronic pain.
1 2 3 4 5

STATEMENT 8: Use of continuous postoperative epidural analgesia leads to improved patient outcomes when compared with parenteral opioids in patients with preexisting cardiovascular and pulmonary disease.
1 2 3 4 5

STATEMENT 9: Opioid-sparing analgesic regimens result in an earlier return of bowel function after major abdominal surgery.
1 2 3 4 5

STATEMENT 10: Postoperative pain can be effectively controlled in patients with opioid tolerance.
1 2 3 4 5

CME Posttest

STATEMENT 1: Use of intravenous PCA leads to improved patient outcomes when compared with nurse-administered parenteral opioids.

1. Use of patient-controlled analgesia after major surgery leads to which of the following changes in patient outcome when compared with nurse-administered parenteral opioids?
   A. Increased patient satisfaction
   B. Reduced postoperative pain
   C. Reduced duration of hospitalization
   D. Earlier return of bowel function
   E. Reduced incidence of nausea and vomiting

STATEMENT 2: Use of continuous regional-analgesic techniques leads to improved patient outcomes.

2. The use of continuous peripheral nerve blocks (perineural analgesia) after major surgery leads to which of the following changes in patient outcome when compared with systemic administration of opioid analgesics?
   A. Reduced incidence of motor block
   B. Earlier postoperative ambulation
   C. Reduced duration of hospitalization
   D. Reduced duration of stay in the Postanesthesia Care Unit
   E. Reduced incidence of opioid-related side effects

STATEMENT 3: The use of multimodal analgesia improves postoperative pain control and reduces analgesia-related adverse effects.

3. The addition of a nonsteroidal anti-inflammatory drug (NSAID) to standard IV PCA for the treatment of postoperative pain results in which of the following?
   A. Reduction in postoperative ileus
   B. Reduction in postoperative opioid requirements
   C. Reduction in postoperative pruritus
   D. Reduction in postoperative blood loss
   E. Reduction in duration of hospitalization

STATEMENT 4: Technology-related problems limit the safety and effectiveness of IV and epidural PCA.

4. Errors that have been reported with the use of infusion devices that are currently used to provide patient-controlled analgesia (PCA) include all of the following EXCEPT:
   A. Errors in programming leading to drug overdose
   B. Errors in programming leading to insufficient analgesia
   C. Errors in route of drug infusion (switch between intended epidural and intravenous route)
   D. Errors in electrical function of the infusion device leading to shock hazard to the patient
   E. Errors in drug administration (hydromorphone used in place of morphine) leading to drug overdose

STATEMENT 5: New and emerging therapies offer advantages over existing analgesic options for treating postoperative pain (grade each therapy).

Iontopheretic transdermal fentanyl
Extended-release epidural morphine

5a. Iontopheretic transdermal fentanyl provides all of the following potential benefits EXCEPT:
   A. Reduced programming errors
   B. Equivalent safety and efficacy to IV PCA morphine
   C. Reduced duration of hospitalization
   D. Needle-free system
   E. Deactivation after 24 hours or 80 doses a day

5b. Extended-release epidural morphine provides all of the following potential benefits EXCEPT:
   A. Extended duration of analgesia
   B. No risk of respiratory depression
   C. Single-dose administration
   D. No need for continuous epidural infusion
   E. Reduced need for supplemental analgesics postoperatively

STATEMENT 6: The creation and dissemination of acute-pain guidelines has improved postoperative-pain management.

6. Many institutions implemented treatment policies guided by patient pain-intensity ratings indexed with a numerical scale. The implementation of such treatment policies has been associated with which of the following?
   A. Improved pain control after surgery
   B. Improved patient satisfaction
   C. Increased events of over-sedation and fatal respiratory depression
   D. Reduced duration of hospitalization after surgery
   E. Reduced use of epidural analgesia

STATEMENT 7: Poorly controlled postoperative pain leads to an increased likelihood of chronic pain.

7. Chronic pain after major surgery is more common in patients who have all of the following characteristics during the intraoperative and postoperative periods EXCEPT:
   A. Higher pain intensity
   B. Larger incisions
   C. Greater opioid use
   D. Higher pain scores
   E. Greater blood loss

STATEMENT 8: Use of continuous postoperative-epidural analgesia leads to improved patient outcomes when compared with parenteral opioids in patients with preexisting cardiovascular and pulmonary disease.

8. Use of epidural analgesia in patients undergoing coronary artery bypass grafting (CABG) is associated with which of the following outcomes?
   A. Reduction in mortality
   B. Reduction in the incidence of myocardial infarction
   C. Reduction in the incidence of cardiac arrhythmias
   D. Reduction in blood loss
   E. Reduction in the incidence of stroke

STATEMENT 9: Opioid-sparing analgesic regimens result in an earlier return of bowel function after major abdominal surgery.

9. Earlier return of bowel function after major abdominal surgery is seen in patients who receive which of the following analgesic regimens when compared with parenteral opioid analgesia alone?
   A. A nonsteroidal anti-inflammatory drug (NSAID) in combination with IV PCA opioid
   B. Acetaminophen in combination with IV PCA opioid
   C. Continuous epidural infusion of opioid analgesic alone
   D. Continuous epidural of a combination of opioid analgesic and local anesthetic
   E. A COX-2 selective inhibitor in combination with IV PCA opioid

STATEMENT 10: Postoperative pain can be effectively controlled in patients with opioid tolerance.

10. All of the following actions have been proposed as means to improve postoperative pain control in patients with opioid tolerance EXCEPT:
    A. Maintain baseline opioid therapy throughout the perioperative period
    B. Use larger than average doses of opioid analgesics
    C. Use peripheral and central neural block whenever appropriate
    D. Administer nonopioid analgesics whenever appropriate
    E. Wean opioid analgesics promptly after surgery

Evaluation Form

Acute Postsurgical Pain Management: A Critical Appraisal of Current Practice

A CME Supplement to *Regional Anesthesia and Pain Medicine* The University of Wisconsin School of Medicine and Public Health respects and appreciates your opinions. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few minutes to complete this evaluation form.

Please answer the following questions by circling the appropriate rating:

5 = Outstanding 4 = Good 3 = Satisfactory 2 = Fair 1 = Poor

Extent to Which Program Activities Met the Identified Objectives After completing this activity, participants should be able to:

Explain the differences in patient outcomes when comparing IV PCA versus nurse-administered parenteral opioids in patients after major surgery
5 4 3 2 1

Describe the changes in patient outcomes when administering perineural analgesia versus systemic administration of opioid analgesics in patients after major surgery
5 4 3 2 1

Explain the impact of multimodal analgesia on analgesia-related adverse effects when compared with standard IV PCA for the treatment of acute postoperative pain
5 4 3 2 1

Discuss the technology-related problems associated with IV and epidural PCA
5 4 3 2 1

Review the advantages potentially offered by newer technologies and emerging therapies
5 4 3 2 1

Discuss the impact of acute-pain guidelines on postoperative pain management
5 4 3 2 1

Describe the consequences of inadequate pain management in the postoperative setting
5 4 3 2 1

Identify the potential benefits to using epidural analgesia versus parenteral opioids in patients with preexisting cardiovascular or pulmonary disease
5 4 3 2 1

Review the effects of opioid-sparing analgesic regimens on return of bowel function after major abdominal surgery
5 4 3 2 1

Describe techniques to effectively manage postoperative pain in the opioid-tolerant patient
5 4 3 2 1

Overall Effectiveness of the Activity

Was timely and will influence how I practice
5 4 3 2 1

Will help me improve patient care
5 4 3 2 1

Stimulated my intellectual curiosity
5 4 3 2 1

Avoided commercial bias
5 4 3 2 1

Will the information presented cause you to make any changes in your practice?
____Yes ____No

If Yes, please describe any change(s) you plan to make in your practice as a result of this activity.

_____

_____

How committed are you to making these changes?
5 (Very committed) 4 3 2 1 (Not at all committed)

Additional comments about this activity:

_____

_____

Do you feel future activities on this subject matter are necessary and/or important to your practice?
____Yes ____No

Please list any other topics that would be of interest to you for future educational activities:

_____

Request for Credit

No prerequisites or fees are required for participating in and receiving CME credit for this activity. During the CME eligibility period of July 2006 to July 2007 participants must (1) study the educational activity, (2) complete the posttest by recording the best answer to each question in the answer key on the bottom of this evaluation form, (3) complete the evaluation form, and (4) mail or fax the evaluation form and answer key to University of Wisconsin School of Medicine and Public Health.

A statement of credit will be issued only upon receipt of a completed activity evaluation form and a completed posttest with a score of 70% or better. Your statement of credit will be mailed to you within 4 to 6 weeks.

I certify my actual time spent to complete this educational activity to be:

☐ I participated in the entire activity and claim 4.0 credits.

☐ I participated in only part of the educational activity and claim _____ credits.

Posttest Answer Key

1	2	3	4	5a	5b	6	7	8	9	10

Degree: ☐ MD ☐ DO ☐ PharmD ☐ RN ☐ RPh ☐ PA ☐ Other _____

Mail or fax your completed evaluation form to:
University of Wisconsin School of Medicine
and Public Health
750 Highland Avenue, Madison, WI 53705
Phone: (608) 263-2850 Fax: (608) 262-8421

Please Print Clearly

_____
Name

_____
Specialty

_____
Street Address Box/Suite

_____
City State ZIP

_____
Phone Number Fax Number

_____
E-mail

Tool: Form for Assigning Key Roles

Role	Name of Individual(s)	Description of Role / Responsibilities
Executive Sponsor		A senior leader who sponsors the overall pain initiative, for example a Chief Nurse Executive, (CNE) and who reports to the Chief Executive Officer (CEO) or Chief Operating Officer (COO).
Pain Project Champion		A middle- or senior-level leader who sponsors a specific pain project, ensuring that resources are available and that cross-functional issues are resolved.
Pain Project Manager		An individual who is responsible for implementing PI pain projects, communicating with the senior leader champion, setting agendas, facilitating the use of PI tools, and providing oversight for project phases.
Interdisciplinary Pain Team Members		Professionals who bring relevant experience or expertise to the management of patients in pain and who work together to provide a pain management system that is safe, effective, and efficient.
Pain Resource Nurse		A designated nurse in each work area who functions as a peer resource for pain management issues.
Process Owner		A professional who is responsible for the business process that is the target of a PI project. For instance, if the pain team implements a change in pain management in the emergency department (ED), the process owner may be the ED director who provides oversight to the change process and is responsible for sustaining the improvement when the project is over.

Key Roles for Pain Management

Executive Sponsor: A senior leader who sponsors the overall pain initiative, for example a Chief Nurse Executive, (CNE) and who reports to the Chief Executive Officer (CEO) or Chief Operating Officer (COO).

Name of Executive Sponsor:

Pain Project Champion: A middle- or senior-level leader who sponsors a specific pain project, ensuring that resources are available and that cross-functional issues are resolved.

Name of Pain Project Champion:

Pain Project Manager: An individual who is responsible for implementing PI pain projects, communicating with the senior leader champion, setting agendas, facilitating the use of PI tools, and providing oversight for project phases.

Name of Pain Project Manager:

Interdisciplinary Pain Team Managers: Professionals who bring relevant experience or expertise to the management of patients in pain and who work together to provide a pain management system that is safe, effective, and efficient.

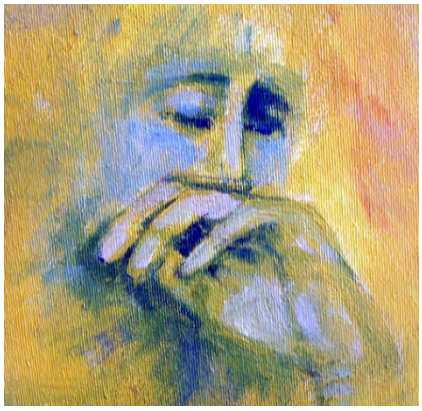
Names of Interdisciplinary Pain Team Managers:

Pain Resource Nurse: A designated nurse in each work area who functions as a peer resource for pain management issues.

Name of Pain Resource Nurse:

Process Owner: A professional who is responsible for the business process that is the target of a PI project. For instance, if the pain team implements a change in pain management in the emergency department (ED), the process owner may be the ED director who provides oversight to the change process and is responsible for sustaining the improvement when the project is over.

Name of Process Owner:



Sample Pain Team Agenda

Date and Time

Team Members Present:

Agenda:

1. Review Team Ground Rules
2. Mission and Vision
3. Pain Team Updates
    - Policies and Procedures
    - Leadership Updates – Structure Outcomes
    - Unit Based Measurement Review
    - Performance Improvements – Process and Outcome Results
4. Hospital Wide Scorecard Review
5. Status Reports (Action Plan)
6. New Opportunities
7. Next Steps

Defining Lean Waste and Potential Failure Modes

Within every process, there are opportunities to eliminate lean waste.

Lean Thinking—or more simply *Lean*—began as Toyota's Production System Model and is a system of tools and principles used to create solutions to problems by increasing the value-added delivery to the customer by reducing waste. Easily recalled by the acronym **DOWNTIME**, waste exists in the following eight forms:

- **D**efects – failure modes, for example:
  - Omission of Pain Medication, Omission of Follow up assessment
  - Incorrect Selection of Medication, Failure to provide Discharge prescriptions
  - Incomplete discharge instructions
  - Failure to assess patient comprehension
  - Omission of Device and Medical Equipment Ordering
- **O**verproduction – overproduction of DC teaching sheets that are not individualized or become outdated
- **W**aiting – wait times for patients, staff and faculty
- **N**on value-added processing – rework and redundancies
- **T**ransportation – not enough wheel chairs creating discharge delays

- **I**nventory – over or under supplying medications or discharge materials
- **M**otion – having to run for things, stoop, stretch, pull or push inappropriately – having supplies/ materials at the point of service will eliminate excess motion
- **E**mployee (underutilizing and/or not using staff-based knowledge) – lean kaizen events use the staff who do the actual “work” to be a part of the problem solving process (all shifts and weekends represented as needed)

After high level maps are created, the team can begin to visualize the various types of waste at each step within the process. The goal of every lean process is to eliminate waste and thereby eliminate any future errors in the process.

Tracer Methodology 101

The Laboratory Tracer

Laboratory tracers are unique because they do not focus solely on direct patient contact as do tracers in other accreditation programs. Instead, the laboratory tracer evaluates the performance of processes, with particular focus on integrating and coordinating distinct but related processes. The tracer also assesses the interrelationships among departments, programs, services, or units to identify strengths and weaknesses and potential concerns in the relevant processes.

The Joint Commission surveyor will, most likely, begin the laboratory tracer with the test result, and then he or she will follow the entire testing process for that patient from preanalytic to postanalytic processes. The surveyor may visit all areas of your laboratory that affect the delivery of service, including areas where orders are written or recorded, specimens are collected and processed, testing is performed, and results are documented and communicated.

In this month's "Tracer Methodology 101" column, we focus on an individual laboratory tracer that involves information management, analytical procedures, and equipment use.

The Scenario

This tracer was conducted during a laboratory survey at a 120-bed hospital. This organization had purchased the only other hospital in the town and converted it into an ambulatory care center where, among other services, outpatient transfusions were performed. The surveyor selected this tracer from a number of suspected transfusion reaction workups that had been conducted by laboratory staff over the past 12 months.

The surveyor chose the closed medical record of a 54-year-old man who received chemotherapy and frequently required transfusions. The surveyor reviewed the tracer patient's closed medical record in the presence of the laboratory director, the director of quality management, and the risk manager. On this particular occasion, the physician had ordered two units of packed cells because the patient's hemoglobin was 6.2 grams. The laboratory performed the type and crossmatch early in the day with plans to administer the two units at the ambulatory care center later in the day. In addition, the laboratory performed a chemistry profile, thyroid profile, and complete blood count (CBC).

The patient received the first unit of packed cells without demonstrating any signs and symptoms of a suspected transfusion reaction according to the organization's own policy. During administration of the second unit, nursing documented a rise in the patient's temperature of 2.5°F (1.4°C), and a suspected transfusion reaction response was initiated. Nursing continued to monitor the patient's vital signs, and the patient's temperature continued to rise—with a total increase of more than 4°F (2.2°C)—even though the administration of the blood had been discontinued. As part of the laboratory's protocol, the laboratory was notified of the suspected reaction. The attending physician made the decision to have the patient transferred from the ambulatory care center to the hospital emergency department via ambulance. On arrival at the emergency department, the emergency physician ordered a basic metabolic panel (BMP) and CBC.

The surveyor asked the laboratory director about its policy for receiving orders for stat tests. He also asked the laboratory director to identify staff members who performed the tests and

The Facts on Laboratory Tracers

When to do this tracer: Any laboratory should conduct this tracer when it wants to assess any aspect of its systems and processes. If you choose to conduct mock tracers, in addition to clinical/service groups, consider criteria such as patient sample testing in laboratory sections (for example, hematology, chemistry, biology, or blood bank), policy and procedures that guide testing performance of patient samples, maintenance of laboratory equipment, or pre- and postanalytical procedures.

asked human resources to pull their files so he could later review their competencies, job descriptions, primary source verification of the licenses, and performance appraisals. Coincidentally, the technologist who performed the first CBC prior to the blood administration had worked for the organization for only four months, so the surveyor asked for documentation of her initial orientation and training.

The surveyor then visited the hematology department and asked about instrument maintenance on the hematology analyzer for the day of testing. Staff showed him the daily start-up and shutdown documentation. They were able to identify all lot numbers of reagents used on the analyzer for this time period. This laboratory's policy was to run all three levels of quality control every eight hours. The surveyor reviewed the appropriate quality control records. The first eight-hour period indicated that the normal control level was performed with results that exceeded that laboratory's two standard deviation quality control range. The normal control was repeated, and the technologist had documented appropriate corrective action. The laboratory submitted quality control results monthly to the instrument vendor for interlaboratory comparison. The surveyor reviewed the report for this month, and all data had agreed with peer data. Calibration of this hematology analyzer was performed every six months, and the hematology supervisor was able to show the surveyor the data.

The surveyor was able to talk with the technologist who performed the BMP on the tracer patient during the emergency department visit. The technologist told the surveyor that two levels of quality control material were run every 24 hours for analytes performed on the chemistry analyzer. Typically, quality control was performed on the third shift; however, on the day the tracer patient was tested, a new lot of reagents had been started for glucose, and quality controls had been repeated after calibration of a new lot number. Each month data from quality control were submitted to the quality control vendor for interlaboratory comparison. The chemistry supervisor located the file and presented it to the surveyor for review. For the particular month when the tracer patient was tested, creatinines were running slightly higher than the peer group. A service call had been initiated on this analyzer, and the surveyor reviewed the report left by the service representative. Apparently, the service representative had to replace a part that he felt had caused a certain amount of carryover between samples and probably caused the elevation noticed when the data were compared to the peer group. As part of the monthly quality control review, a summary of the quality control data, interlaboratory comparison data, and maintenance records was reviewed by the laboratory's administrative director and the medical director. This report included documentation of a discussion of the elevated creatinine results. The medical

(Continued on page 8)

Tips Checklist

Consider the following strategies when conducting a laboratory tracer:

- ***Focus on issues of particular concern for laboratories and process interfaces with clinical staff.*** Consider those issues of particular concern to a laboratory, such as patient identification, quality control, and communication of critical test results. You can use these specific topics to plan a specialized tracer using a closed medical record.
- ***Consider your laboratory's past testing activity as a starting point.*** It can be very informative to conduct a tracer of past testing activity, particularly if a pattern of near-miss reports or quality control problems with a particular test have been observed.
- ***Select the medical record of a patient who received multiple laboratory tests, including tests performed at point-of-care sites.*** This will help you look at multiple processes within your laboratory at one time. Follow the testing from the time of the order to the action taken, if indicated.
- ***Instead of one person conducting the tracer, consider walking through one as a group.*** Having an informal group discussion as you verbally "trace" through a closed medical record can help laboratory staff to better understand tracers. This is also a good opportunity to discuss possible "workarounds" or other potential problems that could result in a negative outcome.
- ***Don't forget to consider the beginning and end of a process, not just the outcome.*** For example, while tracking a specimen, make sure that you are following the work done by staff to both collect and then test that specimen. Observe work done with patients. Observe how patient identification is being performed. It is important to remember that tracers can be used to follow an entire process or system, and your goal should be to determine if there are any gaps or potential missteps.

director had determined that this creatinine elevation was not significant enough to consider a look back at patient results. Daily maintenance was reviewed for the day the tracer patient was tested, and evidence was provided for the results of the daily absorbance testing. This analyzer had been purchased by the laboratory since the previous survey, and appropriate documentation was available for the surveyor's review.

In the blood bank, the surveyor had a chance to review the workup of the suspected transfusion reaction. The laboratory had developed a workup form for the technologist to use. For this particular tracer patient, the blood bank technologist had documented a clerical check only. Although the laboratory had a policy requiring a new patient sample to confirm the blood group, Rh type, and direct antiglobulin test, a posttransfusion sample had never been received. The technologist who performed the workup said he waited for a sample but never received one.

After additional discussion, the surveyor learned that the technologist was unaware that the laboratory had blood samples drawn at the time this patient was seen in the emergency department. The laboratory director later said that the technologist could have searched the laboratory information system to locate a sample that would have allowed him to do the required testing. The record also lacked documentation that the laboratory's medical director reviewed this suspected transfusion reaction for six weeks after the reaction, even though the pathologist is available every weekday. Unfortunately, no one in the laboratory realized that the organization had samples from this very patient and his workup could have been completed. As a result, the medical director was unable to make a definitive diagnosis, which normally would have been included in the patient's medical record.

Sample Tracer Questions

Based on the above scenario, the following are possible questions that could be asked during a laboratory tracer. Use them as a starting point to plan your own tracers. **Note:** *Because the types of questions asked during a tracer can be diverse and depend on the setup at that specific organization, we are providing an online tracer worksheet that includes these sample questions. You can download the worksheet, shown on page 9, and customize it with your own specific tracer questions. Access this tracer worksheet at http://www.jcrinc.com/common/PDFs/Pubs/Periodicals/The-Source/TheSource0910-MockTracerTrackingForm_LaboratoryTracer.doc.*

Questions for the laboratory director:

- Can you describe your laboratory process to handle transfusion reactions?
- What training and orientation have been provided to laboratory staff to handle transfusion reactions?
- What data and analysis have you done on the incidence of transfusion reactions in your organization?
- What measures have you introduced, if any, to reduce the incidence of transfusion reactions?
- What initial assessment do you perform for new transfusion patients?

Questions for the laboratory staff:

- What were the specimen collection requirements for the tests performed for this tracer patient? Where were they collected?
- What process did you follow for preparing blood units for this patient's transfusion in an outpatient setting?
- What instructions did you provide to this tracer patient?
- What is your laboratory's policy for ordering a stat procedure?
- How do you verify orders for laboratory testing? How do you determine who is authorized to give those orders?
- What is your quality control process? When is corrective action required?
- What is your quality control process for the BMP? What is your process for accepting and rejecting of a quality control result?
- What is your process when your quality control data reflect a positive or a negative bias based on interlaboratory data? What do you do when your quality control results are higher than acceptable peer data?

Questions for nursing staff:

- What prompted you to suspect a transfusion reaction in this tracer patient?
- What is your policy for addressing a patient exhibiting signs and symptoms of a suspected transfusion reaction?
- What protocol did you follow to address this patient's continued temperature increase?
- What is your assessment process for a new patient?
- Please describe your entire process for administering blood to a patient.

Questions for blood bank staff:

- What is your organization's process for handling a new patient?
- What is your documentation process? How is that documentation reported?
- If you have a question or a problem with documentation or necessary information, what do you do?
- When you did not receive the expected sample, what protocol did you follow? Who did you notify about this situation?
- What process did you follow to document or handle an incomplete diagnosis or test result for this patient? Would your processes for daily review have detected this? S

Mock Tracer Tracking Worksheet: The Laboratory Tracer

Use this worksheet to record notes and areas of concern that you identify while conducting your organization's mock tracers. This information can be used to highlight a good practice or to determine issues that may require further follow-up. "Yes" or "no" indicates whether the staff member interviewed during the tracer answered the question correctly.

Tracer Team Member: _____ Tracer Patient or Medical Record: _____
Staff Interviewed: _____
Unit or Department Where Tracer Was Conducted: _____

TRACER QUESTIONS	YES	NO	FOLLOW-UP NEEDED	COMMENTS OR NOTES
Describe your laboratory process to handle transfusion reactions.				
What training and orientation have been provided to laboratory staff to handle transfusion reactions?				
What data and analysis have you done on the incidence of transfusion reactions in your organization?				
What measures have you introduced, if any, to reduce the incidence of transfusion reactions?				
What initial assessment do you perform for new transfusion patients?				
What were the specimen collection requirements for the tests performed for this tracer patient? Where were they collected?				
What process did you follow for preparing blood units for this patient's transfusion in an outpatient setting?				
What instructions did you provide to this tracer patient?				
What is your laboratory's policy for ordering a stat procedure?				
How do you verify orders for laboratory testing? How do you determine who is authorized to give those orders?				
What is your quality control process? When is corrective action required?				
What is your quality control process for the basic metabolic panel?				

Acces this entire two-page worksheet at
http://www.jcrinc.com/common/PDFs/Pubs/Periodicals/The-Source/TheSource0910-MockTracerTrackingForm_LaboratoryTracer.doc.

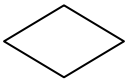
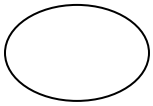
Joint Commission Resources

Instructions for Developing a High Level Process Map and Swim Lane Diagram

Process mapping is a technique for making work visible. A process map shows who is doing what, with whom, when and for how long. It also shows decisions that are made, the sequence of events, and any wait times or delays inherent in the process.

The Process Map is a horizontally aligned flow chart that maps the specific process from start to finish. The facilitator asks the group what the high level steps in the process are and those steps are placed on the flip chart. Once the initial draft of the process map is created, it will be important for the team to verify the map by "going and seeing" what actually happens (Walk the Walk). Invariably, what the team members "think" is happening in the process is not consistent with what they "see" on their walk. The team will then come together again to discuss their findings and redesign their initial process map.

There are a variety of graphical shapes that can be used in flow charting but the most common shapes used are the following:

Box 	Activities, tasks, steps in the process
Diamond 	Decisions
Circle 	Start and end steps
Arrow	To connect each of the activities, decisions or start and end points

Process maps are good for streamlining work activities and telling new people, as well as internal and external customers, "what we do around here." They also can help in the effort to reduce cycle time, avoid rework, eliminate some inspections or quality control steps, and prevent errors.

Steps in creating a Process Map

1. Assemble your team (maximum number 12) of knowledgeable employees of the process
2. Include at least one member of the team who does not know the process (the clueless individual is able to ask questions about why things happen that way and challenge the group to think through the rationale for why things have been created the way they are)
3. Identify a facilitator who is neutral to the process and will facilitate discussion as opposed to participating in actual content discussion
4. Think about the 5-6 high level steps that occur within the process 80% of the time. As a group agree on the 5-6 high level steps (ie. MD admits patient, MD writes orders, care & treatment is provided, the discharge order is written, and the patient is discharged. The beginning and end steps are to be written in a circle. The process steps in between will be written in a square. When decisions are made, triangles will highlight the decision.
5. Connect each activity with an arrow.
6. Ask each discipline to speak to the subprocesses that occur in each step
7. Once a process map is completed, the team that put it together will analyze it.

Steps in creating a Swim Lane Diagram or Cross functional Flow map

The Cross Functional Flowchart or Swim Lanes Diagram is used to map work processes as they occur within functions, disciplines, or separate departments within an organization. When receiving care, patients may see redundancies in care that may be confusing. For example, in the Discharge Process cross functional flow map, both the nurse and physician assess the patient right after one another. Discharge teaching may be delivered inconsistently between the disciplines. The patient may become anxious or worried after having to answer the same questions multiple times and may reasonably assume that the nurse and doctor are not communicating with one another. High level process steps can be discussed by the PI team first, and then each PI team member is asked to document their own individual work steps within their swim lane.
As the PI team compiles their detailed work steps, they begin to understand each others' work requirements and the process from the perspective of the patient.

1. Assemble your team (maximum number 12) of knowledgeable employees of the process.
2. Include at least one member of the team who does not know the process (the clueless individual is able to ask questions about why things happen that way and challenge the group to think through the rationale for why things have been created the way they are).
3. Identify a facilitator who is neutral to the process and will facilitate discussion as opposed to participating in actual content discussion.
4. Think about the 5-6 high level steps that occur within each individual's process 80% of the time. Each staff member will focus on their own work process and their swim lane. (ie. The physician may write: MD admits patient, MD writes orders, provide care & treatment , write the discharge order, and discharge the patient.

5. As in basic flow charting, the beginning and end steps are to be written in a circle. The process steps in between will be written in a square. When decisions are made, triangles will highlight the decision.
6. Connect each activity with an arrow even if they cross swim lanes.
7. Ask each discipline to speak to the sub-processes that occur in each step.
8. Once a swim lane map is completed, the team that put it together will analyze it.

Analysis of Map and Diagram

The analysis is no more than considering the process activities and flow by:

A. Looking at each process step for:

- Bottlenecks
- Sources of delay
- Errors being fixed instead of prevented (rework)
- Role ambiguity (we didn't know who...)
- Duplications
- Unnecessary steps
- Cycle time

B: Looking at each decision for:

- Authority ambiguity (two or more people get to decide...)
- Are the decisions needed at this point?

C: Looking at each rework loop for:

- Possibly eliminating the step(s) or doing in less time, or trying to prevent

D: Using the customer's point of view

Value-added vs. non-value-added steps (from the customer's point of view)

Summary

In summary, process mapping is a technique for making work visible. A process map shows who is doing what, with whom, when and for how long. It also shows decisions that are made, the sequence of events, and any wait times or delays inherent in the process. There is no right or wrong way to build a process map. The “team” process of actually “building” the map is the critical success factor here instead of what the actual map looks like in the end. Process maps should always be built with paper/pen or flipchart/ markers first. If the team insists on using a computer, the process of creating individual swim lanes and actually seeing and learning the process globally, will be lost. Take time to plan your meeting, bring flip charts markers and post it notes, establish ground rules for focused work, and have fun!

Project Charter: Pain Management		Start Date:	July 20XX

Problem/Goal Statement:

Leadership Signoff / Sanction:_____

Stakeholders:

Why is this project important?

Describe the patient benefit:

What will the project achieve?

Describe the organizational benefit:

What is the business case? (ROI)

Project Metrics:

Team Members:

Stage:	Target Date:	Actual Date:
Define		
Measure		
Analyze		
Improve		
Control		

Project Charter: Pain Management Start Date: July 20XX

Leadership Signoff / Sanction:_____

Problem/Goal Statement:

To improve interdisciplinary collaboration among pain resource care providers to prevent medication errors, extended length of stay and overall dissatisfaction of patients, families, providers and staff.

Stakeholders: Primary Care Physicians, Community care providers, patients, families

Describe the patient benefit:

Improved understanding of care needs, medication knowledge, ability to ask questions, and reduced fear of the unknown

Why is this project important?

Successful execution will improve the safety and quality of care provided to all patients in pain

Describe the organizational benefit:

Care coordination, teamwork, retention, market strategy, reduced LOS, accountability measure compliance

What will the project achieve?

Mutual trust, respect and improved communication/teamwork for the integration of the patient care plan

What is the business case? (ROI)

Interdisciplinary team member retention, reimbursement for HCAPHS scores, improved margin and revenue flow

Project Metrics:

Interdisciplinary Team in place, educational programs, available complementary therapies, pharmacy delivery time, EMR information flow, Pain goal accomplishment, Patient perception of teamwork

Nursing documentation of pain assessment, Patient satisfaction with pain management

Team Members:

1. Project Leader:
2. Physician Champion:
3. Executive Champion/Sponsor:
4. Pain resource nurse
5. CNS, Case Manager, Social Worker, Rehab
6. Pharmacist:
7. Surgery, anesthesia, medical reps
8. Others:

Stage:	Target Date:	Actual Date:
Define		
Measure		
Analyze		
Improve		
Control		

UWHC Core Competency: The RN is able to provide safe care to the patient with pain.

Name_____ Employee ID: _____

☐ **Learning Outcome #1:** Appropriately performs and documents pain screening, assessments, and reassessments.
☐ **Learning Outcome #2:** Teaches the patient and family about pain control.
☐ **Learning Outcome #3:** Collaborates with patient, family and health care team to develop pain management plan and define pain relief goals.

Concepts:

- Assessment
- Treatment planning
- Goal determination
- Patient education
- Collaboration and communication

Required Competency Components:

☐ Asks all patients on initial evaluation and routinely as part of a health assessment about the presence of pain.
☐ If pain is present, assesses critical characteristics including: location, quality, intensity, temporal characteristics, alleviating and aggravating factors, impact of pain, past interventions and responses.
☐ Utilizes simple and reliable pain intensity scales appropriate to age and cognitive status (i.e. 0-10 rating, Checklist of Nonverbal Pain Indicators (CNPI), Preverbal/nonverbal or faces, 0-5 scale for pediatric pts).
☐ Teaches patient how and when to report pain including side effects/adverse effects of pain treatment, roles in helping to manage pain, realistic pain relief goals, and how to utilize pain interventions.
☐ Discusses realistic goals with patient.
☐ Communicates and collaborates appropriately with Unit Pain Resource Nurse, Inpatient Pain Consult Service, Acute Pain Service (Anesthesiology), and others.

Resources:

- Policy Administration *Pain Management* 8.76
- Policy Nursing Patient Care *Medication Administration* 10.19 (for fentanyl patch disposal, refer to section E #5-6.)
- Pain Management Resources on UConnect
- Pain Fast Fact *Assessing Pain in the Nonverbal or Cognitively Impaired*
- Pain Fast Fact *Respiratory Depression from Opioids*
- Pain Fast Fact *Establishing Pain Relief Goals*
- Time spent with unit based Pain Resource Nurse
- HFFY # 4922 *Pain Management-What everyone should know*

UWHC Core Competency: The RN is able to provide safe care to the patient with pain.

Name_____ Employee ID: _____

☐ **Learning Outcome #4**: Safely and effectively administers pain treatment plan (including pharmacologic and nonpharmacologic interventions).

Concepts:

- Pharmacologic interventions
- Side effect management
- Nonpharmacologic interventions
- Multimodal treatment

Required Competency Components:

☐ Administers prescribed analgesics as appropriate (i.e., combinations of analgesics, scheduled versus prn, and titrates range orders to meet individual needs).
☐ Assesses patients' response to interventions and documents reassessments in timely manner.
☐ Proactively manages side effects of opioid analgesics.
☐ Utilizes a variety of non-pharmacologic strategies to promote pain relief including: distraction, relaxation, imagery, massage, heat, cold, and positioning.

Resources:

- Drug Policy for *PRN Range Orders for Inpatients*
- Pain Fast Fact: *PRN Range Opioid Orders*
- *Pain Fast Fact: Nonpharmacologic (Mind/Body) Approaches to Pain Management*
- *Pain Fast Fact: Multimodal Analgesia*
- Pain HFFU # 4448 *How to Relieve Pain without Medicines*

☐ **Learning Outcome #5**: Accurately programs and utilizes the PCA pump. ☐ Not Applicable *

Concepts:

- PCA pump programming steps
- Pump Alarms
- Trouble-shooting pump problems

Required Competency Components:

☐ Demonstrates set-up and use of designated IV PCA pump.
☐ Follows policy and procedure 1.17 when caring for patients with IV PCA including appropriate documentation on pain infusion flowsheet.
☐ Defines/recognizes opioid-induced respiratory depression and appropriate interventions.

Resources:

- Policy Nursing Patient Care IV Patient Controlled Analgesia (PCA) 1.17
- HFFY # 4273 *Intravenous Patient Controlled Analgesia (IV PCA)*
- Pocket Guide for PCA Pump Programming provided in RN orientation

UWHC Core Competency: The RN is able to provide safe care to the patient with pain.

Name_____ Employee ID: _____

☐ **Learning Outcome #6**: The preceptee can safely program and utilize the neuraxial pump. ☐ Not Applicable *

Concepts:

- Gemstar pump features
- Trouble-shooting pump problems
- Adverse effect of neuraxial analgesia techniques

Required Competency Components:

☐ Demonstrates set-up and use of Gemstar analgesic pump.

☐ Follows policy and procedure #6.13 when caring for patients with spinal analgesia, including documentation on pain infusion flowsheet.

Resources:

- Policy 6.13 Epidural and Intrathecal analgesia
- HFFY # 4322 *Epidural Analgesia*
- Pocket Guide for Epidural Pump Programming provided in RN orientation
- Uconnect online self directed learning module on Neuraxial Analgesia for Acute Pain

*The following areas have little or no PCA or epidural pumps so it is alright to check the "Not Applicable" box under learning outcome: F4/5 Cardiology, B6/5 Psychiatry, D6/5 Pulmonary/Renal, F6/5 General Medicine, CTRC: Clinical and Translational Research Core, OR, ambulatory areas and clinics.

UWHC Core Competency: The RN is able to provide safe care to the patient with pain.

Name_____ Employee ID: _____

Clinical Thinking Questions	Learner Response
1. When is it appropriate to consult the unit based Pain Resource Nurse versus the Inpatient Pain Consultation Service?	When available, a Pain Resource Nurse can be consulted to problem solve on questions about individual patients or for the unit's population of patients. The Inpatient Pain Consultation Service (pager 1010) is a formal order request that should be used utilized when the interdisciplinary team needs help.
2. Explain the rationale for the reassessment documentation policy?	Parenteral opioids peak approximately 20 minutes after a dose is given, whereas short acting oral opioids peak approximately 1 hour following administration. In the first 24hours of a new therapy to assure both safety and efficacy, document prn interventions within 30 minutes after parenteral opioids or one hour after drug and non-drug interventions.
3. What is the proper procedure for disposing of a fentanyl patch (Duragesic)?	• Every fentanyl patch application must have a witnessed disposal regardless of the amount of time the patch was adhered to the patient. Procedure for disposal of Fentanyl Patches • With gloves on, remove the patch from the patient • After removal of the patch, the patch will be folded so the adhesive side of the patch adheres to itself. • The patch will then be disposed of into the sharps container. The destruction and disposal of the fentanyl patch must be witnessed and documented in AcuDose by two licensed nurses.
4. A patient's respiratory rate is 8 per minute with a sedation score of 4. What actions would you take?	Treatment may include reducing the dose and physically rousing the patient to stay awake. A physician should be notified for any patient with a sedation score of 4. For adults, naloxone 100mcg IV (may repeat every 3 minutes X 4) is recommended if sedation score is 5 **and** respirations are **less** than 8/minute

UWHC Core Competency: The RN is able to provide safe care to the patient with pain.

Name_____ Employee ID: _____

I am able to provide safe care to the patient with pain.

_____ _____
Employee (printed name) Date (mm/dd/yyyy)

_____ _____
Employee signature Date (mm/dd/yyyy)

_____ is able to provide safe care to the patient with pain.

_____ _____
Preceptor (printed name) Date (mm/dd/yyyy)

_____ _____
Preceptor signature Date (mm/dd/yyyy)

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UW Health
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Health Facts *for you*

What You Should Know about Pain Management

There are many different causes and kinds of pain. Pain can be caused by injury, illness, sickness, disease, or surgery. Treating pain is the responsibility of your doctor, nurse, and other caregivers. You can help them by asking questions and finding out more about how to relieve your pain. This brochure has some questions and answers to help you do that.

Questions to Ask Your Caregivers

- What pain medicine is being ordered or given to you?
- Can you explain the doses and times that the medicine needs to be taken?
- How often should you take the medicine?
- How long will you need to take the pain medicine?
- Can you take the pain medicine with food?
- Can you take the pain medicine with your other medicines?
- Should you avoid drinking alcohol while taking the pain medicine?
- What are the side effects of the pain medicine?
- What should you do if the medicine makes you sick to your stomach?
- What can you do if the pain medicine is not working?
- What else can you do to help treat your pain?

Talking About Your Pain

Is it important for doctors and nurses to ask about your pain?

Yes. This is because pain changes over time or your pain medicine may not be working. Doctors and nurses should ask about your pain regularly.

What do you need to tell your doctor and nurse about your pain?

First, tell them that you have pain, even if they don't ask. Your doctor or nurse may ask you to describe how bad your pain is on a scale of 0 (zero) to 10 with 10 being the worst pain. They may use other pain scales that use words, colors, faces, or pictures. Tell them where and when it hurts. Tell them if you can't sleep or do things like dressing or climbing stairs because of pain. The more they know about your pain the better they can treat it. The following words can be used to describe your pain.

- aching
- bloating
- burning
- cramping
- comes and goes
- constant
- cutting
- dull
- numbing
- pressing
- pressure
- pulling
- radiating
- searing
- sharp
- shooting
- soreness
- stabbing
- throbbing
- tightness

What can you do when your pain gets worse?

Tell your doctor or nurse. Tell them how bad your pain is or if you're in pain most of the time. Tell the doctor if the pain medicine you're taking is not helping.

Should you include pain medicine on your list of medicines or medication card?

Yes! Even pain medicine that you will take for a short time should be listed with all of your other medicines. List all of your pain medicines — those prescribed by your doctor and those you buy over-the-counter on your own.

Managing Your Pain

What can be done to treat pain?

There are many ways to manage your pain. There are medicines that can be used to relieve pain. There are also other ways to treat pain without taking medicine. Your doctor will work with you to find out what works best for you.

What are some of the medicines used to treat pain?

Some pain medicines are acetaminophen, aspirin, ibuprofen, naproxen, and opioids. Opioids include morphine, oxycodone, and hydromorphone. Many of these medicines come in pills, liquids, suppositories, and skin patches. Some pain may be treated with medicines that are not usually thought of as pain relievers. For example, antidepressants.

Are there other ways to relieve pain?

That will depend on your illness or condition and how much pain you have. Sometimes pain can be relieved in other ways. Some other treatments for pain are listed here.

- Acupuncture, which uses small needles to block pain
- Taking your mind off the pain with movies, games, and conversation
- Electrical nerve stimulation, which uses small jolts of electricity to block pain
- Physical therapy
- Hypnosis
- Massage
- Exercise
- Heat or cold
- Relaxation

What are the side effects of pain medicines?

It depends on the medicine. Side effects can include constipation, nausea, vomiting, itching, and sleepiness.

What can you do if you have side effects or a bad reaction?

Call your doctor or nurse as soon as possible. Find out what can be done to treat the side effect. Ask if there is another pain medicine that may work better for you.

Are you afraid to take a pain medicine?

You may have had a bad experience taking pain medicine in the past, such as a side effect or bad reaction. Or you may be taking a lot of other medicines. Your doctor or nurse should be able to ease your fears.

Are you afraid that you'll become addicted to pain medicine?

This is a common concern of patients. Studies show that addiction is unlikely. This is especially true if the patient has never been addicted. Talk to your doctor or nurse about your fears.

Are you afraid that your pain medicine won't work if you take it for a long time?

This is called "tolerance." It means that after awhile your body gets used to the medicine and you need to make a change to get pain relief. It's also possible that the condition causing your pain is getting worse or you have a new type of pain. You may need more medicine or a different kind of medicine to control your pain. Tell your doctor or nurse about your fears.

Can you crush pills if you can't swallow them?

Check with your doctor, nurse or pharmacist. Some medicines can be crushed and some cannot. For example, time-release medicines should not be crushed. Ask your doctor or nurse if the medicine comes in a liquid or can be given another way.

Website - www.jointcommission.org