ICSI

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Guideline:
Adult Low Back Pain

Fourteenth Edition
November 2010

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and the following expert audiences:

- 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
- employee benefit managers.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in your 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. An ICSI Health Care Guideline rarely will establish the only approach to a problem.

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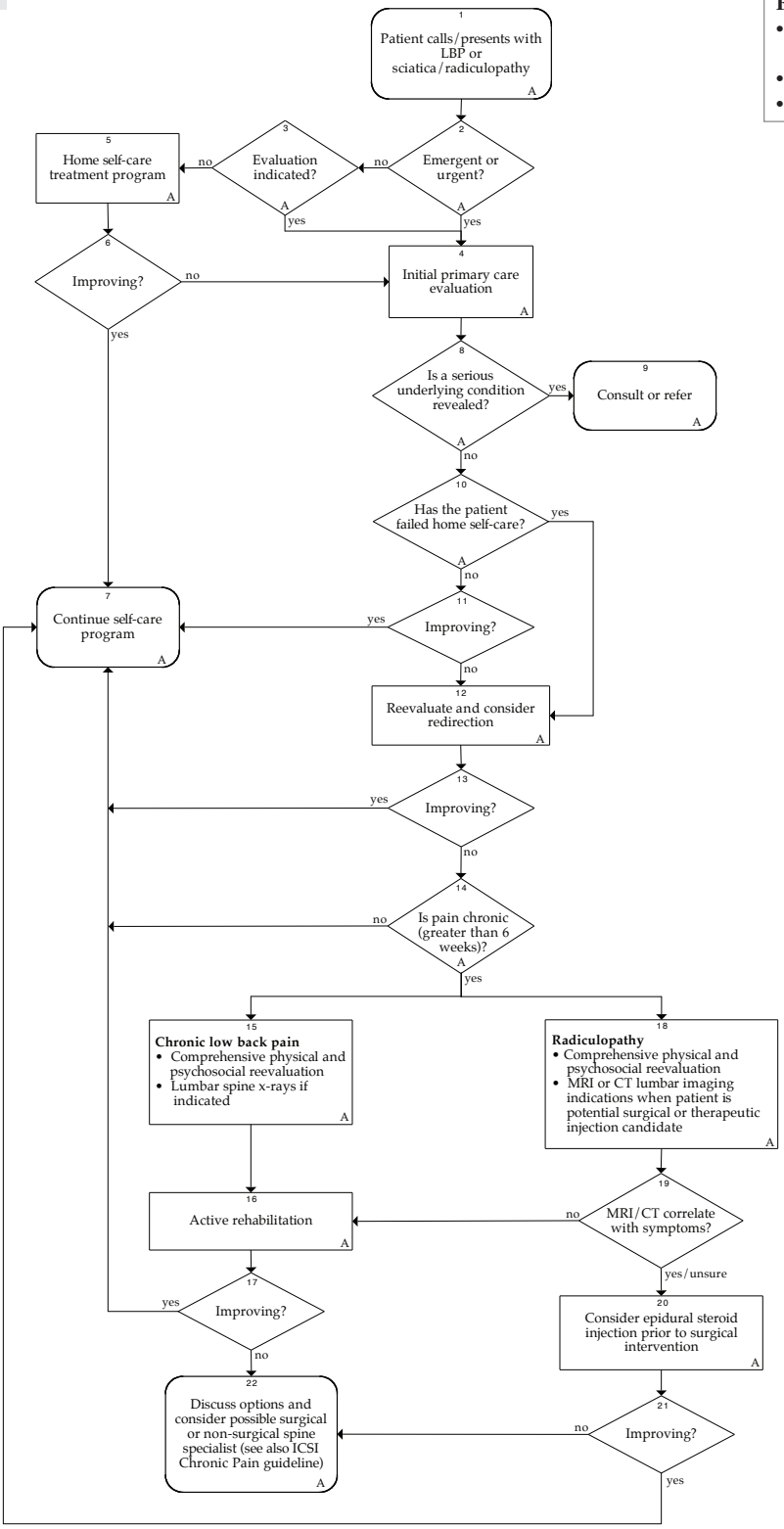
1a
For workers' compensation patients, see the Workers' Compensation treatment parameters at: http://www.workerscompensation.com/workers_comp_by_state.php

1b
Patient education regarding primary prevention, including healthy lifestyle and general aerobic fitness.
Emphasis on:
- Patient responsibility for good back care
- Workplace ergonomics
- Home self-care treatment

14a
Acute Low Back Pain
LBP that does NOT radiate past the knee for ≤ six weeks

Acute Radiculopathy
LBP with radiation past the knee for ≤ six weeks

Chronic Radiculopathy
Above symptoms for > six weeks



A = 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.

Jeffrey Bonsell, DC is a consultant for Midwest Healthcare Consultants, EvaluMed and National Chiropractic Mutual Insurance Corporation.

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

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 case for cauda equina; conservative treatment for low back pain; diagnostic imaging and low back pain; active rehabilitation; diagnostic imaging and radiculopathy; and surgical treatment from January 2008 through April 2010.

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

Evidence citations are listed in the document utilizing this format: *(Author, YYYY [report class]; Author, YYYY [report class] – in chronological order, most recent date first)*. A full explanation of ICSI's Evidence Grading System can be found on the ICSI Web site at http://www.icsi.org.

Class	Description
Primary Reports of New Data Collections	
A	Randomized, controlled trial
B	Cohort-study
C	Non-randomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study
D	Cross-sectional study Case series Case report
Reports that Synthesize or Reflect upon Collections of Primary Reports	
M	Meta-analysis Sytematic review Decision analysis Cost-effectiveness analysis
R	Consensus statement Consensus report Narrative review
X	Medical opinion

Foreword

Introduction

Pain in the lower back is the fifth most common reason for all physician visits in the United States *(Chou, 2007 [M])*. It can be related to certain activities, poor posture, physical stress or psychological stress. Other etiologies include pregnancy; labor; menstrual period; urinary tract problems; stomach upset with nausea, vomiting and diarrhea.

Ninety percent of back pain patients improve within four to six weeks. Approximately two-thirds of the people who recover from a first episode of acute low back symptoms will have another episode within 12 months, and one out of five report substantial limitations in activity. Unless the back symptoms are very different from the first episode or the patient has a new medical condition, improvement can be expected to be similar for each episode *(Chou, 2007 [M]; Hestbaek, 2003 [M]; Pengel, 2003 [M])*.

When pain or weakness lasts longer than six weeks or causes significant disability that interferes with activities of daily living, more specialized treatment(s) may be needed. For this reason it is important for the patient to keep the doctor informed of his or her progress.

Treatment for low back pain has very large direct health care costs. In 1998, the costs of care in the United States were estimated at $26.3 billion. There are also substantial indirect costs related to days lost from work. Approximately two percent of the working population is compensated for back injuries each year *(Chou, 2007 [M])*.

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 acute and chronic management, including indications for medical, non-surgical or surgical referral. For workers' compensation patients, check with state guidelines where the patient resides and where the injury took place: http://www.workerscompensation.com/workers_comp_by_state.php.

The pregnant population is excluded from this guideline; however, the following considerations are noted.

Low back pain (LBP), 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 LBP during pregnancy (*Sabino, 2008 [R]; Pennick, 2007 [M])*, and one study found that approximately 62% of women rated the pain as moderately severe *(Stapleton, 2002 [D])*. Despite the significance of this problem, only one third of pregnant women reported LBP to their prenatal care providers *(Pennick, 2007 [M])*.

The typical course of LBP during pregnancy is that it generally begins in the mid-late 2nd trimester and resolves during the post-partum course and, unfortunately, is likely to return in subsequent pregnancies *(Sabino, 2008 [R])*. As mentioned most cases resolve in the post-partum period, although Norén reported that 20% of women with LBP during pregnancy were found to have LBP three years following delivery *(Norén, 2002 [B])*.

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 LBP, although lumbar flexion will be limited as the pregnancy progresses and the gravid abdominal examination can be challenging *(Sabino, 2008 [R])*.

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 LBP *(Sabino, 2008 [R])*.

According to a Cochrane review, effective treatment of pregnancy-related LBP, as measured by pain reduction and back-pain-related sick leave, included strengthening exercises, sitting pelvic tilt exercises and water gymnastics *(Pennick, 2007 [M])*.

Aims

1. Improve the assessment and reassessment of patients age 18 and older with low back pain diagnosis. *(Annotations #1, 4, 15, 18)*
2. Reduce unnecessary imaging for low back pain patients age 18 and older in the absence of "red flag" indicators or progressive symptoms. *(Annotations #4, 18)*
3. Increase the use of recommended conservative approach as first-line treatment, such as activity, self-care and analgesics for patients age 18 and older with low back pain diagnosis. *(Annotation #5)*

Clinical Highlights

- Back pain assessment should include a subjective pain rating, functional status, patient history including notation of presence or absence of "red flags" (Cauda Equina Syndrome or other conditions noted in Annotation #1) and psychosocial indicators, assessment of prior treatment and response, employment status, and clinician's objective assessment. *(Annotations #1, 4, 15, 18; Aim #1)*
- Reduce unnecessary imaging unless "red flag" indicators exist. (*Annotations #4, 18; Aim #2)*
- A conservative approach should be first-line treatment. Emphasize patient education and conservative home self-care, which includes early ambulation, postural advice, resumption of activities, use of ice and heat, anti-inflammatory and analgesic over-the-counter medications, and early return to work or activities. *(Annotation #5; Aim #3)*
- Patients with acute low back pain should be advised to stay active and continue ordinary daily activity. For chronic back pain, there is evidence that exercise therapy is effective. *(Annotations #10, 16; Aim #3)*
- Consult or refer to spine specialist if conservative treatment fails. *(Annotation #9)*

Related ICSI Scientific Documents

Guidelines

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

Algorithm Annotations

1. Patient Calls/Presents with Low Back Pain or Sciatica/ Radiculopathy

Key Points:

- Perform medical screening for low back pain via triage evaluation.
- If low back pain is possibly a work-related injury or workers' compensation claim, it is important to follow the Workers' Compensation Treatment Guidelines.
- Educate patient on preventive care.

Perform a medical screening via triage evaluation for phone contact and via provider examination for walk-ins. Each medical group may modify this proposed movement as needed.

The triage evaluation should first rule out emergent conditions such as Cauda Equina Syndrome.

Screening for low back pain:

- Recent back procedure or epidural anesthesia
- Location of pain:
  - Low back pain (does not radiate past the knee)
  - Radiculopathy (LBP with radiation past the knee)
- Duration of symptoms, including date of injury or onset of symptoms:
  - Six weeks or less is acute
  - More than six weeks is chronic
- If injury: How did injury occur?
- Severity of pain and degree of disability
- Other medical conditions
- History of previous back pain or surgery
- Psychosocial indications (See Appendix C, "Psychosocial Screening and Assessment Tools.")

For workers' compensation patients, check with state guidelines where the patient resides and where the injury took place: http://www.workerscompensation.com/workers_comp_by_state.php.

Patient Education Regarding Primary Prevention

Providers 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.

(Snook, 1988 [R])

For other patient education resources, please see the Resources Table section of this guideline.

2. Emergent or Urgent?

Emergent – Refer to ER for Immediate Evaluation

- Sudden onset or otherwise unexplained loss or changes in bowel or bladder control (retention or incontinence)
- Back pain secondary to trauma
- Sudden onset or otherwise unexplained bilateral leg weakness
- Saddle numbness

Urgent – Appointment within 24 Hours:

- Fever 38°C or 100.4°F for greater than 48 hours
- Unrelenting night pain or pain at rest
- Severe uncontrolled back or leg pain
- Progressive pain with distal (below the knee) numbness or weakness of leg(s)
- Progressive neurological deficit

If attempts to triage are unsuccessful and the patient still requests a same-day appointment, facilitate this if at all possible.

3. Evaluation Indicated?

Appointment within two to seven days **if the answer to any of the following is positive:**

- Back pain lasting longer than six weeks
- Unexplained weight loss (greater than 10 pounds in six months)
- Over age 50
- History of cancer
- Moderate to severe new onset back pain or leg pain

4. Initial Primary Care Evaluation

Key Points:

- Fear, financial problems, anger, depression, job dissatisfaction, family problems or stress can contribute to prolonged disability. The primary care evaluation includes a history and physical and consideration of psychosocial factors *(Chou, 2007b [M])*. See Appendices A-D for screening and assessment tools.
- Generally AP and LAT X rays are not helpful in the acute setting.

If a serious underlying disease such as cancer, Cauda Equina Syndrome, significant or progressive neurologic deficit, or other systemic illness is present, consult or refer.

Patient history includes:

Cancer risk factors:

- 50 years old or older
- History of cancer
- Unexplained weight loss
- Failure to improve after four to six weeks of conservative LBP therapy

If all four of the above risk factors for cancer are absent, studies suggest that cancer can be ruled out with 100% sensitivity.

Risk factors for possible spinal infection:

- IV drug use
- Immunosuppression
- Urinary infection
- History of turberculosis or active tuberculosis

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 are all common

Signs or symptoms of neurologic involvement:

- Complaint of numbness or weakness in the legs
- Lumbar radiculopathy – a clinical syndrome secondary to compression or irritation of the lumbar nerve root or ganglion. Symptoms most commonly consist of thigh or leg pain, and in varying degrees, sensory changes, weakness, reflex changes, dysesthesias and paresthesias.
- Upper lumbar nerve root involvement may be suggested when pain conforms to L2, L3 or L4 dermatomal distribution and is accompanied by anatomically congruent motor weakness or reflex changes. Because more than 95% of lumbar disc herniations occur at the L4-5 or L5-S1 levels, the neurologic exam should focus on the L5 and S1 nerve roots.

Psychosocial indications:

- Belief that pain and activity are harmful
- "Sickness behaviors," such as extended rest or symptom magnification
- 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
- Unwillingness to comply with treatment

Psychosocial indications can be barriers to recovery. Consider factors such as fear, financial problems, anger, depression, job dissatisfaction, family problems or stress, which can contribute to prolonged disability *(New Zealand Guideline Group, 2004 [R]; Fritz, 2001 [B]; Chan, 1993 [C]; Deyo, 1992 [R]; Bigos, 1991 [B]; Spitzer, 1987 [R])*. Provider may wish to consider using the PHQ2 at the intitial evaluation *(Kroenke, 2003 [C])*. Refer to the ICSI Major Depression in Adults in Primary Care guideline for more information.

For more information on psychosocial indications, see the New Zealand Acute Low Back Pain Guide: Encorporating the Guide to Assessing Psychosocial Yellow Flags in Acute Low Back Pain, 2003.

See Appendix C, "Psychosocial Screening and Assessment Tools."

Include in the physical examination:

- Palpation for spinal tenderness
- Posture, gait and range of motion
- Neuromuscular testing

  Strength testing

  - Ankle dorsiflexion strength (able to heel walk)
  - Great toe dorsiflexion strength
  - Plantar flexion (able to toe walk)
  - Hip flexors

  Reflex testing

  - Ankle and knee reflexes
  - Knee extension

  Sensory testing

  - A sensory exam to evaluate the medial, dorsal and lateral aspects of the foot and the medial and lateral calf.
- 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 [R])*. 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 only provide supporting evidence for a nerve root or discogenic pathology *(Supik, 1994 [C])*.

Surgical consultation is needed if significant or progressive neuromotor deficit is present.

Laboratory evaluation

Consider blood work if cancer or infection is suspected *(Deyo, 2001 [R])*.

Lumbar spine x-ray (AP and LAT views) "red flag" indications

Generally AP and LAT x-rays are *not* useful in the *acute* setting but *may* be warranted with:

- unrelenting night pain or pain at rest (increased incidence of clinically significant pathology),
- history of or suspicion of cancer (rule out metastatic disease),
- fever above 38°C (100.4°F) for greater than 48 hours,
- osteoporosis,
- other systemic diseases,
- chronic oral steroids,
- increased risk of fragility fracture (such as osteoporosis or 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, and
- drug or alcohol abuse (increased incidence of osteomyelitis, trauma, fracture).

Oblique view x-rays are not recommended; they add only minimal information in a small percentage of cases, and more than double the exposure to radiation.

Referral

Consider early referral (within 16 days) to physical therapy or another trained non-surgical spine specialist when the patient presents with severe incapacitating, disabling back or leg pain, or when there is significant limitation of functional or job activities *(Childs, 2004 [A])*. (See Annotation #12, "Reevaluate and Consider Redirection," and Annotation #22, "Discuss Options and Consider Possible Surgical or Non-Surgical Spine Specialist," for details on specialties and treatments.)

5. Home Self-Care Treatment Program

Key Points:

- Low back pain is common and most patients significantly improve in four to six weeks.
- The long-term course of low back pain is typically a return to previous activities.
- Reevaluate patient if there is not significant improvement in one to three weeks or if symptoms progress.
- Most patients who experience low back pain will have a recurrence within 12 months.
- Remaining active leads to a more rapid recovery with less chronic pain.
- Bed rest is not recommended.

If the patient has not been previously evaluated, attempt to differentiate between untreated acute pain and ongoing chronic pain. If a patient's pain has persisted for six weeks (or longer than the anticipated healing

time), a thorough evaluation for the cause of the chronic pain is warranted. See the ICSI Chronic Pain guideline for more information.

When patients are improving, they should continue self-care as outlined *(Chou, 2007b [M])*. Document the phone triage and home self-care treatment in the patient's medical record (e.g., no appointment is needed at this time, patient is improving with home self-care instructions and will call back if questions arise or condition changes).

Instruct the patient to do the following:

- Carefully introduce activities back into his or her day as he or she 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.
- Apply ice packs or heat as preferred on the sore area to keep the inflammation down, and short duration in a position of comfort may be helpful.
- Use over-the-counter anti-inflammatory medication (e.g., aspirin, ibuprofen, naproxen sodium) or acetaminophen to help ease the pain and swelling in the lower back. If stomach complaints persist, call your provider.
- Participate in activity that does not worsen symptoms.
- Identify and manage stressors.

Instruct the patient to call back if

- There is no improvement with home management in one to three weeks
- Pain or weakness worsens, progresses or persists beyond a week
- Bladder or bowel dysfunction develops
- Major weakness develops

Home Self-Care:

- Most patients who seek attention for their back pain will improve within two weeks. Most patients experience significant improvement within four weeks *(Atlas, 2001 [R])*.
- 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 [M]; Pengel, 2003 [M])*.
- Recommend cold packs or heat as preferred by the patient *(Nadler, 2002 [A])*.
- Muscle relaxants are sometimes helpful for a few days but can cause drowsiness *(Deyo, 2001 [R])*.
- Analgesic medication for short-term (less than three months) symptom control.
- Opioid analgesics are rarely indicated in the treatment of acute low back pain. There is insufficient evidence to support opioid use *(Chou, 2007a [M])*. If used, it should be for only short-term intervention (less than two weeks) and accompanied by a comprehensive treatment plan.
- Consider the risk and benefits of any medication and prescribe the lowest effective dose possible *(Nadler, 2002 [A]; Silverstein, 2000 [A]; Henry, 1996 [M])*.

- If the patient has been involved in home care and has had an adequate trial prior to the first visit, consider referral to a spine therapy professional after the initial visit *(Skargren, 1997 [A])*. (See Annotation #12, "Reevaluate and Consider Redirection.")

(Deyo, 1990 [R]; Spitzer, 1987 [R])

Activity recommendations:

Advise patients with acute low back pain to stay active and continue ordinary activity within the limits permitted by the pain. Remaining active leads to more rapid recovery with less chronic disability and fewer recurrent problems than either bed rest or back mobilizing exercises. *[Conclusion Grade I: See Conclusion Grading Worksheet A – Annotation #10 (Home Self-Care)]*

- Activity modification
  - Advise continued routine activity while paying attention to correct posture.
  - Patients with acute low back problems may be more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back, especially while lifting *(Hilde, 2002 [M]; Waddell, 1997 [M])*.
  - Consider the patient's age and general health, and the physical demands of the patient's job when recommending activity for the employed patient with acute low back symptoms *(Malmivaara, 1995 [A])*.
  - Recommend discontinuation any activity or exercise that causes spread of symptoms (peripheralization).
- Bed rest
  - Bed rest is not recommended *(New Zealand Guidelines Group, 2004 [R])*.
  - A gradual return to normal activities is more effective and leads to more rapid improvement with less chronic disability *(Little, 2001 [A]*.
- Exercise
  - Modify activity or exercise that causes spread of symptoms (peripheralization) *(New Zealand Guidelines Group, 2004 [R])*.
  - 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 *(Waddell, 1997 [M])*.
  - Recommend consultation with a non-surgical spine specialist, who can evaluate individual characteristics and symptoms and establish a specific exercise program *(Brennan, 2006 [A]; Hicks, 2005 [B]; Descarreaux, 2002 [A])*.

Self-care brochure (see Quality Improvement Support, "Resources Table"):

In general, brochures and information that place a greater emphasis on reducing fear and anxiety and promoting active self-management have a greater opportunity to improve outcomes than traditional brochures that emphasize anatomy, ergonomics and specific back exercises *(Little, 2001 [A]; Cherkin, 1998 [A])*.

Specific content recommendations include:

- Absence of serious disease is likely when "red flags" are not present.

- Hurt does not equal harm.
- There is a good prognosis for low back pain. The majority of patients experience significant improvements in two to four weeks *(Atlas, 2001 [R])*.
- Bed rest is not recommended and should be limited to no more than two days.
- Light activity will not further injure the spine, and light activity typically helps speed recovery.
- A progressive resumption of work and activity levels leads to better short-term and long-term outcomes.
- Information and advice may be helpful regarding specific painful or limited activities, such as sitting, lifting, getting up from bed.

Return to work:

- Tell 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 *(Von Korff, 1994 [R])*.
- All persons 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.
- Patients can reduce the likelihood of back pain recurrence by making exercise and lifestyle changes, as noted elsewhere.
- Consider using the following questions to guide your discussion about non-physical factors that can significantly impact risk for ongoing disability and return to work *(Bigos, 1992 [R])*:
  - Do you enjoy the tasks involved in your job?
  - Do you get along with your closest or immediate supervisor?

7. Continue Self-Care Program

When patients are improving, they should continue self-care as outlined in Annotation #5, "Home Self-Care Treatment Program." Reinforcement of the self-care program should occur.

8. Is a Serious Underlying Condition Revealed?

Key Point:

- If a serious underlying condition is revealed, refer the patient to the appropriate specialist.

Examples of serious conditions include cancer, Cauda Equina Syndrome, significant or progressive neurologic deficit or other systemic illness.

9. Consult or Refer

Complete a diagnostic workup or refer to the appropriate specialist for serious underlying conditions (e.g., cancer, other systemic illness, or neurological deficit). Each medical group may have other indications for specialty referral.

10. Has the Patient Failed Home Self-Care?

Key Points:

- It is important to evaluate non-physical factors that may impact returning to work or ongoing disability.
- The longer-term course of low back pain is typically of a return to previous activities, though often with incomplete recovery from pain.

Because most patients with acute pain improve by two weeks, a conservative treatment approach is recommended *(Atlas, 2001 [R])*. Advise low back pain patients who are not improving or who experience significant limitation of daily activity at home or work to contact their provider within one to three weeks of the initial evaluation *(Deyo, 2001 [R])*. Advise patients who are improving to continue home self-care.

Review and evaluate red flag and psychosocial indicators at each contact/visit *(New Zealand Guidelines Group, 2003 [R])*. At each visit, do an assessment that includes a subjective pain rating, functional assessment, and a clinician's objective assessment.

Patients who are improving to consider a follow-up with their provider. The benefit is to reinforce education and lifestyle changes that have enabled the patient to improve. This provides for outcome measures to be assessed as identified in the aims and measures sections of the guideline.

12. Reevaluate and Consider Redirection

Key Points:

- When low back pain is the primary complaint, request a non-surgical spine care specialist who demonstrates competency and interest in low back pain and in providing therapies based on continuing education and effective techniques supported by literature.

Choice of the trained professional will be determined by availability and preference of individual medical providers and organization systems. The patient and/or physician 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 manual/manipulative therapies *(Nytendo, 2000 [C]; Nytendo, 2001 [B])*. Participants should be in additional training and in ongoing continuing education courses in manual treatment of the spine. Individuals who may have training in these therapies include physical therapists, chiropractic providers, osteopathic or allopathic physicians.

Consider the following when selecting a non-surgical spine specialist who will effectively evaluate and treat the lumbar spine *(Spitzer, 1987 [R])*:

- Years of experience treating spine patients
- Volume of patients treated for spine dysfunction in the past year
- Number of referrals an individual provider receives on a regular basis
- Provides treatment interventions that include manipulation, exercise and education
- Average number of visits per episode of care for low back pain
- Percentage of patients who return to previous level of activity

Indications for referral include:

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

Include both education and exercise in treatment plans. The treatment plan may include modalities, if necessary, to enable an individual to carry out an exercise program and self-care. It may also include limited passive treatments such as manual therapy (e.g., includes manipulation and mobilization), among others *(Ottenbacher, 1995 [M]; Shekelle, 1992 [M])*. Spinal manipulation should not be done if premanipulative testing peripheralizes symptoms.

Minimize passive treatments and use them only to progress an individual toward independence in exercise and self-care. Active treatment such as exercise must be introduced within a week of initiating passive treatments.

There are no studies the work group is aware of regarding time frames. There is work group consensus on the following:

- Within four visits, the patient must display documented improvement in order to continue therapy. If no improvement is noted, a comprehensive re-evaluation should be performed by the spine care professional for other causes of low back pain, including regional SI joint dysfunction.
- Continued improvement must be documented for continued therapy. Typically no more than four to six visits are needed.
- Somewhere between 9 and 12 visits or between 4 and 6 weeks the patient should be reassessed.

14. Is Pain Chronic (Greater Than Six Weeks)?

A patient with "recurrent acute" episodes will continue a trial of conservative treatment when the current symptoms are six weeks or less from onset. "Recurrent acute" means symptoms at some point improved, separating the current episode from previous episodes. When the current symptoms are more than six weeks from onset, regard the patient as chronic and move to the corresponding sections of the algorithm (Annotation #18 and beyond).

If at initial evaluation the patient is identified as low back pain greater than six weeks see Annotation #15, "Chronic Low Back Pain," and for radiculopathy see Annotation #18, "Radiculopathy."

15. Chronic Low Back Pain

Comprehensive reevaluation, including a general assessment (see Annotation #4, "Initial Primary Care Evaluation"), should be done for patients not improving after six weeks. Most patients with acute back pain will improve within six weeks. Back pain and sciatica that persists longer than six weeks are defined as chronic.

An assessment that includes a subjective pain rating, functional assessment and a clinician's objective assessment should be done.

Psychosocial factors can contribute to prolonged disability as previously noted *(New Zealand Guidelines Group, 2003 [R]; Pincus, 2002 [M]; Fritz, 2001 [B]; Bigos, 1991 [B])*. See Appendix C, "Psychosocial Screening and Assessment Tools." See the ICSI Major Depression in Adults in Primary Care guideline for the diagnosis and treatment of depression.

For patients not improving after six weeks, see "Lumbar Spine X-Rays (AP and LAT views) If Indicated" in this annotation and Annotation #18, "Radiculopathy," for imaging considerations.

Of the 10% of patients with chronic symptoms, 90% fall into the chronic LBP category and only 10% fall into the chronic sciatica category.

Physical factors that may lead to delayed recovery or prolonged disability include malignancy, infection, metabolic or a bio-mechanical condition (e.g., sacroiliac joint dysfunction [SJD]) *(Dreyfuss, 1994 [C]; Riddle, 2002 [C]; Schwarzer, 1995 [D])*. Consider further evaluation for systematic problems.

If the patient is not better, consider other etiologies for low back pain such as:

- Fractures
- Spondylarthopathies
- Infection
- Tumor
- Abdominal/pelvic pathologies
- Other sites of origin for low back pain such as facet syndrome, piriformis syndrome, stenosis or claudication

Lumbar Spine X-Rays (AP and LAT Views) If Indicated

Patients with chronic LBP or acute low back pain who are not improving should be considered for further diagnostic testing. (See Annotation #4, "Initial Primary Care Evaluation.") Oblique view x-rays are not recommended; they add only minimal information in a small percentage of cases, and more than double the exposure to radiation *(Deyo, 1986 [C]; Liang, 1982 [M])*.

Several x-ray findings are of questionable clinical significance and may be unrelated to back pain. These findings include:

- Single disk space narrowing
- Spondylolysis
- Lumbarization
- Sacralization
- Schmorl nodes
- Spina bifida occulta
- Disk calcification
- Mild to moderate scoliosis

16. Active Rehabilitation

Key Points:

- There is strong evidence that exercise therapy is effective for chronic low back pain. However, there is inconclusive evidence in favor of one exercise over the other. *[Conclusion Grade I: See Conclusion Grading Worksheet B – Annotation #16 (Active Rehabilitation)]*.

High-grade mobilization/manipulation has been shown to be effective early in treatment when followed by appropriate active rehabilitation.

Include in the treatment of chronic low back pain:

- Written educational materials and advice by provider *(Burton, 1999 [A])*
- Active self-management
- Gradual resumption of normal light activities as tolerated
- Prevention – good body mechanics
- Exercise – many studies show the benefit of an exercise program with chronic low back pain
  - Inconclusive evidence in favor of one exercise over the other (flexion, extension or fitness) *(Abenhaim, 2000 [M]; Scheer, 1997 [M])*
  - Consider a graded active exercise program *(Lindstrom, 1992b [A])*
  - Consider specific exercises to strengthen the core trunk stabilizing muscles *(Lindstrom, 1992a [A])*
  - Consider intensive exercise program *(Manniche, 1988 [A])*
- Assess and manage psychosocial factors
- A multidisciplinary approach *(Hildebrandt, 1997 [D]; Pfingsten, 1997 [D])*

See also the ICSI Assessment and Management of Chronic Pain guideline.

18. Radiculopathy

Key Points:

- When indicated, MRI is the preferred diagnostic test to evaluate patients. CT myelography is a useful study in patients who have a contraindication or other reason for utilizing MRI.

See Annotation #15, "Chronic Low Back Pain," for a comprehensive physical and psychosocial evaluation, including a subjective pain assessment functional assessment and a clinician's objective assessment.

MRI or Lumbar Spine CT Imaging Indications

MRI and CT generally are not useful in the early evaluation and treatment of low back pain or radiculopathy unless the patient has major or progressive neurological symptoms, or there is a suspicion of cancer or infection. 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. (See Annotation #20, "Consider Epidural Steroid Injection Prior to Surgical Intervention.") Each medical group may have specific arrangements for ordering CT, MRI or other special diagnostic tests prior to referral to a surgical back specialist. See Appendix E, "General Guidelines for CT and MRI Order Sets for Adult Low Back Pain," for order set general guidelines.

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

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 [R]; American College of Radiology, 2006 [R]; Bischoff, 1993 [C]; Modic, 1986 [D])

The Adult 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.

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 [R]; Thornbury, 1993 [C]; Mazanec, 1991 [R])

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 D, "Upright and Positional Imaging," for more information.

20. Consider Epidural Steroid Injection Prior to Surgical Intervention

Key Points:

- Successful epidural steroid injections may allow patients to advance in a conservative treatment program.
- Perform epidural steroid injections under fluoroscopy or CT.

There is limited evidence for epidural steroid injections; therefore, it is important that outcome data be gathered in order to grow the evidence.

The goal of epidural steroid injections in patients with back and leg pain and symptomatic lumbar spinal stenosis or a herniated disc on MRI or CT is pain control and functional improvement. Several studies have shown that a single epidural injection affords short-term relief from pain *(Wilson-MacDonald, 2005 [M]; Cannon, 2000 [R]; Weiner, 1997 [D])* although in one randomized controlled trial, the steroid group seemed to experience a "rebound" phenomenon *(Karpinnen, 2001 [A])*.

There is limited evidence to support one or more epidural injections to control pain and advance appropriate conservative therapy in an attempt to avoid or decrease the incidence of surgical intervention. Buttermann reported on 169 patients who presented for surgical consult with a large disc herniation on MRI *(Buttermann, 2004 [A])*. Sixty-nine of these patients responded to a six-week non-invasive conservative therapy program. The remaining 100 were randomized to discectomy and epidural steroid injection therapy (ESI). The ESI group received multiple (one to three) injections performed with interlaminar approach at or above the level of the disc herniation, and 76% of these were performed with fluoroscopy and contrast. 46% of the ESI therapy group had good or excellent results and experienced the same decrease in pain as the discectomy group. 54% of the ESI group crossed over and underwent surgery at an average of one to three months. This crossover group suffered no adverse outcome as a result of this delay.

Wang, et al., studied 64 patients with symptomatic lumbar disc herniation on MRI and refractory symptoms who presented for surgery *(Wang, 2002 [D])*. They found that 77% of these patients avoided surgery with multiple fluoroscopically-guided contrast-enhanced transforaminal injections at the level of the herniation. Lutz, et al., Botwin, et al., and Vad, et al., in less rigorous studies, also reported a 75%-85% success rate with a multiple fluoroscopically-guided transforaminal injection regimens in patients with refractory radicular pain *(Botwin, 2002 [D]; Vad, 2002 [C]; Lutz, 1998 [D])*.

Riew, et al., in a prospective double-blinded and randomized study of 55 subjects, has shown that a series of injections – one to four over a period of weeks and months – can result in a decrease in the incidence of surgery *(Riew, 2000 [A])*.

A randomized study by Arden, et al., which enrolled 228 patients with sciatica, showed that up to three injections of lumbar epidural steroids (compared to sham treatment) showed a transient benefit at 3 weeks but not at 6 to 52 weeks, and there was no benefit of repeated epidural steroid injections over a single injection *(Arden, 2005 [A])*. The methods section of this paper does not indicate if the injection was done fluoroscopically or with contrast.

Based on limited data, the results appear promising. However, at this time there is insufficient evidence for the efficacy of epidural steroid injections. Only consider epidural steroid injections after initial appropriate conservative treatment program has failed. Successful epidural steroid injections may allow patients to advance in a conservative treatment program. Patients should be made aware of the general risks of short-term and long-term use of steroids.

Perform injections under fluoroscopy and with contrast in order to deliver cortisone as close to the disc herniation, area of stenosis, or nerve root impingement as determined by MRI or CT, and with as little morbidity as possible. In the case of stenosis, an adjacent segment or an alternative approach (interlaminar

versus transforaminal) may be needed to deliver medication to the appropriate level. Failure of treatment may result from a failure to deliver medications to the treatment field or clinical unresponsiveness to catabolic steroid preparations.

No study has shown a clear advantage of one approach (interlaminar, caudal or transforaminal), type of cortisone or volume of injectate *(McLain, 2005 [R]; Cannon, 2000 [R])*. Customize the approach to each patient.

Procedural morbidity also varies with each approach *(McLain, 2005 [R]; Cannon, 2000 [R])*. With interlaminar injections there is a risk of intrathecal injection and subsequent arachnoiditis, as well as post-procedural headaches. With transforaminal injections, patients frequently report significant – although in most cases transient – leg pain and there is a risk of spinal cord infarction when injected above L2 *(Somayaji, 2005 [D]; Tiso, 2004 [D]; Botwin, 2000 [D])*.

Patient selection

- Patients should predominantly have, complaints of radicular pain in the lower extremity in a distribution with or without corroborative examination findings for radiculopathy (reflex changes, possible motor weakness, and root tension signs). 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.
- Corroborative neural axis imaging is required, either MRI or CT, of disk disease or bony stenosis that fits with the clinical syndrome.
- Patients should have no contraindications to injection therapy, including:
  - No signs or symptoms of active infection either systemically or locally
  - No history of bleeding disorders or current use of anticoagulants such as warfarin or clopidogral; allow the patient to "drift" to the lowest effective INR prior to procedure
  - Anticoagulation guidelines:
    - Cervical procedure < 1.2 INR, Lumbar procedure < 1.4 INR
    - Clopidogrel, off one week; Ticlopidine, off two weeks; NSAIDS, no need to stop *(Horlocker, 2010 [R])*.
  - Patients with non-anaphylactic reaction to iodine based contrast may be pretreated with 20 mg IV clopidogrel, 4 mg IV dexamethazone, 50 mg IV diphenhydramine. Those with documented anaphylaxis to iodine based contrast can be treated with a non-iodine based contrast such as gadolinium *(Safriel, 2005 [D])*.
  - No allergies to local anesthetic agents, contrast agents, or corticosteroids
  - No prior complications to corticosteroid injections
- Pregnancy is a contraindication for 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.

22. Discuss Options and Consider Possible Surgical or Non-Surgical Spine Specialist

Key Points:

- The appearance of a disc herniation does not rule out a course of conservative therapy. Unless "red flag" indications are present, all patients should undergo a trial of conservative therapy.
- The decision to operate is a clinical decision based on the presence of severe, uncontrolled pain, profound or progressive neurological symptoms, or a failure to respond to conservative therapy.

Indications for specialty referral may include:

Non-surgical spine specialist

- Back pain for longer than six weeks
- Atypical chronic leg pain
- Chronic pain syndrome
- Rule out inflammatory arthopathy
- Rule out fibrositis/fibromyalgia
- Rule out metabolic bone disease (e.g., osteoporosis)

Surgical spine specialist

- Patient is a surgical candidate
- 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)
- Radiculopathy with positive SLR for longer than four to six weeks
- Uncontrolled pain

(Spitzer, 1987 [R])

Special diagnostic tests can be used to help clinicians decide the appropriate referral to a specialist. To decide which test, consult with subspecialty physicians.

Patients with large, extruded, sequestered or high-signal-intensity disc herniations do not have a worse prognosis than do patients with smaller contained disc herniations or protrusions. The presence of a disc extrusion or sequestration is not an indication for immediate surgery *(Deyo, 1990a [R]; Spitzer, 1987 [R]; Weber, 1983 [A])*.

- The appearance of a disc herniation on MRI/CT (including extruded/sequestered disc) does not determine whether an individual patient will respond to conservative therapy. Assuming that the patient's pain can be controlled and that no "red flags" or contraindications exist, all patients should undergo a trial of conservative therapy *(Henmi, 2002 [D]; Saal, 1996 [R])*.

- The decision to operate is a clinical one, not a radiologic one, and is generally based on the presence of severe, uncontrolled pain, profound or progressive neurological symptoms, or a failure to respond to conservative therapy *(Gundry, 1993 [D]; Bozzao, 1992 [D])*.
- Even though it was not discussed above, it is important to emphasize the concept that a disc herniation on MRI/CT is of relevance only with respect to specific clinical symptoms. Disc herniations can be seen in asymptomatic patients, and one can surmise from the literature quoted that if a patient's symptoms resolve and the disc herniations do not resolve, it will be present on the next examination *(Buttermann, 2002 [C]; Komori, 1996 [D]; Matsubara, 1995 [D])*.

See also the ICSI Assessment and Management of Chronic Pain guideline.

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 assessment and reassessment of patients age 18 and older with low back pain diagnosis. *(Annotations #1, 4, 15, 18)*

   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 physician *(composite measure)*:

      - Pain assessment
      - Functional status
      - Patient history, including notation of presence or absence of "red flags"
      - Assessment of prior treatment and response, and
      - Employment status
      - Psychosocial screening that includes depression and chemical dependency screening (ICSI)

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

      - Pain assessment
      - Functional assessment
      - Clinician's objective assessment, and
      - Psychosocial screening that includes depression and chemical dependency screening

2. Reduce unnecessary imaging for low back pain patients age 18 years and older in the absence of "red flag" indicators or progressive symptoms. *(Annotations #4, 18)*

   Measures for accomplishing this aim:

   a. Percentage of patients with new low back pain who received an imaging study (plain x-ray, MRI, CT scan) conducted on the episode start date or in the 28 days following the episode start date. *(NCQA)*

   b. Percentage of patients who received inappropriate repeat imaging studies in the absence of red flags or progressive symptoms (overuse measure, lower performance is better). *(NCQA)*

   c. Percentage of patients with a diagnosis of back pain for whom the physician ordered imaging studies during the six weeks after pain onset, in the absence of "red flags." (NCQA overuse measure, lower performance is better.)

3. Increase the use of recommended conservative approach as first-line treatment, such as activity, self-care and analgesics for patients age 18 and older with low back pain diagnosis. *(Annotation #5)*

   Measures for accomplishing this aim:

   a. Percentage of patients with medical record documentation that a physician advised them to maintain or resume normal activities. *(NCQA)*

   b. Percentage of patients with medical record documentation that a physician advised them against bed rest lasting four days or longer. *(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 returning to their primary care provider for one to three-week follow-up for reinforcement of treatment recommendations such as self-care, activity and analgesics.

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

Measurement Specifications

Measurement #1a

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

- Pain assessment
- Functional status
- Patient history, including notation of presence or absence of "red flags"
- Assessment of prior treatment and response
- Employment status
- 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

$$\frac{\text{\# of patients who have the six components completed at the initial visit}}{\text{\# of patients with acute low back pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients, 18 and over and low back pain diagnosis, seen in primary care and have following completed at the initial visit with the physician: 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) employment status and 6) psychosocial screening that includes depression and chemical dependency screening.

Denominator: Number of patients with diagnosis of acute low back pain

ICD-9 codes included in the denominator: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9.

Method/Source of Data Collection

Identify a sample of at least 30 patients with with ICD-9 codes: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9. Review records to determine whether the 6 components were completed at the initial visit with the physician. In the numerator include only the records that have all six components completed.

Time Frame Pertaining to Data Collection

The suggested time period is a calendar month; however, data collection can be done more frequently.

Notes

This measures is based on National Committee for Quality Assurance (NCQA) and ICSI Low Back Pain guideline work group recommendations.

This measure is a process and composite measure. All six components need to be completed to include in the measurement. Improvement is associated with a higher score.

Measurement #1b

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

- Pain assessment (subjective pain rating)
- Functional assessment
- Clinician's objective assessment, and
- Psychosocial screening that includes depression and chemical dependency screening

Population Definition

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

Data of Interest

$$\frac{\text{\# of patients who have the four components assessed at follow-up visit}}{\text{\# of patients with acute low back pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients, 18 and over and low back pain diagnosis, seen in primary care and have following assessed at follow visit with the physician: 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 through subjective pain rating.

** Functional assessment can be done with Oswestry Low Back Index.

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

ICD-9 codes included in the denominator: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9.

Method/Source of Data Collection

Identify a sample of at least 30 patients with with ICD-9 codes: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9. Review records to determine whether the four components were completed at follow up visits with the physician, if any follow up visits recorded. In the numerator include only the records that have all four components completed.

Time Frame Pertaining to Data Collection

The suggested time period is a calendar month; however, data collection can be done more frequently.

Notes

This measures is based on National Committee for Quality Assurance (NCQA) and ICSI Low Back Pain guideline work group recommendations.

This measure is a process and composite measure. All four components need to be completed to include in the measurement. Improvement is associated with a higher score.

Measurement #2c

Percentage of patients with a diagnosis of back pain for whom the physician ordered imaging studies during the six weeks after pain onset, in the absence of "red flag." (NCQA overuse measure; see notes below.)

Population Definition

Adult patients age 18 and over in primary care who have symptoms of acute low back pain or radiculopathy (see codes below).

Data of Interest

of patients with acute low back pain or radiculopathy receiving imaging studies (see definitions below)

# of patients with acute low back pain who present to clinic with low back pain six weeks or less from onset of pain without "red flag" indicators (see notes below)

Numerator/Denominator Definitions

Numerator: Acute low back pain patients receiving imaging studies AP or LAT x-ray, CT scan and MRI.

Denominator: Patients who are within six weeks of onset of low back pain, and related symptoms as identified by the following ICD-9 codes: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9.

Method/Source of Data Collection

Identify patients with acute low back pain using the above diagnosis codes. Patients should be included if the onset of symptoms was six weeks or less.

The medical record of each patient is reviewed to determine if the patient meets any of the "red flag" indicators. If none of the "red flag" indicators is present, the chart is further reviewed for use of AP or LAT x-ray, CT scan or MRI.

Time Frame Pertaining to Data Collection

The suggested time period is a calendar month.

Notes

MRI and CT generally are not useful in the early evaluation and treatment of low back pain or radiculopathy unless the patient has major or progressive neurological symptoms, or there is a suspicion of cancer or infection.

Generally AP and LAT x-rays are not useful in the acute setting but may be warranted with:

- unrelenting night pain or pain at rest (increased incidence of clinically significant pathology);
- history of or suspicion of cancer (rule out metastatic disease);
- fever above 38º (100.4º F) for greater than 48 hours;
- osteoporosis;
- other systemic diseases;

- chronic oral steroids;
- 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), and
- clinical suspicion of ankylosing spondylitis.

Other conditions that may warrant AP or LAT x-rays:

- Over 50 years old (increased risk of malignancy, compression fracture)
- Failure to respond after six weeks of conservative therapy
- Drug or alcohol abuse (increased incidence of osteomyelitis, trauma, fracture)

Measurement #3c

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

Population Definition

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

Data of Interest

$$\frac{\text{\# of patients who received low back pain education}}{\text{\# of patients with acute low back pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients, 18 and over and low back pain diagnosis, seen in primary care who receive education on low back pain self-care and the importance of maintaining an active lifestyle.

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

ICD-9 codes included in the denominator: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9.

Method/Source of Data Collection

Identify a sample of at least 30 patients with with ICD-9 codes: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9. Review records to determine whether patients received education on low back pain self-care and active lifestyle.

Time Frame Pertaining to Data Collection

The suggested time period is a calendar month; however data collection can be done more frequently.

Notes

This measure is a process measure. Improvement is associated with a higher score.

Measurement #3e

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

Population Definition

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

Data of Interest

$$\frac{\text{\# of patients who received recommendation to take anti-inflammatory or analgesic medication}}{\text{\# of patients with acute low back pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients, 18 and over and low back pain diagnosis, seen in primary care who receive recommendation to take anti-inflammatory or analgesic medication.

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

ICD-9 codes included in the denominator: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9.

Method/Source of Data Collection

Identify a sample of at least 30 patients with with ICD-9 codes: 720.x, 721.x, 722.x, 724.xx, 847.2, 738.4, 738.5, 738.6, 846.x, 847.2, 847.2, 847.3, 847.4, 847.9. Review records to determine whether patients received recommendation to take anti-inflammatory or analgesic medication.

Time Frame Pertaining to Data Collection

The suggested time period is a calendar month; however data collection can be done more frequently.

Notes

This measure is a process measure. Improvement is associated with a higher score.

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 Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are ***only*** available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Resources, go to http://www.icsi.org/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

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/
	MayoClinic.com	Consumer information on back pain. Topics include definition, causes, risk factors and other topics.	Patients and Families	http://www.mayoclinic.com
	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 entitled Handout or Health: Back. The booklet is for patients and families who have back pain and want to learn more about it.	Patients and Families	http://www.niams.nih.gov
*	Park Nicollet	Low Back Pain; brochure	Patients and Families	http://www.icsi.org/knowledge/ Listed under Patient Education Resources
	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
	Spine Universe in partnership with American Association of Neurological Surgeons, Scoliosis Research Society, AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, International Spinal Injection Society, National Association of Orthopaedic Nurses, National Pain Foundation	Internet-based network dedicated to dissemination of back pain information for clinicians and patients including education, consumer information community resources.	Health Care Professionals; Patients and Families	http://www.spineuniverse.com
	WebMD	WebMD provides services for physicians and consumers on clinical processes and education.	Health Care Professionals Patients and Families	http://www.webmd.com

* Available to ICSI members only.

The subdivisions of this section are:

- Conclusion Grading Worksheet Summary
  - Conclusion Grading Worksheets
- References
- Appendices

Conclusion Grading Worksheet Summary

<Delete page if no Conclusion Grading Worksheets>

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in the Foreword and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols **+**, **–**, **ø**, and **N/A** found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

– indicates that these issues have not been adequately addressed;

ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Conclusion Grading Worksheet A – Annotation #10 (Home Self-Care)

Work Group's Conclusion: Advise patients with acute low back pain to stay active and continue ordinary activity within the limits permitted by the pain. Remaining active leads to more rapid recovery with less chronic disability and fewer recurrent problems than either bed rest or back mobilizing exercises.

Conclusion Grade: I

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Lindström et al. (1992)	RCT	A	0	-Industrial blue-collar workers who were sick-listed 6 wks due to any low back pain diagnosis and no sick leave due to low back pain in the wks before the current episode (sub-acute); examined by orthopedic surgeon -Excluded: low back pain due to disk herniation, spondylolisthesis, stenosis, instability, previous back surgery, vertebral fracture, inflammatory diseases, pregnancy, defined medical or psychiatric diagnoses, drug abuse -After 8 wks of sick leave randomized to activity (evaluation by physical therapist and measurement of functional capacity, workplace visit, back school education, and individual submaximal graded exercise program with goal of returning to work) or control -Both groups evaluated by orthopedic surgeon, social worker and physical therapist at one year	-96% follow-up at 1 year (see NOTES) -No differences at baseline in age, range of motion, forward bending pain, pain behavior, or disability -After treatment (vs. baseline) - activity group improved in spinal mobility (modified Schober, backward bending, lumbar range of motion, rotation, & active leg-lift); strength (arm, back muscle endurance, & lifting capacity); and cardiovascular fitness (all p<0.01) -At one year (vs. baseline) - activity group improved in spinal mobility (finger-floor distance, modified Schober, & lumbar range of motion), strength (abdominal endurance time & lifting capacity), and cardiovascular fitness (all p<0.01) -At one year activity group had greater spinal mobility (modified Schober, backward bending, lumbar range of motion, lateral bend, rotation), greater strength (abdominal muscle endurance, back muscle endurance, & several lifting tasks), and greater cardiovascular fitness (all p<0.01) -Number of sick days before return to work correlated with activity group pre-treatment spinal rotation (r=–0.47), abdominal muscle endurance (r=–0.45), and lifting capacity (r=–0.58) -Activity group returned to work significantly earlier than control group (10 wks vs. 15.1 wks) (p value not reported)	-The graded activity program improved mobility, strength and fitness in the activity group before return to work. The program proved to be a successful method of regaining occupational function and facilitating return to work in patients with sub-acute (8 wks) low back pain. NOTES: no specific number of weeks for activity program; patients continually encouraged to return to work; 2 patients in activity group did not participate in exercise program and did not attend 1-yr follow-up but returned to work after 15 and 29 days; 3 patients in control group did not attend 1-yr follow-up (2 returned to work at 13 and 59 days; one did not return to work)

Author/Year	Design Type	Class	Quality +, –, Ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Faas, Chavannes, van Eijk, & Gubbels (1993)	RCT	A	Ø	-473 patients with new back pain episode who consulted general practitioner -Included: pain between T12 and gluteal folds with or without radiation to upper leg, pain for ≤3 wks, age 16 to 65 -Excluded: radiation of pain below knee, signs of nerve root compression or neurologic deficit, pain caused by trauma, back pain episode within past 2 mos, previous back surgery, suspicion of malignancy or other disease, pelvic obliquity >1.5 cm, gibbus >1 cm, pregnancy -All received standard info. from physician; randomized to usual care, placebo ultrasound or exercise (physician was blinded to treatment group assignment) -Paracetamol given (1st month) - Follow-up at 2 wks, 4 wks and 12 mos; monthly questionnaires -Usual care was information and analgesics on demand -Placebo was lowest possible dose ultrasonography, 20 min, 2x per wk for 5 wks -Exercise was individual instruction 20 min, 2x per wk for 5 wks; 8 exercises and 7 pieces of advice for daily living; advised to repeat daily	-Visual analog pain scale for pain at that moment and maximum pain (previous month); functional health status questionnaire for perceived health (6 dimensions) & influence of perceived health on 7 areas (for condition at that moment and previous month) -Primary outcomes - number and duration of pain episodes and recurrences, change in functional status, mobility problems, and influence on daily life -Groups were comparable at baseline -60 dropped - equal numbers per group, no differences in reasons for or time of dropping out -Did intention to treat analysis, on treatment analysis, and best cases analysis -During treatment 118 of 156 (76%) in exercise group complied as did 145 of 162 (90%) in placebo group; at 3 months 82% of patients said they did exercises in last 2 months and at 12 months this was 54%; 50% stated they had done exercises for ≥7 mos; 50% stated they had applied advice for ≥7 mos -322 had ≥1 recurrence (mean of 1.6 per patient) Usual Care Placebo Exercise Mean duration of pain 57 days 54 days 58 days Duration of recurrence 53 days 41 days 45 days* *p=0.02 vs. usual care No effect modification and no differences with on treatment or best cases analyses -Pain, mobility problems and tiredness improved for all 3 groups; exercise group was significantly different from usual care on tiredness during 1st 3 mos and on emotional problems during the 1st month -No differences between groups on mobility problems, influence on daily life, or between follow-up consultations with physician; more physiotherapy referrals in the usual care group (not significant)	-No positive effects of exercise therapy could be shown on the number of recurrences, functional health status, perceived problems in daily life, and on medical care usage -Since exercise group did not differ from placebo group, positive benefits are a result of the physiotherapist's attention to patient -Patients referred to physiotherapist or to back school receive a lot of needless, expensive attention for complaints that in most cases would have disappeared spontaneously; too much attention to condition is undesirable -Exercise therapy should not be recommended for nonspecific acute back pain *Work Group's Comments:* *-Did sample size estimation* *-Data was mostly self-reported* *-There was lower use of therapy and analgesics in exercise group* *-Little information on other activities (e.g., occupational) of patients*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Malmivaara, Häkkinen, Aro, et al. (1995)	RCT	A	0	-Municipal employees presenting with low back pain as main symptom (acute or exacerbations of chronic pain lasting <3 wks) -Included pain radiating below knee -Excluded: sciatic syndrome, pregnant, history of cancer, lumbar spine fracture, urinary tract disease -Baseline and outcomes researchers were unaware of treatment -Randomized to bed rest (2 days), exercise (1 session of instruction with exercises to be done at home every other hour during the day until pain subsided), or control (usual activities within limits due to pain) -Follow-up visits: 3 and 12 wks -Economic analysis at 12 wks - use and costs of health care services and help at home	-186 were randomized (67 to bed rest, 52 to exercise, 67 to usual activity); 3 wk follow-up from 165 (89%) and 12 wk follow-up from 162 (87%); no baseline differences between those with follow-up and those lost to follow-up -Groups were similar at baseline except more engaged in heavy physical work in control group, more with pain below the knee in bed rest group, and more with prolonged pain in last 12 months in exercise group -Compliance data: Bed Rest Exercise Control Daytime bed rest (hr) 22 5 2 Exercise sessions (#) 8 61 3 Prescribed drugs (%) 93 91 93 -Significant outcomes at 3 wks: Control group had fewer sick days and higher subjective rating of ability to work than bed rest group; control group had fewer sick days, shorter duration of pain, and better back-disability index score than exercise group -Significant outcomes at 12 wks: Control group had fewer sick days, lower intensity of pain, better lumbar flexion, and better back-disability index score than bed rest group; control group had fewer sick days and better lumbar flexion than exercise group -Visits to doctors were more frequent in exercise group than control group but no other significant differences in costs or use of services	-Avoiding bed rest and maintaining ordinary activity as tolerated lead to the most rapid recovery NOTES: was not possible for health care personnel to remain completely unaware of treatment assignments; degree of satisfaction with treatment did not differ among the three groups; compliance was adequate but may have been overestimated (self-report) *Work Group's Comments:* *-Did sample size estimation* *-Occupational health setting*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Ljunggren, Weber, Kogstad, Thom, & Kirkesola (1997)	RCT	A	–	-Patients with "back problems" referred to physiotherapy by general practitioners -All were occupationally active, ages 18-65 years, history of back problems -Excluded patients for whom any of the exercises was contraindicated including root affections, spinal stenosis, spondylolysis, inflammatory rheumatic diseases -Randomized to 2 treatment groups: physiotherapist-designed exercise program (PT) or program on a TerapiMaster apparatus (TM) -Instructed by a therapist and followed for 6 wks (4 telephone contacts and 4 personal visits) -Asked to exercise for 15-30 min 3X per wk; 9 exercises with 3 series of 10 repetitions of each; weights were added if appropriate	-Recorded absenteeism from work, amount of exercise and satisfaction with exercise program -153 were enrolled, 126 (82%) completed the supervised part of the study (6 weeks), 103 (67%) completed the unsupervised part of the study (12 months) -Baseline: difference in gender distribution between the 2 groups (more males in PT program, more females in TM program); height and weight were greater in the PT group; more absenteeism in past 12 months in the PT group (82.5 days vs. 61.6 days, NS); more previous back episodes in TM group (84% vs. 69%, NS); more sick leave in last 12 months in PT group (88% vs. 68%, NS); more on sick leave at inclusion in TM group (27% vs. 14%, NS) -Significant reduction in absenteeism was observed from 82.5 days to 5.7 days (over 12 months unsupervised study) for the PT group and from 61.6 days to 5.6 days for the TM group; non-significant difference between groups -Compliance and patient satisfaction equally good in both groups; amount of exercise and patient satisfaction both decreased during the unsupervised part of the study (compared to the supervised part)	-There is no difference between the 2 exercise programs with regard to their effectiveness in the treatment of back problems NOTES: need more attention to exercise compliance; frequent follow-ups by physiotherapists are probably a prerequisite for good compliance; did not standardize exercise regimens because the ability to tolerate exercises was not uniform among participants; exercises were tailored to individual's strength, endurance, fitness *Work Group's Comments:* *-69% of the patients in the conventional training group and 84% in the TerapiMaster group had previous back episodes resulting in absenteeism* *-There were differences between groups at baseline that, although not significant, were substantial*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Skargren, Öberg, Carlsson, & Gade (1997)	RCT	A	–	-Patients with low back or neck pain referred for treatment from primary care -Included those with no active treatment for low back or neck pain within the past month and no contraindication to manipulation -Excluded those with affected nerve root, osteopenia, suspected infection, another disease, involved in accident in past 10 days, pregnancy, treatments considered irrelevant -Randomized to chiropractic (CP) care or physiotherapy (PT)	-219 randomized to CP and 192 to PT; 179 in CP and 144 in PT participated (323 total) -Assessed pain (intensity, frequency, use of pain killers), function (sick leave, low back pain disability questionnaire), and general health; patients expectations of treatment, fulfillment of expectations, and treatment efficacy; direct and indirect costs -Baseline: PT group reported greater pain intensity ($p \leq 0.05$) and worse general health ($p \leq 0.01$) -CP group received primarily manipulation; PT group received variety of treatments; mean number of sessions during treatment period was higher for PT group (6.4 vs. 4.9, $p \leq 0.001$); all had completed treatment before 6 month follow-up questionnaire -After treatment 13% of CP group and 4% of PT group went back for follow-up visit; 13% of CP group received additional PT treatment and 6% of PT group received CP; the PT group received mean of 7.9 treatment sessions (combined PT and CP) with 7.0 for the CP group -20% of patients in both group used additional health services during treatment; during follow-up additional services were used by 37% of the CP group and 30% of the PT group -No complications due to treatment were reported -Highly significant improvement in pain, function, and general health related to the back or neck problems immediately after treatment and at 6 months (no difference between groups) -Equal numbers of patients reported recurrence -41% of CP group and 24% of PT group reported that treatment fulfilled their expectations ($p<0.01$) -No differences in direct or indirect costs	-No difference in outcome or costs between the 2 groups was identified, nor in subgroups defined as duration, history, or severity of symptoms. *Work Group's Comments:* *-There was no "control" group (i.e., no treatment or usual care)* *-No distinction was made between patients with low back pain and those with neck pain* *-Patients were asked to complete questionnaire and contact therapist themselves - 76 never contacted therapist or withdrew before 1st treatment and 12 withdrew after first treatment*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Waddell, Feder, Lewis (1997)	Systematic Review	M	0	-Reviewed all randomized controlled trials of bed rest and or medical advice to stay active for acute back pain -Included trials where main symptom was back pain of up to 3 months duration, all trials of bed rest, trials where the intervention or control was either bed rest or advice on maintaining normal activity levels, subjects ≥18 yrs -Assessed methodological quality (2 independent reviewers)	-10 trials of bed rest and 8 trials of advice to stay active (2 compared bed rest and advice to stay active and were included in both reviews) -5 of 10 trials of bed rest had methodology score >50% as did 6 of 8 trials of advice to stay active -8 of 10 trials of bed rest showed that bed rest was not effective; 1 of the other trials used young male army recruits in tightly controlled setting and the other compared bed rest with continuous traction vs. bed rest with sham traction and didn't address effect of bed rest itself -8 of 8 trials of advice to stay active showed positive outcomes (with different outcome measures); no evidence of any harmful effect or increased recurrences with early activity -2 trials compared advice to stay active with bed rest and found faster recovery with ordinary activity	-Multiple trials show that bed rest is not an effective treatment but may delay recovery -Advice to stay active and to continue ordinary activity as normally as possible is likely to give faster return to work, less chronic disability, and fewer recurrent problems NOTES: difficult to identify all relevant studies due to indexing in databases; quality of trials was "reasonable" - small sample sizes, insufficient info. about randomization and co-interventions, unblinded assessment of outcomes and no intention-to-treat analysis are limitations
Underwood & Morgan (1998)	RCT	A	–	-Patients with back pain in a general practice -Included: pain for <28 days at time treatment would be given, symptom-free for ≥28 days before this episode, pain from 12th thoracic vert. to buttock folds, ages 16-70, bilateral pain, no peripheralization of pain with 10 repeated extension exercises in standing position -Excluded: inflammatory joint disease, metastases or infection, spondylolisthesis, neurological deficit, osteoporosis, pregnancy, visceral pathology with pain referred to lower back, previous trial entry, intention to seek treatment elsewhere -All patients received general advice about treating back pain -Randomized to intervention (appointment with and group teaching session on McKenzie technique) or control -Questionnaires at 1, 2, 4, 8, 12, and 52 weeks	-Outcomes were Oswestry Low Back Disability Score, visual analog scale for pain, use of pain killers, other therapies, days of back pain over previous 6 months (52 wk questionnaire only) -78 referred for assessment, 3 subsequently excluded (didn't meet eligibility requirements) -35 randomized to treatment of which 32 (91%) attended; both groups returned 84% of possible follow-up questionnaires -Baseline: control group was more likely to have taken pain killers in previous 24 hours ($p<0.03$); control group had higher scores for disability and pain (NS) -No significant differences between groups in numbers of patients with a "good" outcome on the disability score or pain score at any point in study -No differences in proportions reporting they were unable to work at any point in study -At one year more of treated patients recorded that their backs had been no problem to them in preceding 6 months ($p<0.007$) -Number of back pain consultations was same for both groups with more consultations for conditions other than back pain in the control group ($p<0.01$)	-Early intervention with a small class teaching McKenzie back extension exercises did not reduce long-term disability -There was a suggestion that more of the treatment group were free of back problems at 1 year NOTES: goal was 50 subjects per group but this was not achieved because potentially eligible patients were not always referred for assessment and later in study period some patients who would have been eligible had already been included *Work Group's Comments:* *-84% overall return rate on questionnaires (for both groups)*

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Hides et al. (2001)	RCT	A	0	-39 patients; ages 18-45 yrs; males & females; first episode of unilateral mechanical low back pain (<3 wks) -Randomized to 1) Control (medical management with advice on bed rest, absence from work, prescription of medication, and advice to resume normal activity or 2) Specific Exercise (same as Control plus specific localized exercises for multifidus -4 wk intervention; exercise 2x/wk -Assessment: McGill Pain Questionnaire, Visual Analog Scale (pain), Roland Morris Disability Index, range of motion, habitual activity levels, muscle cross-sectional area (with ultrasound) -Telephone interview for 1- and 3-year follow-up of recurrence of low back pain	-19 in control group; 20 in specific exercise group -Groups comparable at baseline in age, gender distribution, height, weight, duration of symptoms, smokers, workers' compensation, pre-morbid activity levels -Weeks 1-4: multifidus size was recovered more completely in the exercise group at 4 wks and at 10 wks ($p<0.01$); pain and disability had completely resolved in 90% of patients (2 groups similar) -39 responses (100%) at 1 yr; 36 (92%) at 3 yrs -Control group 12.4 times more likely to experience recurrences of low back pain (84% vs. 30%; $p<0.001$) in 1st year after initial episode and 9 times more likely in years 2-3 ($p<0.01$) -19% of control group reported traumatic incidence related to recurrence in 1st yr (vs. 67% of exercise group) -Treatment sought by 42% of control group and 15% of the exercise group during 1st yr	-Subjects with acute, first-episode low back pain who received specific exercise therapy in addition to medical management and resumption of normal activity experienced fewer recurrences of low back pain in the long-term than subjects who received medical management only and resumed normal activity. NOTES: assessors were blinded to group allocation and patient presentation; complete short-term results presented in another report

Author/Year	Design Type	Class	Quality +,–,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Little et al. (2001)	RCT	A	–	-Consecutive patients seeking treatment for new low back pain episode (duration less than 3 months or exacerbation of chronic low back pain) -Excluded: stable chronic back pain; age <16 or >80; dementia or other major psychiatric illness; progressive or multilevel neurologic deficit; cauda equina, previous history of cancer or prolonged use of oral steroids, pregnancy, inability to walk 50 yds -Randomized to control, educational booklet, exercise advice, booklet and exercise advice -All groups told to keep as mobile as possible; exercise group told to aim for regular exercise (20 minutes at least 3 times/wk); booklet had information on anatomy, self-management, exercise advice, practical tips for activities of daily living -Pain and function assessed by telephone at 1 wk and 3 wks after entry; questionnaire (for pain, function, satisfaction, and knowledge) given to patients to return after 1 wk	-78 randomized to control group, 81 to booklet, 75 to exercise advice, and 77 to booklet + exercise -Follow-up on 239 patients (59 control, 81 booklet, 61 exercise, 56 booklet + exercise) -Pain/Function score reduced by 8.7% in booklet group (p=0.05), 7.9% in exercise group (p=0.08), and 0.1% in booklet + exercise group; at 3 wks mean changes were 6.3%, 1.4%, and 4.0%, respectively (no differences between groups) -Aberdeen scale results were similar - lower in booklet group (p=0.06) and exercise group (p=0.01) but not booklet + exercise group -No differences in percentage of patients reporting "back to normal" -Overall satisfaction improved by booklet (p=0.02) and advice to exercise (p=0.03); booklet improved satisfaction with amount of information (p=0.003) and content of information (p=0.005) but not with visit or management of back pain; exercise advice improved satisfaction with management of back pain (p=0.03), amount of information (p=0.02), and content of information (p=0.03) -Knowledge was higher for those receiving booklet or booklet and advice than those in control group or advice-alone group	-Advice to exercise or a booklet is likely to increase satisfaction and make modest changes to pain and function, over and above advice to mobilize and use simple analgesia, during the first week after seeking treatment for back pain. It may not be helpful to provide a detailed information booklet and advice together. NOTES: of 315 eligible, 311 participated; assessment was blinded; sample size estimation; combined pain/function score was validated for this study; Aberdeen pain and function scale also used *Work Group's Comments: included both acute and chronic cases; analysis was not by intention-to-treat*

Conclusion Grading Worksheet B – Annotation #16 (Active Rehabilitation)

Work Group's Conclusion: There is strong evidence that exercise therapy is effective for chronic low back pain. However, there is inconclusive evidence in favor of one exercise over the other.

Conclusion Grade: I

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Nelson, O'Reilly, Miller, Hogan, Wegner, & Kelly (1995)	Case Series	D	–	-Patients referred for rehabilitation -Ages 14 to 65 years -Patients had tried an average of 6 different treatments; 89% had failed a "supervised exercise program" -Testing and rehabilitation using a lumbar-extension machine and a torso-rotation machine; average of 2x per wk for 1 hr (also did aerobic exercise and other muscle strengthening) -Watched videos, learned body mechanics and read literature -Given home program and exercise device at end of program -Treatment ended when patient was pain-free (or nearly) and near normal function level, no longer making objective gains, or refused to cooperate or give good effort -Did isometric and dynamic testing, rated back and/or leg pain, rated functional ability -Follow-up questionnaire at 7 to 18 months after discharge	-895 referred: 627 completed program, 107 recommended for inclusion but didn't enroll (control group), 161 began but dropped out -Average of 18 visits -Improvements in static strength ($p<0.001$), sagittal range of motion (17%, $p<0.001$), dynamic strength (sagittal and rotational planes, $p<0.001$) -602 listed low back pain as a significant complaint at baseline; 64% of patients reported substantial decrease in perception of pain (with 12% unchanged, 3% worse) -429 listed leg pain as a significant complaint at baseline; 62% of patients reported substantial decrease in pain (with 13% unchanged, 2% worse) -Correlation between isometric strength and change in low back pain was low ($r=0.32$) -Overall response to treatments was graded as excellent by 46%, good by 30%, fair by 14%, and poor by 8% (excellent or good indicated both substantial pain relief and substantial strength improvement) -Results did not differ for subgroups based on diagnosis; psychosocial factors did affect results with fewer excellent or good results in workers' compensation and/or litigation cases -Data from 495 (79%) of patients at average of 13 months: of those with good or excellent initial results 94% maintained improvement; of those with initial fair or poor results 25% improved -53% reported using home exercise device -Greater utilization of health care system by the control group ($p<0.001$); control group also was less likely to have gotten lasting relief from treatment ($p<0.001$); groups were similar in percent employed	-Data support the use of specific intensive exercise for chronic back pain patients (regardless of underlying condition); program was successful even though majority had previously tried some form of exercise NOTES: control group is not a true control group because selection was not random and treatment was not controlled; possible selection bias in that patients were referred to program; average cost (including all physician fees and home equipment) was $2250 *Work Group's Comments:* *-161 dropped out; data from 122 of those who dropped (76%) indicated that 41% felt the program wasn't helping (authors noted that improvements were often noted only after several weeks of exercise)* *-No indication of what percent were judged to have completed program based on the three criteria* *-It is not clear how many patients rated the overall response to treatment*
Scheer, Watanabe, & Radack (1997)	Systematic Review	M	0	-Literature search from 1975-1993 -Review of RCTs with concurrent controlled subjects that included return-to-work (RTW) outcomes -Used 26-point abstraction system for methodologic rigor -Identified 4 dealing with exercise and chronic low back pain	-2 of the 4 studies were of too low quality to permit inferences on vocational effects -1 of the studies included too few subjects missing work -1 of the studies had an inexplicably prolonged effect over 1 year from only 4 weeks of individualized exercise	-Could not draw conclusions for the value of exercise from such a limited group of studies

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
van Tulder, Koes, & Bouter (1997)	Systematic Review	M	+	-Literature search through 1995 -Included trials: true RCTs, treatment included therapeutic interventions selected for study (including exercise), results concerned acute or chronic low back pain, and article was published in English -Chronic pain was pain persisting for ≥12 wks -Used 100-point methodologic evaluation (2 reviewers)	-Positive studies: Intervention was more effective than reference treatment with regard to at least one important outcome measure -Negative studies: Intervention was no different from or less effective than the reference treatment on at least one important outcome measure -No conclusion if intervention was more effective on one outcome measure but less effective on another -16 RCTs pertaining to exercise and chronic low back pain; methodologic scores ranged from 24 to 61 (3 >50) -8 had positive outcomes (including the 3 with scores >50; see Deyo et al., Hansen et al., & Manniche et al., below) and 8 had negative outcomes	-There is strong evidence that exercise therapy is effective for chronic low back pain. -There is no evidence in favor of one of the exercise programs due to the contradictory results.

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Deyo, Walsh, Martin, Schoenfeld, & Ramamurthy (1990)	RCT	A	0	-Patients (18-70 yrs old) with low back pain ≥3 mos duration; recruit via newspaper advertisement -Excluded: history of cancer, use of corticosteroids or anticoagulants, max. pain above T-12, use of pacemaker, heart disease, severe coexisting disease, previously unevaluated neurologic deficit, previous TENS use, those seeking or receiving disability compensation; also excluded for factors that would impair follow-up -Randomized to 4 groups: TENS + exercise, TENS only, exercise + sham TENS, sham TENS only; other treatments were uniform -Monitored compliance -TENS: conventional high-freq. for 2 wks, instruction in acupuncture-like TENS, self-selected mode for final 2 wks (same instructions given to sham TENS group) -Exercise: 12 sequential exercises-relaxation and flexibility -Interventions for 4 wks; visits 2x per wk for heat treatment, adjustment of TENS electrodes and advice on posture for various activities; home heating pads were used 2x per day for 10 min	-543 responded to advertisement; 145 were enrolled and randomized; 20 (14%) dropped out by 4 wk assessment; 23 (16%) dropped by 2 months after treatment -Assessment: Physical exams and questionnaires at baseline, after 2 and 4 wks of therapy, and 2 months after end of treatment; included functional status, pain ratings, physical measures, and use of medical services -Baseline: Differences between groups in proportion with neurologic deficit and previous hospitalization -Blinding: 100% of the true TENS groups guessed that their TENS unit was functioning properly; 84% of sham TENS groups guessed the TENS unit was functioning properly but their degree of certainty was less -Compliance: Found to be "good" for true TENS, sham TENS, exercise, study visits (mean of 7.2 out of 8 visits) and use of heating pads -Therapeutic Outcomes: All four groups showed significant improvement that progressed from week 2 to week 4 but returned toward baseline at 2 months after treatment; no significant differences in outcomes at 4 weeks between true TENS and sham TENS groups; self-rated activity level, self-rated improvement in pain, visual-analog scale improvement in pain, and frequency of pain were all significantly better ($p<0.05$) in the exercise group than in the no-exercise group; at 2 months after treatment there were no significant treatment effects -Side Effect: 1/3 of TENS subjects reported minor skin irritation at site of electrodes; one had severe dermatitis that required discontinuation of treatment	-There was no apparent benefit of TENS. -There appear to be modest subjective benefits from stretching exercises but few short-term effects on actual behavior. -Treatment with TENS is no more effective than treatment with placebo and TENS adds no apparent benefit to that of exercise alone NOTES: Protocol provided for all patients to have equal time and attention from the research staff; most patients reported moderate or mild pain with previous medical care for low back pain *Work Group's Comments:* *-Analysis was not by intention-to-treat* *-Sample sizes per group were <35 each*

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Hansen, Bendix, Skov, et al. (1993)	RCT	A	0	-Patients ages 21-64 with chronic (current episode of pain lasting 3 mos) or subchronic (≥4 wks with at least 2 pain episodes per month for past year) pain -Excluded those with specific disease (e.g., spondylolisthesis, root compression), collagenosis, osteoporosis, previous spinal fusion, neuromuscular disease of the trunk, malignant disease, uncompensated hypertension, pregnancy or lactation, any disease or malfunction that would hinder treatment -Randomized (blocking on 8 variables) to: a. intensive dynamic back-muscle training (DYN) - 3 exercises, 300 total contractions per session b. standard physical therapy (PT) - standard program (exercises, counseling) plus individual program c. placebo-control (CTRL) - hot packs, traction -All treatments were 1 hour, 2x per wk for 4 weeks	-180 were randomized, 11 never started treatment, 19 dropped out during treatment and 13 dropped out during follow-up period; post-treatment evaluation of 150, 1-month evaluation of 146, 6-month evaluation of 143, 12-month evaluation of 137 (76% of those randomized) -Pain: All groups showed significant ($p<0.01$) reduction in pain (for those completing all follow-ups); both groups responded well to PT ($p<0.01$ for males and $p=0.02$ for females); males also responded to CTRL ($p<0.01$); females also responded to DYN ($p<0.01$); those with moderate/heavy work occupations responded to all treatments ($p\leq 0.05$), those with sedentary/light work occupations responded to DYN & PT ($p\leq 0.01$) -Overall Treatment Effect (self-assessment on visual-analog scale): No significant differences between DYN and PT but both were significantly more effective than CTRL ($p<0.01$) -Functional Status: number of days with pain during the 1-yr observation period was reduced in all treatment groups compared to the 1 yr prior to treatment; no differences between groups	-Patients were successfully treated with PT and DYN; those in the control group had less successful therapy results -There were differences between males and females; DYN had a negative effect for men compared to other treatments; females had a better response to DYN than to placebo -Those with lighter job functions responded better to DYN than those with moderate/hard job functions (who responded better to PT) NOTE: All patients were employed in the Scandinavian Airline System (SAS); pain level in those who were randomized but did not complete treatment was significantly higher than for those who did complete treatment ($p=0.03$) *Work Group's Comments:* *-Analysis was not by intention-to-treat* *-No report of compliance with treatment*

Author/Year	Design Type	Class	Quality +, –, 0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Manniche, Bentzen, Hesselsoe, Christensen, & Lundberg (1988) AND Manniche, Lundberg, Christensen, Bentzen, & Hesselsoe (1991)	RCT	A	0	-Patients with chronic low back pain were referred -Included: chronic low back pain at rest or associated with back strain for ≥ 12 mos; acute pain ≥ 3x in past 6 mos with or without sciatica, ages 20-70; radiological exam of lumbar spine in last 2 yrs -Excluded: evidence of root pressure, spondylolysis, painful hip arthrosis, osteomalacia of spine, malignant disease with poor prognosis, inflammatory disease of joints, mental illness, somatic disease that might interfere with training, inability to cooperate -Randomized to: A. hot compresses, massage, isometric exercises for lumbar spine; 8 sessions over 1 month then no treatment for 2 months B. placebo with modified back strengthening (same exercises as C but 20 reps); 30 sessions over 3 months C. Intensive back strengthening with 3 exercises each done 100 times; 30 sessions over 3 months	-Of 140 referred, 105 were randomized -Measured pain, disability, and physical impairment at baseline, end of treatment (3 months), and 6 months after start of treatment (1988 study); included 1-year follow-up of selected components (1991 study) -Qualitative Assessment (after treatment): more responders (satisfactory evaluation) for group C than group A ($p<0.00005$) or group B ($p<0.05$) with no difference between A and B ($p=0.08$) -Quantitative Assessment (low back pain rating scale): group C was superior both at end of treatment and at 3 months after treatment; scores improved from baseline for groups B and C but not A; at 1 year, those who continued with intensive exercise had a significantly better outcome than those who did not continue; group was also significantly better than group A and tended to be better than group B -Subjective outcome was highly correlated ($r=0.75$) with quantitative outcomes -15 of 105 randomized dropped out before end of treatment and were not included in the statistical tests; if the 6 who dropped because of side effects were assigned the poorest qualitative outcome and included in the analysis, the results would not change	-The results consistently favored intensive exercise. -The intensive exercise regimen was safe with a low frequency of side effects requiring withdrawal (6 patients total, 1 in group A, 3 in group B, and 2 in group C) -Intensive back training ought to continue in a longer and continuous course if lasting result is desired. Notes: The duration of exercise treatment may explain why this study found pronounced differences between groups; cannot say which exercises account for the benefit seen *Work Group's Comments:* *-Analysis was not by intention-to-treat* *-Compliance was not reported except that those who were absent more than 30% were to have been excluded* *-1-year follow-up was done by mail*

Author/Year	Design Type	Class	Quality +,−,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Pfingsten, Hildebrandt, Leibing, Franz, & Saur (1997)	Case Series	D	0	-90 chronic low back pain patients admitted to 8-wk outpatient program: 3 wks of preprogram (education, stretching and calisthenics for 4 hours/day 3x per wk) and 5 wks of intensive treatment (aerobic, functional strength and endurance exercises, back school, cognitive behavioral therapy, relaxation training, vocational counseling for 7 hours/day) -Monitored pain, treatments, time off work, strength and range of motion, depression, disability, coping -Assessed at end of program and 6 and 12 months later	-Significant ($p<0.001$) improvements from baseline in flexibility, strength and endurance -Significant reductions ($p<0.001$) in pain, disability and depression -56/90 (62%) reported significant reduction in subjective pain intensity after program (others had unchanged or greater pain) -"Catastrophizing" and "search for information" (coping activities) were both significantly reduced by 6 months after treatment -42% reduction in use of analgesics; significant reduction in consultation of physicians and physiotherapists in the year following discharge from the program ($p<0.001$) -60% rated the program's success as good or very good, 32% as moderate, and 6% as a complete failure -Probability of a return to work was most likely when patients (prior to treatment) had not applied for pension, had positive outlook concerning return to work, and were not out of work for more than 6 mos -Return to work was more likely if treatment resulted in reduced disability and reduced depression	-Combined functional and psychological treatment resulted in significant improvements among patients. The results were generally maintained at the 6 and 12 month evaluations. Biographical and medical data and a patient's previous medical history did not appear to have an impact on therapeutic success. NOTE: no control group and therefore cannot determine if outcome results were a result of treatment procedures, confounding variables, or the influence of time; cannot differentiate between various forms of treatment
Hildebrandt, Pfingsten, Saur, & Jansen (1997)	Case Series	D	0	-Same as Pfingsten et al. (above) -Continued identification of factors related to treatment success	-A subjective reduction in pain intensity is more likely if a patient has not already applied for a pension, absence from work is <6 mos, previous hospital treatments for back pain were short, patients underwent fewer medical consultations, and patients demonstrated improved performance of trunk extension -Reduction in pain intensity is more likely if disability can be reduced and better trunk flexion and leg press performances are achieved -A subjective rating of successful treatment is more likely if medical consultations were infrequent, overall trunk flexibility was greater, and coping with the disease was less catastrophizing before treatment -A favorable estimation of success was more likely if disability was reduced	-The most important variable in determining a successful treatment of chronic low back pain is the reduction of subjective feelings of disability; physical variables had only limited predictive value

Author/Year	Design Type	Class	Quality +,–,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Frost, Lamb, Klaber Moffet, Fairbank, Moser (1998)	RCT	A	0	-Patients referred to a hospital orthopaedic outpatient dept. -Included: 18-55 years old, mechanical low back pain for ≥6 mos, able to travel independently, medically fit -Excluded: constant or persistent severe back pain due to nerve root irritation, other musculoskeletal disabilities, systemic conditions, major surgery within last year, spondylolisthesis, fractures, physiotherapy in last 3 mos, engaged in moderately strenuous sporting activities at least 2x/wk for last 6 mos, pregnant -Randomly allocated to treatment (back school, advice to carry out specified exercises at home, invitation to attend fitness program) or control (back school and home exercises) -Fitness program was 8 sessions of 1 hr (over 4 wk period); consisted of warm-up, stretching, 15 progressive exercises, aerobic exercise, relaxation -Advised to do home exercises 2x per day; back school was two 90-minute sessions -Assessed at baseline, 6 weeks and 2 years after intervention	-Oswestry Low Back Pain Disability Index (questionnaire) to assess limitations of daily activities -81 patients were recruited, 10 (5 in each group) failed to comply with protocol -86% attendance rate for patients randomized to fitness group; at 6 wks 12 changed from control to treatment group -At 2 yrs, 19 did not complete follow-up (76% response rate) -Treatment and control groups did not differ at baseline -Disability index (% where lower score=less disability), n=31 per group: Baseline 2 years Treatment Group 23.1 15.4 Control Group 24.9 22.5 Difference between groups was significant ($p<0.04$)	-A general, non-specific fitness program designed for patients with chronic low back pain had beneficial outcomes. Patients were supervised and exercising in groups which were likely to help improve their motivation and compliance. -It is most likely that the specific exercises themselves are not as important as the general philosophy of encouraging normal movement without unduly stressing the spine. NOTES: more variables were assessed at baseline (weren't able to assess at follow-up); limited sample size; many patients were not available for follow-up; did not measure adherence to home exercise program; results may be due to supervised exercise program or to affect of additional treatment sessions *Work Group's Comments:* *-Questionnaire was administered in person at baseline and through the mail at follow-up* *-Did not do a true intention-to-treat analysis*
Abenhaim et al. for the Paris Task Force (2000)	Systematic Review	M	0	-Literature search from 1966-1997; reference lists from review articles; personal knowledge of the research (unpublished data) -Evaluated 150 (of 1,141 relevant abstracts) randomized trials, other studies with control groups and case series; 47 articles selected based on epidemiologic methodology and clinical significance -Chronic low back pain defined as >12 wks	-10 randomized trials pertaining to chronic low back pain; variety of exercise programs studied; duration of 4 weeks to 3 months -7 studies found active management superior to control* in range of motion, strength, pain, functional status, stamina -2 studies found exercise no better than control -1 study compared TENS + exercise with placebo TENS + exercise and found no difference *control group not clearly defined in one study	-There is sufficient scientific evidence to support the prescription of physical, therapeutic, or recreational exercise in cases of chronic low back pain except for pain radiating to a precise and entire leg dermatome. No technique has been shown to be clearly superior but there is evidence that programs should combine strength training, stretching and/or fitness. NOTES: also developed recommendations pertaining to activities of daily living and occupational tasks; chronic studies included Deyo et al (1990), Manniche et al. (1991) & Frost et al. (post-tx data) (1998)

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Appendix A – Roland-Morris Disability Questionnaire

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: at www.rmdq.org.

Appendix B – Physical Functional Ability Questionnaire (FAQ5)

A validation study is currently underway for this tool. At this time, work group consensus was to include it as an example due to lack of other validated and easy to use functional assessment tools available for low back pain.

Name: _____

Date: _____

Date of Birth: _____

MR #: _____

Instructions: Circle the number (1-4) in each of the groups which best summarizes your ability.

Add the numbers and multiply by 5 for total score out of 100.

Self-care ability assessment

1. Require total care – for bathing, toilet, dressing, moving and eating
2. Require frequent assistance
3. Require occasional assistance
4. Independent with self-care

Family and social ability assessment

1. Unable to perform any – chores, hobbies, driving, sex and social activities
2. Able to perform some
3. Able to perform many
4. Able to perform all

Get up and go ability assessment

1. Able to get up and walk with assistance, unable to climb stairs
2. Able to get up and walk independently, able to climb one flight of stairs
3. Able to walk short distances and climb more than one flight of stairs
4. Able to walk long distances and climb stairs without difficulty

Lifting ability assessment

1. Able to lift up to 10# occasionally
2. Able to lift up to 20# occasionally
3. Able to lift up to 50# occasionally
4. Able to lift over 50# occasionally

Work ability assessment

1. Unable to do any work
2. Able to work part-time **and** with physical limitations
3. Able to work part-time **or** with physical limitations
4. Able to perform normal work

Physical Functional Ability Score (FAQ5)

Appendix C – Psychosocial Screening and Assessment Tools

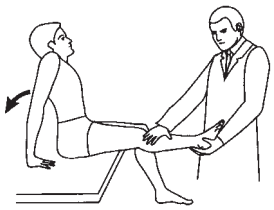
The screening and assessment tools noted below may help identify psychosocial factors for prolonged disability and chronic pain. Treat **OR** refer to the appropriate mental health professional if indicated.

Waddell's Signs

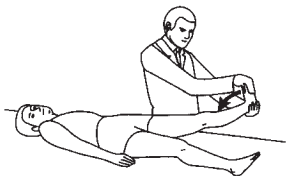
Waddell's Signs assess the possibility of psychological distress or malingering or both by testing the consistency and reproducibility of patient responses to non-organic physical signs. Waddell demonstrates that when three of five tests are positive, there is a high probability of non-organic pathology. 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 LBP 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 LBP 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 (see Annotation #4, "Primary Care Evaluation"). 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."

Straight leg raising



Sitting



Supine

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 [C])

DSM-IV TR Diagnosis Criteria for Depression

Consider psychosocial factors. For a diagnosis of a major depressive episode, at least five of the symptoms listed below must be present nearly every day for at least two weeks and represent a change from previous functioning. At least one of the symptoms must be either be depressed mood or loss of interest or pleasure.

1. Depressed mood
2. Markedly diminished interest or pleasure in all or almost all activities
3. Significant (greater than 5% body weight) weight loss or gain or decrease or increase in appetite
4. Insomnia or hypersomnia
5. Psychomotor agitation or retardation
6. Fatigue or loss of energy
7. Feeling of worthlessness or inappropriate guilt
8. Diminished concentration or indecisiveness
9. Recurrent thoughts of death or suicide

Modified Work APGAR (Adaptation, Partnership, Growth, Affection and Resolve)

	Almost always	Some of the time	Hardly ever
1. I am satisfied that I can turn to a fellow worker for help when something is troubling me.	❑	❑	❑
2. I am satisfied with the way my fellow workers talk things over with me and share problems with me.	❑	❑	❑
3. I am satisfied that my fellow workers accept and support my new ideas or thoughts.	❑	❑	❑
4. I am satisfied with the way my fellow workers respond to my emotions, such as anger, sorrow or laughter.	❑	❑	❑
5. I am satisfied with the way my fellow workers and I share time together.	❑	❑	❑
*6. I enjoy the tasks involved in my job.	❑	❑	❑
*7. Please check the column that indicates how well you get along with your closest or immediate supervisor.	❑	❑	❑

* Modified Work APGAR score assesses job task enjoyment. A low score means that patient rarely enjoys job tasks. Negative responses often indicate a higher risk of chronic back pain/disability. Items 1-5 may be omitted. Items 6 and 7 usually are the most predictive for prolonged disability in low back pain patients.

Used with permission from *Spine* 1991,16:1-6, "A prosective study of work perceptions and psychosocial factors affecting the report of back injury" by Bigos SJ, Battie MC, Spengler DM, et al.

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?

Appendix D – Upright and Positional Imaging

Open Upright 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 [C])*. 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 [D])*.

Zander, et al. noted significant dynamic changes in 33 of 210 patients with back pain, radiculopathy or neurogenic claudication who underwent functional myelography and 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 [D])*. Similar findings were reported in other studies *(Sortland, 1997 [D]; Ping, 1994 [D]; Wilmink, 1983 [D])*.

Axial loaded MRI. Several studies have reported on the presence of additional findings on patients who have undergone MRI, CTM or CT with axial loading applied to simulate weight bearing *(Manenti, 2003 [D]; Danielson, 1998 [D]; Willen, 1997 [D])*. 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 [D])*.

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 [D])*. 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 [D])*.

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 [D])*.

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 [D])*.

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 [D])*.

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 [D])*.

Appendix E – General Guidelines for CT and MRI Order Sets for Adult Low Back Pain

The primary purpose of the initial order sheet is to provide patient identification and the exam requested. Secondary purposes are to provide clinical information to support the appropriateness of the request and to assist the radiologist in the interpretation of the exam. Information on the initial order should assist the radiology department to determine whether the patient has contraindications to the exam or special needs, and to prompt the radiology department to address these needs prior to the patient's appointment.

The initial order sheet should include:

I. Patient Info
   a. Name
   b. Gender
   c. Birth date
   d. Weight and height
   e. Contact information

II. Physician information
   a. Requesting provider
   b. Primary caregiver
   c. Clinic or hospital
   d. Contact information including telephone number and fax.

III. Exam requested from list of offered studies

IV. Insurance information, workers' comp, auto, etc.

V. Clinical symptoms such as
   a. Pain, severity and location (pain diagram is very useful but is easier to obtain on the clinical information form filled out by the patient on check-in; VAS would also be very useful on intake)
   b. Neurogenic intermittent claudication
   c. Neurologic loss
   d. Weakness or difficulty walking
   e. Urinary or fecal incontinence
   f. Functional limitations: e.g., work status, difficulty caring for oneself (Oswestry score would also be very useful to obtain at patient check-in and may be required for future appropriateness reviews)

VI. Suspected diagnosis such as
   a. discogenic pain
   b. disc herniation
   c. stenosis

VII. Response to and duration of prior conservative care

- a. Chiropractic care
- b. Physical therapy
- c. Oral medications

VIII. Relevant history

- a. History and date of previous injury
- b. Prior imaging of the area in question
- c. History of prior surgery in the examined area
- d. Red flags including
  - i. history of trauma
  - ii. IV drug abuse
  - iii. immunosuppression
  - iv. long-term steroid use
  - v. cancer
- e. Claustrophobia
- f. Contraindications to contrast including
  - i. history of renal failure
  - ii. diabetes
  - iii. allergy to iodine or contrast

IX. Special requests

- a. Sedation for claustrophobia, pain control or pediatric imaging
- b. Transportation assistance
- c. Image delivery
  - i. films
  - ii. copy with patient
  - iii. CD-Rom
  - iv. electronic only

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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.

Document Development and Revision Process

The development process is based on a number of long-proven approaches. ICSI staff first conducts a literature search to identify pertinent clinical trials, meta-analysis, systematic reviews, regulatory statements and other professional guidelines. The literature is reviewed and graded based on the ICSI Evidence Grading System.

ICSI facilitators identify gaps between current and optimal practices. The work group uses this information to develop or revise the clinical flow and algorithm, drafting of annotations and identification of the literature citations. ICSI staff reviews existing regulatory and standard measures and drafts outcome and process measures for work group consideration. The work group gives consideration to the importance of changing systems and physician behavior so that outcomes such as health status, patient and provider satisfaction, and cost/utilization are maximized.

Medical groups, who are members of ICSI, review each guideline as part of the revision process. The medical groups provide feedback on new literature, identify areas needing clarification, offer recommended changes, outline successful implementation strategies and list barriers to implementation. A summary of the feedback from all medical groups is provided to the guideline work group for use in the revision of the guideline.

Implementation Recommendations and Measures

Each guideline includes implementation strategies related to key clinical recommendations. In addition, ICSI offers guideline-derived measures. Assisted by measurement consultants on the guideline development work group, ICSI's measures flow from each guideline's clinical recommendations and implementation strategies. Most regulatory and publicly reported measures are included but, more importantly, measures are recommended to assist medical groups with implementation; thus, both process and outcomes measures are offered.

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.

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 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.