Guidelines

An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part I: Introduction and General Considerations

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In 2011, the Institute of Medicine (IOM) re-engineered its definition of clinical guidelines as follows: "clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefit and harms of alternative care options." This new definition departs from a 2-decade old definition from a 1990 IOM report that defined guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." The revised definition clearly distinguishes between the term "clinical practice guideline" and other forms of clinical guidance derived from widely disparate development processes, such as consensus statements, expert advice, and appropriate use criteria. The IOM committee acknowledged that for many clinical domains, high quality evidence was lacking or even nonexistent. Even though the guidelines are important decision-making tools, along with expert clinical judgment and patient preference, their value and impact remains variable due to numerous factors.

Some of the many factors that impede the development of clinical practice guidelines include bias due to a variety of conflicts of interest, inappropriate and poor methodological quality, poor writing and ambiguous presentation, projecting a view that these are not applicable to individual patients or too restrictive with elimination of clinician autonomy, and overzealous and inappropriate recommendations, either positive, negative, or non-committal. Consequently, a knowledgeable, multidisciplinary panel of experts must develop guidelines based on a systematic review of the existing evidence, as recently recommended by the IOM.

Chronic pain is a complex and multifactorial phenomenon associated with significant economic, social, and health outcomes. Interventional pain management is an emerging specialty facing a disproportionate number of challenges compared to established medical specialties, including the inappropriate utilization of ineffective and unsafe techniques.

In 2000, the American Society of Interventional Pain Physicians (ASIPP) created treatment guidelines to help practitioners. There have been 5 subsequent updates. These guidelines address the issues of systematic evaluation and ongoing care of chronic or persistent pain, and provide information about the scientific basis of recommended procedures. These guidelines are expected to increase patient compliance; dispel misconceptions among providers and patients, manage patient expectations reasonably; and form the basis of a therapeutic partnership between the patient, the provider, and payers.

Key words: Evidence-based medicine (EBM), comparative effectiveness research (CER), clinical practice guidelines, systematic reviews, meta-analysis, interventional pain management, evidence synthesis, methodological quality assessment, clinical relevance, recommendations.

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Health care research, practice, and policy focus on improving the organization, delivery, and outcomes of care (1). Critical to achieving these objectives is the need for guidance based on currently available knowledge generated through research, in combination with professional experience and consideration of each individual patient (2-15). Thus, the emphasis on evidence synthesis and development of guidelines continues to grow. In 2011, the Institute of Medicine (IOM) re-engineered its definition of clinical guidelines (16). According to the new definition, "clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." The new definition departs from a 1990 IOM report, which defined guidelines as, "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (17).

The new definition provides a clear distinction between the term "clinical practice guideline" and other forms of clinical guidance derived from widely disparate development processes, such as consensus statements, expert advice, and appropriate use criteria. In addition, the new definition also underscores systematic review and both benefits and harms assessment as essential components of clinical practice guidelines. Although the IOM committee recognized that other forms of clinical guidance may have value, addressing the other forms was considered to be beyond the scope of the report on clinical practice guidelines. In addition, the IOM committee also has acknowledged that, for many clinical domains, high quality evidence is lacking or even non-existent. Consequently, they recommended that, despite such constraints, guideline developers should still be able to produce trustworthy clinical practice guidelines if their development reflects the committee standards as described by the IOM (16).

While guidelines, along with expert clinical judgment and patient preference, are important decision-making tools, their value and impact remain variable due to numerous factors (1,2). For example, a population-based assessment of performance on 439 recommendations for 30 conditions spanning preventive, acute, and chronic care services found that only 55% of patients in the United States received recommended care (18). In addition, the lack of adherence to practice guidelines continues to be identified worldwide across different conditions and settings of care (19-25).

Indeed, any group of individuals can designate itself as an evidence-based medicine (EBM), comparative effectiveness research (CER), or guideline group. Different groups have reviewed the same procedure or problem in interventional pain management and reached vastly different conclusions (15,25-56). Consequently, it is clear that the process of preparation of EBM or CER manuscripts and guidelines is inadequately monitored, and replication, which is the distinguishing characteristic of scientific knowledge and an essential test of the validity of any scientific statement, is essentially impossible. Multiple factors influencing guideline development include the nature of the newly recommended practice or technology itself; characteristics of health care providers; organizational capacity to collect, adapt, share, and apply evidence; system-level environmental factors; and policies dictated by governmental agencies and the insurance community (57,58). These factors, however, are considered to be manifestations of the downstream of guideline development. Consequently, the application of single and combined interventions has been recommended to address these barriers and improve compliance with guideline recommendations, even though their impact can be variable and inconsistent (2,12,13,15,59). Other factors are intrinsic to guidelines and perhaps best addressed at the time of guideline development. These include bias due to various conflicts of interest, variable methodological quality, inappropriate or poor writing, and ambiguous presentation, projecting a view that these are not applicable to individual patients or too restrictive, with reduction or elimination of clinician autonomy and inappropriate overzealous recommendations. The volume of guidelines currently available may be overwhelming, particularly given that recommendations for the same clinical indication may be inconsistent across different guidelines due to individual biases and conflicts of interests (1,2,60-62). The IOM provided guidance for trustworthy guidelines (16), noting that they should be:

- Based on a systematic review of the existing evidence
- Developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups
- Considerate of important patient subgroups and patient preferences, as appropriate
- Based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest
- Clear in their explanation of the logical relation-

ships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations
- Reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

As a result, researchers, clinicians, professional organizations, and governments in the United States and other countries are looking for a sensible approach to health care with practicable and replicable EBM and CER. Multiple frameworks have been developed to improve the ability to implement clinical guidelines by developing national and international standards (63-71). Even so, there are conflicting opinions about whether guidelines are a solution to rationing or politics disguised as science (63). According to Saarni and Gylling (64), EBM is often seen as a scientific tool for quality improvement, even though its application requires consideration of scientific facts along with value judgments and the cost of different treatments. Thus, guideline development depends on whether we approach the problem from the perspective of individual patients, doctors, or public health administrators. The EBM exerts a fundamental influence on certain key aspects of medical professionalism. Thus, each segment has its own interpretation and agenda, often seemingly based on factors other than science and best care for the patient. The actual value of evidence is related to the application and circumstances in which and for whom it will be used. It is also essential to remember that the value of evidence is only as good as the type of evidence reviewed, the methodology utilized, the knowledge and experience of the reviewers, and many other factors, including bias, self-interest, and financial factors. EBM begins with the assertion that it is a shift in medical paradigms and is about solving clinical problems (63). In order for clinicians to interpret the results of clinical research effectively, a formal set of rules must complement medical training and common sense (63). Thus, knowing the tools of evidence-based practice is necessary, but not sufficient, for delivering the highest quality of patient care. It therefore continues to be a challenge for EBM, CER, and interventional pain management to better integrate new scientific innovations with the time-honored craft of caring for the sick (63). Even though some have characterized EBM as a stick by which policymakers and academicians beat clinicians (65-67), there is an extensive role for EBM, CER, and clinical guidelines based on EBM in interventional pain management (2,6-9,15,25-31). EBM is commonly defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (63). The term is loosely used and can include conducting a statistical meta-analysis of accumulated research, promoting randomized clinical trials (RCTs), supporting uniform reporting styles for research, or having a personal orientation toward critical self evaluations (59). EBM was initially defined as counter to clinical experience, while more recent definitions have emphasized the complementary character of both and have aimed to improve clinical experience with better evidence (64).

In contrast, CER is defined as "the generation and synthesis of evidence that compares the benefits and harms of alternate methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care" (30).

The influence of EBM and clinical guidelines on clinical practice and health policy is enormous. However, the process of guideline development has been, and remains, essentially unregulated (68-72). Sniderman and Furberg (72) have examined the sources of guideline authority; identified major limitations of the present process; addressed the issue of conflict of interest, both for the individuals who staff the committees and the organizations that govern them; and provided suggestions for reform that may help improve the management of the process. It has been stated that critics of EBM mostly come from within the medical professions (59). In addition to the many scientific challenges related to creating sound guidelines when evidence is weak, Sniderman and Furberg (72) stress the destructive effects of standards at the local level. Consequently, in an age of mandated cost control, managed care, and resource limitation, many practitioners "in the trenches" believe that, instead of revolutionizing care, EBM threatens to bring about stagnation, bland uniformity, and denial of coverage, and has been derogatorily characterized as "cookbook medicine" (59). Ironically, EBM may also result in a lower standard of safety and economy by de-skilling practitioners and increasing costs. In contrast, supporters tend to see EBM and guidelines as a panacea for the problems of rising costs, and the inequity and variability plaguing the health care field (59). Supporters contend that individual clinicians using EBM will be able to draw upon the objective experience of many researchers working with accepted scientific standards of evidence. Thus, this evidence is related to an assessment of the

patient's circumstances and the practitioner's clinical experience, improving efficacy by allowing providers to divert scarce resources away from ineffective clinical practices and toward practices whose effectiveness has been conclusively demonstrated. Consequently, the specific clinical recommendations that are contained within the practice guidelines must have been systematically developed by panels of experts who have access to the available evidence, have an understanding of the clinical problem, and have clinical experience with the subject procedure and the relevant research methods to make considered judgments. These panels are expected to be objective and to produce recommendations that are unbiased, up-to-date, and free from conflicts of interest.

The notion that EBM promises to create better informed patients and clinicians by offering collectively agreed upon and publicly available information about treatment options is contradicted by a significant proportion of physician providers. In practice, EBM clinical practice guidelines are created by a small group of interested parties. Even so, there has been an explosion in the development of clinical practice guidelines, as well as the literature focusing on EBM and CER, all of which is unregulated and unchecked.

Appropriately developed guidelines must incorporate validity, reliability, reproducibility, clinical applicability and flexibility, clarity, development through a multidisciplinary process, scheduled reviews, and documentation (17,33,73,74). When appropriately applied, rigorously developed guidelines have the potential to reduce undesirable practice variation, reduce the use of services that are of minimal or questionable value, increase utilization of services that are effective but underused, and target services to those populations most likely to benefit (2-11,14,16,75-93).

In fact, the IOM committee on clinical practice guidelines (16) described 8 standards for developing trustworthy clinical practice guidelines, including transparency, conflict of interest, group composition, clinical practice guidelines-systematic review interception, articulation of recommendations, external review, and updating. Furthermore, the committee has focused increased attention on aspects of conflicts of interest, such as details of guideline development group exclusions; aspects of guideline group composition, including training of patient and consumer representatives in evidence appraisal, the specific nature of working relationships between systematic review teams and clinical pain guideline developers; critical steps in establishing evidence foundation for clinical recommendations and rating recommendations strength; external review of clinical practice guidelines including specifying mechanisms for ensuring public stakeholder comment; and elements essential to clinical practice guideline updating, including ongoing monitoring and review of the clinical guideline-relevant scientific literature and factors indicating the need for updates. Unlike many development methodologies, which are specific to a particular guideline development, entity, and clinical problem, the 8 standards described by the IOM provide sufficient flexibility to be applicable to all guideline development groups, whether evidence in a particular clinical area is lacking or abundant.

Finally, many barriers to evidence-based interventional pain management research exist. They include numerous factors, such as funding, time, infrastructure, patient preference, ethical issues, and, additionally, barriers associated with specific attributes related to researchers, methodologies, or interventions. It has been demonstrated that poorly or inadequately performed RCTs and meta-analysis can give rise to incorrect results and thus fail to inform clinical practice or revise policies (94-99). The same issues apply to interventional pain management. These barriers can be overcome by training, not only academicians, but also practitioners, in research methodology and data interpretation to ensure that trials are conducted correctly and evidence is adequately synthesized and disseminated. In a recent systematic review (100), multiple barriers to a general practitioner's use of EBM were illustrated. Another systematic review (101) compared the insufficient evidence for clinical practice published in 2004 by Cochrane reviews with current evidence in 2011. After analyzing 1,128 completed systematic reviews, only 45% concluded that the intervention studies were likely to be beneficial, of which only 2% recommended no further research. In total, 45% of the reviews reported that the evidence was neither beneficial nor harmful, of which 0.8% did not recommend further studies and 0.4% recommended no further research. Consequently, it was concluded that only a small number of the Cochrane collaboration systematic reviews support clinical interventions with no need for additional research.

Varma et al (102) described common pitfalls in the application of EBM, along with the reasoning behind them. The authors concluded that it is impossible to answer every potential clinical question through RCTs. Consequently, assumptions, rational thinking, logic, and reasoning are used to make recommendations. However,

these methods may interfere with the judicious application of EBM, and may result in logical fallacies. Furthermore, the authors described that extrapolations of study content and confusing associations with causation are common pitfalls in the application of the EBM process. In addition, personal bias can be another barrier, since it may be difficult to modify despite the evidence and because keeping up with the medical literature in a busy practice can be daunting. Rosner (103) described numerous problems besetting EBM. He pointed out that the canonical pyramid of EBM excludes numerous sources of research information, such as basic research, epidemiology, and health services research. Models of EBM commonly used by third party payers have ignored clinical judgment and patient values and expectations, which together form a tripartite and more realistic guideline to effective clinical care. Compounding these issues is the fact that enhanced placebo treatments and experimentation may obscure treatment effects commonly seen in actual practice. In addition, poor systematic reviews, which comprise a significant portion of published EBM, are prone to subjective bias in their inclusion criteria and methodological scoring, which has been shown to skew outcomes. Finally, Rhee and Daramola (104) provided reassurance that there is no need to fear EBM, as it aims only to apply the best available evidence gained from the scientific method to clinical decision-making. The authors explain that, while the notion of EBM seems noble in its purpose, there are still some apprehensions and misconceptions among physicians, especially those in a predominantly surgical field. Consequently, this may also apply to interventional pain management. Developing a sophisticated understanding of the inherent biases and limitations of EBM will become increasingly important for the researcher and practicing physician as they strive to improve the rigor of their studies and produce noteworthy scientific evidence that improves health outcomes.

Recently, multiple manuscripts have described the development of clinical practice guidelines, along with the development of international standards and the updating of clinical practice guidelines (69,70,105). Woolf et al (105) once again described that clinical practice guidelines are one of the foundations of efforts to improve health care. Guideline development methodology has progressed, both in terms of methods and necessary procedures, since they authored a manuscript about the topic in 1999 (106). In addition, the context for guideline development has changed with the emergence of guideline clearinghouses and large-scale guideline production organizations, such as the Agency for Healthcare Research and Quality (AHRQ) (11) and the National Institute for Health and Clinical Excellence (NICE) (107). The authors discussed issues related to identifying and synthesizing evidence: deciding what type of evidence and outcomes to include in guidelines; integrating values into a guideline; incorporating economic considerations; synthesizing, grading, and presenting evidence; and moving from evidence to recommendations (105). These recommendations are similar to the statements made by the IOM (16). In addition, there has also been a movement toward international standards for clinical practice guidelines (70). The development of guidelines within coordinated programs can facilitate the achievement of quality standards by enabling the efficient sharing of resources and expertise (108). International collaboration offers additional opportunities to enhance guideline development. Standards for guideline development can help organizations assume that recommendations are evidence-based and can help users identify high-quality guidelines. Several groups, such as the IOM (16), the World Health Organization (WHO) (109), NICE (107), the Scottish Intercollegiate Guideline Network (SIGN) (110), the National Health and Medical Research Council (NHMRC) (111), many medical societies, and others, have proposed standards for guideline developers. It is also noteworthy that the IOM's recent reports identifying criteria for trustworthy clinical practice guidelines and systematic reviews (16,112) have received both praise and criticism. Much of the concern about the IOM's criteria centers on the feasibility of implementing the long list of criteria and the application of these criteria to diverse settings (113). The same criticism applies to the international network of various guidelines where clinicians, patients, and other stakeholders struggle with numerous and sometimes contradictory guidelines of variable quality (108). Qaseem et al (70) proposed a set of key components for guideline development addressing panel composition, the decision-making process, conflicts of interest, guideline objectives, development methods, evidence review, basis of recommendation, ratings of evidence and recommendations, guideline review, the updating process, and funding.

Alonso-Coello et al (69) published insight from an international survey in reference to updating clinical practice guidelines. This appears to be the first study to describe the process of updating clinical practice guidelines. They concluded that there is an urgent need to develop rigorous international standards for updating

clinical practice guidelines and minimizing the duplication of efforts internationally.

1.0 Definitions

1.1 Chronic Pain

Chronic pain is defined as a complex and multifactorial phenomenon with pain that persists 6 months after an injury and/or beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathology and may not be amenable to routine pain control methods with healing never occurring (42,114).

1.2 Interventional Pain Management

The National Uniform Claims Committee (NUCC) (115) defined interventional pain management as the discipline of medicine devoted to the diagnosis and treatment of pain and related disorders by the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatments.

1.3 Interventional Techniques

The Medicare Payment Advisory Commission (MedPAC) (116) described interventional techniques as minimally invasive procedures, such as needle placement of drugs in targeted areas, ablation of targeted nerves, and some surgical techniques, such as discectomy and the implantation of intrathecal infusion pumps and spinal cord stimulators.

1.4 Evidence-based Medicine

EBM is defined as a conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (64).

1.5 Comparative Effectiveness Research

Comparative effectiveness research is defined as the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care (117).

1.6 Clinical Practice Guidelines

In 2011, the IOM committee on clinical practice guidelines defined clinical practice guidelines as statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (16).

1.7 Systematic Reviews and Meta-analyses

A systematic review is defined as "the application of scientific strategies that limit bias by the systematic assembly, critical appraisal, and synthesis of all relevant studies on a specific topic" (118,119).

The IOM described a systematic review as a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies (112).

Meta-analysis, in contrast to a systematic review, is the statistical pooling of data across studies to generate a summary (pooled estimates of effects) (119).

The IOM defines meta-analysis as the progression of a systematic review to include quantitative synthesis, depending on the available data (112).

1.8 Randomized Controlled Trials

An RCT is defined as any research study that randomly assigns human participants or groups of humans to one or more health-related interventions versus a placebo to evaluate the effects on health outcomes (120-122).

1.9 Observational Studies

An observational study is defined as an etiologic or effectiveness study, a cross-sectional study, a case series, a case-control design, a design with historical controls, or a cohort design (123).

1.10 Diagnostic Studies

A diagnostic study is a study of diagnostic accuracy, in which results from one or more tests are compared with the results obtained with the reference standard on the same subject (124).

2.0 Basic Considerations of Guidelines for Interventional Techniques

2.1 Purpose

Evidence-based clinical practice guidelines for interventional techniques in the management of chronic spinal pain are statements developed to improve the quality of care, patient access, treatment outcomes, appropriateness of indicated and medically necessary care,

and efficiency and effectiveness, as well as achieve cost containment by improving the cost-benefit ratio (42).

2.2 Focus

These updated and revised guidelines focus on a range of interventions that are the essential elements of the effective management of chronic spinal pain.

2.3 Objectives

The objectives of the American Society of Interventional Pain Physician's (ASIPP) updated guidelines for interventional techniques are to provide a set of recommendations that can support existing and future guidelines by:

The objectives of ASIPP's updated guidelines for interventional techniques are to provide a set of recommendations that can support existing and future guidelines by:

- Providing strategies to manage chronic spinal pain and/or its consequences in the general populations to improve the quality of clinical care
- Providing recommendations that are generally acceptable to a wide range of specialties and agencies
- Developing methods that are sound and transparent and highlight areas where deficiencies in knowledge merit further research;
- Utilizing a process that is valid, reliable, reproducible, clinically applicable, and flexible, in conjunction with a scheduled review
- Systematically assessing the clinical and cost effectiveness of treatments and management strategies with an evidence-based approach through the use of systematic reviews, existing evidence-based guidelines, and individual clinical studies
- Increasing compliance, dispelling misconceptions, contributing to appropriate patient expectations, and facilitating an enhanced relationship between patients, physicians, and payers.

2.4 Population and Preferences

The population covered by these guidelines includes all patients suffering from chronic spinal pain who are eligible to undergo commonly utilized and effective interventional technique(s). The treatment plan, evidence, patient preferences, and risk-benefit ratio must all be taken into consideration.

2.5 Implementation and Review

The following dates for implementation and review were established:

- Effective date – January 1, 2013
- Expiration date – December 31, 2015
- Scheduled review – April 2014

2.6 Application

While these guidelines may be applied by any specialty, they are specifically intended for use by interventional pain physicians. These guidelines do not constitute inflexible treatment recommendations. It is expected that a provider will establish a plan of care on a case-by-case basis, taking into account an individual patient's medical condition, personal needs, and preferences, and the physician's experience. Based on an individual patient's needs, treatment different from that outlined here could be warranted. Consequently, these guidelines do not represent a "standard of care."

The goal of these guidelines is to provide practitioners and payers with information to determine whether the available evidence supports the notion of a "standard" for interventional techniques. "Standard" refers to what is applicable to the majority of patients, with a preference for patient convenience and ease of administration without compromising treatment efficacy or safety. It is essential to recognize the difference between "standard" and "standard of care," as utilized as a legal definition.

3.0 Rationale for Development of Interventional Techniques Guidelines

3.1 Chronic Pain

Chronic pain is defined by the International Association for the Study of Pain (IASP) as "pain that persists beyond an expected time frame for healing (125)." Recognizing the complexity of chronic pain, ASIPP defines chronic pain as, "pain that persists 6 months after an injury and beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathologies; may not be amenable to routine pain control methods; and healing may never occur" (42,114). Based on multiple regulations and definitions, "chronic" may be considered to be continued pain after 90 days.

The IOM report on relieving pain in America (126) noted that, not only is the magnitude of pain in the United States astounding, with more than 100 million Americans with pain that persists for weeks to years,

but that estimated financial costs range from $560 billion to $630 billion per year, with Americans constituting only 4.5% of the global population. Freberger et al (127), in an evaluation of North Carolina households conducted in 1992 and repeated in 2006, showed a significant and rapid overall increase for low back pain of 162%, from 3.9% in 1992 to 10.2% in 2006. These findings have been echoed in numerous studies. Hoy et al (128-130), in multiple publications evaluating spinal pain, showed variable prevalence with a significant recurrence of 24% to 80%; a significant increase in prevalence as the population ages. Studies of the prevalence of low back and neck pain (131,132) and its impact in the general population have shown 23% of patients reporting Grade II to IV low back pain with a high pain intensity and disability compared to 15% with neck pain (Fig. 1). In addition, the age-related prevalence of persistent pain has been shown to be more common in the elderly when associated with functional limitations and difficulty in performing daily life activities. Chronic persistent low back and neck pain is seen in 25% and 60% of patients, respectively, one year or longer after the initial episode.

Chronic pain is often confused with chronic pain syndrome (114). Chronic pain syndrome has been defined as a complex pain condition with physical, psychological, emotional, and social components. Even though both chronic pain and chronic pain syndrome can coexist and are defined in terms of duration and the persistence of the sensation of pain and the presence or absence of psychological and emotional components, they are 2 separate entities. Unlike chronic pain, chronic pain syndrome encompasses the added components of certain recognizable psychological and socioeconomic influences and characteristic psychological and sociological behavioral patterns. These features, which to some extent may characterize both conditions, overlap each other in multiple aspects.

Chronic pain is associated with significant economic, societal, and health outcomes (133-173). Leigh et al (143) published 1992 data for occupational injury and illness in the United States, including estimated costs, morbidity, and mortality with 6,500 job-related deaths from injury, 13.2 million non-fatal injuries, 60,300 deaths from disease, and 862,200 illnesses occurring annually in the civilian American workforce, with total

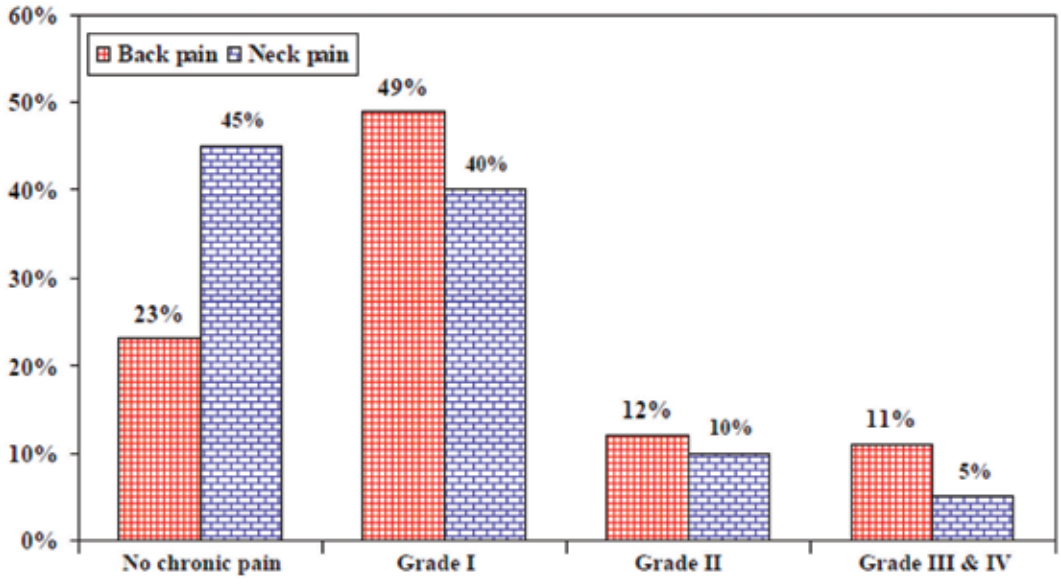


Fig. 1. *Severity of low back and neck pain (age standardized rate).*

Adapted and modified from Cassidy JD et al. The Saskatchewan Health and Back Pain Survey. The prevalence of low back pain and related disability in Saskatchewan adults. Spine (Phila Pa 1976) 1998; 23:1860-1867 (131) and Côté P et al. The Saskatchewan Health and Back Pain Survey. The prevalence of neck pain and related disability in Saskatchewan adults. *Spine(Phila Pa 1976)* 1998; 23:1689-1698 (132).

costs of $171 billion. Martin et al (133) evaluated 2005 health care expenditures in the United States for treating back and neck problems and reported total expenditures to be approximately $86 billion. Leigh (135), in a 2011 publication assessing data from 2007, updated their earlier study evaluating the economic burden of occupational injury and illness in the United States (143), revealing costs of $290 billion. Furthermore, disability secondary to spinal pain is enormous (174-180). The proportion of disabled individuals, along with costs related to disability, is increasing in the United States. Disability manifests as physical and psychological impairment in chronic pain patients.

Opioid effectiveness, use, abuse, and related fatalities have been well described (46,47,181-211). Evidence illustrates that opioid prescriptions have been escalating at a rapid rate, and opioid-related fatalities amount to 60% of deaths from appropriate prescriptions for chronic pain compared to 40% due to abuse, with all deaths exceeding deaths due to motor vehicle injuries. A direct correlation has been established among opioid-related deaths, treatments, and admissions, along with opioid-related sales. The opioid epidemic has not only been an issue for the United States; it is a global issue as well. Figure 2 illustrates rates of opioid pain reliever overdose deaths from 1999 to 2010 in the United States (212).

3.2 Interventional Pain Management as an Emerging Specialty

Increasing health care costs are a major issue across the globe (133-137). The United States spends more on health care than does any other country. Interventional pain management is no exception. Consequently, expenses in managing chronic pain and chronic spinal pain have been escalating. Martin et al (133) estimated that treatment for back and neck pain problems accounted for $86 billion in health care expenditures in the United States in 2005. This was associated with a 65% increase in expenditures; a 49% increase in the number of patients seeking spine-related care from 1997 through 2006 was the biggest contributor to the increase in expenditures. Rates of imaging, interventional techniques, drug use, chiropractic, physical therapy, alternative complementary therapy, and surgery for spine problems have increased substantially over the past decade (46,47,54,79-93,147-212). Spinal interventional techniques are thus considered one of the major components contributing to increased health care costs among patients with chronic spinal pain (79-93).

As an emerging speciality, interventional pain management faces multiple challenges that may be disproportionate compared to established medical specialities. Due to its emergent nature, interventional pain management is challenged with increasing the ap-

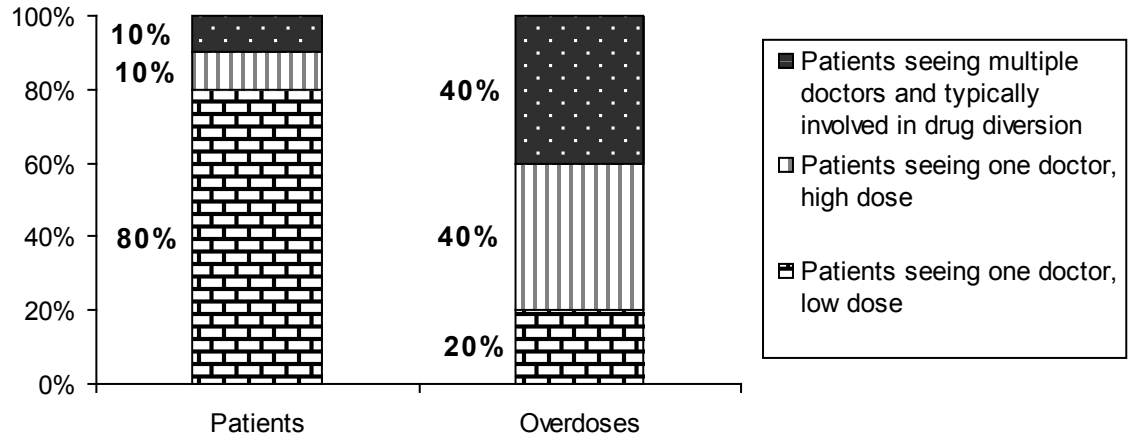


Fig. 2. *Percentage of patients and prescription drug overdoses, by risk group – United States.*

Source: Centers for Disease Control and Prevention. CDC grand rounds: Prescription drug overdoses – a U.S. epidemic. MMWR Morb Mortal Wkly Rep 2012; 61:10-13 (212).

propriate utilization of effective safe techniques and identifying potentially inappropriate care that may be ineffective or unsafe. Currently, the available evidence documents a wide degree of variance in the definition and practice of medicine in general and interventional pain management in particular (2,3,25-49). The application of interventional techniques by physicians of different specialties is highly variable for even the most commonly performed procedures and treatable conditions (79-93).

Abbott et al (88), in a descriptive analysis of utilization patterns between 2003 and 2007, reported that the mean number of procedures across all categories performed per patient during the 12-month inclusion period was 4.46 ± 6.44. They also reported that neurologists and pain management specialists were the only provider groups in which the mean number of procedures per patient exceeded the overall mean. The highest 10% of providers, which encompassed those providers performing a mean greater than or equal to 5.08 procedures per patient per year, performed 36.6% of the total spinal procedures performed. The highest 20% of providers, which encompassed those providers with a mean greater than or equal to 3.75, accounted for 57.6% of all spinal procedures.

Manchikanti et al (87) analyzed spinal interventional pain management techniques utilization trends and Medicare expenditures from 2000 to 2008. They showed that Medicare recipients receiving spinal interventional techniques increased 107.8% from 2000 through 2008, with an annual average increase of 9.6%; whereas spinal interventional techniques increased 186.8%, an annual average increase of 14.1% per 100,000 beneficiaries. They concluded that there was an explosive increase in spinal interventional techniques from 2000 to 2008, which tapered off in later years. This assessment also showed that, in 2000, the majority of procedures were performed in hospital outpatient department settings (HOPDs), compared with 15.3% in ambulatory surgery centers (ASCs) and 24.3% in-office settings.. However, in 2008, office procedures (47%) exceeded both HOPDs (28.3%) and ASCs (24.7%). An assessment of the expenses showed that the total allowed charges increased 300% for ASC settings, 151% for HOPD settings, and 422% for in-office settings. In addition, the charges were highest in HOPD settings and lowest in in-office settings per patient, visit, or procedure. Charges in ASC settings declined 5% to 25%, whereas in HOPD settings, they increased from 63% to 88%.

In another paper, Manchikanti et al (79) assessed all interventional techniques except for implantables, continuous epidurals, intraarticular injections, trigger point and ligament injections, peripheral nerve blocks, and vertebroplasty procedures, and reported an overall increase of 228% for interventional pain management services from 2000 to 2011, and an overall increase of 177% per 100,000 Medicare beneficiaries. Annual increases with geometric average calculations were 11.4%, ranging from a decrease of 1.4% to an increase of 30.3% year to year. This evaluation also showed an increase in epidural injections of 127% per 100,000 in the Medicare population, 310% for facet joint interventions and sacroiliac joint blocks, and 111% for other types of nerve blocks, with a total increase of 177% per 100,000 in the Medicare population. The number of procedures performed in the Medicare population increased from approximately 1.5 million to 5 million in 2011 (Fig. 3). This translates to approximately 20 million interventional technique procedures per year in the U.S. population. From 2000 to 2011, increases for specialties including interventional pain management, anesthesiology, physical medicine and rehabilitation, and neurology were 199% per 100,000 in the Medicare population, compared to 98% for neurological and orthopedic surgery, 166% for radiologic specialties, 48% for other physicians, and 246% for non-physician providers (Fig. 4).

The Office of Inspector General (OIG), Department of Health and Human Services (HHS), has reported startling data: Medicare Part B payments for facet joint injections have increased from $141 million in 2003 to $307 million in 2006 (89). During the same period, the number of Medicare claims for facet joint injections increased by 76%. They also found that 63% of facet joint injection services allowed by Medicare in 2006 did not meet the Medicare program requirements, resulting in approximately $96 million in improper payments. In addition, Medicare also allowed an additional $33 million in improper payments for associated facility claims. Regarding errors, 38% of facet joint injection services had a documentation error, 31% a coding error, 8% did not establish medical necessity, and 14% had overlapping errors. They also showed that approximately 50% of procedures and most of the coding errors were performed by non-interventional pain physicians.

An OIG report on transforaminal epidural injections titled "Inappropriate Medicare Payments for Transforaminal Epidural Injection Services" reported that 34% of transforaminal epidural injection services allowed by Medicare in 2007 did not meet Medicare requirements,

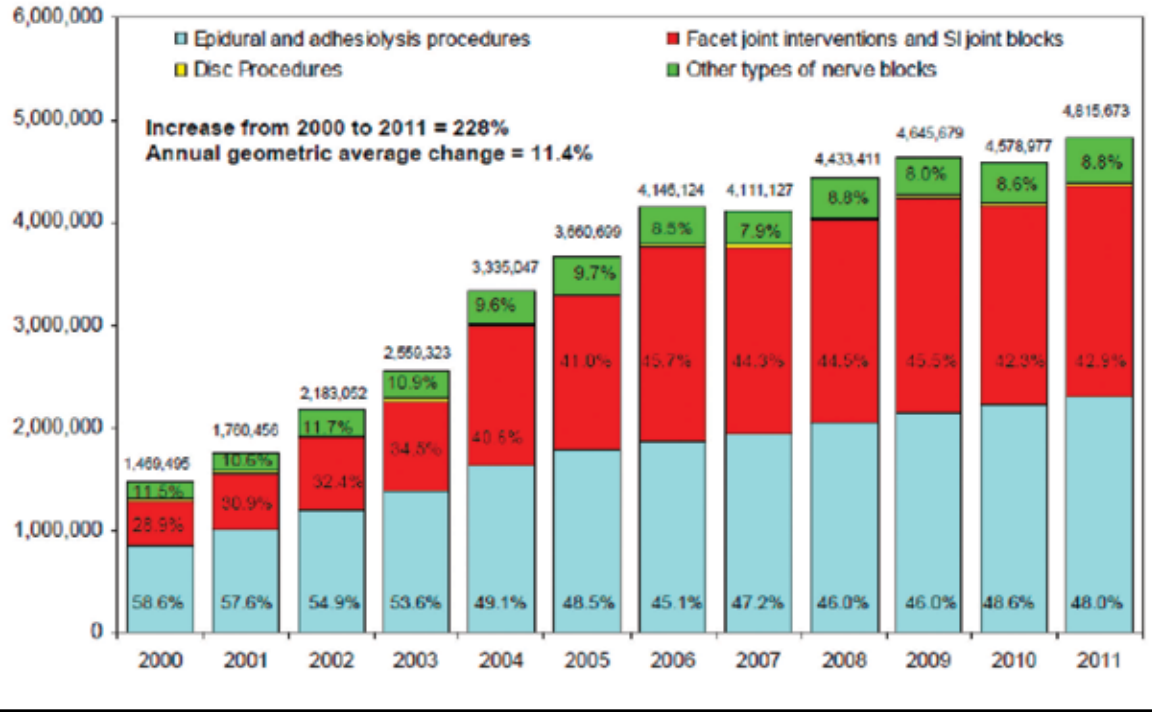


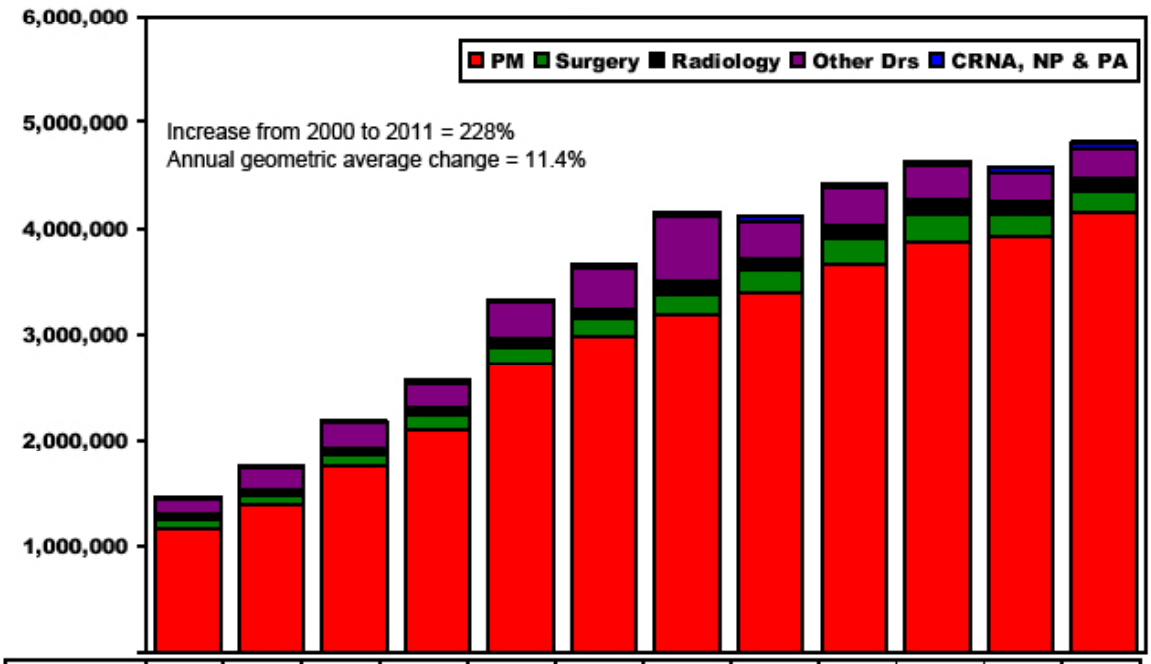
Fig. 3. *Illustration of distribution of procedural characteristics by type of procedures from 2000 to 2011.*

resulting in approximately $68 million in improper payments (90). The number of Medicare physician claims for transforaminal epidural injection services increased by 130% from 2003 to 2007. Over 295,000 Medicare beneficiaries received transforaminal epidural injection services in 2007. Nineteen percent of transforaminal epidural injection services had a documentation error, which was more likely to occur in office settings. Thirteen percent of transforaminal epidural injection services had a medical necessity error, 8% had a coding error, and 7% had overlapping errors.

3.3 Importance

Many of the causes of spinal pain and other chronic pain conditions are considered to be either acute recurrent problems characterized by periods of quiescence punctuated by flare-ups, or chronic diseases, like diabetes or hypertension, requiring long-term treatment with ongoing care. The importance of interventional techniques in managing chronic spinal pain has been established based on advances in imaging, neuroanatomic findings, new discoveries in chemical mediation, the development of precision diagnostic and therapeutic injection techniques, and reported non-operative treatment successes. Numerous guidelines, systematic reviews, Cochrane Reviews, randomized trials, and observational studies pertaining to all aspects of interventional pain management have been published (2,25-54,213-398). However, most of these are ambiguous and may not be applicable for chronic spinal pain management utilizing contemporary interventional pain techniques. Furthermore, there are quality issues related to the inclusion or exclusion of significant literature, such as observational studies.

Thus, the quality of systematic reviews, guidelines, and policies has been questioned, and concerns have been raised regarding non-applicability across populations, bias, and alleged major shortcomings with potentially harmful health care implications for patients (2,25-54,399). As a result, ASIPP has developed a strict, ongoing process of evidence synthesis and guideline preparation with appropriate updating since 1999 (25,42,46,47,400-407). The interventional techniques guidelines and opioid guidelines developed by ASIPP have been listed on the AHRQ/National Guideline Clearinghouse (NGC) web site (408,409).



Specialty (%)	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Pain Management	80.1%	78.9%	80.4%	82.0%	81.5%	81.3%	77.1%	82.8%	82.8%	83.5%	85.6%	86.4%
Surgery	5.7%	5.6%	5.3%	4.9%	4.8%	4.8%	4.7%	5.0%	5.2%	5.7%	4.7%	4.1%
Radiology	2.8%	2.8%	2.9%	3.0%	2.8%	2.8%	2.7%	2.7%	2.6%	2.7%	2.6%	2.6%
Other Physicians	10.4%	11.6%	10.4%	9.2%	10.1%	10.3%	14.7%	8.5%	8.3%	7.2%	6.0%	5.6%
CRNA, NP & PA	1.0%	1.2%	1.1%	0.9%	0.8%	0.8%	0.9%	1.0%	1.0%	1.0%	1.1%	1.3%

Fig. 4. *Utilization of interventional pain management techniques by speciality from 2000 to 2011, in Medicare recipients.*

3.4 Technology

Diagnostic and therapeutic interventional techniques in the management of chronic spinal pain have been evaluated. These include facet joint interventions, sacroiliac joint interventions, epidural injections, lumbar epidural adhesiolysis, discography and intradiscal therapies, and implantable therapies.

4.0 Methodology of Guideline Development

In recent years, there have been substantial increases in the number of treatment alternatives available to providers and patients, the proportions of patients receiving interventional pain management services, the volume of studies describing the effectiveness (or ineffectiveness) of those options, guidelines, and systematic reviews (2,25-54,79-83,213-398). The body of available evidence is becoming more complex, conflicting, and difficult to manage for most providers. Thus, guidelines have become a critical tool for comprehensively summarizing the available literature and organizing it in a format that is accessible to interventional pain management physicians. It has been demonstrated that systematic reviews are outdated after 2-3 years (410-412). Further, assessment and rapid development of systematic reviews have been published (413-416). Due to the wealth of emerging literature, this is especially true for specialties such as interventional pain management, where reviews may be outdated after as little as one year.

4.1 Essentials of Guideline Development

Several groups, including IOM, WHO, NICE, and

NHMRC have provided appropriate guidance in preparing trustworthy guidelines. An additional source, founded in 2002, is Guidelines International Network (G-I-N) – a network of guideline developers composed of 93 organizations and 89 individual members representing 46 countries (414). This organization also has developed a set of key components for guideline development.

4.1.1 Institute of Medicine Guidance

While there are numerous guidelines developed by multiple organizations, most suffer from shortcomings in the guideline development process, often compounding the limitations inherent in their scientific evidentiary reference basis (16). The IOM explained that in order to be trustworthy, guidelines must be

- Based on a systematic review of existing evidence
- Developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups
- Considerate of important patient subgroups and patient preferences, as appropriate
- Based on an explicit and transparent process that minimizes distortion, biases, and conflicts of interest
- Clear in their explanation of logical relationships between alternative care options and health outcomes, providing ratings of both the quality of evidence and the strength of recommendations
- Reconsidered and revised as appropriate when important new evidence warrants modifications and recommendations.

The IOM also described the multiple factors commonly undermining the quality and trustworthiness of clinical practice guidelines, including:

- Variable quality of individual scientific studies
- Limitations of systematic reviews upon which clinical guidelines are based
- Lack of transparency of development groups' methodologies, particularly with respect to evidence quality and strength of recommendation appraisals
- Failure to convene multi-stakeholder and multidisciplinary guideline development groups, and resulting non-reconciliation of conflicting guidelines
- Unmanaged conflicts of interest
- Overall failure to use rigorous methodologies during development

In addition, the IOM committee noted that evidence supporting clinical decision-making and clinical practice guideline development relevant to subpopulations, such as patients with comorbidities, the socially and economically disadvantaged, and those with rare conditions, is usually absent. Overall the committee concluded that the quality of clinical practice guideline development processes and guideline developer adherence to quality standards have remained unsatisfactory and unreliable for decades. Non-standardized development results in significant variation in clinical recommendations. Even though the IOM once again depended on unreliable tools and evidence, they have formulated a new definition and also developed standards for trustworthy clinical practice guidelines (CPG). The committee's 8 proposed standards are reproduced herewith (16):

STANDARD 1:
Establishing transparency

1.1 The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible.

STANDARD 2:
Management of conflict of interest (COI)

2.1 Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG.

- Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), non-commercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the CPG.

2.2 Disclosure of COIs within GDG

- All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work.
- Each panel member should explain how their COI could influence the CPG development process or specific recommendations.

2.3 Divestment

- Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activi-

ties or advisory boards of, entities whose interests could be affected by CPG recommendations.

2.4 Exclusions

- Whenever possible GDG members should not have COI.
- In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
- Members with COIs should represent not more than a minority of the GDG.
- The chair or co-chairs should not be a person(s) with COI.
- Funders should have no role in CPG development.

STANDARD 3:
Guideline development group composition

3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG.

3.2 Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient and a patient advocate or patient/consumer organization representative in the GDG.

3.3 Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.

STANDARD 4:
Clinical practice guideline–systematic review intersection

4.1 CPG developers should use systematic reviews that meet standards set by the Institute of Medicine's Committee on Standards for Systematic Reviews of Comparative Effectiveness Research.

4.2 When systematic reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach, and output of both processes.

STANDARD 5:
Establishing evidence foundations for and rating strength of recommendations

5.1 For each recommendation, the following should be provided:

- An explanation of the reasoning underlying the recommendation, including:
- A clear description of potential benefits and harms.
- A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
- An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation.
- A rating of the strength of the recommendation in light of the preceding bullets.
- A description and explanation of any differences of opinion regarding the recommendation.

STANDARD 6:
Articulation of recommendations

6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed.

6.2 Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.

STANDARD 7:
External review

7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public.

7.2 The authorship of external reviews submitted by individuals and/or organizations should be kept confidential unless that protection has been waived by the reviewer(s).

7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers' comments.

7.4 A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.

STANDARD 8:
Updating

8.1 The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.

8.2 Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.

8.3 CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm, that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective, or that a recommendation can be applied to new populations.

Finally, the committee derived several recommendations directly relevant to the ultimate effectiveness of the 8 standards in increasing the quality and trustworthiness of CPGs and enhancing health care quality in patient outcomes. Thus, to be trustworthy, a CPG should comply with the proposed standards from 1 to 8 as shown above. The ASIPP guideline development process has followed the majority of these recommendations.

4.1.2 Guidance from Guidelines International Network

The G-I-N (70,414) described the following key components of a high-quality and trustworthy guideline as shown in Table 1.

The 11 key components described include multiple aspects similar to other guidance:

- Composition of Guideline Development Group
- Decision-Making Process
- Conflicts of Interest
- Scope of a Guideline
- Methods
- Evidence Reviews
- Guideline Recommendations
- Rating of Evidence and Recommendations
- Peer Review and Stakeholder Consultations
- Guideline Expiration and Updating
- Financial Support and Sponsoring Organization.

Table 1. *Key components of high-quality and trustworthy guidelines.*

Component	Description
Composition of Guideline Development Group	A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients
Decision-Making Process	A guideline should describe the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process should be established before the start of guideline development.
Conflicts of Interest	A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.
Scope of a Guideline	A guideline should specify its objective(s) and scope.
Methods	A guideline should clearly describe the methods used for the guideline development in detail.
Evidence Reviews	Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.
Guideline Recommendations	A guideline recommendation should be clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.
Rating of Evidence and Recommendations	A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.
Peer Review and Stakeholder Consultations	Review by external stakeholders should be conducted before guideline publication
Guideline Expiration and Updating	A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.
Financial Support and Sponsoring Organization	A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.

Source: Qaseem A, et al. Guidelines International Network: Toward international standards for clinical practice guidelines. Ann Intern Med 2012; 156:525-531 (70).

4.1.3 American Society of Interventional Pain Physicians Guideline Development Process

ASIPP launched the development of practice guidelines for interventional techniques in the management of chronic pain in 1999 and published the first guideline in 2000 (400). These guidelines were developed to help practitioners by synthesizing the available evidence. The authors stated that these clinical practice guidelines for interventional techniques in the management of chronic pain were professionally developed utilizing a combination of evidence and consensus.

The synthesis of evidence, committee composition, and development process have been revised, refined, and expanded with evaluation at least once every 3 years.

ASIPP guidelines meet all 8 criteria described by the IOM (16). In developing ASIPP guidelines, all aspects from multiple guidelines were considered. ASIPP guidelines also meet the majority of the criteria described by other guidelines.

5.0 Development of ASIPP Guidelines

Recommendations of the IOM, which essentially incorporate all other guidance for guideline development, were applied in the preparation of ASIPP guidelines. As all of the guidelines share a similar philosophy, this guideline development process uses the IOM's 8 proposed standards (16).

5.1 Transparency

The ASIPP guidelines development process is a project undertaken by the Board of Directors and membership of ASIPP, a not-for-profit organization, to provide a set of recommendations that can support existing and future guidelines to provide appropriate strategies to manage chronic spinal pain and improve the quality of clinical care. Even though ASIPP is an American society, its membership consists of multiple specialties across the globe. The majority of the specialists include interventional pain physicians derived primarily from the specialties of anesthesiology, physical medicine and rehabilitation, and neurology and psychiatry.

There has been no external funding from any type of industry to support the preparation of these guidelines. All participation has been on a voluntary basis. All participants have been requested to provide their COIs.

5.2 Management of Conflict of Interest

Conflicts were managed by limiting the involvement of individuals with COI and re-evaluating the evidence provided by those with COI, even though there was no direct funding received for this project. Consequently, we have also undertaken extensive efforts to avoid direct as well as indirect, internal, and external COI. Prior to inclusion in the guideline development group, all individuals considered for membership declared in writing all interests and activities potentially resulting in COI with development group activity. Disclosures reflected all current and planned commercial, including services from which a clinician derives a substantial portion of income, non-commercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the clinical practice guidelines. As there were no significant COI among the members, there was no necessity for divestment or exclusion. Even then, care was exercised to avoid any conflicts not disclosed by the usual disclosure procedure.

5.3 Guideline Development Group Composition

ASIPP convened a multidisciplinary panel of 51 experts in various fields to review the evidence and formulate recommendations for interventional techniques in managing chronic spinal pain. The panel was instructed to answer questions and develop evidence pertaining to important aspects of spinal interventional techniques. Members of the panel were also requested to develop comprehensive systematic reviews on various related subjects in preparation for the development of spinal interventional techniques guidelines (185-313). Other independent systematic reviews were also considered. The panel convened in person on 3 occasions at ASIPP workshops in Memphis, TN, and also had 6 webinars and/or telephone conferences. The majority of participants attended multiple meetings.

The committee provided a broad representation of academic and non-academic clinical practitioners, reflecting a variety of practices and geographic areas, all with interest and expertise in interventional techniques and chronic pain management. The committee formulized the elements of the guideline preparation process, including literature searches, literature synthesis, consensus evaluation, open forum presentations, and formal endorsement by the ASIPP Board of Directors and peer review. However, there were no patients and patient advocates or patient/consumer organizations included in the guideline development process, which may be considered as a deficiency.

5.4 Systematic Reviews

The IOM developed standards for systematic reviews (112). It described the function / purpose of a systematic review as a tool to identify, select, assess, and synthesize the findings of similar but separate studies and to help clarify what is known and not known about the potential benefits and harms of drugs, devices, and other health care services. Systematic reviews can be helpful for clinicians who want to integrate research findings into their daily practices, for patients to make well-informed choices about their own care, and for professional medical societies and other organizations that develop clinical practice guidelines (112). In developing standards for systematic reviews, the IOM committee defined a "standard" as "a process, action, or procedure for performing systematic reviews that is deemed essential to producing scientifically valid, transparent, and reproducible results."

IOM standards for systematic reviews (112) described multiple standards as reproduced here with modifications in numbering to conform to the text in this manuscript.

1.0 STANDARDS FOR INITIATING A SYSTEMATIC REVIEW

STANDARD 1.1

Establish a team with appropriate expertise and experience to conduct the systematic review

1.1.1 Include expertise in the pertinent clinical content areas
1.1.2 Include expertise in systematic review methods
1.1.3 Include expertise in searching for relevant evidence
1.1.4 Include expertise in quantitative methods
1.1.5 Include other expertise as appropriate

STANDARD 1.2

Manage bias and conflict of interest (COI) of the team conducting the systematic review

1.2.1 Require each team member to disclose potential COI and professional or intellectual bias
1.2.2 Exclude individuals with a clear financial conflict
1.2.3 Exclude individuals whose professional or intellectual bias would diminish the credibility of the review in the eyes of the intended users

STANDARD 1.3

Ensure user and stakeholder input as the review is designed and conducted

1.3.1 Protect the independence of the review team to make the final decisions about the design, analysis, and reporting of the review

STANDARD 1.4

Manage bias and COI for individuals providing input into the systematic review

1.4.1 Require individuals to disclose potential COI and professional or intellectual bias
1.4.2 Exclude input from individuals whose COI or bias would diminish the credibility of the review in the eyes of the intended users

STANDARD 1.5

Formulate the topic for the systematic review

1.5.1 Confirm the need for a new review
1.5.2 Develop an analytic framework that clearly lays out the chain of logic that links the health intervention to the outcomes of interest and defines the key clinical questions to be addressed by the systematic review
1.5.3 Use a standard format to articulate each clinical question of interest
1.5.4 State the rationale for each clinical question
1.5.5 Refine each question based on user and stakeholder input

STANDARD 1.6

Develop a systematic review protocol

1.6.1 Describe the context and rationale for the review from both a decision-making and research perspective
1.6.2 Describe the study screening and selection criteria (inclusion/exclusion criteria)
1.6.3 Describe precisely which outcome measures, time points, interventions, and comparison groups will be addressed
1.6.4 Describe the search strategy for identifying relevant evidence
1.6.5 Describe the procedures for study selection
1.6.6 Describe the data extraction strategy
1.6.7 Describe the process for identifying and resolving disagreement between researchers in study selection and data extraction decisions
1.6.8 Describe the approach to critically appraising individual studies

1.6.9 Describe the method for evaluating the body of evidence, including the quantitative and qualitative synthesis strategies
1.6.10 Describe and justify any planned analyses of differential treatment effects according to patient subgroups, how an intervention is delivered, or how an outcome is measured
1.6.11 Describe the proposed timetable for conducting the review

STANDARD 1.7

Submit the protocol for peer review

1.7.1 Provide a public comment period for the protocol and publicly report on the disposition of comments

STANDARD 1.8

Make the final protocol publicly available, and add any amendments to the protocol in a timely fashion

2.0 STANDARDS FOR FINDING AND ASSESSING INDIVIDUAL STUDIES

STANDARD 2.1

Conduct a comprehensive systematic search for evidence

2.1.1 Work with a librarian or other information specialist trained in performing systematic reviews to plan the search strategy
2.1.2 Design the search strategy to address each key research question
2.1.3 Use an independent librarian or other information specialist to peer review the search strategy
2.1.4 Search bibliographic databases
2.1.5 Search citation indexes
2.1.6 Search literature cited by eligible studies
2.1.7 Update the search at intervals appropriate to the pace of generation of new information for the research question being addressed
2.1.8 Search subject-specific databases if other databases are unlikely to provide all relevant evidence
2.1.9 Search regional bibliographic databases if other databases are unlikely to provide all relevant evidence

STANDARD 2.2

Take action to address potentially biased reporting of research results

2.2.1 Search grey literature databases, clinical trial registries, and other sources of unpublished information about studies
2.2.2 Invite researchers to clarify information about study eligibility, study characteristics, and risk of bias
2.2.3 Invite all study sponsors and researchers to submit unpublished data, including unreported outcomes, for possible inclusion in the systematic review
2.2.4 Handsearch selected journals and conference abstracts
2.2.5 Conduct a web search
2.2.6 Search for studies reported in languages other than English if appropriate

STANDARD 2.3

Screen and select studies

2.3.1 Include or exclude studies based on the protocol's prespecified criteria
2.3.2 Use observational studies in addition to randomized clinical trials to evaluate harms of interventions
2.3.3 Use two or more members of the review team, working independently, to screen and select studies
2.3.4 Train screeners using written documentation; test and retest screeners to improve accuracy and consistency
2.3.5 Use one of two strategies to select studies: (1) read all full-text articles identified in the search or (2) screen titles and abstracts of all articles and then read the full text of articles identified in initial screening
2.3.6 Taking account of the risk of bias, consider using observational studies to address gaps in the evidence from randomized clinical trials on the benefits of interventions

STANDARD 2.4

Document the search

2.4.1 Provide a line-by-line description of the search strategy, including the date of every search for each database, web browser, etc.
2.4.2 Document the disposition of each report identified including reasons for their exclusion if appropriate

STANDARD 2.5

Manage data collection

2.5.1 At a minimum, use two or more researchers, working independently, to extract quantitative and other critical data from each study. For other types of data, one individual could extract the data while the second individual independently checks for accuracy and completeness. Establish a fair procedure for resolving discrepancies—do not simply give final decision-making power to the senior reviewer

2.5.2 Link publications from the same study to avoid including data from the same study more than once

2.5.3 Use standard data extraction forms developed for the specific systematic review

2.5.4 Pilot-test the data extraction forms and process

STANDARD 2.6

Critically appraise each study

2.6.1 Systematically assess the risk of bias, using predefined criteria

2.6.2 Assess the relevance of the study's populations, interventions, and outcome measures

2.6.3 Assess the fidelity of the implementation of interventions

3.0 STANDARDS FOR SYNTHESIZING THE BODY OF EVIDENCE

NOTE: The order of the standards does not indicate the sequence in which they are carried out.

STANDARD 3.1

Use a prespecified method to evaluate the body of evidence

3.1.1 For each outcome, systematically assess the following characteristics of the body of evidence:

- Risk of bias
- Consistency
- Precision
- Directness
- Reporting bias

3.1.2 For bodies of evidence that include observational research, also systematically assess the following characteristics for each outcome:

- Dose-response association
- Plausible confounding that would change the observed effect
- Strength of association

3.1.3 For each outcome specified in the protocol, use consistent language to characterize the level of confidence in the estimates of the effect of an intervention

STANDARD 3.2

Conduct a qualitative synthesis

3.2.1 Describe the clinical and methodological characteristics of the included studies, including their size, inclusion or exclusion of important subgroups, timeliness, and other relevant factors

3.2.2 Describe the strengths and limitations of individual studies and patterns across studies

3.2.3 Describe, in plain terms, how flaws in the design or execution of the study (or groups of studies) could bias the results, explaining the reasoning behind these judgments

3.2.4 Describe the relationships between the characteristics of the individual studies and their reported findings and patterns across studies

3.2.5 Discuss the relevance of individual studies to the populations, comparisons, cointerventions, settings, and outcomes or measures of interest

STANDARD 3.3

Decide if, in addition to a qualitative analysis, the systematic review will include a quantitative analysis (meta-analysis)

3.3.1 Explain why a pooled estimate might be useful to decision makers

STANDARD 3.4

If conducting a meta-analysis, then do the following:

3.4.1 Use expert methodologists to develop, execute, and peer review the meta-analyses

3.4.2 Address the heterogeneity among study effects

3.4.3 Accompany all estimates with measures of statistical uncertainty

3.4.4 Assess the sensitivity of conclusions to changes in the protocol, assumptions, and study selection (sensitivity analysis)

4.0 STANDARDS FOR REPORTING SYSTEMATIC REVIEWS

- STANDARD 4.1

Prepare final report using a structured format

4.1.1 Include a report title

4.1.2 Include an abstract
4.1.3 Include an executive summary
4.1.4 Include a summary written for the lay public
4.1.5 Include an introduction (rationale and objectives)
4.1.6 Include a methods section. Describe the following:
- Research protocol
- Eligibility criteria (criteria for including and excluding studies in the systematic review)
- Analytic framework and key questions
- Databases and other information sources used to identify relevant studies
- Search strategy
- Study selection process
- Data extraction process
- Methods for handling missing information
- Information to be extracted from included studies
- Methods to appraise the quality of individual studies
- Summary measures of effect size (e.g., risk ratio, difference in means)
- Rationale for pooling (or not pooling) results of included studies
- Methods of synthesizing the evidence (qualitative and meta-analysis)
- Additional analyses, if done, indicating which were prespecified

4.1.7 Include a results section. Organize the presentation of results around key questions. Describe the following (repeat for each key question):
- Study selection process
- List of excluded studies and reasons for their exclusion
- Appraisal of individual studies' quality
- Qualitative synthesis
- Meta-analysis of results, if performed (explain rationale for doing one)
- Additional analyses, if done, indicating which were prespecified
- Tables and figures

4.1.8 Include a discussion section. Include the following:
- Summary of the evidence
- Strengths and limitations of the systematic review
- Conclusions for each key questions
- Gaps in evidence
- Future research needs

4.1.9 Include a section describing funding sources and COI

STANDARD 4.2

Peer review the draft report

4.2.1 Use a third party to manage the peer review process
4.2.2 Provide a public comment period for the report and publicly report on disposition of comments

STANDARD 4.3

Publish the final report in a manner that ensures free public access

The IOM Committee concluded that systematic reviews should be used to inform health care decision-makers about what is known and not known about the effectiveness of health interventions (112). Patients expect that their doctors and other health care providers know what type of treatment to recommend. In reality, however, the evidence that informs current health care decisions is often incomplete and may be biased, and there are no standards in place to ensure that systematic reviews of the evidence are objective, transparent, and scientifically valid (11). Better-quality systematic reviews have the potential to improve the decisions made by clinicians, to better inform patient choice, and to provide a more trustworthy basis for decisions by payers and policy makers.

5.4.1 Methodology

Evidence assessment for systematic reviews was based on methodological quality assessment criteria recommended for randomized trials, observational studies, and diagnostic studies (417-437). The methodology utilized in the systematic reviews followed the review process derived from evidence-based systematic reviews and meta-analyses of randomized trials and observational studies (26,42,123,417,434-437), Consolidated Standards of Reporting Trials (CONSORT) guidelines for the conduct of randomized trials (121,438-440), Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (441-443), Cochrane guidelines (417,444), Standards for Reporting of Diagnostic Accuracy (STARD) studies (422), Quality Assessment of Diagnostic Accuracy Studies (QUADAS) (423), Quality Appraisal of Reliability Studies (QAREL) (425), and Chou and Huffman's guidelines (54).

5.4.1.1 Criteria for Considering Studies

- **Types of Studies**

  RCTs

  Nonrandomized observational studies

  Diagnostic accuracy studies

  Case reports and reviews for adverse effects

  - Types of Patients
  - Patients of interest were adults aged at least 18 years with chronic spinal pain of at least 3 months duration.
  - Patients must have failed previous pharmacotherapy, exercise therapy, etc., prior to starting interventional pain management techniques.

- **Types of Interventions**

Diagnostic and therapeutic spinal interventions appropriately performed with proper technique under image guidance (fluoroscopy, computed tomography [CT], or magnetic resonance imaging [MRI]) were included. Ultrasound-guided interventions or interventions without fluoroscopic or CT guidance were excluded.

- **Diagnostic Outcome Measures**

  For facet joint and sacroiliac joint interventions:

  - The primary outcome measure was pain relief concordant with the type of controlled diagnostic blocks performed.
  - The secondary outcome measure was the ability to perform previously painful movements without significant pain or complications.

  For discography:

  - The primary outcome measure was either pain provocation and/or provocation pain relief concordant with the type of discography performed.

  For all diagnostic interventions:

  - At least 2 of the review authors independently, in an unblinded standardized manner, assessed the outcomes measures. Any disagreements between reviewers were resolved by a third author and consensus.

- **Types of Therapeutic Outcome Measures**
  - The primary outcome parameter was pain relief with short-term defined as up to 6 months and long-term defined as 12 months.
  - The secondary outcome measures were functional improvement; change in psychological status; return to work; reduction or elimination of opioid use, other drugs, or other interventions; and complications.
  - At least 2 of the review authors independently, in an unblinded standardized manner, assessed the outcomes measures. Any disagreements between reviewers were resolved by a third author and consensus.

5.4.1.2 Literature Search

Searches were performed from the following sources without language restrictions:

1. PubMed from 1966
   www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. EMBASE from 1980
   www.embase.com
3. Cochrane Library
   www.thecochranelibrary.com/view/0/index.html
4. U.S. National Guideline Clearinghouse (NGC)
   www.guideline.gov
5. Previous systematic reviews and cross references
6. Clinical Trials
   clinicaltrials.gov

The search period included articles from 1966 through 2012.

5.4.1.3 Search Strategy

The search strategy emphasized treating chronic spinal, non-cancer pain of various origins and spinal interventions.

At least 2 of the review authors independently, in an unblinded standardized manner, performed each search. All searches were combined to obtain a unified search strategy. Any disagreements between reviewers were resolved by a third author and consensus.

5.4.1.4 Data Collection and Analysis

The reviews focused on randomized trials, observational studies, diagnostic accuracy studies, and reports of complications. The population of interest was patients suffering from chronic pain of spinal origin. Only epidural interventions, facet joint interventions, sacroiliac joint interventions, discography, vertebroplasty, kyphoplasty, percutaneous disc decompression, spinal cord stimulation, and implantable infusion systems were included. Reports without appropriate diagnosis, nonsystematic reviews, book chapters, and case reports were excluded.

- **Selection of Studies**
  - In an unblinded, standardized manner, 2 review authors screened the abstracts of all identified studies against the inclusion criteria.
  - All articles with possible relevance were then retrieved in full text for a comprehensive as-

sessment of internal validity, quality, and adherence to inclusion criteria.

- **Inclusion and Exclusion Criteria**

The following inclusion and exclusion criteria were established.

1. Are the patients described in sufficient detail to allow you to decide whether they are comparable to those that are seen in interventional pain management clinical practice?
   A. Setting – office, hospital, outpatient, inpatient
   B. Physician – interventional pain physician, general physician, anesthesiologist, physiatrist, neurologist, rheumatologist, orthopedic surgeon, neurosurgeon, etc.
   C. Patient characteristics - duration of pain
   D. Previous noninterventional techniques or surgical intervention
2. Is the intervention described well enough to enable you to provide the same for patients in interventional pain management settings?
   A. Nature of intervention
   B. Frequency of intervention
   C. Duration of intervention
3. Were clinically relevant outcomes measured?
   A. Proportion of pain relief
   B. Disorder/specific disability
   C. Functional improvement
   D. Allocation of eligible and ineligible patients to return to work
   E. Ability to work

5.4.1.5 Clinical Relevance

- The clinical relevance of the included studies was evaluated according to 5 questions recommended by the Cochrane Back Review Group (Table 2) (418). Each question was scored as positive (+) if the clinical relevance item was met, negative (–) if the item was not met, and unclear (?) if data were not available to answer the question.

5.4.1.6 Study Design Assessment

RCTs are considered to provide the most internally valid evidence for medical decision-making. In the specialty of interventional pain management, results from clinical trials, both randomized and observational, with substantial impact on patient care, have been ruled ineffective based on flawed methodology of evidence synthesis (34,50,52,404,444-460). Smith and Pell (461) in their famous metaanalysis, proved that the evidence from randomized trials may be inaccurate. They attempted a metaanalysis, reviewing the available randomized trials supporting the use of parachutes to prevent injuries caused by jumping out of an airplane. There were no trials available which had been done, and they concluded that there was insufficient evidence to recommend the use of parachutes. Realizing that very few interventions in medicine work quite as definitively as parachutes, this attempted metaanalysis reminds us that some interventions are of such intuitive value that they do not require RCTs.

The WHO defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (120)." Very few studies in interventional pain management are RCTs and treatments even in surgery are only half as likely to be based on RCTs as treatments in internal medicine (34,50,52,445-460,462-465). There are multiple studies and opinions for and against randomized trials and observational studies and their importance.

Table 2. *Clinical relevance questions.*

	P (+)	N (-)	U (unclear)
A) Are the patients described in detail so that one can decide whether they are comparable to those who are treated in clinical practice?			
B) Are the interventions and treatment settings described in sufficient detail to apply its use in clinical practice?			
C) Were clinically relevant outcomes measured and reported?			
D) Is the size of the effect clinically meaningful?			
E) Do the likely treatment benefits outweigh the potential harms?			

Scoring adapted and modified from Staal JB, et al. Injection therapy for subacute and chronic low-back pain. *Cochrane Database Syst Rev* 2008; 3:CD001824 (418).

Two components of a randomized trial include randomization and a control group. The randomization and a control group is always a critical decision in designing a clinical trial, as the choice effects the inferences that can be drawn from the trial. However, many ignore the fact that there are various types of control designs in randomized trials. These are placebo control, active control, dose response, placebo + active, placebo + dose response, active + dose response, and finally the best design being placebo + active + dose response. Table 3 shows specific control types based on objectives (466). Most commonly utilized designs in clinical research are placebo control and active control; however, due to various difficulties with designing a true placebo in interventional pain management, active control designs are utilized. An active control design shows existence of effect and also compares therapies in contrast to a placebo control which measures absolute effect size and shows existence of effect. Both have their advantages and disadvantages.

It is essential in interventional pain management or any type of analysis to realize the difference between placebo control and active control. Many researchers have been tending to consider active controls as placebo controls and one of the treatments as placebo. It has been repeatedly shown that local anesthetics and steroids both provide long-term relief (42,213,214,237,245,265,267,276,314-319-340,345,400-402,467-492). Overall there is no significant evidence that steroids provide long-term relief compared to local anesthetic only except in very specific circumstances.

However, placebo-control is an extremely difficult issue with interventional trials as demonstrated by Gerszten et al (493). Furthermore, there is a great deal of misunderstanding in relation to active-control trials and placebo-control trials. This misunderstanding continues to emerge in interventional pain management, resulting in inappropriate analysis of the evidence. In fact, multiple studies that have considered themselves as placebo-controlled in interventional pain management settings (2,29,54,454,494-499) have utilized local anesthetic injection, in essence producing a facet joint nerve block. As the literature illustrates, a facet joint nerve block can provide on average 13 to 16 weeks of prolonged relief (335,337,338). This may have been problematic in interpretation in many placebo controlled interventional trials (395-397,500-503). Consequently, these studies could be construed as active-control trials even though sham treatment was utilized. Similarly, multiple studies in the evaluation of epidural treatment have utilized local anesthetic and called them placebo studies. Proper terminology may be that these are sham-controlled but not placebo-controlled. It is not always feasible to perform placebo-controlled studies in an interventional setting, and the absence of these studies has led to some third party payers denying payment for effective therapies.

It has been widely reported by Cochrane reviewers and others that placebo effect studies are susceptible to response bias and to other types of biases. Hróbjartsson et al (504) reviewed the pervasive and complex connection between the placebo effect and bias. Ever since the concept of the placebo was brought to the attention of the medical community by Beecher (505) in his classic 1955 JAMA article, "The Powerful Placebo," in which he presented a review of assorted placebo-control trials, and argued that the substantial improvement in the condition of patients receiving placebo was caused by the placebo intervention. Nevertheless, Beecher's analysis committed the very fallacy that underlies the need for controlled trials. The observed response to placebo in randomized trials does not itself provide any reli-

Table 3. *Description of specific control types based on objectives.*

Trial Objective	Type of Control						
	Placebo Control	Active Control	Dose Response (D/R)	Placebo + Active	Placebo + D/R	Active + D/R	Placebo + Active + D/R
Measure *Absolute* effect size	Y	N	N	Y	Y	N	Y
Show existence of effect	Y	Y	Y	Y	Y	Y	Y
Show dose-response relationship	N	N	Y	N	Y	Y	Y
Compare therapies	N	Y	N	Y	N	P	Y

Source: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline. Choice of Control Group and Related Issues in Clinical Trials E10. July 20, 2000 (466).

able, unbiased, evidence of a placebo effect —an outcome caused by receiving a sham treatment disguised to be indistinguishable from an active medical intervention. Further, unbiased assessment of the placebo effect requires comparison of placebo interventions with a suitable control group in order to distinguish an effect of the placebo intervention from confounding factors, for example the natural history of the condition under investigation or regression to the mean (506). Even though Beecher's approach were clearly recognized as flawed in the late 1990's (507), by that time the notion of 'powerful placebo' became deeply rooted. Meanwhile methodologists haven't started anchoring to every study results to the natural history of the condition under investigation or regression to the mean. However, Krogsbøll et al in (508) reference to spontaneous improvement in randomized clinical trials and metaanalysis of 3-armed trials comparing no treatment, placebo, and active intervention, dispelled these myths. They showed that the conditions that had most pronounced spontaneous improvement were nausea 45%, smoking 40%, depression 35%, phobia 34%, and acute pain 25%. They also showed that overall, across all conditions and interventions there was a statistically significant change from baseline in all 3 arms. However, for chronic pain no treatment contributed to very small improvement and placebo response was also less than 30%, whereas active treatment showed effect of 60%. Assessment of standardized mean difference for changes from baseline group by acute or chronic conditions showed no change in the no treatment group. Consequently, authors concluded that spontaneous improvement and effect of placebo contributed importantly to the observed treatment effect in actively treated patients, but the relative importance of these factors differed according to clinical condition and intervention. Further, in 2001, in sharp contrast, the power of placebo was challenged by a systematic review published in the New England Journal of Medicine (509). This review identified 114 randomized clinical trials including placebo and no treatment groups, and reported no evidence of overall effects of placebo for objective and binary outcomes and a small, and doubtfully clinically relevant, effect for continuous subjective outcomes, such as pain. These findings are clearly incompatible with Beecher's classic position and present methodologists view of spontaneous improvement of the disorder or disease. While some academic commentators either pointed out that worthwhile effects could still exist in some settings (510), or saw the review as a necessary scientific correction to set the bar differently for claims concerning placebo (511), some media commentators interpreted the result as demonstrating the placebo effect to be a myth (512). Even though review which was updated in 2004 showed similar findings (513), the latest update from 2010 reported more multifaceted results (514). The recent systematic review showed that large analgesic effects of placebo interventions were found in several well conducted trials and a considerable variation in effect could in part be explained by differences in trial design, for example, effect of placebo was larger when the intervention was a device as compared with pill placebo. Overall popular fascination with the placebo effect, specifically methodologists who do not like any type of interventions in medicine, fueled fascination with the placebo effect with unrealistic assessments of its therapeutic effects to rule out any treatment effects. On the same token, some have suggested the therapeutic potential of placebos (515). However, all the metaanalysis (511,513,514) involving progressively larger number of studies and subjects, performed for Cochrane review, challenges the belief that in general that the placebo is powerful. Consequently, estimating the size of the effect of placebo is not only subject to considerable uncertainty, but seems to be almost impossible. Hróbjartsson et al (504) in their methodological analysis and discussion of placebo effect studies and their susceptibility to response bias and to other types of biases, showed that the difference between placebo and no-treatment remains an approximately and fairly crude reflection of the true effect of placebo intervention. They showed that a main problem is response bias in trials with outcomes that are based on patient's reports. Other biases involve differential co-intervention and patient drop-outs, publication bias, and outcome reporting bias, however, they have ignored the bias of the methodologists and improper analysis, and lack of consideration of injection of an inactive solution into active structure. Consequently, extrapolation of results to clinical settings are challenging because of lack of clear identification of the causal factors in many clinical trials, and the non-clinical settings and short duration of most laboratory experiments. They (504) concluded that creative experimental efforts are needed to assess rigorously the clinical significance of placebo interventions and investigate the component elements that may contribute to therapeutic benefit. In fact, nonanalgesic solutions (e.g., saline) injected into painful structures have been reported to result in significant activity or even pain relief not only for spinal pain, but also for

other chronic pain conditions (516-526). The placebo and nocebo effects, and decisions to consider all local anesthetic injections as placebo, are due to a lack of understanding about the scientific basis for placebo and nocebo (50,518,519,527-541). Further, the hazards of evidence-based medicine have been well described in the literature. Thus, it is essential to understand not only the study design but placebo and nocebo influences on the outcomes.

5.4.1.7 Methodological Quality or Validity Assessment

The methodological quality assessment was performed by 2 review authors who independently assessed, in an unblinded standardized manner, the internal validity of all the studies. The methodological quality assessment was performed in such a manner as to avoid any discrepancies, which when identified were evaluated by a third reviewer and settled by consensus. Authors with a perceived COI for any manuscript were recused from reviewing the manuscript.

For adverse effects, confounding factors, etc., it was not possible to use quality assessment criteria. Thus, these were considered based on the interpretation of the reports published and critical analysis of the literature.

The quality of each individual article used in this analysis was assessed using Cochrane review criteria (Table 4) (417) for randomized trials, the Newcastle-Ottawa Scale for observational studies (Tables 5 and 6) (419), and the QAREL checklist for diagnostic accuracy studies (Table 7) (425). For nonrandomized observational studies, the patient population was required to have at least 50 total or at least 25 in each group if there were comparison groups. Even though none of these instruments or criteria has been systematically assessed, the advantages and disadvantages of each system were debated.

Each study was evaluated by at least 2 authors for stated criteria and any disagreements discussed with a third reviewer.

The QAREL checklist (425) has been validated and also utilized in multiple systematic reviews (421-426). Each study in the final sample of eligible manuscripts was assessed using a 12-item appraisal checklist designed to assess the quality and applicability of studies. The face validity of these checklists was established by consultation with methodology experts (425) and comparison with quality appraisal checklists used in other systematic reviews examining diagnostic reliability (420,427-434). This checklist was also developed in accordance with the Standards for the Reporting Studies of Diagnostic Accuracy Studies (STARD) (422) and the QUADAS (423) appraisal tool. Studies were not given an overall numeric quality score; instead, each item was considered separately and graded as "yes," "no," "unclear," or "not applicable."

All studies were required to meet a minimum of 50% of applicable criteria. Studies scoring less were also described and provided with an opinion and a critical analysis.

5.4.1.8 Measurement of Treatment Effect in Data Synthesis (Meta-Analysis)

Data were summarized using meta-analysis when at least 5 studies per type of disorder were available meeting the inclusion criteria.

5.4.1.9 Outcome Measures

Conclusions of both qualitative and quantitative outcome measures were evaluated. Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. Random-effects meta-analysis to pool data was also used (542-544).

The minimum amount of change in pain score to be clinically meaningful has been described as a 2-point change on a scale of 0 to 10 (or 20 percentage points), based on findings in trials studying general chronic pain (545), chronic musculoskeletal pain (546), and chronic low back pain (26,434,436,547,548). However, recent studies evaluating interventional techniques have used > 50% pain relief as the cutoff threshold for clinically meaningful improvement in pain relief or functional status (276,304-306,311,314-321,323-330,333-340,345,549). Consequently, for analysis in these systematic reviews, we utilized clinically meaningful pain relief of at least a 3-point change on an 11-point scale of 0 to 10, or 50% pain relief from the baseline, and/or a functional status improvement of 40% or more as clinically significant.

Outcomes may be assessed between the groups or in the same group from baseline to post treatment, however, some methodologists tend to focus only on between the groups. This essentially provides lack of improvement or lack of difference between the groups in an active control trial, non-inferiority, or equivalence trial. Thus, it is essential that outcomes be monitored pretreatment and posttreatment rather than between the groups or utilizing both methodologies. Conse-

Table 4. Randomized controlled trials quality rating system.

A	1. Was the method of randomization adequate?	A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a die (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments. Examples of inadequate methods are: alternation, birth date, social insurance/ security number, date in which they are invited to participate in the study, and hospital registration number.	Yes/No/ Unsure
B	2. Was the treatment allocation concealed?	Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.	Yes/No/ Unsure
C	Was knowledge of the allocated interventions adequately prevented during the study?		
	3. Was the patient blinded to the intervention?	This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.	Yes/No/ Unsure
	4. Was the care provider blinded to the intervention?	This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.	Yes/No/ Unsure
	5. Was the outcome assessor blinded to the intervention?	Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or: –for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes" –for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination –for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome –for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" (caregivers) is scored "yes" –for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data.	Yes/No/ Unsure
D	Were incomplete outcome data adequately addressed?		
	6. Was the drop-out rate described and acceptable?	The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature).	Yes/No/ Unsure
	7. Were all randomized participants analyzed in the group to which they were allocated?	All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.	Yes/No/ Unsure
E	8. Are reports of the study free of suggestion of selective outcome reporting?	In order to receive a "yes," the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.	Yes/No/ Unsure
F	Other sources of potential bias:		
	9. Were the groups similar at baseline regarding the most important prognostic indicators?	In order to receive a "yes," groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).	Yes/No/ Unsure
	10. Were co-interventions avoided or similar?	This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.	Yes/No/ Unsure
	11. Was the compliance acceptable in all groups?	The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.	Yes/No/ Unsure
	12. Was the timing of the outcome assessment similar in all groups?	Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.	Yes/No/ Unsure

Adapted and modified from Furlan AD, et al; Editorial Board, Cochrane Back Review Group. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine (Phila Pa 1976)* 2009; 34:1929-1941 (417).

Table 5. *Newcastle-Ottawa quality assessment scale: Case control studies*.

Selection
1) Is the case definition adequate?
a) yes, with independent validation *
b) yes, e.g. record linkage or based on self reports
c) no description
2) Representativeness of the cases
a) consecutive or obviously representative series of cases *
b) potential for selection biases or not stated
3) Selection of Controls
a) community controls *
b) hospital controls
c) no description
4) Definition of Controls
a) no history of disease (endpoint) *
b) no description of source
Comparability
1) Comparability of cases and controls on the basis of the design or analysis
a) study controls for _____ (Select the most important factor.)*
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)
Exposure
1) Ascertainment of exposure
a) secure record (eg surgical records) *
b) structured interview where blind to case/control status *
c) interview not blinded to case/control status
d) written self report or medical record only
e) no description
2) Same method of ascertainment for cases and controls
a) yes *
b) no
3) Non-Response rate
a) same rate for both groups *
b) non respondents described
c) rate different and no designation

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (419).

quently, in all the systematic reviews and the evidence assessment for interventional pain management, the outcomes have been assessed based on the design between the groups and in the same group pre and post treatment.

5.4.1.10 Outcome of the Studies

Randomized trials were judged to be positive if the intervention was clinically relevant and effective, either with a placebo control or an active control. This indicates that the difference in effect for the primary

Table 6. *Newcastle-Ottawa quality assessment scale for cohort studies.*

Selection
1) Representativeness of the exposed cohort
a) truly representative of the average _____ (describe) in the community *
b) somewhat representative of the average _____ in the community *
c) selected group of users e.g. nurses, volunteers
d) no description of the derivation of the cohort
2) Selection of the non exposed cohort
a) drawn from the same community as the exposed cohort *
b) drawn from a different source
c) no description of the derivation of the non exposed cohort
3) Ascertainment of exposure
a) secure record (eg surgical records) *
b) structured interview *
c) written self report
d) no description
4) Demonstration that outcome of interest was not present at start of study
a) yes *
b) no
Comparability
1) Comparability of cohorts on the basis of the design or analysis
a) study controls for _____ (Select the most important factor.)*
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)
Outcome
1) Assessment of outcome
a) independent blind assessment *
b) record linkage *
c) self report
d) no description
2) Was follow-up long enough for outcomes to occur
a) yes (select an adequate follow up period for outcome of interest) *
b) no
3) Adequacy of follow up of cohorts
a) complete follow up - all subjects accounted for *
b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) *
c) follow up rate < ____% (select an adequate %) and no description of those lost
d) no statement

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (419).

outcome measure is statistically significant on the conventional 5% level. In a negative study, no significant difference between the treatment groups or no improvement from baseline is identified.

Observational studies were judged to be positive if the intervention was effective, with outcomes reported at one month, 3 months, 6 months, and one year.

The outcomes were judged as improvement in at

Table 7. *Quality Appraisal of Diagnostic Reliability (QAREL) checklist.*

Item	Yes	No	Unclear	N/A
1. Was the test evaluated in a spectrum of subjects representative of patients who would normally receive the test in clinical practice?				
2. Was the test performed by examiners representative of those who would normally perform the test in practice?				
3. Were raters blinded to the reference standard for the target disorder being evaluated?				
4. Were raters blinded to the findings of other raters during the study?				
5. Were raters blinded to their own prior outcomes of the test under evaluation?				
6. Were raters blinded to clinical information that may have influenced the test outcome?				
7. Were raters blinded to additional cues, not intended to form part of the diagnostic test procedure?				
8. Was the order in which raters examined subjects varied?				
9. Were appropriate statistical measures of agreement used?				
10. Was the application and interpretation of the test appropriate?				
11. Was the time interval between measurements suitable in relation to the stability of the variable being measured?				
12. If there were dropouts from the study, was this less than 20% of the sample.				
TOTAL				

Lucas N, et al. The development of a quality appraisal tool for studies of diagnostic reliability (QAREL). *J Clin Epidemiol* 2010; 63:854-861 (425).

Table 8. *Method for grading the overall strength of the evidence for an intervention.*

Grade	Definition
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality RCTs or studies of diagnostic test accuracy).
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher-quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).
Limited or poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Adapted from methods developed by U.S. Preventive Services Task Force (54,550).

least 40% of patients at distinct reference points with positive or negative results reported at one month, 3 months, 6 months, and one year.

Outcomes included the prevalence of pain and false-positive rate. Based on the above parameters, the reliability of the data derived from each study was assessed.

The advantages and disadvantages of various methodologies available are too extensive to be described in this manuscript. These have been described in various other manuscripts in the past (28-31,69-72).

5.4.1.11 Analysis of Evidence

Evidence analysis was performed based on United States Preventive Task Force (USPSTF) criteria as illustrated in Table 8, which has been utilized by multiple authors (550).

The analysis was conducted using 3 levels of evidence ranging from good, fair, and limited or poor.

5.4.2 Grading Recommendations

As recommended by the IOM, for each recommendation, information was provided with an explanation

of the reasoning underlying the recommendation, including a clear description of potential benefits and harms; a summary of relevant available evidence, description of the quality, quantity, and consistency of the aggregate available evidence; an explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendations; a rating of the level of confidence, a rating of the strength of recommendation, and a description and explanation of any differences of opinion regarding the recommendation.

In grading recommendations, the grading of recommendations from USPSTF was utilized (Table 8).

5.4.3 External Review

All the systematic reviews underwent peer review prior to publication. The guidelines were posted for comment from the ASIPP membership and others on the website and also widely advertised in the ASIPP newsletter for comments.

5.4.4 Updating

Updating of clinical practice guidelines is crucial. Clinical practice guidelines have become increasingly popular over the last 2 decades, with evolving methodologies to develop guidelines. In the preparation of these guidelines, we have not only given significant attention to the selection and appraisal of the available literature through systematic reviews, through the utilization of appropriate grading systems, which continue to evolve, and through assessment of the strength of recommendations; since the first guideline, ASIPP has focused on updating them. Each guideline has included a timeline for updating. These guidelines become effective January 1, 2013, and expire December 31, 2015. Meanwhile, the updating process will be initiated and completed. In a recent international survey, Alonso-Coello et al (69) found that, among the institutions responding, 92% reported updating their guidelines, with 86% reporting a formal procedure for doing so. However, only 53% had a formal process for deciding when a guideline becomes out of date. Interventional pain management, as an evolving specialty, continues to progress with publications. Even though we have decided on updating in 3 years, we will once again assess the evidence within one year and re-evaluate the timeline.

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Disclaimer

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The authors are solely responsible for the content of this article. No statement on this article should be construed as an official position of ASIPP. The guidelines do not represent "standard of care."

Conflict of Interest:

Dr. Falco is a consultant for St. Jude Medical Inc. and Joimax Inc.

Dr. Benyamin is a consultant with Bioness and Nevro; serves on the advisory boards of Vertos Medical and Nuvo Pharma; teaches/lectures for Vertos Medical, Boston Scientific, Neurotherm, and Bioness; and receives research/grants from Alfred Mann Foundation, Teknon Foundation, Spinal Restoration, Inc., Bioness, Boston Scientific, Vertos Medical, Medtronic, Kimberly Clarke, Epimed, BioDelivery Sciences International, Inc., Theravance, Mundipharma Research, Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP.

Dr. Helm is a clinical investigator with Epimed and receives research support from Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP. He has attended an advisory group meeting for Activas.

Dr. Caraway is a consultant for Medtronic, Inc., Spinal Modulation, Inc., and Vertos, Inc.

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