

SYSTEMS IMPROVEMENT

## **Health Care Guideline:**

# **Adult Acute and Subacute Low Back Pain**

Fifteenth Edition January 2012

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- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- · medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
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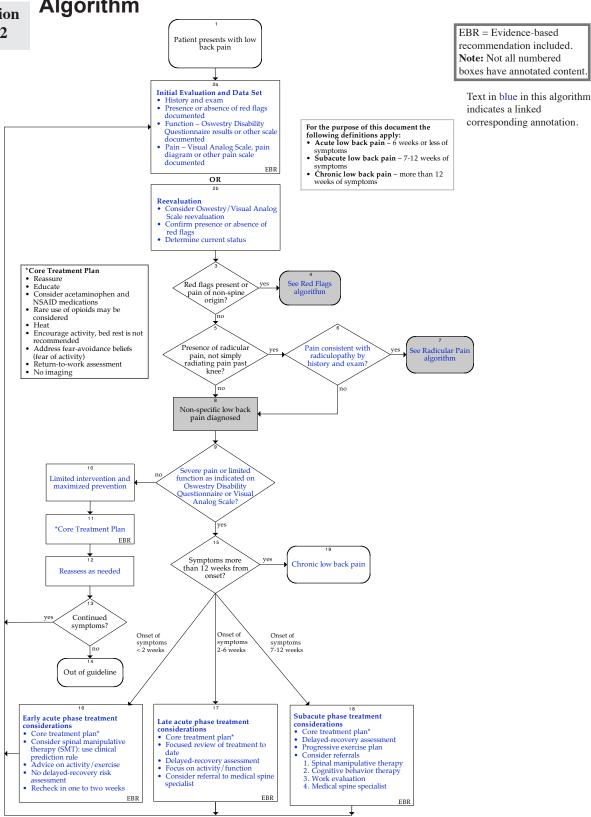


#### **Health Care Guideline:**

# Adult Acute and Subacute Low Back Pain

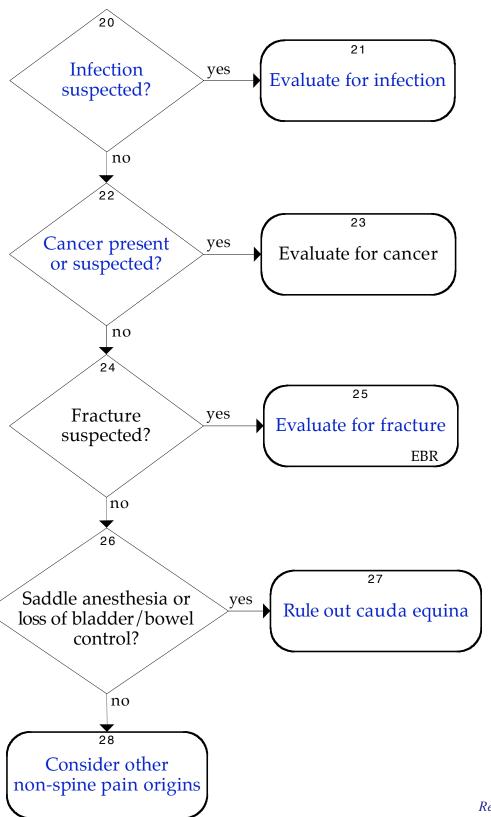
INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Fifteenth Edition January 2012 **Core Treatment of Non-Specific Low Back Pain Algorithm** 



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# **Red Flags Algorithm**



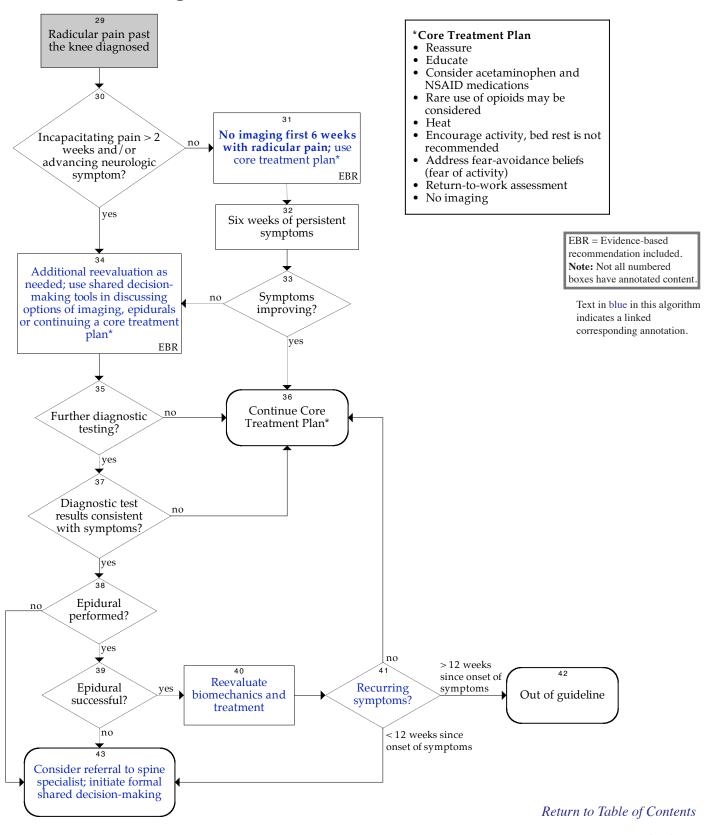
EBR = Evidence-based recommendation included.

Note: Not all numbered boxes have annotated content.

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

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## **Disclosure of Potential Conflict of Interest**

In the interest of full disclosure, ICSI has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. It is not assumed that these financial interests will have an adverse impact on content. They are simply noted here to fully inform users of the guideline.

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No other work group members have potential conflicts of interest to disclose.

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# **Evidence Grading**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. Literature search terms for the current revision of this document include epidural steroid injections, modified Oswestry scale, acute low sacral dysfunction, PHQ2, conservative care for cauda equina, conservative treatment for low back pain, diagnostic imaging and low back pain, active rehabilitation, diagnostic imaging for radiculopathy and surgical treatment from January 2008 through April 2010.

In 2011, ICSI began its transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system as a method of assessing the quality of evidence and writing recommendations.

GRADE has many advantages over other systems including these:

- Developed by a widely representative group of international guideline developers
- Explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings
- Clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations
- Clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients, and policy makers
- Explicit acknowledgement of values and preferences, and
- Explicit evaluation of the importance of outcomes of alternative management strategies.

In the GRADE process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated with randomized control trials or observational studies. The evidence

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addresses the same population, intervention, comparisons and outcomes. The overall body of evidence for each topic is then given a quality rating.

Once the quality of the evidence has been determined, recommendations are formulated to reflect their strength. The strength of a recommendation is either strong or weak. Only outcomes that are critical are considered the primary factors influencing a recommendation and are used to determine the overall strength of this recommendation. Each recommendation answers a focused health care question.

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

#### **Supporting Literature**

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature are used to direct the reader to other topics of interest. This literature is not given an evidence grade and is instead used as a reference for its associated topic. These citations are noted by (*author*, *year*) and are found in the references section of this document.

#### **Recommendations Table**

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

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation	Strength of Recommendation	Annotation Number	Relevant References
Activity	Moderate	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.	Strong	11, 16, 17, 18	Dahm, 2010
Acupuncture	Low	Acupuncture may be used as an adjunct treatment for subacute low back pain.	Weak	18	Chou, 2007b; Chou, 2009a; Furlan, 2008
Bed Rest	Moderate	Bed rest is not recommended.	Strong	11, 16, 17, 18	Dahm, 2010
Clinical prediction rule	Low	At this point evidence is not sufficient to strongly recommend the clinical prediction rule. However, studies are currently underway which may add further support. Therefore, we suggest consideration of the clinical prediction rule in the category of early low back pain patients.	Weak	16	Brennan, 2006; Childs, 2004; Fritz, 2005; Kent, 2010
Cognitive behavioral therapy	Moderate	Clinicians should consider cognitive behavioral therapy in the treatment of subacute low back pain.	Weak	18	Hansen, 2010; Karjalainen, 2003; Lamb, 2010
Cold therapy	Low	The use of cold therapy is not recommended.	Weak	11, 16, 17, 18	French, 2006
Delayed- recovery assessment	Low	Delayed-recovery assessment is not fully developed, however, much progress has been made and it is recommended that the clinician use one or more approaches to identify a patient who is at risk and intervene with specific interventions.	Weak	17, 18	Hayden, 2010; Heymans, 2004; Hilfiker, 2007; Pincus, 2002; Steenstra, 2005
Education	Moderate	Clinicians should educate patients as an adjunct to other treatment. No standardized form of education is suggested.	Strong	11, 16, 17, 18	Engers, 2008; Heymans, 2004
Epidural steroid injections	Moderate	Epidural steroid injections may be used for low back pain with a radicular component to assist with short term pain relief.	Weak	34	Laiq, 2009; Manchikanti, 2010; Parr, 2009; Sayegh, 2009; Staal, 2008
Exercise for prevention	Moderate	Exercise is recommended to reduce the recurrence of low back pain, however, no specific exercise is preferred.	Strong	11, 16, 17, 18	Choi, 2010
Exercise for treatment	Moderate	Exercise is recommended in the treatment of subacute low back pain.	Strong	18	Hayden, 2005; Kool, 2007; Schaafsma, 2010; Wright, 2005
Heat	Moderate	Heat should be used for pain relief.	Strong	11, 16, 17, 18	French, 2006
Imaging for non-specific low back pain	Moderate	Imaging is not recommended for non-specific low back pain.	Strong	2a, 11, 16, 17, 18, 31	Chou, 2011; Chou, 2009b; French, 2010
Imaging to rule out underlying pathology	Moderate	Imaging may be considered to rule out underlying pathology or for those who are considering surgery or when fracture is suspected.	Strong	25, 34	Chou, 2011; Chou, 2009b; French, 2010
Muscle relaxants	Moderate	Muscle relaxants may be used as an option in treating acute low back pain, however, possible side effects should be considered.	Weak	11, 16, 17, 18	Bernstein, 2004; Malanga, 2009; Pareek, 2009; Ralph, 2008; Toth, 2004; van Tulder, 2003
NSAIDs	Moderate	NSAIDs may be used for short-term pain relief in patients with acute and subacute low back pain.	Weak	11, 16, 17, 18	Hancock, 2009; Roelfs, 2008; Yakhno, 2006
Opioids	Low	Rare use of opioids may be considered for those patients with severe disabling pain not controlled with acetaminophen and NSAIDs, at a minimum dose, for a limited period of time.	Strong	11, 16, 17, 18	Chou, 2007a; Chou, 2007c; Cifuentes, 2010; Franklin, 2008; Palangio, 2002; Perrot, 2006; Rhee, 2007; Volinn, 2009; Webster, 2007
Spinal manipulative therapy	Moderate	Spinal manipulative therapy should be considered in the early intervention of low back pain.	Strong	16, 18	Assendelft, 2008; Dagenais, 2010; Jüni, 2009; Santilli, 2006; Walker, 2010
Traction	Low	Clinicians should not prescribe or recommend traction for the treatment of acute low back pain.	Weak	11, 16, 17	Clarke, 2007

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# **Foreword**

#### Introduction

#### **Pathophysiology**

It is estimated that only 15% of all low back pain has an identifiable anatomic explanation. The other 85% is identified as non-specific low back pain. Since the identification of the disk herniation in 1934 by Mixter and Barr, low back pain has been considered structural, and specific low back structures have been identified as "pain generators" by individuals such as Bogduk and Schwarzer. The concept of the "pain generator" as the cause of chronic low back pain was recently brought into question at a North American Spine Society symposium conducted by Staedart. It is clear that there is no consensus in this area. Studies in neurophysiology and genetics point to individual's response to painful stimuli as accounting for up to two-thirds of the components of chronic low back pain (Costigan, 2009). It has been known for many decades that psychosocial factors also play a component in the development of chronic low back pain.

#### Causation

Multiple factors have been identified as relating to the onset of low back pain (*Hall*, 1998). Most individuals consider pain to be associated with an injury. However, a specific event is associated with the onset of pain in only about one third of the cases. This challenges the concept that low back pain is an injury associated with mechanical force such as lifting or position. Further work is necessary in this area if we are to understand this multifactorial condition (*Rubin*, 2007).

The concept that low back pain is related to injury is challenged by the recent work of multiple authors showing a limited relationship between low back pain and physical exposures (*Roffey*, 2010; *Wai*, 2010a; *Wai*, 2010b; *Bakker*, 2009). The discussion of the pathophysiology indicates that it is a multifactorial symptom, which may start with an injury reaction but is exacerbated by concomitant factors that may extend symptoms far past the normal healing time for injured tissues. Co-factors that contribute to persistent pain may include deconditioning, psychological issues, other chronic illnesses, genetics and even culture.

#### **Natural history**

The majority of individuals with an episode of acute low back pain improve and return to work within the first two weeks (*Pengel*, 2003). The probability of recurrence within the first year ranges from 30 to 60% (*Hayden*, 2010). Most of these recurrences will recover in much the same pattern as the initial event. In as many as one third of the cases, the initial episode of low back pain persists for the next year. Most of these individuals continue to function with only limited impairment.

#### Cost

Most of the total cost for low back pain is dedicated to the small percentage of sufferers whose condition has progressed to the chronic disabling stage (pain for more than 12 weeks). The medical costs for low back pain in general were estimated at \$26.3 billion in 1998 (*Chou*, 2007c) and now are one third to one fourth of the total cost of care. Lost production and disability account for other costs. Disability alone claims 80% of the total expense of this condition. Expenditures for medical care and disability continue to increase (*Luo*, 2004). The human cost is equally significant, low back pain is currently the second most common cause of disability in the United States and is the most common cause of disability in those under age 45 (*Centers for Disease Control and Prevention*, 2009).

#### Impact for primary care

Of the 354 million patient visits per year for acute care in the United States only 42% are seen by primary care providers: 28% are seen in the emergency room and 20% are seen by specialists (*Weinick*, 2010).

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Visits to primary care clinicians for low back pain are equally split between chiropractors and allopathic clinicians, with low back pain is the fifth most common reason for an office visit to all clinicians (*Deyo*, 2006). The majority of these visits are not because of pain but rather due to the disability associated with the low back symptoms (*Ferreira*, 2010).

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# **Scope and Target Population**

Adult patients age 18 and over in primary care who have symptoms of low back pain or radiculopathy. The focus is on the acute (pain for up to 7 weeks) and subacute (pain for between 7 and 12 weeks) phases of low back pain. It includes the ongoing management, including indications for spine specialist referral within the first twelve weeks of onset.

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## **Aims**

- 1. Improve the evaluation and reevaluation of patients 18 years and older with acute and subacute low back pain diagnosis. (Annotations #2a, 2b)
- 2. Reduce or eliminate imaging for non-specific low back pain diagnosis in patients 18 years and older in the absence of "red flag" indicators. (*Annotations #11, 16, 17, 18*)
- 3. Delay imaging in patients with radicular pattern pain until after six weeks to allow for resolution that usually occurs within this period. (*Annotation #31*)
- 4. Increase the use of a core treatment plan as first-line treatment. This includes activity, heat, education, exercise and analgesics for patients 18 years and older with low back pain diagnosis. (Annotations #11, 16, 17, 18, 31)
- 5. Limit the use of opioids to the appropriate management of acute or subacute low back pain. (*Annotations #11, 16, 17, 18*)
- 6. Increase the utilization of validated pain and function scales to help differentiate treatment approaches in order to improve the patients ability to function. (Annotations #2a, 2b, 9)
- 7. Increase the use of collaborative decision-making to allow patients to make more informed decisions about their care. Focus on shared decisions related to imaging, interventions and surgery for radicular pain diagnosis. (*Annotations #34, 43*)

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# **Clinical Highlights**

- Low back pain assessment should include a subjective pain rating, functional status, patient history including notation of presence or absence of "red flags," psychosocial indicators, assessment of prior treatment and response, employment status, and clinician's objective assessment. (Annotations #2a, 2b; Aims #1, 6)
- Reduce or eliminate imaging unless "red flag" indicators exist. (Annotation #11; Aims #2, 3)
- A conservative approach should be first-line treatment. Emphasize patient education and a core treatment plan, that includes encouraging activity, use of heat, no imaging, rare use of opioids, anti-inflammatory and analgesic over-the-counter medications and return to work assessment. (Annotation #11; Aims #4, 5)
- Patients with acute or subacute low back pain should be advised to stay active and continue ordinary daily activity as tolerated. (Annotations #11, 16, 17, 18; Aim #4)

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# **Related ICSI Scientific Documents**

#### Guidelines

- Major Depression in Adults in Primary Care
- Assessment and Management of Chronic Pain

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## **Definitions**

For the purpose of this document, these terms are defined as follows:

**Acute Low Back Pain** – Low back pain present for up to six weeks. The *early acute phase* is defined as less than two weeks and the *late acute phase* is defined as two to six weeks secondary to the potential for delayed-recovery or risk phases for the development of chronic low back pain. Low back pain can occur on a recurring basis. If there has been complete recovery between episodes it is considered acute recurrent.

Chronic Low Back Pain – Low back pain more than 12 weeks in duration. Chronic low back pain is frequently experienced as chronic symptoms that are significant enough to impact function or quality of life. It also is cyclical with intermittent exacerbations. These exacerbations are acute overlying chronic symptoms. For the purposes of this document these episodes are considered exacerbations of chronic low back pain and not acute episodes.

**Cognitive Behavior Therapy** – A psychotherapeutic approach, a talking therapy, that aims to solve problems concerning dysfunctional emotions, behaviors and cognitions through a goal-oriented, systematic procedure.

**Conservative Care** – Non-surgical treatment measures such as exercise, physical therapy, heat therapy and spinal manipulation therapy.

**Delayed-Recovery** – An increase in the time to return to normal activities as compared to the recovery expected from the natural history of radicular or non-specific low back pain.

**Delayed-Recovery Assessment or Disability/Chronic Pain Risk Assessment** – Identification of risk factors that increase the likelihood of chronic low back pain or disability. These factors frequently include "yellow flags" or psychosocial risk factors. The assessment also may include workplace or administrative factors.

**Fear-Avoidance Belief** – The belief that pain is harmful, resulting in fear of movement or re-injury and thus pain-avoidance behavior, such as guarding.

**Functional Restoration** – A specific vigorous, individualized psychosocial and physical reconditioning program supervised by a multidisciplinary team. The purpose is to enhance job performance skills and improve strength, endurance, flexibility, and cardiovascular fitness in injured workers. It is also called physical conditioning, work hardening or work condition.

**Medical Spine Specialist** – Professional who provides non-surgical evaluation and treatment of low back pain utilizing evidence-based treatments.

**Onset of Pain** – The time frames from onset of low back symptoms. The individual being evaluated may be seen for the first time in either the acute, subacute or chronic stage of low back pain. Evaluation and treatment on the first visit should adjust to the stage of back pain.

Oswestry Disability Questionnaire – Used to measure a patient's permanent functional disability. It is designed to give information about how a patient's back pain affects his or her ability to manage in everyday life.

**Radiculopathy** – Dysfunction of a nerve root often caused by compression. It is associated with pain, sensory impairment, weakness, or diminished deep tendon reflexes in a nerve root distribution.

**Red Flags** – Clinical features observed in the history taking and physical examination that could indicate a serious spinal pathology and require further investigation. Examples are age over 50 years, unexplained weight loss, previous history of cancer, no improvement in low back pain after a month, recent history of trauma and prolonged use of corticosteroid.

**Spinal Manipulative Therapy** – The generic term commonly given to a group of manually applied therapeutic interventions. These interventions are usually applied with the aim of inducing intervertebral movement by directing forces to vertebrae, and include spinal manipulation and mobilization.

**Subacute Low Back Pain** – Low back pain with duration of greater than six weeks after injury, but no longer than 12 weeks after onset of symptoms.

**Visual Analogue Scale (VAS)** – A scale consisting of a 10 cm line with two end-points representing "no pain" and "pain as bad as it could possibly be." Patients are asked to rate their pain by placing a mark on the line corresponding to their current level of pain. The distance along the line from the "no pain" marker is then measured with a ruler, giving a pain score out of 10.

**Yellow Flags** – Indicators of psychosocial, workplace and other factors that increase the risk of developing persistent low back pain.

**Worksite Assessment** – Visits of an occupational therapist or physiotherapist to a worker's workplace to obtain an overview and determine the availability of suitable duties.

# **Algorithm Annotations**

# **Core Treatment of Non-Specific Low Back Pain Algorithm Annotations**

#### 2a. Initial Evaluation and Data Set

#### **Recommendation:**

• Imaging is not recommended for non-specific low back pain (*strong recommendation*, moderate quality evidence) (Chou 2011; French 2010; Chou 2009b)

Given that low back pain is overall a benign condition, the first task of the evaluation is to identify and address potential red flags that would require further investigation. The second recommended task is to address the potential for radiculopathy with neurologic deficit. These first two groups encompass approximately 10 to 15% of all low back pain. The majority 85 to 90% is non-specific low back pain. For all low back pain, but particularly those with non-specific low back pain, it is important to identify pain intensity and impaired function. The initial exam should document evidence that would suggest the presence or absence of findings that would influence medical decision-making (neurologic deficits, muscle weakness, mental status affecting recovery, comorbid conditions) as well as establish a baseline for future comparisons.

Two tools that have been identified for evaluating and documenting the perceived disability are the Visual Analog Scale and the Oswestry Disability Questionnaire. The Oswestry Disability Questionnaire is used to assess the patient's subjective rating of perceived disability and helps the clinician address the limitations of function. The Visual Analog Scale quantifies the patient's perception of pain and helps the provider address the pain and establishes a baseline for future reference. There are many other tools that are acceptable.

In addition, it is also important to consider potential risk factors for delayed-recovery. Identification of these risk factors is usually limited in the first two weeks or first two months of symptoms. As symptoms persist to six weeks, this becomes more important. The identifying and quantifying tools may need to be repeated during the course of care. If symptoms are not improving, consider that there may be a wrong diagnosis, a wrong treatment, the patient is not invested in care, or there are alternative non-spine-related factors inhibiting recovery.

#### History and exam

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

- Pain characteristics location, character, intensity, exacerbating and alleviating factors and duration
   – should be noted. Mechanical low back pain may radiate past the knee. This is not by definition
   radicular and must be correlated with other history and examination before it should be considered
   as such. If there is any activity associated with the onset it should also be noted.
- Sensory changes the specific distribution and character should be noted.
- Strength changes should be noted. A generalized sense of weakness should be differentiated from focal change such as the ability to dorsal or plantar flex the foot or great toe.
- Job and activity associations should be considered and noted.
- History and review of systems should be sufficient to address the primary red flags as identified in "Presence or absence of red flags documented" later in this section.

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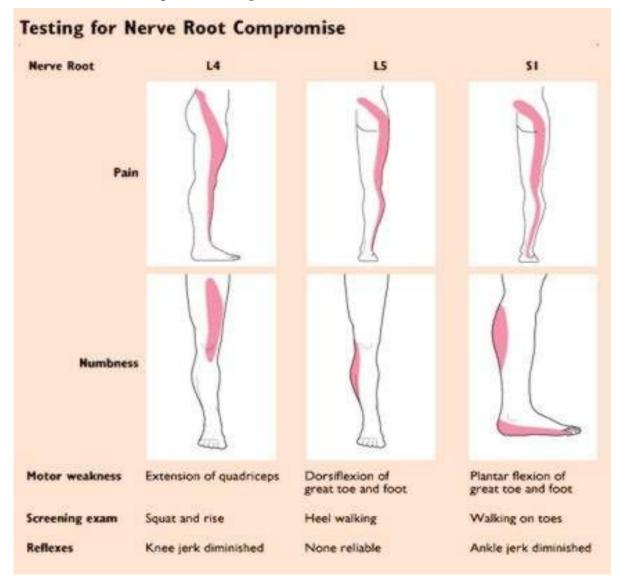
- Delayed-recovery risk factors should be considered on the initial visit. Depending on the time from onset of symptoms, this becomes more or less necessary. After even two weeks of severe pain or impairment in function the examiner should start a formal delayed-recovery assessment and consider intervention. See Annotation #17, "Late Acute Phase Treatment Considerations." Prior to two weeks, a focus on fear-avoidance beliefs should be a standard at any initial visit. The PHQ-2 and PHQ-9 are recommended as tools for screening for the risk of depression; see Appendix A, "Psychosocial Screening and Assessment Tools." The clinician may wish to consider using the PHQ-2 at the initial evaluation (*Kroenke*, 2003). Refer to the ICSI Major Depression in Adults in Primary Care guideline for more information.
- Ask the patient if he or she has any specific questions or expectations from this visit.

#### **Exam components**

- Observation of movements for asymmetry or inconsistency.
- Palpation for localized tenderness with percussion.
- Range of motion testing.
- Neurologic exam focusing on sensation, strength and reflexes with emphasis on the L4, L5 and S1
  nerve roots for primary dermatomal mapping and correlation of strength and reflexes and possible
  nerve root compromise.
  - See Table 1, "Nerve Root Compromise Testing" for more information.
- Neural tension test (straight leg raise, slump, prone knee bend, femoral stretch) performed bilaterally to assess the mechanics and physiology of the respected neural system (*Butler*, 2000).
  - A positive test should reproduce symptoms or associated symptoms. This information should be compared to the opposite side along with history and other objective findings. A positive test can provide only supporting evidence for a nerve root or discogenic pathology (*Supik*, 1994). The absence of a positive test is useful in ruling out discogenic source of pain.
- Additional examination including respiratory, gastrointestinal or genital urinary examination recommended as indicated by history.
  - Other examination of joints also is indicated by history and initial exam.
- Additional testing such as Waddell's signs to document non-physiologic exam.
  - See Appendix A, "Psychological Screening and Assessment Tools" for further information.
- Laboratory work dependent on history and examination suggestive of red flags or specific diagnosis associated with low back pain.
- IMAGING IS NOT RECOMMENDED FOR NON-SPECIFIC LOW BACK PAIN.

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**Table 1. Nerve Root Compromise Testing** 



Bigos S, Bowyer W, Braen G, et al. Acute low back problems in adults. Clinical Practice Guideline No. 14. AHCPR Publication No. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. December 1994.

#### Presence or absence of red flags documented

At each visit, evaluate for presence or absence of red flags and document findings. Red flags include the following:

- Risk factors for cancer including age 50 years old or older with a history of cancer, unexplained
  weight loss and failure to improve after four to six weeks of conservative low back pain therapy.
  If all three of these risk factors for cancer are absent, studies suggest that cancer can be ruled out
  with 100% sensitivity.
- Risk factors for possible spinal infection including intravenous drug use, immunosuppression, urinary infection, fever above 38°C (100.4°F) for greater than 48 hours, and history of tuberculosis or active tuberculosis.

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- Signs or symptoms of Cauda Equina Syndrome:
  - new onset of urinary incontinence
  - urinary retention (if no urinary retention, the likelihood of Cauda Equina Syndrome is less than 1 in 10,000)
  - saddle anesthesia, unilateral or bilateral sciatica, sensory and motor deficits, and abnormal straight leg raising
- Increased risk factors for fragility fracture such as these:
  - osteoporosis,
  - history of steroid use,
  - immunosuppression,
  - serious accident or injury (fall from heights, blunt trauma, motor vehicle accident) this does not include twisting or lifting injury unless other risk factors are present (e.g., history of osteoporosis),
  - clinical suspicion of ankylosing spondylitis, or
  - drug or alcohol abuse (increased incidence of osteomyelitis, trauma, fracture).
- Unrelenting night pain or pain at rest (increased incidence of clinically significant pathology).
- Consideration of other non-spine origins.

Refer to Annotation #28, "Consider Other Non-Spine Pain Origins," for further information.

#### **Function**

The Oswestry Disability Questionnaire is used to assess the patient's subjective rating of perceived disability related to his or her functional limitiations e.g., work status, difficulty caring for oneself. The higher the score the more perceived disability. Using this test at the initial visit helps the examiner understand the patient's perception of how his or her back pain is affecting his or her life. There are two ways that this test aids in the treatment of back pain. A higher score is indicative of the need for more intensive treatment such as spinal manipulative therapy and education to help the patient understand the low likelihood of disability related to back pain and understanding the low likelihood helps prevent the fear of disability from becoming a barrier to improvement. People with higher disability should be managed more aggressively with a heightened sense of urgency to avoid the negative aspect of prolonged pain and disability. The use of anticipatory guidance and early return to work with appropriate restrictions are important aspects. By tracking these scores, improvement can be documented and monitored.

Score	Perceived Disability Level
0-20	Minimum disability
20-40	Moderate disability
40-60	Severe disability
60-80	Crippling disability
80-100	Bedridden

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#### Pain

The Visual Analog Scale is a numerical pain scale (usually from 0 to 10, with 10 being the worst pain imaginable) that is used to understand the patients perception of their pain severity at it's worst and at the current time. It is also used to make decisions regarding treatment needs and to monitor improvement. Patients with a high pain scale need to understand what is being done to improve their pain, including use of manual therapy, medications, exercise and activity restrictions. The management of the patient's pain is an important part of each visit and should be a part of the care plan for recovery. A pain drawing is also recommended to facilitate pain evaluation. Compare the pain diagram to your exam and note consistencies or inconsistencies. Use it to monitor patterns and types of pain as well as to demonstrate change and improvement.

The Roland-Morris Disability Questionnaire is another tool available for pain assessment. See Appendix B.

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#### 2b. Reevaluation

Reevaluation of low back pain should include the following:

- Pain reassessed with a repeat Visual Analog Scale and Oswestry Disability Questionnaire
- Sensory changes
- Strength changes
- Job and activity associations considered and noted
- · Presence or absence of red flags and psychosocial indicators confirmed
- After two weeks of severe pain or impairment in function, the examiner should start a formal delayed-recovery assessment and consider intervention. See Annotation #17, "Late Acute Phase Treatment Considerations."

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# 6. Pain Consistent With Radiculopathy by History and Exam?

Pain radiating past the knee does not constitute radiculopathy. Radiculopathy is defined as pain which is dermatomal and it may or may not be accompanied by sensory or strength deficit or change in reflex. Diffuse or not organic sensory or strength changes are not considered radicular and if noted should be treated as non-specific low back pain.

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# 9. Severe Pain or Limited Function as Indicated on Oswestry Disability Questionnaire or Visual Analog Scale?

#### **Oswestry Disability Questionnaire**

The Oswestry Disability Questionnaire is used to assess the patient's subjective perception of his or her disability. The higher the score the more perceived disability. Using this test at the initial visit helps the examiner understand the patient's perception of how his or her back pain is affecting his or her life. A higher score is indicative of the need for more intensive treatment such as spinal manipulative therapy and education to help the patient understand the low likelihood of disability related to back pain. Understanding the low likelihood helps prevent the fear of disability from beginning a barrier to improvement.

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Score	Perceived Disability Level
0-20	Minimum disability
20-40	Moderate disability
40-60	Severe disability
60-80	Crippling disability
80-100	Bedridden

#### **Visual Analog Scale**

Patients with a high pain scale need to understand what is being done to improve their pain including use of spinal manipulative therapy, medications, exercise and activity restrictions. The scale ranges from 0 to 10, with 10 being the worst pain imaginable.

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#### 10. Limited Intervention and Maximized Prevention

Those individuals who have minimal limitation in function and/or minimal pain typically need education and reassurance and in general have better outcomes. For this reason, the core treatment plan is recommended in the context that intensive treatment is not necessary in this group and may in fact impair recovery. Follow-up typically is not necessary. See Annotation #11, "Core Treatment Plan."

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#### 11. Core Treatment Plan

#### **Recommendations:**

- Clinicians should educate patients as an adjunct to other treatment. No standardized form of education is suggested (*strong recommendation*, *moderate quality evidence*) (*Engers*, 2008; *Heymans*, 2004).
- Non-steroidal anti-inflammatory drugs may be used for short-term pain relief in patients with acute and subacute low back pain (*weak recommendation, moderate quality evidence*) (*Hancock, 2009; Roelfs, 2008; Yackhno 2006*).
- Muscle relaxants may be used as an option in treating acute low back pain; however, possible side effects should be considered (*weak recommendation, moderate quality evidence*) (*Malanga*, 2009 Pareeck, 2009; Ralph, 2008; Bernstein, 2009; Toth, 2004; vanTulder, 2003).
- Rare use of opioids may be considered for those patients with severe disabling pain not controlled with acetaminophen and NSAIDs, at a minimum dose, for a limited period of time (strong recommendation, low quality evidence) (Cifuentes, 2010; Volinn, 2009; Franklin, 2008; Chou, 2007a; Chou, 2007c; Rhee, 2007; Webster, 2007; Perrot, 2006; Palangio, 2001).
- Heat should be used for pain relief (strong recommendation, moderate quality evidence) (French, 2006).
- The use of cold therapy is not recommended (weak recommendation, low quality evidence) (French, 2006).

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- 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 (strong recommendation, moderate quality evidence) (Dahm, 2010).
- Exercise is recommended to reduce the recurrence of low back pain, however, no specific exercise is preferred (*strong recommendation, moderate quality evidence*) (*Choi*, 2010).
- Bed rest is not recommended (strong recommendation, moderate quality evidence) (Dahm, 2010).
- Clinicians should not prescribe or recommend traction for the treatment of acute low back pain (*weak recommendation*, *low quality evidence*) (*Clarke*, 2007).
- Imaging is not recommended for non-specific low back pain (*strong recommendation*, *moderate quality evidence*) (*Chou*, 2011; *French*, 2010; *Chou*, 2009b).

Patients are interested in being included in decision-making options including pain relief. Questions frequently asked include concern that the pain is severe so there must be something seriously wrong. Imaging is frequently requested to "find out what is causing the pain." They need reassurance that the pain does not represent harm and that activity is okay. They frequently need information on when they can return to work. Finally, many are interested in how to prevent future episodes.

The core treatment plan addresses the need for patient education, reassurance and expectations. Patient satisfaction is dependent on a clear diagnosis with information and instructions on how to handle their low back pain. A care plan should include the following:

- Answers to questions addressed by the patient.
  - In general this should include discussion of causation and the natural history of low back pain. It may need to include reasons for not ordering tests such as laboratory or imaging.
- Instructions on pain and activity management.
  - Include positional and exercise components as well as work recommendations or limitations.
- Instructions on treatment recommendations including medications and/or therapy recommendations.
- Follow-up and contact information in response to desire for further reassurance or education, and descriptions of specific warning signs, which may require earlier evaluation.
  - Pain doesn't seem to be getting better after two to three weeks
  - Pain traveling down the leg below the knee
  - Leg, foot, groin or rectal area feels numb
  - Unexplained fever, nausea/vomiting, stomach aches, weakness or sweating
  - Loss of control of urine or stool
  - Pain is so intense you can't move around or get comfortable
  - Redness or swelling on the back or spine

Provide patients with brochures and information that place a greater emphasis on reducing fear and anxiety and promote active self-management and incorporate the following components of care. See Appendix C,"Patient Brochure Example."

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#### Reassure

There is a good prognosis for low back pain. The majority of patients experience significant improvements in two to four weeks (*Atlas*, 2001). Most patients who seek attention for their back pain will improve within two weeks and most experience significant improvement within four weeks (*Hayden*, 2010; *Kent*, 2005; *Atlas*, 2001).

Approximately two-thirds of the people who recover from a first episode of acute low back symptoms will have another episode within 12 months. Unless the back symptoms are very different from the first episode or the patient has a new medical condition, expect improvement to be similar for each episode (*Hestbaek*, 2003; *Pengel*, 2003).

All patients recovering from back pain should understand that episodes of back pain may recur but can be handled similarly to the one from which they are recovering.

#### **Educate**

Clinicians in clinic systems are encouraged to provide primary education through other community education institutions/businesses to develop and make available patient education materials concerning back pain prevention and care of the healthy back. Emphasis should be on patient responsibility, workplace ergonomics, and home self-care treatment of acute low back pain. Employer groups should also make available reasonable accommodations for modified duties or activities to allow early return to work and minimize the risk of prolonged disability. Education is recommended for frontline supervisors in occupational strategies to facilitate an early return to work and to prevent prolonged disabilities. Identify and manage stressors.

Patient educational materials should emphasize these points:

- Back pain is common, and usually improves quickly.
- Patients should actively participate in, and be responsible for, their back rehabilitation program.
- Patients should try to remain active, and resume normal light duty activities as soon as possible.
- A regular fitness program and a healthy lifestyle.

#### Acetaminophen and non-steroidal anti-inflammatory medication

All medications have potential benefits and risks that patients should be aware of. Short-term use of medications (less than two weeks) may reduce some of the risks.

Use over-the-counter short-term acetaminophen or non-steroidal anti-inflammatory (NSAID) drugs to help ease the pain and/or inflammation in the lower back. Patients need to be aware that all NSAIDs have a risk of gastritis and gastrointestinal bleed, and possible cardiovascular implications. Acetaminophen has the risk of serious liver disease.

#### Muscle relaxants

Muscle relaxants may be useful for short-term relief of acute low back pain. The use of muscle relaxants is an option that needs to be weighed against the possible side effects and contraindications.

#### Rare use of opioids

Opioids frequently are prescribed for acute and subacute low back pain, despite low quality supporting evidence. The evidence of effectiveness of opioids on acute low back pain is inconclusive (*Chou*, 2007). No randomized control trials have shown opioids to improve function (*Sanders*, 2005). There is also an overriding national public health concern regarding widespread abuse of prescription pain medications.

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Our consensus opinion is that opioids are rarely indicated. However, the judicious use of opioids for severe acute and subacute low back pain, for limited periods of time (usually less than one to two weeks) may be considered. Clinicians may consider using low potency opioids, using the lowest daily dose possible. Always assess risk before ordering opioids. Opioids should only be used as one part of a comprehensive care plan for the patient with acute and subacute low back pain.

#### Heat

Apply heat as preferred on the sore area for a short duration in a position of comfort to assist with pain management. Cold therapy is not recommended.

#### Encourage activity; bed rest is not recommended

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 get back into action. Participate in activity that does not worsen symptoms.

Advise to stay active and to continue ordinary activity as normally as tolerated to give faster return to work, less chronic disability and fewer recurrent problems.

Patients with acute low back pain may experience small benefits in pain relief and functional benefits from advice to stay active. Patients should also be provided information about effective self-care options.

Exercise over no intervention is useful for reducing the rate of low back pain recurrence.

Bed rest is not recommended. A gradual return to normal activities is more effective and leads to more rapid improvement with less chronic disability.

#### Address fear-avoidance beliefs (fear of activity)

The fear that activity will increase the pain is common in acute low back pain sufferers. In most people this will recede as the individual finds that he or she can maintain at least some level of activity. A significant percentage of the population suffers from persistent or dysfunctional fear avoidance beliefs. Fear-avoidance beliefs can be defined as a dysfunctional interpretation that physical or social activities will worsen the pain and/or cause harm. Individuals with these beliefs may be identified early in the course of their low back pain episode as those who state these fears about continued activity. They frequently believe that complete avoidance of activity or even bed rest is necessary to heal. Individuals who demonstrate fear-avoidance beliefs may need closer follow-up and education on the natural history and typically benign course of low back pain. They should be informed of the potential harm of no activity and the dangers of deconditioning. They should be urged to return to modified work. See Appendix D, "Fear-Avoidance Beliefs Questionnaire," for more information.

Just as a percentage of the population has elevated fear-avoidance beliefs it is true of clinicians at various levels (*Coudeyre*, 2006; *Linton*, 2003). If the clinician has these beliefs, he or she may transmit them to the patient and may increase the likelihood of delayed-recovery. This can trigger iatrogenic disability. It is important for the clinician to have confidence in the core treatment recommendations. The placebo effect of clear, confident and consistent recommendations and education can influence the outcome positively just as clinician expression of fear-avoidance beliefs can play a part in effecting a poor outcome (*Gollub*, 2011).

#### Return-to-work assessment

Educate patients experiencing an episode of acute back pain that their pain is likely to improve and that a large majority of patients 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. Working despite some residual discomfort poses no threat and will not harm them (*Gatchel*, 2003; Von Korff, 1994). Even though this is not a workers compensation guideline,

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if there are issues with the employer, it may be necessary to contact the employer to provide guidance on safe activities or restrictions.

The return to work and resumption of normal 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 deconditioning disability. 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.

#### No imaging

The use of imaging including computed tomography (CT), magnetic resonance imaging (MRI) and x-ray is not recommended for non-specific low back pain.

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#### 12. Reassess as Needed

Instruct the patient to return for the following reasons:

- Pain that doesn't seem to be getting better after two to three weeks
- Pain 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 you can't move around or get comfortable
- Redness or swelling on the back or spine
- Desire for further reassurance or education

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# 16. Early Acute Phase Treatment Considerations

#### **Recommendations:**

Recommenations in this phase include those found in Annotation #11, "Core Treatment Plan," in addition to the following:

- Spinal manipulative therapy should be considered in the early intervention of low back pain (strong recommendation, moderate quality evidence) (Dagenais, 2010; Walker, 2010; Juini, 2009; Assendelft, 2008; Santilli, 2006).
- At this point evidence is not sufficient to strongly recommend the clinical prediction rule. However, studies are currently underway which may add further support. Therefore, we suggest consideration of the clinical prediction rule in the category of early low back pain patients (weak recommendation, low quality evidence) (Kent, 2010; Brennan, 2006; Fritz, 2005; Childs, 2004).

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For those patients who are seen within the first two weeks from onset of symptoms and have severe pain or physical impairment, the following approaches are recommended:

#### **Core Treatment Plan**

Refer to Annotation #11, "Core Treatment Plan," for more information.

#### **Consider Spinal Manipulative Therapy: Use Clinical Prediction Rule**

The clinical prediction rule is used to identify a subgroup of patients by several criteria (see Table 2, "Clinical Prediction Rule"). The rule which projects successful treatment of low back pain with spinal manipulative therapy at greater than 90%. Although much work has been done related to the clinical prediction rule (*Fritz*, 2007; *Fritz*, 2005; *Childs*, 2004; *Flynn*, 2002), at this point, evidence is not sufficient to strongly recommend it. However, studies currently underway may add further support. Therefore, we suggest consideration of this rule in this category of early low back pain patients.

#### **Table 2. Clinical Prediction Rule**

Patients with four or more of the following criteria have a greater likelihood of success	
with manipulation:	

Durations of symptoms < 16 days

At least one hip with less than 35 degrees of medial (internal) rotations

Lumbar hypomobility

No symptoms distal to the knee

Fear-Avoidance Beliefs Questionnaire work subscale score < 19. (See Appendix D)

#### Advice on Activity/Exercise

Shaw, et al. (2009), as well as the Flags Think Tank Group (*Kendall*, 2009), encourage a phased approach to risk intervention, particularly for those who have significantly curtailed their normal activities including work. For those off of work within the first two weeks of symptoms, working with the individual and his or her employer to find appropriate accommodations can limit future risk (*Franche*, 2005). 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.

#### No Delayed-Recovery Risk Assessment

Delayed-recovery risk assessment is not typically productive in the first two weeks from onset of symptoms.

#### Recheck in One to Two Weeks

Patients should be encouraged to follow up with their health care provider in one to two weeks. Although there is limited evidence to support this, the work group concludes that the benefits of reinforcing education and activity for patients who are improving outweigh the risk and potential costs. For patients who are not improving, the follow up visit will serve as a reevaluation and may help the clinician's decision-making to redirect the plan of care. See Annotation #2b, "Reevaluation," for more information.

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#### 17. Late Acute Phase Treatment Considerations

#### **Recommendation:**

Recommenations in this phase include those found in Annotation #11, "Core Treatment Plan," in addition to the following:

• Delayed-recovery assessment is not fully developed; however, much progress has been made and it is recommended that the clinician use one or more approaches to identify a patient who is at risk and intervene with specific interventions (*weak recommendation*, *low quality evidence*) (*Hayden*, 2010; *Hilfiker*, 2007; *Steenstra*, 2005; *Heymans*, 2004; *Pincus*, 2002).

#### **Core Treatment Plan**

Incorporate core treatment plan into plan of care. See Annotation #11, "Core Treatment Plan," for more information.

If the patient presents with low back pain symptoms for two to six weeks of severe limits in function and/ or severe pain, add the following care to the core treatment plan.

#### **Focused Review of Treatment to Date**

Complete a focused review of treatment to date to determine successes and failures in treatment modalities thus far.

#### **Delayed-Recovery Assessment**

Because the majority of acute low back pain sufferers improve within the first two weeks from onset, it is difficult to identify before this time the 10-15% who will experience chronic pain or disability (*Kovacs*, 2005). The period from two to six weeks is a key time to assess for risk factors and if possible, to begin approaches to manage them. Though progress has been made over the last 20 years, this is still an imprecise process. Work has progressed on identifying stronger risk factors and the development of several tools, as well as linking risk factors with interventions (*Nicholas*, 2011). The following chart describes three approaches – structured self report, open questions and observation – that can be used to assess risk. Each approach can increase focus and in many situations trigger an intervention plan to address the risk early in the continuum of disability and pain.

In 2009 an international group, the Flags Think Tank, published "Tackling Musculoskeletal Problems." It identified subcategories of risk factors or "Flags." Yellow flags are individual factors, blue are work-place factors, and black are contextual factors that may include societal, family or other organizational problems. Key to this publication is the inclusion of suggestions on specific approaches that can be used to address the identified Flags.

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#### Who identifies what and how

	Information about the	Player most involved	Optimal evaluation method	Important obstacles to identify (alphabetical)	Management implications
<u> </u>	Person	Healthcare provider Clinicians of all types Occupational health professionals	Stepped approach combining information from more than one method, usually in the following sequence:  • Structured self-report  • Open questions  • Observation  (Note: questionnaires can be used but they are not sufficient by themselves)	Anxiety and depression Catastrophising Distress and low mood Dysfunctional beliefs and expectations about pain, work and healthcare Extreme symptom report Fear of movement Negative expectation of recovery Passive coping strategies Preoccupation with health Uncertainty (about what's happened, what's to be done, and what the future holds)	Yellow Flags indicate a need for reassurance and positive advice. They also point to the potential need for approaches using cognitive-behavioural principles.  This means cognitive and behavioural principles are integrated into healthcare and workplace management.  It does not mean cognitive-behavioural therapy (CBT) per se is required.  This can be combined with other types of treatment and management. Communication with workplace
<b> </b>	Workplace	Employer Especially line managers or supervisors Human Resources, Personnel departments or occupational health professionals in larger companies	Stepped approach combining information from more than one method, usually in the following sequence:  • Observation  • Open questions  • Structured self-report  (Note: questionnaires can be used but they are not sufficient by themselves)	Lack of job accommodations/modified work Fear of re-injury High physical job demand Lack of communication with employees Low expectation of resuming work Low job satisfaction Low social support or social dysfunction in workplace Perception of high job demand/'stress'	Blue Flags indicate potential need for enhanced workplace management, integrated with healthcare.  Note  This means combining work-focused healthcare with an accommodating workplace.  Communication with employee, graded return to work, transitional work arrangements (temporary).  Communication with healthcare to discuss RTW plan/ person's needs.
-	Context	Case Managers  Employment Advisors  Social Workers  Significant others: spouse, family members, co-workers, etc	Combining information from both of the following methods:  • Open questions  • Observation	Disputes between key players (e.g. between employee and employer, or with healthcare). Financial and compensation problems. Process delays (e.g. due to mistakes, waiting lists, or claim acceptance). Responding to sensationalist media reports. Spouse, family member with negative expectations, fears or beliefs. Social isolation, social dysfunction. Unhelpful company policies/procedures	Black Flags indicate potential need to involve significant others and/or other professionals.  Influences within the person's social milieu (both private and professional) can sabotage progress.

Tackling Musculoskeletal Problems - Guidance about Psychosocial Flags for the Clinic and Workplace. December 2008

Individual risk factors with stronger predictive ability include the following:

- Fear-avoidance beliefs
- Catastrophizing
- Somatization
- Depressed mood
- Distress and anxiety
- Early disability or decreased function
- High initial pain levels
- Increased age
- Radiation of pain
- Poor general health status
- Non-organic signs

Another approach has been the development of tools to identify an individuals overall risk for chronic pain or disability. Tools such as the Back Disability Risk Questionnaire (BDRQ), Örebrö Musculoskeletal Pain Screening Questionnaire (ÖMPSQ) and the Keele STarT Back Screening Tool (KSBST) have been more recently been proposed. The SBST is a brief nine-question tool that ranks physical and psychosocial risk into high, medium or low risk of poor prognosis while the ÖMPSQ uses 25 questions. See Appendix E, "The Keele StarT Back Screening Tool and Scoring System," and Appendix F, "Örebrö Musculoskeletal Pain Screening Questionnaire (ÖMPSQ)," for further information (*Hockings*, 2008).

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Precise risk assessment is not fully developed, but much progress has been made. It is recommended that the clinician use one or more of the previously mentioned approaches to identify a patient who is at risk and to intervene with specific actions. Interventions start with the core treatment plan as previously described (see Annotation #11, "Core Treatment Plan"); it deals with fear avoidance and catastrophizing and the need to maintain activity to avoid deconditioning.

#### Focus on Activity/Function

Identify home or work activities that are problematic, and address any ergonomic or work issues that maintain daily function. An ergonomic evaluation or contacting the workplace may be necessary. Even in non-workers' compensation cases, an employer's lack of work accommodation may slow recovery if it keeps the worker from the job.

#### **Consider Referral to Medical Spine Specialist**

Choice of the trained professional will be determined by availability and preference of individual medical providers and organization systems. The patient and/or clinician should request a trained non-surgical spine specialist who demonstrates competency in providing therapies for patients with low back pain based on effective techniques supported by literature, as outlined in this guideline. These therapies include education, exercise programs and appropriate use of manipulative therapies (*Nyiendo*, 2001; *Nyiendo*, 2000). The specialist should also be conversant in risk assessment and intervention as well as the process of shared decision-making. See Annotation #18, "Subacute Phase Treatment Considerations," for more information.

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#### 18. Subacute Phase Treatment Considerations

#### **Recommendations:**

Recommenations in this phase include those found in Annotation #11, "Core Treatment Plan," in addition to the following:

- Delayed-recovery risk assessment is not fully developed; however, much progress has been made and it is recommended that the clinician use one or more approaches to identify a patient who is at risk and intervene with specific interventions (weak recommendation, low quality evidence) (Hayden, 2010; Hilfiker, 2007; Steenstra, 2005; Heymans, 2004; Pincus, 2002).
- Exercise is recommended in the treatment of subacute low back pain (strong recommendation, moderate quality evidence) (Schaafsma, 2010; Kool, 2007; Hayden, 2005; Wright, 2005).
- Spinal manipulative therapy should be considered in the early intervention of low back pain (strong recommendation, moderate quality evidence) (Dagenais, 2010; Walker, 2010; Juni, 2009; Assendelft, 2008; Santilli, 2006).
- Clinicians should consider cognitive behavioral therapy in the treatment of subacute low back pain (*weak recommendation, moderate quality evidence*) (*Hansen, 2010; Lamb, 2010; Karjalainen, 2003*).
- Acupuncture may be used as an adjunct treatment for subactue low back pain (*weak recommendation*, *low quality evidence*) (*Chou*, 2009a; *Furlan*, 2008; *Chou*, 2007b).

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#### **Core Treatment Plan**

Initiate or continue the core treatment plan. See Annotation #11, "Core Treatment Plan," for further information.

#### **Delayed-Recovery Assessment**

Refer to Annotation #17, "Late Acute Phase Treatment Considerations," for further information.

#### **Progressive Exercise Plan**

The use of a progressive exercise program in the treatment of subacute low back pain is supported. Progressive exercise is based on a number of variables that include but are not limited to increasing physical activity, education regarding pain and an exercise program that is graded with a de-emphasis on pain.

#### **Consider Referrals**

#### • Spinal manipulative therapy

Spinal manipulative therapy has been shown to be effective early in treatment when followed by appropriate active rehabilitation.

#### Cognitive behavioral therapy

There is evidence that cognitive behavioral programs improve function and decrease chronic pain in subacute low back pain cases (*Karjalainen*, 2003). A structured cognitive behavioral approach that addresses catastrophizing, passive coping, fear avoidance and depression, can lead to either decreased activity levels or over activity in some low back pain patients (*Hansen*, 2010). The goal is to increase activity levels without periods of over activity. The program addressed catastrophizing and fear avoidance as well as coping skills in six 1-1/2 hour sessions. A randomized control trial confirmed the benefit in reducing disability scores in a cost-effective manner (*Lamb*, 2010).

#### Work evaluation

In this period, a focused identification of risk factors should be performed and a structured intervention plan formulated. Intensive multidisciplinary rehabilitation programs (*Karjalainen*, 2003; *Hlobil*, 2007) are more successful for restoring function and reducing pain. It is less clear whether they facilitate earlier return to work. Effective communication and collaboration are key in this process.

#### Medical spine specialist

Choice of the trained professional who utilizes evidence-based treatment will be determined by availability and preference of individual medical providers and organization systems. The patient and/or physician should request a trained medical spine specialist who demonstrates competency in providing therapies for patients with low back pain based on effective techniques supported by literature, as outlined in this guideline. These therapies include education, exercise programs and appropriate use of manipulative therapies (*Nyiendo*, 2001; *Nyiendo*, 2000). The specialist should also be conversant in risk assessment and interventions as well as the process of shared decision-making.

Indications for referral include these:

- Failure to make improvement with core treatment plan (home self-care) after two weeks (*Shekelle*, 1994)
- Severe incapacitating and disabling back or leg pain
- Significant limitation of functional or job activities

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- Elevated delayed-recovery risk
- Situations in which collaborative or shared decision-making is appropriate, e.g., persistent neuromotor deficit after four to six weeks of the core treatment plan (this does not include minor sensory changes or reflex changes).

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#### 19. Chronic Low Back Pain

The treatment of chronic back pain falls out of this guideline. See ICSI Assessment and Management of Chronic Pain guideline for more information.

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# **Red Flags Algorithm Annotations**

# 20. Infection Suspected?

Uncommon but serious causes for back pain include infection. A spinal infection such as vertebral osteomyelitis or spinal epidural abscess can give chronic back pain with fever, an elevated white count and elevated erythrocyte sedimentation rate. Plain spinal films and magnetic resonance imaging (MRI) may be necessary for diagnosis. Tuberculosis of the spine is well known but uncommon (in the West) as a cause for back pain. Pyelonephritis causes back pain, which is localized to the affected side. Risk factors for infectious causes for back pain include immunocompromised status, diabetes, human immunodeficiency virus (HIV) infection, tuberculosis and intravenous drug abuse history. Clues to the diagnosis include fever and a gradual onset of symptoms as well as symptoms unrelated to mechanical movement.

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#### 21. Evaluate for Infection

Specific treatments exist for all bacterial causes for back pain. Consider blood work if infection is suspected. Consultation with a surgeon may be indicated for suspected bony infection (*Deyo*, 2001).

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# 22. Cancer Present or Suspected?

Recurrent metastatic cancer must be considered in all cases of back pain in cancer survivors. Cancers frequently metastatic to the spine include breast, lung, gut, prostate, renal and thyroid. Clues to the diagnosis include a gradual onset of symptoms and a history of cancer.

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#### 25. Evaluate for Fracture

#### **Recommendation:**

• Imaging may be considered when fracture is suspected (strong recommendation, moderate quality evidence) (Chou, 2011; French, 2010; Chou, 2009b).

Fracture of a vertebral body is an uncommon cause of back pain, which is seen in only a few settings. Fracturing a vertebra in an otherwise healthy person requires such as a fall from a height or a motor vehicle accident. Conversely, in a person whose bones are compromised due to steroid use or osteoporosis, minimal (or even unrecognized) trauma is sufficient to cause fracture and back pain. An x-ray is a diagnostic tool that can rule out fracture.

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# 27. Rule Out Cauda Equina

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 urgent surgical consultation.

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# 28. Consider Other Non-Spine Pain Origins

Two percent of low back pain is due to visceral disease including but not limited to the following:

- 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

(Goldman, 2011)

## **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 (*Pennick*, 2008; *Sabino*, 2008), and one study found that approximately 62% of pregnant women suffering from low back pain rated it as moderately severe (*Stapleton*, 2002). Despite the significance of this problem, only one third of pregnant women reported low back pain to their prenatal care providers (*Pennick*, 2008).

The typical course of low back pain during pregnancy is that it generally begins in the mid-late 2nd trimester and resolves during the postpartum period and, unfortunately, is likely to return in subsequent pregnancies (Sabino, 2008). Although most cases resolve in the postpartum period, although 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 non-pregnant 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).

According to a Cochrane review, effective treatment of pregnancy-related low back pain, as measured by pain reduction and back-pain-related sick leave, included strengthening exercises, sitting pelvic tilt exercises and water gymnastics (*Pennick*, 2008).

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# **Radicular Pain Algorithm Annotations**

# 31. No Imaging First Six Weeks with Radicular Pain; Use Core Treatment Plan

#### Recommendation:

• Imaging (computerized tomography, magnetic resonance imaging or x-ray) is not recommended for non-specific low back pain (*strong recommendation, moderate quality evidence*) (Chou, 2011; French, 2010; Chou, 2009b).

Most patients with radiculopathy supported by exam findings consistent with history will recover within several weeks of onset. The majority of disc herniations regress or reabsorb by eight weeks from onset (Autio, 2006; Henmi, 2002; Bozzao, 1992). In the absence of red flags or progressive neurologic deficit there is no evidence that the delaying surgery worsens outcomes (Chou, 2011). The use of the core treatment plan is recommended. Refer to Annotation #11, "Core Treatment Plan."

With this in mind, in the face of radiculopathy there is no benefit and there is possible harm (*Chou*, 2011) in obtaining a magnetic resonance imaging prior to six weeks. The exception to this is a progressing neurologic deficit or persistent disabling pain.

If the patient has demonstrable leg weakness that is disabling or is worsening, further evaluation with imaging and consultation with a spine specialist would also be indicated.

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# 34. Additional Reevaluation as Needed; Use Shared Decision-Making Tools in Discussing Options of Imaging, Epidurals or Continuing a Core Treatment Plan

#### **Recommendations:**

- Imaging may be considered to rule out underlying pathology or for those who are considering surgery (*strong recommendation, moderate quality evidence*) (*Chou, 2011; French, 2010; Chou, 2009b*).
- Epidural steroid injections may be used for acute low back pain with a radicular component to assist with short-term pain relief (*weak recommendation, moderate quality evidence*) (*Manchikanti, 2010; Laiq, 2009; Parr, 2009; Sayegh, 2009; Staal, 2008*).

For selection of type of imaging please see Appendix G, "Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Guidelines" and Appendix H, "Upright and Positioned Imaging."

When further evaluation options such as imaging and epidurals can be considered, a clinician/surgeon-centric approach to the recommendation of and decision about having these done, should be discussed collaboratively through shared decision-making. Shared decision-making is the process by which a health care clinician communicates to the patient personalized information about available treatment options, their outcomes and potential benefits and harms. The patient communicates his or her values and the relative importance he or she places on benefits and harms. With this sharing of information the clinician and patient have a better basis for communication and the result is a high quality decision with better patient investment. There are now a variety of resources (see Appendix I, "Shared Decision-Making Tools and Resources," for more information) that can help facilitate a high-quality decision matched to patient preferences. The expected benefit is that of higher patient satisfaction with the quality of the decision made.

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#### **Epidural Steroid Injections**

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 non-surgical 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-term 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. There is insufficient evidence to recommend one approach over another (*McLain*, 2005; *Cannon*, 2000). The different approaches allow the treatment to be tailored to the needs of the individual.

Procedural morbidity is extremely low and also varies with each approach (*McLain*, 2005; Cannon, 2000). With interlaminar injections there is a potential risk of intrathecal injection. If this occurs a small fraction (<1%) of patients may develop a post-procedural dural leak headache. These nearly always resolve spontaneously with conservative treatment within 48 hours. In the past there was also concern about arachnoiditis with this approach. It is believed that this occurred due to preservatives formerly used in the steroid and saline preparations. Preservative-free preparations should be used to avoid this potential complication. With the transforaminal approach, patients may report worsening of radicular symptoms for several days after the injection. This is believed to occur from either the volume of injectate compressing an already inflamed nerve or a reaction to the steroid. There is no risk of post dural puncture headache with this approach. There is, however, an extremely small but very real risk of spinal cord infarction leading to permanent spinal cord injury. With each of the three approaches – caudal, transforaminal and interlaminar – there is the typical risk of bleeding, infection, and nerve damage. Again, the risk is much less one in ten thousand. Patients should be informed of the possible risks that could occur using each of the three approaches (*Somayaji*, 2005; *Tiso*, 2004; *Botwin*, 2000).

#### Patient selection for epidurals

- 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 required either magnetic resonance imaging or computerized tomography to rule out other causes of pain (e.g., infection, cancer).
- Steroid injections should not be given for two weeks following the flu vaccine. Also wait for one month
  after a steroid injection to receive the flu vaccine. Therapeutic corticosteroid injections may temporarily
  suppress the body's immune response and may compromise the ability to develop the expected immune
  protection from a flu vaccine. This is based on recommendations from the Centers for Disease Control
  and the International Spine Intervention Society.
- Patients should have no contraindications to an injection, including these:
  - No signs or symptoms of active infection either systemically or locally.

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- No history of bleeding disorders or current use of anticoagulants such as warfarin or clopidogrel.
  - Allow the patient to "drift" to the lowest effective international normalized ratio (INR), prior to the procedure. Consult with the individual performing the procedure for appropriate anticoagulation guidelines.
- Patients with non-anaphylactic 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.

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#### 40. Reevaluate Biomechanics and Treatment

Continue to stress a progressive exercise program, appropriate body mechanics and general healthy lifestyle (see Annotation #11, "Core Treatment Plan," for more information).

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# 41. Recurring Symptoms?

#### No Recurrence

If there is no recurrence of symptoms, advise patient to continue the core treatment plan with emphasis on exercise as a preventive measure.

#### **Less Than 12 Weeks Since Onset of Symptoms**

Individuals with more severe functionally limiting recurrence may require additional diagnostic and therapeutic measures including referral to a specialist. See Annotation #43, "Consider Referral to Spine Specialist; Initiate Formal Shared Decision-Making," for more information.

#### **Greater Than 12 Weeks Since Onset of Symptoms**

Recurrent low back pain persisting beyond three months falls outside of this guideline. Please see ICSI Assessment and Management of Chronic Pain guideline for more information.

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# 43. Consider Referral to Spine Specialist; Initiate Formal Shared Decision-Making

#### **Shared Decision-Making**

Though it occurs in a small percentage of those with acute or subacute low back pain the decision to have low back surgery is key to the patient's quality of life. Though surgery for radiculopathy secondary to disc herniation is generally successful, the current clinician/surgeon-centric approach to the recommendation of and decision to have surgery is currently under intense discussion. The Dartmouth Atlas (*Brownlee*, 2011) shows large variation in surgical rates. As already stated, patients expect and want to be more involved in decisions about their health care. While clinicians routinely attempt to include patient input in decisions, it has been suggested that in some decisions there is a mismatch between the patient's preferences and the clinician's understanding of the preferences (*Lee*, 2010). There is also evidence that suggests there is a mismatch between primary care and specialist expectations. There is now a variety of resources that can help facilitate a high-quality decision. The expected benefit is that of higher patient satisfaction with the quality of the decision made. See Appendix I, "Shared Decision-Making Tools and Resources," for more information.

Shared decision-making has been defined as an integrative process between patient and clinician that engages the patient in decision-making, provides the patient with information about alternatives, and facilitates the incorporation of patient preferences and values into the medical plan. Shared decision-making is the process by which a health care clinician communicates to the patient personalized information about available treatment options, their outcomes and potential benefits and harms. The patient communicates his or her values and the relative importance he or she places on benefits and harms. With this sharing of information, the clinician and patient have a better basis for communication and the result is a high-quality decision with better patient investment.

Shared decision-making is a process still being explored for low back pain (*Légaré*, 2010). Many communities have limited resources for referral, and tools for the primary care clinician may not be readily available. For this reason the committee recommends this integrative and collaborative approach with the understanding that the concept is still in development and does not have a sufficient evidence base for a strong recommendation. Please see Appendix J, "ICSI Shared Decision-Making Model," for further information. Referral to a medical spine specialist for discussion about potential surgery is suggested.

#### **Medical Spine Specialist**

The choice of a trained professional who utilizes evidence-based treatment will be determined by availability and preference of individual medical providers and organization systems. The patient and/or clinician should request a trained medical spine specialist who demonstrates competency in providing therapies for patients with low back pain based on effective techniques supported by literature, as outlined in this guideline. These therapies include education, exercise programs and appropriate use of manipulative therapies (*Nyiendo*, 2001; *Nyiendo*, 2000).

Indications for referral include these:

- Failure to make improvement with the core treatment plan after two weeks (Shekelle, 1994);
- Severe incapacitating and disabling back or leg pain
- Significant limitation of functional or job activities
- Elevated delayed-recovery risk

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Situations where collaborative or shared decision-making is appropriate, e.g., persistent neuromotor
deficit after four to six weeks of conservative treatment (this does not include minor sensory changes
or reflex changes).

Indications for specialty referral may include the following:

- Medical spine specialist
- Atypical chronic leg pain
- Chronic pain syndrome
- Ruling out inflammatory arthopathy
- Ruling out fibrositis/fibromyalgia
- Ruling out metabolic bone disease (e.g., osteoporosis)

Surgical spine specialist:

- Cauda Equina Syndrome
- Progressive or moderately severe neuromotor deficit (e.g., foot drop or functional muscle weakness such as hip flexion weakness or quadriceps weakness)
- Persistent neuromotor deficit after four to six weeks of conservative treatment (does not include minor sensory changes or reflex changes)
- Uncontrolled radicular pain with defined lesion on imaging

(Spitzer, 1987)

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# **Quality Improvement Support:**

# **Adult Acute and Subacute Low Back Pain**

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
  - Measurement Specifications
- Implementation Recommendations
- Resources
- Resources Table

# **Aims and Measures**

1. Improve the evaluation and reevaluation of patients 18 years and older with acute and subacute low back pain diagnosis. (Annotations #2a, 2b)

Measures for accomplishing this aim:

- a. Percentage of patients with a low back pain diagnosis who have all of the following at the initial visit with the clinician (*composite measure*):
  - Pain assessment using the Visual Analog Scale, pain diagram or other assessment tool
  - Functional status using the Oswestry Disability Questionnaire or other assessment tool
  - Patient history, including notation of presence or absence of "red flags"
  - Assessment of prior treatment and response
  - Job and activity association
  - Psychosocial screening that includes depression and chemical dependency screening
- b. Percentage of patients with low back pain diagnosis who have a reassessment at each follow-up visit that includes (composite measure):
  - Pain assessment using the Visual Analog Scale, pain diagram or other assessment tool
  - Functional assessment using the Oswestry Disability Questionnaire or other assessment tool
  - Clinician's objective assessment, and
  - Psychosocial screening that includes depression and chemical dependency screening
- 2. Reduce or eliminate imaging for non-specific low back pain diagnosis in patients 18 years and older in the absence of "red flag" indicators. (Annotations #11, 16, 17, 18)

Measures for accomplishing this aim:

- a. Percentage of patients with a diagnosis of non-specific back pain for whom the clinician ordered imaging studies during the six weeks after pain onset, in the absence of "red flags."
- b. Percentage of patients with non-specific back pain diagnosis who received inappropriate repeat imaging studies in the absence of "red flags" or progressive symptoms.
- 3. Delay imaging in patients with radicular pattern pain until after six weeks to allow for resolution that usually occurs within this period. (*Annotation #31*)

Measure for accomplishing this aim:

a. Percentage of patients with radicular pain for whom the clinician ordered imaging studies during the six weeks after pain onset.

4. Increase the use of a core treatment plan as first-line treatment. This includes activity, heat, education, exercise and analgesics for patients 18 years and older with low back pain diagnosis. (*Annotations #11*, 16, 17)

Measures for accomplishing this aim:

- a. Percentage of patients with medical record documentation that the clinician advised them to maintain or resume normal activities. (NCQA)
- b. Percentage of patients with medical record documentation that the clinician advised them against bed rest. (NCQA)
- c. Percentage of patients with low back pain diagnosis who received patient education regarding low back pain self-care and the importance of maintaining an active lifestyle.
- d. Percentage of patients with low back pain diagnosis who received recommendation to take an antiinflammatory or analgesic medication.
- 5. Limit the use of opioids to the appropriate management of acute low back pain. (*Annotations #11, 16, 17, 18*)

Measure for accomplishing this aim:

- a. Percentage of patients with low back pain diagnosis who are prescribed opiates.
- 6. Increase the utilization of validated pain and function scales to help differentiate treatment approaches in order to improve the patients ability to function. (Annotations #2a, 2b, 9)

Measures for accomplishing this aim:

- a. Percentage of patients with low back pain diagnosis who have their functional status assessed using the Oswestry Disability Questionnaire or other assessment tool.
- b. Percentage of patients with low back pain diagnosis who have their pain status assessed using the Visual Analog Scale, pain diagram or other assessment tool.
- 7. Increase the use of collaborative decision-making to allow patients to make more informed decisions about their care. Focus on shared decisions related to imaging, interventions and surgery for radicular pain diagnosis. (Annotations #34, 43)

Measures for accomplishing this aim:

- a. Percentage of patients with non-specific low back pain diagnosis who have had collaborative decision-making with regards to referral to a specialist.
- b. Percentage of patients with radicular pain diagnosis who have had collaborative decision-making with regards to imaging, intervention and/or surgery.

## **Measurement Specifications**

#### Measurement #1a

Percentage of patients with low back pain diagnosis who have all of the following at the initial visit with the clinician (composite measure):

- Pain assessment using the Visual Analog Scale, pain diagram or other assessment tool
- Functional status using the Oswestry Disability Questionnaire or other assessment tool
- Patient history, including notation of presence or absence of "red flags"
- Assessment of prior treatment and response
- Job and activity association
- Psychosocial screening that includes depression and chemical dependency screening

## **Population Definition**

Patients age 18 and over seen in primary care diagnosed with acute low back pain or radiculopathy.

#### **Data of Interest**

# of patients who have the six components completed at the initial visit

# of patients with acute low back pain diagnosis or radiculopathy

#### **Numerator/Denominator Definitions**

Numerator:

Number of patients who have following completed at the initial visit with the clinician: 1) pain assessment,\* 2) functional status,\*\*\* 3) patient history (including notation of presence or absence of "red flags"), 4) assessment of prior treatment and response, 5) job and activity association 6) psychosocial screening that includes depression and chemical dependency screening.

- \* Pain assessment can be done using the Visual Analog Scale, pain diagram or other assessment tool.
- \*\* Functional assessment can be done using the Oswestry Disability Questionnaire or other assessment tool

Denominator:

Number of patients with diagnosis of acute low back pain or radiculopathy.

#### Method/Source of Data Collection

Identify the number of patients with acute or subacute low back pain diagnosis or radiculopathy diagnosis seen in primary care. Out of that number, determine the number of patients who had the following components completed at the initial visit with the clinician:

- Pain assessment
- Functional status
- Patient history, including notation of presence or absence of "red flags"

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- Assessment of prior treatment and response
- Job and activity association
- Psychosocial screening that includes depression and chemical dependency screening

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is a process and composite measure. All six components need to be completed to include in the measurement. Improvement is noted as increase in the rate.

#### Measurement #1b

Percentage of patients with low back pain diagnosis who have a reassessment at each follow-up visit that includes (*composite measure*):

- Pain assessment using the Visual Analog Scale, pain diagram or other assessment tool
- Functional assessment using the Oswestry Disability Questionnaire or other assessment tool
- Clinician's objective assessment, and
- Psychosocial screening that includes depression and chemical dependency screening

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with acute or subacute low back pain or radiculopathy.

#### **Data of Interest**

# of patients who have the four components assessed at follow-up visit

# of patients with acute or subacute low back pain diagnosis or radiculopathy

#### **Numerator/Denominator Definitions**

Numerator:

Number of patients who have following assessed at follow visit with the clinician: 1) pain assessment\*, 2) functional assessment\*\*, 3) clinician's objective assessment, 4) psychosocial screening that includes depression and chemical dependency screening.

- \* Pain assessment can be done using the Visual Analog Scale, pain diagram or other assessment tool.
- \*\* Functional assessment can be done with the Oswestry Disability Questionnaire or other assessment tool.

Denominator:

Number of patients with diagnosis of acute low back pain or radiculopathy.

#### Method/Source of Data Collection

Identify the number of patients with acute or subacute low back pain diagnosis or radiculopathy diagnosis seen in primary care. Out of that number, determine the number of patients who had the following components completed at the initial visit with the clinician:

- Pain assessment
- Functional assessment
- · Clinician's objective assessment, and
- Psychosocial screening

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is a process and composite measure. All four components need to be completed to include in the measurement. Improvement is noted as increase in the rate.

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#### Measurement #2a

Percentage of patients with a diagnosis of non-specific back pain for whom the clinician ordered imaging studies during the six weeks after pain onset, in the absence of "red flags."

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with non-specific back pain diagnosis.

#### **Data of Interest**

# of patients for whom imaging studies were ordered during the six weeks after pain onset, in the absence of "red flags"

# of patients with non-specific back pain diagnosis

#### **Numerator/Denominator Definitions**

Numerator: Number of patients for whom the clinician ordered imaging studies during the six weeks after

pain onset, in the absence of "red flags."

Denominator: Number of patients with non-specific back pain diagnosis.

#### Method/Source of Data Collection

Identify the number of patients with non-specific back pain diagnosis seen in primary care. Out of that number, determine the number of patients who had imaging studies ordered during the six weeks after pain onset, in the absence of "red flags."

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is an outcome measure on overuse of diagnostic imaging. Improvement is noted as decrease in the rate.

#### Measurement #2b

Percentage of patients with non-specific back pain diagnosis who received inappropriate repeat imaging studies in the absence of "red flags" or progressive symptoms.

## **Population Definition**

Adult patients age 18 and over seen in primary care and diagnosed with non-specific back pain.

#### **Data of Interest**

# of patients who have repeat imaging in the abscence of "red flags" or progressive symptoms

# of patients with non-specific back pain

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who have repeat imaging studies in the absence of "red flags" or

progressive symptoms.

Denominator: Number of patients with diagnosis of non-specific back pain.

#### Method/Source of Data Collection

Identify the number of patients with non-specific back pain diagnosis seen in primary care. Out of that number, determine the number of patients who had repeat imaging in the absence of "red flags" or progressive symptoms.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is an outcome measure on overuse of diagnostic imaging. Improvement is noted as decrease in the rate.

#### Measurement #3a

Percentage of patients with radicular pain for whom the clinician ordered imaging studies during the six weeks after pain onset.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with radicular pain.

#### **Data of Interest**

# of patients for whom imaging studies were ordered during the six weeks after pain onset

# of patients with radicular pain diagnosis

#### **Numerator/Denominator Definitions**

Numerator: Number of patients for whom the clinician ordered imaging studies during the six weeks after

pain onset.

Denominator: Number of patients with radicular pain diagnosis.

#### Method/Source of Data Collection

Identify the number of patients with radicular pain diagnosis seen in primary care. Out of that number, determine the number of patients who had imaging studies ordered during the six weeks after pain onset.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is an outcome measure on overuse of diagnostic imaging. Improvement is noted as decrease in the rate.

#### Measurement #4a

Percentage of patients with medical record documentation that the clinician advised them to maintain or resume normal activities.

#### **Notes**

This is a process measure from Physician Measures Set by National Committee for Quality Assurance (NCQA) for 2011.

Full specifications for this measure can be obtained from NCQA at http://www.ncqa.org.

#### **Measurement #4b**

Percentage of patients with medical record documentation that the clinician advised them against bed rest.

#### **Notes**

This is a process measure from Physician Measures Set by National Committee for Quality Assurance (NCQA) for 2011.

Full specifications for this measure can be obtained from NCQA at http://www.ncqa.org.

#### Measurement #4c

Percentage of patients with low back pain diagnosis who received patient education regarding low back pain self-care and the importance of maintaining an active lifestyle.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with acute or subacute low back pain or radiculopathy.

#### **Data of Interest**

# of patients who received low back pain education

# of patients with acute or subacute low back pain diagnosis

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who received education on low back pain self-care and the importance of

maintaining an active lifestyle.

Denominator: Number of patients with diagnosis of acute or subacute low back pain or radiculopathy.

#### Method/Source of Data Collection

Identify the number of patients with acute or subacute low back pain diagnosis or radiculopathy diagnosis seen in primary care. Out of that number, determine the number of patients who received education on low back pain self-care and the importance of maintaining an active lifestyle.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is a process measure. Improvement is noted as increase in the rate.

#### Measurement #4d

Percentage of patients with low back pain diagnosis who received recommendation to take an anti-inflammatory or analgesic medication.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with acute or subacute low back pain or radiculopathy.

#### **Data of Interest**

# of patients who received recommendation to take anti-inflammatory or analgesic medication

# of patients with acute low back pain diagnosis or radiculopathy

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who received recommendation to take anti-inflammatory or analgesic

medication.

Denominator: Number of patients with diagnosis of acute or subacute low back pain or radiculopathy.

#### Method/Source of Data Collection

Identify the number of patients with acute or subacute low back pain diagnosis or radiculopathy diagnosis seen in primary care. Out of that number, determine the number of patients who received recommendation to take anti-inflammatory or analgesic medication.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is a process measure. Improvement is noted as increase in the rate.

#### Measurement #5a

Percentage of patients with low back pain diagnosis who are prescribed opioids.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with acute or subacute low back pain or radiculopathy.

#### **Data of Interest**

# of patients prescribed opioids

# of patients with acute or subacute low back pain diagnosis or radiculopathy

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who were prescribed opioids.

Denominator: Number of patients with diagnosis of acute or subacute low back pain or radiculopathy.

#### **Method/Source of Data Collection**

Identify the number of patients with acute or subacute low back pain diagnosis or radiculopathy diagnosis seen in primary care. Out of that number, determine the number of patients who received opioid prescription.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is an outcome measure on misuse of opioid substances for management of acute low back pain. Improvement is noted as decrease in the rate.

#### Measurement #6a

Percentage of patients with low back pain diagnosis who have their functional status assessed using the Oswestry Disability Questionnaire or other assessment tool.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with acute or subacute low back pain or radiculopathy.

#### **Data of Interest**

# of patients who have their functional status assessed

# of patients with acute or subacute low back pain diagnosis or radiculopathy

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who have their functional status assessed using the Oswestry Disability

Questionnaire or other assessment tool.

Denominator: Number of patients with diagnosis of acute or subacute low back pain or radiculopathy.

#### Method/Source of Data Collection

Identify the number of patients with acute or subacute low back pain diagnosis or radiculopathy diagnosis seen in primary care. Out of that number, determine the number of patients who have their functional status assessed using the Oswestry Disability Questionnaire or other assessment tool.

## Time Frame Pertaining to Data Collection

Monthly.

#### **Notes**

This measure is a process measure. Improvement is noted as increase in the rate.

#### **Measurement #6b**

Percentage of patients with low back pain diagnosis who have their pain status assessed using the Visual Analog Scale, pain diagram or other assessment tool.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with acute or subacute low back pain or radiculopathy.

#### **Data of Interest**

# of patients who have their functional status assessed

# of patients with acute or subacute low back pain diagnosis or radiculopathy

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who have their pain status assessed using the Visual Analog Scale, pain diagram

or other assessment tool.

Denominator: Number of patients with diagnosis of acute or subacute low back pain or radiculopathy.

#### Method/Source of Data Collection

Identify the number of patients with acute or subacute low back pain diagnosis or radiculopathy diagnosis seen in primary care. Out of that number, determine the number of patients who have their pain status assessed using the Visual Analog Scale, pain diagram or other assessment tool.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is a process measure. Improvement is noted as increase in the rate.

#### Measurement #7a

Percentage of patients with non-specific low back pain diagnosis who have had collaborative decision-making with regards to referral to a specialist.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with non-specific low back pain.

#### **Data of Interest**

# of patients who have had collaborative decision-making done

# of patients with non-specific low back pain

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who have had collaborative decision-making done with regards to referral

to a specialist.

Denominator: Number of patients with diagnosis of non-specific low back pain.

#### Method/Source of Data Collection

Identify the number of patients with non-specific low back pain diagnosis seen in primary care. Out of that number, determine the number of patients who have had collaborative decision-making done with regards to referral to a specialist.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is a process measure. Improvement is noted as increase in the rate.

#### Measurement #7b

Percentage of patients with radicular pain diagnosis who have had collaborative decision-making with regards to imaging, intervention and/or surgery.

## **Population Definition**

Patients 18 years and older seen in primary care and diagnosed with radicular pain.

#### **Data of Interest**

# of patients who have had collaborative decision-making done regarding imaging, intervention and surgery

# of patients with radicular pain

#### **Numerator/Denominator Definitions**

Numerator: Number of patients who have had collaborative decision-making done regarding imaging,

intervention and/or surgery.

Denominator: Number of patients with diagnosis radicular back pain.

#### Method/Source of Data Collection

Identify patients with radicular back pain diagnosis seen in primary care. Out of that number, determine the number of patients who have had collaborative decision-making done regarding imaging, intervention and/or surgery.

## **Time Frame Pertaining to Data Collection**

Monthly.

#### **Notes**

This measure is a process measure. Improvement is noted as increase in the rate.

## Resources

#### **Criteria for Selecting Resources**

The following resources were selected by the guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

## **Resources Table**

Author/Organization	Title/Description	Audience	Web sites/Order Information
Center for the Advancement of Health	This Web site contains a series of studies on health behavior change in the clinical setting for chronic back pain.	Health Care Professionals	http://www.cfah.org/
Cochrane	Web site provides systematic reviews on evidence-based medicine.	Health Care Professionals	http://www.cochrane.org
emedicine.com	Web site provider inforamtion on back pain.	Patients and Families	http://www.emedicine.com
MayoClinic.com	Consumer information on back pain. Topics include definition, causes, risk factors and other topics.	Patients and Families	http://www.mayoclinic.com/ health/back=pain/DS00171
National Library of Medicines MEDLINE Plus/National Institutes of Health	Federal government source of back health-related information and research, related links.	Patients and Families; Health Care Professionals	http://www.nlm.nih.gov/ hinfo.html
NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Diseases	Web site provides a PDF document enti- tled 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
Spine-Health	Web site provides patients and families with comprehensive, highly informative and useful information for understanding, preventing and seeking appropriate treatment for back and neck pain.	Patients and Families	http:www.spine-health.com
UpToDate	Web site 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



## **Supporting Evidence:**

# **Adult Acute and Subacute Low Back Pain**

The subdivisions of this section are:

- References
- Appendices

## References

Links are provided for those new references added to this edition (author name is highlighted in blue).

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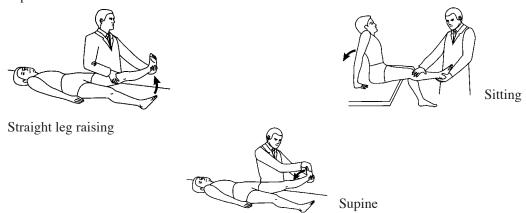
# Appendix A – Psychosocial Screening and Assessment Tools

The screening and assessment tools noted below may help identify psychosocial factors for prolonged disability and chronic pain. Treat **OR** refer to the appropriate mental health professional if indicated.

## Waddell's Signs

**Waddell's Signs** assess the possibility of psychological distress or malingering or both by testing the consistency and reproducibility of patient responses to non-organic physical signs. Waddell demonstrates that when three of five tests are positive, there is a high probability of non-organic pathology. Three positive tests identify the individual who needs further psychological assessment.

- **1. Tenderness:** Positive is generalized tenderness overlying the entire lumbar area when skin is lightly pinched or rolled.
- **2. Simulation**: The object of these tests is to give the patient the impression that a specific test is being performed when in fact it is not.
  - Axial loading: Positive when low back pain is reported on vertical loading over the standing patient's skull by the examiner's hands. Neck pain is common and should be discounted.
  - Rotation: Positive if low back pain is reported when shoulders and pelvis are passively rotated in the same plane as the patient stands relaxed with feet together.
- 3. **Distraction:** The object of this test is to distract the patient in such a way that a positive result under normal testing circumstances becomes negative in the distracted patient. The most useful test involves Straight Leg Raising (SLR). When the patient complains of pain doing SLR while supine but does not complain of pain doing SLR while sitting, the test is positive. This test is commonly referred to as the "flip test."



- **4. Regionalization:** Pain distributions are a function of known anatomic pathways and structures. Interpretation of the exam depends on patient giving non-anatomic or non-physiologic responses to testing.
  - Weakness: Positive test is a voluntary muscle contraction accompanied by recurrent giving way, producing motions similar to a cogwheel. Patient may show weakness on testing but have adequate strength spontaneously.
  - Sensory: Alterations in sensibility to touch and pinprick occur in a non-anatomic pattern (stocking-glove distribution or diminished sensation over entire half or quadrant of body).
- **5. Overreaction:** Disproportionate verbalization, facial expression, muscle tension, tremor, collapsing or sweating. Consider cultural variations.

(Waddell, 1980)

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## **Psychological Risk Factors**

There is work group consensus that the following factors are important to note and consistently predict poor outcomes:

- Belief that pain and activity are harmful
- "Sickness behaviors," such as extended rest
- Depressed or negative moods, social withdrawal
- Treatment that does not fit best practice
- Problems with claim and compensation
- History of back pain, time off or other claims
- Problems at work or low job satisfaction
- Heavy work, unsociable hours
- Overprotective family or lack of support

#### **Groups of Risk Factors**

Clinical assessment of risk factors may identify the risk of long-term disability, distress and work loss due to:

- Attitudes and beliefs about back pain
- Emotions
- Behaviors
- Family
- Compensation issues
- Work
- Diagnostic and treatment issues

#### How to Judge If a Person Is at Risk

A person may be at risk if:

- there is a cluster of a few very salient factors, or
- there is a group of several less important factors that combine cumulatively.

#### **Six Specific Screening Questions**

Suggested questions (to be phrased in treatment provider's own words):

- Have you had time off work in the past with back pain?
- What do you understand is the cause of your back pain?
- What are you expecting will help you?
- How is your employer responding to your back pain? Your co-workers? Your family?
- What are you doing to cope with back pain?
- Do you think you will return to work? When?

## PHQ-2

Use the Patient Health Questionnaire (PHQ) two-question tool in routine screening settings.

Over the past two weeks, have you been bothered by:

- Little interest or pleasure in doing things?
- Feeling down, depressed or hopeless?

If the patient answers "yes" to either of the above questions, administer the full PHQ-9 depression instrument.

## PHQ-9

PATIENT HEALTH QUESTIONNAIRE-9							
Over the <u>last 2 weeks</u> , how often have you been bothered by any of the following problems?		Several days	More than half the days	Nearly every day			
Little interest or pleasure in doing things		1	2	3			
2. Feeling down, depressed, or hopeless		1	2	3			
3. Trouble falling or staying asleep, or sleeping too much		1	2	3			
4. Feeling tired or having little energy	0	1	2	3			
5. Poor appetite or overeating		1	2	3			
Feeling bad about yourself — or that you are a failure or have let yourself or your family down		1	2	3			
Trouble concentrating on things, such as reading the newspaper or watching television		1	2	3			
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3			
Thoughts that you would be better off dead or of hurting yourself in some way		1	2	3			
	FOR OFFICE CODING						
		+ + +					
		=	Total Score	e:			
If you checked off <u>any</u> problems, how <u>difficult</u> have these pr work, take care of things at home, or get along with other pe		ade it for y	ou to do y	our			
	Very fficult □		Extreme difficu	•			
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#### **INSTRUCTIONS FOR USE**

for doctor or healthcare professional use only

#### PHQ-9 QUICK DEPRESSION ASSESSMENT

#### For initial diagnosis:

- 1. Patient completes PHQ-9 Quick Depression Assessment.
- **2.** If there are at least  $4 \checkmark$ s in the two right columns (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.
- 3. Consider Major Depressive Disorder
  - if there are at least  $5 \checkmark$ s in the two right columns (one of which corresponds to Question #1 or #2).

#### Consider Other Depressive Disorder

• if there are 2 to 4  $\checkmark$ s in the two right columns (one of which corresponds to Question #1 or #2).

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician, and a definitive diagnosis is made on clinical grounds, taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient. Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

# To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

- 1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.
- **2.** Add up  $\checkmark$ s by column. For every  $\checkmark$ :

"Several days" = 1 "More than half the days" = 2 "Nearly every day" = 3

- 3. Add together column scores to get a TOTAL score.
- **4.** Refer to accompanying PHO-9 Scoring Card to interpret the TOTAL score.
- **5.** Results may be included in patients' files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

#### PHQ-9 SCORING CARD FOR SEVERITY DETERMINATION

for healthcare professional use only

#### Scoring—add up all checked boxes on PHQ-9

For every  $\checkmark$ : Not at all = 0; Several days = 1; More than half the days = 2; Nearly every day = 3

#### **Interpretation of Total Score**

## Total Score Depression Severity

0-4 None

5-9 Mild

10-14 Moderate

15-19 Moderately severe

20-27 Severe

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# Appendix B – Roland-Morris Disability Questionnaire (RDQ)

When your back hurts, you may find it difficult to do some of the things you normally do. This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*.

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

- 1. I stay at home most of the time because of my back.
- 2. I change position frequently to try and get my back comfortable.
- 3. I walk more slowly than usual because of my back.
- 4. Because of my back I am not doing any of the jobs that I usually do around the house.
- 5. Because of my back, I use a handrail to get upstairs.
- 6. Because of my back, I lie down to rest more often.
- 7. Because of my back, I have to hold on to something to get out of an easy chair.
- 8. Because of my back, I try to get other people to do things for me.
- 9. I get dressed more slowly then usual because of my back.
- 10. I only stand for short periods of time because of my back.
- 11. Because of my back, I try not to bend or kneel down.
- 12. I find it difficult to get out of a chair because of my back.
- 13. My back is painful almost all the time.
- 14. I find it difficult to turn over in bed because of my back.
- 15. My appetite is not very good because of my back pain.
- 16. I have trouble putting on my socks (or stockings) because of the pain in my back.
- 17. I only walk short distances because of my back.
- 18. I sleep less well because of my back.
- 19. Because of my back pain, I get dressed with help from someone else.
- 20. I sit down for most of the day because of my back.
- 21. I avoid heavy jobs around the house because of my back.
- 22. Because of my back pain, I am more irritable and bad tempered with people than usual.
- 23. Because of my back, I go upstairs more slowly than usual.
- 24. I stay in bed most of the time because of my back.

#### **Note to users:**

The score of the RDQ is the total number of items checked - i.e., from a minimum of 0 to a maximum of 24. The questionnaire may be adapted for use online or by telephone. Thirty-six translations and adaptations are available.

This questionnaire is from Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. *Spine* 1983;8:141-44. The original questionnaire and all translations are in the public domain. No permission is required for their use or reproduction. More information can be found at: http://www.rmdq.org.

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Open Upright Magnetic Resonance Image (MRI) is an evolving modality using a 0.63T solid magnet and an architecture that allows imaging with the patient lying flat, sitting or standing in the neutral, extended and/or flexed positions. This system can be and is often used for routine MRI imaging of the spine. Merl, et al., in a prospective study, compared the accuracy of MRI on a low field strength 0.2T system to that on conventional high field strength systems and found no significant difference in accuracy (Merl, 1999). Open Upright MRI is also very useful for imaging patients with severe claustrophobia, patients who are too large to fit into conventional closed MRI systems, or in patients who have difficulty lying flat because of severe pain. Open Upright MRI may also be useful in patients with dynamic spondylolisthesis and dynamic stenosis.

#### **Evaluation of Dynamic Stenosis**

**Functional myelography.** Initial reports of dynamic narrowing of the central canal were made with standing flexion and extension radiographs following myelography, which has been referred to as functional myelography. Sortland, et al. reported the results of static and dynamic myelography in patients with a clinical diagnosis of spinal stenosis, and compared these findings to those in a control group of patients with back pain without a diagnosis of spinal stenosis. In this study, patients with a clinical diagnosis of spinal stenosis frequently demonstrated narrowing of the canal that worsened significantly in extension. In 8/36 stenosis patients, a complete myelographic block was seen on the images obtained in extension but not on images with the patient in the neutral position. Only small differences in canal dimensions with flexion and extension were noted in the control group (Sortland, 1997).

Zander, et al. noted significant dynamic changes in 33 of 210 patients with back pain, radiculopathy or neurogenic claudication who underwent functional myelography and Computed Tomography (CT) myelography. At five levels, stenosis of 70% or more seen on flexion-extension myelography measured less than 50% on supine CT scans (*Zander*, 1998). Similar findings were reported in other studies (*Sortland*, 1997; *Ping*, 1994; *Wilmink*, 1983).

**Axial loaded MRI.** Several studies have reported on the presence of additional findings on patients who have undergone MRI, CT myelography or CT with axial loading applied to simulate weight bearing (*Manenti*, 2003; *Danielson*, 1998; *Willen*, 1997). Willen et al., in a study of 172 patients, reported significant changes on axial CT in 69% of patients with neurogenic intermittent claudication and 0% of patients with isolated back pain (*Willen*, 2001).

Hiwatashi, et al., in a study of 20 patients, showed that the additional information obtained with axial loading on MRI can influence treatment decisions by neurosurgeons. In five of these patients, all three neurosurgeons changed their treatment plans from conservative therapy to surgical decompression after reviewing the findings on the axial loaded exams. One or two of the neurosurgeons changed their treatment plan in another five patients (*Hiwatashi*, 2004). The significance of these findings relative to the patients' outcome has not been addressed.

**Open Upright MRI.** Open Upright MRI can image patients in anatomic positions of axial loading such as sitting and standing, in flexion and extension, and in positions that might reproduce pain.

Zamani, et al., examined 30 patients with Open Upright MRI using sitting neutral and sitting flexion and extension images. Fifteen of these patients also underwent conventional high field strength imaging. The authors noted a decrease in the size of the central canal in 50% of patients and the foraminal canal in 27% of patients with extension. These changes were most notable at levels with disc dessication. The authors also noted some decrease in image quality compared with the conventional images. They did not quantitate or determine the significance of the changes on Open Upright MRI relative to the patients' symptoms. Patients were not consecutive, and interpretation of the images were not blinded to the results of the high field strength exams (Zamani, 1998).

Wildermuth, et al. examined 30 consecutive patients with functional myelography and Open Upright flexion and extension MRI. They found a high correlation of the measured AP dural sac diameter on the two techniques. The authors also reported positional changes in foraminal size in a small number of patients. Patients were recruited in a consecutive manner after completion of the myelographic examination (*Wildermuth*, 1998).

Weishaupt, et al. examined 30 patients with chronic low back or leg pain unresponsive to conservative therapy and disc protrusions and/or extrusions without neural compression on routine supine MRI. The authors found that positional dependent changes in nerve root impingement and foraminal size were frequent, and correlated with the severity of patient symptoms. Patients were not consecutive and were recruited after completion of the supine recumbent exam. Blinding of results of the conventional imaging is not noted (Weishaupt, 2000).

Ferriro Perez, et al. evaluated the differences in findings between supine recumbent and upright sitting neutral images in 89 patients, 45 of whom underwent studies of the lumbar spine. Twenty-four disc herniations were seen in the lumbar spine, 2 (8%) of which were only seen on the upright exam, and 14 (58%) of which increased in size on the upright exam. Anterior spondylolisthesis was seen in 13 lumbar spine cases, was only seen on the upright exam in 4 (31%), and increased in severity on the upright exam in 7 (54%). Patients were not consecutive, and findings were not correlated with symptoms. Motion artifact prohibited accurate measurements in 20% of images. Blinding of results of the conventional imaging is not noted (Ferriro Perez, 2007).

Vitzthum, et al. studied 50 healthy volunteers and 50 patients who suffered from symptoms correlating to monosegmental disease awaiting surgical decompression (41 disc herniations, 5 lateral recess stenosis, 4 degenerative spondylolisthesis). The authors felt that the dynamic open upright flexion-extension MRI added important additional information in 32 patients. Rotational examinations contributed important additional information in 5 patients. The authors did not note whether the patients were consecutive, and did not detail the nature of the important additional information. They did note an increase in the rotation at degenerated segments with a decrease segmental flexion-extension (*Vitzthum*, 2000).



# **Appendix C – Patient Brochure Example**

#### **Acute Low Back Pain**

Pain in the low back is very common. Most people experience back pain at some point in their lives. Fortunately, 90% of people who have low back pain get better within four to six weeks. The majority can return to work within the first two weeks of onset. Understanding what causes low back problems, how simple home self-care can relieve low back pain and what to do if your pain does not improve is important. This brochure provides information on low back pain and various treatments as well as low back exercises to help improve and prevent back pain from returning are also included.

#### What Are Different Types of Low Back Pain?

**Acute low back pain** – Acute low back pain, also referred to as lumbar muscle strain or backache, lasts for six weeks or less. The pain does not extend below the knees. Although acute low back pain is quite painful, usually it improves.

**Acute radiculopathy** – Acute radiculopathy is low back pain that also lasts for six weeks or less, but the pain extends below the knees. This type of low back pain also improves with in the majority of patients. Irritation of nerves in the lower back often causes radiculopathy.

#### What Are Common Causes of Low Back Pain?

Inflammation (swelling) of joints, muscles or soft tissue structures in the back often causes low back pain. Poor posture and physical activities, such as repetitive lifting, bending and twisting, can worsen low back pain. Rarely do serious problems, such as infection or other medical conditions, cause low back pain.

#### How Do I Know If I Have a Serious Problem?

In rare situations, your doctor may want to do tests to rule out any uncommon causes for your back pain. Contact your doctor within a week if the pain is not noticeably improving. Call your doctor immediately if you have any of the following:

- Unexplained weight loss
- Constant night pain
- Fever of 100.4° F or higher for more than 48 hours
- New onset of urinary incontinence
- Urinary retention
- Weakness or numbness in your legs

A history of cancer may also be a factor in low back pain.

#### **Should I Have X-rays Performed?**

**Imaging is not recommended.** X-rays usually are not necessary when you first develop lower back pain. You may need x-rays...

- If you have experienced a significant injury, such as a fall or car accident
- Are 50 years or older
- Have other medical problems
- Low back pain lasting longer than six weeks

#### What Is the Treatment?

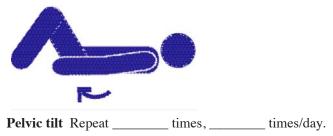
- Apply heat. A hot bath or a heating pad on your lower back may help reduce pain and stiffness.
- Improving posture. Good posture keeps your body's weight aligned (straight) and reduces stress on the back muscles. To help reduce the stress that sitting puts on your low back, use a chair with back support. Change positions frequently, preferably every 20-30 minutes.
- Avoid bedrest. Staying in bed or avoiding general activity may increase your pain and stiffness. Mild activity that does not significantly worsen your pain has been shown to be beneficial.
- Continue everyday activities. Resume your daily activities as the worst of your pain eases. Staying active helps prevent your back from becoming weak and stiff. While you can expect some discomfort, avoid activity that significantly worsens your pain. Depending on your job, you may need to temporarily modify your responsibilities or limit your hours at work. Avoid lifting heavy objects, repetitive or sustained bending and twisting.
- Use medication. Anti-inflammatory medication, such as ibuprofen can help ease the pain and swelling in the lower back. If ibuprofen upsets your stomach, use acetaminophen.
- Manage stress. Family and work problems, financial pressures and depression can affect your back
  pain. Learning to manage everyday stress can help your recovery. Take time to relax. A heightened state
  of tension can make your back feel worse. Do not smoke.
- **Spinal Manipulative Therapy.** Spinal manipulative therapy may be considered in the early and late phases of acute low back symptoms.

#### How Do I Know If I Need Surgery?

Surgery rarely is needed for back pain or radiculopathy. Only 5 to 10% of people with radiculopathy need surgery. Non-surgical treatments and exercise often are as helpful in relieving pain and preventing pain from returning.

#### **Exercise to Keep Fit**

To help in your recovery and to prevent further back problems, keep your back, abdominal muscles and legs strong. Walk daily as soon as you can. Gradually add other physical activities, such as swimming and biking, which can help improve lower back strength. Begin as soon as you can do them comfortably. Do not do any exercises that make your pain a lot worse. The following are some back exercises that can help relieve low back pain.

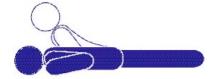


Lie flat on your back (or stand with your back to a wall), knees bent, feet flat on the floor, body relaxed. Tighten your abdominal and buttock muscles and tilt your pelvis. The curve of the small of your back should flatten towards the floor (or wall). Hold 10 seconds and then relax.



**Knee raise** Repeat \_\_\_\_\_ times, \_\_\_\_ times/day.

Lie flat on your back, knees bent. Bring one knee slowly to your chest. Hug your knee gently. Then lower your leg toward the floor, keeping your knee bent. Do not straighten your legs. Repeat exercise with other leg.



Partial press-up Repeat \_\_\_\_\_ times, \_\_\_\_ times/day.

Lie face down on a soft, firm surface. Do not turn your head to either side. Rest your arms bent at the elbows alongside your body. Relax for a few minutes. Then raise your upper body enough to lean on your elbows. Relax your lower back and legs as much as possible. Hold this position for 30 seconds at first. Gradually work up to five minutes. Or try slow press-ups. Hold each for five seconds and repeating five to six times.



## **Appendix D – Fear-Avoidance Beliefs Questionnaire**

Name:	Date:		/	/	
	_	mm	dd	уу	

Here are some of the things other patients have told us about their pain. For each statement please circle the number from 0 to 6 to indicate how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

		Completely Disagree			Unsure			Completely Agree
1.	My pain was caused by physical activity.	0	1	2	3	4	5	6
2.	Physical activity makes my pain worse.	0	1	2	3	4	5	6
3.	Physical activity might harm my back.	0	1	2	3	4	5	6
4.	I should not do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6
5.	I cannot do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain.

	Completely Disagree			Unsure			Completely Agree
6. My pain was caused by my work or by an accident at work.	0	1	2	3	4	5	6
7. My work aggravated my pain.	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain.	0	1	2	3	4	5	6
9. My work is too heavy for me.	0	1	2	3	4	5	6
10. My work makes or would make my pain worse.	0	1	2	3	4	5	6
11. My work might harm by back.	0	1	2	3	4	5	6
12. I should not do my regular work with my present pain.	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain.	0	1	2	3	4	5	6
14. I cannot do my normal work until my pain is treated.	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work.	0	1	2	3	4	5	6

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#### **Scoring:**

Fear-avoidance beliefs about work (scale 1) = (points for item 6) + (points for item 7) + (points for item 9) + (points for item 10) + (points for item 11) + (points for item 12) + (points for item 15)

Fear-avoidance beliefs about physical activity (scale 2) = (points for item 2) + (points for item 3) + (points for item 4) + (points for item 5)

Items not in scale 1 or 2: 1, 8, 13, 14, 16

#### **Interpretation:**

- Minimal scale scores: 0
- Maximum scale 1 score: 42 (7 items)
- Maximum scale 2 score: 24 (4 items)
- The higher the scale scores the greater the degree of fear and avoidance beliefs shown by the patient.

#### References:

Waddell G, Newton M, 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. (Appendix page 166).

# **Appendix E – The Keele STarT Back Screening Tool and Scoring System**

		Disagree	Agree
		0	1
1.	My back pain has spread down my leg(s) at some time in the last two weeks		
2.	I have had pain in the <b>shoulder</b> or <b>neck</b> at some time in the last two weeks		
3.	I have only walked short distances because of my back pain		
4.	In the last two weeks, I have <b>dressed more slowly</b> than usual because of back pain		
5.	It's not really safe for a person with a condition like mine to be physically active		
6.	Worrying thoughts have been going through my mind a lot of the time		
7.	I feel that my back pain is terrible and it's never going to get any better		
8.	In general I have not enjoyed all the things I used to enjoy		

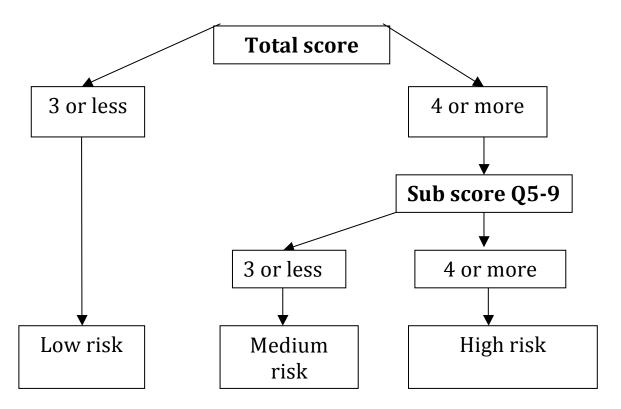
9. Overall, how bothersome has your back pain been in the last two weeks?

Not at all	Slightly	Moderately	Very much	Extremely
0	0	0	1	1
Total score (all 9): _		Sub Score	e (Q5-9):	

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# The STarT Back Tool Scoring System



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# Appendix F – Örebrö Musculoskeletal Pain Screening Questionnaire (ÖMPSQ)

The Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ) is a screening tool that assesses the risk that a worker will develop long-term disability or fail to return to work following a musculoskeletal injury. It consists of 21 questions that address psycho-social factors (yellow flags), including beliefs and expectations that may influence recovery and return to work.

Ideally, this questionnaire should be completed between 4 and 12 weeks following a musculoskeletal injury. The screening tool enables a practitioner to identify possible risks factors and apply appropriate interventions (for instance, use of activity programs based on cognitive behavioral strategies, addressing fear-avoidance or 'catastrophizing') to reduce the risk of long-term disability in injured workers. Evidence indicates that these factors can be changed if they are addressed early in the recovery process.

#### **Scoring instructions**

For question 1, count the number of pain sites and multiply by two – this is the score (maximum score allowable is 10).

For questions 2 and 3 the score is the number bracketed after the ticked box.

For questions 4, 5, 6, 7, 9, 10, 11, 14, 15 and 16 the score is the number that has been ticked or circled.

For questions 8, 12, 13, 17, 18, 19, 20 and 21 the score is 10 minus the number that has been circled.

Write the score in the shaded area beside each item.

Add up the scores for questions 1 to 21 – this is the total ÖMPSQ score.

#### **Interpretation of scores**

Higher scores are associated with increased risk of long-term disability or failure to return to work. A score of 105 or above indicates persons who are at risk of disability/failure to return to work. These people may require referral to an allied health professional such as a psychologist.

Responses to individual questions may provide the practitioner with useful information about beliefs and attitudes that may influence recovery.

#### **Instructions**

These questions and statements apply if you have aches or pains, such as back, shoulder or neck pain. Please read and answer questions carefully. Do not take too long to answer the questions, however it is important that you answer every question. There is always a response for your particular situation. 1. Where do you have pain? Place a tick for all appropriate sites.

2x (max 10)

Neck Shoulder Arm Upper back

Lower back Leg Other (state)

- 2. How many days of work have you missed because of pain during the last 18 months? Tick one.
  - 0 days (1) 1-2 days (2) 3-7 days (3) 8-14 days (4)
  - 15-30 days (5) 1 month (6) 2 months (7) 3-6 months (8)
  - 6-12 months (9) over 1 year (10)
- 3. How long have you had your current pain problem? Tick one.
  - 0-1 weeks (1) 1-2 weeks (2) 3-4 weeks (3) 4-5 weeks (4)
  - 6-8 weeks (5) 9-11 weeks (6) 3-6 months (7) 6-9 months (8)
  - 9-12 months (9) over 1 year (10)
- 4. Is your work heavy or monotonous? Circle the best alternative.

012345678910

Not at all

Extremely

- 5. How would you rate the pain that you have had during the past week? Circle one.
  - 012345678910

No pain

Pain as bad as it could be

6. In the past three months, on average, how bad was your pain? Circle one.

012345678910

No pain

Pain as bad as it could be

7. How often would you say that you have experienced pain episodes, on average, during the past three month? Circle one.

 $0\ 1\ 2\ 3\ 4\ 5\ 6\ 7\ 8\ 9\ 10$ 

Never

Always

8. Based on all things you do to cope or deal with your pain, on an average day, how much are you able to decrease it? Circle the appropriate number.

012345678910

Can't decrease it at all

Can decrease it completely

9. How tense or anxious have you felt in the past week? Circle one.

012345678910

Absolutely calm and relaxed

As tense and anxious as I've ever felt

Continued on next page

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10. How much have you been bothered by feeling depressed in the past week? Circle one.				
0 1 2 3 4 5 6 7 8 9 10				
Not at all				
Extremely				
11. In your view, how large is the risk that your current	pain may become persistent? Circle one.			
0 1 2 3 4 5 6 7 8 9 10				
No risk				
Very large risk				
12. In your estimation, what are the chances that you will be able to work in six months? Circle one.  0 1 2 3 4 5 6 7 8 9 10	10 – x			
No chance				
Very large chance				
13. If you take into consideration your work routines, management, salary, promotion possibilities and work mates, how satisfied are you with your job? Circle one.	10 – x			
012345678910				
Not satisfied at all				
Very large chance				
Here are some of the things that other people have told us about their pain. For each statement, circle one number from 0 to 10 to say how much physical activities, such as bending, lifting, walking or driving, would affect your pain.				
14. Physical activity makes my pain worse.				
0 1 2 3 4 5 6 7 8 9 10				
Completely disagree				
Completely agree				
15. An increase in pain is an indication that I should stop what I'm doing until the pain decreases.				
0 1 2 3 4 5 6 7 8 9 10				
Completely disagree				
Completely agree				
16. I should not do my normal work with my present pain.				
0 1 2 3 4 5 6 7 8 9 10				
Completely disagree	Completely disagree			
Completely agree				

Continued on next page

Here is a list of five activities. Circle the one number that best describes your current ability to participate in each of these activities.						
17. I can do light work for an hour.	17. I can do light work for an hour. $10 - x$					
0 1 2 3 4 5 6 7 8 9 10						
Can't do it because of pain problem						
Can do it without pain being a problem						
18. I can walk for an hour.	10 - x					
0 1 2 3 4 5 6 7 8 9 10						
Can't do it because of pain problem						
Can do it without pain being a problem						
19. I can do ordinary household chores.	10 - x					
0 1 2 3 4 5 6 7 8 9 10						
Can't do it because of pain problem						
Can do it without pain being a problem						
20. I can do the weekly shopping.	10 - x					
0 1 2 3 4 5 6 7 8 9 10						
Can't do it because of pain problem						
Can do it without pain being a problem						
21. I can sleep at night.						
0 1 2 3 4 5 6 7 8 9 10						
Can't do it because of pain problem						
Can do it without pain being a problem						

Source: Linton SJ, Boersma K. Early identification of patients at risk of developing a persistent back problem: the predictive validity of the Orebro Musculoskeletal Pain Questionnaire. *Clin J Pain* 2003;19:80-86.

Continued on next page



# Appendix G – Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Guidelines

#### **MRI or Lumbar Spine CT Imaging Indications**

When indicated, MRI is the preferred diagnostic test in the evaluation of patients with low back pain with or without radiculopathy.

Generally, cross-sectional imaging is indicated when initial non-invasive conservative regimens have failed and surgery or a therapeutic injection are considerations. If there is uncertainty, consider consulting with the appropriate professional when the patient meets surgical referral criteria.

CT myelography is a useful study in patients who have a contraindication to MRI, for whom MRI findings are inconclusive, or for whom there is a poor correlation between symptoms and MRI findings. CT myelography shows comparable accuracy and is complementary to MRI. CT myelography is invasive, however, and invokes the risk of allergic reaction to contrast and post-myelographic headache.

Plain CT is a useful study in patients who have a contraindication to MRI, for whom MRI findings are inconclusive, for whom there is a poor correlation between symptoms and MRI findings, and for whom CT myelogram is deemed inappropriate. CT can be used in the initial evaluation of patients with back pain and/or radiculopathy when high-quality MRI is not available.

(North American Spine Society, 2007; American College of Radiology, 2006; Bischoff, 1993; Modic, 1986)

The Adult Acute and Subacute Low Back Pain guideline work group has listed advantages for both CT and MRI imaging and a list of conditions for each. This list is not meant to be comprehensive but to aid the clinician in making a decision.

#### **MRI** indications:

- Major or progressive neurologic deficit (e.g., foot drop or functionally limiting weakness such as hip flexion or knee extension)
- Cauda Equina Syndrome (loss of bowel or bladder control or saddle anesthesia)
- Progressively severe pain and debility despite conservative therapy
- Severe or incapacitating back or leg pain (e.g., requiring hospitalization, precluding walking or significantly limiting the activities of daily living)
- Clinical or radiological suspicion of neoplasm (e.g., lytic or sclerotic lesion on plain radiographs, history of cancer, unexplained weight loss or systemic symptoms)
- Clinical or radiological suspicion of infection (e.g., endplate destruction of plain radiographs, history
  of drug or alcohol abuse, or systemic symptoms)
- Trauma (fracture with neurologic deficit, compression fracture evaluation in elderly patients with question of underlying malignancy, characterization in anticipation of vertebroplasty/kyphoplasty, stress fracture or subacute spondylosis in a patient less than 18 years of age)
- Moderate to severe low back pain or radicular pain, unresponsive to conservative therapy, with indications for surgical intervention or therapeutic injection

For patients with mild to moderate claustrophobia, administering benzodiazepines an hour prior to scan may be effective. Patients who receive benzodiazepines should not drive.

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#### MRI advantages:

- Better visualization of soft tissue pathology; better soft tissue contrast
- Direct visualization of neurological structures
- Improved sensitivity for cord pathology and for intrathecal masses
- Improved sensitivity for infection and neoplasm
- No radiation exposure
- Safer than CT for women who are pregnant, especially in the 1st trimester, due to no radiation exposure

#### CT/CT myelography indications:

- Major or progressive neurologic deficit (e.g., foot drop or functionally limiting weakness such as hip flexion or knee extension)
- Cauda Equina Syndrome (loss of bowel or bladder control or saddle anesthesia)
- Progressively severe pain and debility despite conservative therapy
- Severe or incapacitating back or leg pain (e.g., requiring hospitalization, precluding walking or significantly limiting the activities of daily living)
- Clinical or radiological suspicion of neoplasm (e.g., lytic or sclerotic lesion on plain radiographs, history of cancer, unexplained weight loss or systemic symptoms)
- Clinical or radiological suspicion of infection (e.g., endplate destruction of plain radiographs, history of drug or alcohol abuse, or systemic symptoms)
- Bone tumors (to detect or characterize)
- Trauma (rule out or characterize fracture, evaluate for healing)
- Moderate or severe low back pain or radicular pain, unresponsive to conservative therapy, with indications for surgical intervention or therapeutic injection

#### CT advantages:

- Better visualization of calcified structures
- Direct visualization of fractures
- Direct visualization of fracture healing and fusion mass
- More accurate in the assessment of certain borderline or active benign tumors
- More available and less costly
- Better accommodation for patients over 300 pounds and patients with claustrophobia
- Safer for patients with implanted electrical devices or metallic foreign bodies
- Less patient motion particularly useful for patients who cannot lie still or for patients who cannot cooperate for an MRI

(Deyo, 2001; Thornbury, 1993; Mazanec, 1991)

#### **Open upright MRI**

Open Upright MRI systems, as currently configured with 0.5T and 0.63T magnets, are useful modalities for routine imaging of the lumbar spine, particularly for patients with severe claustrophobia, patients who cannot fit into conventional magnets, and patients who cannot lie flat because of severe pain. There is some evidence that imaging patients in the upright position or with axial loading (i.e., functional myelography, axial loaded CT or MRI, or Open Upright MRI) yields significant additional information in older patients with radiculopathy or neurogenic intermittent claudication. There is little to no evidence to support the use of Open Upright MRI in the detection of lumbar instability or in the evaluation of positional low back pain, and these applications should remain investigational.

See Appendix H, "Upright and Positional Imaging," for more information.



## Appendix H – Upright and Positional Imaging

Open Upright Magnetic Resonance Image (MRI) is an evolving modality using a 0.63T solid magnet and an architecture that allows imaging with the patient lying flat, sitting or standing in the neutral, extended and/or flexed positions. This system can be and is often used for routine MRI imaging of the spine. Merl, et al., in a prospective study, compared the accuracy of MRI on a low field strength 0.2T system to that on conventional high field strength systems and found no significant difference in accuracy (Merl, 1999). Open Upright MRI is also very useful for imaging patients with severe claustrophobia, patients who are too large to fit into conventional closed MRI systems, or in patients who have difficulty lying flat because of severe pain. Open Upright MRI may also be useful in patients with dynamic spondylolisthesis and dynamic stenosis.

#### **Evaluation of Dynamic Stenosis**

Functional myelography. Initial reports of dynamic narrowing of the central canal were made with standing flexion and extension radiographs following myelography, which has been referred to as functional myelography. Sortland, et al. reported the results of static and dynamic myelography in patients with a clinical diagnosis of spinal stenosis, and compared these findings to those in a control group of patients with back pain without a diagnosis of spinal stenosis. In this study, patients with a clinical diagnosis of spinal stenosis frequently demonstrated narrowing of the canal that worsened significantly in extension. In 8/36 stenosis patients, a complete myelographic block was seen on the images obtained in extension but not on images with the patient in the neutral position. Only small differences in canal dimensions with flexion and extension were noted in the control group (Sortland, 1997).

Zander, et al. noted significant dynamic changes in 33 of 210 patients with back pain, radiculopathy or neurogenic claudication who underwent functional myelography and Computed Tomography (CT) myelography. At five levels, stenosis of 70% or more seen on flexion-extension myelography measured less than 50% on supine CT scans (*Zander*, 1998). Similar findings were reported in other studies (*Sortland*, 1997; *Ping*, 1994; *Wilmink*, 1983).

**Axial loaded MRI.** Several studies have reported on the presence of additional findings on patients who have undergone MRI, CT myelography or CT with axial loading applied to simulate weight bearing (*Manenti*, 2003; *Danielson*, 1998; *Willen*, 1997). Willen et al., in a study of 172 patients, reported significant changes on axial CT in 69% of patients with neurogenic intermittent claudication and 0% of patients with isolated back pain (*Willen*, 2001).

Hiwatashi, et al., in a study of 20 patients, showed that the additional information obtained with axial loading on MRI can influence treatment decisions by neurosurgeons. In five of these patients, all three neurosurgeons changed their treatment plans from conservative therapy to surgical decompression after reviewing the findings on the axial loaded exams. One or two of the neurosurgeons changed their treatment plan in another five patients (*Hiwatashi*, 2004). The significance of these findings relative to the patients' outcome has not been addressed.

**Open Upright MRI.** Open Upright MRI can image patients in anatomic positions of axial loading such as sitting and standing, in flexion and extension, and in positions that might reproduce pain.

Zamani, et al., examined 30 patients with Open Upright MRI using sitting neutral and sitting flexion and extension images. Fifteen of these patients also underwent conventional high field strength imaging. The authors noted a decrease in the size of the central canal in 50% of patients and the foraminal canal in 27% of patients with extension. These changes were most notable at levels with disc dessication. The authors also noted some decrease in image quality compared with the conventional images. They did not quantitate or determine the significance of the changes on Open Upright MRI relative to the patients' symptoms. Patients were not consecutive, and interpretation of the images were not blinded to the results of the high field strength exams (Zamani, 1998).

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Wildermuth, et al. examined 30 consecutive patients with functional myelography and Open Upright flexion and extension MRI. They found a high correlation of the measured AP dural sac diameter on the two techniques. The authors also reported positional changes in foraminal size in a small number of patients. Patients were recruited in a consecutive manner after completion of the myelographic examination (*Wildermuth*, 1998).

Weishaupt, et al. examined 30 patients with chronic low back or leg pain unresponsive to conservative therapy and disc protrusions and/or extrusions without neural compression on routine supine MRI. The authors found that positional dependent changes in nerve root impingement and foraminal size were frequent, and correlated with the severity of patient symptoms. Patients were not consecutive and were recruited after completion of the supine recumbent exam. Blinding of results of the conventional imaging is not noted (Weishaupt, 2000).

Ferriro Perez, et al. evaluated the differences in findings between supine recumbent and upright sitting neutral images in 89 patients, 45 of whom underwent studies of the lumbar spine. Twenty-four disc herniations were seen in the lumbar spine, 2 (8%) of which were only seen on the upright exam, and 14 (58%) of which increased in size on the upright exam. Anterior spondylolisthesis was seen in 13 lumbar spine cases, was only seen on the upright exam in 4 (31%), and increased in severity on the upright exam in 7 (54%). Patients were not consecutive, and findings were not correlated with symptoms. Motion artifact prohibited accurate measurements in 20% of images. Blinding of results of the conventional imaging is not noted (Ferriro Perez, 2007).

Vitzthum, et al. studied 50 healthy volunteers and 50 patients who suffered from symptoms correlating to monosegmental disease awaiting surgical decompression (41 disc herniations, 5 lateral recess stenosis, 4 degenerative spondylolisthesis). The authors felt that the dynamic open upright flexion-extension MRI added important additional information in 32 patients. Rotational examinations contributed important additional information in 5 patients. The authors did not note whether the patients were consecutive, and did not detail the nature of the important additional information. They did note an increase in the rotation at degenerated segments with a decrease segmental flexion-extension (*Vitzthum*, 2000).

# Appendix I – Shared Decision-Making Tools and Resources

#### Cochrane

Interventions for improving the adoption of shared decision-making by health care professionals:

http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD006732/frame.html

#### **Dartmouth-Hitchcock**

Center for Shared Decision-Making:

http://patients.dartmouth-hitchcock.org/shared\_decision\_making.html

#### **Ottawa Hospital Research Institute**

Patient Decision Aids:

http://decisionaid.ohri.ca/index.html

#### **Minnesota Shared Decision-Making Collaborative**

Patient Decision Aids:

http://www.msdmc.org

#### **Foundation for Informed Medical Decision-Making**

Shared decision-making information and decisions support aids available. Cost may be incurred for some services.

http://www.informedmedicaldecisions.org

#### Healthwise

Shared decision-making products available for a cost.

http://www.healthwise.org

# Appendix J - ICSI Shared Decision-Making Model

The technical aspects of Shared Decision-Making are widely discussed and understood. **Decisional conflict** occurs when a patient is presented with options where no single option satisfies all the patient's objectives, where there is an inherent difficulty in making a decision, or where external influencers act to make the choice more difficult. **Decision support** clarifies the decision that needs to be made, clarifies the patient's values and preferences, provides facts and probabilities, guides the deliberation and communication, and monitors the progress. **Decision aids** are evidence-based tools that outline the benefits, harms, probabilities and scientific uncertainties of specific health care options available to the patient.

However, before decision support and decision aids can be most advantageously utilized, a Collaborative Conversation<sup>TM</sup> should be undertaken between the provider and the patient to provide a supportive framework for Shared Decision-Making.

#### Collaborative Conversation<sup>TM</sup>

A collaborative approach toward decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation<sup>TM</sup> is an inter-professional approach that nurtures relationships, enhances a patient's knowledge, skills and confidence as vital participants in his/her health, and encourages him/her to manage his/her health care. Within a Collaborative Conversation<sup>TM</sup>, the perspective is that both the patient and the provider play key roles in the decision-making process. The patient knows which course of action is most consistent with his/her values and preferences, and the provider contributes knowledge of medical evidence and best practices. Use of Collaborative Conversation<sup>TM</sup> elements and tools is even more necessary to support patient, care provider and team relationships when patients and families are dealing with high stakes or highly charged issues. A diagnosis of a life-limiting illness presents such a circumstance.

The overall framework for the Collaborative Conversation<sup>TM</sup> 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. A rote script or a 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 involved in making a decision: cognitive, affective, social and spiritual.

**Key communication skills** help build the Collaborative Conversation<sup>TM</sup> approach. These skills include many elements, but in this appendix only the questioning skills will be described. (For complete instruction, see 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?*, *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 provider should use his/her own words rather than just parroting what he/she heard.

**Reflection of feelings** usually can be done effectively once trust has been established. Until the provider 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 is appropriate. Reflection in this manner communicates that the provider understands the patient's feelings and may work as a catalyst for further problem solving. For example, the provider identifies what the person is feeling and responds back in his/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 provider 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 situations 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 provider accurately understands a patient or family member, and may be used as a summary or reflection. They are used to verify that the provider is interpreting the message correctly. The provider 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 provider 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 provider to supplement the patient's 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 provider.

**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 provider's view of the patient's reaction. For instance, the provider can say, "You seem to understand the facts and value your daughter's advice."

#### **Additional Communication Components**

Other elements that can impact the effectiveness of a Collaborative Conversation<sup>TM</sup> include:

- Eye contact
- Body language consistent with message
- Respect
- Empathy
- Partnerships

Self-examination by the provider involved in the Collaborative Conversation<sup>TM</sup> can be instructive. Some questions to ask oneself include:

- Do I have a clear understanding of the likely outcomes?
- Do I fully understand the patient's values?

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- Have I framed the options in comprehensible ways?
- Have I helped the decision-makers recognize that preferences may change over time?
- Am I willing and able to assist the patient in reaching a decision based on his/her values, even when his/her values and ultimate decision may differ from my values and decisions in similar circumstances?

#### When to Initiate a Collaborative Conversation<sup>TM</sup>

A Collaborative Conversation<sup>TM</sup> can support decisions that vary widely in complexity. It can range from a straightforward discussion concerning routine immunizations to the morass of navigating care for a life-limiting illness. Table 1 represents one health care event. This event can be simple like a 12 year old coming to the clinic for routine immunizations, or something much more complex like an individual receiving a diagnosis of congestive heart failure. In either case, entering the clinic or receiving a diagnosis of a life-limiting illness is the catalyst that starts the process represented in this table. There are cues for providers and patient needs that exert influence on this process. They are described below. The heart of the process is the Collaborative Conversation<sup>TM</sup>. The time the patient spends within this health care event will vary according to the decision complexity and the patient's readiness to make a decision.

Regardless of the decision complexity, there are cues applicable to all situations that indicate an opportune time for a Collaborative Conversation<sup>TM</sup>. These cues can occur singularly or in conjunction with other cues.

#### **Cues for the Care Team to Initiate a Collaborative Conversation**<sup>TM</sup>

- **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.
- Change in medical evidence or interpretation of medical evidence: Providers can clarify the change and help the patient understand its impact.
- **Provider/caregiver contact:** Each contact between the provider/caregiver and the patient presents an opportunity to reaffirm with the patient that his/her care plan and the care the patient is receiving and consistent with his/her values.

Patients and families have a role to play as decision-making partners, as well. The needs and influencers brought to the process by patients and families impact the decision-making process. These are described below.

#### Patient and Family Needs within a Collaborative Conversation<sup>TM</sup>

• 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, exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Generational and cultural influencers may act to inhibit the patient from actively participating in care discussions, Often patients need to be given "permission" to participate as partners in making decisions about his/her care.

Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When the patient expresses a need for information regarding options and his/her potential outcomes, the patient should understand the key facts about 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 the preferences, value clarification can be achieved through a Collaborative Conversation<sup>TM</sup> and by the use of decision aids that detail the benefits and harms of potential outcomes in terms the patient can understand.
- **Trust:** The patient must feel confident that his/her preferences will be communicated 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/she receives throughout the care continuum.

The Collaborative Conversation<sup>TM</sup> Map is the heart of this process. The Collaborative Conversation<sup>TM</sup> Map can be used as a stand-alone tool that is equally applicable to providers and patients as shown in Table 2. Providers use the map as a clinical workflow. It helps get the Shared Decision-Making process initiated, and once on its way, provides navigation for the process. Care teams can used the Collaborative Conversation<sup>TM</sup> to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation<sup>TM</sup> Map in his/her 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 his/her loved ones.

#### **Evaluating the Decision Quality**

Adapted from O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007].

When the patient and family understand the key facts about the condition and his/her options, a good decision can be made. Additionally, the patient should have realistic expectations about the probable benefits and harms. A good indicator of the decision quality is whether or not the patient follows through with his/her chosen option. There may be implications of the decision on patient's emotional state such as regret or blame, and there may be utilization consequences.

Decision quality can be determined by the extent to which the patient's chosen option best matches his/her values and preferences as revealed through the Collaborative Conversation $^{\text{TM}}$  process.

#### Table One

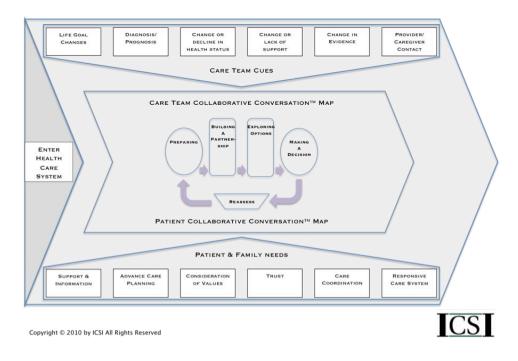
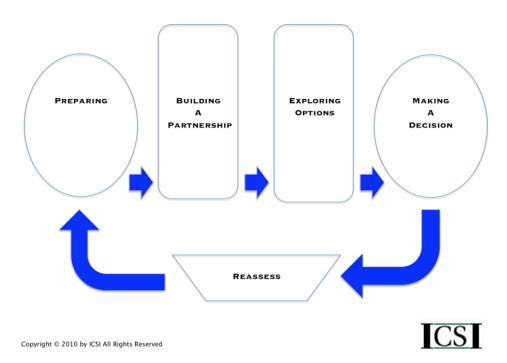


Table Two

#### SDM COLLABORATIVE CONVERSATION™ MAP



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## **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, implementation strategies and barriers to implementation. 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 which have been formally evaluated and tested. Measures are included which 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 every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group mid-cycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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## **Acknowledgements**

#### **ICSI Patient Advisory Council**

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Adult Acute and Subacute Low Back Pain guideline and thank them for their suggestion(s) to improve the motivation and compliance in patients from the providers with their home-based rehabilitation programs. This included keeping a journal to share with the provider, frequent follow-up from the provider such as a call, having a DVD that demonstrates exercises, and considering the patient's daily routine and living situations.

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

We want to thank the following for reviewing and commenting on this document:

#### **ICSI Member Groups/Sponsors**

Marshfield Clinic
Stillwater Medical Group
Center for Diagnostic Imaging
MAPS Medical Pain Clinics
Midwest Spine Institute
Minnesota Association of Community Health Centers
Family Health Services Minnesota
Fairview Mesaba Clinics
Hennepin Faculty Associates
Mayo Clinic
Lakeview Clinic
Medical Health Plan
HealthPartners Medical Group and Regions Hospital

#### Other

Individual who is a researcher and consumer advocate ChiroCare MN Back to Wellness Clinic Institute of Health Economics