

Diagnosis Algorithm

Sixteenth Edition
March 2018

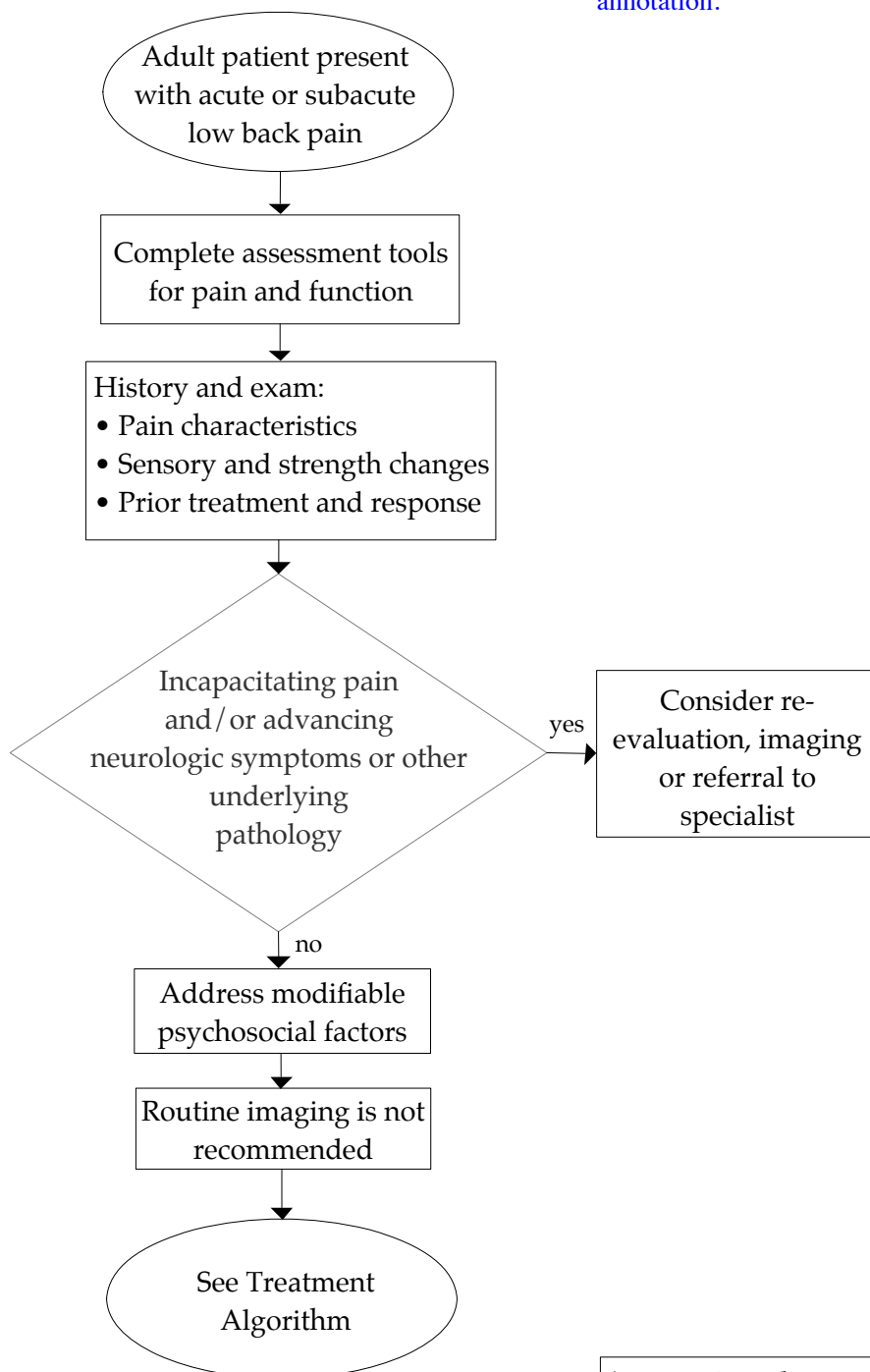
Text in blue in this algorithm indicates a linked corresponding annotation.

Red Flags for Underlying Pathology

- Cauda equina symptoms
- Cancer risk
- Spinal infection risk
- Fragility fracture risk
- Unrelenting pain
- Progressive neurologic deficit
- Trauma

Yellow Flags (Psychosocial Factors)

- Work place
- Attitudes and beliefs
- Social/family
- Behaviors
- Affective/emotions



Acute < 4 weeks
Subacute 4-12 weeks
Chronic ≥ 12 weeks

Treatment Algorithm

Yellow Flags (Psychosocial Factors)

- Work place
- Attitudes and beliefs
- Social / family
- Behaviors
- Affective/emotions

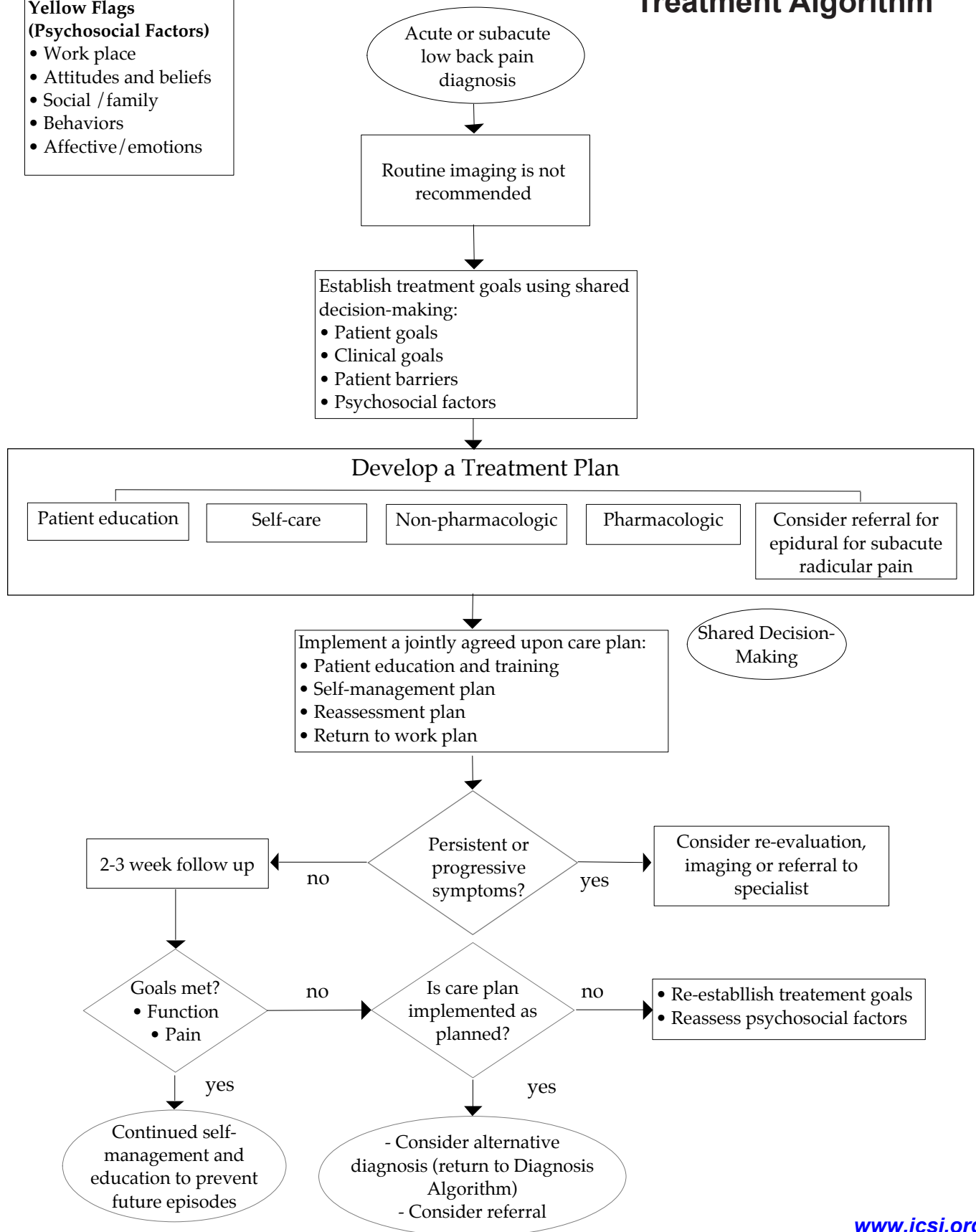


Table of Contents

Work Group Leader

David Thorson, MD
*Sports Medicine, Entira
Family Clinics*

Work Group Members

3M

Robb Campbell, MD, MPH
Occupational Medicine

CentraCare Health System

Michael Massey, DO

Pain Medicine

Becky Mueller, DO

*Family Medicine/Sports
Medicine*

Fairview Health Services

Becky McCathie, MEd, ATC

Specialty

Heidi Richards, PT, MHA

Physical Therapy

OSI Physical Therapy

Steven Peterson

Physical Therapy

Park Nicollet Health

Services

Chris Kramer, PT, DPT, OCS,

FAAOMPT

Physical Therapy

Physicians' Diagnostics &

Rehabilitation Clinics

Todd Ginkel, DC

Spine Rehabilitation

ICSI

Jodie Dvorkin, MD, MPH

*Project Manager/Health Care
Consultant*

Senka Hadzic, MPH

*Clinical Systems Improvement
Facilitator*

Audrey Hansen, BSN, MA,

PMP

*Project Manager/Health Care
Consultant*

Algorithms and Annotations	1-25
Algorithm – Diagnosis	1
Algorithm – Treatment	2
Evidence Grading	4
Recommendations Table	5-6
Foreword	
Introduction	7
Scope and Target Population	7
Aims	7
Related ICSI Scientific Documents	7
Definition	8
Annotations	9-25
Initial Evaluation	9-15
Treatment Plan	15-22
Re-evaluation	23
Radicular Pain - Special Considerations	23-24
Quality Improvement Support	26-31
Aims and Measures	27
Measurement Specifications	28-29
Implementation Tools and Resources	30
Implementation Tools and Resources Table	31
Supporting Evidence	32-43
References	33-36
Appendices	37-43
Appendix A – Patient Handout	37
Appendix B – ICSI Shared Decision-Making Model	38-43
Disclosure of Potential Conflicts of Interest	44-46
Acknowledgements	47
Document History and Development	48-49
Document History	48
ICSI Document Development and Revision Process	49

Evidence Grading

Literature Search

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. Literature searches for this guideline were done under the following parameters:

- Time frame: January 1, 2000 – May 1, 2017.
- Types of studies searched for: systematic reviews and meta-analysis, randomized controlled trials and observational studies (case-control, cohort and cross-sectional studies).
- Population: adults, 18 years of age and over, with acute and subacute low back pain or radiculopathy.
- All studies were published in English and included humans.

In addition to the literature searches, articles were obtained by work group members and ICSI staff. Those vetted by the work group were included in the guideline when appropriate.

Literature search terms used:

STarT Back screening tool; Keele stratified care model; imaging for low back pain; imaging for low back radiculopathy; red flags; clinical prediction rule; fear avoidance; modifiable risk factors; cognitive behavioral therapy; mindfulness-based stress reduction therapy; patient education; education; normal activity vs. staying active; activities of daily living; exercise for prevention; exercise for treatment; bed rest; acupuncture; dry needling; heat therapy; cold therapy; healing efficacy of cold therapy; traction; physical therapy/spinal manipulation therapy/chiropractic care; NSAIDs for treatment; anti-inflammatories; Tylenol for treatment; corticosteroids for treatment; opioids for treatment; tramadol for treatment; muscle relaxants; benzodiazepines; weight loss for treatment to prevent recurrence of low back pain; obesity and acute/subacute low back pain; obesity and chronic low back pain; acceptance and commitment therapy; regenerative medicine/stem cells/platelet-rich plasma/prolotherapy; medial branch blocks; rhizotomy; functional restoration program for subacute low back pain; cold laser therapy; radiofrequency ablation; low back pain in pregnancy.

Methodology

ICSI utilizes a modified version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology system. GRADE involves systematically evaluating the quality of evidence (high, moderate, low, very low) and developing a strength of recommendation (strong, weak). For more detailed information on GRADE, please visit <http://www.gradeworkinggroup.org/>.

When there was a paucity of systematic reviews and randomized controlled trials, the work group could not apply the GRADE methodology. In these cases, the work group used the best available evidence to reach consensus recommendations. For each consensus recommendation, the relevant resources used to support that recommendation are noted.

Recommendations Table

The following table is a list of evidence-based recommendations for adult acute and subacute low back pain.

Topic	Recommendation	Quality of Evidence (For GRADE Recommendations)	Strength of Recommendation (For GRADE Recommendations)	Relevant Resources
Initial Evaluation	For patients with acute and subacute low back pain, a biopsychosocial assessment should be performed.	N/A (Consensus Recommendation)		<i>Papageorgiou, 1998 (Observational Study); Waddell, 1987 (Report); Waddell, 1992 (Report)</i>
Imaging	Clinicians should not routinely recommend imaging (x-ray, computed tomography [CT], magnetic resonance imaging [MRI] for patients with nonspecific or radicular low back pain with an absence of red flags on clinical presentation.	Quality of Evidence: Moderate	Strong Recommendation	<i>Chou 2009 (Systematic Review and Meta-analysis); Patel, 2016 (Guideline)</i>
Education	All patients should receive appropriate education on the treatment and recovery expectations for acute and subacute low back pain.	Quality of Evidence: Moderate-High	Strong Recommendation	<i>Traeger, 2015 (Systematic Review and Meta-Analysis)</i>
Heat	Heat may be used for pain relief for acute and subacute low back pain.	Quality of Evidence: Moderate	Weak Recommendation	<i>Chou, 2016 (Comparative Effectiveness Review)</i>
Cold	Cold therapy may be used for pain relief.	N/A (Consensus Recommendation)		<i>Chou, 2016 (Comparative Effectiveness Review)</i>
Activity	Clinicians should advise patients with acute and subacute low back pain to stay active and continue activities of daily living within the limits permitted by their symptoms.	Quality of Evidence: Moderate	Strong Recommendation	<i>Dahm 2010 (Systematic Review); McIntosh 2011 (Systematic Review)</i>
Spinal Manipulation	Spinal manipulation should be considered in early intervention for acute and subacute low back pain.	Quality of Evidence: Low-Moderate	Strong Recommendation	<i>Paige, 2017 (Systematic Review and Meta-Analysis); Chou, 2016 (Comparative Effectiveness Review)</i>
Acupuncture	Acupuncture should be considered for subacute low back pain.	Quality of Evidence: Low	Weak Recommendation	<i>Chou, 2016 (Comparative Effectiveness Review)</i>
NSAIDS	Non-steroidal anti-inflammatory medication may be used for short-term relief in patients with acute and subacute low back pain. Patient should be counseled on potential side effects.	Quality of Evidence: Moderate	Strong Recommendation	<i>Chou, 2016 (Comparative Effectiveness Review)</i>

Topic	Recommendation	Quality of Evidence (For GRADE Recommendations)		Strength of Recommendation (For GRADE Recommendations)
Acetaminophen	Acetaminophen may be used as an option for pain relief in patients with acute and subacute low back pain. Patients should be counseled on potential side effects.	N/A (Consensus Recommendation)		<i>Chou, 2016 (Comparative Effectiveness Review; Saragiotto, 2016 (Systematic Review))</i>
Muscle Relaxants	Muscle relaxants may be used as a short-term option (< one week) in the treatment of acute low back pain. Possible side effects should be considered.	Quality of Evidence: Moderate	Weak Recommendation	<i>Chou, 2016 (Comparative Effectiveness Review)</i>
Opioids	In general, opioids are not recommended for acute and subacute low back pain.	N/A (Consensus Recommendation)		<i>Chou, 2016 (Comparative Effectiveness Review)</i>
Epidural Steroid Injections	Epidural steroid injections may be used as an adjunct treatment for acute and subacute low back pain with a radicular component to assist with pain relief.	Quality of Evidence: Moderate	Strong Recommendation	<i>Chou, 2015 (Technology Assessment); Manchikanti, 2016 (Systematic Review)</i>

Foreword

Introduction

Studies have estimated the one-year incidence of a first-ever episode of low back pain ranges between 6.3% and 15.4%, while estimates of the one-year incidence of any episode of low back pain range between 1.5% and 36% (*Hoy, 2010*).

Once a patient experiences back pain he or she is more likely to experience it again. Estimates of recurrence at one year range from 24% to 80% (*Hoy, 2010*). Many environmental and personal factors influence the onset and course of low back pain. Studies have found the incidence of low back pain is highest in the third decade, and overall prevalence increases with age until the 60-65 year age group and then gradually declines (*Hoy, 2010*).

An acute episode can lead to chronicity. Factors that influence chronicity include depression, employment status, chemical dependency and failure to treat acute episodes as indicated. Chronic low back pain (pain lasting greater than 12 weeks) is a leading cause of disability and cost. The total costs of low back pain in the United States exceed \$100 billion per year. Two-thirds of these costs are indirect, due to lost wages and reduced productivity. Each year, fewer than 5% of the patients who have an episode of low back pain account for 75% of the total costs (*Katz, 2006*). Understanding how to identify and classify low back pain will help develop a treatment plan that can reduce chronicity, decrease costs, and improve health and function.

Low back pain is classified as either non-specific low back pain or radicular low back pain. This guideline will focus on pathways used to define acuity and chronicity, the limited scenarios when diagnostic testing is indicated, and how to develop a treatment plan that is comprehensive and evidence-based. Embedded in the guideline are clinical decision points that will help direct the clinician in a treatment path that will improve outcomes, decrease inappropriate imaging and medications, and help patients understand and partner in their treatment. Tools for assessing biopsychosocial health and the impact that the pain has on quality of life are recommended. The treatment plan should always include patient education. In addition, self-care, non-pharmacologic modalities and pharmacologic options may be offered.

Scope and Target Population

Adult patients age 18 and over who have symptoms of low back pain or radiculopathy. The focus is on the acute (pain for up to 4 weeks) and subacute (pain for between 4 and 12 weeks) phases of low back pain. Chronic pain (after 12 weeks) is beyond the scope of this guideline.

Aims

1. Decrease the percentage of adult patients with acute or subacute low back pain with or without radiculopathy who have imaging ordered for low back pain in the absence of red flags at the initial visit.
2. Decrease the percentage of adult patients with acute or subacute low back pain with or without radiculopathy who are prescribed opioids.

Related ICSI Scientific Documents

Guidelines

- Major Depression in Adults in Primary Care
- Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management

Definition

Clinician – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

Annotations

Initial Evaluation

Low back pain is overall a benign condition, with a majority being nonspecific low back pain. Radiculopathy is defined as pain that is dermatomal; it may or may not be accompanied by sensory or strength deficit or change in reflex. Diffuse or nonorganic sensory or strength changes are not considered radicular, and if noted should be generally be treated as nonspecific low back pain. However, in rare cases it may represent myelopathy or higher cord lesions

Initial evaluation should look to identify and address potential underlying pathology that would require further investigation or radiculopathy with neurologic deficit. For all low back pain, but particularly those with non-specific low back pain, it is important to do a thorough biopsychosocial evaluation. In addition, patient engagement is crucial for not only the proper assessment but also the treatment for low back pain. At the onset, clinicians should ask the patient if he or she has any specific questions or expectations from the visit.

Consensus Recommendation
For patients with acute and subacute low back pain, a biopsychosocial assessment should be performed.
Benefit Standardized assessment tools offer consistency for the documentation of biopsychosocial risk factors.
Harm Using one measure of assessment in isolation of the clinical examination or other biopsychosocial risk factors could lead to an ineffective care plan for the patient.
Benefits/Harms Assessment Validated and comprehensive tools provide accurate information for the creation and the ultimate success of progress with a treatment plan. If no tools are utilized, the assessment becomes subjective. See “Evaluate Function” and “Yellow Flags (Psychosocial Indicators)” section for reference to possible tools.
Relevant Resources <i>Papageorgiou, 1998 (Observational Study); Waddell, 1992 (Report); Waddell, 1987 (Report)</i>

History

The initial history evaluation of low back pain should include the following:

- History and review of systems including assessment for underlying pathology (e.g., cauda equina syndrome, cancer, fracture, infection)
- History of previous low back pain, prior treatment and response
- Pain characteristics (location, character, intensity, exacerbating and alleviating factors, and duration); of note, pain that radiates past the knee can be mechanical or radicular in origin; if there is any activity associated with the onset of the pain or unrelenting night pain, it should be noted
- Sensory changes (the specific distribution and character)
- Strength changes (a generalized sense of weakness should be differentiated from focal change such as the inability to dorsal or plantar flex the foot or great toe)
- Indicators of psychosocial, workplace and other factors that increase the risk of develop persistent low back pain
- Screen for depression

Algorithm Annotations

- Psychological factors play a significant role not only in chronic pain, but also in the etiology of acute pain, particularly in the transition to chronic problems. Specific types of psychological variables emerge and may be important in distinct developmental time frames, also implying that assessment and intervention need to reflect these variables (*Linton, 2000*). A cohort study involving 221 primary care patients with acute or subacute low back pain found that reciprocal effects of depressive symptoms and low back pain seem to depend on time under medical treatment. Thus, clinicians should screen for and treat depressive symptoms at the first consultation to improve the low back pain treatment (*Elfering, 2014*). In another cohort study of 286 patients with acute low back pain, the course of recovery was slower in depressive patients. Depression was associated with low back pain, especially after six weeks (*Melloh, 2013*). Tools such as the PHQ-2 and PHQ-9 may be used in screening. Refer to the ICSI Major Depression in Adults in Primary Care guideline for more information.

Red Flags

It is important to evaluate patients for underlying pathology that may warrant urgent workup and/or referral. While the presence of red flags may raise suspicion, it is important to recognize that they do not completely rule in or rule out a particular condition. Therefore, the clinician must take into consideration the full clinical picture and exercise judgment when choosing when a patient might benefit from further diagnostic workup.

It is the consensus of this work group that the following red flags warrant consideration for **urgent** workup and/or referral:

- Bowel/bladder dysfunction (most commonly urinary retention)
- Progressive neurologic weakness
- Saddle anesthesia
- Bilateral radiculopathy
- Incapacitating pain
- Unrelenting night pain

Additional red flags associated with malignancy and fracture are listed in the sections below.

Serious Causes of Low Back Pain**Cauda equina syndrome**

Cauda equina syndrome is compression of the lumbosacral nerve roots that form the cauda equina. Signs or symptoms of cauda equina syndrome, in addition to low back pain, include:

- Bladder/bowel dysfunction (most commonly urinary retention)
- Motor deficits (lower extremity weakness, depressed deep tendon reflexes)
- Sensory deficits (saddle sensory loss)

All patients with back pain should be asked about urinary retention. Those reporting this symptom should be examined for bilateral leg weakness, depressed leg deep tendon reflexes, and perineal numbness. These patients may report bowel, bladder and sexual dysfunction, and severe pain. This syndrome is rare but catastrophic and requires emergent surgical consultation.

Malignancy

Two systematic reviews found that a history of malignancy increases the likelihood of spinal malignancy (Downie, 2013; Henschke, 2013). The review by Downie (2013) found that other red flags cited in some guidelines such as older age, weight loss and failure to improve after one month had post-test probability point estimates below 3% (Downie, 2013). A Cochrane review found that insidious onset, older age (> 50) and failure to improve after one month had high false-positive rates. The authors concluded that red flags may be useful when combined or with a history of cancer, but by themselves will result in overtesting (Henschke, 2013).

Fracture

Single red flags that increase the likelihood of spinal fracture in a patient with low back pain include older age, prolonged corticosteroid use, severe trauma and the presence of contusion or abrasion. These red flags increased the probability of fracture to between 10% and 33% (Downie, 2013).

In addition, probability of fracture was higher (increased to between 42% and 90%) with the coexistence of multiple red flags, specifically: (Downie, 2013)

- The combination of any four of leg or buttock pain, female, older age, BMI < 23, gait abnormality, no regular exercise, sitting pain or osteoarthritis
- Any three of female, age > 70, severe trauma, prolonged use of corticosteroids
- Trauma with neurological signs

Note: There is not sufficient data on a history of osteoporosis as a specific risk factor.

Infection

An uncommon but serious cause for back pain is infection. A spinal infection such as vertebral osteomyelitis or spinal epidural abscess can present as back pain with a fever.

Consideration of other non-spine origins

Low back pain can be due to visceral disease. Examples include (Goldman, 2011):

- Disease of pelvic organs (prostatitis, endometriosis, chronic pelvic inflammatory disease)
- Renal disease (nephrolithiasis, pyelonephritis, perinephric abscess)
- Aortic aneurysm
- Gastrointestinal disease
- Pancreatitis
- Cholecystitis
- Penetrating ulcer
- Cardiac or pericardial disease
- Pulmonary or pleural disease

Evaluate Function

Using tools can help with proper management of low back pain. The following are some of the available tools for low back pain evaluation. Other validated tools may be used, as well.

Algorithm Annotations

PEG [Pain intensity, interference with enjoyment of life and interference in general activity (PEG)] is a three-item scale used to assess pain intensity and interference using scales of 0-10. Adding scores and then dividing the total by three allows you to track change over time. It is recommended that you also document all three scores individually in order to understand the key issue. The PEG is freely available in the public domain (*Krebs, 2009*).

Keele STarT Back Screening Tool (SBST) is a simple prognostic questionnaire that helps clinicians identify modifiable risk factors (biomedical, psychological and social) for back pain disability. Information is available at <https://www.keele.ac.uk/sbst/startbacktool/>.

Modified Oswestery Disability Questionnaire is used to assess the patient's subjective rating of perceived disability related to his or her functional limitations (e.g., work status and difficulty caring for oneself). The higher the score, the more perceived disability the patient has. Using this test helps the examiner understand the patient's perception of how back pain is affecting his or her life. This tool has at least four versions/formats in English and more in other languages (*Fairbank, 2000*).

Roland-Morris Disability Questionnaire is another tool available for the assessment of low back pain disability. A substantial number of papers have been published on the psychometric properties, validity and reliability of the RMDQ. The original questionnaire and all translations are in the public domain (*Roland, 1983*). Information is available at <http://www.rmdq.org>.

Fear-Avoidance Beliefs Questionnaire (FABQ) is used to assess fear avoidance beliefs (*Williamson, 2006; Waddell, 1993*). Information is available at https://www.tac.vic.gov.au/files-to-move/media/upload/fear_avoidance.pdf

Yellow Flags (Psychosocial Indicators)

Waddell published the importance of the biopsychosocial approach to low back pain over 30 years ago (*Waddell, 1987*). Psychosocial indicators (yellow flags) include a patient's attitudes, emotions, behaviors, and family and workplace factors. They may lead to an increased risk of progression to long-term distress and disability. In patients with low back pain up to six months duration, fear-avoidant beliefs negatively impacted pain and/or disability as well as return to work (*Wertli, 2014*). Further, high levels of fear-avoidance beliefs occur early in low back patients (*Coudeyre, 2007*). George et al. (2015) found that psychological risk status, depressive symptoms and pain intensity were predictive of six-month recovery status. Furthermore, elevated fear-avoidance, kinesiophobia and depressive symptoms co-occurred with nonrecovery at six months (*George, 2015*).

Objective measurement of a range of yellow flags can be captured by a validated, comprehensive and reliable tool such as the STarT Back Tool (*NICE, 2016*). This tool is designed to allocate patients into low, medium and high-risk groups. In a cross-sectional study of 244 primary care patients, Hill et al. (2010) found that agreement of expert clinicians and a formal tool such as STarT Back occurred only in about half the patients. Results of the study found that clinicians made inconsistent treatment decisions. While tools such as STarT Back may help standardize decision-making, the study also found weaknesses of the tool. It failed to identify in some cases high-risk patients who had non-pain psychosocial stress or hard life circumstances that clinicians were able to identify (*Hill, 2010*). In addition, the STarT Back Tool was not able to make a high-level synthesis of patient expectations, preferences and previous treatment history. Thus, the authors caution that tools should be used in conjunction with, not instead of, clinician judgment (*Hill, 2010*).

Stratified management of low back pain has been found to be a cost-effective approach for patients at high risk of permanent disabling low back pain, but not for those at low to medium risk (*Whitehurst, 2015*).

Exam

The purpose of the exam is to identify and document neurologic deficits, muscle weakness and biomechanical dysfunction.

Algorithm Annotations

The exam should expand upon a patient's history and pain drawing, and include test and measures that assess neurologic, musculoskeletal and biomechanical dysfunction.

The following are components of the low back pain exam:

- Neurologic evaluation, including reflex sensation, and neural tension and strength
 - straight leg raising
 - ability to walk on heels and toes
 - symmetrical great toe extensor strength
- Palpation of related structures
- Assessment of posture
- Evaluation of lumbar spine range of motion (quantity and quality, asymmetry/inconsistency)
- Evaluation of hip range of motion
- Single leg balance and ability to maintain level pelvis for 30 seconds (lateral hip pain within 30 seconds may suggest gluteal tendinopathy) (*Grimaldi, 2017*)
- Other examination of joints as indicated by history and initial exam
- Additional examination including respiratory, gastrointestinal or genital urinary examination recommended, as indicated by history

Poor lumbar segmental motion without neurologic findings could represent nonspecific or mechanical low back pain. The presence of focal neurologic signs could suggest nerve impingement.

Imaging

Recommendation	Quality of Evidence and Strength of Recommendation
Clinicians should not routinely recommend imaging (x-ray, computed tomography [CT], magnetic resonance imaging [MRI]) for patients with nonspecific or radicular low back pain and an absence of red flags on clinical presentation.	Quality of Evidence: Moderate Strength of Recommendation: Strong
<p>Benefit In general, imaging for low-back pain without indication(s) of serious underlying conditions does not improve clinical outcomes. In addition, not imaging will avoid potential exposure to radiation.</p> <p>Harm Some underlying conditions may be missed by not imaging.</p> <p>Benefits/Harms Assessment In general, routine imaging for acute/subacute low back pain has been shown to be ineffective in altering the course of treatment in the first six weeks. Harms of imaging include possible radiation exposure as well as potential decreased sense of well-being by the patient. In general, these harms outweigh the benefits for patients with uncomplicated low back pain and the absence of red flags on clinical presentation.</p>	
Relevant Resources: <i>Chou, 2009 (Systematic Review and Meta-Analysis); Patel, 2016 (Guideline)</i>	

Clinicians should not recommend imaging (including computed tomography [CT], magnetic resonance imaging [MRI] and x-ray) for patients with non-specific or radicular low back pain and an absence of red flags on clinical presentation (*Patel, 2016; Chou 2009*).

Algorithm Annotations

A 2009 meta-analysis of six randomized trials comprising 1,804 patients with primarily acute or subacute low back pain and no clinical or historical features that suggested a specific underlying condition, found no differences between routine lumbar imaging (radiography, MRI or CT) and usual care without routine imaging in terms of pain, function, quality of life or overall patient-rated improvement. For short-term outcomes (three months), trends slightly favored usual care without routine imaging (*Chou, 2009*). The conclusions of the meta-analysis did not seem to be affected by whether radiography or advanced imaging (MRI or CT) was evaluated. With regards to radicular pain, the American College of Physicians 2011 Guideline on imaging for low back pain stated that the results of this meta-analysis could probably be generalized to some degree to patients with or without radiculopathy, because most of the trials enrolled at least some patients with radiculopathy (*Chou, 2011*).

Regarding patient sense of psychological well-being, a prospective randomized study of patients with acute low back pain and/or radiculopathy found that patient knowledge of imaging findings did not alter outcome and were associated with a lesser sense of well-being (*Ash, 2008*).

According to the American College of Radiology Appropriateness Criteria (2016), imaging for uncomplicated acute and subacute low back pain or radiculopathy with no red flags and no prior management is usually not appropriate for the general patient. **However, imaging for acute and subacute low back pain is usually appropriate for the following populations (*Patel, 2016*):**

- Elderly, and patients with low-velocity trauma, osteoporosis and chronic steroid use
- Patients in whom there is a suspicion of cancer, infection or immunosuppression
- Patients who are surgical or intervention candidates with persistent or progressive symptoms during or following 6 weeks of conservative management
- Patients with new or progressing symptoms or clinical findings with history of prior lumbar surgery
- Low back pain with suspected cauda equina syndrome or rapidly progressive neurologic deficit

Special Population: Pregnancy

Low back pain, alone or in combination with pelvic pain, is a common problem suffered by women during pregnancy. Studies estimate 50-80% of women will suffer from low back pain during pregnancy (*Sabino, 2008*), and one study found that approximately 62% of pregnant women suffering from low back pain rated it as moderately severe (*Stapleton, 2002*).

The typical course of low back pain during pregnancy is that it generally begins in the mid-late second trimester, resolves during the postpartum period and, unfortunately, is likely to return in subsequent pregnancies (*Sabino, 2008*). Although most cases resolve in the postpartum period, Norén reported that 20% of women with low back pain during pregnancy were found to have low back pain three years following delivery (*Norén, 2002*).

The clinical history and physical examination should include elements that focus on the mother and the fetus, and the medical care provider should consider a broad differential. The physical examination is similar to nonpregnant patients with low back pain, although lumbar flexion will be limited as the pregnancy progresses. The gravid abdominal examination can be challenging (*Sabino, 2008*).

Lumbar radiographs are routinely avoided during pregnancy due to concern for fetal health. Magnetic resonance imaging is the test of choice for severe pregnancy-related low back pain (*Sabino, 2008*).

A 2015 systematic review of 34 randomized trials involving 5,121 pregnant woman found low-quality evidence that exercise (any exercise on land or in water) may reduce pregnancy-related low-back pain and moderate- to low-quality evidence suggesting that any exercise improves functional disability and reduces

sick leave more than usual prenatal care. Evidence from single studies suggests that acupuncture or cranio-sacral therapy improves pregnancy-related pelvic pain, and osteomanipulative therapy or a multimodal intervention (manual therapy, exercise and education) may also be of benefit (*Liddle, 2015*).

Treatment Plan

Education Is Treatment

Recommendation	Quality of Evidence and Strength of Recommendation
All patients should receive appropriate education on the treatment and recovery expectations for acute and subacute low back pain.	Quality of Evidence: Moderate-High Strength of Recommendation: Strong
Benefit Patients who receive appropriate education about acute and subacute low back pain have improved outcomes and less unnecessary health care utilization, and safely return to work with fewer missed days.	
Harm Minimal (if any) adverse effects of appropriate patient education. Harm can occur with inappropriate patient education such as not fully addressing the recommendations above or avoiding altogether.	
Benefits/Harms Assessment Appropriate patient education is an effective treatment strategy in primary care.	
Relevant Resources: <i>Traeger, 2015 (Systematic Review and Meta-Analysis)</i>	

Patients who seek care for an episode of low back pain are frequently concerned about their current level of pain or dysfunction. Patient education in primary care should be tailored to the individual patient's needs, specifically when reassuring and helping the patient set appropriate expectations for the current episode of low back pain. Studies show objectively identifying and specifically addressing fear-avoidant, catastrophizing or anxious behavior improves patient outcomes in acute and subacute low back pain (*Chou 2010, Dupeyron 2011, Traeger 2015*). Therefore, implementation of screening tools such as the PEG or STartBack Tool may be part of an effective educational care plan.

The educational treatment plan should reassure the patient and help the patient set appropriate expectations. It should be delivered in a respectful way the patient can understand.

An educational care plan for patients with acute and subacute low back pain should include the following:

- Reassurance that there is a good outcome for nonspecific low back pain
- Reassurance that pain doesn't mean harm and that the majority of back pain cannot be attributed to a specific cause
- Informing patients that imaging is not helpful in the diagnosis or management of low back pain unless the provider is concerned about a serious underlying cause such as infection, fracture or cancer
- Ensuring that patients understand the role of medications for the treatment of low back pain
- Instructions on activity management, as well as work recommendations or limitations
- Patients with back pain should get back to normal activities of life as soon as possible and know that experiencing some discomfort during activities may be expected
- Follow-up and contact information in response to descriptions of specific warning signs of underlying pathology that may require earlier re-evaluation

Please see Appendix A for an example of a patient educational handout on low back pain.

Return-to-Work Assessment/Social Activities

Educate patients experiencing an episode of acute back pain that their pain is likely to improve and that a large majority of patients can return to work quickly. They should understand that complete pain relief usually occurs after, rather than before, resumption of normal activities, and their return to work can be before they have complete pain relief. Even though this is not a workers' compensation guideline, if there are issues with the employer, it may be necessary to contact the employer to provide guidance on safe activities, restrictions or job modifications.

The return-to-work and resumption of normal daily activities should be based on what the clinician feels can be performed safely. The importance of return to work should not be underestimated. The patient who does not return to modified work or activity quickly begins to view him- or herself as disabled, and begins fear of activity and may become deconditioned. It is important that the employer and all other stakeholders support the concept of rapid safe reintegration into activities and that employers are encouraged to allow return to work with modifications so this can be done safely.

If a clinician feels uncomfortable with defining work activities, referral to a person experienced in defining work activities could be considered. We encourage engagement with employers to develop a return-to-work plan.

Patient Barriers

Assessing the patient's resources is an important component of developing a treatment plan. Socioeconomic factors may play a large role in whether a patient is able to adhere to the treatment plan. These factors may include but are not limited to income, education, social support, housing and transportation. Understanding and assisting with these patient barriers are critical to any treatment plan and the patient's overall well-being.

Self-Care**Heat therapy**

Recommendation	Quality of Evidence and Strength of Recommendation
Heat may be used for pain relief for acute/subacute low back pain.	Quality of Evidence: Moderate Strength of Recommendation: Weak
Benefit Heat therapy is low cost and easy to apply. Harm Harms of heat therapy are rarely reported, but possible overexposure to heat could cause a burn. Benefits/Harms Assessment Overall, there may be some benefit to heat with low risk of harm. It is an easy, cheap treatment that is a reasonable option for patients.	
Relevant Resources: Chou, 2016 (Comparative Effectiveness Review)	

A 2016 AHRQ systematic review found that heat wrap can be more effective compared to placebo for pain relief at five days, decreased pain intensity at three to four days and disability at four days in patients with acute and subacute low back pain. One study found pain relief at eight hours (Chou, 2016). When compared with other treatments, a single trial has found some effectiveness of heat therapy in pain relief and disability when combined with exercise versus exercise without heat, heat with a non-steroidal anti-inflammatory drug (NSAID) and an NSAID without heat. In addition, single trials have found heat to be more effective than acetaminophen or ibuprofen in pain relief and disability (Chou, 2016). One single trial found no difference in heat versus exercise in pain relief or function (Chou, 2016). The trials included in the systematic review did not find evidence of serious adverse events of applying heat (Chou, 2016).

Cold therapy

Consensus Recommendation
Cold therapy may be used for pain relief.
<p>Benefit Some patients may find pain relief with cold therapy.</p> <p>Harm Ice burns can occur with direct application of cold to the skin. However, if applied appropriately, cold therapy poses minimal risk.</p> <p>Benefits/Harms Assessment There is insufficient evidence on efficacy cold therapy versus placebo or no cold treatment in pain relief or function improvement. However, given the low risk of harm, it is the consensus of the work group that cold therapy may be used for pain relief.</p>
Relevant Resources: <i>Chou, 2016 (Comparative Effectiveness Review)</i>

There is insufficient evidence on efficacy cold therapy versus placebo or no cold treatment in pain relief or function improvement. The evidence is either lacking or the existing evidence has serious methodological limitations (*Chou, 2016*). However, given the low risk of harm, it is the consensus of the work group that cold therapy may be used for pain relief.

Physical Activity**Activity as treatment**

Clinicians should advise patients to stay active and continue ordinary activity as tolerated (*Dahm, 2010; McIntosh, 2011*). Patients with acute low back pain may experience small benefits in pain relief and function from advice to stay active compared with advice to rest in bed. Back exercises may decrease recovery time compared with no treatment, but there is considerable heterogeneity among studies with regard to the definition of back exercise (*McIntosh, 2011; Dahm, 2010*). A gradual return to normal activities is beneficial and leads to more rapid symptom improvements, faster return to work, less chronic disability and fewer recurrent problems. Carefully introduce activities as the patient begins to recover from the worst of the back pain episode. Light-duty activities and regular walking are good ways to reintroduce activity. Participation in activity that does not worsen symptoms.

Exercise as prevention

Currently the evidence suggests that exercise alone or in combination with education is effective for preventing low back pain (*Steffens, 2016*). There is moderate quality evidence that post-treatment exercises were more effective than no intervention for reducing the rate of recurrence at one year (*Choi, 2010*). There was moderate quality evidence that the number of reoccurrences were significantly reduced in two studies at one-half to two years follow-up (*Choi, 2010*). According to a randomized trial of 600 patients with recurrent low back pain, exercise frequency is more important than exercise type, duration or intensity in low back pain prevention (*Steffens, 2016; Aleksiev, 2014*).

Non-pharmacologic Treatments**Directed physical activity**

Physical activity/exercise may be done by the patient as part of self-care or as part of an active rehabilitation program with a therapist. A study by Fritz (2012) found that early-intervention patients were less likely to have imaging, additional physician visits, surgery, injections and opioid medications compared with those patients with delayed physical therapy (*Fritz, 2012*).

Please see “Self Care – Physical Activity” for more information about the effectiveness of activity for both prevention and treatment of low back pain.

Spinal manipulation

Recommendation	Quality of Evidence and Strength of Recommendation
Spinal manipulation should be considered in early intervention for acute and subacute low back pain.	Quality of Evidence: Low-Moderate Strength of Recommendation: Strong
<p>Benefit Among patients with acute low back pain, spinal manipulative therapy is associated with modest improvements in pain and function at up to six weeks.</p> <p>Harm Minor transient adverse events such as increased pain, muscle stiffness and headache were reported.</p> <p>Benefits/Harms Assessment Spinal manipulative therapy demonstrates a safe and effective treatment modality for the reduction of acute low back pain. It is effective without the risks associated with pharmacologic intervention. It can be combined with pharmacologic treatment if desired but does not replace an active exercise program to avoid deconditioning.</p>	
Relevant Resources: <i>Paige 2017 (Systematic Review and Meta-Analysis); Chou, 2016 (Comparative Effectiveness Review)</i>	

Spinal manipulation is a hands-on treatment directed toward the spine. Manipulation is a passive technique whereby the clinician applies a specifically directed manual impulse, or thrust, to a joint at or near the end of the passive (or physiological) range of motion that can but does not have to be accompanied with an audible crack (*Rubinstein, 2013*). The most notable professions that utilize spinal manipulation are physical therapists, chiropractors and osteopaths (*Rubinstein, 2013*). However, the focus of the treatment, education, diagnostic procedures, treatment objective, and techniques as well as the philosophy of the various professions can vary greatly (*Rubinstein, 2013*).

A 2017 systematic review of 15 randomized trials involving 1,711 patients found that among patients with acute low back pain, spinal manipulative therapy was associated with modest improvements in pain and function at up to six weeks, with transient musculoskeletal harms (*Paige, 2017*).

A 2016 AHRQ systematic review found that for acute low back pain, spinal manipulation compared to sham manipulation was associated with better effects on function; effects on pain favored manipulation but were small and statistically insignificant. There were no differences between spinal manipulation and inert treatment in pain relief at one week, but better longer-term pain relief is possible. There were no differences in function at one week or three months. There was no difference between spinal manipulation versus other active interventions in pain relief at one week, one month, three to six months or one year. Spinal manipulation plus either exercise or advice was associated with greater improvement in function at one week versus exercise or advice alone, but there were no differences at one month or three months. For radicular low back pain, spinal manipulation plus home exercise and advice was associated with greater improvement in leg and back pain at 12 weeks versus home exercise and advice alone, but effects were smaller and no longer statistically significant at 52 weeks. Harms were not well reported in the studies, but most adverse events were related to muscle soreness and transient increases in pain (*Chou, 2016*).

Traction

Traction is generally not recommended for the treatment of acute low back pain (*Wegner, 2013*).

The current evidence indicates that traction as a single treatment or in combination with physiotherapy (physical therapy) is no more effective in treating low back pain than sham treatment, physiotherapy without traction or other treatment methods including exercise, laser, ultrasound and corsets. These conclusions are valid for people with and without radicular symptoms. There was no difference regarding the type of traction manual or mechanical (*Wegner, 2013; Chou, 2016*).

Acupuncture

Recommendation	Quality of Evidence and Strength of Recommendation
Acupuncture should be considered as treatment for subacute low back pain.	Quality of Evidence: Low Strength of Recommendation: Weak
Benefit Acupuncture was found to have a small beneficial effect on subacute low back pain.	
Harm The most commonly reported harms of acupuncture include gastrointestinal problems, changes in energy, mild bleeding at the needling site and temporarily increased pain.	
Benefits/Harms Assessment Given the low risk of harm and possible benefit, it reasonable for acupuncture to be considered among the treatment options for subacute low back pain.	
Relevant Resources: <i>Chou, 2016 (Comparative Effectiveness Review)</i>	

Acupuncture may be described by the practice of stimulating or sedating specific points on the body by inserting filiform needles or by other means. These points may be well defined along channels or meridians. However, there are different schools or methods of acupuncture such as articular and the use of musculo-skeletal tender points (*Ah Shi*).

A 2016 AHRQ systematic review found that acupuncture had a small beneficial effect on pain compared to sham for subacute low back pain and a slightly higher likelihood of improvement compared to NSAID for acute low back pain (*Chou, 2016*). In three of the trials, the most common adverse events from acupuncture included gastrointestinal problems, changes in energy, mild bleeding at the needling site and temporarily increased pain (*Chou, 2016*). Furthermore, a 2013 systematic review of 11 randomized trials involving 1,139 patients concludes that acupuncture may be more effective than medication in symptom improvement and pain relief; however, more investigation is encouraged (*Lee, 2013*).

A 2007 randomized controlled trial of 444 patients found that patients had higher satisfaction with acupuncture as an adjunct to care for acute low back pain despite no clinical or subjective improvements in symptoms and higher cost of care (*Eisenberg, 2007*).

Dry needling

Dry needling is a skilled intervention that uses a thin solid-filament needle to penetrate the skin and stimulate underlying myofascial trigger points and muscular and connective tissues for the management of neuromusculoskeletal pain and movement impairments (*APTA Resource Paper, 2013*). Dry needling and acupuncture overlap with respect to needling techniques using solid-filiform needles as well as some fundamental theories. Dry needling should be recognized as one subcategory of Western medical acupuncture (*Zhou, 2015*).

Dry needling of myofascial trigger points as an adjunct to other treatments has been shown to reduce the intensity of low back pain at post-intervention. However, the effects on function and long-term symptom reduction are unclear (*Liu, 2017*). Dry needling may enhance improvements in pain and function when used in conjunction with standard conservative approach in the management of discogenic radiating low back pain (*Mahmoudzadeh, 2016*).

Yoga

A review of literature yielded no studies that evaluated yoga for the treatment of acute low back pain. All of the studies evaluated efficacy of yoga for chronic low back pain (*Chou, 2016; Goode, 2016*).

Massage

Research does not support massage as an effective treatment in the management of acute low back pain. In a 2015 systematic review, massage was found to be beneficial in reducing pain in the short term in subacute and chronic low back pain when no other interventions or inactive interventions were administered (*Furlan, 2015*). Similarly, a 2016 AHRQ systematic review found benefit on pain relief and function of massage in the short term for subacute to chronic low back pain when used either or alone or in combination with other therapies, especially exercise (*Chou, 2016*).

Cognitive behavioral therapy (subacute pain only)

The evidence surrounding cognitive behavioral therapy (CBT) for subacute low back pain is mixed.

A 2011 systematic review found insufficient evidence to determine whether CBT is more effective than traditional care (analgesics plus back exercises until pain subsides) at reducing low back pain at nine to 12 months (*McIntosh, 2011*). There was low-quality evidence that CBT plus generic back exercise compared with no exercise or CBT alone or CBT plus neuromuscular training may be more effective at reducing pain intensity at seven days (*McIntosh, 2011*).

A randomized controlled trial of 701 adults with troublesome subacute or chronic low back pain found that the group CBT intervention in addition to best practice advice had a sustained effect at a low cost to provider over a one-year period (*Lamb, 2010a*). Analysis of the same trial also found long-term effectiveness and cost-effectiveness of CBT in treating subacute or chronic low back pain. Short-term (three-month) clinical effects were similar to those found in high-quality studies of other therapies, and benefits were maintained and increased over the long term (12 months). Cost per quality-adjusted life year (QALY) was about half that of competing interventions for low back pain (*Lamb, 2010b*).

Pharmacologic Treatments**Non-steroidal anti-inflammatory medication**

Recommendation	Quality of Evidence and Strength of Recommendation
Non-steroidal anti-inflammatory medication may be used for short-term pain relief in patients with acute and subacute low back pain. Patients should be counseled on potential side effects.	Quality of Evidence: Moderate Strength of Recommendation: Strong
Benefit NSAIDs have shown to have small beneficial effect on pain and function. Harm Harms of NSAIDs include but are not limited to gastritis, gastrointestinal bleeding, and possible cardiovascular complications. Benefits/Harms Assessment After discussing possible side effects with patients, it is reasonable to offer NSAIDs for short-term pain relief.	
Relevant Resources: <i>Chou, 2016 (Comparative Effectiveness Review)</i>	

A 2016 AHRQ systematic review found that NSAIDs may have small beneficial effect on pain intensity and function in patients with acute low back pain and a small positive effect on radicular pain (*Chou, 2016*). However, this same systematic review found that NSAIDs were associated with more side effects than placebo (*Chou, 2016*). Patients need to be aware that all NSAIDs have harms that include but are not limited to gastritis and gastrointestinal bleed, and possible cardiovascular implications.

Acetaminophen

Consensus Recommendation
Acetaminophen may be used as an option for pain relief in patients with acute and subacute low back pain. Patients should be counseled on potential side effects.
Benefit Some patients may find pain relief with cold therapy. Harm High doses of acetaminophen can lead to liver dysfunction. Benefits/Harms Assessment There is insufficient evidence on efficacy of acetaminophen. However, given the low risk of harm compared to other pharmacologic agents, it is the consensus of the work group that acetaminophen may be used for pain relief.
Relevant Resources: <i>Chou, 2016 (Comparative Effectiveness Review); Saragiotto, 2016 (Systematic review)</i>

There is not a lot of literature examining the effectiveness of acetaminophen for low back pain. Based on low-quality evidence, two recent systematic reviews suggest that acetaminophen is not more effective than placebo (*Chou 2016; Saragiotto, 2016*). Clinicians and patients should be aware that acetaminophen has the risk of serious liver disease. One trial found no difference between scheduled acetaminophen, as-needed acetaminophen and placebo in risk of adverse events. In addition, the 2016 AHRQ systematic review found that acetaminophen was associated with lower risk of side effects than NSAIDs (*Chou, 2016*).

Based on consensus, the work group recommends that acetaminophen may be used as an option for pain relief in patients with acute and subacute low back pain.

Muscle relaxants

Recommendation	Quality of Evidence and Strength of Recommendation
Muscle relaxants may be used as a short-term option in the treatment of acute low back pain; however, possible side effects should be considered. Sedative hypnotics should be rarely used and if so, for short-term (< 1 week) treatment of muscle spasms related to acute pain. Use of non sedative hypnotic muscle relaxants are of low benefit, but if used, limit to less than four weeks.	Quality of Evidence: Moderate Strength of Recommendation: Weak
Benefit Skeletal muscle relaxants have been found to help with short-term pain relief in acute low back pain. Harm Muscle relaxants are central nervous system (CNS) depressants and cause additive sedation and other adverse effects, especially in combination with opioids. Sedative hypnotics have significant side effects, specifically in the geriatric population. Additive side effects when taken with other CNS depressants are potential for dependence and withdrawal symptoms. Benefits/Harms Assessment Muscle relaxants should not be used as the standard first-line treatment but may provide short-term benefit in some patients. Risk of significant side effects, and potential for dependence and withdrawal outweigh the benefit for long-term use.	
Relevant Resources: <i>Chou 2016 (Comparative Effectiveness Review)</i>	

In addition, it is the consensus of this work group to recommend against the use of carisoprodol for pain.

Muscle relaxants should not be used as the standard first-line treatment but may provide short-term benefit (less than one week) in some patients. Risk of significant side effects, and potential for dependence and withdrawal outweigh the benefit for long-term use.

A 2016 AHRQ systematic review found muscle relaxants were superior to placebo for short-term pain relief (*Chou, 2016*). There was no difference between a skeletal muscle relaxant plus NSAID and NSAID alone in

Algorithm Annotations

the likelihood of experiencing pain relief, though the estimate favored combination therapy. There were no differences in outcomes among different muscle relaxants for acute or chronic low back pain (*Chou, 2016*).

Most muscle relaxants are central nervous system (CNS) depressants and cause additive sedation and other adverse effects, especially in combination with opioids (*Chou, 2016*). Sedative hypnotics have significant side effects, specifically in the geriatric population. Benzodiazepines should rarely be used and if so, for short-term (<1 week). Additive side effects when taken with other CNS depressants are potential for dependence and withdrawal symptoms (*Chou, 2016*).

Corticosteroids

A 2016 AHRQ systematic review found low evidence based on two RCTs that compared to placebo, systemic corticosteroids had no effect on pain or function (*Chou, 2016*). For radicular pain, there was moderate evidence based on five RCTs that showed no effect on pain or function (*Chou, 2016*). A randomized trial of 269 adults with radicular pain found that patients with acute radiculopathy from a herniated lumbar disk who received a short course of oral steroids had modest improvement in function with no improvement in pain and no reduction in surgery incidence (*Goldberg, 2015*).

Corticosteroids have side effects that patients need to be aware of, including osteonecrosis, mood changes, anxiety, blurred vision, numbness or tingling in the arms or legs, swelling of the extremities, insomnia, appetite changes, increased sweating and acne (*Buchman, 2001*).

Opioids

Consensus Recommendation
In general, opioids are not recommended for acute and subacute low back pain. If non-opioid options have been tried and the clinician feels that a trial of opioids are necessary, the first opioid prescription for acute pain should be the lowest possible effective strength of a short-acting opioid, not to exceed 100 MME total. Patients should be instructed that three days or less will often be sufficient.
Benefit Restricting opioid prescriptions will lead to decreased adverse events from opioids, including those as significant as addiction and death.
Harm There are some patients who may benefit from opioids for pain relief.
Benefits/Harms Assessment In general, the risks of opioids outweigh the pain relief that opioids may provide. Non-pharmacologic and other pharmacologic treatments should be used.
Relevant Resources: <i>Chou, 2016 (Comparative Effectiveness Review)</i>

In general, opioids are not recommended for acute and subacute low back pain. If non-opioid options have been tried and the clinician feels that a trial of opioids are necessary, the first opioid prescription for acute pain should be the lowest possible effective strength of a short-acting opioid, not to exceed 100 MME total. Patients should be instructed that three days or less will often be sufficient. Please see the ICSI Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management Guideline for detailed recommendations on opioid prescribing.

Evidence of efficacy of opioids in acute low back pain is insufficient (*Chou, 2016*). A 2016 AHRQ systematic review found one trial that showed no significant differences between opioids and acetaminophen in days to return to work (*Chou, 2016*). This same review found two trials that showed buprenorphine patches were associated with greater short-term improvement in pain versus placebo patches for subacute or chronic low back pain; effects on function showed no clear effect or were unclearly reported (*Chou, 2016*). Moderate-quality evidence suggests that short-term use of opioids was associated with higher risk of side effects such as nausea and dizziness. There were no trials that assessed risks of overdose, abuse and addiction, or long-term harms (*Chou, 2016*).

Re-evaluation

If symptoms are not improving, consider that there may be a misdiagnosis, inadequate treatment, patient barriers or alternative non-spine-related factors inhibiting recovery.

It is the expert opinion of this working group to instruct the patient to return for the following reasons:

- Pain that doesn't seem to be getting better after two to three weeks
- Pain and weakness traveling down the leg below the knee
- Leg, foot, groin or rectal area feeling numb
- Unexplained fever, nausea/vomiting, stomachaches, weakness or sweating
- Loss of control of urine or stool
- Pain is so intense the patient can't move around or get comfortable
- Redness or swelling on the back or spine
- Desire for further reassurance or education

Re-evaluation of low back pain should include the following:

- Pain reassessed
- Sensory changes
- Strength changes
- Job and activity associations considered and noted
- Presence or absence of underlying pathology and psychosocial factors

Radicular Pain – Special Considerations

Referral

When there is concern for underlying pathology for radicular pain, urgent referral to a specialist is needed. In addition, if improvement is not seen in four to six weeks, referral for a spine expert may be appropriate. The subacute phase of low back pain is the optimum time to decide whether a patient may benefit from surgery or an interventional pain procedure.

Treatment Options

The initial treatment for radicular pain includes the same options as for nonspecific low back pain. Please refer to those sections for more detailed information.

- Self-Care
- Non-pharmacologic Treatment
- Pharmacologic Treatment

Epidural Steroid Injections

Recommendation	Quality of Evidence and Strength of Recommendation
Epidural steroid injections may be used as an adjunct treatment for acute and subacute low back pain with a radicular component to assist with short-term pain relief.	Quality of Evidence: Moderate Strength of Recommendation: Strong
Benefit Epidural steroid injections may offer short-term pain relief for acute and subacute low back pain with radicular component. Harm Adverse effects of epidural steroid injections include bleeding, infection and nerve damage. Benefits/Harms Assessment For selected patients, epidural steroid injections are a reasonable adjunct to help with radicular pain.	
Relevant Resources: <i>Chou, 2015 (Technology Assessment); Manchikanti, 2016 (Systematic review)</i>	

The recent literature reviews on epidural steroid injections are mixed, with significant differences in methodology. Most studies focus on chronic low back pain.

In a 2015 technology assessment of 23 RCTs, Chou et al. concluded that epidural corticosteroid injections for radiculopathy are associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits are small and not sustained, and there is no effect on the long-term risk of surgery (*Chou, 2015*). Moreover, the effectiveness did not seem to vary based on injection technique, corticosteroid, dose or comparator (*Chou, 2015*). For nonradicular back pain and spinal stenosis, there was limited evidence that epidural steroid injections are not effective (*Chou, 2015*). In addition, they found that there were no serious adverse events and few harms associated with epidural steroid injections, although for some studies, methods for assessing harms were not always well reported and harms data was sparse (*Chou, 2015*).

A comparative systematic review and meta-analysis of 39 RCTs found that for radiculopathy or spinal stenosis, injections with sodium chloride solution or bupivacaine were ineffective. However, lidocaine alone or lidocaine in conjunction with steroids were significantly effective for pain and function with a minimum 12-month follow-up (*Manchikanti, 2016*).

Given these conflicting evidence reviews, it appears the magnitude of benefit of epidural steroid injections is unclear. However, with low risk of serious adverse events, the work group concludes that epidural steroid injections may be used as an adjunct treatment for acute and subacute low back pain with a radicular component to assist with pain relief.

Consider epidural steroid injections after initial appropriate conservative treatment program. How long to wait until offering an injection is a matter of clinical judgment. For instance, in cases of severe symptoms, injections are often performed earlier in the treatment course. If the patient responds to the epidural steroid injection, it may allow him or her to advance in a nonsurgical treatment program and avoid surgery. It is generally agreed that if possible, epidural steroid injections should not be used as a monotherapy. Patients should be made aware of the general risks of short- and long-term use of steroids – particularly temporary alterations in glucose control.

It is now considered standard of care to perform the injections under image guidance and with contrast in order to deliver the injectate as close to the disc herniation, area of stenosis or nerve root impingement as determined by advanced imaging.

There are three approaches to the epidural space: interlaminar, transforaminal and caudal (*McLain, 2005; Cannon, 2000*). The different approaches allow the treatment to be tailored to the needs of the individual. With each of the three approaches – interlaminar, transforaminal and caudal – there is the typical risk of

Algorithm Annotations

bleeding, infection and nerve damage. Patients should be informed of the possible risks that could occur using each of the three approaches (*Somayaji, 2005; Tiso, 2004; Botwin, 2000*).

Please see the ICSI Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management Guideline section on “Interventional Treatments” for more detailed discussion of epidural steroid injections as well as other interventional pain treatment.

The following may be considered when referring a patient for epidural steroid injection. The final decision of whether a patient is appropriate for the procedure will be made by the specialist.

- Patients typically have symptoms of radicular pain. Examination findings for radiculopathy (reflex changes, possible motor weakness and root tension signs) need not be present. In addition, the pain should be of a severity that significantly limits function and quality of life, and that has not responded to oral analgesic medications and other conservative care measures.
- Advanced imaging is needed – either magnetic resonance imaging or computerized tomography to rule out other causes of pain (e.g., infection, cancer).
- Patients should have no contraindications to an injection, including these:
 - No signs or symptoms of active infection either systemically or locally.
 - No history of bleeding disorders or current use of anticoagulants such as warfarin or clopidogrel. Epidural injections carry a higher risk of bleeding. Patients taking antithrombotics have an increased risk, and the standard of care should be followed. Guidelines have been developed to limit the risk. Assessment of the risk versus benefit should be done prior to the procedure. Consult with the individual performing the procedure for appropriate anticoagulation guidelines.
- Patients with nonanaphylactic reaction to iodine-based contrast may still be treated. Consult with the provider performing the procedure. Those with documented anaphylaxis to iodine-based contrast can be treated with a non-iodine-based contrast such as gadolinium (*Safriel, 2006*).
- No allergies to local anesthetic agents, contrast agents or corticosteroids.
- No prior complications to corticosteroid injections.
- Pregnancy is a contraindication due to the use of fluoroscopy.
- Use caution in diabetic patients because of altered glycemic control, which is typically transient. Patients with diabetes need to be informed and aware that their blood glucose levels will rise and alterations in sliding scales will likely be needed.
- Patients with congestive heart failure need to be aware of steroid-induced fluid retention.
- Though NSAID use is not a contraindication to injections, some practitioners discontinue NSAIDs several days prior to injection.

The Aims and Measures section is intended to provide protocol users with a menu of measures for multiple purposes that may include the following:

- population health improvement measures,
- quality improvement measures for delivery systems,
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative, and
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources
- Implementation Tools and Resources Table

Aims and Measures

1. Decrease the percentage of adult patients with acute or subacute low back pain with or without radiculopathy who have imaging ordered for low back pain in the absence of red flags at the initial visit.

Measure for accomplishing this aim:

- a. Percentage of patients with acute or subacute low back pain with or without radiculopathy who have imaging ordered for low back pain in the absence of red flags at the initial visit.
2. Decrease the percentage of adult patients with acute or subacute low back pain with or without radiculopathy who are prescribed opioids.

Measure for accomplishing this aim:

- a. Percentage of patients with acute or subacute low back pain with or without radiculopathy who are prescribed opioids.

Measurement Specifications

Measurement #1

Percentage of patients with acute or subacute low back pain with or without radiculopathy who have imaging ordered for low back pain in the absence of red flags at the initial visit.

Population Definition

Patients, 18 years and older, seen in primary care and diagnosed with acute or subacute low back pain with or without radiculopathy.

Data of Interest

of patients who have imaging ordered for low back pain in the absence of red flags

of patients with acute or subacute low back pain diagnosis with or without radiculopathy

Numerator and Denominator Definitions

Numerator: Number of patients who have imaging ordered for low back pain in the absence of red flags.

Red flags:

- Bowel/bladder dysfunction (most commonly urinary retention)
- Progressive neurologic weakness
- Saddle anesthesia
- Bilateral radiculopathy
- Incapacitating pain
- Unrelenting night pain

Denominator: Number of patients with acute or subacute low back pain with or without radiculopathy diagnosis.

Method/Source of Data Collection

Query EMR for the number that meets the denominator criteria for population as defined in Population Definition. Out of that number, identify the number that meets the numerator criteria.

Notes

This is a process measure, and improvement is noted as a decrease in the rate.

Aims and Measures

Measurement #2

Percentage of patients with acute or subacute low back pain with or without radiculopathy who are prescribed opioids.

Population Definition

Patients, 18 years and older, seen in primary care and diagnosed with acute or subacute low back pain with or without radiculopathy.

Data of Interest

of patients prescribed opioids

of patients diagnosed with acute or subacute low back pain with or without radiculopathy

Numerator/Denominator Definitions

Numerator: Number of patients who were prescribed opioids.

Denominator: Number of patients diagnosed with acute or subacute low back pain with or without radiculopathy.

Method/Source of Data Collection

Query EMR for the number that meets the denominator criteria for population as defined in Population Definition. Out of that number, identify the number that meets the numerator criteria.

Time Frame Pertaining to Data Collection

Monthly.

Notes

This is a process measure, and improvement is noted as a decrease in the rate.

Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the guideline were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content are included where possible.
- The content is clear about potential biases and conflicts of interests and/or disclaimers are noted where appropriate.

Implementation Tools and Resources Table

Author/Organization	Title/Description	Audience	Web Sites/Order Information
General			
Cochrane	Website provides systematic reviews on evidence-based medicine.	Health Care Professionals	http://www.cochrane.org
National Library of Medicines MEDLINE Plus/National Institutes of Health	Federal government source of back health-related information and research, related links.	Health Care Professionals; Patients and Families	http://www.nlm.nih.gov/hinfo.html
NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Diseases	Website provides a PDF document entitled "Handout or Health: Back." The booklet is for patients and families who have back pain and want to learn more about it.	Patients and Families	http://www.niams.nih.gov
UpToDate	Website provides information for health professionals related to evidence-based clinical information. There may be a fee for access.	Health Care Professionals	http://www.uptodate.com

The subdivisions of this section are:

- References
- Appendices

References

- Aleksiev AR. Ten-year follow-up of strengthening versus flexibility exercises with or without abdominal bracing in recurrent low back pain. *Spine* 2014;39:997-1003.
- American Physical Therapy Association. Description of Dry Needling in Clinical Practice: An Educational Resource Paper 2013.
- Ash LM, Modic MT, Obuchowski NA, et al. Effects of diagnostic information, per se, on patient outcomes in acute radiculopathy and low back pain. *AJNR Am J Neuroradiol* 2008;29:1098-103.
- Botwin KP, Gruber RD, Bouchlas CG, et al. Complications of fluoroscopically guided transforaminal lumbar epidural injections. *Arch Phys Med Rehabil* 2000;81:1045-50.
- Buchman AL. Side effects of corticosteroid therapy. *J Clin Gastroenterol* 2001;33(4):289-94.
- Cannon DT, Aprill CN. Lumbosacral epidural steroid injections. *Arch Phys Med Rehabil* 2000;81:S87-98.
- Choi BK, Verbeek JH, Tam WW, Jiang JY. Exercises for prevention of recurrences of low back pain. *Cochrane Database Syst Rev* 2010;(1):CD006555.
- Chou R, Deyo R, Friedly J, et al. Noninvasive treatments for low back pain. Rockville (MD): Agency for Healthcare Research and Quality (US). Report No. 16-EHC004-EF. 2016
- Chou R, Fu R, Carrino JA, Deyo RA. Imaging strategies for low-back pain: systematic review and meta-analysis. *Lancet* 2009;373(9662):463-72.
- Chou R, Hashimoto R, Friedly J, et al. Pain management injection therapies for low back pain. Technology Assessment Report ESIB0813. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. HHS 290-2012-00014-.) Rockville, MD: Agency for Healthcare Research and Quality; July 2015.
- Chou R, Qaseem A, Owens DK, Shekelle P, Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med* 2011;154(3):181-9.
- Chou R, Shekelle P. Will this patient develop persistent disabling low back pain? *JAMA* 2010;303:1295-302.
- Coudeyre E, Tubach F, Rannou F, et al. Fear-avoidance beliefs about back pain in patients with acute LBP. *Clin J Pain* 2007;23:720-25.
- Dahm KT, Brurberg KG, Jamtvedt G, Hagen KB. Advice to rest in bed versus advice to stay active for acute low back pain and sciatica. *Cochrane Database Syst Rev* 2010;(6):CD007612.
- Downie A, Williams CM, Henschke N, et al. Red flags to screen for malignancy and fracture in patients with low back pain: systematic review. *BMJ* 2013;347:f7095.
- Dupeyron A, Ribinik P, Gélis A, et al. Education in the management of low back pain: literature review and recall of key recommendations for practice. *Ann Phys Rehabil Med* 2011;54:319-35.
- Eisenberg DM, Post DE, Davis RB, et al. Addition of choice of complementary therapies to usual care for acute low back pain: a randomized controlled trial. *Spine* 2007;32:151-58.
- Elfering A, Käser A, Melloh M. Relationship between depressive symptoms and acute low back pain at first medical consultation, three and six weeks of primary care. *Psychol Health Med* 2014;19:235-46.
- Fairbank JC, Pynsent PB. The Oswestry disability index. *Spine* 2000;25:2940-52.

References

Friedman BW, Esses D, Solorzano C, et al. A randomized placebo-controlled trial of single-dose IM corticosteroid for radicular low back pain. *Spine* 2008;33:E624-29.

Fritz JM, Childs JD, Wainner RS, Flynn TW. Primary care referral of patients with low back pain to physical therapy: impact on future health care utilization and costs. *Spine* 2012;37:2114-21.

Furlan AD, Giraldo M, Baskwill A, et al. Massage for low back pain. *Cochrane Database Syst Rev* 2015;(9):CD001929.

George SZ, Beneciuk JM. Psychological predictors of recovery from low back pain: a prospective study. *BMC Musculoskelet Disord* 2015;16:49.

Goldberg H, Firtch W, Tyburski M, et al. Oral steroids for acute radiculopathy due to a herniated lumbar disk: a randomized clinical trial. *JAMA* 2015;313:1915-23.

Goldman L. In *Goldman's Cecil Medicine* 24th Edition. 2011.

References

- Goode AP, Coeytaux RR, McDuffie J, et al. An evidence map of yoga for low back pain. *Complement Ther Med* 2016;25:170-77.
- Grimaldi A, Mellor R, Nicolson, et al. Utility of clinical tests to diagnose MRI-confirmed gluteal tendinopathy in patients presenting with lateral hip pain. *Br J Sports Med* 2017; 519-24.
- Henschke N, Maher CG, Ostelo RW, et al. Red flags to screen for malignancy in patients with low back pain. *Cochrane Database Syst Rev* 2013;(2):CD008686.
- Hill JC, Vohora K, Dunn KM, et al. Comparing the STarT back screening tool's subgroup allocation of individual patients with that of independent clinical experts. *Clin J Pain* 2010;26:783-87.
- Hoy D, Brooks P, Blyth F, Buchbinder R. The epidemiology of low back pain. *Best Pract Res Clin Rheumatol* 2010;24:769-81.
- Katz JN. Lumbar disc disorders and low back pain: socioeconomic factors and consequences. *J Bone Joint Surg Am* 2006;88:21-24.
- Kent P, Mjøsund HL, Petersen DHD. Does targeting manual therapy and/or exercise improve patient outcomes in nonspecific low back pain? A systematic review. *BMC Medicine* 2010;8:22.
- Krebs EE, Lorenz KA, Bair MJ, et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. *J Gen Intern Med* 2009;24:733-38.
- Lamb SE, Hansen Z, Lall R, et al. Group cognitive behavioural treatment for low back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. *Lancet* 2010a;375:916-23.
- Lamb SE, Lall R, Hansen Z, et al. A multicentred randomised controlled trial of a primary care-based cognitive behavioural programme for low back pain: the back skills training (BeST) trial. *Health Technol Assess* 2010b;14:1-253, iii-iv.
- Lee JH, Choi TY, Lee MS, et al. Acupuncture for acute low back pain: a systematic review. *Clin J Pain* 2013;29:172-85.
- Liddle SD, Pennick V. Interventions for preventing and treating low back and pelvic pain during pregnancy. *Cochrane Database Syst Rev* 2015;(9):CD001139.
- Linton SJ. A review of psychological risk factors in back and neck pain. *Spine* 2000;25:1148-56.
- Liu L, Huang QM, Liu QG, Thitham N, Li LH, Ma YT, Zhao JM. Evidence for dry needling in the management of myofascial trigger points associated with low back pain: a systematic review and meta-analysis. *Arch Phys Med Rehabil* 2017.
- Mahmoudzadeh A, Rezaeian ZS, Karimi A, Dommerholt J. The effect of dry needling on the radiating pain in subjects with discogenic low-back pain: a randomized control trial. *J Res Med Sci* 2016;21:86.
- Manchikanti L, Knezevic M, Boswell M, et al. Epidural injections for lumbar radiculopathy and spinal stenosis: A comparative systematic review and meta-analysis. *Pain Physician* 2016; 19:E365-E410.
- McIntosh G, Hall H. Low back pain (acute). *BMJ Clin Evid* 2011;2011.
- McLain RF, Kapural L, Mekhail NA. Epidural steroid therapy for back and leg pain: mechanisms of action and efficacy. *Spine J* 2005;5:191-201.
- Melloh M, Elfering A, Käser A, Salathé CR, Barz T, Aghayev E, Röder C, Theis JC. Depression impacts the course of recovery in patients with acute low-back pain. *Behav Med* 2013;39(3):80-9.
- National Guideline Centre (UK). Low back pain and sciatica in over 16s: assessment and management. London: National Institute for Health and Care Excellence (UK). 2016.

References

- Norén L, Östgaard S, Johansson G, Östgaard HC. Lumbar back and posterior pelvic pain during pregnancy: a 3-year follow-up. *Eur Spine J* 2002;11:267-71.
- Paige NM, Miake-Lye IM, Booth MS, et al. Association of spinal manipulative therapy with clinical benefit and harm for acute low back pain: systematic review and meta-analysis. *JAMA* 2017;317:1451-60.
- Papageorgiou AC, Croft PR, Thomas E, et al. Psychosocial risks for low back pain: are these related to work? *Ann Rheum Dis* 1998;57:500-02.
- Patel ND, Broderick DF, Burns, et al. ACR appropriateness criteria low back pain. *J Am Coll Radiol* 2016;13:1069-78.
- Roland MO, Morris RW. A study of the natural history of back pain: part I: development of a reliable and sensitive measure of disability in low back pain. *Spine* 1983;8:141-44.
- Rubinstein SM, Terwee CB, Assendelft WJ, et al. Spinal manipulative therapy for acute low back pain: an update of the cochrane review. *Spine* 2013;38:E158-77.
- Sabino J, Grauer JN. Pregnancy and low back pain. *Curr Rev Musculoskelet Med* 2008;1:137-41.
- Safriel Y, Ali M, Hayt M, Ang R. Gadolinium use in spine procedures for patients with allergy to iodinated contrast – experience of 127 procedures. *Am J Neuroradiol* 2006;27:1194-97.
- Saragiotto BT, Machado GC, Ferreira ML, et al. Paracetamol for low back pain. *Cochrane Database Syst Rev* 2016;(6):CD012230.
- Somayaji HS, Saifuddin A, Casey ATH, Briggs TWR. Spinal cord infarction following therapeutic computed tomography-guided left L2 nerve root injection. *Spine* 2005;30:E106-08.
- Stapleton DB, MacLennan AH, Kristiansson P. The prevalence of recalled low back pain during and after pregnancy: a South Australian population study. *Aust NZ J Obstet Gynaecol* 2002;42:482-85.
- Steffens D, Maher CG, Pereira LS, et al. Prevention of low back pain: a systematic review and meta-analysis. *JAMA Intern Med* 2016;176:199-208.
- Tiso RL, Cutler T, Catania JA, Whalen K. Adverse central nervous system sequelae after selective transforaminal block: the role of corticosteroids. *Spine J* 2004;4:468-74.
- Traeger AC, Hübscher M, Henschke N, et al. Effect of primary care-based education on reassurance in patients with acute low back pain: systematic review and meta-analysis. *JAMA Intern Med* 2015;175:733-43.
- Waddell G. 1987 Volvo award in clinical sciences: a new clinical model for the treatment of low back pain. *Spine* 1987;12:632-44.
- Waddell G. Biopsychosocial analysis of low back pain. *Baillieres Clin Rheumatol* 1992;6:523-57.
- Waddell G, Newton M, Henderson I, et al. A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52:157-68.
- Wegner I, Widyahening IS, van Tulder MW, et al. Traction for low back pain with or without sciatica. *Cochrane Database Syst Rev* 2013;(8):CD003010.
- Wertli MM, Rasmussen-Barr E2, Weiser S, et al. The role of fear avoidance beliefs as a prognostic factor for outcome in patients with nonspecific low back pain: a systematic review. *Spine J* 2014;14:816-36.
- Whitehurst DG, Bryan S, Lewis M, et al. Implementing stratified primary care management for low back pain: cost-utility analysis alongside a prospective, population-based, sequential comparison study. *Spine* 2015;40:405-14.
- Williamson E. Fear avoidance beliefs questionnaire (FABQ). *Aust J Physiother* 2006;52:149.
- Zhou K, Ma Y, Brogan MS. Dry needling versus acupuncture: the ongoing debate. *Acupunct Med* 2015;33(6):485-90.

Appendix A – Patient Handout

Get Back to Life!

Low back pain is a very common condition. Similar to the common cold, low back pain usually resolves on its own and is rarely dangerous. In most cases of back pain, the specific cause is unknown, but the good news is that similar things will help you get back to enjoying life sooner.

What can I do?

Don't worry!

- o Knowing that your back pain isn't serious is the first step.

Hurt doesn't equal harm!

- o Pain is a normal experience. Get back to activities; pain will get better with time and movement.

Be active!

- o It might sound odd to move when you have pain, but your body was made to move. You should walk for several minutes at a time, walking more minutes each day. If you sit during the day, getting up to move will help. It will lessen your pain if you stand or walk each hour.

Have a good outlook!

- o You will start to feel better when you get moving and have a positive outlook.

What should I avoid?

Bed rest

- o Even if it bothers you to be active, walking and doing your normal activities are the best forms of treatment.

Pain medicines

- o Prescription medication is usually not needed in management of low back pain.

Imaging is generally not helpful.

How can I lower my chances of back pain in the future?

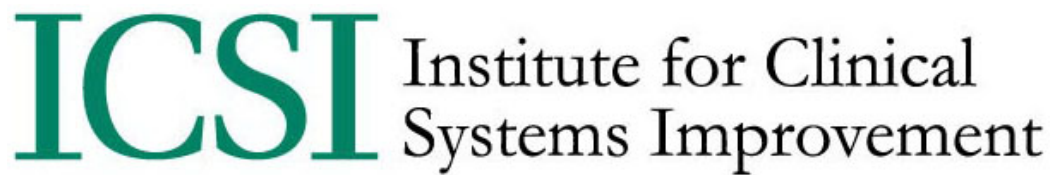
Stay active and be positive about the outlook. You may have pain for a few weeks again, but it should get better like it did last time.

When should I call my provider?

Your back pain should get better over a few weeks, but call your provider if:

- o If you lose your ability to control your bladder or bowels; call immediately
- o You feel generally unwell or sick
- o You feel tingling in your groin or legs
- o Your pain spreads down your leg and into your foot
- o Your toes, feet or legs feel weak
- o Your pain gets worse, not better

Appendix B – ICSI Shared Decision-Making Model



The Collaborative Conversation™ Shared Decision-Making and the Translation of Evidence into Practice

A consistent finding from clinical and health services research is the failure to translate research into practice. The translation of evidence into practice can be advanced through the use of shared decision-making since shared decision-making results in evidence being incorporated into patient and clinician consultations.

Shared decision-making (SDM) is a process in which patient and clinicians collaborate to clarify all acceptable options, ensure that the patient is well-informed and chose a course of care consistent with patient values and preferences and the best available medical evidence. (Minnesota Shared Decision-Making Collaborative [MSDMC], 2011).

Evidence-based guidelines may recommend the use of shared decision-making for decisions in instances where the evidence is equivocal, when patient action or inaction (such as medication adherence or lifestyle changes) can impact the potential outcome, or when the evidence does not indicate a single best recommendation.

SDM is a patient-centered approach that involves a conversation between the patient and the clinician. It is ideal to involve caregivers and family members in these conversations as well. Family members and caregivers can participate in discussions, ask questions, hear content the patient may miss and provide invaluable support in decision follow-through. Although only patients and clinicians are specifically mentioned throughout this document for brevity purposes, this does not diminish the importance of caregivers and families in patient-centered care.

Both the patient and the clinician bring expertise to the shared decision-making conversation. Clinicians' expertise includes disease etiology, prognosis, options for treatment including the burden and benefit to the patient, and outcome probabilities. Patients' expertise lies in their knowledge of their risk tolerance, body, priorities, family and financial issues, as well as their daily experience with the condition (adapted from Making Shared Decision-Making a Reality. No decision about me, without me. Coulter, A., Collins, A., The King's Fund 2011).

Treatment options vary in their burden on a patient. SDM offers an opportunity to help the patient select a treatment to which they can adhere. When conversations discussing options occurs, patients and clinicians are actively engaged while considering the attributes and issues of the available options. This empathic approach results in the clinician and patient co-creating a decision and a plan of care (adapted from Montori, V., the Mayo Clinic KER UNIT, April 2015). Decision aids can be supportive of this conversation when they communicate the best available evidence to inform the patient and clinician discussion.

Without a conversation, clinicians may make assumptions about what the patient prefers. This creates the potential for discrepancies between what clinicians assume and what patients want, resulting in a "preference misdiagnosis" (adapted from Health Policy Publishing, LLC, May 2013).

Difficulty in initiating a conversation is cited by patients and clinicians as one of the barriers to shared decision-making. To address this impediment, ICSI worked with patients, practicing clinicians, and other stakeholders to develop the Collaborative Conversation™ model for use across the care continuum.

Collaborative Conversation™

A collaborative approach towards decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an interprofessional approach that nurtures relationships; enhances patients' knowledge, skills and confidence as vital participants in their health; and encourages them to manage their health care. Within a Collaborative Conversation™, the perspective is that the patient, rather than the clinician, knows which course of action is most consistent with the patient's values and preferences.

Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care clinician and team relationships when patients and families are dealing with high stakes or highly charged issues. A diagnosis of a life-limiting illness is one example of such a circumstance.

The overall objective for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences, along with the best available evidence. A rote script, completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects of the person involved in making a decision: cognitive, affective, social and spiritual.

Key communication skills help build the collaborative conversation approach. These skills include (Adapted from O'Connor, Jacobsen Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting their Health [2007], and Bunn H, O'Connor AM, Jacobsen MJ Analyzing decision support and related communication [1998, 2003])

1. Listening skills

Encourage patient to talk by providing prompts to continue such as *go on, and then? and uh huh* or by repeating the last thing a person said, *It's confusing*.

Paraphrase content of messages shared by patient to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The clinician should use their own words rather than just parroting what they heard.

Reflection of feelings usually can be done effectively once trust has been established. Until the clinician feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the clinician understands the patient's feelings and may work as a catalyst for further problem solving. For example, the clinician identifies what the person is feeling and responds back in his or her own words like this: *"So, you're unsure which choice is the best for you."*

Summarize the person's key comments and reflect them back to the patient. The clinician should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situation rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is *"You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks."*

Perception checks ensure that the clinician accurately understands a patient or family member perspective, and may be used as a summary or reflection. They are used to verify that the clinician is interpreting the message correctly. The clinician can say, *"So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?"*

2. Questioning Skills

Open and closed questions are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be, *“What else would influence you to choose this?”* Closed questions are appropriate if specific information is required, such as *“Does your daughter support your decision?”*

Other skills such as summarizing, paraphrasing, and reflection of feeling can be used in the questioning process so that the patient doesn’t feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the clinician saying, *“You mentioned earlier...”*

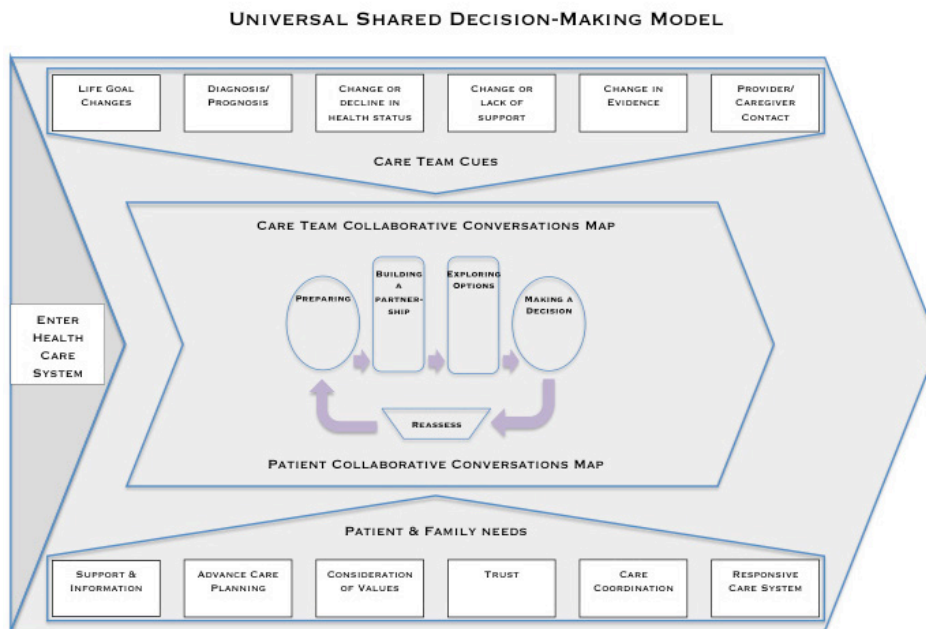
3. Information-Giving Skills

Providing information and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a clinician to supplement his or her knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient’s unique goals and values, and places it on those of the clinician.

Providing information can be sharing facts or responding to questions. An example is *“If we look at the evidence, the risk is...”* **Providing feedback** gives the patient the clinician’s view of the patient’s reaction. For instance, the clinician can say, *“You seem to understand the facts and value your daughter’s advice.”*

When to Initiate a Collaborative Conversation™

Certain seminal events occur along the care continuum, creating especially opportune times for collaborative conversations. More than one of these opportunities may present at a time, and they will occur in no specific order.



Copyright © 2010 by ICSI All Rights Reserved

ICSI Institute for Clinical
Systems Improvement

Table 1

[Return to Table of Contents](#)

www.icsi.org

Cues for the Care Team to Initiate a Collaborative Conversation™:

- Life goal changes: *Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.*
- Diagnosis/prognosis changes: *Additional diagnoses, improved or worsening prognosis.*
- Change or decline in health status: *Improving or worsening symptoms, change in performance status or psychological distress.*
- Change or lack of support: *Increase or decrease in caregiver support, change in caregiver, change in caregiver status, change in financial standing, difference between patient and family wishes.*
- Disease progression: *Change in physical or psychological status as a result of the disease progression.*
- Clinician/caregiver contact: *Each contact between the clinician/ caregiver presents an opportunity to reaffirm with the patient that the care plan and the care he or she is receiving are consistent with his or her values.*

Patient and Family Needs within a Collaborative Conversation™

- Request for support and information: *Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values, or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When patient expresses a need for information regarding options and their potential outcomes, the patient should understand the key facts about the options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.*
- Advance Care Planning: *With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis of a life-limiting illness.*
- Consideration of Values: *The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize his or her preferences, value clarification can be achieved through the use of decision aids, detailing the benefits and harms of potential outcomes in terms of how they will directly affect the patient, and through collaborative conversations with the clinician.*
- Trust: *The patient must feel confident that his or her preferences will be communicated to and respected by all caregivers.*
- Care Coordination: *Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Further, the care delivery system must be capable of delivering coordinated care throughout the continuum of care.*
- Responsive Care System: *The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he or she receives throughout the care continuum.*

ICSI Shared Decision-Making Model

The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation Map™ can be used as a stand-alone tool that is equally applicable to clinicians and patients, as shown in Table 2. Clinicians use the map as a clinical workflow. It helps get the shared decision-making process initiated and provides navigation for the process. Care teams can use the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.

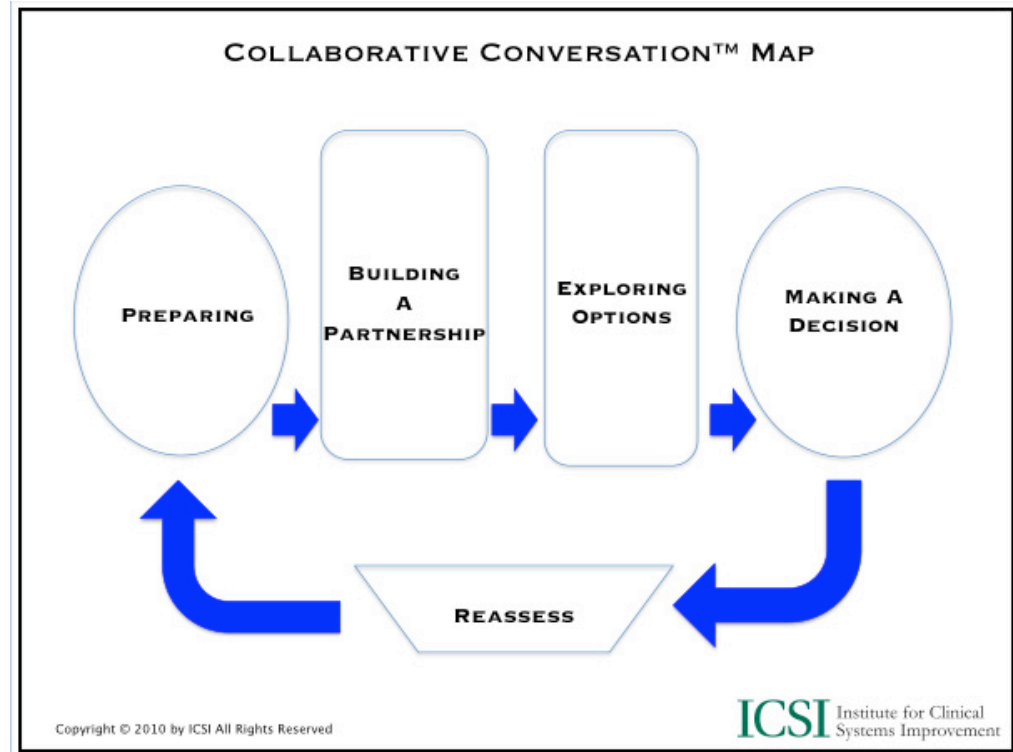


Table 2

Evaluating Shared Decision-Making

It has proven challenging to assess shared decision-making. Measuring shared decision-making remains important for continued adoption of shared decision-making as a mechanism for translating evidence into practice; promoting patient-centered care; and understanding the impact of shared decision-making on patient experience, outcomes and revenues. Many assessments exist, but they are often proxy measures.

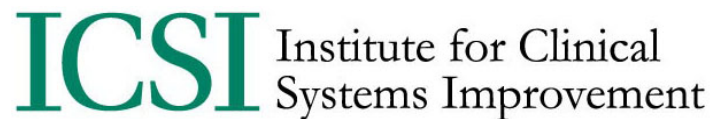
Two suggested methods for measuring shared decision-making are the CollaboRATE tool and the SURE Test. These two tools measure different aspects of shared decision-making, as described below.

The [CollaboRATE tool](http://www.collaboratescore.org/) measures the level of shared decision-making in the clinical encounter from the patient's perspective. It is a brief patient-reported measure of shared decision-making. The tools and guidance on their use can be found at <http://www.collaboratescore.org/>.

The [SURE Test](#) is a brief screening questionnaire the patient uses to assess his or her readiness and capacity to make a decision or to determine whether he or she is comfortable with the choice that was made. In other words, it provides information on how likely a patient may be experiencing decisional conflict. If the SURE Test indicates decisional conflict may exist, the [Decisional Conflict Scale](#) should be completed in order to assess clinically significant decisional conflict.

Shared decision-making is a useful mechanism for translating evidence into practice. While research on the impacts of shared decision-making continues to grow, there is mounting evidence that both patients and clinicians benefit from SDM. Shared decision-making offers the opportunity to bring evidence and the patient's values into the patient/clinician discussion of health choices.

Copyright © 2012, 2016 by Institute for Clinical Systems Improvement. All rights reserved.



8009 34th Avenue South, Suite 1200 • Bloomington, MN 55425 • Phone: 952-814-7060 • www.icsi.org

© 2012 Institute for Clinical Systems Improvement. All rights reserved.

ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, *Clinical Practice Guidelines We Can Trust* (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at <http://bit.ly/ICSICOI>.

Funding Source

The Institute for Clinical Systems Improvement provided the funding for this guideline revision. ICSI is a not-for-profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and three sponsoring health plans in Minnesota. Individuals on the work group are not paid by ICSI but are supported by their medical group for this work.

The only exception to this, patient and public members of a work group, are provided with a small stipend to cover meeting attendance.

ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Disclosure of Potential Conflicts of Interest

Robb Campbell, MD, MPH (Work Group Member)

Senior Occupational Physician, Occupational Medicine; 3M

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: Received stock options as part of compensation. This member works for a large employer in the Twin Cities and is a stockholder in Glaxo Smith Kline.

Todd Ginkel, DC (Work Group Member)

Spine Rehabilitation, Physicians' Diagnostics & Rehabilitation Clinics

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

Chris Kramer, PT, DPT, OCS, FAAOMPT (Work Group Member)

Physical Therapist, Park Nicollet Health Services

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

Michael Massey, DO (Work Group Member)

Medical Director, Pain Medicine, CentraCare Health System

National, Regional, Local Committee Affiliations: Board of Trustee NWHSU

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

Becky McCathie, MEd, ATC (Work Group Member)

Senior Project Manager, Fairview Health Services

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: Participates on the Minnesota Community Measurement Low Back Pain work group

Research Grants: None

Financial/Non-Financial Conflicts of Interest: Two scientific journal citations

Becky Mueller, DO (Work Group Member)

Physician, Family Medicine/Sports Medicine, CentraCare Health System Becker

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

Steven Peterson (Work Group Member)

Clinic Manager, Physical Therapy, OSI Physical Therapy

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

Heidi Richards, PT, MHA (Work Group Member)

Clinic Administrator, Fairview Health Services

National, Regional, Local Committee Affiliations: None

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: None

David Thorson, MD (Work Group Leader)

Medical Director, Sports Medicine, Entira Family Clinics

National, Regional, Local Committee Affiliations: President – MN Medical Association (MMA)

Guideline Related Activities: None

Research Grants: None

Financial/Non-Financial Conflicts of Interest: Financial relationship with Twin Cities Orthopedics -
Outpatient visit in senior living center for post-op joint replacement

ICSI seeks review from members and the public during the revision process.

Member Review

All ICSI documents are available for member review at two points in the ICSI revision process. The ICSI Response Report is sent to members at the beginning of a document revision. The goal of this report is to solicit feedback about the guideline, including but not limited to the algorithm, content, recommendations, and implementation. Members are also welcome to participate in the public comment period (see below).

The work group would like to thank the following organizations for participating in the pre-revision review:

- *Hudson Physicians*
- *Stillwater Medical Group*

Public Comment

ICSI makes a draft of the guideline available to the public on the ICSI website. The public is invited to comment in an effort to get feedback prior to its finalization. All comments will be reviewed by the ICSI facilitator and work group members when needed. ICSI work group may or may not make changes to the guideline based on public comment responses.

The work group would like to thank all those who took time to thoughtfully and thoroughly review our draft and submitted comments for the depression guideline.

Invited Reviews

For some guidelines, ICSI will invite experts in the community to comment on a guideline draft prior to finalization. This is done during the public comment period.

The work group would like to thank the following individual for participating in an invited review:

Brian Bonte, DO, Hutchinson Health

ICSI Patient Advisory Council (PAC)

The ICSI Patient Advisory Council responds to any guideline review requests put forth by ICSI facilitators and work groups. The PAC members may be involved at the beginning, middle, and/or end of the revision process. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document.

The ICSI Patient Advisory Council provided feedback at the onset of the revision process.

Document History and Development: Adult Acute and Subacute Low Back Pain

Document Drafted
Apr – Jul 1993

First Edition
Jun 1994

Second Edition
Aug 1995

Third Edition
Dec 1996

Fourth Edition
Nov 1997

Fifth Edition
Dec 1998

Sixth Edition
Dec 1999

Seventh Edition
Jun 2001

Eighth Edition
Oct 2002

Ninth Edition
Oct 2003

Tenth Edition
Oct 2004

Eleventh Edition
Oct 2005

Twelfth Edition
Oct 2006

Thirteenth Edition
Dec 2008

Fourteenth Edition
Dec 2010

Critical Review
Aug 2011

Fifteenth Edition
Dec 2012

Public Comment
Nov 2017

Sixteenth Edition
Dec 2017

Original Work Group Members

Mark DePaolis, MD
Family Practice
Park Nicollet Medical Center

Sherwin Goldman, MD
Orthopedic Surgery
Mayo Clinic

Brenda Gorder, RN
Facilitator
Group Health, Inc.

Robert Gorman, MD, MPH
Occupational Medicine, Work Group Leader
Park Nicollet Medical Center

Fred Hamacher
Business Health Care Action Group
Dayton Hudson Corporation

Michael Koopmeiners, MD
Family Practice
Group Health, Inc.

Dominic Korbuly, MD
Radiology
Park Nicollet Medical Center

George Kramer, MD
Physical Medicine and Rehab
Park Nicollet Medical Center

Kathy Kurdelmeier, PT
Physical Therapy
Park Nicollet Medical Center

Steven Lewis, DC
Chiropractics
Group Health, Inc.

Peter Marshall, MD
Family Practice
Group Health, Inc.

Jane Norstrom
Health Education
Park Nicollet Medical Foundation

David C. Thorson, MD
Sports Medicine
MinnHealth, P.A.

Catherine Wisner, PhD
Measurement Advisor
Group Health Foundation

Document History

- This document underwent a complete revision and was rewritten in 2011. The GRADE methodology for reviewing evidence was also incorporated.

◀ The next revision will be no later than April 2023.

Contact ICSI at:

8009 34th Avenue South, Suite 1200; Bloomington, MN 55425; (952) 814-7060; (952) 858-9675 (fax)
Online at <http://www.ICSI.org>

ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI health care guideline is intended primarily for health professionals and other expert audiences.

This ICSI health care guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI health care guideline and applying it in their individual case.

This ICSI health care guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations and implementation strategies. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals for any pertinent evidence that would affect a particular guideline and recommendation.