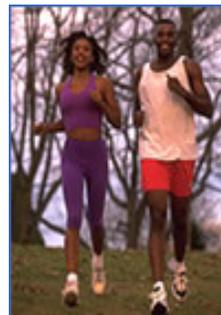


Low Back Pain Clinical Improvement Team

Final Report *January 2007*





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Low Back Pain Clinical Improvement Team Executive Summary – December 2006

The Puget Sound Health Alliance's Low Back Pain Clinical Improvement Team (CIT) was convened in March 2006 to: (1) identify standardized clinical guidelines and performance measures, and (2) identify practical strategies to influence preferences, choices, and processes regarding appropriate prevention, treatment and self-management of low back pain.

Low back pain was identified as a high priority condition, since it is a leading cause of work-related disability and workers' compensation for people under age 45, affecting about two-thirds of all adults at some point in time. Even though initial episodes of acute low back pain are likely to improve within six weeks without medical intervention, a substantial portion of people with low back pain will go on to have more persistent back problems. Medical costs associated with back pain are in excess of \$25 billion per year, and employers face huge costs in lost productivity and disability payments. In the early 1990s, the U.S. had the highest rate of spine surgery of all industrialized nations, with a rate five times that of Great Britain.

The Low Back Pain CIT consisted of community members, representing clinical specialists, complementary and alternative medicine practitioners, patients, purchasers, health plans, and clinical researchers. The members met six times from March through October of 2006. The Low Back Pain CIT chose to limit its focus to acute axial low back pain without radiculopathy, with an emphasis on preventing acute pain from becoming chronic. The CIT's recommendations do not apply to more serious conditions that are indicated by certain "red flags." The CIT chose to focus its work on working-age adults who are commercially insured who receive services or care for low-back pain in outpatient settings, with an emphasis on primary care.

The CIT chose not to endorse a specific clinical guideline for low back pain, as many are not up-to-date for the primary management of back pain. However, the proposed National Committee for Quality Assurance (NCQA) Spine Care Recognition Program was identified as a high quality *framework* for the CIT's recommended performance measures and change strategies. Once finalized, the proposed NCQA Spine Care Recognition Program will likely be regarded as a high quality set of standards and measures.

The CIT members agreed on several quality improvement recommendations for providers and patients, which are consistent with a conservative

approach to the treatment of low back pain during the first six weeks. The CIT's recommendations for improvement fall into two categories: (a) treatment of low back pain during the first six weeks, and (b) preventing acute back pain from becoming chronic.

Recommendations for the treatment of low back pain during the first six weeks include:

1. All patients presenting with low back pain should have a complete assessment to determine whether there are any red flag conditions.
2. In the absence of red flag conditions, patients should be thoroughly assessed for history of back pain and responsiveness to therapy during any previous episodes.
3. In the absence of red flag conditions, imaging should not be done during the first six weeks following the onset of acute axial low back pain.
4. Surgery in the first six weeks in the absence of red flags or progressive symptoms is not recommended.
5. Generally, providers should follow a conservative approach to treatment of low back pain during the first six weeks (when red flag conditions are not present), with the goal of preventing re-injury.

Recommendations for preventing acute back pain from becoming chronic include:

1. Providers should assess all patients with low back pain for emotional status and work-life issues, provide reassurance to reduce fear and anxiety, and promote active self-management.
2. In the absence of red flag conditions, bed rest is not recommended and patients should be advised to remain active, returning to normal activity as soon as possible.
3. Patients with back pain who smoke should be assisted with smoking cessation.
4. Patients with low back pain should be assessed for functional status, using commonly available tests (such as the SF-36 or SF-12 Health Survey).

The CIT agreed upon the use of two clinical performance measures to determine the rates of unnecessary imaging and unnecessary surgery within six weeks after the first visit. In order to remain consistent with national efforts, the Alliance will initially use the corresponding NCQA-HEDIS measures in the performance reports.

The Back Pain CIT concluded its work by developing specific change strategies and tools to guide stakeholders in implementing the recommendations. The CIT agreed that preventing unnecessary imaging would have one of the largest impacts on improving the quality and reducing the cost of back pain management.



Low Back Pain Clinical Improvement Team Final Report – December 2006

I. Background

In December 2003, King County Executive Ron Sims convened a broad-based leadership group, *The King County Health Advisory Task Force*, to develop an integrated strategy to address the systemic problems facing the health care system in the Puget Sound region. In particular, Executive Sims requested that the Task Force focus on three inter-related issues: the increase in health care costs for employees and employer purchasers, quality of care, and the importance of improving the health of the community.¹

The Task Force described the current system of health care as a “series of disconnected strategies all working concurrently but without a system steward, or neutral leader, to coordinate them and ensure that they are achieving the optimal mix of cost, quality, and health outcomes.”¹ As part of their recommendation to develop an integrated strategy, the Task Force advised creating a regional partnership to provide the necessary leadership to forge changes in the existing system.

The Puget Sound Health Alliance (the Alliance) was created to fill this role, with the bold vision to develop a state-of-the-art health care system that provides better care at a more affordable cost, resulting in healthier people in the Puget Sound Region. Its mission is to build a strong alliance among patients, doctors and other health care providers, hospitals, employers and health plans to promote health and improve quality and affordability by reducing overuse, under-use and misuse of health services.

The Alliance, in existence since 2005, has developed an extensive membership of providers, employer/purchasers, hospitals, health care associations, health plans and individual consumers in a five county region in northwest Washington composed of Snohomish, King, Kitsap, Pierce and Thurston counties.

¹ King County Health Advisory Task Force Final Report, June 2004 [Accessed online November 7, 2006, <http://www.pugetsoundhealthalliance.org/about/documents/KCTaskForceReport.pdf>]

The Alliance and its participants support the use of evidence to identify, measure, and report on the quality, cost, and patient experience in local health care. The Alliance will identify and recommend practical strategies to change preferences, choices, and processes regarding appropriate prevention, treatment and self-management of chronic diseases. The changes that the Alliance will recommend are intended to align incentives so that everyone involved -- patients, employers and other purchasers, providers, hospitals, health plans, and companies that produce or offer health care services or products -- is more likely to engage in activities that promote good health, reduce waste, and improve the affordability of health care.

At the June 2005 Alliance Board meeting there was consensus among Board members that the Alliance would initially focus on four conditions: heart disease, diabetes, low back pain and depression. Later, prescription drugs was added as a fifth area of focus. Clinical Improvement Teams (CITs) for each clinical priority have been formed. The CITs report to the Quality Improvement Committee and develop recommendations to the Board on evidence-based guidelines, performance metrics and measurement approaches, and implementation strategies for quality improvement in each area.

II. Defining the Problem: Low Back Pain

A. General

Low back pain is a leading cause of work-related disability and workers' compensation for people under age 45, affecting about two-thirds of all adults at some point in time.² Low back pain commonly occurs between the ages of 35 to 55.³ Unlike conditions such as diabetes or heart disease, back pain is not a condition with one or two specific causes and a well-defined set of signs and symptoms. Low back pain may be caused by systemic conditions such as osteoporosis, cancer, or anatomic problems such as fracture, but the vast majority of low back pain cannot be identified as having a single pathophysiologic cause. Such nonspecific back pain occurs in approximately 85 percent of patients with back pain.⁴

The human response to pain is to seek relief and to try to fix the condition causing the problem. There are now available numerous technologies and procedures to locate, diagnose and treat a wide variety of problems, and practitioners are expected to use any available resource and the newest technology to relieve the pain and fix the problem. However, there is evidence

² Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370. [Andersson GBJ. Epidemiologic features of chronic low back pain. *Lancet*. 1999;354:581-585.]

³ Koes B and van Tulder M. Low back pain (acute). *Clin Evid Concise* 2006; 15:416-418.

⁴ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

that approximately 90 percent of nonspecific low back pain improves within six weeks without medical intervention or management.⁵

Even though initial episodes of acute back pain are likely to improve, a substantial portion of people with low back pain will go on to have more persistent back problems, chronic recurrences, or continuous pain of varying or constant intensity.^{6,7} These recurrences of acute back pain are estimated to affect 40 percent of patients within six months⁸ and 50 to 80 percent of patients within one year.⁹ While only two to seven percent of acute back pain sufferers actually develop chronic pain,¹⁰ recurrences of acute pain may lead patients to perceive that they have a chronic condition, analogous to asthma, which will continue indefinitely without intervention.¹¹ Many patients expect that every available resource and new technology ought to be used and these expectations have led to an overuse of available resources and high costs.

Back pain is the most expensive cause of work-related disability.¹² The medical costs associated with back pain are in excess of \$25 billion per year, and employers also face huge costs in lost productivity and disability payments.¹³ Low back pain costs \$50 billion to as high as \$100 billion annually in direct medical and indirect costs.¹⁴

Patients with back pain seek relief from a wide variety of practitioners, including primary care physicians, surgeons, physical therapists, chiropractors, osteopaths, and others. Similarly, treatments for low back pain vary widely and include but are not limited to spinal mobilization, exercise, massage, acupuncture, ergonomics, and electromyographic biofeedback. Because of the wide range of providers and therapies available for the management of back pain, programs aimed at educating consumers, promoting consistency in the delivery of back pain-related care, and promoting quality care are difficult to plan and administer.

Traditionally the emphasis has been on determining the pathophysiology or systemic cause of a patient's back pain, usually with the use of imaging tests. However, studies have shown that many of the abnormalities shown on imaging tests and previously thought to be the cause of patients' back pain

⁵ Koes B and van Tulder M. Low back pain (acute). *Cin Evid Concise* 2006; 15:416-418.

⁶ Croft PR, Macfarlane GJ, Papageorgiou AC, Thomas E, Silman AJ. Outcome of low back pain in general practice: a prospective study. *BMJ*. 1998 May 2;316(7141):1356-9.

⁷ Von Korff M. Studying the natural history of back pain. *Spine*. 1994 Sep 15;19(18 Suppl):2041S-2046S.

⁸ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

⁹ Koes B and van Tulder M. Low back pain (acute). *Cin Evid Concise* 2006;15:416-418.

¹⁰ Koes B and van Tulder M. Low back pain (acute). *Cin Evid Concise* 2006;15:416-418.

¹¹ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

¹² Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370. [Andersson GBJ. Epidemiologic features of chronic low back pain. *Lancet*. 1999;354:581-585.]

¹³ Frymoyer JW, Cats-Baril WL. *Orthop Clin North Am*. 1991 Apr;22(2):263-71.

¹⁴ Frymoyer JW, Cats-Baril WL. *Orthop Clin North Am*. 1991 Apr;22(2):263-71.

(such as annular tears and disc bulges) are in fact common findings in individuals without low back pain.^{15,16,17} While some anatomic findings, such as moderate to severe central stenosis, nerve root compression, and disc extrusions, are likely associated with current pain, studies have found that factors such as depression are more important predictors of new back pain than many of the anatomic abnormalities found on imaging tests.¹⁸

In the early 1990s, the U.S. had the highest rate of spine surgery of all industrialized nations with a rate five times that of Great Britain.¹⁹ Spine surgery has increased steadily during the past decade, and Medicare spending for inpatient spine surgery has more than doubled during that time.²⁰ Though spending for lumbar discectomy and laminectomy declined by more than 10 percent, spending for lumbar fusions increased more than 500 percent during the past decade, reaching \$482 million in 2003. In 1992, lumbar fusions accounted for 14 percent of total spending for spine surgery; by 2003, they represented 47 percent.²¹

B. Washington State

The prevalence of back pain and its associated costs in Washington are difficult to determine as back pain has no consistent presentation and cause. Non-work-related back pain is not a reportable condition, nor is there a registry of patients with back pain.

For work-related injuries, surveillance data from the Washington State Department of Labor and Industries for 1995-2003 show that, of the 354,770 State Fund accepted claims for work-related musculoskeletal disorders of the neck, back and upper extremity, 52.6 percent were claims for back disorders.²²

¹⁵ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

¹⁶ Jordan J, Konstantinou K, Morgan TS, Weinstein J. Herniated lumbar disk. *Clin Evid Concise* 2006;15:405-408. <http://www.aafp.org/afp/20060401/bjm.html>

¹⁷ Patel AT and Ogle AA. Diagnosis and management of acute low back pain. *Am Fam Physician* 2000;61:1779-1786,1789-1790. <http://www.aafp.org/afp/20000315/1779.html>

¹⁸ Jarvik JG, Hollingworth W, Heagerty PJ, Haynor DR, Boyko EJ, Deyo RA. Three-year incidence of low back pain in an initially asymptomatic cohort: Clinical and imaging risk factors. *Spine* 2005;30(13):1541-1548.

¹⁹ Cherkin DC, Sherman KJ, Deyo RA, Shekelle PG. A Review of the Evidence for the Effectiveness, Safety, and Cost of Acupuncture, Massage Therapy, and Spinal Manipulation for Back Pain. *Ann Intern Med.* 2003;138(11):898-906.

²⁰ Dartmouth atlas of health care. Spine surgery: A report by the Dartmouth Atlas of Health Care CMS-FDA Collaborative. http://www.dartmouthatlas.org/atlas/Spine_Surgery_2006.pdf

²¹ Dartmouth atlas of health care. Spine surgery: A report by the Dartmouth Atlas of Health Care CMS-FDA Collaborative. http://www.dartmouthatlas.org/atlas/Spine_Surgery_2006.pdf

²² Silverstein B and Adams D. Work-related musculoskeletal disorders of the neck, back, and upper extremity in Washington state, 1995-2003. Technical Report Number 40-9-2005. SHARP Program, Washington State Department of Labor and Industries. December 2005 <http://www.lni.wa.gov/Safety/Research/Files/WmsdSummary2005.pdf>

State and local spine surgery rates are available through the Dartmouth Atlas Project which provides ongoing population-based monitoring of rates in the fee-for-service Medicare population.²³ The Dartmouth Atlas Project (DAP) focuses on data collected by the Centers for Medicare and Medicaid Services (CMS) for every person and provider using Medicare health insurance, a uniform national claims database available for research purposes. There is no counterpart to this database for the commercially insured population. However, similar studies done by the DAP using state all-payer data in Pennsylvania and Virginia, and Blue Cross Blue Shield data in Michigan, have shown similar variations among the under-65 population.²⁴

Dartmouth Atlas Project data show that there is considerable regional variation in surgery rates. The national average rate of spine surgery was 4.0 per 1,000 in 2003, ranging from 1.6 per 1,000 enrollees to 9.4. Washington had the 14th highest back surgery rate of all states and the District of Columbia, with a back surgery rate of 4.85 per 1,000 Medicare enrollees.²⁵ The Seattle Hospital region had a spine surgery rate of 4.27 per 1,000 Medicare enrollees compared to a U.S. rate of 3.97. Seattle's lumbar discectomy/laminectomy rate per 1,000 Medicare enrollees was 2.66 compared to a U.S. rate of 2.13, while the lumbar fusion rate was 0.85 per 1,000 enrollees compared to a U.S. rate of 1.02.²⁶

III. The Low Back Pain Clinical Improvement Team

The Low Back Pain Clinical Improvement Team (CIT) members represented primary care providers of various types, surgeons, health plans, purchasers, and consumers.

The members of the Low Back Pain CIT are listed in Appendix I.

²³ Dartmouth Atlas of Health Care. Spine surgery: A report by the Dartmouth Atlas of Health Care CMS-FDA Collaborative. http://www.dartmouthatlas.org/atlas/Spine_Surgery_2006.pdf

²⁴ Dartmouth Atlas of Health Care. Frequently Asked Questions. <http://www.dartmouthatlas.org/faq.shtm>. Accessed online: October 18, 2006.

²⁵ Dartmouth Atlas of Health Care: Data tables. <http://cecsweb.dartmouth.edu/release1.1/datatools>

²⁶ Dartmouth Atlas of Health Care. Spine surgery: A report by the Dartmouth Atlas of Health Care CMS-FDA Collaborative. http://www.dartmouthatlas.org/atlas/Spine_Surgery_2006.pdf

IV. Area of Focus and Objectives

A. Disease Scope

The Low Back Pain CIT chose to limit its focus to acute* axial* low back pain *without* radiculopathy,*

- with an emphasis on preventing acute pain from becoming chronic, and
- excluding cancer, traumatic fracture, osteomyelitis,* and other pathophysiologic conditions.

The intent of the recommended disease scope is to include acute low back pain involving the trunk and lasting up to six weeks duration that results from mechanical or behavioral processes, and to exclude low back pain accompanied by pain radiating down the legs, chronic* pain, and pain resulting from malignancy, fracture, and other pathophysiologic conditions. The CIT noted that while the natural history of back pain with radiculopathy is similar to that of back pain without radiculopathy, the prognosis and treatment options are different and potentially more complex. Therefore, radiculopathy was determined to be outside the scope of these recommendations.

The presence of certain signs and symptoms in a patient with back pain increases the likelihood that the back pain results from a distinct pathophysiologic condition that may require prompt evaluation and treatment. These signs and symptoms are commonly known as ‘red flags’ or ‘red flag conditions,’ and patients with red flag conditions are excluded from the scope of this report. Red flag conditions include the following:

Red Flag Conditions (Excluded from CIT’s Disease Scope)

- Back pain of more than six weeks duration not responding to conservative care
- Neurogenic claudication [Leg pain that mimics arterial claudication. Usually refers to intermittent cramping pain and weakness in the legs and especially the calves on walking that disappears after rest.]
- Saddle anesthesia [Numbness in the perineal area]
- Recent onset of urinary retention, increased frequency, overflow
- Bowel incontinence

* ‘acute’—duration of six weeks or less

* ‘axial’—pertaining to the trunk

* ‘radiculopathy’—a pathologic condition affecting the nerve roots, also refers here to pain extending beyond the trunk

* ‘osteomyelitis’—inflammation of the bone marrow

* ‘chronic’—lasting greater than six weeks

- Severe or progressive neurological deficit in the lower extremity [Severe or progressive weakness or changes in sensation in the legs]
- Upper motor neuron findings [suggesting cerebral cortex or spinal cord involvement]
- Major trauma [e.g., motor vehicle accident, fall from height]
- Minor trauma or strenuous lifting in a person age less than 20 yrs. or greater than 70 yrs. or with osteoporosis
- Possible tumor
- History of cancer
- Constitutional symptoms [e.g., recent fever, chills, unexplained weight loss]
- Risk factors for spinal infection [e.g., recent bacterial infection such as urinary tract infection intravenous drug abuse; immune suppression as a result of steroid use, transplant, HIV, etc.]
- Pain that worsens when supine [when lying on the back]
- Severe nighttime pain

Additional terminology can be found in Appendix II.

B. Target Population

The Low Back Pain CIT chose to focus its work on working age adults who are commercially insured.

It was agreed that an age range helps define the focus but it was felt that a specific age range (e.g. age 18-65 years) may be too limiting. In many cases, the age of the patient does not affect the diagnosis or treatment. However, co-morbidity issues do increase with age as may the number of red flag conditions. Therefore, it was agreed that the focus should be on working age adults with the additional comment that these recommendations could apply outside that age range if co-morbidity related issues are taken into account.

C. Setting

The Low Back Pain CIT chose to focus on outpatient management of low back pain, with an emphasis on the primary care setting.

V. Recommendations for Improvement

A. Treatment of Low Back Pain During the First Six Weeks

At the outset of their work, the CIT members agreed on several key quality improvement recommendations aimed at providers and patients, which are consistent with a conservative care approach to the treatment of low back pain during the first six weeks.

Recommendations:

- 1. All patients presenting with low back pain should have a complete assessment to determine whether there are any red flag conditions.**
- 2. In the absence of red flag conditions, patients should be thoroughly assessed for history of back pain and responsiveness to therapy during any previous episodes.**
- 3. In the absence of red flag conditions, imaging should not be done during the first six weeks following the onset of acute axial low back pain.**
- 4. Surgery in the first six weeks in the absence of red flags or progressive symptoms is not recommended.**
- 5. Generally, providers should follow a conservative approach to treatment of low back pain during the first six weeks (when red flag conditions are not present), with the aim of preventing re-injury and changing behavior. A conservative approach should:
 - a. Advise patients to remain active and return to normal activities as soon as possible.**
 - b. Evaluate patients for emotional status and work-life issues, and promote active self-management.**
 - c. Attempt a course of non-invasive treatment before considering costly interventions (such as MRIs or surgery) that, in the absence of certain defined conditions, have not been shown to improve patient outcomes.**
 - d. Avoid imaging.****

Explanation:

The conservative approach to treatment of low back pain has been clearly defined by organizations such as the Institute for Clinical Systems Improvement (ICSI). The priority aims of ICSI's guideline align with the overarching recommendations of the Alliance's Clinical Improvement Team.

For example, ICSI aims to increase the use of the recommended conservative approach as first-line treatment – such as activity, self-care and analgesics – for patients with low back pain.²⁷ ICSI also aims to reduce unnecessary imaging studies in patients with acute low back pain.²⁸ The algorithm included on page 13 is from ICSI’s Adult Low Back Pain Health Care Guideline and is an excellent example of a conservative approach.²⁹

Preventing Unnecessary Imaging

Preventing unnecessary imaging was identified as one of the single most important areas where simple behavioral changes could make a huge difference in how back pain is managed and in the costs associated with the management of back pain. There is no evidence that imaging is needed in patients with acute back pain of less than six weeks duration unless history and physical examination suggest underlying systemic disease or neurologic involvement.³⁰ When imaging is done prematurely [possibly at the insistence of the patient] incidental findings may lead to inaccurate diagnosis, increased patient anxiety, and unnecessary tests or treatment.³¹

In patients with history or examination findings suggesting underlying systemic disease or neurologic involvement, or with persistent pain that does not improve with conservative therapy, plain radiographs (x-rays) and a normal erythrocyte sedimentation rates and/or c-reactive protein are recommended tests to evaluate for systemic disease while CT or MRI can be considered for persistent sciatica (pain along the sciatic nerve) or symptoms of spinal stenosis (narrowing of the lumbar spinal column that produces pressure on the nerve roots).³²

²⁷ The Institute for Clinical Systems Improvement. Adult Low Back Pain Guideline. Released September 2006. <http://icsi.org/knowledge/detail.asp?catID=29&itemID=149>. Accessed online October 17, 2006. Copyright 2006 by ICSI. Used with permission. ICSI retains all rights to the material. This material will in no way be used to determine provider compensation.

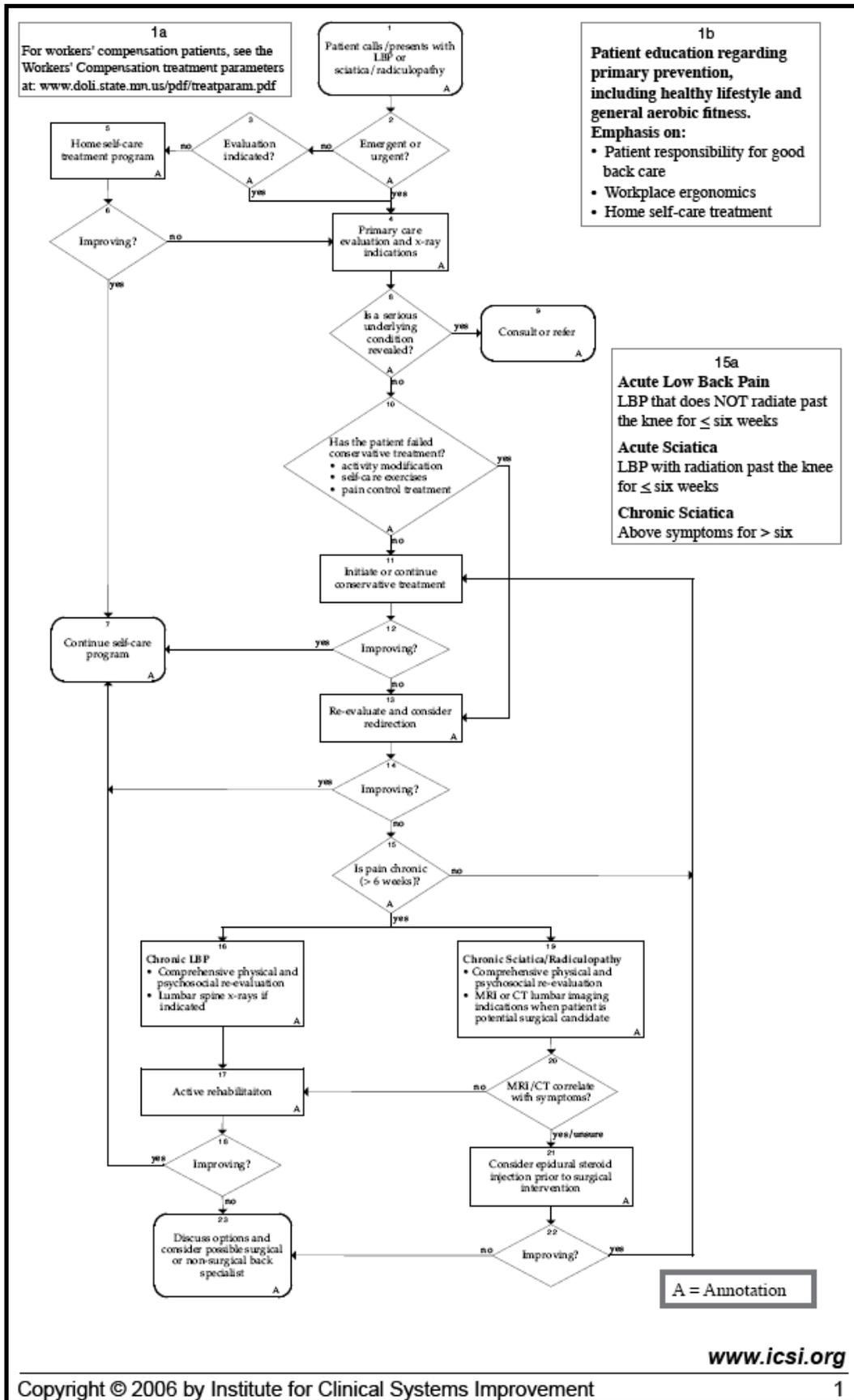
²⁸ The Institute for Clinical Systems Improvement. Adult Low Back Pain Guideline. Released September 2006. <http://icsi.org/knowledge/detail.asp?catID=29&itemID=149>. Accessed online October 17, 2006. Copyright 2006 by ICSI. Used with permission. ICSI retains all rights to the material. This material will in no way be used to determine provider compensation.

²⁹ The Institute for Clinical Systems Improvement. Adult Low Back Pain Guideline. Released September 2006. <http://icsi.org/knowledge/detail.asp?catID=29&itemID=149>. Accessed online October 17, 2006. Copyright 2006 by ICSI. Used with permission. ICSI retains all rights to the material. This material will in no way be used to determine provider compensation.

³⁰ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

³¹ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

³² Jarvik JG and Deyo RA. Diagnostic evaluation of low back pain with emphasis on imaging. *Ann Intern Med* 2002;137:586-597.



A comparison of international guidelines on the management of low back pain concludes that, for the diagnosis of low back pain, work-up should include diagnostic triage.³³ Diagnostic triage includes history and physical exam to determine if any red flag conditions are present and evaluation of patients' emotional status and presence of work-life issues, stress, and anxiety.³⁴ Plain radiographs (x-rays) are recommended *only* in patients with suspected underlying pathologic changes (red flag conditions) and imaging may be considered in patients with persistent low back pain lasting longer than six weeks.³⁵ U.S. and U.K. guidelines specifically advise against imaging for acute, nonspecific low back pain in the absence of red flag conditions.³⁶

Imaging guidelines from the American College of Radiology (ACR) were reviewed to see if they could be endorsed as a guide to help reduce unnecessary imaging in patients with back pain.³⁷ However, the ACR guidelines only look at applicability of different imaging techniques for certain conditions. They also were not evidence-based; they were developed through an informal process of consensus, and did not take costs into account.

Most guidelines do not recommend a scan within the first six weeks of onset of back pain if red flag conditions are absent. However, expert members of the CIT estimated that currently up to 40 percent of patients with low back pain without red flag conditions receive an MRI within the first six weeks of diagnosis. The CIT agreed that the presence or absence of red flag conditions could be used as a primary indicator for when imaging is or is not appropriate. Red flag conditions are well-established, should be well-publicized, and their use in determining the suitability of imaging encouraged through incentives. Disincentives to discourage the ordering of inappropriate scans should also be considered.

Imaging is frequently used to help place epidural injections in patients with pain. However, epidural injections (and the imaging tests that go with it) are not recommended in patients with acute low back pain during the first six weeks as there is good evidence that 90 percent of nonspecific back pain improves within six weeks without medical intervention or management.³⁸

³³ Koes BW, van Tulder MW, Ostelo R, Kim BA, Waddell G. Clinical guidelines for the management of low back pain in primary care: An international Comparison. *Spine* 2001;26(22):2504-2513.

³⁴ Koes BW, van Tulder MW, Ostelo R, Kim BA, Waddell G. Clinical guidelines for the management of low back pain in primary care: An international Comparison. *Spine* 2001;26(22):2504-2513.

³⁵ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

³⁶ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Koes BW, van Tulder MW, et al. Clinical guidelines for the management of low back pain in primary care: an international comparison. *Spine* 2001;26:2504-2514]

³⁷ American College of Radiology (ACR) Appropriateness Criteria—Acute Low Back Pain. 2005. http://www.acr.org/s_acr/bin.asp?CID=1205&DID=11801&DOC=FILE.pdf

³⁸ Koes B and van Tulder M. Low back pain (acute). *Cin Evid Concise* 2006;15:416-418.

Also, there is no evidence that epidural injections are effective in patients with acute low back pain in the absence of radiculopathy.³⁹

Preventing Unnecessary Surgery

Preventing unnecessary surgery was another area identified where behavioral changes could have an impact, as the majority of non-specific low back pain improves on its own within six weeks. There is no evidence from clinical trials or cohort studies that surgery is effective for patients who have low back pain unless they have sciatica [pain along the course of a sciatic nerve especially in the back of the thigh], pseudoclaudication [cramping and weakness], or spondylolisthesis [forward displacement of a lumbar vertebra on the one below it].⁴⁰ These conditions are indicated by specific red flags. Only about 10 percent of patients with herniated discs have sufficient pain after six weeks to make surgery a consideration.⁴¹

Studies have indicated no clear advantage for surgery, and comparisons of conservative and surgical treatment outcomes in patients with back pain have found that the outcomes appear to be roughly equivalent.⁴² Patients with herniated discs as the specific cause of their back pain and who undergo surgery, do not return to work more quickly than those receiving conservative therapy, though they may have better symptomatic and functional outcomes.⁴³

There are also various risks and costs associated with back surgery. There are risks associated with the procedure itself, such as infection or spinal cord damage, and risks associated with anesthesia such as poor oxygenation, brain damage, and reactions to anesthetic agents. There are also the risks that the surgery may not be effective or have the desired outcome. According to the Washington State Department of Labor and Industries, “a recent review of department data documented that 68 percent of workers with occupational low back pain conditions undergoing lumbar fusion surgery remained off work two years after surgery.”⁴⁴ Costs associated with surgery include hospital costs and costs associated with rehabilitation from surgery.

Among international guidelines there appears to be consensus that unless patients have progressive neurologic deficits requiring immediate surgical evaluation, most low back pain should be managed in a primary care setting

³⁹ Koes B and van Tulder M. Low back pain (acute). *Cin Evid Concise* 2006;15:416-418.

⁴⁰ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

⁴¹ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

⁴² Patel AT and Ogle AA. Diagnosis and management of acute low back pain. *Am Fam Physician* 2000;61:1779-1786,1789-1790. <http://www.aafp.org/afp/20000315/1779.html>

⁴³ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

⁴⁴ Franklin GM, Haug J, Heyer NJ, McKeefrey SP, Picciano JF. Outcome of lumbar fusion in Washington State workers' compensation. *Spine*. 1994;19(17):1897-903.

with referral to a specialist if red flag conditions are present⁴⁵ or if a conservative care approach has been tried and has failed. Conservative care approaches may include but are not limited to pharmacologic therapy, activity modification, massage therapy, acupuncture, physical therapy modalities such as ultrasound, exercise, patient education, and consideration of coping styles and work-life issues such as stress, fear, frustration and anger.⁴⁶

B. Preventing Acute Back Pain from Becoming Chronic

A second area of focus, preventing acute back pain from becoming chronic, encompasses a range of approaches to back pain management that in the long term could decrease the incidence of back pain and its recurrence and cost. Even though initial episodes of acute back pain are likely to improve, a substantial fraction of persons will go on to have more persistent back problems, recurrent back pain, or continuous pain of varying or constant intensity.^{47,48} While only five percent of people with back pain are temporarily or permanently disabled, these patients account for 75 percent of the costs of back pain management.⁴⁹

One of the strongest predictors of onset of low back pain and of the transition from an acute episode of low back pain to chronic low back pain is the patient's emotional status and the presence of work-life issues. These issues strongly predict both long- and short-term disability events, duration, and health-care visits for low back pain problems.⁵⁰ Studies have shown that factors such as attitude, fear, depression, anxiety, distress, and related emotions are strongly associated with reported onset of back pain and are clearly linked to the transition from acute to chronic pain disability.⁵¹ A purely biomedical approach may miss these important factors in the treatment of low back pain.

⁴⁵ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Koes BW, van Tulder MW, et al. Clinical guidelines for the management of low back pain in primary care: An international comparison. *Spine* 2001;26:2504-2514]

⁴⁶ Patel AT and Ogle AA. Diagnosis and management of acute low back pain. *Am Fam Physician* 2000;61:1779-1786,1789-1790. <http://www.aafp.org/afp/20000315/1779.html>

⁴⁷ Croft PR, Macfarlane GJ, Papageorgiou AC, Thomas E, Silman AJ. Outcome of low back pain in general practice: a prospective study. *BMJ*. 1998 May 2;316(7141):1356-9.

⁴⁸ Von Korff M. Studying the natural history of back pain. *Spine*. 1994 Sep 15;19(18 Suppl):2041S-2046S.

⁴⁹ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references American Academy of Orthopaedic Surgeons and North American Spine Society. Clinical Guideline on Low Back Pain—Phase 1 (First Contact Physician). 1996]

⁵⁰ Carragee EJ, Alamin TF, Miller JL, Carragee JM. Discographic, MRI and psychosocial determinants of low back pain disability and remission: a prospective study in subjects with benign persistent back pain. *Spine J*. 2005 Jan-Feb;5(1):24-35.

⁵¹ Linton SJ, Nordin E. A 5-year follow-up evaluation of the health and economic consequences of an early cognitive behavioral intervention for back pain: a randomized, controlled trial. *Spine*. 2006 Apr 15;31(8):853-8.

The focus of preventing acute back pain from becoming chronic emphasizes practice of appropriate, evidence-based management, including not recommending bed rest, promoting exercise and smoking cessation, and preventing unnecessary imaging and unnecessary surgery.⁵² The patient's emotional state and work-life issues can worsen the condition of acute back pain and should also be assessed as part of the treatment protocol.

Recommendations:

- 1. Providers should assess all patients with low back pain for emotional status and work-life issues, provide reassurance to reduce fear and anxiety, and promote active self-management.**
- 2. In the absence of red flag conditions, bed rest is not recommended and patients should be advised to remain active, returning to normal activity as soon as possible.**
- 3. Patients with back pain who smoke should be assisted with smoking cessation.**
- 4. Patients with low back pain should have assessment of functional status, using valid and reliable tests that are commonly available (such as the SF-36 Health Survey⁵³).**

Explanation:

The CIT recognizes that emotional, social, and environmental factors play a large role in the prevention and improvement of back pain,⁵⁴ and that depression,⁵⁵ anxiety and sleep disruption have significant impact on patient health and response to therapy. While providers still need to rule out pathophysiologic causes of back pain, evaluations of emotional, social and environmental factors and functional status are crucial in preventing back pain recurrence, chronicity, and disability.⁵⁶ Tools for evaluating patients for the

⁵² NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006.

⁵³ Devilly, G.J. (2004). Assessment Devices. Accessed November 7, 2006, from Swinburne University, Clinical & Forensic Psychology Web site:

<http://www.swin.edu.au/victims/resources/assessment/health/sf-36-questionnaire.html>

⁵⁴ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Koes BW, van Tulder MW, et al. Clinical guidelines for the management of low back pain in primary care: An international comparison. *Spine* 2001;26:2504-2514; Loisel P, Buchnbinder R, et al. Prevention of work disability due to musculoskeletal disorders: the challenge of implementing the evidence. *J Occu Rehab* 2005;15(4): 507-524]

⁵⁵ Jarvik JG, Hollingworth W, Heagerty PJ, Haynor DR, Boyko EJ, Deyo RA. Three-year incidence of low back pain in an initially asymptomatic cohort: Clinical and imaging risk factors. *Spine* 2005;30:1541-1548.

⁵⁶ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Beurskens AJ, De Vet HC, et al. Measuring the functional status of patients with low back pain: Assessment of the quality of four disease-specific questionnaires. *Spine* 1995;20:1017-1028; Delitto A. Are measures of function and disability important in low back care? *Phys Ther* 1994;74:52-62; Deyo

presence of depression, emotional well-being, coping styles, and other work-life issues, are readily available and may help identify such barriers to improvement. These and other tools can also help caregivers evaluate patients' abilities to do normal activities and at the same time help measure patients' functional status and progress with treatment.

One of the main reasons patients consult healthcare providers is for information and reassurance.⁵⁷ Patients need information to help them make informed, meaningful decisions about their care, to learn what to expect and what they can do. Educated patients have a better understanding of their treatment options and the likely outcome of each option, and a more balanced picture of the risks and benefits of these options. When given up-to-date information on a condition, the available options, and likely outcomes, patient perceptions are more likely to be realistic and patient satisfaction is more likely to improve.⁵⁸

Broadly focused educational approaches targeted to patients have limited value on their own.⁵⁹ The Institute for Clinical Systems Improvement (ICSI) has found that brochures which place an emphasis on reducing fear and anxiety and promoting active self-management have a greater opportunity for improving outcomes than traditional brochures that emphasize anatomy, ergonomics and specific back exercises. ICSI encourages health care professionals to have patient education materials and make them available throughout the community (including employers and local businesses).⁶⁰ Specific patient education content recommendations from ICSI include:⁶¹

- Absence of serious disease is likely when red flag conditions are not present.
- Hurt does not equal harm.
- There is a good prognosis for low back pain. The vast majority of patients experience significant improvements in four to six weeks.

RA. Measuring the functional status of patients with low back pain. *Arch Phys Med Rehabil* 1988 68:1044-53]

⁵⁷ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Von Korff M, Saunders K. The course of back pain in primary care. *Spine* 1996;21:2833-2837]

⁵⁸ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references O'Connor AM, Llewellyn-Thomas HA, Flodd AB. Modifying unwarranted variations in health care: Shared decision making using patient decision aids. *Health Affairs* 7 October 2004 web exclusive]

⁵⁹ Deyo RA, Schall M, Berwick DM, Nolan T, Carver P. Continuous quality improvement for patients with back pain. *J Gen Intern Med* 2000;15:647-655.

⁶⁰ Institute for Clinical Systems Improvement. Healthcare guideline: Adult low back pain. 12th edition, September 2006 http://www.icsi.org/knowledge/browse_bydate.asp?catID=29 Copyright 2006 by ICSI. Used with permission. ICSI retains all rights to the material. This material will in no way be used to determine provider compensation.

⁶¹ Institute for Clinical Systems Improvement. Healthcare guideline: Adult low back pain. 12th edition, September 2006 http://www.icsi.org/knowledge/browse_bydate.asp?catID=29 Copyright 2006 by ICSI. Used with permission. ICSI retains all rights to the material. This material will in no way be used to determine provider compensation.

- 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.

An example of a back pain patient education hand-out used by Minnesota's Park Nicollet Health Services is provided on ICSI's website:⁶²
<http://icsi.org/knowledge/detail.asp?catID=240&itemID=2039>

Several studies suggest that smoking is an independent risk factor for low back pain.⁶³ Other studies point out that smoking delays wound healing and that smokers have poorer clinical outcomes and longer recovery periods.⁶⁴ The reported health status of patients with spinal problems who smoke is significantly lower than that of those who do not smoke.⁶⁵ Therefore the CIT agreed that smoking cessation should be emphasized.

Similarly, bed rest not only does not increase rate of recovery from low back pain but sometimes delays recovery⁶⁶ and may have adverse effects including increased stiffness, muscle wasting, loss of bone mineral density, pressure sores, and thrombosis.⁶⁷ Remaining active leads to more rapid recovery, less chronic disability, and recurring problems.⁶⁸ Patients should be encouraged to remain active and return to normal activity, though patients may temporarily modify their activity within their pain limits.

⁶² Institute for Clinical Systems Improvement. Patient Education Resources, Low Back Pain (by Park Nicollet Health Services) <http://icsi.org/knowledge/detail.asp?catID=240&itemID=2039>. Accessed October 19, 2006. Copyright 2006 by ICSI. Used with permission. ICSI retains all rights to the material. This material will in no way be used to determine provider compensation.

⁶³ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006.

⁶⁴ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Glassman SD, Rose SM, et al. The effect of post-operative nonsteroidal anti-inflammatory drug administration on spinal fusion. *Spine* 1998;23:834-838; Hadley MN, Reddy SV. Smoking and the human vertebral column: a review of the impact of cigarette use on vertebral bone metabolism and spinal fusion. *Neurosurgery* 1997;41:116-124]

⁶⁵ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Vogt MT, Hanscom B. Influence on smoking on the health status of spinal patients: The national spine network database. *Spine* 2002;27(3):313-319]

⁶⁶ Deyo RA and Weinstein JN. Low back pain. *N Engl J Med* 2001;344(5):363-370.

⁶⁷ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006. [references Tulder van MW, Koes B. Musculoskeletal Disorders: Low back pain and sciatica (acute). *Clin Evid* 2004;12:1643-1658]

⁶⁸ Institute for Clinical Systems Improvement. Healthcare guideline: Adult low back pain. 12th edition, September 2006 http://www.icsi.org/knowledge/browse_bydate.asp?catID=29 Copyright 2006 by ICSI. Used with permission. ICSI retains all rights to the material. This material will in no way be used to determine provider compensation.

VI. Review of Evidence-based Clinical Guidelines

The Puget Sound Health Alliance is committed to promoting the use of evidence-based medicine in the Puget Sound region, and the team generally agreed that selecting and endorsing evidence-based guidelines for the primary management of low back pain was an important part of its work. It was agreed that there would be greater provider buy-in if the Alliance were to endorse well-defined treatment guidelines that focus on getting patients to resume normal activity as quickly as possible.

A search of the National Guideline Clearinghouse⁶⁹ (NGC) for “back pain” guidelines found 218 related guidelines. Narrowing the NGC search to “low back pain” resulted in 157 related guidelines. Therefore the CIT was unable to review all guidelines. The team considered the adoption of the Agency for Health Care Policy and Research (AHCPR) clinical practice guidelines for management of acute low back pain in adults.⁷⁰ These are broadly known, general guidelines with established care pathways. However, they were published in 1994 and are no longer considered up-to-date for current medical practice. New treatments such as injections are not included and some of the terminology is outdated. Team members reviewed the AHCPR guidelines with the idea that they might be adapted and brought up-to-date for use by Alliance members. After considerable review it was concluded that significant work would be required to bring the guideline up-to-date. It was agreed that such extensive guideline development work was beyond the scope of the CIT and the Alliance.

After lengthy discussion, the CIT chose not to endorse any specific set of guidelines, but rather to recommend that guidelines selected for use by providers be evidence-based, with the evidence graded as to quality and clearly referenced.

The team reviewed the *proposed* NCQA Spine Care Recognition program for sub-acute and chronic back pain (released in draft form for public comment May 2006). The program comprises a set of measures, supported by the best available clinical evidence, promotes a model of care based on systematic patient assessment, patient education, limited use of imaging, and the use of surgery only after other options have been fully explored. The NCQA program does not endorse any one set of clinical guidelines and is open to physicians

⁶⁹ National Guideline Clearinghouse, <http://www.guideline.gov>. Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. Accessed online: October 13, 2006.

⁷⁰ Bigos S, Bowyer O, Braen G, et al. Acute Low Back Problems in Adults. Clinical Practice Guideline, Quick Reference Guide Number. 14. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, AHCPR Pub. No. 95-0643. December 1994. <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.34262>

and chiropractors. [Note: The NCQA has other programs already in place for diabetes, heart/stroke, and physician practice connections (the latter provides recognition to promote adoption of clinical information systems, patient education and support, and care management). Doctors and clinics choose to be a part of the programs and self-report chart data. Those that meet a certain threshold of quality performance receive recognition from the NCQA. The bar for recognition is set high but is achievable as evidenced by the 2700+ medical groups and individual physicians nationwide who have already achieved recognition in one or more of the three NCQA programs currently in place. [Note: The Alliance has developed promotional materials for the Diabetes and Heart/Stroke NCQA Physician Recognition programs and is assessing the related Bridges to Excellence program as a link to pay-for-performance for quality in these clinical focus areas.]

Overall the NCQA proposed Spine Care program notes that, “while there are relatively few evidenced-based guidelines that specify care that *is* effective for back pain, there is substantial evidence of the use of services or interventions that have little or no effectiveness. For example, during the acute phase, there is ample evidence that in nearly all cases:

- physicians should advise patients that extended bed rest is not beneficial and may be harmful;
- patients should resume normal activity within a few days;
- except under specific circumstances, patients do not need imaging or surgery.⁷¹”

The Low Back Pain CIT agreed that the proposed NCQA Spine Care Recognition program reflects the appropriate emphasis and approach in the primary management of low back pain and should be used as a *framework* for the CIT’s recommended performance measures and change strategies to influence improved quality. The CIT agreed that, once finalized, the NCQA standards and measures will have high credibility as they will be widely recognized and will be based on recent review of the evidence, current existing guidelines from various sources, and consensus of nationally recognized experts.

Recommendation:

The CIT recommends adopting the NCQA Spine Care Recognition Program (SCRIP) standards as a *framework* for the CIT’s recommended measures and interventions.

It is expected that the Spine Care Recognition Program will be finalized by April 2007. [Note: The CIT’s recommended adoption of the NCQA SCRIP standards as a *framework* does not indicate an endorsement of a specific guideline or care pathway.]

⁷¹ NCQA Spine Care Recognition Program Report – Draft for Public Comment, May 2, 2006.

VII. Recommended Performance Measures

One of the goals of the Puget Sound Health Alliance is to publish comparative performance reports on providers' achievement on selected clinical performance measures. The Alliance strives to build on the work of others, to aim for consistency within the region and nationally, and to ease, rather than increase, the reporting burden on providers. Towards that end, the Low Back Pain CIT was charged with the task of selecting clinical performance measures for the treatment of low back pain. The Low Back Pain CIT reviewed existing published measures from a variety of sources, including the Institute of Medicine, the Institute for Clinical Systems Improvement, and NCQA, particularly in the areas of reducing unnecessary imaging and surgery. The existing measures were evaluated for their feasibility, ease of measurement, and clinical relevance.

In December 2005, the Puget Sound Health Alliance adopted the Institute of Medicine's "starter set" of over 200 clinical performance measures. These measures were intended by IOM to become the national standards for quality measurement. The measures are derived from a number of agencies and organizations with which the IOM collaborated, including the National Committee for Quality Assurance (NCQA-HEDIS measures), the Ambulatory Care Quality Alliance (AQA), the National Quality Forum (NQF) and the Centers for Medicare and Medicaid Services (CMS). The Institute of Medicine starter set includes one performance measure relating to back pain. This HEDIS measure⁷² pertains to the use of imaging studies for low back pain. Its purpose is to assess whether imaging studies are overused when evaluating patients with acute low back pain.

Other performance measures relating to the management of back pain also have been proposed by the Institute for Clinical Systems Improvement (ICSI). ICSI is an independent, non-profit collaborative of medical groups, hospitals and health plans working to improve health care services in Minnesota and adjacent areas in surrounding states.⁷³ A core part of its strategy is the production of evidence-based guidelines that are updated annually by health care professionals of member organizations. The guidelines include suggested performance measures as tools to help implement the recommendations of the guidelines into current clinical practice. ICSI's back pain guidelines include measures for promoting a conservative approach to the management of back pain, preventing unnecessary imaging, assessing patients with chronic low back pain, and using appropriate outcome tools.⁷⁴

⁷² National Committee for Quality Assurance (NCQA). HEDIS 2006. Health plan employer data & information set. Vol 2, Technical specifications. Washington (DC): National Committee for Quality Assurance (NCQA); 2005. 350 p.

⁷³ <http://www.icsi.org/index.asp>

⁷⁴ Institute for Clinical Systems Improvement. Healthcare guideline: Adult low back pain. 12th edition, September 2006 http://www.icsi.org/knowledge/browse_bydate.asp?catID=29 Copyright 2006 by ICSI.

As part of its Spine Care Recognition Program, the NCQA proposed nine measures for management of acute back pain and 13 measures for the management of subacute and chronic back pain. The NCQA is currently revising its program measures based on feedback during the public comment period, and plans to issue a final program in April 2007.⁷⁵ Therefore, because they were in draft form, the Low Back Pain CIT felt that they could not endorse the specific measures proposed although they agreed that the measures were directionally correct.

It is important to note that both the ICSI and proposed NCQA measures require chart review for data abstraction, collection and reporting. The Alliance is developing an analytic infrastructure to measure and report performance in the Puget Sound region based on selected clinical measures. Initially the Alliance plans to use claims-based data with the expectation that future data collection can be strengthened by including information from other sources when it is possible to *electronically* extract and aggregate the information. Over time the Alliance may include data from laboratories, pharmacies, electronic health records, and electronic patient registries for specific chronic conditions.

With the Alliance's plans in mind, the CIT proposes two measures similar in scope and direction to the ICSI, NCQA and IOM measures with the understanding that claims-based data will be the basis for the Alliance's *initial* comparative reports. The CIT acknowledges that this is not ideal and can only provide information on general trends and major outliers. However, it is a start until the time when clinical data can be reliably collected through use of electronic means. With these points in mind, the following performance measures are recommended:

Recommended Measure: Preventing Unnecessary Imaging

1. The percentage of people 18-50 years of age who had an episode of acute low back pain with no risk factors or signs of serious pathology identified in the diagnostic visit and did not receive an imaging study in the following six weeks.⁷⁶

Recommended Measure: Preventing Unnecessary Surgery

2. Percentage of patients with acute back pain who had surgery in the six weeks after first visit. [Note: Measure needs technical specifications development]

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⁷⁵ http://www.ncqa.org/communications/news/scrp_publiccomment.htm

⁷⁶ National Committee for Quality Assurance - Health Plan Employer Data and Information Set (NCQA-HEDIS) Measures Specifications 2006.

Comments on performance measures:

These measures would give an indication of the current usage of imaging and surgery in patients with low back pain during the first six weeks. Approximately 5% of patients with low back pain in a primary care setting have back pain resulting from cancer, spinal infection, osteoporotic compression fractures, ankylosing spondylitis, or cauda equina syndrome, conditions likely to present with red flags.⁷⁷ Percentages higher than this 5% *may* indicate unnecessary testing but would need to be evaluated carefully to better understand the patient population and practice type (e.g., primary care vs. spine surgeon).

When specialists require a recent scan of an imaging test before they will evaluate a patient, they will typically instruct the referring provider to order the imaging test. This may have a negative showing on the referring provider as the provider will be seen as ordering multiple tests. This should be taken into account when evaluating performance data.

VIII. Recommended Change Strategies

Approaches to managing back pain vary considerably among providers. Strategies that have focused *solely* on guideline distribution, that have not been supported by clinic leaders and clinical staff, have not been very successful.⁷⁸ Likewise, efforts to minimize variation that concentrate *solely* on broadly educating physicians and patients also have been largely unsuccessful at changing provider or patient behavior.⁷⁹ Much of the information available to patients emphasizes new technologies, therapies and procedures. Most of this information is not evidence-based and often promotes specific therapies, drugs or procedures. These “advertisements” are difficult and expensive to counteract.

The most successful intervention programs for the management of back pain have included changes in how patients are handled at the time they contact the medical system. This includes changes to diagnostic or treatment protocols, timing of visits, and/or protocols for referral to specialists. Such system changes are effective because the desired behavior becomes part of the care management process.⁸⁰

⁷⁷ Jarvik JG and Deyo RA. Diagnostic evaluation of low back pain with emphasis on imaging. *Ann Intern Med* 2002;137:586-596.

⁷⁸ Deyo RA, Schall M, Berwick DM, Nolan T, Carver P. Continuous quality improvement for patients with back pain. *J Gen Intern Med* 2000;15:647-655.

⁷⁹ Deyo RA, Schall M, Berwick DM, Nolan T, Carver P. Continuous quality improvement for patients with back pain. *J Gen Intern Med* 2000;15:647-655.

⁸⁰ Deyo RA, Schall M, Berwick DM, Nolan T, Carver P. Continuous quality improvement for patients with back pain. *J Gen Intern Med* 2000;15:647-655.

In developing its list of suggested change strategies, the CIT considered numerous options. Because the issue of back pain management is so broad and so complex, and the resources of the Alliance limited, the CIT agreed to focus on developing a few key change strategies as fully as possible. The CIT considered individual team members' past experiences with various types of change strategies (successful and not successful), and published evidence for effectiveness where available. Those strategies proposed here are those which the majority of team members agreed likely to be the most effective given the current system of procedure-oriented reimbursement.

As a first priority, the CIT agreed to focus on providing opportunities for consumer education at "teachable moments," i.e., when patients are most receptive to receiving new information. In the case of low back pain, patient education should focus on managing expectations and misconceptions at the time of the initial visit when decisions are often made regarding imaging and/or the appropriateness of exploring a surgery option. This is a time when patients are typically in a lot of pain. Their expectations are frequently unrealistic, leading them to ask for unnecessary imaging tests and surgical procedures, with the belief that they will feel better immediately as a result of such interventions. Additional opportunities for patient education occur during the ongoing care management process when guidance can be given regarding activity levels.

As a second priority, the CIT agreed to focus on creating an incentive for change. In considering financial incentives the CIT concluded that while financial rewards for evidence-based behavior may be desirable, financial *disincentives* for *non*-evidence-based behavior may be equally effective in discouraging non-evidence-based behavior among providers, especially when these disincentives are supported by health plans and insurers. The CIT also agreed that while financial disincentives could be introduced to discourage patient requests for diagnostics and procedures that are not supported by evidence, costs are frequently not a disincentive for patients if they are experiencing significant discomfort and believe their health is in jeopardy. Therefore any financial incentives should address provider rather than patient behavior.

As a final note, the CIT is aware that there are community and professional groups attempting to develop standards for conservative care of back pain. Therefore, while not proposing a specific change strategy for promoting standards for conservative care, the CIT recommends that the Alliance and its members support and collaborate with community and professional groups promoting and developing holistic, multidisciplinary, conservative care approaches to the management of back pain.

With these points in mind, the Low Back Pain CIT recommends the following change strategies:

Recommended Change Strategies

- 1. Use an imaging checklist to reduce unnecessary imaging. The use of an imaging checklist will simultaneously engage the patient with low back pain and the primary care provider in the decision-making process around whether to order an imaging test.**
 - a. When low back pain imaging reports are indicated by the presence of red flag conditions, it is recommended that imaging centers promote quality imaging reports that help providers interpret imaging test results by including the prevalence of “abnormal” findings within the normal population.**
- 2. Use a return-to-activity form to assess patients’ functional abilities, communicate to patients how much activity they can do, and help patients plan for gradual return to normal activities.**
- 3. Reward or recognize providers achieving NCQA Physician Recognition for Spine Care with a pay-for-performance mechanism such as Bridges to Excellence.**
- 4. Change benefit design to include the use of health risk assessments in patients with acute low back pain to help providers screen for the presence of work-life issues and emotional states such as fear and anxiety that may impact a patient’s back pain and response to treatment.**

Note that the CIT agreed that *preventing unnecessary imaging* would have the substantial impact on improving quality and safety and reducing costs of back pain management. Therefore the principal change strategy proposed by the CIT relates to this area of focus.

1. Use an imaging checklist

Recommendation. It is recommended that a one-page imaging checklist with information on red flag conditions be used to engage *simultaneously* the patient with back pain and the primary care provider in the decision-making process around whether to order an imaging test (see Appendix III: Sample Imaging Checklist). The checklist would move the provider and patient through an assessment of whether red flag conditions as described previously in this report are present before a decision is made as to whether to order an imaging test. The checklist would be used to educate patients regarding the appropriate use of imaging tests in diagnosing and managing back pain while at the same time guiding providers’ decisions on the appropriateness of ordering an imaging test.

How it could work. The CIT suggests that the imaging checklist could be used as follows:

1. Professional associations, provider groups, and health plans would encourage providers to use the checklist during visits with patients presenting with low back pain at a time when they [the providers] are considering whether to order an imaging test;
2. Health plans would state in their contracts with health providers their expectations that an imaging checklist be routinely used by providers when reviewing imaging options with patients with acute back pain and when ordering imaging studies for these patients;
3. Health plans would strongly encourage imaging providers to routinely include on or with their imaging order sheets an imaging checklist, and ask for completed checklists from providers prior to doing an imaging study;
4. Imaging providers would request on their imaging order forms that a checklist be completed prior to scheduling an imaging test;
5. Providers would utilize the checklist with patients to: (a) review whether red flag conditions are present and imaging is needed, and (b) decide whether to order an imaging test;
6. The provider would send a completed checklist to the imaging provider with the request for an imaging study; and
7. Health plans and insurers would do random spot audits to see if completed imaging checklists have been sent in with requests for imaging tests.

Rationale. The CIT concluded that consumers are most likely receptive to education about back pain management at the time they first seek relief for their back pain. Therefore education about imaging in a patient with low back pain would optimally take place when the provider and the patient discuss whether to order an imaging test. The CIT agreed that a checklist—used by the provider as part of the ordering process—would accomplish several goals: educating patients, guiding providers’ decision-making, and promoting evidence-based practice.

While checklists have been implemented in the past with limited success, CIT members agreed that the ones that do succeed engage both the patient and the provider *simultaneously* at the point of decision-making.

The CIT acknowledged that while most valid reasons for requesting an imaging test are covered by the list of red flag conditions, there are always rare exceptions not covered by the list. Any checklist would need to include an ‘other’ option that would give a provider the latitude to order imaging studies in exceptional situations.

The team noted that the checklist should have the following characteristics:

- It should clearly state that its purpose is educational, and that it should be used to instruct and guide patients and promote active self-management with the goal of preventing acute back pain from becoming chronic;
- It must promote clinical quality, for example, clearly noting that relating the presence of red flag conditions to orders for imaging tests is an *evidence-based* best practice rather than a cost reduction issue;
- It should explain why imaging may not only be unnecessary but also potentially detrimental;
- It should list red flag conditions and define them in lay terms; and
- It should be incorporated into the practice flow either on paper or electronically (order entry system).

The CIT discussed whether providers ordering imaging tests in the absence of red flag conditions should be required to consult with a specialist before ordering the imaging test. It was agreed that requiring consultation with an imaging or other specialist would increase the number of requests for consultation and increase overall costs. Therefore this is not recommended.

The CIT agreed that random spot audits by health plans and insurers would encourage the use of the imaging checklist and recommends that purchasers voice their support for a random audit process.

The CIT also discussed the possible use of ICD9 codes to better identify the presence of red flags. This did not seem practical, as there are few codes accurate enough to be helpful, and CIT members felt that doctors would rarely use them.

a. Promote quality imaging reports

Supplemental recommendation. When low back pain imaging reports are indicated by the presence of red flag conditions, it is recommended that imaging centers include information that would help providers interpret imaging test results.

How it could work. The CIT suggests the following activities to promote quality imaging reports:

1. Health plans and insurers would ask the local radiology professional association to:
 - a. standardize imaging reports to include information about prevalence of certain conditions, for example, disc herniation in patients *without* low back pain; and
2. Health plans and insurers would do random spot audits to see if imaging reports include the information requested.

Rationale. The CIT agreed that imaging reports should include the findings of the study, any recommendations for additional diagnostic (not therapeutic) studies, and epidemiologic information that may be useful in the clinician’s interpretation of the findings, for example how prevalent these findings are in normal, healthy, pain-free individuals.

2. Use a return-to-activity coaching form

Recommendation. It is recommended that a simple, one-page, standardized return-to-activity coaching form be used by providers to help assess patients’ functional abilities, communicate to patients how much activity they can do, and help patients plan for gradual return to normal activities.

How it could work. The CIT suggests that the return-to-activity coaching form could be used as follows:

1. Providers would have pads of a standardized return-to-activity coaching form available (or alternatively as an electronic form in the EMR);
2. Providers would go through the form with the patient to assess a patient’s ability to do normal activities, teach the patient how to do normal activities such as lifting, and develop a plan for return to normal activity levels;
3. The provider would give the patient a copy of the completed coaching form (alternatively print out the form as part of the after-visit summary from the EMR) to help them remember how they should plan and manage their activities;
4. At subsequent visits the provider would use the coaching form to help reassess the patient’s activity status, discuss any activity modifications with the patient, and revise the activity plan if necessary.

Rationale. The CIT agreed that it would be very helpful to have available a simple, standardized, one-page tool available for providers to assist them in helping patients plan their return to normal activities after an episode of low back pain and monitor patient progress. The return-to-activity coaching form would accomplish several goals: educating patients, guiding providers’ decision-making, and promoting evidence-based practice.

The CIT noted that the Washington State Department of Labor and Industry currently has a draft “Activity Prescription Form” for managing return to work for patients with work-related back pain.⁸¹ This form is being revised and is tentatively scheduled for re-issue in early 2007. Other organizations such as King County use similar forms to help evaluate and estimate employee’s physical capabilities. While all of these forms are useful, the CIT agreed that a simpler format where information on functional assessments and activity

⁸¹ <http://www.lni.wa.gov/ClaimsIns/Files/Providers/ohs/245-066-000Legal.pdf>

recommendations for sequential visits could be shown on one page could effectively help patients and providers discuss, plan, and monitor patient progress in resuming normal activities.

A return-to-activity coaching form should be completed at each patient visit and should include any activity restrictions and goals for the period until the next patient visit, and the date of the next visit. An *example* of a return-to-activity coaching form is shown in Appendix IV.

3. Reward or recognize providers achieving NCQA Physician Recognition for Spine Care with a pay-for-performance mechanism such as Bridges to Excellence

Recommendation. It is recommended that the Alliance endorse the NCQA Spine Care Physician Recognition Program when it is finalized. It is further recommended that employers and health plans recognize providers who achieve NCQA Physician Recognition for Spine Care and reward them via a pay-for-performance program such as Bridges to Excellence. Such a program would promote the delivery of evidence-based healthcare and improve the consistency and quality of healthcare delivered in the Puget Sound region.

How it could work. The CIT suggests that provider reward and recognition could be done as follows:

1. The Alliance, employers and health plans would encourage providers to participate in NCQA's Spine Care Recognition Program;
2. The Alliance, employers, and health plans would advertise and make available to employees and subscribers the names of providers achieving NCQA Physician Recognition; and
3. Employers, health plans, and the Alliance would encourage and assist in the development of a community-wide approach to pay-for-performance, such as Bridges to Excellence, that includes a component specifically targeted at low back pain treatment.

Rationale. The NCQA Spine Care Recognition Program previously described has not yet been finalized and launched at the time of this writing. The CIT acknowledged that the final form and specific content of the measures are as yet unknown. However, as it will be a nationally recognized program based on the guidance of nationally recognized experts and feedback from public comment nationwide, the CIT agreed that it will have significant credibility and a high probability of acceptance among providers.

4. Change benefit design to include the use of health risk assessments in patients with acute low back pain

Recommendation. It is recommended that employers and purchasers include in their plans, and insurers and health plans include in their benefit designs, the use of standardized health risk assessments in patients presenting with acute back pain. The use of a health risk assessment tool when patients first present with back pain will enable providers to screen for the presence of work-life issues and emotions such as fear and anxiety that may impact a patient's back pain and response to treatment.

How it could work. The CIT suggests that benefit designs be changed as follows:

1. Employers and purchasers include in their health plans health risk assessments in patients presenting with acute back pain
2. Health plans and insurers include in their benefit designs health risk assessments for patients presenting with acute back pain
3. Health plans and insurers include in their benefit designs the use of standardized functional assessment tools during follow-up assessments of patients with continued or recurrent back pain at six weeks after initial visit

Rationale. Currently some employers build risk assessment into their health plans, but many don't, even when insurers offer it as an option. The CIT agreed that restructuring benefits coverage to include the use of tools that promote risk assessment and disease management would be a strong incentive for encouraging healthcare providers to use such tools. There are a variety of risk assessment tools available. Standardized health status questionnaires such as the SF-36 Health Survey⁸² measure several aspects of general health status—functional ability, general physical health, and emotional well-being. The Distress Risk Assessment Method (DRAM) measures depression and somatic anxiety.⁸³ Using these tools can help providers screen for the presence of depression, work stress, or other work-life issues that may impact on a patient's back pain and response to treatment.

Most claims data and performance measures around back pain measure processes, but little data is collected on outcomes. Improvement or change in a patient's function can be measured using standardized assessment tools such

⁸² Devilly, G.J. (2004). Assessment Devices. Accessed November 7, 2006, from Swinburne University, Clinical & Forensic Psychology Web site:

<http://www.swin.edu.au/victims/resources/assessment/health/sf-36-questionnaire.html>

⁸³ Main CF, Wood PL, Hollis S, Spanswick CC, Waddell G. The Distress and Risk Assessment Method: A simple patient classification to identify distress and evaluate the risk of poor outcome. *Spine* 1992;17(1):42-52.

as the Oswestry Disability Index⁸⁴, the Roland Morris Disability Questionnaire, or other functional status scales before and after treatment. These tools not only help providers evaluate patient functional status but also allow them to objectively assess improvement and document outcomes after treatment. The CIT agreed that these tools would be useful in monitoring functional status and improvement in patients with continued back pain at six weeks or with recurrent back pain.

⁸⁴ Australian Physiotherapy Association, http://apa.advsol.com.au/independent/documents/outcome_measures/Oswestrydisability.pdf, Accessed November 7, 2006.

[References: Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. Spine, 25(22):2940-2953. Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. Physical Therapy 2002;82:8-24.]

Appendix I: Members of the Back Pain Clinical Improvement Team

Name	Job Title	Business
Ray Baker	Clinical Professor of Anesthesiology	University of Washington
Lydia Bartholomew	Sr. Medical Director	Qualis Health
Dianna Chamblin	Director	The Everett Clinic Occupational Health Center
Dan Cherkin	Researcher	Group Health Cooperative, Center for Health Studies
Andrew Cole	Physiatrist	Northwest Spine & Sports Physicians
Richard Deyo	Co-director Robert Wood Johnson Clinical Scholars Program	UW School of Public Health & Community Medicine
Andrew Friedman	MD	Virginia Mason Medical Center
David Hanscom	Orthopedic Surgeon	Swedish Medical Center
Roger Herr	Physical Therapist	Home Care Association of Washington/Physical Therapy Association of Washington
Jeffrey Jarvik	Professor of Radiology and Neurosurgery, Adjunct Professor Health Services Chief of Neuroradiology; Co-Director, Radiology Health Services Research Section	University of Washington
Sharon McCallum	Physical Therapist	Virginia Mason
Tom McCarthy	Senior Vice President	First Choice Health Network
Andrew McIntyre	Clinical Faculty, Acupuncture and Oriental Medicine	Bastyr University
Sohail Mirza	Surgeon	UW Associate Professor, Orthopedics and Sports Medicine
Robert Mootz	Associate Medical Director for Chiropractic	Department of Labor & Industries
Andrew Oliveira	MD, Medical Director	Aetna US Healthcare
Steven Overman	Medical Director Rheumatology, Director Musculoskeletal Planning and Development, Clinical Associate Professor of Medicine	Northwest Hospital and Medical Center, University of Washington Medical Center
Sandy Rankins	Transit Operator	King County Metro
Kerry Schaefer	Manager, Compensation & Benefits	King County
Peter West	Associate Medical Director	First Choice Health
Siiri Bennett	Consultant, Low Back Pain CIT Lead	Puget Sound Health Alliance
Susie Dade	Quality Improvement Director	Puget Sound Health Alliance
Jane Keary	Research Analyst	Puget Sound Health Alliance
Kaj Trapp	Committee Coordinator	Puget Sound Health Alliance

Appendix II: Definitions of Key Terms

Acute	Lasting six weeks or less.
Axial	Pertaining to the trunk.
Chronic	Lasting greater than six weeks.
Evidence-based guidelines	A set of systematically developed statements, based on quality clinical evidence, to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. Guidelines briefly identify, summarize, and evaluate the best evidence and most current data about prevention, diagnosis, prognosis, therapy, risk/benefit, and cost/effectiveness. They define the most important questions related to clinical practice, identify possible decision options and their outcomes, and provide evidence-based recommendations.
Measure	A tool derived from practice guidelines and recommendations that defines a specific, measurable element of care that is used to measure the quality of care provided by practitioners.
Osteomyelitis	Inflammation of the bone marrow.
Pathophysiologic	The functional changes that accompany a particular syndrome or disease.
Radiculopathy	A pathologic condition affecting the nerve roots; also refers to pain extending beyond the trunk.
Red flag or Red flag condition	Those signs or symptoms in a patient with back pain whose presence increases the likelihood that the back pain results from a distinct pathophysiologic condition that may require prompt evaluation and treatment.
Sciatica	Pain along the course of a sciatic nerve especially in the back of the thigh caused by compression, inflammation, or reflex mechanisms; <i>broadly</i> : pain in the lower back, buttocks, hips, or adjacent parts.
Scope	The parameters of the work, including area of interest (e.g. back pain) and target population.

Appendix III: Sample Imaging Checklist (Adapted from AHCPR Guidelines, Noridian, Medicare)

Spine MRI Ordering Sheet

Date: _____ / _____ / _____ Patient Name: _____
DOB: _____ / _____ / _____ ID#: _____
Last exam date: _____ / _____ / _____

Purpose of the Imaging Checklist. The purpose of the Imaging Checklist is to help providers instruct and guide patients, help providers and patients decide if imaging is necessary, and promote evidence-based practice. It can also be used to help promote patient self-management of back pain with the goal of preventing back pain from becoming chronic.

There is no clinical evidence that imaging is needed in patients with acute back pain of less than six weeks duration unless history and physical examination suggest underlying systemic disease or nerve involvement. When imaging is done prematurely incidental findings may lead to inaccurate diagnosis, increased patient anxiety, and unnecessary tests or treatment.

The presence of certain signs and symptoms in a patient with back pain increases the likelihood that the back pain results from a condition that may require prompt evaluation and treatment. These signs and symptoms are commonly known as 'red flags' or 'red flag conditions'. Red flag conditions are listed below. One or more red flag conditions must be present for any request for a Spine MRI. In general, non-traumatic axial back pain for < 6 weeks is not an indication for an imaging study. Back pain which does not involve numbness or weakness of the leg is generally not an indication for MRI.

[insert standard screening MRI questions here, e.g. pacemaker, vascular clips, etc]

Prescreening indications (Red Flags) - Please briefly describe the patient's signs and symptoms and indicate what appeared to trigger the back pain, if any trigger was identified.

Indication, presumed diagnosis: _____

Clinical Findings: _____

Red Flags for MRI Back Imaging

The patient must have one of the following in order for a Spine MRI to be performed without physician to physician consultation (please check all those that apply):

- Back pain of more than 6 weeks duration not responding to conservative care
- Neurogenic claudication (intermittent cramping pain and weakness in the legs and especially the calves on walking that disappears after rest)
- Saddle anesthesia (numbness at or around the tail bone)
- Recent onset of urinary retention, increased frequency, overflow incontinence
- Bowel incontinence
- Severe or progressive neurological deficit in the lower extremity (severe or progressive weakness or sensory deficits in the legs)
- Upper motor neuron findings (suggesting brain or spinal cord involvement)
- Major trauma (for example, from a motor vehicle accident, a fall from height)
- Minor trauma or strenuous lifting (age < 20 yrs or > 70 yrs or osteoporosis present)
- Possible tumor or infection risk factors
 - History of cancer; constitutional symptoms (for example, recent fever, chills, unexplained weight loss); risk factors for spinal infection (for example, recent bacterial infection such as urinary tract infection; intravenous drug abuse; immune suppression as a result of steroid use, organ transplant, HIV infection); pain that worsens when lying down; severe nighttime pain
- Other: _____

Signature _____

Appendix IV: Sample Return-to-Activity Coaching Form

Patient Name: _____ DOB: ____/____/____ ID#: _____

The purpose of this record sheet is to help providers assess patients' functional abilities, communicate to patients how much activity they can do, and help patients plan for gradual return to normal activities.

Instructions

For each patient visit, complete one column:

1. Note date of visit
2. Go through the list of activities with the patient, discussing with the patient any activity restrictions for period until next visit
3. Note date of next visit
4. Give copy of completed form to patient
5. At subsequent visits, use the form to help reassess the patient's activity status, discuss any activity modifications with the patient and revise activity plan.

	Date of 1 st visit:	Date of 2 nd visit:	Date of 3 rd visit:
Consider the following activities: <ul style="list-style-type: none"> • Sit • Stand • Walk • Drive • Climb stairs • Bend/stoop • Kneel • Crouch/squat • Operate foot controls • Operate hand controls • Reach above shoulder height • Reach shoulder to waist height • Reach below waist • Lift/carry 1-10 lbs. • Lift/carry 11-20 lbs. • Lift/carry 21-50 lbs. • Lift/carry 51-100 lbs. • Lift/carry over 100 lbs. • Push/pull weighted objects • Other 	Activity plan and any restrictions:	Activity plan and any restrictions:	Activity plan and any restrictions:
	Date of next visit:	Date of next visit:	Date of next visit: