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Back Pain Management Study

Prepared by: The Back Pain Management Task Force Of The Greater Flint Health Coalition

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Greater Flint Health Coalition Back Pain Management Task Force Greater Flint Health Coalition Cost & Resource Planning Committee Greater Flint Health Coalition Board of Directors

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INTRODUCTION

The Greater Flint Health Coalition¹ convened a Back Pain Management Task Force to study the status of back pain management in Genesee County and to make recommendations for possible improvement. This Task Force was created subsequent to a meeting of clinical practitioners on March 29, 2001. This meeting had been called by the Greater Flint Health Coalition to discuss the high rates of spinal surgery in Genesee County, as presented by the Cost and Resource Planning Committee and its Data Review Subcommittee. At the March 29, 2001 meeting, it was suggested that if the Coalition was to study spine care that it should be more broadly focused on back pain management, rather than focused solely on spinal surgery rates.

The initial meeting of the **Back Pain Management Task Force** was held on December 6, 2001. The Committee, chaired by Wilbur Boike, M.D., is represented by numerous medical specialties, including neurosurgery, orthopedic surgery, neurology, physical medicine and rehabilitation, family practice, occupational medicine, and radiology/injection therapy. In addition, the Committee has included a clinical psychologist, a chiropractor, physical therapists, as well as representatives from interested parties and organizations.

From the onset, it was decided that the Committee should focus on evidence-based medicine, and where evidence-based medicine was lacking, to attempt to achieve a consensus among the Task Force participants. Two primary sources of evidence-based medicine were identified early, and were heavily utilized throughout the Task Force's proceedings. First of all, the publication Acute Low Back Pain in Adults - Clinical Practice Guideline, published by the U.S. Department of Health and Human Services, was extensively reviewed. This guideline was developed by an independent multidisciplinary panel of private sector clinicians and other experts convened by the Agency for Health Care Policy and Research (AHCPR). The panel employed explicit science based methods and expert clinical judgment to develop specific statements on acute low back problems in adults. Extensive literature searches were conducted, and critical reviews and synthesis were used to evaluate empirical evidence and significant outcomes. In addition, peer review was undertaken to evaluate the validity, reliability, and utility of the quideline in clinical practice. It was specifically noted that "the panel's recommendations are primarily based on the published scientific literature." Also heavily utilized by the Task Force was the book Neck and Back Pain: The Scientific Evidence of Causes, Diagnosis, and Treatment, edited by Alf Nachemson and Egon Jonsson. This book purports to have extensively reviewed the literature and to present "scientific background information derived from relevant studies in various fields in which different types of studies have been evaluated using modern epidemiological principles." The work of the group authoring this book took four years. The entire group met eight times for two days each, and individual meetings among authors of various chapters were even more numerous. This group was particularly interested in those studies, which employed randomized clinical trials. In addition to the two sources listed above, various Task Force members offered literature for Task Force review. In addition, the Surgical Subcommittee recommended the following text: Low Back Pain: A Scientific and Clinical Overview, edited by James W. Weinstein, D.O., M.S., and Steven L. Gordon, Ph.D. This publication was based on a workshop entitled "New Horizons in Low Back Pain" that was held in November 1995 in San Diego, California, and sponsored by the American Academy of Orthopaedic Surgeons, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and National Institutes of Health.

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¹ The Greater Flint Health Coalition is a multi-faceted partnership of Flint-area health providers, insurers, government, business and labor organizations, and community members whose mission is to improve the health status of area citizens, as well as the quality and cost effectiveness of the county's health care system.

The **Task Force** was given specific directives by the **Greater Flint Health Coalition** in its "Terms of Reference." Specifically, it was the goal "to improve the effectiveness and efficiency of back pain management for residents of Genesee County." To accomplish this goal it was decided that the **Task Force** should assess and describe the current system of back pain management, assess the determinants of variation, design strategies to target causes, and develop interventions. In addition, the **Task Force** was charged with the responsibility to implement the use of best practices by all providers of back pain management, and to educate patients and employers on back pain prevention and management.

To accomplish the Goals of the **Task Force**, study groups were established. One group addressed the general topic of nonsurgical acute low back pain management, while another group addressed the issue of surgical intervention for spinal disorders. The entire group subsequently addressed factors, which were involved in the transition from acute to chronic spinal difficulties, and approaches to the individual with chronic spinal disability. Finally, the entire group discussed possible implementation strategies, whereby the recommendations of the group could be presented to the **Greater Flint Health Coalition**, general medical community, patients, insurers, and other interested parties.

CONCLUSIONS AND RECOMMENDATIONS

The **Task Force** was asked to assess and describe the current system of back pain management and the determinants of variation within our health care community. This assessment relied upon the observations and experiences of Task Force participants. Numerous and detailed discussions were held on this topic. Task Force members concluded that there was significant variation in the provision of spine care within this community. Patient access to care givers varies widely, with some individuals seeing a specialist early in their clinical course, while others do not. The nature of the initial physician interface, including the evaluation process, initial treatment plan, instructions given by the physician, and judgments concerning work status, medication use, etc., is highly variable within this community. Also highly variable are subsequent referral patterns. Many individuals are quickly referred to a surgical specialist, while other individuals are referred to an injectionist as an initial intervention. In addition, the nature and quality of physical therapy is quite variable, with many physical therapy facilities relying upon "modality" care, with others following more evidence-based guidelines. Depending upon the primary care physician, and subsequent specialist access by a given patient, there is considerable variation in the nature of services rendered, as it relates to surgery, the type of surgery performed, the type of physical therapy, the duration of therapy, and recommendation regarding work absence, medication prescription. and injectionist intervention. It is the conclusion of the Task Force members that a true "standard of care" is not readily apparent within this community, and that current practice patterns do not consistently conform to the guidelines delineated by this Task Force.

In attempting to identify determinations of variation in spine care in this community, **Task Force** members concluded that variables such as patient sophistication, patient motivation/intentions, and the degree of physician expertise/experience/"philosophy" all contribute to the variation of care. In addition, it was noted that individual physician hospital affiliation, insurance restraints, and patient and physician access to specific spine care services are additional factors. Finally, **Task Force** members agreed that marketing pressures from various health care vendors frequently influence physician behaviors in the provision of spine care and the nature of referral patterns.

The Greater Flint Health Coalition Back Pain Management Task Force notes that numerous authors have concluded that the actual incidence of spinal pain has not increased over time, but that the incidence of spinal disability has increased markedly in recent times in modern societies, including our own. Paradoxically, this explosion of spinal disability occurs against a backdrop of major technological advances, including the widespread availability of sophisticated imaging techniques, ready access to spine surgeons, a seemingly endless proliferation of new surgical techniques and materials, and a considerable expansion of pharmacological agents. Given this paradox, Task Force members readily concurred that a renewed commitment to evidence-based medicine² is not only medically indicated, but socially and morally imperative. The reader of this document is encouraged to review the entire report of this Task Force, but a concise declaration of major Task Force recommendations is warranted, and is the subject of this particular report section. Major conclusions of the Back Pain Management Task Force are as follow:

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² Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence from clinical care research in the management of individual patients.

- 1. Physician behaviors can materially influence the probability of spinal disability. The medical literature strongly supports a constellation of proven practice behaviors while simultaneously demonstrating the lack of proven efficacy for others. Each health care provider needs to be cognizant of the impact that his/her comments may have on the subsequent clinical course experienced by a patient with back pain problems. The most important treatment intervention for most patients with acute low back pain problems is the initial physician evaluation, at which time the vast majority of patients can be reassured of the benign nature of their condition after a careful history and physical examination screens for "red flags," and can be advised regarding appropriate physical activities.
- 2. Physicians are urged to become familiar with the Clinical Practice Guidelines prepared by the AHCPR (#14, Acute Low Back Pain Problems in Adults). These guidelines have been largely summarized within the body of this report. The Task Force strongly suggests that Neck and Back Pain, the Scientific Evidence of Causes, Diagnosis, and Treatment (Nachemson, et al) is an excellent reference text for this problem. This text is referenced frequently within this Task Force's report.
- 3. Physicians should screen for psychosocial issues that are likely to impact the clinical course. An extensive body of research indicates that psychosocial issues are the primary variable involved in the transition from acute to chronic spinal disability. An attempt should be made by physicians involved in the care of spine patients to identify such issues, and to address them appropriately. A failure to do so may seriously compromise a patient's clinical course.
- 4. Primary care physicians are urged to make appropriate early referral to surgical specialists when certain "red flags" have been identified upon initial evaluation (i.e., cauda equina syndrome, major limb motor weakness, tumor, fracture, spinal infection).
- 5. For patients not requiring early referral to surgical specialists because of the presence of "red flags," referral to non-surgical spine specialists should be considered if an individual's spinal difficulties have not largely resolved within a relatively brief period of time (four to six weeks). Non-surgical spine specialists routinely evaluate the myriad physical, psychological, and social issues that often underlie subacute and chronic spinal problems. Non-surgical spine specialists are experienced in utilizing multidisciplinary interventions to reduce disability and promote functional recovery.
- 6. Chronic disabling low back pain should be referred to a comprehensive multidisciplinary treatment facility. The medical literature clearly indicates that such referral is warranted, and that chronic disabling low back pain is frequently associated with prominent psychosocial distress, which is most appropriately addressed within a treatment program utilizing multidisciplinary care.
- 7. Narcotics, sedatives, and muscle relaxants are best avoided if possible, and their chronic use is likely to be counterproductive, as significant side effects and/or physical addiction are common with these agents.

- 8. The use of physical agents and modalities in the treatment of acute low back problems is of insufficiently proven benefit to justify their cost. No well designed controlled trials support the use of physical agents and modalities as treatments for acute low back problems. Physical agents and modalities include ice, heat (including diathermy), massage, ultrasound, cutaneous laser treatment, and electrical stimulation. In addition, transcutaneous electrical nerve stimulation (TENS) is not recommended in the treatment of patients with acute low back problems. Self-administered home programs involving the application of heat or cold can be considered for symptomatic relief. Physicians are urged to be cognizant of the type of services provided by treatment facilities, and to insist upon adherence to evidence-based guidelines.
- 9. Injection therapy should have a limited role in the care of individuals with back pain problems. Epidural steroid injections have a recognized role in the treatment of acute radicular symptomatology, but injection therapy for isolated back pain, whether acute or chronic, is not recommended. Early referral to an injection therapist is typically not warranted, unless done so by a spinal specialist. The practice of repeated series of spinal injections is seldom warranted. It is recommended that patients are evaluated by a spinal specialist before an anesthesiologist is asked to perform spinal injections.
- 10. Avoid unnecessary Magnetic Resonance Imaging (MRI) scanning and other imaging modalities. The medical literature indicates that there is a high frequency of incidental "abnormalities" found in asymptomatic adults. Premature or unwarranted MRI scanning frequently identifies such "abnormalities," which are often of doubtful clinical significance, but, nevertheless, prompts subsequent additional evaluation and/or treatment, which frequently has a negative overall impact on the clinical course. The indications for plain spine films are well delineated. At the present time, plain spine films appear to be significantly overutilized in clinical practice.
- 11. **Electromyography (EMG) should have a limited role in spine care.** EMG should not be used as a screening tool for the detection of spinal pathology. Serial EMG testing should be discouraged. As practiced within our community, EMG testing appears to have a very high false positive rate. Conversely, normal EMG testing does not exclude significant spinal pathology or the need for surgical intervention.
- 12. Surgery plays an important role in well-selected patients with spine pain. Surgical intervention (discectomy) is clearly of value in that subset of patients with severe radicular pain and appropriate anatomical abnormalities. Because the majority of patients with symptomatic disc herniations respond adequately to conservative treatment, surgery typically follows a trial of conservative management, unless pain severity does not allow such an approach, or there is clinical evidence of a significant neurological deficit. Surgery for radicular symptoms is most effective at reducing the pain complaint, and, in appropriately selected individuals, an improvement in overall function. It is noted that over time the distinction between surgically and conservatively treated patients tend to blur with regards to work status, pain complaints, etc. Although not well supported by the medical literature, it is the opinion of this Task Force that decompressive spinal surgery for persistent and severe symptomatology resulting from spinal stenosis is often of significant utility in older individuals whose overall medical condition allows for safe surgical intervention.

13. The role of Fusion surgery, with and without instrumentation, remains controversial. Specific indications for spinal fusion are discussed in the surgical section of this publication.

The **AHCPR** panel indicated that in the absence of fracture, dislocation, or complications of tumor or infection, the use of spinal fusion was not recommended for the treatment of low back problems during the first three months of symptoms. It was further noted that spinal fusion should be considered following decompression at a level of increased motion due to degenerative spondylolisthesis. Although it was explained that the usual stated reasons for doing spinal fusion for degenerative problems were instability of the spine and disc disease, it was noted that there was lack of scientific agreement on how to define spinal instability. Evidence remains weak that patients who undergo fusion will return to their prior functional level.

Surgery for primarily **axial** low back pain, including fusion and intradiscal electrothermal therapy (IDET), is controversial, and will be discussed in greater detail within the section on surgery.

14. Spinal surgeons are urged to consider those psychosocial issues known to impact surgical outcome. The medical literature clearly identifies psychosocial risk factors that routinely compromise surgical outcomes. It is essential that surgeons consider such issues, and actively solicit their identification, in formulating a "risk/benefit" analysis. Many individuals with prominent psychosocial distress do benefit from surgery, but outcomes are enhanced if these issues are adequately addressed pre- and post-operatively, and such factors should be considered when attempting to determine the likelihood that a given patient will respond to surgery (i.e., pain reduction, return to work and active lifestyle, etc.).

EVALUATION AND TREATMENT OF ACUTE LOW BACK PROBLEMS IN ADULTS

The Agency for Health Care Policy and Research (AHCPR) identified four principle reasons that acute low back problems had been selected as a subject for guideline development. First of all, the prevalence of low back problems is high, with a general yearly prevalence in the U.S. population of 15-20%. Back symptoms are the most common cause of disability for persons under age 45, and at any given time about 1% of the U.S. population is chronically disabled because of back problems, with another 1% temporarily disabled. A second reason prompting guideline formulation is the cost associated with low back problems. Low back problems are expensive, measured both from economic and social perspectives. Low back problems are the second most common symptomatic reason expressed by patients for visits to primary care physicians. In addition, low back problems rank as the third most common reason for surgical procedures. Although medical costs are high, loss of time from work, as well as the disability payments for work related low back problems, can cost up to three times as much as medial treatment. In addition, non-monetary costs of low back problems can also be substantial, with a significant impact on both individuals so affected, as well as their families. A third reason for guideline development cited by the AHCPR was "the increasing evidence that many patients with activity tolerance due to low back symptoms may be receiving care that is inappropriate or at least less than optimal." Noting that there are dramatic regional variations in rates of hospitalization, surgery, and even types of testing performed, the AHCPR felt that such variations reflected a lack of consensus about appropriate assessment and treatment. It was furthermore noted that some patients appear to actually be "more disabled" subsequent to treatment than before. Surgery, extended bed rest, and "extended use of high dose opiates" were all identified as possible culprits.

Alf Nachemson, within the introduction chapter of Neck and Back Pain – The Scientific Evidence of Causes, Diagnosis, and Treatment, indicates that "with our present knowledge, it could be stated that part of the enormous scope of the problem is iatrogenic, that is, created by these various professional views..." It was further stated that the "concentration solely on the presumed structural features of the symptoms of spinal pain created a model that totally missed the important psychosocial part of the personal experience of pain." Dr. Nachemson, further states:

"It is clear that we need a shift of paradigm from a pure pathoanatomic model to a more biopsychosocial model of disease and pain in particular. Functional disability, particularly work disability, and pain are not directly related. Loss of working ability depends in varying degrees on patients' and societies' attitudes and beliefs. Thus, in many studies, psychological factors have been demonstrated to be more important than physical changes in the spine and patients with disability resulting from back pain."

The **AHCPR** defines "back problems" as activity intolerance due to back related symptoms and "acute" as limitations of less than three months duration. Back symptoms include pain, primarily in the back, as well as back related leg pain (sciatica). The overall intent of the **AHCPR** was to "change the paradigm of focusing care exclusively on the pain of low back problems to one of helping patients improve their activity tolerance."

The initial assessment of an individual with low back symptoms consists of a focused medical history and clinical examination. Medical history and physical findings are sought that might suggest a serious underlying spinal condition such as fracture, tumor, infection, or cauda equina syndrome. These features of the history and/or physical examination which would suggest such an entity are termed "red flags." The history and examination also assess for non-spinal conditions that might cause referred low back symptoms (vascular, urinary, intra-abdominal, or pelvic pathology). Once the physician has ruled out "red flags" and non-spinal pathology, the symptoms can be categorized as either sciatica or non-specific back pain. Neither routine nor special testing is required in the first month of symptoms for either problem in the absence of red flags. Most patients will recover spontaneously from activity limitations within one month.

Initial Assessment Methods

The AHCPR guidelines are as follows:

- Information about the patient's age, duration and description of symptoms, impact of symptoms on activity, and response to previous therapy are important.
- Inquiries about history of cancer, unexplained weight loss, immunosuppression, intravenous (IV)
 drug use, history of urinary tract infections (UTI), pain increased by rest, and presence of fever
 are recommended to elicit red flags for possible cancer or infection, especially in patients over
 age 50.
- Inquiries about signs and symptoms of cauda equina syndrome, such as bladder dysfunction and saddle anesthesia, in addition to major limb motor weakness, are recommended to elicit red flags for severe neurological risks to the patient.
- Inquiries about history of significant trauma relative to age are recommended to avoid delays in diagnosis of fracture.
- Attention to psychological and socioeconomical problems in the individual's life is recommended since such nonphysical factors can complicate both assessment and treatment.
- Use of instruments such as a pain drawing or visual analog scale is an option to augment the history.
- Straight leg testing is recommended in the assessment of sciatica in young adults.
- A neurological examination emphasizing ankle and knew reflexes, ankle and great toe dorsiflexion strength, and distribution of sensory complaints is recommended to document the presence of neurological deficits.

In <u>Neck and Back Pain</u> (Nachemson, et al), it is stated that the following are the most common indications from history and examination for pathological findings needing special attention and sometimes immediate action, including imaging:

- Back pain in children less than 18 years with considerable pain or onset after 55 years.
- History of violent trauma.
- Constant progressive pain at night.
- History of cancer.
- Systemic steroids.
- Drug abuse, HIV infection.
- Weight loss.
- Systemic illness.
- Persisting severe restriction of movement.
- Intense pain for minimal motion.
- Structural deformity.
- Difficulty with micturition.
- Loss of anal sphincter tone or fecal incontinence; saddle anesthesia.
- Widespread progressive motor weakness or gait disturbance.
- Inflammatory disorders (ankylosing spondylitis) suspected.
- Gradual onset less than 40 years of age.
- Marked morning stiffness.
- Persisting limitation of movement.
- Peripheral joint involvement.
- Iritis, skin rashes, colitis, urethral discharge.
- Family history.

Many authors now recommend that so-called "yellow flags" also be assessed. Yellow flags are psychological risk factors for the development of chronic spinal difficulties. In a recent article in SPINE ("A Systematic Review of Psychological Factors as Predictors of Chronicity/Disability in Prospective Cohorts of Low Back Pain"), Pincus, et al, indicate that "psychological factors (notably distress, depressive mood, and somatization) are implicated in the transition to chronic low back pain. In a related article in SPINE ("Cognitive-Behavioral Therapy in Psychosocial Factors in Low Back Pain"), Pincus, et al, state "there is good evidence to support the role of psychosocial risk factors at early stages of low back pain in the development of long-term disability." These authors indicate that "a summary of the current state of knowledge about psychological factors and low back pain is based on the following five assumptions:

- Impairment, pain, and disability are conceptually related, but are also distinct.
- 2. Impairments (such as disc prolapse) are not caused by psychosocial factors, whereas the perception of pain is always subjective and is influenced readily by such factors.
- 3. The report of injuries and pain, and the seeking of health care, usually is mediated by the complex interaction of medical, work related beliefs and behavior, and other psychosocial factors.

- 4. Disability, including work loss and reduction in activity, is commonly influenced by a diverse range of psychosocial factors. These include attitudes and beliefs held by the patient, behavior, compensation litigation issues, diagnosis and the behavior of treatment providers, emotions, such as fear or low mood, family members' behavior, such as a solicitous spouse, and work factors.
- 5. The presence of specific disease does not mean that psychosocial factors are unimportant."

Pincus, et al, point out that psychosocial factors include psychological factors such as attitudes (i.e., catastrophosizing), beliefs (i.e., fear avoidance), mood state (i.e., anxiety and depression), social factors, such as family (i.e., social support), and work (i.e., job satisfaction). The authors conclude that psychosocial factors appear to be important markers for the risk of developing long-term disability. Attempts to identify depression/distress and fear avoidance are felt to be justified.

Clinical Care Methods

In the absence of red flags, treatment is similar for most patients with activity intolerance due to an acute episode of low back symptoms. The patient should be assured that there is no hint of a dangerous problem, and that a rapid recovery is expected. Accurate patient information about low back problems is provided, symptoms are controlled, and recommendations regarding activity modification are given.

It is crucial that physicians provide accurate information to individuals with acute low back symptoms. These should include:

- Expectations of both a rapid recovery and recurrence of symptoms based on natural history of low back symptoms.
- Safe and effective methods of symptomatic control.
- Safe and reasonable activity modifications.
- Best means of limiting recurrent low back problems.
- The lack of need for special investigations unless red flags are present.
- Effectiveness and risk of commonly available diagnostic and further treatment measures to be considered should symptoms persist.

The **AHCPR** concludes "evidence indicates that educating patients about back problems may reduce use of medical resources, decrease patient apprehension, and speed recovery."

Regarding symptom control with medications, the **AHCPR** guidelines indicated acetaminophen is reasonably safe and acceptable for treating patients with acute low back problems. Nonsteroidal anti-inflammatory drugs (NSAIDS) are also acceptable, but have a number of potential side effects, especially gastrointestinal irritation. Muscle relaxants are also a treatment option, but have not been shown to be more effective than NSAIDS. Furthermore, no additional benefit was noted for using muscle relaxants in combination with NSAIDS over using NSAIDS alone. Muscle relaxants have potential side effects, most commonly drowsiness.

Opiate analgesics are considered with an option in the management of patients with acute low back pain, but only when prescribed for a "time-limited course." Furthermore, it was noted that opiates do not appear to be more effective in relieving low back symptoms than safer analgesics, and that opiates have significant side effects, including decreased reaction time, clouded judgment, and drowsiness. Finally, it was recommended that patients be warned about potential physical dependence and the danger associated with the use of opiates while operating heavy equipment or driving.

Oral steroids and antidepressant medications were not recommended for the treatment of acute low back problems.

Symptom Control – Physical Treatments

The **AHCPR** panel indicated that manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. There was insufficient evidence to recommend manipulation for patients with a radiculopathy. Efficacy of manipulation in patients without radiculopathy with symptoms longer than a month has not been proven. If manipulation has not resulted in symptomatic improvement that allows increased function after one month of treatment, such treatment should be stopped and the patient re-evaluated.

The panel found that the use of physical agents and modalities such as ice, heat, massage, ultrasound, cutaneous laser treatment, electrical stimulation, and TENS was of insufficiently proven benefit to justify their cost.

Lumbar corsets and back belts were found to not have been proven beneficial for treating patients with acute low back problems. With regards to traction, the panel indicated that "spinal traction is not recommended in the treatment of patients with acute low back problems." Likewise, biofeedback was not recommended. Similarly, trigger point injections and ligamentous and sclerosant injections were not recommended for the treatment of patients with acute low back problems. Facet joint injections were also not recommended for use in the treatment of patients with acute low back problems, and the panel found no evidence to support the use of epidural injections as a treatment for acute low back pain without radiculopathy, but did note that the use of epidural steroid injections were an option for short-term relief of radicular pain after failure of conservative treatment and as a possible means of avoiding surgery." Invasive needle acupuncture and other dry needling techniques were not recommended.

Activity Modifications

The **AHCPR** panel indicated that a gradual return to normal activities was more effective than prolonged bed rest. It was noted that prolonged bed rest for more than four days may lead to debilitation, and should be avoided. It was further stated that the majority of low back patients do not require bed rest at all, but that in patients with severe initial symptoms of primarily leg pain a brief period of bed rest may be a treatment option.

The panel noted that low stress aerobic exercise can prevent debilitation and may help to return patients to the highest level of functioning appropriate to their circumstances. Aerobic exercise programs can be started during the first two weeks for most patients with acute low back problems. If symptoms persist, conditioning exercises for trunk muscles are helpful. Back specific exercise machines do not appear to provide benefit over traditional exercise.

The panel indicated that patients with acute low back problems are sometimes more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, and that activity recommendations for employed individuals need to consider the patient's age and general health, as well as the physical demands of the required job tasks.

SPECIAL STUDIES IN DIAGNOSTIC CONSIDERATIONS

If the patient is limited by back symptoms for more than one month, special diagnostic and treatment procedures may need to be considered. Tests may be required to demonstrate physiological dysfunction, such as neurological dysfunction, infection, inflammation, malignancy, or other systemic illness. Other types of tests are utilized to define a potential anatomical region for the dysfunction such as a herniated disc, spinal stenosis, etc. Except when serious underlying pathology is suspected (i.e., "red flags") special diagnostic tests are usually not needed during the first month.

Electrophysiological Tests

If the diagnosis of radiculopathy is obvious and specific on clinical examination, electrophysiologic testing is not recommended. EMG testing may be useful in assessing questionable nerve root dysfunction in patients with leg symptoms lasting longer than four weeks. Surface EMG and F wave tests are not recommended for assessing patients with acute low back symptoms. EMG testing is not recommended as a screening tool in patients with spinal complaints. Serial EMG testing is rarely warranted. There appears to be a significant percentage of "false positive" EMGs within our community, and the absence of EMG abnormalities does not exclude significant spinal pathology, even pathology which requires surgical intervention.

Bone Scan

A bone scan is recommended to evaluate acute low back problems when spinal tumor, infection, or occult fracture is suspected from "red flags." Thermography is not recommended for assessing patients with acute low back problems.

Plain X-Rays

Plain x-rays are not recommended for routine evaluation within the first month of symptoms unless a red flag is noted on clinical examination. Plain x-rays are recommended for ruling out fractures in the setting of appropriate red flags (i.e., history of trauma, prolonged steroid use, osteoporosis, patient over age 70). Utilizing plain x-rays in combination with Complete Blood Count (CBC) and Erythrocyte Sedimentation Rate (ESR) can be useful for ruling out tumor or infection in patients with acute low back problems and certain red flags (prior cancer, recent infection, fever, IV drug abuse, prolonged steroid use, unexplained weight loss, low back pain worse with rest). If plain x-rays are negative, if red flags are present other imaging studies such as bone scan, Computed Tomography (CT), or MRI may be clinically indicated.

CT, MRI, Myelography, and CT Myelography

The AHCPR panel indicates that in the setting of suspected cauda equina syndrome or progressive major motor weakness the proper use of one of the above imaging techniques is recommended. Consultation with a surgeon is advised. Routine spinal imaging tests are not generally recommended in the first month of symptoms except in the presence of red flags for serious conditions. After one month of symptoms, an imaging test is acceptable when surgery is being considered. MRI with contrast appears to be the imaging test of choice to distinguish disc herniation from scar tissue in individuals with prior spine surgery. CT myelography and myelography are invasive and have an increased risk of complications. These tests are indicated only in special situations for preoperative planning. There is a significant incidence of disc herniations in asymptomatic adults. Over 20% of adults without a history of significant spinal difficulties are found to have lumbosacral disc herniation on MRI scanning. For individuals over 60 years of age the incidence is over 35%. MRI typically provides a greater degree of anatomical detail, and typically is preferable to plain CT scanning in identifying disc herniation/nerve root compression.

Discography

The role of discography is discussed in the surgery section of this report.

PSYCHOLOGICAL RISK FACTORS FOR NECK AND BACK PAIN

There is a considerable amount of research implicating various psychological risk factors for the development of spinal pain, and the subsequent transition to chronic spinal disability. In **Neck and Back Pain (Nachemson**, et al), it is stated:

"The results of this review suggest the need for major changes in the way in which we view and clinically deal with neck and back pain disability. The data clearly show that psychosocial factors are important not only in the development of long-term disability resulting from neck and back pain, but also in the earliest stages. Consequently, approaches to prevention, initial treatment, and rehabilitation may benefit for incorporating this knowledge into practice. The research indicates that psychosocial factors are not simply an "overlay," but rather they are an integral part of the pain disability process that includes emotional, cognitive, and behavioral aspects. Because psychosocial factors were found to have more impact on disability than biomedical variables, treatment and preventive approaches that only address biomedical factors may be questionable. Rather, psychosocial factors may need to become a normal part of a comprehensive assessment and treatment routine even in patients with early neck and back pain. Including psychosocial factors in medical practice may give insight into the patient's problem and may provide new avenues for treatment and management. Moreover, preventive efforts may benefit greatly from incorporating these factors into their programs."

Nachemson, et al, further state:

- "1. There is strong evidence that psychosocial variables are strongly linked to the transition from acute to chronic pain disability.
- 2. There is strong evidence that psychological factors can be associated to the reporting of the onset of back and neck pain.
- 3. There is strong evidence that psychosocial variables generally have more impact than biomedical or biomechanical factors on back pain disability.
- 4. There is no evidence to support the idea of a "pain prone" personality, and the results are mixed with regard to personality and personality trait as risk factors.
- 5. There is strong evidence that attitudes, cognitions, and fear avoidance beliefs are strongly related to the development of pain and disability.
 - A. There is strong evidence that passive coping is strongly related to pain and disability.
 - B. There is strong evidence that pain cognitions, such as catastrophizing, are strongly related to pain and disability.
 - C. There is little evidence concerning acute pain.
- 6. There is strong evidence that depression, anxiety, distress, and related emotions are strongly related to pain and disability.
- 7. There is limited evidence that sexual and/or physical abuse may be related to chronic pain and disability.
- 8. There is evidence that poor self-perceived health is moderately related to chronic pain and disability.
- 9. There is evidence that psychosocial factors are moderate predictors for long-term pain and disability."

TREATMENT OF CHRONIC LOW BACK PAIN

In <u>Neck and Back Pain: The Scientific Evidence of Causes, Diagnosis, and Treatment</u>, the authors reviewed the literature concerning treatment efficacy for chronic low back pain. Various interventions were reviewed, including medications, epidural steroid injections, exercise therapy, "back schools," behavioral therapy, manual therapy, electromyographic biofeedback, traction, orthoses, TENS, acupuncture, and multidisciplinary pain treatment programs. The authors indicated that:

"Strong evidence was found for the effectiveness of manual therapy, exercise therapy, multidisciplinary treatment programs, and spa therapy, especially with regard to short-term effects. We only found moderate evidence for the effectiveness of behavioral therapy and limited evidence for back schools in an occupational setting. According to international guidelines, the major goal in the treatment of chronic low back pain is return to work or usual activities, and additional therapeutic options for symptomatic pain relief may facilitate this process. The available evidence suggests that NSAIDS may be effective for this purpose, but not physical modalities such as TENS, EMG biofeedback, acupuncture, and orthoses. There is no evidence to support any form of long-term maintenance therapy."

Specific recommendations concerning information, drug therapy, manual therapy, exercise therapy, and multidisciplinary treatment were offered. It was stated:

"The most important objective is to prevent or reduce disability, both physically and mentally, and to improve the patient's quality of life and functioning. Dependence on medical treatment should be prevented and avoided. The emphasis should be on coping with the symptoms together with control of pain."

"Long-term drug treatment should be avoided. If necessary, analgesics should be prescribed only to facilitate a gradual increase in activities, and they should be prescribed for a fixed period at fixed times, independent of the presence of pain."

"The patient should be referred for manual therapy for pain relief. There is no evidence to support the recommendation of one specific type of manual therapy."

"The patient should be referred for exercise therapy to improve daily functioning. No evidence supports the recommendation of one specific type of exercise. The intensity of the exercise should be gradually increased at fixed times for effectiveness, independent of the presence of pain."

"Patients with severe, long-lasting low back pain and disability, or high use of medical services for back pain, should be referred to a multidisciplinary treatment program aimed at functional restoration, behavioral management, or pain management."

As such, a review of the World's literature indicates that the treatment for chronic low back pain should focus on disability management, and that many of the treatment recommendations advise against reliance upon pain complaints, per se. The use of narcotics on a long-term basis is not recommended. There was felt to be "moderate evidence that epidural steroid injections are not effective for chronic low back pain without radicular symptoms," and there was no evidence that passive modality physical therapy was useful. In those instances in which chronic low back pain results in significant "disability" or high utilization of medical services, those individuals should be referred to a multidisciplinary treatment program aimed at "functional restoration, behavioral management, or pain management."

SURGERY

Surgery is an important intervention for a small percentage of well selected patients with spinal difficulties. There are very few randomized clinical trials (RCT) that specifically address the utility of surgery for a number of spinal conditions, just as there is a paucity of RCT regarding effectiveness of a number of non-surgical interventions. The lack of RCT evidence of surgical effectiveness does not mean, of course, that many individuals do not benefit from any number of surgical procedures, but the lack of RCT evidence certainly mandates a full consideration of non-surgical treatment interventions, and a diligent attempt to identify known poor prognostic factors in the selection of surgical patients.

There is significant variation in the incidence of surgery in the United States compared to Europe, as well as in different regions within the United States. It is clear that the most important factor responsible for this variation is the practice philosophy of the surgeon. This **Task Force** strongly recommends that when considering neurosurgical consultation a referring physician should utilize the service of spine surgeons whose practice philosophy parallels evidence-based medicine.

A broad spectrum of anatomic pathology is addressed by surgical intervention. Some indications for surgical intervention are well accepted, while others are more controversial. There clearly is a significant difference between surgical intervention for well defined radicular leg pain in the setting of disc herniation and various fusion surgeries for presumed discogenic low back pain. We will attempt to address the issue of surgical intervention for a number of commonly encountered clinical problems.

As indicated within the conclusion portion of this report, urgent consultation with a surgeon is recommended for conditions with "**red flags**." These include:

- 1. Tumor
- 2. Fracture
- Infection
- 4. Cauda equinal compression

When initiating a referral to a consultant, it is imperative that the referring physician communicates thoroughly as to the patient's known medical conditions and psychosocial risk factors, as well as all results of diagnostic testing and therapeutic trials to date.

Lumbar Herniated Disc with Radiculopathy

The natural history of sciatica and disc herniation is favorable, with recovery in approximately 50% of patients within the first two weeks and 70% within six weeks. In the absence of trauma, tumor, or infection, a conservative approach for individuals with sciatica and/or low back pain is appropriate. Emergent diagnostic testing is typically only indicated in the face of trauma, cauda equina syndrome, suspected tumor or infection, or progressive neurological loss. Accordingly, most patients with radicular leg pain should be managed conservatively for at least six to eight weeks. In appropriately selected patients, disc excision for sciatic symptoms is often successful. As indicated by Edward Hanley, M.D., in Chapter 8 of Low Back Pain, A Scientific and Clinical Overview (edited by James Weinstein, D.O., et al), approximately 60% of patients will have complete relief of radicular symptoms with surgery, but, of the remaining 40%, approximately 15% will have persistent disabling symptoms. "Thus, under the best of situations, 15% of patients undergoing this procedure will fall into the category of failed back patients." Recurrent disc herniation occurs in approximately 5-10% of individuals that have undergone lumbosacral discectomy.

It was also noted by Dr. Hanley that "long-term studies comparing surgical and non-surgical treatment for radiculopathy show no statistically significant difference in outcome." Various authors have shown that the relative benefit of surgical intervention tends to diminish over time. Dr. Hanley concludes "thus, the only real benefit from surgery for most patients is quicker relief from sciatic pain. It is, therefore, the clinician's task to select for surgery those patients in whom non-surgical measures are likely to fail and who can be reasonably expected to have symptomatic relief and a return to relatively normal function after a procedure." Dr. Hanley notes that prolonged symptomatology, abnormal illness behavior, a compensable work situation, cigarette smoking, and age greater than 40 may contribute to a negative surgical outcome, and that these factors should be considered in surgical selection. The symptom most responsive to surgical intervention for herniated disc is radicular leg pain. Back pain is less responsive to surgery, and in those individuals in whom leg pain is minimal surgical intervention is not indicated.

Weinstein, et al, are of the opinion that for patients who have undergone discectomy and have residual low back pain that fusion is not generally recommended. For individuals being considered for repeat surgery, positive prognostic factors include surgery performed after a long asymptomatic interval, a new herniation in a new location, or a new and correctable pathological condition. Chronic radiculopathy, a failed previous surgical fusion, and negative psychosocial characteristics are negative factors. It is noted that "the number of surgical successes clearly diminishes proportional to the number of procedures performed."

The treatment of patients with recurrent radiculopathy and low back pain presents more of a challenge, and some surgeons will consider concurrent fusion. It is stated by Dr. Hanley that "for individuals with low back pain occurring after discectomy, fusion is not generally recommended... Fusion is not recommended for an individual undergoing primary disc excision..." For individuals with recurrent disc herniation with back pain and radicular symptoms, fusion may be considered. If fusion is being considered, it is essential that patients have exhausted quality non-surgical treatment, have "stable psychometrics," and the intervention should be approached with both caution and realistic expectations. It is acknowledged that the role of fusion, which often brings into play discography, is controversial within the surgical and non-surgical spine community.

Percutaneous suction or laser discectomy or arthroscopic discectomy have much lower success rates compared to microdiscectomy, and often require subsequent microdiscectomy.

In considering an individual for surgery for disc herniation, it must be remembered that disc herniation occurs in a substantial percentage of the general population, with more than 25% of adults demonstrating asymptomatic disc herniation. The overall figure is approximately 36% for individuals over 60 years of age. As such, it is essential for the surgeon to carefully correlate radiological findings, subjective complaints, and physical findings, and to consider surgery only in those cases in which leg pain is the predominant complaint.

Lumbar Disc Degeneration (Internal Disc Disruption)

Harry Herkowitz, M.D., notes, in Chapter 28 of Weinstein, et al, "...lumbar disc degeneration is a physiological process associated with aging." He notes that "most patients with lumbar disc degeneration are asymptomatic," and that it is difficult to determine which degenerated discs are painful, what is the basis for such discomfort, which individuals are good surgical candidates, and that it is difficult to determine whether surgical treatment can provide results better than the natural history of presumed discogenic discomfort. Dr. Herkowitz concludes "it is because of the lack of conclusive data to answer the above questions that the surgical treatment of idiopathic low back pain is controversial." Dr. Herkowitz concludes "surgical treatment is rarely indicated for discogenic pain." He also notes that "lumbar fusions across several motion segments for multilevel disc degeneration are associated with poor outcomes. The difficulty associated with the treatment of chronic discogenic pain lies in identification of the true pain generator." He notes that the only "provocative in-vivo test available for identification of the pain source is the discogram. Its role, however, is quite controversial..."

Dr. Herkowitz notes that "the natural history of discogenic pain is relatively unknown, with some series demonstrating a substantial improvement (68%) in patients with untreated discogenic pain at five year follow up. He furthermore noted that a large percentage of patients who did not improve during the follow up period were found to have underlying psychiatric diagnoses. Many individuals do report an improvement in their condition with fusion, but given the natural history of "discogenic pain" Dr. Herkowitz rightly notes "...randomized trials comparing conservative and surgical treatment of discogenic pain are needed in order to determine whether surgery can improve over the natural history of discogenic pain." He further notes "the entity and symptom being treated in these patients is pain. The perception of pain differs from patient to patient and varies among different ethnic groups. Also, psychosocial factors and secondary gain issues, such as workers' compensation and litigation, may alter a patient's pain perception and response to treatment. As such, these issues need to be resolved prior to surgical treatment of discogenic pain. Patient selection is extremely important to prevent failure of surgical outcome."

Discography

As stated by **Nachemson**, et al, "one of the most controversial diagnostic tests is discography, a method by which fluid with or without contrast media is injected into presumed degenerated and painful discs, as a preoperative test for performing fusion or as a method of choosing the level of fusion. When the patient recognizes the pain exactly (pain provocation positive), and the disc also shows sign of degeneration, as the test can demonstrate, this method has been used by many authors as an indication for lumbar or cervical fusion for patients with chronic pain."

The authors point out, however, that it has not been demonstrated that discography helps in the outcome of lumbar fusion, a procedure that the authors also note has not been proven effective in patients with chronic low back pain. After a lengthy discussion, **Nachemson**, et al, concludes regarding discography "its clinical utility remains unproven."

Other authors (Weinstein, et al) agree that discography is controversial, but note that it is the only provocative test available to localize presumed discogenic pain in patients with multiple levels of disk degeneration. It is noted that many variables can influence the results of the test, and to decrease false positive results standardization of the pressure during the disc injection is recommended via manometry. It is also recommended that familiar pain reproduction rather than nerve pain or some other type of discomfort is important to identify, as is the utilization of adjacent disc testing. It is noted that discograms should not be performed on individuals with normal appearing disc or MRI scanning.

Acknowledging the ambiguity and controversy inherent in treating chronic idiopathic low back pain surgically, proponents of surgery for this condition agree that relative indications for such surgery include:

- 1. Unremitting pain and disability for more than a year.
- 2. Failure of aggressive physical conditioning and conservative treatment lasting more than four months.
- 3. Advanced single level disc degeneration on MRI with concordant pain response on discography.
- 4. Absence of psychiatric or secondary gain issues."

Spinal Stenosis

As noted in Weinstein, et al, degenerative lumbar spinal stenosis is an increasingly common source of pain and disability in the elderly. The actual prevalence of symptomatic spinal stenosis is unknown, but in asymptomatic individuals greater than 60 years of age the prevalence of radiologically defined spinal stenosis on MRI scanning is about 20%. The most useful historical feature in identifying symptomatic spinal stenosis is a history of pain on standing or walking, with absence of leg pain in the sitting position. In some cases neurological deficits may be identified. The natural history of untreated spinal stenosis is essentially unknown, as most individuals do receive some treatment. There are no adequate controlled studies for either surgical or non-surgical treatment of symptomatic spinal stenosis.

Some studies note that aggressive non-surgical treatment is often effective in symptomatic spinal stenosis, with improvement in walking tolerance. In those patients being considered for surgery, surgical treatment of lumbar spinal stenosis can be broadly divided into decompressive procedures with and without concomitant fusion.

In general, individuals with spondylolisthesis and obvious radiological instability seem to benefit from decompressive surgery and simultaneous fusion. In individuals without the presence of spondylolisthesis, there does not appear to be a role for fusion.

It is the consensus of this **Task Force** that individuals with classic lumbar neurogenic claudication secondary to spinal stenosis, whose symptoms persist for at least three months, and whose quality of life is markedly impacted, should be considered for surgical intervention, especially if they have not responded to an aggressive non-surgical treatment approach.

"IDET" (Intradiscal Electrothermal Therapy) for "Internal Disc Disruption"

A relatively new intervention has been developed for individuals with chronic low back pain of presumed discogenic origin. This procedure involves the introduction of an electrical catheter into a selected intervertebral disc, with heating of the disc. This procedure has been suggested, by its advocates, as having a role in the treatment of individuals with chronic back pain. It is the opinion of this Task Force that this procedure has not been thoroughly evaluated, and there is no convincing data upon which to either recommend or discourage the use of IDET. It should be noted, however, that the developers of this technique (Drs. Saal and Saal) list specific inclusion criteria, including unremitting, persistent low back pain of at least six months continuous duration; no satisfactory improvement with a comprehensively applied non-operative care program, including back education, activity modification, progressive intensive exercise; at least one epidural injection; a trial of manual physical therapy; and anti-inflammatory medications. It is also noted that inclusion criteria included a normal neurological examination, negative straight leg raising, and an MRI scan which did not demonstrate a neural compressive lesion. Other authors have used as exclusion criteria: intervertebral disc herniations greater than 4 mm, sequestered intervertebral disc herniations, previous lumbar surgery, vertebral canal stenosis, spondylolisthesis at the painful segmental level, scoliosis, compressive radiculopathy, ambulatory dysfunction, new lumbar disc injury, pregnancy, workers' compensation, litigation, disability renumeration, etc. As such, it would appear that even if eventually accepted by the spine care community, the role of IDET will likely be extremely limited.

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